

Third international Conference for Improving Use of Medicines  
*Informed Strategies, Effective Policies, Lasting Solutions*

**ABSTRACTS**

November 14-18, 2011  
Antalya, Turkey



## ABSTRACTS LISTED BY ABSTRACT NUMBER

107	Effect of Multiple Micronutrient Supplements for Improving Anaemia of Preschool Age Children in Rural, Lao People's Democratic Republic: A Randomized Trial	26
111	Availability and Rational Use of Essential Drugs in the PHC Facilities in Bangladesh: Are We on the Right Track?	26
113	Medicine Outlets and Their Practitioners in Malaria Control in Ghana	27
114	Facilitators and Barriers for Generic Drug Use Among General Practitioners in Northern State of Malaysia: Findings from a Cross-Sectional Mail Survey	27
115	Public Knowledge and Attitudes Toward Antibiotic Usage: Findings from a Cross-Sectional Survey in the State of Penang, Malaysia	28
120	The Role of Pharmaco-Economics in the Decision Tasks to Improve the Quality of Medical Care in Kazakhstan Republic	29
125	Evaluation of Prescribing Practices by Assistant Medical Officers at Malaysian Public Health Care Facilities	29
126	Antimalarial Prescribing and Dispensing Practices in Health Centres of Khartoum State, 2003–04	30
127	Impact of Strategies to Improve Collection and Reporting of Logistics Information for Managing Essential Medicines in Developing Countries	30
128	The Evaluation of Compliance to an Essential Medicine Programme: Use of Standard Treatment Guidelines in South Africa's State Health Facilities of eThekweni	31
129	Unnecessary Antibiotic Use for Mild Acute Respiratory Infections in a 28-Day Follow-Up of 823 Children under Five in Rural Vietnam	31
132	Improvements in Access to Malaria Treatment in Tanzania Following Community, Retail Sector and Health Facility Interventions—A User Perspective	32
143	CBIA-Pregnancy to Improve Skills of Pregnant Mothers in Selecting OTC Common Cold Preparations	33
144	A Rapid Assessment Protocol for Improving Access (RAPIA) to Medicine and Care for Children living with a Chronic Condition (Congenital Adrenal Hyperplasia) in Vietnam	33
146	CEMA-Community to Improve Knowledge and Skills in Evaluating Medicine Advertisements	34
148	Improving Diabetic Patients' Adherence to Treatment Program by Using CBIA-DM Strategy in Hospital- Based Patient Community	35
152	Irrational Use of Diabetes Medicines in Resource-Poor Settings	35
164	Extension of market exclusivity and its impact on the accessibility to essential medicines, and drug expense in Thailand: Analysis of the effect of TRIPs-Plus proposal	36
173	Quantifying the Impoverishing Effects of Purchasing Medicines: A Cross-Country Comparison of the Affordability of Medicines in the Developing World	36
176	Effect of IEC Intervention on Awareness about Rational Pharmacy Practice in Pharmacy Students	37
180	Interventional Study on Self Medication in Commonly Occurring Illnesses in Nonmedical Staff of a Tertiary Care Teaching Hospital	38
185	Use of Prophylactic Oxytocin by Health Care Providers in Northeast Argentina as Part of Active Management of the Third Stage of Labor	38

<b>186</b> .....	<b>39</b>
Overview of Systematic Reviews on Pharmaceutical Policy and Their Relevance to Low- and Middle-Income Countries	
<b>189</b> .....	<b>40</b>
Cost Analysis of Management of Malaria Using ACT in the Private Sector of Zimbabwe: A Regulatory Implication	
<b>192</b> .....	<b>41</b>
Medicine Prices, Availability, and Affordability in Vietnam	
<b>193</b> .....	<b>41</b>
Corruption and High Medicine Prices in Vietnam: A Qualitative Study	
<b>194</b> .....	<b>42</b>
Promoting Rational Antibiotic Prophylaxis in Clean Surgeries in China	
<b>195</b> .....	<b>43</b>
A Survey on the Quality of Anthelmintic Medicines in Cambodia	
<b>199</b> .....	<b>43</b>
Antibiotics and Pediatric Acute Respiratory Infections in Rural Vietnam: Health Care Providers' Knowledge, Practical Competence, and Reported Practice	
<b>200</b> .....	<b>44</b>
Rapid Assessment Methods for Monitoring Pharmaceutical Policy	
<b>203</b> .....	<b>45</b>
Essential Medicine Concept as a Core of Drug Policy: Impact on Costs, Availability of Quality Medicines, and Their Rational Use in Delhi (India)	
<b>204</b> .....	<b>45</b>
Differences in the Availability of Medicines Used for Noncommunicable and Communicable Conditions in the Public and Private Sectors of Developing Countries	
<b>210</b> .....	<b>46</b>
Quality of Medicines in South Africa: Perceptions vs. Reality	
<b>211</b> .....	<b>46</b>
Pharmaceutical Services for Uncomplicated Malaria by <i>P. vivax</i> and <i>P. falciparum</i> in High-Risk Municipalities of the Brazilian Amazon: Organization of Services, Prescribing, Dispensing, and Adherence to Treatment	
<b>213</b> .....	<b>47</b>
Health Insurance Systems in Five Sub-Saharan African Countries: Medicines Benefits and Data for Decision-Making	
<b>217</b> .....	<b>48</b>
Planning for Sustainability of ARV Provision: A Study in Peru, Bolivia, and Mozambique	
<b>219</b> .....	<b>48</b>
The Good, the Bad, and the Ugly: A System-Based Three-Pronged Strategy to Combat Substandard and Counterfeit Medicines in Low-Resource Countries	
<b>220</b> .....	<b>49</b>
Controlling Medicine Prices in Sudan: The Challenge of a Recently Established Medicines Regulatory Agency	
<b>235</b> .....	<b>50</b>
Effects of Two Educational Programs Aimed at Improving the Utilization of Non-opioid Analgesics in Family Medicine Clinics in Mexico	
<b>236</b> .....	<b>50</b>
Active Pharmaceutical Management Strategies of Health Insurance Systems to Improve Cost-Effective Use of Medicines in Low- and Middle-Income Countries: A Systematic Review of Current Evidence	
<b>241</b> .....	<b>51</b>
Taking Stock: Provider Prescribing Practices in the Presence and Absence of ACT Stock	
<b>243</b> .....	<b>52</b>
Comparison of the Public Procurement Prices of Essential Medicines in China with Other Western Pacific Developing Countries and Its Implication	
<b>246</b> .....	<b>52</b>
Characteristics and Outcomes of Public Campaigns with the Aim to Improve Outpatient Antibiotic Use in High Income Countries	
<b>248</b> .....	<b>53</b>
A Risk-Based Cost-Effective Approach to Medicines Quality Monitoring in Resource-Limited Countries	
<b>254</b> .....	<b>54</b>
International Comparison of Generic Medicine Prices	
<b>256</b> .....	<b>54</b>
Priority Setting for Implementation of Artemisinin-Based Combination Therapy Policy in Tanzania: Evaluation against Accountability for Reasonableness Framework	
<b>257</b> .....	<b>55</b>

Do European Rheumatoid Arthritis Patients Have Equal Access to Treatment with New Medicines?	
<b>262</b> .....	<b>55</b>
Comparison of Different Inappropriate Prescribing Screening Tools Used for Assessment of Inappropriate Drug Prescription in the Elderly	
<b>264</b> .....	<b>56</b>
Parasitological Assessment of Two-Dose and Monthly Intermittent Preventive Treatment of Malaria During Pregnancy with Sulphadoxine-Pyrimethamine (IPTp-SP) in Lagos, Nigeria	
<b>265</b> .....	<b>57</b>
Exploring Traditional Medicines Use by Ghanaian Households	
<b>266</b> .....	<b>57</b>
Pharmacoepidemiologic Study of Potential Drug Interactions in Hospital Inpatients	
<b>267</b> .....	<b>58</b>
Low Reliability of Home-Based Diagnosis of Malaria in a Rural Community in Western Kenya	
<b>269</b> .....	<b>58</b>
Where There Are No Pharmacists	
<b>270</b> .....	<b>59</b>
Health Care Payments in the Asia Pacific: Validation of Five Survey Measures of Economic Burden	
<b>271</b> .....	<b>59</b>
Factors Influencing Prescribing Behaviour of Physicians in Greece and Cyprus	
<b>275</b> .....	<b>60</b>
Impact of Generic Substitution Practice on Care of Diabetic Patients	
<b>276</b> .....	<b>60</b>
Health Care Payments in the Asia Pacific: Validation of Five Survey Measures of Economic Burden	
<b>278</b> .....	<b>61</b>
Trends in Pricing Policy of Generics: Global Implications	
<b>279</b> .....	<b>62</b>
Intensity of Reforms Resulting in Considerable Differences in Generic Utilisation across Europe; Implications for Others	
<b>281</b> .....	<b>62</b>
Risk-Sharing Arrangements—Opportunity or Threat to Fund New Medicines?	
<b>282</b> .....	<b>63</b>
Care Needed When Comparing IMS and Administrative Databases in Cross National Comparative Studies?	
<b>283</b> .....	<b>64</b>
Intensity of Individual Reforms Results in Considerable Differences in Subsequent Utilisation; Implications for Countries When Contemplating Future Initiatives	
<b>285</b> .....	<b>65</b>
Out of Pocket and Out of Reach: The Unaffordability and Unavailability of Medicines in Low- and Middle-Income Countries	
<b>286 Policy, Regulation, and Governance</b> .....	<b>66</b>
Measuring Transparency in the Public Pharmaceutical Sector. National Assessment for Costa Rica	
<b>287</b> .....	<b>66</b>
Regulating Supply Chain Mark-Ups to Control Medicine Prices—A Review of the Literature in Low- and Middle-Income Countries	
<b>291</b> .....	<b>67</b>
Randomized Controlled Study of Antibiotic Approval Program on Patients' Clinical Outcomes and Antibiotic Expenditures	
<b>293</b> .....	<b>67</b>
Cost as a Barrier to Access: Availability, Affordability, and Identifying Component Cost of Essential Medicines	
<b>294</b> .....	<b>68</b>
Impact of the WHO Guide to Good Prescribing on Medical Students	
<b>298</b> .....	<b>68</b>
Reimbursement Price, Market Structure, and Pharmaceutical Firm Behavior in Korea	
<b>300</b> .....	<b>69</b>
"I Wish I Had AIDS": Qualitative Study on Access to Health Care Services for HIV/AIDS and Diabetic Patients in Cambodia	
<b>301</b> .....	<b>69</b>
Household Survey on Medicine Use in Oman	
<b>306</b> .....	<b>70</b>
Prophylactic Antimicrobials: Triumph Over Cancer Chemotherapy Complications?	
<b>307</b> .....	<b>70</b>
Effect of Removing Direct Payment for Health Care on Utilization and Health Outcomes in Ghanaian Children: A Randomized Controlled Trial	

<b>309</b> .....	Magnitude of and Contributing Factors to Antibacterial Resistance in Ethiopia	<b>71</b>
<b>312</b> .....	Mapping the Private Sector Distribution Chain to Understand Barriers and Opportunities for Improved Access to Antimalarials in Six Low-income Countries in Africa and South-East Asia	<b>72</b>
<b>313</b> .....	Regionalisation of Pharmacovigilance in Uganda	<b>72</b>
<b>314</b> .....	Feasibility and Impact of Deploying Artemether-Lumefantrine (AL) At Community Level with the Introduction of Rapid Diagnostic Test (RDT)	<b>73</b>
<b>318</b> .....	Household Drug-Storing Practices Among Community Residents in Paknaan, Mandaue City, Philippines, 2010	<b>74</b>
<b>319</b> .....	Identifying Key Beliefs of Self Medication with Antibiotics in Yogyakarta City, Indonesia	<b>74</b>
<b>320</b> .....	Prescribing Pattern of Physicians in Rural Health Insurance Program in Primary Health Care Facilities in Iran	<b>75</b>
<b>323</b> .....	Development and Implementation of an Evidence-Based Drug List for Rural Health Insurance Program in Iran	<b>76</b>
<b>324</b> .....	Effects of an Intervention on the Use of Medicines in Herat Province of Afghanistan	<b>76</b>
<b>326</b> .....	Assessment of the Impact of Market Regulation in Mali on the Price of Essential Medicines Provided through the Private Sector	<b>77</b>
<b>330</b> .....	Editor Training Program	<b>77</b>
<b>334</b> .....	Factors Affecting Patients' Incomplete Understanding of Prescriptions	<b>78</b>
<b>337</b> .....	Progress in Standard Indicators of Medicines Use Over 20 Years	<b>79</b>
<b>338</b> .....	Medicine Use in Children Under 5: 20 Years of Practice Patterns and Intervention Effects	<b>79</b>
<b>339</b> .....	Do Countries with Pharmaceutical Policies Have Better Medicines Use Than Those without?	<b>80</b>
<b>340</b> .....	Surveillance of Antimicrobial Use in Resource-Constrained Community Settings	<b>81</b>
<b>341</b> .....	Surveillance of Antimicrobial Resistance in Resource-Constrained Community Settings	<b>81</b>
<b>343</b> .....	Inefficiencies Due to Poor Access to and Irrational Use of Medicines to Treat Acute Respiratory Tract Infections in Children	<b>82</b>
<b>344</b> .....	Adherence to and Outcome of Isoniazid Preventive Chemotherapy in Household Children Contact with Adults Having Pulmonary Tuberculosis: A Prospective Facility-Based Study in Alexandria, Egypt	<b>82</b>
<b>345</b> .....	The Irrational Use of Drugs in Rural China: Evidences from Two Provinces	<b>83</b>
<b>346</b> .....	Newspaper Column for Consumer Education on Medicine Use—An Indian Columnist's Experience	<b>84</b>
<b>353</b> .....	Does Antimicrobial Use Granger-Cause Community-Based Antimicrobial Resistance?	<b>84</b>
<b>354</b> .....	Behavioural Model for Community-Based Antimicrobial Resistance, Vellore, India	<b>85</b>
<b>356</b> .....	The Dilemma of Price Regulation and Pharmaceutical Centralized Bidding in China	<b>86</b>
<b>357</b> .....	Availability, Price, and Affordability of Cardiovascular Medicines: A Comparison across 36 Countries Using WHO/HAI Data	<b>86</b>
<b>358</b> .....	In Scaling Up Health Related MDGs, How Much More Will It Cost to Procure Essential Medicines for 49 Low-Income Countries?	<b>87</b>
<b>359</b> .....	Challenges When Introducing Generic Policies to Enhance Their Utilisation: Impact and Next Steps	<b>87</b>

<b>360</b> .....	Care Needed When Introducing Generic Policies to Reduce Costs: Experiences From Abu Dhabi	<b>88</b>
<b>363</b> .....	Managing a continuum-of-care with Revolving Drug Fund for People with Diabetes (DM) and Hypertension (HBP) through a Peer Educator Network in rural Cambodia	<b>89</b>
<b>365</b> .....	Peer-to-Peer Counseling: A Model for Improving Male Involvement in ARV Treatment Access and Adherence among PLWHA in Kwara State, Nigeria	<b>90</b>
<b>366</b> .....	Prescribing Pattern and Therapeutic Drug Monitoring of Vancomycin at a Tertiary Hospital in Oman	<b>90</b>
<b>367</b> .....	Health Systems Barriers that Determine Access to Antiretroviral Drugs in Southeast Nigeria	<b>91</b>
<b>371</b> .....	Improving Access to Routine Medication from a Revolving Drug Fund for Chronic Patients in Rural Cambodia	<b>91</b>
<b>374</b> .....	Study on National Essential Medicines Lists from 8 Countries of the Western African Economic and Monetary Union	<b>92</b>
<b>376</b> .....	Assessment of Drug Utilization Patterns in Some Health Insurance Outpatient Clinics in Alexandria	<b>93</b>
<b>377</b> .....	Assessment of Patient Knowledge Regarding Drugs Prescribed and Dispensed in Some Health Insurance Outpatient Clinics in Alexandria	<b>93</b>
<b>378</b> .....	Nonadherence to HAART: A Cross-Sectional Two-Site Hospital-Based Study	<b>94</b>
<b>379</b> .....	Consumption of Antibiotics Before and After Sales Regulations in Chile and Venezuela	<b>94</b>
<b>384</b> .....	Examples of Interventions to Contain AMR based on International Consultations	<b>95</b>
<b>385</b> .....	Commercial Innovation to Improve Health Care Access at the Bottom of the Pyramid in Rural India	<b>96</b>
<b>386</b> .....	Predictors of Antibiotic Use in African Communities: Evidence from Household Surveys in Five African Countries	<b>97</b>
<b>391</b> .....	Medication Administration Management: Assessment of Critical Care Nurses' Baseline Knowledge and Strategies for Building Awareness	<b>97</b>
<b>393</b> .....	Prices of Medicines, Including High-Cost Cancer Medicines, in a Hospital Setting Compared to Outpatient Use	<b>98</b>
<b>395</b> .....	Balancing Gender-Based Inequities to Improve Access and Uptake of TB Treatment	<b>98</b>
<b>397</b> .....	Comparative Analysis of the Medicines Financing System of 11 Countries Included in the Pilot of the "WHO Country Profiles" Project	<b>99</b>
<b>400</b> .....	Policy Making Support by Sharing of Information and Experiences among the PPRI Network	<b>100</b>
<b>404</b> .....	Assessing Local Manufacturing Capacity for Child-Specific Dosage Formulations: The Case of Ghana	<b>100</b>
<b>405</b> .....	Management Information System in Promoting Rational Drug Use in Iran	<b>101</b>
<b>406</b> .....	Can the Application of the International Health Regulations to Antimicrobial Resistance Events Help to Preserve Antimicrobials?	<b>101</b>
<b>407</b> .....	Medicine Use from Birth to Two Years of Age: The 2004 Pelotas (Brazil) Birth Cohort Study	<b>102</b>
<b>408</b> .....	Factors Associated to Medicine Use Among Children from the 2004 Pelotas Birth Cohort (Brazil)	<b>103</b>
<b>409</b> .....	Medicine Utilization in Adolescents Aged 11 from the Pelotas (Brazil) 1993 Birth Cohort Study	<b>103</b>
<b>411</b> .....	Direct-to-Consumer Advertising for Pharmaceuticals in Jordan from a Gender Perspective	<b>104</b>
<b>413</b> .....	Cost Impact of Purchasing Pharmaceuticals Jointly in the Public Health Sector in Jordan	<b>104</b>

<b>414</b> .....	<b>105</b>
A Comparison of Generic and Originator Brand Drug Prices between Jordan and the United Kingdom	
<b>415</b> .....	<b>105</b>
One-Year Assessment of Joint Pharmaceutical Procurement in the Jordanian Public Health Sector	
<b>416</b> .....	<b>106</b>
An Audit of Case Management of Common Childhood Illnesses in Hospitals in Ghana	
<b>420</b> .....	<b>106</b>
Field Testing WHO's Rational Use of Medicines Rapid Assessment Tool in Grahamstown, South Africa	
<b>421</b> .....	<b>107</b>
Assessment of Availability, Price, and Affordability of Medicines for Children In Ghana	
<b>423</b> .....	<b>108</b>
The Rational Use and Access to Medicines by the Citizens: The Greek Experience	
<b>426</b> .....	<b>108</b>
What Is Needed to Sustain a National Academic Detailing Workforce?	
<b>427</b> .....	<b>109</b>
Building Confidence in Generic Medicines	
<b>429</b> .....	<b>109</b>
Perspectives of Rational Use of Medicines in the EU	
<b>433</b> .....	<b>110</b>
Simplifying Vaccine Delivery with Combination Vaccines—Evidence from a Time-Motion Study in India	
<b>434</b> .....	<b>111</b>
Does Artemether-Lumefantrine Subsidy to Private Sector Improve Prompt Access to Antimalarials to Febrile Children in Rural Areas?	
<b>439</b> .....	<b>111</b>
Role of Patient Demand in the Treatment of Uncomplicated Malaria at Public and Private Health Facilities in Southeastern Nigeria	
<b>445</b> .....	<b>112</b>
Preliminary Results of a Systematic Review of the Effectiveness and Costs of Strategies to Improve Health Care Provider Performance in Low- and Middle-Income Countries	
<b>448</b> .....	<b>112</b>
Effectiveness of a Medical Education Intervention to Treat Hypertension in Primary Care	
<b>449</b> .....	<b>113</b>
Up-to-Date, Evidence-Based Advice for Busy Clinicians	
<b>450</b> .....	<b>114</b>
Impact of Comprehensive Efforts on the Performance of a Pharmacovigilance System in Oman	
<b>453</b> .....	<b>114</b>
Evaluation of Prices and Availability of Essential Medicines in Grahamstown, South Africa	
<b>460</b> .....	<b>115</b>
An Action Plan for the Selection of Essential Medicines	
<b>461</b> .....	<b>115</b>
What Do Managers and Prescribers of the Brazilian Health System Think of Essential Medicines? Preliminary Results of a Nationwide Qualitative Study	
<b>466</b> .....	<b>116</b>
Quality of Some Pharmaceutical Products Manufactured in Kenya	
<b>467</b> .....	<b>117</b>
Establishing a Nationally Consistent Approach to Implementing the Principles of Good Prescribing in Health Practitioner Education	
<b>468</b> .....	<b>117</b>
Improving Diabetes Management in Primary Care	
<b>471</b> .....	<b>118</b>
Improving the Rational Medicine Use through the MTP Approach in Cambodia	
<b>473</b> .....	<b>118</b>
Implementation of a Policy for Monitoring Prescribing Practices in Public Health Care Outlets in Nepal	
<b>474</b> .....	<b>119</b>
High adherence to artemether-lumefantrine treatment in children under real-life situation in rural Tanzania	
<b>477</b> .....	<b>120</b>
Is Performance-Based Reward the Strategy of the Future for Strengthening the Quality of Reporting and Immunization Systems?—Experiences from GAVI	
<b>478</b> .....	<b>120</b>
Generic Medicine Pricing Policies Evaluation in Indonesia and the Impact on Availability and Medicine Price in Private Sectors	
<b>483</b> .....	<b>121</b>

Differences in External Price Referencing in Europe—A Descriptive Overview	
<b>484</b> .....	<b>122</b>
How Much of the Price Variance of Medicines Can Be Explained by External Price Referencing?—A price Comparison among 15 European Countries	
<b>486</b> .....	<b>122</b>
Prevalence and Risk Factors of Adverse Effects of Second Line Anti-Tuberculous Medicines In A Treatment Facility in Namibia: 2009-10	
<b>488</b> .....	<b>123</b>
Parents' and Caretakers' Administration Practices and Formulation Preferences of Children's Medicine in Tanzania	
<b>489</b> .....	<b>124</b>
Antibiotic Knowledge and Self-Care for Acute Respiratory Tract Infections in Mexico	
<b>490</b> .....	<b>124</b>
Policies to Increase Use of Generic Medicines in Low- and Middle-Income Countries: A Literature Review of Implementation Research	
<b>492</b> .....	<b>125</b>
A Blended e-Learning Course—"Management of Medicines in International Health"—Contributes to Knowledge Transfer and Improving Medicines Use	
<b>493</b> .....	<b>125</b>
Policy for Rational Regulation and Quality Use of Natural Health Products in the Philippines	
<b>496</b> .....	<b>126</b>
Reasons for Nonadherence to Antiretroviral Therapy among Adult Patients Receiving Free Treatment at a Tertiary Care Hospital in Delhi	
<b>497</b> .....	<b>126</b>
Measuring Access to Essential Medicines in Kenya Using the Standardized WHO Level II Health Facility Assessment	
<b>498</b> .....	<b>127</b>
Taxes on Medicines	
<b>499</b> .....	<b>128</b>
Selection of Essential Medicines	
<b>502</b> .....	<b>128</b>
Process and Lessons from the Philippine Pharmaceutical Sector Scan	
<b>505</b> .....	<b>129</b>
Improving Adherence to Antiretroviral Treatment in Uganda: Facility-Based Minimal-Input Intervention	
<b>507</b> .....	<b>130</b>
The Evolution of Taiwan's National Health Insurance Drug Policy—Review and Analysis	
<b>508</b> .....	<b>130</b>
Genital Ulcer Disease Treatment Policies and Access to Acyclovir in Eight Sub-Saharan African Countries	
<b>509</b> .....	<b>131</b>
Impact of Implementing Antibiotic Sales Restrictions: Reactions of Key Stakeholders and Citizens in Mexico	
<b>510</b> .....	<b>131</b>
"Under the Radar": Nurse Prescribers and Pharmaceutical Industry Promotions	
<b>511</b> .....	<b>132</b>
Developing Superior Screening Technology for Monitoring Medicine Quality in Low-Resource Countries	
<b>513</b> .....	<b>133</b>
Actions of the National Regulatory Authorities in Developing Countries Following US FDA and EMA Safety Alerts on Rosiglitazone	
<b>514</b> .....	<b>133</b>
Spillover Effects of Prescribing Restrictions for Trastuzumab in Australia	
<b>516</b> .....	<b>134</b>
SMS for Life: A Pilot Project to Reduce or Eliminate Stock-outs and Improve Access to Malaria Medicine at the Remote Health Facility Level, Using Innovative SMS, Internet, and Mapping Technologies	
<b>517</b> .....	<b>135</b>
The Knowledge, Perceptions, and Practice of Pharmacovigilance among Community Pharmacists in Lagos State, Southwest Nigeria	
<b>519</b> .....	<b>135</b>
Educational Intervention to Combat Counterfeit Medicines in Selected Areas in the Philippines	
<b>524</b> .....	<b>136</b>
Availability of Children's Medicines in Africa, 2007	
<b>526</b> .....	<b>136</b>
Antibiotic Prescription by Informal Health Providers in Ujjain District, India	
<b>527</b> .....	<b>137</b>

Access and Use of Medicines in Kandy District, Sri Lanka	
<b>528</b> .....	<b>138</b>
Patient Behavior when Prescribed Non-Affordable Drugs in University Hospitals of Alexandria, Egypt	
<b>531</b> .....	<b>138</b>
Pharmaceutical Human Workforce for Access to and Use of Medicines in Countries: Estimate Gaps and Identify Relevant Strategies for Human Resources Development	
<b>532</b> .....	<b>139</b>
Decongesting Public Health Facilities is Associated with Better Clinical Outcomes Among Patients Initiating Antiretroviral Therapy in Uganda	
<b>535</b> .....	<b>140</b>
Baseline Assessment of Pharmaceutical Situation in Southern African Development Community	
<b>537</b> .....	<b>140</b>
Piloting the Development of a Cost-Effective, Evidence-Informed Clinical Pathway: Managing Hypertension in Jordanian Primary Care	
<b>538</b> .....	<b>141</b>
Economic Burden and Health Consequences of Antibiotic Resistance in Patients at a Tertiary Care Hospital, Vellore, South India	
<b>539</b> .....	<b>141</b>
Effectiveness of an Antibiotic Policy in Containing Antibiotic Use at a Tertiary Care Hospital, Vellore, South India	
<b>541</b> .....	<b>142</b>
R&D Pharmaceutical Industry's Partnerships to Improve Developing World Health	
<b>542</b> .....	<b>143</b>
Improving Adherence and Clinic Attendance Among Patients on Antiretroviral Treatment in Kenya: A System Level Intervention	
<b>543</b> .....	<b>143</b>
Routine Assessment of Patients' Attendance and Adherence to Antiretroviral Treatment In Kenya – Providers' Views on Usefulness to Improve Performance	
<b>544</b> .....	<b>144</b>
Improving Appointment Keeping and Adherence Monitoring In HIV Facilities in Kenya: Views of Providers and Patients	
<b>545</b> .....	<b>145</b>
Existing Capacity to Manage Pharmaceuticals and Related Commodities in East Africa: An Assessment with Specific Reference to Antiretroviral Therapy	
<b>546</b> .....	<b>145</b>
Challenges of Building Effective Pharmacovigilance Systems in Resource Limited Settings: A Case Study of Kampala Region, Uganda	
<b>553</b> .....	<b>146</b>
Community Learns Appropriate Antibiotic Use Through Kindergarten Performances	
<b>555</b> .....	<b>146</b>
Access to Essential Medicines as Part of the Right to Health in National Constitutions of 186 Countries	
<b>556</b> .....	<b>147</b>
Trends in Antimicrobial Use Among Outpatients in New Delhi, India	
<b>557</b> .....	<b>147</b>
Pharmaceutical Regulation in 12 Countries	
<b>559</b> .....	<b>148</b>
Pattern of Use of Complementary and Alternative Medicine (CAM) Among Patients with Type 2 Diabetes Mellitus (T2DM) in Alexandria, Egypt	
<b>560</b> .....	<b>149</b>
Role of Free Provision on Household Expenditures for Medicines in Brazil	
<b>563</b> .....	<b>149</b>
Unit Dose System – Implementation in a Secondary, Multispecialty Referral Hospital: Sohar Hospital, Ministry of Health, Sultanate of Oman	
<b>566</b> .....	<b>150</b>
Cost Effectiveness of Simvastatin Compared with Atorvastatin for Low-Density Lipoprotein Cholesterol (LDL-C) in Diabetes Patients with Dyslipidemia at a General Hospital, Northeast of Thailand	
<b>572</b> .....	<b>151</b>
Antibiotics Smart Use Program: A Mixed Model to Promote Rational Use of Medicines	
<b>580</b> .....	<b>151</b>
Pilot study of cohort event monitoring (CEM) on patients treated for malaria with Artemisinin Based Combination Therapies (ACTs) in Nigeria	
<b>582</b> .....	<b>152</b>

Antibiotic Prescribing Practices of Primary Care Prescribers for Acute Respiratory Tract Infections and Diarrhoea in New Delhi, India	
<b>584</b> .....	<b>153</b>
Factors Influencing Antibiotic Prescribing by Primary Care Doctors in Delhi, India: Qualitative Study	
<b>585</b> .....	<b>153</b>
Importance of Monitoring Patients on Atypical Antipsychotics	
<b>587</b> .....	<b>154</b>
Reasons for Rejection of Medications by Patients in Oman	
<b>591</b> .....	<b>154</b>
Medication Adherence: Comparative Study between Institutionalized and Community-Dwelling Elderly	
<b>592</b> .....	<b>155</b>
Financial Impact of Judicious Use of Medicine in Primary Care	
<b>593</b> .....	<b>156</b>
Unbranded Advertising of Prescription Medicines—A Systematic Literature Review	
<b>596</b> .....	<b>156</b>
Integrating Pharmacovigilance in Revised National Tuberculosis Control Programme of India: A Pilot Study	
<b>599</b> .....	<b>157</b>
Marketing and Promotion of the Pharmaceutical Industry: Snapshot of Current Practice Within, or With Possible Implications In, Low- and Medium-Income Countries	
<b>600</b> .....	<b>157</b>
Anecdotal Evidence for Ways in which the Originator Pharmaceutical Industry Has Contributed to Improving the Appropriateness of Medicine Use in Low-Income Countries through Product and Packaging Adaptations	
<b>602</b> .....	<b>158</b>
Survey on the Use of Medicines by Consumers in Federal Territories of Kuala Lumpur and Putrajaya	
<b>604</b> .....	<b>159</b>
Survey on the Use of Medicines by Malaysian Consumers	
<b>606</b> .....	<b>159</b>
In-Service, Problem-Based, Pharmacotherapy Teaching and Clinical Pharmacology Services Contribute to Improved Medicine Use in Children	
<b>607</b> .....	<b>160</b>
Medicines Lists as Policy Instruments in Tatarstan and Russian Federation in the 21st Century	
<b>608</b> .....	<b>161</b>
Availability, Price, and Affordability of Key Essential Medicines for Children in a Resource-Limited Country	
<b>611</b> .....	<b>161</b>
Health Systems Approach to Improving the Use of Medicines in the S.E. Asian Region (SEAR)	
<b>612</b> .....	<b>162</b>
Facilitating the Preparation of Essential Medicines List for Children in India: Lessons Learned	
<b>615</b> .....	<b>163</b>
Better Medicines for Children in India: A Project to Improve Access to Essential Medicines	
<b>617</b> .....	<b>163</b>
Role of Tendering of Medicines in European Countries	
<b>621</b> .....	<b>164</b>
Assessment of Generic Antimicrobial Unit Retail Price Mark-Ups Applied in Public Hospitals in Rwanda	
<b>622</b> .....	<b>164</b>
Impact of Regulatory Requirements on Medicine Access in African Countries: Perceptions and Experiences of Pharma Companies in South Africa	
<b>624</b> .....	<b>165</b>
Relationship Between Tariffs, Prices, and Consumption of Interferon	
<b>627</b> .....	<b>166</b>
Analysis of Clinical Pharmacists' Interventions on Discharged Patients' Prescription in a Tertiary Care Teaching Hospital in Oman	
<b>632</b> .....	<b>166</b>
Caution! Look Alike, Sound Alike Medication	
<b>633</b> .....	<b>167</b>
The Rise and Fall of Supervision in a Project Designed to Strengthen Supervision on the Integrated Management of Childhood Illness (IMCI) Strategy in Benin	
<b>634</b> .....	<b>167</b>
Access to Antimalarial Medicines: The Impact Malaria Approach	
<b>635</b> .....	<b>168</b>
Multifaceted Intervention to Improve Health Worker Adherence to Integrated Management of Childhood Illness Guidelines in Benin	
<b>637</b> .....	<b>169</b>

	Trends of Current Treatment and Outcomes of the Management of Type 2 Diabetic (T2DM) Patients in Egypt: Results from the International Diabetes Management Practices Study (IDMPS)	
<b>638</b>	Access to Medicines in Nigeria – Gender Perspective	<b>169</b>
<b>639</b>	New Method for Identification and Antibiotic Resistance Screening of Bacteria	<b>170</b>
<b>640</b>	Gender and Medicines In HIV/AIDS, Tuberculosis, and Malaria in Low- and Middle-Income Countries: A Systematic Review	<b>170</b>
<b>642</b>	Can the Indian Government Improve Access to Medicines Through Generic Drug Stores?	<b>171</b>
<b>643</b>	Ethical Issues Raised by the Inclusion of Gender in the Implementation of Prevention of Mother-to-Child Transmission of HIV (PMTCT) Program in Burkina Faso	<b>171</b>
<b>647</b>	Comparison of the National List of Essential Medicines (India) with the WHO Model Lists of Essential Medicines and Essential Medicines for Children	<b>172</b>
<b>651</b>	Gender Inequalities in Medicine Expenditure and Family Budget Allocated to Medicines in a Southern Brazilian City: Population-Based Study	<b>173</b>
<b>658</b>	Piloting a Medical Injection Safety Assessment Protocol in Cameroon: Indirect Reuse Represents Risk of Blood-Borne Virus Transmission	<b>173</b>
<b>659</b>	Promoting Proper Use of Medicines in School Children: An Interventional Study	<b>174</b>
<b>664</b>	Knowledges and Attitudes toward Emergency Contraceptive Pill among Thai Men in Bangkok and Its Utilization	<b>174</b>
<b>667</b>	Electronic Monitoring to Assess Adherence and Validate Alternative Adherence Measures in Tuberculosis Patients on Community-Based Directly Observed Treatment	<b>175</b>
<b>668</b>	Use of Antibiotics in the Alexandria Community Setting: Magnitude and Pattern	<b>176</b>
<b>671</b>	Analysis of Clinical Trials in Children Registered in the Clinical Trials Registry of India	<b>176</b>
<b>673</b>	Impact of Standard Treatment Guidelines and Patient Education on Asthma Control and Knowledge in Asthmatic Patients: A Controlled Trial	<b>177</b>
<b>676</b>	Evaluation of Prescribing Pattern of Physicians in Various Health Care Facilities in Turkey with Respect to the Rational Use of Medicines Principles	<b>177</b>
<b>677</b>	Analysis of Medicines Dispensed by Court Order in the Court of Rio De Janeiro: The Application of Scientific Evidence in Decision-Making Process	<b>178</b>
<b>678</b>	Costs and Effects of a Multifaceted Intervention to Improve the Quality of Care of Children in District Hospitals in Kenya	<b>179</b>
<b>679</b>	Brazilian Courts as a Pathway to Medicines which Represent Pharmacotherapeutic Gaps	<b>179</b>
<b>682</b>	The Assessment of Relation between Inappropriate Medication and Health Status Among Elderly Discharged from Hospitals Affiliated with Tehran University of Medical Sciences, through Beers Criteria	<b>180</b>
<b>683</b>	Analysis of NMP Documents of the Region of the Americas	<b>181</b>
<b>690</b>	Drug and Therapeutics Committees in Africa and Asia: From Training to Implementation	<b>181</b>
<b>691</b>	Attitudes, Beliefs, and Prescription Habits of Greek Physicians Regarding Generic Drugs	<b>182</b>
<b>694</b>	Indicator-Based Survey Tool to Determine the Use of Antimicrobials and Knowledge about Drug Resistance in the Community	<b>182</b>
<b>695</b>		<b>183</b>

Steady Persistence While Chasing the Elusive: When Guidelines and Policies for Antimicrobial Use Clash with the 800-Pound Gorilla	
<b>696</b> .....	<b>184</b>
Evaluation of a Continuing Medical Education Program for Primary Care Services in the Hypoglycemic Agent's Prescription in Diabetes Mellitus Type 2	
<b>697</b> .....	<b>184</b>
Access to and Use of Medicines by Households in Armenia: Impact of Current Policy on Reimbursement of Medicines	
<b>699</b> .....	<b>185</b>
Capacity-Building for Country and Regional Level Advocacy and Interventions to Contain Antimicrobial Resistance in Africa	
<b>700</b> .....	<b>185</b>
Access to Medicines in Guatemala, Honduras, and Nicaragua: The Challenge of Adapting Methodologies	
<b>702</b> .....	<b>186</b>
Antibiotic Prescribing in a Teaching and a Non-Teaching Private, Non-Computerized, Tertiary Care Hospital in Ujjain District, India	
<b>703</b> .....	<b>187</b>
Irrational Prescribing Pattern for Children with Upper Respiratory Tract Infection (URTI) in Indonesia	
<b>704</b> .....	<b>187</b>
Retail Drug Market and the Price of Malaria Medicines in Enugu Urban, Southeast Nigeria: Implications for Affordability and Access to Artemisinin-Based Combination Therapy	
<b>705</b> .....	<b>188</b>
Clinical Impact of Adherence to Pharmacotherapeutic Guidelines on the Outcome in Patients with Chronic Heart Failure	
<b>706</b> .....	<b>189</b>
Medicine Prices and Availability in Southern Brazil	
<b>708</b> .....	<b>189</b>
Assessment of the Effectiveness and Safety of Outpatient Treatment of Severe Pneumonia Among Egyptian Children with Oral Amoxicillin	
<b>709</b> .....	<b>190</b>
Effectiveness of Oral Zinc Supplementation in the Treatment of Acute, Watery Diarrhea	
<b>711</b> .....	<b>190</b>
Transparency Monitoring Study: A Rapid Assessment of Transparency in Key Functions of Pharmaceutical Services in 15 Countries	
<b>712</b> .....	<b>191</b>
Evaluating the Impact of Subsidized Artemether-Lumefantrine in the Retail Sector on Coverage of Prompt Effective Treatment of Children Under Five in Kenya- A Cluster Randomized Controlled Trial	
<b>713</b> .....	<b>192</b>
Knowledge, Attitudes, and Perceptions on Antimicrobial Resistance and Antibiotic Use Among Hospital Staff in Kenya	
<b>714</b> .....	<b>192</b>
Pharmacovigilance of Antimalaria Drug Treatment in Enugu State, Nigeria: Community and Health Workers' Perceptions and Suggestions for Reporting Adverse Drug Events	
<b>716</b> .....	<b>193</b>
Evolution of Generic Medicine Market Share in the Pharmaceutical Retail Sector of 21 Low- and Middle-Income Countries Between 1999 and 2009: Time-Series Analysis	
<b>718</b> .....	<b>194</b>
Does Your Health Care Depend on How Your Insurer Pays Providers? Variation in Utilization and Outcomes in Thailand	
<b>721</b> .....	<b>194</b>
Assessing the Readiness of Pharmacy Outlets to Support Chronic Care: Results from a National Assessment in Kenya	
<b>722</b> .....	<b>195</b>
Piloting the Use of Mobile Short Messaging Systems (SMSs) to Improve Access to Medicines: Experiences from Kenya	
<b>727</b> .....	<b>196</b>
Is a Standard Kit an Effective Way to Optimise Use of Limited Resources and Increase Availability of Medicine? Experiences from Reintroducing Standard Kits in Resource-Poor Settings in Uganda	
<b>728</b> .....	<b>196</b>
Impact of Visualizing Performance in Improving Medicines Management in Public Health Sector Facilities in Uganda	
<b>729</b> .....	<b>197</b>

Infectious Diseases, Antibiotic Use, and Antibiotic Resistance in Context of Environmental Changes: Study Among Community Members in Orissa, India	
<b>730</b> .....	<b>197</b>
Comparative Evaluation of Quality of Some Generic Versus Branded Medicines Using Compendia Standard Tests In India	
<b>731</b> .....	<b>198</b>
New Performance-Based Reward Strategy to Improve Pharmacy Practices, Financial Management, and Appropriate Medicines Use in the Public Sector in Uganda	
<b>733</b> .....	<b>199</b>
Pharmaceutical Situation Assessment: Methodological Challenges for Different Contexts	
<b>734</b> .....	<b>199</b>
Two-Year Experience of Antibiotics Smart Use Pilot Project in Saraburi, Thailand	
<b>740</b> .....	<b>200</b>
Antihypertensive Medicines Prescriptions Before and After the Nigeria Hypertension Society Guidelines and Prescriber's Awareness of the Guideline	
<b>741</b> .....	<b>200</b>
Pharmaceutical Situation Analysis of Mongolia	
<b>742</b> .....	<b>201</b>
Use of Antibiotics Among Mothers After Normal Delivery in Two Provinces in Lao PDR	
<b>744</b> .....	<b>202</b>
Effects of a Mobile Phone Short Message Service (SMS) on Antiretroviral Treatment Adherence in Kenya (WelTel Kenya1): A Randomized Trial	
<b>745</b> .....	<b>202</b>
Different Approaches for Delivery of Intermittent Preventive Treatment (IPT) to Pregnant Women in Burkina Faso	
<b>746</b> .....	<b>203</b>
Effectiveness of Using RDTs and ACTs for Home Management of Malaria in Children Under 5 Years Old in Zambia	
<b>747</b> .....	<b>203</b>
External Reference Pricing (ERP): Existing Evidence and Lessons for Developing Countries	
<b>748</b> .....	<b>204</b>
Influence of Mefloquine Malaria Prophylaxis on HIV Disease Progression: A Randomized Placebo-Controlled Trial	
<b>751</b> .....	<b>204</b>
Case Study of the Implementation of Good Governance for Medicines Programme in Mongolia	
<b>754</b> .....	<b>205</b>
Effects of the 2005 Change in National Antimalarial Treatment Policy on Prescribing Practices in Two Referral Hospitals in Benin City, Nigeria	
<b>758</b> .....	<b>206</b>
Antibiotics with Facilitated Referral to a Rural Health Center Using Zambian Trained Traditional Birth Attendants as a Strategy for Reducing Neonatal Mortality	
<b>759</b> .....	<b>206</b>
Implementing an Egyptian Pharmacovigilance System: University and Public Hospitals' Experience	
<b>760</b> .....	<b>207</b>
Social Determinants of Access to Medicines in 3 Central American Countries	
<b>762</b> .....	<b>207</b>
Practice and Predictors of Self-Medication Among Urban and Rural Adults in Sri Lanka Three Decades after Market Economic Reforms	
<b>763</b> .....	<b>208</b>
Assessing the Extent of Pharmaceutical Care Provision in Kigali Community Pharmacies	
<b>764</b> .....	<b>209</b>
Outcomes of Pharmaceutical Care in Schizophrenic Patients	
<b>766</b> .....	<b>209</b>
Awareness and Adherence to Methicillin-Resistant S. Aureus Guidelines, as per WHO, at Alexandria University Hospitals	
<b>769</b> .....	<b>210</b>
Strengthening Pharmacovigilance Systems: Experiences from Kenya	
<b>770</b> .....	<b>211</b>
Human Resources for Health: Preservice Training of Pharmacy Students on Effective Management of Antiretroviral Therapy Commodities in Kenya	
<b>771</b> .....	<b>211</b>
Survey of the Availability and Prices of Children's Medicine in Chhattisgarh State	

<b>772</b> .....	<b>212</b>
Adherence to Treatment Guidelines for Acute Diarrhoea in Children up to 12 Years in Ujjain, India	
<b>773</b> .....	<b>212</b>
Tsunami Drug Donations in Sri Lanka: Have the WHO Guidelines on Drug Donations been Effective in Meeting Public Health Pharmaceutical Needs in Times of Disaster?	
<b>775</b> .....	<b>213</b>
Affordability of Medicines for Treating Chronic Diseases in Southern Brazil	
<b>777</b> .....	<b>214</b>
“A Healthy Box Project” for Improving Self-Administration of Medicines among the Pre-elderly and Elderly with Chronic Diseases: A Case Study in Horathep Subdistrict, Saraburi Province, Thailand	
<b>778</b> .....	<b>214</b>
Using Routine Information for Improving Rational Prescribing	
<b>779</b> .....	<b>215</b>
People Living with HIV/AIDS : Role of Community Pharmacist	
<b>780</b> .....	<b>216</b>
Pattern of Medicine Use Among In-Patients in a Tertiary Health Care Setting Using the WHO Prescribing Indicators	
<b>781</b> .....	<b>216</b>
Teaching Rational Prescribing to Medical Undergraduates: Impact of the Introduction of a Specialized Module	
<b>783</b> .....	<b>217</b>
Evidence on Availability and Stock-Outs of Essential Medicines: A Study of Two Diverse Government Drug Procurement and Distribution Systems in India	
<b>786</b> .....	<b>217</b>
Predictors of Switching Antiretroviral Regimen Among Clients Attending TASO Jinja, Uganda	
<b>787</b> .....	<b>218</b>
Standardization of Prescribing and Using Oral Liquid Dosage Forms (OLDFs)	
<b>788</b> .....	<b>219</b>
Role of Pharmaceutical Industry Marketing Codes in Securing Good Governance	
<b>790</b> .....	<b>219</b>
Empathic Caring Consultation (ECC): Will It Be Able to Reduce the Unnecessary Use of Analgesics?	
<b>792</b> .....	<b>220</b>
Use of Thai Vigibase to Assess the Safety of Antituberculosis Drugs for Thai Patients: Application from Thai Vigibase	
<b>793</b> .....	<b>220</b>
Antibiotic Surveillance in Intensive Care Unit: Quality Assurance of Antibiotic Usage	
<b>794</b> .....	<b>221</b>
Social Disparities in the Use of Prescription Medications: A Population-Based Approach	
<b>795</b> .....	<b>221</b>
Drug System Monitoring and Development Project, Funded by Sin Tax, and the Roles in Promoting Rational Drug Use in Thailand	
<b>796</b> .....	<b>222</b>
Prophylactic Use of Antimicrobials During Surgery	
<b>797</b> .....	<b>223</b>
Mapping Private Sector Pharmacies and their Characteristics in Ujjain District, Central India	
<b>800</b> .....	<b>223</b>
Consumer behavior toward counterfeit drugs: scale development in a developing country setting	
<b>804</b> .....	<b>224</b>
Variation in Service-Providers’ Prescribing Behaviour and Policy Implications for Women with Genitourinary Tract Infections in Ramallah, Occupied Palestinian Territory (oPt)	
<b>806</b> .....	<b>224</b>
Monitoring the Safety of Medicines in Kyrgyzstan	
<b>807</b> .....	<b>225</b>
Using Defined Daily Doses, Pivot Tables, and Charts as a means of Measuring Medicine Utilisation Trends	
<b>810</b> .....	<b>225</b>
Consultation and Dispensing Time at Primary Health Care Facilities in Oman	
<b>811</b> .....	<b>226</b>
Effects of Listing and Delisting in National Essential Medicine List on Utilization Patterns	
<b>812</b> .....	<b>227</b>
Prevalence and Predictors of Potentially Inappropriate Medication Use in Elderly Patients in Two Indian Teaching Hospitals	
<b>813</b> .....	<b>227</b>
Medicines Use in Oman: Public Knowledge, Attitudes, and Practices	

<b>814</b> .....	<b>228</b>
Intensive Hospital-Based Adverse Drug Reactions Monitoring Studies on 5482 Patients of Kashmiri Origin in a Tertiary Care Hospital	
<b>816</b> .....	<b>228</b>
Practice of Community Pharmacists Dispensing Emergency Contraceptive Pills in Chiang Mai, Thailand	
<b>817</b> .....	<b>229</b>
Effects of Patient Tracking Systems and Providers Incentives on Patient Appointment Keeping in Rwanda	
<b>818</b> .....	<b>230</b>
How GGM Program Enhanced National Drug Policy, Thailand Experience	
<b>819</b> .....	<b>230</b>
Universal Health Insurance Coverage and Reimbursement for Medicines in Countries	
<b>822</b> .....	<b>231</b>
Safety and Tolerability Profile of Artemisinin-Based Antimalarial Combination Therapy (ACT) in Adult Nigerians	
<b>825</b> .....	<b>231</b>
Working Together for Mental Health: The Nouadhibou Pilot Experience	
<b>826</b> .....	<b>232</b>
How Sustainable is the EU Regulatory Network in the Context of the Uptake of New Medicines?	
<b>828</b> .....	<b>233</b>
New warnings for medicines labeling and packaging in Brazil	
<b>830</b> .....	<b>233</b>
Successful Intervention to Improve the Pharmaceutical Services in a Region of Brazil	
<b>831</b> .....	<b>234</b>
Medication Among Children in Africa South of Sahara: Qualitative Systematic Review	
<b>832</b> .....	<b>234</b>
A Conceptual Framework for a System-Wide Definition of Access to Medicines	
<b>833</b> .....	<b>235</b>
Bibliometric Study of Publication Patterns in Access to Medicines in Low- and Middle-Income Countries	
<b>834</b> .....	<b>236</b>
Impact of Training, Monitoring, and Mentoring on Drug and Therapeutic Committees in Ghana	
<b>835</b> .....	<b>236</b>
Improving the Use of Artemisinin-Based Combination Therapy in Rural Zambia	
<b>839</b> .....	<b>237</b>
Partnership with State Government to Strengthen HIV/AIDS Commodities Logistics Management System	
<b>840</b> .....	<b>237</b>
Drug Approvals and Medicine Pricing In India	
<b>843</b> .....	<b>238</b>
Quality of Dispensing in Outpatient Pharmacy at Sultan Qaboos University Hospital: Peer Review Audit	
<b>847</b> .....	<b>239</b>
Can Competition Law or Other Competition-Promoting Policies Reduce Medicine Prices in Developing Countries?	
<b>848</b> .....	<b>239</b>
Susceptibility of Methicillin Resistant Coagulase-Negative Staphylococci Isolated from Faecal Samples of Children to Commonly Used Antiseptic Agents	
<b>849</b> .....	<b>240</b>
Pharmaceutical Management Interventions through a Drug and Therapeutics Committee (DTC) in Kabul, Afghanistan: Initial Experience after Decades of Neglect	
<b>850</b> .....	<b>241</b>
Development of a Tool for Simple Visualisation of Periods of ARV Therapy Availability in a Context of Expanding Treatment Coverage	
<b>851</b> .....	<b>241</b>
Is Pediatric Diarrhea Treated Correctly in African Communities? Evidence from Household Surveys in Five African Countries	
<b>852</b> .....	<b>242</b>
Non-Uptake of Antiretroviral Therapy (ART) at a Primary Care Antiretroviral (ARV) Clinic in South Africa	
<b>854</b> .....	<b>242</b>
Are There Gender Differences in Access to Medicines In Africa? Results from 5 Sub-Saharan African Countries	
<b>856</b> .....	<b>243</b>
Partnership on Pharmaceutical Policies in the Caribbean: 2006-2009	
<b>859</b> .....	<b>243</b>

Plasma Drug Level Validation of Self-Reported Adherence Predicts Limited Specificity for Intrinsic Poor Adherence in Resource-Limited Settings	
<b>860</b> .....	<b>244</b>
Exploring a Global Compact to Preserve Novel Antibiotics	
<b>863</b> .....	<b>245</b>
Physician as Primary Target in Improving Antibiotic Use in Primary Care: Review of Behavioural Interventions (CHAMP)	
<b>864</b> .....	<b>245</b>
Exploring the Development, Design, and Implementation of a Pharmacotherapy Knowledge Center – A Qualitative Study	
<b>865</b> .....	<b>246</b>
Availability of Paediatric Medicines and Factors Impacting Availability in Faith-Based Health Facilities in Chad	
<b>866</b> .....	<b>246</b>
Prescribing Pattern of Antibiotics in Health Facilities in Baghdad, Iraq	
<b>867</b> .....	<b>247</b>
Development of the Caribbean Pharmaceutical Policy	
<b>868</b> .....	<b>248</b>
Understanding and Optimising Antibiotic Prescription in Primary Care: Guidelines, Education, and Audit/Feedback in a Multiple Intervention	
<b>870</b> .....	<b>248</b>
Interventions to Improve Medication Safety in a University Hospital in Thailand	
<b>873</b> .....	<b>249</b>
Value for Money Perspective on Global Health Initiative Market-Shaping Impact	
<b>875</b> .....	<b>250</b>
Framework Proposal to Improve Access to Medicines and Routine Care for Patients Living with Chronic Conditions in Low and Middle Income Countries	
<b>876</b> .....	<b>250</b>
Computer Alert System and Telephone Support to Improve Antiretroviral Therapy Adherence	
<b>878</b> .....	<b>251</b>
Changes in Use of Antidiabetic Medications Following Price Regulations in China (1999-2009)	
<b>879</b> .....	<b>251</b>
Compliance of Multidisciplinary Team on Medication Reconciliation Policy at Siriraj Hospital	
<b>880</b> .....	<b>252</b>
Pharmaceutical Situation in Barbados: WHO Level II Health Facilities Survey, 2010	
<b>882</b> .....	<b>253</b>
Proposal for a Baseline Assessment for the Caribbean Pharmaceutical Policy	
<b>883</b> .....	<b>253</b>
Price Information Exchange for Selected Medicines in the World Health Organization Western Pacific Region	
<b>884</b> .....	<b>254</b>
Characterization of Lawsuits for the Supply of Essential Medicines in the State of Rio De Janeiro, Brazil	
<b>885</b> .....	<b>255</b>
Evaluating Pharmacists' Views, Knowledge, and Perception Regarding Generic Medicines in New Zealand	
<b>888</b> .....	<b>255</b>
Pharmaceutical Services and Essential Medicines: Considerations on Access to Medicines and Judicial Demands in Brazil	
<b>889</b> .....	<b>256</b>
WeITel Kenya: Business Case for Using Mobile Phones as a Cost-Effective Health Intervention to Provide Care and Support HIV/AIDS Patients	
<b>890</b> .....	<b>256</b>
The Impact of Evidence-Based Subsidy Restrictions on Prescriber Behaviour and Patient Outcomes: A Case Study of Lapatinib for the Treatment of HER2+ Metastatic Breast Cancer	
<b>891</b> .....	<b>257</b>
Health Litigation and New Challenges in the Management of Pharmaceutical Services	
<b>895</b> .....	<b>257</b>
The Role of Malaysian National Medicines Policy (MNMP) in Improving Overall Use of Medicines	
<b>896</b> .....	<b>258</b>
Impact of Pharmacist's Roles on Reducing Readmission Rate and Promoting Patient Safety in Pediatric Cardiac Patients	
<b>903</b> .....	<b>259</b>
Impact of Community Education Programme on Safe Use of Medicines in Two States of India	
<b>904</b> .....	<b>259</b>
Cost Plus Price Setting of Medicines	

<b>905</b> .....	<b>260</b>
The Impact of the 2008 Economic Recession on the Pharmaceutical Sector in the Baltic Countries	
<b>906</b> .....	<b>260</b>
Pharmacovigilance Reporting in Kwazulu-Natal—Evaluation of a Solicited System of Reporting	
<b>909</b> .....	<b>261</b>
A Prospective Study of Prevalence, Severity and Preventability of Adverse Drug Reactions in Hospitalized Human Immunodeficiency Virus (HIV) Positive Patients	
<b>910</b> .....	<b>262</b>
The Volume Share of Generic Medicines in the Retail Market between 1999 and 2009: a Comparison between Brazil and Mexico	
<b>912</b> .....	<b>262</b>
Using a Rapid Results Approach to Improve Supply Chain Efficiency and Increase Availability of Essential Medicines and Supplies	
<b>913</b> .....	<b>263</b>
The Practice of Community Pharmacists on Emergency Contraceptive Pills Dispensing in a Contraindicated Situation	
<b>918</b> .....	<b>264</b>
Increasing Access to Quality Essential Medicines and Services Provided by Drug Shops in Uganda Through Accreditation and Regulation	
<b>919</b> .....	<b>264</b>
Application of Drug Use Evaluation and Feedback to Promote Rational Antibiotic Prophylaxis in C-Sections in Kenya	
<b>921</b> .....	<b>265</b>
Improving Quality of Malaria Case Management Provided by Drug Shops in Uganda Through Accreditation and Regulation	
<b>922</b> .....	<b>265</b>
Risk of Anemia Associated with Zidovudine (AZT)-based HAART in Namibia	
<b>923</b> .....	<b>266</b>
Effect of Interventions on Misuse of Antibiotics/Antibacterial Drugs in Developing Countries: a Systematic Review	
<b>924</b> .....	<b>267</b>
Draft South African Marketing Code—A New Model for Marketing Ethics	
<b>926</b> .....	<b>267</b>
Antibiotic Resistance Policy in Thailand: Role of Comprehensive Networking Campaign	
<b>929</b> .....	<b>268</b>
The Use of Medicines and Standard Treatment Guidelines in Rural Timor-Leste	
<b>930</b> .....	<b>268</b>
The Namibia Treatment Literacy Approach: Empowering Patients with Knowledge on Antiretroviral Therapy through Audiovisual Materials	
<b>932</b> .....	<b>269</b>
Remedies at Home: Evaluating an Innovative Medicines Provision Program	
<b>933</b> .....	<b>270</b>
Monitoring Medicine Prices and Availability in Kenya Using WHO/HAI Methodology 2009–2010	
<b>934</b> .....	<b>270</b>
Active Enforcement to Code of Conduct and Conflict of Interest Policies Based on Transparency Assessment Study in Jordan	
<b>941</b> .....	<b>271</b>
Prices of Antihypertensive Medicines in Sub-Saharan Africa and Alignment to World Health Organization's Model List of Essential Medicines	
<b>942</b> .....	<b>271</b>
Supporting Adherence to Antiretroviral Therapy Using Mobile Phone Reminders In South India	
<b>944</b> .....	<b>272</b>
East African Health Budgets 2010/2011: An Analysis on Financing for Essential Medicines	
<b>946</b> .....	<b>273</b>
Role of Private Pharmacies in TB Control in Egypt	
<b>947</b> .....	<b>273</b>
Study on the Effect of Zero Mark-up Policy on Medicines in Beijing Community Health Facilities	
<b>950</b> .....	<b>274</b>
Use of Brief Educational Intervention and Academic Detailing to Improve Use of Antidotes for Acute Poisoned Patients in Rural Hospitals in Sri Lanka—A Cluster Randomised Controlled Trial	
<b>953</b> .....	<b>275</b>
Management of Drug-Resistant Tuberculosis Patients, Egypt Experience	

<b>954</b> .....	<b>275</b>
Gender and Access to Medicines in 15 Low- and Middle-Income Countries: Does Physician Prescribing for Men and Women Differ?	
<b>955</b> .....	<b>275</b>
Improving Governance in the Pharmaceutical Sector of Karnataka—the Role of an Anti-Corruption Agency and its Limitations	
<b>957</b> .....	<b>276</b>
Challenges of Health Care Financing and Access to Medicines in Low-income Countries of Asia	
<b>959</b> .....	<b>277</b>
Evaluation of the New Rural Cooperative Medical Scheme Outpatient Capitation Payment Reform in Qianjiang	
<b>961</b> .....	<b>277</b>
Rational Drug Use Policy in Turkey	
<b>964</b> .....	<b>278</b>
Measuring Access to Essential Medicines in Kenya Using the Standardized WHO Level II Household Survey	
<b>965</b> .....	<b>279</b>
Introducing a Revised Model for Pricing and Reimbursement of Medicines in Macedonia	
<b>967</b> .....	<b>279</b>
Country Comparison of MeTA Baseline Pharmaceutical Sector Scan Data	
<b>969</b> .....	<b>280</b>
Modelling the Potential for Market Impact and Supply Security Risks: Focus on Donations with Applications for Differential Pricing	
<b>970</b> .....	<b>281</b>
Access to Medicines For Treating Acute Condition in Three Low- Income Countries In Central America	
<b>971</b> .....	<b>281</b>
Digital authentication of pharmaceutical products	
<b>972</b> .....	<b>282</b>
Assessing Global Health Financing and Policy: Potential Contribution of Pooled Funds	
<b>975</b> .....	<b>282</b>
Government, Civil Society, and WHO Partnership: a Catalyst for Better Access to Medicines In Countries	
<b>976</b> .....	<b>283</b>
Pharmaceutical Advertising and Promotion: Advertising Components Analysis in Five Latin American Countries	
<b>977</b> .....	<b>284</b>
Country Comparison of MeTA Baseline Data Disclosure Surveys	
<b>978</b> .....	<b>284</b>
Effectiveness of Pharmacist Home Health Care for Type 2 Diabetes in Bangkok Metropolitan: A Community Based Study	
<b>979</b> .....	<b>285</b>
Adherence of Prescribers to High Cost Medicines Standard Treatment Guidelines in Rio De Janeiro	
<b>981</b> .....	<b>285</b>
Implementation of Good Governance in Medicine (GGM) Programme in Malaysia to Strengthen Medicines Management	
<b>984</b> .....	<b>286</b>
Priority Policy Research Questions in the Area of Access to Medicines in Cameroon, Chad, Congo, and Gabon	
<b>985</b> .....	<b>287</b>
Tracking of Inter-Facility Patient Transfers and Retention on Antiretroviral Treatment in Namibia	
<b>986</b> .....	<b>287</b>
Self Medication in a Kerala District, India - Prevalence and Analysis	
<b>990</b> .....	<b>288</b>
Using Mobile Technology to Strengthen HIV/AIDS Management in Remote Areas	
<b>997</b> .....	<b>288</b>
Monitoring and Supervision as Tool for Improving Drug Supply Management	
<b>998</b> .....	<b>289</b>
Evolution of the Generic Medicines Market In Brazil, 1998-2010: Antihypertensives, Antidiabetics, and Antibiotics	
<b>999</b> .....	<b>289</b>
An Evaluation of A Clinical Pharmacist Directed-Intervention to Rationalize Overuse of Stress Ulcer Prophylaxis in Intensive Care Unit.	
<b>1002</b> .....	<b>290</b>
Evaluation of Pharmacist Clinical Intervention to Optimize Treatment of Gastritis in the Emergency Department	

<b>1004</b> .....	<b>291</b>
Impacts of Direct Fee-For-Service Payment Insurance on Access and Use of Drug: An Interrupted Time Series Study on Diabetic Care	
<b>1009</b> .....	<b>291</b>
The Effectiveness of Therapeutics Committees (TCs) in Addressing Key Public Health Problems	
<b>1011</b> .....	<b>292</b>
Jumping into the Pool: Is It the Shallow or the Deep End?	
<b>1012</b> .....	<b>293</b>
Experience with the Global Fund's Revised Quality Assurance Policy for Pharmaceutical Products	
<b>1013</b> .....	<b>293</b>
MeTA Baseline Assessments: Experiences and Results	
<b>1014</b> .....	<b>294</b>
Experiences and Challenges of An Accelerated Tracking Approach To Enhance Client Retention in Rural HIV clinics in North East Nigeria	
<b>1015</b> .....	<b>294</b>
Improving Access to ART Services in Namibia through Decentralization	
<b>1016</b> .....	<b>295</b>
Pharmaceutical Advertising and Promotion Regulation of Seven Latin American Countries	
<b>1018</b> .....	<b>295</b>
Development and Application of Selected Indicators to Investigate Antimicrobial Use in Hospitals	
<b>1022</b> .....	<b>296</b>
MMDR–TB Among Children in Moldova	
<b>1024</b> .....	<b>297</b>
Study on Quality Assurance for Essential Medicines other than ARVs, Antimalarial and Antituberculosis Medicines	
<b>1025</b> .....	<b>297</b>
Multi-Stakeholder Collaboration: Can It Improve Transparency, Disclosure	
<b>1033</b> .....	<b>298</b>
Proposed Set of Indicators for Monitoring and Evaluation of Pharmacovigilance Activities	
<b>1034</b> .....	<b>298</b>
The Impact of Universal Coverage on Use of Medicines in Thailand: An Evaluation Using Market Share Data	
<b>1035</b> .....	<b>299</b>
Household Access to and Use of Medicines in Ghana	
<b>1037</b> .....	<b>300</b>
Evaluating the Impact of a Public-Private Partnership for the National Introduction of a New Rotavirus Vaccine: Evidence from a Case-Control Study in Nicaragua (2006–2009)	
<b>1039</b> .....	<b>301</b>
Restricting the Availability of Anti-TB Medicines in the Private Market of Eastern Mediterranean Region Countries: A Call for Policy Intervention	
<b>1040</b> .....	<b>301</b>
Transparency, Governance and Regional Collaboration in Pharmaceutical Procurement in Kenya, Tanzania, and Uganda	
<b>1042</b> .....	<b>302</b>
Demonstrating the Potential Role of Information and Communication Technologies in Improving Management and Use of Antiretroviral Medicines in Resource-Limited Settings	
<b>1044</b> .....	<b>303</b>
Enabling Continuity of a Public Health ARV Treatment Program in a Resource-Limited Setting: The Case of the Transition of the African Comprehensive HIV/AIDS Partnerships (ACHAP) Support to the National ART Program to the Government of Botswana	
<b>1047</b> .....	<b>303</b>
The National Health Insurance Programme in Ghana and Household Access to Medicines	
<b>1049</b> .....	<b>304</b>
Health Facility Pharmaceutical Situation Assessment in Ghana	
<b>1050</b> .....	<b>304</b>
Impact of policy revision on harmonization and transparency of quality assurance criteria for anti-Tuberculosis medicines	
<b>1053</b> .....	<b>305</b>
Monitoring Drug Resistant Tuberculosis Treatment in Brazil through an Innovative Web-Based Information System	
<b>1054</b> .....	<b>306</b>
School-Based Education Program Can Favorably Impact National Public Health Budget	
<b>1057</b> .....	<b>306</b>

Monitoring Antimicrobial Resistance Trends: How the Private Sector Can Contribute to Improved Understanding of Global Trends in Antimicrobial Resistance	
<b>1058</b> .....	<b>307</b>
Increasing Access To Medicines—Taking a Multifaceted Approach	
<b>1059</b> .....	<b>308</b>
Use of Hospital Formulary to Improve Medicine Use at Alexandria Ophthalmology Hospital, Egypt.	
<b>1061</b> .....	<b>308</b>
Characteristics of Medicines Found in the Households of the District of Chimbote – Ancash (Peru), December 2007	
<b>1062</b> .....	<b>309</b>
Assessing How Health Care Providers Use Nevirapine in Malawi	
<b>1064</b> .....	<b>309</b>
Data Disclosure: An Ongoing Process Towards Transparency	
<b>1067</b> .....	<b>310</b>
Encourage Appropriate Use of Pediatric Antiretrovirals With a Demonstration Kit in Pharmacies: Results 18 Months after Kit Was Made Available in 2 HIV/AIDS Pediatric Treatment Centers in Niamey, Niger	
<b>1068</b> .....	<b>311</b>
Application of an ABC Analysis in the Prevention of Antimicrobial Resistance in Tuberculosis Treatment	
<b>1069</b> .....	<b>311</b>
Can the Management of Uncomplicated Diarrhea at the ADDOs in Tanzania be Further Improved?	
<b>1071</b> .....	<b>312</b>
Can ADDO Accomplishments Be Sustained? The Tanzania Experience Six Years Later	
<b>1074</b> .....	<b>312</b>
Improved Safety Monitoring of Second Generation Antipsychotics Following a Rational Prescribing Intervention	
<b>1076</b> .....	<b>313</b>
Improving Access to Oncology Treatments in a Resource-Constrained Setting Using Pharmacoeconomic Analysis	
<b>1077</b> .....	<b>314</b>
Teaching Critical Appraisal of Medicinal Drug Promotion (CADP) in 3 Latin American Countries: A Network Initiative	
<b>1078</b> .....	<b>314</b>
Drugs Identification and Interaction Checker to Reduce Tuberculosis Drug Compliance and Improve Treatment Adherence	
<b>1079</b> .....	<b>315</b>
Application of the Antacid {A02} ATC Review to Achieve Formulary Cost Efficiencies	
<b>1081</b> .....	<b>316</b>
Improving Access to ACTs Through Licensed Chemical Sellers in Ghana	
<b>1083</b> .....	<b>316</b>
Calculation of Tuberculosis Patients' Drug Consumption Using Electronic Nominal Recording–Reporting System at District Level	
<b>1084</b> .....	<b>317</b>
Engaging Private Sector Drug Dispensers to Improve Antimicrobial Use in the Community: Experience from the Tanzania Accredited Drug Dispensing Outlets	
<b>1086</b> .....	<b>317</b>
Role of Pharmacoeconomics in a Developing Country Context	
<b>1089</b> .....	<b>318</b>
Access to and Use of Medicines in Barbados: Evidence from a Household Survey	
<b>1090</b> .....	<b>319</b>
Literature Review of Gender and Drugs in Eastern Mediterranean Region Index Medicus	
<b>1092</b> .....	<b>319</b>
Trends in Antiretroviral Drugs Prescribing at Public Health Facilities in Ethiopia: Compliance to Treatment Guidelines	
<b>1093</b> .....	<b>320</b>
Priority Policy Research Questions in the Area of Access to Medicines in Latin America, Middle East, and Asia	
<b>1094</b> .....	<b>320</b>
The Risk of Getting Anti-TB Drugs as OTC Drugs	
<b>1095</b> .....	<b>321</b>
Cost-Effectiveness of Treating Malaria Following Three Methods of Diagnosis: Implications for Scaling-Up Use of Rapid Diagnostic Tests in Uganda	
<b>1097</b> .....	<b>321</b>
Polypharmacy Among Older Adults in Tehran	

<b>1098</b> .....	Pharmaceutical Situation in the Caribbean as Background for Policy Development	<b>322</b>
<b>1101</b> .....	Conflict of Interest Policies: Do Academic Medical Centers Make the Grade?	<b>323</b>
<b>1102</b> .....	Causes of ATBM Shortages in GFATM and GDF-Supported Countries in the Eastern Mediterranean Region and How to Avoid Them in the Future	<b>323</b>
<b>1104</b> .....	Tackling Medicine Related Issues Affecting the National Health Insurance Scheme in Ghana	<b>324</b>
<b>1106</b> .....	Developing Interdisciplinary Methods for Research to Explain and Enhance Access to Medicines in Africa and South Asia	<b>324</b>
<b>1108</b> .....	Country Comparison of Multi-Stakeholder Process Assessments in the MeTA Baseline	<b>325</b>
<b>1109</b> .....	An Analysis of the Global Fund's Price and Quality Reporting Database	<b>326</b>
<b>1110</b> .....	Patients' Compliance and Adherence to 4-FDCs that are Provided by Global Drug Facility to 15 Countries in the Eastern Mediterranean Region	<b>326</b>
<b>1113</b> .....	Evaluating the Effectiveness of TB Medicine Supply Management Training in Western Cape, South Africa	<b>327</b>
<b>1115</b> .....	Development and Implementation of a Multi-Method Medication Adherence Assessment Tool Suitable for Antiretroviral Therapy Facilities in Resource-Constrained Settings	<b>327</b>
<b>1116</b> .....	Implementing a Self-Assessment and Continuous Quality Improvement Approach to Improve Hospital Infection Control Practices in Africa and Latin America	<b>328</b>
<b>1118</b> .....	Evaluating the Quality of Care for Patients with Type 2 Diabetes Using Electronic Medical Record Information in Mexico	<b>329</b>
<b>1120</b> .....	The Impact of Abuse of Antibiotic Therapies on Inpatient Cost in China	<b>329</b>
<b>1121</b> .....	Intervention Strategy in Improving Art Adherence In Tanzania	<b>330</b>
<b>1122</b> .....	Investigating Medicine Supply as a Rate Limiting Step in the Scale-Up of Isoniazid Preventive Therapy in Kwazulu-Natal, South Africa	<b>331</b>
<b>1123</b> .....	The Effect of Community-Based Support Services on Clinical Efficacy and Health-Related Quality of Life in HIV/AIDS Patients in Resource-Limited Settings in Sub-Saharan Africa	<b>331</b>
<b>1125</b> .....	Promoting Rational Use of ARVs in HIV/AIDS Clinic in Tanzania	<b>332</b>
<b>1126</b> .....	Containing Health Care Costs in Ghana: Role of Evidence-Based Selection of Medicines	<b>332</b>
<b>1127</b> .....	Report Cards and Prescribing Behavior: Assessing the Impacts of Public Disclosure on Antibiotic Prescribing Rates in South Korea	<b>333</b>
<b>1129</b> .....	Provincial Essential Medicine List Comparison among 12 Provinces in China	<b>334</b>
<b>1133</b> .....	Informal Payments for Health Care: Differences in Expenditures from Consumers and Providers Perspectives for Treatment of Malaria in Nigeria	<b>334</b>
<b>1134</b> .....	Rational Use of Antidepressants Combined with Benzodiazepines	<b>335</b>
<b>1135</b> .....	Pharmacovigilance and Risk Management in Thailand	<b>335</b>
<b>1137</b> .....	Improving Quality of Malaria Treatment Services: Assessing Inequities in Consumers' Perceptions and Providers' Behaviour in Nigeria	<b>336</b>
<b>1138</b> .....	Use of Medicines with Unknown Fetal Risk among Pregnant Women from the Pelotas Birth Cohort 2004, Brazil	<b>337</b>

<b>1141</b> .....	<b>337</b>
How the Accredited Drug Dispensing Outlet Program Has Influenced Medicine Access Policies in Tanzania?	
<b>1142</b> .....	<b>338</b>
Antibiotic Policy, Antibiotic Consumption, and Antibiotic Resistance: Situation of Hospitals Participating in the National Antimicrobial Resistance Surveillance Thailand Program	
<b>1143</b> .....	<b>338</b>
Priority Policy Research Agenda to Achieve Access and Rational Use of Medicines in Thailand	
<b>1144</b> .....	<b>339</b>
Assessment of Pharmaceutical Situation in Suriname	
<b>1145</b> .....	<b>340</b>
Medicine Prices in Peru: Validation of the Sampling Approach Used in WHO/HAI Surveys	
<b>1146</b> .....	<b>340</b>
Inappropriate Provision and Treatment of Malaria in Public and Private Sectors in Nigeria: Threat to Malaria Elimination Efforts	
<b>1147</b> .....	<b>341</b>
Assessment of Pharmaceutical Situation in Jamaica	
<b>1148</b> .....	<b>341</b>
Monitoring Medicine Prices with WHO/HAI Surveys: Upsides, Downsides, and Forward-Thinking Strategies	
<b>1150</b> .....	<b>342</b>
Regional Strategy for Implementing the Rational Use of Medicines at the National Level in Latin American Countries	
<b>1152</b> .....	<b>343</b>
Access to Medicines in India: Setting Priorities in Policy Research Issues	
<b>1153</b> .....	<b>343</b>
National Evaluation of Medicines Dispensing within Brazilian AIDS Program	
<b>1154</b> .....	<b>344</b>
Transparency in the Armenian Pharmaceutical Sector	
<b>1155</b> .....	<b>345</b>
Improving Access to Medical Supplies in Emergency Settings by Preparing Humanitarian Responders with Online Medicine Supply Management Training	
<b>1156</b> .....	<b>345</b>
Caribbean Network on Pharmaceutical Education	
<b>1157</b> .....	<b>346</b>
Strengthening Pharmacovigilance at the National Level: Development of an Indicator-Based Pharmacovigilance Assessment Tool to Assess Medicines Safety System at the Level of the Pharmaceutical Industry in Developing Countries	
<b>1158</b> .....	<b>346</b>
2006 Medicare Part D Benefit: Evaluating a Major Expansion of Medicines Insurance for Vulnerable Americans	
<b>1159</b> .....	<b>347</b>
Application of an International Reference Price List to National Medicines Procurement Tenders	
<b>1161</b> .....	<b>348</b>
Good Governance of Medicines System in Thailand: From Assessment to National Policy Agenda	
<b>1162</b> .....	<b>348</b>
Findings from Integrating CVD risk factors screening and services among HIV clients in resources constrained setting	
<b>1163</b> .....	<b>349</b>
Strengthening Patient Adherence Monitoring through the Electronic Dispensing Tool (EDT)	
<b>1164</b> .....	<b>349</b>
Development of a Regional Network of Medicines Information Centres	
<b>1165</b> .....	<b>350</b>
Access to Pharmaceuticals among Adults with Cardiovascular Diseases: An Impact of the Free Medicine Policy in Beijing, China	
<b>1168</b> .....	<b>351</b>
Impact of User Fee Removal on Utilisation of Public Health Services in Zambia	
<b>1172</b> .....	<b>351</b>
Adherence to Antiretroviral Medicines Not Emphasized in Global Fund Grants	
<b>1173</b> .....	<b>352</b>
Efficiency of Public Procurement of Medicines in the Philippines	
<b>1175</b> .....	<b>352</b>
Role of the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance on the Establishment of National Centres in Africa	

<b>1178</b> .....	<b>353</b>
Improving Access and Quality Use of Medicines in Palliative Care within National Drug Policy, Regulatory, and Funding Frameworks	
<b>1184</b> .....	<b>353</b>
Analysis of essential medicine use in primary health care institutions of Beijing	
<b>1186</b> .....	<b>354</b>
Medication Errors of Intravenous Medication in Teaching Hospital in China	
<b>1189</b> .....	<b>354</b>
WHO Good Governance for Medicines Programme: Innovative Approach to Curb Corruption in the Pharmaceutical Sector	
<b>1190</b> .....	<b>355</b>
Prevalence of and Factors Associated with Potentially Inappropriate Medications Use in the Elderly Population in Thailand	
<b>1191</b> .....	<b>356</b>
Pharmaceutical Policies Used by Private Health Insurance Companies in Saudi Arabia	
<b>1193</b> .....	<b>356</b>
Development and Current Status of the National Good Governance for Medicines Initiative in Macedonia	
<b>1197</b> .....	<b>357</b>
Regional Strengthening of Pharmacotherapeutic Committees	
<b>1198</b> .....	<b>358</b>
Estimation of Antibiotic Utilization Patterns in 4 Latin-American Countries	
<b>1199</b> .....	<b>358</b>
Impact of IT based Promotion of Rational Use of Medicine in Indonesia	
<b>1202</b> .....	<b>359</b>
Use of an Indicator-Based System for Assessing, Monitoring, and Improving Pharmacy Practice	
<b>1203</b> .....	<b>359</b>
Cost of ARV Medicines in the Namibian Private Sector: Limitation to Increased Access	
<b>1204</b> .....	<b>360</b>
Compounding Polypharmacy Prescription in Indonesia	
<b>1206</b> .....	<b>361</b>
Outcome of the Live ETV Education on Rational Use of Medicines	
<b>1208</b> .....	<b>361</b>
Evidence on the Use of Medicines to Treat Chronic Diseases from Household Surveys in Seven Low- and Middle-Income Countries	
<b>1209</b> .....	<b>362</b>
A Win-Win Solution? Critical Analysis of Tiered Pricing to Improve Access to Medicines in Developing Countries	
<b>1210</b> .....	<b>362</b>
Incidence and Cost Estimate of Treating Paediatric Adverse Drug Reactions in Lagos, Nigeria	
<b>1211</b> .....	<b>363</b>
Pharmaceutical Situation Assessment: Level II Health Facilities Survey in Syria	
<b>1214</b> .....	<b>364</b>
Treating Acute Fever with Artemisinin-Based Combination Therapy: Prevalence and Predictors in Five African Household Surveys	
<b>1216</b> .....	<b>364</b>
Off-Label and Non-Licensed Endocrinology Medicine Use in Turkey: A Retrospective Analysis of Computer Records in the Turkish Ministry of Health	
<b>1217</b> .....	<b>365</b>
Treatment Cost of Metastatic Colon Cancer in Turkey	
<b>1218</b> .....	<b>365</b>
Cost and Cost-Effectiveness of Training Zambian Traditional Birth Attendants in Interventions Targeting Common Causes of Neonatal Mortality	
<b>1219</b> .....	<b>366</b>
Overview of Drug Tracking System (ITS) in the Pharmacies of Ankara: Preliminary Research	
<b>1220</b> .....	<b>366</b>
Glycemic and Non-glycemic Control in Diabetic Outpatients Receiving Oral Antidiabetic Drugs at Sultan Qaboos University Hospital	
<b>1221</b> .....	<b>367</b>
The Plague of Substandard Medicines in Developing Countries: Evidence for Policy Change	
<b>1222</b> .....	<b>367</b>
Adherence to Artemisinin Combination Therapies (ACTs) Purchased in the Informal Private Sector: Evidence from Soroti District, Eastern Uganda	

<b>1223</b> .....	<b>368</b>
Consumer Knowledge and Perceptions about Medicines: Evidence from Household Surveys in Five Low- and Middle-Income Countries	
<b>1225</b> .....	<b>369</b>
Prescribing Pattern of Psychotropic Substances in a Nigerian Neuropsychiatric Hospital	
<b>1228</b> .....	<b>369</b>
The Science of Quality Improvement (QI) Through Small Tests of Change (STOC) and Modeling of QI Teams to Improve Health Systems in Resource Limited Settings	
<b>1229</b> .....	<b>370</b>
How Far is too Far? Does Distance to Clinic Matter for HIV/AIDS Treatment Adherence?	
<b>1263</b> .....	<b>370</b>
Drugs for Anemia	
<b>1264</b> .....	<b>371</b>
Cost of Care of Rheumatoid Arthritis and Ankylosing Spondylitis Patients in Tertiary Care Rheumatology Units in Turkey	

**ABSTRACTS INDEXED BY PRESENTING AUTHOR**

.....	<b>351</b>
-------	------------

**ABSTRACTS INDEXED BY TRACK**

.....	<b>371</b>
-------	------------

*Keywords:* Anaemia, multiple micronutrient powder, supplementation, preschool aged children, Lao PDR

### **Effect of Multiple Micronutrient Supplements for Improving Anaemia of Preschool Age Children in Rural, Lao People's Democratic Republic: A Randomized Trial**

**Sengchanh Kounnavong<sup>1</sup>, Toshihiko Sunahara<sup>2</sup>, Junko Okumura<sup>2</sup>, Masahiro Hashizume<sup>2</sup>, Kazuhiko Moji<sup>3</sup>, Bounngong Boupha<sup>1</sup>, Taro Yamamoto<sup>2</sup>**

<sup>1</sup>National Institute of Public Health, Ministry of Health, Lao People's Democratic Republic; <sup>2</sup>Department of International Health, Institute of Tropical Medicine (NEKKEN) and the Global Centre of Excellence Program (GCOE), Nagasaki University, Japan; <sup>3</sup>Research Institute for Humanity and Nature, Kyoto, Japan

**Problem statement:** Multiple micronutrient deficiencies, in particular anaemia, constitute a severe public health problem in the Lao People's Democratic Republic (Lao PDR) because of the limitations associated with the use of liquid iron supplements for the treatment and prevention of iron deficiency anaemia in infants and young children. The Ministry of Health Lao PDR approved a low-cost strategy to deal with this problem—a home fortification with multiple micronutrient powder (MMP) sprinkles. Sprinkles have been shown to be efficacious in the treatment of anaemia in many developing countries, but the effectiveness of micronutrient supplementation depends on the local food culture and acceptance by the people. It was unknown how this approach would work in Lao PDR. Therefore, the effectiveness of MMP sprinkles needed to be tested to clarify optimal starting points and duration of supplementation based on individual status or population prevalence.

**Objective:** To compare the effects of twice weekly supplementation (TWS) and daily supplementation with MMP in improving anaemia, haemoglobin concentration, and growth among infants and young children in a rural community of Lao PDR. We also assessed the compliance and acceptability of MMP.

**Methods:** A randomized trial was conducted in 6 rural communities in Savannakhet province, Lao PDR. Children ages 6 to 52 months (n=336) were randomly assigned to either a control group (n=110) or one of two intervention groups (either receiving two sachets per week (TWS) (n=115) or a daily sachet (n=111) supplementation of MMP for 24 weeks; 331 children completed the study. A finger prick of blood was taken at baseline, week 12, and week 24 to determine haemoglobin concentration. Anthropometric measurements were taken every 4 weeks. Compliance was assessed weekly by counting used sachets and acceptability was assessed at the end of the intervention.

**Results:** After weeks 12 and 24, MMP supplementation resulted in significant improvements in haemoglobin concentration and reduction in anaemia prevalence in the two treatment groups compared with the control group (p<0.001). The severe to moderately anaemic children (Hb <100 g/L) recovered more quickly through daily supplementation than by TWS. MMP sprinkles were well accepted, and compliance was high in both treatment groups. Overall, improvement was observed in the weight for age Z-score among three study groups.

**Conclusions:** MMP supplementation had positive effects in the reduction of anaemia prevalence and in improving haemoglobin concentration. For severe to moderate anaemic children daily MMP supplementation was more effective in improving haemoglobin concentration and in reduction in anaemia prevalence. A longer intervention period would be needed to have a positive impact on growth.

*Keywords:* Anaemia, multiple micronutrient powder, supplementation, preschool-age children, Lao PDR

**Ethical approval:** Ethical approval for this study was obtained from the Nagasaki University Ethical Review Board (Japan) and the National Ethic Committee for Health Research of the Ministry of Health (Lao PDR).

**Funding:** This study was conducted as a part of the Eco-Health project of the Research Institute for Humanity and Nature, Kyoto (Japan) in collaboration with the National Institute of Public Health, Lao PDR. Sengchanh Kounnavong received funding from the Asian Health and Education Fund, Tokyo (Japan) and partly of the Institute of Tropical Medicine, Nagasaki University (NEKKEN) Fellowship.

*Keywords:* PHC, essential drugs, rational use of drugs, polypharmacy, Bangladesh

### **Availability and Rational Use of Essential Drugs in the PHC Facilities in Bangladesh: Are We on the Right Track?**

**Syed Masud Ahmed, Shafayetul Islam**

Research and Evaluation Division, BRAC, Bangladesh

**Problem statement:** A baseline survey done in 1994 by WHO at public sector primary health care (PHC) facilities in rural Bangladesh found that the availability and use of essential drugs were low, and irrational use and over-prescribing were common. Evidence shows that the situation has deteriorated over the years.

**Objectives:** This study aimed to explore to what degree the outcome objectives of the National Drug Policy of 1982 in terms of availability, affordability, and rational use of essential drugs have been achieved from a representative sample of public and private sector PHC facilities in rural and urban areas of Bangladesh.

**Design:** This study was designed as a facility-based cross-sectional study that can be easily implemented by individuals without special training or access to many resources.

**Setting:** The study covered a representative sample of Upazila (subdistrict) health complexes (UHCs) (n=30) and drug shops (n=30) in the rural areas plus a sample of urban clinics (UCs) (n=20) in the capital and used observations, exit interviews, and mini-market surveys to collect relevant data.

Study population: From each facility, 30 patients attending outpatient departments for curative services during typical working days were selected through systematic random sampling.

Outcome measures: WHO core indicators (prescribing, patient care, facility) to investigate drug use in health facilities

Results: Average consulting (120 seconds) and dispensing (60 seconds) time in the UHCs appeared to have increased marginally from 1994 levels. Drugs dispensed out of the total prescribed was higher in the UHCs (76%) compared to UCs (44%). Dispensed drugs were not labeled properly, though an improvement in knowledge of correct dosage was observed (from 57% in 1994 to 73% in the UHCs). Polypharmacy was on rise from 5% in 1994 to 33%; in the UHCs and in case of drug shops and urban clinics, polypharmacy was even more prevalent (46–61%). An essential drugs list (EDL) was available in only 55% UCs and 47% UHCs with only two-thirds of the drugs being prescribed from it. Availability of key essential drugs for common illnesses was poor, varying from 6% in the UHCs to 15% in the UCs. Polypharmacy was on rise (from 5% in 1994 to 33% in the UHCs), and on an average 2.2 drugs were prescribed per encounter in the UHCs compared to 1.4 drugs in 1994. In 44% of the encounters in the UHCs and UCs and in 60% in the drug shops, an antibiotic was prescribed. Interestingly, antibiotics were prescribed more frequently for fever (36–40%) and the common cold (26–34%) than for ARI and pneumonia (10–20%). Only 47% of the UHCs and 55% of the UCs had a copy of the EDL. Deterioration was observed in the availability of essential drugs for treatment of common illnesses. Prices of key essential drugs differed by brands, sometimes as high as 500%.

Conclusions: There has been deterioration in the availability and rational use of drugs since 1994 baseline survey and over the 27 years between the 1982 passage of the much acclaimed National Drug Policy in Bangladesh and this study.

Funding source(s): Swedish International Development Agency

### 113

#### Malaria

*Keywords:* medicine outlets, staff resources, anti-malarials, malaria control, Ghana

#### Medicine Outlets and Their Practitioners in Malaria Control in Ghana

**Kwame Ohene Buabeng<sup>1</sup>, Lloyd Matowe<sup>2</sup>, Felicity Smith<sup>3</sup>, Mahama Duwiejua<sup>1</sup>, Hannes Enlund<sup>4</sup>**

<sup>1</sup>Kwame Nkrumah University of Science & Technology (KNUST), College of Health sciences, Kumasi, Ghana.;

<sup>2</sup>Affordable Medicines Facility-malaria (AMFm Unit), The Global Fund to Fight AIDS, Tuberculosis and Malaria, Geneva, Switzerland.; <sup>3</sup>The School of Pharmacy, University of London, UK.; <sup>4</sup>School of Pharmacy (Social Pharmacy), Faculty of Health sciences, University of Eastern Finland, Kuopio, Finland.

Background: Malaria is endemic in Ghana and contributes significantly to infant and maternal deaths. The pharmaceutical sector, and in particular medicine outlets, have been identified as accessible units in the health system, where public health initiatives could be targeted to facilitate greater access to effective tools and interventions for malaria control. Objectives: To assess the medicine outlets set up in both public and private sector facilities in Ghana and to investigate the availability of effective antimalarials and how practices within the outlets could be improved to support the national programme for malaria control

Methods: This study was cross-sectional involving 130 medicine outlets from hospitals/clinics and community-based retail outlets (i.e., community pharmacies and licensed chemical shops) in Ashanti and northern regions of Ghana. From these outlets, data were obtained to assess the available infrastructure and settings for pharmaceutical services, the staff resources available, their practices for malaria control, and the antimalarial products available. The indicators used were based on the national standards for pharmaceutical services, national policy for malaria control, and the WHO-led Roll Back Malaria initiative.

Results: The infrastructure and settings for pharmaceutical services were satisfactory in more than 80% of the outlets assessed. Non-policy recommended and mostly ineffective antimalarials were readily available and often supplied for malaria therapy, particularly in the retail outlets. The availability of policy-recommended antimalarials, in particular the artemisinin-based combination products, was rather poor (i.e., less than 45%). In addition few of the outlets (less than 10%) strictly adhered to policy recommendations for the selection and supply of medicines for malaria therapy. On-staff resources: Greater than 55% had no professional training as pharmaceutical service providers. The majority of the staff (greater than 80%), including both professionals and nonprofessionals, could recognise malaria illness and advise clients on how to avoid further infections, but few (20% and mainly professionals) were adequately skilled to both recognise and manage malarial illness as recommended by national guidelines.

Conclusions: The infrastructure and settings for pharmaceutical services were satisfactory but could be further improved and used to facilitate access to appropriate tools and interventions for malaria control. There were significant shortfalls, regarding the availability and supply of effective antimalarials. Furthermore, the majority of the medicine outlets' staff were inadequately skilled to appropriately manage malarial illnesses. Pragmatic interventions should be directed toward the medicine outlets and their practitioners to enhance their contribution toward malaria control in Ghana.

Funding source(s): Information not provided

### 114

#### Access

*Keywords:* generic medicines, general practitioners, knowledge, perceptions

## **Facilitators and Barriers for Generic Drug Use Among General Practitioners in Northern State of Malaysia: Findings from a Cross-Sectional Mail Survey**

**Mohamed Azmi Hassali, Gin Nie Chua, Asrul Akmal Shafie, Ahmad Awaisu, Imran Masood, Fahad Saleem, Harith Al-Qazaz**

Universiti Sains Malaysia, Malaysia

**Problem statement:** The provision of health care has traditionally been managed based on the philosophy that, where the patient is concerned, price should not be a hindrance. With the global escalation of health care costs, however, governments in many countries have adopted ongoing series of cost-containment attempts in an effort to spend their limited financial resources efficiently so that equitable access to health care can be provided. One of the many ways to control health care expenditure is to promote the use of cheaper generic drugs instead of the more expensive branded equivalents. In the context of Malaysia's health care system, where currently no separation of dispensing has been implemented, the general practitioners (GPs) are important players in the medication distribution chain because their core activities revolve around the prescribing and dispensing of medications. Although, the recently adopted Malaysian National Medicine Policy has advocated generic prescribing and substitution to improve the affordability of medicines, the onus of prescribing and dispensing generics lies on the attending physician. To date, no studies have been done to evaluate the understanding and perceptions of GPs in Malaysia on issues surrounding the safety, efficacy, and quality of generic medicines.

**Objectives:** The present study's objectives are to evaluate perceptions held among general practitioners on the concept of generic medicine use and to assess the current state of knowledge among general practitioners on issues related to generic medicine prescribing.

**Design:** A postal cross-sectional survey involving registered GPs (n=325) in Penang, Malaysia, was undertaken. The survey questionnaire consisted of 23 items, and it was validated accordingly before being sent to the GPs. At the end of the survey period, a total of 87 GPs responded to the survey, a response rate of 26.8%.

**Setting:** The survey was conducted with all registered private GPs who currently practice in the State of Penang, Malaysia.

**Results:** The majority of the respondents (85.1%) claimed that they actively prescribed generic medicines in their practice. Conversely, only 4.6% of the respondents correctly identified the Malaysia's National Pharmaceutical Control Bureau's bioequivalence standard for generic products. The respondents had misconceptions about the concepts of bioequivalence, efficacy, safety, and manufacturing standards of generic medicines. GPs in this survey believed that a standard guideline on brand substitution process, collaboration with pharmacists, patient education, and information on safety and efficacy of generic medicines were necessary to ensure quality use of generics. Furthermore, advertisements and product bonuses offered by pharmaceutical companies, the patient's socioeconomic status, and the credibility of manufacturers were all factors that influenced their choice of medicine.

**Conclusions:** Although it appeared that GPs have largely accepted the use of generic medicines, they still have concerns regarding the reliability and quality of such products. GPs need to be educated and reassured about the generic products approval system in Malaysia concerning bioequivalence, quality, and safety.

**Funding source(s):** No funding was received for this study.

115

### **Drug Resistance**

*Keywords:* antibiotic usage, public knowledge, attitudes, Malaysia

## **Public Knowledge and Attitudes Toward Antibiotic Usage: Findings from a Cross-Sectional Survey in the State of Penang, Malaysia**

**Mohamed Azmi Hassali, Asrul Akmal Shafie, Ahmed Awaisu, Mahmoud Sadi AL-Haddad, Imran Masood, Fahad Saleem, Harith Al-Qazaz**

Universiti Sains Malaysia, Malaysia

**Problem statement:** The public, as the ultimate consumer in the antibiotic utilization pathway, plays a vital role in overcoming the misuse of antibiotics in the community. This study aimed to assess public knowledge and attitudes toward antibiotic usage and could serve as the baseline data at the institutionalized level in Malaysia.

**Methods:** A cross-sectional survey involving 408 respondents was conducted using a validated questionnaire at an outpatient pharmacy department in Penang Hospital, Malaysia, in February and March 2009.

**Results:** Nearly 55% of the respondents had a moderate level of knowledge with a median total score of 6 out of 14. Three-quarters of the respondents (76.7%) could correctly identify that an antibiotic was indicated for the treatment of bacterial infections, but 67.2% incorrectly thought that antibiotics were also used to treat viral infections. About 59.1% of the respondents were aware of the antibiotic resistance phenomenon in relation to overuse of antibiotics. With regard to attitudes, 38% believed that taking antibiotic when having symptoms of cold could help them recover faster, whereas 47.3% expected an antibiotic to be prescribed for common cold symptoms.

**Conclusion:** Age, race, and educational level were among the demographic characteristics significantly associated with knowledge and attitudes toward antibiotic use. Educational interventions are needed to promote the prudent use of antibiotics among the public.

**Funding source(s):** No funding was received for this study.

120

**Economics, Financing, and Insurance Systems***Keywords:* appropriate use, drug information, pharmaceutical policy**The Role of Pharmaco-Economics in the Decision Tasks to Improve the Quality of Medical Care in Kazakhstan Republic****Kulsara Rustembekovna Rustemova, Sadriten Tleukenov, Alfiya Varnavskaya, Laura Kozhageldiyeva, Lyazzat Kosherbayeva**

Scientific-practical centre for standartization and health technology assessment, Kazakhstan

Nowadays the issue of medicines rational use and implementation of different varieties of standards (list of basis essential medicines, clinical guidelines) into the hospitals and primary trust is given a great emphasis. However, the evaluation system and the critical appraisal of information about the effectiveness of drugs is not perfect, that is why formulary lists frequently are developed without any critical comprehension.

'Pharmaco-economical intellection' (which is necessary to be known to administrator, doctor, and patient himself) lets to spend the resources economically with the increase of effectiveness of treatment. Ministry of Health of Republic of Kazakhstan provides organizational and financial support in conducting the applied pharmaco-economic researches in affiliated health facilities, organizes the stuff preparation of this field at universities.

In these days, scientific-practical centre for standardization and health technology assessment (Centre) is the coordination centre for development, improvement and implementation of the medico-economical protocols (MEP) in Kazakhstan Republic. The standardization of hospital medical services reimbursement, on the basis of MEP, gives an opportunity to calculate the real cost of medical services and is the informational source to form the control and medical care quality management program. The final result of the Centre is the development and the approval of the single methodology for development steps, the economical calculation, piloting, expertise, and implementation of MEP into practice, and also the mechanism of continuous revision of MEP, capacity building of the local specialist conducting the pharmaco-economic researches.

Thus, the medicines, diagnostic and treatment methods could be included in the regulatory acts, which standardized MEP, based on the best international experience about the effectiveness and safety and full pharmaco-economic justification.

125

**Access***Keywords:* Prescription Errors, Assistant Medical Officer, Government Health Clinic, Malaysia.**Evaluation of Prescribing Practices by Assistant Medical Officers at Malaysian Public Health Care Facilities****Mohamed Azmi Hassali<sup>1</sup>, Siew Mei Yee<sup>2</sup>, Asrul Akmal Shafie<sup>1</sup>, Jayabalan Tambyappa<sup>1</sup>, Mahmoud Sadi Al-Haddad<sup>1</sup>, Imran Masood<sup>1</sup>, Fahad Saleem<sup>1</sup>, Harith Al-Qazaz<sup>1</sup>**<sup>1</sup>Discipline of Social and Administrative Pharmacy, School of Pharmaceutical Sciences, Universiti Sains Malaysia, Malaysia; <sup>2</sup>School of Pharmacy, Division of Medicine, Pharmacy & HealthSciences

**Background:** Prescribing is one of the primary stages at which errors occur. Prescribing errors occur when the probability that the treatment will be timely and effective is reduced or when the risk of harm, when compared with generally accepted practice, is increased. Prescribing errors can be classified into omission errors and decision errors. Omission errors include incomplete prescriptions, inappropriate use of abbreviations, and illegible hand writing. Decision errors are wrong indications, contraindications, drug-drug interactions, polypharmacy, inappropriate dosing, inappropriate duration of treatment, and inappropriate dosing frequency. In Malaysia, assistant medical officers (AMOs) play an important role in the health setting because of the shortage of medical officials, especially at government health clinics. According to the Malaysia Poison Act of 1952, medical assistants are authorized to prescribe but are limited to certain items at certain premises. It was noted that the medical assistants prescribe medications that are out of their allowed authority.

**Objectives:** To identify the frequency and nature of various types of prescription errors made by AMOs at a government health clinic and a government hospital at Kampar district, to study the prescribing patterns of AMOs, and to determine whether there is an association between prescribing errors and patients' demographics and disease stages

**Methods:** 1,612 prescriptions that were generated within 1 week were screened retrospectively, and 421 prescriptions that met the inclusion criteria were evaluated. During screening, prescribing errors were classified into either omission errors or decision errors. The British National Formulary (edition 56), Lexi-Comp, and other relevant references were used to evaluate prescription errors. Out of the 421 prescriptions being studied, only 13 prescriptions were totally free of errors. All the prescribing errors made were recorded on a data collection form. The data was then analyzed using SPSS (version 12).

**Results:** 1,169 prescribing errors were noted, and about 2.78 prescribing errors were made by AMOs for each prescription generated; 67% were omission errors and 33% were decision errors. Illnesses for which the medication was being prescribed varied from general medical conditions such as the common cold and flu to specialty diseases, such as those involving the cardiovascular or respiratory system, and infections. Most of the errors made were related to anti-infective medications prescribed, and there was a significant association between prescribing errors and the patient's disease stage. Among the 421 prescriptions generated by AMOs, 39% were prescribed with at least one medication categorized as a Group B poison under the First Schedule Poison List of Malaysia Laws on Poison and Sale of Drugs.

Conclusions: Prescribing errors are common and frequent at government health settings in Kampar District. A much wider appreciation is required of the value of focusing on the root causes of errors. Designing initiatives targeting the causes of errors that are most likely to occur would be helpful in reducing them.

Funding source(s): Self-funded

126

### Malaria

*Keywords:* antimalarials, appropriate use, availability, dispensing, indicators, standard treatment guidelines

#### **Antimalarial Prescribing and Dispensing Practices in Health Centres of Khartoum State, 2003–04**

**Abbeer Abuzied Atta A/Mannan<sup>1</sup>, El Fatih Mohammed Malik<sup>2</sup>, Kamil Mergani Ali<sup>3</sup>**

<sup>1</sup>Al Neelain University, Sudan; <sup>2</sup>Federal Ministry of Health; <sup>3</sup>University of Khartoum

**Problem statement:** In Sudan, inappropriate, ineffective, and inefficient use of drugs commonly occurs at health facilities and little is known about the determinants of poor use of antimalarial drugs.

**Objectives:** This study was indicator-based. The main objective was to assess the antimalarial drug prescribing and dispensing practices of health care providers in health centres of Khartoum state and to compare these practices with the national guidelines for malaria treatment.

**Design:** A facility-based, cross-sectional, descriptive, analytical study following WHO guidelines

**Setting:** Khartoum state includes the national capital of Sudan. Its population is a mixture of all Sudanese tribes and ethnic groups. Almost 68% of the population lives in urban areas, 21% live in rural areas, and 11% are displaced people.

**Study population:** 720 patients using the standard cross-sectional survey formula. Two-stage cluster sampling was used. The first stage was the selection of health centres using probability proportional to size, and the second stage was the selection of patients.

**Policies:** The practices described in this study were compared to the national protocol for treatment of malaria at that time before the introduction of the new combination therapy, which was launched late in 2004. The study provided information added to the pool of evidence needed to change the old national treatment guidelines for Malaria.

**Outcome measures:** Measuring WHO drug use indicators. After patients were interviewed, their information was recorded on a standard form (i.e., a patient care form), then their prescriptions were collected; the data extracted were recorded on another form (i.e., a prescribing indicator form). After the required number of patients had been interviewed, information on the types of antimalarial drugs available in stock and the presence of the national protocol poster in the health centre were recorded on a third form (i.e., a facility summary form).

**Results:** Prescribers adhered to national treatment guidelines for only 278 (38.6%) of patients. Although all were treated for malaria, only 77.6% patients had fever or history of fever and only 64.6% had fever and positive blood films. More than 90% of prescriptions prescribed antimalarial drugs by generic names but dosage forms were correctly written in only 60.0%. There was a high rate of prescribing antimalarial injections. Only half the patients had adequate knowledge of their treatment.

**Conclusion:** The study showed inappropriate prescribing practices and consequently inappropriate use of drugs for malaria.

Funding source(s): The National Administration for Control of Malaria, Federal Ministry of Health, Sudan

127

### Access

*Keywords:* essential medicines, supply management, logistics information

#### **Impact of Strategies to Improve Collection and Reporting of Logistics Information for Managing Essential Medicines in Developing Countries**

**Stanley Chindove<sup>1</sup>, Noreen Mdege<sup>2</sup>**

<sup>1</sup>Department of Pharmacy, Ministry of Health, Timor-Leste.; <sup>2</sup>Department of Health Sciences, University of York, United Kingdom.

**Problem statement:** Lack of access to medicines in the public sector in developing countries has been attributed to various factors including lack of accountability and weak procurement and supply management systems. A common problem with logistics management information systems (LMISs) for essential medicines in developing countries has been a lack of standardization of collection and reporting formats.

**Objectives:** To describe and analyze the impact of interventions designed to standardize collection and reporting of logistics data on managing essential medicines in developing countries and to describe lessons learned and identify key factors to successful design and implementation of standardized systems for logistics data collection and reporting

**Design:** The literature was identified from searches of Medline, EMBASE, and Web of Science. Other relevant publications were identified from websites of organizations and contacts working in the study area.

**Setting and population:** Medicine LMISs in the public and nongovernmental sectors in developing countries

**Outcome measures:** The effects of an LMIS intervention to improve collection and reporting of logistics data for essential medicines in developing countries, particularly on availability and quality of logistics data and availability of

essential medicines; a description of key factors for successful design and implementation of standardized systems for logistics data collection and reporting

**Results:** The search identified 358 articles, and 11 of these were selected for inclusion. All articles were before-and-after analyses without control areas. Standardizing collection and reporting of logistics data through automation and manual tools resulted in improvements in the availability of quality logistics data for supply chain decision-making and continual availability of essential medicines. Use of mobile technologies resulted in low error rates in forecasting and demand planning, and significantly reduced decision lead time. 28 countries were reported to have reduced the median forecast error from 35% in 1995 to 25% in 2004 due to improvements in LMIS.

**Conclusions:** The findings from this review suggest that standardization of collection and reporting of logistics data to support decision-making on essential medicine supply can lead to improvements in availability and quality of logistics data and availability of essential medicines. More robust experimental and quasi-experimental studies on the topic are needed, however. Critical factors to successful design and implementation of LMIS include organizational and technical factors as well as customization and adaptation of the LMIS to the context to motivate users and ensure continued use.

Funding source(s): Self-funded

128

### Chronic Care

*Keywords:* treatment guidelines; hypertension; adherence; rational medicine use; WHO Indicators.

### **The Evaluation of Compliance to an Essential Medicine Programme: Use of Standard Treatment Guidelines in South Africa's State Health Facilities of eThekweni**

**Mariam Cassimjee<sup>1</sup>, Fatima Suleman<sup>2</sup>**

<sup>1</sup>Independent Pharmacist, South Africa; <sup>2</sup>University of KwaZulu-Natal, South Africa

**Problem statement:** To promote the rational use of medicines (RUM), the KZN Department of Health, South Africa, adopted the national standard treatment guidelines (STGs) and essential medicine lists in May 1999. The evaluation of this intervention on prescribers had not been done.

**Objectives:** To determine compliance to the STGs in terms of (1) the percentage of RUM, (2) the differences in prescribing and dispensing antihypertensive medicines among practitioners, and (3) the impact of practitioner variables

**Design:** A two-arm study was concurrently conducted: the (A) arm used WHO prescribing indicators and a purposive retrospective sampling of antihypertensive prescriptions, and the (B) arm used a structured questionnaire.

**Setting:** State health facilities in the district of eThekweni, KZN, South Africa

**Population:** In the (A) arm, 2,100 antihypertensive prescriptions were collected across three levels of the health care system. In the B arm, 260 qualifying health care prescribers were interviewed.

**Outcome measure(s):** Percentages of (1) overall compliance to the STGs, (2) compliance to the STGs per category of practitioner, and (3) the impact of practitioner variable(s) on the overall compliance to the STGs

**Results:** Hypertension featured as 57.5% of the diagnoses. For the correct use of the STGs, the diagnosis was identified for 99.9 % of the prescriptions at the primary health care, 91.1% at the community health care centres, 99.0 % at the district hospitals, and 81.7% at the regional hospitals. Of the prescriptions with a diagnosis, the medicines prescribed did not correlate with the condition on 77.9% of the prescriptions. The overall mean result of compliance to the STGs was 22% ( $\pm 20.0$ ). The multiple linear regression equation (MLRE) suggested that the variables selected explained 86.8% of the impact on STG adherence. The mean STG compliance scores were 19.4% ( $\square 19.0$ ), 19.2% ( $\square 18.9$ ), and 18.7 ( $\square 17.9$ ) for nurses, medical doctors, and pharmacists, respectively. The MLRE analysis for the practitioner variables suggested that the impact on compliance to the STGs was only 8.58%, of which knowledge of the STGs had a significant impact,  $X^2(7, N=257)=19.03, p<0.008$ , as with a greater knowledge, compliance increased. Chi square analyses on practitioner type and exposure to private sector experience indicated that there were significant differences between the type of practitioners and experience in private sector,  $X^2(2, N=257)=19.73, p<0.0001$ .

**Conclusions:** The low mean overall results for compliance to the STGs were due to the absence or incomplete diagnoses with additions of medicines for each symptom without due consideration to the RUM. Only three of the eight practitioner variables had an impact on adherence to the STGs. For the correct use of STGs in EDPs, the format and continuity of education need promotion. Implementation strategies must include interventions for each health professional cadre. Diagnoses or diagnosis codes on prescriptions should be mandatory.

Funding source(s): Study grant from the University of KwaZulu-Natal, South Africa

129

### Child Health

*Keywords:* antibiotic use, children under five, ARI, prospective study

### **Unnecessary Antibiotic Use for Mild Acute Respiratory Infections in a 28-Day Follow-Up of 823 Children under Five in Rural Vietnam**

**Chuc Thi Kim Nguyen**

Hanoi Medical University, Viet Nam

**Problem statement:** Few prospective studies about antibiotic use for mild acute respiratory infections (ARIs) have been conducted in community settings.

**Objectives:** To assess knowledge of children's caregivers and actual antibiotic use for children under 5 and to identify associated factors with antibiotic treatment for mild ARIs.

**Design:** Caregivers in 828 households in Bavi, Vietnam, were interviewed using a structured questionnaire regarding the case management of childhood ARI and the selected children's most recent illness assessing both knowledge and practice. Then 823 children were followed for 28 days to collect information regarding symptoms and drug use.

**Setting:** The study setting was Bavi district, 60 km west of Hanoi, where an Epidemiological Field Laboratory (Filabavi) was implemented in 1998. The district covers an area of 410 km<sup>2</sup>, divided into lowland, highland, and mountainous areas according to geographical characteristics.

**Study population:** The sample of 847 children ages 6–60 months was obtained from 847 households in 13 clusters within the Filabavi framework to investigate *Streptococcus pneumoniae* susceptibility from their nasopharyngeal samples.

**Results:** For nonfebrile common colds, 85% of caregivers stated correctly that antibiotics are not required. For febrile colds and pneumonia, 45% and 47%, respectively, stated that they would require antibiotics. Only 13% demonstrated correct overall knowledge that was in accordance with standard guidelines for all three situations. The symptoms of the most recent illness were consistent with mild ARI in 79% of the cases, and antibiotics were used in 71% of these. During the 28-day period, 62% of children had been given antibiotics. Out of all antibiotic courses recorded, 63% were used for mild ARIs. Half of the mild ARI episodes (528/1048) and 63% of the children with mild ARIs (392/623) were treated with antibiotics. **Limitations:** We collected data based on structured interviews with children's caregivers without clinical examination. Furthermore, we did not collect information about the expectations of the parents of receiving antibiotics when seeking care, though this might influence the prescribing pattern of health providers.

**Conclusion:** Most of the children had been administered antibiotics for common colds although most caregivers believed that antibiotics were not required. Antibiotics were unnecessarily recommended at health facilities in the area.

**Funding source(s):** Health Systems Research Project, funded by Sida/SAREC, Sweden and the Ministry of Science and Technology, Vietnam.

## 132

### Malaria

*Keywords:* access to medicines, antimalarials, medicine prices

#### **Improvements in Access to Malaria Treatment in Tanzania Following Community, Retail Sector and Health Facility Interventions—A User Perspective**

**Sandra Alba<sup>1,2</sup>, Angel Dillip<sup>3</sup>, Iddy Mayumana<sup>3</sup>, Christopher Mshana<sup>3</sup>, Ahmed Makemba<sup>3</sup>, Mathew Alexander<sup>3</sup>, Brigit Obrist<sup>1,2</sup>, Alexander Schulze<sup>4</sup>, Christian Lengeler<sup>1,2</sup>**

<sup>1</sup>Swiss Tropical and Public Health Institute, Switzerland; <sup>2</sup>University of Basel, Switzerland; <sup>3</sup>Ifakara Health Institute, Tanzania; <sup>4</sup>Novartis Foundation for Sustainable Development, Switzerland

**Problem statement:** Many African countries have introduced new, highly efficacious artemisinin-based combination therapies (ACTs) for the treatment of malaria thanks to international donor funding. The public health impact of such drugs, however, relies on the patient's ability to access them, and little progress will be made unless broader access issues are considered.

**Objectives:** The ACCESS programme aims to understand and improve access to malaria treatment in a rural Tanzanian setting. Treatment-seeking surveys were conducted in 2004, 2006, and 2008 to evaluate the programme's impact on treatment.

**Design:** An evaluation study based on before-and-after comparisons with no control group

**Setting:** The programme was implemented in the Kilombero and Ulanga districts in south-central Tanzania. Treatment-seeking surveys were conducted in the community.

**Study population:** For every survey, a random sample of 150 recent fever cases (i.e., within previous 2 weeks) was selected from the local demographic surveillance site, which covers both districts (~80,000 people).

**Intervention(s):** At the community level, the programme conducted a social marketing campaign for improved recognition of the disease and more effective care seeking (2004 to 2007). The campaign consisted of road shows, promotional materials, billboards, and posters. Interventions in the public health sector included strengthening of routine supervision and a refresher training based on Integrated Management of Childhood Illness (IMCI) algorithms (2004 to 2005). In parallel, the Accredited Drug Dispensing Outlets (ADDOs) programme was rolled out in the area in 2006 to improve access to quality treatment in the private retail sector.

**Policies:** In 2006 the Government of Tanzania switched from sulfadoxine-pyrimethamine (SP) to artemether-lumefantrine (AL) as first-line treatment for malaria. Subsidised AL was introduced in all public health facilities in January 2007 and made available to all ADDOs in July 2007.

**Outcome measure(s):** The primary outcome measure is the proportion of children under 5 with fever in the past 2 weeks who took a recommended antimalarial within 24 hours of onset of fever

**Results:** The proportion of children treated with an antimalarial within 24 hours increased from 66% (95% CI: 58% to 73%) to 89% (84% to 94%) between 2004 and 2008. Only 51% (42% to 60%), however, were treated according to the new treatment guidelines in 2008 because AL was not widely available in ADDOs

**Conclusions:** An integrated approach aimed at improving understanding and treatment of malaria has led to improvements in treatment outcomes. This testifies that even in a rural African setting, the Abuja targets can be achieved. A higher impact was hindered by the low availability of AL in the private retail sector.

Funding source(s): The ACCESS programme is funded by the Novartis Foundation for Sustainable Development.

143

#### Access

*Keywords:* CBIA-pregnancy, Ante Natal Care, pregnancy, hospital based community, self-medication

### **CBIA-Pregnancy to Improve Skills of Pregnant Mothers in Selecting OTC Common Cold Preparations**

**Sri Hidayati<sup>1</sup>, Titien Siwi Hartayu<sup>2</sup>, Siti Munawaroh<sup>3</sup>, Sri Suryawati<sup>1</sup>**

<sup>1</sup>Gadjah Mada University, Indonesia; <sup>2</sup>Sanata Dharma University, Indonesia; <sup>3</sup>Agency for Women and Community Empowerment, Indonesia

**Problem statement:** Pregnant women may have common cold episodes during pregnancy and need medicine to soothe the symptoms. Therefore, skills in selecting medicines for common cold in pregnancy are important. Mothers' active learning method (known as CBIA) is one of the strategies which is not only improving knowledge but also changing behavior. Since information on the use of medicine in pregnancy is also available in the medicines' package, it is expected that the CBIA-Pregnancy program can be developed and be focused on the medicines used in pregnancy.

**Objective:** To pilot-test CBIA-Pregnancy in improving knowledge and skills of pregnant women to select common cold medicines

**Design:** An intervention study with pre- and post-quasiexperimental design; data collected at baseline, one-day (Post I), 2 weeks (Post II), and 4 weeks (Post III) after intervention

**Setting:** The study was conducted in 2 hospitals in Yogyakarta, Indonesia, Sakina Idaman and Panti Rapih. Women visiting antenatal care (ANC) in Sakina Idaman were assigned as intervention group, and those visiting Panti Rapih were assigned as control.

**Study population:** Pregnant women who visited ANC program in Sakina Idaman and Panti Rapih hospital on regular basis

**Intervention:** CBIA-Pregnancy is a 2-hour small group discussion using information in the medicines' package as training material and the CBIA-Pregnancy module as an activity guide. There were 5 groups of 5–6 participants; midwives in the study hospital served as facilitators. Participants searched information on active compound, indication, dosage, side effects, and contra-indications and also specific information on the use of the medicine during pregnancy.

**Policies:** This strategy will provide hospitals with tools for hospital-based community empowerment and promoting self-learning behavior among the community.

**Outcome measures:** Score of knowledge on the most familiar medicine, percentage of subjects who could select the correct medicine, and feasibility assessment

**Results:** Score of knowledge increased significantly ( $p < 0.05$ ) from  $4.08 + SD 2.42$  at baseline to  $6.88 + SD 2.41$  at Post I, to  $6.92 + SD 2.31$  at Post II, and to  $6.65 + SD 1.72$  at Post III in the intervention group. Percentage of subjects who could select the correct medicine increased significantly after CBIA-Pregnancy training from 46% at baseline to 92% at post I (X2 test  $p < 0.05$ ), to 85% at post II, and to 90% at post III (X2- test,  $p < 0.05$  compared to baseline). Feasibility assessment showed that CBIA-Pregnancy needed less time to conduct and cost less than seminar and was supported by legal statements on medicine and law of consumers' protection.

**Conclusions:** CBIA-Pregnancy improved knowledge and skills of pregnant women on selecting OTC common cold preparations. This strategy is considered easy to follow and feasible to implement in hospitals.

**Funding source(s):** WHO-SEARO

144

#### Child Health

*Keywords:* Children, chronic disease, access, essential medicines, healthcare

### **A Rapid Assessment Protocol for Improving Access (RAPIA) to Medicine and Care for Children living with a Chronic Condition (Congenital Adrenal Hyperplasia) in Vietnam**

**Kate Armstrong<sup>1</sup>, David Beran<sup>2</sup>, Maria Craig<sup>3</sup>, Claire Henderson<sup>1</sup>**

<sup>1</sup>CLAN (Caring & Living As Neighbours), Australia; <sup>2</sup>IIF (International Insulin Foundation), United Kingdom; <sup>3</sup>CHW (Children's Hospital Westmead), Australia

**Problem Statement:** Affordable access to medicine and care are major barriers to survival and quality of life for children with chronic health conditions in resource-poor countries. Congenital adrenal hyperplasia (CAH) is the most common adrenal condition of childhood, with cortisol and aldosterone replacement essential to survival. CLAN advocated for the inclusion of hydrocortisone and fludrocortisone tablets in the WHO essential medicine list for children (EMLC), approved October 2008, but the history of insulin suggests this alone will not achieve affordable access for all.

**Objectives:** The Diabetes RAPIA survey was conducted in Vietnam by the IIF in 2008 to explore barriers to insulin access and diabetes care. CLAN took this opportunity to implement an adapted protocol and clearly identify barriers to accessing medicine and care for children with CAH in Vietnam. Although the exact incidence of CAH in Vietnam is not yet known, initial newborn screening trials in 2007 suggest it may be higher in Vietnam (closer to 1:6000, as is found in the Philippines) than Australia, the United States, and the United Kingdom (generally around 1:18,000).

**Design:** Structured surveys and templates used in the Diabetes RAPIA were adjusted to specifically address CAH. The CAH RAPIA was not a statistical assessment of the Vietnamese health system, but rather a rapid collation of qualitative and quantitative data to analyse CAH in a low-income setting.

**Setting:** The CAH RAPIA was a multi-level assessment of factors influencing access to medicine and care for people living with CAH in Vietnam, and had three components: macro (ministerial levels, private sector), meso (provincial levels and health care settings), and micro (caregivers and people living with CAH). Data were collected in Hanoi, Ho Chi Minh City, Thai Nguyen Province, and Dong Nai Province.

**Study Population:** 204 interviews (for diabetes and CAH) were conducted. Participants were selected on the basis of role (ministerial and health sector) and convenience sampling (CAH families) from the four provinces (two mainly urban and two relatively wealthy and urban).

**Policies:** Key policy aspects focused on registration and importation of hydrocortisone and fludrocortisone and on the financial burdens on CAH families.

**Outcome measure(s):** Understanding key barriers to accessing medicines and care for people living with CAH in Vietnam

**Results:** Although health care workers interviewed stated that more young children with CAH were surviving what was striking was the lack of older children with CAH (over 90% of children with CAH were younger than 15). The majority of families (60%) identify financial burdens (cost of medicines in the main) as their greatest concern. Barriers to affordable access to hydrocortisone and fludrocortisone were a mix of national and international factors: neither drug included in the WHO EMLc, neither drug registered in Vietnam, and variable pricing and quality. Barriers to care included lack of access to trained health professionals, particularly beyond major centres; travel costs; health systems not developed for paediatric chronic disease; clinical infrastructure unavailable; and a mismatch between actual and insurance-approved referral pathways. CAH family support clubs were effective for education and support.

**Conclusions:** Since this assessment, access to hydrocortisone and fludrocortisone has improved in Vietnam, with both medicines now registered, imported, and available through public health facilities. Financial burdens on families remain the biggest threat to child survival and well-being. National and international efforts to promote affordable access to medication and care for children with chronic disease in resource-poor settings are needed to drive policies capable of effecting large-scale, sustainable, and systems-based change.

**Funding source(s):** The CAH RAPIA was funded by CLAN with generous practical support from David Beran of the IIF.

146

### **Policy, Regulation, and Governance**

*Keywords:* community empowerment; medicine advertisements, knowledge, skills, CEMA-community

### **CEMA-Community to Improve Knowledge and Skills in Evaluating Medicine Advertisements**

**Chairun Wiedyaningsih<sup>1</sup>, Nunung Priyatni<sup>2</sup>, Siti Munawaroh<sup>3</sup>, Sri Suryawati<sup>4</sup>**

<sup>1</sup>Faculty of Pharmacy, Gadjah Mada University, Yogyakarta, Indonesia; <sup>2</sup>Magister of Medicine Management and Policy, Faculty of Medicine, Gadjah Mada University, Yogyakarta, Indonesia; <sup>3</sup>Agency for Women and Community Empowerment, Yogyakarta Province, Indonesia; <sup>4</sup>Centre for Clinical Pharmacology and Medicine Policy Studies, Gadjah Mada University, Yogyakarta, Indonesia

**Problem statement:** Since objective information on medicine advertisements is often scarce, medicine advertisements may affect the community's perception and health. The Critical Evaluation Medicine Advertisement by the community (CEMA-community) is a strategy that may empower a community in evaluating medicine advertisements. It was developed based on the previous study targeted at medical students with modifications on the content and the inclusion of local regulation on medicine promotion.

**Objectives:** To evaluate the effectiveness of CEMA-community to improve knowledge and skills of participants in critically evaluating medicine advertisements

**Design:** An intervention study used pre and post in time series with control group design

**Setting:** The study was conducted in collaboration with Family Empowerment and Welfare Organization (PKK) in Yogyakarta municipality, Indonesia.

**Study population:** Women who are involved in the family welfare movement team of the PKK organization

**Method:** The CEMA-community method consisted of two sessions: the first was a brief lecture lasting 45 minutes, and the second involved small-group discussions using printed and audiovisual medicine advertisements in problem-oriented approach for 60 minutes. An activity guide was provided. Recorded radio and television advertisements were displayed by means of portable computer. Data on knowledge were obtained by questionnaires. Data on skills were assessed by the number of inappropriate claims participants could identify the advertisements. All data were collected before intervention, right after intervention, and 2 and 4 weeks after intervention. Effectiveness of the approach was shown by the significance of the increasing level of knowledge and skills after intervention. In-depth interviews with participants indicated feasibility of the approach.

**Policy:** The CEMA-community strategy can be used to empower the communities in critically evaluating medicine advertisements through any possible channel.

**Outcome measure(s):** Scores of knowledge and skills in assessing medicine advertisements

**Results:** Participants' knowledge and skills in the CEMA-community group improved significantly (Wilcoxon test,  $p < 0.05$ ) right after intervention and was maintained at the 2 and 4 weeks follow-up. Score of knowledge in the CEMA-community group (means:  $13.9 \pm 2.52$ ,  $18.0 \pm 2.72$ ,  $19.0 \pm 3.10$ ,  $18.3 \pm 3.74$ , respectively before intervention, right after

intervention, and 2 and 4 weeks after intervention) improved significantly (Mann-Whitney,  $p < 0.05$ ) as compared to the control group. Similarly, scores of skills in the CEMA-community group (means:  $7.8 \pm 6.05$ ,  $16.5 \pm 10.01$ ,  $32.6 \pm 12.89$ ,  $32.2 \pm 13.06$ , respectively before intervention, right after intervention, and 2 and 4 weeks after intervention) also improved significantly (Mann-Whitney,  $p < 0.05$ ) as compared to the control group.

Conclusion: CEMA-community was effective in increasing knowledge and skills to critically evaluate medicine advertisements. CEMA-community also feasible to be implemented among Yogyakarta PKK organization members.

Funding source(s): Information not provided

148

#### Chronic Care

Keywords: CBIA-DM, Diabetes Mellitus, Adherence, Hospital-based patient community, DM club.

### Improving Diabetic Patients' Adherence to Treatment Program by Using CBIA-DM Strategy in Hospital- Based Patient Community

Titien Siwi Hartayu<sup>1,2</sup>, Aji Rustamaji<sup>2</sup>, Nurita Prasadayani<sup>2</sup>, Sri Suryawati<sup>2</sup>

<sup>1</sup>Sanata Dharma University, Indonesia; <sup>2</sup>Gadjah Mada University, Indonesia

Problem Statement: As a chronic disease, diabetes-mellitus is a high risk in complications. In order to reduce diabetes-related complications, adherence to treatment program is necessary. Unfortunately, adherence to treatment program of diabetic patients remains problematic. Therefore, developed a strategy to improve diabetic patients' adherence to treatment program by adapting the CBIA (Mothers' Active Learning Method). The new strategy is called CBIA-DM.

Objectives: To evaluate the impact of CBIA-DM strategy on diabetic patients' knowledge, attitude, practice and adherence to treatment program.

Design: Intervention study, utilizing time series, pre and post quasi-experimental with control group study design.

Setting: The study was conducted in two charity hospitals in Yogyakarta, i.e.: Panti Rapih and Panti Rini hospitals. Panti Rapih DM club was selected as intervention site and Panti Rini DM club was chosen as control site.

Study Population: Members of DM club, and/or their family, and/or their caregiver of Panti Rapih and Panti Rini hospitals.

Intervention: Small group discussion interactive approach in one session program with two hours duration of activities. The activities covered introduction, active self-learning using CBIA-DM package, and wrap up and conclusion by DM experts. Data were collected at pre intervention, immediately, 2 weeks and 4 weeks post intervention. Adherence to treatment program was assessed by calculating the number of remaining tablets on the day pre test and post test, recording patients' recall in diet, exercise and foot care practices per day and per week by nurses. Effectiveness of this hospital-based patient community program in charity hospital setting was assessed based on the increasing of knowledge, attitude, practice, adherence, intervention cost and acceptance of CBIA-DM by providers and participants; using Wilcoxon test,  $p < 0.005$ .

Policy: CBIA-DM strategy can be used as patients' empowerment in hospital setting.

Outcome Measures: Knowledge, attitude, practice and adherence to treatment program, cost of intervention and acceptance of CBIA-DM program by the head of diabetic club and participants

Results: CBIA-DM group significantly improved the knowledge score from 7.7 to 8.6 ( $p < 0.005$ ) and practice from 4.6 to 6.0 ( $p < 0.005$ ) with score range 0-11, but not for the attitude score. Adherence increased from 30% vs. 16.7% at baseline, 46.7% vs. 23.3% at post 1, 30% vs. 13.3% at post 2. CBIA-DM program was conducted in two hours with unit cost US\$ 4.00 per person cheaper than regular seminar in DM Club (US\$ 8.00). Participants and provider expressed that CBIA-DM was easy to be followed and enjoyable.

Conclusions: CBIA-DM package improved patients' knowledge, practice and adherence to treatment program. It is an effective strategy which is easy to be followed and enjoyable. It is also feasible to be implemented in hospital-based setting as medium for RUM (Rational Use of Medicines) education. However, improvement of the program is still needed to sustain the impact of the program.

Keywords: CBIA-DM, Diabetes Mellitus, Adherence, Hospital-based patient community, DM club.

Funding Source: WHO-SEARO.

152

#### Chronic Care

Keywords: access to medicines, appropriate use, drug selection, chronic disease

### Irrational Use of Diabetes Medicines in Resource-Poor Settings

David Beran, Geoff Gill, John S. Yudkin, Harry Keen

International Insulin Foundation, United Kingdom

Problem statement: Access to diabetes care is problematic in many resource-poor settings

Objectives: To clearly identify the barriers to access to diabetes care in resource-poor settings

Design: The Rapid Assessment Protocol for Insulin Access (RAPIA) is a practical field guide composed of a series of data collection tools and structured as a multilevel assessment of the different elements that influence the access to diabetes care. Its aim is to get a picture of the health system and to provide different stakeholders involved in diabetes

with recommendations for action. RAPIA provides information about (1) health service structure and functioning; (2) diabetes policies written and enacted; (3) reported and observed practice for diabetes management; (4) availability of insulin, syringes, medicines, and monitoring equipment; (5) other problems hampering access to diabetes care.

Setting: At least 3 different areas of the following countries: Kyrgyzstan, Mali, Mozambique, Nicaragua, Vietnam, and Zambia

Study population: Convenience sample of the following stakeholders in each country: ministerial levels, private sector, National Diabetes Association, Central Medical Store, educators, provincial health officers, health care settings (e.g., hospitals, clinics, health centres), pharmacies and dispensaries, caregivers (i.e., health care workers and traditional healers), and people with diabetes

Outcome measures: Barriers to diabetes care at different levels of the health system in these countries were identified.

Results: RAPIA has identified a variety of issues that are responsible for poor access to diabetes care. One major contributor to the difficulties is a failure to use the least costly but effective treatments. The purchase of insulin can consume as much as 10% of government expenditure on drugs. Selection of the type of insulin and oral medicines can have a huge impact on cost, with the newer analogue insulin formulations costing between 3 and 13 times more than biosynthetic human insulin. Similar considerations apply to most of the newer treatments for people with Type 2 diabetes, which may cost up to 40 times more than metformin and sulphonylureas. Availability in the public sector and generic substitution also have a large impact on cost to the individual.

Conclusions: A variety of barriers to diabetes care exist in the countries studied. One of these is the irrational purchase and use of insulin and medicines not adapted to the health and economic situation of the given country. What is clear from this research is that multiple health system, economic, and social factors affect diabetes care, and these cannot be considered in isolation from each other.

World Diabetes Foundation, Diabetes Foundation (UK based Charity), Diabetes UK, the World Health Organisation, the Barnett & Sylvia Shine No 2 Charitable Trust, other donations from organisations and individuals and administrative support from University College London.

164

#### Policy, Regulation, and Governance

*Keywords:* access to medicines, medicine prices, pharmaceutical expenditure, TRIPS, generic medicines

#### **Extension of market exclusivity and its impact on the accessibility to essential medicines, and drug expense in Thailand: Analysis of the effect of TRIPs-Plus proposal**

**Chutima Akalephan<sup>1</sup>, Suwit Wibulpolprasert<sup>2</sup>, Rungpetch Sakulbumrungsil<sup>3</sup>, Paithip Luangruangrong<sup>4</sup>, Anchalee Jitraknathee<sup>5</sup>, Achara Aeksaengsri<sup>6</sup>, Siripa Udoksorn<sup>7</sup>, Viroj Tangcharoensathien<sup>1</sup>, Sripen Tantivess<sup>1</sup>**

<sup>1</sup>International Health Policy Program-Thailand, Thailand; <sup>2</sup>Ministry of Public Health, Thailand; <sup>3</sup>Faculty of Pharmaceutical Sciences, Chulalongkorn University, Thailand; <sup>4</sup>Drug and Medical Supply Information Center, Ministry of Public Health, Thailand; <sup>5</sup>Drug Control Division, Food and Drug Administration, Ministry of Public Health, Thailand; <sup>6</sup>Research and Development Institute, Government Pharmaceutical Organisation, Thailand; <sup>7</sup>Faculty of Pharmaceutical Sciences, Prince of Songkla University, Thailand

Background: In Thailand and the US negotiating FTA, the 'TRIPs-Plus' is one of the US proposal which would result in an extension of market exclusivity of innovative drugs. In addition, it would foreseeably lead to high and unaffordable medicine prices and inaccessibility to essential medicines.

Objective: To quantify the impact on medicine expense and medicine accessibility.

Methods: Based on 2000 to 2003 Thai Food and Drug Administration (FDA)'s and the Drug & Medical Supply Information Center (DMSIC), costs and accessibility were estimated upon the price and quantity costing between innovative medicines and their generics plus some parameters found from their competitive behaviour. Thereafter, we simulated the 10-year potential additional expense on the 2003 unit price of the patented and monopolized non-patented medicines.

Results: In 2003, the availability of generics helped to save 104.5% of actual expense and the accessibility would increase by 53.6%. By extension of market exclusivity, given that there were 60 new items approved annually, the cumulative potential expense was projected to be \$US 6.2 million for the first year to \$US 5215.8 million in tenth year.

Conclusion: The TRIPs-Plus proposal would result in a significant increase in the medicine expense; and a delay in the increase in medicines accessibility via generics. Several options as well as other related mechanisms to help reduce the negative impact are proposed.

173

#### Economics, Financing, and Insurance Systems

*Keywords:* affordability - essential medicines - generic medicines - health economics - medicine prices

#### **Quantifying the Impoverishing Effects of Purchasing Medicines: A Cross-Country Comparison of the Affordability of Medicines in the Developing World**

**Laurens Mathieu Niëns<sup>1</sup>, Alexandra Cameron<sup>2</sup>, Van de Poel Ellen<sup>1</sup>, Margaret Ewen<sup>3</sup>, Werner B.F. Brouwer<sup>1</sup>, Richard Ogilvie Laing<sup>2</sup>**

<sup>1</sup>Institute for Medical Technology Assessment and Institute for Health Policy & Management, Erasmus University Rotterdam, The Netherlands; <sup>2</sup>Essential Medicines and Pharmaceutical Policies, World Health Organization, Geneva, Switzerland; <sup>3</sup>Health Action International Global, Amsterdam, The Netherlands

**Problem statement:** In developing countries, medicines make up a large portion of total health care costs. Because insurance often is not available or does not cover the costs of medicines, millions need to pay for their medication out of pocket at the time of illness. Hence, in increasing the access to medicines, the issue of affordability is crucial. In this study we quantify the affordability of medicines in developing countries.

**Design:** A cross-country comparison of the affordability of four essential medicines was carried out. We calculated the percentage of the population that would drop below the poverty line after a hypothetical procurement of a medicine. Thus, we compared pre- and post-payment incomes and set these against the international poverty lines of 1.25–2.00 U.S. dollars. Because availability of medicines in the public sector is low, we focused on the private sector, on which most people in developing countries rely for their medication. We looked at the originator brand (OB) and lowest priced generic (LPG) version of salbutamol 100 mcg/dose inhaler, glibenclamide 5 mg cap/tab, atenolol 50 mg cap/tab, and amoxicillin 250 mg cap/tab. Using prevalence rates for asthma, diabetes and hypertension, we also calculated the number of people already being affected or impoverished due to high medicine costs.

**Study population;** The populations of 16 low- and middle-income countries; in total approximately 775 million people

**Outcome measure:** We calculated the percentage of the population living below the poverty line before a (hypothetical) procurement of a medicine as well as the proportion of the population that would be below the poverty line after the procurement of a medicine. The proportion of the population being pushed below the poverty line, we call impoverish rates. This proportion of the population is at risk of being impoverished.

**Results:** In the 16 countries studied, large portions of the population are at risk of becoming impoverished due to the procurement of medicines. LPGs were much more affordable than OB products. For example in Yemen, a low-income country where 7% of the population lives on a pre-payment income of less than 1.25 U.S. dollars a day, OB glibenclamide purchased in the private sector would impoverish an additional 22% of the population versus 3% for the lowest priced generic equivalent. In Nigeria, a low-income country where 56% of the population lives below 1.25 U.S. dollars per day, OB amoxicillin bought in the private sector would impoverish an additional 23%, whereas when procuring the lowest priced generic equivalent this would be 12%.

**Conclusions;** The high cost of medicines can push large groups of patients into poverty. Our results call for action to make access to medicines a priority. Not only to ensure access to medicines but also as a component in reducing poverty. Possible lines of action include promoting the use of quality-assured, low-cost generics as well as developing, implementing, and enforcing sound national and international price policies such as, for example, restrictions on supply chain mark-ups, tax-exemptions, and regulating prices for end-users.

**Funding source(s):** No direct funding was received for this study. The authors were personally salaried by their institutions during the period of writing.

176

#### Access

*Keywords:* drug information, education, pharmacy training,

### **Effect of IEC Intervention on Awareness about Rational Pharmacy Practice in Pharmacy Students**

**Kunda Jayant Gharpure<sup>1</sup>, Vijay Thawani<sup>2</sup>, Smita Sontakke<sup>1</sup>, Kiran Chaudhari<sup>1</sup>, Mangesh Bankar<sup>1</sup>, Rajendra Diwe<sup>3</sup>**

<sup>1</sup>Department of Pharmacology, Government Medical College, Nagpur, India; <sup>2</sup>Department, VCSGMSRI, Srinagar, Garhwal-246174, Uttarakhand, India.; <sup>3</sup>The Hitavada, Nagpur, India

**Problem statement:** There is growing indifference among pharmacy practitioners towards their duty as information providers to patients. The pharmacy curriculum does not emphasise such practical pharmacy aspects. The patients do not always get enough information about the proper use of medicines from prescribers due to time constraints. This leads to improper use of medicines by patients.

**Objectives:** To collect baseline data from students and to intervene through information, education, and communication (IEC) to raise awareness among pharmacy students about rational pharmacy practice

**Design:** A pre-post design study with two interventions was planned using a sample of local graduate and final year pharmacy students from four colleges. After informed consent was obtained, their base knowledge was assessed through written testing, which comprised 27 objective questions related to awareness and attitude towards rational pharmacy practice. This was followed by the first intervention—publication of seven articles on rational medicine use in a leading local English news daily. The articles were displayed on the students' notice board of their respective colleges, and the participants were reminded when these appeared in print. The second intervention was a half-day interactive session where six short lectures were delivered to participants on right and wrong approaches in pharmacy practice. Posters about do's and don'ts of rational pharmacy practice were displayed at the venue. After the second intervention, repeat testing was done using the same pretest questions to assess change. Pre- and post-intervention data was compared using Fisher's exact test.

**Results:** Awareness about DTCA, off-label use, schedules of medicines, books of reference, and pharmacovigilance was significantly changed post-intervention. False notions about need of medicine for every illness, side effects of OTC medicines, brand versus generic quality, newer and costly medicines, injections, and FDCs significantly changed. Attitudinal change was seen in rechecking doubtful prescriptions with the prescriber, lodging a complaint with FDA for quality check, and repeating prescriptions.

**Conclusions:** The role of pharmacist in health care provision is usually overlooked in India. Rational practice must be included at the student level so that when pharmacists enter the profession they are aware of their responsibilities. This study showed that a properly timed and meticulously constructed intervention brings about positive change in knowledge and attitude.

**Funding source(s):** The study was not funded, and there is no conflict of interest.

**180**

**Access**

*Keywords:* IEC intervention, semi-structured questionnaire, self-medication, nonmedical staff, OTC drugs

**Interventional Study on Self Medication in Commonly Occurring Illnesses in Nonmedical Staff of a Tertiary Care Teaching Hospital**

**Smita dipak Sontakke<sup>1</sup>, Vijay Thawani<sup>2</sup>, Sachi Bang<sup>1</sup>**

<sup>1</sup>Government Medical College, India; <sup>2</sup>Department of Pharmacology, VCSGGMSRI, Srinagar, Pauri-Garhwal, Uttarakhand, India

**Problem statement:** Self medication with prescription medicines is known to occur in developing economies since prescription medicines are freely sold over the counter (OTC) because regulations are not implemented. Self medication may result in health hazards resulting from failure to recognize warning symptoms of a disease, missed diagnosis, incorrect therapy, failure to follow precautions, failure to recognize drug interactions and ADRs, use of an inadequate or excessive dose, use of the same medicine under different brand names, and failure to seek subsequent medical advice.

**Objective:** To study patterns of self medication among nonmedical staff of tertiary care teaching hospital in 5 common illnesses (i.e., diarrhea, constipation, sore throat, common cold, and insomnia) and to evaluate the impact of information, education, communication (IEC) intervention

**Design:** This was a randomized, self-control, interventional, pre-post intervention design. A pretested, semi-structured, open-ended questionnaire was used to assess existing knowledge of 100 randomly selected, nonmedical staff members of a tertiary care teaching hospital of Nagpur, India, about treatment of the specified 5 illnesses. Information was sought about medicines used, dose, and ADRs. Respondents' awareness of the warning symptoms of the disease and knowledge about nonpharmacological measures and precautions to be taken while using medicines were recorded.

**IEC Interventions:** Based on the baseline data obtained after analyzing the pre-intervention questionnaire, small group discussions were conducted. These were followed by distribution of handouts containing information about all issues addressed in the questionnaire. A month after this IEC intervention, the pre-intervention questionnaire was re-administered to see the change.

**Results:** The number of respondents was the same after the intervention. Positive outcomes after intervention included increased awareness about ADRs and knowledge of warning symptoms of disease, non-pharmacological measures, and precautions to be taken while using medicines. Significant positive change in the type of medicine used for constipation was observed after intervention. There was no improvement in the pattern of antimicrobials used, and no reduction in the number of respondents who used prescription medicines OTC. Positive outcomes were observed in the age group of 25–40 years and in graduate respondents. Statistical analysis was done by Fischer's exact test.

**Conclusions:** Patterns of self medication improved after IEC interventions, but some aspects were resistant to change. The problems of using prescription medicines OTC and of inappropriate use of antimicrobials can be controlled only with strict implementation of regulations to prevent their availability OTC.

**Funding source(s):** This study was not funded, and there is no conflict of interest.

**185**

**Access**

*Keywords:* clinical guidelines, dispensing, drug utilization, standards of practice, standard treatment guidelines

**Use of Prophylactic Oxytocin by Health Care Providers in Northeast Argentina as Part of Active Management of the Third Stage of Labor**

**Connie Nguyen<sup>1,2</sup>**

<sup>1</sup>Tulane School of Public Health & Tropical Medicine, United States of America; <sup>2</sup>Institute for Clinical Effectiveness and Health Policy-Buenos Aires, Argentina

**Problem statement:** Postpartum hemorrhage (PPH) is the second leading cause of maternal deaths in Latin America and the primary cause throughout the world. To reduce the incidence of PPH, active management of the third stage of labor (AMTSL) has been widely recommended and accepted as standard care. In many countries, however, particularly in Latin America, AMTSL is not being routinely practiced. In particular, birth attendants are not routinely administering prophylactic uterotonics to mothers in labor as a result of lack of knowledge among health care providers and limited access to drugs, among other reasons.

**Objectives:** The primary objective was to measure and compare birth attendants' knowledge, use, and opinion regarding prophylactic uterotonics, controlled cord traction, and uterine massage from before and after the intervention was administered. The secondary objective was to assess the availability and storage conditions of prophylactic

uterotonics, as well as the existence of clinical guidelines regarding labor and delivery, at each of the participating hospitals.

**Design:** This was a prospective before-and-after study without a control group. We evaluate the efficacy of an intervention through pre- and post-surveys distributed among medical workers in 5 maternity hospitals in Corrientes Province.

**Setting:** The study took place in 5 hospitals located throughout the province of Corrientes, located in northeastern Argentina. Corrientes Province is an economically underdeveloped region that depends mostly on agriculture for subsistence and growth. The participating hospitals were either primary or secondary and are part of the public sector.

**Study population:** We invited all birth attendants, including physicians, midwives, and nurses who work in the participating hospitals to take part in the study. During the baseline period, 30 providers participated in the survey. During the follow-up period, 32 providers participated. For both phases, the mean age was approximately 40. One-third of them were male, and the overwhelming majority were physicians.

**Intervention:** During a 6-month baseline period, we performed an intervention that consisted of training birth attendants on AMTSL, distributing oxytocin-filled vials of Uniject, and employing hospital reminders to reinforce the practice of AMTSL. For the training process, we conducted a 1-day instructional session at each hospital. During the intervention period, 1-ml Uniject devices containing 10 IU of oxytocin as well as oxytocin vials and syringes were distributed to the participating hospitals. The Prevention of Postpartum Hemorrhage Initiative (POPHI), sponsored by USAID, constructed posters that instructed how to practice AMTSL. These posters were then placed in conspicuous locations throughout the hospitals.

**Outcome measurements:** To determine the use of AMTSL, particularly the administration of prophylactic oxytocin, from before and after the intervention, information was collected from the study data forms of 941 women giving vaginal births at the baseline period and 951 at the intervention period.

**Results:** For the most part, providers' knowledge and positive attitude about AMTSL increased from the baseline to the follow-up period, with a few exceptions. Fewer respondents answered "yes" in the post-survey regarding what AMTSL consists of. The percentage of providers who felt that prophylactic uterotonics were effective was higher in the pre-survey than post-survey. These differences were not statistically significant.

The follow-up questionnaire contains a series of questions regarding Uniject that are not included in the baseline one, since the latter was administered prior to the intervention. For these questions, nearly 97% of providers responded that they have used Uniject to administer prophylactic uterotonic. 96% answered that Uniject facilitates the use of prophylactics as part of AMTSL. When asked to compare Uniject to ampoules and syringes, all contested that Uniject was easier to use than the rest. 44% replied that if Uniject was not available, the administration of oxytocin would be reduced.

**Conclusions:** The results from our study indicate an overall increase in the use of AMTSL ensuing the intervention. The area that showed the greatest increase was the administration of prophylactic oxytocin. The percentage of providers who have used controlled cord traction or uterine massage increased as well, although the number was already significantly high prior to the intervention. In conclusion, the intervention yielded mostly positive results. More health care workers in Corrientes Province are aware of AMTSL and how to administer each component. Because the sample size is very small, however, it is recommended that additional surveys be administered on a greater scale, perhaps in other provinces of Argentina to compare if the results remain consistent and to assess the discrepancies from this particular study.

**Funding source(s):** Minority Health International Research Training, National Center on Minority Health and Health Disparities, and the National Institutes of Health, USA

186

### Policy, Regulation, and Governance

*Keywords:* pharmaceutical policies; systematic reviews

## Overview of Systematic Reviews on Pharmaceutical Policy and Their Relevance to Low- and Middle-Income Countries

**Andy Gray<sup>1</sup>, Fatima Suleman<sup>2</sup>**

<sup>1</sup>of Therapeutics and Medicines Management, Nelson R Mandela School of Medicine, University of KwaZulu-Natal, South Africa; <sup>2</sup>School of Pharmacy and Pharmacology, University of KwaZulu-Natal, South Africa

**Problem statement:** The evidence base for large-scale pharmaceutical policy interventions has not been systematically summarised or assessed for relevance in low- and middle-income countries (LMIC).

**Objectives:** To determine the impact of pharmaceutical policies by means of an overview of systematic reviews (SRs) on pharmaceutical policy and to assess the relevance of such evidence in LMICs

**Design:** Relevant databases (e.g., MEDLINE, EconLit, CINAHL, Cochrane, ProQuest, EMBASE, JOLIS, ISI Web of Science, IPA, INRUD, NTIS, PAIS, SourceOECD and WHOLIS) were searched from inception to May 2009 to identify SRs on 13 pre-determined policy categories. Pharmaceutical policies were defined as laws, rules, and financial and administrative orders made by governments, nongovernment organisations, or private health insurers that are intended to directly affect the use or cost of medicines.

**Results:** Searches yielded 7,129 citations; 55 were identified for full text retrieval but 38 were considered relevant only as background material or as policy options that have not yet been applied at scale; 17 were considered for inclusion into the review. Three were subsequently rejected and the findings of 14 SRs were extracted and their applicability in LMICs considered. No SRs assessed patent and profit policies, sales and dispensing policies, policies that regulate the

provision of health insurance including medicines coverage, or policies that deal with the provision of patient information. One SR dealt with registration and classification policies (the scientific basis for generic medicine registration, applicable to all countries); 1 with marketing policies (the effects of direct-to-consumer advertising; though not explicitly allowed in any LMIC, still of relevance); 1 with policies on price and purchasing (reference pricing; of limited applicability in LMICs not using insurance financing); and 2 with prescribing policies that rely on financial incentives (replacing fee-for-service remuneration with alternatives, such as capitation; neither easily applicable in LMICs where there is no separation of health care financing from provision of services). Nine SRs dealt with one or more of the following: prescribing policies that rely on educational or regulatory policies targeting prescribers, policies that determine which medicines are reimbursed, restrictions on reimbursed medicines (such as prior authorization), co-payments, and caps. The dissemination of educational materials alone had little effect. Group education might have some effect, and one-on-one academic detailing, computerised alerts and reminders, and pharmacists' interventions (such as pharmacist-led collaborative care) were effective in changing prescribing behaviour. Application at scale is limited in LMICs by the shortage of trained health professionals and computerisation. Managed care formulary management tools have little direct applicability in LMICs outside of private insurance schemes, and the effects of cost shifting from third-party payers to poor and vulnerable patients need attention. Such tools will be of greater relevance as more middle-income countries introduce national health insurance schemes.

Conclusions: More primary evidence of the application of pharmaceutical policies at scale in LMIC settings needs to be published. LMICs should be encouraged to fund monitoring and evaluation units within their national structures to generate and assess such evidence.

Funding source(s): Alliance for Health Policy and System Research

189

Malaria

Keywords: Cost-analysis, ACTs, drug category, malaria management

### **Cost Analysis of Management of Malaria Using ACT in the Private Sector of Zimbabwe: A Regulatory Implication**

**Travor Mabuqu<sup>1</sup>, Tendai Matsatsa<sup>2</sup>**

<sup>1</sup>University of Zimbabwe, Zimbabwe; <sup>2</sup>Kenlink Pharmacy, Harare, Zimbabwe

**Problem statement:** The development of antimalarial drug resistance has led to increasing calls for the introduction of artemisinin-based combination therapy (ACT). Zimbabwe adopted ACTs as first-line management of malaria with 62% of malaria patients traditionally being managed in the private sector; however, of importance was the issue of accessibility. The previous first-line therapy of chloroquine plus sulfadoxine and pyrimethamine (CQ-SP) was easily accessible with limited financial barriers. ACTs are expensive and have an additional condition to access them. Medicines Control Authority of Zimbabwe (MCAZ) regulation can affect access by changing the category of these regimens from prescription preparation (PP) to household remedy (HR). It is expected that any category chosen by MCAZ has implications for out-of-pocket expenditure per malaria case managed from a patient's perspective. This study aimed at elucidating the variation in costs of management of malaria using ACTs from patient's perspective. Specifically, patient costs associated with different categories from PP, pharmacist initiated medicine (PIM), pharmacy (P), and HR.

**Objectives:** To determine the costs associated with management of a single adult case of uncomplicated malaria using ACTs with ACTs assuming different categories in Zimbabwe (HR, P, PIM, and PP) from a patient's perspective; to determine the costs associated with management of a single adult case of uncomplicated malaria using CQ-SP in Zimbabwe, from a patient's perspective; and to compare these costs and make appropriate recommendations from an economic perspective

**Design:** An activity-based costing (ABC) approach was instituted in this study. The three major activities involved included consultation, diagnosis, and drug treatment, which are major indicators of the out-of-pocket expenditure from the patient perspective. Three possible scenarios for consultation could be assumed depending on the category of the ACT: (1) no consultation required (if a drug is categorized as HR or P), (2) pharmacists' consultation if it is a PIM, and (3) doctor's consultation if it is a PP. Diagnosis has two major routes—either optic microscopy or through rapid diagnostic tests based on lateral flow immuno-chromatography (commonly known as RDTs). Drug treatment could only be equivalent to the drug price of either ACT or CQ-SP. We developed case scenarios for malarial patients in need of malaria health services using various possible routes. These possible routes were valued using market rates in the private sector. All costs were reported in 2010 base year.

**Setting:** Private patient case scenarios were developed to depict the stages of malaria service provision in this sector.

**Study population:** All patients with susceptible malaria episodes who access their services in the private sector (estimated to be 62% of all malaria cases in Zimbabwe)

**Intervention(s):** The intervention of interest was an adult case of malaria managed in the private health sector of Zimbabwe.

**Policies:** Introduction of ACTs, followed by regulatory framework, which required mandatory confirmation by malaria test before commencement of treatment. Furthermore, a requirement of categorization of ACTs was also pending.

**Outcome measure(s):** The extent of variation in financial barriers to access of malarial service in the private health sector of Zimbabwe as approximated by out-of-pocket expenditure on consultation, diagnosis, and drug treatment.

**Results:** The study determined that the decision of how to categorize ACTs has huge implications for access of malarial services in the private health sector of Zimbabwe. Initially, there was no consultation required with the use of CQ-SP in

malaria management. Because these medicines were HR category, they could be accessed in supermarkets. Their cost per adult course was only 2.67 U.S. dollars (USD) (range 2–4USD). If categorized as HR or P, however, ACTs will lead to a total cost per case managed of 15.98 USD (range 12–17USD). If categorized as PIM, an initial consultation will average 1USD (range 0–3USD) plus the diagnosis using RDT of approximately 5USD (range 4–6USD) with additional drug cost averaging 13.48USD. It was also determined that the cost of management of malaria if ACT are categorized as PP will increase to (1) consultation fee of 20USD (range 15–30USD), (2) diagnosis costs of 5USD for RDTs or 12.22USD for laboratory (optic microscopy), and (3) 13.48USD for drug treatment.

Conclusions: It is evident from the results that making the ACTs a PP will yield a total out-of-pocket expenditure of approximately 56USD, which is about 4 times greater than a case with ACT categorized as a HR. This results in enormous financial barriers to access. It is therefore paramount for the regulator (MCAZ) to consider these cost implications if universal access to malaria treatment and care is to be realized. These results, however, need to be weighed in line with other factors such as drug resistance associated with unlimited access, misuse of limited resources associated with uncontrolled access and unconfirmed cases, and training of the public on use of RDTs.

Funding source(s): Health Economics, Research and Information Trust

192

### Economics, Financing, and Insurance Systems

*Keywords:* Access to medicines, medicine prices, availability, affordability, Vietnam.

#### Medicine Prices, Availability, and Affordability in Vietnam

**Tuan Anh Nguyen<sup>1,2</sup>, Rosemary Knight<sup>1</sup>, Andrea Mant<sup>1</sup>, Minh Quang Cao<sup>3</sup>, Martin Auton<sup>4</sup>**

<sup>1</sup>School of Public Health and Community Medicine, University of New South Wales, Australia; <sup>2</sup>Department of Pharmaco-economics and Pharmaceutical Management, Hanoi University of Pharmacy, Vietnam; <sup>3</sup>Ministry of Health of Vietnam, Hanoi, Vietnam; <sup>4</sup>Health Action International, Amsterdam, the Netherlands

Problem statement: Ensuring the availability of affordable medicines is a precondition to realizing the fundamental human right of access to essential health care. Yet, medicine prices are often high and unaffordable for a large segment of the world's population.

Objective: To assess the price, availability, and affordability of a sample of medicines in Vietnam

Methods: Data on the price and availability of 42 medicines were collected in November 2005 using the standard World Health Organization/Health Action International methodology in 5 geographical areas in Vietnam. The median price of these medicines was compared with the Management Science for Health international reference prices, expressed as median price ratios. Affordability was measured as the number of days' wages required for the lowest paid unskilled government worker to purchase one course of therapy. Of the 42 medicines studied, 15 were chosen for international comparison, which were included in at least 80% of other country surveys using this methodology.

Results: Generic medicines were found in 33.6% of public medicine outlets. The median public procurement price was 1.82 times the international reference prices for generics, but for some individual medicines it was less than half of that. The price to patients in public outlets was higher than in private pharmacies. Adjusted for Purchasing Power Parity in 2005, the lowest generic prices in private pharmacies were still 8.3 times higher than the benchmark. Despite the markedly lower prices, medicines in Vietnam were much less affordable than in the comparable Western Pacific Region.

Conclusions: Medicines in Vietnam were high in price, and low in both availability and affordability, especially in the public sector. Access to medicines, therefore, remains a challenge for the Vietnamese Government. To make public facilities a primary treatment option for the poor, Vietnam needs to reduce medicine prices in this sector by improving procurement efficiency, ensuring and promoting low-priced generics, and regulating reasonable mark-ups.

Funding source(s): The World Health Organization (Vietnam Office)

193

### Policy, Regulation, and Governance

*Keywords:* Medicine prices, corruption, accountability, qualitative research, Vietnam

#### Corruption and High Medicine Prices in Vietnam: A Qualitative Study

**Tuan Anh Nguyen<sup>1,2</sup>, Rosemary Knight<sup>1</sup>, Andrea Mant<sup>1</sup>, Minh Quang Cao<sup>3</sup>, Husna Razee<sup>1</sup>**

<sup>1</sup>School of Public Health and Community Medicine, University of New South Wales, Australia; <sup>2</sup>Department of Pharmaco-economics and Pharmaceutical Management, Hanoi University of Pharmacy, Vietnam; <sup>3</sup>Ministry of Health of Vietnam, Hanoi, Vietnam

Problem statement: Medicine prices in Vietnam were unreasonably high. Adjusted for Purchasing Power Parity in 2005, the prices to patients in the public sector were 46.58 and 11.41 times the international reference price for originators and lowest priced generic equivalents, respectively.

Objective: To identify the main reasons for high medicine prices in Vietnam

Method: Semi-structured questionnaires were used to conduct 43 interviews with different stakeholders including pharmaceutical companies' representatives, Ministry of Health officials, and prescribers in Vietnam from April 2008 to December 2009. The interviews were all recorded, transcribed, and coded using NVivo8 software. Ethics approval was obtained from the University of New South Wales.

Results: According to participants' responses, originator medicines in Vietnam were too expensive due to a supplier monopoly. Prices of generic medicines were set at around 80%, sometime even higher than those of corresponding originator medicines due to informal payment to authorities, commissions for prescribers, and kickback to hospital pharmaceutical departments. Pressures for survival arising from an imperfectly competitive pharmaceutical market, among other reasons, were believed to force pharmaceutical companies to be inextricably linked to prescribers. Salary pressures and the perpetual corruption in the absence of penalties in Vietnam were given as the main motives for prescribers to collude with the pharmaceutical industry. The magnitude of reported corruption varied across geographic regions, sectors, and prescriber's specialties. In addition, overreliance on the international market, poor market intelligence, failure to achieve economies of scale due to duplication in drug production and distribution, too many layers in the distribution network, and malfunctioning pricing policies were reported to be non-corruption related causes for the high medicine prices in Vietnam.

Conclusions: Corruption was reported as a main driver for high medicine prices in Vietnam. Although individual factors such as professional ethics and personal value influenced physician behaviours and their response to corruption, entrenched or intractable systemic issues including lack of transparency and accountability and poor legislation enforcement emerged as important factors perpetuating corruption. Addressing the widespread issue of corruption, both individual and systemic factors, is necessary in developing sound medicine pricing policies in Vietnam. Interventions to relieve dependencies for survival of health care services on the corrupt system are needed. Rationalization of the domestic drug production and distribution to achieve economies of scale and reduce wasteful uneconomic competition might be a solution that Vietnam needs to achieve soon.

Funding source(s): The Ministry of Education and Training, Government of Vietnam

## 194

### Drug Resistance

Keywords: drug utilization, standard treatment guidelines, appropriate use

### Promoting Rational Antibiotic Prophylaxis in Clean Surgeries in China

Yingdong Zheng<sup>1</sup>, Jing Sun<sup>2</sup>, Qin Yan<sup>3</sup>

<sup>1</sup>Dept. of Epidemiology and Biostatistics, School of Public Health, Peking University, China.; <sup>2</sup>China National Health Development Research Center, MoH ; INRUD China Core Group Member; <sup>3</sup>National Institute of Hospital Management, MoH, China; INRUD China Core Group Member

Problem statement: An official report shows that 80–90% of the clean surgeries were with irrational antibiotic prophylaxis in Chinese tertiary hospitals in 2007.

Objectives: To promote rational antibiotic prophylaxis in clean surgeries in China

Design: A controlled intervention study. The effect of the intervention was measured and compared before and after intervention, and compared with the control group.

Setting: Public general tertiary hospitals

Study population: The sampling frame is within the National Monitoring Network of Clinical Antibiotics Use (Network) which consists of 164 tertiary hospitals distributed in 31 provinces. All provinces were divided into 3 groups based on their gross domestic product per capita in 2007. Three hospitals were randomly selected from each group, 9 hospitals were selected as intervention group (IG). Three other hospitals voluntarily joined IG, a total of 12 tertiary general hospitals were finally included in IG. Each hospital in IG was required to collect all the medical records of the 3 targeted clean surgeries (i.e., thyroidectomy, mastectomy, and hernia) discharged in the months of March and September 2008, March and June 2009, respectively. All the network hospitals were assigned to control group (CG). Each hospital in CG was required to randomly select 15 surgery cases from all the discharged cases in the 2nd week of the 1st month of each quarter (January, March, June, and September), and report to the Network every half year in June and December. There were 164 hospitals providing data to the Network in March 2008, and 171 hospitals in March and June 2009 (additional hospitals joined the Network). All targeted clean surgery cases were identified from the Network as control sample. 212 cases were identified from Network database in March 2008, which were extracted from the 2008 first half year of reporting; 445 cases were identified from the 2009 first half year of reporting, including the data for March and June 2009. In total, 3,961 and 657 cases identified in IG and CG, respectively, for the study.

Interventions: Circulating and implementing MOH regulations in both IG and CG; launching DTC training course plus circulating related materials and literature of rational antibiotic prophylaxis in clean surgery to physicians in IG. Other interventions in IG include formulating guidelines at hospital level and using the monitoring, training, and planning (MTP) method to comply with the guidelines.

Outcome measure(s): Proportion of antibiotic medication with or without indication was judged. The cases using antibiotics with indication were evaluated with a synthetic score to measure the rationality of antibiotic prophylaxis.

Results: Following three waves of interventions, the proportion of cases not using antibiotics rose from 3.5% to 11.9%, and the average duration of antibiotic medication of IG declined from 4.9 to 4.1 days (Kruskal-Wallis H Test,  $p < 0.05$ ). The proportion of antibiotics use without indication of IG decreased from 61.9% to 60.9%, and the rationality scores of IG increased from 55.4 to 77.0. Comparing the changes of IG with CG during March 2008 and June 2009 following the third intervention, the proportion of antibiotics use without indication decreased from 61.9% (IG) and 84.4% (CG) ( $\chi^2$  test,  $p < 0.01$ ) to 60.9% (IG) and 59.1% (CG) ( $\chi^2$  test,  $p > 0.05$ ); the rationality scores increased from 55.4 (IG) and 57.6 (CG) (t test,  $p > 0.05$ ) to 77.0 (IG) and 64.3 (CG) (t test,  $p < 0.01$ ), respectively. The key irrational antibiotic prophylaxis problems were antibiotic selection, medication given at the wrong time, and the long duration of medication, which held 28.1%, 34%, and 69.6% of the total indicated cases, respectively.

Conclusions: The interventions made limited improvement in not using antibiotics without indication, but significant improvement in using antibiotics with indication toward rationality. There are complicated factors affecting the antibiotics use decision-making beyond the capacity of technical interventions.

Funding source(s): WHO

195

### Policy, Regulation, and Governance

*Keywords:* Access to medicines, retail pharmacy, counterfeit and substandard drugs, Cambodia, anthelmintics

#### **A Survey on the Quality of Anthelmintic Medicines in Cambodia**

**Mohiuddin Hussain Khan,<sup>1</sup> Junko Okumura,<sup>2</sup> Tey Sovannarith,<sup>3</sup> Nam Nivanna,<sup>3</sup> Manabu Akazawa,<sup>4</sup> Kazuko Kimura<sup>1</sup>**

<sup>1</sup>Department of Drug Management and Policy, Institute of Medical, Pharmaceutical and Health Sciences, Kanazawa University, Ishikawa, Japan; <sup>2</sup>Department of International Health, Institute of Tropical Medicine, Nagasaki University, Nagasaki, Japan <sup>3</sup>National Health Product Quality Control Center, Phnom Penh, Cambodia <sup>4</sup>Department of Public Health and Epidemiology, Meiji Pharmaceutical University, Japan

**Problem Statement:** Counterfeit medicine is a global threat to the access of medicines, especially in the developing countries. In response to the counterfeit crisis of Cambodia the Ministry of Health initiated a project in collaboration with Kanazawa University, Japan in 2006. The overall infection rate of intestinal parasite ranged from 26% to 54% in different parts of Cambodia (Stich et al. 1999; Lee et al. 2002; Parak et al. 2004). On these backgrounds in 2008, the anti-counterfeit medicine project investigated the quality of anthelmintic medicines in the private pharmaceutical market, which is the first among such category of medicines in the country.

**Objectives:** The objectives of this survey were to assess prevalence of counterfeit anthelmintic medicines, and to find out influential factors.

**Design:** Cross-sectional study

**Setting:** Private pharmacies of the capital, Phnom Penh and three adjacent provinces, Kandal, Takeo and Kampong Speu of Cambodia.

**Study Population:** Albendazole, mebendazole and metronidazole were selected as candidate medicines from the Essential Drug List of Cambodia. Samples were collected from August 5 to 20, 2008 through a stratified random sampling scheme to cover all types of private drug outlets.

**Intervention(s):** Medicines were carefully observed including their registration labeling. Authenticity investigation was conducted with the respective manufacturers and with the Medicines Regulatory Authorities (MRAs). Analyses of the samples were conducted by High Performance Liquid Chromatography (HPLC) at the National Health Product Quality Control Centre (NHQC), Cambodia. Where appropriate, Fisher's exact test was used to test the significance of categorical variables in 2X2 table, and Tukey's HSD (Honestly Significant Difference) test was applied to identify association among levels of classification variables.

**Results:** A total of 203 samples of anti-helminthics were collected from 137 drug stores. Domestic products constituted 36.9% of the total samples. Unlicensed outlets were significantly more common in rural areas (25%, 25/102) than in urban areas (12%, 12/101) (Fisher's exact test:  $p < 0.05$ ). Out of 196 samples which were verified for registration, 15.8% were not registered. The registration status of medicines was significantly associated with the type of drug outlet (Tukey's HSD,  $p < 0.05$ ), package conditions (Fisher's exact test,  $p < 0.05$ ), and urban/rural area (Fisher's exact test,  $p < 0.05$ ). Among 165 samples, which were successfully investigated for their authenticity, 7 (4.2%) were identified as counterfeit. All of these medicines were purchased as loose conditions in open packs or containers, and most of them were foreign manufactured and/or without registration.

**Conclusion:** The survey urges strict implementation of registration system along with vigilance on the availability of unregistered medicines in the pharmaceutical markets to combat counterfeit medicines in Cambodia.

Funding source: Japan Pharmaceutical Manufacturers Association (JPMA)

199

### Child Health

*Keywords:* antibiotic resistance, knowledge, applied knowledge, reported practice, antibiotic prescribing, antibiotic dispensing

#### **Antibiotics and Pediatric Acute Respiratory Infections in Rural Vietnam: Health Care Providers' Knowledge, Practical Competence, and Reported Practice**

**Chuc Thi Kim Nguyen**

Hanoi Medical University, Viet Nam

**Problem statement:** Acute respiratory infections (ARIs) are among the leading

causes of morbidity and mortality among children in low and middle-income countries. In Vietnam, ARI symptoms are the most common reason for seeking health care for children.

**Objectives:** To assess knowledge, practical competence, and reported practices among health care providers about antibiotics to treat acute respiratory infections in children under 5 in rural Vietnam

**Design:** This is a descriptive cross-sectional study conducted June to July 2007 in Bavi district, Vietnam. Inclusion criteria were all health care providers (HCP) who prescribe or dispense drugs for treatment of children under 5 in the district, excluding traditional healers.

**Setting:** The study setting was Bavi district, 60 km west of Hanoi, where an Epidemiological Field Laboratory (Filabavi) was implemented in 1998. The district covers an area of 410 km<sup>2</sup> divided into lowland, highland, and mountainous areas according to geographical characteristics.

**Study population:** HCPs who provided neither health services nor western drugs for children under 5 were excluded from the study. To check the completeness of the list, communal health staff and Filabavi surveyors travelled around the commune to double-check. In all, of the 457 health care providers on the list, 48 were ineligible due to incorrect address, not treating children, or using only herbal medicines for treatment.

**Results:** Of the total 392 respondents, 27% agreed with statements regarded as correct concerning the consequence of antibiotic resistance, which is ultimate treatment failure for both patients and community. 21% stated antibiotics should be used if the child had cough and runny nose without fever, and 79% in cases where fever is included. In all, 19% of HCP had correct knowledge about the use antibiotics for treatment of ARI among children under 5. The use rate of antibiotics in common colds (81%) was not significantly different compared with that in the pneumonia scenario, if referral cases (87%) are not considered; however, it was significantly lower among those who had correct knowledge. According to reported practice, children in the latest encounters were mild ARI 62%, then severe ARI 19%, and others 19%; of those, the antibiotic use for treatment was 90%, 87%, and 78%, respectively. Beta-lactams were most likely antibacterials used regardless of the severity of the diseases.

**Conclusion:** Antibiotics are commonly dispensed or prescribed unnecessarily for common colds. Continuous training in respiratory syndrome approach and supervision are needed. Furthermore, changes to the motivations and expectations surrounding physician-patient interaction are recommended to improve antibiotic use.

**Funding source(s):** Health Systems Research Project, funded by Sida/SAREC, Sweden and the Ministry of Science and Technology, Vietnam.

## 200

### Policy, Regulation, and Governance

*Keywords:* pharmaceutical policy, evaluation, quality indicators, safety,

#### **Rapid Assessment Methods for Monitoring Pharmaceutical Policy**

---

**Elizabeth E Roughead, Nicole L Pratt**

University of South Australia, Australia

**Problem statement:** The advent of computerised pharmaceutical dispensing data sets enables improved assessment of pharmaceutical policy; however, complex methodological designs can limit use. Methods that can be used by policy makers would facilitate improved monitoring of pharmaceutical policy.

**Objectives:** To provide a rapid assessment method for monitoring quality and safety of pharmaceutical use.

**Design:** We propose prescription sequence symmetry analysis as a potential method for rapid assessment of pharmaceutical use. The advantage of the method is its computational speed and its minimum data set requirement. Analyses can be undertaken within a day, and the method requires no more than three variables: drug name, date of supply, and a patient identifier. Sequence symmetry analysis examines asymmetry in the distribution of an incident event (e.g., either prescription of another medicine or hospitalisation) before and after the initiation of a specific treatment. Asymmetry may indicate an association of the specific medicine of interest with the event. The method uses a within-person design, making it robust towards confounders that are stable over time. A 12-month time window was used for safety assessments. Longer time windows were used for evaluating prior-use policies and quality-of-care indicators.

**Setting:** Australia, Taiwan, Japan

**Results:** A survey of countries participating in the Asian Pharmacoepidemiology Network (ASPEN) demonstrated the required variables are available in Japan, Korea, Taiwan, Sweden, the United States, and Australia. The method is amenable to a distributive network model in which analysis code is distributed to participants and results collated. A proof-of-concept study generated results from Japan, Taiwan, Australia, Korea, Sweden, and the United States. Pilot testing in Australia has shown the feasibility and practicality of the method. Prescription symmetry analysis of the risk of loop diuretics (indicative of heart failure treatment) after initiation of a nonsteroidal anti-inflammatory agents revealed an adjusted sequence rate ratio 1.3 (95% CI 1.20–1.41), which compared to a conventional cohort study of relative risk 1.33 (95% CI 1.10–1.60). Results also supported quality use of medicines assessments with prior-use assessment showing that only 57% of people had ever used atorvastatin prior to being initiated on the combination product, whereas only 46% had used tamoxifen prior to exemestane, despite the existence of a prior-use policy.

**Conclusions:** The use of sequence symmetry analyses provides timely and efficient evidence of safety issues associated with pharmaceuticals. Application using a distributive model overcomes problems of limited pharmacoepidemiological expertise. Modification of the design enables prior-use policies to be evaluated, whereas post-use assessment enables quality-of-care measures to be evaluated.

**Funding source(s):** Libby Roughead is supported by the Australian Research Council.

203

**Policy, Regulation, and Governance***Keywords:* Essential drug program, access to medicines, availability, affordability, appropriate use**Essential Medicine Concept as a Core of Drug Policy: Impact on Costs, Availability of Quality Medicines, and Their Rational Use in Delhi (India)****Vandana Roy, Usha Gupta, Arun Kumar Agarwal**

Maulana Azad Medical College, India

**Problem statement:** Until 1994, in Delhi, it was observed that, despite the government spending about 30% of the health budget on medicines, essential medicines were not available to a large number of needy patients. In 1994, the Government of Delhi implemented a drug policy based on the essential medicine concept. The aim of the policy was to make a limited list of quality medicines available at all HFs.

**Objectives:** To evaluate the impact of the drug policy on availability, accessibility, costs, quality, and rational use of medicines after 12 years of implementation

**Design:** Operational field, randomized, cross sectional study; longitudinal in time series (data prior to 1994 till 2009)

**Setting:** Sample frame was Delhi (area 1483 km<sup>2</sup>), 43 public HFs distributed across all 9 districts of Delhi, with primary (35), secondary (5), and tertiary (3) levels of health care included.

**Study population:** 1,736 patients surveyed; 1,957 prescriptions monitored; 326 doctors and 137 pharmacists interviewed

**Policy change and intervention:** Under the policy, the government took steps such as the preparation of an essential medicine list (EML), establishment of a pooled procurement system for medicines with a central procurement agency, establishment of a good quality assurance system, publication of standard treatment guidelines (STG) and formulary, and training of health professionals in rational use of medicines.

**Outcome measure(s):** WHO's indicators for monitoring national drug policies, drug use in HFs, and drug prices

**Results:** Availability of medicines has improved with 91.2% of prescribed medicines being dispensed to patients. A decrease in the number of days of medicine stock-out from 2,170 □ 681.6 to 1,708.3 □ 687.6 over 3 years (p=0.0001) was observed. Accessibility to medicines has improved in terms of proximity of the patients to the HFs, time taken to reach HFs, expenditures incurred to reach HFs, and availability of medicines, but only 8% of patients had complete knowledge about how to take the prescribed medicines. The total cost of medicines procured through centralized bulk purchase has decreased by 33%. Individual costs of many medicines (57%) have decreased. The costs are lower than through local hospital tender, government retail outlets, retail private pharmacies, and international prices. The quality of medicines has improved. The total number of medicine samples being tested has increased by 204%, and the percentage of medicines failing quality testing decreased from 1.45% to 0.13%. In use of medicines, both an improvement and a decline in prescribing indicators was observed. Prescribing of medicines from the EML has increased and antimicrobial use decreased. Use of generics, however, has decreased and 80% of prescriptions were not written completely. Prescribers: 82.5% of doctors were unaware of the drug policy and 81.6% were not aware of any training programme on rational use of medicines. Only one-third had a copy of the formulary or a copy of the STG. Pharmacists: only 27% of the pharmacists had received any training on storage and dispensing practices.

**Conclusion:** The essential medicine policy has significantly improved availability, cost, and quality of medicines in public HFs in Delhi. Accessibility to medicines has improved in terms of HF infrastructure and availability of medicines, but patients lack knowledge on how to use their medicines. Rational use of medicines requires improvement. A drug policy based on the essential medicine concept is a definite way to improve accessibility to quality, low cost medicines.

**Funding source(s):** Partially funded by the World Health Organization, South East Asia Region through the Delhi Society for Promotion of Rational Use of Drugs

204

**Access***Keywords:* availability, chronic disease, public sector, private sector, generic (multisource) medicines**Differences in the Availability of Medicines Used for Noncommunicable and Communicable Conditions in the Public and Private Sectors of Developing Countries****Alexandra Cameron<sup>1,2</sup>, Ilse Roubos<sup>2</sup>, Margaret Ewen<sup>3</sup>, Aukje Mantel-Teeuwisse<sup>2</sup>, Hubert Leufkens<sup>2</sup>, Richard Laing<sup>1</sup>**

<sup>1</sup>Essential Medicines and Pharmaceutical Policies, World Health Organization, Geneva, Switzerland; <sup>2</sup>Utrecht Institute for Pharmaceutical Sciences, Utrecht University, Utrecht, the Netherlands; <sup>3</sup>Health Action International - Global, Amsterdam, the Netherlands

**Problem statement:** Studies have found that low availability, high prices, and poor affordability are impediments to access to medicines in low- and middle-income countries.

**Objective:** To investigate whether, in these countries, differences exist in the availability of medicines used for noncommunicable diseases (NCDs) compared to those used for communicable conditions

**Design:** A secondary analysis of medicine availability in 40 developing countries was conducted using data from surveys of public and private sector medicine outlets collected with a standard methodology. Availability was compared for 30 commonly surveyed medicines: 15 used for communicable conditions and 15 used for NCDs. The primary outcome measure was the difference in mean availability between the two baskets of medicines (communicable and noncommunicable). In addition, to investigate whether the availability of NCD medicines differed by indication, the mean availability of each therapeutic class represented in the NCD medicines basket was compared to the mean

availability of the 15 medicines in the communicable basket. The ratio of the availability of the communicable medicines basket to the noncommunicable medicines basket was also calculated on a country-by-country basis and analysed by World Bank Income Group and WHO Region.

Setting: Cameroon, Chad, China, Colombia, Congo, El Salvador, Ethiopia, Fiji, Ghana, India, Indonesia, Iran, Jordan, Kazakhstan, Kenya, Kuwait, Kyrgyzstan, Lebanon, Malaysia, Mali, Mongolia, Morocco, Nigeria, Oman, Pakistan, Peru, Philippines, São Tomé and Príncipe, South Africa, Sudan, Syria, Tajikistan, Tanzania, Thailand, Tunisia, Uganda, Ukraine, United Arab Emirates, Uzbekistan, Yemen.

Results: Across the countries studied, generic medicines used for NCDs have significantly lower availability than those used for communicable conditions in both the public sector (36.0% versus 53.5%,  $p=0.001$ ) and private sector (54.7% versus 66.2%,  $p=0.007$ ). In the public sector, the lower the country's income level, the larger the gap in availability between the two treatment types. In lower-middle and low-income countries medicines for communicable conditions are >4 times more available than NCD medicines. In African countries, medicines for communicable conditions are nearly 9 times more available. A similar trend is not observed in the private sector, where results are constant across income groups and regions. In both public and private sectors, antiasthmatics, antiepileptics, and antidepressants had similar low availability (28–30% and 40–45% in the public and private sectors, respectively) and showed the largest difference in availability with the basket of communicable medicines.

Conclusions: Given that NCDs account for 40% of mortality in low-income countries and 25% of mortality in Africa, the observed gaps in public sector availability of medicines for these conditions cannot be justified by current disease patterns. Governments should give greater priority to the supply of medicines for NCDs through the public health system to ensure that those needing treatment are not unduly disadvantaged. International agencies, governments and other stakeholders should also work together to raise the profile of NCDs on health and development agendas.

Funding source(s): None.

## 210

### Policy, Regulation, and Governance

Keywords: generic (multisource) medicines, consumers, substandard drugs, education

#### Quality of Medicines in South Africa: Perceptions vs. Reality

---

**Aarti Patel**<sup>1,3</sup>, **Robin Gauld**<sup>2</sup>, **Pauline Norris**<sup>3</sup>, **Thomas Rades**<sup>3</sup>

<sup>1</sup>Health Research for Action (HERA), Belgium; <sup>2</sup>Department of Preventive and Social Medicine, University of Otago, New Zealand; <sup>3</sup>School of Pharmacy, University of Otago, New Zealand

Problem statement: To date little is known about how consumers and health care providers understand the concept of quality of medicines and/or the extent to which such understandings affect peoples' procurement and use behaviours. Such knowledge is needed, especially in light of the increasing availability of counterfeit and substandard medicines in low- and middle-income countries. Although these resource-limited countries face many challenges in dealing with this issue, one approach is to increase awareness of consumers and providers of the dangers associated with the use of poor-quality medicines. These awareness campaigns must be informed by local norms and practices.

Objective: To explore perceptions of medicines' quality from the perspective of consumers and health care providers and to compare these perceptions to the actual quality of selected medicines in South Africa

Design: Qualitative study involving focus group discussions ( $n=12$ ) and semi-structured interviews ( $n=15$ ) to gain familiarity with perceptions of quality; in vitro analysis performed on 135 generic and brand name medicines (paracetamol, amoxicillin and hydrochlorothiazide) sourced from both the public and private sectors, to determine actual quality Identification and dissolution tests based on BP and USP methods were used.

Setting: Conducted at the local level in three cities: Johannesburg, Durban, and Cape Town

Study population: Purposive sampling was used to recruit consumer participants ( $n=73$ ) representing low, middle, and high socioeconomic status (place of residence and type of employment were used as proxy measures of status: formal and informal). Random sampling was used to recruit health care providers from public and private sectors ( $n=15$ ).

Results: Respondents described drug quality in relation to the effect on symptoms. Consumers preferred getting their medicines from the private sector. They perceived free and generic medicines supplied by the state as inferior, suggesting that their views of the quality of care in general influence their perception of medicines quality. Procurement and use behaviour of health care providers was influenced by prior experience, manufacturers' names, and consumers' ability to pay. All formulations passed the in vitro tests for quality.

Conclusion: The study showed a clear difference between how people perceive the quality of medicines and the actual quality of medicines suggesting deficiencies in public engagement by government regarding the implementation of generic medicines policy. Education and targeted public campaigns specifically addressing the information needs of consumers and health care providers is one solution to addressing the present mismatch between perception and reality.

Funding source(s): University of Otago Grant and School of Pharmacy

## 211

### Malaria

Keywords: malaria, pharmaceutical services, prescribing, dispensing, adherence

## Pharmaceutical Services for Uncomplicated Malaria by *P. vivax* and *P. falciparum* in High-Risk Municipalities of the Brazilian Amazon: Organization of Services, Prescribing, Dispensing, and Adherence to Treatment

**Claudia Garcia Serpa Osorio-de-Castro<sup>1</sup>, Monica Rodrigues Campos<sup>1</sup>, Elaine Silva Miranda<sup>1</sup>, Martha Cecilia Suárez-Múti<sup>2</sup>, Letícia Figueira Freitas<sup>1</sup>, Paula Pimenta de Souza<sup>1</sup>**

<sup>1</sup>Sergio Arouca National School of Public Health/Oswaldo Cruz Foundation, Brazil; <sup>2</sup>Oswaldo Cruz Institute/Oswaldo Cruz Foundation

**Problem statement:** Malaria is a serious public health hazard worldwide. In Brazil the disease is prevalent in the Amazon and the national program rationale is based on early diagnosis and treatment, thus making pharmaceutical services a key element for control.

**Objective:** To evaluate public sector pharmaceutical services for malaria complying with directives of the Brazilian National Medicines Policy

**Design and development, setting, and study population:** An evaluation methodology was developed, and indicators were assigned for the following outcomes: organization of services, prescribing, dispensing, and adherence to treatment. Field work involved a pilot study and visits to 15 public health facilities—primary care facilities or health centers—in 6 high-malaria risk municipalities of the Brazilian Amazon. In total, 15 managers and 601 patients were interviewed; 175 were followed prospectively. All participants gave informed consent. Data were analyzed descriptively.

**Results:** Ten out of 15 facilities presented an environment for receiving patients and for prescribing. National treatment guidelines were present in 12 of 15 facilities. These were over- or under-stocked, and supply was not based on forecasting. Only 2 had a storage area, and in these, Good Storage Practices scored 70%. Only 2 facilities in 2 municipalities provided prescriptions; only 34 patients (5.7% of total) were given a prescription or a written instructions on which medicines to take. Two to three antimalarials were included in 76.4% treatment regimens. Adequate labeling occurred in 44.4% of the cases for artemether-lumefantrine, 12.3% for chloroquine, and 6.9% for primaquine. All other medicines had inadequate or nonexistent labeling. Of 453 patients diagnosed with *P. vivax*, 450 (99.3%) received indication for first-line treatment scheme, and 102 (22.5%) were counseled on medicines. Of 120 *P. falciparum* cases, 57 (47.5%) were indicated for the first-line regimen (quinine-doxycycline-primaquine); 3 (2.5%) were recommended mefloquine and primaquine and 26 (21.7%) lumefantrine-artemether; 34 (28.3%) were indicated non-sanctioned treatments. Of the total number of *P. falciparum* patients, only 44 (36.6%) were counseled. Self-reported adherence was 61.1%, and pill-count adherence was measured at 56.6%. After application of mandatory criteria for adherence percentages fell to 6.7% in self-reporting and 7.3% in pill counts.

**Conclusions:** Pharmaceutical services for malaria in Brazil present problems in organization of services, prescribing, and dispensing. Services lack comprehensiveness and municipalities differ in service quality. Adherence to treatment is low and undermined by lack of service organization. Problems in pharmaceutical services may compromise care, leading to increase in disease prevalence and drug resistance in these municipalities.

**Funding source:** CNPq

213

### Economics, Financing, and Insurance Systems

*Keywords:* Health insurance; Sub-Saharan Africa; medicines benefits; access to medicines

## Health Insurance Systems in Five Sub-Saharan African Countries: Medicines Benefits and Data for Decision-Making

**Joao Carapinha<sup>1</sup>, Dennis Ross-Degnan<sup>2</sup>, Abayneh Tamer Desta<sup>3</sup>, Anita Wagner<sup>2</sup>**

<sup>1</sup>Northeastern University, United States of America; <sup>2</sup>Harvard Medical School and Harvard Pilgrim Health Care Institute; <sup>3</sup>World Health Organization, Regional Office for Africa

**Problem statement:** Medicines benefits through health insurance programs have the potential to improve access to and promote more effective use of affordable, high-quality medicines. Information is lacking about medicines benefits provided by health insurance programs in Sub-Saharan Africa.

**Objectives:** To describe the structure of medicines benefits and data routinely available for decision-making in 33 health insurance programs in Ghana, Kenya, Nigeria, Tanzania and Uganda

**Design:** Survey data of the program structure, characteristics of medicines benefits, and availability of routine data for decision-making in health insurance systems is described, by country, with tables and figures.

**Setting and study population:** A convenience sample of 82 health insurance programs in five Sub-Saharan African countries (Ghana, Kenya, Nigeria, Tanzania, and Uganda) were identified and surveyed, of which 33 (40% of total) submitted data complete enough to be analyzed.

**Intervention:** No intervention was applied and assessed.

**Policy:** No policy change was evaluated.

**Outcome measure(s):** Measures covered program structure, characteristics of medicines benefits, and data available for decision-making.

**Results:** Most programs surveyed were private, for-profit schemes covering voluntary enrollees, mostly in urban areas. Almost all provide both inpatient and outpatient medicines benefits, with members sharing the cost of medicines in all programs. Some programs use strategies that are common in high-income countries to manage the medicines benefit, such as formularies, generics policies, reimbursement limits, or price negotiation. Basic data to monitor performance in

delivering medicines benefits are available in most programs, but key data elements and the resources needed to generate useful management information from the available data are typically missing.

Conclusion: Many questions remain unanswered about the design, implementation, and effects of specific medicines policies in the emerging and expanding health insurance programs in Sub-Saharan Africa. These include questions about the most effective medicines policy choices, given different corporate and organizational structures and resources; impacts of specific benefit designs on quality and affordability of care and health outcomes; and ways to facilitate the use of routine data for monitoring. Technical capacity building, strong government commitment, and international donor support will be needed to realize the benefits of medicines coverage in emerging and expanding health insurance programs in Sub-Saharan Africa.

Funding source(s): The WHO Department of Essential Medicines and Pharmaceutical Policies in Geneva funded the development of the survey. The WHO Regional Office for Africa organized and funded data collection and analysis.

217

#### HIV/AIDS and TB

Keywords: HIV/AIDS, antiretrovirals, medicine supply, essential drug program, sustainability

### **Planning for Sustainability of ARV Provision: A Study in Peru, Bolivia, and Mozambique**

---

**Claudia Garcia Serpa Osorio-de-Castro, Cláudia Du Bocage Santos-Pinto, Elaine Silva Miranda, Thiago Botelho Azeredo, Maria Auxiliadora Oliveira**

Sergio Arouca National School of Public Health/Oswaldo Cruz Foundation, Brazil

Problem statement: The provision of antiretroviral (ARV) medicines is central to HIV/AIDS programs, because of its impact on the course of the disease and on quality of life. Although first-line treatment costs have declined, treatment-associated expenses are steeper each year, not only due to more people living with HIV/AIDS (PLWHA) in need of treatment, but also in the face of new and costlier patented medicines incorporated into treatment guidelines. Provision sustainability is, therefore, an important variable for the success of treatment programs and should be acknowledged during planning and implementation of programs or provision schemes.

Objectives: To investigate the sustainability of ARV provision in three different settings

Design: Policy evaluation by means of a multiple-case study and in-depth analysis. The literature was reviewed for sustainability issues. A conceptual framework on the sustainability of ARV provision was developed, followed by data collection instruments. Analytical categories were identified. Qualitative data were collected through interviews with key actors and analyzed.

Setting: The pilot study was undertaken in Brazil. Three countries—Bolivia, Peru, and Mozambique—were visited. Interviews with key actors involved with HIV/AIDS programs and ARV provision in each country were carried out.

Outcome measure(s): The investigative focus centered on HIV/AIDS programs and the mechanisms undertaken to provide ARVs to PLWHA in each country. Outcome measures were (1) sustainability issues related to ARV provision and (2) routinization events of programs (or country provision schemes, in absence of specific programs).

Results: Evidence of greater sustainability potential of the program was observed in Peru, where provision is implemented and routinized by the national HIV/AIDS program, and expenditures are met by the government. In Mozambique, provision is almost totally dependent on donations and external aid. A large effort is being undertaken to incorporate ARV provision and care into routine health care activities. Bolivia, in addition to having external dependence on financing and management of drug supply, presents problems regarding implementation and routinization of ARV provision activities.

Conclusions: The conceptual framework was useful in recognizing events that may influence sustainable ARV provision in these countries. Planning ahead for sustainable provision, considering the epidemic profile and population needs, is essential, and without it, financing sources and mechanisms are not enough. Furthermore, country programs and provision schemes must consolidate themselves in the structure of health services provision as a whole, especially in limited-resource settings.

Funding source(s): UNAIDS

219

#### Policy, Regulation, and Governance

Keywords: substandard drugs, counterfeit drugs, quality assurance, quality control, regulatory authority

### **The Good, the Bad, and the Ugly: A System-Based Three-Pronged Strategy to Combat Substandard and Counterfeit Medicines in Low-Resource Countries**

---

**Veerle Coignez**

Consultant

Problem statement: The use of substandard and counterfeit medicines (SCM) constitutes an increasing public health problem, especially in low and middle income countries (LMIC). A USAID-USP program has documented cases where over 40% of sampled medicines were of poor quality. Medicines regulatory authorities (MRA) in LMIC often lack the technical, financial, human, and legal capacity to address the problem.

Objective: To present a strategy, and an organizational framework, to help policy makers and implementers address the SCM threat in a comprehensive, systematic, and sustainable manner.

**Design:** This is a technical brief. It builds on experience gained in the management of USAID medicines quality assurance activities, and on reference work by WHO and the U.S. Pharmacopeia.

**Setting:** The strategy and organizational framework adopt a national level perspective, covering the entire medicines supply chain, in the public and private sector.

**Study population:** The target audience is policy makers and program managers in ministries of health and MRAs in LMIC.

**Intervention or policy change:** The three-pronged strategy tackles both the supply of and the demand for SCMs. It consists of three complementary approaches that can best be characterized as “the good, the bad, and the ugly”: improving access to good-quality medicines, targeting substandard and counterfeit medicines, and raising public awareness about the negative (ugly) health consequences of SCM use. The strategy enables stakeholders to go beyond anti-counterfeit sting operations and to adopt a comprehensive approach as well as identify priority activities. The strategy integrates medicines quality assurance activities promulgated by WHO and helps stakeholders understand how these activities contribute to a sustainable reduction in SCM availability. The strategy can be implemented in a flexible manner, in full or in part, depending on the country.

**Outcome measure(s):** Outcome measures can be defined for each strategic prong depending on the country, for example, (1) number of medicines registered based on a process that includes quality control testing or (2) number of substandard lots identified and withdrawn. The strategy’s overall impact can best be measured by reduction over time in the proportion of sampled medicines found to be substandard.

**Results:** Cambodia is the best documented example of success in reducing the ratio of sampled antimalarials that fail basic quality control tests—from 16.9% to less than 1%—between 2003 and 2010 (for details, see abstract 248). Other relevant examples are (1) the renewed focus on establishing a MRA in Liberia and (2) the work on improving the registration process in Ethiopia as part of addressing the SCM problem in each country respectively.

**Conclusions:** Sting operations do not suffice to stem the SCM tide. The three-pronged strategy provides an actionable platform to tackle the problem in a comprehensive, systematic, and sustainable manner. Political commitment is key to success.

**Funding source(s):** USP

## 220

### **Economics, Financing, and Insurance Systems**

*Keywords:* Medicines; Price Control; Affordability;

### **Controlling Medicine Prices in Sudan: The Challenge of a Recently Established Medicines Regulatory Agency**

**Gamal Khalafalla Mohamed Ali<sup>1</sup>, Ahmed Yagoub<sup>2</sup>**

<sup>1</sup>Central medical Supplies Public Corporation, Sudan; <sup>2</sup>National Medicines and Poisons Board

**Problem statement:** The price of medicines is one of several reasons for lack of access to essential medicines. Medicine prices in Sudan have been among the highest in the East Mediterranean Region. According to the Pharmacy and Poisons Act 2001, final consumer prices (retail price) are generally determined by National Medicines and Poisons Board (NMPB)—the medicine regulatory agency of Sudan—committee on medicine pricing. The prices are made up of a combination of the price charged by the manufacturer, pre-shipment inspection fees, freight (C&F) costs, import tariffs, port charges, insurance and clearance costs, a pharmacy board fee, and wholesalers’ and retailers’ mark-up.

**Objectives:** The aim of this study is to evaluate the efficiency current drug pricing system applied by the NMPB in controlling medicine prices. To do so we have checked the conformity of the C&F, whole, and retail prices of medicines with those approved by NMPB. We have also compared prices of generic medicines with those of branded medicines. Finally, prices of selected medicines were compared with those that have been published in the international price indicator guide and BNF (September 2008).

**Design:** The whole and retail prices, which are usually written on the invoice issued by the wholesalers, were evaluated. The actual price displayed on studied products by pharmacy was also reviewed. This evaluation study was based mainly on the records at selected pharmacies, NMPB, and interviews with key informants.

**Setting:** This study was conducted in Khartoum State between July and September 2008. The data were collected by the researchers from the records of 5 pharmacies that purposively selected.

**Study population:** We selected the most sold 50 medicines in 2007 (regardless of their dosage-form, strength, and brands). These medicines have market authorization in Sudan. We ended up with 174 items. The total number of imported medicines that were included in the study was 135 products. 120 (89%) items either generic or branded generics, and 20 products (11%) were innovator brand medicines

**Intervention(s):** NMPB appointed a committee to thoroughly examine the findings of this study and to report back to the board. The NMPB finally has passed new regulations on medicines price, which became in effect since August 2010.

**Policy:** It is now the policy of the government that drug companies charge equal medicine prices for all community pharmacies throughout the country regardless of the distance from their warehouses (i.e., there is a cross-subsidy from closer pharmacies to more remote ones).

**Outcome measure(s):** Enforcement of the medicine price regulations is expected to reduce cost of medicines by up to 50%. This reduction will enhance affordability and thereby access to essential medicines. It will also improve the use of medicines by enabling patients to obtain a complete course of treatment.

Results: The C&F prices of 23% of selected medicines were more than 10 times the International Reference Price. Surprisingly, 71% of these items were generics. The whole price of almost 40% of studied medicines was less than that has been approved by the NMPB. Again, 88% of these medicines were generics. Conversely, the retail price of 47% of drugs was less than that approved by the regulatory authority of Sudan. One of the most striking findings was the fact that the retail price of 7% of the items was three or more times their registered or approved C&F price (i.e., 300% mark-up on the C&F). The retail price of 11 out of 12 originator brands in Sudan was found equal to or more than their prices published in the British National Formulary (BNF, September 2008 edition). The selling price to the public of 82% of these brand medicines was two or more times their prices in the BNF. The actual retail prices of 46% of the selected medicines were twice or more their C&F prices. The price of the medicines distributed by Central Medicines Supplies (a government organisation), on average, was twice their C&F. The mark-up of CMS on the C&F price of selected items ranges from 71 to 2096%.

Conclusions: Price regulation should be considered to avoid stretching what are already inadequate household resources. Lower prices at CMS do not help much in controlling of prices in private sector because retail pharmacies sell the low-cost tender items from CMS at the retail price set by their wholesalers.

Funding source(s): NMPB

## 235

### Chronic Care

*Keywords:* Education, non-opioid analgesics, appropriate use, family doctors, ambulatory patients

#### **Effects of Two Educational Programs Aimed at Improving the Utilization of Non-opioid Analgesics in Family Medicine Clinics in Mexico**

**Svetlana Vladislavovna Doubova<sup>1</sup>, Dolores Mino-León<sup>2</sup>, Hortensia Reyes-Morales<sup>3</sup>, Sergio Flores-Hernandez<sup>1</sup>, Laura del Pilar Torres-Arreola<sup>1</sup>, Ricardo Pérez-Cuevas<sup>1</sup>**

<sup>1</sup>Mexican Institute of Social Security, Mexico; <sup>2</sup>Instituto de Geriátría, SSA, México; <sup>3</sup>Instituto Nacional de Salud Pública, México

Problem statement: There is a high frequency of prescription of non-opioid analgesics (NOAs), second only to cardiovascular drugs. Several studies have reported that medical doctors do not prescribe properly, and patients do not use the NOAs appropriately. This finding is evidenced by overutilization rates of up to 41% and by the frequent appearance of preventable adverse events. As many as 42% of the medical doctors are unaware of the adverse events that NOAs cause. Regarding the patient's side, 34% are unsure about the proper method of taking NOAs, despite the fact that these are among the most common self-medicated drugs.

Objectives: To develop and test two educational programs (interactive and passive) aimed at improving family doctors' (FDs) prescribing practices and patient's knowledge and use of NOAs.

Methods: The educational programs were conducted in two family medicine clinics belonging to the Mexican Institute of Social Security in Mexico City. The study was performed in three stages: (1) baseline evaluation, (2) design and implementation of educational activities, and (3) post-program evaluation. An interactive educational program (IEP) was compared with a passive educational program (PEP); both were attended by FDs and patients. The IEP for FDs comprised of workshops, discussion groups, in-service training, and guidelines, whereas for patients, the IEP consisted of an interactive session with a video, leaflets, and a discussion. The PEP consisted of delivering the guidelines to the FDs and the leaflets to patients. All FDs working at the clinics were invited to participate in the programs, and most (99%) of them accepted the invitation. There were 58 FDs in the IEP group and 52 FDs in the PEP group. The eligibility criteria for patients were as follows: age  $\geq$  50 years, suffered from non-malignant pain syndrome, had received at least one NOA prescription for a period of  $\geq$  7 days, were under the care of the participating FDs, and were able to answer the questions posed during the interview. The baseline and post-program evaluations included 300 patients by group. The effect of the programs on the FDs was measured through the appropriateness of prescriptions of NOA and analyzed using the differences-in-differences estimator (D-in-D), and on patients through changes in self-medication and in their knowledge about the proper use and adverse events by analyzing the inter- and intra-group differences before and after the programs.

Results: The IEP obtained better results to improve appropriate FDs prescription of NOA than PEP (D-in-D=15%). Regarding the patients, the PEP group reached higher reduction of self-medication than the IEP group (13.4 vs. 9.1%); the knowledge of proper NOA use increased by 8.5% in both groups, whereas knowledge of NOA-related adverse events was better in the IEP (39.6%) than in the PEP group (9.2%).

Conclusions: The IEP was better to improve the doctors' abilities to prescribe NOAs, and both programs improved patients' knowledge. Our findings suggest that programs aimed at improving medication use should focus on interactive educational activities.

Funding source(s): The study was supported by grants from the Research Promotion Fund of the Mexican Institute of Social Security (FOFOI IMSS-2005/1/1/201).

## 236

### Economics, Financing, and Insurance Systems

*Keywords:* Essential medicines, Drug utilization, Health insurance, Health policy, Cost effectiveness

## Active Pharmaceutical Management Strategies of Health Insurance Systems to Improve Cost-Effective Use of Medicines in Low- and Middle-Income Countries: A Systematic Review of Current Evidence

Laura Faden Garabedian, Catherine Vialle-Valentin, Dennis Ross-Degnan, Anita Wagner

Harvard Medical School and Harvard Pilgrim Health Care Institute, United States of America

**Problem statement:** Lack of access to essential medicines is a prominent public health problem that disproportionately affects populations in low- and middle-income countries (LMIC). WHO estimates that 30% of the world's population, and over half of the population in the poorest areas of Asia and Africa, lack access to essential medicines. Experts at the 2004 International Conference on Improving Use of Medicines concluded that insurance systems have great potential to improve the use of medicines, which currently consume 25 to 65% of total public and private spending on health in developing countries, and recommended systematic work within insurance systems to leverage better provider prescribing, more cost-effective use by consumers, and lower prices from industry.

**Objectives:** Despite ample evidence from high-income countries, little is known about insurance system strategies targeting medicines in LMIC. This paper provides a critical literature review of these strategies and their impact in LMIC.

**Design:** We conducted a systematic review of published peer-review and gray literature, and organized the insurance system strategies into four categories: medicines selection, purchasing, contracting, and utilization management.

**Setting:** Low- and middle-income countries

**Study population:** Not applicable

**Interventions and policies:** Health insurance strategies to improve use of medicines

**Outcome measure(s):** Cost-effective use of medicines

**Results:** In 63 reviewed publications, we found reasonable evidence supporting the use of insurance as an overall strategy to improve access to pharmaceuticals and outcomes in LMIC. Beyond this, most of the literature focused on provider contracting strategies to influence prescribing. There was very little evidence on medicines selection, purchasing, or utilization management strategies.

**Conclusions:** There is a paucity of published evidence on the impact of insurance system strategies on improving the use of medicines in LMIC. The existing evidence is questionable since the majority of the published studies utilize weak study designs. This review highlights the need for well-designed studies to build an evidence base on the impact of medicines management strategies deployed by LMIC insurance programs.

**Funding source(s):** WHO/HAI Medicines Prices Project

241

Malaria

*Keywords:* malaria case-management, ACTs, stock-out

### Taking Stock: Provider Prescribing Practices in the Presence and Absence of ACT Stock

Bernadette Hensen<sup>1</sup>, Lucy Smith Paintain<sup>1,2</sup>, Rima Shretta<sup>3</sup>, Jane Bruce<sup>1,2</sup>, Alexandra Hyde<sup>1,2</sup>, Caroline Jones<sup>1,2</sup>, Jayne Webster<sup>1,2</sup>

<sup>1</sup>London School of Hygiene and Tropical Medicine, United Kingdom; <sup>2</sup>Pfizer Inc. Corporate Responsibility;

<sup>3</sup>Management Sciences for Health

**Problem statement:** Artemisinin-based combination therapy (ACT) stock-outs are common and adversely affect achievement of prompt and effective treatment of malaria.

**Objectives:** To assess provider prescribing of ACTs and alternative antimalarial medicines in the presence and absence of ACT stock

**Design:** Literature review. Study inclusion criteria: disease of focus was uncomplicated malaria; region of focus was in Africa; country's first-line antimalarial at the time of study was an ACT. The study included an assessment of prescribing practices at time of treatment. Prescribing practices were assessed in the context of ACT stock and stock-outs (with health facility surveys used to collect stock data).

**Setting:** Africa

**Study population:** Populations vary based on studies included in the review.

**Policy change:** To increase the use of process analyses of ACT prescribing in the public sector in order to evaluate current practices and enable the design of evidence-based interventions to improve prescribing practices.

**Outcome measure(s):** Malaria prescribing practices in the presence and absence of ACT stock at time of treatment

**Results:** Only 14 studies evaluating the prescribing of ACTs in the public sector were identified and just 6, from 3 countries (Kenya, Uganda, and Zambia), met the full study inclusion criteria. Across all studies, regardless of stock context, ACT prescribing ranged from 10.7% of children  $\geq 10$  kg (Zambia 2004) to 66.4% of children  $< 5$  years (Uganda 2007), and alternative antimalarial prescribing from 0.4% of children  $< 5$  years prescribed sulfadoxine-pyrimethamine (SP) (Uganda 2007) to 67.5% of children  $\geq 10$  kg prescribed SP (Zambia 2004). Comparing facilities where ACT was in stock to facilities without ACT stock: (1) ACT prescribing was significantly higher in all six studies, increasing by a range of 21.3% for children  $< 5$  years weighing  $\geq 5$  kg ( $p < 0.001$ ; Kenya 2006) to 51.7% for children  $\geq 10$  kg ( $p < 0.001$ ; Zambia 2006); (2) prescribing of SP decreased significantly in five studies, by a range of 14.4% ( $p < 0.001$ ; Kenya 2006) to 46.3% ( $p < 0.001$ ; Zambia 2006); (3) where quinine was an alternative treatment, prescriptions decreased in five of the six studies by 0.1% ( $p = 1.0$ , Kenya 2010) to 10.2% ( $p < 0.001$ ; Zambia 2006). At facilities with no ACT stock on the

survey day, the proportion of febrile patients prescribed ACT was <10% in five of the nine target groups across the six studies; The proportion prescribed ACT ranged from 0 to 28.4% (Uganda 2007).

Conclusions: Prescriber practices in the presence and absence of ACT vary. Although in the presence of ACT stock ACT prescribing increases and alternative antimalarial prescribing decreases, ACTs are prescribed in the absence of stock, and alternative antimalarial drugs are prescribed in the presence of ACT stock. More health facility surveys are needed to understand provider ACT and alternative antimalarial prescribing practices within the context of stock. Without such operational data, there is a risk that interventions will misinterpret needs and bear little impact.

Funding source(s): DFID TARGETS Research Consortium

## 243

### **Economics, Financing, and Insurance Systems**

*Keywords:* access to medicines, essential medicines, medicine prices, medicine supply,

### **Comparison of the Public Procurement Prices of Essential Medicines in China with Other Western Pacific Developing Countries and Its Implication**

---

#### **Jing Sun**

National Institute of Hospital Administration, MoH, P.R.China

**Problem statement:** The Western Pacific Regional Office of WHO established a price information exchange (PIE) system of essential medicine in 2009, aiming to enable the member states to learn the public procurement prices in other countries in the region and to compare their prices with others and international ones, so as to be in a better position in price negotiation, to improve the procurement efficiency, and to provide evidence for setting and adjusting price and procurement regulation policies.

**Objectives:** To show where the essential medicines price level of China stands among its developing neighbors and to learn valuable lessons about medicine price and procurement regulation.

**Design:** A descriptive study based on the information from PIE. Qualitatively reviews the national medicine price and procurement regulation policies, and quantitatively compares the unit public procurement prices (May to September 2009) of 31 essential medicines in these countries, and with the regional and Management Sciences for Health (MSH) generics median prices.

**Setting:** Countries are all members of PIE, excluding the pacific islands. The study focuses on those with similar economic development level, China (Heilongjiang province), Malaysia, Mongolia. and Viet Nam are selected.

**Outcome measure(s):** The proportion of the selected medicines in the public procurement system indicates the availability; comparison of the unit public procurement prices (converted into US dollars) between countries and with the MSH and regional median shows the price level of China within the region and in the world.

**Results:** The availability of 31 medicines in China's public procurement system is 61%, which is the lowest among the 4 countries. Most of the unavailable medicines are with pediatric and specific formulations, or with different strengths from the international standard. 11 products (58%) were procured with generics only, and most were at the MSH and regional median level, such as salbutamol—generics price in China (0.0126) is at the same level of generic price in Mongolia (0.014), MSH (0.009), and regional median (0.0089). Malaysia procured branded salbutamol (0.0049) from India at about 35% of the price of generics procured by China and Mongolia, and at around 50% of the MSH and regional median. Under full competitions, the price of the long-time marketed generics in China is far below the MSH and regional median (0.06/0.0814), such as sodium valproate (0.0296). 3 products (16%) were procured with originators only, such as metformin—originator price in China (0.2053) is about 20 times of the branded generics procured by Malaysia (0.0105), and 7 and 3 times of branded generics procured by Viet Nam (0.0303) and Mongolia (0.0665). 5 products (26%) were procured with both originators and generics. The tiered medicines pricing and procurement policy in China allows the price of the originator ceftriaxone (11.9765) up to 35 times of the generics median (0.3377) and 4 times of the branded one.

**Conclusions:** China needs to strengthen the regulation of dosage form and strength of medicines and to give special attention to pediatric formulations. China's public medicine procurement system procures domestic generics of most of the selected medicines at the MSH and regional median level, which is higher than that of the ones procured by Malaysia from India. There are exceptions that have been marketed for a long time and under full generic competitions, whose prices are far below the world level. The exclusive pricing policy for branded medicines in China puts them at very high price level, even the public medicine procurement system prefers high price branded medicines. When only the branded medicines were procured, or mixed with generics, comparing with its neighbors, China has a higher price level, which contributed mostly by the high-priced branded medicines. The prices of generics under such circumstances are even higher than that of the branded generics procured by Malaysia from Indian. Malaysia sets a good example for enhancing the efficiency of public medicine procurement. Comprehensive policies to promote generics are to be developed in China.

Funding source(s): Chinese government.

## 246

### **Drug Resistance**

*Keywords:* antimicrobials, prescribing, drug utilization, public sector, education

### **Characteristics and Outcomes of Public Campaigns with the Aim to Improve Outpatient Antibiotic Use in High Income Countries**

---

**Stephan Harbarth<sup>1</sup>, Herman Goossens<sup>2</sup>, Theo Verheij<sup>3</sup>, Benedikt Huttner<sup>1</sup>**<sup>1</sup>Geneva University Hospitals, Switzerland; <sup>2</sup>University of Antwerp, Belgium; <sup>3</sup>UMC Utrecht, Netherlands

**Objective:** Public campaigns have attempted to educate the public regarding prudent outpatient antibiotic use. We reviewed characteristics and outcomes of these campaigns as part of an international collaborative project.

**Methods:** Through Medline, internet searches and contact with expert informants, we identified public campaigns aimed at improving antibiotic use conducted on a national or regional level in high-income countries between 1990 and 2007. Campaign managers were contacted to obtain unpublished information. Randomized clinical trials and campaigns carried out on a community level were excluded. Analyses were performed using a mixed approach (quantitative and qualitative methods).

**Results:** We retrieved information on 16 national campaigns and 6 regional campaigns (16 in Europe, 3 in North America, 2 in Oceania and 1 in Israel). All but four campaigns were conducted over more than 1 year (range, 1-13 y) and 12 campaigns were still ongoing in 2007. Most campaigns (n=17) were organized by health authorities and publicly funded. Two national campaigns were entirely funded by the pharmaceutical industry. All campaigns focused on upper respiratory tract infections and used similar key messages. All but one campaign targeted physicians and the public in parallel, with an emphasis on parents of young children (n=17). Interventions were multifaceted and varied in intensity. Distribution of information material was the most common intervention (n=22). Twelve campaigns used television and two campaigns used intensive academic detailing for physicians. Nine campaigns observed a reduction in antibiotic prescriptions and two campaigns in self reported antibiotic use. The impact on antimicrobial resistance was difficult to evaluate because of poor data availability and the concomitant introduction of the pneumococcal conjugate vaccine in several countries. Potential adverse outcomes and sustained effects have not been evaluated systematically.

**Conclusions:** Antibiotic campaigns are widely used and some have resulted in a reduction in antibiotic use, although a clear cause-effect relationship is difficult to establish. The lack of detailed evaluation, the multifaceted approach and the differences in healthcare systems make identifying the most effective interventions a challenge. Although the impact on antibiotic resistance is difficult to assess at the current moment, policy makers and epidemiologists can use our findings to develop initiatives suited to different country settings. In summary, although the most effective interventions and potential adverse outcomes remain unclear, public campaigns can probably contribute to more judicious outpatient antibiotic use, at least in high-prescribing countries.

248

**Policy, Regulation, and Governance***Keywords:* counterfeit drugs, quality assurance, quality control, regulatory authority, substandard drugs**A Risk-Based Cost-Effective Approach to Medicines Quality Monitoring in Resource-Limited Countries****Patrick Lukulay<sup>1</sup>, Veerle Coignez<sup>2</sup>**<sup>1</sup>U.S. Pharmacopeia, Washington DC; <sup>2</sup>Consultant

**Problem statement:** The use of substandard and counterfeit medicines (SCM) constitutes an increasing public health problem, especially in low- and middle-income countries (LMIC). A USAID-USP program has documented cases where over 40% of sampled medicines were of poor quality. Medicines regulatory authorities (MRA) in LMIC often cannot assume their medicines quality assurance role, and many do not even monitor the quality of medicines in the supply chain, due to lack of technical, human, financial, and/or legal capacity.

**Objective:** The study seeks to develop and test a risk-based three-level approach to medicines quality monitoring (MQM) that enables MRAs in LMIC to exercise better oversight over medicines quality in the country. The research questions are (1) can MQM be achieved on a large scale, to the extent it becomes an effective tool to help reduce the availability of poor quality medicines in LMIC? (2) what are the requirements for success?

**Design:** This is an operational research case study. It examines the introduction of a risk-based three-level approach to MQM in two countries: Cambodia and Ghana.

**Setting:** The risk-based approach to MQM can be applied at regional as well as national level, covering medicines throughout the supply chain, in the private and the public sectors.

**Policy change:** Cambodia introduced MQM in 2003 and Ghana in 2009. Both countries used the three-level approach of visual inspection, basic screening tests, and compendial testing. The sentinel sites were carefully selected and the sampling protocol adjusted to national context, allowing the MRAs to spread the net as wide as possible to catch problem medicines with the given resources. The test results were used to take concrete corrective actions, diagnose quality assurance problems, and/or raise public awareness.

**Outcome measure(s):** (1) Proportion of sampled medicines found to be substandard, (2) number of substandard lots withdrawn, (3) number of operators closed, and (4) other MQA improvement measures

**Results:** MQM enabled Ghana to identify and take action against specific counterfeits (including Coartem) in both years of operation. In Cambodia, 16.9% of antimalarials, sampled in 4 provinces, failed quality testing from 2003 to 2004. The failure rate dropped to 9.4% of 470 samples from 6-10 provinces (2005-07) and to 3.4% of 1,715 samples from 8-12 provinces (2008-09). In 2010, 728 antimalarials were sampled in the same 12 provinces: less than 1% failed quality control tests. Cambodia has closed over 1,000 illegal operators in 2009-11.

**Conclusions:** MQM based on the three-level approach enables an MRA to identify poor quality medicines in a country's supply chain, without overwhelming scarce financial, human, and laboratory resources. The prerequisites are careful selection of sentinel sites and samples, appropriate use of screening technology, and an operational basic quality

control laboratory. To have impact on the ground, timely reporting, political will, and a legal basis for corrective actions are key. To sustainably reduce SCM availability, other MQA activities will likely be required (see also abstract 219).

Funding source(s): Promoting the Quality of Medicines (PQM) Program, a USAID cooperative agreement implemented by USP

**254**

#### **Economics, Financing, and Insurance Systems**

*Keywords:* price, generics, index, comparison, Korea

#### **International Comparison of Generic Medicine Prices**

---

**Soonman Kwon, Jaeheon Heo, Sujin Kim, Youn Jung**

Seoul National University, Korea, South (Republic of)

**Problem statement:** Rapid increase in pharmaceutical expenditure is a big concern for health policy, and there is a controversy over whether the price of medicines are adequate in South Korea.

**Objective:** To carry out an international comparison of the prices of generic medicines of 80 molecules that are frequently used in South Korea

**Method:** Using IMS data on ex-manufacturer prices of generic medicines in 15 OECD countries and South Korea in 2008, we performed two analyses. Individual prices of selected molecules (having the same strength and formulation) were compared between South Korea and other countries. Then 4 types of bilateral price indexes for each country were computed relative to South Korea: Laspeyres index, Paasche index, Fisher index, and Walsh index, which are classified by the method of weighting.

**Results:** For the price comparison of individual molecules, the results varied depending on molecules because of the differences in pharmaceutical markets in each country, such as the pattern of preferred molecule and volume. Comprehensive price indexes showed generic prices in foreign countries, except Switzerland and Japan, are about 10–50 percent lower than those in South Korea. And the price indexes using gross domestic product purchasing power parities suggested that South Korea's prices of generic medicines are the highest. Ex-manufacturer prices and consumption volumes of selected molecule-strength-formulation varied substantially between countries.

**Conclusions:** The results show that in South Korea more expensive molecules are consumed, and the overall price of generic medicines are higher than in other advanced countries.

Funding source(s): National Health Insurance Corporation (NHIC), Health Insurance Review and Assessment (HIRA)

**256**

#### **Malaria**

*Keywords:* antimalarials, drug distribution, drug selection, fairness, accountability for reasonableness

#### **Priority Setting for Implementation of Artemisinin-Based Combination Therapy Policy in Tanzania: Evaluation against Accountability for Reasonableness Framework**

---

**Amani Thomas Mori, Eliangiringa Amos Kaale**

Muhimbili University of Health and Allied Sciences, Tanzania, United Republic of

**Problem statement:** Malaria case management by pharmaceuticals is a major challenge in many malaria endemic countries. Old but cheap and effective medicines are increasingly facing resistance, and it is no wonder that by 2009, nearly all *P. falciparum* malaria endemic countries, most of them in sub-Saharan Africa, had changed their treatment policies to artemisinin-based combination therapies. Rapidly raising pharmaceutical expenditures, by contrast, pose another major obstacle and have led to an increased need for prioritization in pharmaceuticals worldwide since not all the available choices can be provided for all who need them. Artemether-lumefantrine was, therefore, prioritized as the first-line drug for management of uncomplicated malaria in Tanzania.

**Objective:** To analyze and evaluate whether the prioritization decision of artemether-lumefantrine satisfies the four conditions of fair process as suggested in the ethical framework of accountability for reasonableness

**Design:** This was a descriptive, cross-sectional study in which data were collected by in-depth interviews with key informants and treatment guideline review.

**Study setting and population:** The study examined the policy decision-making process in the public sector at the national level. We selected the sample of 15 participants from the acknowledgement list in the treatment guideline. Sampling was purposeful to explore the perceptions of people with different backgrounds and perspectives. Key informants represented the national government hospital, National Malaria Control Programme, WHO country office, Ministry of Health and Social Welfare Headquarters, Tanzania Food and Drugs Authority, Medical Stores Department, and Muhimbili University of Health and Allied Sciences.

**Results:** **Publicity:** The decision, but not its rationales, was publicized by radio, television, and newspaper. There was no explicit mechanism to involve the stakeholders, and as a result, the task force lacked professional, institutional, and countrywide representation. Public representation within the task force was insufficient. **Relevance:** The decision was grounded on relevant evidence of clinical efficacy and adequate safety and formulation profile. **Appeals and revision:** There is neither a reliable appeal and revision mechanism to challenge the outcomes of the policy decision nor Enforcement mechanisms to ensure the other three conditions are met.

Conclusions: The prioritization decision of artemether-lumefantrine as a first-line antimalaria drug failed to fully satisfy the four conditions of the accountability for reasonableness framework. In addition to the demand for enhanced stakeholder involvement, publicity, and transparency, the study also calls for the institution of formal appeals and revision, and regulatory mechanisms in future implementation of health policy change processes.

Funding source(s): This was a master's thesis research funded by the Norad's Programme for Masters Studies (NOMA).

257

**Chronic Care**

*Keywords:* access to medicines, availability, clinical guidelines, drug utilization, pharmaceutical policy

**Do European Rheumatoid Arthritis Patients Have Equal Access to Treatment with New Medicines?**

**Joelle M. Hoebert<sup>1</sup>, Aukje K. Mantel-Teeuwisse<sup>1</sup>, Liset van Dijk<sup>2</sup>, Johannes J.W. Bijlsma<sup>3</sup>, Hubert G.M. Leufkens<sup>1</sup>**

<sup>1</sup>Utrecht Institute for Pharmaceutical Sciences, Division of Pharmacoepidemiology and Clinical Pharmacology / Utrecht WHO Collaborating Centre for Pharmacoepidemiology and Pharmaceutical Policy Analysis, Utrecht University, the Netherlands; <sup>2</sup>NIVEL, Netherlands institute for health services research, Utrecht, the Netherlands; <sup>3</sup>Department of Rheumatology & Clinical Immunology, University Medical Center Utrecht, the Netherlands

Problem statement: Health care systems aim to achieve optimal health and economic outcomes for society as a whole as well as for the individual patient. Effective but expensive medicines, such as biologicals, may lead to different measures taken by governments or regulators and prescribers to achieve this goal thereby resulting in differences in access to treatment.

Objectives: Building on previous reports on access to treatment for rheumatoid arthritis (RA), the objective was to further explore the use of the biological tumour necrosis factor alpha (TNFalpha) inhibitors used in the treatment of RA as a proxy of access to treatment with new medicines over time and to add opinions from key leading rheumatologists to put the obtained results into perspective.

Design: Drug utilization study

Setting: This study examines the international use of a relatively new class of medicines in the in- and outpatient public sector in Ireland (IE), the Netherlands (NL), Norway (NO), and Portugal (PT).

Study (population) medicines: Three TNFalpha inhibitors that have been centrally approved in the European Union: infliximab (1999), etanercept (2000), and adalimumab (2003). Major indication for these biologicals is RA.

Intervention and policy change: NA

Outcome measure(s): Utilisation rates in defined daily doses (DDDs) per 1,000 inhabitants per day. Qualitative data such as country characteristics, national health policy characteristics, guidelines and other important policy events were obtained from literature. In addition, interviews were held with leading rheumatologists of each country to put obtained results into (cultural) context.

Results: Prevalence of RA varied between 0.46 (NL) and 0.56 (NO) per 100 inhabitants. Utilisation of TNFalpha inhibitors varied widely from 0.32 (PT) to 1.89 (NO) DDDs/1,000 inhabitants/day (2007). An association between health expenditures per capita and the degree of utilization of TNFalpha inhibitors was found ( $R^2 = 0.81$ ). When the use of TNFalpha inhibitors became more established (increased clinical evidence, increased number of prescriptions, extension of indications), the association was stronger. Differences in health expenditure were nevertheless not the only determinant of usage. Causes of intercountry variation were manifold including differences in guidelines, reimbursement regulations, and according to key rheumatologists, access to rheumatologists (PT), (non)adherence to guidelines (PT, NL), consultation of colleague before initiation (NO), and budgetary constraints.

Conclusions: The prospects of patients receiving TNFalpha inhibitor treatment depend on the country where they are living. If uniformity of management and treatment would be considered to provide health benefits, the extent and the causes of variation should feature prominently in future public health agendas.

Funding source(s): None

262

**Chronic Care**

*Keywords:* Elderly, Inappropriate drug use, india

**Comparison of Different Inappropriate Prescribing Screening Tools Used for Assessment of Inappropriate Drug Prescription in the Elderly**

**Km Mandavi<sup>1</sup>, Sanjay D'Cruz<sup>2</sup>, Atul Sachdev<sup>3</sup>, Pramil Tiwari<sup>4</sup>**

<sup>1</sup>Department of Pharmacy Practice, National Institute of Pharmaceutical Education and Research, S.A.S. Nagar, Punjab, INDIA, India; <sup>2</sup>Department of General Medicine, Government Medical College & Hospital, Sector 32, Chandigarh, INDIA; <sup>3</sup>Department of General Medicine, Government Medical College & Hospital, Sector 32, Chandigarh, INDIA; <sup>4</sup>Department of Pharmacy Practice, National Institute of Pharmaceutical Education and Research, S.A.S. Nagar, Punjab, INDIA, India

Problem statement: A number of studies have documented various levels of inappropriate prescribing (IP) in the elderly using different IP screening tools. Limited data exist, however, regarding comparison of different tools as well as matching with real-time practice.

**Objectives:** To compare the level of IP using the different IP screening tools in a given sample and to match the findings with real-time findings in local practice

**Design:** 1-year prospective interventional

**Setting:** Public teaching hospital (inpatient wards)

**Study population:** Randomly selected inpatients, 60 years or older of either sex (n=500). Only prescriptions with complete information were included.

**Intervention(s):** Provision of continuous feedback; documentation of changes in therapy made by physician

**Policies:** None

**Outcome measure(s):** Comparison of level of IP using 5 different IP screening tools—Improved Prescribing in the Elderly Tool (IPET) 2000, Zhan criteria 2001, Modified Beers' criteria 2003, Health Plan Employer Data and Information Set (HEDIS) 2006, and Screening Tool of Older People's Potentially Inappropriate Prescriptions (STOPP) criteria—and changes in therapy based on real-time practice

**Results:** 500 randomly selected prescriptions out of data pool of 1,000 patient records were subjected to 5 different IP screening tools. The average age of the patients was 66.3±0.3, and number of prescribed drugs was 8.9±0.2. The level of IP observed according to different tools were 29% (Beers' 2003) > 23.6% (STOPP criteria) >11.8% (HEDIS) > 8% (Zhan criteria) > 4.2% (IPET). The IP identified according to real-time practice was 14.4% which closely matched with IP identified by HEDIS criteria. The most common inappropriate drugs recognized by physicians were administration of anticoagulant therapy with aspirin, diazepam, digoxin, diltiazem, codeine, and ferrous sulfate. The Beers' criteria 2003 identified a significantly higher level of IP than other criteria. The higher dose of ferrous sulfate (n=38) was most common drug contributing to higher level of IP. Only 11 prescriptions out of 38 were considered to be an inappropriate drug (ID) in real-time practice. Likewise, other most commonly offending drugs were nitrofurantoin (2 out of 17 accepted ID in real-time practice) and chlorphenamine (none out of 12 accepted ID in real-time practice). In a similar manner, only 5 prescriptions out of 30 accepted theophylline as ID; theophylline is the drug that most contributes to an increased level of IP according to STOPP criteria. The IP level according to IPET and Zhan was lower because the use of IDs of high severity such as nitrofurantoin, anticoagulant in bleeding disorders and the use of anticholinergic agents are not included in these lists.

**Conclusions:** The authors suggest merging the two established criteria namely Beers' criteria and STOPP criteria with a list of IDs identified from real patient care settings in the current study for proper assessment of level of IP in Indian setting.

**Funding source(s):** None

## 264

### Malaria

**Keywords:** Protective efficacy; Malaria in pregnancy; Sulphadoxine-Pyramethamine; Intermittent Preventive treatment of malaria (IPTp); Plasmodium falciparum.

### **Parasitological Assessment of Two-Dose and Monthly Intermittent Preventive Treatment of Malaria During Pregnancy with Sulphadoxine-Pyrimethamine (IPTp-SP) in Lagos, Nigeria**

**Chimere Obiora Agomo<sup>1,2</sup>, Wellington Oyibo<sup>2</sup>, Funke Odukoya-Maije<sup>3</sup>**

<sup>1</sup>Nigerian Institute of Medical Research, Nigeria; <sup>2</sup>Tropical Diseases Laboratory, Department of Medical Microbiology and Parasitology, College of Medicine of University of Lagos, Lagos, Nigeria.; <sup>3</sup>Department of Obstetrics and Gynaecology, Ajeromi General Hospital, Ajegunle, Lagos State

**Problem statement:** IPTp-SP is a key strategy in the control of malaria in pregnancy, but there is paucity of data on the protective efficacy of IPTp-SP in Lagos, Nigeria. High SP resistance reported among Plasmodium falciparum isolates has been reported from clinical trials and molecular studies in children. This has necessitated the continuous monitoring of the efficacy of SP in pregnant women. Reports of malaria prevalence in Nigeria suggest that malaria is hyperendemic in most areas, thus raising concerns on the adequacy of the standard two-dose IPTp-SP strategy adopted for HIV-negative pregnant women.

**Objectives:** To determine the protective efficacy of IPTp-SP and to assess the equivalence of monthly dose to the standard two-dose IPTp-SP in Lagos

**Design:** The study was a longitudinal study. The women were randomly allotted to two arms: two-dose IPTp-SP (arm A) and monthly dose IPTp-SP (arm B).

**Study population:** A total of 259 pregnant women (arm A=122; arm B=137) attending antenatal clinics in two hospitals in Lagos, Nigeria, were recruited. Eligibility criteria were the absence of symptomatic malaria, HIV, and multiple pregnancy.

**Outcome measures:** Absence of malaria parasites in peripheral blood; proportion of live births and low birth weight

**Results:** Baseline parasitaemia (M0) in the two group was 5 (4.1%) and 3 (2.2%) in arms A and B, respectively. Majority of the women did not develop parasitaemia by M1 after the initial dose SP dose, (arm A, 98.3% in arm A and, 98.5% in arm B (P = 0.636). A similar result was obtained at the second month (M2) (P = 0.466); however, none of the women in the monthly IPTp-SP (arm B) developed parasitaemia after M1, whereas a woman became parasitaemic at M2 in the 2-Dose IPTp-SP group (arm A). The monthly dosing was not superior to the two-dose regime. The proportion of live births and low birth weight were similar in the two study arms (P>0.05).

Conclusion: Intermittent preventive treatment of malaria during pregnancy with SP is effective in protecting pregnant women from malaria infection in Lagos. Monthly dose IPTp-SP is equivalent to the standard two-dose IPTp-SP in Lagos, Nigeria.

Funding source(s): Personal finance of authors

265

#### Access

*Keywords:* access to medicines, availability, affordability, traditional/herbal medicine, drug utilization, equity, inequality

### Exploring Traditional Medicines Use by Ghanaian Households

#### Azusa Sato

London School of Economics, United Kingdom

Problem statement: In Ghana, traditional medicines use is both frequent and common, but up-to-date, quantitative data are not currently available, despite the National Drugs Policy actively encouraging the integration of traditional medicines and its practitioners into mainstream, orthodox systems.

Objective: The study explores utilisation of medicines from a household perspective. The primary aim is to address the gap in demand data to complement existing supply and regulatory data. (1) How does need for medicines (both orthodox and traditional) differ from actual utilisation? What characterises those who seek health care from formal institutions and traditional medical practitioners? (2) Given the same need, are the rich more likely to use orthodox medicines than the poor, whilst the poor use traditional medicines? (3) How deep is the inequity in the utilisation of medicines?

Design: The study uses a mixed method approach. The original contribution is quantitative, supported by qualitative reviews of literature. The questionnaire is based on an existing WHO household survey. Cross-sectional data were collected in September and October 2010.

Setting: The survey was administered in two vastly contrasting regions, Greater Accra and Upper West. In each region, two districts were selected.

Study population: 771 households were randomly selected in two purposively chosen regions (four districts) of Ghana. In accordance with WHO methodology, 4 public reference facilities were chosen in each district, from which household clusters were randomly selected. Households and their informants were then chosen according to eligibility criteria.

Outcome measure(s): Utilisation rates and changes in perceived benefits of using traditional medicines measured by satisfaction scores; concentration and horizontal indices to measure inequity

Results: Initial findings suggest that rural households are more frequently using traditional medicines than urban households, but do so in conjunction with accessible formal institutions. Given need, the level of utilisation of is surprisingly high. This is hypothesised to be due to the health insurance system, which covers around 95% of all illnesses in Ghana. Individuals typically use more than one source of care, mixing and matching modern and traditional medicines. In most cases, traditional medicine is a second choice. Utilisation of modern systems in general are biased towards the rich, however, whilst the poor use traditional medicines more often. Such disparities in utilisation are attributable to "non-need" factors (i.e., income) rather than severity of disease and age-sex differences. The perceived benefit and common uses of traditional medicines, however, is very high, especially in rural areas.

Conclusions: Traditional systems—particularly in rural areas—serve as critical sources of health care for many Ghanaians. Income is a key determinant of utilisation. Policymakers cannot afford to ignore this finding. In addition to the cultural importance and reliance on traditional medicines, the role income plays in health care choice will necessarily affect the utilization of orthodox medicines.

Funding source(s): Funded in part by the London School of Economics as part of a PhD project.

266

#### Chronic Care

*Keywords:* drugs interactions, prescriptions, drugs utilization, quality, risk.

### Pharmacoepidemiologic Study of Potential Drug Interactions in Hospital Inpatients

**Dolores Mino<sup>1</sup>, Eugenia Galván-Plata<sup>2</sup>, Svetlana Vladislavovna Doubova<sup>2</sup>, Sergio Flores-Hernandez<sup>2</sup>, Hortensia Reyes-Morales<sup>3</sup>**

<sup>1</sup>Instituto de Geriatria. Institutos Nacionales de salud, Mexico; <sup>2</sup>Centro Médico Nacional Siglo XXI, IMSS; <sup>3</sup>Instituto Nacional de Salud Pública

Problem statement: Prescribing more than one drug increases the risk of potential drug-drug interaction (pD-DI), therapeutic failure, high pharmacological effect, or adverse events.

Objectives: To estimate the frequency of drug-drug interactions in prescriptions for hospitalized patients and to identify the associated factors for these prescriptions

Setting: Mexico City

Study population and method: A secondary data analysis of a cohort was carried out, including 284 patients at the internal medicine ward in a third level hospital in Mexico City (from July 2003 to February 2004). Age, gender, diagnosis at admission, days of hospitalization, prescription, and administration of the drugs were analyzed. The pD-DI were identified and registered according to the severity by using the program Micromedex® DrugReax® System (Healthcare

series 2007). Descriptive and crude association including the outcome variable and co-variables, and Poisson regression analyses were performed.

Results: The median of age was  $53 \pm 18$  years old; 53% of the patients were women, and 34% were older than 65 years of age. 63% of the patients received one prescription identified as pD-DI, and 33.5% of these prescriptions were "major pD-DIs." The most frequently paired drugs prescribed were fluoroquinolones and hypoglycemics (20.5%); enoxaparin, a nonsteroidal anti-inflammatory drugs, or anticoagulants (18.1%); furosemide, an angiotensin converting enzyme inhibitors (ACE inhibitor) (12.2%); allopurinol, also an ACE inhibitor (9%), and spironolactone, another ACE inhibitor (9%). A positive correlation between the number of potential DD-Is and the number of drugs ( $r=0.469$ ;  $p<0.001$ , 95% CI: 0.34-0.55) was observed. The regression analysis showed that men have a 20% higher chance of receiving a prescription with the potential for pharmacological interactions than women (95% CI: 1.01–1.45) and that for each additional drug a patient is prescribed, that patient has a 9% higher chance of receiving a prescription with the potential for pharmacological interactions (95% CI: 1.07–1.12), independent of factors such as being older than 65 years, having a diagnosis of AIDS, days of hospital stay, and number of diagnoses at hospital admission.

Conclusions: The high percentage of prescriptions with pD-DI makes necessary to implement educational programs or alert strategies, including the identified associated factors, aimed at improving the quality of prescriptions and reducing the risks for hospitalized patients.

Funding source(s): Instituto Mexicano del Seguro Social

267

Malaria

Keywords: Malaria, microscopy, home-based diagnosis, treatment.

### Low Reliability of Home-Based Diagnosis of Malaria in a Rural Community in Western Kenya

**Rose Kakai<sup>1</sup>, Josephine Nasimiyu<sup>2</sup>, Wilson Odero<sup>1</sup>**

<sup>1</sup>Maseno University, Kenya; <sup>2</sup>Bokoli Health Centre, Kenya

Problem statement: Home-based management of malaria is promoted as a major strategy to improve prompt delivery of effective malaria treatment in Africa. Definitive diagnosis of malaria infection, however, is still based on identifying plasmodia in blood films. Misdiagnosis of malaria contributes to a vicious cycle of increasing ill health.

Objective: To determine the proportion of children with positive routine light microscopy among those with mothers' home-based diagnosis and treatment of malaria, in a rural community in western Kenya

Design: Descriptive cross-sectional study

Setting: Community-based study conducted at Bokoli location in Bungoma East District between November and December 2007 using quantitative data collection techniques

Study population: A random sample of 96 mothers of children age <5 years with malaria, according to the mothers' diagnosis were interviewed using a questionnaire on demographics and treatment. Blood smears were examined by light microscopy for malaria parasites.

Outcome measure(s): The proportion of mothers who correctly diagnosed malaria in their children.

Results: Only 30/96 (31.2%) specimens were positive for *Plasmodium falciparum*. The mothers' criteria for diagnosis of malaria in their children included most commonly elevated temperature (70/96; 72.9%). In 57 of the 96 cases, information was given by the mothers regarding treatment in the current malaria episode; of these, 10 (17.5%) had received treatment for malaria, but 6 (60%) of these were parasite negative. This means that only 4/21 (19.0%) with positive smear microscopy received treatment ( $p = 0.05$ ). The most common antimalaria drugs used were Fansidar (37.8%) and Metakelfin (29.7%).

Conclusion: The difficulty in making home-based diagnosis of malaria increases the urgent need for improved diagnostic tools that can be used at the community level in poor populations. Intervention measures are needed to increase the treatment rate in order to reduce reservoirs and malaria parasites transmission.

Funding source(s): Information not provided

269

Access

Keywords: Access to medicines, management, pharmacists, health workers, rational use

### Where There Are No Pharmacists

**Beverley Frances Snell, Sarah Ruth Andersson, Kumariah Balasubramaniam**

Health Action International Asia-Pacific, Penang, Malaysia

Problem statement: Several categories of health worker, whose activities involve managing and handling medicines, find themselves in front line health care either without any pharmacy training or, if they have had training, no opportunity at all for continuing their pharmacy education and professional development. Assessments in the field have led to repeated findings that there are severe deficiencies in the way medicines are managed and handled in the long chain from medical stores to rural health clinics and finally, to patients.

Objectives: To see an increase of health workers who (1) responsibly maintain a reliable supply of good quality, essential medicines; (2) manage medicines efficiently by carrying out activities in the best professional way; (3)

accurately dispense them to the community with relevant information; and (4) continue to remain competent in their professional role as managers of medicines.

**Intervention:** A series of simple steps can be taken to strengthen this long chain. Where There Are No Pharmacists is a new and innovative handbook that will help health workers to do exactly that. It has been commissioned by HAI and TWN and written by world experts at a subsidised cost for health workers in resource-poor settings. In easy-to-read language and with illustrations, this step-by-step guide demonstrates what is needed and what can be done by staff in small rural and urban health facilities to improve medicines delivery. A pharmacology and pharmacy glossary provides explanations for technical terms that staff will come across when learning, teaching, and referencing.

**Most important,** Where There Are No Pharmacists provides material for learner-centred education. In their continuous application of what is explained in this book, learners actively and gradually become architects of their own learning.

**Conclusion:** Knowledge associated with medicines and health care should not be a guarded secret among health professionals but freely shared by everyone. There is an increasing need to demystify medicines. People with little or no formal education can be trusted to grasp what is communicated if the communication tool is comprehensive. Where There Are No Pharmacists is such a tool. This book is about managing medicines. It explains in easy language how to order, store, prepare, dispense, and use medicines safely and effectively. It provides information to help communities benefit from the use of medicines. It does not provide clinical advice but emphasises the need to adhere to national standard treatment guidelines or, in their absence, to appropriate texts and guidelines. The aim is to empower whole communities through empowering health workers.

**Funding source(s):** HAI Global Theme—Rational Use of Medicines, funded by the Government of the Netherlands

**270**

**Access**

*Keywords:* access to medicine, multi-stakeholder, ranking, transparency, pharmaceutical

### **Health Care Payments in the Asia Pacific: Validation of Five Survey Measures of Economic Burden**

**Afshin Mehrpouya**

HEC-Paris

**Objective:** Many low- and middle-income countries rely on out-of-pocket payments to help finance health care. These payments can pose financial hardships for households; valid measurement of this type of economic burden is therefore critical. This study examines the validity of five survey measures of economic burden caused by health care payments.

**Methods:** We analyzed 2002–03 World Health Survey household-level data from four Asia Pacific countries to assess the construct validity of five measures of economic burden due to health care payments: any health expenditure, health expenditure amount, catastrophic health expenditure, indebtedness, and impoverishment. We used generalized linear models to assess the correlations between these measures and other constructs with which they have expected associations, such as health care need, wealth, and risk protection.

**Results:** Measures of impoverishment and indebtedness most often correlated with health care need, wealth, and risk protection were as expected. Having any health expenditure, a large health expenditure, or even a catastrophic health expenditure did not consistently predict degree of economic burden.

**Conclusion:** Studies that examine economic burden attributable to health care payments should consider focusing on measures of impoverishment and indebtedness.

**Funding source(s):** Information not provided

**271**

**Access**

*Keywords:* Prescribing behavior, prescribing practice, Greece, Cyprus

### **Factors Influencing Prescribing Behaviour of Physicians in Greece and Cyprus**

**Mamas Theodorou<sup>1</sup>, Vasiliki Tsiantou<sup>2</sup>, Nikolaos Maniadakis<sup>2</sup>, Daphne Kaitelidou<sup>3</sup>, Vasilios Fragoulakis<sup>2</sup>, Elpida Pavi<sup>2</sup>, John Kyriopoulos<sup>2</sup>**

<sup>1</sup>Open University of Cyprus, Cyprus; <sup>2</sup>School of Public Health, Athens, Department of Health Services Organization and Management; <sup>3</sup>Department of Nursing, University of Athens

**Problem statement:** Pharmaceutical and overall health expenditures have risen rapidly over the past few decades in most western countries. This negative development was a reason for serious concern to policy makers, who have reacted with major reforms, using different tools and implementing various measures to increase clinical efficacy and economic efficiency and hence guarantee the sustainability of health care systems.

**Objectives:** To investigate the attitudes and factors influencing physicians prescribing decisions and their drug prescription choices in Greece and Cyprus

**Design:** A cross-sectional study was carried out using a structured questionnaire developed by researchers at the Department of Health Economics at the National School of Public Health in Greece. The questionnaire was being posted to doctors with a prepaid return envelope.

**Setting:** The study was conducted simultaneously in Greece and Cyprus by the National School of Public Health (Greece) and Open University (Cyprus). The participating physicians were working either in the private or in the public sector, as well as in primary or secondary care.

Study population: Sample of 1,463 physicians in Greece and 240 in Cyprus, randomly selected and stratified by sex, specialty, and geographic region

Results: The response rate was 82.3% in Greece and 80.4% in Cyprus. Regarding the finding there were similarities but also many differences between the two countries. Clinical effectiveness is the most important factor considered in drug prescription choice in both countries (94.8% in Greece vs. 93.3% in Cyprus). Greek physicians were significantly more likely to take additional criteria under consideration, such as the drug form, (38.2% vs. 9.8%,  $p < 0.001$ ), the recommended daily dose (35.5% vs. 4.1%,  $p < 0.001$ ), the cost to the patient (41.9% vs. 8.3%,  $p < 0.001$ ), and the patient preferences, (11.0% vs. 0.5%,  $p < 0.001$ ). The main sources of information for physicians include peer-reviewed medical journals (73.7% vs. 58.5%,  $p < 0.001$ ), medical textbooks (60.7% vs. 44.0%,  $p < 0.001$ ), medical congress announcements (70.3% vs. 69.4%), and pharmaceutical sales representatives, (52.0% vs. 61.1%,  $p = 0.016$ ). The majority of doctors in both countries agreed that the effectiveness, safety, and efficacy of generic drugs may not be excellent, but acceptable; however, 66.8% of Cypriot physicians prescribe generics, whereas in Greece the percentage is only 25.2%. The majority of physicians (82.1% vs. 63.2%) believe that new drugs are not always better and their higher prices are not necessarily justified. Regarding adverse drug reactions the majority of physicians are informed primarily by the National Organization of Medicines (65.7% in Greece vs. 48.7% in Cyprus) and secondly by sales representatives (42.6% vs. 42.0%); however, 62.6% of doctors in Greece and 88.1% in Cyprus ( $p < 0.001$ ) do not inform the authorities of such adverse drug reactions.

Conclusions: The present study underlines the attitudes and the factors influencing physicians' behaviour in Greece and Cyprus and may be used for developing policies to improve their choices and to increase clinical and economic efficiency.

Funding source(s): Information not provided

## 275

### Chronic Care

*Keywords:* generics, generic substitution, adherence, confusion, diabetic patients and quality of care

#### **Impact of Generic Substitution Practice on Care of Diabetic Patients**

---

**Olubukola Olusola Oyetunde, Fola Tayo, Bolajoko A. Aina**

Faculty of Pharmacy, University of Lagos, Nigeria

Statement of problem: Patients with chronic diseases such as diabetes mellitus type 2 often have their prescriptions substituted with generic medicines in the course of care. Generic prescribing and substitution are policies that promote the use of generic drugs to save costs. Generic substitution in an environment inundated with branded generics and without guidelines may inadvertently cause confusion (i.e., the inability to identify medications) and nonadherence in patient care.

Objective: To investigate patients' perception of generic substitution on quality use of medicines

Design: The study is a cross-sectional survey of patients attending a diabetic clinic. The structured questionnaire utilized was in four parts addressing patients' demographics, knowledge of generic drugs and practice of generic substitution, impact of generic substitution on drug use, and adequacy of pharmacists' information about generic substitution. The results were basically qualitative.

Setting: The study was carried out in the outpatient diabetic clinic of a public tertiary hospital in Lagos State, Nigeria. A simple random sampling of diabetic patients who were willing to participate was done. In total, 120 patients were surveyed; 103 responses were usable.

Policy: Generic prescribing was mandated by NDP, but generic prescribing is low. Pharmacists, therefore, substituted generics for both the prescribed innovator brands and between branded generics. This practice resulted in tremendous cost savings for patients, but patients' opinion and perception of this practice was not known.

Outcome measure(s): Patients' care was measured by assessing patients' knowledge of generic substitution practice; use of medicines after substitution; confusion about their drugs as a result of generic substitution due to variations in color, size, shapes, and packaging of generic medicines; and increased side effects associated with substitution

Result: More than half (55.6 %) of respondents have noticed brand substitution, 77.5% of respondents were aware of pharmacists' generic substitution practice whereas more than a third (38.6%) of patients surveyed did not know when substitution took place. About one in five (19.6%) patients surveyed reported not using their medicines after substitution because they were not sure of the brand supplied; about a third (35.6%) have rejected substitution at one time and insisted on doctors' prescription. 14.9% of respondents agreed that brand substitution resulted in confusion (identification problems such as changes in color and the absence of score lines on tablets) whereas 24% reported receiving brands that resulted in more side effects. Using Chi square test there was no significant difference in patient-reported confusion in relation to patients' age, sex, and educational level. There was, however, a significant association between patients' brand preference and confusion due to switching of brands.

Conclusion: Generic substitution without adequate information resulted in nonadherence and confusion. Appropriate policy and guidelines for generic substitution are needed.

Funding source(s): No external funding

## 276

### Economics, Financing, and Insurance Systems

*Keywords:* health expenditure, affordability, economic burden, valid measurement, World Health Survey

## **Health Care Payments in the Asia Pacific: Validation of Five Survey Measures of Economic Burden**

**Sheila K. Reiss, Dennis Ross-Degnan, Alan M. Zaslavsky, Stephen B. Soumerai, Anita K. Wagner**

Harvard University, United States of America

**Objective:** Many low and middle-income countries rely on out-of-pocket payments to help finance health care. These payments can pose financial hardships for households; valid measurement of this type of economic burden is therefore critical. This study examines the validity of five survey measures of economic burden caused by health care payments.

**Methods:** We analyzed 2002/03 World Health Survey household-level data from four Asia Pacific countries to assess the construct validity of five measures of economic burden due to health care payments: *any health expenditure*, *health expenditure amount*, *catastrophic health expenditure*, *indebtedness*, and *impoverishment*. We used generalized linear models to assess the correlations between these measures and other constructs with which they have expected associations, such as health care need, wealth, and risk protection.

**Results:** Measures of impoverishment and indebtedness most often correlated with health care need, wealth, and risk protection as expected. Having any health expenditure, a large health expenditure, or even a catastrophic health expenditure did not consistently predict degree of economic burden.

**Conclusion:** Studies that examine economic burden attributable to health care payments should consider focusing on measures of impoverishment and indebtedness.

278

### **Economics, Financing, and Insurance Systems**

**Keywords:** Generics, medicine prices, pharmaceutical expenditure

### **Trends in Pricing Policy of Generics: Global Implications**

**Brian Barr Godman<sup>1</sup>, Bjorn Wettermark<sup>1,2</sup>, Kristina Garuoliene<sup>3</sup>, F Cankat Tulunay<sup>4</sup>, Lesley Tilson<sup>5</sup>**

<sup>1</sup>Karolinska Institutet, Sweden; <sup>2</sup>Medical Knowledge Centre Stockholm Country Council, Sweden; <sup>3</sup>National Health Insurance Fund, Lithuania; <sup>4</sup>Department of Pharmacology, Medical School, Ankara, Turkey; <sup>5</sup>National Pharmacoeconomic Centre, Ireland

**Problem statement:** Generic prices vary appreciably across Europe. Countries can learn from each other to realise considerable savings as resource pressures grow and more standard drugs lose their patents.

**Objective:** To document different pricing policies for generics across Europe in an understandable format and their impact to provide guidance in the future

**Design, setting, and study population:** (1) Documenting generic pricing policies through literature searches and via payers from across Europe; (2) narrative review of the reforms by one of the authors (BBG) and validated by the countries; (3) retrospective observational CNC study using only administrative databases in over 20 European countries or regions for generic PPIs, statins, ACEIs, and SSRIs at ATC Level 5 to determine price reductions over time vs. originator prices (expenditure/DDD) pre-patent loss or in 2001; (4) reimbursed expenditure rather than total expenditure as health authority perspective

**Intervention:** Changes in reimbursed expenditure/DDD (2010 DDDs) for generics in four classes in 2007 vs. pre-patent loss originator prices (2001) alongside documenting the respective generic pricing policies

**Policies:** Pricing policies for each country broken down into understandable categories for comparison

**Outcome measure(s):** (1) Percentage reduction in reimbursed expenditure/DDD for chosen generics in 2007 vs. 2001 originator prices; (2) percentage change in expenditure and utilisation in 2007 vs. 2001 for PPIs and statins; (3) € per 1,000 inhabitants per year in 2007 for PPIs and statins

**Results:** Three principal approaches to generic pricing were used and validated with the various payers in each European country: (1) prescriptive pricing (PP), established (prescriptive) reductions for reimbursement (e.g., up to 85% price reduction in Norway, 33% below for first generic in Turkey); (2) market forces (MF), no fixed amount, but mechanisms to enhance their utilisation to drive down prices (e.g., Sweden and UK); and (3) mixed approach (MA), PP for first generic(s) followed by MF (e.g., in Austria the third generic launched must be priced 60% below pre-patent prices for the originator molecule for reimbursement and market forces after that). Expenditure/DDD for simvastatin in 2007 was 97% below 2001 originator price levels in England (MF), 96% below in Sweden (MF), and 79% below in Lithuania (MA) vs. just over 50% in France (PP). Typically, less marked reductions in expenditure/DDD for generic omeprazole vs. pre-patent prices. There was also appreciable variation in expenditure/DDD for generic ACEIs and SSRIs within and between countries. Country size did not matter in terms of potential price reductions—more the environment to enhance prescribing of generics. These differences plus differences in generic utilisation resulted in considerable differences in reimbursed expenditure between countries for both the PPIs and statins, (e.g., €5832 and €5192/1000 inhabitants/year, respectively, for the PPIs and statins in Sweden in 2007 vs. over €60000 in Republic of Ireland for both—NB highly selective GMS population).

**Conclusions:** The categorisation system for the different approaches to the pricing of generics appears to work and is easily understandable. Considerable differences in reimbursed expenditure/DDD for high volume generics exist across Europe. This coupled with differences in their utilisation provides considerable opportunities for countries to learn from each other to enhance their prescribing efficiency as resource pressures grow.

**Funding source(s):** In part with grants from Karolinska Institutet

279

**Economics, Financing, and Insurance Systems**

*Keywords:* generics, drug utilization, prescribing efficiency

**Intensity of Reforms Resulting in Considerable Differences in Generic Utilisation across Europe; Implications for Others**

**Brian Barr Godman<sup>1</sup>, Bjorn Wettermark<sup>1,2</sup>, Ott Laius<sup>3</sup>, Corrine Zara<sup>4</sup>, Lars Gustafsson<sup>1</sup>**

<sup>1</sup>Karolinska Institutet, Sweden; <sup>2</sup>Medical Knowledge Centre, Stockholm County Council, Sweden; <sup>3</sup>State Agency of Medicines, Estonia; <sup>4</sup>Catalan Health Service, Spain

**Problem statement:** There is appreciable variation in the utilisation of generics across Europe. Countries must learn from each other to fully realise savings from the increasing availability of generics to help combat growing resource pressures. The lessons may also be useful to low- and middle-income countries.

**Objective:** To assess the influence of multiple demand-side measures on the subsequent utilisation of generics vs. patent-protected products once they are available in a class to guide countries in the future

**Design:** Pre- and post-policy-analysis study for the PPIs and statins (ATC Level 5) in over 20 European countries and regions once generic omeprazole and generic simvastatin became available. Classes were chosen as both contain generics and patented products with limited outcome differences between them in the majority of patients. We found considerable price differences once generics are available in a class, however. No time series analysis was performed because typically health authorities and health insurance companies instigated a range of demand-side measures during the study period. In addition, the intensity of some of the demand-side measures may vary between regions. Both situations make time series analyses problematic.

**Setting and study population:** Administrative databases in over 20 European countries or regions mainly covering total populations. Utilisation was measured in DDDs (2010 DDDs) principally from 2001 to 2007. Years were chosen as generic simvastatin and generic omeprazole became available in western EU countries during this time.

**Interventions and policies:** (1) Demand-side reforms based on publications as well as input from payers themselves in each country (principal method); (2) narrative review subsequently undertaken by one of the co-authors (BBG) and validated; and (3) demand-side measures broken down by 4Es (education, engineering, economics, and enforcement) for each country and validated. The 4E approach had previously been used in a number of peer-reviewed publications to provide a comprehensive and easily understandable methodology for categorising and collating the plethora of demand-side measures to compare across countries.

**Outcome measure(s):** Main measure: Percentage change in the utilisation of omeprazole (O) and esomeprazole (E), simvastatin (S), and atorvastatin/rosuvastatin (A/R) in 2007 as a percentage of the total utilisation for class vs. the utilisation patterns seen before generic omeprazole and generic simvastatin became available and were reimbursed. Typically multiple demand-side initiatives were undertaken (broken down by the 4E approach) during the study period in each country.

**Results:** There were considerable differences in the utilisation patterns in 2007 among the various European countries (e.g., utilisation of simvastatin varied between 5% to 85% of all statin utilisation and A/R utilisation varying between 1% to 75% of total statins depending on extent or intensity of the 4 Es): (1) atorvastatin utilisation decreased from over 30% to 10% of total statins in Austria 4 years after prescribing restrictions (enforcement) alongside other measures; simvastatin utilisation increased in Spain (Catalonia), Sweden, and the UK (England and Scotland) with lower or similar utilisation of A/R following a combination of 3 of the 4 Es (not enforcement); similar changes in utilisation were also seen for PPIs (omeprazole and esomeprazole). (2) In France, Turkey, and Ireland, A/R utilisation appreciably increased after generic simvastatin became available with limited demand-side measures to counteract pharmaceutical company activities. Similar patterns seen for PPIs. This led to appreciably higher expenditure (€/1000 inhabitants/year) in these countries than in Spain (Catalonia), Sweden, and the UK: (a) PPIs: €5832 in Sweden and €6186 in England vs. €15,194 in France and over €60,000 in Ireland (selective GMS population) and (b) statins: €5192 in Sweden, €9555 in Austria and €13,439 in England (utilisation increased 5.1 fold in England between 2001 and 2007 vs. 2.5 fold in Sweden, 2.4. fold in Austria and 72% in France) vs. €14,896 in France and over €60,000 in Ireland (7.1 fold; selective GMS population). Reforms in Estonia including obligatory INN prescribing led to statin utilisation increasing nearly twofold in 2007 vs. 2004 with only a 13% increase in reimbursed expenditure.

**Conclusions:** Multiple interventions are typically needed to change physician prescribing behaviours given the complexities involved in prescribing, mirroring other findings. The intensity of the measures is also important to favourably influence utilisation patterns. Countries are already learning from each other, but this needs to accelerate. 4E methodology is comprehensive and easily understandable to contrast the influence of the different demand-side measures and give future guidance. This methodology is also transferable between classes and countries; consequently, it should provide direction to low- and middle-income countries as they seek further initiatives to maximise health gain with available resources.

**Funding source(s):** In part grants from Karolinska Institutet

281

**Economics, Financing, and Insurance Systems**

*Keywords:* risk sharing, financing, pharmaceutical expenditure

**Risk-Sharing Arrangements—Opportunity or Threat to Fund New Medicines?**

**Brian Barr Godman<sup>1,2</sup>, Jakub Adamski<sup>3</sup>, Marija Kalaba<sup>4</sup>, Lars Gustafsson<sup>1</sup>**

<sup>1</sup>Karolinska Institutet, Sweden; <sup>2</sup>Mario Negri Institute, Milan, Italy; <sup>3</sup>Ministry of Health, Warsaw, Poland; <sup>4</sup>Republic Institute for Health Insurance, Serbia

**Problem statement:** Price-volume schemes especially for new drugs are now an integral part of pricing and reimbursement negotiations across a number of European countries to help control drug expenditures. Pharmaceutical companies are seeking new ways to gain reimbursement and funding for new drugs especially where there are concerns with their value (e.g., requested prices vs. the health gain seen). This has resulted in a growth of new arrangements including value based pricing, outcome guarantee, and patient access schemes, but the administrative burden can be intensive. There are also concerns with the variety of definitions that have been used, their probity, and their transparency.

**Objective:** To review available schemes and concerns to provide guidance to health authorities in the future. This includes providing a definition based on logic.

**Design, setting, study population, intervention, and policies:** A thorough literature review was undertaken by one of the authors (BBG) in PubMed, MEDLINE, and EMBASE between 2000 and February 2010 using key words including conditional coverage, conditional reimbursement, risk sharing, coverage with evidence, price volume agreements, value-based pricing, pharmaceuticals, no cure no pay, payback schemes, health impact guarantee, and outcome guarantee. The review was supplemented by unpublished or "grey literature" references known to the 17 co-authors and advisers from across Europe involved with assessing and implementing such schemes on behalf of payers. Only papers documenting the nature and content of actual schemes were considered for possible inclusion in this paper, with no attempt made to assess the quality of the papers.

**Outcome measure(s):** (1) Providing a definition of such schemes based on logic that is acceptable to health authority and health insurance personnel from across Europe; (2) documenting published studies using these definitions broken down by country; (3) summarising conditions and concerns when payers contemplate future schemes; and (4) proposing guidance for payers for the future based on considerable in-house experience among the co-authors

**Results:** Risk-sharing schemes should be considered to be agreements concluded by payers and pharmaceutical companies to diminish the impact on payers' budgets for new and existing schemes brought about by uncertainty and/or the need to work within finite budgets. They can be broken down into financial-based and performance-based or outcomes-based models. There are concerns with existing schemes outside of traditional price-volume arrangements. These include high administration costs, not collecting rebates or refunds, lack of transparency, conflicts of interest, and whether health authorities will end up funding an appreciable proportion of a drug's development costs. The latter is particularly important with provisional coverage schemes. This is illustrated by the scheme for bortezomib in the UK, which is based on a 50% reduction in serum paraprotein levels (M-protein) by the fourth cycle. The NHS will continue funding treatment in responders, with the cost/QALY reduced from £38,000/QALY to a more acceptable £20,700/QALY, with manufacturers refunding the cost of the drug if a 50% reduction was not achieved. This is usually in the form of free drug. The following concerns arise, however: (1) whether M-protein is actually a good surrogate for life expectancy (alongside this, 10–15% of patients do not have measurable serum M-protein levels; (2) capacity to manage such schemes with current staff levels—73% of hospitals in the UK did not have the capacity; (3) lack of communication between physicians and pharmacists; (4) every missed claim loses GB£12000 for the hospital; (5) whether hospitals can in fact accept free goods or rebates from pharmaceutical companies; (6) whether refunds to hospitals are actually passed back to the payers in practice—this is not happening in 47% of UK hospitals with this scheme. The value-based pricing scheme for beta interferon in the UK has also been heavily criticised as unscientific and impractical given the 10-year follow-up period, with an initial assessment in 2009 highlighting important methodological issues with the scheme and the need for longer term follow-up before securing meaningful results.

**Conclusions:** Overall, there is only a limited number of situations where risk-sharing schemes should be considered based on the experiences of health authority and health insurance personnel across Europe, that is, (1) where response to therapy can be determined within a short time; (2) where there is high unmet need with the new technology, which has shown benefit based on translational science and clinical studies; (3) where there is potential for substantially lowering health care costs in targeted patients having factored in all administration costs (4) contain costs for new premium priced products where currently limited demand side measures; and (5) where only a limited time frame (e.g., 10-year UK study for MS drugs seen as far too long). Schemes should be rejected where (1) effective and low cost standards already exist since provisional reimbursement schemes may actually encourage the prescribing of new high-cost drugs vs. existing low-cost standard drugs; (2) patient compliance, which is key, has not been considered in the development of risk-sharing schemes; (3) there is a high administrative burden, (e.g. schemes for bortezomib and beta interferon in the UK); (4) there are concerns with transparency and access to data or data ownership; (5) long follow-up is needed and the number of potential patients is limited; and (6) health authorities will end up funding an appreciable proportion of the development costs.

**Funding source(s):** In part grants from Karolinska Institutet

282

### Economics, Financing, and Insurance Systems

*Keywords:* drug utilisation, IMS, administrative databases

### Care Needed When Comparing IMS and Administrative Databases in Cross National Comparative Studies?

**Brian Barr Godman**<sup>1</sup>, **Kristina Garuoliene**<sup>2,3</sup>, **Jolanta Gulbinovic**<sup>3</sup>

<sup>1</sup>Karolinska Institutet, Sweden; <sup>2</sup>National Health Insurance Fund, Lithuania; <sup>3</sup>Department of Pathology, Forensic Medicine and Pharmacology, University of Vilnius, Lithuania

**Problem statement:** Existing databases for cross national comparative (CNC) studies include administrative databases and commercial sources such as IMS. There can be substantial differences, however, in data collection methods, content, measurement units, and expenditure (e.g., factory, reimbursed, total) between the databases. In addition, there can be volume differences between the databases arising from high patient co-payment levels and prescribing restrictions in some countries. This could have major implications when comparing utilisation rates between countries unless the content of each database has been fully described.

**Objective:** To ascertain the extent of differences in one country and the underlying rationale where it is likely there will be appreciable differences between datasets to provide future guidance. Lithuania was chosen because recent publications have shown appreciable differences in statin utilisation between commercial (Soft Dent database containing data from wholesalers including OTC and self pay) and administrative (Health Insurance Fund) databases.

**Design and policies:** Observational drug utilisation study assessing DDDs in four classes (PPIs, statins, ACEIs/ARBs, and newer anti-depressants—ATC Level 5) between 2004 and 2009 in the Lithuanian Compulsory Health Insurance Database and among commercial databases (IMS—all four, Soft Dent—statins). Soft Dent data were taken from a publication (2005–07); IMS data (2004–09) were supplied directly. Both were converted to 2010 DDDs for comparison with administrative databases. 2010 DDDs were used in accordance with published recommendations. Details of ongoing reforms including prescribing restrictions were taken from published sources and updated by two of the authors (KG and JG). Narrative review of reforms subsequently undertaken by one of the co-authors (BBG).

**Setting:** Lithuania

**Intervention and outcome:** Differences in utilisation (2010 DDDs) rates were examined over the study years for 4 disease areas and databases (ATC Level 5). 4 disease areas were chosen because each one is a high-volume prescribing area in western European countries. Previous publications have shown, however, substantially lower utilisation of PPIs and statins in Lithuania vs. Western European countries.

**Results:** Appreciable differences in utilisation rates were found for the PPIs and statins between administrative and commercial sources; limited differences were found for ACEIs/ARBs and newer anti-depressants: (1) PPIs—five- to seven-fold increase in utilisation in IMS vs. administrative databases. Overall, PPI utilisation in the administrative database varied between 14.5 and 19.0% of IMS utilisation across the study years with no established pattern. (2) Statins—three- to over sixfold increase in utilisation in commercial (IMS and Soft Dent) vs. administrative databases. Overall, statin utilisation in the administrative database varied between 15.1 and 27.4% of IMS utilisation across the study years with no established pattern. (3) ACEIs/ARBs—limited difference between IMS and administrative databases. Overall, utilisation in the administrative database varied between 75.6 and 89.5% of IMS utilisation across the study years with no established pattern. (4) Anti-depressants—limited difference between IMS and administrative databases. Overall, utilisation in the administrative database varied between 70.7 and 88.4% of IMS utilisation across the years, with generally closer alignment in recent years.

**Conclusions:** Possible reasons for appreciable self purchasing of PPIs and statins include at least 50% co-payment for majority of indications (PPIs) and prescribing restrictions for both the PPIs and statins (only reimbursed for secondary prevention and only 6 months for majority of study period with co-payment of 20%). This compares with a median of only 15% in the EuroMedStat study for the statins comparing administrative and IMS databases (western European countries). Possible reasons for closer alignment between IMS and administrative databases for ACEIs/ARBs could be no prescribing restrictions (although still 20% co-payment) and that hypertension seen as a serious disease (less so for hypercholesterolaemia). Limited utilisation generally of anti-depressants in Lithuania due possibly to ongoing stigma associated with psychiatric hospitals (i.e., patients are rapidly transferred to a psychiatrist if they show no clinical improvement with current anti-depressants) and the use of alternative treatment approaches such as benzodiazepines may account for closer alignment in this class. In view of this, knowledge of the content of each database and associated reforms are essential when comparing reimbursed utilisation rates (administrative databases) across countries given the substantial variations seen in some classes. Such knowledge will ensure robust explanations when validating databases and their content. Consequently, this should become a standard validation criteria alongside describing the patient population and their representativeness (ESAC criteria) when undertaking CNC studies.

**Funding source(s):** In part grants from Karolinska Institutet

283

### **Economics, Financing, and Insurance Systems**

*Keywords:* drug utilisation, pharmaceutical policy, efficiency

### **Intensity of Individual Reforms Results in Considerable Differences in Subsequent Utilisation; Implications for Countries When Contemplating Future Initiatives**

**Brian Barr Godman<sup>1</sup>, Bjorn Wettermark<sup>1,2</sup>, Lars Gustafsson<sup>1</sup>**

<sup>1</sup>Karolinska Institutet, Sweden; <sup>2</sup>Medical Knowledge Centre, Stockholm County Council, Sweden

**Problem statement:** Countries need to learn from each other when contemplating future demand-side reforms given appreciable and growing resource pressures, but the influence of even prescribing restrictions will depend on their nature and follow-up.

**Objective:** To assess the influence of different prescribing restriction regulations and their follow-up among different ambulatory care classes and European countries to provide future direction to countries contemplating similar initiatives

**Design:** Pre- and post-policy-analysis CNC study for statin, PPI, and ACEI/ARB utilisation in Austria, Croatia, Finland, and Norway before and after reimbursement restrictions for patent protected products

Setting and study population: Administrative databases covering total populations in each country; utilisation measured in terms of DDDs (2008 and 2010) for all products in the class (ATC Level 5) and as a percentage of total utilisation in the class

Interventions and policies: Details of prescribing restrictions (enforcement criteria) for more expensive patent-protected products in the class principally via payers in each country including peer-reviewed publications and validated with them to enhance the robustness of the findings

Outcome measure(s): Main measure: Percentage change in utilisation of omeprazole (O) and esomeprazole (E), simvastatin (S) and atorvastatin/rosuvastatin (A/R), and ARBs (total including combinations) vs. ACEIs (total including combinations) vs. total utilisation for each class (DDD basis) before and up to 4 years after prescribing restrictions were introduced

Results: Considerable differences were found regarding the influence of prescribing restrictions within and between countries or classes. (1) A/R utilisation decreased from over 30% to 10% of total statins (DDD basis) in Austria (66%) 4 years after prescribing restrictions introduced with patients needing prior authorisation from the Chief Medical Officer (CMO) of their health insurance company for reimbursement. There was a 59% reduction in Finland 1.2 years later with strict criteria on the prescription form for reimbursement (indication and failing on generic statins) but only 44% reduction in Norway 4 years post-intervention with limited follow up and no prior authorisation (PA) scheme unlike Austria. (2) There was greater influence of prescribing restrictions on ARB utilisation in Croatia than Austria because greater follow-up in Croatia (via physicians with the Health Insurance Agency) with potential for fines for continued abuse vs. physician trust and no PA needed in Austria for reimbursement of ARBs. It is acknowledged that this is more difficult to police because an indication for switching is a patient-reported outcome (coughing). (3) We found limited influence also of prescribing restrictions on esomeprazole utilisation in Norway post-intervention because first prescription or recommendation is via hospital specialists where restrictions do not apply.

Conclusions: Prescribing restrictions (enforcement) can be effective in limiting the utilisation of more expensive patent protected products in a class once generics become available. Care is needed, however, because changes in utilisation patterns may be lower than envisaged depending on their nature and follow-up.

Funding source(s): In part grants from Karolinska Institutet

## 285

### Economics, Financing, and Insurance Systems

Keywords: Medicines, prices, availability, affordability, components

#### Out of Pocket and Out of Reach: The Unaffordability and Unavailability of Medicines in Low- and Middle-Income Countries

Margaret Ewen<sup>1</sup>, Alexandra Cameron<sup>2</sup>, Dennis Ross-Degnan<sup>3</sup>, Douglas Ball<sup>4</sup>, Richard Laing<sup>2</sup>

<sup>1</sup>Health Action International, Netherlands; <sup>2</sup>World Health Organization; <sup>3</sup>Harvard Medical School / Pilgrim Health Care;

<sup>4</sup>Independent consultant

Problem statement: High prices matter to the vast majority of the global population who have to purchase medicines through out-of-pocket payments and to governments who have limited pharmaceutical budgets. Medicine availability matters, especially in public sector facilities which the poor rely on to access more affordable treatments. When medicines are unaffordable and unavailable, treatment simply becomes out of reach.

Objectives: To assess the price governments and patients pay for medicines, medicine availability, the affordability of standard treatments, and medicine price components

Design: A secondary analysis of the price and availability of 15 medicines, using data in 45 national and subnational surveys (36 countries) undertaken using the World Health Organization/Health Action International price measurement tool. Data were adjusted for inflation or deflation and purchasing power parity. International reference prices from open international procurements for generic products were used as comparators.

Setting and study population: Public and private sectors in 36 low- and middle-income countries

Outcome measure(s): Median prices (originator brands and lowest priced generic equivalents), median percentage availability, number of days' wages needed by the lowest paid unskilled government worker to purchase standard treatments (affordability), and price components in the supply chain from manufacturer to patient

Policy changes: Policies such as promoting lower priced quality generics and alternative financing mechanisms are needed to improve medicine affordability and availability.

Results: Average public sector availability of generics ranged from 29.4 to 54.4% across WHO regions. Median government procurement prices for generics were 1.11 times corresponding international reference prices, although purchasing efficiency ranged from 0.09 to 5.37 times international reference prices. Low procurement prices did not always translate into low patient prices. Private sector patients paid 9–25 times international reference prices for lowest priced generics and over 20 times international reference prices for originator brands. Treatments for acute and chronic illness were largely unaffordable. Private sector mark-ups ranged from 2 to 380% for wholesalers and 10 to 552% for retailers.

Conclusions: Overall, prices were substantially higher than expected if purchasing and distribution were efficient and mark-ups were reasonable. Availability of medicines in the public sector was poor. Medicines, especially those to treat chronic diseases, were largely unaffordable.

Funding source(s): None

286

### **Policy, Regulation, and Governance**

*Keywords:* transparency assessment, corruption vulnerability, public pharmaceutical sector, good governance

#### **Measuring Transparency in the Public Pharmaceutical Sector. National Assessment for Costa Rica**

---

**Maria Soledad Quesada-Morúa, Luis Guillermo Jiménez-Herrera**

University of Costa Rica, Costa Rica

**Introduction:** Access to good quality medicines remains very limited in many parts of the world due to many causes, one of them being corruption. In 2004, the WHO initiated the Good Governance for Medicines Project in an effort to undermine this problem. Costa Rica is the first country in Central America to carry out the assessment phase of this program. Knowing the weaknesses and strengths of the public pharmaceutical sector can help working on mechanisms for transparent processes that assure safe, available, affordable and good quality medicines.

**Objective:** Measure the level of transparency and vulnerability to corruption of the public pharmaceutical sector in Costa Rica in eight basic functions: registration, licensing, inspection, promotion, clinical trials, selection, procurement and distribution.

The present study is descriptive and qualitative that used semi-structured interviews to Key Informants (KI) to provide information on the vulnerability to corruption, using structural indicators and a quantification of the level of transparency for each function.

These indicators were converted to a 10-point scale to analyze and compare the degree of susceptibility to corruption and to determine the level of transparency in each function, as follows: 0.0-2.0 for extremely vulnerable (EV); 2.1-4.0 for very vulnerable (VV); 4.1-6.0 for moderately vulnerable (MoV); 6.1-8.0 for marginally vulnerable (MrV); and 8.1-10.0 for minimally vulnerable (MiV).

109 KI were interviewed, according to their involvement in the pharmaceutical sector and their knowledge of it. The KI interviewed were from the public sector (85%), private sector (13%), academia and NGOs (2%). For all eight functions a minimum of 8 to 10 interviews were obtained.

**Results:** The assessment on the eight functions revealed that the public pharmaceutical sector of Costa Rica has different vulnerability scores for each function, being the most vulnerable the Inspection of Pharmaceutical Establishments with a score of 4.34 (MoV), followed by Control of Medicine Promotion with a 4.74 (MoV), Medicines Registration with 6.19 (MrV) Licensing of Pharmaceutical Business with a 6.29 (MrV), Distribution of Medicines with 7.83 (MrV), Control of Clinical Trials with 7.85 (MrV), Selection of Essential Medicines with 7.96 (MrV), and the least vulnerable Procurement of Medicines with 8.14 (MiV).

**Conclusions:** The assessment findings allow an overview of the pharmaceutical public sector in Costa Rica, that has a regulatory structure prone to improvement, especially in personnel selection, standard operating procedures, and written guidelines in conflicts of interests specific for each function.

To minimize corruption, a structural platform with transparent processes should be developed, as well as a proper National Drug Policy that helps articulate all the medicines chain, promoting its strengths and diminishing its weaknesses.

Funding Source(s): WHO

287

### **Economics, Financing, and Insurance Systems**

*Keywords:* Medicine prices, regulation, pharmaceutical policy, cost containment, affordability

#### **Regulating Supply Chain Mark-Ups to Control Medicine Prices—A Review of the Literature in Low- and Middle-Income Countries**

---

**Douglas Ball**

Consultants for Health and Development, Netherlands, The

**Problem statement:** Medicine prices are often an access barrier for the poor, especially in low-income countries. In order to increase financial access, policy makers may regulate the prices of medicines using a variety of means. The regulation of supply chain mark-ups is one strategy, but little is known about how common this intervention is in low- and middle-income countries (LMIC) and whether it is effective.

**Objectives:** To describe the evidence base for the regulation of supply chain mark-ups in low- and middle-income countries and whether it leads to lower medicine prices

**Design:** Literature review

**Setting:** International, public, and private sectors

**Study population:** Low- and middle-income countries

**Outcome measure(s):** Number of countries using pharmaceutical mark-up regulation, types of regulation, factors affecting implementation of the policy and its effectiveness

**Results:** Mark-ups are commonly regulated in high-income countries (HIC). Around 60% of LMIC report regulating wholesale or retail mark-ups. HIC use a variety of regulation methods and may apply different mark-ups to separate groups of pharmaceuticals. LMIC commonly use fixed percentage mark-ups, with few applying regressive mark-ups. Mark-up regulation is seldom used as a means to promote generic medicines. Little information is available about the impact of mark-up regulation on medicines prices or supply chain stakeholder viability. Ineffective enforcement and lack

of regulation of manufacturer or retail prices are likely to lead to failure. Mark-up regulation has an impact on wholesaler and retailer viability.

Conclusions: Evidence on the implementation, effect, and enforcement of mark-ups in LMIC is sparse. Regulation of mark-ups as part of comprehensive price regulation will probably lead to reduced medicine prices, but there may be unexpected effects on the supply of medicines. Without regulation of either the manufacturer's selling price or the retail selling price, mark-up regulation is unlikely to be effective. Mark-ups that include a regressive component with or without fixed fees probably lead to better outcomes than fixed percentage mark-ups through their influence on financial incentives.

Funding source(s): Health Action International – Global

291

### Drug Resistance

*Keywords:* antimicrobials, drug utilization, cost containment

## Randomized Controlled Study of Antibiotic Approval Program on Patients' Clinical Outcomes and Antibiotic Expenditures

**Visanu Thamlikitkul, Pinyo Rattanaumpawan, Patama Sutha**

Faculty of Medicine Siriraj Hospital, Thailand

Problem statement: Piperacillin/tazobactam, imipenem, and meropenem were inappropriately used in 50% of hospitalized patients at Siriraj Hospital. Antibiotic approval is a recommended measure for controlling inappropriate antibiotic use. A concern of this measure is it could have a negative effect on clinical outcomes for the patients whose antibiotics are changed or discontinued.

Objective: To determine effectiveness of antibiotic approval program on patients' clinical outcomes and antibiotic expenditures

Methods: Adult hospitalized patients who were prescribed the target antibiotics (i.e., piperacillin/tazobactam, imipenem, or meropenem) from August to November 2007 were randomized to antibiotic approval group (A) or control group (C). An infectious disease specialist was responsible for antibiotic approval in A group. All participating patients were followed for clinical outcomes and antibiotic expenditures.

Results: The target antibiotics were prescribed to 486 patients (516 episodes) in C group and 462 patients (512 episodes) in A group. The patients allocated to A group had more favorable clinical outcome (68.9% vs. 60.5%,  $p < 0.01$ ), shorter duration of target antibiotics (7.5 d. vs. 9.3 d.,  $p < 0.01$ ), shorter duration of all antibiotics (12.7 d. vs. 16.4 d.,  $p < 0.01$ ), and lower mortality due to infections (29.4% vs. 35.4%,  $p < 0.05$ ) than those in C group. Multivariate analysis revealed that unfavorable clinical outcome was significantly associated with the C group and having respiratory tract infections. The costs of the target antibiotics and all antibiotics in A group were much less than those in C group. The actual difference in the cost of antibiotic consumption between A group and C group, cost saving, was 143,793 US dollars.

Conclusions: An antibiotic approval program is an effective measure for reducing antibiotic consumption without compromising the clinical outcomes.

Funding source(s): Faculty of Medicine Siriraj Hospital, Thailand

293

### Economics, Financing, and Insurance Systems

*Keywords:* access to essential medicines, affordability, availability, ability to pay, component cost

## Cost as a Barrier to Access: Availability, Affordability, and Identifying Component Cost of Essential Medicines

**Mohammedsied Nuru Mohammednur<sup>1</sup>, Teferi Gedif<sup>2</sup>, Damen Hailemariam<sup>2</sup>**

<sup>1</sup>Mekelle university, Ethiopia; <sup>2</sup>Addis Ababa university, Ethiopia

Problem statement: WHO reported that one-third of the world's population lacks reliable access to required medicines. The situation is even worse in developing countries, and price is one of the factors that hinder access to essential medicines.

Objectives: To identify barriers in accessibility, availability, affordability, and component cost of essential medicines

Design: A descriptive cross-sectional study design was used. Quantitative methods involved the use of checklist; an exit interview and structured questionnaire were also employed.

Setting: The study was conducted in Addis Ababa (AA), capital city of Ethiopia, and Benishangul Gumuz regional state (BGRS), one of the nine regions in the country. The study included hospitals, health centers, and pharmacies from public, private, and other sectors.

Study population: From the two selected regions, a list of hospitals, health centers, and pharmacies were recorded, and 150 participants were interviewed using an exit interview. Furthermore, from 10 facilities (from each public, private, and other sector), data on availability and price of medicines were collected. For convenience, public health facilities were used to anchor the sample, with other types of medicine outlets chosen by their proximity to these facilities.

Results: In private pharmacies, innovator brand (IB) prices were 27 times higher than the international reference price (IRPs) in AA, whereas generics were 2.7 and 3.6 times higher in AA and BGRS, respectively. In other sector retail

outlets, the figures were 2.52 and 4.9 times higher for generics than the IRPs in AA and BGRS, respectively. Add-on costs had a substantial impact on medicine prices in all sectors. Retail pharmacy markups were 25–55% and 25–247% for IBs and generics, respectively. In the public sector, where medicines are free, availability was low even for medicines on the national essential drugs list. For a month's treatment for peptic ulcer disease and arthritis, people have to pay more than a month's wages when IB was used. In the study of the exit interviews, around 61% of the respondents were able to pay for the prescribed medicines. The most important predictors of ability to pay (ATP) for the prescribed medicine found in this study are type of organization ( $p < 0.015$ ), educational status of the head of the household ( $p < 0.01$ ), amount of payment for the prescribed medicines, and estimated average income of the household ( $p = 0$ ).

**Conclusions:** The availability of lowest price generics was low in the public sectors and prices of IB were very high in the private sector of AA. Markups for generic products are greater than for IBs. Reducing the base price without controlling mark-ups may increase profits for retailers and wholesalers without reducing the price paid by end users. To increase accessibility and affordability, promotion of generic medicines and improved availability of medicines in the public sector are required.

**Funding source(s):** School of Graduate Studies, Addis Ababa University

**294**

#### **Access**

*Keywords:* appropriate use of medicines, drug utilization, education, prescribing, essential medicines, patient safety

### **Impact of the WHO Guide to Good Prescribing on Medical Students**

**Abdelkader Helali, Nadjat Loumi**

Centre National de Pharmacovigilance et de Matériovigilance, Algeria

**Problem statement:** Pharmacotherapy teaching in medicine is characterized by transfer of knowledge about medicines rather than training students to treat methodically and using structured approach. Recently, a six-step problem-solving approach in pharmacotherapy using normative model was suggested by WHO and based on the following steps: (1) define the patient's problem; (2) specify the therapeutic objective; (3) verify the suitability of the P-drug for the individual patient; (4) write a prescription; (5) inform and instruct the patient; and (6) monitor and/or stop the treatment.

**Objectives:** To measure the impact of the WHO Guide of Good Prescribing in short-term pharmacotherapy teaching (a 10-week study)

**Intervention:** A randomized controlled trial was conducted among students divided into two groups: a control group with 65 students and a study group with 133 students. The two groups were assessed through 3 successive tests, each containing open and structured questions about drug treatment of different type of pain. The assessing tests are taken before the training period (T0), six weeks after problem-based training period and at the end of teaching pharmacotherapy (T1), and finally 4 weeks later to assess if they remembered the method studied (T2). The study was conducted over 3 years for controlling the reproducibility of observed data. The scores of control and study groups are compared by using Student's t-test,  $p < 0.05$  is considered as significant.

**Study population:** Students at 6th year of graduate medicine in Algiers, at the clerkship period

**Results:** Data show that students from the study group performed significantly better than those in the control group at all six steps. The students in the study group showed good problem-solving capabilities at T1, and they remembered the method to solve the health problems 4 weeks later at T2. The results confirm the data previously obtained by other authors. Moreover, in our study, the impact of fundamental sciences such as physiopathology to specify the therapeutic objective and pharmacology to verify the suitability of medicine for individual patient constitute a solid bridge between fundamental and clinical knowledge in prescribing and solving problems. The method described in Guide to Good Prescribing reinforce the understanding of the students and the transfer of knowledge to new capabilities improving rational use of medicines ( $p < 0.05$ ).

**Conclusion:** The WHO method of good prescribing is effective and efficient for pharmacotherapy teaching in developing countries and also not expensive as pointed out by certain studies. The method is flexible and adaptable to every country.

**Funding source(s):** Centre National de Pharmacovigilance et de Matériovigilance, NIPA, Dely Brahim Algiers (Algeria)

**298**

#### **Economics, Financing, and Insurance Systems**

*Keywords:* price regulation, market structure, production, Korea

### **Reimbursement Price, Market Structure, and Pharmaceutical Firm Behavior in Korea**

**Jaeheon Heo, Soonman Kwon**

Seoul National University, Korea, South (Republic of)

**Problem statement:** Regulation of reimbursement price for pharmaceuticals in national health insurance is a key issue for the government and pharmaceutical industry in Korea.

**Objective:** To examine the effect on pharmaceutical firm behavior of market structure and reimbursement price regulated by the government in Korea.

**Design:** Using a panel data of frequently used medicines in 2003–07, this study examines the impact of competition and government price regulation on production of pharmaceutical firms.

Outcome measure(s): Based on the structure-conduct-performance framework of industrial organization economics, various measures are used for market definitions (e.g., therapeutic categories, ATC classifications) and concentration indices such as Herfindahl index. Other independent variables include the length of being listed in the benefit package, potential market size, and prescription vs. non-prescription drugs.

Conclusion: The effect of market competition on production varies depending on therapeutic categories, but the reimbursement price regulation by the government has no negative effect on the production of pharmaceutical firms.

Funding source(s): N/A

**300**

### Chronic Care

*Keywords:* access to medicines, chronic disease, equity, affordability, availability

#### **"I Wish I Had AIDS": Qualitative Study on Access to Health Care Services for HIV/AIDS and Diabetic Patients in Cambodia**

##### **Chean Men**

Center for Advanced Study, Cambodia

Problem statement: Poor Cambodians with chronic diseases such as HIV/AIDS or diabetes typically encounter multiple serious barriers to effective care and treatment. This process may extend over many years and involve numerous rounds of diagnosis and treatment as the disease progresses from initial symptoms to longer term complications. Living with both the impact of the disease and this ongoing struggle for care can severely disrupt the everyday life of both sufferers and their families.

Objectives: To explore and document the differences and similarities in the types of barriers to care and treatment at different phases of their illness experience reported by patients with HIV/AIDS or diabetes

Design: This retrospective study adopted qualitative research methods to collect data from HIV/AIDS and diabetic patients enrolled and not enrolled in treatment programs in different institutions in urban and rural setting.

Setting: The study was conducted in urban and rural settings. In the urban area (Phnom Penh), interviewees were selected from patients enrolled in a free care program at the Centre of Hope. This charity hospital is an important provider of treatment and care for both HIV/AIDS and diabetes patients. Similarly, in the rural area (Takeo Province), interviewees were selected from patients enrolled in a free care program at the chronic disease clinic co-managed by the referral hospital and MSF Belgium. Again, this facility provided care and treatment for both disease groups. Patients not enrolled in the treatment program were identified through key informants such as traditional healers and not-for-profit service providers.

Study population: Using purposive and snowball sampling techniques, 25 HIV/AIDS and 45 diabetic patients were recruited. Semi-structured and open-ended interviews were used to collect information on patient experiences of different phases in the ongoing process of seeking care and treatment. Qualitative analysis was done to search for emerging themes, word repetition and local terminology that captured the meaning of patients' experiences.

Results: The findings indicate that both HIV/AIDS and diabetic patients encounter multiple supply- and demand-side barriers to care at different stages of their illness. Moreover, they strongly suggest that supply-side barriers, for example rationing systems or targeting strategies that limit access to free treatment or social assistance, are substantially higher for diabetic patients. This perceived inequity had a profound impact on diabetic patients to the extent that some "wished they had HIV/AIDS."

Conclusions: These findings suggest that there is an urgent need to widen the focus of health care to address the substantial and increasing burden of chronic diseases in Cambodia and many other low/middle income countries.

Funding source(s): This study is an output of the EuropeAID project supported by the European Commission.

**301**

### Chronic Care

*Keywords:* consumers, drug utilization, surveillance, Oman

#### **Household Survey on Medicine Use in Oman**

**Brian Conroy Gunn, Ahmed Abdo-Rabbo, Manal Al-Ansari, Hawraa Al-Lawati, Batool J Suleiman**

Directorate of Rational Use of Medicines, Ministry of Health, Sultanate of Oman, Oman

Problem statement: Irrational use of medicines in the community is a global problem. No national household survey on medicine use has been conducted in Oman, and the few studies in other countries have rarely been published or not fully documented.

Objectives: To investigate the use and storage of medicines in the community and to identify related problems

Methods: A cross-sectional study was performed using a written pre-tested structured interview questionnaire along with direct observations. 1,050 households were chosen from 12 urban and rural villages in 6 willayat (districts) located in 4 health regions in Oman. The storage and use of medicines in the community were investigated.

Results: The key results showed that most of the drugs were stored in relatively inadequate and unsafe places. There were 44.4% of households with members suffering from chronic diseases. In 52.8% of the households, one or more persons used traditional medicines. The most common types of traditional medicines used were herbal medicines (49.8%), and the most common use of herbal medicines was for gastrointestinal tract problems. Modern medicines

were found in 95% of the households. The average number of medicines per household and the maximum number found in one home were 6 and 45 medicines, respectively. The most common therapeutic category encountered was musculoskeletal drugs (24.9%). 45.8% of the households had one or more antibiotics, and the percentage of antibiotics from all medicines found was 12.55%. The percentage of unused and expired medicines were 31.6 % and 12.4%, respectively. The maximum number of antibiotics found in one household was 10. The majority of medicines at homes (86.1% and 70.3%) were advised by physicians and obtained from public pharmacies, respectively. 61.3% of the households kept left-over medicines from previous treatment. The households did not know the indications of 15.4% of the stored medications. 15.5% of the respondents mentioned that they do not check the expiry date, and 12.4% of medicines found were already expired. The percentage of medicines found to be inadequately labeled and the percentage of households' knowledge of correct dosage were 92% and 65.9%, respectively.

Conclusion: The results show, medications were stored in large quantities at homes and in inadequate places. A large percentage was being wasted. Therefore, the need is compelling for promoting rational use of medicines in the community to enable people to store and use medicines in an appropriate, safe, and judicious way.

Funding source(s): Financial support was received from WHO-EMRO under JPRM.

306

### Chronic Care

Keywords: Prophylaxis, cancer, chemotherapy, fluoroquinolones, levofloxacin.

#### Prophylactic Antimicrobials: Triumph Over Cancer Chemotherapy Complications?

**Jyotika Singh, M Joseph John, Dinesh K Badyal**

Christian Medical College and Hospital, Ludhiana, Punjab, India.

Problem Statement: The patients on cancer chemotherapy are at substantial risk of developing febrile episodes, bacteremia and infection related mortalities, yet the prophylactic use of antimicrobials continues to be a controversial issue. Fluoroquinolones are the primary antibiotics considered for prophylaxis, however emergence of resistance, high cost and limited data supporting cost effectiveness in cancer chemotherapy are the main arguments against their use.

Objectives: To evaluate the effect of antimicrobial prophylaxis in cancer chemotherapy.

Design: Prospective, randomized, open label, controlled study.

Setting: This study was conducted in the Medical Oncology and Hemato-Oncology Departments, Christian Medical College and Hospital, Ludhiana.

Intervention: The patients receiving chemotherapy for solid cancers were randomly divided into two groups A and B. Group A patients received cancer chemotherapy and no prophylactic antimicrobials were given. Group B patients were given prophylactic levofloxacin with each cancer chemotherapy cycle.

Outcome measure: Each patient was analyzed for febrile episodes, documented infections and hospitalizations.

Results: Majority of patients were illiterate and belonged to rural population of lower middle socio economic strata.

Number of febrile episodes was significantly higher in group A patients. The relative risk of a clinically documented febrile episode was 0.22 (95% confidence interval 0.08 to 0.56,  $p < 0.001$ ), indicating a 78% reduction in the risk of fever during the first cycle with the use of levofloxacin therapy, as compared with control group.

The documented infections were seen more in group A as compared to group B (relative risk 0.11, 95% confidence interval 0.01-0.84,  $p < 0.05$ ). Resistance to levofloxacin was reported in one patient. Forty eight percent patients (48%) were hospitalized in group A and 18% in group B (relative risk 2.67, 95% confidence interval 1.38-5.15,  $p < 0.01$ ). Average duration of hospital stay was  $3.8 \pm 0.73$  days in group A as compared to  $1.56 \pm 0.56$  days in group B ( $p < 0.05$ ).

Another major advantage of antimicrobial prophylaxis is cost benefit. The total cost of treatment in group A was `4.41 lakhs and `1.45 lakhs in group B. Average cost of treatment per patient per day in two groups was `1269.80  $\pm$  220.32 vs. `372.21  $\pm$  99.23 ( $p < 0.001$ ).

Conclusion: Our study provides ample evidence that antimicrobial prophylaxis is beneficial to patients receiving cancer chemotherapy as it decreases the morbidity, in terms of febrile episodes, infections, hospitalizations and it also reduces the cost of treatment.

307

### Economics, Financing, and Insurance Systems

Keywords: Malaria, Access, Health Outcomes, health service utilization, anaemia

#### Effect of Removing Direct Payment for Health Care on Utilization and Health Outcomes in Ghanaian Children: A Randomized Controlled Trial

**Evelyn Korkor Ansah<sup>1</sup>, Solomon Narh-Bana<sup>1</sup>, Sabina Asiamah<sup>1</sup>, Vivian Dzordzordzi<sup>1</sup>, Kingsley Baintey<sup>1</sup>, Kakra Dickson<sup>3</sup>, John Owusu Gyapong<sup>4</sup>, Kwadwo Ansah Koram<sup>3</sup>, Brian Greenwood<sup>2</sup>, Anne Mills<sup>2</sup>, Christopher JM Whitty<sup>2</sup>**

<sup>1</sup>Dangme West District Health Directorate, Ghana Health Service, Ghana; <sup>2</sup>London School of Hygiene & Tropical Medicine, UK; <sup>3</sup>Noguchi Memorial Institute for Medical Research, University of Ghana, Legon, Ghana; <sup>4</sup>Research and Development Division, Ghana Health Service, Ghana

Problem statement: User fees are a known barrier to accessing health care. Governments are introducing free health care to improve health outcomes. Free health care affects treatment seeking, and it is therefore assumed to lead to

improved health outcomes, but there is no direct trial evidence of the impact of removing out-of-pocket payments on health outcomes in developing countries. This trial was designed to test the impact of free health care on health outcomes directly.

**Objectives:** To compare the prevalence of anaemia (Hb<8g/dl) among children 6–59 months, from households with and without improved financial access to health care

**Design:** A two-arm randomized controlled unblinded trial with a third observational arm made up of households already self-enrolled in the scheme. The main comparison was between the two randomized arms. The self-enrolled arm was included in order to document the differences between households who paid their own premiums and those who had their premiums paid for them as a result of being recruited into the study, as a subsidiary part of the trial.

**Setting:** The Dangme West District in Southern Ghana, a rural district with an estimated population of 115,005

**Study population:** Children <5 years in households who were randomized to receive free enrollment into an existing pre-payment scheme or not, for a period of one year

**Intervention:** Provision of free primary and some level of secondary health care to households randomized to the intervention arm by enrolling them into an existing pre-payment scheme operating in the area. The control group continued to pay for health care out of pocket and received equivalent benefit in the year following the trial.

**Policy:** The direct cost of care is a barrier to the poorest in accessing care, but it is not the only one, and other modifiable barriers have to be addressed if removing the direct cost of care is to have a useful impact on the health of the poorest.

**Outcome measure(s):** The primary outcome was moderate anaemia (Hb, 8 g/dl); major secondary outcomes were health care utilization, severe anaemia, and mortality.

**Results:** 2,194 households containing 2,592 Ghanaian children under 5 years old were randomized into the two trial arms; 165 children from families who self-enrolled formed an observational arm. At baseline, the randomized groups were similar but different from the self-enrolled. Introducing free primary health care resulted in children in the intervention arm utilizing primary care significantly more (2.8 visits/person-year) than those in the control arm (2.5 visits/person-year) [95% CI 1.04–1.20; P=0.001]. There was no measurable difference in any health outcome. The primary outcome of moderate anaemia was detected in 37 (3.1%) children in the control and 36 children (3.2%) in the intervention arm (adjusted odds ratio 1.05, 95% CI 0.66–1.67). There were four deaths in the control; five in the intervention group. Mean Hb concentration, severe anaemia, parasite prevalence, and anthropometric measurements were similar in each group.

**Conclusions:** In the study setting, removing out-of-pocket payments for health care had an impact on health care-seeking behaviour but not on the health outcomes measured.

**Funding source(s):** Gates Malaria Partnership, LSHTM, with funds from the Bill & Melinda Gates Foundation

### 309

#### Drug Resistance

**Keywords:** AMR containment, AMR contributing factors, Adherence to treatment guideline, culture sensitivity, AMR knowledge and perceptions, surgical prophylaxis, Ethiopia

#### Magnitude of and Contributing Factors to Antibacterial Resistance in Ethiopia

**Tenaw Andualem T.<sup>1</sup>, Negussu Mekonnen<sup>2</sup>, Gabriel Daniel<sup>3</sup>, Mohan P. Joshi<sup>3</sup>, Douglas Keene<sup>3</sup>, David Lee<sup>3</sup>**

<sup>1</sup>MSH/SPS, INRUD Ethiopia; <sup>2</sup>MSH/SPS Ethiopia; <sup>3</sup>MSH/SPS USA

**Problem statement:** Bacterial infections are major causes of morbidity and mortality in humans and loss of production in animals. Antimicrobial resistance (AMR) results from use, overuse, and misuse of antibiotics in humans and animals.

**Objective:** To show the magnitude of AMR and contributing factors in Ethiopia

**Design:** (1) Review of 2004–08 census of culture and antibacterial sensitivity records, health professionals' course contents on AMR containment, (2) cross-sectional survey of AMR containment practices in 73 public health facilities, and practices of random samples of 675 health practitioners using interviews and semi-structured observations; (3) analysis of systematic samples of 100 records per health facility and records to assess antibacterials prescribing from surgical and medical wards and outpatient prescriptions in 2006–07; and (4) exit interviews with 1,761 patients to understand their knowledge on the medicines dispensed and perceptions of antibacterial use.

**Setting:** The study was conducted in public hospitals and health centers sampled from nine regional states and two city administrations in Ethiopia in August 2008.

**Study population:** Culture and antibacterial sensitivity records across the country over five years, surgical and medical inpatient and outpatient prescriptions records from 2006–07, and all adult patients who were prescribed and dispensed antibacterial in August 2008 from 73 public health facilities

**Outcome measure(s):** Microorganism growth and sensitivity percentages for antibacterials and percentages of health facilities, practitioners, and patients related to knowledge and practice of AMR containment

**Results:** Out of 52,682 culture and antibiotic sensitivity records, 35.1% showed growth with varying levels of resistance. For example, *Escherichia coli* samples were resistant to amoxicillin (70%), tetracycline (75%), and penicillin G (88%); 18.3% of *Staphylococcus aureus* samples were resistant to vancomycin. Availability of key antibacterials, infection prevention materials, and standard treatment guidelines in health facilities were 73.0%, 82.9%, and 61.0%, respectively. Antibacterials prophylaxis was prescribed for 75.9% of surgical procedures, and antibacterials were prescribed to 70.6% of medical inpatients. Provider adherence to treatment guidelines for pneumonia was 19.6%.

Patients' knowledge about dispensed antibacterials was 82%, whereas 40.2% and 36.3% knew that antibacterials are not used for watery diarrhea and the common cold, respectively.

Conclusions: A high level of microorganisms is resistant to antibacterials in Ethiopia. Contributing factors include poor knowledge and practices among practitioners and patients, health facilities' limited emphasis on preventing and containing AMR, and poor adherence to standard treatment guidelines. These factors require multifaceted interventions that can create synergy to prevent and contain AMR and to promote appropriate use.

Funding source(s): Drug Administration and Control Authority of Ethiopia and U.S. Agency for International Development through MSH/SPS

### 312

#### Malaria

*Keywords:* Antimalarials, Market analysis, Supply chain, Private sector, Access to medicines

#### **Mapping the Private Sector Distribution Chain to Understand Barriers and Opportunities for Improved Access to Antimalarials in Six Low-income Countries in Africa and South-East Asia**

**Benjamin Palafox<sup>1</sup>, Sarah Tougher<sup>1</sup>, Edith Patouillard<sup>1</sup>, Catherine Goodman<sup>1,2</sup>, Kara Hanson<sup>1</sup>, Immo Kleinschmidt<sup>1</sup>, Kate O'Connell<sup>3</sup>, Desmond Chavasse<sup>3</sup>, Martine-Esther Tassiba<sup>4</sup>, Louis-Daniel Akulayi Tshisungu<sup>5</sup>, Sochea Phok<sup>6</sup>, Arogundade Deborah Ekundayo<sup>7</sup>, Peter Buyungo<sup>8</sup>, Felton Mpasela<sup>9</sup>**

<sup>1</sup>London School of Hygiene & Tropical Medicine, United Kingdom; <sup>2</sup>Kenya Medical Research Institute-Wellcome Trust Research Programme; <sup>3</sup>Population Services International; <sup>4</sup>Population Services International (Benin); <sup>5</sup>Association de Santé Familiale (DRC); <sup>6</sup>Population Services International (Cambodia); <sup>7</sup>Society for Family Health (Nigeria); <sup>8</sup>PACE (Uganda); <sup>9</sup>Society for Family Health (Zambia)

Problem statement: In many low-income settings, the private sector plays a crucial role in the delivery of antimalarials, although numerous regulatory challenges have been documented. The operation of the private sector has important implications for antimalarial availability, affordability, quality, and rational use. In the context of the introduction of a global subsidy to improve access to artemisinin-based combination therapies (ACTs), it is particularly important to understand how the private sector operates and how it varies across countries, because this will affect the success of such interventions and, therefore, equitable access.

Objectives: To describe the structure of the private commercial sector distribution chain for antimalarials and the characteristics of wholesale suppliers and to document the availability and mark-ups for antimalarials along the distribution chain

Design: Descriptive cross-sectional study

Setting: Multi-country study in Benin, Cambodia, DR Congo, Nigeria, Uganda, and Zambia

Study population: A key challenge in investigating private sector medicine distribution chains is the lack of an accurate sampling frame from which to draw a representative sample. Within each country, a census of antimalarial retailers was conducted in 19–76 randomly selected geographic areas, and an innovative bottom-up sampling approach was used to trace wholesale suppliers back from their retail customers, with this process repeated until only manufacturers and importers were reached. Across the 6 countries, 688 wholesalers and 7,048 retailers were included in structured surveys.

Outcome measure(s): Structure of private sector antimalarial distribution chain; antimalarial availability and price mark-ups along the chain

Results: We will present maps of the private sector antimalarial supply chains in each country, descriptions of their composition and characteristics, and estimates of availability and price mark-ups for antimalarials. For example, 93.0% of Zambian wholesalers had antimalarials available, but only 72.1% had an ACT in stock—51.2% had an artemisinin monotherapy and 76.7% had a non-artemisinin therapy (e.g., chloroquine). In terms of price mark-up on ACTs, median wholesaler mark-ups (26.7%) were generally lower than median retail mark-ups, which ranged from 42.9% in private pharmacies to 150% in grocery stores. Although nearly all antimalarial wholesalers (97.5%) reported a visit by an inspector over the past 12 months, a smaller proportion (86.1%) was observed to store medicines in appropriate conditions.

Conclusions: Results across countries will be contrasted and implications for interventions to improve ACT access, such as the Affordable Medicines Facility for Malaria, will be explored.

Funding source(s): Bill & Melinda Gates Foundation

### 313

#### Policy, Regulation, and Governance

*Keywords:* Pharmacovigilance, Regionalisation, Uganda

#### **Regionalisation of Pharmacovigilance in Uganda**

**Helen Byomire Ndagije, Huldah Nassali, Victoria Nambasa Bukenya, Evans Kato Tsubira, Angela Bonabana**  
National Drug Authority, Uganda

Problem statement: Uganda is the 57th country worldwide with a critical shortage of health service providers. There is one doctor for every 8,400 Ugandans and one nurse or midwife for every 36,000 Ugandans. The few health workers are overloaded and leave a service delivery gap that is often filled by unqualified personnel, especially in the rural areas. The National Drug Authority (NDA) is mandated by the National Drug Policy and Authority Act (Cap. 206) to

ensure that all medicines, medical devices, and supplies entering Uganda are of good quality and are safe and efficacious. The performance of the over 500 drugs registered in Uganda and especially the newer molecules such as the artemisinin-based combination therapies as well as the highly active antiretroviral therapies need to be closely monitored.

**Objectives:** In an effort to monitor these drugs, a National Pharmacovigilance Centre (NPC) was started in 2005. This centre acquired full membership of the WHO Programme of International Drug Monitoring in 2007. Regional pharmacovigilance centres were established in the national and regional referral hospitals. The primary objectives of regionalizing pharmacovigilance was to increase the number and quality of reports received at the national centre and contribute to improved quality of health service delivery.

**Design:** This was an intervention study conducted to assess the status of pharmacovigilance before and after regionalization.

**Setting:** The regionalisation of pharmacovigilance was introduced in the National and Regional Referral hospitals, where core teams were established and trained in pharmacovigilance and were designated the Regional Pharmacovigilance Centres (RPC). Other regional centres that were a useful resource for the private sector and worked closely with these RPCs were the NDA regional offices.

**Intervention:** Regionalisation involved training core teams of health workers in the regions on the importance of pharmacovigilance, equipping them with Vigiflow skills to report adverse events online and also receiving their workplans. Sensitization meetings held by the NDA regional officers as part of their routine support supervision activities for the private sector facilities (pharmacies and drug shops) also began to include pharmacovigilance.

**Outcome measure(s):** Reporting rates, average time taken to report ADRs, type and seriousness of reports, and number of collaboration on ADR issues

**Results:** By the end of 2010, we had received over 500 suspected reports of ADRs. The time to enter reports into Vigiflow reduces from 31 months to 3 months. Partnerships with various stakeholders have been built; NPC worked with Soroti RPC to investigate cases of suspected disability due to quinine administration. The change in administration site of quinine to the thigh was accommodated in new malaria treatment guidelines.

**Challenges:** Poor quality of reports. There is still underreporting.

**Conclusion:** More collaboration is needed to institutionalize pharmacovigilance in routine health care delivery. Pharmacovigilance must be perceived and implemented as a way of improving quality of care. Enabling laws should be enacted to make reporting compulsory.

**Funding source(s):** National Drug Authority

### 314

#### Malaria

**Keywords:** Malaria, artemether-lumefantrine, community health worker, rapid diagnostic test

#### **Feasibility and Impact of Deploying Artemether-Lumefantrine (AL) At Community Level with the Introduction of Rapid Diagnostic Test (RDT)**

**Hailemariam Lemma Reda<sup>1</sup>, Peter Byass<sup>2</sup>, Alem Desta<sup>1</sup>, Andrea Bosman<sup>3</sup>, Yohannes Ambachew Medhin<sup>3</sup>, Edward Fottrell<sup>2</sup>, Asefaw Getachew<sup>1</sup>, Gianfranco Costanzo<sup>4</sup>, Aldo Morro<sup>5</sup>, Nathan Mulure<sup>6</sup>, Angela Bianchi<sup>7</sup>, Luigi Toma<sup>8</sup>, Anne-Claire Marrast<sup>9</sup>, Gebre Ab Barnabas Gezahegn<sup>1</sup>**

<sup>1</sup>Tigray Health Bureau, Ethiopia, Ethiopia; <sup>2</sup>Umea° Centre for Global Health Research, Umea University, Sweden; <sup>3</sup>Global Malaria Programme/WHO, Geneva; <sup>4</sup>Italian Ministry of Labour, Health and Social Policies, Rome, Italy; <sup>5</sup>Italian Dermatological Center of Mekelle, Tigray, Ethiopia; <sup>6</sup>Novartis Pharma AG, Nairobi, Kenya; <sup>7</sup>Novartis Farma S.P.A, Rome, Italy; <sup>8</sup>San Gallicano Dermatological Institute, Rome, Italy; <sup>9</sup>Novartis Pharma AG, Basel, Switzerland

**Problem statement:** Rural African communities have limited access to health facilities for malaria diagnosis and treatment because of poor communication, lack of knowledge, as well as distance.

**Objective:** To assess the feasibility and impact of deploying artemether-lumefantrine (AL) at the community level with the introduction of rapid diagnostic test (RDT)

**Design:** Two homogenous districts were selected. A two-year interventional and observational study with times series comparison with random assignment of the intervention to one district and the other serving as control.

**Setting:** This community-based malaria control intervention study was conducted in two districts with similar malaria eco-epidemiological features in Tigray region, Ethiopia in 2005–07.

**Study population:** The average population of the intervention and control districts was 89,377 and 118,693, respectively. We consider the population lives below 2,000 masl which was 81% and 98.5%, in respective districts. The basic characteristics of the populations in the two districts were similar.

**Intervention:** AL was dispensed at health facilities in both districts after clinical assessment and/or confirmed. In the intervention district, community health workers (CHWs) dispensed AL based on clinical diagnosis of malaria during year 1. In year 2, 50% of CHWs in the intervention district were equipped with RDTs to dispense AL only to RDT-positive individuals.

**Policy:** The national guideline does not include any intervention on community-based diagnosis and treatment of malaria. Health workers are too overworked, with vast catchment areas and multiple responsibilities. Therefore suspending the CHWs would only be a reasonable compromise, not a substitute for the community-based health service.

Outcome measure(s): Malaria transmission rate, malaria morbidity and admission, malaria specific mortality rate (verbal autopsy), and health care resource utilization

Results: In the intervention district, about 60% of all patients treated for malaria were managed by CHWs, close to home. The prevalence survey revealed that the crude parasite rate was less by threefold (7.4%) in the intervention district vs. 20.8% in the control district despite the fact it was higher in the control before the intervention. Over the two-year study, multivariate modelling indicated no significant difference in risk of all-cause mortality between the intervention and control districts (adjusted incidence rate ratio [aIRR] 1.03, 95% CI 0.87–1.21,  $p=0.751$ ), but risk of malaria-specific mortality was lower in the intervention district (aIRR 0.60, 95% CI 0.40–0.90,  $p=0.013$ ). Use of RDTs by CHWs in year 2 led to exclusion of non-*P. falciparum* in 90% of suspected cases.

Conclusions: AL deployment with RDT at a community level lowered malaria burden and is feasible if CHWs are committed, appropriately trained, well equipped, and supported through frequent supervision.

Funding source(s): Novartis Farma S.P.A., The Italian Ministry of Labour, Health and Social Policies and World Health Organization

318

#### Access

Keywords: access to medicine, consumers, drug utilization, education, self-medication

### Household Drug-Storing Practices Among Community Residents in Paknaan, Mandaue City, Philippines, 2010

Cheryl Galeos David<sup>1</sup>, Ma. Fidelis Espiritu Quiza<sup>1,2</sup>

<sup>1</sup>Cebu (Velez) General Hospital, Philippines; <sup>2</sup>Cebu Institute of Medicine, Philippines

Problem statement: The unrestricted access of home-stocked medicines promotes the practice of self-medication, which is strongly associated with irrational drug use.

Objective: To determine the prevalence and describe the nature and determinants of the practice of household drug-storing

Design: Analytical cross-sectional study

Setting: Community-based study in Barangay Paknaan, Mandaue City, a local community adopted by the Cebu (Velez) General Hospital for its community-outreach health services

Study population: 1,209 adult respondents from households representing 80% of the total household units in the community from April to July 2010. Stratified proportionate sampling by zone of residence followed by simple random sampling was done. The median age of the respondents was 34 years (IQR: 26–44). Most respondents were females, unemployed, and had some high school or had completed high school.

Method: Face-to-face interviews were conducted using a structured data collection form with ocular inspection of the stored drugs and storage areas within the houses. Survey results were validated by a focus group discussion with one participant representing each zone of the barangay. The study was approved by the Ethics Review Board of the Cebu Institute of Medicine, and informed consents were obtained from each respondent

Outcome measure(s): Prevalence of household storage of drugs

Results: The majority (81%) of the households stored drugs. This included expired drugs and drugs without expiry dates or identifying labels. Commonly stored drugs were symptomatic medications, vitamins, and antibiotics. Drug acquisitions were over-the-counter purchases, left-over medications from previous prescriptions, donations from various agencies during free clinics and inter-household drug exchange. Most drugs were kept inside areas associated with eating such as cabinets in dining rooms and in the kitchens. Disposal of stored drugs was commonly done by throwing them in the garbage in their original form (86.5%). Reasons for storing drugs other than for maintenance for a chronic illness included convenience and immediate availability for treatment of common symptoms. Storing drugs in the homes was associated with chronic illness in the family ( $p<0.001$ ) and vocational and increasing educational attainment of the respondent ( $p=0.05$ ).

Conclusion: Prevalence of household drug storage was 81%. Symptomatic drugs were most commonly stored. Kitchen and the dining room cabinets were the more common storage places. A family member with chronic illness and increasing level of educational attainment were significantly associated with home storage of medications. Storage of expired medications for future use, unlabeled medications, and medications without expiry dates were also prevalent. Disposal of drugs was most commonly done by throwing them into garbage bins in their original form. This study provides support for improved patient education regarding proper drug use, storage, and disposal.

Funding source(s): None

319

#### Drug Resistance

Keywords: self medication, antimicrobials, Theory of Planned Behaviour

### Identifying Key Beliefs of Self Medication with Antibiotics in Yogyakarta City, Indonesia

Aris Widayati<sup>1,3,4</sup>, Sri Suryawati<sup>2</sup>, Charlotte de Crespigny<sup>3</sup>, Janet E. Hiller<sup>4,5</sup>

<sup>1</sup>Faculty of Pharmacy Sanata Dharma University Yogyakarta, Indonesia; <sup>2</sup>Faculty of Medicine Gadjah Mada University Yogyakarta, Indonesia; <sup>3</sup>School of Nursing, University of Adelaide Australia; <sup>4</sup>Discipline of Public Health, University of Adelaide Australia; <sup>5</sup>Faculty of Health Sciences, Australian Catholic University Australia

**Problem statement:** Although antibiotics in Indonesia are categorized as prescription-only medicine, self medication with antibiotics (SMA) is common. Beliefs about SMA that might influence SMA behaviour remain unexplored, however.

**Objectives:** To identify key beliefs of SMA based on theory of planned behaviour (TPB), including behavioural, normative, and control beliefs and associations between these beliefs and intention of SMA

**Design:** This descriptive study used an interview guideline informed by TPB and a pre-tested questionnaire developed from findings of the preceding interviews.

**Setting:** This study was a population-based study.

**Study population:** Population included adults (>18 years old). Snowball and cluster random sampling were applied to select 25 participants for semi-structured interview and 640 participants for self-administered questionnaire, respectively.

**Outcome measure(s):** Key beliefs of SMA and their associations with intention of SMA

**Results:** In total, 25 face to face interviews have been conducted. Participants reported that advantages of using non-prescribed antibiotics were to save money and time—as a result of avoiding a medical consultation—and to avoid taking too many types of medicines commonly prescribed by doctors. Fear for adverse effects, poor outcome, and antimicrobial resistance were declared as disadvantages. Availability of antibiotics to be purchased without prescription in pharmacies, drug stores, and shops/kiosks, and previous successful medication use made this behaviour easier. Participants tended to seek advice from medical practitioners for their children's health concerns, however. Family members and friends, especially those with a health education background, were more likely to approve of this behavior. Results of self-administered questionnaire (n = 283 participants who were familiar with antibiotics) showed that, as expected, a range of beliefs of SMA significantly correlates with intention to do SMA. Most participants were aware of the risks of SMA, had no pressure from their social networks to practice SMA, and were reluctant to obtain non-prescribed antibiotics from shops/kiosks. Participants would more likely to have intention to do SMA when they have previous successful experience in using antibiotics and they can purchase antibiotics without prescription from pharmacies with odds ratios of 0.27 (0.06–0.95) and 0.15 (0.03–0.81), respectively.

**Conclusions:** Variety of people's beliefs in using non-prescribed antibiotics revealed by interviews was useful to generate a valid and reliable tool for investigating key beliefs of such use through population-based survey based on TPB. Findings suggest that strengthening people's awareness regarding the harmfulness of SMA may be effective to discourage intention to do so. Since shops/kiosks are not popular as sources of non-prescribed antibiotics, efforts for improving SMA should be focused on pharmacies and drug stores. Underlying factors of such behaviour should be further investigated.

**Funding source(s):** The Indonesia Ministry of Education

## 320

### Economics, Financing, and Insurance Systems

*Keywords:* prescribing pattern, drug formulary, compliance, rural health insurance program, Iran

#### Prescribing Pattern of Physicians in Rural Health Insurance Program in Primary Health Care Facilities in Iran

**Seyed Ali Reza Hosseini, Arash Tehrani Banihashemi, Shadan Darbooy**

Ministry of Health and Medical Education, Iran, Islamic Republic of

**Problem statement:** Rational use of medicines has been one of the policy goals in rural health insurance program in Iran. To promote rational prescribing practice, a new drug list had been introduced and implemented in the program. At the same time, it became mandatory for the physicians to prescribe not more than 3 items in a prescription. Therefore, it was important to check for physician compliance to the new regulation and monitor the suitability of the new drug list in their everyday practice.

**Objectives:** To monitor prescribing patterns in the rural health insurance program by measuring drug use indicators and to get an oversight of compliance to the prescribing regulation introduced

**Design:** This is a cross-sectional study during the period 2005–06 in which prescriptions (Rx) were retrospectively collected and analyzed using a computer program developed for this purpose.

**Setting and study population:** 5,100 Rx from randomly selected primary health care facilities in 18 provinces were sampled. Data were manually punched into the computer program and analyzed, and the results were reported.

**Outcome measure(s):** Average number of drugs per Rx, percentage Rx with >4 drugs, percentage Rx with an injection, percentage Rx containing antibiotics, percentage Rx containing corticosteroids, percentage drugs prescribed from drug list, the most frequently prescribed and expensive medicines in Rx, and average cost of Rx

**Results:** The average number of drugs per Rx: 2.87; Rx with more than 4 drugs: 6.36%; Rx with injection: 38.6%; Rx with antibiotics: 47.6%; Rx containing corticosteroids: 21.5%; and drugs prescribed from the drug list: 96.6%. The most frequently prescribed medicines were: amoxicillin capsule, acetaminophen codeine tablet, and dexamethasone injection, in that order. The top 10 list of the highest frequency prescribed drugs accounted for 35% of the pharmaceutical expenditure, and the average cost of Rx was 11,875 Rials, one third of Rx cost at national level.

**Conclusions:** Prescribing patterns in rural health insurance program demonstrate that despite mandatory regulations and achievements, there is still room for promoting rational prescribing practice considering 35% consumption of the

budget for 10 pharmaceutical items. In addition, although compliance to the new drug list accounts for more than 96% suggesting its suitability, more managerial interventions of an educational nature, including in service training for family physicians in the program, specifically on antibiotics and corticosteroids, are recommended to enhance rational use of medicines.

Funding source(s): Ministry of Health and Medical Education, Iran

### 323

#### **Policy, Regulation, and Governance**

*Keywords:* drug list, rural health insurance program, Iran

#### **Development and Implementation of an Evidence-Based Drug List for Rural Health Insurance Program in Iran**

---

**Seyed Ali Reza Hosseini, Arash Tehrani Banihashemi, Shadan Darbooy**

Ministry of Health and Medical Education, Iran, Islamic Republic of

**Problem statement:** A rural health insurance program launched in 2004 in Iran in which the Medical Services Insurance Organization (MSIO) acted as “purchaser” and the Ministry of Health and Medical Education (MOHME) as “provider” of the health services in target population. An original drug list (DL) of 390 items was introduced by MSIO, extracted from a data base of prescriptions, representing the most frequently prescribed medicines by general physicians (GPs) in the whole country. In this scenario, while MSIO were arguing equality, MOHME considered rationality of DL and the rational use of medicines. We sought to provide evidence for this argument and examine justifications described.

**Objectives:** To evaluate the original 390 items DL and develop an evidence-based, need-oriented DL and to implement it into the program

**Design:** This was a qualitative, questionnaire-based, action research with contribution of different professional stakeholders.

**Setting and study population:** PHCs involved in the program, GPs working in the field, specialists with high reputation from medical universities and other stakeholders

**Interventions:** (1) A questionnaire based on the original DL to categorize the medicines in the list, sent to 60 GPs from randomly selected PHCs, responses collected and analyzed; (2) a set of questionnaires based on 110 disease conditions, defined as the responsibilities of GPs, sent to specialists with high reputation asking to write a prescription for a given condition, responses collected, entered into a computer data base and analyzed; and (3) a panel of stakeholders who reviewed and discussed different reports and made expert decisions on the final outcome, the new DL

**Outcome measure(s):** (1) Drug categories in original DL, by definition: A (necessary), B (no difference) and C (unnecessary); (2) a disease-based DL; and (3) the final DL

**Results:** For the original DL results were A (241), B (78), C (71). The disease-based DL contained 363 items matched > 85% to (A+B) in original DL, and the final DL, which was constructed by merging the two DLs, contained 270 items including core and complementary lists and was approved by the expert panel. The new DL was presented in three seminars at the national level to the stakeholders and decision makers from MSIO and MOHME and was officially released as the new DL of the program.

**Conclusions:** We designed and provided evidence in our setting and developed an evidence-based drug list to achieve rational utilization of resources. Compliance to and regular monitoring and revision of the new DL will guarantee its success.

Funding source(s): MOHME

### 324

#### **Access**

*Keywords:* appropriate use, dispensing, essential medicines, health facilities, indicators

#### **Effects of an Intervention on the Use of Medicines in Herat Province of Afghanistan**

---

**Jawahar Singh Bapna<sup>1</sup>, Inge-Lise Aaen<sup>2</sup>, Saeed Hamed<sup>2</sup>**

<sup>1</sup>Jaipur College of Pharmacy, Jaipur, India; <sup>2</sup>Danish Afghan Committee, Herat, Afghanistan

**Problem statement:** No systematic study on quality of prescribing is available in Afghanistan.

**Objective:** To study the effect of educational intervention on prescribing in selected health facilities in Herat Province, Afghanistan

**Design:** It was a before-and-after face-to-face intervention with no control group. Baseline data on use of medicines, quality of prescribing, dispensing, and stock-outs were collected using WHO/INRUD indicators and the change that occurred after 1 year assessed.

**Setting:** The study was conducted at Herat Province of Afghanistan at public sector health facilities supported by a nongovernmental organization, the Danish Afghan Committee.

**Study population:** All the prescribers, a total of 60 working at 1 district, 2 community health centers, and 5 basic health centers of Herat Province were included in the study.

**Intervention(s):** Participants were trained at two 4-day participatory workshops at the beginning and after 3 months. In the first, the concept of essential drugs and rational drug use was presented to them. In the second, training was given on problem-based learning using Guide to Good Prescribing.

**Outcome measure(s):** The changes in prescribing practices, quality of medical and dispensing services, and stock-outs were measured after 1 year.

**Results:** The pooled data of 30 prescriptions or observations each at 8 facilities were analyzed before and after intervention. Drug use indicators showed a trend toward improvement; however, it was not statistically significant. The average number of drugs per prescription changed from  $2.43 \pm 0.051$  to  $2.59 \pm 0.052$ , generic drugs  $91.17 \pm 0.284$  to  $95 \pm 0.218$ , combinations  $37.9 \pm 0.20$  to  $30.8 \pm 0.19$ , injections  $4.8 \pm 0.009$  to  $6.4 \pm 0.10$ , antibiotics  $19.6 \pm 0.017$  to  $22.2 \pm 0.017$ , drugs from the essential medicines list  $87.5 \pm 0.014$  to  $84.9 \pm 0.014$ , and drugs dispensed  $81.5 \pm 0.016$  to  $82 \pm 0.015$ . Prescribing indicator showed that consultation time per patient increased significantly from  $150.97 \pm 2.23$  to  $174.35 \pm 3.54$  seconds ( $p < 0.05$ ). Dispensing time reduced from  $41.90 \pm 0.092$  to  $37.33 \pm$  seconds. The average number of stock-out days for key drugs decreased from 28.65 to 23.22% of days per year.

**Conclusions:** The study shows that the educational intervention can improve the prescribing practices. The drug use indicator showed a trend toward improvement. Consultation time increased significantly, which is helpful in rational use of drugs. The decrease in stock-outs also helps in promotion of rational prescribing. Training and motivation of prescribers is needed on regular basis to achieve these objectives. This study supports the view that a flash effect of education programs for rational prescription and use exists: immediately after training prescription patterns improve, but prescribers tend to return to old habits after a while, so long-term effects need more sophisticated interventions than just education. Educating patients along with the prescribers may be useful since the patients can be 50% of the problem and their requests are often driving the prescription patterns.

**Funding source(s):** Danish Afghan Committee, Herat, Afghanistan

### 326

#### Policy, Regulation, and Governance

*Keywords:* access to medicines, affordability, availability, cost containment, Private sector

#### **Assessment of the Impact of Market Regulation in Mali on the Price of Essential Medicines Provided through the Private Sector**

**Diadie Maiga, Bryn Williams-Jones**

University of Montreal, Canada

**Problem Statement:** In Mali, public access to generic essential medicines and other prescription drugs occurs both through publicly subsidised institutions ("the public sector") and the private sector. Partly as a means of responding to public concerns about skyrocketing costs of prescription drugs and the negative impact on access to essential medicines, in 2003, the government passed a decree regulating retail prices of essential medicines in public institutions. This measure was partially undermined by the private sector, which purchased from the public wholesaler large quantities of drugs at competitive prices, creating a shortage in the public sector, and then resold the drugs to consumers at higher prices than were permitted in the public sector. Consequently, in 2006, the government sought to further constrain the private sector and fixed maximum prices for 107 generic essential medicines.

**Objective:** The current study assessed the impact of this intervention on the evolution of market prices (wholesale and retail), and the subsequent availability and public access to essential medicines in Mali.

**Methods:** A cross-sectional descriptive survey was conducted in February and May 2006, and January 2009, with 16 wholesalers and 30 private drugstores in Bamako, Mali. Our sample of drugs included 49 of the 107 highest selling generic essential medicines. The variables collected were the availability of the 49 medicines and their wholesale and retail prices.

**Results:** The overall availability of essential medicines at private wholesalers ( $p=1$ ) and pharmacies ( $p=0.53$ ) was identical before and after the enforcement of the 2006 decree fixing maximum drug prices. In private pharmacies, availability of the 49 drugs was estimated to be 66.1% in February 2006, dropping to 58.8% in May 2006, but returning to pre-enforcement levels (66.6%) by January 2009. Median wholesale prices in 2009 were 25.6% less than those fixed by the decree. In private pharmacies, retail prices were only 3% more expensive than the recommended prices, compared with being 25.5% more expensive prior to enforcement of the decree. Before enforcement of the decree, the prices of only six out of 49 drugs (12.2%) accorded with the prices set by the decree; for all the other products the prices were more expensive. In May 2006, however, 85.4% of the drugs respected the maximum price limits. By January 2009, 63.8% of the drugs met the maximum prices.

**Conclusions:** The study shows that prices of essential medicines in Mali have evolved favorably towards the prices recommended by the government decree. Further, the study contributes to mounting evidence that market regulation by governments does not necessarily negatively affect drug availability; in fact, given the reduction in prices, the study shows that Malians arguably have better access to more affordable essential medicines.

**Funding Source:** This study was funded by the Ministry of Health of Mali.

### 330

#### Chronic Care

*Keywords:* Education, clinical guidelines, good governance, other

#### **Editor Training Program**

**Mary Hemming, Carol Norquay**

Therapeutic Guidelines Ltd, Australia

**Problem statement:** Locally produced, independent, high-quality therapeutic information, such as drug bulletins and treatment guidelines, is an essential tool for activities to improve the use of medicines. The production of such information needs to be undertaken by health professionals with appropriate editorial training. Such training, however, is not usually available in developing countries. Therapeutic Guidelines Limited (TGL) is fortunate in that it is financially secure; this has allowed TGL to make a commitment to allocate some of its funds each year to share its expertise in this area and provide training for editors from developing countries.

**Objective:** To provide customised editorial training for health professionals who are currently working as editors in developing countries

**Design:** An editor from a developing country is selected each year to spend two to four weeks at TGL learning about the development of guidelines and associated activities.

**Setting:** TGL is a not-for-profit organisation that writes and publishes therapeutic guidelines. The guidelines provide independent and evidence-based recommendations for patient management for community practitioners. They are based on the latest international literature, interpreted by some of Australia's most eminent and respected experts, with each statement having been examined, subjected to challenge and discussed over a series of day-long meetings. TGL is totally independent. All revenue is derived from sales, and no funding is received from either government or industry. Its strict policy on conflict of interest protects its intellectual independence. TGL employs 20 people, including 8 medical editors, a medical librarian, a senior medical advisor, IT officers, and an electronic publishing staff. The TGL editors have extensive experience in medical writing and editing both for hard copy and electronic publications.

**Intervention:** The editors from developing countries already have some editorial experience so the training program is tailored to suit the specific needs of each visiting editor and to focus on the gaps in their skills. TGL staff members make themselves available for one-on-one personal tuition and supervision.

**Outcome measure(s):** At the conclusion of each training program, the visiting editor is asked to provide TGL with an assessment of the usefulness and value of the training program. This evaluation has taken the form of informal communications immediately after program completion and follow-up e-mails in subsequent months. More formal measures, such as questionnaires to evaluate training, are being developed.

**Results:** Areas that the visiting editors have highlighted as being particularly useful are computer software training, design and layout of text, and marketing techniques. Attending interviews with users of therapeutic guidelines gives the editors an insight into the value of seeking feedback to improve the usability of guidelines. Although the aim of the program is to provide training for visiting editors, TGL staff also benefit by gaining an increased understanding of health systems in countries as diverse as India, Cuba, and Tonga.

**Conclusion:** The visiting editors have all left TGL with an enthusiasm to make use of their new knowledge in their own countries. It is hoped that the training will support the production of clear, concise information to help to improve use of medicines and health outcomes in those countries.

**Funding source(s):** TGL is totally independent. All revenue is derived from sales, and no funding is received from either government or industry. With regard to funding the TGL Editor Training Program, in 2010 and 2011, TGL provided 100% of funding; in 2008 and 2009, TGL provided 60% funding and the International Society of Drug Bulletins provided 40% funding.

**334**

**Access**

*Keywords:* understanding of prescriptions, prescriptions, adherence, compliance, noncompliance

**Factors Affecting Patients' Incomplete Understanding of Prescriptions**

**Gerard Raimon Makinano Saranza, Derick Erl Gonzales Sumalapao, Isidro Sia**

University of the Philippines Manila, Philippines

**Problem statement:** Patients' understanding of prescriptions is one of the key elements to a successful treatment. In the Philippines, patients do not have the benefit of having pharmacists explaining the prescription when they purchase their medicines. Inability to understand and follow prescriptions may, therefore, contribute to medication noncompliance, which leads to unwanted disease progression, complications, and even premature death.

**Objectives:** To assess the understanding of Filipino patients of prescriptions given by their doctors and to identify the factors that significantly affect their understanding

**Methods:** In total, 392 individuals, using systematic random sampling, were purposively sampled and interviewed from pharmacies around a government hospital outpatient department (OPD), a private hospital OPD, private clinics, and local health centers in Manila, Philippines. The patients' knowledge about the proper intake of the prescribed drugs was assessed and the factors that were deemed to affect their understanding were then identified. Crude odds ratios (ORs) and 95% confidence intervals (CIs) were calculated according to the various study factors included in the study to measure the association between each study variable and incomplete understanding of prescriptions. A multivariate logistic regression model was constructed applying a stepwise procedure to enter variables in the model.

**Results:** Among the 392 participants, 219 (55.9%) patients had an incomplete understanding of prescriptions, 176 (44.9%) were not able to identify the correct dose of the prescribed drug, followed by 103 (26.3%) who were not able to identify the name of the drug. Multivariate logistic regression analysis identified only three independent variables to be statistically significant predisposing factors to incomplete understanding of prescriptions: non-legible prescriptions (OR=4.598, 95% CI 2.671–7.913), prescriptions with an incomplete set of written instructions (OR=2.108, 95% CI

1.234–3.601), and patient having had no previous use of the prescribed drug or a similar drug (OR=2.126, 95% CI 1.361–3.320).

Conclusions: The results of this study suggest that physicians play a major role in promoting complete understanding of prescriptions. Non-legible prescriptions and prescriptions with an incomplete set of written instructions were found to significantly affect patients' understanding of prescriptions. Physicians should also be more careful in instructing patients who will take the prescribed medications for the first time. This information may be used to enhance better understanding of prescriptions among patients and thereby prevent noncompliance and treatment failure.

Funding source(s): Self-funded

### 337

#### Access

*Keywords:* appropriate use, drug utilization, primary health care,

#### **Progress in Standard Indicators of Medicines Use Over 20 Years**

**Kathleen Anne Holloway<sup>1</sup>, Verica Ivanovska<sup>2</sup>, Dennis Ross-Degnan<sup>3</sup>**

<sup>1</sup>World Health Organization, Regional Office S.E.Asia, India; <sup>2</sup>World Health Organization, Geneva; <sup>3</sup>Harvard Medical School, Harvard Pilgrim Health Care Institute, Boston, USA

Problem statement: Irrational use of medicines is a global problem, especially in low- and middle-income countries (LMIC) where there is no routine surveillance of medicines use and scant evidence about effective interventions

Objectives: To undertake a systematic review of studies from 1990 to 2009 on patterns of medicines use and intervention effects in LMIC

Design and methods: From published and unpublished studies, we systematically extracted data on commonly used indicators of medicine use, plus study setting, methodology, and interventions. To estimate trends over time, we calculated the average of each indicator (limited to baseline data for interventions) by study year, region, facility ownership, and prescriber type. To estimate intervention impacts, we calculated summary effect sizes for studies meeting accepted design criteria (RCT, pre-post with control, time series). We examined the indicator showing the greatest effects size (GES) and the median effect size (MES) over all indicators.

Setting: Primary care settings in LMIC

Study population: Providers and patients

Intervention(s): Different types of interventions commonly implemented to improve use of medicines

Outcome measure(s): Standard indicators of medicine use developed by the International Network for the Rational Use of Drugs (INRUD) and WHO

Results: Data were extracted for studies conducted in 104 countries that reported data on 1,033 study groups; 70% reported data from the public sector and 30% from the private (mostly) for-profit sector. In all, 405 studies (39%) reported on interventions, but only 110 (27%) used an adequate study design. From 1992 to 2009, the percentage of patients treated in compliance with guidelines was 40–50% in the public sector, but <30% in the private-for-profit sector. Other indicators also showed suboptimal use: average number of medicines per patient increased from 2.1 to 2.8 and the percentage of patients receiving antibiotics from 45 to 54%; however, the percentage of medicines prescribed from an essential medicines list increased from 70 to 87%. Results were similar in all regions. Multi-component interventions tended to have larger effects than single-component ones. The median GES was 38% for multi-component interventions that combined provider and consumer education with supervision, but only 16% for those relying on provider education alone and 4% for printed materials alone. The median MES across all indicators was lower (27%, 7%, and 1%, respectively) for these three types of interventions.

Conclusions: The WHO database can be used to monitor global progress on medicines use. Trends over the past 20 years indicate that irrational use remains a serious global problem. Although some interventions demonstrate positive effects, there are few observable improvements in practice.

Funding source(s): WHO

### 338

#### Child Health

*Keywords:* appropriate use, indicators, primary health care, childhood illness

#### **Medicine Use in Children Under 5: 20 Years of Practice Patterns and Intervention Effects**

**Kathleen Anne Holloway<sup>1</sup>, Verica Ivanovska<sup>2</sup>, Dennis Ross-Degnan<sup>3</sup>**

<sup>1</sup>World Health Organization, Regional Office S.E.Asia, India; <sup>2</sup>World Health Organization, Geneva; <sup>3</sup>Harvard Medical School, Harvard Pilgrim Health Care Institute, Boston, USA

Problem statement: Many low- and middle-income countries (LMIC) have tried to improve treatment of child acute illness, but scant evidence exists about progress.

Objectives: To undertake a systematic review of studies from 1990 to 2009 on medicine use in children under 5 years old in LMIC

Design and methods: From published and unpublished studies, we systematically extracted quantitative data on medicine use, details on study setting, methodology, and interventions. We limited this review to studies on children under 5. To estimate trends over time, we calculated the average of each indicator (limited to baseline data for

interventions) by study year, region, facility ownership, and prescriber type. To estimate intervention impacts, we calculated summary effect sizes for studies meeting accepted design criteria (RCT, pre-post with control, time series). We examined the indicator with the greatest effect size (GES) and the median effect size (MES) over all indicators.

Setting: Pediatric primary care settings in LMIC

Study population: Providers and children under 5

Intervention(s): Different types of interventions commonly implemented to improve use of medicines

Outcome measure(s): Standard indicators of medicine use commonly reported in IMCI and disease control programs

Results: Data were extracted for studies conducted in 78 countries reporting data on 394 distinct study groups; 75% reported data from the public sector and 25% from the private-for-profit sector. In all, 226 studies (57%) reported interventions, but only 45 (20%) used adequate study design. From 1992 to 2009, we observed no improvements in percentage of pneumonia cases treated appropriately with antibiotics (varying over time from 49 to 67%), percentage of non-pneumonia cases receiving inappropriate antibiotics (45–59%), percentage of diarrhea cases treated with ORS (41–59%), or percentage of diarrhea cases treated inappropriately with antibiotics (32–54%). Use of antidiarrheals decreased from >40% of cases pre-1992 to 14% in 2001–03. Practices in all regions were similar, and public sector practices tended to be better than private sector. Multi-component interventions tended to have larger effects than single-component ones. The median GES indicated a 30% improvement in practice for studies examining community case management interventions and 15% for interventions using provider education alone, two common approaches; the median MES across all indicators had similar values (28% and 9%, respectively) for these two types of interventions.

Conclusions: Treatment of child illness remains suboptimal in LMIC, with only use of antidiarrheals showing substantial improvement. Although many well-designed interventions reported positive effects, there has been no observable improvement in practice.

Funding source(s): WHO

### 339

#### Policy, Regulation, and Governance

Keywords: Drug utilization, pharmaceutical policy

#### **Do Countries with Pharmaceutical Policies Have Better Medicines Use Than Those without?**

**Kathleen Anne Holloway**

World Health Organization, Regional Office S.E.Asia, India

Problem statement: Many countries do not implement basic policies to encourage better medicines use possibly due to lack of evidence of their effectiveness.

Objectives: To determine if medicine use is better in those countries with certain pharmaceutical policies compared to those without.

Design: Quantitative public sector medicine use data by country for 2002–8 was extracted from the WHO medicine use database containing data on medicine use extracted from published & unpublished articles & reports. Policy data was extracted from the WHO policy database containing data from 2 surveys sent to Ministries of Health (MOH) in 2003 & 2007. The extracted data were merged to form one database containing policy & medicine use data. Where policy differed in 2003 & 2007, the date of the medicine use survey(s) contributing to the data was determined & the policy chosen that was within one year of the policy survey date, otherwise the policy was marked as unknown. A comparison was undertaken for 12 different medicine use indicators, plus a composite indicator, between countries with & without policies. A difference in medicine use with & without a policy was judged present if 80% of the indicators showed either better or worse use in one group as compared to the other & if the composite indicator showed a difference of more than 10%.

Setting: Public sector in developing & transitional countries

Study population: Providers & consumers in primary care

Policies: All national policies hypothesized to impact on medicines use & for which more than 20 countries responded whether they had such a policy or not.

Outcome Measure(s): Standard indicators of the International Network for the Rational Use of Drugs (INRUD) & the Integrated Management of Childhood Illness (IMCI). A composite indicator was created by ranking all countries for each medicine use indicator & then assigning a number between 1 (worst) & 10 (best use) according to the percentile within which the country lay. Then the median across all indicators measured in that country was taken to give a score out of 10 for medicine use performance in each country.

Results: Data on medicine use & policy was assembled from 59 countries. Policies strongly associated with better use included Drug & Therapeutic Committees, free medicines at the point of provision, training of health professionals on essential medicines & guidelines, a national strategy to contain antimicrobial resistance & a dedicated MOH unit to promote rational use of medicines. Policies strongly associated with worse use included using revenue from medicine sales to supplement salaries & surprisingly, continuing medical education - which needs further investigation.

Conclusions: The WHO databases on medicine use & policy can be used to monitor global progress in terms of medicines use & policy implementation. A suitable national policy framework is extremely important to promote rational use of medicines.

Funding Source(s): WHO

340

**Drug Resistance***Keywords:* Antimicrobials, drug utilization, pharmacoepidemiology, surveillance**Surveillance of Antimicrobial Use in Resource-Constrained Community Settings****Kathleen Anne Holloway<sup>1</sup>, Elisabeth Mathai<sup>2</sup>, Andy Gray<sup>3</sup>**<sup>1</sup>World Health Organization, Regional Office S.E.Asia, India; <sup>2</sup>World Health Organization, Geneva; <sup>3</sup>Nelson R Mandela School of Medicine, University Kwa Zulu Natal, S Africa

**Problem statement:** In resource-constrained settings, antibacterial medicines (ABM) are frequently inappropriately used, contributing to increased antimicrobial resistance. There are few sources of good data on ABM use in such settings, nor are there standard methods for conducting such surveillance to inform public health decision making.

**Objectives:** To assess the feasibility of surveillance of ABM use in the community in 3 resource-constrained settings in India and 2 in South Africa

**Design:** Time series data on monthly ABM use were collected over at least 12 months at each site. Each site sought to document 30 patient encounters where ABMs were provided from 7–30 facilities per month.

**Setting:** Public and private sector primary care facilities in 3 sites, public facilities in one site, and private pharmacies in another site

**Study population:** ABM use data were collected monthly at the 3 Indian sites by interviewing patients exiting from facilities and from the 2 South African sites by extracting data from patient records in the facilities. In addition, 2 Indian sites collected procurement and sales data from public facility records and by interviewing private retailers.

**Intervention(s):** None

**Outcome measure(s):** (1) Percentage patients receiving a specific ABM, (2) number of defined daily doses (DDD) of a specific ABM per 100 patients attending the facility per month, and (3) lessons on setting up surveillance

**Results:** There was extensive use of ABMs in all sites. Older agents such as co-trimoxazole were used more in public facilities and newer agents such as fluoroquinolones in private facilities. Although methodological differences limit comparability of data, use appeared to be higher in India as compared to South Africa for all facility types. It was easier and more reliable to measure ABM use as the percentage of patients receiving an ABM than to determine DDDs per 100 patients per month, although the latter gave more information about dosage and duration. Conducting patient exit interviews was more resource intensive than extracting data from patient records, but the latter was dependent on the completeness of records and could not capture over-the-counter sales. The 2 sites that collected sales and purchase data felt that it was not as reliable as collecting individual patient data. All sites complained that facilities, particularly in the private sector, became fatigued by the data collection process.

**Conclusions:** All 5 pilot sites provided useful data on ABM use but also raised a number of technical and logistical issues related to long-term surveillance in resource-constrained community settings. ABM use measured as the percentage of prescriptions containing a specific ABM is easier and more reliable to use in these settings than DDD methodology.

**Funding source(s):** WHO, USAID. Study reported on behalf of the Surveillance of Antimicrobial Use and Resistance in Resource-Constrained Settings Project Group.

341

**Drug Resistance***Keywords:* Antimicrobial resistance, surveillance**Surveillance of Antimicrobial Resistance in Resource-Constrained Community Settings****Kathleen Anne Holloway<sup>1</sup>, Elisabeth Mathai<sup>2</sup>, Andy Gray<sup>3</sup>**<sup>1</sup>World Health Organization, Regional Office S.E.Asia, India; <sup>2</sup>World Health Organization, Geneva; <sup>3</sup>Nelson R Mandela School of Medicine, University Kwa Zulu Natal, S Africa

**Problem statement:** Antimicrobial resistance (AMR) is increasing rapidly, but there is little good data on AMR in resource-constrained communities to inform public health decision making, nor are there standard methods for conducting such surveillance.

**Objectives:** To develop a community-based surveillance system and collect useful data on AMR in resource constrained settings in 3 Indian and 2 South African sites.

**Design:** Time series where monthly AMR data on target bacteria were collected over at least 12 months at each site. Each site sought to obtain 960 isolates per year.

**Setting:** Outpatient clinics in public, not-for-profit private, and/or for-profit private facilities

**Study population:** E. coli was target bacteria in 4 sites, it being isolated from the urine of pregnant women attending antenatal clinics and those suspected with urinary tract infections in 3 sites and from stool specimens in the other site. One site isolated S. pneumoniae and H. influenzae from the sputum of patients over 12 years with a productive cough. Resistance was determined by disc diffusion in the 4 sites isolating E. coli and by minimum inhibitory concentration (MIC) methods in the other site.

**Intervention(s):** None

Outcome measure(s): (1) percentage of *E. coli* isolates resistant to ampicillin, co-trimoxazole, nalidixic acid, ciprofloxacin, and cefotaxime; (2) percentage of *S. pneumoniae* and *H. influenzae* isolates resistant to co-trimoxazole, chloramphenicol, erythromycin, and ampicillin (*H. influenzae* only); and (3) lessons on setting up surveillance

Results: In South Africa, data were collected for 12 months in one site and 16 months in the other. In India, data were collected for 14 months in one site and 24 months in the other. Only 2 sites collected the required number of isolates. *E. coli* isolates were easier to obtain, and 2 sites developed methods to increase their yield; one site asked women without signs of urinary tract infection to deliberately contaminate their own urine specimens with perineal wipes and the other re-incubated urine specimens that showed no growth after 24 hours. Disc diffusion testing was more reliable and timely than MIC testing. Although methodological differences limit comparability of data, high AMR rates were seen in all sites. Highest rates were seen for those antibiotics historically in longer use. AMR did not vary between isolates from different types of facility within any site. In the 2 sites that distinguished commensal from pathogenic *E. coli*, resistance was higher in the pathogens for all antibiotics.

Conclusions: All 5 pilot sites provided useful data on AMR but also raised a number of technical and logistical issues related to long-term surveillance in resource-constrained community settings. *E. coli* is probably the best indicator bacterium and disc diffusion the easiest method to determine AMR in resource-constrained settings.

Funding source(s): WHO, USAID. Surveillance of Antimicrobial Use and Resistance in Resource-Constrained Settings Project Group

343

### **Economics, Financing, and Insurance Systems**

*Keywords:* access to medicines, appropriate use, cost-inefficiencies, ARI.

#### **Inefficiencies Due to Poor Access to and Irrational Use of Medicines to Treat Acute Respiratory Tract Infections in Children**

**Dele Olawale Abegunde, Kathleen Holloway**

World Health Organization, Switzerland

Background: The extent of the inefficiencies attributable to poor access to appropriate treatment and irrational use of medicines in the developing countries is not well known. Estimation of the level of inefficiencies will provide a strong basis for evaluating the impact of interventions to improve access and rational use of medicines.

Objective: To estimate the level of cost-inefficiency due to irrational use of medicines and poor access to appropriate treatment by comparing cost of medicines to treat acute respiratory infections (ARI) under business-as-usual and treatment according to recommended guidelines scenarios

Design: Applying Bayesian algebra on data obtained from data sources including WHO, and UNICEF, a probability tree is constructed to estimate the cost of medicines for the proportion of new cases that have access to formal care and which obtained treatment in 2010, under business-as-usual or counterfactual scenarios. The counterfactual scenario assumes that new cases were provided the appropriate medicines according to UNICEF/WHO recommended guidelines. Comparing these costs provides a rough indication of waste from inappropriate (ineffective) access to the appropriate medicines for treating ARI.

Setting: A cross-section of the under-5 population in 134, low-, lower middle-, upper middle-, and high-income countries, spanning 9 WHO subregions, at risk of acute respiratory tract infection in year 2010

Outcome measure(s): Acquisition cost of medicines consumed in treating ARI under the comparative scenarios in international procurement prices and dollars

Results: Cost of medicines to treat ARI given the business-as-usual scenario is aggregated to \$21 million, \$4 million of which is due to cost of medicines for the proportion of patient with access to the appropriate (recommended) care and \$17 million represents cost to those who had poor access. The estimated cost of the counterfactual (assuming full coverage to appropriate care) is \$16 million. When compared to the business-as-usual scenario, about \$6 million is wasted on inappropriate treatment. Estimated costs could be much higher if local (marked-up) country prices of medicines were available. Only 17.6% of the estimated cost of medicines is attributable to appropriate access to treatment. Over 80% of the cost of medicines is applied to suboptimal treatments. Total cost of medications giving current treatment scenario is 36% in excess of total cost of medicines that would be incurred if there was full access to appropriate treatment. Estimated cost of irrational use of medicines to treat ARI in the business-as-usual scenario represents 24% of the total cost of medicines if appropriate medicines were used.

Conclusions: Economic inefficiencies from irrational use of medicines to treat ARI could range from 36 to 76%. Costs could be more if health systems cost were fully considered.

Funding source(s): WHO

344

### **HIV/AIDS and TB**

*Keywords:* Key Words: child contact, tuberculosis screening, adherence, isoniazid, preventive chemotherapy

#### **Adherence to and Outcome of Isoniazid Preventive Chemotherapy in Household Children Contact with Adults Having Pulmonary Tuberculosis: A Prospective Facility-Based Study in Alexandria, Egypt**

**Aida Mohey Mohamed**

Alexandria Faculty of Medicine, Egypt

**Problem statement:** Current international guidelines recommend 6–9 months of isoniazid (INH) preventive chemotherapy to prevent the development of active tuberculosis in children exposed to a susceptible strain of M tuberculosis, but this treatment is dependent on good adherence, and retrospective studies have indicated that adherence to unsupervised INH preventive chemotherapy is poor.

**Objectives:** To describe the outcome of screening in children ages <5 years with household exposure to an adult pulmonary tuberculosis index case, to determine the prevalence and possible risk factors of infection among children contacts, and to determine the extent of adherence and outcome in children contacts to 6 months of unsupervised INH prophylaxis

**Methods:** A descriptive facility-based cross-sectional study was adopted from March 2009 to August 2010. Research settings were three of national TB control program chest dispensaries (primary care facilities) in Alexandria City, Egypt. During a 3-month period, facility-based tuberculosis treatment registers were used to prospectively identify all new adult (>15 years) pulmonary tuberculosis cases. All children <5 years old in household contact with index cases were identified and screened for tuberculosis. The child contacts were given unsupervised INH preventive chemotherapy once active tuberculosis was excluded. Adherence to and outcome of preventive chemotherapy were prospectively monitored. Preventive chemotherapy consisted of unsupervised INH monotherapy for 6 months with monthly collection of tablets from the clinic. Adherence was documented after completion of the 6-month preventive treatment period. Adherence will be considered reasonable if tablets were collected for more than 4 months, poor if collection occurred for 2–4 months, and very poor if monthly tablets are collected once or twice only (treatment period <2 months).

**Outcome measure(s):** (1) Prevalence of infection and disease and the possible risk factors, (2) the extent of adherence to and outcome in children contacts to 6 months of unsupervised INH prophylaxis, (3) factors behind poor adherence, and (4) new strategies that improve preventive prophylaxis adherence to be recommended

**Results:** In total, 197 adult tuberculosis index cases from 187 households were identified; 297 children <5 years old experienced household exposure, of whom 252 (84.9%) were fully evaluated. A tuberculin test was positive in 136 of 252 child contacts (54.0%), of which 130 were contacts of sputum-positive patients, while 6 were contacts of sputum-negative patients. The important risk factors for transmission of TB infection were younger age, boy gender, severe malnutrition, absence of BCG vaccination, contact with an adult who was sputum positive, mother as a source case, household overcrowding, and exposure to environmental tobacco smoke. Thirty-three children were diagnosed and treated for tuberculosis at the baseline screening, and 217 received preventive INH chemotherapy. Of the children who received preventive chemotherapy, only 16.6% completed  $\geq 4$  months of unsupervised INH monotherapy. During the subsequent follow-up period, 8 children developed tuberculosis (secondary attack rate for tuberculosis disease was 3.7%) of whom four received no preventive chemotherapy and four had very poor adherence.

**Conclusions:** The prevalence of tuberculosis infection and clinical disease among children in household contact with adult patients is high, and risk is significantly increased due to child contact, index patients, and environmental factors. Adherence to 6 months of unsupervised INH preventive chemotherapy was very poor. Strategies to improve adherence, such as using shorter duration multidrug regimens and/or supervision of preventive treatment require further evaluation, particularly in children who are at high risk to progress to disease following exposure.

**Funding source(s):** Self-funded

**345**

### **Policy, Regulation, and Governance**

*Keywords:* irrational use; drugs; rural; China

#### **The Irrational Use of Drugs in Rural China: Evidences from Two Provinces**

**Qiang Sun, Jia Yin, Genyong Zuo, Qingyue Meng**

Center for Health Management & Policy, Shandong University, Peoples Republic of China

**Problem statement:** Irrational use of drugs is a severe problem in China. The overuse, under use, or misuse of drugs has resulted in wastage of scarce resources, poor-quality treatment, and unnecessary costs of health care.

**Objectives:** To evaluate the basic situation of rational use of drugs in rural China by studying the behavior and perception of health care providers and rural residents

**Design:** It was a policy evaluation study. A cross-sectional study was designed to evaluate the use of drugs in rural China.

**Setting:** This study was conducted in Shandong and Ningxia provinces. In each province, the public hospitals and rural community were the basic study sites.

**Study population:** In each province, 3 counties, 9 towns, and 18 villages were randomly sampled according to the economic level, and in each villages, 30 household were randomly sampled. In total, 13,481 rural residents were investigated. 3,000 prescriptions were randomly sampled and collected at county hospitals, township health centers, and village clinics. 49 health care providers from county, town, and village health institutions were interviewed.

**Policies:** The Ministry of Health has issued policies and carried out health promotion activities for improving the rational use of drugs in hospitals and communities, but the effects of these policies and activities on use of drugs, especially in the rural area in China, are unclear.

**Outcome measure(s):** Primarily, the behavior and perception of health care providers and rural residents on use of drugs were measured.

Results: The results showed that 75.3% and 66.2% of prescriptions sampled from the village clinics have antibiotics in Shandong and Ningxia, respectively, and the antibiotic utilization rate in the village clinics is significantly higher than that in county hospitals and township health centers ( $\chi^2=123.659$ ,  $p<0.001$ ;  $\chi^2=12.735$ ,  $p=0.005$ ). Accustomed prescription practices of rural health providers and economic incentives from selling drugs are the main reasons for the high antibiotic utilization; meanwhile over 50% of surveyed populations don't know consequence of irrational use of antibiotics in the two provinces. Over 50% of prescriptions have the injections in the township health centers and village clinics, which is significantly higher than that in the county hospitals. Our study found that the rural patients actively require using the injections as they believe the effect of injections is better than oral drugs. 54.6% and 60% of the rural patients cannot comply with medical advice to take drugs in Shandong and Ningxia, respectively.

Conclusions: The policies and health promotions do not play certain roles in improving the rational use of medicines in rural China. Implementing trainings on the rational use of drugs and reforming the incentive mechanism for rural health providers are urgent and essential for improving the rational use of drugs in rural China.

Funding source(s): The study is part of a project entitled "Bringing Health Care to the Vulnerable: Developing Equitable and Sustainable Rural Health Insurance in China and Vietnam (RHINCAV)" funded by the European Commission (Specific Targeted Research Project).

346

### **Policy, Regulation, and Governance**

*Keywords:* Newspaper, public education, medicine use

#### **Newspaper Column for Consumer Education on Medicine Use—An Indian Columnist's Experience**

##### **Guru Prasad Mohanta**

Annamalai University, Department of Pharmacy, India

Problem statement: It has been reported that around 50% consumers do not take medicines appropriately. The studies have shown that the consumers in general know very little about the medicines. The regular print media usually focuses on diseases or health conditions and very little on the appropriate use of medicines. Whether the consumers use a formal health care channel or decide to self medicate, they are the ultimate decision makers. Public education has an important role to play to influence these decisions positively.

Objective: To educate the consumers on medicine use through a column in newspaper

Method: Because newspapers are read by average consumers (though literacy level is poor in India), I wrote consumer education materials in my column in one of the widely circulated and read English dailies, The New Indian Express's fortnightly supplement "The Health." A new column "Know Your Medicine" was initiated and covered around 76 articles in a period of around 4 years from 2004 to 2008. The column covered a wide range of themes ranging from consumers' rights on medicine use to storing medicine at home to clinical trials to the use of individual medicine. Articles were written in a simple, user-friendly style.

Results: The articles have been widely accepted and appreciated by various sections of the society. The appreciation and enquiry ranged from asking me to continue to seek information on various aspects of medicines and their use. Some of the inquiries were answered in the column itself. One of the district collectors and joint director of public health, government of India, called me for encouragement and information. The general readers used to provide feedback and sought more information through postcards, telephone calls, and e-mail. The readers' queries were answered through the column using a theme. The pensioner's association asked permission to reproduce one of the articles relating the use of medicines in elderly in their newsletter.

Conclusion: The newspaper itself (the editor) was apprehensive about the need of such column during the beginning, but the readership's survey proved the column's popularity, and the newspaper then expressed the desire to continue the column. Despite of problems associated with publishing a regular column, because of its popularity among the readers, with support from editor, I continued my effort for around four years attempting to empower the public and promote appropriate use of medicines through public education. The continuation of the column for four years itself is a success and signifies its usefulness among the public.

Funding source(s): No funding

353

### **Drug Resistance**

*Keywords:* Antimicrobial use, Resistance, Granger Causality, Vector Autoregression.

#### **Does Antimicrobial Use Granger-Cause Community-Based Antimicrobial Resistance?**

##### **Dele Olawale Abegunde, Kathleen Holloway, Elizabeth Mathai, Clive Ondari**

World Health Organization Geneva, Switzerland

Problem statement: The autoregressive integrated moving average (ARIMA) has become the popular Box-Jenkins time series model for studying AM use and AMR, but they are limited in elucidating some analytical assumptions underlying the dynamic relationship between AMR and AM use. Establishing the causal relationship between use and resistance improves the validity of time-series estimates. We explore the vector autoregressive (VAR) model as an alternative to overcome potential biases in estimation results from ARIMA models. These biases are in part, the consequences of endogeneity or reverse causality between AM use and AMR.

**Objectives:** To determine and test for the presence Granger-causality between AM use and AMR; to demonstrate the presence endogeneity in the temporal relationship between AM use and AMR; and to demonstrate the application of VAR to overcome the problem of endogeneity

**Design:** Longitudinal, non-comparison time-series

**Settings:** We used data from Vellore and Mumbai study centers of the Indian component of a WHO multi-centre study on community AMR and AM use from India and South Africa.

**Study population:** Study isolated commensal *E. coli* from urine samples of pregnant women attending antenatal clinics in Vellore (N=2,026) and from stool samples of individuals (N=1,860) in Mumbai. Monthly AM-use data were obtained from exit interviews from hospitals or PHC clinics (including not-for-profit and for-profit hospitals in the urban area and public sector PHC clinics and a not-for-profit hospital in the rural areas); private sector pharmacies; and private sector general medical practitioners' practices. 21,600 and 24,052 antibiotic-containing prescriptions were obtained from Vellore and Mumbai communities, respectively. Data were collected over a 24-month period.

**Outcome measure(s):** Monthly proportion of isolated *E. coli* resistant to co-trimoxazole, extended spectrum penicillin (ESP) and quinolones; monthly antibiotic use in defined daily doses (DDD) and proportion of patients prescribed antibiotics; presence of endogeneity; and positive Granger-causality

**Results:** Results of VAR suggests the presence of reverse causality between AMR and the two AM-use variables: monthly DDD per patient and monthly proportion of patient on specific antibiotics) or both. AM use did not Granger-cause AMR consistently across the three antibiotic classes and between the centers.

**Conclusions:** ARIMA time-series regression coefficients could be biased and inefficient if endogeneity is unaccounted for. Granger-causality tests are necessary to establish the dynamic temporal relationships between AM use and AMR and to eliminate risk of spurious time series-regression results. VAR models provide improved AM use/AMR time-series analysis tools. Results of this study have implications for the design of community AMR surveillance.

**Funding source(s):** WHO

**354**

#### **Drug Resistance**

*Keywords:* Antimicrobial resistance, Community surveillance

#### **Behavioural Model for Community-Based Antimicrobial Resistance, Vellore, India**

**Dele Olawale Abegunde<sup>1</sup>, Kathleen Holloway<sup>1</sup>, Elizabeth Mathai<sup>1</sup>, Andy Gray<sup>2</sup>, Clive Ondari<sup>1</sup>, Sujith Chandry<sup>3</sup>**

<sup>1</sup>World Health Organization, Switzerland; <sup>2</sup>Nelson Mandela School of Medicine; <sup>3</sup>Christian Medical College Hospital Vellore

**Problem statement:** Resistance to antimicrobial agents compounds the burden of diseases worldwide. Difficulties to estimating the impact of AMR on individuals and the community or the impact of AM use on resistance in resource-constrained settings is compounded by the paucity of community-based data. Robust surveillance data collection methodologies are lacking in such settings. More explorations and improved analytical methods are needed to fully understand trends and impact of AMR on cost of illness and to inform AMR surveillance.

**Objectives:** To determine the behavioural trends—seasonality (periodicity) and the temporal associations—between community-based AMR and AM use; to forecast the short-run pattern in AMR through the behaviour of AMR and the predictors (indicators) of AMR; and to compare the temporal correlation of the trends in DDD and the proportion of patients prescribed antibiotics, with community based AMR

**Design:** Longitudinal, non-comparison time-series

**Settings:** A multi-centre WHO study in India and South Africa. We use AMR surveillance data obtained from Vellore (urban area) and Kuppam (rural area) with a combined population of 500,000 within Vellore District, Tamil Nadu State of southern India.

**Study population:** Study isolated commensal *E. coli* (N=2,026) from pregnant women attending antenatal clinics. Monthly AM-use data were obtained from exit interviews from hospitals or PHC clinics (including not-for-profit and for-profit hospitals in the urban area and public sector PHC clinics and a not-for-profit hospital in the rural areas); private sector pharmacies; and private sector general medical practitioners' practices. Prescriptions containing antibiotics totaling 21,600 were obtained from 52,788 prescriptions. Data were collected in two time periods, from August 2003 to July 2004 and from January to December 2005.

**Outcome measure(s):** Monthly proportion of isolated *E. coli* resistant to co-trimoxazole, extended spectrum penicillin, and quinolones; monthly antibiotic use in DDD and proportion of patients prescribed antibiotics

**Results:** Both AMR and AM use demonstrated lagged trends and seasonality. AMR lags vary between 3 and 5 months of AM use. Impulse-response could last as much as 15 to 45 months. AM use demonstrated significant Granger-causality with AMR in addition to circularity. Both monthly DDD per patient and proportion of patients on specific antibiotics show similar effects on AMR, but DDD per patient appear to demonstrate more reactive effect on AMR.

**Conclusions:** Community AM use can predict AMR. Our results provide additional evidence for estimating the economic impact of AMR and could inform the design of community-based antimicrobial surveillance and interventions in low-resource settings.

**Funding source(s):** WHO

356

### **Economics, Financing, and Insurance Systems**

*Keywords:* medicine prices, public sector; bidding, procurement, pharmaceutical policy

#### **The Dilemma of Price Regulation and Pharmaceutical Centralized Bidding in China**

---

**Genyong Zuo, Qiang Sun**

Center for Health Management and Policy, Shandong University, Peoples Republic of China

**Problem statement:** The pharmaceutical centralized bidding of public hospitals, emerging in 1993, aimed at focusing on the scale of drug procurement and the selection of brands to achieve the purpose of lowering drug prices.

**Objectives:** To investigate the reasons for failure of drug price regulation in the pharmaceutical bidding policy by comparing the price difference between innovator and generic essential medicines in 10 provinces

**Design:** This study evaluates policy on pharmaceutical centralized bidding. We selected 10 provinces in China by a stratified sampling method based on the principles of economic development level and geographical areas. Data of 20 essential medicines were collected from pharmaceutical bidding price database in 2008 in the sampling provinces, and we conducted a cross-sectional study to reveal the current situation of this policy.

**Setting:** This study was conducted on the pharmaceutical bidding of public hospitals at the national level.

**Study population:** The 20 medicines contained in the WHO/HAI core list have been selected by purposive sampling method because they meet the following criteria: representative of the provinces involved, burden of disease (i.e., common conditions, both acute and chronic), availability, and patent status.

**Policy:** Pharmaceutical centralized bidding standardized procurement channels, but didn't control drug price owing to institutional arrangement of this policy.

**Outcome measure(s):** Dependent variable, price difference, is defined as the bidding price difference ratio (e.g., the highest median price/the lowest median price or the innovator medicines price/the generic medicines price) for the same dosage form, strength, and packaging of pharmaceuticals. Independent variables (e.g., dosage form, strength, packaging, and the number of pharmaceutical manufacture) measure the behavior of bidders generated from institutional arrangement of pharmaceutical bidding.

**Results:** Pharmaceutical bidding policy produced too much dosage form, strength, and packaging for the same medicines. Among the 10 provinces, the bidding price difference ratio of the same generic medicines is between 1.08 and 25.00, but this ratio of the same innovator ones is between 1.00 and 1.30. For the comparable seven essential medicines, the price of innovator medicines is 1.70–57.94 times higher than that of generic ones. For the generic drugs, the price with the same manufacturer but in different province, the bidding price difference ratio is between 1.00 and 6.15; however, for these drugs, the price in the same province but with different manufacturers, this ratio is between 1.00 and 3.80.

**Conclusions:** The main reason for policy failure is that the institutional arrangement of pharmaceutical bidding led generic manufacturers to bid alternatively between different dosage forms, strength, and packaging for the same essential medicines.

**Funding source(s):** Ministry of Health, China

357

### **Chronic Care**

*Keywords:* access to medicines, chronic disease, availability, medicine prices, affordability

#### **Availability, Price, and Affordability of Cardiovascular Medicines: A Comparison across 36 Countries Using WHO/HAI Data**

---

**Alexandra Cameron<sup>1</sup>, Maaike van Mourik<sup>2</sup>, Margaret Ewen<sup>3</sup>, Richard Laing<sup>1</sup>**

<sup>1</sup>Essential Medicines and Pharmaceutical Policies, World Health Organization, Geneva, Switzerland; <sup>2</sup>University Medical Center Utrecht, The Netherlands.; <sup>3</sup>Health Action International - Global, Amsterdam, the Netherlands

**Problem statement:** In developing countries, the burden of cardiovascular diseases (CVDs) is growing rapidly, and many countries are already in, or will soon enter, the stage of the epidemiological transition in which cardiovascular diseases are the most important cause of death. Successful treatment of CVD requires adequate pharmaceutical management; however, research has shown that the accessibility of medicines for CVD may be limited in developing countries.

**Objective:** To examine the availability, pricing, and affordability of cardiovascular medicines in developing countries

**Design:** Data on medicine prices, availability, and affordability were obtained through facility-based surveys conducted using a standard methodology developed by the World Health Organization and Health Action International (WHO/HAI). A total of 45 surveys conducted in 36 countries between 2001 and 2006 were included. Five medicines were investigated: atenolol, captopril, hydrochlorothiazide, losartan, and nifedipine. Outcome measures were percentage availability, price ratios to international reference prices, and number of day's wages needed by the lowest paid government worker to purchase one month of treatment. Patient prices were adjusted for inflation and purchasing power, procurement prices for inflation only.

**Results:** For all measures, there was great variability across surveys. Average availability of cardiovascular medicines was poor (26.3% and 57.3% in public and private sectors, respectively). Procurement prices were competitive in some countries (i.e., comparable to international reference prices), whereas others consistently paid high prices. In general, patient prices were substantially higher than international reference prices, but some countries performed well.

Generic products were usually sold at lower prices than originator brands. The private sector consistently had higher prices than the public sector. Chronic treatment with anti-hypertensive medication cost more than one day's wages in many cases. When monotherapy was not sufficient to achieve treatment goals, treatment costs became even less affordable.

Conclusion: The results of this study emphasize the need of focusing attention and financing on making chronic disease medicines accessible, in particular in the public sector. Policy options include improving availability in the public sector by focusing resources on generic essential medicines, and exempting medicines from taxes and duties, which could make medicines less expensive. Regulating mark-ups in a way that does not encourage dispensing more expensive products can help promote the use of generic formulations. Other options for promoting generic uptake include preferential registration procedures; ensuring product quality; and increasing the confidence of physicians, pharmacists, and patients in generic products.

Funding Source(s): None

**358**

### **Economics, Financing, and Insurance Systems**

*Keywords:* MDGs, Cost of medicines, Low-income countries

#### **In Scaling Up Health Related MDGs, How Much More Will It Cost to Procure Essential Medicines for 49 Low-Income Countries?**

**Dele Olawale Abegunde, Clive Ondari, Kathleen Holloway, Fatima Serhan, Barbara Milami, Gojka Roglic, Andreas Ullrich, Eva Mantzouranis, Shanthi Mendis**

World Health Organization, Switzerland

Problem statement: Affordable access to essential medicines is crucial to achieving the health related Millennium Development Goals (MDGs). Financial requirement for providing access to medicines in the low- (and middle-) income countries has not been clearly estimated. Motivated by the need to accelerate the achievement of the MDGs, we have estimated the procurement (acquisition) cost of medicines for 49 low-income countries to achieve MDG 8 target 17.

Objectives: To estimate the cost of procuring essential medicines needed to achieve MDG 8 target 17 as part of estimations to scale up health related MDGs for 49 least developed countries.

Design: Longitudinal cohort model estimating (from 2009 to 2015) the cost of cardiovascular diseases, diabetes mellitus, asthma/COPD, cancers, mental disorders, parasitic infestations (Schistosomiasis), diseases of poor hygiene, gastrointestinal ulcers, and musculoskeletal illness (Buruli ulcer). The estimation model takes a normative view of the medicines required to treat the main diseases that cause the greatest health burden (morbidity and mortality) given feasible coverage, medicine acquisition costs, and possible wastages reflecting the typical health system scenarios. Modeling data were obtained from a number of WHO databases.

Setting: Estimations were aggregated for the 49 low-income countries adjudged least developed from Sub-Saharan Africa, East Asia and the Pacific, Europe and Central Asia, Latin America and the Caribbean, the Middle East and North Africa, and South Asia.

Study population: Aggregated population at risk of the respective diseases in the 49 countries adjusted for access to care (population-based estimation)

Outcome measure(s): Accumulated and incremental number of treatment opportunities; annual and accumulated acquisition cost and per capita cost of medicines; cumulative incremental cost and acquisition cost per capita from 2008 base-year

Results: The procurement cost of medicines accumulates to \$7.4 billion from 2009 to 2015, of which 65% (\$4.7 billion) represents the incremental component. These are \$0.73 and \$0.47 per capita, respectively. These amounts will provide an accumulated 529 million full treatment courses and 257 million additional treatments over the 2008 coverage. Cardiovascular diseases and risk factors, mental health, cancers, and diseases of poor hygiene account for the largest proportion.

Conclusion: We conclude that given innovative financing mechanisms, providing access to essential medicines could be globally affordable and is essential to reaching health-related MDGs. Incremental acquisition costs of medicines per capita is only a fraction of a dollar; however, poor countries may benefit from concerted international arrangements to enhance access to needed medicines to achieve the MDGs.

Funding source(s): WHO

**359**

### **Policy, Regulation, and Governance**

*Keywords:* appropriate use, drug utilization, pharmaceutical policy, generic medicines

#### **Challenges When Introducing Generic Policies to Enhance Their Utilisation: Impact and Next Steps**

**Brian Barr Godman<sup>3</sup>, Mohammed Abuelkhair<sup>1</sup>, Sahar Fahmy<sup>4</sup>, Shajahan Abdu<sup>2</sup>, Lars L Gustafsson<sup>5</sup>**

<sup>1</sup>Health Authority - Abu Dhabi; <sup>2</sup>Health Authority - Abu Dhabi; <sup>3</sup>Karolinska Institutet, Stockholm, Sweden; <sup>4</sup>Health Authority - Abu Dhabi; <sup>5</sup>Karolinska Institutet, Stockholm, Sweden

Problem statement: Perverse incentives and regulations may prevent health authorities from fully realising savings from the increasing availability of generics in a class.

**Objectives:** To document the outcome of recent generic policies introduced by the Health Authority Abu Dhabi (HAAD) on the utilisation and expenditure of high-volume products in ambulatory care; to determine possible reasons behind the findings; to suggest potential reforms that HAAD could implement to achieve desired results in the future

**Design, setting, and study population:** Pre- and post-policy-analysis study of the impact of recent generics policy in HAAD on utilisation patterns for proton pump inhibitors (PPIs), statins, and ezetimibe in ambulatory care (2 highest expenditure areas in 2009) using IMS data for the Abu Dhabi market converted to 2011 DDDs; 12 months to September 2010 compared with 12 months to September 2009; in addition, utilisation and expenditure patterns from 2004 to 2010

**Intervention and policies:** The Unified Prescription Form introduced in March 2009 mandated generic prescribing (INN prescribing) apart from a minority of agreed-upon situations. The comprehensive Generic Drug Policy published in August 2009 sought to further enhance the prescribing and dispensing of generics; however, (1) pharmacists are still free to dispense either the originator or any branded generic and be fully reimbursed although there is a 20–30% co-payment for some patients; (2) originator manufacturers are not obliged to lower prices for continued reimbursement once generics are available, and patients do not have to pay the difference for a more expensive molecule (unlike typically seen across Europe); and (3) no demand-side measures exist directing physician prescribing such as generics first line in a class

**Outcome measure(s):** Principally, changes in utilisation patterns for different PPIs and statins as well as ezetimibe (2011 DDDs) in 12 months to September 2010 vs. 12 months to September 2009

**Results:** (1) PPI utilisation increased by 10% 2010 vs. 2009. Esomeprazole increased by 33% (31% total PPIs in 2010 vs. 21% in 2008), and omeprazole decreased by 10% (40% total PPIs in 2010 vs. 55% in 2008). There was increased utilisation of multi-sourced lansoprazole but from a lower base (6% in 2009) helped by only one generic available in 2010. (2) Statin utilisation increased by 14% 2010 vs. 2009. Atorvastatin/rosuvastatin utilisation increased by 14% (already 88% of total utilisation in 2009), single-source pravastatin by 36%, single-source fluvastatin by 22%, and multi-source simvastatin by only 13%. Utilisation of ezetimibe alone or in combination increased by 62% 2010 vs. 2009, increasing utilisation of lipid-lowering drugs by 17% during this period.

These changes in utilisation patterns following reforms regarding generics match those among Western European countries where currently only limited demand-side controls exist to combat the marketing activities from single-sourced manufacturers. Additional reasons for the limited increases in utilisation of multi-sourced products or even decreases may be concerns among physicians that patients could be dispensed different generic preparations, each prescription with possibly reduced effectiveness and/or increased side-effects. Prescribing of single-sourced patented products alleviates this concern.

**Conclusions:** Anticipated efficiency savings from generic availability in a class have not materialised in Abu Dhabi. Possible future policies that HAAD could implement are being explored based on experiences among European countries. These include reference pricing in a class as well as guidance on first- and second-line drugs in a class possibly backed up by financial incentives. Their influence will be analysed to provide further direction to other health authorities.

**Funding source(s):** Abu Dhabi Health Authority

## 360

### Policy, Regulation, and Governance

*Keywords:* cost containment, pharmaceutical expenditure, generics, pharmaceutical policy

#### Care Needed When Introducing Generic Policies to Reduce Costs: Experiences From Abu Dhabi

**Brian Barr Godman**<sup>3</sup>, **Mohammed Abuelkhair**<sup>1</sup>, **Sahar Fahmy**<sup>2</sup>, **Shajahan Abdu**<sup>4</sup>, **Lars L Gustafsson**<sup>5</sup>

<sup>1</sup>Health Authority - Abu Dhabi; <sup>2</sup>Health Authority - Abu Dhabi; <sup>3</sup>Karolinska Institutet, Sweden; <sup>4</sup>Health Authority - Abu Dhabi; <sup>5</sup>Karolinska Institutet, Sweden

**Problem statement:** Perverse incentives and regulations may prevent health authorities from fully realising savings from the availability of generics.

**Objectives:** To document the outcome of recent generic policies introduced by Health Authority Abu Dhabi (HAAD) on the pharmaceutical market in Abu Dhabi; to determine possible reasons behind the findings; to suggest potential reforms that HAAD could implement to achieve desired results in the future.

**Design, setting, and study population:** Pre- and post-policy-analysis study of the impact of recent generics policy in HAAD for 5 of the top 8 pharmaceutical expenditure areas in ambulatory care. These are proton pump inhibitors (PPIs), statins, NSAIDs, antihistamines, and oral fluoroquinolones.

**Intervention and policies:** The Unified Prescription Form introduced in March 2009 mandated generic prescribing (INN prescribing) apart from a minority of agreed situations. The comprehensive Generic Drug Policy published in August 2009 sought to further enhance the prescribing and dispensing of generics; however (1) pharmacists are still free to dispense either the originator or any branded generic and be fully reimbursed although there is a 20–30% co-payment for some patients; (2) originator manufacturers are not obliged to lower their prices for continued reimbursement once generics are available, and patients do not have to pay the difference for a more expensive molecule than current lowest priced molecule (in addition to any co-payment for the pack); (3) pharmacists can receive appreciable bonuses from manufacturers to preferentially dispense their products; and (4) no demand-side measures exist directing physician prescribing towards prescribing a generic first line where seen as standard treatment.

**Outcome measure(s):** Changes in expenditure (IMS) 12 months to November 2009 vs. 12 months to November 2008 for the chosen classes

Results: (1) Statin expenditures increased by 65% during this period aided by increased expenditure on rosuvastatin (+130%) and atorvastatin (+64%) vs. multi-sourced simvastatin (-2%). (2) PPI expenditure increased by 27% aided by increased expenditure on single-sourced pantoprazole (98%) and esomeprazole (71%) vs. multi-sourced omeprazole (-5%). (3) Expenditure on oral fluoroquinolones increased by 31% aided by, for example, levofloxacin (+81%) and moxifloxacin (+55%) vs. multi-sourced ciprofloxacin (-7%). (4) Overall expenditure in the 5 areas increased by 34% during the study period to \$59.21mn in 2009 up from \$44.07mn in 2008. Possible reasons for the unexpected results could be concerns among physicians that patients would be dispensed different generic preparations every time exacerbated by complaints regarding possibly reduced effectiveness and/or increased side-effect rates. Prescribing of single-sourced products alleviates this. In addition, currently limited demand-side reforms directing physicians to prescribe generics first line—apart from compulsory INN prescribing—to combat pressures from pharmaceutical companies promoting their patent protected products.

Conclusions: Anticipated savings from the generic policies were not realised in HAAD for a number of reasons. Further potential policies are being explored based on experiences among European countries including reference pricing for the molecule as well as prescribing guidance and possibly prescribing restrictions. Their influence will be analysed to provide further direction to other health authorities.

Funding source(s): Health Authority, Abu Dhabi

### 363

#### Chronic Care

*Keywords:* access to medicines, adherence, affordability, chronic disease, community, cost containment, financing, generic medicines, human resources, gender perspective, medicine prices, medicine supply, performance assessment, prescribing, primary health care

#### **Managing a continuum-of-care with Revolving Drug Fund for People with Diabetes (DM) and Hypertension (HBP) through a Peer Educator Network in rural Cambodia**

**Maurits Vanpelt, Ngeav Mao**

MoPoTsyo Patient Information Centre (<http://www.mopotsyo.org>), Cambodia

**Problem Statement:** No affordable care model meets secondary prevention needs of chronic NCD patients in developing countries. The great majority of Cambodian DM and HBP patients lack a continuum-of-care and access to routine prescription medicines.

**Objectives:** Document how a Peer Educator Network (PEN) in a rural Cambodian district delivers an affordable and acceptable continuum-of-care that includes prescription drugs to its community of DM and HBP patients.

**Design:** Intervention effects (before and after, no control group);

**Setting:** A rural district of 133,000 inhabitants mostly served by private health services and to a lesser extent by public health services;

**Study Population:** 1,023 chronic patients among whom 448 have DM;

**Intervention:** During 3.5 years a network of 9 community-based diabetic peer educators (PE) organizes self-screening of the adult population first for DM and later also for HBP. To patients who register as member, the PEN delivers a continuum-of-care consisting of education on lifestyle-changes, DM and HBP self-management skills and materials, as well as information on how to access routine medication from the RDF and other services. PE's do not prescribe medicines, but facilitate access to professional health services, such as laboratory tests and medical consultation, when needed. Individual PE performance is 2 x p/yr assessed, providing data for quality control and learning opportunities. Contracted private pharmacies sell RDF medicines to members based on physician prescription allowing monitoring of treatment adherence by registered members. The Laboratory Services as well as drug sales generate revenue for replenishment of stocks, payment of PE incentives, re-supply of PE's with consumables, supervision of PE's, assessments and to pay part of management costs.

**Outcome Measures & results in numbers and %, by sex:** The 65% female DM and 35% male DM used medical consultation in equal proportions: 3.4 times in 2010. Among HBP, 63% are women. Reported Health Expenditure among DM was equivalent to USD 3.69 per month. Fasting Blood Glucose assessed per July 2010 in a randomly selected sample of 114 DM was 145 mg/dl on average, down from their baseline value of 191 mg/dl. 48% of DM showed FBG of  $\leq 126$ mg/dl (7mmol). In the same sample the proportion of DM with Systolic Blood Pressure  $< 130$  mm Hg had increased from 42% in the baseline to 50%, whereas Diastolic pressure  $< 80$  mm Hg had increased from 32% at baseline to 52%. The BMI improved from 36% to 41% of DM patients with normal values (18.5 - 23.0). The average annual drop-out rate of the DM was just below 10%. 81% of DM patients reported to feel better than before registration and  $> 90\%$  reported to be satisfied with their peer educator. Revenue from providing laboratory services and medicine sales cover the local costs of running the Peer Educator Network, but not the NGO management costs. HBP patients were only registered in year 3 and have begun to benefit from the system. The intervention is being replicated to other districts in the same province.

**Conclusion:** In Cambodia, despite little resources, a PEN can deliver Secondary Prevention services including access to routine medication for DM and HBP patients. Generated service revenue can cover the running costs of a continuum-of-care. If trained and supervised, DM and HBP patients can fill certain gaps in services by taking on care-giver tasks. Three years onwards, the PEN performs a range of effective secondary prevention measures for DM and HBP at low cost that is affordable to many of its members. The main lesson is that a structured membership of chronic NCD patients can trigger and maintain a matching demand for and supply of health services including medicines, making the rural health system more complete, responsive and bringing universal coverage closer in view of rapidly growing health needs

365

#### HIV/AIDS and TB

*Keywords:* PLWHAs, people living with HIV/AIDS

### **Peer-to-Peer Counseling: A Model for Improving Male Involvement in ARV Treatment Access and Adherence among PLWHA in Kwara State, Nigeria**

**Mary Emem Umoh<sup>1</sup>, Motunrayo Adegoke<sup>2</sup>, Tolu Dagunduro<sup>1</sup>, Chioma Nwuba<sup>1</sup>, Sam Faromoku<sup>1</sup>**

<sup>1</sup>Management Sciences for Health, Nigeria; <sup>2</sup>State specialist hospital, Offa, Kwara state

**Problem statement:** Having a large proportion of women living with HIV/AIDS as compared to the men is no news in rural western Nigeria thus the need to increase partner involvement in all areas of care and support. The facility-based support groups established for people living with HIV/AIDS (PLWHA) in the Management Sciences for Health-supported sites in Kwara State provided an avenue to monitor adherence to antiretroviral (ARV) therapy among clients who access care and treatment at these facilities. The low turnout of men at these support group meetings was observed to be a major setback because their absence had a negative impact on partner disclosure, which in turn affected adherence to ARVs among the female clients.

**Objective:** To increase male involvement in HIV treatment access and adherence to ARV therapy

**Methods:** The steps put in place include (1) recognizing male role models among PLWHA who are active members of the support group, (2) holding regular mentoring meetings with the treatment role models to counsel other male PLWHA on the importance of joining the support groups and the benefits of adhering to therapy, and (3) arranging on clinic days for these models to counsel other peers who have been enrolled for treatment and subsequent peer-peer follow up counseling.

**Results:** Over a 3-month period, it was observed that male attendance at the support groups increased from 2 to 16%. In the same vein, rates of partner disclosure increased from 15 to 50%, and the rate of partner testing also increased from 35 to 52.6%.

**Conclusion:** Peer-to-peer counseling is an avenue for increasing gender participation in the care and treatment of HIV-positive persons and leads to improved adherence to treatment, care, and support.

**Funding source(s):** ICIUM scholarship recipient

366

#### Drug Resistance

*Keywords:* vancomycin, utilization, SQUH, HICPAC, TDM.

### **Prescribing Pattern and Therapeutic Drug Monitoring of Vancomycin at a Tertiary Hospital in Oman**

**Samreen Shafiq, Dawood Al Riyami, Badreldin Ali, Mohammad Al Za'abi**

Sultan Qaboos University, Oman

**Problem statement:** Vancomycin resistance is a major impediment and has the potential of rendering vancomycin use to obsolescence. Vancomycin-resistant *Enterococcus faecium* (VRE) is a highly resistant pathogen which is linked to overuse of vancomycin. In response, the Hospital Infection Control Practices Advisory Committee (HICPAC) released guidelines for the proper utilization of vancomycin to restrict and control overuse of vancomycin. Additionally, North American consensus review published guidelines for the proper procedures for vancomycin therapeutic drug monitoring (TDM) to ensure the most efficacious vancomycin therapy.

**Objectives:** To describe the prescribing patterns and TDM of vancomycin at Sultan Qaboos University Hospital (SQUH) and to compare it with HICPAC, North American consensus review for vancomycin TDM and SQUH antibiotic policy

**Design:** The study was an observational study with a retrospective cohort study design.

**Setting:** 518-bed tertiary care hospital in Muscat, Oman

**Study population:** The subjects included were all hospitalized patients who were treated with intravenous and oral vancomycin during a 12-month period, from January 1, 2009, to December 31, 2009. Vancomycin was prescribed to 365 patients. The average age of the subjects was  $26.2 \pm 24.3$  years. The ratio of male-to-female subjects was 52.3:47.7%.

**Interventions and policies:** the use of vancomycin was evaluated according to HICPAC, North American consensus review for vancomycin TDM, and SQUH antibiotic policy.

**Outcome measure(s):** The prescribed vancomycin regimen, vancomycin indications, application and results of TDM, and clinical outcome of vancomycin therapy

**Results:** Inappropriate prescribing of vancomycin was 79.1% and 74.9% according to HICPAC guidelines and SQUH policy, respectively. The most common inappropriate indication practiced was the continued empirical use of vancomycin after obtaining cultures that were negative for  $\beta$ -lactam resistant gram-positive microorganisms. The TDM practices in SQUH were not in line with North American consensus recommendations, but the TDM practices were majorly appropriate according to SQUH guidelines.

**Conclusions:** Inappropriate prescribing of vancomycin existed in all inpatient units of the hospital. Although much of vancomycin utilization was inappropriate according to both HICPAC and SQUH guidelines, we recommend that none of these guidelines should be used solely to prescribe vancomycin. New guidelines should be created with suggestions

from both these guidelines. In addition, the North American TDM consensus protocols are currently being reviewed for possible implementation at SQUH to ensure adequate and safe vancomycin therapy.

Funding source(s): No funding required to conduct this research

**367**

#### **HIV/AIDS and TB**

*Keywords:* health systems, access, antiretroviral, HIV/AIDS, barriers

#### **Health Systems Barriers that Determine Access to Antiretroviral Drugs in Southeast Nigeria**

**Soludo B. Eze<sup>1,3</sup>, Neil Spicer<sup>2</sup>, Obinna Onwujekwe<sup>1,3</sup>, BSC Uzochukwu<sup>1,4</sup>**

<sup>1</sup>Health Policy Research Group, College of Medicine, University of Nigeria, Enugu campus, Nigeria; <sup>2</sup>London School of Hygiene and Tropical Medicine, United Kingdom; <sup>3</sup>Department of Health Administration and Management, University of Nigeria, Enugu campus, Nigeria; <sup>4</sup>Department of Community Medicine, University of Nigeria Teaching Hospital, Ituku-Ozalla, Enugu State, Nigeria

Problem statement:

The policy of free antiretroviral (ARV) drugs access was put in place by the Nigerian government as a response to high cost of diagnosis and treatment for HIV/AIDS. Prior to the free ARV policy, many HIV clients who could not afford the cost of diagnosis, CD4 count tests and treatment for HIV, and were therefore denied access to treatment. Despite the current free ARV policy, many HIV clients continue to experience substantial access barriers to treatment.

Objective: The objective of study was to examine the service delivery factors that promote or limit equitable access to ARVs.

Design: This study applied both the descriptive statistical and qualitative approaches. Pre-tested client structured exit interviews were conducted with 514 adult HIV clients receiving treatment in four selected ARV clinics. Four focus group discussions categorized by sex (male/female) were also carried out (one per facility). Support group coordinators at the ARV clinics were also interviewed.

Setting: The study was carried out at public and private-run ARV clinics in Enugu state, Nigeria.

Study population: This was a cross sectional study that involved 514 adult (18 yrs and above) HIV/AIDS clients whose HIV status were determined through laboratory diagnosis and who at the time of the study were registered and receiving treatment at the selected ARV clinics. They were selected randomly at the facility.

Outcome measure(s): Long queues at ARV clinic affect civil servants in particular, short supply of doctors causes delay, lack of confidentiality on health workers affect clients access to ARV, constant counseling encourages HIV clients.

Results: Key factors undermining access include: fear of loss of confidentiality (65.4%), poor quality treatment services (62.1%), and lack of information to clients (61%). Loss of confidentiality often resulted from paper folders containing patients' medical notes clearly identifying them as HIV-positive. Long queues at treatment centres constitute a major access barrier to different occupational groups especially public and civil servants: results show a statistically significant difference ( $p < 0.05$ ) at 95% CI between civil servants and other occupation groups in terms of the impact of queuing on access. Doctors working in the ARV clinics were found to be in short supply, and oftentimes came late to clinics resulting in clients waiting many hours to receive treatment. Nevertheless, constant counseling of clients was found to boost access to ARV treatment, as did improving attitudes among some health workers.

Conclusion: Access to ARVs can be enhanced if the health systems can streamline services to suit all occupational groups such as civil servants who were disproportionately impacted by long queues for treatment. It is important that aspects of service delivery that may result in loss of confidentiality are addressed. It is also imperative that adequate health workers are posted to work in ARV clinics.

Funding source: Wellcome Trust Fellowship, United Kingdom

**371**

#### **Chronic Care**

*Keywords:* access to medicines, adherence, chronic disease, community, dispensing, supply management

#### **Improving Access to Routine Medication from a Revolving Drug Fund for Chronic Patients in Rural Cambodia**

**Ngeav Mao, Maurits Van Pelt**

MoPoTsyo patient information centre, Cambodia

Problem Statement: A structured 1,023 chronic patient membership-community consisting of Diabetic Mellitus (DM) and High Blood Pressure patients (HBP), has formal arrangements with the Public Hospital services to prescribe the medicines for chronic conditions and with the Private Sector to dispense the prescription medicines in their district. The patient network facilitates access to prescription medication through a Revolving Drug Fund (RDF) having contracted with one private pharmacy. In 2010's first 6 months, this private pharmacy underperformed, leaving uncertainties about adherence and medicine use by the members. Besides, inconsistent health education messages from different sources reaching HBP patients compromised access and their adherence to the continuum of care.

Objectives: To document how both access and adherence to routine prescription medicines from a RDF were improved using a comprehensive set of specific measures. They include expanded roles of chronic patients and Peer Educators

(PE) and also supply-side measures, notably increasing the number of pharmacies and agreeing with service providers on harmonization of specific health education messages.

Design: Before-After Study of Intervention effects

Setting: In a rural Cambodian district of 133,000 people, mostly served by private and to lesser extent by public health services, operates a community-based Peer Educator Network (PEN). The 9 PE's are all diabetic themselves and some of them also have High Blood Pressure. The network facilitates access to health services for DM and HBP patients registered as member of the network and access to a RDF by dispensing from contracted private pharmacies.

Study Population: 1,023 chronic patients, among whom 448 DM and 575 HBP.

Intervention : During second half of 2010, three more pharmacies were contracted of which one was located near the existing central one, one in the Eastern and one in Southern part of the district. As specific measures were introduced throughout the whole operational district: health education messages, increasing the number of specialised consultation sessions, increasing PE incentives for follow-up and for monitoring the RDF.

Outcome Measures : Comparing the RDF sales during first half of 2010 to and by the one pharmacy to the RDF sales to and by the four pharmacies in the first half of 2011, detailing RDF revenue and costs, including PEN incentive costs. Number of dispenses to members by sex and age group compared with their prescriptions in periods before and after the introduction of the measures. Health expenditure, monthly prescription costs, numbers of molecules prescribed.

Results: Among 1,023 registered members, 65% are women and 43% are patients older than 60 years indicating relatively good access by these groups. After introducing the special measures, out of 448 DM members the proportion of those with prescription for using the RDF increased from 58% (260DM) to 67% (302DM) ( $p=0.0047$ ). The proportions of men and women having used medical consultation remained unchanged and relatively proportionate: 73% women and 27% men. Among the DM older than 60 years the proportion with prescription remained low and unchanged: 29%. The average monthly prescription cost increased from USD 4.36 to USD 5.44 (median from 3.66 to 4.94). The number of dispensing invoices by contracted pharmacies tripled from 345 invoices in first half of 2010 to 1,059 invoices in the first half of 2011. The average number of invoices per DM patient with prescription increased from 1.30 in the first half of 2010 to 3.51 in the first half of 2011. In the first half of 2010, only 11 of the 575 registered HBP members had a prescription, but this increased to 63 HBP patients in the first half of 2011 ( $p=0.0001$ ). Invoice based dispensing for them rose from 2 (0.18 times) to 250 (3.97 times) in the first half of 2011. The RDF gross revenue from drug sales to pharmacies rose from USD 2,817 in the first half of 2010 to USD 6,156 in the first half of 2011. The intervention's main costs in first half 2010 and first half 2011 were: the RDF (resp USD 1,087 and USD 2,401), the PEN (resp USD 1,117 and USD 1,359) and organising medical consultation (unchanged at USD 936) and local supervision (USD 708). Costs and revenue related to the laboratory service provision are excluded from the calculations financial figures to show the dynamics related to the RDF in particular.

Conclusions: The overall utilisation increases before and after the intervention suggest that a combination of low cost measures, pulling together demand and service supply sides, can significantly improve access to routine medication for a structured rural membership community of chronic DM patients and has potential to serve an even larger group of HBP patients in the same area, simultaneously improving financial sustainability of the RDF.

### 374

#### Policy, Regulation, and Governance

Keywords: drug selection, essential drug program, essential medicines.

#### Study on National Essential Medicines Lists from 8 Countries of the Western African Economic and Monetary Union

##### Carinne Bruneton

Réseau Médicaments et Développement (ReMeD), France

Problem statement: The countries Benin, Burkina Faso, Ivory Cost, Guinea Bissau, Mali, Niger, Senegal, and Togo, who are members of the West African Economic and Monetary Union (WAEMU), have their own national essential medicines list (NEML) corresponding to their specific health needs and their programmes to promoting rational drug use. A comparative study of these NEMLs was undertaken to measure the impact of the 15th WHO Essential Model List (WHO/EML) in identifying the choice items of essential medicines in drawing up NEML.

Objectives: To compare 8 NEMLs with the 15th WHO/EML promulgated at the period of the study period with comparative analysis of data; to evaluate the level of use of the NEML in each country; to assess the therapeutic guidelines and standard therapeutic diagrams for nurses for promotion these lists; to collect the studies concerning the rational use of medicines in the 8 countries; and to write recommendations of rational use of NEML.

Design: It was a comparative study.

Setting: It was a regional study in western Africa.

Interventions: A circular mission was realized in April 2008 to collect the NEML from 8 countries and therapeutic guidelines on the main diseases (AIDS, malaria, and tuberculosis). A comparative analysis of the situation in each country with production of a temporary report was done. Additionally, a workshop involving pharmacists of the countries and validating the results was organized in February 2009 before the final report.

Results: The number of medicines increases year to year in all the countries, except in Guinea Bissau where the number was diminished slightly; 3 countries have compounds from traditional medicines in their NEMLs. The medicines are not divided in core and complementary list as described by WHO/EML. The demand for anti-infectives, analgesics, cardiovascular, and antineoplastics is very large; 91 medicines registered on the WHO/EML do not appear in the NEMLs, 560 medicines (dosages, pharmaceutical forms, diverse associations) appear in the 8 NEMLs but not in

WHO/EML; 3 lists in the 8 countries contain medical devices in their NEMs, and 3 other lists have traditional medicines.

Conclusions: Distinctions between a core and complementary list are not found in the 8 NEMs, and some medicines existing in WHO/EML are not present in NEM. Traditional compounds from traditional medicines are present in 3 country lists; 560 medicines are included with little evidence of their efficacy and/or safety; and they must be studied in the future in order to remove them from the 8 NEMs.

Funding sources: WAEMU and ReMeD (Network for Medicines and Development)

**376**

**Policy, Regulation, and Governance**

*Keywords:* Drug use patterns, Antibiotics, Drug utilization review

**Assessment of Drug Utilization Patterns in Some Health Insurance Outpatient Clinics in Alexandria**

**Samaa Zenhom Ibrahim**

High Institute of Public Health, Egypt

Problem statement: The selection and rational use of medicines are accepted as key principles of health service quality and management in both the public and private sectors. Many researchers in developing countries, however, have described drug use as irrational, documenting cases of ineffective, unsuitable, suboptimal or unsafe prescribing, supply, and/or consumption of pharmaceutical products.

Objectives: To assess the pattern of drug use concerning prescribing, patient care, and facility standards in the selected outpatient clinics in Health Insurance Organization using World Health Organization (WHO) core indicators of drug use in health facilities

Design: A prospective cross-sectional study design was carried out.

Setting: The study was conducted in five randomly selected Health Insurance outpatient clinics in the Alexandria governorate.

Study population: A random sample of 30 encounters per each physician of all 62 general practitioners, internal medicine, and ENT specialists working in those clinics was carried out as recommended by WHO for studies describing current treatment practice, so the required sample of patients was 1,860.

Results: Results indicated that as regards prescribing indicators, the overall mean number of drugs prescribed per encounter was 2.8, the overall percentage of drugs prescribed by generic name was 61.0%, the overall percentage of prescriptions containing antibiotics was 52.2%, the percentage of encounters where an injection was prescribed was 20.6% overall. As regards health facility indicators, the essential drug list was found only in one clinic and the percentage of drugs prescribed from the list was 100.0% in that clinic. As regards patient care indicators, the overall average consultation time was 3.0 minutes, the mean time taken to dispense medications was 16.9 seconds, and the overall percentage of correct patient knowledge of dosage of prescribed drugs was 69.3%. Additionally in all clinics, the percentage of drugs adequately labeled was 0.0%.

Conclusions: It was concluded that continuous medical education of doctors at all levels of qualification on rational drug use should be instituted and treatment guides and training courses are recommended emphasizing the importance of adequate labeling and instructions to the patient.

Funding source(s): None

**377**

**Chronic Care**

*Keywords:* Patient drug knowledge, Drug dispensing

**Assessment of Patient Knowledge Regarding Drugs Prescribed and Dispensed in Some Health Insurance Outpatient Clinics in Alexandria**

**Samaa Zenhom Ibrahim**

High Institute of Public Health, Egypt

Problem statement: Rational prescription and use of drugs has been a concern in both developed and developing countries during the last two decades and has been promoted by WHO and others. Researchers are generally aware of the relationship between patient knowledge of prescribed and dispensed medications and medication-taking behaviour.

Objectives: To assess patients' knowledge regarding drugs prescribed and dispensed and to identify its determinants

Design: A prospective cross-sectional study design

Setting: A study was conducted at five randomly selected health insurance outpatient clinics in the Alexandria governorate.

Study population: A random sample of 1,860 patients was interviewed about their knowledge of drugs, immediately after dispensing. Mean knowledge scores were calculated based on patient recall of name, dosage of drug, duration of treatment, and reason for prescription (incorrect recall = 0; 1 point for each correct recall attribute; maximum score = 4).

Results: Results indicated that the mean patient knowledge score of dispensed drugs was 2.49 (a score of 2.40 and above was regarded as an acceptable level of knowledge). The highest percentage of knowledge was for the item of duration of treatment (76.9%), followed by dosage of drug (69.3%), reason for prescription (20.1%), and finally name of

drug (49.1%). In relation to factors independently associated with patient knowledge score, multiple regression analysis revealed that two factors were significant, namely patient occupation (where professionals achieved the highest mean knowledge score of 3.63 and housewife groups achieved the lower scores of 1.73) and number of dispensed drugs (where the greater the number of drug items per patient prescribed and dispensed, the lower the mean knowledge score). By contrast, prescribing staff qualification was not independent predictor. The predictors model explained 48% of variance in patient knowledge score. Antihypertensive drugs were the most well-known drugs to patients with the highest mean knowledge score of 2.94.

Conclusions: It was concluded that training of pharmacists to be active members of the health care team and to offer useful advice to patients about health and dispensed drugs is very critical for improvement of the quality of their practice, and it is one of the prerequisites for patient compliance with treatment. Moreover, treatment guides and training courses should emphasize the importance of adequate labeling and instructions to patient.

Funding source(s): None

**378**

#### **HIV/AIDS and TB**

*Keywords:* adherence, affordability, antiretrovirals, HIV/AIDS, hospital

#### **Nonadherence to HAART: A Cross-Sectional Two-Site Hospital-Based Study**

**Vivek Lal<sup>1</sup>, Shashi Kant<sup>2</sup>, Richa Dewan<sup>3</sup>, Sanjay K. Rai<sup>2</sup>, Ashutosh Biswas<sup>2</sup>**

<sup>1</sup>Indian Institute of Health Management Research, Jaipur, India; <sup>2</sup>All India Institute of Medical Sciences, New Delhi, India; <sup>3</sup>Lok Nayak Hospital, New Delhi, India

Problem statement: Initially, AIDS patients had to buy antiretroviral drugs from the open market. The Government of India introduced free HAART through antiretroviral therapy (ART) centers in April 2004. It was expected that the number of these centers would increase substantially in future. There was a concern that free drugs would be less valued and, therefore, adherence was likely to be low.

Objectives: To describe the pattern of adherence to HAART and ascertain factor(s) associated with nonadherence in adults in a typical public sector, tertiary care hospital setting, so that appropriate interventions could be suggested to improve adherence

Design: Cross-sectional hospital-based study

Setting: Study was done at two sites: the All India Institute of Medical Sciences (AIIMS) and the Lok Nayak Hospital (LNJP) at New Delhi. Both hospitals offered tertiary level care in public sector. At the time of the study, AIIMS did not dispense drugs for free; hence patients had to procure the drugs at their own cost. At LNJP, patients were provided free HAART.

Study population: In total, 300 patients were enrolled (200 at LNJP and 100 at AIIMS). These included AIDS patients who attend outpatient clinics, are on self-administered HAART for at least one week, and are age 18 years or older.

Outcome measure(s): Adherence was defined as not having missed even a single pill over the previous four-day period on self-reporting.

Results: The majority of patients at both study sites belonged to the 31–40 age group

and were male. Mean family income of these patients was similar. Pooled adherence for both the study sites was 75.7%. Adherence at AIIMS was 47%, whereas it was 90% at LNJP. This difference was statistically significant ( $p < 0.001$ ). Multiple logistic regression analysis showed that those who reported not having been counseled about the importance of HAART were 9.2 times more likely to report nonadherence than those who reported having been counseled [OR -9.2 (95% CI 3.2–25.8)  $p < 0.001$ ]; those having to pay out-of-pocket for HAART at AIIMS were 7.7 times more likely to report nonadherence than those getting free HAART at LNJP [OR -7.7 (95% CI 3.9–15.1)  $p < 0.001$ ]; and those who reported continued HIV risk behavior even after being started on HAART were 6.3 times more likely to report nonadherence than those who did not report continued risk behavior [OR -6.3 (95% CI 2.1–18.9)  $p = 0.001$ ].

Conclusion: Study provided the much-needed data on adherence among patients receiving free HAART through national program and provided evidence that the concern of low adherence among those receiving free HAART was unfounded. Thus, the national program on HAART was a step in right direction and would be beneficial to AIDS patients. While scaling up of ART program, the government should emphasize simultaneous recruitment of counselors, and physicians should be made aware of the need to inquire about and counsel patients against continued HIV risk behavior.

Funding source(s): None

**379**

#### **Drug Resistance**

*Keywords:* antimicrobials, drug utilization, Latin America, sales regulation

#### **Consumption of Antibiotics Before and After Sales Regulations in Chile and Venezuela**

**Veronika J. Wirtz<sup>1</sup>, Anahi C. Dreser-Mansilla<sup>1</sup>, Yared Santa Ana-Tellez<sup>1</sup>, Ralph Gonzales<sup>2</sup>**

<sup>1</sup>National Institute of Public Health; <sup>2</sup>University of California, San Francisco

Problem statement: In recent years, various middle-income countries have enforced the regulation of antibiotic sales only with prescription, among them Chile in 1999 and Venezuela in 2006. This regulation may have an impact on the use of antibiotics, but there has been little systematic evaluation of their effect over time.

**Objectives:** To analyze the change in consumption of antibiotics (AB) in Chile and Venezuela between 1997 and 2007

**Design:** Interrupted time-series analysis of systemic AB consumption for Chile and Venezuela and six other Latin American countries (Argentina, Brazil, Colombia, Mexico, Peru, and Uruguay) as control group between 1997 and 2007

**Setting:** Analysis was based on the market intelligence data of AB sales aggregated at the national level [World Health Organization (WHO) Anatomic Therapeutic Chemical (ATC) code J01] between 1997 and 2007.

**Study population:** The total AB consumption, and stratification by broad-spectrum therapeutic groups were analyzed: quinolones, macrolides/lincosamides, and third-generation cephalosporins. The trend of consumption of these three groups was contrasted with three narrow spectrum groups: penicillin, trimethoprim-sulfamethoxazole, and first- and second-generation cephalosporins.

**Policies:** Whereas the sale regulation in Venezuela only included the broad spectrum groups, for Chile the regulation affected all AB. The other six countries studied have not implemented sale regulations or other restrictions between 1997 and 2007.

**Outcome measure(s):** Yearly AB sales aggregated by country, expressed in defined daily dose per 1000 inhabitants per day (DDD)

**Results:** Between 1998 and 2000 (immediately following the regulatory change in Chile), total AB consumption in Chile decreased by 33.2% (from 14.4 to 9.6 DDD), but it increased between 2002 and 2007 (9.3 to 12.5 DDD; +25.8%). In Venezuela, consumption increased by 16.8% (13.7 to 16.0 DDD) after regulator changes. The mean consumption for the six other countries studied increased 8.3% (10.4 to 11.3 DDD) in the 10 years analyzed. Within the first two years after regulatory change, the consumption of quinolones increased in Chile from 0.6 to 0.8 DDD (21.0%) and in Venezuela from 1.85 to 2.49 DDD (34.6%). In contrast, the consumption of narrow-spectrum AB, such as penicillin, decreased in Chile 34.4% (8.3 to 5.4 DDD), but not in Venezuela (2.2 to 2.7 DDD; +32.8%).

**Conclusions:** The enforcement of the regulation on the sale of AB with prescription in Chile contributed to a change in trends in total consumption, particularly for narrow spectrum AB, during the first years of implementation, but it did not have medium- to long-term effects. In Venezuela, however, a short-term change in dispensing trends was not observed. Understanding the reasons for these differences can be used to inform the development of policies in other countries and to optimize existing regulations.

**Funding source(s):** Information not provided

### 384

#### Drug Resistance

*Keywords:* Global actions, World Health Organization, innovations, interventions

#### **Examples of Interventions to Contain AMR based on International Consultations**

**Elizabeth Mathai, Gerald Dziekan, the expert working groups on behalf of**

World Health Organization, Switzerland

**Problem statement:** Coherent and coordinated actions to contain AMR are lacking in many parts of the world. Identifying examples of interventions tried by different stakeholders could help in motivating policy makers to address AMR by developing policies and intervention strategies. National as well as international agencies, including WHO, NGOs, academia, professional societies, all have a role in providing leadership and advice, and setting standards.

**Objectives:** To develop a reference book of tried and tested interventions targeting policy makers. The book is building on the WHO Global Strategy for Containment of AMR (2001) as well as the WHO World Health Day six point policy package (2011) by utilizing evidence and experiences from interventions to provide examples of a range of potential interventions applicable to all Member States.

**Design and setting:** The book has been developed following a WHO consultative process with experts in different disciplines related to AMR containment and from different parts of the world over a two-year process.

**Development strategy:** Many international experts and WHO staff took part in the consultative process and contributed to the development of the document. The book is based on information and experience from different socioeconomic and cultural settings in the form of peer-reviewed articles and other forms of publications, expert opinions, and experiences recorded in WHO regions and Member States.

**Outcome measure(s):** Examples of practical interventions in five major areas: surveillance of antimicrobial use and resistance, rational antimicrobial use and regulations, antimicrobial use in animal husbandry, infection prevention and control, and enabling innovations to combat AMR

**Results:** The book discusses interventions and activities, such as country-focused situation analyses on antimicrobial use both in human and animal sectors; enforcement of regulations, creation of multidisciplinary coordination groups at national levels to develop policies, enabling rational prescribing, building infrastructure capacity for infection prevention and control, building coherent surveillance systems, and setting priorities for R&D in health technologies, innovative financing to facilitate progress in drug development, and measures to raise awareness among all stakeholders from policy makers to health care workers to the general public. Gaps and challenges to implementing interventions may include a lack of political will and weakness of health systems, contributing to entrenched human behaviour and perceived resistance to change.

**Conclusion:** Intersectoral and multidisciplinary cooperation at country and global levels seem to be important in implementing the multiple interventions that are urgently required. Health systems strengthening may be an important step toward implementing AMR interventions. This depends to a large extent on commitment from national governments while global agencies have important roles in supporting such activities.

Funding source(s): Funding for the consultation process and the subsequent development of the reference book was provided by WHO. SIDA/ReAct (Sweden) provided a grant to support the book development.

**385**

**Access**

*Keywords:* access to medicines, availability, community, private sector, education

**Commercial Innovation to Improve Health Care Access at the Bottom of the Pyramid in Rural India**

**Anuj Pasrija**

Novartis India Limited

**Problem statement:** For 740 million people in India living on USD 1-3 a day, the idea of accessible and affordable medicines is often as remote as their rural homes. There is less than 1 doctor per 6000 people and 1 hospital bed for 8000 patients. Health is a low priority for mostly illiterate villagers who consider pain and suffering as part of life. Ignorance of disease, weak health care infrastructure, and gender inequality are major obstacles in addition to affordability. Given the low purchasing power of these populations combined with special needs and necessary adaptations to products, efforts by companies to offer medicines and services at the bottom of the pyramid were so far limited.

**Objective:** Improve access to health care and health outcomes for rural populations while running a profitable social business

**Design:** Arogya Parivar is a private sector business linking communities at the bottom of the pyramid with primary care facilities, medical practitioners, hospitals, NGOs, and pharmacies. Cluster with 1 health educator and 1 supervisor cover an area of 25 km radii with approximately 80 villages. Disease awareness sessions are offered to villagers combined with programs to educate physicians supported by local availability of products.

**Social part:** The company provides salary and funding for local health educators and health camps with city doctors, education materials, referral mechanism to doctors and government health institutions, and interaction with NGOs. NGOs work with physicians to track patients and ensure adherence to treatment, especially in case of chronic diseases.

**Business part:** Sales specialists visit pharmacists and doctors to offer a tailored product portfolio. The entire concept is based on the "4As". Awareness: health education focused on local needs is offered in combination with information on where to seek diagnosis and treatment. The key thrust is on preventive measures, like safe drinking water and hygiene, to avoid diseases. Acceptability: individual medicines are available in small packs (where medically appropriate) at affordable prices. The objective is to keep weekly treatment costs below USD 1.25. Availability: programs are held locally so villagers do not need to travel. New distribution networks were established to provide medicines to local pharmacies and physician advice. Adaptability: product portfolio, communications, packaging and training adapted to local conditions, e.g. pictorials, story telling. Even educators and supervisors are hired from within the community.

**Study population:** Low-income rural communities that previously had little or no access to health care

**Intervention:** Health educators, usually women from within the community, raise awareness about local diseases and preventive health measures in local schools and public health centers. They use a referral card system for various diseases to refer patients to doctors for timely diagnosis and treatment. Cooperation with local NGOs ensures follow up with villagers and adherences to treatments. Health supervisors interact with pharmacies, doctors, hospitals, and NGOs to organize health camps in areas without permanent access to physicians where villagers receive treatment and preventive care. The product portfolio covers 12 therapeutic areas offering 79 pharmaceutical, generic, and over-the-counter treatments ranging from anti-infective, diarrhea (ORS and zinc as per WHO recommended formula), diabetes, and pain management to dietary supplements (calcium). Where possible, patients are made aware of government offerings and health services (e.g., TB program, free iron medication). Products are simple to use and tailored to meet the needs of underserved communities with low disposable income while ensuring an effective course of treatment. Alliances with external partners offer access of doctors and pharmacies to additional independent services such as microfinancing to improve local infrastructure (e.g., buying a microscope, EKG, or even essential range of medicines).

**Outcome measures:** Number of people that received health education, number of health patients that benefit from village level health camps, number of doctor referral cards distributed, number of referral cards returned from doctors, and sales achieved; as a next step, we want to prove our impact and better tailor our services and find partners to help research Arogya's health and social impact in detail

**Results:** Improved access to health care for the 42 million people living in 31,000 villages in 11 states. The aim is to reach more than 100 million people by 2012 and to expand it to 4 other countries in Asia and Africa; 18% of participants (680,000 patients) used referral cards from health education sessions to seek advice of independent physicians. About 6000 health camps were attended by an average of 70 villagers in each. More than 12 million people received concrete health education since the program's start in 2006, for example, on early recognition of TB symptoms and the relationship between intestinal worms and malnutrition as well as iron deficiency. Increased income and skills enhancement were provided for rural villagers through provision of jobs as health supervisors and educators. Increased income was provided for pharmacists and doctors. The program is a replicable model. New programs are planned for selected Asian and sub-Saharan African countries. The program is a sustainable business—the initiative returned a profit within 30 months and since 2007 sales have increased 25-fold. The program provides global awards—Award for Social Marketing from the CMO Asia Awards and the Best Long-Term Rural Marketing Initiative by the Rural Marketing Association of India.

**Conclusions:** Arogya Parivar highlights the key role and the commitment of the private sector in developing sustainable models that can alleviate poverty and improve access to health care while providing a modest return to the company.

New tools are needed to evaluate the long-term health and social impact to improve business initiatives and policymaking in this area.

Funding source: Novartis

**386**

### Drug Resistance

*Keywords:* antimicrobials, appropriate use, consumers, drug resistance, education

## Predictors of Antibiotic Use in African Communities: Evidence from Household Surveys in Five African Countries

**Catherine E. Vialle-Valentin<sup>1</sup>, Robert F. LeCates<sup>1</sup>, Fang Zhang<sup>1</sup>, Abayneh Tamer Desta<sup>2</sup>, Dennis Ross-Degnan<sup>1</sup>**

<sup>1</sup>Harvard Medical School, United States of America; <sup>2</sup>World Health Organization, Regional Office for Africa, Brazzaville, Congo

**Problem statement:** Evidence about antibiotic overuse is lacking in low-income countries where reliable antibiotic consumption data are not available.

**Objective:** To generate reliable evidence on antibiotics use at the consumer level. Specific aims are to describe how antibiotics are used in African households and to identify key predictors of antibiotic use.

**Design:** Descriptive, cross-sectional analysis of survey data

**Setting:** Household surveys conducted in five African countries between 2007 and 2008 with an instrument developed by the World Health Organization (WHO) to monitor country pharmaceutical situations at the community level.

**Study population:** Households were selected by multistage cluster sampling (900 to 1,080 households per country). Study population consisted of 2,914 household members with an acute illness in the two weeks preceding the survey; data were collected on all sick members in 3 surveys (Ghana, Kenya, Uganda) or only on the youngest sick member in two surveys (Gambia, Nigeria).

**Outcome measures:** Care seeking outside home for acute illnesses, use of antibiotics to treat acute illnesses

**Results:** Half of the households reported at least one recent acute illness; 19% of illnesses were considered very severe and 48% somewhat severe. A large proportion of sick individuals (90%) sought care outside home, an even greater proportion (95%) took medicines, and 36% took antibiotics. Patients were more likely to seek care outside home if they felt that the closest public facility usually had medicines or that they could usually afford medicines. In adjusted multivariate analyses, the strongest predictor of antibiotic use was the presence of upper respiratory (UR) symptoms (OR: 3.02, CI: 2.36–3.86). Patients who sought care outside home were significantly more likely to receive antibiotics if they had diarrhea or difficulty breathing, but significantly less likely if they had fever. The perception of a severe illness was a strong predictor of seeking care outside home (OR: 3.24, CI: 1.69–6.22). For those seeking care, however, the likelihood of receiving antibiotics was independent of illness severity and highest for patients visiting public hospitals.

**Conclusions:** Our results provide direct evidence about care seeking for acute illness and about community consumption of antibiotics in African countries. They underscore the degree to which antibiotics are misused by consumers, especially for UR symptoms. They highlight the need to educate prescribers, dispensers, and consumers since antibiotics are widely and inappropriately used in all settings.

**Funding source(s):** The WHO Department of Essential Medicines in Geneva organized and funded data collection, with support from the Medicines Transparency Alliance. The WHO African Regional Office funded the study.

**391**

### Access

*Keywords:* drug information, education, medication errors, clinical pharmacy, critical care nurses

## Medication Administration Management: Assessment of Critical Care Nurses' Baseline Knowledge and Strategies for Building Awareness

**Nahla Kandil, Maurice Hall, Ibrahim Labouta**

Andalusia Group, Al-Salama Hospital

**Problem Statement :** Nursing school curricula and hospital continuing education programmes lack sufficient information on the knowledge needed for safe administration of medication by nurses.

**Objectives :** To assess critical care nurses' baseline medication knowledge, practice and skills and their learning needs regarding medication administration. To determine the effectiveness of continuous in-service education as a strategy for building awareness.

**Design :** The study consisted of descriptive and interventional parts. The descriptive part included a cross-sectional study employing both quantitative and qualitative methods of data collection, using survey questionnaire and observation respectively. The interventional part consisted of 7 in-service training modules with pre- and post-intervention assessment using the same preliminary questionnaire.

**Setting :** The study was conducted in the Critical Care Unit of Al-Salama Hospital, Alexandria; Egypt.

**Study Population :** All critical care nurses were invited to participate in this study regardless their degree of education, age, grade or years of experience. Critical care nurses (n=47) participated in answering the pre-questionnaire, but only 27 nurses continued and answered the post-intervention questionnaire. A high dropout was observed (n=20) due to staff leaving the hospital during the 4 months of preparing and conducting the module, or due to other commitments.

**Intervention :** The interventions phase consisted of 3 parts: development, conduction and evaluation of the continuous in-service training module.

**Outcome Measure :** To compare the total and individual section scores of the questionnaire pre- and post-intervention.

**Results :** Inadequate baseline total knowledge scores ( $54.3 \pm 11.7$ ) of study nurses were obtained using the preliminary questionnaire. Nurses' grade (staff, registered, charge or head nurse) was the only factor with significant effect on baseline total knowledge score ( $P < 0.05$ ). Significant improvement of total knowledge scores post-intervention was found compared to pre-intervention using the same preliminary questionnaire ( $P < 0.05$ ). Increasing nurses' age and decreasing baseline total knowledge score were the only significant variables related to such improvement ( $P < 0.05$ ). Other variables, such as nurses' gender, years of total work experience and years of experience at Al-Salama Hospital were not found to influence performance.

**Conclusions :** Critical care nurses have inadequate awareness of the pharmacological and pharmaceutical knowledge that is needed for safe administration of medication. Continuous in-service professional development programme resulted in significant improvement in total knowledge scores ( $P < 0.05$ ). The role of the clinical pharmacist in such educational activities is of paramount importance. There is a need for developing and implementing such programmes.

**393**

### **Economics, Financing, and Insurance Systems**

*Keywords:* medicine prices, hospital, discount, high-cost medicines, pharmaceutical expenditure

#### **Prices of Medicines, Including High-Cost Cancer Medicines, in a Hospital Setting Compared to Outpatient Use**

**Sabine Vogler<sup>1</sup>, Claudia Habl<sup>1</sup>, Christine Leopold<sup>1</sup>, Jan Mazag<sup>2</sup>, Nina Zimmermann<sup>1</sup>**

<sup>1</sup>Gesundheit Österreich GmbH (GÖG), Austria; <sup>2</sup>Slovak Medicines Agency

**Problem statement:** There is poor knowledge of pharmaceutical prices of medicines used in the hospital setting. The treatment in the inpatient sector, however, has consequences for choice of medicines in the outpatient sector.

**Objectives:** To investigate the prices of medicines used in hospitals and to compare them to the outpatient sector

**Design:** Price survey for a selected number of medicines (12 active ingredients), including four cancer medicines and one orphan medicine; original price collection in hospitals, accompanied by qualitative interviews with hospital pharmacists; access to official outpatient prices (countrywide) via the PPI (Pharma Price Information) service run by GÖG

**Setting and population:** A total of 25 hospitals (all public hospitals—24 general hospitals and 1 specialised hospital) in five European countries (Austria, the Netherlands, Norway, Portugal, and Slovakia)

**Intervention:** The price survey and comparison was performed during the period from September 2009 to February 2010, asking for prices as of end of September 2009. A price template was developed for the collection of the prices. In hospitals, both the official hospital price as well as the actual hospital price (i.e., taking discounts and rebates into consideration) were gathered. The pharmacy retail prices were defined as reference in the outpatient sector.

**Outcome measure(s):** Availability of price data for the hospital setting and outpatient sector; cross-country comparison of actual hospital prices; differences between the average hospital list prices and actual hospital prices; comparisons between hospital prices (official and actual) and outpatient prices

**Results:** For some of the selected products actual hospital prices were lower compared to the official hospital list prices and the outpatient prices. Discounts and rebates were observed to be granted, in some cases up to 100% (i.e., cost-free medicines). For the four oncology medicines selected, however, in all cases the actual hospital prices were equal to the official hospital list prices, which corresponded to the outpatient prices.

**Conclusions:** The price reduction granted to hospitals, which eventually leads to a lower price compared to the outpatient sector, depends on the therapeutic class. When only one on-patent product is available (such as for the cancer medicines of the survey), price reductions are less likely. Price reductions, including cost-free medicines, are granted for products that are of strategic relevance for manufacturers (i.e. medicines that are to be continued in the outpatient treatment, e.g., cardiovascular medicines).

**Funding source(s):** European Commission, Executive Agency for Health and Consumers (EAHC); Austrian Federal Ministry of Health

**395**

### **HIV/AIDS and TB**

*Keywords:* Tuberculosis, Inequities, Access, Gender, Action Research

#### **Balancing Gender-Based Inequities to Improve Access and Uptake of TB Treatment**

**Sadique Bhanbhro<sup>1</sup>, Rafiq Wassan<sup>2</sup>, Sayed Sada Shah<sup>3</sup>**

<sup>1</sup>Mehran Research & Development Society, Pakistan; <sup>2</sup>University of Sindh Jamshoro Sindh Pakistan; <sup>3</sup>Mehran Research & Development Society, Pakistan

**Problem statement:** Pakistan ranks 8th on the list of 22 high-burden TB countries in the world, according to the WHO Global Tuberculosis Control 2009. In 2007, an estimated 297,108 people in Pakistan (primarily adults in their productive years) developed TB. The emergence of multidrug-resistant (MDR) TB and TB-HIV co-infection is a growing concern in

the country. Inequities in access to TB treatment are rampant, and place-of-residence and gender-based disparities are deteriorating day by day. A participatory and holistic approach required to address these disparities.

**Objectives:** To identify and analyse inequities in access to TB treatment; to mobilise the community to address existing difference to access TB medicine; to improve access and uptake of TB treatment to rural women by raising awareness of TB and availability of TB treatment through participatory action research activities

**Design:** A participatory action research (PAR) approach, which focuses on research whose purpose is to enable action, was employed. Action is achieved through a reflective cycle, whereby participants collect and analyse data, then determine what action should follow. Social mapping and an illness matrix were used along with key informant interviews. The participants were engaged in monthly participatory sessions for six months, in which role play, workload exercises, and flow diagrams were carried out. Information sheets and pamphlets were distributed.

**Setting:** A rural union council (the smallest administrative unit of district government) of district Hyderabad Sindh Pakistan

**Study population:** A purposive sample of 286 male (n=155) and female (n=131) community members between 18 and 60 years of age were selected on the basis of a simple selection criteria: someone who has diagnosed TB and any one in his or her family with diagnosed or suspected TB.

**Outcome measure(s):** Number of women who received treatment after PAR activities; number of new female TB patients completing treatment (before and after initiative); number of female patients with correct knowledge of treatment duration and importance of adherence; and whether TB was added as key topic in the council meetings and monthly meetings of partnership

**Results:** We found an improvement in female patients' diagnoses and treatment; for example, 65 out of 131 (49.6%) new female patients received TB treatment as compared to 46 out of 155 (29.7%) male patients. There was increased community awareness about TB diagnostic centre and seeking treatment process and centre locations; for example, after intervention, a random sample of 150 out of 286 (52.4%) male and female community members across the villages of targeted Union Council correctly identified treatment duration, location of diagnostic laboratory and treatment centre, and significance of adherence to treatment. At Union Council level, a multi-stakeholders committee of councillors under leadership of deputy mayor was established that will work on health issues mainly TB and hepatitis.

**Conclusions:** For sustainable improvement in TB prevention and control, a system-based holistic approach is needed. Such an approach embeds the best practices and drives cultural change. The study suggested that the overall approach be integrated in existing system such as through the lady health workers, the population welfare workers, the lady health visitors, the local councillors, and community-based organisations.

**Funding source(s):** Union Council Moosa Khatyan and Mehran Research and Development Society

### 397

#### **Economics, Financing, and Insurance Systems**

*Keywords:* Country profiles, medicines financing, medicines coverage, medicines access, medicines policy.

#### **Comparative Analysis of the Medicines Financing System of 11 Countries Included in the Pilot of the "WHO Country Profiles" Project**

**Pooya Parsi<sup>1</sup>, Enrico Cinnella<sup>2</sup>, Aukje Mantel-Teeuwisse<sup>1</sup>, Richard Laing<sup>2</sup>, Gilles Forte<sup>2</sup>**

<sup>1</sup>Utrecht University Collaborating Centre for Pharmacoepidemiology & Pharmaceutical Policy Analysis; <sup>2</sup>World Health Organization, department of Essential Medicines and Pharmaceutical Policies

**Problem statement:** Although considerable information may exist about national pharmaceutical systems and medicines financing, this information is often not accessible.

**Objective:** To collect information on medicines financing in 11 countries and compare situations in different countries

**Design:** This study was conducted through secondary analysis of national data submitted to WHO as part of the Pharmaceutical Country Profiles project. The data were analysed in relation to medicines coverage and exemptions, patient fees and copayments, pricing regulation for the private sector, prices, availability and affordability, medicine price components and affordability, and duties and taxes on pharmaceuticals.

**Setting:** Comparisons of the country data were made directly between the countries on the basis of WB income level group and by WHO regions. If indicators matched, comparisons were also made between the WHO Level I 2007 survey and the 2010 Country Profile data.

**Study population:** The countries included in the study were Argentina, Armenia, Austria, China, Kenya, Maldives, Nigeria, Pakistan, Sri Lanka, Sudan, and Suriname.

**Outcome measure(s) and results:** The free coverage of HIV/AIDS medicines had increased in every region (3–17% absolute increase) compared to the WHO Level I of 2007. Free medicines coverage for pregnant woman, however, decreased (17–38%) since 2007, with the EURO region being the exception where it increased. Public health insurance coverage of medicines did not exist in low-income countries and the AFRO region. Dispensing fees were charged more frequently than consultation fees in the lower-middle and upper-middle income countries (15–50%), whereas the frequency was equal for other income level countries. The AFRO countries surveyed did not have any legal pricing regulations, whereas 50% of the AMRO, EURO, and SEARO countries, and 100% of the EMRO and WPRO countries did have these regulations. Low-income countries did not have legal pricing regulations. If legal pricing regulations existed, this was at the manufacturer, wholesaler, and retailer level. Private sector prices were generally higher than the public sector prices [originator Median Price Ratio (MPR) difference: 7.2–14.5; generic MPR difference: 0.3–9.65]. The only exception was China, where the private sector provided cheaper generics than the public sector (MPR of 1.14 vs.

1.48). In Jordan only, the public patient prices for generics were lower than the International Reference Price (MPR: 0.85); the private patient prices for generics, however, were the highest (MPR: 10.5) among the pilot countries. Nigeria was the only country where the procurement price of generics was higher than the IRP (3.29). There were no duties on pharmaceuticals in the low-income countries surveyed.

Conclusion: It is possible to collect comparative information on medicine financing and pricing from secondary country data included in the country reports.

Funding source(s): Information not provided

#### 400

##### **Economics, Financing, and Insurance Systems**

*Keywords:* network, pharmaceutical policy, country report, pricing, reimbursement

##### **Policy Making Support by Sharing of Information and Experiences among the PPRI Network**

---

**Sabine Vogler<sup>1</sup>, Claudia Habi<sup>1</sup>, Kees de Joncheere<sup>2</sup>, Christine Leopold<sup>1</sup>, Nina Zimmermann<sup>1</sup>**

<sup>1</sup>Gesundheit Österreich GmbH (GÖG), Austria; <sup>2</sup>WHO Regional Office for Europe

Problem statement: There has been growing need and interest in networking on pharmaceutical pricing and reimbursement (P+R) by policy makers. Representatives of European public authorities have asked for both systematic information collection as well as quick answers to ad-hoc queries.

Objectives: To establish and maintain an active and sustainable network for sharing information, best practice, and expertise in pharmaceutical P+R policies; to develop and refine tools and mechanisms to survey, analyse, compare, and benchmark updated pharmaceutical P+R information

Design: Networking initiative complemented by technical work—from 2005 to 2007 in the framework of an EU-funded project and from 2008 on as a member states-driven action

Setting and study population: Network of 38, mostly European, countries; institutions—national competent authorities for pharmaceutical pricing and reimbursement, European and international institutions (i.e., WHO, European Commission services, OECD, World Bank)

Interventions: In total 11 PPRI meetings, with presentations and discussions of policy experience in the host countries, interactive sessions for feedback on documents and needs assessment

Outcome measure(s): Two evaluation surveys in the course of the EU project covering project-relevant indicators such as use of glossary, relevance of reporting template, and meeting information needs

Results: Since its start in 2005, PPRI has produced a range of deliverables, which provide country-specific and cross-country information and have served as basis for decision making on pharmaceutical policies. These include 23 published country reports (PPRI Pharma Profiles), a comparative analysis of P+R information of 27 countries, glossary of key P+R terms, a list of P+R indicators, and around 40–50 ad-hoc queries of pharmaceutical prices and policy experiences per year. The information in the profiles has helped countries in the redesign and implementation of national legislation and policy measures. The ad-hoc queries have supported countries in resolving specific P+R issues at national level.

Conclusions: PPRI has proven to be a growing and active network as well as a sustainable action that has continued after the end of the EU project as a voluntary initiative borne by the network members. The initiative has met needs on information on other countries. Moreover PPRI, which is based on common understanding and trust among its members, offers a platform for open dialogue about the benefits and limitations of policy options as well as for information sharing of experiences in the practical implementation of measures. Network members have regularly expressed a need for the continuation of the initiative. Besides informal information sharing, further and more in-depth analyses are required.

Funding source(s): Austrian Federal Ministry of Health; European Commission, Health and Consumer Directorate-General

#### 404

##### **Child Health**

*Keywords:* access, medicines, children, Local Manufacture.

##### **Assessing Local Manufacturing Capacity for Child-Specific Dosage Formulations: The Case of Ghana**

---

**Edith Aşaabah Annan<sup>1</sup>, Martha Gyansa- Lutterodt<sup>2</sup>, Kwesi Poku Boateng<sup>3</sup>, Brian Adu Asare<sup>2</sup>, Augustina Koduah<sup>2</sup>**

<sup>1</sup>World Health Organization, Ghana; <sup>2</sup>Ministry of Health; <sup>3</sup>Independent Consultant

Problem statement: Reducing child mortality is a global priority expressed in the Millennium Development Goals. Interventions to achieve these goals include the availability of essential medicines for children. In Ghana, infant and under-five mortality rates are estimated at 50 and 80, respectively. Most of these deaths are caused by childhood diseases such as malaria, pneumonia, – diarrhea and neonatal sepsis, which could be averted by the use of safe paediatric formulations of medicines. An assessment was, therefore, undertaken under the Better Medicines for Children's Project to determine the technical capacity of some local pharmaceutical manufacturers to produce a selected list of paediatric dosage formulations.

Objectives: To conduct a situation analysis of the domestic production of medicines made specifically for children

Design: Cross-sectional study using qualitative methods.

Setting: The study was conducted at the national level and was based on local manufacturers' institutions, which were all privately owned.

Study population: The study identified a convenient sample of 22 out of 34 local manufacturers across the country from a database of the Pharmaceutical Manufacturers Association of Ghana. Informed consent was sought from the local manufacturers to be part of the study.

Intervention(s): Data were collected through visits to the selected pharmaceutical manufacturers for key informant interviews. A standardized questionnaire was used to collect background information on the manufacturer, manufacturing and starting materials, and the potential for the manufacturer to produce additional paediatric dosage forms as per a list of target medicines to be used for children.

Outcome measure(s): A mapping of domestic manufacturers in Ghana producing a target list of 26 paediatric medicines

Results: The local manufacturer in Ghana was found to have the capacity to produce medicines containing 20 out of the 26 active pharmaceutical ingredients on the list of dosage forms targeted. It was found that only 27% of the target medicines are produced locally in the required dosage form and strength.

Conclusions: Local manufacturing facilities in Ghana have the capacity to produce medicines in most of the therapeutic categories of the target paediatric medicines. If the potential to produce a majority of the target medicines locally is to be realized, then constraints with regards to equipment, regulatory and international cGMP, low investment in research and development, limited capacity to produce some paediatric dosage forms, and procurement of raw materials from reliable sources need to be addressed.

Funding source(s): Bill and Melinda Gates Foundation

405

#### Policy, Regulation, and Governance

Keywords: drug utilization, information technology, rational drug use, management information system, appropriate use

#### Management Information System in Promoting Rational Drug Use in Iran

**Fatemeh Soleymani<sup>1,2</sup>, Ahmad Fayaz-Bakhsh<sup>1</sup>**

<sup>1</sup>Tehran University of Medical Sciences, Iran, Islamic Republic of; <sup>2</sup>Ministry of Health, Iran, Islamic Republic of

Problem statement: Rational drug use cannot be identified without a method of measurement and a reference standard. These same tools are even more necessary to measure the impact of an intervention; to make comparisons among physicians, districts, or regions; and for supervision purposes. Over the past few years, the International Network for Rational Use of Drug (INRUD) and the WHO Action Program on Essential Drugs have closely collaborated in developing countries to test a set of 5 prescribing indicators to measure some key aspects of prescribing. Collecting the prescriptions data and analyzing them is one way for measuring the above indicators. In Iran, NCRUD (National Committee of Rational Use of Drug) and local committees affiliated to 42 universities of medical sciences were established by Food and Drug Administration of Ministry of Health (MOH) in 1996 throughout the country to implement and promote rational drug use in Iran.

Objective: To collect data on prescribing patterns in Iran and to analyze the data for evidence of irrational use of drugs

Method: To look at the of physicians' prescription patterns, the subcommittee of Computer and Data Analysis of NCRUD was formed to initiate and develop a data warehouse and application software. The intended outcome of such efforts was to gather and analyze prescription data for measuring RUD indicators and strategies to promote rational drug use. After development, the data warehouse, called "Noskhehpardaz (RX Analyzer)," was tested for its validity and reliability in a pilot study in Mashhad University of Medical Sciences in 1996. Currently, the software is in use by universities of medical sciences and health services all over the country

Result: More than 200 million prescriptions, equaling about to 70% of all prescriptions in the country and indicating a good spread in all parts of the country, were collected nationally and analyzed by RX Analyzer software.

Conclusion: NCRUD has 14 years experience in collecting and data analyzing of physicians prescriptions at both national and local levels. In the early years, it was important to inform policy makers about the nation's drug use patterns and to indicate and highlight the gravity of problems in key areas. In the next step, different types of interventions were implemented to improve rationality in drug use. More recently it has been necessary to look at the impact of those interventions on the formation of emerging patterns in drug use. Availability of information on prescriptions seems to have facilitated audit and feedback. It is therefore recommended that decision makers continue to place a greater value on the database in evaluating the impact of interventions.

Funding source(s): This study is the outcome of an in-house non-financially supported study.

406

#### Drug Resistance

Keywords: antimicrobials, drug resistance, surveillance

#### Can the Application of the International Health Regulations to Antimicrobial Resistance Events Help to Preserve Antimicrobials?

**Thomas Haustein, Didier Wernli, John Conly, Stephan Harbarth**

Geneva University Hospitals, Switzerland

**Problem statement:** The public health threat of antimicrobial resistance (AMR) needs to be addressed urgently. In the last decade, challenging multi-resistant bacteria have expanded in the absence of any tangible new antimicrobial drug development or global containment action. Surveillance of AMR pathogens is patchy and limited by financial and technical constraints in large parts of the world. Without a global early warning system, the emergence and spread of AMR often remains unnoticed until a given strain has become endemic.

**Objective:** The International Health Regulations (IHR), a legally binding agreement between 194 States Parties, whose aim is “to prevent, protect against, control and provide a public health response the international spread of disease...” deserve critical examination with regard to their applicability to AMR.

**Methods:** Using the example of carbapenem-resistant Enterobacteriaceae (CRE) as point of departure, we analyze and discuss the potential role of the IHR with respect to AMR. To do so, we assess whether selected CRE events fulfill the four criteria: (1) Is the public health impact of the event serious? (2) Is the event unusual or unexpected? (3) Is there any significant risk of international spread? (4) Is there any significant risk of international travel or trade restrictions? of Annex 2 of the IHR.

**Results:** We argue that many events marking the emergence and international spread of KPC and NDM-1-producing CRE can be considered to fulfill most Annex 2 criteria and WHO should, therefore, be notified. This argument can easily be extrapolated to other types of AMR (and has, in fact, been made for XDR-TB). “New or emerging antibiotic resistance” is one of the examples listed in Annex 2 for application of the first criterion. Still, due to ambiguities in Annex 2 and limited specific WHO guidance, some may counter that CRE (and other AMR) events are irrelevant to the IHR. The final obstacles are a lack of expertise and capacities within WHO. Although WHO vertical programs have successfully focused on drug resistance in selected areas, including malaria and tuberculosis, WHO arguably does not have the means to comply with its IHR mandate of offering assistance to States Parties affected by the spread of multi-resistant bacteria.

**Conclusions:** The global threat posed by the spread of AMR cannot be addressed by individual countries alone, but requires a coordinated international response. Recognizing the applicability of the IHR to AMR will serve as a wake-up call and obligate WHO and States Parties to strengthen surveillance and response, which could in turn contribute to containing the spread of AMR and preserving the efficacy of antimicrobials. Although States Parties and WHO share a collective responsibility in the process, WHO must clearly delineate its position with regard to AMR and the intended role of the IHR in this context.

**Funding source(s):** None

**407**

**Child Health**

*Keywords:* drug utilization, pediatric medicines, pharmacoepidemiology

### **Medicine Use from Birth to Two Years of Age: The 2004 Pelotas (Brazil) Birth Cohort Study**

**Edilson Almeida Oliveira<sup>1</sup>, Marlos Rodrigues Domingues<sup>2</sup>, Iná S Santos<sup>2</sup>, Aluísio J D Barros<sup>2</sup>, Andréa Dâmaso Bertoldi<sup>2</sup>**

<sup>1</sup>Universidade do Vale do Rio dos Sinos; <sup>2</sup>Universidade Federal de Pelotas, Brazil

**Problem statement:** According to data from the World Health Organization (WHO), over 50% of medicines are improperly prescribed or sold, approximately one-third of the population do not have access to essential medicines, and 50% of patients do not take their medicines correctly. International studies indicate that medicine use is high during childhood, especially among children younger than age two years. WHO restricts the use and indication of a number of medicines widely in use by Brazilian children.

**Objective:** To describe medicine use by children at 3, 12 and 24 months of age

**Methods:** We used a prospective birth cohort study in southern Brazil using cross-sectional data collected at the mean ages of 3 months (N=3,985), 12 months (N=3,907), and 24 months (N=3,868). The outcome variable was medicine use in the 15 days prior to the interview, irrespective of reason, indication, or therapeutic group. In all visits, we asked mothers whether the child had received any medicines in the last 15 days. We then asked for the names of the medicines used and for the packages and prescriptions if available. Information on independent variables (e.g., who indicated the medicine, how it was obtained, periodicity of use, and therapeutic group) were collected using a standardized questionnaire administered during a home interview with the child's parents.

**Results:** Prevalence of medicine use at 3, 12, and 24 months were 65.0% (95% CI: 63.5; 66.5), 64.4% (95% CI: 62.9; 65.9), and 54.7% (95% CI: 53.1; 56.2), respectively. As age increased, there was a reduction in the total number of medicines used and an increase in self-medication, which reached 34% at 24 months. Furthermore, frequency of sporadic medicine use increased, whereas that of continuous use decreased. Medicines were purchased mainly using private resources, with roughly 10% of drugs being purchased through the Brazilian National Health Care System. The profile of medicine types used also changed with age. The type of medicine most frequently used were dermatological products (36%) at 3 months; respiratory system drugs (24%) at 12 months; and analgesics (26%) at 24 months of age. Compared to use at 3 months, medicine use at 24 months was characterized by decreased use of digestive tract and metabolism drugs, drugs for the sensory organs, cardiovascular system drugs, and dermatological products, and an increase in systemic anti-infectious drugs, medicine for the skeletomuscular and respiratory systems, analgesics, insecticides, and repellents.

**Conclusions:** The high prevalence of medicine use among children indicates a need for promoting rational use (i.e., use that takes into account cost-benefit relationships) in this age group. Knowledge of the profile of medicine use in a

population-based study of longitudinal design may contribute to the establishment of public policies in this area, aimed at ensuring access to necessary medicines and reducing inappropriate usage.

Funding source(s): World Health Organization, the National Council for Scientific and Technologic Development, the Fundação Nacional de Saúde, and the Pastoral da Criança.

408

#### Child Health

*Keywords:* drug utilization, pediatric medicines, pharmacoepidemiology

### Factors Associated to Medicine Use Among Children from the 2004 Pelotas Birth Cohort (Brazil)

**Edilson Almeida Oliveira<sup>1</sup>, Marlos Rodrigues Domingues<sup>2</sup>, Alicia Matijasevich Manitto<sup>2</sup>, Iná S Santos<sup>2</sup>, Aluisio J D Barros<sup>2</sup>, Andréa Dâmaso Bertoldi<sup>2</sup>**

<sup>1</sup>Universidade do Vale do Rio dos Sinos; <sup>2</sup>Universidade Federal de Pelotas, Brazil

**Problem statement:** Medicine use is reaching high levels in both developed and developing countries. In Brazil, although the population has problems in accessing medicines, use is high in all age brackets. Various factors contribute to this situation, including difficulty in access to health services, lack of adequate pharmacovigilance, unrestricted sale of medicines in pharmacies and drugstores, and current society's steadfast belief in the power of medicines. Since adolescence is a phase of new sensations and experiences, it is considered a risk period for the use of substances, including medicines, and the possible harm related to such use. In Brazil, epidemiological surveys on the use of licit and illicit psychoactive substances have identified medicines (e.g., anabolic steroids and amphetamines), next to alcohol and tobacco, as one of the most frequent substance abuse groups in adolescents.

**Objectives:** To investigate medicine use and associated factors in adolescents; to identify the main pharmacological groups used; to study the reasons for the use of medicines; and to evaluate the source of prescription

**Methods:** We used a prospective study including 4,452 adolescents born in Pelotas, Brazil in 1993, representing 87.5% of the original cohort. We selected variables from the perinatal study and interviews with mothers and adolescents that could be considered possible individual determinants of medicine use. We also described the most widely used pharmacological groups, reasons for use, and origin of the prescription. Statistical significance was evaluated using the chi-square tests for heterogeneity or linear trend in the unadjusted analysis and using Poisson regression in the adjusted analysis.

**Results:** The overall prevalence of medicine use by the adolescents was 30.9%; out of these, 64.7% were prescribed by a physician. The most frequently used pharmacological groups were medicines for the nervous system (35.9%), respiratory system (25.7%), and systemic antibiotics (10.3%). Medicine use was directly associated with socioeconomic status, maternal schooling, and maternal health problems during pregnancy or soon after delivery, resulting in the need of intensive health care. Adolescents who were thin or fat were more likely to use medicines in comparison to those with normal body mass index. A direct association was observed between maternal use of hypnotic drugs and sedatives and adolescent medicine use.

**Conclusions:** Drugs acting on the nervous system were the most widely used group, and analgesics were the most frequent among these. In the current study, about one-third of analgesics had been prescribed by a physician, and although analgesics are relatively safe medicines in this age bracket, chronic use and abuse should be avoided. The results reinforce the family's important role, particularly the mother's, on medicine use among adolescents. Although the prevalence of medicine use in adolescence is lower than in other age groups, it is during this life phase that use begins to increase until adulthood, thus highlighting the extreme importance of educational measures to raise awareness on the risks of improper use such as self-medication and use of medicines for non-therapeutic purposes.

**Funding source(s):** The cohort study is supported by the Wellcome Trust. The initial phases of the cohort were funded by the European Union and the Brazilian National Program for Centers of Excellence, National Research Council, and the Ministry of Health.

409

#### Child Health

*Keywords:* drug utilization, pediatric medicines, pharmacoepidemiology, self-medication

### Medicine Utilization in Adolescents Aged 11 from the Pelotas (Brazil) 1993 Birth Cohort Study

**Andréa Dâmaso Bertoldi<sup>1</sup>, Noemia U L Tavares<sup>2</sup>, Pedro C Hallal<sup>1</sup>, Cora Luiza Araújo<sup>1</sup>, Ana M B Menezes<sup>1</sup>**

<sup>1</sup>Universidade Federal de Pelotas, Brazil; <sup>2</sup>Universidade da Região da Campanha, Brazil

**Problem statement:** Medicine use is reaching high levels in both developed and developing countries. In Brazil, although the population has problems in accessing medicines, use is high in all age brackets. Various factors contribute to this situation, including difficulty in access to health services, lack of adequate pharmacovigilance, unrestricted sale of medicines in pharmacies and drugstores, and current society's steadfast belief in the power of medicines. Since adolescence is a phase of new sensations and experiences, it is considered a risk period for the use of substances, including medicines, and the possible harm related to such use. In Brazil, epidemiological surveys on the use of licit and illicit psychoactive substances have identified medicines (e.g., anabolic steroids and amphetamines), next to alcohol and tobacco, as one of the most frequent substance abuse groups in adolescents.

**Objectives:** To investigate medicine use and associated factors in adolescents; to identify the main pharmacological groups used; to study the reasons for the use of medicines; and to evaluate the source of prescription

**Methods:** We used a prospective study including 4,452 adolescents born in Pelotas, Brazil in 1993, representing 87.5% of the original cohort. We selected variables from the perinatal study and interviews with mothers and adolescents that could be considered possible individual determinants of medicine use. We also described the most widely used pharmacological groups, reasons for use, and origin of the prescription. Statistical significance was evaluated using the chi-square tests for heterogeneity or linear trend in the unadjusted analysis and using Poisson regression in the adjusted analysis.

**Results:** The overall prevalence of medicine use by the adolescents was 30.9%; out of these, 64.7% were prescribed by a physician. The most frequently used pharmacological groups were medicines for the nervous system (35.9%), respiratory system (25.7%), and systemic antibiotics (10.3%). Medicine use was directly associated with socioeconomic status, maternal schooling, and maternal health problems during pregnancy or soon after delivery, resulting in the need of intensive health care. Adolescents who were thin or fat were more likely to use medicines in comparison to those with normal body mass index. A direct association was observed between maternal use of hypnotic drugs and sedatives and adolescent medicine use.

**Conclusions:** Drugs acting on the nervous system were the most widely used group, and analgesics were the most frequent among these. In the current study, about one-third of analgesics had been prescribed by a physician, and although analgesics are relatively safe medicines in this age bracket, chronic use and abuse should be avoided. The results reinforce the family's important role, particularly the mother's, on medicine use among adolescents. Although the prevalence of medicine use in adolescence is lower than in other age groups, it is during this life phase that use begins to increase until adulthood, thus highlighting the extreme importance of educational measures to raise awareness on the risks of improper use such as self-medication and use of medicines for non-therapeutic purposes.

**Funding source(s):** The cohort study is supported by the Wellcome Trust. The initial phases of the cohort were funded by the European Union and the Brazilian National Program for Centers of Excellence (PRONEX), National Research Council (CNPq), and Ministry of Health.

411

#### **Policy, Regulation, and Governance**

*Keywords:* DTCA, pharmaceuticals, gender, Jordan

### **Direct-to-Consumer Advertising for Pharmaceuticals in Jordan from a Gender Perspective**

---

**Hadeel Ashour, Ibrahim Ali Alabbadi**

University of Jordan, Jordan

**Problem statement:** Although the Jordanian Drug and Pharmacy Law prohibits promotion of medicines directly to public for either over-the-counter drugs or prescription-only drugs, consumers in Jordan are directly exposed to the pharmaceutical advertising in different ways. Both patients and physicians agreed that the most drug classes being advertised directly to consumers are vitamins whereas drugs used to treat mental illness are the least advertised. Unexpectedly, the 10 top drug classes (out of 31 investigated) found to be advertised directly to consumers in Jordan were prescription-only drugs such as antibiotics and diabetes drugs.

**Objective:** To investigate to which extent direct-to-consumer advertising (DTCA) for pharmaceuticals is disseminated—if present—in Jordan and to identify gender differences in this regard

**Methods:** The study was conducted on two samples: the first represents the patients (drug consumers) coming to the Jordan University Hospital and the second represents the physicians working there (the prescribers). Two questionnaires were designed. The first was distributed to (550) male and female patients, and consequently, based on its results, a second questionnaire was designed and distributed to (200) male and female physicians. The response rates were high (513 and 144, respectively).

**Results:** Although the results revealed no gender differences toward pharmaceutical DTCA (i.e., no significant statistical differences were found:  $\alpha \geq 0.05$  and in the tools used for pharmaceutical DTCA:  $\alpha \geq 0.05$ ), the results showed a gender gap in the most targeted group exposed to pharmaceutical DTCA. Approximately 45% agreed that women are more likely to be targeted by DTCA than men. Only 2% believed that men are more likely to be targeted by DTCA than women.

**Conclusion:** We concluded that the prohibition of pharmaceutical DTCA did not prevent Jordanians to be exposed to pharmaceutical DTCA.

**Funding source(s):** No information provided

413

#### **Policy, Regulation, and Governance**

*Keywords:* Joint procurement, pharmaceuticals, Jordan, public sector

### **Cost Impact of Purchasing Pharmaceuticals Jointly in the Public Health Sector in Jordan**

---

**Ibrahim Ali Alabbadi**

University of Jordan, Jordan

**Problem statement:** The pharmaceutical sector in Jordan is considered a high priority to be examined by the government because it represents almost 35% of health spending. Double purchase is still considered a major problem that has led to higher spending and poor availability of medicines. The Joint Procurement Directorate (JPD) was established in Jordan in 2004, and the first joint tender was issued in 2007.

**Objective:** To investigate the cost impact of purchasing medicines jointly by the JPD

**Methods:** Medicine lists of purchased quantities and their tender-winning prices were obtained for 2006 and 2007. Defined daily dose (DDD) was used for comparing the costs of purchased drugs in 2006 and 2007 by converting actually purchased quantities into DDDs for each dosage form for each product for 2006 and 2007. Having DDDs for all dosage forms, estimated cost savings were calculated for each product assuming that same quantities purchased by each participating party in 2006 will be purchased through the JPD in 2007.

**Results:** Estimated savings achieved were 5.2%, which could increase to 17% after excluding one item that had had an unusual raw material price increase due to an international shortage.

**Conclusions:** Purchasing pharmaceuticals through JPD is recommended to reduce spending and improve availability.

**Funding source(s):** No information provided

**414**

#### **Economics, Financing, and Insurance Systems**

*Keywords:* price, generic, originator, UK, Jordan

### **A Comparison of Generic and Originator Brand Drug Prices between Jordan and the United Kingdom**

**Faris El-Dahiyat, Reem Kayyali, Ibrahim Ali Alabbadi**

University of Jordan, Jordan

**Problem statement:** When a pharmaceutical patent expires, generic companies may enter the market and start selling copies of the original drug. Because generic drugs contain exactly the same active ingredients, they are certified to be perfect substitutes to the originator branded drugs. In competitive markets, entry of generics would trigger fierce price competition, hence decreasing the monopoly enjoyed by the original patent holder.

**Objective:** To compare the retail prices of five generic and originator brand drugs between Jordan and the United Kingdom (UK); to investigate the relation between number of generics available, the retail price of originator and generic(s), and the effect of time in the market on these prices

**Methods:** Prices of originators and generics and the number of generics available in each market were obtained from the Jordanian Food and Drug Administration, Royal Pharmaceutical Society of Great Britain, British National Formulary, and the Chemist and Druggist generics lists. The prices were converted to British pounds expressed per one-dose unit. All data were tabulated in spreadsheets; prices were compared between the two countries at different preset times.

**Results:** The generics of all drugs investigated appeared in the Jordanian market before patent expiry of their originator worldwide due to lack of patency regulations in Jordan at the launch time of the drugs under investigation (before 2004). Unlike in the UK, the prices of originator drugs in Jordan did not change when the first generic was introduced to the market. The prices of generic drugs dropped dramatically in the UK (by approximately by 90%) at the time of the first generic launch compared to 15% in Jordan. There was no apparent correlation between the numbers of generics available or the number of years of the first generic being on the market and the prices of the drugs investigated in both countries. The current prices of all investigated drugs in Jordan are higher than in the UK, particularly for the generics.

**Conclusion:** Although Jordan has a much lower per capita income, generic drugs are more expensive than the equivalent drugs in the UK.

**Funding source(s):** No information provided

**415**

#### **Policy, Regulation, and Governance**

*Keywords:* DDD, Joint procurement department, Assessment, Jordan, Public health sector

### **One-Year Assessment of Joint Pharmaceutical Procurement in the Jordanian Public Health Sector**

**Ibrahim Ali Alabbadi, Abdelraouf Qawwas, Mahmoud Jaafreh, Taher Abosamen, Maisa Saket**

University of Jordan, Jordan

**Problem statement:** Jordan is one of the fastest growing and modernizing countries in the Middle East. Small in size with a total population of 6 million, it is classified as a lower middle income country. The GDP growth rate in Jordan increased from 3.3% in 2002 to 7.6% in 2006. About 10% of the Jordanian GDP is spent on health, and almost one-third of this amount is spent on pharmaceuticals. The public health sector in Jordan has four main governmental parties that purchase medicines independently. Double purchasing is still considered a major problem that has led to increased spending on drugs and poor availability of medicines. The Joint Procurement Directorate (JPD) was established in Jordan in 2004, and the first tender was issued in 2007 accounting for 15% of the annual pharmaceutical tender.

**Objectives:** To assess the first year of purchasing of pharmaceuticals in the public health sector in Jordan through JPD for the four participating parties compared with their independent purchasing before

**Methods:** A research committee was constituted. The committee revised the lists of purchased quantities of pharmaceuticals and obtained their tender-winning prices for 2006 (from each participating party) and for 2007 (from JPD). A quantity comparison method was used to compare the costs of purchased drugs in 2006 and 2007, and estimated cost savings were calculated for each product for each party for 2006 and 2007, assuming that the same quantities purchased by each participating party in 2006 would be purchased through the JPD (prices of 2007).

Results: The estimated savings achieved were 2.4%, which could increase to 8.9 % after excluding one item in which its raw material prices were increased markedly in 2007 than in 2006 due to an international shortage.

Conclusions: Applying a joint procurement system for pharmaceuticals in the Jordan public health sector has good potential to reduce waste and decrease the negative impact of double purchasing.

Funding source(s): No information provided

416

#### Child Health

Keywords: Clinical guidelines, hospital, performance assessment, quality assurance,

### An Audit of Case Management of Common Childhood Illnesses in Hospitals in Ghana

**Mary Nana Ama Brantuo<sup>1</sup>, Cynthia Bannerman<sup>2</sup>, Isabella Sagoe-Moses<sup>2</sup>, Martha Gyansa-Lutterodt<sup>3</sup>, Edith Andrews-Annan<sup>1</sup>**

<sup>1</sup>World Health Organisation, Ghana; <sup>2</sup>Ghana Health Service; <sup>3</sup>Ministry of Health, Ghana

Problem statement: Poor-quality care for sick children in peripheral hospitals contributes to deaths in the under-five age group. As part of the effort to improve the quality of care for sick children, the Ghana Ministry of Health plans to adapt the WHO pocket book, Hospital Care for Children, to serve as the national standard for managing childhood illness in hospitals. Therefore an audit was required to assess the current practices and services against the set standards, to provide the basis for actions to align practices with the recommended standards.

Objectives: To compare the case management of children in selected hospitals in Ghana against the minimum standards set by WHO

Design: This was a cross-sectional observational survey, comparing existing practices with set standards.

Setting: The assessment was conducted in 5 of 10 regions in Ghana to reflect the different ecological zones in the country. Ten hospitals were purposively selected to reflect rural vs. urban locations, the different levels (i.e., regional, district, and specialist hospitals), and the ownership of facilities (i.e., public and faith-based organization-owned hospitals).

Study population: The study population was hospitals providing care to children. The management of sick children with fever, cough or difficult breathing, HIV/AIDS, neonatal conditions, and malnutrition was assessed through observation and review of records. In each hospital, case management was assessed by reviewing (where available) at least two cases on the ward. If only one case was available, it was reviewed and case notes of previous cases as well. Where cases or case notes were not available, staff were interviewed on the management practices.

Outcome measure(s): The key outcome measures were case management practices including appropriate diagnosis, treatment, monitoring, and supportive care of children under age five who were being treated for the above-listed conditions.

Results: We found some case management practices that were in accordance with the WHO standards. Patients diagnosed with pneumonia in all 10 facilities were treated appropriately with antibiotics such as ampicillin, gentamicin, and ceftriaxone. Co-trimoxazole prophylaxis for children with HIV was correctly administered in all 10 facilities, and antiretroviral treatment in accordance with national guidelines was used in 8 out of the 10 facilities. Some weaknesses in the case management practices were also observed. Monitoring of intravenous fluid use in patients with diarrhoea was poor in 6 of the 10 facilities, and management of electrolyte imbalances in severely malnourished children was poor in 9 of the 10 facilities. Case management practices were better for children with HIV/AIDS, where protocols were available and staff had been trained on their use, and were poorer for diarrhoea and malnutrition cases because protocols and guidelines were often not available.

Conclusion: The assessment showed a significant gap in the clinical practice as against set standards, thus the need to develop or adapt guidelines for inpatient care of sick children.

Funding source(s): Bill and Melinda Gates Foundation

420

#### Policy, Regulation, and Governance

Keywords: access to medicines, essential drug program, availability, health facilities, medicine supply

### Field Testing WHO's Rational Use of Medicines Rapid Assessment Tool in Grahamstown, South Africa

**Sunitha Chandrasekhar Srinivas<sup>1</sup>, Haresh Jangam<sup>2</sup>, M S Ganachari<sup>2</sup>, Kathleen Holloway<sup>3</sup>, Chris Forshaw<sup>4</sup>**

<sup>1</sup>Rhodes University, South Africa; <sup>2</sup>KLE University, India; <sup>3</sup>SEARO, India; <sup>4</sup>Consultant, South Africa

Problem statement: Irrational use of medicines is a global problem with multiple health system causes. Developing suitable strategies to improve use requires a quick snapshot of the policy framework and health system infrastructure underlying irrational use of medicines. WHO developed a draft Rational Use of Medicines Rapid Assessment Tool (RUMRAT) in January 2010.

Objective: To field test part of the RUMRAT tool to identify its effectiveness in data collection and to assess medicines use in Grahamstown's public sector health care system

Design: Interview and observation-based study

Settings: The study was conducted in six primary health care centres, one community health care centre, and one hospital in Grahamstown's public sector health care system.

Study population: Observations regarding services and the availability of an essential medicines list (EML), standard treatment guideline (STG), and stock records were recorded. Key respondent interviews were conducted with the district pharmacist, Makana local services area, Grahamstown, and with the deputy director for pharmaceutical services, Eastern Cape Province, South Africa.

Intervention: N/A

Outcome measure(s): The effectiveness of the tool in collecting the data and the extent to which rational use of medicines strategies are functional at the district level health care system

Results: The tool enabled collection of data to assess medicines use and policies that have an impact on use in health care facilities. The National Medicines Policy and implementation plan for South Africa were released in 1996 with no updates since. The public sector health care system mainly focuses on medicine procurement and stock management, not medicines use. Respondents indicated that regular inspection for pharmaceutical supply system is lacking although the availability of key basket medicines and medical supplies is 81–100%. As expected, based on the local burden of diseases, vaccines, contraceptives, anti-tubercular medicines, and medicines for chronic conditions such as hypertension, diabetes mellitus, and asthma were at the top of ABC analysis list. Pharmacy assistants at health care facilities highlighted that training on STGs and EML use is negligible. Respondents stated that constant monitoring and evaluation and increased resources are required for rational use of medicines activities.

Conclusion: The RUMRAT is effective in data collection because it is feasible to collect data for all indicators and responses required. The tool can be used at the national and provincial levels to identify the problems in rational use of medicines to plan subsequent interventions. The tool has the advantage of assessing the medicines use and the policy framework that have an impact on medicine use.

Funding source(s): Running costs for this study was supported by Mellon's grant as a part of the Vice Chancellor's discretionary funds by Rhodes University.

421

#### Child Health

Keywords: Children, medicine, prices, availability

### **Assessment of Availability, Price, and Affordability of Medicines for Children In Ghana**

**Martha Gyansa-Lutterodt<sup>1</sup>, Edith Andrews Annan<sup>2</sup>, Augustina Koduah<sup>1</sup>, Brian Adu Asare<sup>1</sup>**

<sup>1</sup>Ministry of Health, Ghana; <sup>2</sup>World Health Organisation

Problem statement: The goal of the Better Medicines for Children project funded by the Bill and Melinda Gates Foundation is to improve access to essential medicines for children by addressing issues of availability, safety, efficacy, and price. A study was undertaken to assess the current country situation concerning the availability and costs of medicines for children as part of project activities.

Objectives: To measure availability and patient price of a selection of paediatric medicines from public, private, and mission sectors in the country; to determine the affordability of medicines for children

Design: Descriptive cross-sectional study using quantitative methods

Setting: The country was stratified into three ecological and economic zones. Data were collected from public, private, and mission health facilities; private retail pharmacies; and licensed chemical shops. Data were also collected from the Central Medical Stores (CMS).

Study population: Convenience and random sampling was used to select urban and rural regions and the dispensing outlets in Greater Accra, Ashanti, and Upper West regions. Fifteen public sector, 30 private sector, and 4 mission sector medicine outlets were surveyed.

Intervention(s): The WHO/HAI method for conducting availability and price surveys was used. Data collectors visited facilities in September 2010 to collect data on availability and price. Data were also collected on government procurement prices. For each medicine, data were collected for the originator brand and lowest priced generic equivalent. Affordability was calculated using the number of day's wages needed for the lowest paid government worker to procure standard treatments for diarrhea, moderate pneumonia, and uncomplicated malaria in children.

Outcome measure(s): Availability, price, and affordability of medicines for children

Results: (1) Mean availability of originator brand and generic medicines in the public sector was 2.7% and 19.3%, respectively. In the private and mission sectors, however, the mean availability of originator brand and generic medicines was 9.0% and 17.4%, respectively, for the private sector and 4.6% and 21.7%, respectively, for the mission sector. (2) Final patient prices for generic medicines in the public sector are 3.35 times their international reference prices. (3) The median price ratio of medicines procured at the CMS is 1.4. (4) Final patient prices for originator brands and lowest priced generics in the private sector are about 11.06 and 3.37 times their international reference prices, respectively. (5) In treating common conditions using standard regimen, the lowest paid government worker would need between 0.2 (diarrhea), 0.9 (moderate pneumonia), and 1.3 (malaria) days' wages to purchase lowest priced generic medicines from the private sector.

Conclusions: Availability, price, and affordability of children's medicines in Ghana should be improved to ensure equity in access to basic medical treatments.

Funding source(s): Bill and Melinda Gates Foundation

423

#### Access

*Keywords:* access to medicine, adherence, community, consumers, prescribing, self-medication.

### **The Rational Use and Access to Medicines by the Citizens: The Greek Experience**

---

**Eleni Jelastopulu<sup>1</sup>, Pania Karnaki<sup>2</sup>, Mamas Theodorou<sup>3</sup>, Aris Sissouras<sup>2</sup>**

<sup>1</sup>Department of Public Health, School of Medicine, University of Patras, Greece; <sup>2</sup>Department of Operational Research and Health Management, University of Patras, Greece; <sup>3</sup>Health Management Programme, Open University of Cyprus, Cyprus

**Problem Statement:** Usually the use of medication is seen through a providers' perspective and less from the perspective of consumers and users. Often, patients exhibit behaviors, which do not conform to prescribed guidelines, leading thus to a low level of compliance.

**Objectives:** The aim of this study was to investigate the use and access to medicines in a representative population sample and to evaluate the rational use of drugs. Furthermore, we studied the effect of various factors, such as socio-demographical and insurance coverage, on drug compliance.

**Design:** The investigation was in the context of a cross-sectional descriptive study (household survey) relating to a wider study on the use of health services by the citizens of a community.

**Setting and study population:** The study was conducted at the local level, involving a random sample of near 2000 citizens in Patras, a major city in Western Greece, where opportunities and access to health care services are high and of good quality (medical school, university hospital, highly qualified medical personnel).

**Outcome Measures:** Measurements referred to the use of drugs in the last three months according to gender, age, insurance fund, drug category, prescription by public or private physician and the tendency of patients to provide themselves with medicines without prescription, a usual phenomenon in Greece.

**Results:** More than 66% had used medication in the past three months, while women showed significantly higher use than men (75% vs 55%,  $p < 0.05$ ). Medication use was higher as age increased and reached more than 80% in the age groups >55 years old ( $p < 0.05$ ). The main drug categories used were pain killers (61%), followed by medication for various heart conditions (29%). Nearly 75% obtained their medication through a doctor's prescription, while 22% did not have a prescription. Except for painkillers, substantial number of antibiotics was consumed which were obtained without a prescription. Respondents without a doctor's prescription followed their own advice for purchasing medication (52%) or the advice of their pharmacist (31%). Information regarding correct use of medicines was provided in 85%, counter effects in 31% and side effects in 30% of cases, respectively. About 11% did interrupt their medication as they experienced health problems. Adherence to medication instructions reached 80%, while women were more compliant than men as were older people compared to younger age groups, respectively ( $p < 0.05$ ). Nearly half of the people who used medication reported they kept left over medicine in their houses. Approximately, 65% of medication costs were partially covered by social funds, while 27% were out of pocket expenses.

**Conclusions:** We observed high use of medication in the last three months. With the exception of prescribed drugs a significant percentage of people purchased prescription medication without consulting their doctor. Information campaigns are needed to educate citizens about rational use of medication and stricter measures need to be taken in order to make it less easy to obtain prescription medication without a doctor's prescription. This is particularly important in the case of antibiotics the use of which is high in Greece.

426

#### Policy, Regulation, and Governance

*Keywords:* academic detailing, prescribing, primary health care, sustainability

### **What Is Needed to Sustain a National Academic Detailing Workforce?**

---

**Lynn Weekes, Gwen Higgins**

**NPS: Better choices better health, Australia**

**Problem statement:** Academic detailing has been shown in several studies to be an effective way to improve prescribing and increase compliance with guidelines. It has also been noted to be a costly and resource-intensive activity. NPS has delivered a national academic detailing program for more than 10 years and has identified and met the challenges of sustaining such a service.

**Objectives:** To describe NPS' experience of what is needed to sustain a successful academic detailing program

**Design:** Descriptive study

**Setting:** Primary care in Australia

**Interventions:** NPS partners with local general practice organisations to deliver a nationally coordinated and locally delivered program to improve the use of medicines. Academic detailers, known as facilitators, are provided with a range of support in order to deliver the program, including initial training in theory and practice of academic detailing; training on specific therapeutic topics; regular peer-support meetings by telephone; program resource materials, both print and on-line via their own website; and advanced training opportunities. Facilitators are required to deliver two programs per year and to reach more than 50% of the general practitioners in their catchment area. Seven full-time staff are employed at NPS to support the 160 members of the facilitator workforce.

**Outcome measure(s):** Number of doctors reached by the program per year; indicators of quality of the detailing service (duration of visits); turnover rates of personnel employed in the detailing workforce

Results: The number of doctors reached by the academic detailing program has steadily increased from 2,364 in 1999–2000 to 11,482 in 2009–10. The average duration of visits is 30 minutes (range 20–80 minutes). Almost half of the facilitators (46%, N=73) have been in the role for more than five years, with 17 having been in the role for more than 10 years.

Conclusions: Academic detailing does require intensive support. When this is provided, the reach of the program, the quality of the visits, the longevity of staff, and hence viability can all be maintained over a long period. The academic detailing visits remain the backbone of the NPS program to improve prescribing in general practice, and this program has repeatedly demonstrated changes in prescribing patterns and reduction of costs to government.

Funding source(s): Australian Government Department of Health and Ageing

**427**

### **Policy, Regulation, and Governance**

*Keywords:* generic medicines, consumers, awareness campaign

#### **Building Confidence in Generic Medicines**

---

**Lynn Weekes**

NPS: Better choices better health, Australia

Problem statement: Generic medicines are an important means of keeping medicine costs affordable in most countries. Uptake of generic medicines can be undermined if prescribers and consumers do not believe they are as effective as branded products.

Objectives: To increase confidence and understanding among consumers about safety and efficacy of generic medicines

Design: National campaign based on social marketing principles with process and impact program evaluation

Setting: Community and primary care

Study population: Consumers over 50 years of age who take medicines, people with chronic conditions, caregivers, and people from culturally and linguistically diverse communities

Interventions: The “Generic Medicines Are an Equal Choice” campaign ran from July 2008 to June 2009. The project included a national awareness campaign comprising television and radio advertising, print editorial, and online resources; consumer and health professional information resources; a peer education program for seniors; a digital strategy including social media; education for pharmacy technicians; and in-language resources for non-English speaking communities.

Outcome measure(s): Consumer awareness of campaign messages and consumer reported confidence in using generic medicines based on pre- and post-campaign telephone surveys of a random selection of the population; proportion of generic medicines prescriptions dispensed based on administrative claims data

Results: The campaign achieved high media reach and good uptake in pharmacy. Pre- and post-campaign national consumer surveys of the target populations found that 43% remembered the campaign message that generic medicines are an equal choice and 22% recalled the message that generic medicines contain the same active ingredient as branded products. At the beginning of the campaign, 72% of consumers said they would use a generic medicine and this rose to 80% after the campaign. Generic medicines rose as a proportion of all drugs dispensed on the Pharmaceutical Benefits Scheme after the campaign.

Conclusions: Mass audience campaigns can support policies to increase prescription and use of generic medicines by targeting perceptions of their quality and effectiveness.

Funding source(s): Australian Government Department of Health and Ageing

**429**

### **Policy, Regulation, and Governance**

*Keywords:* rational use, surveillance, generic (multisource) medicines, prescribing, pharmaceutical expenditure

#### **Perspectives of Rational Use of Medicines in the EU**

---

**Nina Zimmermann, Claudia Habl, Bettina Schmickl, Sabine Vogler**

Gesundheit Österreich GmbH, Austria

Problem statement: Under-, over-, and misuse of medicines not only lead to negative implications on public health, but might also have considerable economic impact.

Objectives: To survey the implementation of structures, tools, and practices for improving a rational use of medicines and in the future to assess their impact on pharmaceutical expenditure

Design: A descriptive survey, based on literature and personal contacts (in particular via the Pharmaceutical Pricing and Reimbursement Information network) about institutions and practices for promoting a more rational use of medicines (RUM) was undertaken. Planned activities included a cross-country evaluation of RUM measures with regard to pharmaceutical expenditure, including public pharmaceutical expenditure, and time-series analyses for selected measures.

Setting and study population: Survey at national level for all 27 member states of the European Union (EU)

Interventions: RUM measures surveyed include INN prescribing, prescribing guidelines, prescription monitoring, institutions for RUM monitoring and promotion, pharmaceutical budgets, and information activities targeted to the public

Outcome measure(s): Qualitative assessment if RUM measures exist and how they are implemented and used; additionally, this is planned assessment: the generics market share in value and volume total pharmaceutical expenditure; and public and private pharmaceutical expenditure

Results: Although measures targeting the prescribing behaviour of doctors are quite common (prescribing monitoring in de facto all EU member states, prescription guidelines in 23 countries), budgets for prescribing doctors are rare (6 EU member states). Generics are considered to play a key role in this context, with generic substitution (21 countries) and prescribing by INN (22 countries) being in place. The majority of countries opted for indicative implementation instead of an obligatory one (generic substitution: mandatory for 4 out of 22 countries; prescription guidelines: 9 of 23 countries). Some countries (e.g., Denmark, Italy) have established specific institutions or departments for promoting rational use of medicines.

Conclusions: All EU member states have implemented measures that promote a more rational use of medicines; however, the way they implement and monitor them differs among the countries. Countries that have introduced mechanisms for the enforcement of the RUM measures have seen better outcomes (e.g., achieving higher generics shares). For assessing the economic impact of the measures, further analyses are required.

Funding source(s): Austrian Federal Ministry of Health

433

### Child Health

Keywords: vaccine delivery, combination vaccines, time-motion study

## Simplifying Vaccine Delivery with Combination Vaccines—Evidence from a Time-Motion Study in India

**Karin Anne Wiedenmayer<sup>1</sup>, Svenja Weiss<sup>1</sup>, Mukherjee Ajoy<sup>2</sup>, Kundu Ritabrata<sup>3</sup>, Chattopadhyay Chandon<sup>1,2</sup>, Tanner Marcel<sup>1</sup>**

<sup>1</sup>Swiss Tropical and Public Health Institute, Basel, Switzerland; <sup>2</sup>S.B.Devi Charity Home, Calcutta, India; <sup>3</sup>Institute of Child Health, Calcutta India

Problem statement: Immunization is essential to achieve the Millennium Development Goal (MDG) of reducing child mortality. Technological improvements such as single-vial fully liquid combination vaccines have been developed to rationalize vaccine delivery and to simplify the transport, storage, and administration of vaccines. Simplifying the administration of vaccines reduces the potential for handling errors and facilitates reaching children in remote areas.

Objectives: To understand the implications of a single-vial pentavalent DTP-HepB-Hib vaccine in terms of resource requirements and impact on vaccination programs

Design: We conducted a comparative time-motion study, administering a single-vial fully liquid DTP-HepB-Hib vaccine vs. a lyophilized vaccine with two vials requiring reconstitution. An analysis was done to estimate potential time savings. Questionnaires were used for qualitative data collection from vaccination staff and general observations of the vaccination setting.

Setting: The study was conducted at the Institute of Child Health (ICH) in Calcutta, India. 312 children were vaccinated over 6 weeks in 2006.

Study population: The study population included children attending healthy child clinic as a convenience sample. To increase the vaccination clinic attendance, a public vaccination campaign was organized and free vaccination was offered to parents or guardians of eligible children. There were no specific selection criteria for study participants except for standard clinical considerations.

Interventions: Vaccination staff preparing, administering, and disposing the vaccines and eligible children for the routine childhood vaccination schedule were observed during the immunization procedure by trained data collectors. Every vaccination step was observed, timed, and recorded. Vaccines were alternated.

Outcome measure(s): Timing (seconds and minutes) of each vaccination procedure step, package volumes, time savings (%), qualitative perceptions regarding ease and safety of vaccine delivery.

Results: Study results indicated significant time savings for vaccine preparation and total vaccine consultation for the single-vial pentavalent vaccine of 52% and 23% ( $p < 0.05$ ) as compared to the multiple-vial combination vaccines. At the current vaccine load, time savings at ICH are estimated to be about 20 working days per year. Extrapolated to India, delivery time savings could be around 100,000 working days per year. Package volume is less for a combination vaccine, leading to potential cost savings for storage and distribution. Qualitative data suggest improved handling convenience, absence of dissolution difficulties, and simplicity in supply logistics with less storage space needed.

Conclusions: A single-vial fully liquid pentavalent combination vaccine offers important time gains for vaccine delivery as compared to a multiple vial vaccine requiring reconstitution. Single-injection combination vaccines simplify logistics, training, and delivery management and offer significant time savings, critical for scaling up immunization coverage. Single-vial fully liquid combination vaccines might contribute to better resource management and ultimately improve efficiency of immunization programs.

Funding source(s): Novartis Vaccines

434

**Malaria***Keywords:* Access to medicine, private sector, antimalarials Tanzania**Does Artemether-Lumefantrine Subsidy to Private Sector Improve Prompt Access to Antimalarials to Febrile Children in Rural Areas?****Daudi Omari Simba, Deodatus Kakoko**

Muhimbili University, Tanzania, United Republic of

**Problem statement:** Tanzania, adopted artemether-lumefantrine (ALu) as first-line antimalarial in 2006. A few years after the change, prompt access to ALu is quite low.

**Objective:** To determine the proportion of febrile children accessing ALu by source of care in rural settings, in Kilosa, Tanzania

**Design:** A longitudinal study conducted in 2008 followed by in-depth interviews

**Study settings:** Children were followed up at home, weekly, to establish if they had fever suspected to be malaria, and caretakers were interviewed about the source and type of care received.

**Study population:** In total, 1,200 children under age five were enrolled from stratified, randomly selected 12 out of 161 rural villages. Stratification was done according geographical-climatic condition and availability of a government facility in a village. Children were randomly selected from an updated village register according to village population size. Of the enrolled, 35 children dropped out because they had reached age five or had migrated to another village. In-depth interviews were conducted with 13 providers from government and the private sector to establish reasons for the observed prescribing and dispensing pattern.

**Policy:** ALu has been the first-line antimalarial since 2006 and is provided for free in government and faith-based organisation (FBO) facilities and at a subsidised price in accredited drug dispensing outlets (ADDOs).

**Outcome measure(s):** Proportion of febrile children reported to have had fever and who accessed ALu

**Results:** In total, 607 children had at least one fever episode during study period, and 264 (weighted: 44.8%; 95% CI 40.3–49.4) were taken to government facilities. Whereas only 33.2% (114/607) of the remaining were taken to FBO facilities or ADDOs, 25.2% (153/607) were taken to general stores. Overall, less than half of the children received ALu 268 (weighted: 45.8%; 95% CI 41.2–50.5%). Whereas 88.3 (220/264) of those taken to government facilities received ALu, only 37.0% (41/114) of those taken to FBO facilities and ADDOs received AL. The median expenditure on drugs was 2.5 USD at FBO facilities, 1.6 USD at ADDOs, and zero at government facilities, with the poor paying more (median 0.5 USD) compared to the better-off (median zero). Providers at FBO facilities reported prescribing other antimalarials, arguing that most children had already taken ALu prior seeking care at the facility. Dispensers at ADDOs were reported to dispense antimalarials according to prescription or caretaker's preference.

**Conclusions:** The role of the private sector in improving access to ALu in rural areas was limited by cost, location, and irrational prescription. Strategies to increase access need to include the government meeting the costs for treating children in FBO facilities and strengthening regulatory mechanisms to ensure rational prescribing and dispensing habits in the private sector.

**Funding source(s):** Sida/SAREC

439

**Malaria***Keywords:* antimalarials, clinical guidelines, consumer demand, primary health care, malaria**Role of Patient Demand in the Treatment of Uncomplicated Malaria at Public and Private Health Facilities in Southeastern Nigeria****Lindsay Mangham<sup>1</sup>, Bonnie Cundill<sup>1</sup>, Ogochukwu Ezeoke<sup>2</sup>, Emmanuel Nwala<sup>2</sup>, Benjamin Uzochukwu<sup>2</sup>, Virginia Wiseman<sup>1</sup>, Obinna Onwujekwe<sup>2</sup>**<sup>1</sup>London School of Hygiene and Tropical Medicine, United Kingdom; <sup>2</sup>College of Medicine, University of Nigeria, Nigeria

**Problem statement:** At primary care facilities in Nigeria, national guidelines state that malaria should be symptomatically diagnosed and treated with artemisinin-based combination therapy (ACT). Many patients do not receive the recommended treatment, though little is known about the factors that affect prescribing and dispensing practices and how best to intervene to improve malaria treatment.

**Objective:** To examine the extent to which treatment provided to patients attending health facilities is consistent with national guidelines and whether this is associated with patient demand for specific medicines

**Design:** A multistage cluster survey was conducted with 2,039 patients (or caregivers) exiting public and private health facilities. Data were collected on the patient's prior treatment seeking and use of antimalarials, the consultation, prescriptions and medicines received, costs incurred, and the patient's demographic characteristics.

**Setting:** Data were collected at 20 public health centres, 25 pharmacies, and 55 patent medicine stores located in Enugu State, Nigeria. The survey was conducted in the 16 geographic communities, and sampling was stratified by study site and type of facility.

**Study population:** Adult patients and caregivers of sick children were approached after they had completed the health facility visit and invited to participate in the study if treatment had been sought for a fever or if the patient had received an ACT. Data analyses were conducted on 1,642 eligible febrile patients attending public health facilities (n=466), pharmacies and PMDs (n=1,176).

Policy: Treatment provided to patients was assessed against the national malaria treatment guidelines, which stipulate that in the absence of testing facilities, suspected cases should be treated presumptively with an ACT.

Outcome measure(s): The primary outcome measure is the proportion of patients receiving an ACT. Demand- and supply-side determinants of receiving an ACT were identified.

Results: Although 79.3% of febrile patients received an antimalarial, only 22.4% received an ACT. Many patients (37.9%) received sulfadoxine-pyrimethamine, which is much less effective. A further 13.4% of patients received an artemisinin-derivative as a monotherapy. The odds of a patient receiving an ACT were highly associated with consumer demand (OR:55.5,  $p<0.001$ ). At private facilities an individual was more likely to ask for an ACT if the patient was from an urban area (OR:3.7,  $p=0.020$ ) and of a high socioeconomic status (OR:2.8,  $p=0.027$ ).

Conclusions: Few febrile patients attending health facilities received an ACT, and the use of artemisinin monotherapy and less effective antimalarials is concerning. Our results emphasize the need for interventions that target consumer preferences as well as seek to improve health service provision and that underpin provider and community interventions that have been designed to improve malaria diagnosis and treatment.

Funding source(s): Bill & Melinda Gates Foundation

445

#### Access

Keywords: Developing countries, health services research, quality improvement, systematic review

### **Preliminary Results of a Systematic Review of the Effectiveness and Costs of Strategies to Improve Health Care Provider Performance in Low- and Middle-Income Countries**

**Samantha Y. Rowe<sup>1</sup>, Alexander K. Rowe<sup>1</sup>, David H. Peters<sup>2</sup>, Kathleen A. Holloway<sup>3</sup>, John Chalker<sup>4</sup>, Dennis Ross-Degnan<sup>5</sup>**

<sup>1</sup>U.S. Centers for Disease Control and Prevention, United States of America; <sup>2</sup>Bloomberg School of Public Health, Johns Hopkins University, United States of America; <sup>3</sup>World Health Organization Southeast Regional Office, India; <sup>4</sup>Management Sciences for Health, United Kingdom; <sup>5</sup>Harvard Medical School and Harvard Pilgrim Health Care, United States of America

Problem statement: Health care providers (HCPs) play key roles in improving quality and coverage of health interventions. In low- and middle-income countries (LMICs), however, HCP performance is often inadequate. Existing reviews of strategies to improve performance are outdated or have important methodological limitations.

Objectives: To characterize the effectiveness and costs of strategies to improve HCP performance in LMICs

Design: We conducted a systematic review of 15 electronic databases, 29 document inventories of international organizations, bibliographies of 510 reviews and other articles, the electronic bibliography of the International Network for the Rational Use of Drugs, the World Health Organization's Rational Use of Drugs database, and personal libraries of colleagues. After screening, data from relevant reports are double-abstracted and entered into a database.

Setting: LMICs

Study population: Patients or clients receiving care from the HCPs being studied. HCPs include community health workers, drug shop workers, pharmacists, and health workers in outpatient clinics or hospitals.

Intervention: Studies evaluating any performance improvement strategy for any health condition are eligible for inclusion.

Outcome measure(s): Effect sizes are estimated as absolute changes in performance outcomes (e.g., correct treatment increased by 20 percentage-points [%-points]). Outcomes include HCP practices, patient outcomes (e.g., mortality), and economic outcomes. As studies often use different outcomes, we calculate a summary measure: the median effect size for all primary outcomes from a study.

Results: The search strategy identified >105,000 citations, of which 2,429 were included. Of the 2,429 included reports, 850 (35%) were for studies with methodologically "adequate" designs (e.g., trials with a comparison group). To date, 399 reports on 222 adequate-design studies have been abstracted. A wide variety of performance improvement strategies have been studied, usually with multiple components (commonly including training, supervision, or job aids, but also innovative components such as pay-for-performance or continuous quality improvement). Most strategies had small median effect sizes (<10%-points), although some had large effects (>25%-points). Contextual and methodological heterogeneity makes comparisons across studies difficult. About 30% of studies reported costs or cost-effectiveness.

Conclusions: Early results suggest that effectiveness of performance improvement strategies varies substantially, with many interventions having small effect sizes. Standardization of methods would facilitate efforts to synthesize the evidence. Additional analyses will identify factors associated with increased effectiveness. The evidence base from this review will inform recommendations on how best to improve HCP performance in LMICs.

Funding source(s): Bill & Melinda Gates Foundation, U.S. Centers for Disease Control and Prevention, World Bank

448

#### Chronic Care

Keywords: Continuing medical education, hypertension, program evaluation, primary care, family physicians

### **Effectiveness of a Medical Education Intervention to Treat Hypertension in Primary Care**

**Silvia Martínez Valverde<sup>1</sup>, Hortensia Morales Reyes<sup>2</sup>, Angélica Castro Ríos<sup>3</sup>, Ricardo Pérez Cuevas<sup>3</sup>, Miguel Klunder Klunder<sup>1</sup>, Guillermo Salinas Escudero<sup>1</sup>**

<sup>1</sup>Center for Social and Economic Studies on Health, Hospital Infantil de México Federico Gomez.; <sup>2</sup>Center for Health Systems Research, Instituto Nacional de Salud Pública.; <sup>3</sup>Epidemiology and Health Services Research Unit, Instituto Mexicano del Seguro Social.

**Problem statement:** In Mexico, hypertension (HT) is among the top five causes for visits to primary care clinics; its complications are among the main causes of emergency and hospital care.

**Objectives:** To evaluate the effectiveness of a continuing medical education (CME) intervention to improve appropriate care for hypertension and on blood pressure control of hypertensive patients in primary care clinics

**Design:** A secondary data analysis was carried out using data of hypertensive patients treated by family physicians who participated in the CME intervention. The evaluation was designed as a pre- and post-intervention study with control group in six primary care clinics.

**Setting:** The study was conducted at a national level in six family medical clinics belonging to the Mexican Institute of Social Security (IMSS), the largest public health care system in Mexico.

**Study population:** The analysis included 193 patients with hypertension (intervention group: n = 101 patients; control group: n = 92 patients), who were treated by 90 physicians. The patients were recruited and informed consent was obtained from them in the waiting room at the clinic, where trained nurses interviewed them before and after the medical visit. One or two patients per participating family physician were chosen. This was done in accordance with the number of hypertensive patients visiting the clinic during a typical working day.

**Intervention(s):** The intervention was based on three sequential stages that lasted 3 months. In each setting, a general internal medicine specialist was trained to coordinate the interventions and to work as a clinical instructor. An evidence-based clinical guideline was previously designed and adapted to the family medicine context and served as the groundwork for the intervention.

**Outcome measure(s):** Proportion of patients with uncontrolled blood pressure in the intervention and control groups at baseline and final stages. The operational definition of uncontrolled blood pressure states that the systolic/diastolic figures should be  $\geq 140/90$  mm Hg. The effect of the CME intervention was analyzed using multiple logistic regression modeling in which the dependent variable was uncontrolled blood pressure in the post-intervention patient measurement.

**Results:** The model results were that being treated by a family physician who participated in the CME intervention reduced by 53% the probability of lack of control of blood pressure [OR=0.47 (95% CI, 0.24–0.90)]; receiving dietary recommendations reduced by 57% the probability of uncontrolled blood pressure [OR=0.43 (95% CI, 0.22–0.87)]. Having uncontrolled blood pressure at the baseline stage increased the probability of lack of control in 166%, [OR=2.66 (95% CI, 1.31–5.38)] and per each unit of increase in body mass index, the lack of control increased 7%, [OR=1.07 (95% CI, 1.001–1.143)].

**Conclusions:** CME intervention improved the medical decision-making process to manage hypertension, thus increasing the probability that hypertensive patients would have blood pressure under control.

**Funding source(s):** Information not provided

**449**

### **Policy, Regulation, and Governance**

*Keywords:* appropriate use, clinical guidelines, community, prescribing, drug information

### **Up-to-Date, Evidence-Based Advice for Busy Clinicians**

#### **Mary Hemming**

Therapeutic Guidelines Ltd, Australia

**Problem statement:** Prescribers need to base their therapeutic decisions on the latest and best available medical literature, but the continual surge of medical information (more than 12,000 articles and 300 reports of trials are added to the MEDLINE database each week) means that prescribers cannot, by themselves, keep abreast of the relevant literature.

**Objective:** To provide prescribers with independent, up-to-date, critically appraised therapeutic guidance that is credible, comprehensive, timely for decision making, succinct, and formatted for optimum readability and ease of use

**Setting:** The target audience is primary care clinicians throughout Australia; these include medical practitioners, pharmacists, and other prescribing health professionals. The information is also used by clinicians in hospitals and by educators and students in medical and pharmacy schools. International demand, especially from the developing world, is increasing.

**Design:** Therapeutic Guidelines Limited (TGL), an independent not-for-profit, self-funding organisation, writes and publishes independent and expert advice for prescribers on the best use of medicines, the focus being on the information needs of the end users.

These therapeutic guidelines provide clear and concise, independent, and evidence-based recommendations for patient management. They are produced using a unique process involving Australia's leading experts who, with their many years of clinical experience, work with TGL's medical editors to develop the material. Features of the content development process are (1) extensive literature searches; (2) appraisal of Cochrane reviews, systematic reviews, and any other credible guidelines; (3) a series of day-long face-to-face meetings of the expert writing group over several months to discuss, debate, and challenge draft content; (4) consideration of feedback from a representative group of

users; and (5) peer review. The rigorous process ensures the recommendations that are developed are based on the best available evidence. All topics are regularly updated in iterative cycles. The enterprise has been operating and evolving since 1978.

Outcome measure(s): TGL employs a dedicated evaluation officer to actively solicit feedback from a network of 200 users of therapeutic guidelines. Participants in the network reflect the mix of actual users in both urban and regional or remote areas.

Results: Therapeutic guidelines are used by health professionals at all levels, from undergraduates to opinion leaders, in all public hospitals, in community practice, and in pharmacy and medical schools throughout Australia.

Conclusions: The guidelines are firmly entrenched as part of the Australian medical, pharmacy, and health professional culture. They are valued and respected, and are often referred to by clinicians as a "national treasure."

Funding source(s): No external funding received. All funding comes from the sale of therapeutic guidelines.

#### 450

##### **Policy, Regulation, and Governance**

*Keywords:* Pharmacovigilance, ADR Reporting, Health Care Professionals.

#### **Impact of Comprehensive Efforts on the Performance of a Pharmacovigilance System in Oman**

---

**Shirly Samson Varughese, Mohammed Hamdan Al Rubaiai, Madiha Juma Al Maskari**

Ministry of Health, Oman

Problem statement: Oman is experiencing a need for awareness workshops in pharmacovigilance (PV) to facilitate reporting culture among health care professionals for better use of medicines. Awareness through periodic workshops was not a part of the system prior to 2006, when the events per year would have been two or less for PV.

Objectives: To educate health care professionals about PV, the importance of reporting in general and the significance of reporting suspected adverse drug reactions (ADRs), drug quality reports, therapeutic ineffectiveness, drug interactions, medication errors, and reactions from herbal medicine; to facilitate the reporting; to improve the quality of the reports; and to disseminate clinically useful, new safety information to providers and patients

Design: Qualitative review on intervention

Setting: Health care sector in Oman

Study population: Government institutions, regions, government health centers, private hospitals, clinics, and pharmacies

Intervention: Periodic workshops and training programmes and lectures in continuing professional education programs were conducted on a regular basis among various health care professionals, doctors, pharmacists, assistant pharmacists, and nurses from government and the private sector. Events included workshops to cover all regions in Oman, training courses on PV for coordinators, and training courses for pharmacists in the private sector. Appreciation letters were sent out on receipt, followed by quarterly and annual feedback letters with information on causality assessment of suspected ADR reports.

Outcome measure(s): Enhanced reporting by health care providers.

Results: The reporting rate has consistently increased after introducing periodic workshops from the year 2006 onward. Years 2002, 2003, 2004, and 2005 had 267, 290, 320, and 273 reports, respectively, whereas years 2006, 2007, 2008, and 2009 had 332, 473, 653, and 832 reports, respectively. Though enhanced participation from the government sector is observed, private sector involvement in reporting and PV needs to be improved.

Conclusions: Periodic workshops are an essential tool in health care sector to improve drug use and introduce the concept of PV to health care professionals. Constant reminders and feedback are necessary to encourage reporting.

Funding source(s): Ministry of Health and the private sector

#### 453

##### **Economics, Financing, and Insurance Systems**

*Keywords:* essential medicines, medicine prices, availability, affordability, health facilities,

#### **Evaluation of Prices and Availability of Essential Medicines in Grahamstown, South Africa**

---

**Sunitha Chandrasekhar Srinivas<sup>1</sup>, Viral Patel<sup>2</sup>, M.S. Ganachari<sup>2</sup>**

<sup>1</sup>Rhodes University, South Africa; <sup>2</sup>KLE University, India

Problem statement: The World Health Organisation (WHO) estimates that one-third of the global population lacks reliable access to essential medicines. The situation is even worse in the poorest countries of Africa and Asia, where as much as 50% of the population do not have access to essential medicines.

Objectives: To evaluate prices and availability of essential medicines in the public and private sector health care facilities in Grahamstown, Eastern Cape, South Africa

Design: The survey was undertaken according to the standardized method developed by the World Health Organisation/Health Action International (WHO/HAI) 2008.

Setting: Grahamstown, Eastern Cape Province, South Africa

Study population: Availability and prices of the medicines were collected in the public sector, which consisted of six primary health care facilities, one community health care facility, and one district hospital in Grahamstown. In three retail pharmacies, data were collected for the innovator brand, most sold generic, and lowest priced generic.

Interventions: N/A

Outcome measure(s): Availability and prices of 44 essential medicines were collected. Among the 44 medicines, 11 medicines belonged to the category of “Global core list” recommended by WHO/HAI to enable international comparisons on a global level; 8 medicines were from the “Regional core list” (Sub-Saharan Africa list); and 25 were the supplementary medicines based on local burden of diseases and pharmaceutical procurement in the public sector.

Results: The average availability of medicines in the public sector was 75%; the average availability of innovator brand medicines in the private sector was 78%. The average availability of lowest price generic in private sector was 29.5%. The public sector provides medicines free of cost to its patients, and medicines are not available when there are problems with suppliers. Medicines currently not available in the public sector are paracetamol syrup, ceftriaxone injection, diclofenac tablets, and salbutamol inhaler. When compared to the public sector procurement costs, patients in the private sector pay 7–18 times more.

Conclusion: The availability of medicines in the public sector is commendable irrespective of the challenges faced such as suppliers not delivering on time and lack of sufficient health care professionals, especially pharmacists. In the private sector, innovator brands are more expensive but due to medical aid policies, the option of purchasing generics is available to the patients. The lowest priced generics, however, are not necessarily stocked or dispensed due to perceptions regarding their quality. To increase affordability of medicines in the private sector, policies promoting price controls are essential.

Funding source(s): Running costs for this study was supported by Mellon’s grant as a part of the Vice Chancellor’s discretionary funds by Rhodes University.

460

#### Policy, Regulation, and Governance

*Keywords:* medicines selection, essential medicines, action plan, essential medicines list

#### An Action Plan for the Selection of Essential Medicines

Rachel Magarinos-Torres<sup>1,2</sup>, Vera Lucia Edais Pepe<sup>2</sup>, Claudia Garcia Serpa Osorio-de-Castro<sup>2</sup>

<sup>1</sup>Faculdade de Farmácia - Universidade Federal Fluminense, Brazil; <sup>2</sup>Escola Nacional de Saúde Pública - Fiocruz, Brazil

Problem statement: The essential medicines list (EML) is a tool for guiding the clinical and administrative proceedings on medicines in certain political and clinical settings. Its adoption promotes access and contributes to rational use, to the extent that only essential medicines with verified efficacy, safety, lower cost of treatment per day, and the most appropriate dosage forms are included.

Objectives: The study aimed to present a process for the preparation of the EML for the State of Rio de Janeiro, Brazil, including a detailed plan of action for the process.

Design and setting: A review of management and technical procedures related to medicines selection in the State of Rio de Janeiro was carried out. Legal documents and meeting minutes were consulted. Other methods of data collection included observation and meetings with the responsible departments. Simultaneously, the review process of the Brazilian EML was analyzed. A plan of action for preparation of the final product was formulated.

Results: The plan was organized in three parts, according to the framework of health services evaluation. The first stage was structuring necessary planning activities for the review process, followed by the actual evidence-based review of medicines, seen as the core of the selection process. Finally, the results were worked upon, represented by the actions of promoting and monitoring adherence to the list. Intended objectives, goals, and procedures for each step were drafted, totaling 16 objectives, 8 goals, and 16 sequential and coordinated procedures. Every action was detailed in regard to its contribution to the objective, its implementation methodology and required resources, the estimated period for implementation, and the indicators to measure whether the objectives were achieved.

Conclusions: The EML should include medicines for all levels of health care, which should be made available by the health system. It is estimated that the action plan can support regular reviews of the list, as well as the selection processes in municipalities and state health units.

Funding source: Secretaria de Saúde e Defesa Civil do Estado do Rio de Janeiro–SESDEC RJ

461

#### Policy, Regulation, and Governance

*Keywords:* essential medicines, essential medicines lists, Brazil, prescribers, managers

#### What Do Managers and Prescribers of the Brazilian Health System Think of Essential Medicines? Preliminary Results of a Nationwide Qualitative Study

Rachel Magarinos-Torres<sup>1,2</sup>, Vera Lucia Edais Pepe<sup>2</sup>, Claudia Garcia Serpa Osorio-de-Castro<sup>2</sup>

<sup>1</sup>Faculdade de Farmácia - Universidade Federal Fluminense, Brazil; <sup>2</sup>Escola Nacional de Saúde Pública - Fiocruz, Brazil

Problem statement: The adoption of the concept of essential medicines by health systems starts with the development and use of essential medicines lists (EML). In Brazil there are legal provisions for the development of EMLs in the

health sector of the three levels of government and in health institutions. Studies have pointed to a low level of adherence to the EML, however, by managers and by prescribers.

Objectives: To describe, analyze, and discuss the knowledge and perceptions of managers and prescribers of the Brazilian Health System (SUS) in regard to the essential medicines concept and to the national, state, and local EMLs

Design: We present an exploratory qualitative study.

Setting and study population: 20 state and federal managers and 60 SUS prescribers from the five administrative regions of the country were sampled through a national health facilities database. Data were collected during the second semester of 2010 by means of participants' responses to a questionnaire and interviews. Interviews were recorded and transcribed, with informed consent from interviewees. Analysis was done using content analysis technique.

Results: 30 health facilities were visited, in 15 different municipalities. Of these, 15 were hospitals of different levels of care, and 15 were primary health care units. Five state managers and 15 municipal managers were interviewed. Prescribers totaled 11 in the state of Rio Grande do Norte (Northeast), 13 in Acre (North), 12 in Goiás (Mid-west), 12 in Minas Gerais (Southeast), and 12 in Santa Catarina (South). All participants gave informed consent. Managers and prescribers associate essential medicines with primary health care, especially for treatment of hypertension and diabetes. Managers have some knowledge regarding the Brazilian national EML, but the importance given to essential medicines is mainly related to their financing quotas. Prescribers apparently do not employ the EML in their daily practice and do not recognize its value. Perceptions are that the lists are a restriction to prescribing, with perceived gains only for management and not for clinical practice.

Conclusions: Great effort has been channeled into the development and review of EMLs and to the adoption of the essential medicines concept throughout Brazil in the past 12 years. Nevertheless, adherence to these is still lacking. The results indicate that either these efforts have not been sufficient or strategies must be redirected. Further analysis is needed to understand which strategies have been useful and whether the relationship between levels of government and between prescribers and managers may enhance adherence to the list, fostering more positive attitudes and gains for the health system and for users.

Funding source: CAPES—Programa de Excelência Acadêmica PROEX/CAPES

#### 466

##### Policy, Regulation, and Governance

Keywords: Pharmaceutical products quality, Good manufacturing practices, generic medicines, industry, access to medicines

##### Quality of Some Pharmaceutical Products Manufactured in Kenya

**Jennifer Akinyi Orwa<sup>1,2</sup>, Lucia Keter<sup>2</sup>, Sams Ouko<sup>2</sup>, Geoffrey Rukunga<sup>2</sup>, Isaac Kibwage<sup>3</sup>**

<sup>1</sup>INRUD-KENYA, Kenya; <sup>2</sup>Kenya Medical Research Institute (KEMRI); <sup>3</sup>University of Nairobi, School of Pharmacy

Problem statement: The safe and effective use of medicines depends, first, on their quality. Whereas the pharmaceutical industries strive to manufacture quality drugs, this has remained a challenge for industries in the developing countries like Kenya.

Objective: To establish the quality of pharmaceutical products manufactured by the respective industries in Kenya. The results would help in recommending strategies to ensure that good manufacturing practices are adhered to and quality products are released to the consumer.

Design: Cross-sectional study

Setting: This study was conducted at the national level. Nairobi being the province where all the pharmaceutical manufacturing industries in Kenya are situated, the test samples were obtained from industries as well as community pharmacy outlets in Nairobi province. Laboratory analysis was carried out at Kenya Medical Research Institute and University of Nairobi.

Study population: Convenience sampling of commonly used pharmaceutical products was done. 63 samples of 14 selected pharmaceutical products were obtained from 17 manufacturing plants and 9 retail outlets.

Interventions: Medicines were sampled and analyzed for their quality according to their respective monographs.

Outcome measure(s): Quality analysis of products involved the establishment of the chemical content, dissolution profile, friability, uniformity of weight, and identity. For antibiotic suspensions, the stability after reconstitution was also determined.

Results: Out of 63 samples, compliance with quality specifications for content, dissolution and uniformity of weight was 92%, 82%, and 73%, respectively. All 13 samples tested complied with the test for identification and all the antibiotic suspensions tested complied with pharmacopoeia specification for stability test.

Conclusions: There were products with too much and with too little active content identified from among the samples that failed to comply with respective pharmacopoeia limits for chemical content. This may indicate that failure to comply with specification for active content was probably not due to poor-quality raw materials but rather to poor quality control during the manufacturing process. Failure to comply with pharmacopoeia specification for dissolution and uniformity of weight may be attributed to problems in formulation procedures. Although most of the products examined showed general attributes of good quality, there are some cases where there is need for improved manufacturing practices to achieve product quality.

Funding source(s): This work was supported by funds from Drug Agency International and Kenya Medical Research Institute.

467

**Policy, Regulation, and Governance***Keywords:* prescriber education, online learning**Establishing a Nationally Consistent Approach to Implementing the Principles of Good Prescribing in Health Practitioner Education****Jonathan Dartnell, Michelle Koo, Lynn Weekes**

NPS: Better Choices, Better Health, Australia

**Problem statement:** Despite prescribing being a fundamental task for many health practitioners, education and training to support good prescribing has not been a priority and new prescribers have reported being inadequately prepared to practice prescribing. In addition, the roles of several health practitioners are expanding to include prescribing. Is a nationally consistent approach to implementing the principles of good prescribing feasible?

**Objectives:** To develop online learning modules to support a nationally consistent approach to implement the principles of good prescribing in health practitioner education

**Design:** NPS: Better Choices, Better Health is a not-for-profit organisation that implements activities that aim to enable the best possible decisions about medicines by consumers and health professionals. The National Prescribing Curriculum (NPC) is a series of clinical, case-based, online learning modules that mirror the decision-making process outlined in the WHO Guide to Good Prescribing. The NPC emphasis is on learners building their own personal formulary of preferred drugs for specific conditions. The modules are based on real-life situations and include complex, authentic tasks.

**Setting:** Universities

**Study population:** Medical, pharmacy, nurse practitioner students

**Intervention:** The NPC online learning modules were introduced in 2002 and are now available to all Australian medical, pharmacy, and nurse practitioner schools. Individual schools determine how the NPC is utilised and assessed within the curriculum. This has included use in face-to-face tutorials, assessment with multiple choice questions on selected NPC topics, and oral examination on selected NPC topics. The NPC has been used to support good medication management practice as well as in the development of good prescribing practice.

**Outcome measure(s):** Uptake of NPC by health practitioner schools, student satisfaction

**Results:** In 2004, the modules were used in 9 of the 12 medical schools, compared with 16 of the 18 schools in 2011. The number of student users has increased from 1,100 in 2004 to >2,500 in 2011. The uptake of the modules by pharmacy, nurse practitioner, and dental schools is recent. In 2011, 6 of the 13 pharmacy schools and 5 of the 14 nurse practitioner schools used the modules. In an online survey in 2010, 95% of students found the modules engaging, clear, and relevant, and >90% reported that use of the NPC had improved their confidence and knowledge of therapeutics and prescribing.

**Conclusions:** The uptake of the NPC in medical schools is comprehensive and use in pharmacy and nurse practitioner and schools is being established. The model may be of assistance to other countries that are considering a national approach to implementing the principles of good prescribing.

**Funding source(s):** NPS is funded by the Australian Government Department of Health and Ageing.

468

**Chronic Care***Keywords:* chronic disease, health economics, multifaceted interventions**Improving Diabetes Management in Primary Care****Jonathan Dartnell, Yeqin Zuo, Weekes Lynn, Azam Roshmeen**

NPS: Better Choices, Better Health, Australia

**Problem statement:** Diabetes has been an Australian national health priority. Metformin is a cost-effective first-line therapy for type 2 diabetes; however, uptake has not been optimal.

**Objectives:** To demonstrate the impact of a national program to improve management of diabetes in primary care

**Design:** NPS: Better Choices, Better Health implemented 3 national programs to improve management of type 2 diabetes: 2001–03 (#1), 2005–06 (#2), and 2007–08 (#3). Key messages focused on encouraging lifestyle interventions, management of risk factors, and first-line use of metformin. Programs were evaluated to measure changes in knowledge and prescribing practice. Computer simulation modelling, based on risk reductions achieved through use of metformin in overweight patients in the UKPDS study, was used to evaluate the likely impact of increased use of metformin on progression of diabetes and its complications.

**Setting:** Primary care

**Study population:** General practitioners (GPs) and their patients

**Intervention:** For each program, NPS deployed a range of activities to deliver key program messages. NPS facilitators based in local areas conducted face-to-face visits with practitioners and small group case study discussions. Clinical audits with feedback were available to help clinicians reflect on their practice. Information resources on the management of diabetes were distributed to support good decisions by health professionals and consumers.

**Outcome measure(s):** Prescribing rate change, knowledge of health professionals

Results: The numbers of GPs who participated were 6,704 (#1); 6,965 (#2); and 8,746 (#3)—approximately a third of the Australian GP population. Between 2001 and 2007, the mean prescribing rate increased from <20 to >25 metformin prescriptions per 1,000 consultations per month on the national Pharmaceutical Benefits Scheme. Time-series analysis did not confirm a statistically significant increase associated with NPS active program interventions. A random sample of 2,000 GPs was surveyed before and after the implementation of program #2. The proportion of respondents who selected metformin correctly in the management of a hypothetical patient was significantly higher in the post-survey (42% vs. 55%). Based on the survey and clinical audit results of program #2, it was estimated 3,000 additional patients were prescribed metformin. Computer simulation modelling projected that the additional use would result in 231 myocardial infarctions prevented, 370 premature deaths averted, and 1,719 life years saved.

Conclusions: National use of metformin has increased substantially and is likely to have major benefits for patients. Although the impact of NPS programs was not able to be demonstrated using available nationally aggregated data, audit and survey data demonstrated an impact. NPS experience should be of benefit to other countries to promote better diabetes care.

Funding source(s): NPS is funded by Australian Government Department of Health and Ageing.

#### 471

##### Drug Resistance

Keywords: MTP approach, training and rational used of medicine, injections and i.v. use

##### Improving the Rational Medicine Use through the MTP Approach in Cambodia

**Sokhan Chroeng<sup>1,2</sup>, Sokunna Sau<sup>1,2</sup>, Oudamroath Or<sup>2</sup>, William Mfuko<sup>3</sup>**

<sup>1</sup>INRUD Cambodia, Cambodia; <sup>2</sup>Ministry of Health, Department of Drugs and Food; <sup>3</sup>World Health Organization

Problem statement: The monitoring, training, and planning (MTP) approach for improving the rational use of medicines in public health facilities in Cambodia was introduced and implemented since 2001 with the support of WHO. The approach sought to address a host of irrational drug use problems such as poly-pharmacy, inappropriate use of antimicrobials, over-use of injections, non-adherence to clinical guidelines, and inappropriate dosing regimens, among others. With over 9 years of accumulated data and experience on the approach, this paper provides some evidence on the effectiveness of this approach in improving the rational use of medicines in the country.

Objectives: To use the MTP approach to improve, on sustainable basis, prescribers' skills in identifying and resolving irrational medicines use problems at provincial referral hospitals through hospital Medicines Therapeutic Committees (MTC). Evidence on the effectiveness of the approach in reducing irrational use of medicines with indicators and targets defined by MTC at provincial referral hospitals is provided.

Design: Interventional, time-series with baseline data for comparison

Setting: Public sector: provincial referral hospitals

Study population: Prescribers and members of MTC at 55 public provincial referral hospitals

Intervention and method: A problem-solving approach as provided by the MTP method was systematically implemented from 2001 to 2010 to prescribers to improve rational use of medicines. Members of participating hospital MTCs identified medicines use problems, quantified those using suitable indicators, identified their possible causes, and agreed on appropriate solutions to resolve them. Outcome of their effort were reviewed at MTC monthly meetings.

Outcome measure(s): Proportion of patients (in %) receiving antibiotics, IV fluid, and injection formulations compared, on quarterly basis, to baseline data, including an assessment of the duration of treatment, correctness of diagnoses, and medication prescribed.

Results: Among other favorable outcomes, in 2001, for example, the use of IV in normal delivery in one province declined by 100% (from 70 to 0%) and in other three provinces the unnecessary use of antibiotics during delivery and various trauma cases declined by an average of 63% (range: 37–85%). Between 2005 and 2008, the average reduction in injudicious use of antibiotics (in medicine, pediatric, surgery, and maternity wards) was 48% (range: 3–82%).

Conclusions: Given the opportunity and training, hospital members of the MTC using the MTP approach can reduce the magnitude of irrational medicines use in a hospital setting.

Funding source(s): Ministry of Health of the Royal Government of Cambodia, GFATM, and WHO

#### 473

##### Access

Keywords: Key words: self monitoring and peer-group discussion, prescribing, bottom-up approach, treatment protocol

##### Implementation of a Policy for Monitoring Prescribing Practices in Public Health Care Outlets in Nepal

**Kumud Kumar Kafle<sup>1</sup>, Naveen Shrestha<sup>1</sup>, Shib Bahadur Karkee<sup>1</sup>, Gajendra Bahadur Bhujju<sup>1</sup>, Radha Raman Prasad<sup>1</sup>, Prabhakar Lal Das<sup>1</sup>, Bhuwaneshwori Datta Chataut<sup>1</sup>, Parasuram Shrestha<sup>2</sup>, Achyut Lamichhane<sup>2</sup>, Jivan Kumar Malla<sup>2</sup>**

<sup>1</sup>INRUD Nepal, Nepal; <sup>2</sup>Department of Health Services, Nepal

Problem statement: To improve the quality of health care in Nepal, periodic supervision of health facilities by district supervisors (i.e., the top-down approach) has been in practice. The implementation has not been found effective, however, because of the time required of district health officials, financial constraints, and the terrain of the country. A

bottom-up approach consisting of self-monitoring and peer-group discussions was tested and piloted in some districts (2004), and the Ministry of Health and Population (MOHP) decided to incorporate the strategy into its Three-Year Plan (2007–10). The aim of this presentation is to describe the processes and the success of the implementation.

**Objective:** To improve the quality of care by monitoring prescribing practices and the availability of essential free drugs at PHC outlets in the country

**Setting:** All PHC outlets of 75 districts of Nepal

**Study population:** Paramedical health workers of all sub-health posts, health posts, primary health care centers (PHCs), and district hospitals; medical doctors of PHCs and district hospitals; and supervisors including district public health officers of all districts

**Policy and intervention:** MOHP approved a training curriculum, developed and published training manuals, conducted training of trainers (TOT) and district level trainings in districts, and distributed carbon-copy prescriptions for self-monitoring. Health workers participated with self-monitoring results in bimonthly peer-group discussion meetings organized at each district health office and discussed the results among the prescribers in the presence of a district health officer, who gave feedback on the results and instruction on the use of treatment protocols.

**Results:** The government allocated the budget for fiscal year 2009/10 to implement the strategy in all 4,085 PHC outlets including the district hospitals of all districts and assigned the responsibility of the implementation to the Management Division. In the same year, 281 persons from different health care levels received the TOT training. Besides the TOT, district-level trainings were also organized for all prescribers of the PHC outlets. Although, self-monitoring and peer group discussions were planned for all districts, during the fiscal year only one district could implement the district-level peer-group discussion. The remaining districts could not implement the strategy because of budgetary limitations. Both activities were monitored from the central and district level. In 2010–11, because of financial constraints, the government could allocate the budget for only 10 districts to implement the strategy, but the MOHP budget could not be released until the last quarter of the fiscal year. Immediately after release of budget, eight districts completed only 1 or 2 self-monitoring activities or peer-group discussions. The government also shifted the implementation responsibility to a newly established PHC Revitalization Division. The government has allocated the budget also for the current fiscal year (2011/12).

**Conclusion:** The activities could not be fully implemented as planned. Those districts that did implement it, however, followed the major processes and aspects of the strategy effectively. The government is committed to implementing the strategy, but the financial constraint is the limiting factor. The process of an evidence-based strategy, if implemented by the government, can be successfully adopted.

**Funding source(s):** Regular budget of Ministry of Health and Population, Nepal

**474**

#### **Malaria**

*Keywords:* adherence, artemisinin-combination therapy, health systems, blood lumefantrine analysis

### **High adherence to artemether-lumefantrine treatment in children under real-life situation in rural Tanzania**

**Daudi Omari Simba, Deodatus Kakoko**

Muhimbili University, Tanzania, United Republic of

**Problem statement:** Artemether-lumefantrine (ALu) is highly efficacious in treating uncomplicated *Plasmodium falciparum* malaria. It is, however, questionable if the high levels of adherence observed under research conditions can be achieved in a real-life situation, in rural remote settings where the malaria burden is highest and access to the drug is limited.

**Objective:** To determine the level of adherence to an ALu treatment schedule in a real-life situation in rural settings and its determinants

**Design:** A longitudinal study conducted in 2008

**Study settings:** A community-based study conducted in Kilosa district, Tanzania

**Study population:** Stratified cluster sampling was done in which three of the 30 rural villages in wet-lowland areas were selected—one from villages with and two from villages without a health facility. Two nearby semi-urban villages were later added for comparison.

**Method:** Children were followed up for 12 months. Those who developed fever diagnosed as malaria, using a rapid diagnostic test, and treated with ALu, were identified from outpatient registers in facilities serving the respective villages. These were traced at their homes on day 7 to determine adherence to treatment using caretaker's report and pill count. The majority of caretakers were found to have discarded packets on day 7, and a mini-study was conducted to verify adherence using pill count, on day 4. Blood samples were collected using a field-adapted blood sampling capillary method and analysed for lumefantrine blood concentration using the high-pressure liquid chromatography method. Multiple logistic regression analysis was done to determine factors influencing adherence, and log-transformation of lumefantrine concentration was done to correct for skewed distribution.

**Policy:** Tanzania adopted ALu as first-line antimalarial in 2006.

**Results:** The majority of the children (88%; 392/444) received all the doses on time irrespective of whether they resided in rural (87.5%; 281/321) or semi-urban (90.2%; 111/123) areas, *p*-value >0.05. Except for one child, nonadherence was due to off-schedule dosing, and the number was higher in the last two doses. A higher level of adherence (96%; 120/126) was found in the mini-study, thus, confirming findings from the main study. No statistically significant difference was found in the mean blood lumefantrine concentrations between children reported to adhere to ALu

treatment and those who did not. The corresponding median lumefantrine concentration was 286 nmol/L and 261 nmol/L, respectively. Children from better-off households (quintile 1–2) were more likely to adhere to treatment schedule (OR 2.45; 95% CI 1.35–4.45; adjusted OR 2.23; 95% CI 1.20–4.13) compared to the poor (quintile 3–5).

Conclusion: The high level of adherence to ALu, in rural areas is encouraging. Further research is required on the usefulness of blood lumefantrine concentration in predicting adherence in community-based studies.

Funding source(s): Sida/SAREC

477

#### Child Health

*Keywords:* Immunization system, Immunization reporting, Quality improvements, Performance-based financial reward strategy, GAVI

### Is Performance-Based Reward the Strategy of the Future for Strengthening the Quality of Reporting and Immunization Systems?—Experiences from GAVI

**Rete Trap<sup>1,2</sup>, Birna Trap<sup>3,2</sup>, Torsten Wind Hansen<sup>2</sup>, Ebba Holme Hansen<sup>4</sup>**

<sup>1</sup>Aabenraa University Hospital, Denmark; <sup>2</sup>Euro Health Group, Denmark; <sup>3</sup>Management Sciences for Health, SURE Program, Kampala, Uganda; <sup>4</sup>Faculty of Pharmaceutical Sciences, Department of Pharmacology and Pharmacotherapy, University of Copenhagen

**Problem statement:** Global coverage of childhood diphtheria-tetanus-pertussis (DTP3) immunization increased to 80% in 1990, after which immunization rates declined considerably in many countries. Several initiatives have been introduced to strengthen immunization. The Global Alliance for Vaccines and Immunization (GAVI), a public-private global health partnership, was established in 1999 for strengthening immunization service support (ISS). The GAVI initiative has been introduced in over 75 countries and is linked to performance-based reward strategy, a scheme that pays a fixed fee for children immunised with DTP3 as reported by the country. The effectiveness of this costly initiative, however, needs to be further investigated.

**Objectives:** To assess whether linking the GAVI ISS with performance-based interventions has improved immunization reporting and system quality

**Design:** A retrospective study based on immunisation data quality following a combined managerial and reward based strategy

**Method:** We used a data quality audit (DQA), a validated standardized indicator-based performance assessment, to evaluate reporting consistency and accuracy and the quality of the immunisation system, with the aim of improving immunisation coverage.

**Study population:** Nine developing countries having had two consecutive DQA's in the period 2002 to 2005

**Interventions:** GAVI ISS including a performance assessment (i.e., DQA) and system improvement recommendations and implementations support, combined with financial reward

**Outcome measure(s):** Reporting quality (verification factor) and system set-up quality (quality scores).

**Results:** Both reporting and system quality improved following the GAVI ISS intervention. Immunisation coverage improved in all but one of the nine countries from the initial DQA to the following DQA. The improved reporting quality was associated with improved overall quality of the immunisation system. Correlation was found between verification factor and immunisation coverage.

**Conclusions:** The study indicates that the combined GAVI ISS performance-based reward intervention strategy is effective, resulting in increased immunization coverage, improved reporting quality, and improved quality of the immunizations system set-up at all levels of health care. High-quality reporting with accurate and consistent data is instrumental in targeting and focusing immunization management toward increased coverage, demonstrated by the correlation between increased reporting quality and immunization coverage. To ensure sustainable immunisation system improvements, repeated assessments are recommended. To further explore the applicability of the performance-based reward system in other areas of supply chain and medicines managements, the SURE project in Uganda has applied a performance assessment reward project, in an attempt to strengthen medicines management. The applicability of the performance-based reward system to other areas of supply chain and medicines management needs to be explored.

**Funding source(s):** Aabenraa Regional Hospital, Denmark, Euro Health Group, Denmark and Pharmaceutical University of Copenhagen, Denmark

478

#### Economics, Financing, and Insurance Systems

*Keywords:* Evaluation, generic medicines price, pricing policy.

### Generic Medicine Pricing Policies Evaluation in Indonesia and the Impact on Availability and Medicine Price in Private Sectors

**Yusi Anggriani<sup>1</sup>, Mohamed Izham Mohamed Ibrahim<sup>2</sup>, Sri Suryawati<sup>3</sup>, Martuti S Budiharto<sup>4</sup>, Asrul Akmal Shafie<sup>5</sup>**

<sup>1</sup>Faculty of Pharmacy Pancasila University, Indonesia, School Of Pharmaceutical Science, University Sains Malaysia, Penang, Malaysia; <sup>2</sup>Department of Pharmacy Practice, College of Pharmacy, Qassim University, Al Qassim, Saudi Arabia; <sup>3</sup>Center for Clinical Pharmacology and Medicine Policy Studies, Gadjah Mada University, Yogyakarta,

Indonesia; <sup>4</sup>National Institute Of Health Research and Development, Ministry of Health, Jakarta, Indonesia; <sup>5</sup>School Of Pharmaceutical Science, University Sains Malaysia, Penang, Malaysia

**Problem statement:** The government of Indonesia has given a political commitment to the provision of affordable medicines. Pricing policies on generic medicines that have been implemented by MoH need to be evaluated.

**Objectives:** To evaluate generic medicines price policies and the impact on the price and availability of selected medicines in private sectors

**Design:** Policy evaluation, cross-sectional study

**Setting:** Survey was conducted in 52 private pharmacies from 4 provinces in Indonesia.

**Study population:** Five generic medicine price policies from the period 2005–10 and 50 medicines (14 global, 15 regional, and 21 supplementary) were evaluated.

**Policies:** Medicine price policy in Indonesia set maximum prices for generic medicine for procurement and retail. Public sectors procurement price must comply with the policy. Retail price of private sector cannot be more than maximum price.

**Outcome measure(s):** Number of items in price policy, trend of MoH generic medicine price, comparison of generic medicines price at private pharmacies with MoH maximum price, MPRs of latest MoH procurement price, MPRs and availability of generic medicine in private sectors. The 2009 International Reference Price (IRP) was used to compare MoH procurement price and retail price.

**Results:** Only 42 generic medicines price were evaluated; 8 global and regional medicines were not on the MoH list. 153 medicines were regulated in 2005 price policy. From 2006 to 2010, items on the policy nearly tripled over the number on the 2005 list. There were 387, 458, 455, and 453 items in 2006, 2006, 2008, and 2010, respectively. The trend of generic medicine prices showed that the highest medicine prices were in 2005. After the 2006 policies were enacted, most generic medicine prices decreased significantly from 2005 MoH prices. The changes in prices in 2006 were based on HAI and WHO survey recommendations in Indonesia on 2005. Two years after prices decreased, a new price policy was implemented in 2008. When comparing 2006 and 2008 MoH prices, 32 items did not change, 6 items increased, and 4 items decreased. When comparing current (2010) policy with 2008 price, 33 items did not change, 6 items decreased, 3 items increased. Of 42 items, only 36 items were calculated for MPRs, 6 items were not in IRP 2009. 25 items' MPRs of MoH procurement price were >IRP, and 9 items MoH procurement price were <IRP. Most of medicine prices in the private sector were more than the MoH maximum price; only 2 items had MPRs <IRP and 34 items had MPRs >IRP. The availability of 42 medicines was very low for 11 items (26.2%), low for 5 items (11.9%), fairly high for 15 items (35.7%), and high for 11 items (26.2%).

**Conclusions:** MoH generic medicine prices 2005–10 tend to decrease. MPRs of MoH procurement prices were higher than IRP 2009. Most of retail prices in the private sector exceeded MoH maximum price. At private sector facilities, generic medicine prices in Indonesia are still expensive, and availability is still a problem.

**Funding source(s):** Self-funded

483

### Economics, Financing, and Insurance Systems

**Keywords:** Pharmaceutical policy, pricing, external price referencing, Europe

#### Differences in External Price Referencing in Europe—A Descriptive Overview

**Christine Leopold<sup>1,2</sup>, Sabine Vogler<sup>1</sup>, Aukje Mantel-Teeuwisse<sup>2</sup>, Kees de Joncheere<sup>3</sup>, Richard Laing<sup>4</sup>, Bert Leufkens<sup>2</sup>**

<sup>1</sup>Gesundheit Österreich GmbH (GÖG), Austria; <sup>2</sup>Utrecht Institute for Pharmaceutical Sciences, the Netherlands; <sup>3</sup>WHO Regional Office for Europe, Denmark; <sup>4</sup>WHO Department of Essential Medicines and Pharmaceutical Policies, Switzerland

**Problem statement:** Various pricing policies are applied in European countries; external price referencing (EPR)—the mechanism of setting and/or negotiating the price on the basis of the price in other countries—is the most common pricing policy in Europe with many national specifications.

**Objective:** To provide an up-to-date description as well as comparative analysis of the national characteristics of EPR in Europe.

**Design:** Cross-country descriptive study; review of the country-specific Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Profiles as well as personal contacts with members of the PPRI network

**Setting and study population:** 27 EU countries as well as Norway

**Interventions:** N/A

**Policy:** EPR, the policy under investigation in this study, is defined by the glossary of the European PPRI network as “the practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.”

**Outcome measure(s):** The outcome was the number of countries that applied EPR in 2010 as well as the number of countries with the most common mechanisms within the EPR methodology.

**Results:** 24 European countries have implemented EPR in 2010. The majority of countries had statutory rules to enforce EPR. Most countries had less than 10 countries in the reference basket; five countries defined between 10 and 20 countries in their basket, and three countries had more than 20 countries in their basket. Taking the average price of all countries in the basket as the basis to calculate the price was the most common strategy (n=8). The methodology of

EPR has changed in most European countries (n=19) over the past 10 years. Two countries have decided to abolish EPR as means of national price setting for medicines, but Malta decided in 2010 to implement EPR for regulating the prices of new medicines.

Conclusions: EPR is a widely used pricing policy. Important differences were observed between countries in the way they carry out this pricing policy. A trend on including more reference countries in the basket was recognised. The widespread use of this policy may serve to save public funds by efficient price setting but may also result in prices tending to converge without taking into account different countries' ability to pay.

Funding source(s): Self-funded

484

#### **Economics, Financing, and Insurance Systems**

*Keywords:* Pharmaceutical policy, price comparison, external price referencing, Europe

### **How Much of the Price Variance of Medicines Can Be Explained by External Price Referencing?—A price Comparison among 15 European Countries**

**Christine Leopold<sup>1,2</sup>, Sabine Vogler<sup>1</sup>, Leonhard Seyfang<sup>1</sup>, Aukje Mantel-Teeuwisse<sup>2</sup>, Kees de Joncheere<sup>3</sup>, Bert Leufkens<sup>2</sup>, Richard Laing<sup>4</sup>**

<sup>1</sup>Gesundheit Österreich GmbH (GÖG), Austria; <sup>2</sup>Utrecht Institute for Pharmaceutical Sciences; <sup>3</sup>WHO Regional Office for Europe, Denmark; <sup>4</sup>WHO Department of Essential Medicines and Pharmaceutical Policies, Switzerland

Problem statement: Regulating medicine prices by the implementation of pricing policies such as external price referencing (EPR) is widespread in Europe. The assumption is that countries that apply EPR have lower medicine prices than countries without EPR.

Objectives: To examine the impact of EPR on the average price level of 15 European countries in 2007 and 2008

Design: Cross-country volume-weighted price analysis of a basket with 20 products in 15 countries in 2007 and 2008. Multivariable analysis was performed to account for differences on the gross domestic product, total pharmaceutical expenditure, and the national employment in the pharmaceutical industry.

Setting and study population: 20 products in 15 countries (11 applying EPR and 4 countries without EPR) in 2007 and 2008 were investigated. The unit ex-factory prices of each product were weighted according to their sales volume. The prices were compared between the two groups of countries with and without EPR as well as over time. For some countries, such as the United Kingdom, the prices were adjusted to exchange rate fluctuations.

Interventions: N/A

Policy: EPR, a policy in which the price(s) of a medicine in one or several countries is used to set or negotiate the price of the product in a given country, is only applicable for prescription-only or reimbursable medicines in the majority of EU countries.

Outcome measure(s): The average price level in the countries with and without EPR

Results: Data will be presented showing that, in principle, the average prices were lower in countries with EPR. This outcome was especially true for on-patent reimbursable products, which showed a less erratic picture, although considerable variation was observed between individual products and countries. Regulatory safety discussion (e.g., for Avandia and Actos) also had an influence on the price development of the products. Products that already had generic alternatives on the market had, in general, lower prices in all countries whether EPR was applied or not.

Conclusions: Countries with EPR seemed to have more erratic prices. More specifically, EPR seemed to be a reasonable pricing policy for on-patent reimbursable medicines to have moderate prices.

Funding source(s): Self-funded

486

#### **HIV/AIDS and TB**

*Keywords:* Pharmacovigilance; Adverse Events (AEs); Drug-resistant (DR) TB; Second line anti-TB medicines; Medicine safety

### **Prevalence and Risk Factors of Adverse Effects of Second Line Anti-Tuberculous Medicines In A Treatment Facility in Namibia: 2009-10**

**Evans Luvaha Sagwa<sup>1,2,3</sup>, Dhliwayo Panganai<sup>4</sup>, Farai Mavhunga<sup>5</sup>, Nunurai Ruswa<sup>5</sup>, Jean Paul Musasa<sup>5</sup>**

<sup>1</sup>Management Sciences for Health, Namibia; <sup>2</sup>University of the Western Cape, South Africa; <sup>3</sup>Utrecht University, Netherlands; <sup>4</sup>TBCAP Namibia; <sup>5</sup>Ministry of Health & Social Services, Namibia

Problem Statement Namibia reported 372 cases of DR-TB in 2009. Second-line TB medicines have more frequent and serious adverse effects (AEs). The high TB/HIV co-infection (58%) is a further complicating factor.

With little documented information on the profile and risk factors of these AEs, managers of tuberculosis control programs, clinicians and patients face challenges in optimizing treatment outcomes.

Objectives 1) To determine the types and frequency of AEs of second-line anti-TB medicines in a selected DR-TB treatment facility; 2) Identify the AE risk factors

Design Cross-sectional. Data were collected from patient's treatment records using a structured form. Descriptive statistics applied to profile AEs. Logistic regression was used to calculate Odds ratios (OR; 95% confidence interval,  $p < 0.05$ ) in risk factor analysis.

Setting A district TB treatment facility.

Study Population All patients treated for DR-TB at the study facility from Jan-2008 to Feb-2010.

Outcome Measure(s) Occurrence and characterization of AEs.

Results *Demographics* : Male (M) 64%; Age (mean years  $\pm$  SD),  $36.9 \pm 8.4$  (M),  $31 \pm 10.2$  (F); Initial weight (mean kgs  $\pm$  SD),  $53.6 \pm 7.8$  (M) and  $49.8 \pm 16.4$  (F)

A total of 141 AEs were experienced in 90% (53/59) patients. GIT events were 64%; tinnitus 45%; joint pain 28% and decreased hearing 25%. In 53% of patients, AEs resolved within 3 months. AEs were severe, requiring discontinuation of suspected medicine in 15% of patients, 9% recovering with sequelae.

#### *Risk-factor analysis*

Moderate-severe AEs were associated with HIV co-infection (OR 3.12; 95% CI 1.04 – 9.33,  $p=0.04$ ). AEs lasting  $> 3$  months were associated with ARV co-medication (OR 7.88; 95% CI 1.11 – 56.12,  $p=0.04$ ). GIT effects were mostly experienced in the first month of DR-TB treatment (OR 4.29; 95% CI 1.25 – 14.73,  $p=0.02$ ). Nausea was associated with AZT-based HAART (OR 7.50; 95% CI 1.09 -51.51,  $p=0.04$ ) and joint pains with the use of cycloserine-containing regimens (OR 6.35; 1.56 – 25.84,  $p=0.01$ ). Rash in females was (OR 15.86; 95% CI 1.75 – 143.74,  $p=0.01$ ).

In 18 patients with mono/poly-resistant TB, low baseline body weight ( $\leq 45$  kgs) increased risk of GIT events (OR 16.50; 95% CI 1.10-250.2,  $p=0.04$ ) and decreased hearing (OR 36.00; 95% CI 1.71 – 756,  $p=0.02$ ). Amikacin (OR 12.00; 95% CI 1.29 – 111.32,  $p=0.03$ ) and ciprofloxacin (OR 27; 95% CI 1.98 – 368.28,  $p=0.01$ ) increased ototoxicity.

Among 37 MDR-TB patients, HIV co-infection increased risk of experiencing  $3 \geq$  AEs (OR 8.00; 95% CI 1.28 – 50.04,  $p=0.03$ ), mostly moderate-severe (OR 10.42; 95% CI 1.62 – 66.90,  $p=0.02$ ). Joint pains occurred in cycloserine-based regimens (15.67; 95% CI 1.70 – 144.35,  $p=0.02$ ) and efavirenz-based HAART (OR 13.46; 95% CI 1.02 – 178.30,  $p=0.05$ ).

Conclusions Although AEs were highly prevalent in DR-TB chemotherapy, 85% of patients tolerated them. GIT effects and hearing loss were commonest. Findings of risk-factor analysis are statistically imprecise, inconclusive and require further study.

488

#### Child Health

*Keywords:* pediatric medicines, access to medicines, formulary, preferences

### Parents' and Caretakers' Administration Practices and Formulation Preferences of Children's Medicine in Tanzania

**Lisa Virginia Adams<sup>1</sup>, Sienna R. Craig<sup>2</sup>, Elia John Mmbaga<sup>3</sup>, Helga Naburi<sup>3</sup>, Rodrick Kisenge<sup>3</sup>, Stephen P. Spielberg<sup>4,5</sup>**

<sup>1</sup>Dartmouth Medical School, United States of America; <sup>2</sup>Dartmouth College; <sup>3</sup>Muhimbili University of Health and Allied Sciences; <sup>4</sup>Institute for Pediatric Innovation; <sup>5</sup>Mercy Children's Hospital

Problem statement: The lack of medicines formulated for children contributes to the high mortality rate of children under age five. There are no data describing the current administration practices and formulation preferences for children's medicines from parents and caretakers in resource-limited settings. Information on current practices and preferences can be used to guide new formulation development to ensure access, proper dosing, improved adherence, and optimal therapeutic outcomes.

Objectives: To determine parents' and caretakers' current administration practices of children's medicines and their preferences for formulation, taste, and method of administration

Design: A descriptive cross-sectional survey using a validated questionnaire

Setting: Ten randomly selected regions throughout Tanzania, with one urban and one rural census enumerated area per region based on National Bureau of Statistics data

Study population: A sample totaling 202 parents or caretakers with children under age 12, randomly selected from households and outpatient health care facilities

Intervention: A validated questionnaire was administered by trained interviewers during the period March 15 through July 6, 2010.

Outcome measure(s): Current and preferred methods of administration of children's medicines and preferred formulations and taste

Results: Parents and caretakers report administering medicines to their children by having them swallow pills whole (48, 24%) or having them swallow crushed or broken tablets mixed with water (59, 34%). Parents and caretakers report having administered a range of pill fractions to their children. In contrast to this information, the majority of parents and caretakers (155, 80%) reported that they prefer sweet-tasting medicines for children, with far fewer preferring no taste (13, 7%), deferring to the child's preferences (9, 4.5%), and preferring bitter tasting medicines (2, 1%). Formulations preferred included syrups (172, 85%), suppositories (73, 36%), chewable tablets (64, 32%), and pills (24, 12%). Preferred methods of administration of children's medicines vary by age group. Most preferred to administer syrups to newborns (178, 96%), infants (177, 93%), and toddlers (147, 76%), but to crush and dissolve a pill for preschoolers (93,

48%). Swallowing a whole pill was the preferred method for primary school-age children (165, 85%). Practices and preferences did not vary between urban and rural settings.

Conclusion: Parents and caretakers in Tanzania prefer sweet liquids for younger children and swallowing whole pills for primary school aged children. Parents and caretakers are unfamiliar with dispersible tablets.

Funding source(s): Better Medicines for Children, World Health Organization

489

#### Drug Resistance

Keywords: Antibiotics, Acute Respiratory Tract Infections, Self-Medication; Drug Utilization

### Antibiotic Knowledge and Self-Care for Acute Respiratory Tract Infections in Mexico

Ralph Gonzales<sup>1</sup>, Alma López-Caudana<sup>2</sup>, Tulia González<sup>3</sup>, Janaki Jayanthan<sup>4</sup>, Kitty Corbett<sup>4</sup>, Hortensia Reyes-Morales<sup>5</sup>

<sup>1</sup>University of California, San Francisco. USA; <sup>2</sup>Instituto Mexicano del Seguro Social, Mexico; <sup>3</sup>Universidad de Guanajuato, Mexico; <sup>4</sup>Simon Fraser University, Burnaby, BC. Canada; <sup>5</sup>National Institute of Public Health, Mexico

Problem statement: Community-acquired infections caused by antibiotic-resistant microbes are a major and growing threat to global public health. Self-treatment with antibiotics is a concern not only because the antibiotics are frequently unnecessary, but also because even if the person actually needs antibiotics, he or she may be taking the wrong antibiotic.

Objective: To examine knowledge of and self-treatment with antibiotics among medically insured adults in Mexico

Methods: We conducted a cross-sectional, interviewer-administered survey among patients seeking care for acute respiratory tract infections (ARIs) in a family medicine clinic in Cuernavaca, Morelos, Mexico. The study population consisted of a convenience sample of patients over 13 years of age with ARIs who were seeking medical attention for their illness. Antibiotic knowledge scores were calculated as a composite of correct, incorrect, and "don't know" responses to 4 common antibiotics and 8 common non-antibiotics. Factors associated with antibiotic knowledge and antibiotic self-treatment were explored with bivariate analyses.

Results: 101 participants completed the surveys. 47% of participants were taking antibiotics before the visit, and 20% were self-treating with antibiotics. Antibiotic knowledge was highly variable. Notably, high proportions of participants believed common non-antibiotic treatments for colds and coughs were antibiotics, such as ambroxol (45%), Desenfriol (45%), and paracetamol (44%). Older participants (>40 years) had much higher knowledge scores compared with younger participants. There was little difference in antibiotic knowledge scores by gender, education level, and prior antibiotic use or self-care with antibiotics.

Conclusion: Self-treatment with and misperceptions about antibiotics are common among medically insured patients in Mexico. Self-treatment behaviors with antibiotics among Hispanic communities in the United States may reflect a deeper sociocultural phenomenon rather than a response to limited access to physician services.

Funding source(s): This study was funded in part by a Fulbright Garcia-Robles All Disciplines award #8584 (RG).

490

#### Policy, Regulation, and Governance

Keywords: pharmaceutical policy, access to medicines, promotion

### Policies to Increase Use of Generic Medicines in Low- and Middle-Income Countries: A Literature Review of Implementation Research

Warren Kaplan<sup>1</sup>, Veronika Wirtz<sup>2</sup>, Lindsay Ritz<sup>1</sup>, Marie Vitello<sup>1</sup>

<sup>1</sup>Center for Global Health & Development, Boston University School of Public Health, United States of America;

<sup>2</sup>Instituto Nacional de Salud Publica, Cuernavaca Mexico

Problem statement: In large part due to the creation of the WHO Essential Medicines Concept, for several decades now many countries have been implementing pharmaceutical policies to encourage use of generic medicines. Monitoring and evaluating the implementation of such policies has taken place in the United States and the European Union, and there is a reasonably rich literature on this subject. It is not clear how much implementation research on the impact of pro-generic medicines policies has taken place in low- and middle-income countries (LMICs) and which policy options should be given priority in LMICs.

Objectives: To determine the extent of implementation research on pro-generic medicine policies in LMICs since 2000; to determine if the existing generic medicines policies in the United States and the European Union would be applicable in LMICs; and to suggest a minimum repertoire of pro-generic medicine policies suitable for all LMICs

Design: Literature review and bibliometric analysis looking at both supply side and demand side policies

Setting: High-income and LMICs as defined by the World Bank

Study population: Databases: PubMed, CINAHL, Popline, EMBASE, PAIS, ISI Web of Science, LILACS, and ScieLo (Latin America).

Intervention: Public policies introduced to promote the use of generic medicines

Outcome measure(s): Implementation research investigating the impact of pro-generic medicine policies on changes in price or volume share as a result of the policy change(s) (i.e., before-and-after study with or without control group, time-series analysis).

Results: (1) Out of a total of 439 relevant articles retrieved, 74 focused exclusively on LMIC and only 7 were implementation research. (2) Many policies in the United States and the European Union have been implemented via public health services or private insurance systems. (3) Medicines regulatory authorities play an important role to ensure quality of generic medicines and provide reliable information to all actors in the pharmaceutical sector.

Conclusions: There is very little implementation research on pro-generic medicine policies in LMICs, notwithstanding the fact that such policies have been in place in some countries for many years. Results of policy impact evaluation to promote generic medicines in LMIC would allow providing more support for LMIC in search for ways to effectively implement these policies. Given the general lack of insurance systems and prescriber, dispenser, and consumer education about generic medicines in many LMICs, not all US and EU policies would be successful there. Basic conditions for successful pro-generic policies in LMICs include (1) a medicines regulatory system that people trust, (2) sufficient in-country competition among generic manufacturers, and (3) alignment of financial incentives of prescribers or dispensers and consumers with regard to generics.

Funding source(s): World Health Organization and Health Action International

492

#### Access

Keywords: online training, medicines' management and use, training outcomes

### **A Blended e-Learning Course—"Management of Medicines in International Health"—Contributes to Knowledge Transfer and Improving Medicines Use**

Reinhard Huss<sup>1</sup>, Frans Stobbelaar<sup>2</sup>, Rob Summers<sup>3</sup>, Karin Anne Wiedenmayer<sup>4</sup>

<sup>1</sup>Nuffield Centre for International Health and Development, Leeds, United Kingdom; <sup>2</sup>AGEG Consultants eG, Kirchheim unter Teck, Germany, on behalf of InWEnt – Capacity Building International, Germany; <sup>3</sup>University of Limpopo, Medunsa Campus, Department of Pharmacy, Pretoria, South Africa; <sup>4</sup>Swiss Tropical and Public Health Institute, Basel, Switzerland

Problem statement: Internationally, undergraduate training of health professionals in the management of medicines (MM) is often neglected. We therefore designed a supervised peer-to-peer, work-based, blended learning course, "Management of Medicines in International Health" (MMIH), with InWEnt using its learning platform Global Campus 21. MMIH consists of online modules, problem-based exercises, virtual group work, and chats. Participants learn about MM affecting medicine access and use and develop a project intervention during the contact course to improve MM in a specific context.

Objectives: To assess the course and its outcomes, including medicines use

Design: An outcome and impact evaluation with no control group using OECD DAC evaluation quality standards was developed.

Setting: The evaluation was conducted in 2009 as an international online survey of 67 participants from 18 countries and an outcome workshop in Tanzania with 18 participants from five countries, primarily in Africa and Asia. The respondents worked in the public, social, and private health sector.

Study population: The study population was 117 students from 27 countries from three MMIH courses between 2005 and 2008. All alumni were invited by e-mail to participate in an online survey with a 61% response rate. 63% were male; 94%, from Africa and Asia; 54%, pharmacists; and 26%, medical doctors.

Interventions: The evaluation included quantitative and qualitative data from an online questionnaire, semi-structured interviews of resource persons, an outcome workshop with 18 selected survey respondents, and analysis of projects presented by the respondents.

Outcome measure(s): Recorded changes in job situation; personal development in terms of knowledge, skills, and attitude; relevance and applicability of the course and specific components, sharing of knowledge and skills in the work environment, use of the Internet, and networking for professional development and projects to improve MM

Results: Two-thirds of respondents reported job changes, the majority of which were linked to the course. Almost 80% spent more time on MM than previously. 94% advocated MM to improve access. The topic of rational use was highly rated for relevance and applicability. More than half (53%) had initiated and 18% completed an MM project. Eleven of the 22 listed projects focused on improving medicines use.

Conclusions: The course responds to a need, and alumni feel empowered to work in MM. The course was more relevant for professional development and less for current work situations. Nevertheless, a number of projects were listed as being initiated, half of which addressed medicines use. The actual outcomes of these projects and the transfer of skills into practice still have to be measured. Course development needs to include promotion and dissemination skills and should widen the application perspective to work environments and country situations to improve its impact. Regional satellite courses can further strengthen the impact of the course.

Funding source(s): Federal Ministry for Economic Cooperation and Development (BMZ), Germany

493

#### Policy, Regulation, and Governance

Keywords: regulation, traditional/herbal medicines

### **Policy for Rational Regulation and Quality Use of Natural Health Products in the Philippines**

Isidro Cabuyao Sia

University of the Philippines Manila, Philippines

**Problem statement:** There has been an intense use of natural health products in the Philippines. In 2007, more than 5 billion Philippine pesos (USD 114 million) was spent for herbs, food supplements, and other natural products. These products had been registered with the Philippine Food and Drug Administration as food supplements and are not allowed to make any therapeutic claims. Such products are heavily advertised, however, and Filipinos use them for a myriad of medical indications. There is need to rationalize the regulation and use of said products.

**Objective:** To craft policy recommendations for the rational regulation and quality use of natural health products

**Design:** Multi-stakeholder consultation and consensus-building toward policy recommendations based on previous studies, available scientific literature, and the sociocultural context of the Filipino use of natural health products

**Study participants:** The stakeholders shall come from government regulatory authority, industry, academia, health care professions, consumer groups, and media.

**Methods:** Focus group discussions with the stakeholders consisting of the regulatory authority, industry, academia, health care practitioners, consumers, and media. Key informant interviews with opinion leaders from government, industry, academia, health professions, and consumer groups.

**Results:** The policy recommendations for the evaluation and registration of natural products were congruent with the proposed guidelines of the ongoing ASEAN harmonization of evaluation of traditional medicines and health supplements. These include procedures for quality, safety, and efficacy requirements for traditional medicines and health supplements, as well as claim requirements for the said groups of natural products.

**Funding source(s):** National Institutes of Health of the University of the Philippines, Manila

**496**

**HIV/AIDS and TB**

*Keywords:* adherence, antiretrovirals, HIV/AIDS, hospital, public sector

### **Reasons for Nonadherence to Antiretroviral Therapy among Adult Patients Receiving Free Treatment at a Tertiary Care Hospital in Delhi**

**Vivek Lal<sup>1</sup>, Shashi Kant<sup>2</sup>, Richa Dewan<sup>3</sup>, Sanjay K. Rai<sup>2</sup>**

<sup>1</sup>Indian Institute of Health Management Research, India; <sup>2</sup>All India Institute of Medical Sciences, New Delhi, India; <sup>3</sup>Lok Nayak Hospital, New Delhi, India

**Problem statement:** Adherence to therapies is a primary determinant of treatment success in HIV/AIDS. Poor adherence attenuates optimum clinical benefits and therefore reduces the overall effectiveness of health systems. India-specific data on adherence is sparse. In light of the expansion of free antiretroviral therapy (ART) in the country, there is a need to learn what works and what does not. The reasons for nonadherence to ART need to be studied to identify patients who may need support in maintaining adherence and explore the means to do so.

**Objectives:** To ascertain self-reported reasons for nonadherence to ART by adult patients receiving free ART

**Design:** Cross-sectional, hospital-based study

**Setting:** ART Clinic of Lok Nayak Hospital (LNJP) at Delhi. LNJP is a tertiary care, government hospital. This hospital was identified by the Government of India as one of the first sites to offer free ART. The clinic has been functional since April 2004. The clinic provides free ART to patients.

**Study population:** HIV/AIDS patients attending OPD clinics, on self-administered ART for at least one week, and of age 18 years or older were included in the study. Consecutive sampling procedures were adopted, and OPD cards were marked to ensure that each patient was interviewed only once. The period of data collection was from January 2005 to December 2005.

**Outcome measure(s):** Adherence was assessed retrospectively over the previous four-day period, as used in the AIDS Clinical Trials Group (ACTG) follow-up questionnaire. Respondents self-reported when they last missed an antiretroviral (ARV) dose and, using a checklist, indicated the common reasons as to why they skipped their medication.

**Results:** In total, 200 patients were interviewed. The mean age was 33.3 years. The majority of patients were male and belonged to the age group 31–45 years. It was found that 90% had been adherent over the previous four-day period. 30% of the patients claimed to have ever missed a dose. Multiple responses were allowed for the patients in response to the reasons for ever having missed an ARV dose. The most commonly cited reasons were “away from home” and “simply forgot.” All the patients reported having been told about proper dosing, yet 6.5% reported having ever missed a dose when they felt sick.

**Conclusion:** Study results showed a high level of adherence over the previous four-day period (90%); however, 30% of patients reported having ever missed a dose. The data prove that free ART has been taken up well by the patients and lend support to the decision of the scaling-up of free ART. At the same time, these findings put greater responsibility on the system in terms of sustainability of the free ART program and support through formal counseling sessions to help patients to continue to adhere to this lifelong therapy.

**Funding source(s):** None

**497**

**Access**

*Keywords:* access to medicines, pharmaceutical policy, health facilities, human resources, indicators

## Measuring Access to Essential Medicines in Kenya Using the Standardized WHO Level II Health Facility Assessment

**Regina M Mbindyo<sup>1</sup>, Fred M Siyoi<sup>2</sup>, Njeri Mucheru<sup>3</sup>, Christa Cepuch<sup>4</sup>, Joan Wakori<sup>5</sup>**

<sup>1</sup>WHO, Kenya; <sup>2</sup>Pharmacy and Poisons Board - Kenya; <sup>3</sup>Ministry of Medical Services, Department of Pharmacy - Kenya; <sup>4</sup>Health Action International-Africa; <sup>5</sup>Kenya Medical Supplies Agency

**Problem statement:** Access to essential medicines (EMs) is a stated goal for Kenya's health system. Pharmaceuticals are complex, and multiple and cross-cutting factors influence access. A pharmaceutical situation assessment was undertaken in Kenya in October 2008, as a critical tool in determining the extent to which existing policies are contributing to access and providing evidence for policy development and strategic planning.

**Objectives:** To determine whether EMs to treat common conditions at primary care level (1) are available and affordable in facilities, (2) are properly managed, and (3) are prescribed and dispensed appropriately and by qualified personnel

**Design:** Cross-sectional study; adapted WHO Level II Health Facility Assessment tool; before-and-after comparison of public sector findings with similar 2003 study

**Setting:** National survey covering public facilities, faith-based health services (FBHS) facilities, and private sector facilities in 18 districts from 6 of the 8 provinces. Survey sites were hospitals, health centers and dispensaries, central warehouses, and retail pharmacies.

**Study population:** 108 facilities (36 per sector) and two central warehouses. Sampling of facility records and patients followed standard INRUD methodology.

**Policy change:** National Drug Policy 1994 under review. Health sector SWAp implemented within the second Health Sector Strategic Plan. Public supply of EMs being integrated centrally, with partial roll-out of the inventory-based ordering (pull) system. Some increase in medicines financing from the government and donors.

**Outcome measure(s):** Availability, affordability, prescribing, dispensing, health professional profiles

**Results:** For public, FBHS, private indicators: (1) percentage of availability of 15 basic EMs: 87 (93), 93, 93; (2) percentage of availability of 36 EMs: 67 (n/a), 66, 8; (3) stock-out days of 15 basic EMs (central): 0 (n/a)-0; (4) stock-out days of 15 basic EMs (facilities): 46 (25), 14; (5) centralized procurement MPR: 0.44 (n/a), 0.61, (n/a); (6) percentage of medicines issued for free: 89 (n/a), 15, 0; (7) affordability of selected individual treatments: <1 days' reference wage (all sectors) (<1); (8) percentage of adequacy of storage (central): 50 (n/a), 100 (n/a); (9) percentage of adequacy of storage (facilities): 60 (75), 75, 80; (10) percentage of adequacy of labeling: 5 (13), 21, 40; (11) percentage of antibiotics prescribing: 77 (78), 68 (n/a); (12) percentage of prescribing according to EML: 93 (81), 79, (n/a); (13) percentage of facilities complying with dispensing law: 38 (n/a), 31, 81; (14) percentage of unqualified personnel dispensing: 42 (n/a), 25, 14; and (15) percentage of untrained staff prescribing: 14 (n/a), 6 (n/a).

**Conclusions:** (1) Basic EMs are available in all sectors; a broader scope of EMs is less available. (2) Public and FBHS centralized procurement systems are price-efficient; they procure almost exclusively generics. (3) Frequent, sometimes critical stock-outs occur in public facilities. (4) Public sector has low or no price barriers to accessing EMs. (5) Public sector medicines storage infrastructure is critically deficient. (6) Critical shortage of pharmaceutical personnel hinders services. (7) The mixed performance on RUM may reflect lack of clear strategies. (8) Regulatory requirements are not effectively enforced in public and FBHS facilities. (9) Public sector indicators show stagnation or deterioration compared to 2003. (10) Pharmaceutical services are poorly integrated in health sector coordination mechanisms.

**Funding source(s):** The survey was conducted with financial support—through WHO—from the UK Department for International Development (DFID) project on Access to Essential Medicines and the European Commission's EC/ACP/WHO Partnership on Pharmaceutical Policies. WHO provided technical support in collaboration with HAI-Africa, in the context of the DFID-supported WHO/HAI collaboration project on Access to Essential Medicines.

498

### Economics, Financing, and Insurance Systems

*Keywords:* Access to medicines, financing, health economics

### Taxes on Medicines

**Margaret Ewen, Andrew Lacey Creese**

Health Action International, Amsterdam

**Problem statement:** Price is an obstacle to access to medicines, and in many countries, taxes add 25 to 30% to the retail price of medicines. Yet the epidemiology of medicine taxation has barely been studied, and policy experience with tax changes and tax policy options is little documented.

**Objective:** To identify, describe, analyse, and discuss sales taxes on medicines, their impact on revenue generation and on medicine affordability, and their impact (positive and negative) when reduced, abolished, or reintroduced

**Design:** Descriptive study based on literature review and analysis of the WHO/HAI database on medicine prices

**Setting:** Over 60 countries at all income levels were studied for tax practices as applied to medicine, and literature was reviewed on evidence of price-responsiveness to medicine price changes.

**Results:** Medicine tax data are presented for over 60 countries. Taxes are often the third biggest component in a medicine's retail price, after manufacturer's selling price and distribution mark-ups. Taxes are often levied cumulatively at local, state, and national levels. Medicine taxes yield between 0.5 and 1.6% of total government revenue for a sample of countries assessed. Countries at all income levels raise taxes from the sales of medicine. Yet some countries, including low-income countries, specifically exempt medicines from all taxes. The price-responsiveness of

demand for medicines has been measured in several settings and shown to be positive but less than one, meaning that an increase in price, other things being equal, will reduce demand and vice-versa. Some groups of people (i.e., the poor and the elderly) are more sensitive to price changes than others.

Conclusion: Evidence about peoples' price-responsiveness for health care in general and medicines in particular is reviewed, and the economic case for and against taxing medicines is assessed. Arguments for orienting tax systems away from medicines and toward health- and welfare-damaging goods and actions are presented, with some estimates of the magnitude of potential revenue generation. Higher taxes on alcohol, tobacco, sugary soft drinks, and fatty foods are shown to have sufficient potential to offset tax losses from reductions in tax on medicines in different settings.

Funding source(s): Health Action International, Amsterdam

**499**

### **Policy, Regulation, and Governance**

*Keywords:* essential medicines; access to medicines; selection; pharmaceutical policy

#### **Selection of Essential Medicines**

---

**Aukje Kaija Mantel-Teeuwisse<sup>1</sup>, Rianne van den Ham<sup>1</sup>, Richard Laing<sup>2</sup>**

<sup>1</sup>Utrecht Institute for Pharmaceutical Sciences, Utrecht University, Utrecht, the Netherlands; <sup>2</sup>World Health Organization, Geneva, Switzerland

Problem statement: Essential medicines are defined as those that satisfy the priority health care needs of the population. Since 1977, a WHO expert committee has developed a Model List of Essential Medicines every 2 years (Model EML). The Model EML serves as a tool for countries to develop their own essential medicines list (EML).

Objectives: To describe the evolution of the Model EML over time (1977–2009) and to compare national EMLs and the Model EML to verify how countries use the Model EML for their own decision making

Design: Descriptive study

Setting: International (Model EML) and national (EML) level

Study population: WHO Model EMLs between 1977 and 2009 were assessed. In addition, 12 national EMLs (equal representation of the 6 WHO regions) from the year 2006 and 2007 were selected and compared to the 2005 Model EML.

Intervention(s): N/A

Policy: An EML is a helpful tool to achieve better health care, better drug management, and lower costs. The contents of the WHO Model EML and the selection process itself should serve as model. Over the years, the selection process used by WHO changed fundamentally over time. Selection is based on the underlying evidence rather than experience of committee members.

Outcome measure(s): WHO Model EML: both the quantitative (e.g., number of molecules and formulations, dosages, and their ratio) and qualitative changes (e.g., additions and deletions of specific medicines). Differences in medicines included in the Model EML and the 12 national lists.

Results: The number of molecules listed on the Model EML increased between 1977 and 2009 from 204 to 355 molecules, excluding duplicates. The list expanded mainly due to the growth of specific sections and the incorporation of the EML for children. Comparison with national EMLs showed that 42% of these EMLs contained fewer medicines than the 312 medicines that were present on the WHO Model List of 2005. The ratio of dosage forms to medicines ranged from 1.2 to 2.1 for national EMLs compared to a ratio of 1.7 in the WHO Model EML 2005. Examples of medicines that appeared on none of the national EML's were anti-infectives such as triclabendazole and levofloxacin, cytotoxic medicines such as chlormethine and levamisole, and the combination mifepristone-misoprostol, used for early pregnancy termination. Alternatively, some medicines that appeared on the national EMLs but not on the 2005 Model EML, did appear on the 2009 Model EML, such as omeprazole.

Conclusions: The WHO Model EML expanded considerably between 1977 and 2009. Undesirable differences between the Model EML and national EMLs were observed. Reasons for countries not to include specific medicines may be the variety in burden of disease costs, unavailability, or cultural unacceptability of the medicine. The selection process should not be determined by an expert's opinion and experience but should be the result of a systematic review of the underlying evidence.

Funding source(s): None

**502**

### **Policy, Regulation, and Governance**

*Keywords:* medicines access, transparency, rational use, regulation, pharmaceutical scan

#### **Process and Lessons from the Philippine Pharmaceutical Sector Scan**

---

**Noel Reyes Juban, Vincent Bryan Salvador, John Timojin Tawasil, Rex Justin Lim**

College of Medicine, University of the Philippines - Manila, Philippines

Problem statement: In the Philippines, medicines access, use, and regulation remain an important part of the health care system, but consolidated information about and the level of transparency between the parties involved (i.e., the public, drug companies, and government) have not yet been thoroughly investigated. The Pharmaceutical Sector Scan is one of the tools of the Medicines Transparency Alliance (MeTA) developed to gauge the extent of available

information on medicines access, use, and regulation in the country. The data collated are envisioned to assist the national MeTA stakeholder groups in their efforts to improve transparency in the pharmaceutical sector and to set priorities for future activities.

**Objectives:** To provide experience with the tool that might be helpful for future use in other countries and highlight difficulties encountered during the process

**Design:** A standardized, user-friendly data collection tool, and methodology developed by the Harvard Group helped in the systematic collection and analysis of data about medicines access, use, and regulation through literature reviews, existing documents, and interviews with key informants; adapted to local setting and conditions

**Setting:** National level, with an examination of data from both public and private sectors

**Study population:** Key informants including heads of government agencies, representatives of the pharmaceutical sector, and other stakeholders involved in medicines access, use, and regulation were interviewed.

**Outcome measure(s):** Targeted outcome information was tabulated in the 8 different topic categories and referenced accordingly based on the different sources of information. If no information was available even after exhausting all possible sources, it was noted accordingly.

**Results:** The investigating team, composed of 3 full-time researchers, completed the gathering of data within 1 month. Much of the information collected was widely available on the Internet. The rest was obtained from key informant interviews. Some key information points differed for international and locally derived data, mostly due to the differences in methodologies or definitions. For analysis and validation of results, verification of the collated data from the sources agencies and public presentation through a roundtable discussion with stakeholders were done. Of 270 data fields to be filled, 221 (81.85%) had clear information, 7 (2.59%) were based on estimates from experts, and 9 (3.33%) were not disclosed due to privacy reasons and need to be requested. 31 (11.48%) had no actual data compiled from government agencies, private sectors, or public health studies. The stakeholders of MeTA Philippines have been informed of the results of the scan.

**Conclusions:** The scan tool is comprehensive and user-friendly for gathering key information and their sources.. An extensive source of data can be obtained, majority complete with details and explanatory notes, but some data were aggregates and at times, multiple sources show conflicting results. Performance of the sector based on indicators of good governance and transparency were described. Gaps in information were identified and some obstacles to a total transparency exist.

**Funding source(s):** MeTA

## 505

### HIV/AIDS and TB

*Keywords:* adherence, antiretrovirals, HIV/AIDS, health facilities

#### **Improving Adherence to Antiretroviral Treatment in Uganda: Facility-Based Minimal-Input Intervention**

**Celestino Obua<sup>1</sup>, Joshua Kayiwa<sup>2</sup>, Paul Waako<sup>1</sup>, Göran Tomson<sup>3</sup>, Hudson Balidawa<sup>4</sup>, John Chalker<sup>5</sup>, Dennis Ross-Degnan<sup>6</sup>, Rolf Wahlstrom<sup>3</sup>**

<sup>1</sup>Makerere University, College of Health Sciences, Uganda; <sup>2</sup>Data Department, Joint Clinical Research Centre, Kampala Uganda; <sup>3</sup>Karolinska Institutet, Department of Public Health Sciences, Division of Global Health, Stockholm, Sweden;

<sup>4</sup>The AIDS Control Programme, Ministry of Health, Kampala Uganda; <sup>5</sup>Centre for Pharmaceutical Management, Management Sciences for Health, Arlington Virginia, USA; <sup>6</sup>Department of Population Medicine, Harvard Medical School, Boston USA

**Problem statement:** Adherence to antiretroviral therapy (ART) is crucial to successful treatment outcomes. Initiatives to address the factors influencing adherence in resource-limited settings often rely on heavy financial inputs, which may be unsustainable.

**Objective:** To determine if reducing facility congestion by using minimal-input interventions improves ART adherence in Uganda

**Design:** This was a facility-based interventional, longitudinal, staggered-entry, no-control, pre- and post-intervention assessment of two patient cohorts. Demographic and treatment history were retrospectively extracted from medical records for 6 months pre- and 11 months post-intervention.

**Setting:** Six district-level public facilities providing ART, ranked with poor adherence in a previous national survey were included.

**Study population:** Records for 720 experienced patients who had been on treatment 6 months prior to baseline and 761 newly treated patients who initiated treatment 6 months after baseline onward were examined.

**Interventions:** An appointment system was introduced, under which refill-only patients would be fast-tracked through the facilities' workflows. We also recommended that clinicians increase the dispensed medication days for patients whom they deemed to be stable and reliable from the traditional 30 days to either 60 or 90 days.

**Outcome measures:** We determined (1) the percentage of patients who missed scheduled visits and had medication gaps of 3 or more days over time, using mixed-effects models; (2) the percentage of experienced patients with increased days of dispensed medicines; and (3) the events of having a medication gaps of 7 or more and 14 or more days during the first 120 days of treatment in the newly treated cohort, using Cox proportional hazards models.

**Results:** Among the experienced and newly treated cohorts, there were significant percentage reductions of 5.6% [95% Confidence Interval (CI): 3.8–7.4% decrease] and 6.3% (95% CI: 2.2–10.4% decrease) in missed scheduled visits;

5.0% (95% CI: 3.2–6.9% decrease) and 7.2% (95% CI: 3.0–11.8% decrease) among patients with medications gaps of 3 days or more. The interventions led to significant 4.6% increase (95% CI: 3.4–5.9% increase) in the percentage of experienced patients receiving more than 30 days of dispensed medication; significant 44% [hazard ratio (HR): 0.56, 95% CI: 0.42–0.74] and 38% (HR: 0.62, 95% CI: 0.45–0.85) reductions in the hazards of experiencing a medication gap of 7 or more and 14 or more days, respectively, among the newly treated cohorts.

Conclusions: This study demonstrated that minimal-input interventions designed to reduce crowding at public health facilities are effective in improving ART adherence among patients in Uganda.

Funding source(s): Swedish International Development Cooperation Agency and World Health Organization through Management Sciences for Health.

507

### Economics, Financing, and Insurance Systems

Keywords: Drug Utilization, Health Insurance, Medicine Prices, Pharmaceutical Policy, Pharmaceutical Expenditure

#### The Evolution of Taiwan's National Health Insurance Drug Policy—Review and Analysis

---

**Chih-Sheng Hsu, Shan Jiang**

National Taiwan University, Taiwan, Republic of China

Problem statement: The rapid growth of medical costs is an issue faced by all countries, especially the growth of pharmaceutical costs. To lessen the increasingly heavy financial burden, the BNHI has implemented a series of drug policies, including Global Budget Payment System, Drug Payment System, Drug Reimbursement Rate Adjustment Policy mechanism, and Drug Copayment System.

Objectives: To systematically review Taiwan's NHI system related drug policy development and evolution to analyze the implications, reasons, and benefits of the promotion of the four policies above, discuss the influence and impact that arise, following the policy implementations, and finally propose appropriate recommendations targeting Taiwan's NHI drug policy

Design: A large number of history archives were collected. The qualitative analysis methods were adopted, including (1) a comparative method, (2) the historical research approach, and (3) the literature review method. Under the NHI system, the past and present of the drug policies were probed into and recommendations for the future were proposed.

Setting: The scope of this study focuses on the drug policies of Taiwan's NHI system. This research was conducted at the national level.

Policies: The study covers a comprehensive review of Taiwan's NHI in terms of changes in the four drug policies.

Results: (1) Taiwan's Global Budget Payment System was implemented in phases. All Western medical institutions fully implemented it in July 2002. (2) Taiwan's NHI Drug Payment System can be divided into four phases: before the national health insurance implementation, the internal audit price, the uniform price, and the benchmark drug prices. (3) Since April 1, 2000, the BNHI has implemented six drug price surveys, and the new drug reimbursement rate were announced and implemented. (4) The drug copayment displays significant effects on short-term drug price reduction, but the long-term effect is less significant.

Conclusions: Through analysis of the major drug policies, including the history, the problems faced in the pharmaceutical industry, the main issues related to the drug policies, the policy implementation motives and reasons, the decision model of the plan, the impact assessment, the drug economy, the performance and reasonability, and so on, a detailed discussion was conducted from the retrospective perspectives. In addition, the study gained an insight into the policy implementation effectiveness and impacts.

Funding source(s): None

508

### Chronic Care

Keywords: acyclovir, access to medicines, cost, genital herpes, policy, essential medicines

#### Genital Ulcer Disease Treatment Policies and Access to Acyclovir in Eight Sub-Saharan African Countries

---

**Catherine Wairimu Corbell<sup>1</sup>, Andreas Stergachis<sup>2,3</sup>, Francis Ndowa<sup>4</sup>, Patrick Ndase<sup>2</sup>, Linda Barnes<sup>2</sup>, Connie Celum<sup>2,3,5</sup>**

<sup>1</sup>Department of Pharmacy, University of Washington, Seattle, WA, USA; <sup>2</sup>Department of Global Health, University of Washington, Seattle, WA, USA; <sup>3</sup>Department of Epidemiology, University of Washington, Seattle, WA, USA;

<sup>4</sup>Department of Reproductive Health & Research, World Health Organization, Geneva, Switzerland; <sup>5</sup>Department of Medicine, University of Washington, Seattle, WA, USA

Problem statement: World Health Organization 2003 guidelines for sexually transmitted infections (STIs) recommend acyclovir as first-line syndromic treatment of genital ulcer disease (GUD) in countries with high herpes simplex virus-2 (HSV-2) prevalence (i.e.,  $\geq 30\%$ ). Surveys conducted between 2004 and 2006 suggested that the recommendations for use of acyclovir in GUD had not been implemented in public sectors of low-income countries.

Objective: To assess the extent of adoption of acyclovir as syndromic treatment in countries with high HSV-2 prevalence and to describe procurement, distribution, and cost of acyclovir in the public and private sectors.

Design: This was a descriptive study using structured interviews.

**Setting:** The study was conducted in Botswana, Kenya, Malawi, South Africa, Tanzania, Uganda, Zambia and Zimbabwe. Organizations and entities included were ministries of health, central and regional medical stores, regional and district hospitals, private pharmacies, and private health institutions including for-profit and non-profit organizations.

**Methods:** A convenience sample of ministry of health (MoH) officials, pharmacists, and other pharmacy workers based in the public and private sectors was selected for interviews. A 26-item standardized questionnaire with questions regarding (1) the extent of implementation of the 2003 WHO STI treatment guidelines about acyclovir in country-specific essential medicines lists (EMLs) and national STI guidelines and (2) acyclovir procurement, cost, and distribution was administered to MoH officials. We also administered to pharmacists and other pharmacy workers in public and private health facilities a 27-item questionnaire on the availability and retail cost of acyclovir. Acyclovir price data were collected in local currencies and converted to US dollars using the 2007 exchange rate. Price comparisons were conducted using the 2007 median international reference price (IRP) for acyclovir.

**Results:** In total 100 interviews were conducted with MoH officials and pharmacy personnel. Four of the eight African countries surveyed had adopted acyclovir as first-line syndromic GUD treatment in both their EMLs and STI guidelines. With the exception of Zambia, acyclovir was routinely procured for the public sector in countries where acyclovir was first-line treatment for GUD in the EML. Public health facilities faced cost and regulatory barriers, however, that impeded the requisitioning of acyclovir from the central medical stores. Acyclovir was available in private pharmacies and health institutions but at a median retail cost ranging from 5.85 to 9.76 times the median IRP.

**Conclusions:** Systems for drug procurement, distribution and access in sub-Saharan African countries need strengthening for a GUD treatment policy using acyclovir to be effective.

**Funding source(s):** World Health Organization

## 509

### Drug Resistance

*Keywords:* antimicrobials, regulation, self-medication, retail pharmacy

#### **Impact of Implementing Antibiotic Sales Restrictions: Reactions of Key Stakeholders and Citizens in Mexico**

**Anahí Dreser-Mansilla, Veronika J. Wirtz, Edna Vazquez-Velez, Midiam Ibañez-Cuevas, Sandra Treviño-Siller**

National Institute of Public Health, Mexico

**Problem Statement.** In many low / middle-income countries regulations of medicines sale with prescription are not enforced. There is little research regarding the barriers and opportunities to enforce efficiently these regulations. In March 2010 the Mexican government announced the enforcement of antibiotic sales regulations in pharmacies only with prescription. Analysis of the impact of its implementation in terms of stakeholders' and citizens' reactions can provide relevant lessons for other countries to anticipate barriers and take advantage of facilitating factors.

**Objectives.** To analyze the factors that affect the implementation of antibiotic sales regulation only with prescription in Mexico, focusing in the position and strategies developed by stakeholders, and in the reactions of the population.

**Design.** Stakeholder analysis of the position adopted and strategies developed by key actors: Pharmacies / medicines outlet associations (POA), Ministry of Health (MoH), pharmaceutical industry (PI), medical and pharmaceutical associations (MA and PA), academic institutions (AI), consumers associations (CA). Discourse analysis exploring citizens' perceptions of the regulation. Data were derived from a revision of newspapers coverage on the issue and from an on-line newspaper discussion forum. A priori defined and emerging thematic codes were used.

**Setting.** Mexico

**Population.** 304 newspaper articles and 387 commentaries from the discussion forum retrieved between March 25 and December 31 2010.

**Policy Change.** Ministerial decree enforcing the regulation of antibiotic sales only with prescription, requiring to retain and register prescriptions.

**Outcomes.** Reactions of key stakeholders and citizens that could act as barriers or opportunities for its implementation.

**Results.** The MoH promoted the regulation arguing the dangers of self-medication and antibiotic resistance. POA were the leading opponents arguing that it diminishes their revenues, creates logistical difficulties and corruption, and has negative health and economic impact for the population given the limited access to medical care. Strategies developed were creating alliances attempting to delay implementation, press round-ups emphasizing negative impacts, and creating clinics in pharmacies. MA and AI manifested the concomitant need to improve prescription and create public awareness. Within the discussion forum, the majority of comments were against the regulation arguing negative impact on expenses (due to high cost of private services and prescriptions) and on health (lack of access and discontent with medical services) and distrust of the real reasons underlying the regulation.

**Conclusions.** Active opposition of key stakeholders and negative perceptions of the regulation among citizens hindered implementation. It is important to create awareness among the population and involve stakeholders and citizens to achieve successful implementation.

**Funding** National Institute of Public Health

## 510

### Policy, Regulation, and Governance

*Keywords:* appropriate use, education, pharmaceutical marketing, nurse prescribing

## **“Under the Radar”: Nurse Prescribers and Pharmaceutical Industry Promotions**

---

**Elissa Ladd<sup>1</sup>, Diane Mahoney<sup>1</sup>, Emani Srinivas<sup>2</sup>**

<sup>1</sup>MGH Institute of Health Professions, United States of America; <sup>2</sup>Brigham and Womens Hospital

**Problem statement:** Multiple studies have shown that physicians' prescribing decisions are affected by non-scientific factors such as patients' requests for medications as well as pharmaceutical company promotions (i.e., gifts, meals, and continuing education programs). Although there has been extensive research on the effect that pharmaceutical promotions have on physician prescribing, there has been a paucity of empirical data on nurse prescribing behaviors in relation to pharmaceutical marketing.

**Objectives:** To assess nurse interactions with pharmaceutical industry promotions and evaluate the effect of an educational intervention on the perception of industry sponsored drug information and self-reported prescribing behaviors

**Design:** Randomized baseline, post 1 and post 2 intervention without control

**Setting:** National online survey of public and private sector nurse prescribers

**Study population:** Nationally representative randomized sample of 263 nurse prescribers at baseline and 208 at post-intervention

**Intervention:** Web-based educational intervention on pharmaceutical marketing, conflicts of interest, and evidence-based prescribing

**Outcome measure(s):** Change in perceptions and attitudes regarding pharmaceutical marketing; self-reported changes in prescribing behaviors

**Results:** Almost all of the respondents (96%) reported regular contact with pharmaceutical sales representatives, and the majority (71%) reported receiving information on new drugs directly from pharmaceutical sales representatives some or most of the time. A large portion (66%) gave out drug samples regularly to their patients, and 73% felt that samples were somewhat or very helpful in learning about new drugs.

Post-intervention there was a statistically significant ( $p < .01$ ) increase between baseline and post 1 for prescribers who reported challenging information provided by pharmaceutical representatives, the use of evidence-based drug information, and the use of generic drugs. There was also a statistically significant decrease ( $p < .01$ ) in the acceptability of the use of sample medications, the reported use of highly marketed drugs and the favorable perception of the reliability of information provided at industry sponsored meal and continuing education events.

**Conclusions:** Nurse prescribers had extensive contact with the pharmaceutical industry's sponsored promotional activities. The educational intervention resulted in a significant change in attitudes and self-reported prescribing behaviors. The findings of this study demonstrate that nurse prescribers and/or nurses who recommend drugs for their patients are shown to be as susceptible to pharmaceutical industry promotions as their physician colleagues. This finding is significant because nurses represent the largest segment of the global health care workforce and therefore can have substantial influence on rational medication selection.

**Funding source(s):** Attorneys General Consumer and Prescriber Grant Program

511

### **Policy, Regulation, and Governance**

*Keywords:* quality control, counterfeit medicines, dissolution, chemical separation, microfluidics

## **Developing Superior Screening Technology for Monitoring Medicine Quality in Low-Resource Countries**

---

**Darash Desai<sup>1</sup>, Patrick Lukulay<sup>2</sup>, Veerle Coigne<sup>3</sup>, Muhammad Zaman<sup>1</sup>**

<sup>1</sup>Boston University, United States of America; <sup>2</sup>US Pharmacopeia; <sup>3</sup>USAID

**Problem statement:** Substandard and counterfeit medicines are a serious public health problem in resource-limited countries where there is little oversight of the pharmaceutical market. Simple and qualitative tools exist for screening the quality of medicines on the market, but none offer a complete test, covering all important quality attributes. Further testing is costly, time consuming, and not scalable. Consequently, many substandard medicines pass through the net of medicines quality screening.

**Objectives:** To develop and implement an improved, easy-to-use, portable, and cost-effective microfluidic technology for comprehensive and effective screening of all important quality attributes of medicines.

**Design:** A low-cost microfluidic chip was designed to conduct both dissolution testing and chemical separation to quantify drug release kinetics and drug composition. Dissolution testing was conducted using fluorescent markers and a simple LED coupled with a cheap CCD chip. Separated drug components and related substances were quantified using standard colorimetric chemistry.

**Setting:** The final solution is designed for use in low-resource settings with unreliable power, extreme weather, and limited technical capacity. The chip was designed to be robust enough for use in the field.

**Outcome measure(s):** We characterized the effectiveness of our device by testing its ability to assess drug quality among a range of counterfeit, substandard, and authentic drugs. We compared our results to standard TLC and hand-held spectroscopic methods used in current, in-field screening tests.

**Results:** We were able to design and build a working prototype of our device. The dissolution component was able to quantify drug release kinetics to within 3% of standard USP Apparatus I tests. The chemical separation component

demonstrated superior results to standard TLC techniques that serve as the current standard in resource-limited settings.

Conclusions: Our integrated microfluidic device is able to quantitatively identify substandard medicines by performing both dissolution testing and chemical separation on a single, portable chip. The dissolution test provided similar results to standard techniques, but used a fraction of the reagents and solvents due to the microfluidic platform. Chemical separation was achieved with higher precision than current field methods. This test will both improve accuracy and significantly lower testing costs. With these solutions offered on a single chip, this device offers a promising improvement to field-based counterfeit and substandard medicine screenings.

Funding source(s): USP, USAID, Coulter Foundation

513

### Policy, Regulation, and Governance

Keywords: rosiglitazone, safety alert

#### Actions of the National Regulatory Authorities in Developing Countries Following US FDA and EMA Safety Alerts on Rosiglitazone

**Jude Nwokike<sup>1</sup>, Andy Stergachis<sup>2</sup>**

<sup>1</sup>Management Sciences for Health (MSH), United States of America; <sup>2</sup>Global Medicines Program, University of Washington

Problem statement: On September 23, 2010, the US FDA announced that it will require a restricted access program as part of a risk evaluation and mitigation strategy for the elevated risk of cardiovascular events associated with rosiglitazone. On the same day, the EMA recommended the suspension of the marketing authorizations for rosiglitazone-containing anti-diabetes medicines. Before these regulatory actions, safety concerns had caused global sales of rosiglitazone to slide dramatically from \$2.2 billion in 2006 to \$1.2 billion in 2009. One of the core indicators of the indicator-based pharmacovigilance assessment tool (IPAT) used for assessing pharmacovigilance systems in developing countries is the average time lag between the identification of safety signal of a serious ADR or significant medicine safety issue and communication to health care workers and the public.

Objectives: To identify the time lag between the announcements on rosiglitazone by stringent regulatory authorities (SRA), as represented by the FDA and EMA, and actions by national regulatory authorities (NRA) from selected developing countries.

Design: We reviewed the Global Regulatory Activity Digest that contains global regulatory updates. We also searched the websites of 12 NRAs including their lists of registered medicines, where available, and followed up with key-informant interviews to validate responses and collect additional information, as appropriate. We calculated the average lag time in days from the date of the first announcement by the SRAs (September 23, 2010, used as the index date) to the date of regulatory action by the NRAs. We considered actions as any communication related to safety of rosiglitazone.

Study population: NRAs

Outcome measure(s): Safety alerts and related communications pertaining to rosiglitazone

Results: We studied regulatory actions related to the safety of rosiglitazone from the FDA, EMA, and 10 national regulatory authorities; 3 NRAs from outside Africa and 7 NRAs from Africa. The NRAs outside of Africa had all taken regulatory actions related to the safety alert to rosiglitazone. Of particular interest, Saudi Arabia took regulatory action to suspend rosiglitazone on March 17, 2010, approximately 190 days before the SRAs. Indonesia took regulatory action a day after the SRAs and India 14 days after. For the 7 African NRAs that registered rosiglitazone, we could confirm regulatory action only for those from Namibia and Kenya. From the index date until December 2, 2010, when the most recent information was collected, only 2 out of 7 (29%) African NRAs had taken regulatory action or reacted to that of the SRAs.

Conclusions: The average lag time between the identification of safety signal of a serious ADR or significant medicine safety issue and communication to the public is shorter for NRAs outside of Africa. Even after 70 days from the index date, many African NRAs had no communication to consumers or health care providers pertaining to the safety of rosiglitazone. This IPAT indicator provides a way for assessing timely communication of safety information.

Funding source(s): The authors were supported by the USAID-funded Strengthening Pharmaceutical Systems program.

514

### Chronic Care

Keywords: pharmaceutical policy, prescribing, cancer, Australia

#### Spillover Effects of Prescribing Restrictions for Trastuzumab in Australia

**Christine Y Lu, Preeyaporn Srasuebkul, Anna Drew, Robyn Ward, Sallie-Anne Pearson**

Lowy Cancer Research Centre and Prince of Wales Clinical School, University of New South Wales, Australia

Problem statement: Trastuzumab, a recombinant monoclonal antibody, is used routinely to treat HER2+ metastatic and early stage breast cancer worldwide. In Australia, its use in these two settings has been subsidised since 2001 and 2006, respectively. Over this period, there have been ongoing concerns about the medicine's cardiac safety. Consequently, at the time of listing trastuzumab for the treatment of early stage disease on Australia's national drug

program (October 2006), a requirement for cardiac function assessment before and every 3 months during treatment was introduced.

**Objectives:** To determine the spillover impact of a policy for “regular” cardiac monitoring in patients treated with trastuzumab for early stage disease on monitoring rates in patients treated with trastuzumab in the metastatic setting

**Setting:** Australia has a universal health care system. Both the Herceptin Program (a separate program to the national drug coverage program) and the Medicare Benefits Scheme (that covers cardiac function tests) are publicly funded, nationwide programs. The Herceptin Program enrolment data and the medical service claims data were linked via unique person identifier.

**Study population:** All women treated with trastuzumab for HER 2+ metastatic breast cancer via the Herceptin Program between December 2001 and February 2010 (n=3,779); median age 55 years (range 21–95)

**Design:** Interrupted time-series analysis

**Outcome measure(s):** Proportion of patients by quarter receiving cardiac function tests before initiating trastuzumab therapy and receiving cardiac monitoring during therapy

**Results:** After the policy was introduced, we found an immediate 8% increase (95% CI, 2–14; p=0.02) in cardiac monitoring before initiating trastuzumab therapy without a significant change in the trend. Monitoring rates during therapy increased steadily from early 2005, coinciding with the release of interim results from several trials involving trastuzumab that included data on its cardiac safety. The policy was also associated with an immediate 7% increase (95% CI, 3–10; p<0.01) in cardiac monitoring during therapy, which remained stable till the end of the observation period.

**Conclusions:** We identified a positive spillover effect of a policy, but our study highlights the need for research to evaluate intended and unintended consequences of prescribing restrictions on patterns of care and patient outcomes.

**Funding source(s):** Australian National Health and Medical Research Council Public Health Training Fellowship (CL) and Cancer Institute New South Wales Career Development Fellowship (SAP)

## 516

### Access

*Keywords:* access to medicine, antimalarials, supply management, health facilities, malaria,

### **SMS for Life: A Pilot Project to Reduce or Eliminate Stock-outs and Improve Access to Malaria Medicine at the Remote Health Facility Level, Using Innovative SMS, Internet, and Mapping Technologies**

**James Martin Barrington<sup>1</sup>, Olympia Wereko-Brobby<sup>1</sup>, Peter Ward<sup>2</sup>, Winfred Mwafongo<sup>3</sup>, Seif Kungulwe<sup>4</sup>**

<sup>1</sup>Novartis Pharmaceuticals AG, Switzerland, Switzerland; <sup>2</sup>IBM (UK) Ltd, MP9, PO Box 31, Birmingham Rd, Warwick, CV34 5JL, UK; <sup>3</sup>National Malaria Control Program, Ministry of Health & Social Welfare, Ocean Road - NIMR Offices, Box 9083, Dar-es-Salaam, Tanzania; <sup>4</sup>Lindi District Council, P.O. Box 328, Lindi, Tanzania

**Problem statement:** Maintaining adequate supplies of antimalarial medicines at the health facility level in rural sub-Saharan Africa is a major barrier to effective management of the disease. Lack of visibility of antimalarial stock levels at the health facility level is an important contributor to this problem.

**Objectives:** To demonstrate that visibility of weekly stock levels of key antimalarial medicines at the health facility level will promote action to eliminate and/or reduce stock-outs and to demonstrate that a state-of-the-art data gathering infrastructure can be made available via simple tools such as SMS and mobile telephones, the Internet, and Google mapping in remote locations in sub-Saharan Africa

**Design:** A 21-week pilot study, “SMS for Life,” was undertaken during 2009–10 in three districts of rural Tanzania, involving 129 health facilities, covering a total population of 1.2 million. The pilot project was undertaken through a collaborative partnership of public and private institutions, consisting of the Tanzanian Ministry of Health and Social Welfare, the Roll Back Malaria Partnership, Novartis Pharma AG, Vodafone Global Enterprise, and IBM. Each partner funded its own activities. SMS for Life used mobile telephones, SMS messages, and electronic mapping technology to facilitate provision of comprehensive and accurate weekly stock counts from all health facilities to each district management team. The system covered stocks of the four different dosage packs of artemether-lumefantrine (AL) and quinine injectable. Results were evaluated using various methods including interrupted time series analysis.

**Results:** Stock count data were provided in 95% of cases, on average. A high response rate (≥93%) was maintained throughout the pilot. The error rate for composition of SMS responses averaged 7.5% throughout the study; almost all errors were corrected and messages re-sent. Data accuracy, based on surveillance visits to 90% of participating health facilities, was 94%. District stock reports were accessed on average once a day. The proportion of health facilities with no stock of one or more antimalarial medicines (i.e., any of the four dosages of AL or quinine injectable) fell from 78% at week 1 to 26% at week 21. The proportion of health facilities with no stock of any dose form of ACT fell from 26% to 1%. In Lindi Rural district, stock-outs were eliminated by week 8 with virtually no stock-outs thereafter. During the study, AL stocks increased by 64% and quinine stock increased 36% across the three districts.

**Conclusions:** The SMS for Life pilot provided visibility of antimalarial stock levels to support more efficient stock management using simple and widely available SMS technology. The SMS for Life system has the potential to alleviate restricted availability of antimalarial drugs or other medicines in rural or under-resourced areas. Country-wide implementation (ca. 4,500 health facilities) of SMS for Life is ongoing in Tanzania with a scheduled completion date of October 2011. New pilots with slightly different scope were initiated in Ghana and Kenya July and August 2011, respectively.

Funding source(s): Each of the partners of the pilot project provided the funding of their respective contributions.

517

**Policy, Regulation, and Governance**

*Keywords:* Pharmacovigilance, Community Pharmacists, adverse drug reactions

**The Knowledge, Perceptions, and Practice of Pharmacovigilance among Community Pharmacists in Lagos State, Southwest Nigeria**

**Ibrahim Adekunle Oreagba<sup>1,3</sup>, Julius Olajide Ogunleye<sup>2</sup>, Oluwafemi Sunday Olayemi<sup>1</sup>**

<sup>1</sup>University of Lagos, Nigeria; <sup>2</sup>Faculty of Clinical Pharmacy, West African Postgraduate College of Pharmacists.;

<sup>3</sup>National Pharmacovigilance Centre. National Agency For Food and Drug Administration and

**Problem statement:** Adverse drug reactions (ADRs) are significant causes of morbidity and mortality. ADRs may cause many hospitalizations and lead to large economic burdens to patients and to society. Since pharmacovigilance plays an essential role in the outcome of therapy, its evolution and its importance as a science are critical for effective clinical practice and public health science. Spontaneous reporting of ADRs remains the cornerstone of pharmacovigilance and is important in maintaining patient safety. The success of this activity, however, is dependent on the frequency of reporting by the health care professionals, under-reporting being the main disadvantage. Community pharmacists both have an important responsibility in monitoring the ongoing safety of medicines and are widely accessible to do it.

**Objectives:** To investigate the knowledge, perceptions and practice of pharmacovigilance among community pharmacists in Lagos State, southwest Nigeria

**Design:** A descriptive, cross-sectional study

**Setting:** The study was carried out in private community pharmacies in Lagos, one of the largest metropolitan cities in Nigeria, located in the southwest.

**Study population:** A multistage random sampling technique was employed in the selection of 420 community pharmacists in Lagos

**Outcome measure(s):** Knowledge of pharmacovigilance, practice of pharmacovigilance

**Results:** About 55% of respondents had ever heard of the word pharmacovigilance out of which less than half (representing only 18% of all respondents) could define the term. 40% of the respondents stated that patients reported ADRs to them at least once a month, and 20% reported to the relevant authorities, but only 3% of respondents actually reported an ADR to the National Pharmacovigilance Centre. The most important reason for poor reporting was lack of knowledge about how to report ADRs (44.6%). Meanwhile, 90% of respondents believed that the role of the pharmacists in ADR reporting was important. Most community pharmacists were willing to practice pharmacovigilance if they were trained.

**Conclusions:** Community pharmacists in Lagos had poor knowledge about pharmacovigilance. The reporting rate was also poor. There is an urgent need for educational programs to train pharmacists about pharmacovigilance and ADR reporting. The problem of underreporting can be considerably reduced by actively involving community pharmacists in the surveillance of drug safety within the context of the pharmaceutical care they provide. Pharmacovigilance and knowledge about risks of ADRs should be part of the undergraduate and postgraduate pharmacy education curriculum and ADR reporting, part of a pharmacist's basic tasks

**Funding source(s):** Self-funded

519

**Access**

*Keywords:* counterfeit drugs, consumers

**Educational Intervention to Combat Counterfeit Medicines in Selected Areas in the Philippines**

**Rainier Galang<sup>1</sup>, Isidro Cabuyao Sia<sup>2</sup>, Ophelia Mendoza<sup>1</sup>**

<sup>1</sup>National Drug Information Center, Philippines; <sup>2</sup>University of the Philippines Manila

**Problem statement:** The continued proliferation of counterfeit medicines has been a public concern for the Philippines. It was estimated that almost 10% of the available medicines in the Philippines are counterfeit.

**Objective:** To determine the effects of an educational intervention on the knowledge and behavior of consumers on counterfeit medicines

**Design:** This was an intervention study that involved drug sellers and consumers.

**Setting:** The study was done in 2007 in three areas in the Philippines: the national capital city, a provincial city, and 2 rural municipalities in a province.

**Study population:** The study population consisted of clients from randomly selected drug stores and neighborhood grocery stores, using a 3-stage systematic sampling design.

**Intervention:** The intervention consisted of development and distribution of a brochure and poster on counterfeit medicines and orientation-training for drug sellers on the meaning of messages in the brochure and poster.

**Outcome measure(s):** The outcome measures consisted of the difference in the proportion of consumers, before and after the intervention, who were aware of the existence of counterfeit medicines, who inspected medicines for signs of being counterfeit during purchase, who inquired from the drug sellers about counterfeit medicines during purchase, and

who received advice or information material on counterfeit medicines from the drug seller. Post-intervention measurement was done one to two months after the intervention.

Results: Responses were taken from 667 consumers before intervention, and 708 after intervention. On baseline, 92.7% of respondents were aware of existence of counterfeit medicines (compared with 99.6% post-intervention), 66.3% inspected drugs for signs of being counterfeit (versus 64.4% post-intervention), 10.0% inquired from the drug seller about counterfeit medicines during purchase (vs. 23.3% post-intervention), and 5.2% received advice or information on counterfeit medicines from the drug seller (vs. 37.0% post-intervention).

Conclusions: The intervention showed improvement in the increase in awareness of the existence of counterfeit medicines and interest in inquiring about counterfeit medicines among the respondents. Likewise, there was a reported increase in proactive interaction by the drug sellers in terms of sharing advice or information materials on counterfeit medicines. There was no change in the proportion of consumers who inspected drugs for signs of being counterfeit during the purchase.

Funding source(s): World Health Organization, Western Pacific Regional Office

**524**

### Child Health

*Keywords:* availability, paediatric medicines

#### **Availability of Children's Medicines in Africa, 2007**

**Jane Robertson<sup>1</sup>, Gilles Forte<sup>2</sup>, Suzanne Hill<sup>2</sup>**

<sup>1</sup>University of Newcastle, Australia; <sup>2</sup>World Health Organization, Geneva

Problem statement: Data on the availability and cost of paediatric medicines are limited.

Objectives: To assess availability and cost of children's medicines in 14 African countries

Design: The 2007 survey included 17 different medicines (20 formulations), two metered-dose inhalers, and up to five country-specific paediatric medicines. Data collectors recorded if the medicines were included in national essential medicines lists (EMLs) and standard treatment guidelines (STGs), availability in selected public and private medicine outlets, and cost to the patient.

Setting: WHO-HAI pricing survey methods were used to select 12 capital city medicine outlets: 1 Central Medical Store (CMS), 1 NGO health facility, 1 teaching hospital, 1 district hospital, 3 primary health care clinics (PHCs), and 5 private or retail pharmacies (RPs).

Outcome measure(s): Proportions (i.e., percentage) of the 20 paediatric medicine formulations in national EMLs and STGs; proportions available in each country by facility surveyed

Results: Proportions of medicines in EMLs ranged 50–90% with a match between EML and STGs in four countries. Availability varied by country and medicine outlet: CMS (15–75%), NGO facility (10–65%), teaching hospital (15–70%), district hospital (10–80%), PHCs (18–48%), RPs (38–62%). Cost data were limited. Often medicines were free to children in public sector outlets. Variability in costs was greater and prices generally higher in the private sector. Survey tools and methods were acceptable and effective; little training and support for data collectors was required. Extending surveillance to regional and rural areas would add to survey costs but would provide more complete coverage of the country situation. Participants identified a large number of country-specific medicines that could be included in future surveys.

Conclusions: Availability of children's medicines in these 14 countries was variable and generally poor. Surveys were conducted only in capital cities; this is likely to represent the most optimistic picture of medicines availability. Further work is required to understand both supply- and demand-side mechanisms operating in each country. Interventions to increase availability are needed as is a commitment to ongoing and regular surveys to measure improvements over time. This study has demonstrated the development of easy-to-use data collection tools that can be adapted to local circumstances. Costs of surveys should not preclude regular monitoring of country-specific circumstances. This study has led to the development of WHO guidance (2009) on methods for medicines availability and pricing surveys of children's medicines. Methods propose not more than 30 medicines be surveyed (7 are country-specific); sectors are extended to include licensed drug shops and dispensing doctors, and scope increased to include urban, peri-urban, and rural regions.

Funding source(s): WHO, Geneva

**526**

### Drug Resistance

*Keywords:* Informal Health Providers, India, antibiotic prescription, resistance, rural

#### **Antibiotic Prescription by Informal Health Providers in Ujjain District, India**

**Vishal Diwan<sup>1,2</sup>, Maysa Mohammed Abdel Aziz<sup>2</sup>, Yogesh Sabde<sup>3</sup>, Gaetano Marrone<sup>2</sup>, AJ Tamhankar<sup>4,5</sup>, Cecilia Stalsby Lundborg<sup>2</sup>**

<sup>1</sup>Department of Public Health and Environment, R.D. Gardi Medical College, Ujjain, India; <sup>2</sup>Division of Global Health (IHCAR), Department of Public Health Sciences, Karolinska Institutet, Stockholm, Sweden; <sup>3</sup>Department of Community Medicine, R.D. Gardi Medical College, Ujjain, India; <sup>4</sup>Department of Environment Medicine, R.D. Gardi Medical College, Ujjain, India; <sup>5</sup>Indian Initiative for Management of Antibiotic Resistance (IIMAR), N.G. Acharya and D.K. Marathe College, Chembur, Mumbai, India

**Problem statement:** Informal health care providers lack state accredited medical qualifications. These providers mostly practice allopathic medicine and prescribe antibiotics and other drugs without relevant training. These providers, however, work in the deprived, poor, and rural areas, where qualified providers generally are not available to serve this highly needy population. In spite of their magnitude and influence on health care system in low- and middle-income settings, systematic research on these providers is scarce, and studies are needed on all aspects of this phenomena to devise effective policy interventions.

**Objectives:** To present and describe the antibiotic prescription by informal health care providers in rural Ujjain in India

**Design:** Cross-sectional study

**Setting and study population:** Six selected villages in the Ujjain District of the State of Madhya Pradesh in India. Target population was informal health care providers: 25 were approached and given specially designed prescription pads in duplicate to fill in.

**Intervention:** This study is part of the information gathering for planning locally sustainable interventions aimed at providers and the community on rational antibiotic use.

**Outcome measure(s):** Logistic model to test the causal relationship between the providers' and the patients' characteristics; two separate binary outcomes: the antibiotic prescription (yes or no) and the number of antibiotic prescribed (one or more than one).

**Results:** All the providers were male. Numbers of practicing years and education of providers were not associated with the changes in the antibiotics prescription patterns. In total, 565 patients prescription were collected and analyzed. Symptoms related to the cardiopulmonary system were the most frequent complaint (31.7%). Ciprofloxacin was the most frequently prescribed antibiotic (20.1%). 31.1% of the patients received antibiotics by intramuscular route. Patients without infections were significantly less likely to be prescribed antibiotics ( $p < 0.001$ ). For the patients who were prescribed antibiotics (one or more than one), availability of a pharmacy in the village was significantly associated with prescribing one antibiotic.

**Conclusion:** This study provided evidence that informal providers prescribed lot of drugs, including antibiotics. It exposes the need for urgent interventions through the development of a means to absorb the informal health care providers into the health system after relevant training. This study has raised some important points that may be helpful in understanding this highly under-researched but influential group in rural areas, where more than 70% of the Indian population lives and visits these informal providers regularly.

**Funding source(s):** Swedish Research Council; first author is the recipient of Erasmus Mundus Scholarship

**527**

#### Access

*Keywords:* access to medicines, availability, affordability, household

#### Access and Use of Medicines in Kandy District, Sri Lanka

**Theresa Nimal Athuraliya<sup>1,2</sup>, Jane Robertson<sup>1</sup>, Sisira Dharmaratne<sup>2</sup>**

<sup>1</sup>University of Newcastle, Australia; <sup>2</sup>University of Peradeniya, Sri Lanka

**Problem statement:** Household surveys are an important tool to obtain accurate information on how people obtain and use medicines.

**Objectives:** To assess geographical access, availability, and affordability of medicines in the Kandy District, Sri Lanka

**Design:** Household survey (pilot study)

**Setting:** Kandy District, central province of Sri Lanka; Gampola Base Hospital was the reference facility

**Study population:** Clusters of households up to 15 km from the reference health facility (WHO guidelines)

**Method:** The best household informant was identified; 2 trained interviewers completed a structured paper questionnaire on the family's behalf.

**Outcome measures:** Proportion (%) of households reporting recent acute and chronic conditions; sources of care used; access to, use, and affordability of medicines

**Results:** We screened 27 households (117 individuals); 26 (22%) household members reported an acute illness in the prior 2 weeks. Of those, 14 (54%) were children and had mainly suffered upper respiratory tract infections; 16 (56.3%) sought care from a public hospital, 2 (12.5%) a health centre or dispensary, and 4 (25%) a traditional healer; 88.9% reported easy access to the closest government hospital. Most patients (14/16, 88%) reported taking all medicines as prescribed. Of 117 household members, 13.7% reported a chronic illness (hypertension, diabetes, and heart disease were most common) and 81% received prescribed medicines; 56.3% of those with chronic illness reported purchasing all prescribed drugs. Most (81.5%) could afford their medicines. Drug costs were 26.2% per month of total household expenditure. None had insurance coverage. Labelling and storage of drugs issued by public hospitals was poor. Most were loose tablets or capsules in clear polythene bags with minimum written instructions. Of 82 medicines, 39.2% with appropriate labelling and packaging were purchased privately. Few participants had comments on cost and quality of drugs and quality of health care services, and most had limited knowledge of generic drugs. Respondents noted that Gampola has many health facilities. Convenient opening times and quality of services influenced facility choices. Methodological issues include possible concerns by household members on selection of the household; signing consent forms; divulging information on chronic diseases; selection of a single informant to provide information on costs, quality of drugs, and health service, given the shared responsibilities on household health care.

Conclusions: Pilot data show access and use of medicines are generally good in the Kandy District. Although health care is free in Sri Lanka, a substantial proportion of people with chronic diseases pay for their medication. Despite poor labelling, adherence to drug regimens was satisfactory, indicating people take note of verbal instructions. The survey tool needs modifications, and additional interviewer training is required to address some culturally sensitive issues in Sri Lanka.

Funding source: University of Newcastle, Australia

**528**

### **Chronic Care**

*Keywords:* affordability, CRN, cost containment, medicine prices, prescribing

### **Patient Behavior when Prescribed Non-Affordable Drugs in University Hospitals of Alexandria, Egypt**

**Hatem Beshir, Ahmed Kamal, Ahmed ElKhanany, Ahmed Bassiouni**

Faculty of Medicine, University of Alexandria, Egypt

Problem statement: Increasing drug costs is a constant challenge to health care delivery, and patients respond in turn by employing various cost-reducing strategies. By far, cost-related nonadherence (CRN) is the main strategy described. In Egypt, many factors contribute to a high prevalence of CRN. A careful analysis of these factors should allow better interventional recommendations tailored to the Egyptian community. Inadequate doctor-patient interaction regarding drug costs (DPI) is a major factor in CRN. This study investigates the impact of drug costs on patients' behavior, most notably CRN, and DPI's role in minimizing it.

Objectives: (1) Identify cost-reducing strategies, including CRN, employed by chronically-ill patients presenting to Alexandria University Hospitals; (2) examine factors affecting prevalence of CRN; (3) explore impact of better DPI on CRN; and (4) pinpoint best DPI methods that minimized CRN

Design: Cross-sectional study

Setting and population: Study included 5 public hospitals serving all classes and districts of Alexandria. A randomly selected sample of 300 patients aged 18 years or more, treated as either inpatients or outpatients, that are publicly, privately, or noninsured. To be eligible, patients must have used prescription medication during the past 6 months for any of these chronic diseases: hypertension, heart disease, diabetes, depression, chronic lung disease, or chronic liver disease. Data were collected over 4 months via an interviewer-administered questionnaire.

Outcome measures: Frequency of CRN methods; impact of factors such as education, insurance, income, and DPI, on CRN rates; frequency of DPI methods

Results: Data gathered from 300 questionnaires showed that 84% of patients employed at least 1 method of CRN (termed CRN+). Of those, up to 66% postpone buying prescriptions, 58% skip their doses, and 26% ignore buying it altogether. CRN+ patients were then given a score according to the number of different CRN methods used. We found significant relationships between lower CRN scores and higher education ( $p < .001$ ), better insurance coverage ( $p < .001$ ), lower values of "drug cost to monthly income" ratios ( $p = .001$ ), lower number of prescribed drugs ( $p = .003$ ), and better DPI regarding drug costs ( $p = .004$ ). Only 54% of CRN+ patients reported having DPI. In CRN = 1 patients who reported having DPI, the most common methods were doctors showing sympathy towards patients' drug costs (78%), ensuring patients' affordability of drugs (55%), and mentioning drugs that must not be skipped (50%). And in those who reported not having DPI, the most cited cause was "being embarrassed" to ask about drug costs (75%).

Conclusions: Future policies should focus on improving DPI, a modifiable factor, to lower CRN. Ensuring patient education on drug costs, showing strong emotional support, and reducing polypharmacy can significantly lower CRN. Encouraging patients to ask for cheaper alternatives can also help.

Funding source: Self-funded

**531**

### **Access**

*Keywords:* Pharmaceutical human resources Pharmacy workforce; Human resources for health planning; Human resources for health management; Human resources for health development; Pharmacist; Pharmacy technician; Pharmacy assistant

### **Pharmaceutical Human Workforce for Access to and Use of Medicines in Countries: Estimate Gaps and Identify Relevant Strategies for Human Resources Development**

**Helen Lega Tata<sup>1</sup>, Tana Wuliji<sup>2</sup>, Enrico Cinnella<sup>1</sup>, Forte Gilles<sup>1</sup>**

<sup>1</sup>World Health Organization, Switzerland; <sup>2</sup>Consultant, USA

Problem statement: The pharmaceutical human resources is a vital part of the architecture of pharmaceutical systems in countries that contribute to improve access and use to quality medicines. Little is known about the HR situation in countries though it has been repeatedly identified that limitations in medicines supply system performance and medicines use may be due to HR competency gaps, shortages, inequitable distribution, and inadequate skill mix.

Objectives: This study sought to identify the nature of the gaps to be addressed to strengthen pharmaceutical HR and improve access to medicines in countries. To estimate available pharmaceutical sector human resources (PHR) and identify key PHR issues and gaps to address, which will inform PHR planning as part of national human resources planning for health in Ghana, Nigeria, Sudan and Tanzania.

**Design:** Quantitative descriptive assessment of pharmaceutical sector HR, and a modified Delphi approach to reach national consensus on policies to address identified key pharmaceutical HR issues

**Setting:** Study carried out at the national administrative level, public and private sector health facilities at all levels: pharmacies, warehouses, and pharmaceutical manufacturers. Key stakeholders consultations at the national level.

**Study Population:** Countries were self-selected based on the interest of the Ministries of Health. Six regions in each country were selected to purposively include regions with the capital city and/or main economic city as well as the most rural or poorest region, with random selection of the remaining regions. Facilities in these regions (Ghana – 103, Nigeria – 307, Sudan – 205, Tanzania – 187) were both purposively and randomly selected. All available pharmacists, technicians and assistants were surveyed in these facilities.

**Outcome Measures:** Main Part 1 outcome measures included: Pharmaceutical sector HR densities per 10,000 population for each pharmaceutical cadre; % of facilities with job descriptions, and % of total positions vacant.

**Results:** All countries had inequitable distribution with up to ten fold differences in HR densities between regions. Public sector facilities in Ghana, Nigeria and Tanzania had pharmacist vacancy rates of 40 – 55%, whilst private sector facilities had vacancy rates of 7 – 13%. Vacancy rates in Sudan were generally lower (public – 17%, private 1%). There were high pharmacy technician vacancy rates in Nigeria: 64%, 49%, and 44%, and Tanzania: 56%, 53% and 79% in the public, private and pharmaceutical manufacturers respectively. On average, 80% of facilities in Tanzania and Sudan had no pharmaceutical HR job descriptions. The density of both public and private sector pharmacies per 10,000 population was between 0.31 and 1.37 in the four countries involved; while the density of pharmacists per 10,000 ranged from 0.16 to 1.8. All countries successfully reached consensus on a strategic framework for pharmaceutical HR planning, management and development to respond to key issues.

**Conclusion:** There is a shortage of pharmaceutical sector HR in Ghana, Nigeria and Tanzania, and inequitable geographical distribution of pharmaceutical HR in all four countries studied. Pharmaceutical HR assessment and planning need to be integrated into the wider human resources for health development plan in order to improve access to medicines.

**Funding source:** European Commission

## 532

### HIV/AIDS and TB

**Keywords:** Adherence, Antiretrovirals, Affordability, Health Facilities, HIV/AIDS

### **Decongesting Public Health Facilities is Associated with Better Clinical Outcomes Among Patients Initiating Antiretroviral Therapy in Uganda**

**Joshua Kayiwa**<sup>1</sup>, **Celestino Obua**<sup>2</sup>, **Dennis Ross Degnan**<sup>3</sup>, **John Chalker**<sup>4</sup>, **Paul Waako**<sup>2</sup>, **Hudson Balidawa**<sup>5</sup>, **Goran Tomson**<sup>6</sup>, **Rolf Wahlström**<sup>6</sup>

<sup>1</sup>Data Department, Joint Clinical Research Centre, Kampala Uganda; <sup>2</sup>Department of Pharmacology and Therapeutics, College of Health Sciences, Makerere University, Kampala Uganda; <sup>3</sup>Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston USA; <sup>4</sup>Center for Pharmaceutical Management, Management Sciences for Health, Arlington Virginia, USA; <sup>5</sup>AIDS Control Programme, Ministry of Health, Kampala Uganda; <sup>6</sup>Department of Public Health Sciences, Karolinska Institutet, Stockholm, Sweden

**Problem statement:** In resource-poor settings, public health facilities providing antiretroviral therapy (ART) are frequently overwhelmed with patients seeking health care and medicines. This has implications on the quality of services delivered, clinic-running costs, and subsequently, treatment outcomes.

**Objectives:** We aimed to discover the extent to which simple, low-cost, and minimal-input interventions intended to reduce daily patient loads would impact on weight retention among patients initiating ART, as a marker of treatment progress.

**Design:** This was a longitudinal cohort study involving 761 patients initiating ART. Demographic and treatment history information were retrospectively extracted from medical records. Data on appointment keeping and weight changes were collected for 6 months before and 11 months after the intervention.

**Setting:** The study was conducted in six public ART-providing health facilities in Uganda. The interventions were implemented at clinic level, mainly through dialogue with the facility staff.

**Study population:** Eligible facilities had been ranked with poor adherence in a prior baseline survey. Recruited patients were aged 18+ years who had initiated ART 3 months prior to baseline or during follow-up. These were conveniently identified from outpatient registers.

**Interventions:** We first introduced an appointment system under which stable patients were classified as refill-only patients who would be fast-tracked through the facilities' workflows. We also asked clinicians to increase dispensed medication days for patients whom they deemed to be stable on treatment from the traditional 30 days to either 60 or 90 days. The overall aim was to decongest the facilities.

**Outcome measures:** We examined the effect of the interventions on the event-rates of patients experiencing non-declining weight changes during the first 90 days of treatment by using Mantel-Haenzel methods and Cox proportional hazards models. Effects were adjusted for patient-level characteristics.

**Results:** Patients' mean age was 35.8 ± 12.5 years; mean baseline weight was 51.4 ± 12.7 kg; 68.0% were female; 58.8% commenced treatment with Zidovudine-Lamivudine-Nevirapine. The rates (95% confidence interval) per 1000 person-years of experiencing non-declining weight changes pre- and post-interventions were 10.8 (8.3 to 14.2) and

22.8 (17.6 to 29.6), respectively ( $p < 0.0001$ ). The interventions were associated with a significant 2.2 (95% confidence interval: 1.5 to 3.2) increase in the hazards of experiencing nondeclining changes in weight.

Conclusions: These findings suggest that interventions instituted at public health facilities to reduce patient loads are effective in improving treatment outcomes among ART-initiating patients in resource-poor settings.

Funding sources: This work was made possible through support from the Swedish International Development Cooperation Agency and the World Health Organization through Management Sciences for Health.

535

#### Policy, Regulation, and Governance

*Keywords:* SADC, Essential medicines, pharmaceutical profile, baseline assessment.

#### **Baseline Assessment of Pharmaceutical Situation in Southern African Development Community**

**Enrico Cinnella<sup>1</sup>, Gilles Forte<sup>1</sup>, Abayneh Desta<sup>2</sup>, Richard Laing<sup>1</sup>**

<sup>1</sup>World Health Organization, Switzerland; <sup>2</sup>World Health Organization, AFRO

**Problem statement:** The Southern African Development Community (SADC) is one of the regions in Africa with the highest prevalence of HIV/AIDS and has shown slow progress in meeting the health-related MDGs. The SADC Secretariat and its member states have agreed on a pharmaceutical business plan to improve availability and affordability of medicines for priority diseases. Up-to-date and quality information on access, quality, and use of medicines should be collected to help identify priority interventions to address weaknesses of the pharmaceutical sector in SADC.

**Objectives:** In 2009, countries in SADC embarked on a pharmaceutical sector baseline assessment; the results were to inform the pharmaceutical business plan's priority setting and allow effective monitoring and implementation of the plan.

**Design:** Questionnaires on pharmaceutical sector structures, processes, and outcomes were developed covering areas such as policies, regulations, etc. All questionnaires were prefilled with data available from previous studies. The Ministry of Health in each recipient's country was requested to validate and/or amend as necessary the prefilled information and to complete and endorse the finalized questionnaire.

**Setting:** The study was conducted in 15 SADC countries—Angola, Botswana, Democratic Republic of Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, United Republic of Tanzania, Zambia, and Zimbabwe.

**Study population:** All SADC member states participated in the study, representing a great diversity of population size, economic development, health, and pharmaceutical issues.

**Outcome measure:** The data collected were presented in the form of individual profiles for each of the responding countries and a sub-regional report providing comparative analysis on the pharmaceutical situation across SADC countries.

**Results:** Comprehensive data outlining the pharmaceutical situation of all SADC countries are the result of this study. Each country presents strengths and weaknesses, and the value of key indicators varies considerably; for example, pharmaceutical personnel per 10,000 populations ranged from 7.6 in Seychelles to only 0.3 in Lesotho and Malawi. Similarly, public annual expenditure per capita on pharmaceuticals ranged from USD 0.1 to 136. Other differences were found in regulation, such as fees for medicines registration (from USD 150 to 30,000) and number of medicines registered (from 1,400 to over 12,000).

**Conclusions:** The purpose of this study was to improve availability of quality pharmaceutical information in SADC countries to identify priority interventions to support implementation of national essential medicines programs, within the framework of the SADC pharmaceutical business plan. The study provided a better understanding of the challenges and opportunities for improving access to essential medicines across the SADC region.

Funding sources: WHO, DFID UK

537

#### Chronic Care

*Keywords:* Cost-effectiveness, Hypertension, treatment guidelines, evidence-based medicine, Jordan, NICE

#### **Piloting the Development of a Cost-Effective, Evidence-Informed Clinical Pathway: Managing Hypertension in Jordanian Primary Care**

**Kalipso Chalkidou, Joanne Lord, Nour Obeidat, Ibrahim Alabbadi, Adrian Stanley, Rania Bader, Ayman Momani, Rachel O'Mahony, Lara Qatami, Derek Cutler**

University of Jordan, Jordan

**Objectives:** The UK's National Institute for Health and Clinical Excellence (NICE) and the Jordan office of the Medicines Transparency Alliance embarked on a pilot project to design an evidence-based guideline for cost-effective pharmacological treatment of essential hypertension in Jordan. The project's objectives were to directly address a major health problem for Jordan by producing a guideline and to delineate the strengths and weaknesses of Jordan's health care process to allow similar future efforts to be planned more efficiently.

**Methods:** The pilot spanned a period of approximately 8 months. Activities were overseen by local technical and guideline development teams, as well as experts from NICE. NICE's hypertension guidelines and economic model were used as a starting point. Parameters in the economic model were adjusted according to input and feedback from local

experts with regards to Jordanian physician and patient practices, resource costs, and quality of life estimates. The results of the economic model were integrated with the updated available clinical trial literature.

Results: The outputs of the economic model were used to inform recommendations, in the form of a clinical algorithm. A report of the process and the strengths and weaknesses observed was developed and recommendations for improvements made.

Conclusions: The pilot represented the start of what is intended to be a health care process change for the country of Jordan. Issues emerged that can inform strategies to ensure a more cohesive and comprehensive health care approach to the cost-effective use of appropriate drugs in managing chronic disease. The project highlighted how countries with relevant experience in evidence-informed policy making in health care can assist others in strengthening their decision-making systems.

Funding sources: NICE International (JL), WHO (NO), World Bank (NO, RO), Medicine Transparency Alliance-Jordan (IA), UK Department of Health (RO), UK Department for International Development (RO); some authors did not report funding sources.

**538**

### Drug Resistance

*Keywords:* drug resistance, prescribing, antibiotic use, cost, burden

#### **Economic Burden and Health Consequences of Antibiotic Resistance in Patients at a Tertiary Care Hospital, Vellore, South India**

**Sujith John Chandy<sup>1,2</sup>, Thomas Kurien<sup>1</sup>, Thomas Nalloor<sup>1</sup>, V Balaji<sup>1</sup>, Solomon Christopher<sup>1</sup>, Cecilia Stalsby Lundborg<sup>2</sup>**

<sup>1</sup>Christian Medical College, Vellore, India; <sup>2</sup>Karolinska Institutet, Stockholm, Sweden

Problem statement: The phenomenon of antibiotic resistance is rising, which has not just health consequences, but cost implications, especially in low- and middle-income countries like India, where many patients cannot afford basic hospital treatment. It is important to study the extra costs patients have to bear due to bacterial resistance. This information could be used to convince policy makers about the need for stricter guidelines and awareness programs on rational use of antibiotics.

Objective: To estimate the economic burden and health consequences due to antibiotic resistance in hospital inpatients in a tertiary care hospital at Vellore, South India

Design: Descriptive cost analysis

Setting: Christian Medical College (CMC) Hospital, a private, mission university teaching hospital in Vellore, South India with 1,957 beds and 4500 outpatients per day that caters to all strata of society.

Study population: All inpatients admitted to the medical wards of CMC during a one- year period with a diagnosis of septicemia, prescribed an empirical antibiotic, and with a culture and sensitivity test report were included in the study which is ongoing.

Outcome measures: Information on admission details, diagnosis, co-morbidities, medicine use, culture and susceptibility results, intensive care admission, and time to hospital discharge were collected through the hospital computer system. The costs of antibiotics, other medicines, labor, laboratory, bed and dietary charges, intensive care, and other miscellaneous charges were determined. To assess the economic burden of resistance, the overall cost to patients when empirical antibiotic therapy is effective was compared with the overall cost to patients for whom the empirical antibiotic had to be changed due to resistance. Intensive care admissions and hospital stay were also compared.

Results: Among the 204 patients, 36% had E. coli as the main infective organism (isolated through blood) and 27% received piperacillin-tazobactam as the main empirical antibiotic. Costs for patients in the resistant group were 44% more than for those in the susceptible group, which amounts to approximately Rs. 37,804. Though there was no appreciable difference in mortality and length of stay, intensive care unit admission, antibiotic costs, the costs of oxygen, ventilator support, intensive care, medicines, special procedures, dialysis, and laboratory work were all higher for resistant patients compared to the susceptible group. This demonstrates that there are also appreciable differences in health consequences.

Conclusion: Bacterial resistance has a significant impact on the cost burden to patients and their health. Policy makers can use the evidence presented here to strategize interventions and key messages.

Funding source: EMECW Lot 15 scholarship was granted to first author. Permission was granted by IRB, CMC Hospital, Vellore.

**539**

### Drug Resistance

*Keywords:* drug resistance, antibiotic use, hospital, guidelines, stewardship

#### **Effectiveness of an Antibiotic Policy in Containing Antibiotic Use at a Tertiary Care Hospital, Vellore, South India**

**Sujith John Chandy<sup>1,2</sup>, Kurien Thomas<sup>1</sup>, Reni Charles<sup>1</sup>, L Jeyaseelan<sup>1</sup>, Cecilia Stalsby Lundborg<sup>2</sup>**

<sup>1</sup>Christian Medical College, Vellore, India; <sup>2</sup>Karolinska Institutet, Stockholm, Sweden

**Problem statement:** Infections occupy a prominent place in most hospitals of low- and middle-income countries such as India. This invariably means using a large amount of antibiotics and consequently, the emergence of resistance to life-saving antibiotics. An antibiotic policy is one of the strategies employed by hospitals to contain resistance. In our hospital a policy was initiated and a manual published in 2005. The question remains, however, whether this is an effective strategy for containing antibiotic use.

**Objective:** To evaluate the role of an antibiotic policy in containing antibiotic use at a tertiary care hospital in Vellore, South India

**Design:** Interrupted time series (ITS) for policy evaluation

**Setting:** Christian Medical College (CMC) Hospital, a private, mission university teaching hospital in Vellore, South India with 1,957 beds and 4,500 outpatients per day that caters to all strata of society.

**Study population:** Antibiotics dispensed for hospital inpatients at CMC in a 7-year period, from 2003 to 2009, were included.

**Policy evaluation:** To assess impact of antibiotic policy on antibiotic density, monthly antibiotic consumption was calculated to provide data points before and after intervention in 2005. Antibiotic use in inpatients was calculated using the pharmacy computer system. Consumption of antibiotics was calculated as defined daily doses and normalized per 100 bed-days. Segmented regression analysis was done to assess how much the policy changed antibiotic density over time. Changes in level and slope after intervention were compared to level and slope before intervention.

**Results:** Newer and older antibiotics such norfloxacin and chloramphenicol were evaluated. For chloramphenicol, there was a significant difference in slope before and after intervention ( $p = 0.007$ ). The difference between pre- and post-intervention level was  $-0.176$  (SE 0.032;  $P = 0.000$ ; CI  $-0.240, -0.112$ ). For norfloxacin, there was no significant difference in slope before and after intervention ( $p = 0.597$ ). However, there was a significant difference between pre- and post-intervention level =  $-0.529$  (SE 0.059;  $P = 0.000$ ; CI  $-0.646, -0.412$ ). The densities of relatively newer antibiotics, however, showed increasing antibiotic consumption over the years.

**Conclusion:** Though some antibiotics are contained by the policy, many are not. Policy therefore may need to be constantly upgraded based on changing resistance patterns. Other strategies to contain antibiotic use and resistance in hospitals such as hygiene should be given urgent consideration.

**Funding source:** EMECW Lot 15 scholarship was granted to first author. Permission was granted by IRB, CMC Hospital, Vellore.

541

#### Access

*Keywords:* Access to medicines, HIV/AIDS, tuberculosis, malaria, industry

### **R&D Pharmaceutical Industry's Partnerships to Improve Developing World Health**

---

#### **Mario Ottiglio**

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Switzerland

**Problem statement:** The UN Millennium Development Goals aim to mobilize the public and private sectors worldwide to address poverty and poor health in developing countries. Research-based pharmaceutical companies help address the health-related MDGs (4, 5, 6 and 8e) and other global health challenges via a significant and growing range of philanthropic or not-for-profit partnership programs to help improve health in developing countries. However, the scale and scope of these activities are not well known.

**Objectives:** To outline the evolving scale and scope of research-based pharmaceutical companies' developing world health partnership programs

**Design:** The presentation will show how the industry's engagement has grown and broadened, with more companies working with more expert partners, including intergovernmental organizations, national governments, and civil society. For example, the total number of industry programs documented by the IFPMA has grown from 36 in 2003 to 213 in 2010. The expansion of the range of health issues addressed by company programs, from infectious diseases such as HIV/AIDS, TB, and malaria to child and maternal health and chronic diseases, will be examined. The range of activities undertaken within such programs will be reviewed, showing how access to medicines is complemented by health care capacity-building, education, and R&D for developing world health needs. The sustainability of programs, some of which significantly predate the MDGs, will be reviewed, as will their geographic distribution. Program trends will be evaluated for evidence of lessons learned and new thinking. The presentation will principally involve analysis of information gathered by the IFPMA in its Developing World Health Partnerships Directory, its 2010 IFPMA Health Partnerships Survey, and its Status Report on R&D for Diseases of the Developing World, covering 10 main diseases.

**Setting:** All programs undertaken by industry to help improve health in low- or middle-income countries worldwide, as classified by the World Bank, are eligible for inclusion in the IFPMA Developing World Health Directory and for the IFPMA Health Partnerships Survey.

**Study population:** Industry programs cover all low- and middle-income countries

**Intervention(s):** The range of program activities documented in the cited IFPMA sources.

**Policies:** Policies vary considerably, but trends and outliers will be identified.

**Outcome measures:** Number of programs, number of treatments made available, value of cash and in-kind assistance provided, numbers of R&D projects, range of partner organizations, program duration, etc.

**Results:** Numbers of people treated, disease elimination progress, new medicines developed

Conclusions: The industry's developing world health partnership effort has increased considerably in size and scope over the period 2000–2009.

Funding sources: IFPMA

542

#### HIV/AIDS and TB

*Keywords:* Adherence, health systems strengthening, appointment keeping, adherence monitoring, system level intervention

### Improving Adherence and Clinic Attendance Among Patients on Antiretroviral Treatment in Kenya: A System Level Intervention

**Patrick Kibiwott Boruett<sup>1</sup>, Susan Njogo<sup>2</sup>, Dorine Kagai<sup>2</sup>, Peter Nguhiu<sup>1</sup>, Lillian Gitau<sup>1</sup>, Christine Awuor<sup>2</sup>, John Chalker<sup>1</sup>, Dennis Ross-Degnan<sup>3</sup>, Goran Tomson<sup>4</sup>, Rolf Wahlstrom<sup>4</sup>**

<sup>1</sup>Management Sciences for Health/Strengthening Pharmaceutical Systems; <sup>2</sup>National AIDS/STI Control Program, Kenya; <sup>3</sup>Harvard Medical School and Harvard Pilgrim Health Care, USA; <sup>4</sup>Division of Global Health (IHCAR), Karolinska Institutet, Sweden

**Problem statement:** With the recent rapid increase in access to antiretroviral therapy (ART), there is a need to address adherence to ART, which is critical to treatment outcomes. Few published studies to date have assessed the impact of health systems interventions to improve adherence.

**Objectives:** To measure the effectiveness of a health systems intervention to monitor patient adherence and clinic attendance

**Design:** A quasi-experimental study with 2 patient cohorts, using time series analysis

**Setting:** 12 government district hospitals, 6 for the intervention and 6 controls, in 3 regions

**Study population:** Adult patients who (1) had experience of treatment more than 6 months (n = 605) or (2) initiated treatment at the facility with no prior exposure to ART (n = 845).

**Intervention:** In April 2009, a tool for tracking patient clinic attendance and a modified national form to monitor appointment keeping and self-report on adherence were introduced, combined with training of health workers. Support visits were conducted to reinforce the implementation.

**Outcome measures:** Percentage of patients (1) attending the clinic on or before, or within 3 days of, the scheduled appointment date and (2) with a gap in medication of 15 days or more. Data were collected from 6 months before the start of the intervention until 12 months after the end of the intervention month.

**Results:** In experienced patients, the change in level and trend increased significantly for patients attending clinic on or before scheduled appointment by 5.7 percentage units (95% CI 2.1, 9.4) from a pre-intervention level of about 80%, and 1.03% per month (95% CI 0.6, 1.5), respectively, and for those keeping appointments within 3 days by 4.2 percentage units (95% CI 1.7, 6.8) and 0.82 (95% CI 0.56, 1.1). A reduction by 9.4 percentage units (95% CI -16.5, -2.4) in medication gap greater than 15 days from a pre-intervention level of about 25% was observed in the experienced patients cohort. There were no significant changes observed in trend and level for the new cohort during the study period.

**Conclusions:** The limited improvement in both trend and level of adherence measures after introducing an appointment tracking system are still of national interest for scaling up because all possible mechanisms should be utilized to minimize nonadherence to treatment.

**Funding sources:** The study is part of the INRUD Initiative on Adherence to Antiretrovirals funded by the Swedish International Development Cooperation Agency with additional funding from the USAID-funded Strengthening Pharmacy Systems Project through Management Sciences for Health.

543

#### HIV/AIDS and TB

*Keywords:* Adherence, health systems strengthening, appointment keeping, adherence monitoring

### Routine Assessment of Patients' Attendance and Adherence to Antiretroviral Treatment In Kenya – Providers' Views on Usefulness to Improve Performance

**Lilian Nyambura Gitau<sup>1</sup>, Susan Njogo<sup>2</sup>, Dorine Kagai<sup>2</sup>, Peter Nguhiu<sup>1</sup>, Patrick Boruett<sup>1</sup>, Christine Awuor<sup>2</sup>, John Chalker<sup>1,4</sup>, Göran Tomson<sup>3</sup>, Rolf Wahlström<sup>3</sup>**

<sup>1</sup>Management Sciences for Health/Strengthening Pharmaceutical Systems Program; <sup>2</sup>National AIDS/STI Control Program, Kenya; <sup>3</sup>Division of Global Health (IHCAR), Karolinska Institutet, Sweden; <sup>4</sup>International Network for the Rational Use of Drugs (INRUD) – IAA

**Problem statement:** The Kenya National AIDS Control Program has identified problems in identifying and tracking defaulters, weak community linkages, and lack of national guidelines and tools on adherence monitoring as challenges at the facility level for quality of care of patients on antiretroviral treatment (ART). Routinely collected data is often not used to improve performance.

**Objective:** To assess the implementation of facility-based appointment-keeping systems and the use of adherence-based indicators to inform decisions for performance improvement

**Design:** Qualitative explorative part of a quasi-experimental study

**Setting:** Six conveniently sampled health facilities in Kenya located in the Rift Valley, Central Province, and Eastern Province

**Study population:** We conducted in-depth interviews with 58 health care providers and reviewed the clinic appointment diaries in each facility. Minutes of facility meetings were examined for evidence of use of appointment-keeping indicators.

**Intervention:** We introduced an appointment diary in each facility to schedule patient visits. The two adherence indicators monitored each month were the percentage of patients who attended the clinic (1) on or before the day of their appointment and (2) within 3 days of their appointment. The indicators were calculated by trained facility staff using a summary sheet and were intended to inform multidisciplinary team meetings.

**Outcome measures:** Use of intervention tools and description of facilitating and hindering factors for successful monitoring and follow-up

**Results:** All facilities implemented the diary and monitored the two appointment-keeping indicators. Trends generated were discussed in the monthly team meetings at the clinic. This helped to motivate providers and empower them to initiate corrective measures. The diaries helped detect clients' missing appointments and enabled timely actions. Information on individual patient attendance helped facility staff to provide targeted counseling and adjusting intervals of patient visits. Monitoring of the number of patients scheduled to visit on a given day was used to spread their workload. Data generated helped to establishing linkages with other neighbouring facilities for referral.

**Conclusion:** The use of intervention tools generated information, which led to better use of data in the decision-making process. The monitoring of routinely collected data plays a vital role in influencing health-seeking behavior of patients such as clinic attendance and adherence to medication.

**Funding sources:** The study is part of the INRUD Initiative on Adherence to Antiretrovirals funded by the Swedish International Development Cooperation Agency with additional funding from the USAID funded Strengthening Pharmacy Systems Project through Management Sciences for Health.

544

HIV/AIDS and TB

*Keywords:* cost-effectiveness, pharmacoeconomics, statins, dyslipidemia, hospital

### **Improving Appointment Keeping and Adherence Monitoring In HIV Facilities in Kenya: Views of Providers and Patients**

**Susan Muthoni Njogo<sup>1</sup>, Dorine Kagai<sup>1</sup>, Lillian Gitau<sup>2</sup>, Peter Nguhiu<sup>2</sup>, Patrick Boruett<sup>2</sup>, Christine Awuor<sup>1</sup>, John Chalker<sup>1,5</sup>, Dennis Ross- Degnan<sup>4,5</sup>, Göran Tomson<sup>3</sup>, Rolf Wahlström<sup>3</sup>**

<sup>1</sup>National AIDS/STI Control Program (NAS COP), KENYA; <sup>2</sup>Management Sciences for Health/Strengthening Pharmaceutical Systems Program; <sup>3</sup>Division of Global Health (IHCAR), Karolinska Institutet, Sweden; <sup>4</sup>Harvard Medical School and Harvard Pilgrim Health Care, USA; <sup>5</sup>International Network for the Rational Use of Drugs (INRUD) – IAA

Special Notice: cost-effectiveness study

**Problem statement:** Adherence monitoring and tracking appointment keeping for patients on antiretroviral therapy (ART) is challenging in Kenya because of lack of an efficient recording system. The focus of the national HIV/AIDS program is to increase the number of patients on treatment. However, there are limited systems to support monitoring of the quality of care.

**Objective:** To explore providers' and patients' views on introduction of an appointment keeping and adherence monitoring system

**Design:** Qualitative explorative part of a quasi-experimental study

**Setting:** 6 public hospitals at district level conveniently sampled  
**Study Population:** 30 service providers and 12 patients were interviewed; focus group discussions (N = 6) conducted with patients

**Intervention:** A clinic patient appointment diary and revised patient clinic card were introduced at the HIV clinics. The diary was to track patients' clinic visits longitudinally. The adherence indicator monitored monthly was the percentage of patients who attended the clinic within 3 days of their scheduled appointment. The revised patient card included a question that focused on patients recall on missed ARV doses in the past 3 days.

**Outcomes:** Description of facilitating and hindering factors for successful implementation of intervention components

**Results:** The appointment diary was perceived to be useful for monitoring of patients appointment keeping behavior. Standardization of question on patients self-report was reported to be more accurate. Facilities reported to have generated actual retention rates. Factors perceived to lead to missed appointments by patients included clinic operation days and hours, lack of transport, confidentiality, nonintegrated HIV services, nondisclosure and stigma. Staff reported a considerable increase in workload mainly due to staff shortage, however, they considered this extra workload manageable.

**Conclusion:** Monitoring of defaulters helps in establishing or reinforcing adherence support and defaulter tracing. This information informs policy on quality of care improvement, specifically adherence and appointment keeping, and considerations should be made for national roll out to all facilities providing ART.

**Funding sources:** This is part of the INRUD Initiative on Adherence to Antiretrovirals funded by the Swedish International Development Cooperation Agency (Sida) with additional funding from the USAID-funded Strengthening Pharmacy Systems Project through Management Sciences for Health.

545

**HIV/AIDS and TB***Keywords:* capacity, human resource, pharmaceuticals, East Africa, antiretrovirals**Existing Capacity to Manage Pharmaceuticals and Related Commodities in East Africa: An Assessment with Specific Reference to Antiretroviral Therapy****Paul John Waako<sup>1</sup>, Richard Odoi-adome<sup>1</sup>, Celestino Obua<sup>1</sup>, Erisa Owino<sup>1</sup>, Winnie Tumwikirize<sup>1</sup>, Jasper Ogwal-okeng<sup>1</sup>, Willy Anokbonggo<sup>1</sup>, Lloyd Matowe<sup>2</sup>, Onesky Aupont<sup>3</sup>**<sup>1</sup>Makerere University College of Health Sciences, Uganda; <sup>2</sup>Management sciences for health, Washington, USA;<sup>3</sup>Harvard University, Boston, Massachusetts, USA

**Problem statement:** East African countries have in the recent past experienced a tremendous increase in the volume of antiretroviral drugs. Capacity to manage these medicines in the region remains limited with recent history of medicines stock outs and expiries in the region.

**Objectives:** The initiative conducted a regional assessment to determine the existing capacity for the management of antiretroviral drugs and related commodities.

**Design:** This is a cross-sectional descriptive survey of 50 HIV/AIDS programs and institutions accredited to offer antiretroviral services in Uganda, Kenya, Tanzania, and Rwanda.

**Setting:** Makerere University, with technical assistance from the USAID-supported ) Program, established a network of academic institutions to build capacity for pharmaceutical management in the East African region. The initiative includes institutions from Uganda, Tanzania, Kenya, and Rwanda and aims to improve access to safe, effective, and quality-assured medicines for the treatment of HIV/AIDS, TB, and malaria through spearheading in-country capacity.

**Study population:** Heads and implementing workers of HIV/AIDS treatment programs were key informants in face-to-face interviews guided by structured questionnaires.

**Outcome measures:** The assessment explored categories of health workers involved in the management of ARVs; their knowledge and practices in selection, quantification, distribution, and use of ARVs; the nature of existing training programs; training preferences; and resources for capacity building.

**Results:** Inadequate human resource capacity including inability to select, quantify, and distribute ARVs and related commodities and irrational prescribing and dispensing were some of the problems identified. A competence gap existed in all four countries with nurses and midwives constituting 51% of all health care professionals involved in the supply and distribution of ARVs. Training opportunities and resources for capacity development were limited, particularly for workers in remote facilities. On-the-job training and short courses were the preferred modes of training.

**Conclusion and recommendation:** Capacity for managing medicines and related commodities in East Africa is inadequate. Training in pharmaceutical management for different categories of health workers is urgently needed. Skills-building activities that do not take health care workers from their places of work are preferred.

**Funding source:** Management Sciences for Health RPM-Plus Program

546

**Policy, Regulation, and Governance***Keywords:* pharmacovigilance, health facilities, resource limited settings**Challenges of Building Effective Pharmacovigilance Systems in Resource Limited Settings: A Case Study of Kampala Region, Uganda****Paul John Waako<sup>1</sup>, Byomire Hellen Ndagijje<sup>2</sup>, Winnie Tumwikirize<sup>1</sup>, Dan Kibuule<sup>1</sup>, Godfrey Bbosa<sup>1</sup>, Grace Nakanwagi<sup>3</sup>**<sup>1</sup>Makerere University College of Health Sciences, Uganda; <sup>2</sup>Department of Medicines information, National Drug Authority, Kampala Uganda; <sup>3</sup>Malaria Consortium, Kampala, Uganda

**Problem statement:** Countries around the world are scaling up and expanding treatment programs. Some of the drugs used in these programs are relatively new, hence the need for effective pharmacovigilance systems to monitor drug safety.

**Objectives:** We conducted an assessment to establish some of the barriers to an effective pharmacovigilance system in Uganda. A cross-sectional study was carried out in the Kampala region where almost half of the health providers in the country are based. The study focused on awareness, resources, and possible approaches to improvement of the pharmacovigilance system.

**Design:** 24 conveniently selected health facilities were surveyed; interviews of key informants and structured observations were used

**Results:** Only 14% of the respondents had received sensitization on pharmacovigilance; 61.7% of the units had reporting forms. The majority of the facilities had computers (81.5%) although only 40% were linked to the Internet and 41% of the respondents indicated they could access the computer. Work load, limited training, and sensitization about adverse drug reactions (ADRs) were some of the issues reported as barriers to efficiency. Respondents suggested continuous sensitization, establishment of pharmacovigilance contact persons in each facility, increasing awareness about ADRs among the public, and integration of ADR reporting in the health management information system as possible ways of ensuring efficiency.

Conclusions and recommendations: We conclude that awareness about pharmacovigilance is inadequate among health providers greatly limiting ADR reporting. Organizational structures in health facilities to address pharmacovigilance issues must be established. Strengthening and orientation of medicine and therapeutics committees in health facilities to support pharmacovigilance seem to be an option.

Funding source: Department for International Development (DFID), United Kingdom

553

### Drug Resistance

*Keywords:* education, consumers, children, antimicrobials

#### **Community Learns Appropriate Antibiotic Use Through Kindergarten Performances**

---

**Natalia Cebotarenco, Patricia Bush, Vera Grigorchuk, Anaida Aivazyan, Svetlana Shetina**

CoRSUM - Coalition for Rational and Safe Use of Medicines, Moldova, Republic of

**Problem statement:** One of the recommendations of ICIUM 2004 was, "Children can be effective change agents to improve community medicine use. Countries should consider school-based education programs that involve children as a way for key messages to reach parents". Currently, children and adolescents have few opportunities to learn to use medicines appropriately, although use of medicines is a common everyday activity throughout the world. In 2002–2004, CoRSUM designed and implemented an innovative school-based, peer-taught program in Moldova middle schools that decreased antibiotic use for colds and flu among students and parents. Kindergarten students were the focus of the next program aimed at decreasing inappropriate antibiotic use.

**Objectives:** Design and implement an educational interactive program for kindergarten children and their parents to reduce inappropriate antibiotic use for colds and flu.

**Design:** Before–after intervention study with no control groups

**Setting:** Moldova communities of Tiraspol (18 kindergartens) and Briceni (3 kindergartens)

**Study population:** Convenience sample of 85 teachers, 54 health care workers, 1,200 parents and grandparents, and 548 children in the period 2006–2007

**Intervention:** Phase I: three focus group discussions (FGDs) with parents of kindergarten children (7 years old); four FGDs with kindergarten methodologists to assist development of appropriate scenarios for students; three meetings with Ministry of Education officials to obtain support. Phase II: 45 minute performances conducted with the active participation of the kindergarten children and parents and attended by health professionals, community residents, and administrators; each kindergarten presented a unique program within scenario guidelines; follow-up workshops with parents and teachers discussed the performances. Phase III: June 2007, a national conference introduced the program and promoted its dissemination.

**Policy:** Implementation of ICIUM 2004 recommendations re dissemination of the kindergarten program

**Outcome measure(s):** Parents knowledge of inappropriate antibiotic use for colds and flu

**Results:** A pre-intervention questionnaire given to the children's parents indicated that 72% of the children had a cold or flu the prior winter. Of these, 76% had been given an antibiotic with 69% obtained via doctor's prescription. At the end of the performances, which presented the primary message in various entertaining ways, the parents came to the stage to answer questions by lining up behind signs (Yes, No, DK), e.g., Do antibiotics kill viruses? It was clear that parents had learned the message, "Don't take antibiotics for colds and flu."

**Conclusions:** Kindergarten is not too young for health messages; parents will come to see their children perform; learning can be fun and children can serve as conduits to carry important public messages to their communities.

**Funding source(s):** CoRSUM

555

### Access

*Keywords:* access to medicines, human rights, legislation

#### **Access to Essential Medicines as Part of the Right to Health in National Constitutions of 186 Countries**

---

**Katrina Perehudoff<sup>1</sup>, Richard O. Laing<sup>2</sup>, Hans V. Hogerzeil<sup>2</sup>**

<sup>1</sup>Faculty of Exact and Life Sciences, Free University, Amsterdam, Netherlands; <sup>2</sup>World Health Organization, Switzerland

**Problem statement:** Constitutional guarantee of access to essential medicines has been identified as an important indicator of government commitment to the progressive realization of the highest attainable standard of health (in short, "the right to health"). The objective of this study was to identify national constitutions that include a reference to access to essential medical goods and services and to identify good examples of constitutional text that can be used as a model for other countries.

**Methods:** From an inventory of constitutional texts from WHO member states, relevant articles were selected and assessed for the application of health and human rights principles.

**Results:** Health rights were mentioned in 135 (73%) of 186 national constitutions studied, while 95 (51%) mention the right to access to health facilities, goods, and services. Only four (2%) constitutions specifically mention access to essential medicines as part of the right to health. In Panama ". . . the State is primarily obligated to develop the following activities [ . . . ] supply medicines to all the people." In the Philippines, "The State shall . . . endeavour to make

essential goods, health and other social services available to all people at affordable cost.” In the Syrian Arab Republic, “The state protects the citizens’ health and provides them with the means of protection, treatment, and medication,” and in Mexico, “[women] are entitled to medical and obstetrical attention, medicines, nursing aid, and infant care services. Members of a worker’s family shall be entitled to medical attention and medicines, in those cases and in the proportions specified by law.” The constitution of South Africa can serve as a model text to reflect the principle of progressive realization.

Conclusion: Many constitutions do not include any reference to the right to health, and over half do not refer to universal access to health facilities, goods and services. The examples of existing text on access to essential goods and services, principles of equity and non-discrimination, focus on poor and disadvantaged groups and the need for national medicine policies that are identified in this study can serve as a model for policy makers, legislators and advocacy groups when seeking to align their constitutional aspirations with modern principles of universal access to health facilities, goods and services as part of the progressive realization of the right to health.

Funding source: WHO

## 556

### Drug Resistance

*Keywords:* Antimicrobials, community, drug resistance, primary health care, private sector, retail pharmacy

#### Trends in Antimicrobial Use Among Outpatients in New Delhi, India

**Anita Kotwani<sup>1</sup>, Kathleen Holloway<sup>2</sup>**

<sup>1</sup>V. P. Chest Institute, University of Delhi, Delhi, India; <sup>2</sup>World Health Organization, Regional Office for South East Asia, New Delhi, India

**Problem statement:** The overall volume of antimicrobial consumption in the community is one of the foremost causes of antimicrobial resistance. Enhanced surveillance is one of the strategies to control antimicrobial overuse or misuse. The ability to undertake extensive surveillance is lacking in resource-constrained settings, hence the lack of community-based databases. We conducted a detailed survey of antimicrobial use in the community by utilizing a recently established methodology of exit patient interviews for resource-constrained settings.

**Objective:** To determine the pattern and consumption of antibiotic use in the public and private sectors over one year (December 2007–November 2008) in New Delhi, India.

**Design:** Exit interviews of patients prescribed/dispensed/purchasing any antibiotic

**Settings:** 10 primary care public facilities, 20 private clinics, and 20 private retail pharmacies in 4 residential localities of Delhi

**Study population:** Outpatients visiting the enrolled facilities; 30 exit interviews/month/ public facility and private retail pharmacies; approximately 10–12 exit interviews/private clinic/month

**Outcome measures:** The Anatomical Therapeutic Chemical (ATC) Classification and the defined daily dose (DDD) measurement units were assigned to the data. Antibiotic use was measured as DDD/1000 patients visiting the facility and also as a percentage of patients receiving an antibiotic.

**Results:** Out of the patients visiting private retail pharmacies (17,995), public facilities (9,205), and private clinics (5,922) during the data collection period, 39% of the patients attending private retail pharmacies and public facilities and 43% of patients visiting private clinics were prescribed at least one antibiotic. The consumption pattern of antibiotics was similar at private retail pharmacies and private clinics where fluoroquinolones (J01MA), cephalosporins (J01DA), and extended spectrum penicillins were the 3 commonly prescribed groups of antibiotics. At public facilities, there was a more even use of all the major antibiotic groups including fluoroquinolones, penicillins (J01C), macrolides (J01FA), tetracyclines, cephalosporins, and Co-triamoxazole. Newer members from each class of antibiotics were prescribed. Not much seasonal variation was seen, but a relatively higher consumption of antibiotics, mainly fluoroquinolones, was observed during the rainy (hot and humid) season and few classes of antibiotics, such as penicillins, macrolides, Co-triamoxazole, and tetracyclines were used more in winter season.

**Conclusions:** A very high consumption of antibiotics was observed in both public and private sectors in the outpatient setting. Study shows a high use of broad spectrum and newer antibiotics consumption in the community. Suitable and sustainable interventions should be implemented to promote rational use of antibiotics that will help in decreasing the menace of antibiotic resistance.

Funding source: WHO

## 557

### Policy, Regulation, and Governance

*Keywords:* Regulation, pharmacovigilance, registration, marketing authorization, clinical trials

#### Pharmaceutical Regulation in 12 Countries

**Paul Gamelie Ashigbie**

Boston University School of Public Health, United States of America

**Problem statement:** To obtain data on pharmaceutical systems of its’ member states, the World Health Organization (WHO) in July 2010 conducted a pilot survey to develop model pharmaceutical profiles for 13 countries (Argentina, Armenia, Austria, China, Jordan, Kenya, Maldives, Nigeria, Pakistan, Sri Lanka, Sudan, Solomon Islands, and Suriname). We analyzed the pharmaceutical regulatory section of the survey on 12 out of the 13 study countries.

**Study objective:** To highlight the experiences of the pilot countries in medicine regulation and draw generic conclusions from which other countries and policy makers can learn

**Setting and study population:** The pilot study evaluated the regulation of private and public pharmaceutical sectors. The study countries were purposively selected from all the geographical regions of WHO to provide different regulatory environments.

**Design:** We reviewed the 2010 pharmaceutical country profile pilot study instrument and the supporting documents submitted by the study countries. In addition, we searched the websites of the medicines regulatory authorities (MRAs) for supplementary information.

**Legislation evaluated:** We evaluated the existence and functioning of the following legal and administrative provisions on pharmaceutical regulation: regulatory framework and capacity, marketing authorization, licensing of premises, import control, regulatory inspection, medicines advertisement and promotion, controlled substances, market control and quality control, clinical trial, and pharmacovigilance.

**Results:** All of the 12 countries had legal provisions establishing their MRAs. Also, 9 of the 12 MRAs had their own websites. Although legal provisions on the other regulatory functions widely existed in the study countries, pharmacovigilance and clinical trials were less governed by legislation. Legal provisions more widely existed on Good Manufacturing Practices (GMPs) than Good Distribution Practices (GDPs) (11/12 and 6/12, respectively). Legal provisions for publishing GMP and GDP requirements, the list of registered pharmaceutical products, and summary product characteristics of registered medicines were less common whereas quality testing results were published in only 2 countries. Only 7 of the countries reported assessing their regulatory system within 5 years prior to the study. The average ratio of the fee for registering a new chemical entity to that of a generic was 3, which may not favor generics enough.

**Conclusions:** The study countries generally had legislative structures for pharmaceutical regulation. However there were gaps in legal provisions governing pharmacovigilance and clinical trials. Furthermore, the publication of some regulatory documents, which could improve transparency in regulation, was not common in the study countries.

**Funding source:** WHO

## 559

### Chronic Care

*Keywords:* Complementary/Alternative Medicine, Diabetes Mellitus, Adherence, Glycemic Control, Egypt.

### **Pattern of Use of Complementary and Alternative Medicine (CAM) Among Patients with Type 2 Diabetes Mellitus (T2DM) in Alexandria, Egypt**

**S.H. Assaad-Khalil<sup>1</sup>, A. Zaki<sup>2</sup>, A.M. Ibrahim<sup>3</sup>, A.M. El-Moughazi<sup>3</sup>, A.M. Khater<sup>3</sup>, A.T. El-Sa'ed<sup>3</sup>, E.M. Rashed<sup>3</sup>, A.M. Youssif<sup>3</sup>**

<sup>1</sup>Unit of Diabetes & Metabolism, Department of Internal Medicine, Faculty of Medicine, Alexandria University.

Alexandria, Egypt.; <sup>2</sup>Department of Bioinformatics and Medical Statistics, Medical Research Institute, Alexandria

University, Alexandria, Egypt.; <sup>3</sup>Students of the 5th year, Faculty of Medicine, Alexandria University, Alexandria, Egypt.

**Problem statement:** Despite the fact that the use of CAM is a common public practice, it has been seldom studied in diabetic patients in our community.

**Objectives:** To determine the pattern and determinants of the use of CAM among patients with T2DM in Alexandria, Egypt, and its impact on compliance to pharmacotherapy

**Design:** Cross-sectional study

**Setting:** Outpatient clinics

**Study population:** Randomly selected 1,100 patients with confirmed T2DM from among attendants of outpatient clinics in Alexandria. Clinics affiliated with the University Hospital, health insurance, MOH, and private health sectors were randomly selected from all major districts of Alexandria. The study was carried out between September and October 2010. Data was collected by trained medical students using a pre-tested questionnaire. Data collected included detailed information about socio-demographic variables (age, sex, and occupation), duration of diabetes, history of DM complications, medical care affordability, and the patients' most recent laboratory investigations. We used the self-reported Morisky score to evaluate patients' compliance with DM medications. Data was analyzed with SPSS-18. A pilot study (n = 217) was conducted to calculate the size of the study population and to refine the questionnaire.

**Results:** The rate of use of CAM was found to be 41.7% (26.3% regular users). The main 3 reasons patients gave for using CAM were believing in its benefits (80%), preferring natural products (20%), and being uncontrolled with drug therapy (13%). Patients acquired their knowledge of CAM mainly from friends and neighbors (59.2%), family (32.3%), and mass media (18.1%). The most commonly used CAMs: white lupine (43%), fenugreek (42.5%), onion (34.4%), and remedies for which patients are unaware of its components (29%). Higher rates of using CAM were associated with longer duration of diabetes (p < .001), presence of complications (p < .01), and medical care affordability problems (p < 0.05). As regards socioeconomic indicators, no significant association was found between use of CAM and education (p > .05), but it was more associated with white collar occupations than blue collar ones or nonworkers (p < .05). Considering the attitude of physicians toward CAM: 43.2% were in favor, 27.4% indifferent, and 29.5% against. Poor compliance to pharmacotherapy was significantly more reported in CAM users (p < .05). Complete stopping of the pharmacotherapy on their own was reported in 31.1% of the users and 22.5% of the nonusers (p < .005). Poor glycemic control and higher rates of diabetic complications were significantly associated with the use of CAM (p < .05 and .01, respectively).

Conclusion: The use of CAM is prevalent among patients with T2DM in Alexandria, Egypt. This has a significant impact on their compliance to pharmacotherapy and their risk of suffering diabetic complications. Awareness of physicians and patient education about the rational use of CAM is needed in our community.

Funding: Self-funded project

## 560

### Economics, Financing, and Insurance Systems

*Keywords:* access to medicines, medicine supply, pharmaceutical expenditure, pharmacoepidemiology, primary health care

#### **Role of Free Provision on Household Expenditures for Medicines in Brazil**

**Andréa Dâmaso Bertoldi<sup>1</sup>, Aluísio J D Barros<sup>1</sup>, Aline Lins Camargo<sup>2</sup>, Pedro C Hallal<sup>1</sup>, Sotiris Vandoros<sup>3</sup>, Anita Wagner<sup>4</sup>, Dennis Ross-Degnan<sup>4</sup>**

<sup>1</sup>Universidade Federal de Pelotas, Brazil; <sup>2</sup>Universidade Federal de Ciências da Saúde de Porto Alegre, Brazil; <sup>3</sup>The London School of Economics and Political Sciences, UK; <sup>4</sup>Harvard Medical School and Harvard Pilgrim Health Care, USA

Problem statement: Medicine expenses contribute significantly to health care expenditures worldwide. In Brazil, among all health care expenses, medicines account for the largest share (41% in 2002/2003). The Brazilian national health system (SUS, Sistema Único de Saúde) is committed to supporting free access to medicines. To date, information is lacking about household spending on health care and medicines, particularly on who is getting free medicines supplied by SUS and how much households are saving because SUS is providing medicines for free.

Objectives: To investigate across different socioeconomic groups how much households spent on medicines and how much the Brazilian national health system supplied free of charge

Design: Cross-sectional study

Setting: This study was carried out in Porto Alegre, Brazil, from July to September 2003 and included 56 units of the Family Health Program (PSF, Programa Saúde da Família) from the Brazilian Public Health System. A two-stage sampling strategy was employed, with areas covered by the PSF constituting the primary sampling units. From the 56 units, 45 were selected with probability proportional to size and 20 households from each area were sampled.

Study population: All individuals living in the selected households were included in the study. Individuals older than 13 years were interviewed face-to-face and mothers of younger subjects responded on their behalf. Using a pre-coded questionnaire, we asked individuals about the use of medicines during the past 2 weeks and requested to see the medicines' packaging and prescriptions. For each reported medicine, we asked how the medicine was obtained and when and the amount bought or obtained free of charge. A total of 869 households were visited and 2,988 individuals were interviewed.

Outcome measures: We defined two expenditure variables: "out-of-pocket medicines value" (sum of retail prices of all medicines used by family members within the previous 15 days and paid for out-of-pocket) and "free medicines value" (similar definition for medicines obtained without charge).

Results: The Brazilian national health system provided free of charge 78% of the monetary value of medicines reported (79% in the bottom wealth quintile and 32% in the top ones); 73% of the medicines for continuous use were provided free of charge, whereas the equivalent proportion for medicines for acute use was 58%. Of the products listed on the essential medicines list, 86% were provided free of charge. The mean out-of-pocket expense for medicines was 6 times greater among the top wealth quintiles as compared to the worse-off ( $P < 0.001$ ), but free medicines constituted a 3-fold greater proportion of potential medicines expenditures among the bottom quintile than among the better-off.

Conclusions: In Brazil, free provision of medicines, along with other economic incentives, may improve access and avoid high medicines expenditures for poor people.

Funding source: TheWorld Bank through the "Reaching the Poor" program

## 563

### Access

*Keywords:* unit dose, prescription errors, ministry guidelines, pharmacist intervention, reduction in consumption

#### **Unit Dose System – Implementation in a Secondary, Multispecialty Referral Hospital: Sohar Hospital, Ministry of Health, Sultanate of Oman**

**Mona Mohammed Ali Al shizawi**

Sohar Hospital, Oman

Problem statement: The ward stock system of drug supply could not ensure prompt supply of medications to patients nor appropriate utilization; in addition, medication monitoring was inadequate.

Objective: The objective of the project was to ensure the 5 rights of drug delivery. To achieve this objective, it was decided to supply medication for each admitted patient in the ward based on their 24-hour requirement from an inpatient pharmacy.

Introduction: The ward stock system of drug supply was being practiced at Sohar Hospital from the time it opened in 1997 (408 beds). To ensure proper supply of medications and that the ministry guidelines regarding drug use were

being implemented, the hospital decided to implement the unit dose system (UDS) of drug supply in 2008. During the first phase, only the general wards were included in the scheme. Critical areas were to be included in the next phase.

Settings: The first phase of the system has been implemented in 8 general wards. The specialties included medical, surgical, pediatrics, and gynecology. The total number of beds covered is 280.

Intervention: Utilize the services of a pharmacist before the prescribed medication is administered to the patient.

Methods: A UDS was set up comprised of 5 pharmacists and 12 assistant pharmacists. An area was set apart for setting up the unit. Trolleys with removable labeled cassettes to contain medicaments of individual patients were procured. The pharmacy works around the clock all days of the week. During rounds, physicians entered prescriptions in the patients' files in the computer system. These authorized prescriptions received online in the inpatient pharmacy. After rounds, the nursing staff sent the trolleys with the labeled cassettes to the pharmacy. The pharmacist checks the prescriptions in the system and then prints the labels for the medications. The labels contain the name of patient, hospital number, sex, bed number, drug name, strength, dose, and frequency. The labels are then attached to the medication envelopes or bottles.

Policy: To replace the current ward stock system with UDS

Outcome: Better availability of medications to patients and meeting the 5 rights of drug delivery

Results: The system was appreciated by doctors and nurses. Regular supplies of prescribed medications were made available to all patients. Prescription errors were reduced and ministry policies regarding prescriptions were also closely adhered. There was a reduction in the consumption pattern of antibiotics and other medications. All the relevant data required for evaluating the intervention was obtained from the computer system as all patient records in the hospital are computerized.

Conclusion: Implementation of UDS increased the availability of medications to patients, reduced prescription errors, improved policy compliance, and reduced overall consumption of medicaments in the wards.

Funding source: MOH–Sultanate of Oman

566

#### **Economics, Financing, and Insurance Systems**

*Keywords:* cost-effectiveness, pharmacoeconomics, statins, dyslipidemia, hospital

### **Cost Effectiveness of Simvastatin Compared with Atorvastatin for Low-Density Lipoprotein Cholesterol (LDL-C) in Diabetes Patients with Dyslipidemia at a General Hospital, Northeast of Thailand**

**Nuengruthai Phunpha<sup>1</sup>, Chanuttha Ploylearmsang<sup>1</sup>, Siritree Suttajit<sup>1</sup>, Jeerapa Clungsang<sup>2</sup>**

<sup>1</sup>Social Pharmacy Research Unit, Faculty of Pharmacy, Maharakham University, Thailand

<sup>2</sup>Pharmacy Department, Roi-Et hospital

Problem statement: Statins are effective medicine for lowering LDL-C in dyslipidemia. 3 statins in a general hospital formulary are simvastatin, atorvastatin and rosuvastatin. Even simvastatin is in Thai National Drug List 2004 (NDL) and its bioequivalent generic products are available, but branded atorvastatin and rosuvastatin still are prescribed with high expenditure. Economic evaluation is needed to support Pharmacy and Therapeutic Committee (PTC) for promoting rational use of medicine.

Objective: to analyse cost-effectiveness of simvastatin compared with atorvastatin for lowering LDL-C in diabetes patients with dyslipidemia.

Design: 6-month follow up, retrospective cohort study was performed during 1 July and 31 December 2006. Samples were included in 2 months of May and June 2006. Two components of operating cost for 6-month treatment, including labor cost and material cost (drug and laboratory cost) were assessed in the provider perspective.

Setting: A general hospital in NorthEast of Thailand.

Study population: 110 diabetes outpatients who were diagnosed to be dyslipidemia in May and June 2006 and prescribed oral simvastatin or atorvastatin 10-20 mg tablet per day.

Interventions: 5 patterns of statins treatment (1) atorvastatin only, (2) simvastatin only, (3) atorvastatin switching to rosuvastatin, (4) simvastatin switching to rosuvastatin and (5) simvastatin switching to atorvastatin.

Policy: strengthening PTC, supporting NDL and generic substitution

Outcome: LDL-C level reaching the goal of treatment (<100 mg/dl).

Results: all 110 patients (66.4% female, average age of 57.6 years) showed five patterns of statins treatment (1) 69.1% simvastatin only (2) 24.5% atorvastatin only (3) 1.8% atorvastatin switching to rosuvastatin (4) 3.6% simvastatin switching to rosuvastatin and (5) 0.9% simvastatin switching to atorvastatin. The percentage of labor cost and material cost in each pattern were 4.6 : 95.4, 41.5 : 58.5, 5.5 : 94.5, 11.1 : 88.9, 18.5 : 81.5 respectively. The order of cost-effective treatment was simvastatin only, atorvastatin switching to rosuvastatin, simvastatin switching to atorvastatin, simvastatin switching to rosuvastatin and atorvastatin only. The cost of treatment for a reached goal of LDL-C were 1,955.27, 2,765.15, 6,131.76, 8,140.09, and 12,419.51 Baht respectively. The incremental cost-effectiveness ratio of switching simvastatin to atorvastatin was 6,183.58 Baht. The sensitivity analysis found whether the cost of atorvastatin is reduced more than 90% (off-patent), its will be cost-effective.

Conclusion: The medication with simvastatin in diabetes patients with dyslipidemia showed the most cost-effective. PTC should promote generic products of simvastatin, and concern the accessibility of this medicine in all diabetes patients in the different health insurance systems.

Funding source: Faculty of Pharmacy, Mahasarakham University, Thailand

572

### Drug Resistance

Keywords: antimicrobials, appropriate use, drug resistance, prescribing, community

#### Antibiotics Smart Use Program: A Mixed Model to Promote Rational Use of Medicines

**Nithima Sumpradit<sup>1,2</sup>, Pisonthi Chongtrakul<sup>3</sup>, Kunyada Anuwong<sup>4</sup>, Somying Pumtong<sup>4</sup>**

<sup>1</sup>Food and Drug Administration, Ministry of Public Health, Thailand; <sup>2</sup>International Health Policy Program, Ministry of Public Health, Thailand; <sup>3</sup>Faculty of Medicine, Chulalongkorn University; <sup>4</sup>Faculty of Pharmacy, Srinakharinwirot University

Problem statement: The Antibiotics Smart Use Program (ASU) was originated to develop methodologies to promote rational use of medicines (RUM). This study assumed that RUM is behavior oriented; it cannot be achieved unless irrational drug use behaviors are changed into rational ones. ASU offered a mixed model for RUM by initiating attitude and behavior changes at an individual level and then scaling up and sustaining achievement via 3 strategies—development of a collaborative network, policy advocacy, and forming a social norm. Antibiotics were prioritized for this study because of the urgency and severity of the antimicrobial resistance situation pressing serious health threats.

Objective: To develop and test a mixed model of ASU in promoting RUM

Design: ASU used a quasi-experimental design aiming at reducing unnecessary use of antibiotics in upper respiratory infections, acute diarrhea, and simple wounds. The PRECEDE-PROCEED model and selected constructs from health behavior theories were used to plan the program. ASU has 3 phases. Phase I aimed to test interventions by changing antibiotics prescribing behavior (2007-8). Phase II aimed to test feasibility of scaling up the program (2008-9). Phase III is on-going and aims to promote program sustainability (2010-12).

Settings: Phase I was conducted in 1 province covering 10 district hospitals and 87 health centers. Phase II involved 3 provinces (large, medium, and small) and 2 hospital networks (public and private hospitals) covering 44 hospitals and 627 health centers.

Population: Health professionals and patients in the targeted sites

Intervention: Phase I used multifaceted interventions (e.g., treatment guideline, herbal substitutes for antibiotics, and patient education) to change prescribing behavior and was based on the pre-test and post-test design with a control group. In phase II, the decentralized networks between local and central partners were developed to scale up the program. Local partners adapted the concept to suit the local context. Central partners provided technical support, promoted the sense of local ownership, and advocated policy.

Policies: ASU was integrated in the pay-for-performance criteria for community hospitals in 2009 by the National Health Security Office (NHSO), which is responsible for the universal coverage scheme. In 2010, the criteria were expanded to cover all hospital levels.

Outcome measure: Reduction in the number of antibiotic prescriptions, improved patients' health and satisfaction (phase I); expansion of ASU program (phase II)

Results: Phase I showed an 18%-46% reduction in antibiotic use; 97% of 1,200 targeted patients recovered or felt better regardless of taking antibiotics. Phase II indicated an increased diffusion of ASU to 22 local projects in 15 provinces. Recent data indicated that 95.6% of some 637 hospitals under NHSO contract implemented ASU at a certain level.

Conclusions: A mixed model of ASU can reduce unnecessary antibiotics use and can be scaled up to the national level. A bottom-up approach targeted at the individual is important in initiating behavioral change. A top-down approach (i.e., policy support) and decentralized networks are crucial for scaling up and sustaining the program.

Funding sources: Thai Food and Drug Administration, WHO, Health Systems Research Institution, NHSO, Drug System Monitoring and Development Centre, Thai Health Promotion Foundation

580

### Malaria

Keywords: Malaria, Safety monitoring ACTs, CEM.

#### Pilot study of cohort event monitoring (CEM) on patients treated for malaria with Artemisinin Based Combination Therapies (ACTs) in Nigeria

**Peter Usman Bassi<sup>1</sup>, Adeline Osakwe<sup>2</sup>, Ambrose Isah<sup>3</sup>, Comfort Suku<sup>2</sup>, Musa Kalat<sup>2</sup>, ILIYA Jalo<sup>4</sup>, Robinson Wammanda<sup>5</sup>, Chika Ogochukwu<sup>6</sup>, Olubukola Adesina<sup>7</sup>, Etim E Nyong<sup>8</sup>, Frank Osungwu<sup>9</sup>, Pal Shanti<sup>10</sup>, Oslsson Sten<sup>11</sup>, David Coulter<sup>12</sup>, Maganus Wallberg<sup>11</sup>, Sylvester Nwoasu<sup>1</sup>**

<sup>1</sup>College of Medical Sciences University of Maiduguri, Nigeria; <sup>2</sup>National Pharmacovigilance centre NAFDAC Abuja, FCT; <sup>3</sup>Clinical Pharmacology Unit, University of Benin teaching hospital, Benin, Edo state; <sup>4</sup>Department of Paediatrics Federal Medical Centre Gombe, Gombe State; <sup>5</sup>Department of Paediatrics Ahmadu Bello University Teaching Hospital, Zaria Kaduna State; <sup>6</sup>Department of Paediatrics Nnamdi Azikwe Teaching Hospital Enugu, Enugu State; <sup>7</sup>Department of Obstetrics and Gynaecology, University College hospital Ibadan, Oyo State; <sup>8</sup>University of Uyo Teaching Hospital,

Akwa- Ibom State; <sup>9</sup>NIPRD MOPD Clinic, Idishin Abuja – FCT; <sup>10</sup>Quality Assurance and Safety of Medicines, WHO – Geneva, Switzerland.; <sup>11</sup>Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring; <sup>12</sup>Committee on safety of medicinal Products, WHO. New Zealand.

**Problem statement:** The emergence and spread of parasites resistant to available antimalarial drugs necessitated a shift in the malaria treatment policy by the federal government from the use of chloroquine and S-P as first-line treatment to the ACTs. Initial reports following deployment of the ACTs raised safety concerns regarding use in clinical settings. Moreover, the OTC classification of these medicines has made them readily available to Nigerians. Although, artemisinin and its derivatives are generally thought to be safe, there is currently little or no data on its safety among populations in Nigeria.

**Objectives:** The CEM provides a tool for proactively determining the adverse event (AE) profile of ACTs.

**Study design:** The study was observational, longitudinal, prospective, and inceptional whereby patients were observed under real life situations.

**Setting:** This CEM pilot was conducted across the 6 Nigerian public health facilities on patients who were treated for malaria with ACTs on the basis of 1 per geo-political zone. This provides a representation of cultural, ethnic, and religious diversity, which are strong considerations in Nigeria.

**Study populations:** A total of 3010 patients treated for malaria with ACTs were enrolled. All patients with a clinical diagnosis of malaria for whom artesunate amodiaquine (AA) or artemether-lumefantrine (AL) was prescribed were recruited, irrespective of age and sex. They were reviewed on days 3 and 7 following commencement of ACT treatment.

**Outcome measure:** Patients were evaluated for any clinical event/experience they had following the use of ACTs.

**Results:** The 5 common AEs seen in the two drugs AA/AL included general body weakness 388 (38%)/36 (4 %), dizziness 165 (16%)/16 (2%), vomiting 93 (9.0%)/11 (1.0%), abdominal pain 34 (3.4%)/11 (1.0%), and loss of appetite 39 (3.4%)/10 (1.0 %), respectively. The mean duration of events was 3 days. The events were more common in the AA group than the AL group. The study also shows that AL has a better safety profile than AA, however, both drugs demonstrate good clinical treatment outcome.

**Conclusion:** This pilot study suggests that AEs in ACTs are common, but that severe, life-threatening events are not. The mean duration of AEs is 3 days, after which clinical symptoms subsided in most subjects, suggesting that ACTs have a tolerable safety profile among Nigerians.

**Funding sources:** NAFDAC, WHO, NMCP, SFH, and YGC

## 582

### Drug Resistance

*Keywords:* Antimicrobials, appropriate use, drug resistance, primary health care, surveillance

### Antibiotic Prescribing Practices of Primary Care Prescribers for Acute Respiratory Tract Infections and Diarrhoea in New Delhi, India

**Anita Kotwani<sup>1</sup>, Ranjit Roy Chaudhury<sup>2</sup>, Kathleen Holloway<sup>3</sup>**

<sup>1</sup>V. P. Chest Institute, University of Delhi, Delhi, India; <sup>2</sup>Apollo Hospitals Educational and Research Foundation, New Delhi, India; <sup>3</sup>World Health Organization, Regional Office for South East Asia, New Delhi, India

**Problem statement:** The rapid emergence of antimicrobial resistance in the community has become a major global health problem. Excessive use of antibiotics in ambulatory care settings, especially for conditions that do not require antibiotics, is one of the major contributing factors to the emergence and spread of antibiotic-resistant bacteria in the community.

**Objective:** To obtain information on current prescribing rates of antibiotics in acute respiratory tract infections (ARIs) and acute diarrhoea in the community, conditions where misuse of antibiotics are common.

**Design:** Cross-sectional study

**Setting:** 10 primary care public facilities and 20 private clinics in 4 residential localities of Delhi

**Study population:** After consultation with a prescriber, patients were asked if they had cough/common cold/sore throat (symptoms of ARI) or acute diarrhoea without any blood. Patients with any of these symptoms were enrolled for an exit interview and his/her prescription was monitored. Antibiotic use data was collected per month over one year (December 2007–November 2008).

**Outcome measure:** The percentage of patients receiving antibiotics and the pattern of consumption of antibiotics was analyzed by using the Anatomical Therapeutic Chemical classification and the defined daily dose.

**Results:** At public facilities, 45.3% (746/1646), and at private facilities, 56.7% (259/457), of patients with ARIs were prescribed at least one antibiotic. In the public sector, macrolides, J01FA (29.3%), penicillins, J01C (26.3%), and cephalosporins, J01DA (16.2%); and in the private sector, cephalosporins (40%), fluoroquinolones (21.7%), and penicillins (19.7%) were mainly prescribed. At public facilities, the main members from macrolides were roxithromycin and erythromycin; for penicillins, amoxicillin and amoxicillin+clavulanic acid; for cephalosporins, cefuroxime and cephalexin were used. At private clinics, for cephalosporins, cefuroxime, cefpodoxime proxetil, cefixime, cefixime+clavulanic acid; for fluoroquinolones, levofloxacin and ofloxacin; and for the penicillins group, amoxicillin+clavulanic acid were prescribed. For acute diarrhoea, at public facilities 43% (171/398) and at private facilities 69% (76/110) of patients were prescribed at least one antibiotic. The number of diarrhoea patients increased during the humid summer months. The main antibiotic class that was prescribed in both public and private sector facilities was fluoroquinolones, J01MA (91.5% and 96%). In the private sector, pediatricians prescribed antibiotics to

51.5% (17/33) of children, and in the public sector, antibiotics (fluoroquinolone) were prescribed to 23% of children with diarrhoea. At public facilities, the most commonly prescribed fluoroquinolone was norfloxacin, followed by ofloxacin and ciprofloxacin. At private clinics, it was ofloxacin followed by ciprofloxacin.

Conclusions: This study clearly shows irrational use of antibiotics for treatment of acute diarrhoea and ARI that warrants interventional strategies.

Funding source: WHO

**584**

#### Drug Resistance

*Keywords:* Antimicrobials, appropriate use, drug resistance, primary health care, prescribing

#### Factors Influencing Antibiotic Prescribing by Primary Care Doctors in Delhi, India: Qualitative Study

**Anita Kotwani<sup>1</sup>, Chand Wattal<sup>2</sup>, Shashi Katewa<sup>3</sup>, P. C. Joshi<sup>3</sup>, Kathleen Holloway<sup>4</sup>**

<sup>1</sup>V. P. Chest Institute, University of Delhi, Delhi, India; <sup>2</sup>Sir Ganga Ram Hospital, New Delhi, India; <sup>3</sup>Department of Anthropology, University of Delhi, Delhi, India; <sup>4</sup>World Health Organization, Regional Office for South East Asia, New Delhi, India

**Problem statement:** To support the rational use of antibiotics, it is important to collect information on patterns of drug prescriptions and on factors influencing prescribing decisions. A pilot study conducted in New Delhi, India, showed high levels of antibiotic use and resistance in the community. It is necessary to understand physicians' prescribing behaviour to develop interventions that will effectively improve the use of antibiotics.

**Objectives:** To explore the factors that influence primary care physicians to prescribe antibiotics and to investigate possible interventions to promote rational use of antibiotics

**Design:** Qualitative study

**Setting:** Focus group discussions (FGDs) of primary care doctors of the public and private sectors from five municipal wards (residential localities) of Delhi

**Study population:** Public sector doctors were invited from 10 public health facilities from which data on antibiotic drug use were collected. For the private sector, 60 doctors who were practicing in the survey area and were members of the doctors' association were approached. All 10 doctors from the public sector participated, but only 26 of 60 doctors invited from private sector facilities participated in the FGDs. One group was composed exclusively of private sector doctors (n = 18), one group exclusively of public sector doctors (n = 8), and the third group contained doctors from both public (2) and private (8) facilities.

**Outcome measure:** The data from 3 FGDs were analysed by grounded theory. The method of 'constant comparison' was central to the process generating various themes and codes.

**Results:** Three broad themes were identified—behavioural characteristics of doctors and patients, laxity in regulation of prescribing and dispensing antibiotics; and intervention strategies to decrease misuse of and resistance to antibiotics. Important factors identified for antibiotic prescriptions by doctors were diagnostic uncertainty, perceived demand and expectation from the patients, practice sustainability and financial considerations, influence from medical representatives, and inadequate knowledge. For public sector doctors, besides the above, overstocked and near-expiry drugs and lack of time were the factors that promoted antibiotic overuse. Doctors also identified certain patient behaviour characteristics and laxity in regulation for prescribing and dispensing of antibiotics as aggravating the problem of antibiotic misuse. Interventions like continuing medical educations for doctors, raising awareness of patients, shared decision making, and stricter rules and regulations for antibiotic dispensing without prescription were suggested to promote rational use of antibiotics in the community.

**Conclusion:** Exploration of doctors' antibiotic use practices and possible interventions will be helpful in carrying out interventions to promote appropriate use of antibiotics in the community.

Funding source: World Health Organization

**585**

#### Chronic Care

*Keywords:* Atypical antipsychotics, olanzapine, side effects, diabetes, pharmaceutical care

#### Importance of Monitoring Patients on Atypical Antipsychotics

**Brian Conroy Gunn, Hawraa Al-Lawati, Ahmed Abdo-Rabbo, Batool Jaffer Suleiman, Manal Al-ansari**

DRUM, Ministry of Health, Sultanate of Oman, Oman

**Background:** Atypical antipsychotic use has been rising rapidly in Oman since 2000. Concern about potential side effects and the high cost of these drugs prompted a preliminary investigation into their use. A report was produced with recommendations and a preliminary guideline was prepared in consultation with the chief consultant psychiatrist. In subsequent years, use continued to rise and concern was growing about emerging diabetogenic side effects.

**Problem statement:** Although atypical antipsychotics like olanzapine have proven to be a great improvement in psychotherapy, they are not free of side effects and have their own spectrum of adverse reactions, especially associated with the endocrine system.

**Objectives:** Examine the pharmaceutical care given to patients receiving olanzapine therapy, in particular to monitor weight gain, loss of blood glucose control, and changes in lipid profile

**Design:** Patients' records were examined retrospectively in 2009. In Muscat, the hospital had a computerized medical records system and in Sohar, a manual system is still in use.

**Setting:** Two of the largest psychiatric institutions in the public sector in Oman, the Ibn Sina Hospital in Muscat and the Sohar Polyclinic in Sohar

**Study population:** A total of 359 psychiatric patients in both hospitals were studied out of 704 patients on olanzapine throughout Oman.

**Results:** Of the studied patients, 70% had no weight recorded, 58% had no blood glucose measurement, and 98% had no lipid profile checked; some patients also received traditional antipsychotics and many other co-medicines, which were documented. The reasons for some of these failings were explored.

**Conclusion:** In spite of the availability of specific protocols and referral forms which ask for such information, monitoring of patients on olanzapine is suboptimal and there is a considerable risk of diabetogenic side effects in these patients which can lead to a considerable economic burden if it continues unchecked.

**Funding sources:** MoH general budget

**587**

### **Chronic Care**

*Keywords:* adherence, appropriate use, public education

#### **Reasons for Rejection of Medications by Patients in Oman**

---

**Brian Conroy Gunn, Abdul Rasoul Wayyase, Batool Jaffer Suleiman**

DRUM, Ministry of Health, Sultanate of Oman, Oman

**Problem statement:** Patient adherence to medications is one of the most critical aspects of therapy. It has been calculated that globally, there is an enormous waste of vital medicine. If patients fail to take medicine properly, it could increase morbidity and mortality and add to the general economic burden.

**Objectives:** To examine and quantify why many patients in Oman reject their prescribed medicines at the pharmacy.

**Background:** This research originated from observations that, on occasion, prescriptions were marked "patient refused" or "patient rejected". As the drugs refused were usually associated with serious and often chronic conditions, it was decided to investigate further the reasons for this refusal. It was also hoped to establish the extent of this phenomenon throughout the Sultanate.

**Methodology:** Assistant pharmacists working in the field were recruited and trained as researchers for this study. A structured fill-in form in English and Arabic with 17 possible reasons for rejection was used, one reason being a 'catch all'. The assistant pharmacist had to interview any patient who rejected or returned their medicines at the dispensing counter and ask for details with the patient's permission. A total of 607 patients from 14 different facilities covering 8 health regions of Oman were interviewed about their rejections.

**Results:** The results indicate that most medicines are rejected because the patient already has a stock of the same medicine at home (41%). In several cases, the nature of the medicine itself adds an extra dimension of concern. For example, rejection of antibiotics, insulins, oral antidiabetic medicines, antihypertensives, and other drugs raises serious alarm about patient concordance. Other reasons given were no faith in a medicine they had received before (11.5%) and fear of side effects (10%). The overall result raises possible issues for the rational use of medicines in Oman. Some possible causes are lack of communication between doctor and patient, patient "drug shopping" at multiple facilities, faulty distribution of referral medicines, and patients not understanding their disease and the need to take their medicines.

**Outcome:** The current research revealed a rejection rate of 1.5% overall average at an approximate value of 85,000 Omani Rial (USD 221,000) per annum. This result is considered a minimum and it is possible that there may be many more occurrences of rejection of medicine once patients have left the facility. This could mean a fairly serious wastage of resources in addition to exposing flaws in patient care and health education.

**Funding source:** MoH general budget

**591**

### **Chronic Care**

*Keywords:* Medication adherence, institutionalized elderly, community dwelling elderly

#### **Medication Adherence: Comparative Study between Institutionalized and Community-Dwelling Elderly**

---

**Heba Mahmoud El Kady, Moatza M. Abdel Wahab, Noha S. Moustafa**

High Institute of Public Health, Egypt

**Background:** Adherence to a prescribed medication regimen is difficult for all patients and particularly challenging for the elderly who suffer from multiple chronic diseases requiring long-term drug therapy. Non-adherence to medications reduces treatment benefits, can confound clinicians' assessments of therapeutic effectiveness, and is thought to account for 30–50% of cases where medicines fall short of their therapeutic goals. Studies about non-adherence in elders emphasize that no single reason fits all patients.

**Objective:** To study self-reported medication adherence and its predictors among community dwelling in comparison to institutionalized elderly

**Design:** Comparative cross sectional

**Setting:** Sekina village (a slum area in Alexandria) and two governmental institutions for elderly in Alexandria, Egypt.

**Study population:** 50 community-dwelling elderly (60 years and above) as a part of the annual health survey conducted by the HIPH in slum areas and a sample of 50 institutionalized elderly selected by simple random sampling from two government homes for the elderly; all elders were interviewed by using a prescheduled questionnaire designed by the researchers covering socio-demographic characteristics, source of income and treatment expenses, and medical history

**Outcome measure:** Self-reported degree of adherence to treatment regimens; statistical analyses were performed by using the z test of proportion and logistic regression

**Results:** Self-reported medication adherence in the total sample was 76.6%. Adherence was higher among the institutionalized group (81.4%) in comparison to home dwellers (73.8%). Yet, the difference was not statistically significant ( $z = 0.8416$ ). The main mentioned reasons for non-adherence were the cost of the medication (93.3%), side effects (33.3%), forgetfulness (13.3%), and lack of accessibility to buy the medications (13.3%). There was no significant difference between both groups as regards non-adherence reasons. Factors that favored adherence were pension as the basis for income, hypertensive or neurologic patients, and having a son, daughter, or nurse responsible for administration of medication. Meanwhile, none of them was a significant predictor on the basis of logistic regression.

**Conclusion:** Based on self reporting, medication adherence was better among institutionalized than among community-dwelling elderly, yet the difference was not statistically significant. Sex, marital status, income, education, and living with someone were not significant determinants for adherence; neither were the type of disease, number of medications, their route to the pharmacy, nor expenses. We suggest further research for nonstudied determinants, namely, psychological aspects, depression scores, and perception of treatment benefits.

**Funding sources:** HIPH supported the community dwelling part of the study and the institutionalized part was based supported by personal funds.

## 592

### Policy, Regulation, and Governance

**Keywords:** primary health care; financing; drug utilization; pharmaceutical expenditure

#### Financial Impact of Judicious Use of Medicine in Primary Care

**Yegin Zuo, Stephen Morrell, Jonathan Dartnell, Lynn Weekes**

NPS: Better Choices, Better Health, Australia

**Problem statement:** Many policies and guidelines have been developed to promote the judicious use of medicines. Funding large-scale programs to implement these policies remains challenging. NPS has worked at the national level to address quality use of medicine in the last 12 years.

**Objectives:** To assess the financial impact of NPS programs on expenditures by the Australian Pharmaceutical Benefit Scheme (PBS) between 2007 and 2009

**Design:** Time series modeling was used to assess the association between general practitioner (GP) participation in NPS programs and PBS expenditures, controlled for underlying trends, seasonality, autocorrelation, and medicine price changes. PBS monthly time trends over 1999–2009 in utilization of antithrombotics, antihypertensives, analgesics, antidepressants, and proton pump inhibitors (PPI) were analyzed.

**Setting:** Primary care

**Study population:** All Australians entitled to PBS subsidies

**Intervention(s):** The interventions aimed at GPs included educational visits, case studies, clinical audits, and group discussions. Key messages relevant to reducing suboptimal use of medicines included the following: (1) reserve clopidogrel for those unable to take aspirin; (2) avoid fixed-dose combination products in the initiation of antihypertensives; (3) limit the role of tramadol for mild to moderate pain management; (4) use psychological therapies as first-line treatments in mild depression; and (5) step down the dosage of PPIs to intermittent, symptom-driven therapy.

**Policy:** Evidence-based prescribing

**Outcome measure(s):** Difference in PBS expenditure on targeted medicines attributable to the intervention

**Results:** The GP participation rates were between 29% (5,956) and 52% (8,358) of all GPs. We found a significant correlation between GP participation and decreased PBS expenditures on targeted medicines ( $p < 0.0001$  to  $< 0.05$ ). We noted a significant increase in the effect of interventions in the initial period following implementation. For example, the annual PBS expenditure saving on antidepressants increased from 7% in 2008 to 12% in 2009 (last GP enrollment in May 2008); however, 2 years after implementation, the PPI program showed signs of waning. Annual cost savings decreased from 13% in 2008 to 12% in 2009 (last GP enrollment in April 2007). Overall, we estimate a mean annual PBS expenditure reduction of 16% (AU \$18.4 million) per program per drug group attributable to NPS interventions.

**Conclusions:** Comprehensive programs in primary care can reduce inappropriate prescribing and lead to substantial national cost savings. Program for some drug groups may need refresher interventions every 2–3 years to sustain the impact.

**Funding source(s):** NPS is funded by the Australian Government Department of Health and Ageing.

593

**Policy, Regulation, and Governance**

*Keywords:* Unbranded advertising, prescription-only medicines, pharmaceutical promotion

**Unbranded Advertising of Prescription Medicines—A Systematic Literature Review**

**Teresa Leonardo Alves<sup>1,3</sup>, Barbara Mintzes<sup>2</sup>, Aukje K. Mantel-Teeuwisse<sup>3</sup>, Hubert G.M. Leufkens<sup>3</sup>**

<sup>1</sup>Health Action International Europe, Amsterdam, the Netherlands; <sup>2</sup>Department of Anesthesiology, Pharmacology and Therapeutics at the University of British Columbia, Canada; <sup>3</sup>Utrecht WHO Collaborating Centre for Pharmacoepidemiology and Pharmaceutical Policy Analysis, the Netherlands

**Problem statement:** Various forms of promotion of prescription medicines to the general public have become increasingly common. These include an increasing volume of 'disease-oriented' campaigns that discuss a condition a medicine treats without mentioning a specific brand name. The claimed benefit of disease-awareness campaigns is that the public becomes more aware of untreated health problems and seeks effective care at an earlier stage, leading to better health. However, serious information deficiencies have been identified in campaigns, raising questions about potential benefits versus harm. A key concern is that the context in which this information is provided could be biased towards supporting treatment with the sponsor's product.

**Objectives:** To investigate whether advertising of prescription medicines through unbranded condition-oriented campaigns is associated with effects on health services use and health outcomes

**Design:** Systematic literature review

**Setting:** Published literature on unbranded advertising of prescription medicines identified by using Medline, Embase, Web of Science, Cochrane Systematic Review, all from January 1980 to December 2010. Searches will be supplemented with grey literature identified by the authors and experts. Data will be independently abstracted and logged into a data extraction form by 2 of the authors and any disagreements will be resolved by consensus.

**Study population:** Articles published in English, Dutch, French, Spanish, and Portuguese, describing the effects on health services use and health outcomes brought about by condition-oriented advertising campaigns of prescription medicines conducted by or on behalf of pharmaceutical companies and disseminated in any media (broadcast and printed).

**Outcome measure(s):** Effects on health services use and health outcomes; (1) measures of health service use are rates of first consultations, prescribing and dispensing rates, pharmaceutical expenditures, and sales volume; (2) health outcomes include increases or decreases in the rate of serious adverse events, non-serious, and total adverse events and quality of life, including outcomes associated with the condition being treated and/or drug therapy

**Results:** Published materials are limited and grey literature resources outweigh peer-reviewed articles. A detailed analysis of the published items will be provided, describing the focus, nature, and methodology of the different studies; in addition, selected outcome measures, academic or industry sponsorship, and type of publication/journal will be provided.

**Conclusions:** The literature review will inform current policy discussions on the impact of unbranded campaigns by the pharmaceutical industry in the direct provision of information about their medicinal products to the public.

**Funding source:** HAI receives funding from the Dutch Ministry of Foreign Affairs programme MFS1. HAI Europe has been awarded an operating grant for 2011 by the European Health and Consumers Agency.

596

**HIV/AIDS and TB**

*Keywords:* Pharmacovigilance, patient safety, tuberculosis

**Integrating Pharmacovigilance in Revised National Tuberculosis Control Programme of India: A Pilot Study**

**Parthasarathi Gurumurthy<sup>1,2</sup>, Niveditha Harapanahalli<sup>1</sup>, Anand Harugeri<sup>1</sup>, Madhan Ramesh<sup>1,2</sup>**

<sup>1</sup>JSS College of Pharmacy, JSS University, Mysore, India; <sup>2</sup>JSS Medical College Hospital, JSS University, Mysore, India

**Problem statement:** The Directly Observed Treatment Short Course (DOTS)/Revised National Tuberculosis Control Programme (RNTCP) of India is one of the largest public health care programmes in the world. About 3,500 patients are initiated on antituberculosis therapy (ATT) every day at DOTS centres in India. Safety information of DOTS in the local population is lacking and pharmacovigilance needs to be integrated into the DOTS programme.

**Objectives:** To develop DOTS centres as sentinel sites for monitoring adverse drug reactions (ADRs) to ATT

**Design:** A prospective study

**Setting:** 10 DOTS centres attached to government primary health care centres in Mysore, India

**Study population:** Medical officers, pharmacists, and TB health visitors of DOTS centres

**Intervention:** Workshops for training on safety monitoring of antitubercular therapy (SMART) were organized. Pre- and post-workshop assessments without control were conducted. A SMART trigger tool was developed and implemented to assist the sites' personnel in detecting ADRs to ATT. Personnel monitored the ADRs in patients receiving DOTS between September 2009 and February 2010. ADR reporting forms and patient information leaflets regarding adverse

reactions to ATT were made available at all selected sites. Investigators visited the sites periodically to further train and assist site personnel in detecting and reporting ADRs.

Outcome measures: Awareness about ADRs to ATT; detection and reporting of ADRs to ATT

Results: 44 health care professionals from 10 DOTS/RNTCP centres were trained on ADR detection, reporting, and medication safety counseling; pre- and post-workshop assessments found a 25% increase in the understanding of ADRs to ATT and 68% of the participants detected the ADRs to ATT in dummy TB patients by using the trigger tool developed for the study. The participants of the programme opined that the project helped them to develop their skills in patient safety monitoring. The programme did not necessitate employing any extra human resource at the sites. Of the 274 patients treated with DOTS at the sentinel sites during the study period, 201 adverse reactions to ATT were detected/reported from 112 patients (prevalence 40.9%) in the post-training period. Completion of TB treatment by 98% (110) of patients who experienced ADRs demonstrated the effectiveness of the programme.

Conclusion: Extension of the sentinel site approach in a phased manner to other DOTS/RNTCP centres will improve patient safety monitoring in a large population. SMART workshops can enhance the understanding of ADRs to ATT among the health care professionals of DOTS/RNTCP centres. Our approach to safety monitoring of ATT may prove useful to integrate pharmacovigilance in public health care programmes in resource poor settings.

Funding source: Mysore Physicians Medical Research Trust, Mysore sponsored workshops for training on SMART

**599**

### **Policy, Regulation, and Governance**

*Keywords:* rational use, marketing, promotion, private-sector, pharmaceutical, regulation

### **Marketing and Promotion of the Pharmaceutical Industry: Snapshot of Current Practice Within, or With Possible Implications In, Low- and Medium-Income Countries**

**Suzanne Elizabeth Edwards<sup>1</sup>, Afshin Mehrpouya<sup>2</sup>, Frans Westerbos<sup>1</sup>**

<sup>1</sup>Access to Medicine Foundation, Netherlands, The; <sup>2</sup>MSCI Group - ESG Research

Problem statement: Developing countries often have more constrained regulatory enforcement, information systems, and consumer protection. These countries' health care professionals and patients can be more dependent on medical information from and the self-regulation of companies themselves. Stakeholders, including the WHO, have highlighted concern over the possible risks this situation may pose for rational prescription and use of medicines.

Objectives: To use data from the Access to Medicine Index 2010, a bi-annual pharmaceutical industry benchmarking tool, to provide a baseline snapshot of current average and leading sector practice in the area of marketing and promotion (M&P) in index countries (ICs).

Design: A sub-analysis of 7 qualitative indicators relating to M&P. Data was obtained through public and engagement-based disclosure for the 2008 and 2009 financial years. Analysis focused on governance, policies, and operations in or with impact on ICs—88 countries based on the UN HDI list of low- and medium-income countries and for products targeting 33 high-priority diseases (in ICs).

Study population: 20 largest originator pharmaceutical companies in 2009

Policy change: By transparently measuring and benchmarking companies we aim to build a deeper and broader understanding of the current situation and practice in this area. The bi-annual nature of the survey and the use of consistent metrics will, in the future, allow evaluation of changes over time to facilitate policy development and evaluation both within and external to the industry.

Results: Currently 100% (20) of companies analysed commit to adherence with at least 1 recognised global M&P code and also have an employee code of conduct which includes M&P. Seven companies do not currently demonstrate evidence of the existence of mechanisms to monitor and ensure compliance in IC markets. Eight companies commit to demanding ethical marketing from their third parties. Of these, 4 currently ensure this by either making it contractual or by providing evidence of compliance mechanisms. Of the 12 companies with no commitment, 5 have general recommendations in place. At present, not one company analysed discloses or reports their approach, the nature of the M&P activities, or resources dedicated to M&P in ICs. During the period of analysis, no major litigation in the ICs was found regarding M&P activities. All companies disclose this information to a level legally mandated.

Conclusions: Currently, no company discloses any information regarding their M&P approach, activities, or financing in ICs. Internal governance of M&P appears less robust for companies' IC operations, with robustness lower still for M&P occurring through third parties. Examples of leading practice are found, which may indicate growing company attention to these issues and stimulate more rapid sector-wide adoption. The index has an ongoing role in policy development and evaluation in this area by facilitating greater transparency, communicating clear stakeholder expectations, and evaluating behaviour change over time.

Funding sources: Bill & Melinda Gates Foundation, UK Department for International Development, Dutch Ministry of Foreign Affairs

**600**

### **Access**

*Keywords:* development, formulation, packaging, pharmaceutical, rational

## **Anecdotal Evidence for Ways in which the Originator Pharmaceutical Industry Has Contributed to Improving the Appropriateness of Medicine Use in Low-Income Countries through Product and Packaging Adaptations**

**Suzanne Elizabeth Edwards, Frans Westerbos**

Access to Medicine Foundation, Netherlands, The

**Problem statement:** At the level of the product, the main mechanisms originator pharmaceutical companies can use to positively influence rational use of medicines (RUM) are through the optimisation of product quality, product appropriateness, and patient compliance. We present some examples of positive emerging practices in the latter areas of adaptive R&D and product packaging.

**Objectives:** Use data from the Access to Medicine Index 2010 to highlight average and leading practices to make needs-based adaptations to both packaging and already approved products to meet index country (ICs) needs.

**Design:** This sub-analysis of index 2010 data takes data gathered from 3 indicators—one for needs-based packaging adaptations and the remaining indicators capturing companies' commitments, transparency, and performance with respect to 'adaptive R&D' for products targeting 'high-priority' diseases.

**Study population:** The 20 largest originator pharmaceutical companies. Based on their 2008 and 2009 activities with respect to ICs, this works out to 88 countries based on the UN HDI list of low and medium income countries.

**Policy(ies):** Index 2010 represented the first time both of these areas were included in the methodology, based on stakeholder feedback regarding their expectations of companies. By publishing index data we hope to provide a clearer picture of current sector practice. The bi-annual nature of the index and use of consistent indicators will inform policy development and evaluation overtime, encourage peer-based learning to motivate more rapid adoption of leading practices within-sector, and act as a decision support tool for other interested stakeholders.

**Results:** At present only one company, GSK, makes specific, detailed commitments to undertake 'adaptive' R&D based on IC needs. Currently 10/20 companies are known to be conducting adaptive R&D for IC-relevant drug development. Of the (approximately 31) products that were disclosed to us, 80% of these were for HIV/AIDs. Children were the most frequent target of adaptive efforts. Evidence of needs-based packaging was found for 25% of the companies. Largely these efforts involved the inclusion of pictograms or colour coding to facilitate compliance and appropriate dosing. Although welcome, presently these efforts are mainly specific to a single product from each company's portfolio. A number of cases of leading practice and innovative approaches are demonstrated.

**Conclusions:** Examples of needs-driven adaptations of preapproved products are relatively nascent across the sector but may be a growing trend which can offer significant benefits in ICs for patients, HCP, and health systems. Wider commitment to and adoption of these leading practices across companies' portfolios and the sector would be welcomed by stakeholders who have also raised concern around the need to balance these incremental product improvements with affordable pricing. Although the data are likely an underestimation of companies current efforts, collaboration and partnering in this area can provide incentives to companies and clearer mapping of the 'need gaps' may further facilitate efforts.

**Funding sources:** Bill & Melinda Gates Foundation, UK Department for International Development, Dutch Ministry of Foreign Affairs

**602**

**Access**

*Keywords:* cost-effectiveness, pharmacoeconomics, statins, dyslipidemia, hospital

## **Survey on the Use of Medicines by Consumers in Federal Territories of Kuala Lumpur and Putrajaya**

**Salimah Bahri<sup>1</sup>, Sook Tze Lai<sup>1</sup>, Yee Woon Yap<sup>1</sup>, Min Wei Ching<sup>1</sup>, Nadira Ahmad Khidzar<sup>1</sup>, Jennifer Kua<sup>2</sup>**

<sup>1</sup>Federal Territories Of Kuala Lumpur & Putrajaya Health Department, Malaysia; <sup>2</sup>Kuala Lumpur Hospital

**Problem statement:** Rational medicines use by consumers has become a major concern both in developed and developing countries. To date, there is limited local study to determine consumers' knowledge and awareness with regards to rational medicines use. Also, no constructive interventions have been implemented to further enhance the quality use of medicine.

**Objectives:** To identify current medicine use patterns among consumers and assess the efficacy of the 'Know Your Medicine' campaign on patients' understanding and knowledge of rational medicine use and sources of medicine information.

**Design:** Longitudinal, pre-post design survey was conducted from August 2007 till December 2009 with potential consumers in Federal Territories of Kuala Lumpur and Putrajaya.

**Setting and population:** Single-stage, random clusters sampling technique with 240 consumers

**Interventions:** The 'Know your Medicines' campaign was implemented through exhibitions, seminars, media, and various channels to educate consumers.

**Outcome measures:** Quantitative indicators of medicine use and effectiveness of the campaign.

**Results:** The descriptive data has shown consumers' level of understanding on medicines use in terms of dosage was 74.6%, followed by 92.5% on frequency, and 97.9% in method of administration; however, only 41.3% of consumers know about medicine/food interactions. There were statistically significant improvements in consumers' knowledge after the intervention, namely, generic name (27.9% vs. 48.3%,  $p < 0.05$ ), trade name (40.4% vs. 80%,  $p < 0.05$ ), side effects

(32.7% vs. 51.7%,  $p < 0.05$ ), and storage (59.4% vs. 73.8%,  $p < 0.05$ ). Only 35.4% of consumers stopped taking medicine when feeling well compared to 74.7% ( $p < 0.05$ ) before the campaign. Approximately 33.8% admitted that they shared their medicines with others, an improvement from 37.1% ( $p < 0.05$ ), and 19.6% took modern and traditional medicines together compared to previously 23.7%. Although doctors remained the preferred person for medicine information, there was significant improvement in pharmacists as referral person after the intervention (16.8% vs. 36.7%,  $p < 0.05$ ). Consumers' attendance at the talks and exhibitions were significantly associated with their ability to recognise generic names ( $p < 0.001$ ), understanding the requirement that traditional and modern medicines be registered ( $p < 0.001$ ), and knowledge of the use of Meditag in ascertaining the authenticity of the products ( $p < 0.001$ ).

Conclusions: Overall, 70% of the consumers have better understanding and knowledge on medicines use after implementation of the campaign. However, enhancements to the campaign are needed to increase awareness and knowledge of Malaysian consumers', focusing on aspects with low awareness, particularly medicine/food interactions. Involvement of pharmacists in educating the public on rational use of medicine plays a vital role in achieving this end.

Funding source: Pharmaceutical Services Division, Federal Territories of Kuala Lumpur and Putrajaya Health

604

#### Access

Keywords: Medicines, Consumers, Use, Pattern, Knowledge

### Survey on the Use of Medicines by Malaysian Consumers

**Salmah Bahri<sup>1</sup>, Nour Hanah Othman<sup>1</sup>, Mohamed Azmi Ahmad Hassali<sup>2</sup>, Asrul Akmal Shafie<sup>2</sup>, Mohamed Izham Mohamed Ibrahim<sup>2</sup>**

<sup>1</sup>Pharmaceutical Services Division, Ministry of Health Malaysia; <sup>2</sup>Discipline of Social & Administrative Pharmacy, School of Pharmaceutical Sciences, Universiti Sains Malaysia

Problem statement: There are serious problems related to the inappropriate use of medicines globally among consumers. Within this context, Malaysia is no exception. To date, there has not been a comprehensive nationwide study conducted to examine consumer knowledge and awareness on the rational use of medicines. Hence, this study is conducted to obtain current data so that health authorities are able to plan necessary strategies to enhance consumer understanding of the rational use of medicines in line with the Malaysian National Medicines Policy.

Objectives: To identify prescription and nonprescription medicine use patterns among consumers, look at the current knowledge of consumers on medicine usage, and identify the sources of information

Design: Descriptive, exploratory, cross-sectional survey was conducted November 2007–January 2008 in 14 states of Malaysia

Setting and population: Using one-stage, random cluster sampling, two clusters represented by two government health care facilities in each state (mostly rural and urban populations) were chosen by using population datasets from the Malaysia Department of Statistics. For each state, at least 200 consumers were included and a total of 3,014 consumers nationwide participated.

Interventions/policy change: Strategies for the quality use of medicines (QUM) which have been documented in the National Medicines Policy are institutionalised and implemented nationwide.

Outcome measures: Quantitative indicators of medicine use

Results: Approximately 32% of consumers surveyed are currently using medicines to treat their chronic diseases, followed by 43% of consumers using health supplements and 26% of them using traditional medicines. Although Malaysians do spend on health, their knowledge on medicine usage appears to be inadequate because 55.6% of consumers did not understand the proper use of their medicines. Additionally, the study has shown that 51% and 65.7% consumers are unable to recognise medicines' trade and generic names, respectively. Also, this survey revealed that 34% and 26% of consumers found it difficult to obtain medicine information from doctors and pharmacists from the private sector; 74% of consumers preferred written medicine information from health care providers and 73% of them agreed that counselling sessions are necessary to help them in taking their medication.

Conclusions: QUM strategies identified in the National Medicines Policies should be implemented to ensure that Malaysian consumers are well informed about the medicines they are taking. Also, involvement of health care providers in educating the general public on the principles of rational use of medicines is important to increase awareness on the safe and rational use of medicines.

Funding source: Pharmaceutical Services Division, Ministry of Health Malaysia

606

#### Child Health

Keywords: appropriate use, drug resistance, health facilities, prescribing, child care, treatment outcomes

### In-Service, Problem-Based, Pharmacotherapy Teaching and Clinical Pharmacology Services Contribute to Improved Medicine Use in Children

**Liliya Eugenevna Ziqanshina<sup>3</sup>, Elvira Grigorievna Alexandrova<sup>3</sup>, Rimma Gabdulbarovna Gamirova<sup>3</sup>, Ekaterina Victorovna Yudina<sup>3</sup>, Irina Vladimirovna Prokhorova<sup>2</sup>, Asiya Ildusovna Safina<sup>1</sup>, Olga Ivanovna Picusa<sup>2</sup>**

<sup>1</sup>Kazan State Medical Academy, Russian Federation; <sup>2</sup>Kazan State Medical University, Russian Federation; <sup>3</sup>Kazan Federal University, Russian Federation

Problem statement: Prescribing in child care remains problematic.

**Objectives:** To evaluate the impact of in-service pharmacotherapy training by clinical pharmacologists on medicine use and treatment outcomes. Reinforcement of clinical pharmacology services was intended to lead to better prescribing and treatment outcomes.

**Design:** Controlled intervention study of policy to strengthen clinical pharmacology

**Setting:** Provincial level, primary, secondary, and tertiary health facilities in the public sector

**Study population:** Medical records of 920 infants with confirmed iron-deficiency anemia (2003-2005); children with epilepsy—417 hospitalized and 1266 outpatients (2003-2007); and 750 children with urinary tract infections (2002-2008) were randomly selected and studied.

**Intervention:** Baseline medicine use patterns and outcomes determined in all health facilities. At selected health facilities, intervention was carried out by clinical pharmacologists. Training sessions consisted of 2-week problem-based learning courses and a series of patient rounds. Post-training medicine use was evaluated within a year to three years after completion of intervention. In matched health facilities with the same patient burden, medicine use was monitored at the same time intervals.

**Outcome measures:** Patterns of medicine use; primary treatment outcome for anemia –recurrence of anemia within a year; for epilepsy – remission lasting over 1 year; and for urinary infections – clinical-laboratory remission.

**Results:** In polyclinics with trained staff, infants with confirmed anemia were treated with ferrous (II) salts in the majority of cases, while in control settings, reinforced diet was used and ferrous (III) preparations were preferred prescriptions. The risk ratio (RR) of anemia recurrence with diet versus ferrous salts was 1.62 (95% CI) [1.23 to 2.14]. No advantages of heavily promoted ferrous (III) preparations versus ferrous (II) salts were shown. Intervention resulted in larger proportions of epileptic children treated with monotherapy, namely, with carbamazepine, valproates, and phenobarbital. There was no difference in efficacy between valproates and carbamazepine; topiramate was not more effective than carbamazepine or valproates. For valproates versus phenobarbital, valproates were less effective with RR 0.68 [0.42 to 1.09] P = 0.1. Adverse effects were more common with polytherapy versus any monotherapy, RR 2.12 [1.12 to 4.00]. In-service training by clinical pharmacologists contributed to better antibiotic use for urinary infections; in prospectively followed cohort treated in control facilities, decrease in aminopenicillin use and increase in cefalosporins-III use was associated with increase in E. coli resistance and proportion of Gram-positive pathogens.

**Conclusions:** In-service problem-based pharmacotherapy training delivered by clinical pharmacologists proved to be effective in improving prescribing and patient outcomes.

**Funding source:** No specific funding

## 607

### Policy, Regulation, and Governance

*Keywords:* drug selection, essential medicines, formulary, health reform, public sector

#### **Medicines Lists as Policy Instruments in Tatarstan and Russian Federation in the 21st Century**

**Liliya Eugenevna Ziganshina<sup>1,2</sup>, Veronica Nikolaevna Khaziakhmetova<sup>1,2</sup>, Elvira Grigorievna Alexandrova<sup>1,2</sup>, Tatiyana Rudolfovna Abakumova<sup>1,2</sup>**

<sup>1</sup>Kazan Federal University, Russian Federation; <sup>2</sup>Ministry of Health, Republic of Tatarstan

**Problem statement:** The pharmaceutical situation in Russia has changed dramatically since the early 1990s. The number of registered medicines has kept increasing with over 19,000 registered products by 2010. It is time to reevaluate strategic approaches to health. Government funds have been allocated and projects to provide supplementary medicines for selected patient categories and project "Health" have been initiated, with introduction of the corresponding medicines lists.

**Objectives:** To compare medicine lists in Tatarstan and Russia with the WHO Model List of Essential Medicines (EML) and identify problems in medicine selection. Because the latest Russian EML (REML) was developed with the sole purpose of regulating medicine prices, the comparative analysis was intended to assess if this policy could contribute to better access and use of medicines.

**Design:** Descriptive study

**Setting:** The study was conducted at the national and provincial level in the public sector.

**Outcome measure(s):** We analyzed increments in numbers on the lists as compared to WHO EML from 2000. We compared medicines lists effective in Tatarstan in 2009 with the 16th WHO EML, the 2009 REML, the 2008 Russian Supplementary Medicines List (RSML), the 2009 Tatarstan Supplementary Medicines List (TSML), and the 2009 Tatarstan Formulary List (TFL). We used Microsoft Access for list comparisons and developed a database of lists. We calculated portions (percentages) of coincidences and discrepancies. We performed quality analysis of discrepancies according to the WHO Essential Medicines Concept.

**Results:** The expansion rates over the last 10 years exceeded the WHO EML expansion rate (320 to 349); by 3 times (TFL, 578 to 695); by 8 times (REML, 421 to 658); and by 10 times (RSML, 367 to 493). TSML had the highest percentage of WHO essential medicines (45%) and the TFL had the broadest EML coverage (67%). The RSML had the lowest indices for both WHO essential medicines inclusion (26%) and the EML coverage (27%). Comparison of listed medicine numbers revealed discrepancies. The discrepancies were uniform through the lists with RSML being the most problematic and reflected vulnerability to pharmaceutical promotion.

**Conclusions:** Development of national pharmaceutical policy was urgently needed with adoption of WHO Essential Medicines Concept as the core component of health reform.

Post script: These results were presented at the conference Quality Information for Quality Use of Medicines in October 2010 and published in the conference proceedings, which were forwarded to the ministers of health and social development, of science and education, and to the head of the federal vigilance body with the conference resolution. The outcome was that the federal meeting on development of Russian pharmaceutical policy was scheduled for December 10, 2010.

Funding source: No specific funding

608

#### Child Health

*Keywords:* access to medicines, availability, affordability, essential medicines, pediatric medicines

### Availability, Price, and Affordability of Key Essential Medicines for Children in a Resource-Limited Country

**Ramasamy Balasubramaniam<sup>1</sup>, BVSH Beneragama<sup>2</sup>, Shalini Sri Ranganathan<sup>1</sup>**

<sup>1</sup>Department of Pharmacology, Faculty of Medicine, University of Colombo, Sri Lanka; <sup>2</sup>2. Division of Medical Supplies and Technology, Ministry of Healthcare and Nutrition, Sri Lanka

**Problem statement:** WHO recommends that the first step in promoting access to essential medicines for children is to assess the current situation of their availability, prices, and affordability. This study reports such an assessment from a resource-limited country, which, to our knowledge, is the first reported survey, though similar surveys are ongoing in a few other countries.

**Objective:** To investigate the availability, price, and affordability of key essential medicines for children in Sri Lanka; we intend to use the survey results to plan strategies to ensure "better medicines for children" in Sri Lanka.

**Design:** The WHO and Health Action International Medicine Price methodology has been used for the first time for a country survey to evaluate whether the purpose of the essential medicines list has been achieved in Sri Lanka with regard to children.

**Study setting, population, and sample:** A representative sample of 40 public hospitals (OPD pharmacies) and 40 private and 8 State Pharmaceutical Corporation (Osusala) pharmacies were selected from the entire country by using a multistage, clustered approach (one province was excluded because of civil war).

**Intervention:** Survey medicines comprised 25 key essential medicines for children; availability data from the public sector; availability and price data from the private sector

**Outcome measures:** Mean percent availability of survey medicines in each outlet, percentage of outlets that had the survey medicines, median price ratio, and number of days the lowest paid unskilled government worker must work to buy standard drug therapy for common illnesses.

**Results:** Mean percent availability was 52% (SD = 14) in public hospitals, and 80% (SD = 11) in private pharmacies and 88% (SD = 9.5) in Osusala pharmacies. The wide gap in availability between the public and private sectors was observed mainly for liquid dosage forms of anti-infectives and inhaled dosage forms of anti-asthmatics. Amoxicillin suspension was available in 45% of public hospitals compared to 100% of private and Osusala pharmacies. Availability of beclomethasone and salbutamol inhalers was 50% and 37.5%, respectively, in public hospitals; 87.5% and 95%, respectively in private pharmacies; and 87.5% and 100%, respectively, in Osusala pharmacies. In the private sector, parents have to pay 0.05-3.75 times the international reference prices for lowest-priced generics and 0.23-20 times for originators. Mean percent difference in price between originator and lowest-priced generic products was 365% (range -21, 2343). Treatments for common diseases were unaffordable, especially for chronic diseases requiring liquid or inhaled dosage forms.

**Conclusions:** The purpose of the essential medicines list has not been achieved in Sri Lanka with regard to key essential medicines for children. In the public sector, the availability was poor, whereas in the private sector, the prices vary and are largely unaffordable. The wide gap between the prices of originator and lowest-priced generics calls for intervention.

Funding source: WHO/Sri Lanka, SEARO

611

#### Policy, Regulation, and Governance

*Keywords:* pharmaceutical policy, regulation, supply management, essential drug program, prescribing.

### Health Systems Approach to Improving the Use of Medicines in the S.E. Asian Region (SEAR)

**Kathleen Anne Holloway<sup>1</sup>, Krisantha Weerasuriya<sup>2</sup>, Chinta Abayawardana<sup>3</sup>, Selina Ahmed<sup>4</sup>, J.M.Faridur Rahman<sup>4</sup>**

<sup>1</sup>World Health Organization, S.E.Asia Regional Office, New Delhi, India; <sup>2</sup>World Health Organization, HQ, Geneva;

<sup>3</sup>World Health Organization, Country Office, Sri Lanka; <sup>4</sup>World Health Organization, Country Office, Bangladesh

**Problem statement:** WHO recommends national programs to improve medicines use, deciding actions based on a situational analysis, but few low- and middle-income countries are doing this.

**Objectives:** To develop (1) a regional strategy and (2) country plans of action based on a national situational analysis

**Design:** A regional meeting to improve medicines use was held in July 2010. Thereafter a situation analysis was done in Sri Lanka and Bangladesh. The process was guided by a checklist and included a workshop/debriefing meeting to develop a national roadmap for action.

**Setting:** Pharmaceutical sector in SEAR countries

**Study population:** Public and private facilities, MOH departments, academia, and other stakeholders

**Intervention(s):** The situation analysis involved visits to the MOH (medicine supply, distribution, and regulation), public and private facilities, medical/pharmacy association and council, academia (clinical pharmacology, pharmacy, medicine), and discussion of the results with stakeholders.

**Outcome measure(s):** (1) Major determinants and factors in the pharmaceutical sector affecting medicines use and (2) recommendations for action

**Results:** In July 2010, 9 countries attended a regional meeting where it was recommended that (1) a health systems integrated approach was needed and that this approach required doing systematic situational analyses and (2) all MOHs have a unit dedicated to improving medicines use, guided by a multidisciplinary body. We then made visits, at the invitation of MOH, to Sri Lanka and Bangladesh to conduct a rapid situational analysis. Both countries have a good health service delivery infrastructure and a recently updated National Medicines Policy, although many components are not yet implemented. Weaknesses in both countries included (1) insufficient availability of essential medicines in the public sector, (2) lack of an electronic medicine inventory system to monitor consumption, (3) lack of updated national treatment guidelines, and (4) inadequate regulatory systems with severe human resources deficiencies. Regulatory problems included (1) too many brands on the market (8,000–23,000), (2) lack of pharmacists in shops to supervise dispensing, (3) lack of an updated over-the-counter (OTC) list with the availability of many prescription-only medicines OTC, and (4) inadequate monitoring of medicine promotional activities. Stakeholders in both countries appreciated the situational analysis findings and how it facilitated planning. Recommendations included (1) setting up a dedicated MOH unit to monitor medicines use, (2) initiating an electronic medicine inventory system, and (3) strengthening the medicine regulatory authority. Recommendations will be used for MOH and WHO planning for the pharmaceutical sector.

**Conclusions:** A country situational analysis is extremely useful in understanding the pharmaceutical situation and, in the absence of routine monitoring, is necessary to identify a roadmap for action for both public and private sectors. Resource mobilization for this roadmap is urgently needed.

**Funding source(s):** WHO

**612**

### **Child Health**

*Keywords:* access to medicines, essential medicines, pediatric medicines, drug selection

## **Facilitating the Preparation of Essential Medicines List for Children in India: Lessons Learned**

**Gitanjali Batmanabane, Kathleen Anne Holloway**

World Health Organization - South East Asia Regional Office, India

**Problem statement:** The Better Medicines for Children in India project was initiated by WHO to improve access to essential children's medicines in India. Comparison of the National Essential Medicines List of India and the Essential Medicines List (EML) of the two empowered action-group states of Orissa and Chhattisgarh with the WHO Model Essential Medicines list for children (EMLc) showed that the majority of children's medicines were not on the lists.

**Objectives:** The objective was to facilitate the preparation of an EMLc for children in India, at the national level and in the two states of Orissa and Chhattisgarh.

**Design:** The study describes the process of facilitating the preparation of an EML at national and state levels and the issues related to them.

**Setting:** The Indian Academy of Paediatrics (IAP; 18,000 members) agreed to prepare the national list by involving its various chapters, each of which focuses on one area of pediatric medicine. In Chhattisgarh, the director of the State Health Resource Centre coordinated the whole process with the help of a subcommittee for essential medicines where all stakeholders were represented. In Orissa, the medical officer for the State Drug Medicinal Unit (SDMU) coordinated the preparation of the EMLc. He sent letters to the pharmacology departments of all medical colleges in the state and asked them to submit an EMLc.

**Study population:** The stakeholders who prepared the list.

**Policy(ies):** The WHO Model EMLc was taken as the baseline document for the preparation of all 3 lists.

**Intervention(s):** An EMLc or an EML with the inclusion of appropriate children's formulations was the expected outcome. The process of selection of medicines for inclusion/deletion was also observed.

**Results:** The IAP prepared an EMLc that underwent major revisions 3 times because it contained too many expensive medicines which could not be termed as essential. This occurred because only specialists were involved in the selection of the medicines, and clinicians from the peripheral areas were not included in the deliberations. The final draft list was prepared by an independent clinical pharmacologist based on the suggestions of international and national experts, with major input from IAP. The final draft list with 113 medicines is yet to be ratified by the IAP; from inception to final draft version took 1 year. Chhattisgarh state incorporated paediatric medicines into its EML, stating that they wanted a single list that could then be used for procurement; this list was prepared in 7 months. Orissa prepared an EMLc with 117 medicines which took 11 months to complete. Chhattisgarh did not take as long because of the participation and engagement of all stakeholders from the very beginning. In Orissa, the SDMU delegated responsibility to the medical colleges where no one was ready to take the responsibility.

Conclusions: The preparation of an EMLc is possible only if all interested stakeholders are involved, and it is driven by a single person or a group of persons who have a thorough, basic understanding of the principles of selection of essential medicines.

Funding source(s): WHO through the Bill & Melinda Gates Foundation

615

#### Child Health

*Keywords:* access to medicines, availability, pediatric medicines, medicine prices

### **Better Medicines for Children in India: A Project to Improve Access to Essential Medicines**

**Gitanjali Batmanabane, Kathleen Anne Holloway**

World Health Organization - South East Asia Regional Office, India

**Problem statement:** A comparison of the National Essential Medicines List of India and the essential medicines lists (EML) of five empowered action-group states in India showed that children's medicine formulations were found lacking in all 6 lists. The high cost of children's formulations and unavailability in the public sector necessitates the use adult formulations in children.

**Objectives:** To improve the availability of children's medicines, it was decided to prepare and implement an EML for children (EMLc) in Orissa and Chhattisgarh and to compare the availability and prices of a limited list of essential children's medicines before and after the implementation of such a list.

**Design:** In each state, 2 committees were formed, 1 for the preparation of the EMLc and the other for conducting the pricing and availability survey. In Chhattisgarh, both activities were under the direction of 1 coordinator whereas in Orissa there were 2 (one for each activity). The pricing and availability surveys were done according to the WHO-Health Action International protocol for pricing and availability surveys.

**Setting:** The study was conducted in the states of Chhattisgarh and Orissa and was based in the community. Primary, secondary, and tertiary care facilities belonging to the public sector, pharmacies and dispensaries in the private sector, and nongovernmental organizations were included. The study examined both the public and private sectors.

**Study population:** The surveys were conducted in 6 geographical regions of both states with a minimum of 28 facilities per region from where data was collected. Public health facilities such as primary health centres, community health centres, and district hospitals as well as private facilities such as chemist shops were included.

**Policy(ies):** Procurement will be based on the EMLc prepared by the state.

**Outcome measure(s):** Intervention(s): The changes in the availability and prices of the list of essential medicines will be documented before and after implementation of the EMLc prepared by each state, after allowing sufficient time for procurement to be initiated.

**Results:** The baseline surveys in Chhattisgarh and Orissa show that availability of essential children's medicines is very poor in the public sector, where medicines are given totally free of cost to patients, with only 17% availability in both states. In the for-profit private sector, availability was 46% in Chhattisgarh and 38.5% in Orissa. Simple antibiotics like Co-trimoxazole are not available whereas more expensive antibiotics, like the amoxicillin-clavulanic acid combination, are widely available. In Orissa, very poor availability of essential medicines in the public sector, such as zinc for acute diarrhoea (2.4%), contrasted with the good availability of ofloxacin (84.1%). In Chhattisgarh, 29% of public facilities had zinc, though it was unavailable in the private sector. There were no paediatric antiepileptic formulations available in the public sector in both states. Even though the EMLs have been prepared in both states, procurement based on the list is yet to begin. Hence the second part of the study, a post-procurement survey, could not be done.

**Conclusions:** Conducting a pricing and availability survey as the first step toward the implementation of an EMLc highlights the lack of access to essential medicines.

Funding source(s): WHO through the Bill & Melinda Gates Foundation

617

#### Policy, Regulation, and Governance

*Keywords:* tendering, procurement, Europe, pharmaceutical policy, purchasing

### **Role of Tendering of Medicines in European Countries**

**Sabine Vogler, Claudia Hahl, Christine Leopold, Nina Zimmermann**

Gesundheit Österreich GmbH (GÖG), Austria

**Problem statement:** In many countries the world over, tendering is a major policy for procuring medicines for the public sector. For Europe, there were indications that tendering seems to be a key policy for the hospital sector. In fact, the actual use of this policy was not well known for the hospital sector nor for the outpatient sector.

**Objectives:** To assess the importance of tendering as a national procurement policy in European countries

**Design:** Cross-country descriptive study; outpatient sector, questionnaire survey; inpatient sector, pharmaceutical health information system hospital pharma reports based on defined indicators

**Setting and population:** Outpatient survey: 30 countries of the European Union and European Economic Area; response rate, 19 countries; inpatient survey, all EU member states (response rate: 25 countries) plus Norway and Turkey

**Intervention:** The investigation on tendering in the outpatient sector was performed in the first half of 2008. The inpatient sector survey was undertaken from summer 2009 to spring 2010. Respondents were country representatives of public medicines authorities, supported by hospital experts.

**Outcome measures:** Use of tendering as procurement policy, regulation on tendering, organisational aspects (individual/joint tendering)

**Results:** In the outpatient sector, a rather small number of countries (Belgium, Cyprus, Estonia, Ireland, Malta, Romania, Iceland) use tendering for procuring medicines. The use of this purchasing policy in the outpatient sector is usually connected to specific products (e.g., medicines defined in national pandemic plans) or defined patient groups (e.g., military, pensioners). In the hospital sector, tendering is a major policy, however, it is usually not the sole procurement policy. Negotiations usually undertaken by hospitals are a common complementary policy. Only in 8 of the 27 countries is tendering the sole procurement policy. Tendering is either performed at a national level by a national procurement agency or at institutional or regional level by hospitals or hospital groups.

**Conclusions:** The approach for procuring medicines in Europe differs from the rest of the world. Tendering has its relevance for the hospital sector. For medicines used in the outpatient sector, however, tendering is predominantly only applied if stipulated by law and/or for procuring medicines of strategic relevance (from a public health view or with strong budgetary impact).

**Funding source:** Austrian Federal Ministry of Health; European Commission, Executive Agency for Health and Consumers (EAHC); European Social Insurance Platform (ESIP)

**621**

### **Drug Resistance**

*Keywords:* access to medicine, medicine prices, public sector, antimicrobials, affordability

### **Assessment of Generic Antimicrobial Unit Retail Price Mark-Ups Applied in Public Hospitals in Rwanda**

**Patrick Gaparavi<sup>1</sup>, Joseph Kabatende<sup>2</sup>, Felix Hitayezu<sup>1</sup>, Gege Buki<sup>1</sup>, John Patrick Mwesigye<sup>2</sup>**

<sup>1</sup>MSH/SPS, Rwanda; <sup>2</sup>Ministry Of Health, Rwanda

**Problem statement:** Evidence-based medicine pricing policies for both branded and generic medicines can prevent high-price disparities among suppliers while increasing medicine accessibility. To date, little is known about how public hospital pharmacies conform to the 2007 Rwanda ministerial circular letter that fixes the maximum mark-up for medicines in the public sector.

**Objectives:** To assess the level of compliance to the ministerial circular letter on the maximum allowable medicine price mark-ups in public hospitals that use a set of antimicrobials

**Design:** A price survey was conducted to review the current generic antimicrobial price mark-up applied on health insurance and public hospital tariffs. We collected updated retail price lists of the 10 most used generic antimicrobials from 10 public hospital pharmacies and 4 health insurance institutions working with public hospitals. The theoretical retail prices for comparison were calculated by applying the maximum allowable mark-up of 20% on the average selling prices from 5 wholesale depots selected randomly.

**Setting:** We assessed prices in 10 public hospitals composing our convenience sample. The wholesale prices used came from the public medicine procurement agency (CAMERWA) and from 4 private wholesale depots.

**Study population:** Not applicable

**Outcome measures:** Average of wholesale and retail unit prices with allowable mark-up percentages applied

**Results:** By considering only the CAMERWA price list, mark-ups on medicine retail unit prices are significantly higher than our theoretical retail unit price. On average, a mark-up of 112% above the maximum allowable mark-up was found, with slight variations across studied products (SD = 1.5, Max = 1,118%, Min = -66.1%). By using the average selling prices from both private and public wholesale depots, we observed an average increase of 109% (SD = 1.6, Max = 1,128.1%, Min = -66.1%) above the maximum allowable mark-ups. Only one product (metronidazole inj.) was, on average sold at a lower price than the theoretical value (33.1% below the allowable mark-up), whereas the highest mark-ups were applied to gentamycine inj. (average of 214.7% above the allowable value).

**Conclusions:** Deviations to the allowable mark-ups applied to generic medicine prices exist in public hospital in Rwanda, which can negatively affect patients' ability to afford treatment. Potential savings and increase of medicine accessibility can be maximized by reinforcing the current medicine pricing instructions and promoting transparency and fair competition between suppliers.

**Funding sources:** US Agency for International Development Strengthening Pharmaceutical Systems Program through Management Sciences for Health

**622**

### **Policy, Regulation, and Governance**

*Keywords:* access to medicines, industry, pharmaceutical policy, registration, regulatory authorities

### **Impact of Regulatory Requirements on Medicine Access in African Countries: Perceptions and Experiences of Pharma Companies in South Africa**

**Kirti Narsai**

## PIASA, South Africa

**Problem statement:** The impact of varied medicine registration policies in African countries poses a challenge for market access in these countries, although little is known about this from a pharma company viewpoint. The recent African Medicines Registration Harmonisation Initiative has increased the focus on the need for harmonisation of regulatory requirements to improve resource utilisation and operational efficiency. The South African pharma industry is well established with a broad representation of local, multinational, and generic companies. Many of these companies have started supplying medicines to African countries, therefore increasing the focus on regulatory requirements in these countries.

**Objective:** To determine the nature and extent of regulatory hurdles experienced by pharma companies that wish to register and supply medicines to African countries by looking at the nature of regulatory requirements, implementation, and impact on access to medicines

**Design:** Study was descriptive, qualitative, and conducted using an online survey tool, viz. SurveyMonkey.

**Setting:** Pharma companies (local, multinational, innovator, and generic) based in South Africa with responsibilities for African markets, supplying both public and private sectors

**Study population:** Employees of PIASA member companies with medicine registration or commercial responsibilities in African countries

**Intervention:** Survey was formulated using SurveyMonkey and distributed to relevant employees of PIASA member companies via email. Questions focused on general regulatory requirements and regional and country-specific requirements across SADC, EAC, ECOWAS, and ECCAS. Open-ended questions were included to allow respondents to express their views freely.

**Outcome measure:** Impact of medicine registration policies across African countries on pharma companies in registering and marketing medicines

**Results:** 33 responses were received, including 26 regulatory respondents; 1 response per company was allowed. In particular, GMP inspections, GMP inspection fees, and country-specific labeling requirements were cited as key problems; 89.5% of respondents indicated that country-specific requirements are problematic to implement. Of the respondents, 57-86% stated GMP inspection requirements are a barrier to medicine registration; 46-70% believe GMP inspection fees are too high; and 50-62.5% stated that international standards were sometimes recognised.

**Conclusion:** Country-specific regulatory requirements are problematic and impede market access of medicines. Recognition of international standards is important in countries with resource constraints and contribute to companies' ability to comply. Harmonisation should be preceded by interim agreements between regulators in Africa to facilitate medicine registration and access.

**Funding sources:** PIASA

## 624

**Economics, Financing, and Insurance Systems**

*Keywords:* Access to medicines,

**Relationship Between Tariffs, Prices, and Consumption of Interferon****Amanullah Saif**

Ministry of Health, Government of Pakistan, Pakistan

**Problem statement:** Patients suffering from hepatitis-C confronted with high cost of medications and lack of supplies in government health care facilities.

**Objectives:** Increase usage of interferon to treat patients suffering from hepatitis-C.

**Setting and population:** Study was conducted at the national level. Usage of interferon in the private sector was measured from sales data compiled by Information Medical Statistics (IMS) over a period of 6 years (July 2004–June 2005 and July 2009–June 2010). In the public sector, the procurement data and prices were obtained from programs for hepatitis control and prevention at federal and 3 provincial government levels.

**Intervention(s)/policy(ies):** (1) Reduction in tariffs (custom duty) on import of interferon from 10% to 0 in July 2006 to increase usage of interferon; (2) regulatory intervention in July 2007 to reduce prices of originator brand from Rs. 1,074.16 to Rs. 980.00 (10%) and of the top selling brand from Rs. 979.00 to Rs. 879.00 (11%). Other factors—increased budgetary allocations in the public sector and growing awareness among patients for treatment of disease.

**Outcome measures(s):** (1) Number of units sold in the private market; (2) number of units purchased by the public sector; (3) total number of units consumed in the country

**Results:** (1) Despite 10% reduction in the tariffs, the private sector did not reduce prices of interferon until regulatory intervention. (2) In private sector, sales increased by 40% in 2007-08 (1,515,175 vials) compared to 2006-07 (1,029,251 vials) after a decrease in prices. (3) Increase in sales and decrease in prices in the private sector helped decrease prices for public sector procurement by 28% in Pak Rupee and 89% in USD (Pak Rupee devalued by 40%) over a period of 3 years (2009-10 vs. 2006-07) despite the fact that 100% requirement met was met through imports during these years. Reduction in price further led to increased procurement in public sector (337,816 vials in 2006-07 vs. 3,766,120 vials in 2009-10). (4) Total consumption of interferon in the country increased by 280% from 1,367,067 vials in 2006-07 to 5,195,196 vials in 2009-10. Increased availability (by 1000% in 2009-10 from 2006-07) in the public sector reduced out of pocket purchase by the patients by 6% (1,429,076 vials in 2009-10 as compared to 1,515,175 vials in 2007-08).

Conclusions: Usage of expensive medications can be increased by reducing tariffs and regulatory intervention of reduction in prices. Decrease in prices helps increase usage of the medicines in the private sector. Decrease in prices and increased volumes in the private sector further helps decrease prices in public sector procurement.

Funding source(s): No funding for the study. Author conducted the study to evaluate the impact of policy and regulatory interventions on usage of interferon.

627

#### Access

Keywords: prescribing, medication error, patient safety, pharmacist, pharmacy practice

### **Analysis of Clinical Pharmacists' Interventions on Discharged Patients' Prescription in a Tertiary Care Teaching Hospital in Oman**

**Nasra Khalfan Al-Sharji<sup>1</sup>, Maryam Zahran Al-Kindi<sup>2</sup>, Badriya Ali Al-Zadjali<sup>2</sup>**

<sup>1</sup>Dubai Pharmacy College, Dubai, UAE; <sup>2</sup>Sultan Qaboos University hospital, Muscat, Sultanate of Oman

Problem statement: Clinical pharmacists in Sultan Qaboos University Hospital (SQUH) have developed a form to document their interventions and measure the clinical significance of their service. In addition, discharge patients' prescriptions are reviewed by the clinical pharmacists before dispensing to the patients to make sure medications are appropriate.

Objectives: (1) To analyze clinical pharmacists' interventions on discharged patients' prescriptions and determine classification, type, and clinical relevance; (2) to find out the reasons for delay in reviewing the prescriptions if the review took more than 10 minutes

Methods: This was a three-week study (April 2010) conducted at SQUH, a 500-bed tertiary care teaching hospital in Muscat, Oman. Clinical pharmacists used a standard manual intervention documentation form. The form classified the interventions into five groups, namely; medicine choice, medicine regimen, monitoring, information, and prescribing issues. A peer review consisted of four clinical pharmacists who analyzed the clinical and cost significance and graded the clinical significance of each intervention.

Results: A total of 462 prescriptions were reviewed. Seventy-two prescriptions (15.5%) had interventions. The total number of interventions was 118 (mean = 1.6 interventions/prescription). The age of the patients ranged between 2 weeks and 85 years with mean age of 26 years. Most of the interventions were performed on prescriptions from general pediatrics (47%). The top medicine class with the highest number of interventions was antimicrobials (16%). Dose change (n = 37; 31%), addition of a medicine (n = 20; 17%), and frequency change (n = 15; 13%) were the most frequent interventions performed. Efficacy was improved and toxicity risk was reduced in 44% and 30% of the interventions, respectively. Death, major permanent injury, or organ damage was avoided in 0.8% of the cases whereas interventions of major significance were recorded in 30% of the interventions. On average, each prescription took 50 minutes to resolve the interventions, ranging from 3 minutes to 2 hours. Forty-seven prescriptions (65%) took more than 10 minutes from the start of the review to the time it was delivered to the outpatient pharmacist. The most common reason for delay was that the prescriber did not respond straight away to the pager (n = 28; 59%).

Conclusion: The above data show that there is a major problem with prescribing for discharged patients, especially in general pediatrics, and most of the interventions were for medicine doses. On some occasions, review of the prescriptions by the clinical pharmacist took more than 10 minutes because the prescribing physician did not immediately respond, which could be related to the communication system in the hospital. The clinical pharmacists play a significant role in medicine safety and efficacy and as part of health care team; they are reliable source of information on medicine-related issues.

Funding source: Self-funded

632

#### Policy, Regulation, and Governance

Keywords: education, medication errors, patient safety

### **Caution! Look Alike, Sound Alike Medication**

**Badriya Ali Al-Zadjali, Samiya Al-Ajmi, Khalid Al-Siyabi, Shahida Rauf, Khalid Al-Zadjali**

Sultan Qaboos University Hospital, Muscat, Oman

Problem statement: Look alike, sound alike (LASA) medications are medications with generic or proprietary names that look alike (appearance and name) or sound like (pronunciation) other medication names leading to avoidable mix-ups. It also includes medications that have similar packaging, but are different. With tens of thousands of medicines currently on the market, the potential for error due to LASA is significant. Every year, Food and Drug Administration reviews approximately 400 brand names for drugs before they are marketed. Approximately 33% of these drug names are rejected. Sometimes names are changed after marketing. Sultan Qaboos University Hospital (SQUH) is a 500-bed tertiary care teaching hospital in Muscat, Sultanate of Oman. There are more than 1000 medications included in the hospital formulary. Medications are purchased from different companies from all over the world.

Objectives: To share the experience of SQUH in dealing with medication errors due to LASA medication names/packages

Methods: The hospital formulary was reviewed by four pharmacists and LASA medication names were identified. In addition, all similar medication packages were identified and separated from the others.

Results: There were a total of 38 pairs of confusing names and 99 medications with similar packaging identified in the hospital formulary. Examples of LASA medication names include Budesonide/Buserelin, Tamoxifen/Tenoxicam, and Azithromycin/Azathioprin. A “red alert” sticker was developed to be placed on LASA medications and shelves, and similar medication packages were placed on different shelves.

Conclusion: The existence of LASA medications is one of the most common causes of medication errors and is of concern worldwide. SQUH has implemented some strategies, including use of tall man lettering, double checking medications before dispensing, routine audits of medications storage areas, etc. Educational posters for pharmacy staff and other health care providers were developed and placed in pharmacies and all wards and units to improve staff awareness.

Funding source: Self-funded

**633**

#### Child Health

*Keywords:* Clinical guidelines, health facilities, health workers, quality assurance, supervision

### **The Rise and Fall of Supervision in a Project Designed to Strengthen Supervision on the Integrated Management of Childhood Illness (IMCI) Strategy in Benin**

**Alexander Rowe<sup>1</sup>, Faustin Onikpo<sup>2</sup>, Marcel Lama<sup>3</sup>, Michael Deming<sup>1</sup>**

<sup>1</sup>U.S. Centers for Disease Control and Prevention, United States of America; <sup>2</sup>Direction Départementale de la Santé Publique de l'Ouémé et Plateau, Benin Ministry of Health; <sup>3</sup>Africare-Benin, Porto Novo, Benin

Problem statement: In developing countries, supervision is a widely recognized strategy for improving health worker performance; and anecdotally, maintaining regular, high-quality supervision is difficult. However, there has been little in-depth research to explore why supervision is so challenging.

Objective: During a trial to improve health worker adherence to IMCI guidelines and strengthen supervision, we studied the supervision process and identified contextual factors associated with strengths and weaknesses.

Design: Case study from 2001–2004 with prospective data collection via record reviews, focus group discussions, key informant interviews, and cross-sectional surveys

Setting: 130 outpatient health facilities in southeastern Benin

Study population: District supervisors and their superiors

Interventions: First, a 1-week workshop with supervisors to design (1) a supportive supervision protocol that recommended 2 supervision contacts with health workers every 3 months, (2) a supervision checklist, and (3) supervision of supervisors by a senior pediatrician to improve technical and interpersonal skills. Second, short workshops (1–3 days) held quarterly for planning and problem-solving.

Outcome measures: Percentage of planned supervision visits of IMCI-trained workers that actually occurred

Results: Initially, little supervision occurred. The frequency increased substantially after implementing the quarterly workshops, but then deteriorated. Quantitative and qualitative data revealed obstacles to supervision at multiple levels of the health system. Based on supervisors' opinions, the main problems were poor coordination; inadequate management skills and ineffective management teams; a lack of motivation; problems related to decentralization; occasional resistance by health workers to IMCI implementation; and less priority given to IMCI supervision because of incentives for nonsupervision activities, a lack of leadership, and an expectation of integrated supervision. To this list, based on our observations, we add the increasing supervision workload, time required for nonsupervision activities, project interventions not always implemented as planned, and the loss of particularly effective supervisors. In terms of correctly completing steps of the supervision process, the quality of supervision was generally good.

Conclusions: Managers should monitor supervision, understand the evolving influences on supervision, and use their resources and authority to both promote and remove impediments to supervision. Support from leaders can be crucial; donors and politicians should thus help make supervision a true priority. As with front-line clinicians, supervisors are health workers who need support. We emphasize the importance of research to identify effective and affordable strategies for improving supervision frequency and quality. This study was published in *Health Policy and Planning* (2010; 25:125–134).

Funding source: USAID

**634**

#### Malaria

*Keywords:* Access to medicines, antimalarials, malaria

### **Access to Antimalarial Medicines: The Impact Malaria Approach**

**François Bompert, Martin Bernhardt**

Sanofi-aventis, France

Problem statement: Effective malaria control programs require broad partnerships.

Design: The Sanofi Impact Malaria program is one of the initiatives of the Access to Medicines department. As such, it is based around 4 strategic levers: (1) a tiered-pricing policy that includes “no profit-no loss” prices for antimalarial drugs for the poorest patients; (2) a broad set of information and educational tools to promote comprehensive management of diseases; (3) partnerships to maximize impact; and (4) R&D programs to answer future medical needs.

Results: One of the key achievements of this program is the development, in partnership with the Drugs for Neglected Diseases initiative (DNDi), of a new, non-patented, antimalarial medicine—the fixed-dose combination of artesunate-amodiaquine (Coarsucam® or Artesunate-Amodiaquine Winthrop® [ASAQ Winthrop]). This medicine is specifically adapted to the needs of African patients, in particular children, who are the first victims of malaria. ASAQ Winthrop dosing is very simple (1 or 2 tablets, once a day, for 3 days) and tablets are dissolved in water. It was prequalified by WHO in 2008 and is registered in 30 countries in Africa and India. Among the Impact Malaria initiatives, two deserve a particular mention—(1) a complete offer of information materials and tools for the prevention and management of malaria, adapted to all the links in the healthcare chain, including scientific specialists, doctors, nurses, and community health agents, up to families and school children. By mobilizing the expertise of Sanofi and that of numerous partners, we help fight malaria on all fronts, according to our conviction that “drugs alone are not enough”; (2) an innovative field surveillance program of ASAQ Winthrop which contains several studies in diverse African countries, conceived in close collaboration with the National Malaria Control Programs of the concerned countries. With more than 20,000 episodes of malaria treated by ASAQ Winthrop, it is the most ambitious proactive program of pharmacovigilance ever launched in Africa for any type of medicine. Through this initiative, Sanofi contributes to building capacity in Africa in the field of pharmacovigilance, adapted to the needs and to resources of countries. This initiative is financially supported by DNDi and by Medicines for Malaria Venture (MMV). Since its launch in 2007, over 80 million ASAQ Winthrop treatments have been distributed in sub-Saharan Africa.

Conclusion: This success shows that this drug adequately meets the needs of patients and health care providers. It can also be attributed to the numerous partnerships developed by Impact Malaria and by its approach that promotes a comprehensive fight against malaria, beyond the provision of drugs.

Funding source: Sanofi, DNDi, MMV

635

#### Child Health

Keywords: Clinical guidelines, health facilities, health workers, quality assurance

### Multifaceted Intervention to Improve Health Worker Adherence to Integrated Management of Childhood Illness Guidelines in Benin

**Alexander Rowe<sup>1</sup>, Faustin Onikpo<sup>2</sup>, Marcel Lama<sup>3</sup>, Dawn Osterholt<sup>1,4</sup>, Samantha Rowe<sup>1</sup>, Michael Deming<sup>1</sup>**

<sup>1</sup>U.S. Centers for Disease Control and Prevention, United States of America; <sup>2</sup>Direction Départementale de la Santé Publique de l'Ouémé et Plateau, Benin Ministry of Health; <sup>3</sup>Africare-Benin, Porto Novo, Benin; <sup>4</sup>Division of General and Community Pediatric Research, Cincinnati Children's Hospital, USA

Problem statement: The World Health Organization's Integrated Management of Childhood Illness (IMCI) strategy aims to improve child health in developing countries by encouraging use of evidence-based guidelines for managing the leading causes of child mortality. Although studies have showed that training health workers on IMCI guidelines can improve the quality of care at health facilities, these studies also revealed substantial room for improvement in adherence to the guidelines.

Objective: Evaluate an intervention to support health workers after IMCI training

Design: Randomized trial; in 1999, we assessed health care quality before IMCI training with a health facility survey that involved observing consultations, re-examining patients, and interviewing caretakers and health workers. Follow-up surveys were conducted in 2001, 2002, and 2004.

Setting: 130 public and licensed private outpatient health facilities in 16 districts in southeastern Benin

Study population: Ill children <5 years old seen at health facilities and the health workers who performed the consultations

Intervention: Health workers received standard 11-day IMCI training plus either usual supports (control group) or a package of study supports that included job aids (IMCI patient register and a counseling guide), nonfinancial incentives (framed certificate of merit distributed at a ceremony), and supervision of workers and supervisors.

Outcome measures: Children with a potentially life-threatening illness (PLTI; e.g., malaria or pneumonia) who received recommended treatment; children with a PLTI who received recommended or adequate treatment; and for all children, an index of overall guideline adherence (percentage of all IMCI-recommended tasks that were performed)

Results: We analyzed 1,244 consultations performed by 267 health workers; 1,101 children had a PLTI. Performance improved in both intervention and control groups with no significant differences between groups. However, training proceeded slowly, and low-quality care from health workers without IMCI training diluted intervention effects. Per-protocol analyses revealed that workers with IMCI training plus study supports provided better care than did those with training plus usual supports for all 3 outcomes, ranging from an improvement of 15–27 percentage points. Additionally, IMCI-trained health workers outperformed non-IMCI-trained workers for all 3 outcomes by 19–50 percentage points. All results but one were statistically significant ( $p < 0.05$ ). Compared with usual supports, study supports cost USD 0.58 per additional child with a PLTI receiving recommended treatment (95% confidence interval: USD 0.36–1.46).

Conclusions: IMCI training was useful but insufficient. Relatively inexpensive supports can lead to additional improvements. This study was published in the American Journal of Public Health (2009; 99:837–846).

Funding source: United States Agency for International Development

637

**Chronic Care***Keywords:* chronic disease, management, Egypt**Trends of Current Treatment and Outcomes of the Management of Type 2 Diabetic (T2DM) Patients in Egypt: Results from the International Diabetes Management Practices Study (IDMPS)****Samir Helmy Assaad-Khalil<sup>1</sup>, Adel Zaki<sup>2</sup>, Magdy Helmy Megallaa<sup>1</sup>**<sup>1</sup>Unit of Diabetes & Metabolism, Department of Internal Medicine, Faculty of Medicine, Alexandria University, Alexandria, EGYPT; <sup>2</sup>Department of Bioinformatics and Medical Statistics Medical Research Institute, Alexandria University, Alexandria, EGYPT

**Problem statement:** Numerous epidemiological studies have been conducted in western countries to assess the quality of medical care in diabetic patients. In most of the developing countries, including Egypt, these data are scarce. This article presents the results of T2DM data in Egypt collected from the cross-sectional component of the IDMPS.

**Objectives:** To assess the trends of current treatment and outcomes of management of T2DM patients in Egypt

**Design:** Cross-sectional descriptive study

**Setting:** The study was conducted at the national level including public and private sectors.

**Study population and methodology:** A total of 28 physicians (13 diabetologists and 15 GPs, internists, and cardiologists) and 289 T2DM patients were recruited. A cross-sectional survey of socio-demographic factors, management practices, and metabolic control has been conducted for all patients.

**Results:** The patients' mean age was  $54.25 \pm 10.73$  years, females represented 54.7%, and patients living in urban areas 91.9%. Their mean BMI was 32.08 kg/m<sup>2</sup> and the mean waist circumference was 104.89 cm. The mean duration of diabetes was  $9.25 \pm 7.76$  years with approximately 69.5% of a positive family history of diabetes. About 12.7% of the patients were illiterate, with most of the subjects (64%) having no health insurance. Insulin was more frequently described by diabetologists. The pre-mixed insulin was the most prevalent (diabetologists 50.0% and other specialties 66.7%). Screening for chronic diabetic complications was sub-optimal, with 33.6% of patients never screened for cardiovascular disease, 48.1% never for retinopathy, 49.6% never for neuropathy, and 66.4% never for diabetic foot disease. More than one-third of the patients never had their HbA1c measured during the previous year, only 60.7% of them were assessed for their lipid profile at least one time, and 60.3% of them have never had their urinary albumin measured. Approximately 88% of patients were never subjected to any form of therapeutic patient education and only 31% of them reported the performance of the SMBG. Almost none (0.4%) of the patients achieved the 3 ADA treatment targets (HbA1c, BP, and LDL-C), with 57.6% of them not achieving any of the targets. Only 16.5% of the patients had HbA1c < 7%. The prevalence of retinopathy, nephropathy, and neuropathy was 18.3%, 15.9%, and 46.0% respectively, with 31.8% of them having coronary artery disease. Hospitalization in the 3 months prior to enrollment was reported in 13.6% of patients, heart disease being the most common reason (80.7%).

**Conclusion:** In Egyptian patients with T2DM, metabolic control and prevention of complications are unsatisfactory. Thus, measures should be undertaken to elaborate a national program addressing adaptation of guidelines, continuous professional development, patients' education, and tackling the barriers of good health care provision and patients' empowerment.

**Funding source:** IDMPS was funded by Sanofi-Aventis International

638

**Access***Keywords:* Access Access to Medicines, Malaria, HIV/AIDS, Reproductive Health, Gender Perspective**Access to Medicines in Nigeria – Gender Perspective****Ukamaka Gladys Okafor<sup>1</sup>, Olanike Adedeji<sup>2</sup>**<sup>1</sup>Pharmacists Council of Nigeria; <sup>2</sup>Sky Sea and Sand Ltd Nigeria

**Problem statement:** In a country of over 100 million people (2005), Nigerian women are approximately 49% of the population, most of whom are poor, uneducated, reside in rural areas and have limited access to basic health care.

**Objectives:** This study focuses on Nigerian women's access to medicines and explores how gender influences access to malaria management, HIV treatment, and reproductive health including family planning techniques. Disparities between different parts of the country and between rural versus urban populations were also explored.

**Design:** The study was exploratory in nature and based on an extensive review of literature because of the large pool of primary data available in the country. The main sources of information were the 1990, 2003, and 2008 Nigeria Demographic Health Survey (NDHS). Attempts were made to compare the statistics on access from 1990-2008 to determine if there had been any significant differences.

**Settings:** The study was limited to internationally accepted research work conducted in Nigeria between 1990 and 2008 with particular reference to malaria, HIV/AIDS and reproductive health

**Study population:** The 2003 and 2008 NDHSs were based on a nationally representative samples of over 7000 and 34,070 households, respectively.

**Results:** Access to reproductive health was measured by antenatal clinic attendance and household wealth in 1990 and was compared to 2008. In 2008, only 42% of women who did not participate in any decision in the household accessed antenatal care from a health worker whereas 73.4% of women who participated in at least 3 key decisions in the household had accessed antenatal care from a health worker. According to the 2008 NDHS results, prompt treatment

of fever increases with wealth quintile. The NARHS 2007 report shows that more females (4.0%) were infected than males (3.2%). Barriers to preventive and curative health especially for Nigerian women include, but are not limited to, low income and poverty, long geographical distances to health facilities, less education (affecting health seeking behavior), rural locations (unequal distribution of health resources and concentration in urban locations), cultural barriers, attitudes of health workers, ratio of health workers to population [leading to burnout], inadequate Government funding for health, and decline in use of maternal services following introduction of user fees in 1994.

Conclusions: Poor access to health services including medicines for women is mostly due to low income and poor level of education. Lack of awareness of their rights and poverty makes it even less possible for women to assert such rights in a society where wealth and power are inexorably linked. Recommendations include increased Government funding for health, health insurance/subsidies for women and children, increased community awareness and age appropriate reproductive health education for women and girls, domestication of CEDAW into the Nigerian system, and deliberate policies to promote female participation in decision making.

Funding sources: Pharmacists Council of Nigeria, the Society for Family Health and Women's SocioEconomic Rights Agenda (WOSERA) provided data and technical support.

**639**

### **Drug Resistance**

*Keywords:* antimicrobials, drug resistance, appropriate use, diagnostics

#### **New Method for Identification and Antibiotic Resistance Screening of Bacteria**

**Anna Zorzet<sup>1</sup>, Jenny Göransson<sup>2</sup>, Erik Gullberg<sup>1</sup>, Rongqin Ke<sup>2</sup>, Mats Nilsson<sup>2</sup>, Dan Andersson<sup>1</sup>**

<sup>1</sup>Department of Medical Biochemistry and Microbiology, Uppsala University, Sweden; <sup>2</sup>Rudbeck Laboratory, Uppsala University, 751 85 Uppsala

**Problem statement:** In many countries, there is an overuse of antibiotics that can drive development of antibiotic resistance. One part of the problem is diagnostic uncertainty, which leads to empirical use of antibiotics. The response time from the clinical microbiology lab back to the treating physician is 2-3 days if an antibiotic susceptibility profile is performed, and in this time, the patient has usually already been started on an antibiotic. The empiric antibiotic may be of no use if the bacteria are resistant to that antibiotic or if the infection is viral. In addition, most empiric antibiotics are broad-spectrum, but in many cases, a narrow-spectrum antibiotic could have been used instead, if the species and resistance pattern had been known.

**Objective:** We are developing a novel method that will enable diagnosis and antibiotic susceptibility profiling in hours instead of days. Our method is based on phenotypic screening where the sample will be grown only for a few hours, in the presence or absence of different antibiotics. Then, a sensitive probing technique utilizing padlock probes allows for the simultaneous detection of both the species of bacteria and the resistance pattern. The only technical equipment needed are heating blocks, which makes the method suitable for use in low-income countries.

**Results:** We have obtained positive results from two applications of the method. (1) Reliable detection and antibiotic susceptibility profiling of urinary tract infection (UTI) pathogens; several UTI pathogens were detected down to a concentration of 10<sup>4</sup> cfu/mL. A panel of the most used antibiotics for treating UTIs was used and the antibiotic resistance pattern was correctly determined (compared to standard methods). (2) Sensitive detection of the Crimean-Congo haemorrhagic fever virus (CCHFV); several different strains of the CCHFV from patient sera were correctly diagnosed (compared to RT-PCR, the existing diagnostic method). The limit of detection was as low as that for RT-PCR, 10<sup>3</sup> pfu/mL. The manuscript has been accepted for publication in Journal of Clinical Microbiology.

Funding source: Uppsala University

**640**

### **Access**

*Keywords:* disparities, gender perspective, HIV/AIDS, malaria, tuberculosis

#### **Gender and Medicines In HIV/AIDS, Tuberculosis, and Malaria in Low- and Middle-Income Countries: A Systematic Review**

**Joao Carapinha<sup>1</sup>, Dennis Ross-Degnan<sup>2</sup>, Catherine Vialle-Valentin<sup>2</sup>, Anita Wagner<sup>2</sup>**

<sup>1</sup>Northeastern University; <sup>2</sup>Harvard Medical School and Harvard Pilgrim Health Care Institute

**Problem statement:** Medicines are essential tools that improve health in low and middle-income countries, and numerous studies have established their impact in the management of HIV/AIDS, tuberculosis, and malaria. Studies suggest that there are socioeconomic, geographic, institutional, and sectoral differences in medicine access and use, yet few explore gender differences, and no systematic review is available to summarize such differences.

**Objectives:** To systematically search and summarize literature that describes gender differences in medicine access and use in HIV/AIDS, tuberculosis, and malaria in low- and middle-income countries and to highlight opportunities for further research

**Design:** Systematic review of published literature

**Setting and study population:** Studies that describe gender differences in the HIV/AIDS, tuberculosis, and malaria population in low- and middle-income countries

**Outcome measures:** A conceptual framework that delineates an access and care-seeking pathway was used to categorize all literature, and key characteristics are described by disease area, geographic region, research design, and quality of evidence.

Results: We found 1,057 studies using popular citation databases, institutional databases, and web archives of key multilateral and donor organizations. All studies were manually searched; and 40 met our search criteria, 21 of which reported gender differences as a primary research concern and the remaining studies included some gender results. Most studies describe gender differences in sub-Saharan Africa (n = 10), Southeast Asia (n = 7), and Latin America (n = 2). Many are concerned with HIV/AIDS (n = 19); 1 study reports gender differences in tuberculosis, and no studies are available for malaria. Studies explore access (n = 12), adherence (n = 2), and acceptability (n = 1) of medicines from a gender perspective, and most describe the influence of livelihood assets (n = 10), transforming structures and processes (n = 4), and livelihood outcomes (n = 7). Some studies had acceptable research designs, either time-series (n = 6), pre-post design with a control group (n = 1), cross-sectional (n = 4), or qualitative research (n = 11).

Conclusion: The results of our systematic review suggest that gender research about medicines is dominated by access studies in HIV/AIDS in sub-Saharan Africa and Southeast Asia. Little is known about gender differences in Asia-Pacific, Latin America, and the Middle East. Studies that adopt a gender perspective employ time-series and qualitative research designs to explore social and individual resources that impact medicine access and use. Further research is required to understand contextual factors that determine gender differences, and more attention is required to understand such differences in tuberculosis and malaria. Capacity building, institutional commitment, and donor support will be required to resource and expand gender research.

Funding source: Grant from the United Kingdom Department for International Development

642

#### Access

*Keywords:* access to medicines, affordability, generic medicines, pharmaceutical policy, quality assurance

### **Can the Indian Government Improve Access to Medicines Through Generic Drug Stores?**

**Anita Kotwani**

V. P. Chest Institute, University of Delhi, Delhi, India

Problem statement: A key challenge for health care policy makers of developing countries is to increase the availability and affordability of essential medicines. In spite of the huge generic drug industry in India, access to essential medicines for the common citizen is still an issue.

Objective: To evaluate the policy of the Department of Pharmaceuticals (DoP) to open generic drug stores to improve access to essential medicines

Design: Policy evaluation

Setting: Generic drug stores called Jan Aushadhi stores (Jan = people and Aushadhi = medicines)

Study population: Generic drug stores opened by DoP operating in public facilities

Policy: DoP, Government of India has launched the Jan Aushadhi program to open generic drug stores in every district of India and make medicines available at prices that are lower than the popular brands available in the private sector. Five recently revived public sector drug manufacturing companies under DoP are the main suppliers of generic medicines to these stores. Few state governments have provided space for generic drug stores within the premises of public hospitals, and NGOs run these stores at reasonable margins.

Results: As of September 2010, approximately 45 such generic drug stores were opened in 6 states of India in public facilities where the Government is supposedly providing free medicines to the population. These stores sell limited numbers of generic medicines, mainly antibiotics, analgesics, antipyretics, combinations of analgesics and anti-inflammatory medicines, and anti-allergy medicines. Sales at these stores are minimal as we found out from a few stores. Patients who visit public facilities either want free medicines supplied through the facilities' pharmacies, or if they can afford it, they purchase branded or branded-generic medicines from private retail pharmacies. Patients have little or no faith in the quality of generic medicines available at public facilities, but poor patients who cannot afford to purchase medicines have no choice but to take free medicines available. These stores are opened in big cities, where medicines are commonly available in private retail outlets.

Conclusion: The vulnerable population who rely on free medicines supplied at public facilities are not going to benefit from this scheme. The public also has doubts about the quality of generic medicines sold at public facilities. Quality testing of all the medicines being supplied to generic stores should be done and widely publicized. Advocacy and awareness for generic medicines should be preceded by opening generic drug stores. The Government should open generic drug stores either in remote places or along with the private sector. This would be a step in the right direction, but its implementation requires serious thought to make it a success. The current generic drug store policy will increase access of limited medicines for a very limited population, but not for the vulnerable population of India.

Funding source: None

643

#### HIV/AIDS and TB

*Keywords:* HIV/AIDS; ethics; gender perspective; health reform; human rights

### **Ethical Issues Raised by the Inclusion of Gender in the Implementation of Prevention of Mother-to-Child Transmission of HIV (PMTCT) Program in Burkina Faso**

**Nadia Djenebou Yabila, Patrice Sanon, Simon Kabore**

Access To Essential Medicines Network, Burkina Faso

**Problem statement:** The PMTCT program's implementation faces enormous challenges related to non-involvement of men. Yet their involvement is more than necessary in the context where they are heads of households in Burkina Faso. Ethics and laws issues can arise because of the strategies used to involve men in PMTCT.

**Objectives:** Main objective of this analysis is whether the strategy of involving men alongside women in the program meets with ethical principles and health rights. In addition, the real causes of non-involvement of men in the program have been determined and solutions that can lead to real change have been found.

**Design:** This evaluation is both quantitative and qualitative, and the goal is to evaluate the ethical aspects of the implementation of the PMTCT program policy.

**Setting:** The study has been conducted in Ouagadougou and Bobo-Dioulasso, where the population concentration and access to medical care are higher. It involved both public and private sectors and also the associative sector. The peculiarity of this analysis has directly affected the main program and thereby excludes any foreign persons.

**Study population:** The sample was chosen from women who had ever participated in PMTCT or were included; spouses whether they agreed to support women during the process or not; health workers involved in PMTCT in health facilities or associations taking care of people living with HIV; and the leaders of those associations. In total, 119 persons were recruited.

**Intervention:** Data collections were conducted from August to September 2010 by 4 investigators, 2 in each city. The collection consisted of individual interviews with semi-structured questionnaires administered by the investigators. Questionnaires contained open and closed questions and were sent to women participating in PMTCT, their partners, health workers practicing in health centers, and those working in associations, and the associations' leaders. Meetings were initiated with the authorities responsible for implementing the program to get their opinions.

**Results:** We note that the strategy of involving men does not always respect legal and ethical principles, such as free and informed consent or free screening. The main reasons people do not accept involvement in the process of PMTCT are fear, lack of information, and the idea that pregnancy only concerns women. Recommendations, such as men's awareness, making antenatal accessible to men, and creating a consultation framework for men, have been identified to improve implementation.

**Conclusion:** These issues should be raised with political leaders so that guidelines can be revised for implementation of the program.

**Funding source:** Funded entirely by SIDACTION, through its support to projects on ethics

**647**

#### **Policy, Regulation, and Governance**

*Keywords:* Essential medicines list, rational use of drugs, India.

#### **Comparison of the National List of Essential Medicines (India) with the WHO Model Lists of Essential Medicines and Essential Medicines for Children**

**S. Manikandan<sup>1</sup>, Gitanjali Batmanabane<sup>2</sup>**

<sup>1</sup>Indira Gandhi Medical College & Research Institute, India; <sup>2</sup>World Health Organization, Regional Office for South East Asia

**Problem statement:** Essential medicines lists (EML) have been proven to improve access to medicines and facilitate rational use. The Ministry of Health, Government of India, revised the National List of Essential Medicines of India (NLEMI) in June 2011, 8 years after the previous list was published. This list was found to have improper selection, significant errors, and omissions. Because the EML is also advocated to be used for procurement of drugs in the public sector, there is an immediate need to analyse the lacunae in the present NLEMI so that these can be rectified.

**Objectives:** To review NLEMI in comparison with the 17th Model WHO EML and 3rd WHO Model EML for children (EMLc) and to identify areas of discordance and list major errors

**Design:** Descriptive study comparing NLEMI with WHO EML and EMLc in terms of proper selection, suitability of dose, and dosage forms

**Methodology:** The 17th Model WHO EML and 3rd EMLc were taken as basic templates, and NLEMI was compared to them. A table was prepared to permit easy comparison.

**Outcome measures:** Areas of discordance between NLEMI and WHO EML and EMLc

**Results:** There is evidence that the selection criteria of essential medicines as defined by WHO and the methods used to develop a list were overlooked when NLEMI was prepared. Obsolete medicines such as ether and tincture benzoin are included in NLEMI. Pantoprazole and famotidine have been added when omeprazole and ranitidine are already on the list; 5 antihistamines are listed in NLEMI whereas WHO EML and EMLc list 1. There are 7 iodine containing radiocontrast media in NLEMI, but 1 in WHO EML and none in EMLc. For many drugs, the information provided is incomplete. The strength of oral rehydration salts is mentioned as 'As per IP'. Similarly, for premix insulin, it is not specified which of the 2 insulin preparations are mixed. There are also significant omissions of medicines which are listed in the national programmes (e.g., fixed dose combinations of antituberculosis medicines, iron and folic acid). Many drugs do not have either the dose or dosage form appropriate for children. Spelling mistakes in the name of the drugs and the more serious errors in the dose and factual errors are plenty. Inadequate formatting and lack of an index adds to the issues in NLEMI.

**Conclusion:** The basic considerations of efficacy, safety, suitability, and cost were not rigorously applied when the NLEMI was prepared. Greater accountability of those involved in its preparation is called for and an immediate revision is warranted.

Funding sources: World Health Organisation - SEARO

651

**Access**

*Keywords:* drug utilization, equity, gender perspective, pharmaceutical expenditure

**Gender Inequalities in Medicine Expenditure and Family Budget Allocated to Medicines in a Southern Brazilian City: Population-Based Study**

**Alexandra Crispim Boing<sup>1</sup>, Karen Glaser Peres<sup>1</sup>, Andréa Dâmaso Bertoldi<sup>2</sup>**

<sup>1</sup>Universidade Federal de Santa Catarina, Brazil; <sup>2</sup>Universidade Federal de Pelotas, Brazil

**Problem statement:** Gender inequalities are considered one of the main barriers for human development. Gender inequalities have been reported in the literature in different areas of knowledge, including the health sector. Recently, with the change in the social and economical positions of women, studies in the health field have explored in what manner and in what intensity men and women present unequal outcomes in health. However, there is a gap in the knowledge about gender differences related to medicine utilization, expenditures with medicines, and the proportion of the family income spent on medicines.

**Objectives:** To describe gender inequalities regarding the use of medicines and out-of-pocket expenses with medicines in an adult population

**Design:** Cross-sectional, household-based study

**Setting:** Multi-stage sampling strategy was used. Census tracts (delimited areas comprising approximately 300 households each) were the primary sampling units and the households were the secondary units. Utilization and expenses of medicines in the previous 30 days were investigated with a pre-tested questionnaire. Use of medicines and absolute and proportional values of out-of-pocket expenses for medicines were analyzed according to family income and gender, taking the clustering of the sample into account.

**Study population:** Adults aged 20 to 59 years, living in the urban area of Florianópolis, a medium-sized city in the south of Brazil, with an estimated population of 410,000 inhabitants; the final sample was made up of 2,016 people and the data were collected from September 2009 to January 2010.

**Outcome measures:** Use of medicines and absolute and proportional out-of-pocket expenses with medicine in the previous 30 days. All the values spent on medicines by each member of the family in the previous 30 days were added and divided by the per capita family income and shown as percentages. The proportion of the family income spent on medicines was also calculated considering a cut-point higher or equal to 10% of the per capita family income.

**Results:** The response rate was 85.3% (n = 1,720). The prevalence of medicine use was 77.4% (95% CI 74.8 to 80.0) and was higher among women (85.9% vs. 66.8%; p < 0.01). The average monthly expenditure on medicine was USD 26.7, with higher rates among women as compared to men (USD 31.8 vs. USD 20.2; p < 0.01). Although only 8.8% (95% CI 6.1 to 10.7) of the men committed more than 10% of their income to purchasing medicine, this figure reached 15.2% (95% CI 12.9 to 17.6) in women. Besides that, women committed 5.8% of their income and men 3.0% (p < 0.01). After unsuccessful attempts to obtain medicines in the public health service, the proportion of people who paid for medicines was higher among women.

**Conclusions:** There is significant gender inequality in the use of medicines and out-of-pocket expenses for medicines, with the worst results among women.

**Funding source:** Brazilian National Council for Scientific and Technological Development (CNPq)

658

**Access**

*Keywords:* injections, corruption, quality control, patient safety, good governance

**Piloting a Medical Injection Safety Assessment Protocol in Cameroon: Indirect Reuse Represents Risk of Blood-Borne Virus Transmission**

**Savanna Rose Reid<sup>1</sup>, Mbah Patrick Okwen<sup>2</sup>, Ngem Bedes Y<sup>3</sup>, Fozao Adolph<sup>3</sup>, Mireille Capo<sup>2</sup>**

<sup>1</sup>University of Nevada at Las Vegas, United States of America; <sup>2</sup>Netherlands Development Organization, Bamenda, Cameroon; <sup>3</sup>Bali District Health Services, Bali, NWR, Cameroon

**Problem statement:** Unsafe reuse of injection equipment continues to compromise patient safety, but the extent of this problem is difficult to measure. Standard WHO injection safety assessment protocols are problematic because health workers often behave differently under observation by visitors.

**Objectives:** The objective of this study is to pilot a new instrument to assess the extent of unsafe injection equipment reuse.

**Design:** Literature review and cross-sectional survey of injection providers

**Setting:** The injection safety assessment instrument was piloted at all public hospitals in 2 health districts in the Northwest Province of Cameroon.

**Study population:** The injection providers surveyed were a convenience sample of full-time and part-time staff working in the maternity and pediatric wards.

Outcome measure(s): The proportion of respondents changing the needle to reuse the syringe was compared with the ratio of needles to syringes used at each hospital. Other forms of reuse observed included reuse of the needle after changing the syringe, reusing both needle and syringe, and reusing injection equipment to access an IV line.

Results: Overall, 44% of injection providers practiced some form of injection equipment reuse, 36% changed the needle to reuse the syringe, and hospitals ordered 23% more needles than syringes.

Conclusions: National Service Provision Assessments report that 17–40% of clinics in 6 countries in sub-Saharan Africa for which data are available lack sterilization equipment. Although some such clinics utilize boiling pans, others only rinse equipment between uses. In Cameroon, injection equipment reuse without sterilization also occurs at hospitals with working sterilizers. Misconceptions about injection safety that lead to reuse without sterilization were widespread in high-income, developed countries less than 20 years ago. Reuse without sterilization usually occurs when health workers mistakenly believe that (1) it is safe to reuse a syringe after changing the needle, (2) it is safe to reuse a needle or syringe on the same patient, re-entering a multi-dose vial or saline bag with a used needle or syringe, (3) it is safe to reuse a needle or syringe when accessing an IV port, or (4) it is safe to reuse finger-stick devices without sterilization. The use of autodisable syringes could significantly improve patient safety in Cameroon. Policy makers should also address governance issues and corruption which also contribute to unsafe practices.

Funding source(s): The Netherlands Development Organization

659

#### Child Health

Keywords: appropriate use, education

### **Promoting Proper Use of Medicines in School Children: An Interventional Study**

---

**Mangesh Anandrao Bankar, Vijay Thawani, Kunda Gharpure**

Government Medical College, Nagpur, Maharashtra, India., India

Problem statement: People use medicines not as per doctors' direction, but per their own will. For safe and proper use of medicines, the proper way of taking medicines must be understood. Teaching proper use of medicines is the most neglected domain of the school health curriculum, especially in developing economies. Children mainly gain knowledge about medicine use by observing health practices of their parents. Also, many advertisements by pharmaceutical companies mainly target school children because they can influence their parents to buy medicines. So, this study targeted school children, because the earlier the intervention—teaching them about proper medicine—the longer lasting, health-related behavior can be successfully inculcated into them.

Objectives: To study the base level knowledge about use of medicines in school children; implement an intervention in the form of information, education, and communication (IEC) to increase medicine knowledge among school children; and see the effect of IEC on the awareness about proper use of medicines in school children

Design: This was an interventional, questionnaire-based (qualitative) study in which the level of awareness about the proper use of medicines in school children was compared before and after giving an intervention in the form of lectures to the children.

Setting: This study was conducted at local level; children in IXth and VIIIth standard were selected from 3 different schools of Nagpur.

Study population: The data was collected from 500 school children after obtaining permission and informed consent from the school authorities.

Interventions: After explaining about the research project to the children, pretesting was done by administering a questionnaire containing 24 questions to assess the children's base level knowledge about medicine use. Teaching material related to rational use of medicines was distributed to teachers who were requested to teach children daily for 15-30 minutes for 1 week. After a week, a one-hour lecture on rational use of medicine was given to the children and the same questionnaire was again administered to judge the improvement.

Results: It was observed that the interventions brought about a positive change in the knowledge of the students as well as increased awareness about proper use of medicines.

Conclusion: This study showed that a properly timed and meticulously implemented intervention can bring about a positive change in the attitude and knowledge of school children.

Funding source: This study was not funded by any funding agency.

664

#### Access

Keywords: Emergency Contraceptive Pills (ECP), Emergency Contraceptive Pill Utilization, Attitude toward ECP, Knowledges about ECP, Thai Men

### **Knowledges and Attitudes toward Emergency Contraceptive Pill among Thai Men in Bangkok and Its Utilization**

---

**Tanattha Kittisopee, Hathairat Jitlamun**

The Faculty of Pharmaceutical Sciences, Chulalongkorn University, Thailand

Problem statement: Emergency contraception pills (ECPs) are available without prescription in Thailand. Use of the wrong dose and irrational use were found among teenagers. Males always bought ECP from drug stores for their

female partners. As such, how much do Thai men know about the use of oral contraceptives for emergency contraception and what do they think about it? Do people with access to the regimen consider it a useful and appropriate method of fertility control? No research has previously assessed knowledge and opinions on the emergency contraceptive pill among Thai men.

**Objectives:** Explore knowledge and attitude toward ECPs in the male population in Bangkok and to investigate determinant and pattern of ECP in Thai women that were induced to use the pill by their partners

**Method:** An anonymous questionnaire was used to survey a convenient sample of 400 men from 7 administrative districts in Bangkok, the metropolitan area in Thailand. The questionnaire consisted of 45 questions: 5 inquired about males' contraceptive behaviors; 8 asked males' emergency contraceptive behaviors; 15 tested males' knowledge on ECP; 12 investigated their attitude toward ECP; and 5 inquired about demographic information. Descriptive analysis was used to illustrate contraceptive and emergency contraceptive behaviors and attitudes toward and knowledge about ECP. Pearson's  $r$  coefficient was used to test the correlation between knowledge and attitude.

**Results:** The most common contraception was a condom (40%); 50% of men know ECP and 41.5% had used ECP with their sexual partners in the last 6 months. Major sources of information about ECP were friends (57%), pharmacists (17%), school (15%), TV/radio (14%), newspaper/magazines (11%), and parents (4%). Forty one percent of men knew the exact correct time for using it (within 72 h following an unprotected sex) and only 31% knew that ECP should not be used more than 4 tablets a month. Twenty five percent of them understood that ECP was able to prevent sexual transmitted disease. The better knowledge men had about ECP, the less shamed they felt about consulting doctors and pharmacists ( $r = -0.242$ ;  $p = 0.01$ ), the less likely that they will encourage their sexual partner to use ECP ( $r = -0.266$ ;  $p = 0.000$ ), and the more likely that it is needed to consult doctors and pharmacists before using ECP ( $r = -0.174$ ;  $p = 0.015$ ).

**Discussion and conclusion:** Because of its adverse effects, interactions with other pharmaceutical products, and ethical misgivings about the regimen, the results in the present study support that it is important to educate and counsel men about ECP so that they do not influence their partners to use it as a habitual anti-conceptive method.

**Funding source:** Chulalongkorn University

**667**

#### **HIV/AIDS and TB**

**Keywords:** adherence, tuberculosis, community-based Directly Observed Treatment (DOT), Medication Event Monitoring System (MEMS)

### **Electronic Monitoring to Assess Adherence and Validate Alternative Adherence Measures in Tuberculosis Patients on Community-Based Directly Observed Treatment**

**Josy van den Boogaard<sup>1,2</sup>, Ramsey Lyimo<sup>2</sup>, Boeree Martin<sup>1</sup>, Gibson Kibiki<sup>2</sup>, Rob Aarnoutse<sup>1</sup>**

<sup>1</sup>Radboud University Nijmegen Medical Centre, Netherlands, The; <sup>2</sup>Kilimanjaro Clinical Research Institute, Kilimanjaro Christian Medical Centre, Moshi, Tanzania

**Problem statement:** Community-based directly observed treatment (DOT) can be an effective strategy to improve adherence to tuberculosis (TB) treatment in settings where facility-based DOT is causing overburdened health care facilities. However, the strategy may lead to irregular drug intake in practice. This is difficult to prove in the absence of a simple and valid adherence measure.

**Objectives:** We assessed adherence rates of TB patients on community-based DOT by using the medication event monitoring system (MEMS bottles), and we used MEMS as a reference standard to determine the validity of alternative adherence measures.

**Design and setting:** This was a longitudinal study among outpatients attending 4 public TB clinics in Tanzania's Kilimanjaro region. The Tanzanian TB programme allows patients to choose between facility- and community-based DOT. Patients on community-based DOT have to select a treatment supporter (usually a relative or spouse) to provide DOT in the home setting.

**Study population:** Adult TB patients who presented with newly diagnosed TB between February and May 2010 and who had chosen community-based DOT were eligible to participate. Of the 50 patients enrolled, 37 completed treatment, 6 died, 3 defaulted, and 4 dropped out.

**Outcome measures:** MEMS data was used to calculate adherence rates by dividing the number of days on which at least one bottle opening was registered by the total number of monitored days, multiplied by 100%. Adherence rate cut-off values of 100% and 95% were used to differentiate between adherence and non-adherence and to determine the validity and accuracy of the test measures. The test measures included a urine test for isoniazid, urine colour test for rifampicin, Morisky scale, brief medication questionnaire, adapted version of the AIDS clinical trials group (ACTG) adherence questionnaire, pill counts, and clinic attendance for medication refills.

**Results:** Adherence rates ranged from 50.0 to 100% (median 98.4%) in all patients, and from 89.3 to 100% (median 98.4%) in the patients who completed treatment. In the latter group, 70% of patients were less than 100% adherent and 19% less than 95%. The ACTG questionnaire and urine colour test had the highest sensitivity (70-100%) but lowest specificity (20-37%) for detecting non-adherence, and the Morisky scale and clinic attendance the highest specificity (80-100%) but lowest sensitivity (14-35%). The sensitivity of the routinely used combination of pill counts and clinic attendance improved when the ACTG questionnaire was added.

**Conclusions:** The high adherence rates suggest that the Tanzanian model of community-based DOT can be an effective strategy to prevent non-adherence. Studies in patient populations with a wider range of adherence rates are

needed to confirm the validity of (combinations of) adherence measures that are feasible for use in resource-limited settings.

Funding source: KNCV Tuberculosis Foundation, The Netherlands

**668**

#### **Drug Resistance**

*Keywords:* Antibiotics, antimicrobial resistance, pattern and magnitude, self-medication, community setting

#### **Use of Antibiotics in the Alexandria Community Setting: Magnitude and Pattern**

**Sawsan Mahfouz Serour<sup>1</sup>, Zahira Metwally Gad<sup>1</sup>, Labiba Khalil El-Khordagui<sup>2</sup>**

<sup>1</sup>Alexandria University, High Institute of Public Health, Epidemiology Department; <sup>2</sup>Alexandria University, Faculty of Pharmacy, Pharmaceutics Department

**Problem statement:** Overuse and misuse of antibiotics result in worldwide antimicrobial resistance (AMR) and a great waste of resources. The frequency of resistant bacteria is considerably higher in countries with greater antibiotic consumption. At ICIUM 2004, it was stated that the nature and magnitude of antibiotic use in the community and institutional settings are among the key questions to be addressed to further understand emergence and control of AMR.

**Objectives:** To assess the use of antibiotics in the community setting in Alexandria Governorate, Egypt, in terms of magnitude and pattern

**Design:** Descriptive cross sectional

**Setting:** Using systematic random sampling (WHO), 22 private pharmacies in the seven districts of Alexandria Governorate were selected. The number of pharmacies in each district was calculated using cluster sampling technique.

**Study population:** 660 community pharmacy customers purchasing antibiotics with or without prescription; 30 customers/pharmacy (WHO)

**Outcome measures:** Magnitude and pattern of antibiotic purchasing and use

**Results:** Antibiotic purchasers constituted 32.6% of all purchasers; antibiotics formed 20.1% and cost 27.6% of purchased medicines. All participating pharmacies dispensed antibiotics without prescription; most of them dispensed individual doses, sometimes as a component of what is known locally as "the cold collection". Antibiotic purchasing and self medication were greater in rural areas. Among antibiotic purchasers: 41.4% purchased antibiotics without prescription, 71.8 % have previously done that, 63.3% discontinued antibiotics as soon as they felt better, 65.6% kept the leftover of capsules for similar future complaints. Purchasers of 1-4 and 5-8 doses represented 16.2% and 16.0% of purchasers, respectively. Antibiotics were purchased within a few hours of the complaint in 9.5% of the cases; 34.5% was for upper respiratory tract problems. Bacterial cell-wall synthesis inhibitors were the most purchased antibiotic class (48.5%) whereas the most purchased dosage forms were capsules and tablets (51.8%). Distribution of antibiotic users according to their age, gender, education, and occupation regarding the presence or absence of a prescription showed that the difference was statistically significance among them all. Further, children under 5 years were the top user age category (20.5%). Brand names were used in almost all antibiotic prescriptions, 68.3% of which did not specify treatment duration. Regarding dispensing, 39.8% of antibiotic purchasers were not instructed about the dose and dosing interval, and the duration of therapy was not specified at all.

**Conclusions:** Antibiotics are used irrationally in the Alexandria community setting with children constituting the top user age category. Potential causes include irrational antibiotic prescribing and dispensing; attitude and poor knowledge of the public; the pharmaceutical industry; and poor legislation enforcement.

Funding source: Self-funded

**671**

#### **Child Health**

*Keywords:* Pediatric trials, International Clinical Trial Registry, clinical trials, Clinical trial registry of India

#### **Analysis of Clinical Trials in Children Registered in the Clinical Trials Registry of India**

**S. Manikandan<sup>1</sup>, M. Jayanthi<sup>1</sup>, B. Gitanjali<sup>2</sup>, G. Sivagnanam<sup>1</sup>**

<sup>1</sup>Indira Gandhi Medical College & Research Institute, Pondicherry, India; <sup>2</sup>Technical Officer - Essential Drugs and Other Medicines (EDM), World Health Organisation - Regional Office for South East Asia, New Delhi, India.

**Problem statement:** India launched a freely accessible online 'Clinical Trials Registry – India' (CTRI) in 2007 to inform the public and health professionals about the clinical trials being conducted in India. Pediatric clinical trials are scarce because of the inherent difficulties involved in conducting studies in children. It has been observed that the information provided in trial registries is insufficient and out of date, thus undermining the expected benefits of trial registration.

**Objectives:** To analyse clinical trials in children registered in CTRI with regard to completeness, transparency, currency of information, concordance of data with WHO's Trial Registration Data Set (TRDS) and to suggest measures to improve the CTRI

**Design:** Descriptive study of clinical trials in children registered in CTRI

**Setting:** Conducted at a national level because the CTRI permits registration of clinical trials conducted all over India

**Study population:** Children up to 18 years; all clinical trials conducted on children registered in the CTRI were included

**Intervention:** The trials conducted on children (up to 18 years) from its inception until August 15, 2010, were retrieved from the CTRI website and included in the analysis. All the eligible 81 trials were scrutinized by 2 independent observers who scored each of the 36 items requested in the CTRI portal. The method of scoring was defined a priori for each of the items.

**Outcome measures:** The completeness of reporting, appropriateness, and degree of concordance of CTRI data with WHO-TRDS items were analyzed.

**Results:** The CTRI portal has 36 items, of which 23 are marked as WHO portal items. However, only 20 of them qualify as WHO-TRDS. All 20 are considered mandatory in the WHO International Clinical Trial Registry portal, though only 7 items are marked as mandatory in CTRI. Out of the 36 items, only 9 have 100% and 4 have near complete (99%) concordance. In 43 trials, the date of last update is mentioned even before the date of registration. Regulatory approval is needed for 41 trials of which 9 (22%) have not obtained it. There are 23 placebo controlled trials of which 7 (30%) could be considered unethical because the control arm were/denied active or most appropriate intervention. The results and adverse events of the trials are not provided.

**Conclusion:** The level of concordance of WHO-TRDS and non-WHO-TRDS items in CTRI is unsatisfactory and the quality of information available in the registry is poor. An urgent revision and modification of CTRI and stricter scrutiny of applications prior to registration are required. The registration of trials in children which are overtly unethical raises serious doubts over the competence of the ethics committees that has approved these projects and whether such trials should be banned from being conducted

**Funding source:** World Health Organization, SEARO

**673**

#### Chronic Care

*Keywords:* appropriate use, chronic disease, education, standard treatment guidelines, standards of practice

### **Impact of Standard Treatment Guidelines and Patient Education on Asthma Control and Knowledge in Asthmatic Patients: A Controlled Trial**

**Anita Kotwani<sup>1</sup>, Vandana Tayal<sup>2</sup>, S. K. Chhabra<sup>1</sup>**

<sup>1</sup>V. P. Chest Institute, University of Delhi, Delhi, India; <sup>2</sup>Maulana Azad Medical College, New Delhi, India

**Problem statement:** The prevalence of asthma is growing in developing countries. Evidence suggests that poor knowledge of the disease process, medication use, and poor self-management are some of the frequent reasons for increased morbidity in asthma and can be largely tackled by following standard treatment guidelines (STGs) and providing asthma education to patients.

**Objectives:** To evaluate the impact of STGs and additional asthma education program on asthma control and knowledge about asthma and its treatment

**Design:** Intervention non-randomized controlled study

**Setting:** Outpatient department of V. P. Chest Institute, Delhi, a tertiary care referral public hospital

**Study population:** A convenience sample of 50 patients visiting the referral facility the first time for asthma treatment were enrolled after confirming the diagnosis of asthma by symptoms and reversible spirometry; 38 patients completed the study (March 2006-December 2006).

**Intervention:** Patients were interviewed at week 0 (baseline) with 3 researcher-administered questionnaires that addressed asthma management, asthma control (questionnaire; ACQ), and asthma knowledge (questionnaire; AKQ). Of these, ACQ is a standardized, widely available instrument. The other two questionnaires were based on guidelines-recommended management and were developed for an Indian clinical setting. All patients were given inhalation medication according to STG and routine patient education. Alternate patients were given an additional face-to-face educational intervention on etiology, pathophysiology, symptoms, treatment, and self-management of asthma. Patients were asked to come for follow up at 2, 4, 8, and 12 weeks and the ACQ was used at each visit. The AKQ was reassessed at week 12 for all patients.

**Outcome measure:** Changes in all domains of asthma control and asthma knowledge

**Results:** Patients' responses to quality of treatment questionnaire indicated poor asthma care by previous health care providers. Improvement in various domains of asthma control (i.e., wheezing, shortness of breath, limitation in activities, average awakeness in morning and at night) started by week 2, became significant ( $P = 0.0001$ ) by week 4, and persisted until the week 12 in all patients. Assessment of asthma knowledge at week 12 revealed significant ( $P < 0.05$ ) improvement in knowledge about pathophysiology, symptoms, and assessment of severity and prevention of asthma compared to week 0. Furthermore, for patients who received additional asthma education, their knowledge about pathophysiology at week 12 was significantly more than the patients who did not receive additional education.

**Conclusions:** The study provides the evidence of a poor standard of asthma care and poor knowledge of asthma in patients. STGs have a significant impact on asthma control and knowledge. This study also confirms that a single session of asthma education has little impact on treatment outcomes.

**Funding sources:** HAI-Asia Pacific

**676**

#### Access

*Keywords:* Prescription, Rational use of medicines, Physician

## Evaluation of Prescribing Pattern of Physicians in Various Health Care Facilities in Turkey with Respect to the Rational Use of Medicines Principles

Salih Mollahaliloglu<sup>1</sup>, Ali Alkan<sup>1</sup>, Senay Ozgulcu<sup>1</sup>, Basak Donertas<sup>2</sup>, Ahmet Akici<sup>2</sup>

<sup>1</sup>School Of Public Health, Ankara, Turkey; <sup>2</sup>Marmara University School of Medicine Department of Pharmacology, Istanbul, Turkey

**Problem statement:** Irrational use of medicines is regarded as a severe health problem in Turkey. The Turkish Ministry of Health (MoH) is planning to conduct a series of activities for the purpose of rolling out rational use of medicines (RUM).

**Objectives:** Prior to the national campaign, this study aimed to evaluate the prescribing performance of physicians, who practice in various health care facilities, within the framework of RUM principles.

**Design:** Prescriptions were retrospectively collected in the randomly selected pharmacies, servicing in selected 10 provinces across Turkey.

**Setting:** Collected prescriptions were written out by physicians practicing in 5 different health care facilities (family health centers [FHCs], health centers [HCs], public hospitals, private hospitals, and university hospitals [UH]). Approximately 100 prescriptions per each facility were collected. The list of gold standard (GS) medicines, which are based on the standard treatment guidelines and expert views for 10 pre-identified diagnoses, were prepared. The prescribed medicines for these indications were checked for compatibility with GS. Average medicine cost per prescription was calculated according to the retail sales price of the drugs.

**Study population:** There were not HCs and UHs in 8 provinces and there were not FHCs in 2 provinces when the survey was conducted. A total of 3201 prescriptions covering all indications were reviewed.

**Intervention:** No interventions were made into physicians' prescriptions.

**Policy:** It is expected that the results of this survey paves the way for a national program for rolling out RUM.

**Outcome measure:** Average number of medicines and average medicine cost per prescription (NMPP and MCPP), pharmaceutical categories of prescribed medicines, and GS-compatibility of these medicines were evaluated for each health care facility.

**Results:** It was found that the most commonly prescribed medicines were respiratory system medicines (ATC code R) in HCs and FHCs, and musculoskeletal system medicines and alimentary tract and metabolism (ATC codes M and A) at hospitals. NMPP was  $2.8 \pm 1.1$  and the highest ratio was for prescriptions written out for A. Sinusitis in HCs ( $3.8 \pm 0.4$ ). MCPP was found to be USD 54.9; 39.8% of medicines prescribed for 10 indications in all health care facilities were GS-compatible. It was noted the physicians prescribing GS-compatible medicines differed by health care facilities and UHs had the highest ratio (50.6%) in prescribing GS-compatible medicines.

**Conclusions:** This study made clear the types of medicines being prescribed by physicians in primary care or hospitals did not follow the goals of RUM and that physicians did not necessarily respect GS medicine lists when prescribing, which indicates the urgent need for RUM promotion. In addition, major differences were noted among diagnoses reviewed for RUM. As a result, our findings may serve as a guide for the development of prescription audit systems.

**Funding source:** Turkish MoH

677

### Policy, Regulation, and Governance

*Keywords:* Pharmaceutical Services, Legalization of Health, Right to Health, Evidence-Based Medicine

## Analysis of Medicines Dispensed by Court Order in the Court of Rio De Janeiro: The Application of Scientific Evidence in Decision-Making Process

Tatiana Aragão Figueiredo<sup>1</sup>, Vera Lucia Edais Pepe<sup>2</sup>, Claudia Garcia Serpa Osorio-de-Castro<sup>3</sup>

<sup>1</sup>Master of National School of Public Health Sergio Arouca (ENSP / FIOCRUZ); <sup>2</sup>Collaborating Center on Health Surveillance (Cecovisa / ENSP / FIOCRUZ); <sup>3</sup>Nucleus for Pharmaceutical Care (NAF / ENSP / FIOCRUZ)

**Problem Statement:** The Brazilian law guarantees the right to Pharmaceutical Assistance (PA), but there are still gaps in the effectiveness of the state citizens' access to medicines, so the medicines' lawsuits have played an important role as an alternative to medicines in Brazilian Health System (SUS). This type of lawsuit is increasing annually and aims to both the medicines that are missing from the public as yet not incorporated into the health system.

**Objective:** To assess the medicines present in the lawsuits from the county Rio de Janeiro Central of Warrants referred to the Department of Health and Civil Defense of the State of Rio de Janeiro (SESDEC / RJ), from July 2007 to June 2008, compared to therapeutic alternatives present in the lists of public and in the light of scientific evidence.

**Methods:** This is a retrospective cross sectional study, the unit of analysis was the patient, the author of the judicial process. We analyzed the medicines registered in the Central of Warrants in SESDEC / RJ referring to 281 patients.

**Results:** There were 804 requests for medicines, corresponding to 356 medicines and 269 drugs, with an average of 2.8 medicine per patient. They were part of the National List of Essential Medicines 23.9% and 66.6% of medications were missing in the component of funding for pharmaceutical services. The main subgroups therapeutic / pharmacological medicines were used for diabetes, eye care and drugs for diseases of airway obstruction.

With regard to the medications required, there was also a myriad of categories when considering the available evidence and existing information. Most of the medications they needed was not financed by the health system and between them stands out: 1) medications required with health information registered in the National Sanitary Agency (ANVISA) with scientific evidence and that presenting alternative therapies funded by the system, 2) medicines for which

the evidence in long term are not yet well established, 3) medications for indications not approved by ANVISA, 4) medicines unregistered at Anvisa and 5) there are medicines without evidence for use or are not recommend their use.

Conclusion: The search for scientific evidence is extremely important for the medicines that are not present in the public lists and who also have no therapeutic alternatives.

In confronting the phenomenon of "court decisions, especially regarding the lawsuit of medicines, the approach of the Health System with the Judiciary is essential to guarantee the right to health without compromising the principles of the SUS and the management of pharmaceutical services.

Funding Source: National Council for Scientific and Technological Development (CNPq).

678

#### Child Health

*Keywords:* economic evaluation, cost effectiveness analysis, complex interventions, health care evaluation, package of care, clinical practice guidelines

### Costs and Effects of a Multifaceted Intervention to Improve the Quality of Care of Children in District Hospitals in Kenya

**Edwine Barasa<sup>1</sup>, Philip Ayieko<sup>1</sup>, Susan Cleary<sup>2</sup>, Mike English<sup>1,3</sup>**

<sup>1</sup>KEMRI Centre for Geographic Medicine Research – Coast, and Wellcome Trust Research Programme, Nairobi, Kenya; <sup>2</sup>Health Economics Unit, University of Cape Town, Cape Town, South Africa; <sup>3</sup>Department of Pediatrics, University of Oxford, Oxford, UK

**Problem statement:** It is estimated that more than 8.8 million children die globally before they reach the age of 5. In Kenya, the under 5 mortality rate was 74 per 1000 children in 2008. To improve the quality of care for seriously ill children, a multifaceted approach employing clinical practice guidelines, training, supervision, feedback, and facilitation was developed; for brevity, the strategy is called Emergency Triage and Treatment Plus (ETAT+).

**Objectives:** To assess the costs and efficiency of delivery of the ETAT+ strategy in district hospitals in Kenya

**Methods:** A cost-effectiveness analysis from the provider's perspective was conducted alongside a cluster randomized study that compared the delivery of ETAT+ in 4 district hospitals in Kenya to 4 control district hospitals receiving a partial version of the intervention between 2005 and 2009. The 8 rural district hospitals were identified on the basis of district-specific criteria, from 4 of Kenya's 8 provinces. Effectiveness of the intervention was measured using 14 process measures that capture improvements in quality of care and span the assessment, diagnosis, and treatment on admission for diseases resulting in 60% of inpatient deaths in children under 5. The economic cost of development, implementation, and treatment of sick children in intervention and control hospitals was estimated through interviews with implementers of the intervention, accounting, and clinical record reviews. An annual discount rate of 3% was used and one-way sensitivity analyses were used to assess uncertainty. Incremental cost-effectiveness ratios (ICERs) were defined as the cost per percentage improvement in quality of care as measured from the 14 process measures in control and intervention hospitals.

**Findings:** The cost per child admission was USD 54.74 in intervention hospitals compared to USD 31.06 in control hospitals, while quality of care as measured by the 14 process measures was 25.01% higher in intervention hospitals than in the control hospitals. These results suggest an additional cost of USD 0.78 per child admitted to achieve a percentage improvement in quality of care.

**Interpretation:** Our findings indicate that the delivery of ETAT+ as a multifaceted intervention yields significant improvements in quality of care of sick children but at a higher cost. Knowing what value decision makers place on quality improvement and their preferences for attributes of this and similar quality of care interventions would be useful in making decisions about their adoption explicit. Also of importance is assessing the costs of scaling up to assess the feasibility of implementation of ETAT+ on a national scale.

**Funding sources:** Funds from a Wellcome Trust Senior Fellowship awarded to Dr. Mike English (#076827) made this work possible.

679

#### Policy, Regulation, and Governance

*Keywords:* right health, essential medicines, access to medicines

### Brazilian Courts as a Pathway to Medicines which Represent Pharmacotherapeutic Gaps

**Mércia Pandolfo Provin, Rita Goreti Amaral**

Universidade Federal de Goiás, Brazil

**Problem statement:** The Brazilian health system is universal and grants therapeutic assistance to its users, including pharmaceutical assistance. Those medicines considered essential are freely distributed in public health service units. During the last decade, a number of Brazilian citizens have initiated civil court actions to gain access to medicines prescribed to them. This phenomenon has raised lots of discussions among jurists, health managers, and professionals.

**Objective:** To evaluate the medicines requested via court actions and provide patients with public pharmaceutical assistance coverage

**Methodology:** Data were collected from the state pharmaceutical file that is responsible for the distribution of medicines requested through court order in Goiânia-GO, Brazil. We considered as variables in this study the social-demographic

characteristics of the requiring parties, the diseases, the prescribed medicines, the origin of the treatment (public or private), and the court action. The requested medicines were compared with the official lists of free distribution. The requesting parties' addresses were georeferenced to infer their socio-economical condition.

Results: We collected data from 1553 judicial writs, and among them, 1378 had requested medicines. Among the requiring parties, we found 20.9% children, 26.2% elderly, and 54.5 % females in the considered group. The most frequent illnesses were insulin-dependent diabetes mellitus which represents 24.7% of the cases, followed by primary hypertension with 9.45%, humor disturbances (ill humor) with 6.36%, non insulin-dependent diabetes mellitus with 4.4% and lactose intolerance and gastro-esophageal reflux disease with 4.24%. The prescriptions which had originated the court actions came from the private health system in 58.3% of the cases, 18.5% came from the public system, and in 23.2% of the cases it was not possible to determine their origins. We verified that 40.5% of the medicines requested were not present or did not have any other therapeutic alternative in the lists of free official distribution and therefore they were considered pharmacotherapeutic gaps. Through geoprocessing resources, we identified that the requiring parties, in a general sense, lived in places that represent good social-economical conditions, however, when analyzing the gaps in assistance, we found that most of the requiring parties lived in places where the median household income was not higher than USD 1,482.00.

Conclusion: Despite the public health service's universal and integral assistance, there are gaps in pharmaceutical assistance which do not allow the state to accomplish this proposal in an efficient way. This has made the justice courts a pathway to obtain those medicines , mainly for poorer citizens.

Funding source: Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq)- Brazil

682

### Chronic Care

*Keywords:* Consumption, Inappropriate Medication, Beers criteria, Health, Elderly

## **The Assessment of Relation between Inappropriate Medication and Health Status Among Elderly Discharged from Hospitals Affiliated with Tehran University of Medical Sciences, through Beers Criteria**

**Leila Vali, Abolghasem Pourreza, Batoul Ahmadi, Abbas Rahimi Froushani**

Tehran University of Medical Science, Islamic Republic of Iran

**Problem Statement:** Studies demonstrated that chronic diseases are more frequent among elderly than other groups of population. Therefore, it seems plausible that more pharmaceuticals are consumed by them than by other groups of patients. Iran has witnessed a demographic transition and now about 7 millions of the population are above 60. Considering the fact that they use more health cares and hence more medications, addressing this issue regarding the limited financial resources of health sector seems logical and necessary. There are several methods available for assessing inappropriate medication use in elderly (for example, zhan 2001 and McLeod1997). In this study , Beers Criteria has been selected as the methodology for some reasons : It is similar to the pharmacopoeia of Iran, being used in Asian and European countries and getting updated periodically .

**Objectives:** Assessing of inappropriate medication use in elderly people with using Beers Criteria. Assessing relationship between inappropriate medication use and health satatus in elderly people

**Design:** For the purpose of the present study 212 patients aged 60 and more discharged from 4 general hospitals affiliated with TUMS selected. Nottingham Health Profile(NHP),and Beers Criteria were employed to assess the health status and inappropriate use of pharmaceutical of the sample, respectively.

**Setting:** 4 (2 teaching and 2 non-teaching) general hospitals affiliated with TUMS

**Study population:** elderly people

**Results:** Findings reveal that there was a significant relation between the level of income and inappropriate use of pharmaceutical among the sample( $P=0/041$ ).Moreover, the elderly who had less income used drugs inappropriately, 2.35 times more than the elderly with high income (CI: 1.099-5.064). The elderly with low income are less willing to go to see the doctor due to the cost. They try to buy their ex-prescribed medications without re-consultation with their physicians. The other reason is less support from children of poor elderly. The most frequent inappropriate use of drug belongs to Alprozolam (16/66%), Chlordiazpoxide (14/28%), Fluoxetine (11/90%) and Oxazepam (11/90%) respectively. Sleep and emotional reactions were 2 dimentions of NHP which developed significant relation with inappropriate use of drugs among the study population( $P=0/013$  and  $P=0/041$ ). The mentioned inappropriate medications are used for relieving pain, eliminating insomnia and stress. In this study, 28/8 % of the sample suffer from insomnia and 15/1 % experience depression. In addition, 40 % Of them complain of connective tissue diseases. The insomnia, depression and decrease of quality of care are the consequences of the pain resulting from these kind of diseases. Clopidogrel was determined as the most interactive drug with heart disease(23/8%). Benzodiazapine recognized as the most frequent class of pharmaceuticals consumed by the patient(47/72%) and the mean age for study population equaled 69/32 years

**Conclusions:** consumption of inappropriate medication use was relatively high among the study population, in comparison to other countries(for example Mexican,Norway,Denmark,Iceland were 12%, 7.5%, 11.5%, 17.8% respectively). Benzodiazepines were recognized as the most frequent drugs used inappropriately by the sample. Such a behavior may position the elderly to unpredicted and unpleasant side effects resulted from drugs interaction. Training physicians and medical students in this respect is suggested.

683

**Policy, Regulation, and Governance***Keywords:* medicines policy, policy guideline, NMP, Region of the Americas**Analysis of NMP Documents of the Region of the Americas****Claudia Garcia Serpa Osorio-de-Castro<sup>1</sup>, Angela Esher<sup>1</sup>, Elaine Silva Miranda<sup>1</sup>, Paula Pimenta de Souza<sup>1</sup>, Letícia Figueira Freitas<sup>1</sup>, Nelly Marín<sup>2</sup>**<sup>1</sup>Sergio Arouca National School of Public Health/Oswaldo Cruz Foundation, Brazil; <sup>2</sup>Medicines and Health Technologies, Pan American Health Organization, WHO Regional Office for the Americas

**Problem statement:** Specific priorities and different contexts in terms of pharmaceutical policies have resulted in different levels of pharmaceutical policy development and implementation by countries in the region of the Americas. There is a perceived need in this region for a review of the WHO pharmaceutical policy guide.

**Objective:** We analyze pharmaceutical policy documents in the region of the Americas as a first step to updating the WHO policy guide for the region.

**Design and setting:** Search for policy documents was undertaken and centralized by PAHO, selected as the sole information source. Policy documents were included only if they were available as an official NMP document; no draft policies were analyzed. An analytical matrix was developed; analytical categories applicable to the information retrieved in the matrix were also developed by using the conceptual framework of content analysis and based on categories of the original WHO guideline document.

**Outcome measures:** Content of the introduction, topics and concepts in the documents, consistency of organization, references to WHO and national guidelines, and innovative issues present in the policies

**Results:** Of 17 countries with existing NMP documents, 14 were studied. All documents mention policy objectives and commit to implementation, but few cite explicit implementation plans with goals, policy development and stakeholders, review, and implementation strategies. There was no discernible standard in frequency of policy topics. Country NMPs generally adhered to WHO guideline structure. Some policy documents use pivotal topics around which they organize policy structure, such as generics. Concepts or ideals related to the essential medicines concepts, generic medicines, medicines selection committees, and market authorization must be reviewed in medicines policies in the future. Various extra issues not present in the WHO guideline were introduced by countries. Contributions in the 3 dimensions of access, quality, and rational use were found, although quality had fewer innovative ideas.

**Conclusion:** Documents were drafted in different contexts and periods. Differences in writing traditions may account for more or less emphasis on certain topics and in expressing country context. The 14 policies make up a fairly substantial sample of medicines policies in the region of the Americas. We propose that the instrument developed to analyze NMP was effective in revealing updating requirements for a new region-focused NMP guideline.

**Funding source:** PAHO

690

**Access***Keywords:* Drug & Therapeutics Committees, DTC, antimicrobial resistance, AMR, rational medicine use**Drug and Therapeutics Committees in Africa and Asia: From Training to Implementation****Terry Green<sup>1</sup>, Mohan P. Joshi<sup>1</sup>, Niranjan Konduri<sup>1</sup>, Kathy Holloway<sup>2</sup>**<sup>1</sup>Strengthening Pharmaceutical Systems (SPS) Program, Management Sciences for Health (MSH), Arlington, VA, USA;<sup>2</sup>World Health Organization, SEARO, New Delhi, India

**Problem statement:** The World Health Organization (WHO) and ICIUM recommend the establishment of drug and therapeutics committees (DTCs) to improve medicine use and contain antimicrobial resistance. However, many low-resource countries lack DTCs or face challenges to manage them efficiently.

**Objective:** To show how in-country stakeholders can be capacitated to implement DTCs and how DTCs can implement medicine use activities in low-resource countries

**Setting and population:** Pharmacists, physicians, nurses, hospital managers, and policy-makers in hospitals in low-resource countries in Africa and Asia

**Interventions:** Since 2001, MSH's SPS Program and its predecessor, RPM Plus, collaborated with ministries of health (MoH), WHO, and other in-country organizations to conduct DTC training courses, including training of trainers, for 945 participants from 70 countries. After the trainings, SPS/RPM Plus provided follow-up technical assistance to implement DTC activities in the participants' respective settings.

**Outcome measures:** Number of DTCs established and number of DTC-led activities that contribute to improving the use of medicine and cost savings

**Results:** Data show DTC course participants have developed and implemented 209 DTCs. These DTCs developed 49 hospital formularies, 23 standard treatment guidelines, and 13 adverse medicine reaction reporting systems. They conducted 35 medicine use studies, 21 medicine use evaluations, 17 training programs on rational medicine use, and 57 DTC trainings provided by participants. Specific results include a DTC in a large private hospital in Nairobi reducing the use of three injection products, saving \$4,091 over six months and deleting 20 pediatric cough and cold medicines from the formulary. Based on a medicine use evaluation, another DTC established a protocol for cesarean section antibiotic prophylaxis that is projected to save the hospital \$23,970 a year. In China, a course participant collaborated with the MoH to organize three regional DTC courses resulting in a pool of trainers. In one hospital, prescription review by clinical pharmacists decreased major prescription errors and irrational use. As a result of advocacy and local

evidence, MoHs in Afghanistan, Ethiopia, and Rwanda have institutionalized DTCs by including them in guidelines or policies.

Conclusions: In-country stakeholders in resource-limited countries have made progress in establishing DTCs and implementation of interventions to improve the use of medicines, including antimicrobials. Although initial trainings are important to help jump-start the process, ongoing technical support is critical to ensure continuing motivation and effective implementation.

Funding sources: MSH/SPS and RPM Plus through US Agency for International Development, WHO

691

#### Access

*Keywords:* prescribing, primary health care, generic drugs, safety

### Attitudes, Beliefs, and Prescription Habits of Greek Physicians Regarding Generic Drugs

**Eleni Jelastopulu<sup>1</sup>, Georgios Mantzouranis<sup>1,2</sup>, Christina Androutsopoulou<sup>1</sup>, Ioannis Lentzas<sup>3</sup>, Dimitris Lianas<sup>4</sup>, Charalambia Sampazioti<sup>5</sup>, Zoi Kontou<sup>2</sup>, Zafiro Tsantoula<sup>6</sup>, Georgios Tsiros<sup>1,7</sup>**

<sup>1</sup>University of Patras, School of Medicine, Greece; <sup>2</sup>Rural Medical Dispensary of Evinochori, Health Center of Aitoliko, Greece; <sup>3</sup>Rural Medical Dispensary of Andravida, Health Center of Gastouni, Greece; <sup>4</sup>Health Center of Erymanthia, Greece; <sup>5</sup>Rural Medical Dispensary of Kalanos, Health Center of Chalandritsa, Greece; <sup>6</sup>Department of Radiology, Patras University Hospital, Greece; <sup>7</sup>Rural Medical Dispensary of Chavari, Health Center of Gastouni, Greece

Problem statement: During the last decade, a remarkable entry of generic drugs to the market of prescription medicines has been observed in many countries of the world. However, Greece's highly developed pharmaceutical market is characterized by low penetration of generic drugs.

Objectives: Investigate the attitudes, beliefs, and prescription habits of Greek physicians toward generic drugs.

Design: Questionnaire-based, cross-sectional descriptive study

Setting: The study was conducted at the regional level, including several prefectures of Greece. It was based in primary care facilities, such as rural health centers and medical dispensaries as well as in urban health care facilities, both primary and hospital care. Both public and private sectors were examined.

Study population: A questionnaire of 25 questions was distributed to 210 randomly selected physicians of all specialties working in various health care facilities in several regions.

Outcome measures: Measurements referred to the prescription habits of Greek physicians regarding generics according to gender, age, specialty, health care facility, and work place. Furthermore, knowledge and beliefs related to safety, effectiveness, side effects, and bioequivalence were recorded as well as the impact of their scientific prestige when prescribing generics.

Results: Out of 185 physicians, 41.6% were specialized and 58.4% were doctors-in-training. The majority (47%) was working in university hospitals, 25% in district hospitals, 18% in public primary care facilities, and 10% in the private sector. Of the doctors, 23% declared that they never prescribed generic drugs, whereas 55% reported the percentage of generics prescribed was < 10% of their total prescriptions. Mainly women prescribe generics less frequently (48% vs. 64%,  $p = 0.006$ ). General practitioners are more likely to prescribe generics than other specialties (60% vs. 38%,  $p = 0.004$ ). Of the doctors, 44% consider generics to be of the same effectiveness and safety as brand name drugs. However, a significant difference between specialized and physicians-in-training is observed regarding the effectiveness and the safety ( $p < 0.05$ ). More side effects of generics are observed by GPs in comparison to other specialties (47% vs. 28%,  $p < 0.05$ ). More than 50% consider the prescription of generics as having a negative effect on their scientific prestige, mainly doctor-in-training compared with the specialists (64% vs. 40%).

Conclusions: A high percentage of Greek physicians do not prescribe and hold negative views of generics. They believe that generics are less effective and safe. Information about the safety and effectiveness of generic drugs may be particularly important information to convey to physicians to encourage them in prescribing generic drugs.

Funding sources: none

694

#### Drug Resistance

*Keywords:* Antimicrobial resistance, population-based survey, household survey, questionnaire, antimicrobial

### Indicator-Based Survey Tool to Determine the Use of Antimicrobials and Knowledge about Drug Resistance in the Community

**Mohan P. Joshi<sup>1</sup>, Ani Hyslop<sup>2</sup>, Luis Ochoa<sup>2</sup>, Adrienne Cox<sup>2</sup>, Niranjana Konduri<sup>1</sup>, Nchimunya Nkombo<sup>3</sup>, Oliver Hazemba<sup>4</sup>**

<sup>1</sup>Strengthening Pharmaceutical Systems (SPS) Program, Management Sciences for Health (MSH), Arlington, VA, USA; <sup>2</sup>ICF Macro, Calverton, MD, USA (LO is a former employee); <sup>3</sup>Central Statistical Office, Lusaka, Zambia; <sup>4</sup>MSH/SPS, Lusaka, Zambia

Problem statement: Designing and evaluating effective consumer-focused, drug-resistance interventions requires quantifying the community's awareness of drug resistance and knowledge and use of antimicrobials. However, survey tools that can help make such quantifications possible and are suitable for resource-constrained settings do not exist.

Objective: The field test's objective was to validate an antimicrobial resistance (AMR) survey tool to quantify drug-resistance knowledge and antimicrobial use in the community.

**Setting and population:** The module was field-tested in Zambia in a convenience sample of 242 urban and rural households.

**Interventions:** Initially, we designed a questionnaire module to incorporate into a population-based survey and obtained AMR expert review. To validate the draft questionnaire module, we field-tested it in collaboration with the Central Statistical Office (CSO) of Zambia; nurses, pharmacists, and CSO survey and senior research staff acted as interviewers. The English AMR module was translated into three local languages—Nyanja, Bemba, and Tonga. The accuracy of the local translation and the adaptation of the questions were verified through a mini-test in 20 households in Lusaka. The field test was conducted in urban and rural areas of Lusaka. We held a structured feedback session with the interviewers to elicit their observations and experiences in implementing each component of the questionnaire. Based on the field-test experience, we finalized the module.

**Outcome measures:** Validated AMR module for population-based surveys available for global use

**Results:** The field test allowed validation, revision, and finalization of the module and the data collectors' guide. The AMR tool consists of a module description (including the indicators), tabulation plan, questionnaire module, data collectors' guide, and pretest of the module in Zambia. The questionnaire has a total of 24 questions and takes about 15 minutes to administer. The questionnaire items provide quantitative information on 10 indicators pertaining to antimicrobial medicine knowledge and use; AMR knowledge; and current use of medicines. The finalized AMR module is now available for country-level use on the Demographic and Health Survey website ([http://www.measuredhs.com/aboutsurveys/dhs/docs/AMR\\_Mod\\_8\\_5\\_8\\_FINAL.pdf](http://www.measuredhs.com/aboutsurveys/dhs/docs/AMR_Mod_8_5_8_FINAL.pdf)).

**Conclusions:** The AMR module fills the need for a population-based survey tool suitable for use in resource-constrained countries. Surveys using the module will generate household-level knowledge and behavior information, which can support advocacy, policy establishment, intervention development, and evaluation of AMR containment efforts among the general community.

**Funding sources:** MSH/Rational Pharmaceutical Management Plus and SPS through US Agency for International Development

695

### Drug Resistance

*Keywords:* clinical guidelines, antimicrobials, drug and therapeutics committee

## Steady Persistence While Chasing the Elusive: When Guidelines and Policies for Antimicrobial Use Clash with the 800-Pound Gorilla

Gerald Yonga<sup>1</sup>, Sital Shah<sup>1</sup>, Niranjana Konduri<sup>2</sup>

<sup>1</sup>Aga Khan University Hospital, Kenya; <sup>2</sup>Management Sciences for Health, United States of America

**Problem statement:** The 2001 WHO Global Strategy for Antimicrobial Resistance highlighted key interventions reinforced by proceedings from the 2004 ICIUM conference. Experience from the Aga Khan University Hospital's Drug and Therapeutics Committee (DTC) show mixed progress in implementing policies due to complex system-related challenges. Foremost, 465 private doctors refer patients to the hospital and continue to treat them there compared with the 190 hospital-employee doctors.

**Objectives:** To correlate antimicrobial policies and multifaceted interventions with trends in antimicrobial consumption

**Setting:** 270-bed private hospital in Nairobi, Kenya

**Study population:** Convenience sample of physicians

**Intervention:** The DTC established a multidisciplinary antimicrobial subcommittee in February 2006. After much negotiation with outside private physicians, the DTC launched several interventions. First, the hospital's proposed antibiotic treatment guidelines went through a one year (November 2006–October 2007) revision process with a diverse group of physicians, especially those from the private sector, to promote ownership. Second, the hospital implemented an antimicrobial order sheet that restricted the use of meropenem and 6 other antimicrobials. Third, 6 hospital department heads who were designated champions of antimicrobial policy with support from an infectious disease physician organized a series of 10 educational sessions on specific antibiotic guidelines over 10 months in 2006–2007. Rotation of antimicrobials, uptake of in-house microbiology services, and access to prescribing information was widely promoted in the hospital. From 2008–2010, each department head organized peer feedback to improve antimicrobial prescribing in addition to conducting an average of 3 annual educational sessions.

**Outcomes measured:** Percentages of medicine use indicators

**Results:** In 2006, the hospital experienced a 62% decrease in consumption of meropenem compared to 2005 as a result of periodic education and guideline implementation. However, in 2007, there was a slight increase in consumption (22%) compared to 2006; a dramatic 106% increase in consumption in 2009 compared to 2008; and a 49% increase in 2010. Overall antimicrobial consumption remained at high levels in 2005–2010 with an average of 8 antimicrobials (range of 7 to 10) appearing in the list of 20 most-used medications, representing an average of 16.2% of the medicines budget (range = 9.26–25.77%). Audit data of 8,390 antimicrobial order sheets for the first 3 quarters in 2010 revealed poor compliance with documenting the patient's weight (24%), height (11%), and creatinine levels (1%).

**Conclusions:** Irrational use of antimicrobials remains a challenge despite multifaceted interventions. Managing patient referrals by outside private physicians requires a unique strategy.

**Funding sources:** Institutional

696

### Chronic Care

*Keywords:* appropriate use; prescribing; drug selection; hypoglycemic agents; education; type 2 diabetes; chronic disease

#### **Evaluation of a Continuing Medical Education Program for Primary Care Services in the Hypoglycemic Agent's Prescription in Diabetes Mellitus Type 2**

**Angelica Castro-Ríos<sup>1</sup>, Hortensia Reyes-Morales<sup>2</sup>, Ricardo Perez-Cuevas<sup>1</sup>**

<sup>1</sup>Mexican Institute of Social Security, Mexico; <sup>2</sup>National Institute of Public Health, Mexico

**Problem statement:** The organizational conditions and the lack of utilization of evidence-based clinical recommendations affect the potential effectiveness of treatments for diabetes. In Mexico, only 21% of public primary care physicians provide proper care to diabetic patients.

**Objectives:** To evaluate in primary care clinics the impact of a continuing medical education intervention in the prescription of hypoglycemic drugs.

**Design:** We conducted an observational study with 2 control/intervention groups with before and after periods. The groups correspond to patients treated in primary care clinics; the design matched the clinics geographically, by infrastructure and annual budget. The unit of analysis was the drug prescription of each visit.

**Setting:** The study took place in 4 primary care clinics belonging to the Mexican Institute of Social Security.

**Study population:** Patients with less than 10 years with type 2 diabetes diagnosis were included. Regarding the clinical homogeneity of the sample, patients with chronic complications of diabetes were excluded. The patients' selection was a nonrandom sample by quotes with proportional distribution by primary care room. The sample size was 431 participants in each group using the formula for difference of proportions; assuming confidence of 95%, proportion of proper prescription 20%; effect of the program 10%; and non-response 10%.

**Intervention:** The intervention included two phases; the first one consisted of training physicians from the referral hospital as clinical instructors. The second phase consisted of training family physicians through sequential activities performed with the clinical instructor. An evidence-based clinical guideline was previously designed and served as the groundwork for the intervention.

**Outcome measure:** The outcome variable was the proportion of patients with proper hypoglycemic prescription. Two criteria served to evaluate the prescription: the selection of the drug and the indication of dose and interval. Three logistic regression models and the double differences technique were applied to determine the impact of the intervention on the improvement of each prescription criteria and the general prescription.

**Results:** The information of 2,116 visits relative to 824 patients served for the analysis. The intervention increased the probability of proper selection of the hypoglycemic drug by 78% [OR = 1.78 (95% CI, 1.1-2.9)] and the probability of proper prescription in patients with obesity by 185% [OR = 2.85 (95% CI, 1.8-4.4)]. These results were equivalent to an increase of 11% on the proportion of patients with proper selection of the drug and 0.6% on the proportion of patients with proper prescription (selection and indication).

**Conclusions:** The continuing medical education intervention for primary care services increased the proportion of proper prescription of hypoglycemic agents.

**Funding source:** Information not provided

697

### Access

*Keywords:* access to medicines, affordability, dispensing, indicators

#### **Access to and Use of Medicines by Households in Armenia: Impact of Current Policy on Reimbursement of Medicines**

**Irina Kazaryan (Ghazaryan)<sup>1</sup>, Anahit Sevikyan<sup>1</sup>, Lusine Vardanyan<sup>1</sup>, Anahit Amirkhanyan<sup>2</sup>, Margarita Melikyan<sup>2</sup>**

<sup>1</sup>National Institute of Health, Armenia; <sup>2</sup>Drug Utilization Research Group PO, Armenia

**Problem statement:** Access to medicines remains a serious challenge in Armenia. To improve the situation, the Government approved a decree covering a policy on reimbursement of medicines, and the Ministry of Health introduced a mechanism for implementation. The impact of this policy is insufficient; however, it has not been studied and evaluated. Because changing the current policy is being considered, previous experience in pharmaceutical reimbursement needs to be assessed.

**Objectives:** To evaluate access to and use of medicines by households in Armenia as well as to identify the impact of the policy on medicines reimbursement

**Design:** Policy evaluation, household survey

**Setting:** The survey was implemented in all 11 regions including Yerevan, the capital of Armenia.

**Study population:** Members of households who are the main health care decision makers in 864 randomly selected households.

**Policy:** According to the approved decree, patients from socially vulnerable groups (invalids of first and second groups, children under 7, etc.) are eligible to receive medicines free of charge or with a certain discount; patients with some diseases can receive medicines only for treating this disease (mental diseases, cancer, etc).

Outcome measure(s): The set of indicators was developed using a draft of the WHO household manual. Specific indicators were used to identify the impact of policy on medicines reimbursement as well as to assess issues related to labeling, medicines dispensing, disposal of medicine, and so forth.

Results: Analysis showed that about half of respondents believe that they usually can afford to buy medicines they need. More than 90% of all medicines for treating acute and chronically ill patients were bought out-of-pocket. Patients with certain diseases who are eligible to get pharmaceuticals free of charge according to the Government decree received without payment only 23.0% of medicines used. These were mainly insulin and pharmaceuticals for treating epilepsy. The majority of households having patients with periodical disease and diabetes bought medicines out-of-pocket. For chronically ill patients, 4.8% did not receive any medicine; 67.9% of all prescription medicines, including antibiotics, purchased for chronically ill patients were obtained without prescription; 39.2% of medicines for patients with acute diseases were prescribed by physician; 18.2% were self-administered; 42.7% of all medicines used were from the Armenian Essential Medicines List. The top 3 medicines available at home were paracetamol, tincture of Valeriana, and acetylsalicylic acid.

Conclusions: The current reimbursement policy is poorly implemented and the majority of eligible patients still buy medicines out-of-pocket. Additional study to identify the reasons would be useful. Also, patients from some vulnerable groups, in particular, very poor households cannot purchase the pharmaceuticals they need, but are not eligible for free medicines. Policy recommendations were developed and will be presented to the Ministry of Health.

Funding source(s): None

## 699

### Drug Resistance

Keywords: Antimicrobial resistance, drug resistance, AMR, Ethiopia, Zambia

### Capacity-Building for Country and Regional Level Advocacy and Interventions to Contain Antimicrobial Resistance in Africa

**Mohan P. Joshi<sup>1</sup>, Terry Green<sup>1</sup>, Oliver Hazemba<sup>2</sup>, Rosalind Kirika<sup>3</sup>, Tenaw Andualem<sup>4</sup>, Wonder Goredema<sup>1</sup>, Gabriel Daniel<sup>1</sup>, Negussu Mekonnen<sup>4</sup>**

<sup>1</sup>Strengthening Pharmaceutical Systems (SPS) Program, Management Sciences for Health (MSH), Arlington, VA, USA; <sup>2</sup>MSH/SPS Zambia; <sup>3</sup>MSH/SPS Kenya; <sup>4</sup>MSH/SPS Ethiopia

Problem statement: Antimicrobial resistance (AMR) has made many first-line treatments ineffective. Recent XDR-TB outbreaks highlight the severity of the problem; however, AMR containment activities are insufficient in resource-limited countries because of inadequate local capacity and little advocacy.

Objective: To build country and regional capacity to generate coalitions for AMR advocacy and interventions

Setting: Country-level interventions in Zambia and Ethiopia; regional interventions through two regional bodies—the faith-based Ecumenical Pharmaceutical Network (EPN) located in Kenya and the government-affiliated Regional Pharmaceutical Forum (RPF) located in Tanzania

Interventions: We conducted a rapid appraisal to identify key issues and players affecting AMR and to form a multidisciplinary local champion group. Based on the findings, SPS and its predecessor, RPM Plus, helped initiate the coalition-building process by facilitating advocacy and stakeholder meetings. As a result, Zambian and Ethiopian stakeholders formed country-level AMR working groups—Zambia's was voluntary and Ethiopia's was institutionalized by the Drug Administration and Control Authority. EPN and RPF stakeholders embraced AMR activities as crucial to their existing goal of promoting rational medicine use. These country and regional stakeholders expanded advocacy, coalitions, and actions to support AMR containment.

Outcome measures: AMR advocacy activities and interventions carried out by country and regional stakeholders in Africa

Results: The Zambian and Ethiopian working groups, EPN, and RPF generated widespread advocacy through their AMR call-to-action meetings and documents. The Zambian working group facilitated other in-country stakeholders to revise the national standard treatment guidelines; improve the medicine quality assurance system through document and visual inspection and Minilab testing; increase public awareness of AMR through mass media; and reform the medical curriculum to include AMR topics. The Ethiopian working group catalyzed a national AMR baseline survey, developed intervention plans, and facilitated journalist training, which led to AMR media coverage. Following the initial support from SPS, EPN spearheaded sustained advocacy and actions through its members. For example, participants of a regional EPN–SPS AMR workshop carried out more than 40 AMR-related activities within one year. RPF revised its regional pharmaceutical strategy to include AMR components and advocated for AMR through presentations at high-level meetings.

Conclusions: The Zambia, Ethiopia, EPN, and RPF experiences show that an initial capacity-building step to bring together local stakeholders to a common platform helps them generate a viable, multifaceted response to preserve antimicrobial effectiveness and contain AMR. The capacity-building process also facilitates South–South collaboration.

Funding sources: MSH/RPM Plus and SPS through US Agency for International Development

## 700

### Access

Keywords: access to medicines, rational use, affordability, availability, indicators, health facilities

## Access to Medicines in Guatemala, Honduras, and Nicaragua: The Challenge of Adapting Methodologies

**Nelly Marin<sup>1</sup>, Cecilia Acuña<sup>1</sup>, Adriana Mendoza<sup>1</sup>, Vera Luiza<sup>2</sup>, Emmerick Isabel<sup>2</sup>**

<sup>1</sup>Pan American Health Organization; <sup>2</sup>National School of Public Health/Oswaldo Cruz Foundation, Brazil

**Problem statement:** Equitable access to medicines is one of the greatest challenges in the Americas. The 45<sup>o</sup> Directing Council of PAHO/WHO urged member states to address it as a priority, with emphasis on poor and marginalized populations. A better understanding on access (ATM), quality, and rational use of medicines (RUM) can support policymaking to face problems related to these aspects.

**Objectives:** Describe the pharmaceutical situation in 3 Central American countries and identify the barriers related to ATM and RUM, comparing the pharmaceutical status of the related indicators in each country with the proposed standards.

**Design:** Approach based on the WHO Pharmaceutical Situation Level II package. Additional questions and performance reference were proposed. Each country was a unit of study and results compared among them. Indicators reorganized according to the dimensions of ATM adapted from Penchansky (1981).

**Setting:** Guatemala, Honduras, and Nicaragua

**Study population:** An average of 36 public health care facilities with their respective pharmacies, 5 public warehouses, and 30 private pharmacies were surveyed per country.

**Intervention(s):** Data collected from December 2007 to April 2008; observations were guided by checklists, documents consultation, patient exit interview, and secondary database consultation. Stakeholders of all 3 countries and local PAHO officers were identified and involved in all phases.

**Policy(ies):** Access to medicines

**Outcome measure(s):** Dimensions of ATM: availability, affordability, acceptability, and geographical accessibility

**Results:** The results shown poor ATM in all dimensions—prices are much higher in the private sector than the international reference prices (IRPs); shortages of medicines in both the public and private sectors; geographical access difficulties; no pharmacist in almost half of the pharmacies; high proportion of prescribers without training in RUM. Results were acceptable in regards to adherence to the prescription, prescriptions using generics, and the percentage of medicines dispensed in the public sector. There was a lack of uniformity of international standards and recommendations for comparing results, which made it difficult to qualify the situation in some dimensions, such as availability, IRPs, and percentage of antibiotics prescribed.

**Conclusions:** The comparison of results in these countries was facilitated because of their similarities in geographical area and socioeconomic status. The presentation of the results sensitized the national authorities on the need to review public policies and strengthen public pharmaceutical services, health and economic regulation of medicines, as well as human resources. Based on the results, Nicaragua already decided to review its National Drug Policy, which was started in 1996. Another lesson learned was the need to review the appropriateness of the WHO indicators for measuring different dimensions of ATM and to standardize the criteria and expected performance for indicators.

**Funding sources:** Pan American Health Organization .

## 702

### Drug Resistance

**Keywords:** Antibiotic prescribing, private hospitals, teaching and non-teaching hospitals, inpatients, India

### Antibiotic Prescribing in a Teaching and a Non-Teaching Private, Non-Computerized, Tertiary Care Hospital in Ujjain District, India

**Megha Sharma<sup>1,2</sup>, Surya Prakash Dhaneria<sup>1</sup>, Gaetano Marrone<sup>2</sup>, Cecilia Stålsby Lundborg<sup>2</sup>**

<sup>1</sup>Department of Pharmacology, R D Gardi Medical college, Ujjain, M.P., India; <sup>2</sup>Division of Global Health (IHCAR), Department of Public Health Sciences, Karolinska Institutet, Sweden

**Problem statement:** Antibiotics are drugs used to treat all kinds of infections, but their indiscriminate use leads to bacterial resistance. Hospitals are key places for antibiotic use and thereby places for the spread of resistant bacteria among patients and finally to the community. Extensive use of antibiotics in India has been reported, but limited studies describe antibiotic prescribing in inpatients in the private sector.

**Objective:**The objective of the study was to describe and compare antibiotic prescribing patterns in 2 private hospitals in Ujjain district, India, and to use the results to formulate relevant prescribing guidelines for common infections.

**Design:**A longitudinal, observational study was conducted for 5 months in 2008. The instrument was a form specifically developed for the study. In both non-computerized hospitals, the forms were updated for each patient daily by the nursing staff from the day of admission until discharge. Anatomical Therapeutic Chemical/defined daily dose (DDD) classifications for prescribed antibiotics were used and DDD was calculated per patient per day.

**Setting:**The study was carried out in 2 private, non-computerized, tertiary care hospitals in the Ujjain district, India; 1 was a teaching hospital (TH) and the other was non-teaching (NTH).

**Study population:**All the consecutive inpatients who stayed for at least 1 night in a department of the hospital were included in the study.

**Intervention:**The results of the study are being used to formulate contextualized antibiotic prescribing guidelines for common infections.

Outcome measures: Percentages of patients prescribed antibiotics, adherence to the National List of Essential Medicines (NEDL), percentages of generics prescribed, and groups and types of antibiotics prescribed

Results: A total of 8385 inpatients were admitted during the study period; 3004 in the TH and 5381 in the NTH. From the TH, 82% of inpatients and from the NTH 79%, were prescribed antibiotics. The most commonly prescribed antibiotic groups in the TH were fluoroquinolones and aminoglycosides; in the NTH, third-generation cephalosporins and combinations of antibiotics (not listed by WHO). Parenteral prescribing was more in the NTH (87%) than in the TH (51%,  $p$ -value<0.001). Trade name prescribing was higher in the NTH (96%) compared to the TH (63%,  $p$ -value<0.001). Adherence to NEDL was lower in the NTH (53%) than in the TH (82%,  $p$ -value<0.001).

Conclusions: The study reveals a high rate of antibiotic prescribing in both hospitals. The study also shows lower adherence to NEDL and extensive use of higher groups and newer combinations of antibiotics in the NTH. The high percentages of trade names prescribed in both hospitals may be due to the influence of pharmaceutical industries. There is an urgent need to develop and implement relevant prescribing guidelines along with a similar longitudinal study.

Funding source: Swedish Research Council; MS received the Erasmus Mundus Scholarship

### 703

#### Child Health

*Keywords:* appropriate use, prescribing, consumers, patient safety, pediatric medicine

#### **Irrational Prescribing Pattern for Children with Upper Respiratory Tract Infection (URTI) in Indonesia**

**Purnamawati Pudjiarto, Yulianto Santoso Kurniawan, Windhi Kresnawati**

Concern and Caring Parent Foundation

Problem statement: Many parents do not have sufficient knowledge in URTI guidelines and rational use of medicine (RUM). Most pediatric URTI consultations are treated with numerous medications.

Objectives: To obtain the prescribing pattern of URTIs in the pediatric population based on prescriptions submitted by parents

Design: Descriptive cross-sectional study; data is collected from prescriptions emailed and posted by parents of under-5 children who suffer from coughs and cold who join sehat@yahoo.com mailing list, the first IT-based approach in promoting RUM in Indonesia. Inclusion criteria is the prescription or a copy from the pharmacy for pediatric under-5 children with cough and cold < 7D.

Setting: The study collected prescriptions from parents in Jakarta and 17 other cities (later will be grouped as other cities) during 2008-2009.

Study population: Total sample is 583 prescriptions

Results: Drugs that are prescribed in pediatric URTI (Jakarta vs. other cities): antibiotics 67.3% vs. 78.4% (mostly cephalosporin-cefadroxil, cefixime); antihistamine 81.5% vs. 75.9%; steroid 58.3% vs. 56.9% (mostly branded triamnicolone); mucolytic/expectorant 61.5% vs. 69.1%; bronchodilator 57.5% vs. 51.4%; decongestant 48.8% vs. 47.2%; antipyretic 40.7% vs. 40.5%; antitussive 21.6% vs. 27.4%; supplement 39% vs. 35%; anticonvulsant 24.2% vs. 12.2%. Average number of drugs in URTI prescription is 5 vs. 5; average number of active substances in prescription is 6 vs. 6. Average URTI prescription cost is IDR 137.573 vs. 112.512. Generic use in URTI prescription 28.3% vs. 16.25%. Compounding drug preparation 91.9% vs. 88.6%.

Conclusions: Promoting RUM through active interaction in a health-based mailing list can be used as a new approach in raising community awareness. Patients as health consumers can participate in promoting RUM through such prescription pattern study. This study shows a high prescription rate of unnecessary and off-label use of medicines such as antibiotics, antihistamines, steroids, mucolytics/expectorants, bronchodilators, and compounded drug preparations; use of these should be discouraged until the safety profiles are known. These prescribing practices strongly suggested noncompliance with the URTI guideline. This study also shows that this polypharmacy prescribing occurs not only in big cities, but is also common in smaller cities. Both the low-rate use of generic drugs and the high-cost prescription (7.05% in Jakarta vs. 5.76% in other cities of GNI per capita annually) should alert health agencies, health institutions, and health professional organizations to reevaluate medicine use and health system audit policy. This finding should be followed up by a large prospective study to detect related factors influencing this prescription pattern. Integrated intervention to ensure RUM should be done to prevent antibiotic resistance, risks of adverse drug reactions, and costly health care.

Funding sources: Concern & Caring Parent Foundation

### 704

#### Malaria

*Keywords:* Retail market, antimalarials, medicine prices, affordability, access to medicines

#### **Retail Drug Market and the Price of Malaria Medicines in Enugu Urban, Southeast Nigeria: Implications for Affordability and Access to Artemisinin-Based Combination Therapy**

**Charles C Ezenduka**

Health Policy Research Group, University of Nigeria Enugu Campus

Problem statement: The majority of malaria services are provided through retail outlets in developing countries, yet limited information exists on the characteristics of the local market and its impact on the price, availability, and affordability of malaria medicines.

**Objectives:** Investigate the retail market to determine the influence on prices and affordability of malaria medicines in relation to the goals of malaria control measures and the use of ACTs and identify opportunities for improved coverage and access to quality malaria medicines

**Design:** Economic analysis; the study combined qualitative and quantitative methods, using an economic framework of structure-conduct-performance to explore the relationship between the local drug market and price and affordability of malaria medicines

**Setting:** Enugu urban, targeting retail drug outlets comprising private pharmacies and patent medicine vendors

**Study population:** Seven categories of antimalarials were surveyed in a sample of 50 out of 384 retail outlets. A stratified random sampling technique was adopted to survey the outlets by type and location. Data were collected by structured interviews, in-depth interviews, and retail audits from both the private and public sectors.

**Outcome measures:** Malaria drugs prices, availability, affordability

**Results:** The local market showed low concentration for malaria medicines comprising a wide range of products with variable and competitive prices. High competition reduced the contribution of mark-up to about 17% of final prices, making procurement costs the most important factor contributing over 75% of the final price of malaria medicines. Market segmentation was minimal with prices of antimalarials ranging from \$0.2 to \$7.68 per adult oral dose. ACTs were the most expensive antimalarials with a median price of \$3.80 (\$2–7.68) in a country where over 50% of the population lives below \$1 a day, making them unaffordable for the majority of the low-income population. High prices were most likely to reduce the proportion of patients seeking care. The market is highly influenced by a large informal segment lacking in government regulation with implications for provision of quality malaria treatment.

**Conclusions:** Findings suggest measures to reduce procurement costs and enhance competition, such as government involvement in commercial distribution of medicines as currently implemented in the public sector with reduced costs of medicines. Expansion into the private sector could be achieved through enhanced public-private partnership to reduce costs through subsidy and improve access to malaria medicines. Introduction of other financing mechanisms such as a social/community health insurance system is also a popular option. Regular monitoring and effective regulation are key to achieving quality malaria treatment.

**Funding source:** Information not provided

## 705

### Chronic Care

*Keywords:* Chronic heart failure, Pharmacotherapy, Guideline adherence, Clinical outcome

### **Clinical Impact of Adherence to Pharmacotherapeutic Guidelines on the Outcome in Patients with Chronic Heart Failure**

**Suntheep Batra<sup>1</sup>, Surarong Chinwong<sup>2</sup>**

<sup>1</sup>Faculty of Pharmacy, Payap university, Thailand; <sup>2</sup>Faculty of Pharmacy, Chiangmai university, Thailand

**Problem statement:** There is robust evidence for effective pharmacotherapy of chronic heart failure (CHF) which has been integrated into the guidelines, but many surveys have shown a suboptimal utilization of recommended medications. Furthermore, the impact of guidelines adherence on clinical outcomes has never been evaluated in Thailand.

**Objectives:** Investigate the impact of adherence to CHF guidelines on the rate of cardiac events

**Design:** Retrospective cohort observational study

**Setting:** Nakornping Hospital (tertiary care, provincial hospital, public sector)

**Study population:** 331 consecutive CHF patients (mean age 68.7; 49.8% males; New York Heart Association I: 16.0%, II: 42.9%, III: 29.0%, and IV: 12.1%) who were admitted to Nakornping Hospital between October 2005 and December 2007 for HF exacerbation were enrolled; patients who were provided health services or HF medications from any other health care facility, contraindicated for all 4 major HF medications (ACEIs, ARBs, beta-blockers, and aldosterone antagonists), or have valvular heart disease were excluded. The guidelines adherence was assessed after hospital discharge for at least 3 months by calculating a guideline adherence indicator (GAI-3, range 0-100%) based on prescription of ACEIs/ARBs, beta-blockers, and aldosterone antagonists

**Outcome measure:** Cardiac events (composite endpoint of CHF hospitalization or cardiovascular death) were followed-up until June 30, 2009. Survival was analyzed with the Kaplan-Meier method, log-rank test, and Cox regression analysis.

**Results:** Adherence to guidelines for ACEIs, ARBs, ACEIs/ARBs, beta-blockers, aldosterone antagonists, and diuretics was 67.5%, 100.0%, 71.6%, 41.8%, 76.4%, and 100.0%, respectively. The median GAI-3 was 50.0%. High, medium, and low cardiac event rates in GAI-3 categories were 47.4, 67.5, and 97.1 per 100 person-years, respectively. High GAI-3 significantly delayed time to cardiac events compared with medium and low GAI-3 (20.3 vs. 10.6 vs. 4.9 months, respectively,  $P = 0.004$ ). In multivariable analysis, patients with medium and high GAI-3 had markedly lower cardiac event risks than patients with low GAI-3 (medium GAI-3: HR 0.21; 95%CI:0.10-0.44,  $P < 0.001$  and high GAI-3: HR 0.16; 95%CI:0.03-0.97,  $P = 0.047$ ).

**Conclusions:** The present study has demonstrated that adherence to pharmacotherapeutic guidelines for CHF was a significant predictor of fewer cardiac events in clinical practice in Thailand. This information will be useful for guiding and raising the awareness of physicians in practice for the treatment of CHF and will also lead to decreased re-hospitalization and death of patients.

**Funding source:** Faculty of Pharmacy, Chiangmai University

706

**Economics, Financing, and Insurance Systems***Keywords:* access to medicines, affordability, availability, generic (multisource) medicines, medicine prices**Medicine Prices and Availability in Southern Brazil****Andréa Dâmaso Bertoldi<sup>1</sup>, Ana Paula Helfer<sup>2</sup>, Aline Lins Camargo<sup>3</sup>, Noemia U L Tavares<sup>4</sup>, Panos Kanavos<sup>5</sup>**<sup>1</sup>Universidade Federal de Pelotas, Brazil; <sup>2</sup>Universidade do Vale do Rio dos Sinos, Brazil; <sup>3</sup>Universidade Federal de Ciências da Saúde de Porto Alegre, Brazil; <sup>4</sup>Universidade da Região da Campanha, Brazil; <sup>5</sup>The London School of Economics and Political Sciences, UK

**Problem statement:** Although in theory, the Brazilian health system (SUS) should be able to provide essential medicines for free to the entire population, medicines are often not available when needed. If medicines are not available in public sector facilities, patients purchase them out-of-pocket in the private market, which may also lead to excessive out-of-pocket spending. The availability of medicines, particularly in the public sector, and their prices in the private sector are important determinants of access to medicines.

**Objectives:** To evaluate medicine prices in private pharmacies and availability in the public and private sectors, considering the differences across 3 types of medicines available in the Brazilian market (originator brands, generics, and similar medicines)

**Design:** Descriptive study, using a HAI/WHO standardized methodology

**Setting:** The current study was drawn in the South region of Brazil, which is one of 5 geographical regions of the country. It includes 6 cities in the state of Rio Grande do Sul, which has a total population of 10.5 million inhabitants, representing 5.7% of the country's total population. Data were collected from the beginning of November 2008 to the end of January 2009.

**Study population:** In each of the 6 cities, 4 public sector facilities with pharmacies were randomly selected (n = 22). The only exception was São Leopoldo, where only 2 health facilities dispensed medicines; 5 private pharmacies per city were also selected (n = 30).

**Outcome measure(s):** Prices and availability of 50 medicines were investigated. Of these, 29 medicines were part of the WHO/HAI global and regional core lists whereas the remainder (supplementary list) were selected from the Brazilian national and municipal lists of essential medicines. For each selected medicine, data for the following variables were obtained: availability at each sampled outlet, patient price for the originator brand, the lowest-price generic, and the lowest-price, similar medicine. Availability was defined as the proportion of pharmacies in which the medicines were available at the time of the survey. Prices were presented as median price ratios (MPR). The MPR is the ratio of a medicine's median price divided by the median international reference price. The 3 types of medicines evaluated are originator brands, generics (unbranded medicines interchangeable with the originator brand), and similar medicines (all the other medicines available in the market).

**Results:** In the private sector, prices were 8.6 MPR for similar medicines, 11.3 MPR for generics, and 18.7 MPR for originator brands. Mean availability was 65%, 74%, and 48% for originator brands, generics, and similar medicines, respectively. The mean overall availability in the public sector ranged from 68.8% to 81.7%; mean availability of similar medicines was 2-7 times higher than that of generics.

**Conclusions:** This analysis finds that availability of medicines in the public sector does not meet the challenge for supplying essential medicines to the entire population, as stated in the Brazilian constitution. Policies targeted to reduce the prices of generics need to be implemented in Brazil, as well as making generics more widely available.

**Funding source:** This project was supported by a grant from the Brazilian Conselho Nacional de Pesquisa e Desenvolvimento – CNP and is a product of the post-doctoral internship of the first author at the London School of Economics and Political Science – LSE Health, funded by the Brazilian Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – CAPES.

708

**Child Health***Keywords:* pneumonia, amoxicillin, IMCI, effectiveness, safety.**Assessment of the Effectiveness and Safety of Outpatient Treatment of Severe Pneumonia Among Egyptian Children with Oral Amoxicillin****Hesham Ahmed Fathey Mohamed El-Sayed<sup>1</sup>, Narendra Arora<sup>2</sup>, Ahmed El-Gohary<sup>1</sup>**<sup>1</sup>Faculty of Medicine, Suez Canal University, Egypt; <sup>2</sup>INCLIN Trust, New Delhi, India

**Problem statement:** Pneumonia is an important cause of morbidity and mortality in young children in developing countries. Although a recent RCT-demonstrated, home-based treatment of WHO-defined severe pneumonia with oral amoxicillin was equivalent to hospital-based therapy and parenteral antibiotics, it may have had limited generalizability. We sought to determine if home-based treatment had similar rates of treatment failure and safety

**Objectives:** To assess the effectiveness and safety of home-based, 5-day treatment with oral amoxicillin for curing severe pneumonia in children

**Design:** A single-arm, cohort prospective intervention study

**Setting:** Outpatient clinics of 7 primary health centers in Isamilia governorate, Egypt

Participants: 237 children aged 3-59 months, with a mean age of  $12.42 \pm 10.05$  months

Intervention: Oral amoxicillin was provided in a total dose of 80-90 mg/kg/day for 5 days in 12-hourly doses

Main outcome measurement: Treatment failure defined as clinical deterioration occurring at any time after enrollment, inability to take oral medication due to persistent vomiting, or change or addition of antibiotics for any reason. Patients lost to follow-up and hospitalized patients were considered treatment failures. Treatment failure was assessed on days 6 and relapse on day 14.

Results: Clinical cure rate with 5 days of amoxicillin therapy at day 6 was 90.7%; 3 patients were lost to follow up (1.3%), 3 patients were hospitalized (1.3%), and there were no deaths. No difference was observed between cured or failed, treated patients on antibiotics before therapy identified by urine antibacterial activity test. Adverse effects occurred in 14 treated children (5.9%) in the form of mild diarrhea with vomiting and diarrhea in one patient. There were 8 relapses (3.4%) at day 14. Clinical failure was associated with rapid respiratory rate ( $> 50/\text{minute}$ ) ( $p < 0.0000$ ) and with low body weight ( $p < 0.01$ ).

Conclusion: Oral amoxicillin is effective and safe in treating severe pneumonia in children in ambulatory setting, when given for 5 days in a dose of 80-90 mg/kg/day in 2 divided doses. Minor adverse effects occurred in small proportion of treated patients and did not affect cure rate.

Recommendations: We recommend a 5-day course of amoxicillin for treating children with severe pneumonia in an ambulatory setting, because it was effective and safe in this community-based study. These findings, if proved to be compatible with findings presented in other centers, could have global implications for a cost-effective management of childhood pneumonia.

Funding source: INCLIN-Inc/JHU through USAID grant No. GHS-A-00-03-0020-00

**709**

#### **Child Health**

*Keywords:* acute diarrhea, zinc, ORS, therapy, effectiveness.

### **Effectiveness of Oral Zinc Supplementation in the Treatment of Acute, Watery Diarrhea**

---

**Hesham Ahmed Fathey Mohamed El-Sayed, Abdul-Majeed Ahmed, Suzan Gad**

Faculty of Medicine, Suez Canal University, Egypt

Problem statement: Oral rehydration solution (ORS) has been successfully used around the world and has been responsible for reduction of diarrheal deaths in the last 2 decades. In spite of the success of ORS in prevention of dehydration, there is still a demand for medicines that will reduce the duration and severity of diarrhea. Consequently, many cases are treated with antibiotics and other medicines. Zinc has been shown to be efficacious in reducing the duration of diarrhea and associated mortality.

Objective: To determine the effectiveness of oral zinc supplementation with locally developed, culturally specific educational messages in the treatment of acute watery diarrhea; to assess adherence to zinc therapy, the impact of zinc therapy on the duration of diarrheal episodes, the use of ORS, and the usage of antibiotics and/or "antidiarrheal" medicines

Design: Randomized, controlled effectiveness trial

Setting: Four primary health centers in Ismailia governorate, Egypt

Participants: 412 children aged 2-60 months were enrolled in the study; 222 children received zinc therapy and 190 were controls. Mean age of the recruited children was  $16.9 \pm 12.5$  months

Methodology: Children with diarrhea in the intervention group were treated with zinc sulfate (20 mg/day once daily for 14 days) and ORS, while children in the control group were treated with ORS alone. The primary outcome measurements were the duration of diarrheal episodes, acceptability of zinc by the treated children, ORS use, and the use of antibiotics or "antidiarrheal" medications.

Results: The study showed high adherence to zinc therapy, as 73% of the children consumed more than 80% of the zinc effervescent tablets. The results showed that zinc supplementation caused significant reduction in the duration of diarrheal episodes of about 24% in the zinc-treated group. The study also showed significant reduction in the use of antidiarrheals and/or antibiotics use rate in the zinc study group compared to controls (7.7% vs. 20.6%). Frequency of ORS use during diarrheal episodes was the same in the 2 study groups.

Conclusions: Oral zinc supplementation, in under-5 children suffering from acute watery diarrhea, is efficacious in reducing the duration of diarrheal episodes and in reducing the misuse of "antidiarrheals" and antibiotics, with no decrease in the frequency of ORS use. Children showed good adherence and acceptance to zinc therapy without considerable side effects.

Funding source: USAID-CHR, Washington (via INCLIN Trust) and Johns Hopkins University

**711**

#### **Policy, Regulation, and Governance**

*Keywords:* Monitoring Progress, Transparency, Policy change, Good Governance, Corruption

### **Transparency Monitoring Study: A Rapid Assessment of Transparency in Key Functions of Pharmaceutical Services in 15 Countries**

---

**Rasha Saadi Hamra, Alessandra Ferrario, Maryam Bigdeli, Guitelle Baghdadi-Sabeti**

World Health Organization/Alliance for Health Policy and Systems Research, Lebanon

**Problem statement:** WHO launched Good Governance for Medicine program with goal to contribute to health system strengthening and prevent corruption by promoting good governance: 26 countries joined since 2004. First step was to conduct a national assessment of level of transparency and potential vulnerability to corruption in pharmaceutical sector. A standardized instrument was designed to measure transparency in 8 functions of medicine chain: registration, licensing, inspection, promotion, clinical trials, selection, procurement and distribution. The assessment provides a baseline for countries to revise, adjust their laws, policies, administrative structures and processes. It measures vulnerability in systems at time of assessment and vulnerability scoring can be used to monitor progress over time.

**Objectives:** Analyze data on transparency for baseline and 2010 status; provide recommendations for improving GGM policies

**Design:** Comparative analysis between baseline transparency indicators with 2010 status. Indicators checklist was developed to collect data for 2010 based on the original Transparency Assessment Instrument indicators.

**Setting:** Public pharmaceutical sector.

**Study population:** All 26 countries that conducted Transparency assessment initially, were asked to participate on voluntary basis and were sent checklist to fill, but some choose not to participate in 2010 analysis for various reasons; not a priority, short time given to fill the checklist, change of focal points. Data were received from 15 countries: Benin, Bolivia, Cameroon, Costa Rica, Indonesia, Jordan, Lao, Lebanon Macedonia, Malaysia, Moldova, Mongolia, Philippine, Thailand, and Zambia.

**Policies:** Initial findings of assessments enabled ministries of health and national regulatory authorities to identify weaknesses and gaps in systems and develop strategies to address them. Current study will show which policies were addressed most and which were given least attention.

**Outcome measures:** Improvement in indicators across the 8 pharmaceutical functions and overall improvement in transparency and vulnerability to corruption of a given function.

**Results:** Improvement in pharmaceutical functions was most seen in selection, procurement and registration. Some improvement was seen in inspection and promotion as well. Improvement in licensing and control of clinical trials cannot be seen since we had complete data for baseline and status only for 3 countries to compare. Countries' efforts to improve good governance consisted in making information publicly available, accountability of committee members, and participation of different stakeholders in various committees. Many pre-existing written documents, procedures and guidelines were made publicly available to increase transparency. Some countries worked on developing detailed terms of reference and guidelines for different committees.

**Conclusions:** Transparency assessment had power to initiate change at different levels and across various functions of the public pharmaceutical sector. Findings of this analysis gave a clear visualization of policy changes in different functions of pharmaceutical systems. The change introduced and documented will lead countries to further acknowledge importance of good governance. Results of this analysis and future ones will help in identifying agendas for policy change and setting realistic priorities for action in the pharmaceutical sector.

**Funding source:** AHPSR-WHO

712

Malaria

*Keywords:* access to medicines, antimalarials, malaria, private sector

### **Evaluating the Impact of Subsidized Artemether-Lumefantrine in the Retail Sector on Coverage of Prompt Effective Treatment of Children Under Five in Kenya - A Cluster Randomized Controlled Trial**

**Beth B. Pamba Kangwana<sup>1</sup>, Sarah V. Kedenge<sup>1</sup>, Abdisalan M. Noor<sup>1,7</sup>, Victor A. Alegana<sup>1</sup>, Andrew J. Nyandigisi<sup>2</sup>, Jayesh Pandit<sup>3</sup>, Mbogo Bunyi<sup>4</sup>, Manya Andrews<sup>5</sup>, Greg W. Fegan<sup>1,7</sup>, Simon Brooker<sup>1,6</sup>, Robert Snow<sup>1,7</sup>, Catherine A. Goodman<sup>1,6</sup>**

<sup>1</sup>KEMRI-Wellcome Trust Research Programme, Kenya; <sup>2</sup>Division of Malaria Control, Kenya; <sup>3</sup>Pharmacy and Poisons Board, Kenya; <sup>4</sup>Population Services International, Kenya; <sup>5</sup>M\*Power Consulting, Kenya; <sup>6</sup>London School of Hygiene and Tropical Medicine, United Kingdom; <sup>7</sup>Centre for Tropical Medicine, Nuffield Department of Clinical Medicine, University of Oxford, CCVTM, Oxford, United Kingdom

**Problem statement:** Despite public sector distribution of the artemisinin-based combination therapy (ACT) artemether-lumefantrine (AL) for the treatment of uncomplicated malaria in Kenya since 2006, access still remains low, with the country being far from achieving the Roll Back Malaria (RBM) target of 80% of malaria cases treated with effective treatment within 24 hours.

**Objective:** To evaluate to what extent the provision of prepackaged, subsidized AL delivered through private sector retailers would improve the coverage of prompt effective antimalarial treatment

**Design:** The evaluation employed a pre-post randomized cluster controlled design with 9 clusters (sub-locations) randomly allocated to each of the intervention and control arms groups. Cross-sectional household surveys were conducted before and 9 months after implementation in 3 randomly selected enumeration areas (EAs) per cluster.

**Setting:** 3 rural districts in Western Kenya which experience high levels of malaria transmission

**Study population:** About 43 homesteads were randomly selected per EA. All household heads and caregivers of children below 5 years resident in the homestead were interviewed.

**Intervention:** The 3 main components of the intervention were subsidized packs of pediatric AL under the brand name Tibamal® provided to retail outlets (drug and general stores), training of retail outlet staff, and community awareness activities. No interventions were implemented in the control sub-locations, and the policy of providing free AL at government facilities continued unchanged in both arms.

**Outcome measure:** The proportion of children under 5 years with fever in the past 2 weeks who began treatment with AL the same or following day of fever onset.

**Results:** Data were collected on 2,749 children aged 3–59 months at baseline and 2,662 at follow-up. On average, 29% of children experienced fever within 2 weeks prior to the interview. At follow-up, the percentage of children receiving AL on the same day of fever development or the following day had risen by 14.6% points in the control arm (from 5.3% [SD: 3.2] to 19.9% [SD: 10.0]) and 40.2% points in the intervention arm (from 4.7% [SD: 3.4] to 44.9% [SD: 11.7]). The percentage of children receiving AL in the intervention arm at follow-up was significantly greater than in the control, with a difference between arms of 25.0% points (95% CI: 14.1, 35.9;  $p = 0.0002$ ). No significant differences were observed between arms in where caregivers sought treatment for their child's fever or in the child's adherence to AL ( $p > 0.05$ ).

**Conclusion:** The pilot demonstrates that subsidizing ACT in the retail sector can significantly increase coverage of prompt effective treatment of malaria in rural areas. The increase in coverage observed in the control area probably reflected improved availability of AL in the public sector, highlighting that ensuring health facility AL stocks is also essential for improving AL access.

**Funding source:** The UK Department for International Development, the United States Agency for International Development and the Wellcome Trust.

713

### Drug Resistance

*Keywords:* antimicrobials, resistance, hospital, prescribing

### Knowledge, Attitudes, and Perceptions on Antimicrobial Resistance and Antibiotic Use Among Hospital Staff in Kenya

**Donna Asimwe Kusemererwa, Anke Meiburg**

Ecumenical Pharmaceutical Network, Kenya

**Problem statement:** Antimicrobial resistance (AMR) is a global problem, however, little is known about the perceptions of health professionals in Africa on the phenomenon and the extent to which it influences their clinical practice.

**Objectives:** To establish the perceptions and beliefs of hospital staff in Kenya on AMR; the perceived drivers of antibiotic use; the possible existence of facility-level practices and interventions that contribute to the development or containment of AMR; and the presence or absence of incentives for such practices/interventions

**Design:** Exploratory descriptive study undertaken in April and May 2010

**Setting and study population:** 125 hospitals in two provinces, Nairobi (41 hospitals) and Nyanza (84 hospitals), formed the study population; 22 hospitals were chosen through purposive convenience sampling with roughly equal numbers of government, private, and faith-based institutions

**Intervention:** Face-to-face interviews were conducted with a clinician, a pharmacy professional (or staff), a laboratory professional, and a representative of accounts/administration in each hospital. The 86 staff interviewed were each nominated by a member of hospital management.

**Results:** 92.6% of interviewees considered AMR a significant national problem but only 63.8% considered it a problem in their hospital; clinicians were consistently more likely to consider AMR a problem than the other professionals interviewed; 80% of the health professionals rated the knowledge and awareness of their professional colleagues in the hospital on AMR as average or lower. Infection control in the hospitals was, in general, perceived as satisfactory and this perception was consistent across professions, regions, and facility types. At least 16 out of 22 hospitals reported having some form of infection control policies and structures in place although written guidelines were only seen in 1 hospital. Culture and sensitivity testing was common (80% of hospitals), but only 1 hospital appeared to have an AMR surveillance system in place. The most important driver of choice for an antibiotic for prescribers was the patient's clinical presentation, and profit for the hospital or clinician were reported as having little influence on choice. Controls on the use of antibiotics were not common, and only 20% of the hospitals reported restricting the prescribing of selected antibiotics to certain groups.

**Conclusion:** The professionals interviewed appear to be aware of the seriousness of AMR as a national-level problem, but far less as a problem at the facility level. In addition, practices known to promote development of resistance are thought not to be common in these hospitals. Future studies may need to go beyond simple interviews to include observational studies on actual practices and resistance trends.

**Funding sources:** CDDEP, SPS/MSH, and ReAct

714

### Malaria

*Keywords:* Keywords: Pharmacovigilance, antimalarials, affordability, malaria, surveillance.

### Pharmacovigilance of Antimalaria Drug Treatment in Enugu State, Nigeria: Community and Health Workers' Perceptions and Suggestions for Reporting Adverse Drug Events

**Miriam Obinwanne Ajuba<sup>1,3</sup>, Benjamin Chudi Uzochukwu<sup>1,2</sup>, Emmanuel Obinna Onwujekwe<sup>1,4</sup>**

<sup>1</sup>Health Policy Research Group, Enugu Nigeria.; <sup>2</sup>Department of Community Medicine, College of Medicine, University of Nigeria Enugu Campus, Nigeria; <sup>3</sup>Department of Community Medicine, Enugu State University Teaching Hospital, Parklane Campus, Enugu State Nigeria, <sup>4</sup> Department of Health Administration & Management, University of Nigeria Enugu Campus, Nigeria

**Problem statement:** Pharmacovigilance of antimalarial treatment is important to both the individual and the community. Detecting, assessing, understanding, and preventing the adverse reactions of antimalarial medicines are crucial because these medicines are so frequently used because of malaria's endemicity in Nigeria.

**Objectives:** To determine the communities' level of awareness of adverse drug reactions (ADRs) in malaria treatment and the reporting systems available; the communities' attitudes; and their problems in reporting adverse events so that suggestions can be provided to alleviate these problems

**Design:** Cross-sectional descriptive study

**Setting:** Community based

**Study population:** 422 mothers and 60 health workers in Enugu South local government area of Enugu State, Nigeria

**Outcome measure(s):** Community and health workers' perceptions of pharmacovigilance for antimalarial treatment in Enugu and suggestions for reporting adverse events

**Results:** All the respondents have had malaria once. Most people (97.2%) have heard of ADRs—42.2% heard through friends, 29.3% through a doctor. Most respondents (54.7%) used chloroquine; others used sulfadoxine-pyrimethamine, ACTs, and halfan. The most common adverse effect was itching (35.6% mainly with chloroquine), and the least noticed adverse effects were blurred vision, rashes, and fainting (1.7%). Most respondents (47%) did nothing about the adverse effects and very few (1.7%) reported to a doctor. The popular reasons for doing nothing were lack of funds (38.8%) and ignorance (36.5%). Problems that affected reporting of ADR included ignorance (55.5%), lack of funds (26.3%), lack of access to health centers (14.9%), and self medication (3.3%). Community suggestions for solving the problems were public awareness (58.8%), provision of accessible health centers (23.2%), provision of free treatment (13.8%), and prevention of self medication (4.2%). For the health workers, about 80% had knowledge of ADRs and the spontaneous reporting system. Most of our respondents (43.3%) each reported only one case of ADRs to antimalarials in the past 1 year; 13.3% reported 2 cases; 5.0%, 3 cases; and 1.9%, 4 cases. A spontaneous reporting system was used for these cases. Problems that affected reporting the adverse effects were ignorance (75%), lack of access to health centers (15%), lack of funds (6.7%), and stress (3.3%). Suggestions for solutions included ensuring public awareness (83.3) and provision of accessible health centers (16.7%).

**Conclusion:** The major problems that affected the reporting of adverse drug events were ignorance, lack of funds, and lack of access to the health centers. Information, education, and communication programs in the communities and among the health workers should be improved. Funds should be made available to health workers to enable timely reporting of adverse events. Community surveillance is necessary to ensure timely reporting by the community.

**Funding source(s):** This study was self funded and was carried out as a medical school project.

## 716

### Economics, Financing, and Insurance Systems

*Keywords:* generic medicines, pharmaceutical policy, private sector, pharmacoepidemiology

### Evolution of Generic Medicine Market Share in the Pharmaceutical Retail Sector of 21 Low- and Middle-Income Countries Between 1999 and 2009: Time-Series Analysis

**Veronika J. Wirtz<sup>1</sup>, Dennis Ross\_Degnan<sup>2</sup>, Peter Stephens<sup>3</sup>, Warren Kaplan<sup>4</sup>**

<sup>1</sup>National Institute of Public Health, Mexico, Mexico; <sup>2</sup>Harvard Medical School and Harvard Pilgrim Health Care Institute; <sup>3</sup>IMS Health; <sup>4</sup>Center for Global Health and Development, Boston University

**Problem statement:** Pro-generic medicines policies have been promoted as core strategies to achieve more cost-effective use of medicines in all national health systems. However, there is little published evidence of their effect over time in many low- and middle-income countries (LMICs). As a first step, it is important to describe the evolution of the generic medicines markets in various LMICs over time.

**Objectives:** To study the market share by volume sales of generic medicines (both branded and unbranded) versus total pharmaceutical retail sector of 21 LMICs between 1999 and 2009

**Design:** Time-series analysis of annual sales volume in standard units, by region and country

**Setting:** Retail sales data obtained from IMS Health

**Study Population:** 21 LMICs as defined by the World Bank from 3 different geographical regions: Latin America (LAC: Argentina, Brazil, Chile, Colombia, Dominican Republic, Ecuador, Mexico, Peru, Uruguay, and Venezuela); Middle East plus South Africa (ME: Egypt, Jordan, Morocco, Tunisia, and South Africa); Asia (Bangladesh, Indonesia, Malaysia, Pakistan, Philippines, and Thailand).

**Outcome:** (1) "Generic market share" defined as the percentage of aggregate annual sales volume of generic medicines (sold under proprietary name) plus unbranded generic medicines (sold under their international non-proprietary name) out of total annual medicines sales volume (innovator medicines plus all generic medicines); (2) "unbranded generic market share" defined as the percentage of annual sales volume of unbranded generic medicines out of total medicines sales volume

**Intervention:** No specific interventions identified, but at least 15 of the 21 study countries have a national medicines policy, which typically includes pro-generic policies.

Results: The share of the total market volume of the 21 countries studied relegated to generic (unbranded and branded) medicines increased from 67% to 76% in this 10-year period, with the largest increase in the LAC region (from 60% to 76%). Notably, total market fraction of unbranded generic medicines for LAC nearly tripled from 8% to 22.5% during this time period, with Venezuela, Peru, Brazil, and Colombia showing large individual increases. Asian countries had the highest generic volume share over time; however, volume share of unbranded generics decreased in Asia in the study period (from 11% to 7%). For the ME, the volume share of generic medicines was relatively constant over time.

Conclusions: Volume share of generic medicines differs substantially by country and region, as does the share of branded versus unbranded products. The large increase in LAC might be a result of more comprehensive pro-generic policies, but this requires far more rigorous and in-depth economic and policy analyses. Retail sales data provide an important tool for pharmaceutical policy evaluation and a promising mechanism to examine the impacts of specific pro-generic policies in each country.

Funding source: Information not provided

718

### **Economics, Financing, and Insurance Systems**

*Keywords:* health insurance, payment methods, drug utilization, access, efficient healthcare treatment

#### **Does Your Health Care Depend on How Your Insurer Pays Providers? Variation in Utilization and Outcomes in Thailand**

**Sanita Hirunrassamee<sup>1</sup>, Sauwakon Ratanawijitrasin<sup>2</sup>**

<sup>1</sup>Pharmacy division, Phramongkutklao Hospital, Thailand; <sup>2</sup>Faculty of Social Sciences and Humanities, Mahidol University, Thailand

Problem statement: In Thailand, recent reform has changed the environment in which hospitals operate. With the 3 major health insurance schemes employing different payment mechanisms, hospitals are faced with multiple payment incentives. Whether and how this change affects the use of health resources, as well as what health outcomes it has produced, are important policy questions.

Objective: To examine resource utilization patterns and health outcomes under the multiple payment methods in Thailand, focusing on assessing access to medicines and other medical technologies, treatment outcomes, and efficiency in resource use among beneficiaries of the 3 government health insurance schemes in Thailand

Methodology: Electronic dispensing database and medical records (in hard copy) during fiscal years 2003-2005 from 3 government hospitals were used in the assessment. Acute upper gastrointestinal bleeding (AUGIB), chronic epilepsy, and non-small cell lung cancer were employed as tracer diseases. Outcome measures in this study follow key outcomes identified in standard practice guidelines. Costs are hospital costs. Chi-square and odd ratio were used to assess the effects of payment methods on access to care. Cost-effectiveness technique was used to assess impacts of payment methods on efficiency of health care services.

Results: Where new versus conventional medicines are both available, patients whose insurer pays on a fee-for-service basis tended to have greater access to new drugs (31% for epileptic drugs and 67% for lung cancer drugs), compared to patients whose insurer pays on a capitated or case basis (19% and 13% for epileptic drugs and 10% and 19% for lung cancer drugs). Similar patterns were found where there are options between originator versus generic drugs, drugs in different dosage forms, and more versus less advanced diagnostic technologies. For AUGIB and lung cancer, treatments in the closed-end insurance programs were more efficient. For epilepsy, the open-end system rendered more efficient services; 20% more epileptic patients in the open-end payment scheme became seizure-free than those in the closed-end systems.

Conclusion: The utilization of more expensive items differs between patients whose insurers pay on a closed- or open-end basis. Effects of insurance payment are more pronounced where price gaps among the medical technologies are significant. Efficiency results are mixed, depending on nature of the disease conditions and type of resources required for treatment.

Funding source: No funding support

721

### **Chronic Care**

*Keywords:* Pharmacy Services, Access, Chronic care

#### **Assessing the Readiness of Pharmacy Outlets to Support Chronic Care: Results from a National Assessment in Kenya**

**Josephine Maundu, Peter Nguhiu, Charles Ouma**

Management Sciences for Health/Strengthening Pharmaceutical Systems (MSH/SPS) Program, Nairobi, Kenya

Problem statement: Pharmacy services are an underutilized resource that could contribute more to improving access to medicines and health care in developing countries. In Kenya, little is known about the scope and quality of pharmacy services, particularly in private sector outlets, and their potential contributions to patient-centered care, especially those on prolonged treatment for chronic diseases.

Objectives: To determine readiness and willingness of pharmacy outlets in the private, public, and faith-based sectors to provide pharmaceutical care; specific objectives were to determine readiness in terms of staff skills, qualifications, and perceptions and facility infrastructure.

**Study design:** Cross-sectional observational study conducted in August 2009; self-administered questionnaire based on key indicators was used to obtain data, which was analyzed using SQL Server Views and Stata Version 11

**Setting:** 501 study sites were selected to represent a wide range of pharmacy practice centers including public, private, and faith-based health facilities, retail pharmacies, and pharmacy training institutions in rural and urban settings in all 8 provinces

**Study population:** 469 pharmacy staff sampled from the selected study sites

**Outcome measure:** Percentages of the study population responding to questions related to readiness to provide pharmaceutical care

**Results:** Apart from routine dispensing, staff also offered clients drug information and patient education. Most of the respondents (92.9%) stated that, in their opinion, they provided pharmaceutical care with 82.3% indicating that they had adequate skills and knowledge to provide the service. However, perception of what constitutes this service varied; 80.0% were either pharmacists or pharmaceutical technologists. Almost all respondents (97.3 %) indicated that they felt pharmaceutical care was important in the current pharmacy practice environment in Kenya. Most (89%) of the practice facilities had a sizeable waiting area for patients at the pharmacy; 62% had private patient counseling areas, of which 84% were considered appropriate for confidential medicine counseling; 62% of the respondents stated that they used computers at their workplace. However, only 29.8% of the facilities had specialized dispensing software installed.

**Conclusions:** The basic elements required for pharmacy services to support chronic care are in place. The majority of dispensing staff are in pharmaceutical cadres who have the required knowledge and skills.. Readiness to provide pharmaceutical care is further evidenced by positive attitudes, willingness, and availability of suitable infrastructure. In Kenya, provision of chronic care services can be enhanced by fully utilizing the capacity of pharmacy to support the service and strengthened by addressing specific gaps in health worker skills as well as improving institutional capacity to provide an optimum standard of care.

**Funding source:** USAID-Kenya

**722**

**Access**

*Keywords:* Information Technology, Medicines, Access

### **Piloting the Use of Mobile Short Messaging Systems (SMSs) to Improve Access to Medicines: Experiences from Kenya**

**Tony Njoroge, Josephine Maundu, Mary Wangai**

Management Sciences for Health/ Strengthening Pharmaceutical Systems (MSH/SPS) Program, Nairobi, Kenya

**Problem statement:** Accurate and timely information on medicine consumption and use is necessary to inform national forecasting and procurement. However, in Kenya, reporting on medicines consumption from rural health facilities is very poor, and when reports are received, they are often delayed and incomplete. This results in stock-outs and hence limits access to medicines.

**Objective:** The intervention objective was to determine the effectiveness of using SMS to improve medicine consumption data reporting.

**Setting:** Rural primary health care facilities in Thika, Muranga South and Kiambu districts

**Intervention:** SPS program worked with district health management teams (DHMTs) in 4 districts to pilot primary health care facilities' use of SMSs to report medicines consumption. The pilot targeted monthly reporting for priority public health programs—antiretroviral, antituberculosis, and selected malaria and family planning medicines. Health facilities sent information on medicine consumption via SMS, using phones linked to a central server and computers at district health information offices. The system logged SMS transmission details including the sender, source facility, district, and date of data receipt. The software also enabled synchronization and aggregation of data at central and district levels and notification of facilities in case of delay or absence. In addition SPS helped train DHMT and facility staff and provided technical assistance for monthly DHMT data review meetings and direct financial support for the costs of SMSs.

**Outcome measures:** Number of health facilities reporting using SMSs; accuracy, timeliness, and completeness of data received

**Results:** Within 6 months after the intervention, 176 rural facilities representing over 80% of rural health facilities in the 3 districts were using SMSs to send medicine consumption data. Reporting rates using the SMSs had reached 100% for sites that provided antiretroviral treatment and for all facilities with laboratories. Review of the systems showed improved quality, timeliness, and completeness of data received from the reporting sites. Access to this information also strengthened DHMTs' management role because they had data to inform basic decisions such as redistribution of stock from overstocked to understocked facilities.

**Conclusion:** This pilot demonstrated the feasibility and effectiveness of using simple SMS mobile technology to report medicine consumption data for improved medicine quantification and availability. Although set-up and maintenance costs may hinder scale-up efforts particularly in the public sector because of resource constraints, public-private partnerships can be used to support such innovations.

**Funding source:** PEPFAR

727

**Access**

*Keywords:* kit, push, access to medicines, supply management, medicine supply

**Is a Standard Kit an Effective Way to Optimise Use of Limited Resources and Increase Availability of Medicine? Experiences from Reintroducing Standard Kits in Resource-Poor Settings in Uganda**

**Dorthe Konradsen<sup>1</sup>, Rebecca Copeland<sup>2</sup>, Pito Jjemba<sup>1</sup>, Timothy Nuwagaba<sup>1</sup>, Birna Trap<sup>1</sup>**

<sup>1</sup>Management Sciences for Health, Uganda; <sup>2</sup>USAID Uganda

**Problem statement:** Funding for essential medicines and health supplies (EMHS) in Uganda's public sector is limited, being only \$0.7 per capita. Supply chain management capacity assessed at all levels of care is weak with stock cards kept for only 68% of EMHS and only 51% of stock cards with the correct balance. The financial gap combined with weak pharmaceutical management at the facility level contributes to low availability of EMHS. The average availability of the 6 tracer drugs was only 72% in a 6-month period in 2010. A standard kit system was introduced at the primary health care (PHC) level to increase availability of EMHS.

**Objective:** To assess the appropriateness of the kit system in Uganda in increasing availability of lifesaving EMHS

**Design:** Randomized before and after intervention study to assess impact of policy change using an indicator-based data collection tool; no control was available as the kits were introduced nationwide.

**Setting:** 35 PHC units situated in 9 districts out of 110 covering all 5 supply regions

**Study population:** 2 districts from 4 regions and 1 district from the central region were selected using a stratified population-based sampling method; within each district, 2 facilities were randomly selected from health centre (HC) levels 2 and 3, respectively.

**Intervention:** Changing from a pull to a push-based (kit) logistic system to increase availability of EMHS and optimize use of limited financial resources in PHC facilities

**Policy:** HC2 and HC3 kits containing 34 and 74 medicines, respectively, and 22 and 41 sundries, respectively, were introduced to replace facility orders. Each health facility receives 1 kit (according to the level of care) 6 times yearly, regardless of patient figures. The values of the kits were \$470 and \$825 for levels 2 and 3, respectively.

**Outcome measures:** Assessment of pharmaceutical management practices, EMHS availability, supply imbalances, prescription practices, content, staff view, and financial feasibility

**Results:** Of facility staffs, 27% were trained in stock management, and none could correctly calculate quantities to order EMHS. Kit introduction increased funding per patient by 38% and increased availability of items by reducing overall stock-out days 69% for vital items; 63% of items were oversupplied and expiry of extreme oversupplied items (> 12 months supply bimonthly) is estimated to cost \$1.5 million per year nationwide. Kits include 59% vital items, and 80% of items were right for the level of care. Less than half of EMHS items had stock cards with a quarter having correct stock card balance. Two-thirds of staffs preferred kit system, because it had improved their supply situation.

**Conclusion:** Kit introduction increased funding and thereby availability of EMHS. Cost-effectiveness is questionable because of increased risk of wastage from oversupply with need for redistribution.

**Funding source:** United States Agency for International Development

728

**Access**

*Keywords:* performance assessment, supervision, GPP, medicines management, performance visualization

**Impact of Visualizing Performance in Improving Medicines Management in Public Health Sector Facilities in Uganda**

**Khalid Mohammed, Victoria Nakiganda, Dorthe Konradsen, Richard Semakula, Birna Trap**

Management Sciences for Health, Uganda

**Problem statement:** Pharmaceutical supervision has been practiced in Uganda for a long time. Though effectiveness of supervision in improving medicines management has been documented, Uganda continues to struggle with weak medicines management. Although a performance-based reward system has proven successful in strengthening vaccine management, its efficiency in improving medicines management is not known. The impact of supervision much depends on implementation modality. To strengthen the effect of supervision and improve medicines management, trained medicines management supervisors (MMSs) applied an indicator-based data collection and assessment tool to assess good pharmacy practices. The tool visualises performance in a spidograph, allowing the health worker to better see performance and assess progress. The impact of the standardised, indicator-based performance assessment and visualising tool combined with supervision is not known.

**Objective:** To establish the impact of performance assessment and visual feedback on medicines management implemented by trained supervisors

**Design:** A controlled, pre-post intervention study with randomisation by facility; performance assessment is based on a set of 25 qualitative and quantitative indicators covering medicines management. Data collection is undertaken as baseline at the initial facility visit and at each of the following 2 supervisory visits at least a month apart.

**Setting:** The study is implemented in 9 districts (December 2010– September 2011) situated in the central region including 60 (83%) public and 12 private not-for-profit health intervention facilities covering all levels of care and in 12 control districts (March–August 2011) in the eastern region including 61 control facilities.

Intervention: All 72 facilities (level II to hospital) within each of the 15 health subdistricts are randomly assigned to 1 of 2 intervention groups—1 group (35) having performance assessment, visual feed back and supervision and the other group (37) having performance assessed and supervision. Performance was assessed in the control facilities only once.

Outcome measures: The primary outcome measures include assessment of stock and storage management, ordering and reporting quality, and dispensing and prescribing quality.

Results: Results will become available for ICIUM 2011

Funding sources: United States Agency for International Development through Securing Ugandans' Right to Essential Medicine program

## 729

### Drug Resistance

*Keywords:* Environment, climate variability, infectious diseases, antibiotic resistance, qualitative

### Infectious Diseases, Antibiotic Use, and Antibiotic Resistance in Context of Environmental Changes: Study Among Community Members in Orissa, India

**Krushna Chandra Sahoo<sup>1</sup>, A. J. Tamhankar<sup>2</sup>, Eva Johansson<sup>1,3</sup>, Cecilia Stålsby Lundborg<sup>1</sup>**

<sup>1</sup>Division of Global Health (IHCAR), Department of Public Health Sciences, Karolinska Institutet, Stockholm, Sweden;

<sup>2</sup>Department of Environmental Medicine, R.D. Gardi Medical College, Ujjain, Indian Initiative for Management of Antibiotic Resistance (IIMAR) India; <sup>3</sup>Nordic School of Public Health, Gothenburg, Sweden

Problem statement: Environmental change and antibiotic resistance are some of the main challenges for global health. To improve antibiotic use, community understanding of health, diseases, and medicines in relation to changing environment is valuable.

Objectives: To explore community members' perceptions of human health, infectious diseases, antibiotic use, and resistance development in the context of environmental changes

Design: Qualitative exploratory study; 8 focus groups discussions (FGDs) and 10 key informant interviews were conducted. Data were analyzed using content analysis.

Setting: 2 environmentally different districts, Khurda and Malkangiri of Orissa, India

Study population: 63 community members of different sex (32 male, 31 female), age (18 to 65 years), educational background (31 illiterate, 32 literate), and occupation (Government and private employees, farmers, labourers, housewives, and students) were selected based on a purposive sampling strategy to include as much variety as possible; among the participants, 33 were from Khurda and 30 were from Malkangiri

Results: The participants perceived an interrelationship between environment, infectious diseases, and medicines. Their perceptions on infectious diseases, antibiotics use, and resistance varied according to their social environment, i.e. urbanization and education. Most of the educated participants, viewed that an incomplete course of antibiotics (because of poverty and high cost), self-medication, and irrational treatment by untrained prescribers are responsible factors for resistance development. Some of the participants realized that although untrained prescribers were giving irrational treatment they were still helping people where lack of healthcare facilities (remote areas). Participants suggest supporting trainings for untrained prescribers.

Conclusions: Among our study participants, it was perceived that climate variability was increasing, which has health consequences for community members. Improved sanitation, choice of herbal treatment, practice of yoga and pranayam, awareness and education among the community, and orientation to trained and untrained prescribers on rational use of antibiotics were viewed as probable ways to minimize unnecessary use of antibiotics to prevent antibiotic resistance.

Funding sources: KCS received a scholarship from Erasmus Mundus External Cooperation Window Lot 15, India, and is associated with the Swedish Research School for Global Health.

## 730

### Access

*Keywords:* Key words: generic (multisource) medicines, Good Manufacturing Practices (GMP), pharmaceutical policy, promotion, quality assurance

### Comparative Evaluation of Quality of Some Generic Versus Branded Medicines Using Compendia Standard Tests In India

**Girdhari Lal Singal<sup>1</sup>, Anita Kotwani<sup>2</sup>, Arun Nanda<sup>1</sup>**

<sup>1</sup>Faculty of Pharmaceutical Sciences, M.D.University, Rohtak, Haryana, India; <sup>2</sup>Department of Pharmacology, VP Chest Institute, University of Delhi, Delhi, India

Problem statement: Generic medicines are an affordable alternative to the costlier branded medicines. However, doubt about the quality and therapeutic efficacy of generics by doctors and other stakeholders sends the majority of Indian population to costly branded medicines for which they must pay out-of-pocket. Recently, to improve access to medicines for the population at large, the Department of Pharmaceutical, Government of India, has launched novel scheme of a Jan Aushadhi Store (medicines for common man) or generic drug stores. At these generic drug stores, limited generic medicines are available at lower prices than equivalent popular brands available at private retail stores. Quality factor and awareness about generics is creating hurdles in success of the scheme.

**Objective:** To compare the quality of few generic medicines of Jan Aushadhi Store with branded versions manufactured by reputed pharma companies in India

**Setting:** Government recognized regional laboratory of Haryana State, India

**Study population:** 4 pairs of commonly used medicines available at Jan Aushadhi Store (manufactured by public sector units) and branded or popular version available at private retail stores (manufactured by reputed companies). All the medicines were manufactured by companies with Good Manufacturing Practices (GMP) certificate that is required by law. The 4 pairs of medicines were Alprazolam tablets 0.25 mg, Cetrizine tablets 10 mg, Ciprofloxacin tablets 500 mg, and Fluoxetine capsules 20 mg.

**Outcome measures:** Methods described for qualitative and quantitative tests in Indian Pharmacopoeia 2007 were used for all 4 pairs of medicines. The tests performed were identification, chemical composition, uniformity of content, uniformity of weight, and dissolution.

**Results:** All the 4 pairs of medicines gave positive identification tests on high-pressure liquid chromatography (HPLC) or IR. Quantitative analysis by HPLC, uniformity of content and weight, and dissolution tests for all 4 pairs of medicines were well within the prescribed range of the Indian Pharmacopoeia.

**Conclusion:** The findings of the study highlight that generics are as good as popular branded products in quality for all prescribed tests. The Government should conduct more such studies and publish the results widely in scientific journals and other electronic media and start awareness and advocacy on generics for the public and prescribers to make their program on Jan Aushadhi a success.

**Funding source:** None

### 731

#### **Policy, Regulation, and Governance**

*Keywords:* performance assessment, financial management, supervision, computerisation, medicines management

#### **New Performance-Based Reward Strategy to Improve Pharmacy Practices, Financial Management, and Appropriate Medicines Use in the Public Sector in Uganda**

**Birna Trap<sup>1</sup>, Richard Semakula<sup>1</sup>, Martin Oteba<sup>2</sup>, Kate Kikule<sup>3</sup>, Belinda Blick<sup>1</sup>**

<sup>1</sup>Management Sciences for Health, Uganda; <sup>2</sup>Ministry of Health, Pharmacy Division, Uganda; <sup>3</sup>National Drug Authorities, Uganda

**Problem statement:** Ensuring availability and appropriate use of essential medicines is crucial if limited resources are to be used optimally. Although training of health workers has been underway for a long time, taken since long, significant and sustainable improvements in availability and medicines management have not been achieved, and new interventions are needed. Increasingly, countries are finding it difficult to ensure sufficient funding for medicines; at the same time, the financial management (FM) capacity among pharmaceutical staff is weak. The use of a performance-based reward strategy (PBRS) has proven successful in strengthening vaccine management. The effect of capacitating pharmaceutical staff in FM and applying PBRS still needs to be assessed in regard to improving medicines management.

**Objective:** To assess impact of PBRS and FM in improving pharmacy practices (PP) and appropriate medicines use (AMU), implemented by trained medicines management supervisors (MMSs)

**Design:** A randomized longitudinal intervention study with randomization by districts; 25 indicators will be applied to assess good PP and AMU after educational, managerial, regulatory, and financial (reward) interventions were implemented. Data collection is undertaken as baseline at the initial facility visit, and several follow-up supervisory visits will also be made. Prior to each supervisory visit, performance will be assessed; this information will become part of the data along with the information collected during the visit. Supervisory visits are expected to continue for up to 2 years.

**Setting:** The study includes 45 intervention and 15 control districts with 1,482 public and 443 private not-for-profit, all-level health facilities; on average, 39 (11-105) facilities per district.

**Intervention:** The intervention districts are randomly assigned to 1 of 3 intervention groups: (1) supervision in supply chain management targeted at accreditation in good PP, (2) additional supervision in FM targeted at certification in good FM, and (3) additional stores computerization—all compared to a control group of facilities. Accreditation in good PP is undertaken by the national drug authority and harmonized with the licensing criteria applied in private sector pharmacies; 146 MMSs will be trained as district and health subdistrict supervisors. The reward system for MMSs comprises items such as motorbikes, computers, Internet access, personal training, and e-based learning, and for the facilities, accreditation, certification, technical manuals, continued education, and computerization, all with community involvement.

**Policy:** The strategy is built on the basis of the essential medicines concept with development of essential medicines, supplies, and the laboratory supplies list, classified according to health impact and importance in saving lives, which will guide procurement at all levels.

**Outcome measures:** The primary outcome measures included PP, FM, and AMU.

**Results:** Method description and baseline data available for ICIUM 2011. Results will only start to become available from mid 2011.

**Funding source:** United States Agency for International Development through Securing Ugandans' Right to Essential Medicine (SURE) Program.

733

**Policy, Regulation, and Governance***Keywords:* access to medicines, Public health facilities, Pharmaceutical Situation Assessment, sample error**Pharmaceutical Situation Assessment: Methodological Challenges for Different Contexts****Monica Rodrigues Campos, Isabel Cristina Martins Emmerick, Vera Lúcia Luiza**

Oswaldo Cruz Foundation, Brazil

**Problem statement:** The Pharmaceutical Situation Assessment (PSA) package is an approach proposed by the World Health Organization broadly and increasingly used by countries worldwide. The methodological approach is designed to be easily implemented by countries with low resources and scarcity of planning data. The sampling for the level II approach is defined considering the population of public health facilities (PHF) and is based on the premise of a low variability of indicators among PHF in a country. The current approach proposes 30 PHF, 6 in 5 country regions, independently of a country's characteristics. The experience of supporting Latin American and Caribbean (LAC) and Portuguese-speaking countries allowed us to see that many times the utilization of results in the decision-making process is impaired by questions presented by local stakeholders in relation to reliability and validity of data and representativeness of sampling.

**Objectives:** Based on actual data, to present a sampling exercise to calculate the maximum error, ( $e_{max}$ ) considering the parameter for the proportion of indicators as 50% ( $p = 0.5$ ) and estimate the error "esample" for selected indicators, considering the results found in 11 country surveys

**Design:** Exploratory study using actual data from PSA-level II applied in 11 countries; to calculate  $e_{max}$ , the population and sample of PHF in each country was used. To calculate esample, selected indicators were organized in groups of measurement (organization, access, quality, and rational use) that express their use by countries. The esample was calculated to the median value in each group of indicators.

**Setting:** Selected LAC countries (10) and Portuguese-speaking countries (1)

**Study population:** PHFs

**Outcome measure(s):** Considering the parameter as 50% ( $p = 0.5$ ),  $e_{max}$  and esample for selected indicators

**Results:** The  $e_{max}$  varies across countries from 6% to 17%. The esample varied according to the group of indicators measured—"Organization" 0% to 17%; "Access" 3% to 10%; "Quality" 6% to 14%; and "Rational Use" 6% to 17%.

**Conclusions:** The  $e_{max}$  was low when the total number of PHF (population) in a country was small. The esample indicates that the homogeneity varies according to groups of indicators. Higher homogeneity was observed for access. Lower homogeneity was observed for rational use, because this group includes a greater number of indicators and because sources of data are diverse. The results point to the importance of considering error variability as well as actual indicator measurement for each indicator group. We propose to include information on the error associated with each sample size in the WHO standard methodology, which should consider the total number of PHFs. These possibilities must be negotiated with local stakeholders.

**Funding source(s):** Oswaldo Cruz Foundation – Ministry of Health of Brazil

734

**Drug Resistance***Keywords:* antibiotic, antibiotics smart use, rational drug use**Two-Year Experience of Antibiotics Smart Use Pilot Project in Saraburi, Thailand****Somying Pumtong<sup>1</sup>, Kunyada Anuwong<sup>1</sup>, Nithima Sumpradit<sup>2,3</sup>, Pisonthi Chongtrakul<sup>4</sup>**<sup>1</sup>Srinakharinwirot University, Thailand; <sup>2</sup>Ministry of Public Health, Thailand; <sup>3</sup>International Health Policy Program, Thailand; <sup>4</sup>Chulalongkorn University, Thailand

**Problem statement:** Excessive use of antibiotics led to a national crisis of antibiotic resistance in Thailand. Therefore, the Antibiotics Smart Use (ASU) project was piloted by the Thai Food and Drug Administration (FDA) in 2007.

**Objectives:** To reduce irrational antibiotic prescriptions for upper respiratory tract infection, acute diarrhoea, and simple wounds

**Design:** 1 group pretest–post-test design

**Setting:** Saraburi Province, Thailand

**Study population:** All public health care settings and health care professionals (87 health centers and 10 district hospitals)

**Intervention:** In the first year of operation, multifaceted interventions, including a clinical treatment guideline, training programs, patients' education materials, and non-antibiotic substitution, were implemented to change prescribers' behaviour. There was no additional specific intervention strategy in the second year; 27 items of antibiotics prescribed for outpatients were collected and compared (1) before (December 2006–May 2007) and after (December 2007–May 2008) implementing the pilot and (2) between the first (December 2007–May 2008) and second (June 2008–May 2009) years of the ASU operation. In addition, pretest–post-test questionnaires were done among health care professionals after the training sessions (N1st year = 315 and N2nd year = 296).

**Outcome measures:** The amount of antibiotic prescribing and knowledge and attitude of prescribers.

**Results:** In the first year of the ASU pilot, findings showed a considerable decrease in antibiotic prescribing (18–46%) in 52 settings (44 health centers and 8 hospitals) and better prescribers' knowledge as well as a positive attitude after the

training sessions ( $p < 0.001$ ). In the second year, a follow-up study was still conducted to monitor project sustainability after the pilot project and centrally supportive interventions ceased. It was found that the quantity of antibiotics prescribed increased from the first year, but was still lower than that prescribed in the period before the intervention. Prescribers' knowledge and attitude were slightly decreased from the first year ( $p < 0.05$ ).

Conclusion: The ASU pilot was successful on reducing unnecessary antibiotics use, so it should be continued. The results generate crucial issues of sustainability of the project which could be achieved through national policy and collaborative networks.

Funding sources: Thai Food and Drug Administration and World Health Organization

## 740

### Chronic Care

*Keywords:* Hypertension guidelines, antihypertensives, policy compliance.

### **Antihypertensive Medicines Prescriptions Before and After the Nigeria Hypertension Society Guidelines and Prescriber's Awareness of the Guideline**

---

**Abimbola Olowofela, Ambrose. O Isah**

Clinical Pharmacology and Therapeutics Unit, Department of Medicine, University of Benin Teaching Hospital, Benin City, Nigeria

Problem statement: The Nigerian hypertension guideline (2005) was based on 1999 ISH/WHO and the 2003 sub-Saharan Africa hypertension guidelines. The changes in the prescribing pattern of physicians following the introduction of these guidelines in Southern Nigeria are unknown.

Objectives: To assess changes in prescribing of antihypertensives prior to and after the 2005 guideline as well as physicians' awareness of the guidelines

Design: A policy evaluation and descriptive study and a cross-sectional study of the physicians' awareness of the guidelines

Setting: The study was carried out at the University of Benin Teaching Hospital (UBTH), a 620-bedded tertiary health facility in Southern Nigeria.

Study population: The study evaluated 3,379 hypertensive patients and 48 post registration doctors working in UBTH. The study reviewed the case records (1999–2008) of hypertensive patients who had attended the medical outpatient clinic. All cases were selected using a convenience sampling method. A self-administered semi-structured questionnaire was administered to the doctors to assess awareness.

Policies: The Nigerian hypertension guideline (2005) recommended the use of diuretics as first-choice antihypertensives in uncomplicated hypertension.

Outcome Measures: The study's primary outcome was to determine if diuretics were the most prescribed group of antihypertensives since the release of the guideline; also to determine if diuretics would be the most preferred antihypertensives by doctors.

Results: Annual prescriptions of diuretics increased steadily from 38% in 1999 to a peak of 58% in 2005. The values were sustained in 2006 (57%), 2007 (55%), and 2008 (55%). The calcium channel blockers were the most prescribed class over the entire period (44.7%–69.2%), while the prescriptions for angiotensin converting enzyme inhibitors increased by 327% rising from the 5th most prescribed medicine (1999) to the 3rd (2008). The prescription level for beta blockers changed slightly throughout the study period. The use of 2 or more medicines also increased from 78.9% to 85.9%; however, a decrease (69.1% to 54.0%) in the proportion of patients using fixed-dose combinations was observed. A total of 37/48 returned the filled questionnaire (response rate 77.1%). A high proportion (32/37; 86.5%) of the doctors were aware of the national guidelines but only 13/37 (35.1%) were satisfied with the recommendations. Diuretics were stated as the most preferred class of antihypertensive medicines by 26/37 (70.3%) of respondents.

Conclusions: The findings suggest a less than optimal compliance with the guidelines with preference for newer medicines. There was a disconnect in the prescribers' knowledge of recommendations in the guidelines, their stated preferences for medicines, and the observed findings in the case records. This may be due in part to the observed dissatisfaction of doctors with the guidelines.

Funding source: Private (self)

## 741

### Policy, Regulation, and Governance

*Keywords:* affordability, appropriate use, availability, pharmaceutical policy

### **Pharmaceutical Situation Analysis of Mongolia**

---

**Munkhdelger Chimedtseren<sup>1</sup>, Tsetsegmaa Sanjjav<sup>2</sup>**

<sup>1</sup>Ministry of Health, Mongolia; <sup>2</sup>Pharmacy School, Health Sciences University, Mongolia

Problem statement: This is the second assessment of the pharmaceutical sector completed at the end of 2009. Previous study was conducted in 2004.

Objectives: To identify the strengths and the weakness of the policy in the pharmaceutical sector and to produce recommendations for future improvement and possible interventions

Design: The standard questionnaires prepared by WHO were translated into Mongolian and used for the assessment.

Settings: As recommended in the WHO operational package for assessing, monitoring, and evaluating country pharmaceutical situations, the study was conducted in 5 geographical areas and Ulaanbaatar (UB), the capital city.

Study population: According to the WHO guide, large public health facilities (PHF) should be selected. In UB, the largest public hospitals with the closest private drug outlets were selected. The largest warehouse in the region and the closest warehouse to each PHF were selected for the survey. We have selected 30 patients with varying diagnoses seen during the survey period, prospectively in the chosen health facilities.

Results: The percentage availability of key medicines was 80.00 % in PHFs, 86.75% in private pharmacies, and 88.7% in warehouses. Since the last assessment conducted in 2004, several improvements have been observed. The availability of essential medicines (EMs) was 64.52%, ranging from 43.56-91.7% at aimag and soum levels, and 41.58-70.4% in UB. As a result of this survey, the affordability of key EMs was estimated at facility levels as 1.7 days' wages in the PHF and 1.8 days' wages in the private facility for adults. The geographical accessibility of facilities was determined by interviewing patients; 6.7% of patients in PHF dispensaries and 3.3% of patients at private drug outlets spent more than 1 hour to travel to the facilities. The quality of medicines is best in private retail pharmacies, as the study team has found no expired medicines during the survey, but is least in wholesaling companies (3.20%). The average presence of expired medicines was 1.96% in 2009, down from 8.32% in 2004. The average number of medicines per prescription at PHF was 2 and 3 in private dispensaries. This finding can be assessed as good because it complies with the requirements of the National Standard on Prescription. The prescribed medicines dispensed or administered to patients at PHF dispensaries was 97.5%. And 81.8% of facilities dispensed more than 75% of prescribed medicines.

Conclusion: This study has shown that the NMP is being successfully implemented in terms of changes and improvements related to structures and mechanisms. Nevertheless, the deficiencies in the implementation of the NMP should be emphasized. Inadequate stock management in health facilities, especially in rural areas, should also be emphasized. The availability of EMs varied at all level.

Funding source: WHO

## 742

### Drug Resistance

Keywords: antibiotics, normal delivery, self-medication, Lao PDR

#### Use of Antibiotics Among Mothers After Normal Delivery in Two Provinces in Lao PDR

**Bounxou Keohavong<sup>1</sup>, Amphoy Sihavong<sup>1</sup>, Thongphout Soukhaseum<sup>1</sup>, Phatsaly Oudomsak<sup>1</sup>, Khampon Souliyavong<sup>1</sup>, Khouanchay Soundavong<sup>1</sup>, Saykeo Voradeth<sup>1</sup>, Sengchanh Kounnavong<sup>1</sup>, Keonakhone Houamboun<sup>1</sup>, Bounngong Boupha<sup>1</sup>, Kongsap Akkhavong<sup>1</sup>, Rolf Wahlstrom<sup>2</sup>, Bo Eriksson Eriksson<sup>2</sup>, Cecilia Stalsby Lundborg<sup>2</sup>**

<sup>1</sup>Ministry of Health, Laos; <sup>2</sup>IHCAR, Karolinska Institute, Sweden

Problem Statement: Self medication with antibiotics is widespread in low-income countries, including Laos. Such use might be irrational and increase the risk of appearance of resistant bacterial strains. A particular concern in Laos is the use of antibiotics by the woman after normal delivery. A population-based study on the use of antibiotics among mothers after normal delivery had not been carried out in Lao PDR.

Objectives: To describe the use of antibiotics among mothers after normal delivery in two provinces in Laos and to assess their knowledge about antibiotics, in order to give evidence to policy makers for further interventions.

Design: Cross-sectional survey with structured questionnaires including closed and open-ended questions. Women who had had a normal delivery in the 12 months preceding the study were interviewed in their homes.

Setting and Population: Forty-three villages in four districts (two urban and two rural districts) in Luangprabang (LPB) and Champasack (CPS) provinces. A total of 300 mothers were interviewed, 237 had delivered at homes and 63 in hospitals.

Intervention: The study was part of an information and education strategy to increase knowledge and awareness about risks and benefits of using antibiotics.

Outcome Measures: Percentage of mothers using antibiotics after normal delivery, percentage of advisers for using antibiotics, percentage of kind of antibiotics used, and percentage of sources of information received.

Results: Fifty-eight of 237 women (25%) delivering at home used antibiotics, significantly ( $p < 0.05$ ) more often in CPS (40%) than in LPB (8%). Twenty-four of these women (41%) had been advised by health workers to use antibiotics, while the others used it after their own decision or the advice from relatives or friends. Fifty of the 63 mothers (79%), who had normal deliveries at hospitals, received antibiotics. This was significantly ( $p < 0.05$ ) higher than for those who had normal deliveries at homes (24.5%). Ampicillin was the most commonly used antibiotic, followed by Amoxicillin and Tetracyclin. Few women knew about the reasons for treatment with antibiotics and even fewer about antibiotic resistance. Thirty-seven percent of the mothers had ever heard information about drugs, mostly through television and radio.

Conclusions: The inappropriate use of antibiotics after normal delivery should be discouraged, and obstetric practitioners should be more restrictive in prescribing antibiotics. Standard treatment guidelines for post partum women should be developed. The Food and Drug Department needs to develop more appropriate health messages and feasible methods to increase accessibility of the information for the people in rural areas.

Funding sources: Swedish International Development Cooperation Agency (Sida) and Ministry of Health, Lao PDR.

744

#### HIV/AIDS and TB

*Keywords:* adherence, HIV/AIDS, technology, access to medicines, mobile phones

### **Effects of a Mobile Phone Short Message Service (SMS) on Antiretroviral Treatment Adherence in Kenya (WelTel Kenya1): A Randomized Trial**

**Richard T. Lester<sup>1</sup>, Anthony Kariri<sup>2</sup>, Sarah Karanja<sup>2</sup>, Edward J. Mills<sup>1</sup>, Paul Ritvo<sup>2</sup>, Michael H. Chung<sup>2</sup>, Mohsen Sadatsafavi<sup>1</sup>, Marta Ackers<sup>3</sup>, Francis A. Plummer<sup>4</sup>**

<sup>1</sup>University of British Columbia, Canada; <sup>2</sup>University of Nairobi, WHO Collaborative Centre for HIV/STD Research and Training, Kenya; <sup>3</sup>US Centers for Disease Control and Prevention, Kenya Branch; <sup>4</sup>University of Manitoba, Canada

**Problem statement:** Mobile (cell) phone communication has been suggested as a method to improve delivery of health services; however, data on the effects of mobile health technology on patient outcomes in resource-limited settings are limited.

**Objectives:** We aimed to assess whether mobile phone communication between health care workers and patients starting antiretroviral therapy in Kenya improved medicine adherence and suppression of plasma HIV-1 RNA load.

**Design:** We conducted a multisite 1:1 randomized controlled adherence-support intervention trial.

**Setting:** Three different HIV clinics in Kenya were recruited. One university clinic serves a very low-income population in Nairobi. A second operates out of a faith-based hospital located in a higher income area of Nairobi. The third is a government health centre in a large rural district.

**Study population:** Patients were eligible to participate if they were initiating ART and if they owned a cell phone or shared access with a consenting partner. Consecutive enrolment was attempted. Between May 2007 and October 2008, 581 patients were screened, and we randomly assigned 538 to the SMS intervention (n = 273) or to standard care (n = 265). Of these, 222/275 (81%) and 204/265 (77%), respectively, completed the study.

**Intervention:** Patients in the intervention group received weekly SMS message inquiries from a clinic nurse and were required to respond within 48 hours. Patients that indicated a problem or did not respond were called to help triage any problem. Advice was given when appropriate.

**Policy:** Routine cell phone communication with patients was not part of standard care.

**Outcome measures:** Primary outcomes were self-reported ART adherence (>95% of prescribed doses in the past 30 days at both 6- and 12-month follow-up visits) and plasma HIV-1 viral RNA load suppression (<400 copies/mL) at 12 months. The primary analysis was by intention to treat.

**Results:** Adherence to ART was reported in 168 of 273 patients receiving the SMS intervention compared with 132 of 265 in the control group (relative risk [RR] for nonadherence 0.81, 95% CI 0.69–0.94; p = 0.006). Suppressed viral loads were reported in 156 of 273 patients in the SMS group and 128 of 265 in the control group, (RR for virologic failure 0.84, 95% CI 0.71–0.99; p = 0.04). The number needed to treat (NNT) to achieve greater than 95% adherence was 9 (95% CI 5.0–29.5), and the NNT to achieve viral load suppression was 11 (5.8–227.3).

**Conclusions:** Patients who received SMS support had significantly improved ART adherence and rates of viral suppression compared with the control individuals. Mobile phones might be effective tools to improve patient outcomes in resource-limited settings.

**Funding source(s):** US President's Emergency Plan for AIDS Relief

745

#### Malaria

*Keywords:* malaria, access to medicines, adherence, pregnancy

### **Different Approaches for Delivery of Intermittent Preventive Treatment (IPT) to Pregnant Women in Burkina Faso**

**Alphonse Ouédraogo**

Centre National de Recherche et de Formation sur le Paludisme, Burkina Faso

**Problem statement:** In Africa, the burden of malaria in pregnancy is highest in rural areas. In many sub-Saharan African countries, intermittent preventive treatment/sulfadoxine pyrimethamine (IPTp/SP) is being adopted to replace chloroquine chemoprophylaxis, which has been shown to be inefficacious. The new strategy is being implemented, but no delivery approach was defined, and IPTp/SP is only delivered to pregnant women presenting at antenatal clinic (ANC) visits. Weak health services may limit the effectiveness of this strategy.

**Objectives:** To compare 3 approaches of IPTp/SP delivery to pregnant women in terms of improving coverage and compliance

**Design:** It is an open, randomised, controlled clustered trial comparing 3 arms. Each community clinic and its catchment areas were considered as a cluster. Clusters were randomly assigned to 2 intervention arms and 1 control arm. Two cross-sectional surveys were planned to measure key outcome indicators; one at the beginning of the trial and the second one at the end of the study (post-intervention). Clinical and biological data were collected (parasitemia and haemoglobin).

**Setting:** The study took place in the health district of Saponé in Burkina Faso. The study was implemented in 12 community clinics randomly selected. It was based in the community and the public primary care facilities.

**Study population:** Four clusters were assigned to the community distribution arm with 1767 expected pregnant women, 4 clusters to the outreach approach with 1781 expected pregnancies, and 4 others to the control arm covering 1698

expected pregnancies. All pregnant women residing in the study area who consented to participate in the study and met the criteria were included in the study. Inclusion criteria were pregnant women who have gestational age of 15 weeks or more at the time of the visit and who were not allergic to sulphonamide-containing drugs (SP). For the evaluation surveys, we included all women present the day of ANC and who gave their consent to participate in the study.

Intervention: There are 2 intervention arms and 1 control arm. The first one is the extended delivery approach including outreach services. The second is the community-based distribution delivery approach. SP is distributed at the community level by community health workers.

Outcome measure: IPTp/SP coverage and compliance

Results: The mean coverage of 2 doses of IPT is higher in the community-based arm than in the control group (33% vs. 24%;  $P < 0.001$ ). The compliance was better in the control group than intervention groups ( $P = 0.001$ ). After the intervention, there was a decrease in peripheral parasitemia from 32.2% at health units to 25.9% with the community-based approach ( $P = 0.03$ ). There was also a decrease in anemia from 68.1% at outreach distribution approach compared to health units at 81.5% ( $P = 0.01$ ).

Conclusions: A combination of health facility-based and community-based approaches might be needed to maximise the impact of IPTp.

Funding source: University of Copenhagen/Denmark; WHO/TDR

## 746

### Malaria

*Keywords:* malaria community health workers, RDT Coartem, effectiveness

#### **Effectiveness of Using RDTs and ACTs for Home Management of Malaria in Children Under 5 Years Old in Zambia**

##### **VICTOR CHALWE**

TROPICAL DISEASES RESEARCH CENTRE, Zambia

Problem statement: Malaria is the highest cause of morbidity and mortality in Zambia. Malaria prevalence is now 385 per 1,000 population and 8,000 deaths are recorded each year due to malaria. The country has now changed its first-line malaria treatment policy to Coartem®, (artemether-lumefantrine; AL) an artemisinin-based combination therapy (ACT) because of widespread parasite resistance to chloroquine. One of the goals of the health reforms in Zambia is 'to provide equity of access to quality health care as close to the family (home) as possible'. The home management of malaria strategy is a WHO tool that identifies high-risk groups, such as children and pregnant women, and prescribes pre-packed antimalarial drugs for the treatment of fevers at home by way of community drug distributors. This strategy has been successfully tested in rural areas but evidence remains low on how this strategy could be used in settings adopting expensive antimalarial combination strategies in rural areas where the community health worker (CHW) is the first point of contact.

Method: This was an interventional study to evaluate the clinical outcome of children under the age of 5 years treated with AL after RDT diagnosis of malaria at community level and to assess the ability of a CHW to appropriately prescribe AL.

Results: The proportion of malaria cases among patients presenting to CHWs was 67.0%. Males had slightly higher positive rate of 68.9% (66.0-72.0%) compared to females with 66.6% (63.9-69.3%). Children under 5 represented 52.9% of the fever disease burden compared to patients older than 5 years (47.1%). Proportions of malaria cases rose up to the age of 5 (from 68% to 90%) before declining in those older than 5 years. There was a difference between peri-urban (58.0%) and rural sites (73.6%;  $p < 0.00001$ ). The sensitivity and specificity of using the CHWs as a delivery channel were 98.5% and 63.1%, respectively. Predictive values for a positive and negative test result for the same were 84.7% and 95.3%, respectively. The probability to test malaria positive with RDT for a younger patient from rural area presenting with fever was 0.8304.

Conclusion: There is justification for home management of malaria in endemic areas such as our sites, going by the heavy burden of malaria in under-fives. The use of CHWs is feasible and their adherence to instructions was reflected by predictive values of a positive and negative test results.

Funding source: World Bank

## 747

### Economics, Financing, and Insurance Systems

*Keywords:* drug price regulation, external reference pricing, international price benchmarking, developing countries

#### **External Reference Pricing (ERP): Existing Evidence and Lessons for Developing Countries**

**Jaime Espín<sup>1</sup>, Joan Rovira<sup>2</sup>, Antonio Olry de Labry<sup>1,3</sup>**

<sup>1</sup>Andalusian School of Public Health, Spain; <sup>2</sup>University of Barcelona; <sup>3</sup>CIBER Epidemiología y Salud Pública (CIBERESP), Spain

Problem statement: ERP can be defined as "the practice of using the price(s) of a pharmaceutical product in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country." Although many countries use ERP, information on how ERP is applied and on the impact of this approach is limited, especially in developing countries.

**Objective:** Describe, analyse, and discuss the use and impact of ERP with a particular focus on low- and middle-income countries

**Design:** (1) Literature search and synthesis of the international literature on the application and impact of ERP. (2) A 27-question survey was designed with 11 multiple choice questions and 16 open questions. A pilot test was done in July 2009 to a subgroup of 3 countries. Based on previous studies on price regulation policies and other information provided by HAI and WHO, all countries apparently using ERP and the appropriate contact persons from the drug price regulatory agencies were identified. The questionnaire was sent to 11 countries, 9 of which responded—Brazil, Czech Republic, Hungary, Iran, Jordan, Lebanon, South Africa, Sultanate of Oman, and United Arab Emirates; Colombia and Mexico did not respond.

**Results:** Most of the surveyed countries use ERP for all medicines, the exceptions being Brazil, which applies it only to on-patent products, and the Czech Republic, which restricts ERP to publicly reimbursable medicines. Iran states that ERP is used only for imported medicines. The countries used as references are usually selected from the same region and from similar income levels. However, some countries from other regions are often used (i.e., Spain, France, United Kingdom) because they have low prices and good availability of information. The sources of information are mainly the manufacturers' price certificates and websites of the reference countries. Some countries claim to expect price decreases, but none provides empirical evidence of the said effect. Studies found in the literature search find that ERP seems to cause price convergence as well as launch delays in low-price countries.

**Conclusions:** ERP does not have a clear economic rationale. In spite of its widespread and increased use, there is limited evidence on its intended and unintended effects, which are likely to depend on the particular way it is applied—selection of reference countries, formula to derive the target price, etc. It can nevertheless be a pragmatic option for countries unable to apply alternative pricing mechanisms and willing to rely on other countries' pricing policies.

**Funding source:** WHO/HAI

**748**

#### **HIV/AIDS and TB**

*Keywords:* HIV Malaria interactions prophylaxis control

### **Influence of Mefloquine Malaria Prophylaxis on HIV Disease Progression: A Randomized Placebo-Controlled Trial**

**Victor Chalwe**

Tropical Diseases Research Centre, Zambia

**Problem statement:** Malaria and HIV are 2 important diseases in sub-Saharan Africa. Malaria infection leads to transient increase of HIV-1 viral load and decrease of the absolute CD4 count. Therefore, malaria might accelerate HIV diseases progression in co-infected patients.

**Objective:** To evaluate the impact of mefloquine (MQ) prophylaxis on the progression towards AIDS in HIV-infected individuals

**Materials and methods:** A randomized, double-blind placebo-controlled trial of weekly MQ prophylaxis in asymptomatic HIV-positive individuals was carried out in Luanshya, Zambia. Inclusion criteria were HIV infection with a CD4 cell count  $\geq 350/\mu\text{L}$ . CD4 count and clinical examination was carried out every 6 months. Cox regression models were used to estimate the time to AIDS or low CD4 count and repeated measurements modeling to assess CD4 count decline.

**Results:** Median CD4 count at enrolment was  $471/\mu\text{L}$ . The median duration of follow-up was 16 months (range: 24 months). In the placebo group, 14.8% (22/149) reached a CD4 cell count of  $< 200/\mu\text{L}$  or developed AIDS stage III/IV compared to 19.5% (29/149) in the MQ group ( $p = 0.27$ ). The placebo group had a CD4 count decline to 49 cells/ $\mu\text{L}/\text{year}$  compared with 53 cells/ $\mu\text{L}/\text{year}$  in the MQ group ( $p = 0.21$ ). Haemoglobin increased from 12 g/L to 14.5 g/L in the placebo compared to 12.5 g/L to 13.5 g/L in the MQ group over the period of follow-up ( $p = 0.14$ ).

**Conclusions:** In HIV-infected individuals, MQ chemoprophylaxis did not have any effect on the evolution towards AIDS. The result could be underpowered as the malaria transmission decreased enormously during the short period of the study because of scale-up of malaria control interventions. Furthermore, only participants with high CD4 count, still immune competent and semi-immune for malaria, were selected. Malaria might still have an impact on immune-suppressed patients but these are eligible for antiretroviral treatment and Co-trimoxazole prophylaxis, an antibiotic with antimalarial properties.

**Funding sources:** DGCD funded framework agreement between ITM and TDRC

**751**

#### **Policy, Regulation, and Governance**

*Keywords:* access to medicines, community, good governance, ethics, private sector, transparency, Mongolia

### **Case Study of the Implementation of Good Governance for Medicines Programme in Mongolia**

**Tsetsegmaa Sanjiv<sup>1</sup>, Munkhdelger Chimedsuren<sup>2</sup>**

<sup>1</sup>Health Sciences University of Mongolia, Mongolia; <sup>2</sup>Ministry of Health, Mongolia

**Problem statement:** Increasing awareness among the stakeholders about corruption in the pharmaceutical sector and its impact on health systems is of high importance for enhancing transparency and accountability in medicines regulatory authorities and supply management systems and for developing the national capacity of the GGM regulation system.

**Objective:**To assess the impact of GGM programme in Mongolia through a survey of health care providers and the community

**Methods and study population:** Data were obtained from health care providers and the community by using a questionnaire (WHO) in 2006; 44 key informants were interviewed—27 (61.4%) were public/governmental servants, 5 (11.4%) were officers from governmental share-holding companies, 6 (13.6%) were from private pharmaceutical companies, and 4 (9.1%) were from NGOs, of which 2 (4.5%) were from international organizations.

**Results:** The results were drug registration 6.3; promotion 4.4; inspection 7.8; drug selection 5.9; and procurement 6.2. The Ethical Committee of MoH is responsible for implementation of the GGM programme in Mongolia since April, 2008. The code of conduct of pharmacists was adopted in 2006. The results of the national transparency assessment were officially published in 2008. A feedback meeting was held on April 21, 2009. A seminar for the private sector was organized in January 2010 to enhance the knowledge and awareness about the GGM programme among private pharmaceutical companies and to improve their collaboration with GGM. Several national standards on pharmaceutical activities were revised and approved. Registration of special permission to conduct professional activities in medical field and licensing to import medical equipment and pharmaceuticals is electronically available (<http://www.moh.mn/licemed/>). The elements of national ethical infrastructure were introduced to the pharmacy curriculum (2008). The amendment to the drug law, approved by the Parliament of Mongolia in 2010, incorporates the conflict of interest declaration forms in the drug committees. Time was lost in the establishment of the GGM committee, consisting of high-level officials, due to changes in the government, political instability, and epidemics.

**Conclusions:** Overall, both improvements and shortages regarding implementation of the GGM program have been observed in Mongolia. Selection, registration, and procurement areas need improvement. Although the appropriate regulations have yet to be developed, a particular criterion has to be included in the bidding document for medicines tendering procedures. Further studies and interventions are required.

**Funding source:** WHO

## 754

### Malaria

*Keywords:* National antimalarial treatment policy, malaria

#### **Effects of the 2005 Change in National Antimalarial Treatment Policy on Prescribing Practices in Two Referral Hospitals in Benin City, Nigeria**

**Stephen, Airmuanwonsa Ayinbuomwan, Ambrose, O Isah**

Clinical Pharmacology and Therapeutics Unit, Department of Medicine, University of Benin Teaching Hospital, Benin-City, Nigeria.

**Problem statement:** The increasing difficulty in the management of multidrug resistant falciparum malaria led to the recommendation of Artemisinin-based Combination therapy (ACT) by the WHO. This change in treatment policy was adopted by Nigeria in 2005. Antimalarial prescriptions are expected to be influenced by this change in policy in order to improve the prevailing malaria morbidity and mortality.

**Objective:**To evaluate the prescription of antimalarial medicines a year prior to and for three years following the change in the National antimalarial policy.

**Design:** A pre- and post intervention, descriptive study. The study was carried out in the out-patient department of the University of Benin Teaching Hospital and Central Hospital, both in Benin City, Nigeria.

**Study population:** The study evaluated a total of 2343 case records of adult patients ( $\geq 18$  yrs) treated for uncomplicated malaria from 2004 to 2008. Case records were selected by systematic sampling. Information extracted were patient's age, gender, diagnosis type of antimalarial medicine prescribed.

**Intervention:** The National Antimalarial Treatment Policy was published and circulated by the Federal Ministry of Health in 2005. The demerits of the continuous prescription of chloroquine for the treatment of malaria was emphasized and the need to use the ACTs recommended.

**Policy:** The policy recommended the use of Artemether-Lumefantrine (AL) as the first-line medicine for treating uncomplicated malaria. Other ACTs recommended include Artesunate-Amodiaquine (AA) and Artesunate-Mefloquine (AM).

**Outcome measures:** The study outcome was to ascertain the shift to ACTs in the management of uncomplicated malaria.

**Results:** Prior to the policy change (2004), Artesunate monotherapy was the most prescribed antimalarial (37.3%), followed by Sulphadoxine-Pyrimethamine (SP) and Chloroquine (CQ) monotherapies, 19.8% and 19.0% respectively. AL constituted 0.8%. Three years into the change in policy, AL was the most prescribed, with > 300% increase from 2004 ( $p < 0.05$ ). This was followed by AA and AM, 24.3% and 23.6% respectively. Artemisinin monotherapies dropped to 10.4% and non-ACT combinations rose to 5.1% of prescribed Antimalarials.

**Conclusion:** This study showed good adherence of prescribers to the change in antimalarial policy in hospital settings. The study also highlights that chloroquine, the medicine of first choice in the previous policy was undermined by prescribers who opted for artesunate monotherapy prior to the ACT era. There is need for stiffer regulations to limit the use of Artemisinin monotherapies if successful case management of malaria is to be sustained.

**Funding source:** Personal

758

### Child Health

**Keywords:** Neonatal sepsis, neonatal mortality, traditional birth attendant, lunesp, zambia, antibiotics with facilitated referral,

### **Antibiotics with Facilitated Referral to a Rural Health Center Using Zambian Trained Traditional Birth Attendants as a Strategy for Reducing Neonatal Mortality**

**Christopher J. Gill<sup>1</sup>, William B MacLeod<sup>1</sup>, Nicholas G. Guerina<sup>2</sup>, Mark Mirochnick<sup>3</sup>, Arthur Mazimba<sup>1</sup>, Anna Knapp<sup>1</sup>, Davidson H. Hamer<sup>1</sup>**

<sup>1</sup>Boston University School of Public Health, United States of America; <sup>2</sup>Tufts University School of Medicine; <sup>3</sup>Boston University School of Medicine

**Problem statement:** Neonatal sepsis is a major cause of neonatal mortality. In communities with limited access to health care, early identification of bacterial infections and initiation of antibiotics could be lifesaving.

**Setting:** Lufwanyama—an underdeveloped, impoverished, rural agrarian district in Zambia

**Study population:** Trained traditional birth attendants (TBAs); mothers/infants that they worked with

**Design:** Nested observational descriptive analysis within a cluster randomized controlled study (The Lufwanyama Neonatal Survival Project)

**Intervention:** The intervention TBAs were trained to recognize any of a set of cardinal symptoms and signs of possible neonatal infection; if any were observed in the first 4 weeks of life, intervention TBAs were to administer a 500 mg dose of oral amoxicillin and facilitate referral (AFR) to the nearest health facility. The current analysis aims to better characterize the AFR process, with the ultimate goal of identifying areas that could be improved.

**Outcome measures:** Frequency of postpartum visits by intervention TBAs to the mother/infant pair; utilization of AFR; reasons for AFR; proportions of completed referrals; proportions of infants who later died who had been referred or treated

**Results:** In the month after delivery, intervention TBAs conducted a median of 4 (IQR 2-6) home visits (49% occurred in week 1, 51% in weeks 2-4 postpartum). TBAs who referred had nearly always given amoxicillin (96.8% [214/221]), and TBAs who gave amoxicillin nearly always referred (95.3% [204/214]). The most frequent reasons for referral were 'cough' 39.7% (75/189), 'baby felt too hot' 38.6% (73/189), 'mother thought baby looked sick' 35.5% (67/189) and 'difficulty breathing' 24.3% (46/189). A lower proportion of mothers completed the referral (75% [165/221]). Compared with live-born infants who survived, those who later died were significantly more likely to have been referred by the TBA compared with those who survived (RR 13.9; 95% CI 6.8-28.3), and were more likely to have been given amoxicillin (RR 9.2; 95% CI 4.6-18.4). However, only 2/3rd of live-born infants who died were referred, and only ~50% received amoxicillin.

**Conclusions:** The TBAs maintained frequent contact with the mother/infant pair after delivery. Referral and amoxicillin use occurred at similar rates, suggesting that the TBAs were correctly identifying many sick infants and responding appropriately. Further work is needed to improve the effectiveness of TBAs in reducing neonatal mortality and to understand why mothers often declined referral.

**Funding source:** USAID, NIH/NIAID

759

### Policy, Regulation, and Governance

**Keywords:** pharmacovigilance, education, antimicrobials

### **Implementing an Egyptian Pharmacovigilance System: University and Public Hospitals' Experience**

**Sawsan Aboul-fotouh El-Said<sup>1</sup>, Amr Saad<sup>2</sup>, Ahmed Nouredin Hassan<sup>1</sup>, May Hamza<sup>1</sup>, Ahmed Mohyeldin Abdel-tawab<sup>1</sup>**

<sup>1</sup>Faculty of Medicine, Ain Shams University, Cairo, Egypt, Egypt; <sup>2</sup>Egyptian Pharmacovigilance Center (EPVC), Ministry of Health, Cairo, Egypt.

**Problem statement:** Underreporting of adverse drug reactions (ADRs) has put a huge burden on the health care system in Egypt. Three years ago, the Clinical Pharmacology Unit (CPU) developed a mechanism for ADR-reporting involving different departments at Ain Shams University Hospitals (ASUH). Recently, a partnership was established between CPU and the newly established Egyptian Pharmacovigilance Center (EPVC). The later constructed a nationwide ADR-reporting system. Training and advocacy of health care professionals (HCPs) on pharmacovigilance (PV) sought to enhance reporting of ADRs.

**Objectives:** To assess the impact of PV training modules on the attitude of current and future HCPs towards reporting ADRs

**Design:** Comparative cross-sectional surveys

**Setting:** One setting included government medical school and hospital and a private school of pharmacy; the other setting included public hospitals.

**Study population:** The first cohort included physicians and pharmacists (n = 27) participating in the Searching and Appraising the Literature on Antibiotic Medication (SALAM) workshop, final-year pharmacy students (n = 93), and a cluster sample of third-year medical students (n = 325). The other cohort included practicing hospital pharmacists (n = 240) in public hospitals.

**Intervention(s):** Real cases from ASUH were presented as case scenarios on ADR reporting using yellow cards and causality assessment by searching different databases and applying probability scales. This training was delivered to

undergraduate students as a part of their clinical pharmacology (CP) course; HCPs during the 6-day SALAM workshop; and hospital pharmacists during a 5-day PV module.

Outcome measure(s): Attitude towards ADR reporting and willingness to participate in the national mechanism for ADR reporting

Results: The mean  $\pm$  SD years of experience was  $10.2 \pm 8.4$  in the first setting compared with  $7.4 \pm 4.6$  in the second setting. Only 40.7% vs. 31.2% were familiar with the mechanism of ADR reporting and only 14.8% vs. 10.4% have previously reported an ADR to a PV center, in the first and second cohorts, respectively. After the SALAM workshop, 96.3% were willing to participate in the national mechanism for ADR reporting in the future. At the end of the CP course, 92.2% of medical students and 75% of pharmacy students learned how to fill an ADR report. The percentage of medical and pharmacy students willing to participate in the national mechanism for ADR reporting were 83.9% and 74.2%, respectively. On the other hand, at the end of PV training for the hospital pharmacists, 90.8% learned how to report ADRs, 87.1% were willing to report them, and 81.7% believed that this will positively influence health policy and costs in Egypt; 21 and 80 valid ADR reports were received following this advocacy by the CPU and EPVC, respectively

Conclusions: Training and advocacy on PV systems has positively influenced the attitude toward reporting ADRs in both settings.

Funding source: Information not provided

## 760

### Access

Keywords: access to medicines, consumers, disparities, social determinants

### Social Determinants of Access to Medicines in 3 Central American Countries

**Maria Cecilia Acuna<sup>1</sup>, Nelly Marin<sup>1</sup>, Adriana Mendoza<sup>1</sup>, Celia Landman<sup>2</sup>, Thiago Azeredo<sup>2</sup>**

<sup>1</sup>PANAMERICAN HEALTH ORGANIZATION, United States of America; <sup>2</sup>OSDWALDO CRUZ FOUNDATION, Brazil

Problem statement: Health systems' equity, efficiency, and quality as well as patients' satisfaction will be difficult to achieve without making medicines accessible for all those who need them. One of the biggest gaps identified in reaching the MDGs by 2015 is the progress towards achieving access to essential medicines. Although this issue has been analyzed from different perspectives—such as price, availability and quality of medicines—the factors that influence people's behavior regarding access to medicines have been poorly explored. This study examines social determinants that affect people's behavior in relation to seeking and obtaining the medicines they need.

Objective: Assess the impact of social determinants on access to medicines

Design: Cross-sectional study

Setting: The study was conducted at the national level in Guatemala, Honduras, and Nicaragua. It examines both the public and the private sectors.

Study population: A total of 2,779 households were selected through a random sample. An average of 36 public health care facilities with their respective pharmacies, 5 public warehouses, and 30 private pharmacies per country were selected through a convenience sample.

Intervention: Data collection conducted from December 2007 to April 2008 included household and health services surveys and review of secondary sources. Stakeholders of all 3 countries and local PAHO officers were involved in all phases of the study. Each country was a unit of study and the results were compared among them.

Outcomes measures: Impact of the economic condition and characteristics of the household as well as sex, age, ethnic background, education level, and employment status of the head of the household over the seeking behavior/demand for and access to health care and medicines

Results: The outcomes of the multivariate logistic regression model using principal components show that the main determinant of exclusion from access to medicines is the lack of access to institutional care (OR 4.102, CI 95%); other determinants of access to medicines are the characteristics of the household (OR 0.747, CI 95%), the head of the household being employed in the formal economy (OR 0.707, CI 95%), and the socioeconomic condition of the household (OR 0.462, CI 95%)

Conclusion: Formal employment, good socioeconomic conditions, and basic amenities in the household (potable water, sanitation, electricity, adequate number of bedrooms) foster medicines seeking behavior and increase the probability of accessing medicines. On the contrary, exclusion from health care is a powerful predictor of lack of access to medicines. Policies to improve access to medicines should take this findings into account.

Funding source: Swedish International Development Agency

## 762

### Access

Keywords: self-medication, predictors, medication use, Sri Lanka, prevalence

### Practice and Predictors of Self-Medication Among Urban and Rural Adults in Sri Lanka Three Decades after Market Economic Reforms

**Pushpa Ranjan Wijesinghe**

Ministry of Health, Sri Lanka

**Problem statement:** Self medication is practiced in all communities to varying degrees and information about it in Sri Lanka is scarce in the period of post-market economy reforms.

**Objective:** To describe the current practice and predictors of self-medication in a selected urban and rural area

**Study design:** Community-based, analytical cross-sectional survey

**Study setting:** The predominantly urban Gampaha district has a well developed health and pharmaceutical care network whereas the rural Polonnaruwa district has a less developed health and pharmaceutical network with poor access to medicines.

**Study population:** Adults over 18 years of age, irrespective of sex, permanently residing in the selected districts over a period of 1 year. A population sample of 1800 adults were selected by a stratified, multi-stage, probability proportional sampling procedure.

**Outcome measures:** Medication use in the 2-week period prior to the interview was ascertained. Additionally, access to medical care and satisfaction with available pharmaceutical care were measured. To determine the predictors of medication use, medication use was modeled as a function of predisposing, enabling, and need variables.

**Results:** Self-medication was practiced by 12.2% of urban and 7.9% of rural adults ( $p < 0.05$ ). A majority had self-medicated for acute onset conditions of short duration (urban 58%; rural 67%) and conditions perceived as non-severe (urban 55%; rural 64%). Fewer symptoms, perceived low acceptability of services, and being a member of a small household emerged as significant predictors of self-medication in the urban sector. Inability to afford medical care, perceived higher technical competence of the pharmacy staff, and fewer symptoms were significant predictors in the rural sector.

**Conclusion:** Prevalence of self-medication, which is higher in the urban sector, is lower than the estimates reported for developed countries. Adults self-medicate mainly for conditions of acute onset, short duration, and less severity. Although medical services are available, poor acceptability of services prompted urban individuals to self-medicate. Inability to afford medical services and perceived higher technical competence of pharmacy staff prompted rural individuals to self-medicate. Findings are important to shape policy changes related to the implementation of the cosmetic devices and drug act in the country and design programs to educate consumers who are moving towards self-medication, especially in urban areas where the pharmacy trade is thriving as a profit maximization business.

**Funding source:** By the authors

763

**Access**

*Keywords:* adherence, appropriate use, patient safety, pharmacy practice, retail pharmacy

### **Assessing the Extent of Pharmaceutical Care Provision in Kigali Community Pharmacies**

**Morris Ndekwe<sup>1</sup>, M.Monique Rwabuhungu<sup>1</sup>, Patrick Gaparayi<sup>2</sup>, Ntokamunda Kadima<sup>1</sup>**

<sup>1</sup>National University of Rwanda, Rwanda; <sup>2</sup>Management Sciences for Health, Strengthening Pharmaceutical Systems-Rwanda

**Problem statement:** Despite the fact that Rwanda currently has health policies and health insurance schemes that ensure access to essential medicines, there is no published data about the level of pharmaceutical care services provision in community pharmacies to ensure that patients are receiving intended quality care and services.

**Objective:** To establish the extent to which each of the formal elements in the pharmaceutical care process is practiced and to determine the evolution of the role of pharmacist toward patient-centred care

**Design:** An observational study was conducted in 31 private community pharmacies after receiving their voluntary agreement to participate. Using a standardized checklist adapted from the patient care process by R. Cipolle et al. (2004), we observed pharmacist-patient interactions to acquire data as it actually happened. To avoid biases due to our presence in the pharmacy, we eliminated the first 5 interactions per pharmacy. Using an open ended questionnaire, we also conducted in-depth interviews with pharmacists to obtain their opinions about pharmaceutical care as well as information about available resources facilitating patient-centered care.

**Setting:** 31 randomly selected, private community pharmacies located in all 3 districts of Kigali City

**Study population:** In total, 279 patients with prescriptions who interacted only with the pharmacist during the medicine dispensing time were included in our study.

**Results:** In general, the study showed that pharmaceutical care services were provided at an extent of 23.7%, concentrating more on basic pharmaceutical care. Taken individually, patient care elements were performed at different levels—building therapeutic relationship between patient and pharmacist (50.4%), assessing drug therapy needs (19.8%), developing a care plan (29.4%), communicating with patients (18.7%), and follow-up evaluation (0.4%). The average pharmacist-patient interaction time was 2 minutes 23 seconds, less than the recommended 5–10 minutes for basic pharmaceutical care provision. Moreover, none of the respondents documented pharmaceutical care provided to their patients whereas 48.4% of the pharmacies did not have any private area to facilitate pharmaceutical care provision. Finally, 93.6% of the respondents stated that they did not provide any service to their patients beyond medicine dispensing.

**Conclusion:** The provision of pharmaceutical care in community pharmacies in Kigali City is not formalized; to fill the identified gaps to optimize patient-centered care, policy makers need to (1) prioritize pharmaceutical care as an urgent interventional area for investing resources, (2) incorporate pharmaceutical care into the pharmacy practice policy, (3) establish strategies to foster adoption (acceptance and demand creation) of pharmaceutical care practice, and (4) capacitate community pharmacists to provide pharmaceutical care.

Funding source: National University of Rwanda

**764**

### Chronic Care

*Keywords:* pharmaceutical care, schizophrenia, clinical outcomes, humanistic outcomes, cost effectiveness

### Outcomes of Pharmaceutical Care in Schizophrenic Patients

**Juntip Kanjanasilp, Chanuttha Ployleumsang**

Maharakham university, Thailand

**Problem Statement:** Drug related problems of schizophrenic patients causes to increase the recurrent rate, the suicide rate and increase the cost of treatment. Pharmaceutical care is a process to identify, resolve, and prevent the drug related problems and improve the quality of life.

**Objectives:** The purpose of this experimental study was to examine the outcomes of pharmaceutical care in schizophrenic patients (clinical, humanistic, economic outcomes).

**Design:** Randomized controlled trial

**Setting:** 3 psychiatric hospitals in Northeast of Thailand

**Study Population:** The schizophrenic patients who visited the outpatient department of 3 psychiatric hospitals in Northeast of Thailand were recruited. Ninety-three patients were randomly assigned to receive pharmaceutical care (intervention group) and 95 patients received usual care (control group) both of them matching by the severity of disease and the right of treatment.

**Intervention(s):** Pharmaceutical care (obtaining medication history; Identifying, resolving and preventing for the patients' DRPs; monitoring patients for desired and undesired outcomes) for 1 month

**Policy(ies):** Improvement for pharmaceutical services in the psychiatric hospital, especially for schizophrenic patients.

**Outcome Measure(s):** Clinical outcome(Drug related problems),humanistic outcomes( knowledge, quality of life, adherence), economic outcomes(cost)

**Results:** Number of drug related problems decreased in both groups (the intervention group decreased 107 DRPs (62.9%) and the control group decreased 15 DRPs (14.3%). The most DRPS was failure to receive drug in both groups. The mean knowledge score of schizophrenia and antipsychotics used statistical significantly increased in both groups (the intervention group  $6.7 \pm 1.68$  to  $8.2 \pm 1.48$  ( $p < 0.001$ ); the control group ( $7.1 \pm 1.73$  to  $7.6 \pm 1.75$  ( $p=0.010$ )). The mean score of quality of life was in the moderate level in both group, however, it tended to increase in the intervention group especially the physical domain and mental domain increase significantly( $p < 0.001$ ). The average total costs in the pharmaceutical care group and usual care group were 16.19 and 14.03 USD/patient, respectively. The proportion of labour costs : material cost : capital cost for pharmaceutical care and usual care were 6.61: 92.96 : 0.43 and 5.05 : 94.92 : 0.03, respectively. The medication adherence and quality of life in the pharmaceutical care group had 97.8 % and 93.5% of successful patients, respectively, whereas the usual care group showed 87.4% and 93.7 %, respectively. Cost-effectiveness ratios (CER) of pharmaceutical care and usual care for good medication adherence was 16.54 and 16.06 USD/successful patient, respectively and CER for improved quality of life was 17.30 and 14.98 USD/successful patient, respectively. Incremental cost effectiveness ratio (ICER) of pharmaceutical care compared with usual care for improved adherence was 20.58 USD/successful patient.

**Conclusions:** In summary, the overall results of the study showed that pharmaceutical care can reduce the number of drug related problems, and increase knowledge of schizophrenia and antipsychotics used and quality of life especially in the physical and mental domain. However, 1-months of pharmaceutical care is not cost-effective, but if in the long time pharmaceutical care can increase the number of successful patients more than usual care by at least 20 cases, it will be cost-effective.

**Funding Source(s):** Maharakham university

**766**

### Drug Resistance

*Keywords:* MRSA, Guidelines, Awareness, Adherence, Alexandria.

### Awareness and Adherence to Methicillin-Resistant S. Aureus Guidelines, as per WHO, at Alexandria University Hospitals

**R.M. Abu-Youssef<sup>1</sup>, G.S. Soliman<sup>1</sup>, B.F. Saleib<sup>1</sup>, A.M. El-Moughazi<sup>1</sup>, A. Zaki<sup>2</sup>**

<sup>1</sup>Alexandria University, Faculty of Medicine; <sup>2</sup>Alexandria University, Department of Bioinformatics and Medical Statistics, Medical Research Institute.

**Problem statement:** MRSA is believed to be the result of decades of antibiotic misuse. A study done at Alexandria University Hospital in 2009 reported that 71 out of 100 S. aureus isolates were MRSA. Clinicians must be aware of the potential danger of MRSA infection.

**Objectives:** Assess the awareness and adherence to MRSA control guidelines among the medical staff and unveil the reasons, if any, for non-adherence.

**Design:** Descriptive cross-sectional study

**Setting:** Local level; examines the public sector health care staff at Alexandria Main University Hospital & Pediatrics/Obstetrics Hospital

**Study population:** The study was conducted from September 2010 to November 2010. A sample of 158 physicians and 47 nurses were randomly selected from among medical staff working in the departments of Anesthesiology, Cardiothoracic Surgery, Coronary Care Unit (C.C.U.), General Intensive Care Unit (I.C.U.), Neonatal I.C.U., Pediatric I.C.U., and Pulmonology. Data was collected using a pretested self-administered questionnaire covering detailed questions about the magnitude of the problem of MRSA, awareness about routes of transmission, available guidelines and the rate of adherence to the guideline recommendations.

**Results:** Overall awareness of MRSA control guidelines was 67.3%. The highest rate of awareness of MRSA was found among medical staff in the Neonatal I.C.U. (85.7 %), and the lowest among Anesthesia staff (45%), ( $p < 0.05$ ). Medical staff with more than 3 years experience were significantly more aware about MRSA guidelines as compared to less experienced staff ( $p < 0.01$ ). The three main reasons for lack of awareness were lack of infection control teaching program (72%), unavailable guidelines on department walls (49%) and work overload (34%). 55% knew the correct MRSA transmission routes. 86% were aware that washing hands after removing gloves is obligatory, while 70% supported screening of high-risk patients to help early detection. 70% acknowledged the use of new gloves with each procedure done on the patient. Regarding guideline implementation, 31.2% of the medical staff believed that the guidelines are implemented. Non adherence to recommendations was mostly observed in the lack of proper utilization of equipment (81%), isolation measures (56%) and hand-washing (35%). The three main reasons for poor adherence to guidelines' recommendations were unavailability of resources (58%), lack of awareness (33%) and lack of supervision (18%). 98% ( $p > 0.05$ ) of interviewees agreed on the importance of the guidelines, while 91% ( $p < 0.05$ ) believed that they adhere to them.

**Conclusions:** The study showed low levels of awareness and poor adherence to MRSA-related guidelines. Efforts should be exerted to maintain an influential infection control team whose responsibility is reinforcement of guideline implementation as well as undertaking of periodic health education programs.

**Funding source:** Self-funded

**769**

#### **Policy, Regulation, and Governance**

*Keywords:* Pharmacovigilance, patient safety, adverse effects

#### **Strengthening Pharmacovigilance Systems: Experiences from Kenya**

**Ndinda Kusu<sup>1</sup>, Jayesh Pandit<sup>2</sup>, George Muthuri<sup>2</sup>, Janet Kimeu<sup>1</sup>, Dorine Kagai<sup>3</sup>, Lilian Gitau<sup>1</sup>, Mary Wangai<sup>1</sup>, Fred Siyoi<sup>2</sup>**

<sup>1</sup>Management Sciences for Health, Kenya; <sup>2</sup>Pharmacy and Poisons Board; <sup>3</sup>National AIDS and STI Control Program

**Problem statement:** Global initiatives to address public health priorities in developing countries such as HIV/AIDS, malaria, and tuberculosis (TB) have increased access to medicines. This has subsequently created the need to monitor and promote the safety and effectiveness of these medicines via national pharmacovigilance programs. However, many developing countries lack the appropriate structures, systems, and resources to systematically support the detection and prevention of adverse drug reactions (ADRs) and other medicine-related problems.

**Objective:** To promote patient safety by implementing a nation-wide pharmacovigilance system

**Design:** Intervention under the stewardship of the Pharmacy and Poisons Board (PPB). MSH/SPS worked with the PPB to implement a "one-national" integrated pharmacovigilance system.

**Setting:** Public, faith-based, and private sector health facilities throughout Kenya

**Intervention:** In collaboration with other stakeholders, MSH/SPS supported the development of national pharmacovigilance guidelines, reporting tools, training materials, and job aids. The national launch of the pharmacovigilance program was in June 2009. A national rollout was planned and initiated with dissemination of guidelines and reporting tools plus capacity building of regional trainers..MSH/SPS and PPB used a systematic capacity building approach that ensures that both institutional and human resource capacities are strengthened to become robust and functional. Strengthening structures, roles, responsibilities, staff, and infrastructure addressed institutional capacity, while tools and skills focused on health worker capacity. These activities required coordination among different public health programs and were supported by a variety of donors.

**Outcome measures:** Number of reports, regulatory actions taken, number of staff trained, and activities undertaken.

**Results:** By December 2010, Kenya became the 98th full member of WHO Programme for International Drug Monitoring and over 5000 staff were trained on pharmacovigilance. A post-market surveillance strategy was developed and undertaken for anti-TB and antiretrovirals (ARVs).The PPB has received over 100 reports of poor quality medicines and over 1000 reports on ADRs; 60% of ADR reports are ARV-related. Twelve sites have been identified to provide ARV ADR sentinel surveillance and facility medicines and therapeutic committee representatives trained. The PPB has a drug safety review committee and a communication mechanism that promotes timely and regular information feedback. A consumer reporting system for poor quality medicines and ADRs is now in place.

**Conclusion:** It is possible to leverage support from partners and parallel funding streams for comprehensive pharmacovigilance system strengthening. Involving the PPB built country ownership and is a sustainable approach to promote access to quality medicines and patient safety in resource-limited settings.

**Funding source:** Information not provided

770

**HIV/AIDS and TB***Keywords:* Pre-service training, pharmaceutical management, medicines**Human Resources for Health: Preservice Training of Pharmacy Students on Effective Management of Antiretroviral Therapy Commodities in Kenya****Ndinda Kusu<sup>1</sup>, Richard Kolute<sup>2</sup>, Lilian Gitau<sup>1</sup>, Julie Ogolla<sup>2</sup>, Charles Onudi<sup>2</sup>, Janet Kimeu<sup>1</sup>, Mary Wangai<sup>1</sup>, Sarah Muniu<sup>3</sup>**<sup>1</sup>Management Sciences for Health, Kenya; <sup>2</sup>Kenya Medical Training College; <sup>3</sup>Kenyatta National Hospital

**Problem statement:** Assessment of pharmaceutical services in Kenya has revealed inadequate training and skills among health care providers. In particular, the lack of preservice training on pharmaceutical management is a significant weakness.

**Objective:** To determine acceptability and knowledge gained during a 5-day, rapid orientation preservice pharmaceutical management course among diploma pharmacy students

**Design:** A before and after training assessment using scored pre- and post-training tests and a post-training course evaluation

**Setting:** 3 Kenya medical training college campuses in August 2009 and July 2010

**Study population:** Graduating diploma in pharmacy students of 2009 and 2010

**Interventions:** 5-day training course on effective management of ART commodities covering an overview of HIV and AIDS, antiretroviral drugs, commodity management, inventory management, rational use of medicines, pediatric ART, drug interactions, and adverse effects; this course incorporated classroom learning, exercises, case studies, and practicum

**Results:** A total of 297 students were trained in 2009 and 2010 and a pre-post test covering the key course content was administered on both occasions. In 2009 (n = 101), the mean score for the pretest was 65.2% and the mean score for the post-test was 79.4%. In 2010, (n = 196), the mean score for the pretest was 64.5% and the mean score for the post-test was 75.9%. In 2009, the ranges of pre- and post-test marks were 38–78% and 60–93%, respectively. In 2010, the ranges of pre- and post-test marks were 44–86% and 60–98%, respectively. Of the 297 students, 96% proposed that the course content be included in the diploma curriculum and 78% recommended the inclusion of the course within year 3 of the diploma in pharmacy course.

**Conclusions:** Students responded positively to this course and recommended that it be institutionalized in the diploma curriculum. The training improved students' knowledge and skills on effective management of ART and other medicines as evidenced by the improvements in post-test scores. A preservice curriculum for pharmaceutical cadres should include key topics of pharmaceutical management to equip future health workers with appropriate and relevant knowledge and skills.

**Funding source:** The President's Emergency Fund for HIV/AIDS (PEPFAR) through USAID and the Kenya Medical Training College

771

**Child Health***Keywords:* Medicine Price Ratio, Availability of Medicine, Essential Medicine List for Children, Out of Pocket Expenditure.**Survey of the Availability and Prices of Children's Medicine in Chhattisgarh State****Antony Kollannur, Virendra Jain, Puni Kokho, Kamlesh Jain**

State Health Resource Centre, Chhattisgarh, India, India

**Problem statement:** Children are therapeutic orphans, lacking appropriate clinical trials, licensed medicines, formulations, information, etc. In Chhattisgarh, only 33% of children with diarrhoea receive ORS and only 66% receive treatment for ARI. High child mortality, preventable with appropriate and timely use of essential medicines, which is highly priced and therefore, increasing out-of-pocket expenditures are a concern.

**Objectives:** To document the availability and price of key essential medicines for children in public and private health facilities in the state of Chhattisgarh

**Design:** A facility-based, cross-sectional study of the availability, price, affordability, and price components of selected children's medicines was undertaken using a standardized methodology from WHO-Health Action International. The prices, including government procurement prices, and availability of 50 paediatric medicines were collected from a random sample of 75 public sector facilities, 60 retail pharmacies, and 25 other private sector outlets (private clinics, nursing homes, dispensing doctors, and health facilities run by nongovernmental organizations), totaling 160 dispensing sites. A price components survey was also conducted to identify the add-on costs in the supply chain that contribute to final patient prices.

**Setting:** The study covering both private and public sectors was conducted in 6 geographical sites (districts) in Chhattisgarh state, India.

**Study population:** A total of approximately 160 outlets were randomly sampled among 28 types of medical dispensing sites from October to November 2010.

**Policy:** Need of centralised procurement and logistics systems for children's medicine

Outcome measure(s): For each medicine, data were collected on the highest-priced and lowest-priced product found at each facility. Medicine prices are expressed as median price ratio (MPR), which are ratios relative to the MSH international reference prices for 2009. Using the salary of the lowest-paid, unskilled government worker, affordability was calculated as the number of days' wages needed to purchase medicines for standard treatments of common conditions.

Results: The average availability of lowest-priced paediatric medicines in the public sector and NGO/mission sectors was only 17%. In the public sector, more than half (29/50) of the study medicines were not available in any of the facilities surveyed. In retail pharmacies and other private, for-profit outlets, availability was higher at 46% and 35%, respectively, for lowest-price medicines and the availability of highest-price medicines was 14% and 7%, respectively. Overall, the public procurement agency is purchasing medicines with reasonable efficiency at prices that are just under international reference prices (MPR = 0.96). Patients in private pharmacies are paying 1.82 and 1.38 times the international reference price, on average, to purchase highest-priced and lowest-priced products whereas in private hospitals and nursing homes, it's 2.59 times. The manufacturer's selling price (MSP) and mark-ups for wholesalers and retailers are principal contributors to the final patient price. For originator brand and branded generic products, the total cumulative mark-up from MSP to final price ranged from 34% to 46%, whereas for unbranded generics, it ranged from 376% to 413%.

Conclusions: The average availability of children's medicines was poor in all sectors, with high mark-up in pricing, emphasising the need for a centralised procurement and logistics system for EML for children in Chhattisgarh.

Funding source: WHO-New Delhi

772

### Child Health

Keywords: acute diarrhoea, children, prescriptions, guidelines, adherence, India

#### **Adherence to Treatment Guidelines for Acute Diarrhoea in Children up to 12 Years in Ujjain, India**

**Ashish Pathak<sup>1,2</sup>, Deepali Pathak<sup>1,3</sup>, Gaetano Marrone<sup>1</sup>, Vishal Diwan<sup>1,4</sup>, Cecilia Stålsby Lundborg<sup>1</sup>**

<sup>1</sup>IHCAR, Division of Global Health, Karolinska Institutet, Sweden, India; <sup>2</sup>Department of Paediatrics, R.D. Gardi Medical College, Ujjain, India; <sup>3</sup>Grasim Trust's G.D. Birla Memorial Hospital, Ujjain, India; <sup>4</sup>Department of Public Health and Environment, R.D. Gardi Medical College, Ujjain, India

Problem statement: In India, diarrhoea accounts for 20% of all paediatric deaths. WHO recommendations, the Indian Academy of Paediatrics, and the Government of India treatment guidelines are in place, but few children receive low osmolarity oral rehydration solution (ORS) and zinc.

Objective: Analyze prescriptions for acute diarrhoea for adherence to guidelines with respect to the proportion of ORS, zinc, and antibiotics and the factors affecting prescribing

Design: Cross-sectional study done June to August 2010; data collection instrument was designed to include all possible medications given for an episode of acute diarrhoea in children. Pharmacists in pharmacies and resident medical officers in hospitals transferred the information of the diarrhoeal episode and the treatment given to the data collection instrument.

Setting: Pharmacies and major hospitals of Ujjain, Madhya Pradesh, India

Study population: We included prescriptions from modern medicine, ayurveda, homeopathy, and informal health care providers (IHPs) for children up to 12

Outcome measures: Prescription of ORS alone and ORS with zinc; prescriptions containing antibiotics; factors affecting prescription of ORS along with zinc and also antibiotic prescribing

Results: Information was collected from 843 diarrhoea prescriptions. We found only 6 prescriptions with the recommended treatment (ORS along with zinc) with no additional probiotics, antibiotics, racecadotril, or antiemetics (except Domperidone for vomiting). ORS alone was prescribed in 58% of the time, where as ORS with zinc was prescribed 22%. However these also contained other drugs not included in the guidelines. Antibiotics were prescribed in 71% of prescriptions. Broad-spectrum antibiotics were prescribed and often in illogical fixed-dose combinations, such as ofloxacin with ornidazole (22% of antibiotics prescribed). Practitioners from alternate systems of medicine and IHPs are significantly less likely (OR 0.13, 95% CI 0.04-0.46, P = 0.003) to prescribe ORS and zinc than pediatricians. Practitioners from 'free' hospitals are more likely to prescribe ORS and zinc (OR 4.94, 95% CI 2.45-9.96, P < 0.001) and less likely to prescribe antibiotics (OR 0.01, 95% CI 0.01-0.04, P < 0.001) compared to practitioners from 'charitable' hospitals. Accompanying symptoms (fever, pain, blood in the stool, and vomiting) significantly increased antibiotic prescribing.

Conclusion: This study demonstrated low adherence to STGs for management of acute diarrhoea in children under 12 years in Ujjain, India. Key public health concerns were the low use of zinc and the high use of antibiotics found in prescriptions from specialist paediatricians and practitioners from alternate systems and IHPs. To improve case management of acute diarrhoea, continuing professional development targeting practitioners of all systems of medicine is necessary.

Funding source: Information not provided

773

### Policy, Regulation, and Governance

Keywords: access to medicines, drug donation, medicine supply, pharmaceutical policy

## **Tsunami Drug Donations in Sri Lanka: Have the WHO Guidelines on Drug Donations been Effective in Meeting Public Health Pharmaceutical Needs in Times of Disaster?**

**Rohini Fernandopulle<sup>1</sup>, Hemantha Beneragama<sup>2</sup>, Priyadarshini Gallappathy<sup>1</sup>, Nilesh Fernandopulle<sup>2</sup>**

<sup>1</sup>Faculty of Medicine, University of Colombo, Sri Lanka; <sup>2</sup>Ministry of Health

Problem statement: Noncompliance with WHO good donation practices resulted in inappropriate donations

Objective: To determine compliance with WHO guideline for donations received by the Ministry of Health (MOH) following the tsunami in Sri Lanka in 2004

Design: Pharmaceutical policy analysis

Setting: State sector; private organizations were excluded.

Methodology: Data was collected using investigator administered questionnaires from March to July 2005. A product that had the same drug substance, in the same dosage form and in the same strength irrespective of their brand name and package size, was classified as a 'unique drug product' (UDP). The UDPs were then classified according to the 4 categories of the donation guideline (selection, quality assurance and shelf life, presentation packing and labelling, and information and management). Selection was determined on the Anatomical Therapeutic Chemical classification status in the WHO model list of essential drugs (2003), the MOH expressed list, the hospital formulary list (2004), the WHO/UNICEF emergency list, Sri Lanka registered medicines list and the British National Formulary (March 2005). Destroying costs were calculated using documents available.

Outcome measure(s): Percentage compliance with WHO guideline

Results: Of all the UDPs, 80% were unsolicited and arrived unannounced in unsorted boxes, 86% of which were under an individual's name or donated to international focal points (~50%). The balance was donated by governments (8.4%) or national or multinational pharmaceutical firms (5.6%); 53% of UDPs belonged to the 'non-list' category; 38% of INNs were unregistered in the country; 50.5% (28 metric tons) did not have expiry dates. Among those with an expiry date, 6.5% had expired on arrival and only 67% complied with the guideline of a remaining shelf life of at least 1 year; 62% of UDPs were labelled in a non-understandable language, 81% were without package inserts, and 15% were without generic names. Medicines purchased after consulting with the MOH and over 90% of the donations sent directly by governments had the required shelf life of over 1 year and were 100% utilized. The value of 1 donation claimed by the donor was 50% of the public sector drug budget, but the budget for 2005 was reduced only by 4%. Cost of destruction of unwanted medicines was approximately SLR 2.5 million and was borne by Sri Lanka.

Conclusions: The WHO guidelines are comprehensive and would have prevented the burden of useless donations if adhered to, but total reliance on donor compliance resulted in inappropriate donations. The lack of a policy on acceptance of donations was a major contributory factor. Donors failed to comply with the guidelines on matters of selection, quality assurance and shelf-life, presentation, packaging, labelling, language, information and disposal.

Recommendations: MOH should have a written policy on drug donations based on the WHO drug donation guidelines and should strictly enforce adherence to the guidelines when donations are received.

Funding source(s): World Health Organization

## **775**

### **Chronic Care**

*Keywords:* affordability, medicine prices, access to medicines, generic (multisource) medicines, chronic disease

## **Affordability of Medicines for Treating Chronic Diseases in Southern Brazil**

**Ana Paula Helfer<sup>1</sup>, Andréa Dâmaso Bertoldi<sup>2</sup>, Aline Lins Camargo<sup>3</sup>, Noemia U L Tavares<sup>4</sup>**

<sup>1</sup>APESC – Hospital Santa Cruz, Brazil; <sup>2</sup>Universidade Federal de Pelotas, Brazil; <sup>3</sup>Universidade Federal de Ciências da Saúde de Porto Alegre, Brazil; <sup>4</sup>Universidade da Região da Campanha, Brazil

Problem statement: By evaluating the affordability of medicines for treating chronic diseases, we can measure the impact of drug prices on family income. All Brazilian citizens are eligible for receiving medicines included in the national list of essential medicines free of charge through the public health system (SUS). SUS should be able to provide essential medicines for free, but if medicines are not available in public sector facilities, patients need to purchase them out-of-pocket in the private market.

Objectives: To evaluate affordability of medicines used for treating chronic diseases across the 3 types of medicines in the Brazilian market (originator brands, generics and "similar"- other brands)

Design: Cross-sectional study

Setting: Southern region of Brazil using the HAI/WHO methodology; included 6 cities in the Rio Grande do Sul state. The total population of these 6 cities represents one-quarter of the state's total population. Data were collected from the November 2008 to January 2009.

Study population: In each of the 6 cities, 5 private pharmacies were selected (N = 30).

Outcome measure(s): Prices of 21 medicines, used for the treatment of asthma, depression, diabetes, dyslipidemia, epilepsy, hypertension, and peptic ulcer were investigated. For each selected medicine, data for the following variables were obtained: patient price for the originator brand, the lowest-priced generic, and the lowest-priced similar medicine. Affordability was estimated as the number of days that the lowest-paid unskilled government worker earning the minimum monthly wage would need to work in order to purchase a complete course of treatment in a private pharmacy.

Results: The affordability of originator brand medicines used to treat chronic diseases ranged from 0.4 to 21.1 working days; for similars, 0.3 to 7.5; and for generics, 0.2 to 16.8. The number of working days needed to pay for a complete

medicine treatment varied considerably across therapeutic classes and type of medicine. For example, in a 30-day diabetes treatment with glibenclamide 5 mg, the differences between the 3 types of medicines were very small. However, a 30-day ulcer treatment with ranitidine 150 mg would cost 9.2, 3.3, and 3.0 days for originator brand, generics, and similar medicines, respectively.

Conclusions: Affordability is directly related to market prices and may cost up to 50% of the monthly income of the lowest-paid unskilled government worker. An overall reduction in medicine prices should be a key priority in Brazil. High prices, poor availability in public sector facilities, and low affordability suggest a number of policy implications for the Brazilian government.

Funding source: This project was supported by a grant from the Brazilian Conselho Nacional de Pesquisa e Desenvolvimento – CNP and is a product of the post-doctoral internship of the first author at the London School of Economics and Political Science – LSE Health, funded by the Brazilian Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – CAPES.

777

#### Chronic Care

Keywords: Self –Administration Ability of Medicines Used, Elderly, Chronic Diseases

### **“A Healthy Box Project” for Improving Self-Administration of Medicines among the Pre-elderly and Elderly with Chronic Diseases: A Case Study in Horathep Subdistrict, Saraburi Province, Thailand**

**Prachuab Seangdao<sup>1</sup>, Chonthicha Singthern<sup>1</sup>, Ratana Somrongthong<sup>2</sup>**

<sup>1</sup>Horathep Health Promoting Hospital Saraburi Province, Thailand; <sup>2</sup>College of Public Health Sciences, Chulalongkorn University, Thailand

Problem statement: Chronic disease patients, particularly the pre-elderly and elderly patients at Horathep subdistrict, often received prescriptions for more than 1 medication. The capacity to self-administer with complex medical regimens is limited with increasing age. Therefore, “a healthy box project” was initiated.

Objectives: To improve the self-administration of medicines among the pre-elderly and elderly with chronic diseases and care takers

Design: A pilot project with pre-post testing was employed

Setting: This study was taken place at Horathep subdistrict, Saraburi Province, Thailand.

Study population: All chronic disease patients aged 50 and over residing at Horathep subdistrict who were referred from the community hospital for continuing treatment were recruited (n = 62). For those aged 80 or more, the key informants were the care takers (n = 8). Most (91.9%) were diagnosed with hypertension, followed by diabetes mellitus (19.4%), heart disease (17.7%), and hyperlipidemia (14.5%). In terms of co-morbidity, 69.4% of the subjects had a single disease, however, 19.6 % of them suffered with 2 or more diseases. The types of medicines used by the subjects was 2-12.

Intervention(s): A healthy box project was initiated in August 2010. Plastic boxes with medicine image stickers for keeping all medicines were distributed. In addition, periodic home visits by trained village volunteers (for mild, chronic diseases) and health officers (for severe cases) were conducted. The healthy box was kept where it could be seen easily by the subjects. Follow-up was done in 2 months at Horathep Health Promoting Hospital for pill counting, self reporting, assessment of blood pressure, and rapid blood testing.

Outcome measure(s): Adherence to the regimen under study by pill counting, self-reporting, and biological markers (blood pressure measurement and dextrostix testing)

Results: Most of the subjects (61 out of 62) reported that they had taken medicines completely according to the prescription. They stated that the healthy box helped them remember to take their medicines. In pill counting, leftover medicines were found for only 1 participant who was very old. The care taker stated that she forgot to prepare medicines for her mother because she was away from home. The biological markers indicated that blood pressure and the blood sugar levels were in control for most of them.

Conclusion: The preliminary finding showed that “a healthy box project” was likely to improve self-administration of medicines used among the subjects. However, the sample size is too small in this study; therefore, a larger sample size and 1-year follow-up are needed to provide quantitative information.

Funding source: Chulalongkorn University

778

#### Drug Resistance

Keywords: appropriate use, health workers, performance assessment

### **Using Routine Information for Improving Rational Prescribing**

**Abdullah Masoud, Mohammad Zafar, Mohammad Fahim, Paul Ickx**

Management Sciences for Health, Afghanistan

Problem statement: Routine health information systems often do not contain the detailed information needed for analyzing irrational prescribing. In Afghanistan, the morbidity data in the HMIS is limited to several priority conditions, and medicine use data is limited to reported stock-outs of tracer medicines. In 13 of the 34 provinces, quantities distributed on a quarterly basis to each province are available.

**Objectives:** To improve rational use of antibiotics by regularly tracking distributed quantities against general patient load in different facilities

**Design and setting:** The USAID-funded Tech-Serve Project, through the Ministry of Public Health (MoPH), ensures pooled procurement of essential medicines for organizations that are contracted by the government to implement the Basic Package of Health Services in 13 of the 34 provinces of Afghanistan. Medicines are distributed quarterly, based on quantifications made by the NGOs implementing the contracts. Ad hoc reports mention gross overprescribing of antibiotics, but the available routine data does not allow a straightforward prescription analysis and, until very recently, available funding did not allow regular field assessments.

**Intervention:** Once every quarter, the total number of full-course antibiotic treatments distributed to each NGO is compared with total patient visits reported through the routine HMIS of the MoPH, allowing an estimate of what proportion of the patients might have gotten a full treatment of antibiotics. This provides a rough estimate of the degree of overprescribing of antibiotics at health facilities based on readily available data. The findings are analyzed by the NGO managers and possible actions for improvement are identified. In the process, NGO managers learn how to apply the same analysis to each facility.

**Outcome measure(s):** Over a two year period, by using this process, we observed a remarkable decline in irrational prescribing.

**Results:** The calculation method most likely underestimates the actual overprescribing. However, the high level of overprescribing identified in the last quarter of 2006 made it clear that something needed to be done. The results are now being discussed routinely with the NGOs and, as a result, they are now analyzing prescribing practices in all their facilities. The data for monitoring overprescribing is readily available from the routine HMIS, and thus the same approach is used by the MoPH's Health Economics and Finance Department during their routine performance monitoring of the contracted NGOs.

**Conclusions:** In spite of the absence of detailed, disease-specific or actual prescribing data, overall improvement in prescribing practices can be made by drawing attention to the overprescribing of antibiotics by using data that are easily available.

**Funding source:** Activities were funded by USAID through the Associative Cooperative Agreement No. 306-A-00-06-00522-00 Technical Support to the Central and Provincial Ministry of Public Health (Tech-Serve) under the Leader Cooperative Agreement No. GPO-A-00-05-00024-00 Leadership and Management Sustainability (LMS) Project.

**779**

#### **HIV/AIDS and TB**

*Keywords:* HIV/AIDS, access to medication, antiretrovirals, pharmacist, Health facilities.

### **People Living with HIV/AIDS : Role of Community Pharmacist**

**Nahla Maher Hegab, Ahmed Ali Ahmed**

College of pharmacy, University of Alexandria.

**Problem statement:** All people living with HIV should have a core set of interventions to prevent opportunistic infections, maximize their health, prevent further HIV transmission and in some cases delay the progression of the disease. In Egypt people living with HIV/AIDS receive the proper medication according to the national HIV/AIDS guidelines. Although the prevalence of HIV/AIDS in Egypt is low but there is a limited access health services due to discrimination, social marginalization and unfavorable legalization.

**Objectives:** To identify the role of community pharmacists to encourage suspected HIV/AIDS patients to seek healthcare service available in the national HIV/AIDS programme.

**Design:** A questionnaire was designed to evaluate the community pharmacists in Alexandria information about HIV/AIDS and availability of medication.

**Study population:** 100 community pharmacists in Alexandria governorate, Egypt were randomly selected.

**Policy:** The questionnaire is a primary evaluation of community pharmacists' knowledge about HIV/AIDS, national guidelines, anti retroviral drugs, patient counseling and whether they are willing to join the national campaign to encourage people living with HIV/AIDS to seek medication within the national programme.

**Outcomes:** community pharmacist participation in national programme to encourage suspected HIV/AIDS Egyptian patients to seek healthcare within the national programme.

**Results:** It was found that 80% of community pharmacist know definition of HIV/AIDS, 70% of them don't know the available anti retroviral drugs and that the medication is available in the national HIV/AIDS programme, 100% of them never dealt with any HIV/AIDS patient . Only 65% of community pharmacists are willing to participate in the national campaign to encourage people living with HIV/AIDS to seek medication within the national programme in public sector hospitals.

**Conclusion:** Community pharmacists are potential partners that can be deployed highly effectively and they can play a key role in controlling AIDS epidemic in Egypt . It is important to provide them with appropriate knowledge about the disease , social aspect , treatment guidelines and bridging the gap between sexual and reproductive health and HIV. The contribution of community pharmacist can improve the number of people seeking access to proper medication at the national HIV/AIDS programme health facilities.

**Funding source:** Information not provided

780

**Access**

*Keywords:* Indicators, in-patients, rational drug use.

**Pattern of Medicine Use Among In-Patients in a Tertiary Health Care Setting Using the WHO Prescribing Indicators**

**Ehizokhale Peter Akhideno, Ambrose O Isah**

Clinical Pharmacology and Therapeutics Unit, Department Of Medicine, University of Benin Teaching Hospital, Nigeria

**Problem statement:** Irrational use of medicines exemplified by polypharmacy, overuse of injections and antimicrobials have resulted in increased morbidity, mortality and cost burden for patients. This is especially more so in developing countries where in-patient medicines use are poorly characterized. This study evaluates the use of medicines amongst in-patients in a tertiary health care setting using the WHO drug use indicators.

**Objectives:** To outline the pattern of use of medications using the WHO prescribing indicators among in-patients in a tertiary health care setting with a view to attain a rational and safer pharmacotherapy for in-patients.

**Design:** A descriptive prospective study of patients admitted into the adult medical wards of a tertiary health care setting in Nigeria.

**Setting:** This study was conducted at the University of Benin Teaching Hospital, a 620-bed tertiary health care setting.

**Study population:** All patients admitted into the adult medical wards over a period of 9 months, numbering 507 were included in the study. Males were 269 and females 238. The mean age of participants was 48.9±17.8 years ranging from 17- 89 years.

**Policies:** The WHO indicator was designed for out-patient encounters. Some studies including this, have modified the indicators for use in in-patient setting. Admitted patients were evaluated on days 0, (day of admission), 1, 3, 7, 10, 14 and weekly thereafter and at discharge. All medicines prescribed for patients were noted. Doses, frequency, and route of administration were recorded.

**Outcome measures:** The WHO drug use indicator values.

**Results:** The average number of medicines used per patient for the period of admission was 9.1±3.8 (median 8); The number of drugs rose from 4.2 on admission to 8.3 on day 28, reducing to 6.3 on discharge. The percentage of medicines prescribed from essential medicines list was 88.1% while the percentage of medicines prescribed by generic name was 85.6%. The total percentage of admissions with injectables prescribed was 89.3%. This decreased from 75.1% on admission day to 48.7% on discharge, while the total percentage of admissions with antimicrobials prescribed was 61.9%, rising from 41.2% on admission to 68.4% on day 28, reducing at discharge to 49.3%. The percentage of admissions with antimalarials prescribed was 18.9%.

**Conclusion:** The WHO indicators would serve usefully perhaps with some modification in the study of drug use among in-patients. The rates of prescriptions of medicines on the EM list and use of generic names were fairly high, however the WHO recommendation is 100% leaving room for improvement. The rates of use of antimicrobials and injectables were high, suggesting overuse among in-patients. There is however a need to develop standard values for the basis of comparison as in-patients and out-patients differ in profile and severity of illness.

**Funding source:** Private (personal)

781

**Access**

*Keywords:* teaching, prescribing, rational use of medicines, critical-appraisal, performance assessment

**Teaching Rational Prescribing to Medical Undergraduates: Impact of the Introduction of a Specialized Module**

**Jatinder Singh, Inderpal Kaur, IPS Grover**

Department of Pharmacology, Government Medical College, India

**Problem statement:** The system of teaching pharmacotherapy in Indian medical schools has shown a gradual shift from traditional curricula to a more prescribing oriented approach aimed at inculcating life-long learning skills. However, this effort requires guiding principles and standardization, given the large number of medical schools in different regions of the country.

**Objectives:** (1) To develop and implement a problem-based pharmacotherapy teaching module that could be seamlessly incorporated into the existing curriculum for undergraduate medical students which would empower them to prescribe drugs rationally; (2) to develop analytical, critical appraisal, and communication skills of medical students

**Design:** This was an interventional before–after study with no control group, conducted over 3 years during 2007-2009 with a group of medical students studying pharmacology as a core subject in the third year of medical school.

**Setting:** The study was conducted at the Government Medical College, Amritsar, India, a tertiary care teaching facility that caters to teaching undergraduate and postgraduate medical students.

**Study population:** 150 third-year students enrolled for the undergraduate medical programme leading to the MBBS degree were enrolled for the study each year; this was a convenience sample based on the number of students enrolled

**Intervention:** A module based on the WHO guide to good prescribing was formulated in 2009 and pretested on a small group of volunteer students. The final form of this module was used for the study. Core components of this module included an overview of irrational practices, the P-drug concept, prescription writing, sources of drug information, critical

appraisal, pharmacovigilance, essential medicines concept, and prescription audit. Students who had completed their core pharmacology classes were split into small groups for the study. The total duration of the module for each batch was 12 hours split over a period of 6 weeks.

Policy: The supplementation of the present pharmacology curriculum with this module on a permanent basis has been recommended.

Outcome measure: A change in the awareness about the concept of rational drug use, critical appraisal techniques, and sources of drug information, resulting in refined prescribing practices.

Results: The prescribing skills of the participants increased from a mean score of 43% to 91% after finishing the module, using a predetermined rating scale.

Conclusions: The inclusion of a standardized module into the curriculum for third-year medical students resulted in a significant improvement in prescribing skills.

Funding source(s): None

**783**

#### Access

*Keywords:* Procurement, Stock Out, Essential Medicines,

### **Evidence on Availability and Stock-Outs of Essential Medicines: A Study of Two Diverse Government Drug Procurement and Distribution Systems in India**

**Sakthivel Selvaraj, Habib Hasan**

Public Health Foundation of India, India

Background: Access to medicines can be enhanced by scaling up public expenditure on drugs, improving drug procurement and distribution systems, encouraging rational use of medicines and removing barriers from a stringent product patent regime. India's government health care system is diverse, given the diversity of practices, strategies and policies pursued in the health care system by various states in India. The heterogeneity in drug procurement and distribution models in various states of India reflects this phenomenon. This has implication for availability and stock-outs of essential drugs in frontline public health facilities.

Objective: To examine the availability and stock-outs of essential drugs in public health facilities in the state of Bihar and Tamil Nadu, India.

Design: Cross-sectional analytic study.

Setting: The study was conducted across 60 public health facilities.

Study Population: The public health facilities were selected through a stratified random sampling procedure which accounted for regional and economic diversity in each state. The selected health facilities are first level referral units (called as Referral Hospitals in Bihar and Upgraded PHCs in the state of Tamil Nadu) and are essentially 30-bedded hospitals which cater to about 100,000 populations. Data on drug availability on the day of the survey, medicine stock-out position for the last 6 months and other indicators were collected during the facility survey through a structured questionnaire.

Policy: Enhancing efficiency of supply chain management is crucial for availability of drugs and access to health care

Outcome Measure(s): Availability/unavailability of essential medicines on the day of survey, stock-outs during previous 6 months and average duration of stock-outs.

Results: Our findings reveal that the mean availability of "basket of drugs" for Bihar was about 43% as against roughly 88% for Tamil Nadu. Also, in terms of the stock-outs, Bihar's health facilities registered an average of about 42% stock-outs of drugs with a mean duration of 105 days in the previous 6 months of the survey period. The proportion of stock-out for Tamil Nadu stood at around 17% with a mean duration of 50 days. An examination of medicines on the basis of therapeutic categories reveals that the availability of the most important class of drugs, namely, Antibiotic's and Antipyretic's was low at 40% in Bihar. The evidence from Tamil Nadu suggests that almost all the broad therapeutic categories had more than 80% availability.

Conclusions: The key to improving access to medicines depends not only on high public expenditure on medicines but also on robust procurement and distribution system. Best practices learned from Tamil Nadu can be replicated to enhance Bihar's drug supply system.

Funding Source(s): Transparency and Accountability Programme, Results for Development, Washington, DC

**786**

#### HIV/AIDS and TB

*Keywords:* Antiretroviral combination, switching

### **Predictors of Switching Antiretroviral Regimen Among Clients Attending TASO Jinja, Uganda**

**Justine Mirembe<sup>1</sup>, Sarah Khanakwa<sup>1</sup>, Vincent Batwala<sup>2</sup>**

<sup>1</sup>The AIDS Support Organisation (TASO) Jinja Centre, Uganda; <sup>2</sup>Mbarara University of Science and Technology

Problem statement: The Uganda Ministry of Health recommends AZT/3TC or TDF/3TC or TDF/FTC or D4T/3TC + NVP or EFV as first-line antiretroviral drug combinations for treatment of HIV. Information from clinical practice indicates that HIV positive clients are switched onto these drugs without following guidelines.

**Objective:** To assess the predictors of switching antiretroviral drug combinations among clients attending The AIDS Support Organisation (TASO) Jinja centre

**Design:** This was a policy evaluation that assessed the predictors of switching antiretroviral drug combinations in facility-based and home-based intervention models in August-December 2008.

**Setting:** TASO Jinja centre is located in eastern Uganda and serves a catchment population of 1.5 million. As of July 2008, the total number of active HIV positive clients was 9,068. The Jinja centre is one of the branches of TASO with headquarters in Kampala. This is a local, private, not-for-profit organization, providing HIV services using facility-based and home-based models.

**Study population:** A computer-generated random sample of 326 HIV positive registered clients on antiretroviral drugs was retrieved.

**Policy:** TASO follows the national guidelines on antiretroviral therapy (ART). Clinicians are encouraged to make a collective decision regarding replacement of 1 or 2 component drugs within the combination on a case-by-case basis. The current study reports that some of the replacements/switches did not meet the guidelines, resulting in abuse of antiretroviral drugs.

**Outcome measures:** Switching antiretroviral regimen

**Results:** 31 (11.4%) clients were in WHO clinical stage 4, 115 (35.3%) in stage 3, 126 (38.7%) in stage 2, and 1 (0.3%) in stage 1; 150 (46.0%) received drugs under the home-based model; the proportion of clients on first-line ART was 325 (99.7%); 142 (43.6%) were started on AZT, 3TC, and NVP; 132 (40.4%) on d4T, 3TC, and NVP; 26 (8.0%) on d4T, 3TC, and EFV; 24 (7.4%) on AZT, 3TC, and EFV; and 2 (0.6%) on TDF, 3TC, and NVP. About 60.3% developed side effects (peripheral neuropathy 93 [28.5%], anemia 27 [8.3%]), skin rash 10 [3.1%], lipodystrophy 5 [1.5%]) following ART initiation; 63 (19.3%) had their first antiretroviral drug combinations switched either by clinicians (48; 14.3%), pharmacy technicians (1; 0.3%), nurses (3; 0.9%), or field officers (5; 1.8%); 22 (6.7%) had their antiretroviral drugs switched for the second time, 7 (2.1%) for the third time, and 3 (0.9%) for the fourth time. All switches were within the first-line ART combinations. The antiretroviral drug combination that the client was started on (d4T/3TC/NVP;  $p = 0.002$ ), development of side effects ( $p < 0.001$ ) and lack of a medicine companion or treatment supporter ( $p = 0.039$ ) were associated with switching of antiretroviral drugs.

**Conclusion:** The first antiretroviral drug combination, development of side effects, and lack of a treatment supporter were significantly associated with switching of antiretroviral drugs within the first-line regimen. To control the switching of drugs, ART team members should be involved in decision making.

**Funding source:** TASO Uganda

**787**

#### **Child Health**

*Keywords:* Oral Liquid Dosage Forms (OLDFs),measure(s),pharmacist,physician(s)

### **Standardization of Prescribing and Using Oral Liquid Dosage Forms (OLDFs)**

#### **Moslem Movahed**

Department of Medical Management of Province of Qom's, social security organization, Iran, Islamic Republic of

**Problem statement:** Various factors affect the correct dosing and measuring of OLDFs, excluding drops, thereby leading to adverse effects or preventing the desired results to be obtained in treatment.

**Objective:** This study aims to evaluate the current situation in dosing OLDFs in Qom, Iran.

**Study population:** Includes all oral liquid products manufactured in Iran; 20 physicians (16 GPs and 4 pediatricians), 2000 OLDF prescriptions, 20 community pharmacists, and 60 literate mothers

**Results:** (1) Only 60% of the oral liquid products (including antibiotics, even those presented as powder for suspension) are offered with a measure; 8 kinds of medicine (33 products) come with varying measures, of which some are a spoon with a capacity of 5 mL and others are in a cylindrical shape, with 4 capacities ranging from 5 to 20 mL. (2) Many physicians and pharmacists are not aware of the current diversity in measures whereas nearly all the physicians and pharmacists conventionally and practically presume a 5 mL measure. (3) In the group of mothers, 50% fill 10 mL measures completely and 10% fill 20 mL measures up to 15 mL when they are advised to use 1 measure of the drug; 5 mL measures pose no problems. (4) Although 5 sizes of domestic spoons are used by patients, prescribers ignore this diversity by reducing it to 3 sizes only. (5) Although pediatricians have a good knowledge of domestic spoon capacities, many GPs and most of the pharmacists overestimate them, leading to underdosage for adults, especially in cough preparations with low drug content. (6) Less than 10% of adults' prescriptions come with precisely specified dosages in mL whereas 90% have unclear volume. For children, 27% of the dosages are clear and 73% remain unclear.

**Conclusion:** A number of dosing problems in manufacturing, prescribing, and using OLDFs cause overdosing or underdosing which can lead to adverse effects or treatment failure in children; for example, if the intended prescription is 5 mL 3 times a day (but written as "3 measures a day") and the consumer is given a 20 mL measure. In addition, treatment fails in many cases due to underdosing of cough preparations and acetaminophen elixirs. To improve the current situation and prevent problems, it is suggested that (1) OLDFs be offered with a syringe (the best choice), or uniform and/or unisize (preferably 5 mL) measures, or even no measure at all; (2) physicians be advised to prescribe the OLDFs in exact volumes (mL or cc) and avoid prescribing in terms of "measure" or domestic spoons (this should be included in physicians' and pharmacists' education); (3) cough preparations be produced in higher concentration and volume for adults; and (4) parents be advised to use appropriate syringes (without a needle) instead of spoons or other measures.

Funding source: Department of Medical Management of Province of Qom's (Iran) Social Security Organization

**788**

### **Policy, Regulation, and Governance**

*Keywords:* Ethics, marketing, promotion, marketing codes, pharmaceutical industry, self-regulation, governance, transparency

#### **Role of Pharmaceutical Industry Marketing Codes in Securing Good Governance**

---

**Richard Bergstrom**

EFPIA, Brussels

**Problem statement:** The health sector is a major part of all national economies. Emerging economies are investing in health as a means to meet citizen's demands and to boost economic growth. There is concern that spending in the health sector is not always rational and may suffer from poor governance. One particular concern is the promotional activities of pharmaceutical companies directed at health care professionals. Undue influence on prescribers can lead to irrational use of medicines and unnecessary costs for payers and governments.

**Objectives:** To discuss how self-regulatory measures, such as industry marketing codes, can contribute to ethical behaviour of the pharmaceutical industry; to explore how national "platforms" that include health care professionals and other stakeholders can be very effective in securing good governance in the health sector

**Design:** This oral presentation will illustrate the commitment of the research-based pharmaceutical industry to self-regulate by using marketing codes to set standards that go beyond national legislation and what can be effectively enforced in many jurisdictions. Examples from countries such as Mexico, South Africa, and Thailand show that industry self-restraint is an effective complement to government initiatives and legislation.

**Setting:** The session has a global scope.

**Study population:** Examples from a wide range of countries

**Intervention(s):** Different types and self- and co-regulatory models will be explored.

**Policies:** Governments and international associations should consider what role the private sector itself plays in achieving good governance.

**Conclusions:** Company compliance measures and industry-wide codes – and particular multi-stakeholders initiatives – should be seen as a complement to legislation. Self-regulation may provide better enforcement, especially in countries with issues on governance and transparency.

**Funding sources:** IFPMA

**790**

### **Chronic Care**

*Keywords:* appropriate use, chronic disease, primary health care, prescribing,

#### **Empathic Caring Consultation (ECC): Will It Be Able to Reduce the Unnecessary Use of Analgesics?**

---

**Johana E. P. Hadiyono**

Gadjah Mada University, Indonesia

**Problem statement:** Myalgia complaints and the use of analgesics were high in health centers in Sleman District, DIY, Indonesia. Using analgesic prescriptions to manage pain without considering patients' other illnesses increases clinical risk, such as liver damage, and has adverse economic impact. The question is whether psychological intervention, or ECC, can play a role in improving specific cases of myalgia that are affected, in part, by the emotional turmoil of every day life.

**Objectives:** To assess the efficacy of ECC to improve the quality of care in the health centers

**Design:** Retrospective randomized controlled trial

**Setting:** 4 public health centers in 1 district randomized into 2 intervention and 2 control groups in June-July 2009

**Intervention:** Prescribers in the intervention group attended training workshops in ECC that consisted of active listening, expressions of empathy using selected words and facial expressions and gestures, and a short version of deep muscle relaxation. They also received refresher training in prescribing skills and in giving proper information regarding the use of analgesics, including the side effects of the drugs.

**Outcome measures:** Samples were 30 prescriptions per center per month for myalgia cases. In October 2009, a prescribing survey and observation of health centers' services, specifically patient-provider interactions, 3 months before and 3 months after the intervention, were conducted by the Sleman District Health Office. Rates of analgesics per prescription were computed separately for each center. Time-series analyses in each health center were presented to see the trends of the analgesics used.

**Results:** No effect of ECC on the use of analgesics was found at the study sites. For myalgia cases, almost all patients were treated with analgesics before and after the intervention in all 4 health centers. Patients' perceptions toward the quality of care in the intervention groups improved slightly. Health providers in the intervention groups showing more concern (by using nonverbal communication) were perceived as more empathetic. They also referred more cases to the psychologists when needed.

Conclusions: This study was a replication of the previous study, yet neither result was conclusive (see Prawitasari-Hadiyono, Tana, and Sunartono, 2004). More thorough study and extensive observations are needed if ECC is to be used to lessen the use of analgesics and become an indicator of success. Methodologically, the use of in-depth understanding of the phenomenon must be explored using a qualitative approach, such as in-depth interviewing of health providers, management, and policy makers at the District Health Office; reviewing documents; on-site observation of health providers; and focus group discussions of policy makers, such as those at WHO and involved in INRUD.

Funding source: Professor Research Grant, Faculty of Psychology, UGM

## 792

### HIV/AIDS and TB

*Keywords:* pharmacoepidemiology, pharmacovigilance, tuberculosis

#### **Use of Thai Vigibase to Assess the Safety of Antituberculosis Drugs for Thai Patients: Application from Thai Vigibase**

##### **Wimon Suwankesawong**

Food and Drug Administration, Thailand

Problem statement: Antituberculosis drugs therapy is currently the most effective option for tuberculosis (TB) patients in Thailand. Although it is effective in treating patients with TB, it is associated with many serious adverse drug reactions (ADRs) which in turn results in discontinuation or non-compliance. Treatment failure and/or fatal outcomes among these patients were detected. Furthermore, concomitant drug therapy, antiretroviral therapy drug, in HIV-positive TB patients could lead to an increase serious or unexpected ADRs. The ThaiVigibase, the national ADRs data base of the National Health Product Vigilance Center (the HPVC), can be used to evaluate the safety of anti-tuberculosis drugs for Thai patients.

Objective: To describe and characterize ADRs associated with anti-tuberculosis drug for Thai patients

Design: All reports about anti-tuberculosis drugs (ATC code J01GA and J04) from the ThaiVigibase during 1984-June 2010 were retrieved. Reported ADRs associated with anti-tuberculosis drugs were analyzed using descriptive statistics.

Setting: Thai National ADRs Database (Thai Vigibase) at the National Health Product Vigilance Center, Food and Drug Administration, Ministry of Public Health, Thailand.

Results: A total of 8,714 reports related to anti-tuberculosis drugs were reported during the study period. 581(6.7%) were reported as HIV positive, and 7,014 (80.5%) reports, describing 10,695 ADRs, were associated with anti-tuberculosis drugs. 53.3% of the 7,018 patients were male. Most were >65 years of age. 31.2% required inpatient care or prolongation of existing hospitalization, and 1.3% died. Stevens -Johnson Syndrome and hepatitis resulting in death were reported for patients who took rifampicin, ethambutol, isoniazid and pyrazinamide. Anaphylactic shock was reported for patients treated with injected streptomycin. According to system organ classes, the most frequently reported ADRs were: skin and appendages (48.9%); liver and biliary system (17.9%); gastro-intestinal system (9.4 %); and body as a whole-general (6.9%) consequently. The trend of reporting rate was increased, from 2.2 to 5.1 in 2009, since the intensive ADRs monitoring for these patients were promoted during 2005-2009.

Conclusion: Serious ADRs associated with anti-tuberculosis drugs were commonly reported among Thai patients. Some of these led to hospitalization and death. Continuous intensive monitoring of these patients is needed for early detection of ADRs to prevent serious consequences, such as death or poor compliance to treatment regimens, resulting in treatment failure.

Funding source: There is no funding source and the authors have no conflict of interest in this study.

## 793

### Drug Resistance

*Keywords:* cost containment, drug selection, drug utilization, quality assurance, surveillance,

#### **Antibiotic Surveillance in Intensive Care Unit: Quality Assurance of Antibiotic Usage**

##### **Zunilda Djanun<sup>1</sup>, Rudyanto Sedono<sup>1</sup>, Yulia Rosa Saharman<sup>1</sup>, Bakti Wahyuningrum<sup>2</sup>**

<sup>1</sup>Faculty of Medicine, Indonesia University/Cipto Mangunkusumo Hospital, Indonesia; <sup>2</sup>Cipto Mangunkusumo Hospital, Indonesia

Problem statement: MOH of Indonesia requires that every hospital implements an antimicrobial resistance control program and report their work yearly. The ICU is one of the service clusters in hospitals that has high antibiotics consumption because critically ill patients are particularly susceptible to nosocomial infection.

Objectives: The primary objective was to determine the quality of antimicrobial (AM) use according to Gyssens criteria as part of AM surveillance activities. The result will also be compared with that from a pilot surveillance conducted in 2009 that was followed by interventions.

Design: Cross-sectional prospective observational study using patient's chart and staff verification

Setting: ICU at the national central hospital in Jakarta, Indonesia

Study population: All patients admitted to the ICU at Cipto Mangunkusumo Hospital (CMH) in the first 2 months of 2010

Methods: Data on demography, admission and discharge dates, diagnoses prior to and during ICU admissions, reasons for transfer to ICUs, names, dosages, durations and reasons for AM prescriptions, microbiological test results,

and outcomes of care were collected. AM prescriptions were classified into 4 categories—prophylaxis, empiric, definitive, and “not known”.

Outcome measures: Pattern of J01 class of AM; the quality of usage was assessed by a clinical pharmacologist using 2 standard references. AM use in 2010 and 2009 were compared to see the impact of feedback and intervention.

Results: 165 patients, 134 surgical and 31 medical, were admitted to the ICU during the surveillance period; 269 AM usages were found in 138 patients; 28 out of the 134 surgical patients did not received prophylaxis AMs, but 21 of them received AMs postoperatively. There were 25 kinds of AMs used for the 4 categories. AM prescriptions in 2010 were better than that in 2009 (e.g., less). AMs were prescribed for unknown reasons (22.3% vs. 38.5%). Ceftriaxone, ceftazidime, cefoperazone, meropenem, metronidazole, cefotaxime, and levofloxacin were the most frequent prescribed AMs in 2010, which differed slightly from 2009. About 18.8% AB were used appropriately (cat. I), 16.3% were inappropriate in dosaging and route of administration (cat. II); 22.8% were used for too long or too short a period (cat. III); 19.1% were selected inappropriately (cat. IV); and 16.4% were used without any reason (cat. V). When looking at the use of the 5 most frequently prescribed AMs, one can see that more AMs were prescribed appropriately in 2010 (e.g., more meropenem and levofloxacin fell into category I of Gyssens' categorization whereas neither fell into category V). There must be more cost containment. MRSA, *A. baumannii*, *Ps. aeruginosa*, and *Klebsiella pneumoniae* were the isolates most frequently identified, mostly from sputum. Patients with MRSA infections were successfully treated with vancomycin. The daily “case morning parade” was implemented after the 2009 surveillance, so the impact of the intervention was reflected in the 2010 data. Although the case parade has not involved the surgery department yet, clinical pharmacologists, clinical microbiologists, and clinical pharmacists are regular contributors at the meetings. Screening of MRSA has also become a routine measure for indicated cases since 2009.

Conclusion: The quality of AM use in ICU CMH was improved, probably because of feedback and interventions that have been made.

Funding source: Cipto Mangunkusumo Hospital

## 794

### Access

*Keywords:* access to medicines, affordability, disparities, pharmacoepidemiology

### **Social Disparities in the Use of Prescription Medications: A Population-Based Approach**

Dima Qato<sup>1</sup>, Danya Qato<sup>2</sup>

<sup>1</sup>University of Chicago, United States of America; <sup>2</sup>Brown University, United States of America

Problem statement: Social disparities in the use of prescription medication may be an important, yet overlooked, contributor to persistent social disparities in health. The majority of existing data sources for which prescription medication use measures are derived, however, are not population-based and therefore disproportionately exclude data on the most socially disadvantaged populations (including racial/ethnic minorities) that may experience limited access to prescription medications. Thus, information on social disparities in the use of prescription medications is incomplete. This information is particularly important for the development of pharmaceutical policies intended to improve access to prescribed medications in these populations.

Objectives: This study will use population-based medication data to describe patterns in the use of prescription medications by socioeconomic status and race/ethnicity and to identify social and health care factors associated with racial/ethnic disparities in the use of prescription medications.

Design, setting, and study population: In-home interviews were administered between June 2005 and March 2006 to 3005 community-residing individuals, aged 57–85 years, drawn from a cross-sectional, population-based sample of the United States. Prescription medication use was defined as the use of at least 1 prescription medication. Multistage, multivariable logistic regression models were developed to examine the social and health care factors associated with racial/ethnic disparities in the use of prescription medications.

Outcome measures: Prevalence of prescription medication use by socioeconomic status and race/ethnicity

Results: Individuals living in poverty were 60% less likely to use prescription medications in comparison to their non-poor counterparts (OR 0.40 [CI 0.24, 0.68]). After adjusting for differences in age and health status, Black and Hispanic minorities were 40% and 45% less likely, respectively, to use prescription medications in comparison to their Caucasian counterparts. Racial/ethnic differences in the use of prescription medications are reduced after the introduction of factors representing poverty and access to primary care. In contrast to previous studies, insurance status and educational attainment did not explain racial/ethnic disparities in the use of prescription medications.

Conclusions: This study provides population-based evidence of social disparities in the use of prescription medications among older adults in the United States. These findings suggest that policy efforts to improve access to prescription medications in minority communities need to address factors beyond insurance-centered affordability, including barriers associated with poverty (e.g., geographic access to pharmacies) and access to primary health care. In addition, social disparities in access to prescription medications should be incorporated into models examining social determinants of health in the US and globally.

Funding source: Information not provided

## 795

### Policy, Regulation, and Governance

*Keywords:* Drug system, Monitoring, Development, Antibiotic Resistance

## **Drug System Monitoring and Development Project, Funded by Sin Tax, and the Roles in Promoting Rational Drug Use in Thailand**

---

**Niyada Kiatying-Augsulee, Yupadee Sirisinsuk**

Faculty of Pharmaceutical Sciences, Chulalongkorn University, Thailand

**Problem statement:** The drug system in Thailand is faced with several problems, including availability of unsafe drugs in the market and irrational drug use. Since 2008, Thai Health Promotion Foundation (ThaiHealth), funded by a sin tax, has supported a drug system monitoring and development project (DMD) to monitor the drug system's situation and implement interventions to further develop the system.

**Objectives:** To review the activities of DMD

**Design:** The study design was descriptive. Data were collected by document reviews and self assessment among the staff.

**Setting:** The study was carried out at the central office of the DMD.

**Study population:** All DMD activities were included in the study.

**Program:** DMD has been granted 53.05 million Baht from ThaiHealth, Chulalongkorn University, and WHO for a 3-year project (2008–2011).

**Outcomes measured:** The Center for Drug Monitoring and Development has been set up. The networks of both professional and civic groups have been formed and perform the key functions of monitoring and developing the drug system at the community, hospital, and country levels. The models to monitor and develop the drug system are applicable at several levels.

**Results:** DMD has 5 strategies—knowledge management, pilot model development, networking, public communication, and national drug policy and strategies advocacy. DMD performance in drug monitoring, especially unsafe drugs, has been recognized by the Center for Drug Monitoring and Development. DMD's priority issues include drug selection to eliminate unsafe drugs, drug procurement to increase efficiency, drug distribution to protect against unethical dispensing, and drug use, especially promoting rational drug use in preventing antibiotic resistance and unethical drug promotion. Several network groups have been formed, including a pharmaceutical and therapeutic committee network, drug use evaluation pharmacist network, drug procurement network, community hospital pharmacist network, and the Public Health Provincial pharmacist network, as well as civic groups concerned with both patients and consumers. The networks have monitored and developed the drug system in their areas of interests. Initial pilot models for monitoring drug problems in the communities have been created, and specific interventions to solve problems were forthcoming. The major theme for DMD's 2010–2011 campaign has been to promote the rational use of antibiotics. Interventions have focused on several levels, including national drug policy, prescribers, patients, and consumers.

**Conclusions:** DMD and its networks have joined hand in hand to monitor and develop the Thai drug system. Nowadays, DMD is recognized by the government as the responsible body in drug system monitoring and development.

**Funding source:** ThaiHealth

**796**

### **Drug Resistance**

*Keywords:* antimicrobials, drug utilization, hospital, standards of practice

### **Prophylactic Use of Antimicrobials During Surgery**

---

**Brian Conroy Gunn<sup>1</sup>, Ahmed Abdo-Rabbo<sup>1</sup>, Batool Jaffer Suleiman<sup>1</sup>, Syed Asrar Ali<sup>2</sup>**

<sup>1</sup>Directorate of Rational Use of Medicines, Ministry of Health, Sultanate of Oman, Oman; <sup>2</sup>Directorate of Communicable Disease, Ministry of Health, Sultanate of Oman

**Problem statement:** There is widespread concern about the rising rate of antimicrobial resistance, therefore rational use of antimicrobials is a high priority area for research. One of the most controversial uses of antimicrobials is for prophylaxis in various surgeries. Many questions arise about the overall need, the subsequent choice of antimicrobial (if deemed necessary), and then the dose, duration, and timing of administration. As the Oman Ministry of Health chemotherapeutic guidelines were last updated in 1998, it was considered apt to investigate the current practice.

**Objectives:** To investigate the antimicrobials used perioperatively in lower segment Cesarean section (LSCS), timing, and doses administered

**Design:** Retrospective study of defined patient group using manual or computerised records

**Setting and population:** 4 major hospitals throughout Oman with a systematic, random sample of 510 patients undergoing emergency or elective LSCS surgery

**Results:** There was a surprising diversity in the regimes from each hospital and only 1 had written guidelines. Although a cephalosporin was used in the majority of cases, there was little consistency in the generation prescribed with second-generation cefuroxime being the most popular (47% of all cases). The majority of cases also had metronidazole added. In 1 hospital, ampicillin was the prophylactic of choice and was routinely combined with oral amoxicillin. There were very few cases where only a single dose was given with most receiving at least 3 doses. In 1 extreme case, the majority of patients received 5 days of prophylaxis with a third-generation cephalosporin! The timing of the dose was usually stated as after clamping of the umbilical cord, but it was often difficult to determine exactly, especially when multiple dosing had been performed.

**Conclusion:** It appears that protocols for antimicrobial prophylaxis have developed in an ad hoc fashion over time. It was found that none of the studied hospitals followed the MoH guidelines for prophylactic use of antimicrobials, nor

were they using any international defined standard or recommendation. Based on the available infection rates, a consistent policy with written guidelines appears to lead to the best outcomes for patients. The results have wide implications for future policy directions.

Addendum: A recent (2011) review of the study hospitals showed that they have all adopted new and very similar protocols and all now have a written policy in place

Funding source: MoH General Budget

**797**

**Access**

*Keywords:* access to medicines, availability, equity, Geographic Information System (GIS), private sector

**Mapping Private Sector Pharmacies and their Characteristics in Ujjain District, Central India**

**Yogesh Damodar Sabde<sup>1</sup>, Vishal Diwan<sup>1,3</sup>, Vivek Saraf<sup>2</sup>, Vijay Mahadik<sup>1</sup>, Ayesha De Costa<sup>1,3</sup>**

<sup>1</sup>R.D.Gardi Medical College, Ujjain, India; <sup>2</sup>National Center for Human Settlement & Environment, Bhopal, India; <sup>3</sup>Division of Global Health (IHCAR) Karolinska Institutet, Sweden.

**Problem Statement:** Private pharmacies are the critical establishments that ensure rational use of drugs prescribed by physician. They have an important potential role in public private partnerships, as they touch patients at every level from high ended hospitals to the doorstep where they provide medications in the community. However, in India, these pharmacies have diverse characteristics & variously qualified staff which needs to be studied to a) tapping the potential of such establishments in partnerships b)regulation c)studying access the population groups have to medicines. Mapping the location & characteristics of such pharmacies is an essential pre-requisite in this task.

**Objectives:** a) To map using GIS technology, the geographic location of private sector pharmacies in Ujjain district (1.7 million) b) To compare the access to medicines as reflected by the availability of pharmacies, in rural & urban areas c) To describe the characteristics of the mapped pharmacies (clientele, infrastructure, & human resources).

**Design:** Cross-sectional

**Setting:** Ujjain district, Madhya Pradesh, Central India. July-Nov 2010.

**Intervention:**

This study of pharmacies was a part of larger cross sectional survey carried out in to map all the health care services in Ujjain district (population 1.9 million) onto a GIS. The present study was conducted to map all private sector pharmacies in Ujjain district, Central India onto Geographic Information System (GIS) and study their locational preferences and other characteristics like staff, infrastructure, clients and availability of tracer drugs.

**Outcome Measure:** Pharmacies mapped on digitized map, access to medicines for population sub groups, characteristics of pharmacies

**Results:** A total 475 private pharmacies were identified in the district. Three-quarter were in urban areas, where they were concentrated in the around physician practices. In rural areas, pharmacies were located along the main roads. A majority of pharmacies simultaneously retailed medicines from multiple systems of medicine. Availability of tracer parenteral antibiotics and injectable steroids averaged 80% in both urban and rural pharmacies. Approximately 40% of clients did not have a prescription. Only 12% of staff had formal pharmacist qualifications. Power outages were a significant challenge.

**Conclusion:** This is the first mapping of pharmacies & their characteristics in India. It provides evidence of the urban dominance and close relationship between provider location and pharmacy location. The implications of this relationship are discussed. The study reports a lack of qualified staff in the presence of a high proportion of clients without a prescription. The study highlights the need for the better implementation of regulation of pharmacies. Besides facilitating regulation & partnerships, the data also provides a sampling frame for future interventional studies on these pharmacies.

**Funding:** Res Council Sweden Problem

**800**

**Policy, Regulation, and Governance**

*Keywords:* Counterfeit Drugs , Consumer, Behavior, Scale.

**Consumer behavior toward counterfeit drugs: scale development in a developing country setting**

**Abubakr Abdelraouf Alfadi<sup>1</sup>, Mohamed Izham Ibrahim<sup>2</sup>, Mohamed Azmi Hassali<sup>1</sup>**

<sup>1</sup>Universiti Sains Malaysia, Malaysia; <sup>2</sup>Qassim University, Saudi Arabia, Universiti Sains Malaysia, Malaysia

**Introduction:** Counterfeiting of medicines in developing countries has been reported as a distressing issue. Moreover, although desperate need and drug counterfeiting are linked, no much study has been carried out to cover this area, and there is a lack of proper tool and methodology.

**Objective:** The objective of this research is to develop a valid and reliable scale based on the currently accepted scale development paradigm to operationalize the main construct.

**Design, Study Settings and Population:** This is a quantitative survey conducted in Sudan through two rounds; pilot (n = 100), and final survey (n = 1003). Sampling approach was based on the availability of participants.

**Results:** The raw data were analyzed using SPSS version 16. Internal consistency was examined and improved. Cronbach's alpha improved from 0.818 to 0.862. Finally, convergent and discriminant validity was demonstrated.

**Conclusion:** To the authors' knowledge, this is the first work attempt to conceptualize and operationalize consumer behavior toward counterfeit drugs. High reliability and demonstration of convergent and discriminant validity indicated that the "Consumer Behavior toward Counterfeit Drugs Scale" is a valid, reliable scale existing within a solid theoretical base. Ultimately, the study offers public health policy makers and marketing managers a valid measurement tool to build a better understanding of the demand side of counterfeit drugs and hence aids in developing more effective strategies to combat the problem.

**Keywords:** Counterfeit drug, Consumer, Behavior, Scale

**Funding Sources:** Federal Ministry of Health – Sudan

**804**

#### **Chronic Care**

*Keywords:* Reproductive and urinary tract infections, antibiotics prescribing, inappropriate prescribing, Palestine

### **Variation in Service-Providers' Prescribing Behaviour and Policy Implications for Women with Genitourinary Tract Infections in Ramallah, Occupied Palestinian Territory (oPt)**

---

**Rula A Ghandour, Rana A Khatib**

Institute of Community and Public Health-Birzeit University, Palestine

**Problem statement:** Worldwide, infections of the reproductive and urinary tracts are reasons women most often seek health care. These infections are associated with adverse pregnancy outcomes and negatively affect the quality of life. Resistance to antibiotics that are active against uropathogens has been noted worldwide, but few data for microbial resistance patterns in Ramallah, West Bank, oPt, are available. Although some treatment guidelines for infections of the reproductive and urinary tracts might have been available in clinics in 2010 when the study was undertaken, practitioners were generally not aware of the existence of such guidelines. The aim in this study was to assess variations in service-providers' prescribing behaviours for infections of the genitourinary tract in selected women's health clinics in Ramallah and to provide evidence needed to inform improvements in policy and practice.

**Methods:** Women and service providers in 11 clinics that provide women's health services in Ramallah were interviewed in a survey. Ministry of Health, UN Relief and Works Agency, and nongovernmental clinics in urban, rural, and refugee camps also took part in the survey. Data for 100–120 cases per clinic were gathered during 4 months. Women were interviewed by use of a pretested structured questionnaire, and physicians completed a pretested form. Appropriateness of treatment was determined by the drugs selected, dose regimens, and duration of treatment, assuming that the diagnosis was correct.

**Findings:** 162 (15%) of 1052 women were diagnosed with any urinary or reproductive tract infection; their mean age was 31 years (SD 9); 156 (96%) women were married and in the low and middle socioeconomic groups (67 [43%] and 75 [48%], respectively). The drugs prescribed to 132 (81%) of 162 women at the time of diagnosis were not in accord with treatment guidelines. Inappropriate drugs were prescribed to 62 (70%) of 89 women with reproductive tract infections, 56 (95%) of 59 with urinary tract infections, and all 14 with both infections (women with both infections were not included in the other two categories); 65 (40%) of 162 women were prescribed drugs that were inappropriate for their indications, 22 (14%) for dose regimen, and 81 (50%) for duration of treatment.

**Interpretation:** Written treatment protocols informed by results of studies of local microbial resistance patterns, with mechanisms to ensure implementation, are needed to guide practitioners in providing the correct treatment and avoiding the emergence of resistant bacterial strains. Provision of continued education for physicians, with feedback and supervision, especially about rational antibiotic use, is essential.

**Addendum:** Published in *The Lancet Online*, July 2011; available from:

<http://download.thelancet.com/flatcontentassets/pdfs/palestine/palestine2011-5.pdf>

**Funding source:** Ford Foundation, as part of a larger study of women's health services in Ramallah

**806**

#### **Policy, Regulation, and Governance**

*Keywords:* drug information, education, health reform, health workers, patient safety

### **Monitoring the Safety of Medicines in Kyrgyzstan**

---

**Saltanat Moldoisaeva, Ashirali Zurdinov**

Kyrgyz State Medical Academy, NGO "For rational and safety use of the medicines", Kyrgyzstan

**Problem statement:** This research concerns the problem of monitoring the safety of medicines in Kyrgyzstan. The mortality rate connected with use of medicines all over the world remains high, and consequently, timely detection of adverse drug reactions (ADRs) has great value. Kyrgyzstan has been a full participant in the safety of medical products monitoring program since 2003; however, the gathering of spontaneous reports has still not been adequately implemented.

**Objectives:** We investigated the level of activity of doctors in the safety monitoring system.

**Design:** The type of study was pharmacovigilance policy evaluation. The specially developed questionnaires were sent out to 1195 doctors in Bishkek City and the regions. The findings were worked up with the SPSS for Windows 13.00 statistical program.

**Setting:** The study was conducted at the national level and involved a variety of specialized practitioners in the city's and regions' government hospitals.

**Intervention(s):** It was anonymous, confidential questioning on a voluntary basis. The study was conducted from April to October 2010.

**Results:** Our research has shown that 2/3 of doctors observed ADRs in their practice. These doctors were then asked whether they registered ADRs in medical cards. Only 49 % of the doctors answered yes, and thus more than half of respondents, 51 %, answered that they seldom or do not register in general. Doctors were also asked if they filled out yellow cards upon the development of ADRs; only 9 % answered positively; 72 % of doctors do not fill out these cards and 17 % refrained from answering. According to doctors, the principal causes of the low level of ADR registration are (1) a lack of information for detecting the relationship of cause and effect between use of medical products and development of ADRs; (2) the erroneous opinion that all medical products registered in our state medical system are safe; and (3) the fear of having to answer to the hospital administration.

**Conclusions:** The problem of monitoring ADRs in our country remains unresolved. As shown by our research, doctors have a serious deficiency of knowledge about ADRs, which is the principal cause of the low level of registration. From this, it follows that measures directed toward improving the knowledge of medical workers in clinical pharmacology must be implemented, that motivation of workers in public health services must be increased, and that information transfer mechanisms must be reformed.

**Funding source(s):** Kyrgyz State Medical Academy, NGO "For Rational and Safety Use Of the Medicines"

**807**

### **Policy, Regulation, and Governance**

*Keywords:* drug utilization, pharmacoepidemiology, surveillance,

### **Using Defined Daily Doses, Pivot Tables, and Charts as a means of Measuring Medicine Utilisation Trends**

**Brian Conroy Gunn, Batool Jaffer Suleiman**

Directorate of Rational Use of Medicines, Ministry of Health, Sultanate of Oman, Oman

**Problem statement:** Measuring the trends in medicine utilisation is a vital means of control for ensuring the rational use of medicines. The defined daily dose (DDD) is a relatively underused and poorly understood tool for assessing medicine use and comparing trends.

**Objectives:** To set up a relatively simple and ongoing medicine utilisation trend analysis using DDDs and Excel pivot tables and charts

**Resources:** National data on medicine consumption in the public sector was obtained from the Director General of Medical Supplies and the Director of Information Technology at the autonomous Royal Hospital, Muscat, Oman. DDDs were obtained from the WHO Collaborating Centre for Drug Statistics Methodology using their ATC/DDD index. Excel 2003 or Excel 2007 spreadsheets were used to create the database and pivot tables for analyses.

**Methods:** Using raw consumption data from the above sources (manual or computerised), an Excel database was designed to permit the rapid generation of the most useful information. Total DDDs for the majority of medicines were calculated and then the internationally recognised standard formula DDD per 1000 population per day was calculated. The methodology is flexible enough to be adapted for other useful formulae to be calculated, such as DDD per 100 bed days, or DDD per 100 admissions for hospital inpatient use, or DDDs per inhabitant per year.

**Results:** Trends in medicine use have now been calculated for the public sector in Oman since 1999 with the most comprehensive results for 2006–2009. The results are best displayed as a series of column or stacked column pivot charts for each therapeutic group. Also, pivot tables showing the top 10 or 20 medicines used or the top 10 antibiotics are rapidly generated. An annual report with the most significant charts is produced highlighting positive and negative results. The trends can be looked at from several viewpoints. Positive trends are generally indicative of good prescribing rather than a decline in morbidity. In many cases there may be an increase in morbidity but the prescriber's choice of therapy is considered rational and appropriate. A negative trend sometimes indicates an increased use of a drug pointing to an increase in morbidity, which is "bad" by itself rather than "bad prescribing" or it could be due to a poor choice of therapy. The relative results are usually more significant for comparison than the absolute values.

**Conclusions:** The methods used have enabled the rapid assessment of the trends in medicine use in the public sector of Oman over several years. Excel pivot tables and charts can produce an almost infinite number of views of the data with a few keystrokes. The results can be used by policy makers, planners, and researchers. It is hoped that as many as possible of the neighbouring countries can adopt similar methodology for reporting so that regional comparisons can be made.

**Funding sources:** MoH General Budget

**810**

### **Access**

*Keywords:* access to medicines, health workers, performance assessment

### **Consultation and Dispensing Time at Primary Health Care Facilities in Oman**

**Ahmed Abdo-Rabbo, Manal Al-ansari, Brian Conroy Gunn, Batool Jaffer Suleiman, Hawraa Al-Lawati**

Directorate of Rational Use of Medicines, Ministry of Health, Sultanate of Oman, Oman

**Background:** In Oman, the public primary health care (PHC) facilities are located in both urban and rural areas. Access to secondary and tertiary facilities cannot be acquired easily without referral from PHC or emergency services.

**Problem statement:** Information on medicine use regarding patient care by health care providers in Oman is lacking. However, it is essential for strategic planning. The time that prescribers and dispensers spend with each patient, as well as the accessibility of medicines, sets important limits on the potential quality of patient care and therefore should be adequate.

**Objectives:** Evaluate some of the outpatient care practices provided to patients by health providers in PHC facilities

**Methods:** A prospective cross-sectional survey was conducted in 44 PHC facilities from all health regions of Oman. The health facilities were selected by stratified random sampling including urban and rural areas. The study was restricted to a sample of general medical visits representing a mix of health problems, ages, and sex. The WHO/INRUD patient care indicators were used. The consultation time (CT) is the time that medical personnel spends with patients for the purpose of consultation and prescribing. The dispensing time is the time that dispensers spend with patients in the dispensing process. Direct observation of the consultation and dispensing times for 100 patients per facility was measured. Also, 100 prescriptions per facility were used for the analysis of the percentage of medicines actually dispensed. The data was collected during the patients' visits that took place on the days of the investigators' surveys.

**Results:** The overall mean consultation and dispensing times were 5.69 min (range: 2.00 – 12.90) and 102.23 sec (range: 30.2 – 351.60), respectively. The percentage of medicines actually dispensed was 99.09% (range: 95.04 – 100%). The CT and DT were longer when paper prescriptions were used than with electronic prescribing. The larger the number of average daily OPD visits, the shorter the mean CT and DT. Also, the larger the average number of medicines per prescription dispensed, the longer the mean DT.

**Conclusion:** Almost all medicines prescribed were dispensed. Like many other countries in the region, consultation and dispensing times in Oman are short and insufficient for active patient care. Qualitative studies are necessary to evaluate the different factors involved and to plan interventions. Continuing education, monitoring, and supervision would be beneficial.

**Funding sources:** Directorate of Rational Use of Medicines, Ministry of Health, Oman

**811**

### **Policy, Regulation, and Governance**

*Keywords:* drug utilization, National Essential Medicine List, Segmented regression analysis

### **Effects of Listing and Delisting in National Essential Medicine List on Utilization Patterns**

**Sauwakon Ratanawijitrasin<sup>1</sup>, Sanita Hirunrassamee<sup>2</sup>**

<sup>1</sup>Faculty of Social Sciences and Humanities, Mahidol University, Thailand; <sup>2</sup>Pharmacy division, Phramongkutklao Hospital, Thailand

**Problem statement:** The National Essential Medicine List (NEML) has been a major policy instrument that the Thai Government has employed to regulate the use of medicines in government health facilities since 1982. Recent changes made in the 2008 NEML, from the previous 2004 edition, include addition and deletion of a number of medicines.

**Objectives:** This study examines the effects of NEML listing and delisting on utilization patterns and compares delisted drugs with remaining or added medicines and, where applicable, "non-essential" medicines (NEM; not listed in both NEML editions) in the same pharmacological category.

**Methodology:** Comparisons were made on 3 groups of medicines: (1) statins: Atorvastatin (delisted), Simvastatin (listed 2004 and 2008), and Rosuvastatin (NEM); (2) ACEIs and AIIAs: Enalapril and Losartan (listed 2004 and 2008) and Valsartan (delisted); and (3) antiepileptics: valproic acid (listed 2004 and 2008), Gabapentin (indication changed), and Levetiracetam (added 2008). Outpatient electronic dispensing databases from 9 government hospitals were used. Segmented regression analysis of interrupted time-series data was employed. The number of patients prescribed each of the medicines 14 months before and 10 months after the policy change were traced. This comprises a total of 24 months of time-series data points, with 130,287 patients in this dataset prescribed the statins, 85,349 patients prescribed the ACEIs and AIIAs, and 31,739 patients prescribed the antiepileptics. Comparisons of the percentages of patients in the 3 major health insurance schemes prescribed the delisted medicines were also conducted.

**Results:** Time-series plots of the number of patients prescribed each studied medicine per month exhibit no apparent change in the utilization patterns for all the items before and after the switch from 2004 to 2008 NEML. The statistical analyses of the listed, delisted, and non-listed medicines showed no significant difference before and after the introduction of the 2008 NEML. Further examination of utilization patterns among beneficiaries of the 3 major health insurance schemes revealed differences in the percentage of patients in different groups being prescribed these medicines. Before the new NEML, Atorvastatin was prescribed to 31.5%, 3.8%, and 0.6% of patients in the Civil Service Medical Benefits Scheme, Social Security Scheme, and the 30-Baht Scheme, respectively. After the new NEML, these numbers changed only slightly to 31.1%, 3.3%, and 0.6%. Similar discrepancies among schemes were also found in the prescribing patterns of Losartan, Valsartan, and Gabapentin.

**Conclusion:** No statistical significant changes in the utilization patterns of the listed, delisted, and non-listed medicines occurred after the introduction of the 2008 NEML. Discrepancies in utilization were found among patients in different health insurance systems. It appears that health insurance policy exerts greater influence on utilization patterns than essential medicine policy.

**Funding source:** Information not provided

812

**Chronic Care***Keywords:* inappropriate use, prescribing, elderly, drug utilization, pharmacovigilance,**Prevalence and Predictors of Potentially Inappropriate Medication Use in Elderly Patients in Two Indian Teaching Hospitals****Parthasarathi Gurumurthy<sup>1,2</sup>, Anand Harugeri<sup>1</sup>, Madhan Ramesh<sup>1,2</sup>, Guido Shoba<sup>3</sup>**<sup>1</sup>JSS College of Pharmacy, JSS University, Mysore, India; <sup>2</sup>JSS Medical College Hospital, JSS University, Mysore, India; <sup>3</sup>St Johns Medical College, Bangalore, Bangalore, India

**Problem statement:** Geriatrics is an emerging clinical specialty in India. Information about the appropriateness of prescription medication use among the elderly in India is limited.

**Objectives:** To determine the prevalence and predictors of potentially inappropriate medication (PIM) use and assess the relationship between PIM use and adverse drug reactions (ADRs) in hospitalized elderly.

**Methods:** Patients aged > 60 years admitted to medicine wards at 2 medical college hospitals in southern India between January 2008 and June 2009 were included randomly (convenience sample collected opportunistically). These patients were reviewed by the clinical pharmacist for PIM use according to the Beers criteria 2003; severity of PIM use was classified as high or low. ADRs observed in the study patients were also recorded.

**Statistical analysis:** Association between ADRs and PIM use was assessed using chi square test. Bivariate analysis and subsequently multivariate logistic regression was used to identify predictors of PIM use.

**Results:** PIM use was observed in 191 of 814 enrolled patients. At least one PIM was received by 2.4% (20) and 22.1% (180) of patients at admission and during hospital stay, respectively. Highly severe PIM use showed a higher prevalence [26.8% (218) compared to low severity 5.5% (45)]. Among the patients who received polypharmacy (> 5 concurrent medications), 1.4% (5/362) and 22.1% (163/736) of patients received PIMs correspondingly at admission and during hospital stay, respectively. Use of aspirin/clopidogrel/diclofenac in the presence of blood clotting disorder or anticoagulant therapy (8.3%) was the most commonly observed PIM use. Compared to medications listed in Beers criteria, medications not listed were associated with increased occurrence of ADRs (349 vs. 11) ( $\chi^2 = 98.4$ ,  $p < 0.001$ ). Use of > 9 medications during the stay in medicine wards was identified as an influential predictor of PIM use (odds ratio: 1.9, 95% confidence interval: 1.34-2.69,  $p < 0.001$ ) in hospitalized elderly.

**Conclusion:** PIM use was common (23.5%) among the elderly patients during their stay in medicine wards in 2 tertiary care hospitals. Focus of measures targeted to reduce the risk of ADRs in elderly should not be limited to Beers criteria medications.

**Key lessons and implications:** PIM prescribing is highly prevalent in hospitalized Indian elderly patients. The number of medications used can predict PIM prescribing in the elderly. Interventions targeted only at Beers criteria medications may do little to change the risk of ADRs in the elderly.

**Future research agenda:** Assess the usefulness of tools other than Beers criteria to arrive at a gold standard to assess PIM use. Health-related adverse consequences of PIM prescribing in the Indian elderly population should be evaluated.

**Funding source:** None

813

**Access***Keywords:* Health knowledge, attitudes and practice, dosage forms**Medicines Use in Oman: Public Knowledge, Attitudes, and Practices****Ahmed Abdo-Rabbo, Manal Al-ansari, Brian Conroy Gunn, Batool Jaffer Suleiman**

Directorate of Rational Use of Medicines, Ministry of Health, Sultanate of Oman, Oman

**Problem statement:** Public knowledge, attitudes, and practices (KAP) influence the use of medicines in the community. The Oman National Medicines Policy (NMP) as formulated in 2000 contains guidelines for rational use of medicines (RUM) by both health care providers and the public. Investigations of medicines in the community and public education have not been allocated the necessary human and financial resources.

**Objectives:** Identify common medicine use problems in the community to improve the appropriate use of medicines

**Methods:** A cross-sectional, pilot-tested questionnaire was administered to patients or their accompanying caretakers at the patient exit of 75 primary health care centres from all 10 health regions in Oman. A total of 6,675 Omani respondents participated in the study.

**Results:** 66% of the respondents visited multiple facilities on the same date for the same complaint and 51% failed to go for follow up to the same facility; 39% did not accept non-medicine-therapy and 30% preferred prescriptions of 3 or more medicines per visit. Many failed to ask how or when to take the medicines and where to store them and to mention any current therapies they were taking. A total of 70% stopped taking their medicines when symptoms disappeared; 26% were unaware that most medicines have sideeffects and 61% did not realise that injections are the riskiest dosage form. A total of 54% had definite colour or taste preferences; 43% practised self-medication and 68% never consulted the dispenser when self-medicated; 36% choose medicines based on previous experience, and 33% exchanged medicines with others; 55% stored all their medicines in a fridge and 17% do not check the expiry date; 45% threw unused medicines away; 41% kept them for future use and only 12% returned them to a public pharmacy or health care facility.

Conclusion: There is a widespread lack of public knowledge about the appropriate use of medicines in Oman. This is compounded by certain attitudes and beliefs, which can contribute to health risks and unnecessary expenditures. Many of these results could be improved by a well-targeted, public education campaign. Also, changes in practices of health care professionals, especially doctors, nurses, and pharmacists, are expected.

Funding sources: Directorate of Rational Use of Medicines, Ministry of Health, Oman

814

#### Policy, Regulation, and Governance

Keywords: adverse drug reaction monitoring, intensive, hospital-based, tertiary care hospital, SKIMS, Kashmiri Patients

### Intensive Hospital-Based Adverse Drug Reactions Monitoring Studies on 5482 Patients of Kashmiri Origin in a Tertiary Care Hospital

**Mohammad Ishaq Geer<sup>1</sup>, Mohammad Yasin Shah<sup>1</sup>, Parvaiz Ahmad Koul<sup>2</sup>, Shafiq Aslam Tanki<sup>3</sup>**

<sup>1</sup>Dept. of Pharmaceutical Sciences, University of Kashmir, India; <sup>2</sup>Dept. of Internal Medicine, Sher-i-Kashmir Institute of Medical Sciences, Srinagar, J&K, India; <sup>3</sup>Dept. of Clinical Pharmacology, Sher-i-Kashmir Institute of Medical Sciences, Srinagar, J&K, India

Problem statement: Prior to this study, there was no provision for monitoring drugs for their adverse effects in any of the leading hospitals of Kashmir division of the J&K state.

Objectives: To assess the prevalence, preventability, category, costs, and severity of drug-related adverse effects in Kashmiri patients at a Srinagar-based tertiary care hospital, Sher-i-Kashmir Institute of Medical Sciences (SKIMS)

Design: Prospective, observational, cohort study with follow-up

Setting: All adult patients admitted to internal medicine IPD, presenting to internal medicine OPD, and those visiting the accident and emergency department of SKIMS over a 270-day period were included in the study.

Study population: A total of 5482 adult, Kashmiri patients of both sexes were screened and monitored on a daily basis for the occurrence of any ADRs.

Intervention: Data was recorded using structured forms and then scrutinized for various assessment parameters by a multidisciplinary medical team consisting of a senior consultant in medicine, a clinical pharmacologist, and a pharmacist. Interventions relating to detection and management of ADRs were undertaken on a case-to-case basis. The study led to the establishment of a full-fledged pharmacovigilance centre in the hospital besides initiation of Pharmaceutical Care Services in its Internal Medicine ward.

Policies: No hospital drug policy or ADR monitoring policy/framework was available in SKIMS at the time of this study.

Outcome measures: Causality assessment, severity assessment, preventability assessment, extension of hospital stay, and cost due to ADRs

Results: ADRs account for 6.23% of Kashmiri patients visiting a tertiary care hospital like SKIMS, either for referral or hospitalization, with the majority (81.57%) of these ADRs being preventable; 23.68% of patients had mild ADRs, 69.29% had ADRs of moderate severity, and 7.01% had severe ADRs. The 4 classes of drugs most frequently suspected in admissions due to ADRs were anti-infective agents (40.92%) including anti-tubercular drugs (13.15%), steroids (14.03%), anti-coagulants (8.77%), and NSAIDs (7.89%). Increasing age and female gender were identified as risk factors. The organ systems most commonly affected were gastrointestinal (81%), dermatological (43%), central nervous (40%), hematological (34%), metabolic (33%), cardiovascular (22%), urinary (18%), ENT (18%), immunological (11%), and respiratory (10%) systems. The total cost to the hospital due to hospitalization of patients presenting with ADRs over the 9-month period in the internal medicine IPD was USD 22469.

Conclusions: The present work is the maiden pharmacovigilance study conducted on Kashmiri patients, especially at a tertiary care teaching hospital such as SKIMS that has provided baseline information about the prevalence of ADRs and their distribution among different age groups, genders, organ systems affected, and therapeutic classes of medicines. The data collected will be useful in the future for long term and more extensive ADR monitoring on Kashmiri patients and will also be useful in framing policies toward the rational use of drugs.

Funding sources: Nil

816

#### Access

Keywords: appropriate use, dispensing, pharmacist, pharmacy practice, emergency contraceptive pills

### Practice of Community Pharmacists Dispensing Emergency Contraceptive Pills in Chiang Mai, Thailand

**Surarong Chinwong, Napatsawan Akemanee, Piyanan Pothakieng, Pimploy Lertwanich**

Faculty of Pharmacy, Chiang Mai University, Thailand

Problem statement: Emergency contraception plays an important role in lowering the rate of unintentional pregnancies. In Thailand, emergency contraceptive pills (ECPs) are available in community pharmacies and by law, community pharmacists must take responsibility for dispensing ECPs. Therefore, the practice of pharmacists in dispensing ECPs is crucial to ensure the appropriate use of ECPs.

Objectives: To investigate the practice of community pharmacists dispensing ECPs

Design: Cross-sectional study

**Setting and study population:** The population was community pharmacists working in pharmacies located in Amphur Muang, Chiang Mai Province, Thailand. The study aimed to target 48 community pharmacists (working at 48 pharmacies) using the quota sampling technique.

**Method(s):** The secret shopping technique was used in this study. During June to August 2010, 2 well-trained secret shoppers visited each community pharmacy to assess practices of pharmacists by asking for ECPs. The pharmacist would be asked how to use ECPs if they did not provide sufficient information. This study was approved by the Human Ethic Committee of the Faculty of Pharmacy, Chiang Mai University.

**Outcome measure(s):** Appropriateness of screening, medical history-taking, and advice-giving on how to use ECPs, their side effects, other methods for pregnancy prevention, and prevention of sexually transmitted infections (STIs) were measured.

**Results:** Forty-three community pharmacists were included for data analysis; 5 pharmacies were excluded because of the absence of a pharmacist on duty during the secret shopping. The result showed that the majority of pharmacists did not identify the clients and did not ask about the history of contraceptive use. Only 1 pharmacist asked about the time of the unprotected intercourse and drug allergies. Most of the pharmacists provided the clients with the correct time frame for effective use of ECPs; however, 60% gave the advice after being asked. About 90% of pharmacists did not give advice on side effects, other pregnancy prevention methods, and the prevention of STIs. In addition, none of the pharmacists identified contraindications to ECP use or asked the clients about underlying diseases and current medication used; none suggested to test for pregnancy if their period was more than a week late.

**Conclusions:** The majority of pharmacists gave insufficient and unclear information about ECPs; the consequences could be ineffective protection against pregnancy and taking a medication that could be dangerous. The study has identified opportunities for improving the quality of providing ECPs and educating clients by community pharmacists. To improve use of ECPs and ensure that clients receive appropriate information and care, the education of community pharmacists about ECPs should be reinforced.

**Funding sources:** Faculty of Pharmacy, Chiang Mai University, Thailand

817

#### HIV/AIDS and TB

*Keywords:* Patient tracking, provider's incentives, appointment keeping

### Effects of Patient Tracking Systems and Providers Incentives on Patient Appointment Keeping in Rwanda

**Jose Nyamusore**<sup>1</sup>, **Corine Karema**<sup>1</sup>, **Ruton Hinda**<sup>1</sup>, **Patrick Gaparayi**<sup>4</sup>, **Vincent Mutabazi**<sup>1</sup>, **Sabin Nsanzimana**<sup>1</sup>, **Anitakatharina Wagner**<sup>3</sup>, **Dennis Ross-Degnan**<sup>3</sup>, **John Chalker**<sup>3</sup>, **Agnes Binagwaho**<sup>2</sup>

<sup>1</sup>TRAC Plus/Ministry of Health, Rwanda; <sup>2</sup>Ministry of Health/Rwanda; <sup>3</sup>International Network for Rationale of Use of Drug -IAA; <sup>4</sup>Management Sciences for Health

**Problem statement:** Evidence is lacking on system-level interventions to improve adherence to antiretroviral therapy (ART) and retention in care in Rwanda.

**Objectives:** The study aimed to assess the effects of a pharmacy-based patient tracking system and HIV clinic incentives on appointment keeping and retention in care.

**Design:** This was a 25-month longitudinal cohort study that employed both quantitative and qualitative methods. We analyzed changes in adherence and retention using segmented regression of interrupted time-series data and survival analysis. Patient and clinic staff interviews at baseline and follow-up and review of national and local changes in policy and care provided contextual information.

**Setting:** HIV/AIDS care and treatment clinics in Rwanda

**Study population:** Adults diagnosed with HIV/AIDS who were either on treatment for at least 6 months at the start of the study or newly started on treatment during the 25-month follow-up.

**Intervention:** 6 randomly selected facilities (group 1) received training, pharmacy-based patient tracking tools, and financial incentives; 6 facilities (group 2) received training and tracking tools only; the remaining 6 served as controls

**Outcome measures:** We measured 3 indicators using information in pharmacy appointment registers: percentage of visits occurring on and before the scheduled date (indicator 1), percentage within 3 days after the scheduled date (indicator 2), and percentage between 3-30 days (indicator 3). We also measured loss to follow-up, defined by the national program as a gap of more than 90 days in treatment.

**Result:** A total of 3,223 adults, experienced and newly treated patients, from 18 health facilities were enrolled over time. Demographic characteristics were similar across cohorts. Baseline attendance rates in all facilities were high: 82.5% of visits on or before scheduled date, 91.4% within 3 days; 97.8% within 30 days. Despite high baseline rates, time-series models indicated statistically significant improvements in appointment keeping on or before, within 3 days after, and within 30 days after scheduled visit dates among experienced and newly treated patients in group 1 and control facilities. No statistically significant changes occurred among patients in group 2 facilities which received only training and tracking tools. Results for survival analysis corroborated these findings. Qualitative results indicated unintentional spillover of the intervention in 2 control facilities.

**Conclusion:** Despite high attendance rates prior to the intervention, provision of financial incentives, together with tracking tools and staff training, resulted in improved appointment keeping of patients on ART.

**Funding source:** The study is part of the INRUD Initiative on Adherence to Antiretrovirals funded by the Swedish International Development Agency and Management Sciences for Health.

818

### **Policy, Regulation, and Governance**

*Keywords:* Good Governance for Medicine, Transparency, Pharmacy Information Center, WHO transparency assessment, Drug management reform

#### **How GGM Program Enhanced National Drug Policy, Thailand Experience**

---

##### **Chanvit Tharathep**

Ministry of Public Health, Thailand

Even Thailand has implemented the national drug policies (1981), national essential drug list (1981-2008), drug management reform (1981-2008), the MoPH still faced with scandals regarding medicine supplies (1997). The health expenditure was still rising.

Objective: To improve transparency, GGM infrastructure for more efficient, effective.

Design: Descriptive study, policy evaluation. (2004)

Setting: Studies conducted by MoPH, GGM WHO.

Study Population: MoPH hospitals who owns 65% of the total beds and provides more than 80% of the health and medical services in Thailand. GGM team who direct and guide the MoPH's pharmacists. The NGOs (PReMA) are also involved.

Interventions: 2004-2005 Transparency assessment (WHO started supporting). 2005-2006 Situation analysis then national GGM framework (WHO GGM framework template) and GGM strategic formulation. 2006-2008 Implementation GGM program to fill the gaps of the selection, registration, procurement, promotion and other processes. 2009-2010 Expanded GGM into the MoPH hospitals, prescription, education program and national policy.

Policies: National drug policy: New single price program for monopoly drugs. Drug management reform policy: promote drug pool purchasing at a provincial level and regional level, pharmacy information center for dissemination of comprehensive pharmaceutical information including prices from companies, hospitals. National GGM framework implementation: Code of conducts including pharmaceutical companies association. Supplement GGM principle in a professional meeting. Promotion of moral leadership. Conflict of interest forms for registration, selection, national essential drug list and also standard drug price committees. MoPH co-operated with Anticorruption organization to initiated guideline of procurement. GGM strategic formulation and Team setting. Transparent practices and regulations were initiated.

Outcome Measure: Improving in GGM infrastructure (code of conduct, conflict of interest declaration, moral leadership at the provincial level, committee basis for decision making) and more transparent system (pharmaceutical information center) which can improve our registration, selection, procurement and also promotion and prescription.

Results: The interventions improved effective and efficient of the drug management The pool purchasing demonstrated controllable prices of common drugs over the last 10 years. The Monopoly drugs management was already implemented. All purchasing prices were shown on the website.

The health care environment should be evaluated and priority setting should be done at first, the strategy should be formulated to support and transfer into operation, transparency is the most effective, efficient and feasible for a good governance implementation.

Conclusions: The GGM program can improve and enhance national drug policy. The interventions can increase transparent, efficient, effective. We still need more evaluation.

Funding Source(s):WHO, MoPH.

819

### **Economics, Financing, and Insurance Systems**

*Keywords:* Medicines, Health Insurance, Population Coverage, Countries.

#### **Universal Health Insurance Coverage and Reimbursement for Medicines in Countries**

---

##### **Dele Olawale Abegunde, Runo Onosode, Clive Ondari**

World Health Organization, Switzerland

Background: To achieve the MDGs and optimal care, the WHO World Health Report 2010 emphasizes universal coverage for health care services including reimbursement for medicines in countries. In 2005, WHO member states committed to developing their health financing systems to improve access to care. The majority of the burden of diseases in low- to middle-income countries can be assuaged with access to appropriate medicines, yet in a limited number of countries where there are insurance systems in place, coverage for medicines can be limited in scale and scope. Given this background, this study attempts to map the extent of insurance coverage for medicines in countries.

Objectives: To evaluate and compare the extent of insurance coverage for medicines and health care especially in low- and middle-income countries

Design: Cross-sectional descriptive evaluation of countries according to World Bank income grouping; data obtained from reviews of published and grey literature including country reports

Settings: Includes all 193 UN member countries and the types of health insurance cover

Study population: Estimates of coverage for health and medicines were denominated by countries and regional (aggregated) population.

Outcome measure(s): Number and proportion of countries with some forms of health insurance and medicines coverage; population coverage and types of health insurance schemes by countries and income group

Results: Universal health coverage has been achieved in only 65 (35%) UN member states, the majority (78%) of which are in the high-income group. Partial coverage has been achieved in about 86 (45%) of the 193 countries. Although almost all the population (93% population coverage) are covered in a form of health insurance in the high-income countries, only a relatively meager 14% coverage is achieved for the population in low-income countries. Medicines are covered for reimbursement in 46 of the 47 (92%) high-income countries. Although 35 of the 46 upper middle-income countries (76%) and 31 of the 54 (57%) of the upper middle- and lower middle-income countries, respectively, have established a form of health insurance, fewer (27 of 46 [27%] and 31 of 54 [35%]) have medicines benefits in their insurance system. These results indicate the existing global inequalities in access to health care services. Community-based insurance schemes are more common and increasing in the lower-income countries compared to social and private health insurance schemes which are present in higher-income countries.

Conclusions: Although community health insurance is growing in low- and middle-income countries, the majority of countries and populations have no access to health insurance compared to high-income countries. Coverage for medicines remains much more limited relative to coverage for health. Providing optimal health care and achieving MDGs in low- and middle-income countries could be doubtful without concerted global efforts.

Funding source: Information not provided

**822**

### Malaria

*Keywords:* Adverse Events, Artemisinin- Based Combination Therapy

### **Safety and Tolerability Profile of Artemisinin-Based Antimalarial Combination Therapy (ACT) in Adult Nigerians**

**Stephen, Airmuanwonsa Ayinbuomwan, Ambrose, O Isah**

Clinical Pharmacology and Therapeutics Unit, Department of Medicine, University of Benin Teaching Hospital.

Problem statement: Malaria remains a major public health concern in tropical and sub-tropical regions of the world especially sub-Saharan Africa. The Artemisinin-Based Combination Therapy (ACT) has recently been introduced due to *P. falciparum* resistance to chloroquine following recommendations by the WHO. The use of these medicines raised safety concerns with tolerability, undermining therapy.

Objective: To characterize the safety and tolerability profile related to the use of the ACTs in our environment

Design: A longitudinal cohort and descriptive study.

Setting: The study was carried out in the Out-patient Department of the University of Benin Teaching Hospital and Central Hospital, both in Benin City, Edo state, Nigeria.

Study Population: Adult patients ( $\geq 18$  years) with a diagnosis of uncomplicated malaria and treated with ACTs were recruited for the study.

Policy: The WHO in 2001 advocated Antimalarial Combination Therapy especially those containing an Artemisinin derivative to countries experiencing resistance to Antimalarial monotherapies. Nigeria adopted Artemether-Lumefantrine (AL) as the first-line Antimalarial in 2005. Other ACTs adopted include Artesunate-Amodiaquine (AA) and Artesunate-Mefloquine (AM).

Outcome measures: The safety and tolerability profile of ACTs amongst the treated patients. ADRs were classified using the WHO causality assessment.

Results: 500 patients were enrolled for this study – AL (179), AM (149), AA (134). The mean age was 32.6 years (range 18-68 years). One hundred and eighty-eight (37.6%) patients reported at least one AE: 61% in the AA, 60% in the AM, 58% in the AL. AA treatment was associated with a significant higher risk of Gastrointestinal symptoms, Dizziness and Pruritus than AL and AM ( $p < 0.05$ ). Those treated with AM had a higher incidence of generalized weakness although it was not statistically significant. Moderate to severe AEs were observed in five patients each treated with AA and AM respectively, and in one patient treated with AL.

Conclusion: This study confirms the safety and tolerability of AL. AA and AM although safe are less well-tolerated, and this may affect patients' adherence with its attendant consequences.

Funding sources: Personal

**825**

### Chronic Care

*Keywords:* access to medicines, chronic disease

### **Working Together for Mental Health: The Nouadhibou Pilot Experience**

**Daniel Gérard<sup>1</sup>, Ahmed Ould Hamady<sup>2</sup>, Robert Sebbag<sup>1</sup>**

<sup>1</sup>Sanofi-aventis, France; <sup>2</sup>Neuropsychiatric center, Nouakchott, Mauritania

Problem statement: Although mental disorders are a major contributor to the Global Burden of Diseases, mental health care in many developing countries is accessible only to a minority of patients. With the creation of the Global Fund,

dramatic progress has been made in ensuring access to medicines in HIV, TB, and malaria. Major pharmaceutical companies have played a crucial role in this positive evolution through public-private partnerships (PPP). However, psychiatric diseases do not benefit from PPPs that could be decisive levers in improving access to care and promoting psychosocial rehabilitation. In 2005, an international conference held in Nouakchott underlined that improving mental health care in Mauritania, as in other low-income countries, will require changing legislation and policies, setting up services, getting funding, training health care professionals, and making medicines accessible. Through its Access to Medicines department, Sanofi has launched initiatives to improve access to medicines in certain therapeutic domains including mental health. These initiatives consist of both the development of adapted information, education, and communication tools and the implementation of a preferential pricing policy for Sanofi's antipsychotic medicines.

**Intervention:** A PPP between the Mauritanian Ministry of Health and Sanofi was set up in October 2008 for developing access to mental health care. It was decided to pilot in the Nouadhibou province and to focus on schizophrenia as a first step.

**Objective:** The Nouadhibou Pilot Experience is a demonstration project which is intended to prove that access to care for schizophrenic patients could be improved drastically by simple, assessable, and adaptable programs.

**Design:** The program combines actions dedicated to advocacy efforts toward political and administrative decision makers; increased awareness in communities of mental health issues; development of users' associations; education of patients and families; training health care professionals; and organizing a sustainable supply of high-quality antipsychotics. These actions are conducted in liaison with local NGOs, patients, families, and the Nouadhibou city civil services with the goal of finally promoting rehabilitation.

**Results:** In May 2009 the baseline assessment indicated a treatment gap of 93% in psychosis. From May 2009 to May 2010, outpatient facilities have been progressively opened in 7 centers. After 18 months, in October 2010, the treatment gap has already been decreased by 28%. The results after 2 years will be presented, including the burden of the disease on the families through the involvement evaluation questionnaire.

**Conclusion:** This program is a model of PPP serving the "Make Mental Health a Global Priority" objective at the country level. Lessons drawn from the Nouadhibou Pilot Experience will be useful to the expansion of such approaches to other locations.

**Funding source:** Sanofi

826

#### Access

*Keywords:* access to medicines, availability, drug utilization, marketing authorization, regulatory authority

### **How Sustainable is the EU Regulatory Network in the Context of the Uptake of New Medicines?**

**Joëlle Hoebert<sup>1</sup>, Aukje Mantel-Teewisse<sup>1</sup>, Liset van Dijk<sup>2</sup>, Hubert Leufkens<sup>1</sup>**

<sup>1</sup>Utrecht University/Utrecht WHO Collaborating Centre for Pharmacoepidemiology and Pharmaceutical Policy Analysis, The Netherlands; <sup>2</sup>NIVEL, Netherlands institute for health services research, Utrecht, the Netherlands

**Problem statement:** The system of rapporteurs is seen as the backbone of the European Union (EU) Centralised Procedure, although there is increasing concern about the large variation among EU member states (MSs) regarding their individual contributions in terms of the number of rapporteur roles. The future strategy paper of the European Medicines Agency (EMA) aims to strengthen the European regulatory network and its contributions to patients' access to medicinal products.

**Objectives:** In this study, we looked at variations in rapporteur contributions to the EU regulatory network between EU MSs in light of the uptake of new medicines approved in 2004 as measured through IMS data.

**Design:** Drug utilization study

**Setting:** Contributions to the EU regulatory network and international utilisation of newly approved medicines in both public and private sectors in 23 European MSs

**Study population:** All 24 medicines that received a central market authorisation by EMA in 2004

**Outcome measures:** The total number of (co-)rapporteurships of each EU MS between 2004 and 2009 was determined using the European Public Assessment Reports of all centrally authorised medicines. Data on medicines usage by volume in various EU MSs was collected from IMS data. A medicine was defined as available if consumption in a certain year was  $\geq 100$  standard units (IMS volume measure). For each medicine, the volumes (per 1000 inhabitants/day) consumed in 2009 across all countries were divided into 4 equal parts (quartiles). Each EU MS was then ranked according to their consumption into a quartile. Finally, the average ranking (minimal 1, maximal 4) per country was set out against the number of (co-)rapporteurships.

**Results:** A crucial factor in the uptake of medicines is the actual availability of medicines. In some countries (e.g., Portugal and the Baltic States), over 40% of these medicines were not available 5 years after market authorization. Furthermore, a distinction was seen between newer and older EU member states. Newer EU MSs showed almost no variation in their (low) contribution in terms of number of rapporteurships (range 0-10) to the regulatory system but did show large variation in the relatively low uptake of new medicines (range average ranking 1.3–2.7). Older EU MSs showed large variation in their large contributions in terms of the number of rapporteurships (range 15-58), but almost no variation in their high uptake of these medicines (range average ranking 2.4–3.3).

**Conclusions:** Innovative medicines are not available for all citizens in the EU in a timely and equitable manner. The valuable input of high-quality specialist expertise provided by the MSs is limited to just some countries, mainly the older

EU MSs. This phenomenon may fuel the debate around the current EU procedures that might not be sustainable if not all resources from all EU MSs are mobilized.

Funding sources: None

**828**

**Policy, Regulation, and Governance**

*Keywords:* drug information, appropriate use, regulation, patient safety

**New warnings for medicines labeling and packaging in Brazil**

**Carolina Fracalossi Rediquieri, Elizabete Regina Viana Freitas, Livia Santos Ramalho, Daniela Barros Rocha, Carolina Souza Penido, Marisa Moraes Lisboa**

Brazilian Health Surveillance Agency, Brazil

**Problem statement:** Since 2003 Brazil has legislation about specific warnings that must be highlighted on labels of medicines. This legislation, named as RDC 137/2003, covers 27 substances, including active and inactive ingredients. However, users of medicines have been complaining that some of those warnings should be present on the outer face of the medicines packaging and many substances and warnings needed to be included. Furthermore, other stakeholders of pharmaceutical assistance think some warnings are archaic. This study describes the process of elaboration of a new legislation on mandatory warnings for labeling and packaging of medicines.

**Objective:** To revise warnings present in the RDC 137/2003 and raise other important ones that should be present on many medicines labeling and packaging available in Brazilian market in order to promote the rational use of medicines, avoid self-medication or, if it still happens, to minimize its risks.

**Design:** Critical substances were identified and their warnings and contraindications were searched on labels and official documents available in the FDA, EMA, WHO, TGA and ANVISA websites. The association between the substances identified and their critical problems were searched in the literature (Google Scholar, Pubmed, Micromedex and Cochrane), as well as the frequency and severity of those problems. Based on findings, the warnings were revised and new warnings were elaborated.

**Setting:** Brazilian pharmaceutical market.

**Study population:** Ingredients present in medicines registered in Brazil which are known to be harmful if used when certain conditions are not observed.

**Results:** The study revised 27 warnings present in the RDC 137/2003 and added other 50 substances and 18 therapeutic classes that needed warnings highlighted on labels. Out of those, 13 substances and 6 therapeutic classes needed warnings on packaging as well, such as acetaminophen, ethanol, NSAIDs and their contraindication in stomach ulcer and dengue disease (a major public health problem in Brazil), antimicrobials and the risk of resistance, X and D pregnancy risk factors, dyes and others. A total of 108 warnings were revised or elaborated using plain and accessible language. The warnings were included in a new legislation to make it mandatory for medicines labeling and packaging.

**Conclusions:** Many important warnings must be present and highlighted in labeling and packaging for medicines in order to improve their rational use. Therefore, a new legislation was elaborated to make those warnings mandatory to marketed medicines in Brazil. The new legislation went through public consultation in December 2010 and the final version will be published in March 2011.

**Funding Source:** Brazilian Health Surveillance Agency (ANVISA), Brazil.

**830**

**Access**

*Keywords:* health facilities, primary health care, health workers, pharmaceutical policy, education

**Successful Intervention to Improve the Pharmaceutical Services in a Region of Brazil**

**Rafael Mota Pinheiro<sup>1</sup>, Karen Miranda<sup>2</sup>, Fabiana Saraiva<sup>2</sup>, Carolina Araujo<sup>1</sup>, Simone Borba<sup>1</sup>, Daniel Cattini<sup>1</sup>, Naiguel de Sousa<sup>1</sup>, Nãna dos Santos<sup>1</sup>, Inayan Lopes<sup>1</sup>, Angélica Lucas<sup>1</sup>, Mariana Ribeiro<sup>1</sup>, Luciane Kopittke<sup>3</sup>**

<sup>1</sup>University of Brasilia - Brazil; <sup>2</sup>State Department of Health - Federal District; <sup>3</sup>Grupo Hospitalar Conceição - Ministry of Health of Brasil

**Problem statement:** The Brazilian constitution establishes a universal health system in which the health care provided to almost 100 million Brazilians is based on primary care and sheltered by the Family Health Program, which is based on a multidisciplinary team. Implementation of pharmaceutical services is considered a key process in primary care renewal and therefore contributes to the achievement of better health outcomes.

**Objectives:** This paper aims to describe the reorganization process and qualification of pharmaceutical services in a primary care service in Brazil.

**Design:** We conducted an interventional before and after study. The situational analysis of pharmaceutical services was materialized using instruments adapted from MSH. We have outlined goals for the reorganization of pharmaceutical services while collecting the before (current) stage of development of capacities related to pharmaceutical services; 15 indicators divided into 5 dimensions (programming, storage, prescription, dispensing, and human resources) were used.

**Setting and study population:** The study was carried out in a primary care facility. The health unit has 8 teams of the family health team supplemented by health technicians and community health agents.

**Interventions:** The interventions were carried out by a team formed by two pharmacists, a physician, a nurse, and 8 undergraduate students in pharmaceutical sciences over the course of a year. The intervention consisted of educational interventions to promote rational use of medicines, development of technical support tools, and advocacy standards for pharmaceutical services.

**Outcome measure:** Stage of development of capacities related to the 15 indicators studied

**Results:** All indicators analysed were improved by at least 1 level after the intervention and all the goals were achieved. Of the 25 interventional actions planned, 7 were related to development of technical support tools, 9 were educational interventions, and 9 documents were forwarded to the local health team and health managers to advocate for improved programming, storage, prescription, dispensing, and human resources to improve rational use of medicines.

**Conclusions:** The interaction between university and first-level facilities has a huge potential. Despite the bureaucracy, when designing intervention programs in partnership with the public health system, we could well handle it and by the end of only 1 year, we observed that the partnership has generated important mechanisms for monitoring, evaluation, and other processes. Also, the methodology for situational analysis of pharmaceutical services is reproducible and can be used in other parts of the country. The Educational Program for Health at Work (PET-Saúde) can guarantee the expected sustainability, reproducibility, and expansion of this project in other parts of the country.

**Funding source:** University of Brasilia, Fundação de Apoio à Pesquisa do Distrito Federal, Brazilian Ministries of Health and Education

**831**

### **Child Health**

*Keywords:* Africa south of Sahara, child, medication, pediatric medicines, pharmacoepidemiology

## **Medication Among Children in Africa South of Sahara: Qualitative Systematic Review**

---

**Ebba Holme Hansen, Susan R. Whyte**

University of Copenhagen, Denmark

**Problem statement:** The use of medicines is an important aspect of child health. Medication behaviour established in childhood and adolescence may track into adulthood. However, this topic has been sparsely dealt with in international research, not least in low-income societies.

**Objective:** To provide an overview of empirical evidence on children and medication in Africa south of Sahara

**Design and material:** Systematic literature review; searches were conducted in Medline, Embase, and Psychinfo without restrictions, applying the same terms and combinations in all databases. In all searches, “children” and “Africa, south of Sahara” were combined with medication defined by 80 different search terms. Children were defined as 0–18 years. Primary exclusion criteria were immunisation programmes; preventing mother-to-child transmission of HIV; traditional medicine; efficacy studies; and clinical trials with clinical endpoints. Secondary exclusion criteria after reading abstracts were drug abuse; purely diagnostic studies; purely economic studies; and mixed children-adults studies.

**Data handling and extraction:** Titles and abstracts were first assessed for eligibility. Next, relevant full-text articles were acquired and information extracted on data sheets, one for each study.

**Setting:** Africa south of Sahara

**Outcome measures:** Medication theme; dosage form; country; study design; data collection period; population; results; and quality of study

**Results:** 1530 potentially relevant references were identified including 719 duplicates; after secondary exclusion, 132 studies remained for analysis. The illnesses dealt with were primarily malaria (63 studies), diarrhoea (27), fever (13), ARI/pneumonia (9), asthma (4), HIV/AIDS/ART (3), and epilepsy (2). Studies were carried out in 24 countries, primarily Kenya (24), Nigeria (17), Tanzania (14), South Africa (11), Ghana (9), Ethiopia (8), and Uganda (8); 9 countries had 1 study only. Most studies recognised 2 or more sources of treatment; 55% of studies included solely children under 5 and 38 studies did not specify the age group. Gender was not an issue. Almost half of studies focused on appropriate prescribing and use, but we identified only 2 studies on dosage regimes, 2 on medicine use in the population, and 1 on compliance.

**Conclusions:** Studies on children and medication in Africa south of Sahara focus primarily on 2 symptoms/conditions (malaria/fever and diarrhoea) and primarily deal with children under 5. Major research gaps include medication issues specific to children over 5, the importance of dosage forms for children, and acute conditions, other than malaria/fever and diarrhoea.

**Funding source:** Copenhagen University's Global Health Cluster temporary fund provided partial funding.

**832**

### **Access**

*Keywords:* Access to Medicines, Health System Strengthening

## **A Conceptual Framework for a System-Wide Definition of Access to Medicines**

---

**Maryam Bigdeli<sup>1</sup>, Richard O Laing<sup>2</sup>, Abdul Ghaffar<sup>1</sup>**

<sup>1</sup>Alliance for Health Policy and Systems Research, World Health Organization, Switzerland; <sup>2</sup>Department of Essential Medicines and Policies, World Health Organization, Switzerland

**Problem statement:** WHO considers medicines and technologies as one of the six building blocks of health systems. Most health systems strengthening interventions are designed within single building blocks of the system and interconnections between systems components are not adequately considered. In particular, complex relationships between medicines and health financing, human resources, health information and service delivery are not straightforward. The role of medicines is narrowed down to a system input, a commodity that should be available to allow service delivery. As a consequence, populations access to medicines is addressed mainly through fragmented, often vertical approach usually focussing on supply, unrelated to the wider issue of access to health services and interventions. Access to Medicines (ATM) should address supply, quality assurance and use. This shortfall has considerable consequences: with a vertical and isolated approach, interventions and policies aiming at improving ATM can only have a limited and short-term effect in resource constrained settings. This phenomenon results in the current lack of access to essential medicines for vulnerable populations in low and middle income countries

**Objectives:** The objective of this work is to provide a conceptual framework defining ATM in the broader context of health systems strengthening and equitable access to health services and interventions.

**Design:** We identified available definitions ATM in the published literature and systematically analyse their strength and weaknesses. We extended this analysis to definitions of equitable access to health services and interventions for the poor and we extract from these definitions the missing elements allowing us to complete our definition of ATM. We conceived and proposed an extended framework which provides a system-wide definition of ATM, taking into account interconnections between medicines and all other elements of a responsive and functioning health system.

**Intervention or policy change:** We will use this framework to conduct health system and policy research in the area of ATM and generate evidence for more effective policy formulation and health systems interventions

**Results:** The framework defining ATM will be presented at the conference. It will examine ATM with regard to: A- The determinants of ATM: health system issues and barriers in access to medicines, B- The impact of medicines on the health system: components of the pharmaceutical sector that impact health system in a positive or negative manner, and that will in turn generate a system reaction that will impact ATM.

**Conclusions:** There is an urgent need to formulate policies and design interventions that support adequate access to medicines for vulnerable populations. A wider holistic definition of ATM would ensure that these policies and interventions are more effective at the system level and bear longer term equitable and sustainable results.

833

**Access**

*Keywords:* Access to Medicines, evidence base, systematic search

### **Bibliometric Study of Publication Patterns in Access to Medicines in Low- and Middle-Income Countries**

**Maryam Bigdeli, Saad Ahmad, Taghreed Adam**

Alliance for Health Policy and Systems Research, World Health Organization, Switzerland

**Problem statement:** Low- and middle-income countries (LMICs) face many challenges in accessing medicines. One of the main issues is limited evidence and knowledge base on what works to improve access to medicines (ATM) in resource-poor settings.

**Objectives:** Search existing evidence base on ATM and ATM barriers in LMICs; analyse publications patterns, with attention to the origin of publications and publication topics, with the aim of assessing areas where information gaps exist

**Design:** Literature search and analysis

**Setting:** LMICs

**Interventions:** A PubMed search was conducted to retrieve publications on ATM between 1999 and 2009, using a systematic search strategy based on Cochrane Reviews. Retrieved articles were categorized by publication year, country of residence of corresponding author, and publication topic. Patterns of publications were analysed with respect to these categories.

**Outcome measures:** Number of publications on ATM between 1999-2009 according to publication year; country of residence of the corresponding author; classification of that country as low income, lower middle income, upper middle income, or high income; and publication topic (selection, intellectual property, regulation and quality assurance [QA], monitoring, financing and insurance, access, procurement and distribution, supply, policy reform, pharmacists, prescribing and utilization, information, marketing)

**Results:** Overall, 5491 publications on ATM were retrieved for the period 1999-2009. Publications on ATM have increased in the past 10 years, from 40 in 1999 to 111 in 2009; 48.27% of all publications originate from high-income countries, 18.8% from higher middle-income countries, and only 18.55% of evidence originates from low-income countries. The majority of publications relate to monitoring and regulation and quality assurance; together, 73.5% of available evidence on ATM. However, these categories are also those in which LMICs have the lowest input—only 5.53% of publications on monitoring and 7.87% of publications on regulation and QA. LMICs are very active in the fields of selection of medicines and general access issues; 46.87% and 42.97%, respectively, of publications in these areas originate from LMICs. Areas of concern, such as prescribing and utilization or financing and insurance, are underrepresented in the available evidence, with only minimal input from LMICs.

**Conclusions:** The majority of evidence on ATM originates from high-income countries, in areas where results and recommendations are irrelevant in resource-constrained settings (e.g., regulation and QA). There is a need to support more research in LMICs and extend this effort to publication and dissemination of research findings and

recommendations for larger use in comparable contexts. Neglected areas of research, such as rational use or financing, lead to important evidence gaps; these areas need to be prioritized in future research and publications.

Funding source: None

**834**

**Malaria**

*Keywords:* drug and therapeutic committee (DTC), antimalarials, appropriate use,

### **Impact of Training, Monitoring, and Mentoring on Drug and Therapeutic Committees in Ghana**

**Chinwe Ugochi Owunna<sup>1</sup>, Emmanuel Kwesi Eghan<sup>2</sup>, Johannes Addison<sup>3</sup>**

<sup>1</sup>Management Sciences for Health, United States of America; <sup>2</sup>Management Sciences for Health, Ghana; <sup>3</sup>Consultant

**Problem statement:** Although Ghana's antimalaria drug policy (AMDP) was changed in 2004 to include use of artemisinin-based combination therapy (ACT) to treat uncomplicated malaria, monotherapies were still in circulation, particularly in the private sector. Also, locally manufactured amodiaquine-artesunate (AS/AQ) tablets at a higher than recommended strength resulted in negative publicity for ACTs due to adverse drug effects. The AMDP was revised again to include 2 second-line ACTs—artemether-lumefantrine (AL) and dihydroartemisinin-piperazine—but health facilities still did not comply with the AMDP recommendations.

**Objectives:** To improve facility drug and therapeutics committee (DTC) understanding of the new AMDP and highlight their role in supporting health facility compliance; to improve rational medicine use and compliance to AMDP at public and private health facilities

**Setting:** 48 public and private health facilities in Greater Accra, Western, and Central regions in Ghana; the post-intervention study was conducted in 2 health facilities, Maamobi and Kaneshie polyclinics, in the Greater Accra region. Public and private health facilities were selected based on criteria that included their level within the Ghana Health Services hierarchy, such as tertiary and primary facilities, and presence or absence of a functional DTC.

**Study population:** Doctors, pharmacists, administrators, procurement officers, nurses, medical assistants, technical officers, and pharmacy assistants

**Intervention:** Trained 155 DTC members from 48 facilities on rational medicine use and the new AMDP; conducted supportive supervisory visits at 20 of the 48 health facilities and mentored DTC members to improve practices

**Outcome measures:** Percentages of indicators related to AMDP compliance

**Results:** Maamobi polyclinic baseline: 85% of prescriptions for uncomplicated malaria cases conformed to AMDP (prescribed ACTs); 20% of cases were prescribed AS/AQ, while 80% were prescribed AL. Post-intervention, AMDP conformity increased to 92%; prescriptions for AS/AQ increased to 65% and AL decreased to 35%. Kaneshie polyclinic baseline: AMDP conformity was 80%; 53% of cases were prescribed AS/AQ and 47% were prescribed AL. The post-intervention visit showed that prescriptions conforming to AMDP increased to 87%; AS/AQ prescriptions increased to 75% and AL prescriptions decreased to 25%.

**Conclusions:** Although training, supervisory visits, and mentoring can be resource-intensive, the survey showed that these interventions improve rational medicine use in health facilities.

Funding source: United States Agency for International Development-President's Malaria Initiative

**835**

**Malaria**

*Keywords:* malaria, children, rapid diagnostic test, community health worker, artemether-lumefantrine

### **Improving the Use of Artemisinin-Based Combination Therapy in Rural Zambia**

**Kojo Yeboah-Antwi<sup>1,2</sup>, Portipher Pilingana<sup>3</sup>, William Macleod<sup>1,2</sup>, Katherine Semrau<sup>1,2</sup>, Kazungu Siazele<sup>3</sup>, Davidson Hamer<sup>1,2</sup>**

<sup>1</sup>Center for Global Health and Development, Boston University, Boston, MA, USA; <sup>2</sup>Department of International Health, Boston University School of Public Health, Boston, MA, USA; <sup>3</sup>Chikankata Mission Hospital, Chikankata, Zambia

**Problem statement:** Zambia, like many malaria endemic sub-Saharan African countries, has changed its first-line drug for uncomplicated malaria to the more expensive and effective artemether-lumefantrine (AL). There are valid concerns about potential overuse of AL and development of resistance if AL use at the community level by community health workers (CHWs) is not guided by rapid diagnostic tests.

**Objectives:** The primary objective was to assess whether the use of RDTs by CHWs will reduce the overuse of AL. The secondary objective was to assess the feasibility and safety of CHWs performing RDTs.

**Design:** This was a cluster randomized, controlled trial with a cluster defined as the catchment area of a community health post. CHWs in control clusters prescribed AL to all children with fever whereas those in intervention clusters used RDTs to guide treatment with AL. We also carried out focus group discussions and in-depth interviews to assess the community's opinions and perceptions about the intervention.

**Setting:** The study was conducted in the Chikankata Mission Hospital catchment area (estimated population 70,000), which extends across parts of Siavonga and Mazabuka Districts in Zambia's Southern Province. The study area is a typical rural area with poor roads, which is served by the mission hospital and 5 official Ministry of Health rural health centers. Most sick children are seen by CHWs who work in a fixed location called the community health post, which serves a number of villages.

Study population: Children aged between 6 months and 5 years who presented to a CHW at a health post with fever were enrolled. Children with signs or symptoms of severe illness were excluded and referred; 3125 children were enrolled over a 12-month period in both the intervention and control arms.

Intervention: Both the intervention and control CHWs received 4 days of training in classification and treatment of febrile children and were supplied with AL. The intervention arm received an additional half-day training in the performance and interpretation of RDT results and how to respond to both positive and negative results. They were also supplied with RDTs.

Outcome measure: Proportion of children presenting with fever who received AL

Results: The proportion of children presenting with a history of fever that received AL in the intervention arm was 27.5% compared to 99.1% in the control arm (RR 0.23, 95% CI 0.14–0.38). Minor side effects associated with the pricking the finger for RDT included bleeding longer than caregiver's expectation (1.5%), bruises (0.4%), and local skin infection (0.2%). Caregivers and community leaders indicated their acceptance for CHWs to perform RDTs and prescribe antipyretics for children with RDT negative results.

Conclusions: The potential for CHWs to use RDTs to guide prescription of AL for treatment of malaria at the community level is promising and has great potential to reduce overuse of AL.

Funding sources: United States Agency for International Development and the President's Malaria Initiative

839

#### HIV/AIDS and TB

*Keywords:* PARTNERSHIP, GOVERNMENT, STRENGTHEN, LOGISTICS, MANAGEMENT

### Partnership with State Government to Strengthen HIV/AIDS Commodities Logistics Management System

**Monday Salifu<sup>1</sup>, Eric Lugada<sup>2</sup>, Patrick Okoh<sup>1</sup>, Dada Abdulwahab<sup>1</sup>**

<sup>1</sup>AXIOS Foundation Nigeria, c/o Management Sciences for Health, Nigeria; <sup>2</sup>AXIOS Foundation, Nigeria

Problem statement: Donor-funded HIV/AIDS programs in Nigeria typically operate their own logistics systems to avoid the inadequacies of government-managed systems. This situation leads to unnecessary duplication of systems and structures and contributes to poor government ownership of the HIV/AIDS program.

Objectives: This partnership is expected to strengthen government-managed commodity logistics systems, eliminate duplications, improve program ownership, and foster sustainability.

Design: This is a retrospective account of an intervention to strengthen the capacity of the State Ministry of Health (SMoH) to operate a unified health commodity logistics management system by Axios Foundation and Management Sciences for Health (MSH) in Nigeria.

Setting: The intervention was carried out in conjunction with Niger SMoH, North Central Nigeria.

Interventions: Axios Foundation/MSH local teams worked with the State Health Commodity Logistics teams to secure the buy-in of key stakeholders in the health sector. After conducting a baseline assessment to identify infrastructural gaps, renovations were carried out in hospital pharmacies and laboratories to improve site storage conditions. The State Central Medical Store in Minna, Niger State, was refurbished and upgraded to an integrated model warehouse and was fitted with new shelves, refrigerators, air conditioners, and a power generator set. Also, real time on-line inventory software for stock management was installed. Trainings were conducted for the state health logistics managers and hospital staffs on commodity logistics, updating their knowledge on best practices.

Policy change: A technical working group on health logistics was set up by SMoH, and hospital-level logistics managers were directed to take charge of all HIV/AIDS-related logistics systems in their hospitals.

Results: The unified health commodity logistics system is now fully in operation in Niger State. Health commodities from both donor-funded and government HIV/AIDS programs are pooled together and managed centrally in the integrated model warehouse and then distributed to all the health facilities providing HIV/AIDS care and treatment services in the state. Logistics for other health programs are also managed by the model warehouse. From the review of the tally cards in the last year, there has been no incidence of drug stock-outs of full-supply commodities, and stock expiration rates are far less than previously reported. Most expired items are those withdrawn from use by the project (e.g., Zidovudine syrup formerly used for prevention of mother-to-child transmission of HIV/AIDS and stavudine-based regimen). The level of documentation and reporting has improved greatly because all the inventory management tools are being used and updated regularly. These actions have informed the increase in government investment in the funding for HIV/AIDS commodities in the state. For instance, in 2010, the state house of assembly passed a budget of one hundred million naira (\$667,000) for the implementation of HIV/AIDS programs, including drug procurement compared to the four million naira (\$27,000) approved in 2009 fiscal year.

Conclusions: Appropriate skills and adequate government supervision are cardinal to strengthening HIV commodities logistics management. Partnership with the state government can greatly increase government ownership and strengthen commodities logistics for sustainability of HIV/AIDS programs.

Funding source: USAID through LMS Pro-ACT, MSH

840

#### Economics, Financing, and Insurance Systems

*Keywords:* drug approval, medicine prices, disease burden, median price ratio, public sector

## **Drug Approvals and Medicine Pricing In India**

**Santosh Ramesh Taur, Nithya Jaideep Gogtay, Sheetal Vitthalrao Chandan, Urmila Mukund Thatte**

Seth GS Medical College and KEM Hospital, Parel, India

**Problem statement:** The disease burden (DALYs/1000) in India is due to diarrhea (15), respiratory infections (7.9), cardiovascular (4) and psychiatric disorders (2.4). Although over 200 new drugs are approved annually and over 1000 clinical trials are being conducted in the country, it is doubtful whether the health needs of people are met. Although the government makes efforts through price control and cheaper generics are available, affordability remains a challenge.

**Objectives:** - Are new drug approvals and clinical trials in the country commensurate with the health needs of the people? - Compare prices of selected essential medicines across public and private sectors in Mumbai and explore impact of government price control policy.

**Design:** Pharmaceutical situation analysis

**Setting and methods:** A national level study was conducted to analyze drug approvals in last 6 years in India. The clinical trials being conducted in India and registered at national and international registries were examined. Medicines prices of selected medicines in Mumbai were surveyed using the WHO and Health Action International methodology. For each medicine, the prices of innovator brand (IB), most sold generic (MSG) and lowest priced generic (LPG) were obtained and the median price ratio (MPR) was calculated using the international reference price (IRP). The study was conducted at randomly selected public hospitals and private pharmacies in Mumbai.

**Policy:** The impact of price control was evaluated by comparing the MPR of price controlled and uncontrolled medicines.

**Outcome measures:** The drug approvals and clinical trials pattern in India were studied. The MPR was compared between price controlled and uncontrolled medicines as well as between public and private sector.

**Results:** Currently 1552 trials are being conducted in India in the fields of oncology (21%), diabetes mellitus (16%), arthritis (5.1%), psychiatric illnesses (4.9%), and hypertension (4.7%). Out of total 1117 new drug approvals, majority belonged to therapeutic areas like acid peptic diseases (13.9%), central nervous system diseases (12.9%), cardiovascular disorders (10.4%), arthritis (8.5%) and oncology (7.9). Thus drug approvals and clinical trials in India were incongruent with the health needs of the people. The MPR of IB, MSG and LPG of medicines in the private sector were higher for price uncontrolled medicines (9.59, 2.17 and 2.42 resp.) compared to price controlled (1.19, 1.18 and 1.22 resp.). MPR in public sector (0.015) was far below IRP. In the private sector, MPR for IB, MSG and LPG were 1.69, 1.68 and 1.49 respectively.

**Conclusions:** India's health needs and drug development activities are not in synchrony. There is a need to address this issue so that more relevant drugs are made available. Public procurement prices were lower than the private sector prices and that while the price control has successfully brought down prices, more medicines need to be covered to increase affordability.

**Funding source:** Information not provided

**843**

### **Policy, Regulation, and Governance**

*Keywords:* Out-patient; pharmacy; SQU hospital; peer review; adherence.

## **Quality of Dispensing in Outpatient Pharmacy at Sultan Qaboos University Hospital: Peer Review Audit**

**Issa Sulaiman Al-Rashdi, Aqeela Taqi, Amna Al-Hashar, Manal Hatrush, Ibrahim Al-Zakwani**

SQU, Oman

**Problem statement:** The major activity of the outpatient (OP) pharmacy is dispensing prescriptions from different outpatient specialists' clinics and discharge prescriptions from inpatient wards. Around 500 prescriptions are dispensed each day. The approved dispensing process is a stepwise work flow that incorporates best practices. It starts from receiving a prescription, validating and authorizing (station A), assembly of items (station B), and finally dispensing it to the right patient (station C).

**Aim and objectives:** The aim of this peer review audit is to assess the rate of adherence to the approved dispensing guideline at the OP pharmacy. The objectives include identifying dispensing and processing failures, recognizing staff abilities, and fixing the gaps to improve the quality of dispensing and processing prescriptions after the audit.

**Setting:** Sultan Qaboos University (SQU) hospital, pharmacy department, Oman

**Methods:** 120 prescriptions were audited by an independent auditor who was a staff member of a different pharmacy section (medicine information) over a period of 1 week; these prescriptions were processed by around 20 staff, each being allocated to the different dispensing processes or stations. A standard was set on the consensus of the senior pharmacist and an approved dispensing process (adopted from JCI standards) for each processing and dispensing step, against which the actual practice was compared. Data were collected from hard copies of prescriptions and from the computer system (TrakCare®) by filling a data collection form and analyzed using SPSS-12.

**Outcome measure:** Rate of adherence to the stated guidelines measured and the dispensing process at OP pharmacy evaluated

**Results:** The overall adherence to the approved dispensing process was 88%, while the overall set standard was 96%. Results showed that most non-adherences were at station B (74.5%) and that the most adherences were at station C (97%). Moreover, receiving and query stations also showed the highest adherence at 100%.

Conclusion and recommendations: This audit had enabled us to evaluate the dispensing process at the OP pharmacy. A follow-up audit is planned after giving feedback to individual staff members on their specific performance. Continuous awareness was always considered and a thorough education about station B for new staff and trainees was implemented.

Funding source: None

**847**

### **Economics, Financing, and Insurance Systems**

*Keywords:* competition law, competition policies, medicine prices

## **Can Competition Law or Other Competition-Promoting Policies Reduce Medicine Prices in Developing Countries?**

---

**Loraine Hawkins**

Independent, United Kingdom

**Problem statement:** Medicine prices for originator brands and generics in many developing countries' pharmaceutical markets are a high multiple of prices paid in competitive international procurement. A wide range of prices is observed for generic substitutes. This paper is one of a series of reviews of the evidence for policies to reduce medicine prices in developing countries, consistent with the goals of availability and quality.

**Objectives:** The paper reviews evidence on the impact of competition in pharmaceutical markets at each stage of the supply chain on medicine prices and the conduct of pharmaceutical companies in developing countries. The paper has a particular focus on the use of competition law, but also comments on other policies that affect medicines price competition.

**Design:** Literature review and case study of the application of competition law to the pharmaceutical market in South Africa since 1998

**Settings:** South Africa was selected for case study as one of very few middle-income countries with actively implemented competition law, applied to multiple pharmaceutical cases.

**Policies:** Competition law, other competition-promoting policies

**Results:** Good evidence is available from OECD countries for the potential benefits of use of competition law to deter or counteract anticompetitive behaviour in medicines markets. But few developing countries have been able to implement competition law effectively. South Africa's competition law has been applied to landmark cases involving multinational firms, local generic manufacturers, wholesaling/distribution, private sector retail pharmacy, and public procurement. There is some theory and evidence that in countries with weak legal systems and state institutions, powerful business interests, and lack of political will to confront these interests, competition law may be ineffective or have unintended effects.

**Conclusions:** It is difficult for developing countries to implement competition law effectively until certain preconditions are in place, including an adequately functioning judicial system; effective third-party enforcement of law and regulation; and adequate human and budget resources for competition authorities. Middle- and low-income countries with sufficient institutional capacity could learn from South Africa's experience with building specialist capacity for implementation of competition law, choosing strategically important cases to create precedents and provide guidance to improve the functioning of competition. In countries with weak institutions, other policy levers may be more feasible and effective in promoting generic competition, such as increasing openness to imports of quality-assured generics, and deregulation to allow consolidation of retail pharmacy so as to increase efficiency and increase buyer power to obtain discounts from suppliers.

**Funding sources:** Health Action International Europe and WHO

**848**

### **Drug Resistance**

*Keywords:* surveillance, antimicrobials, drug resistance, efficacy, patient safety

## **Susceptibility of Methicillin Resistant Coagulase-Negative Staphylococci Isolated from Faecal Samples of Children to Commonly Used Antiseptic Agents**

---

**Ezekiel Olugbenga Akinkunmi, Adebayo Lamikanra**

Obafemi Awolowo University, Ile-Ife, Nigeria, Nigeria

**Problem statement:** Increased minimum inhibitory concentrations (MICs) for methicillin resistant *Staphylococcus aureus* (MRSA) strains have been reported for some antiseptics. However, there is little information on the susceptibility to antiseptics by methicillin resistant coagulase-negative staphylococci (MRCoNS) strains, which are by no means of less clinical significance.

**Objectives:** The susceptibility of MRCoNS isolates from faecal samples of children to commonly used antiseptic agents was determined with a view to ascertaining the ability of the antiseptics to inhibit their proliferation.

**Design:** This is an antimicrobial resistance surveillance study. The MRCoNS isolates were from faecal samples of children in Ile-Ife, Nigeria. The organisms were identified by phenotypic and genotypic methods and screened against oxacillin antibiotic and 5 antiseptic agents.

**Setting:** The study was carried out in Ile-Ife, a semi-urban town in Osun State of Nigeria and surrounding villages located at 7–8° north latitude and 4–5° east longitude.

**Study population:** Samples were collected from 293 children of both sexes below 3 years of age selected randomly. All subjects were reported not to have taken any antimicrobial agent in the last 2 weeks preceding sampling. Data about children were collected through the parents or guardians of the children and all specimens were collected with the informed consent of the parents or guardians.

**Methods:** 149 coagulase-negative staphylococci (CoNS) strains recovered from the faecal samples of the children were screened against oxacillin by disc diffusion and agar screening methods; and against 5 antiseptic agents namely, benzalkonium chloride, cetrimide, chlorhexidine gluconate, gentian violet, and acriflavine by the agar dilution method. Oxacillin resistant isolates were also screened for the *mecA* gene by polymerase chain reaction.

**Results:** For all the antiseptic agents, decreased susceptibility was more prevalent in MRCoNS than in methicillin susceptible CoNS (MSCoNS). There was a significant decrease in susceptibility to cetrimide ( $p = 0.000108$ ), gentian violet ( $p = 0.000234$ ), and acriflavin ( $p = 2.48693 \times 10^{-7}$ ) between MRCoNS and MSCoNS. CoNS isolates generally showed highest susceptibility to chlorhexidine gluconate while they are least susceptible to gentian violet. *Staphylococcus hominis* strains were the most susceptible of all the CoNS isolates to chlorhexidine gluconate whereas *S. saprophyticus* were the most resistant to this agent.

**Conclusion:** Results showed that the gastrointestinal tracts of children could serve as a reservoir for CoNS with reduced susceptibility to commonly used antiseptic agents. The concentration of antiseptics used in the prevention of the transmission of infectious agents may have to be raised to cope with the possible presence of MRCoNS in patients coming into hospital.

**Funding source:** The study was sponsored by the authors.

849

#### Policy, Regulation, and Governance

*Keywords:* pharmaceutical management, drug and therapeutics committees, fragile states, Afghanistan

### Pharmaceutical Management Interventions through a Drug and Therapeutics Committee (DTC) in Kabul, Afghanistan: Initial Experience after Decades of Neglect

**Abdul Zahir Siddiqui<sup>1</sup>, Fahima Habibi<sup>2</sup>, Noorulhaq Yousufzai<sup>3</sup>, Lutfullah Ehsaas<sup>1</sup>, M. Zafar Omari<sup>1</sup>, Nirranjan Konduri<sup>1</sup>, Terry Green<sup>1</sup>**

<sup>1</sup>Strengthening Pharmaceutical Systems (SPS) Program, Management Sciences for Health (MSH); <sup>2</sup>General Directorate of Pharmacy Affairs (GDPA), Ministry of Public Health (MOPH), Afghanistan; <sup>3</sup>Indira Gandhi Institute of Child Health (IGICH), Kabul, Afghanistan

**Problem statement:** Although primary health care provision in Afghanistan has significantly improved since 2001, hospital services in Kabul have not kept pace with demand. Hospital pharmacy systems are badly disorganized with poor record keeping, resulting in confusion over which medicines are available and influencing physicians' prescribing behavior. With a meager budget for medicines for these hospitals, patients are often asked to purchase medicines from the burgeoning private sector. Selection and prescribing of medicines are erratic, which is compounded by a lack of an official formulary list. Antiquated stock management practices are associated with weak decision making and compromised patient care.

**Objectives:** To implement prioritized pharmaceutical management interventions to improve medicine use

**Setting and population:** Physicians, pharmacists, and administrators in three public sector hospitals

**Intervention:** Through a new DTC at each hospital, physicians and pharmacists who rarely talked to each other collaborated to solve problems in meetings facilitated by the MOPH and the SPS Program. Each hospital DTC worked together to develop their first official formulary list based on agreed-upon criteria and discussed options for improving pharmaceutical management. The storage mechanism was upgraded. Daily consumption registers, tally sheets, and stock cards were introduced, and SPS provided on-the-job training and supportive supervision visits to ensure their correct use. DTCs oversaw the revision of patient discharge slips to incorporate complete prescription information with corresponding records for the hospital.

**Outcome measure:** Evidence-based formulary list, number of interventions implemented

**Results:** Formulary lists have been developed that include a reduction in therapeutic duplications and deletion of non-licensed medicines. The dispensing area is now separate from the bulk store with clear labels and completed stock cards. Medicines at risk of expiry are easily noticed and managed. Pharmacists reported a 30% reduction in time spent managing medicine stock, which had been stored in scattered places. Data on weekly and monthly medicine consumption are now readily available to guide decision making on selection and procurement. The hospitals' patient files and the patients' discharge slips include name, dose, and duration of the prescribed medicines, allowing for better follow-up.

**Conclusions:** Incremental improvements in pharmaceutical management are feasible in a neglected hospital system with many medicine use problems. Hospital DTCs now encourage their physicians to adhere to the formulary list and better communicate with donors regarding their choice of medicines. Using DTCs, senior hospital physicians, who initially resisted change, are recognizing the importance of pharmaceutical management and its effect on patient care and improving medicines use.

**Funding sources:** MSH/SPS through US Agency for International Development

850

**HIV/AIDS and TB***Keywords:* HIV/AIDS, ARV, supply management, stock-outs, dashboard**Development of a Tool for Simple Visualisation of Periods of ARV Therapy Availability in a Context of Expanding Treatment Coverage****Etienne Guillard<sup>1</sup>, Xavier Paris<sup>1</sup>, Sophie Ouvrard<sup>2</sup>, Mouslihou Diallo<sup>3</sup>, Louis Pizarro<sup>1</sup>**<sup>1</sup>Solthis, France; <sup>2</sup>Solthis, Niger; <sup>3</sup>Solthis, Guinea

**Problem statement:** The increase in active patient files results in an increase in the supplies of ARV needed as well as in the complexity of evaluating coverage of needs. This lack of visibility makes it difficult to anticipate shortages and compromises the implementation of emergency procurement mechanisms.

**Objectives:** Our aim was to develop a simple tool to measure the period of availability of ARV supplies in a structure, a region, or a country, which takes into account the increase in ARV needs associated with expanding treatment coverage and to test it in Guinea and Niger.

**Design:** Intervention descriptive study

**Setting:** This intervention was conducted in collaboration with the National HIV/AIDS Control Program from Niger and Guinea.

**Method:** For each molecule the period of availability (n) can be determined from 3 parameters: monthly needs for treatment initiation (a); needs for patients already receiving treatment, determined with either morbidity or AMC data (b); available stock (AS). The model of the sum of needs during a period N corresponds to:  $a \times \text{factor time-inclusion} + b \times n$ ; factor time-inclusion is the total number of months during which patients who are included for the period n will need treatment. This factor can be obtained by the formula:  $n \times (n+1) / 2$ . The resulting equation is:  $an^2 + (a+2b)n - 2AS = 0$  and n is obtained by:  $n = [-(a+2b) + \sqrt{(a+2b)^2 + 8aAS}] / 2a$ . Using a spread sheet, the periods of coverage for all ARV treatment can be obtained and visualized graphically. The number of patients concerned and stock-out beginning estimated date are mentioned in order to help decisions. Tests were performed to validate the results.

**Intervention(s):** This tool has been use at a national level in Guinea and Niger with National HIV AIDS Control Program with both available stock and short term orders.

**Results:** The use of this tool in Niger and Guinea allowed national partners to visualize the periods of ARV availability, to share this information easily, and to speed up ongoing procurement orders. Although this model is simple to use, a minimum of quality data are necessary

**Conclusions:** By its graphic representation, this tool makes it possible to have a rapid clear image of periods of ARV coverage and of the number of patients concerned by each drug, within the context of extending treatment. It also makes it possible to notify all the actors involved in case of impending shortages or oversupply, which was possible in Niger and Guinea. Nevertheless, precision of the results is correlated to the quality of data. To act effectively on stock-outs or overstocks, it is essential to regularly update this tool and to act at different stages of the procurement and supply management cycle (accelerate ongoing procurement orders, emergency procurement). To optimize supply management of HIV medical products, opportunistic infections drugs, reagents, and diagnostics, similar tools have been developed by Solthis.

**Funding source:** Solthis/Fondation Bettencourt Schueller (France)

851

**Child Health***Keywords:* pediatric medicines, standard treatment guidelines, affordability**Is Pediatric Diarrhea Treated Correctly in African Communities? Evidence from Household Surveys in Five African Countries****Catherine E. Vialle-Valentin<sup>1</sup>, Robert F. LeCates<sup>1</sup>, Fang Zhang<sup>1</sup>, Abayneh Tamer Desta<sup>2</sup>, Dennis Ross-Degnan<sup>1</sup>**<sup>1</sup>Harvard Medical School, United States of America; <sup>2</sup>World Health Organization, Regional Office for Africa, Brazzaville, Congo

**Problem statement:** Evidence from studies conducted in health care facilities in low- and middle-income countries suggests that prescribing for diarrhea in children has not improved during the last 20 years (WHO, 2009).

**Objective:** To generate reliable evidence for policy makers in Africa about how diarrhea is actually treated at the community level

**Design:** Descriptive, cross-sectional analysis of survey data

**Setting:** Household surveys conducted in 5 African countries between 2007 and 2008 with a survey instrument developed by WHO

**Study population:** Households were selected by multistage cluster sampling (900 to 1080 households per country). Study population consisted of 348 children under age 5 with diarrhea symptoms in the 2 weeks preceding the survey; data were collected on all sick children in 3 surveys (Ghana, Kenya, Uganda) or only on the youngest sick child in 2 surveys (Nigeria, Gambia).

**Outcome measures:** Use and cost of medicines to treat diarrhea

**Results:** Almost every child under 5 with diarrhea was treated with medicines (97%); less than 2 in 10 received oral rehydration salts (ORS), while 42% received antibiotics, and 7% received antidiarrheals. Instances of children receiving zinc tablets were exceedingly rare. Although the likelihood of receiving ORS was similar regardless of prescribers, over

two-thirds of children who received ORS obtained their medicines in the public sector or a mission hospital. Antibiotics were prescribed more frequently by doctors/nurses than by untrained providers (62% vs. 38%). This was also true for anti-diarrheals (73% vs. 27%). The percentage of children receiving free medicines varied from 0% (Nigeria) to 78% (Gambia). The average cost of medicines purchased to treat 1 episode of diarrhea was \$6.40 in households of lower socioeconomic status.

Conclusions: Our results indicate that African countries are far from achieving universal access to ORS for children with diarrhea. The cost of treating diarrhea is prohibitive, especially for the poor, and often involves paying for unnecessary and costly antibiotics or anti-diarrheals. Our results highlight the importance of free access to essential medicines in public health facilities for all children under 5 and the value of education campaigns targeting prescribers, dispensers, and care givers about the benefits of ORS and the risks of antibiotics and anti-diarrheals. They provide evidence in support of a recent proposal by WHO/UNICEF to package ORS and zinc tablets together in free treatment kits that could be delivered by health workers or distributed directly to the community through education campaigns.

Funding source: The WHO Department of Essential Medicines in Geneva organized and funded data collection, with support from the Medicines Transparency Alliance. The WHO African Regional Office funded the study.

**852**

#### **HIV/AIDS and TB**

*Keywords:* ARV, non-uptake, public sector, Africa

### **Non-Uptake of Antiretroviral Therapy (ART) at a Primary Care Antiretroviral (ARV) Clinic in South Africa**

**Beverley Summers, Gift Baloyi, Katekani Baloyi, Makhosazana Dikiza, Fatima Gabajesane, Nishita Girdharlal, Afsana Moosa, Misa Qatyana, Sifundo Zwane**

Medunsa Campus, University of Limpopo, South Africa, South Africa

Problem statement: The South African Government has initiated major campaigns to encourage voluntary counseling and testing (VCT) for HIV and progression to ARV treatment. There is little information on the loss to follow-up from VCT to ARV treatment (i.e., non-uptake of ART). In the ARV clinic attached to our teaching hospital, from 2004 to 2008, over 5000 patients commenced ART but further 2092 (29.5%) patients were lost to follow-up prior to ART initiation. Reasons for this loss required identification.

Objectives: To identify the size of the non-uptake problem at the clinic and to characterise patients demographically and identify reasons for non-uptake of ART for (1) 2004 to 2008 and (2) 2007 and 2008; for 2009, to investigate patients' expectations at their first visit to the ARV clinic

Design: Descriptive retrospective and concurrent quantitative and qualitative with systematic sampling

Setting: Primary care public sector ARV clinic in Gauteng Province of South Africa

Population: (1) Non-uptake: a stratified sample of 96 non-uptake patients for 2004 to 2008 and 100 patients for 2007 and 2008; (2) patient expectations: a sample of 34 patients who attended the ARV clinic for the first time in 2009

Results: For 2004 to 2008, 29.5% of patients did not initiate ART. Of the 96 non-uptake patients sampled from 2004-08, over 65% of patients had died; 56% of those who died had done so within a year of their first visit. The majority of patients (60%) had defaulted after their first visit to the clinic. For 2007/2008, only 12% of patients (582) did not proceed to ART initiation; a considerable reduction over 2004/2008. Of the 100 non-uptake patients sampled from 2007/2008, 55% had died; 76% had defaulted after their first visit to the clinic. New patient interviews (23) showed that of the 34 items listed as entry expectations, only 8 (24%) had been met during the first visit.

Conclusion: The patient demographics generally reflect those of the HIV positive population. A high percentage of patients had died, but it was not possible to determine whether they died due to default or were lost to follow-up as a result of death. It is a major concern that 60% and 76% of patients, respectively, defaulted after their first visit. The large loss after the first visit indicates that this visit is critical to patient retention. Patient interviews at their first clinic visit clearly illustrated a mismatch between expectations and treatment/information received. Identification and meeting individual patient expectations at an early stage may be key to patient retention. Patients are not normally counselled at the first visit (a purely clinical work-up) and are not given a specific opportunity to ask questions. This approach must be changed.

Funding source: Information not provided

**854**

#### **Access**

*Keywords:* gender, access to medicines, Africa

### **Are There Gender Differences in Access to Medicines In Africa? Results from 5 Sub-Saharan African Countries**

**Aakanksha Pande, Anita Wagner, Robert LeCates, Dennis Ross-Degnan, Catherine Vialle-Valentin**

Harvard Pilgrim Institute and Harvard Medical School, United States of America

Problem Statement: Access to medicines is critical to health care. At present there is limited evidence on whether gender disparities exist in this area, and if they differ by socio-demographic characteristics.

Objectives: To examine gender disparities in a seven-stage health care pathway specific to medicines and tested for age-gender differences.

**Setting and Study Population:** Data were analyzed from a population-based medicines survey in five sub-Saharan African countries (Gambia, Ghana, Kenya, Nigeria and Uganda). The sample (n=5,161) comprised respondents to the Medicines Transparency Alliance (MeTA) and WHO Household Medicines Access Surveys from 2007-2008.

**Design and Outcome Measure(s):** We used multinomial logistic regression models based on a recent Institute of Medicine conceptual framework to examine gender disparities in three outcomes related to access: source of care, source of prescriptions, and source of obtaining medicines.

**Results:** Overall, we observed significant gender differences in fewer than 10 per cent of outcomes examined. Bivariate associations showed boys (under age 5) more likely to receive prescriptions from doctors or nurses and girls from more informal sources of care, but no other significant gender differences were seen in health seeking behavior, sources of care, numbers or cost of medicines, or adherence, for either adults or children. Controlling for health status and country-specific effects, no significant gender disparities for the three access to medicines outcomes were evident.

**Conclusion:** While it is generally assumed that gender disparities exist at all stages of the health care pathway, we found no evidence of gender disparities in access to medicines in these five Anglophone African countries. Further research is needed to determine whether this finding is replicated in other regions, and if care received by both genders is of similar quality.

**Funding Sources:** Funding was provided by the Department for International Development, Harvard Merit Fellowship, and Harvard Medical School and Harvard Pilgrim, Department of Population Medicine, Pharmaceutical Policy Research Fellowship.

**856**

### **Policy, Regulation, and Governance**

*Keywords:* Caribbean, Caribbean Cooperation Health, Pharmaceutical Policies

#### **Partnership on Pharmaceutical Policies in the Caribbean: 2006-2009**

**Adriana Mitsue Ivama<sup>1</sup>, Gilles Forte<sup>2</sup>, Enrico Cinnella<sup>2</sup>, James Fitzgerald<sup>3</sup>, Nelly Marin<sup>3</sup>, Jose Luis Castro<sup>3</sup>, Nora Giron<sup>3</sup>, Jose Maria Parisi<sup>3</sup>, Malek Sbih<sup>3</sup>, Jaume Vidal<sup>3</sup>, Bernadette Theodore Gandi<sup>4</sup>, Dalia Castillo<sup>5</sup>**

<sup>1</sup>Pan American Health Organization/World Health Organization (PAHO/WHO), Office of Caribbean Programme Coordination (CPC); <sup>2</sup>World Health Organization (WHO), Medicine Programme Coordination (MPC); <sup>3</sup>Pan American Health Organization/World Health Organization (PAHO/WHO), Medicines and Technologies; <sup>4</sup>Pan American Health Organization/World Health Organization (PAHO/WHO), Representative Trinidad and Tobago; <sup>5</sup>Pan American Health Organization/World Health Organization (PAHO/WHO), Dominican Republic

**Problem Statement:** WHO and the European Union signed an agreement in 2004 for the EC/ACP/WHO Partnership on Pharmaceutical Policies, whose purpose was to enhance accessibility, quality, and use of essential medicines and other key pharmaceuticals in African, Caribbean, and Pacific Island countries. In the Caribbean, the project was shaped by the mandates from PAHO/WHO as well as by sub-regional mandates and country priorities.

**Objective:** Assess the Partnership on Pharmaceutical Policies in the Caribbean from October 2006 to September 2009

**Design:** The basis for the assessment was the project framework inclusive of objectives and indicators for years 3–5. Quantitative information on targets met, activities carried out, and financial expenditures as well qualitative data was collected through interviews with stakeholders.

**Setting:** The project involved all CARICOM countries and Dominican Republic.

**Study population:** The CARICOM countries involved in the project are mostly small-island states with medium- to high-income level. Because of their size, they are less likely than other countries in the Americas to have key structures for the pharmaceutical sector.

**Results:** The expenditure in the Caribbean during years 3–5 was USD 1,215,203. The execution increased from USD 227,239 in year 3 to USD 651,787 in year 5. Half of the activities were implemented at the sub-regional level and the other half was related to country support. Most activities in the Caribbean were concentrated within 3 areas of the project framework, namely, pharmaceutical policies (27.5% of expenditure), rational use by health professionals and control of antimicrobial resistance (25.8%), and medicines regulation (22.6%). The key results of the project allowed concluding that the project met its targets. Both stakeholders and partners in Caribbean countries agreed with this conclusion. When interviewed, they considered that the project contributed to strengthen the technical capacity in the pharmaceutical sector in the Caribbean. The main contribution was the increase in the use of evidence for policy development and decision making at both sub-regional and national levels. Evidence also had an important role as the basis for the development of the Caribbean Pharmaceutical Policy.

**Conclusions:** Despite of the progress observed, there is still a lot of work to be done. The main strategies proposed to face the identified challenges are (1) to increase the profile of pharmaceutical policies and essential medicines to decision makers, (2) to support the strengthening of networking/collaboration, and (3) to provide country support in strategic areas, with an interprogrammatic and intersectoral approach.

**Funding source:** The EU/ACP/WHO Project Partnership on Pharmaceutical Policies was funded by the European Union.

**859**

### **HIV/AIDS and TB**

*Keywords:* adherence, HIV/AIDS, drug resistance,

## **Plasma Drug Level Validation of Self-Reported Adherence Predicts Limited Specificity for Intrinsic Poor Adherence in Resource-Limited Settings**

**Celestino Obua<sup>1</sup>, Robert Balikuddembe<sup>1</sup>, Joshua Kayiwa<sup>2</sup>, Muhammad Ntale<sup>1</sup>, David Musoke<sup>3</sup>, Paul Waako<sup>1</sup>**

<sup>1</sup>Makerere University, College of Health Sciences, Uganda; <sup>2</sup>Data Department, Joint Clinical Research Center, Kampala Uganda; <sup>3</sup>Department of Pharmacology and Therapeutics, Gulu University, Uganda

**Problem statement:** Adherence to antiretroviral therapy (ART) in low-income countries is mainly assessed by self-reported adherence (S-RA) because drug-level determination is expensive. Non-adherence is an important factor in the emergence of resistance to ART, presenting a need for drug-level analysis.

**Objective:** We set out to establish the relationship between plasma drug levels of stavudine and S-RA among patients on a stavudine-containing regimen. The secondary aim was to validate S-RA against the actual detected plasma drug concentrations.

**Design:** Cross-sectional investigation involving 234 patients; demographic characteristics, treatment history, and 3 months of S-RA levels were extracted from patient records. Good adherence was defined as S-RA  $\geq$  95%. Plasma stavudine concentrations were determined from venous blood drawn at least 1.5 hrs after the last dose and analysed by high-performance liquid chromatography. Stavudine concentration values in plasma samples were categorized as below, above, or within the normal therapeutic range (36-2400 nM/mL).

**Setting:** Patients were recruited from the Mengo HIV/AIDS clinic of the Joint Clinical Research Centre in Uganda between June 2006 and June 2007.

**Study population:** A total of 248 clients consented to participate. However, 14 were excluded because of insufficient clinical and/or S-RA data. Recruited patients were aged 18-50 years, had been on a stavudine-containing regimen for at least 3 months, and were willing to give written consent.

**Interventions:** No interventions were implemented in this study.

**Outcome measures:** In this population, we compared plasma levels of stavudine with S-RA using multivariable logistic regression models. The primary exposure was the stavudine plasma concentrations. The sensitivity and specificity of S-RA in predicting actual drug administration was also computed.

**Results:** Of the 234 patients, 194 (82.9%) had good S-RA with a median [IQR] stavudine concentration of 640.1 [66.1, 1331.1] nM/mL, while 40 (17.1%) had poor S-RA with median [IQR] plasma stavudine levels of 0 [0, 397.7] nM/mL. Patients with good S-RA were almost 7 times more likely to have stavudine levels within normal therapeutic range (adjusted odds ratio: 6.72, 95% confidence interval: 3.2 to 14). S-RA had high (91.6%) sensitivity for adherence, but limited (38.2%) specificity for intrinsic poor adherence.

**Conclusions:** Self-reported adherence is a good tool for assessing adherence, but has low specificity in detecting non-adherence (intrinsic non-adherence), which has implications for emergence of resistance.

**Funding sources:** This work was made possible through support provided by the World Health Organization and the Department of Pharmacology and Therapeutics, Makerere University.

**860**

### **Drug Resistance**

*Keywords:* Antibiotics, antimicrobial, resistance, AMR, ABR, prudent use, rational use, industry

## **Exploring a Global Compact to Preserve Novel Antibiotics**

**Richard Bergstrom**

EFPIA, Belgium

**Problem statement:** The growth of antibiotic resistance (ABR) and the declining investments in R&D for novel antibiotic classes pose a major health threat. The lack of new antibiotics in the development pipeline augments the problem and must be addressed from a political level. This has now been acknowledged by the Health Ministers of the European Union through council conclusions that call upon the European Commission to develop an EU Action Plan on ABR by the end of 2011, including proposals regarding incentives for research into new antibiotics. In parallel, a trans-Atlantic EU-US task force is currently exploring avenues to combat antimicrobial resistance (AMR) and how to stimulate the development of new antibiotics. If the pipeline of new antibiotics can be replenished—through greater precompetitive collaboration and through intelligent push- and pull-incentives—misuse and overuse of the resulting new products must be prevented in order to preserve their effectiveness for future generations. Distribution and wider access solutions must be analysed at this stage to provide important input to policy makers working on incentives and other measures.

**Objectives:** To analyse the distribution and access challenges for priority agents that need to be used in a prudent manner; to discuss how the pharmaceutical industry can contribute not only to the development of new agents, but also the agreed and managed entry of these to the global market; to explore the feasibility of a global compact including governments, international associations, industry, NGOs, professionals, and patient groups to preserve new antibiotics

**Design:** This oral presentation will expand on earlier statements made by EFPIA, including at the landmark conference organised by ReAct (and with support from the Swedish government) in Uppsala in September 2010. It will explore practical models for controlling use of medicines, including references to risk-management schemes in the EU and US. Practical challenges will be discussed pertaining to distribution and prescribing issues in least-developed countries and emerging economies.

**Policies:** The market failure in the antibiotics field stems from a failure of policy makers to create mechanisms to stimulate R&D combined with rational use of current agents. Learning from the past, new antibiotics must be introduced

in a new manner. The session seeks to explore how past experiences and those of today can be used to design alternative models for the future.

Conclusions: The research-based pharmaceutical industry is willing to discuss alternative ways to introduce new antibiotics in the future. These must deal with practical access and distribution challenges and build on a shared commitment to prudent use to preserve new antibiotics for future generations.

Funding sources: Information not provided

863

### Drug Resistance

*Keywords:* antimicrobials, appropriate use, drug resistance, education, primary health care

#### Physician as Primary Target in Improving Antibiotic Use in Primary Care: Review of Behavioural Interventions (CHAMP)

**Alike W. van der Velden<sup>1</sup>, Marijke M. Kuyvenhoven<sup>1</sup>, Paul Little<sup>2</sup>, Theo J.M. Verheij<sup>1</sup>**

<sup>1</sup>University Medical Center Utrecht, The Netherlands, Julius Center for Health Sciences and Primary Care; <sup>2</sup>University of Southampton, UK, Primary Care Department

**Problem statement:** Overuse of antibiotics is a global problem resulting in resistance, unnecessary costs, and patients' re-consultation. Guidelines on appropriate antibiotic treatment of infectious diseases, of which numerous were published, appeared not sufficient to restrict antibiotic use. Literature reviews are ambiguous in which interventions are most effective in improving antibiotic prescription.

**Objective:** To present an up-to-date overview of interventions to improve antibiotic prescribing for respiratory tract infections in primary care, with analyses on effectiveness and its determinants.

**Design and setting:** Literature review on studies targeted at primary care physicians and their patients in high-income countries (1990-2009). A broad range of designs was included: (quasi) randomised controlled trials, controlled before-after studies, and interrupted time series.

**Methods:** The extracted outcome was prescription of (first choice) antibiotics in DDD, packages or percentages. The intervention effectiveness was determined by the difference of differences (studies with a control group), or the difference (studies without a control group or without a before measurement). Associations of intervention characteristics and elements with effectiveness were analysed in multivariate regression analysis.

**Results:** 58 useful papers described 87 interventions, containing an average of 3 interventional elements; most often used elements were educational material for physicians (70%), educational material for patients (61%), educational meetings (56%), and audit/feedback (37%). Interventions aimed at decreasing overall prescription were more frequently effective (73%) than interventions aimed at increasing first-choice prescription (32%). On average, total antibiotic prescription was reduced by 11.6% (range: -72%-19%), and first-choice prescription increased by 9.6% (range: -5%-41%). Multiple interventions (OR: 6.5; 90% CI: 2-24) with at least 'educational material for the physician' (OR: 5.5; 90% CI: 2-18) are most often effective. No significant added value was found from multifaceted interventions containing patient-related elements. Furthermore, 'near-patient testing' and 'training communication skills' seem very promising; high effectiveness was seen in the limited number of studies using these elements.

**Conclusions:** This review emphasises the importance of physician education in improving rational use of antibiotics. Therefore, the physician should have a central role in giving access to antibiotics. The first steps in the comprehensive multilevel approach to decrease antibiotic use will be providing guidelines and teaching these guidelines and their background to (primary care) physicians. Monitoring of prescribing will be essential. Provision of near-patient tests (strep A, procalcitonin, C-reactive protein) will provide the physician with effective (communication) tools.

**Funding sources:** Work described is part of the CHAMP project (Changing Behaviour of Health Care Professionals and the General Public Towards a More Prudent Use of Antimicrobial Agents), a European Union 6th framework programme.

864

### Policy, Regulation, and Governance

*Keywords:* pharmacotherapy, change management, implementation, design development, organizational innovation

#### Exploring the Development, Design, and Implementation of a Pharmacotherapy Knowledge Center – A Qualitative Study

**Therese Kardakis<sup>1</sup>, Göran Tomson<sup>1</sup>, Björn Wettermark<sup>2</sup>, Pia Bastholm Rahmner<sup>2</sup>**

<sup>1</sup>Karolinska institute, Sweden; <sup>2</sup>Stockholm County Council

**Problem statement:** Problems of irrational prescribing and use of drugs are associated with morbidity, mortality, medicalization, adverse drug reactions, increasing drug resistance, and increased expenditure on drugs. There are potential strategies for improvement. In recent years, computerized clinical decision support systems have been introduced to support evidence-based decision-making. The design of knowledge systems and implementation of change and innovations is complex. In Stockholm, Sweden, there is a successful example of an established pharmacotherapy center (PTC) which started to use computer-assisted support systems very early (around 1996) and developed a range of important service products—the e-prescription; the Wise Drug List of recommended drugs; the Janusinfo, a noncommercial website providing drug information; electronic decision-support system integrated into the medical record; knowledge databases on drugs and interactions, lactation, and environmental hazards. Through a close

collaboration with the regional drug committee the PTC also provides continuous professional education and information.

**Objective:** Explore the development, design, and implementation of a PTC and to analyze important factors to the design

**Design:** We used a qualitative approach to get a deeper understanding of the design. Archival data was collected from organization plans and annual reports. Further data was collected face-to-face using semi-structured interviews. The empirical material was analyzed by using thematic data analysis. Participants were purposively selected and included key individuals involved in the establishment of the PTC. They represented academia, regulatory agencies, and practitioners in the county council and amounted to  $n = 11$ .

**Results:** The external context emphasized clinical pharmacology as an important discipline and the need to counterbalance a powerful pharmaceutical industry with noncommercial interests. A few key individuals with the right knowledge and interest in information technology found financial resources and political support. In the beginning, they were given some "time and space" of creativity and risk taking. The mixed competence and working in teams as a whole made a difference as well as the visionary and dedicated leadership with a capacity to forecast the development. The leader was seen as quite controversial by some. The successful development and implementation of different computer-assisted support systems depended a lot on the relative advantages these products gave the end users. The design process involved the prescribers' needs from the beginning and a great amount of time was spent in dissemination efforts with the help of particular drug therapeutic committees.

**Conclusion:** Individuals can make a difference in introducing a multifaceted intervention using computer-assisted support systems to rationalize use of drugs as well as using drug committees and information to the public.

**Funding source:** Vinnvård Sweden

**865**

#### **Child Health**

*Keywords:* paediatric medicines, availability, health facilities, essential medicines, access to medicines

### **Availability of Paediatric Medicines and Factors Impacting Availability in Faith-Based Health Facilities in Chad**

**Anke Meiburg, Donna Asimwe Kusemererwa**

Ecumenical Pharmaceutical Network, Kenya

**Problem statement:** The majority of deaths among children under 5 could be prevented or treated if paediatric medicines were available and accessible. MDG 4 on reducing child mortality and 6 on combating HIV/AIDS, malaria, and other diseases will not be attained if children's medicines are not available. Although paediatric medicines increasingly figure on essential medicines lists, little is known whether these medicines are available at the facility level.

**Objectives:** To determine the level of availability of selected paediatric medicines in faith-based health facilities in Chad and investigate factors impacting availability

**Design:** Exploratory descriptive study; data collection was done in July and August 2010

**Setting:** Faith-based health facilities in 6 regions in Chad

**Study population:** 31 institutions were selected from 117 existing faith-based facilities through convenience sampling, including 7 hospitals and 24 health centres

**Intervention:** Face-to-face interviews were conducted with facility and/or pharmacy in charge; availability of 28 medicines in 34 dosage forms was physically verified

**Results:** Average availability of general medicines (excluding ARVs, TB, and malaria medicines) was 44% for all facilities (range 0–90%). Only 5 medicines were available in more than 50% of institutions, namely oral rehydration salt (90%), mebendazole 100 mg chewable tablet (87%), salbutamol 2 mg tablet (87%), diazepam 10 mg injection (81%), and tetracycline 1% eye ointment (68%). Medicines with an availability of less than 10% were ceftriaxone 250 mg injection (7%), vitamin A capsule 100,000 IU (7%), and chlorpheniramine syrup 2 mg/5 mL (0%). Availability of antibiotic syrups was 45% for amoxicillin 125 or 250 mg/5 mL, 39% for cotrimoxazole 240 mg/5 mL, and 13% for metronidazole 200 mg/5 mL. Zinc 20 mg tablet was only found in 10 facilities (32%). Average availability of medicines for priority diseases was 43% for ARVs (range 0–86%), 21% for TB medicines (range 0–43%), and 16% for malaria medicines (range 7–39%). Only 11 respondents (36%) reported that their facility had received medicines via national programmes; 19 institutions (61%) purchased 100% of the medicines they supplied with their own funding. Reasons for not being able to procure paediatric medicines were lack of funds (58%), availability of adult formulation to substitute (48%), and unavailability at the supplier (36%). Management tools for medicines like stock cards were only used in 19 institutions (61%). Only 2 facilities (7%) had pharmaceutically trained staff employed.

**Conclusion:** Availability of paediatric medicines was rather low. The study identified factors at facility and policy level that might have contributed to the low availability. Facilities should strive to improve management of medicines and policymakers should consider subsidizing paediatric medicines and ensure national programmes reach all facilities.

**Funding sources:** ICCO, WEMOS, and UCC

**866**

#### **Drug Resistance**

*Keywords:* Drug resistance, Antibiotics, Prescribing pattern, Rational drug use, public sector

## Prescribing Pattern of Antibiotics in Health Facilities in Baghdad, Iraq

**Ezechiel Bisalinkumi<sup>1</sup>, Abdul Rasoul Wais<sup>2</sup>, Manal M. Yunis<sup>3</sup>**

<sup>1</sup>WHO Iraq Country Office, Jordan; <sup>2</sup>Ministry of Higher Education, Iraq; <sup>3</sup>Ministry of Health Iraq

**Problem statement:** Widespread drug resistance has been observed in Iraq's health facilities. No systematic approach to identifying the magnitude of this problem has been followed. Antibiotics are among the most highly misused and irrationally prescribed medicines by health professionals, which directly contributes to the drug resistance problem.

**Objectives:** To investigate the prescribing pattern of antibiotics in various levels of health facilities in the Baghdad Governorate region and to quantify the magnitude of antibiotic misuse

**Design:** A retrospective study of the antibiotic prescribing pattern was conducted in 22 randomly selected health facilities in Baghdad Governorate. The health facilities studied included primary health care centres (n = 16) and general hospitals (n = 6). Prescriptions were randomly collected and analysed using the WHO standard method of investigating drug use in health facilities; 300 prescriptions were selected from a pool of 3 months of prescriptions for each health facility.

**Setting:** The study was conducted in the public sector health facilities in the Grand Baghdad region, which is the largest city in Iraq with a population of more than 5 million. This region is served by about 200 PHCs and 30 hospitals (secondary and tertiary).

**Results:** Analysis of the data revealed that more than 70 % of prescriptions contain antibiotics, which is a high percentage compared to similar countries in the region. The rate was higher at PHCs than at outpatient clinics in hospitals. However, in both cases, the rate is considered higher than practically acceptable in such medical service settings, and this pattern is likely to be the same in other regions in Iraq.

**Conclusion:** Nationwide studies are needed to identify the pattern of antibiotic prescribing and to evaluate the interventional approaches to achieve a more rational use and prescribing of antibiotics.

**Funding source:** Information not provided

867

### Policy, Regulation, and Governance

*Keywords:* Caribbean, Caribbean Cooperation Health, Pharmaceutical Policies

## Development of the Caribbean Pharmaceutical Policy

**Adriana Mitsue Ivama<sup>1</sup>, Miriam Naarendorp<sup>2</sup>, Princess Thomas-Osborne<sup>3</sup>, Maryam Hinds<sup>4</sup>, Lucette Cargill<sup>5</sup>, Richard Aching<sup>6</sup>, Francis Burnett<sup>7</sup>, Rudolph Cummings<sup>8</sup>, Malcom Spence<sup>9</sup>, Rhonda Wilson<sup>10</sup>, Nelly Marin<sup>11</sup>, James Fitzgerald<sup>11</sup>**

<sup>1</sup>Pan-American Health Organization/World Health Organization (PAHO/WHO), Office of Caribbean Programme Coordination (OCPC); <sup>2</sup>Ministry of Health of Suriname; <sup>3</sup>Ministry of Health of Jamaica; <sup>4</sup>Barbados Drug Service, Ministry of Health of Barbados; <sup>5</sup>Caribbean Regional Drug Testing Laboratory (CRDTL); <sup>6</sup>Intellectual Property Office/ Ministry of Legal Affairs of Trinidad and Tobago; <sup>7</sup>Organization of Eastern Caribbean States/Pharmaceutical Procurement Service (OECS/PPS); <sup>8</sup>Health Desk, CARICOM Secretariat; <sup>9</sup>Office of Trade Negotiations, CARICOM Secretariat; <sup>10</sup>External Economic and Trade Relations, CARICOM Secretariat; <sup>11</sup>Pan American Health Organization/World Health Organization (PAHO/WHO), Medicines and Technologies

**Problem statement:** Ministers of Health (MOH) of Caribbean Community (CARICOM) in April 2003 established a technical advisory group (TAG) to improve access to quality, safe, and cost-effective essential medicines and to promote rational use.

**Objective:** To describe the development of the Caribbean Pharmaceutical Policy (CPP)

**Design:** Descriptive study of the policy development

**Setting:** CARICOM countries and Dominican Republic

**Study population:** Policy includes CARICOM countries

**Intervention:** TAG commissioned 2 studies in 2009, namely, a regional assessment of drug regulatory and registration systems and a regional assessment on patent and related issues and access to medicines in the CARICOM and Dominican Republic. PAHO/WHO published the Pharmaceutical Situation in the Caribbean Countries from the WHO level I survey. Based on findings of the 3 publications, the CPP was developed.

**Results:** The results were discussed by TAG members and based on that, a policy paper was presented to the 18th meeting of CARICOM chief medical officers, who endorsed it. A draft CPP was prepared and discussed in a stakeholders' workshop in July 2010. After amendments, it was circulated to countries and presented to the 19th caucus of CARICOM of MOH in September 2010. The CPP goal is, "to guide Caribbean countries to ensure: access, quality and rational use". It is guided by the main principle of access to medicines as a Human Right, the values and principles of Public Health and the renewed Primary Health Care strategy. The seven objectives are organized under four strategic areas, namely: Pharmaceutical Policy Scope; Regulatory Framework; Access; and Rational Use of Medicines.

**Mechanisms for implementation:** An implementation plan is under development with indicators for monitoring and evaluation. It is proposed as an oversight mechanism with the Expanded Technical Advisory Group on Pharmaceutical Policy (TECHPHARM), with shared responsibilities with the national authorities and regional institutions, CARICOM Secretariat, and PAHO/WHO.

Conclusions: The CPP was developed using the existing evidence and it represents the necessary framework for collaborative action and includes the development of several networks and regional platforms of work that are already under development. Considering that most of the Caribbean countries are small islands development states and there are several constraints for development of the activities on their own, there is a willingness to collaborate expressed both at the technical and political levels that can facilitate CPP implementation.

Funding source: The activity was part of the EU/ACP/WHO Project Partnership on Pharmaceutical Policies funded by the European Union.

**868**

#### **Drug Resistance**

*Keywords:* antimicrobials, drug resistance, education, primary health care, prescribing

### **Understanding and Optimising Antibiotic Prescription in Primary Care: Guidelines, Education, and Audit/Feedback in a Multiple Intervention**

**Alike W. van der Velden, Marijke M. Kuyvenhoven, Theo J.M. Verheij**

University Medical Center Utrecht, The Netherlands, Julius Center for Health Sciences and Primary Care

Problem statement: The Netherlands has a tight primary care organisation with its own guidelines. Within Europe, The Netherlands has the lowest antibiotic use. Respiratory tract infections (RTIs), mostly viral and self-limiting, are nonetheless often treated with antibiotics, despite numerous studies concluding that treatment effects are modest to negligible.

Objectives: The ARTI (antibiotics in RTIs) project, consisting of 4 consecutive studies, aims to assess over-prescription of antibiotics for RTIs and to investigate the effectiveness of multiple interventions to optimise prescription of antibiotics for RTIs.

Designs: 1 observational study, 1 controlled before-after study, 2 randomised controlled trials (RCT)

Setting: Primary care practices in The Netherlands

Intervention: The interventions consisted of education of general practitioners (GP) by using guidelines, literature and communicative aspects, audit/feedback on prescribing data/behaviour, and information material for patients.

Outcome measures: Antibiotic prescription (rates or via pharmacies) and prescribing behaviour via registration (otitis, tonsillitis, sinusitis, bronchitis), were collected the year before and after the intervention

Results: GPs registered 2800 RTI consultations (patient characteristics, clinical presentation, management), revealing that 50% of prescriptions were not in accordance with Dutch guidelines. Overprescribing was highest for bronchitis and was independently associated with inflammation signs, the GPs' perception of the severity of illness, and the GPs' perception of the patients' wish for an antibiotic. The first RCT (90 GPs) investigating the effectiveness of the multiple intervention showed a decrease of 12% in the antibiotic prescribing rate (95% CI: 4-19) without affecting patients' satisfaction. In the CBA study (141 practices), education was given to larger groups of GPs, without feedback on prescribing behaviour. This larger scale implementation showed no reduction in antibiotic prescription. In the currently running RCT (90 practices), education is given at practice level and includes detailed feedback. In addition, a practice-specific antibiotic improvement plan is embedded within the quality assurance cycle of the Dutch college of GPs. The year after the intervention, prescription of antibiotics for RTIs and prescription of second-choice antibiotics decreased by 12% and 13.5%, respectively, whereas in the control group a decrease of 3% ( $p = 0.03$ ) and an increase of 1% ( $p = 0.03$ ) were seen.

Conclusions: GPs overestimate symptoms and patients' expectations when choosing antibiotic therapy for RTIs. Education based on guidelines is not enough to change their prescribing behaviour. Monitoring and detailed feedback during an interactive education significantly reduce antibiotic prescription. Education should contain a patient-centred element on how to efficiently communicate a clear take-home message and how to deal with patients' concerns and expectations.

Funding source: ZonMw, The Netherlands organisation for health research and development (implementation)

**870**

#### **Policy, Regulation, and Governance**

*Keywords:* drug utilization, information technology, education, pharmacist, quality assurance, standards of practice

### **Interventions to Improve Medication Safety in a University Hospital in Thailand**

**Wimon Anansakunwatt, Uraiwan Silpasupagornwong, Umporn Yoobang, Nareumon Dhana, Monwarat Laohajeerapan**

Pharmacy Department, Siriraj Hospital, Mahidol University, Thailand

Problem statement: Adverse drug events were found to be a major complication for hospitalized patients and most of them were preventable. Several interventions were implemented in Siriraj Hospital during 2000-2010. Medication error (ME) reporting system, drug information service and poison control center (DIS&PCC), adverse drug reaction (ADR) monitoring, and staff and patient education programs were implemented. Some of these interventions are highly accepted and successful, but there is no study to compare and conclude the success factors.

Objectives: To study common success factors of interventions to improve medication safety

Design: Observational descriptive study

Setting: Siriraj Hospital, the 2,300 beds tertiary-care teaching hospital of Mahidol University, Thailand

Study population: Interventions used for medication safety improvement in the hospital during 2000 to 2010

Method: Reports and minutes of team meeting review and discussion with key persons of each team

Policy: Patient safety is a goal of the hospital administration.

Outcome measures: Number of ME reports, ADR prevention reports, phone calls to DIS&PCC, scores of tests in education programs, and factors influenced success of each intervention

Results: ME reporting increased significantly when the manual reporting was changed to an on-line system and manual monthly reports were gathered from nursing and pharmacy departments and sent to the risk management office ( $p < 0.05$ ). The number of phone calls received by DIS&PCC increased from 2,057 calls to 20,054 calls per year, after the service was changed from 8 hours to 24 hours; the services of toxicologists and staff education programs were also provided. The ADR monitoring team could prevent more repeated known allergy from 152 cases to 3,139 cases per year after a computerized alert in the pharmacy prescription process was implemented and patients were asked a prime question for known allergies. Staff education programs were provided and scores were significantly increased from pre-test to post-test, 68.1% to 88.7% and 63.5% to 81.8% in high-alert drugs and drug administration training, respectively. Patients were empowered to use their medicines correctly and monitor themselves. Patients increased their knowledge scores from 29% to 55% ( $N = 70$ ,  $p < 0.05$ ) and from 58.60% to 93.33% ( $N = 1,502$ ,  $p < 0.05$ ) in the transplant clinic and anticoagulation clinic drug counseling program, respectively. There were the terms of standards, quality, accreditation survey, multidisciplinary, computer program, counseling, and education in the meeting minutes and discussions. Key persons of each intervention worked after office hours to improve the interventions.

Conclusion: Accreditations from external organizations, multidisciplinary team approach, information technology, patient participation, and devoted personnel are common success factors of interventions to improve medication safety.

Funding source: No funding for this study

873

### Economics, Financing, and Insurance Systems

Keywords: Health systems evaluation, health technologies, market dynamics

#### Value for Money Perspective on Global Health Initiative Market-Shaping Impact

Cheri L Grace<sup>1</sup>, Walker Saul<sup>2</sup>

<sup>1</sup>HLSP Institute, United Kingdom; <sup>2</sup>UK Department for International Development

Problem statement: In the past decade, the global architecture around access to medicines for neglected diseases has changed, in particular with the rise of global health initiatives (GHIs) as major sources of health technology funding. However, our knowledge of the impact of GHIs on access to medicines as an essential part of functioning health systems is limited. The Lancet paper written by the Positive Synergies Collaborative Group had little to say about medicines and especially about GHI impact on upstream supply markets, even though such impact is important to understand from a pricing and supply security point of view.

Objectives: In the current economic environment, donors are under increasing pressure to demonstrate value for money (VFM). As a large portion of the money spent by major GHIs is on health technologies, an obvious question is, "are GHIs influencing market dynamics in ways that encourage VFM, and if so, how?" The objectives of the work included—to understand the methodological challenges of evaluating the market impact of GHIs from a VFM perspective and to guide donors and GHIs in their construction of monitoring and evaluation frameworks focused on VFM.

Design: This study employs inductive forms of analysis; conclusions are not drawn from statistical inference, but from analytical generalisation, a process by which theoretical insights are derived from comparable analysis across multiple cases. Interrelationships that were consistent within all technology sectors were identified as well as challenges in evaluating impact that were consistent across sectors. These repeated interrelationships and evaluation challenges were abstracted into a VFM conceptual framework. Case study material that illustrates the interrelationships and evaluation challenges across technology sectors are presented.

Results: If we map standard VFM dimensions (as defined by the UK Audit Commission) against GHI market shaping activities, then the 'economy' category would relate to the price of the health technology and cost to deploy it. 'Efficiency' can be translated as 'lowest cost per effective use', highlighting the importance of non-price features which promote product acceptance and uptake. Looking further down the impact chain, quality becomes paramount as a contributor to the effectiveness goal of 'lowest cost per desired health impact'. The paper presents many examples of interventions undertaken by GHIs to shape markets in pursuit of 1 or several parameters affecting VFM. Attribution of market impact resulting directly from a given GHI intervention is challenging, because of system interdependencies on two levels: (1) interdependencies between policies and interventions of different groups shaping the market and (2) the relationship (often inverse) between interventions that attempt to impact price balanced against those that aim to impact parameters of overall effectiveness, e.g., supply security, quality, acceptability, and delivery. Given these challenges, case study methodology, involving interviews with GHIs, independent experts, and industry, is an important method for determining relative influence and attribution of GHIs and others on the market. There is also a need for a comprehensive approach to monitoring and measuring the market impact of GHIs, focusing not only on static price impact, but balanced by evaluation of impact on other parameters important to achieving supply security and health impact over time.

Conclusions: Donors are increasingly under pressure to demonstrate that funds for medicines are being used in the most efficient way, placing emphasis on the role of GHIs in shaping markets. Price sometimes dominates these

discussions, but price needs to be seen in relation to the other objectives driving health outcomes and also the importance of seeking dynamic as well as static improvements in health technology markets.

Funding sources: UK Department for International Development

875

### Chronic Care

*Keywords:* chronic disease, access to medicines, primary health care, community, health workers

## Framework Proposal to Improve Access to Medicines and Routine Care for Patients Living with Chronic Conditions in Low and Middle Income Countries

**Veronika J. Wirtz<sup>1</sup>, Yared Santa Ana-Tellez<sup>2</sup>, Warren A. Kaplan<sup>3</sup>, Ruy Lopez-Ridaura<sup>4</sup>**

<sup>1</sup>Center for Health Systems Research, National Institute of Public Health, Mexico; <sup>2</sup>Center for Evaluation and Survey Research, National Institute of Public Health, Mexico; <sup>3</sup>Center for Global Health and Development, Boston University, USA; <sup>4</sup>Center for Population Health Research, National Institute of Public Health, Mexico

**Problem Statement:** In many Low and Middle Income Countries (LMICs) chronic diseases are already the most prevalent causes of morbidity and mortality. Traditional health system structures in many LMICs are not designed to provide long-term care as they lack a comprehensive approach to provide access to treatment for patients with chronic diseases. Further, global efforts to improve access to medicines have focused mainly on HIV, tuberculosis and malaria.

**Objectives:** To propose a framework of chronic care and disease management that may be applied in resource poor settings, in order to improve access of patients living with chronic conditions to routine care and essential medicines.

**Design:** Systematic Literature review

**Setting:** LMICs as defined by the World Bank classification

**Study Population:** Databases: PubMed, EMBASE, ISI Web of Science and the International Network for Rational Use of Drugs (INRUD).

**Intervention:** Not applicable

**Outcome:** 1. Descriptive and interventional studies on access to medicines and routine care for diabetes, asthma and depression in LMICs and 2. publications proposing chronic care management models with particular focus on LMICs.

**Results:** 1. The barriers to access of essential medicines and routine care for diabetes, asthma and depression in LMICs are similar to those for acute diseases: affordability of medicines, accessibility in public health services, inefficient procurement systems, scarcity of diagnostic, administration and monitoring equipment or facilities, lack of trained human resources to provide treatment, paucity of patient empowerment strategies among others. However, these barriers have different implications for chronically ill patients, health services and society in general. 2. Most chronic care models in general have limited applicability to resource poor settings: a) they do not describe in detail how they intend to improve pharmacotherapy and b) as most are designed for health systems in high income countries, they primarily focus on improvement of quality of care rather access or affordability. A framework of chronic care and disease management for LMICs to improve access to medicines and routine care would do well to improve care coordination among health professional teams, strengthen self-care and create chronic disease partnerships between local communities and private for-profit corporations or non-profit organizations.

**Conclusions:** Improving access to essential medicines and routine care for patients with chronic diseases goes beyond provision of supply of medicines, diagnostics and monitoring equipment and requires the rigorous evaluation of new care models designed for long-term treatment and provision of prepaid medicines. Education and training of human resources seems to be one necessary but not sufficient condition to improve quality of treatment.

876

### HIV/AIDS and TB

*Keywords:* HIV, adherence, medical informatics, phone intervention, Argentina

## Computer Alert System and Telephone Support to Improve Antiretroviral Therapy Adherence

**Gustavo Guillermo Kasparas<sup>1</sup>, María del Carmen Iannella<sup>2</sup>, Gabriela Bugarin<sup>1</sup>, Roxana Miro<sup>1</sup>, Marcela Belforte<sup>1</sup>, Hugo Visciglio<sup>3</sup>, Rosa Bologna<sup>1</sup>, Isabel Cassetti<sup>1</sup>**

<sup>1</sup>Helios Salud, Argentina; <sup>2</sup>Universidad de Buenos Aires; <sup>3</sup>Infhos

**Problem statement:** Poor adherence to antiretroviral therapy (ART) is a major obstacle to successful treatment outcomes. There is evidence that telephone support improves adherence. In developing countries, mobile phones are widely used and are emerging as a new tool in health care communication. The registry of medication dispensed is an indirect method to assess adherence with acceptable sensitivity and specificity.

**Objectives:** To evaluate the efficacy of strategies of a computer alarm system and telephone support implemented to increase and maintain ART adherence

**Design:** Retrospective intervention comparative cohort study; the comparator referred to is year 2006. In 2007, a newly installed computer alert system began to identify any delay of ART dispensing. Adherence strategies of telephone support were applied. Results for 2007, 2008, and 2009 were compared to 2006. The rates of dispensed ART were compared as indirect indicators of adherence.

**Setting:** This study was realized at a private, specialized, medical center in Buenos Aires City and affiliates in the provinces where interdisciplinary HIV/AIDS attention is provided.

Study population: The whole population in follow-up was retrospectively studied from 2006 to 2009. At baseline year 2006, there were 3,319 patients being followed up: mean age (SD) 37.0 (11.5) years, male 67.8%, ART 75.5%. In 2007 3,430 patients, 37.3 (11.3) years, male 66.9%, ART 77.5%; in 2008, 4,040 patients, 37.7(11.2) years, male 67.7%, 76.5% on ART; in 2009, 4,584 patients, 38.4 (11.4) years, male 67.5%, ART 77.2%.

Intervention: A computer program was designed to alert health staff about a delay in patients' visits for medication dispense for the following period. Psychologists, social workers, and peer support were trained to contact those patients.

Outcome measure: To assess efficacy of intervention in the yearly rate of pharmacy dispensing visits with respect to baseline

Results: The rate of medication dispensing visits showed a statistically significant increase with respect to baseline in 2007 (81.4%; 95% CI: 80.97-81.88;  $p = 0.001$ ), 2008 (81.0%; CI: 95%: 80.52 - 81.37;  $p = 0.004$ ), 2009 (83.2%; CI: 95%: 82.85-83.60,  $p < 0.001$ ), and the first 4 months in 2010 (88.9%; CI: 95%: 88.33-89.40,  $p < 0.0001$ ). The rate of viral load was  $< 50$  copies/mL; lab results showed a statistically significant increase with respect to the baseline. The rate of CD4 T-cell count remained stable or slightly increased with no statistical significance.

Conclusions: Findings show that centralized data generation of pharmacy dispensing, computer alarm for any delay and telephone support improves long-term adherence to ART and clinical outcomes.

Funding sources: Helios Salud

## 878

### Economics, Financing, and Insurance Systems

Keywords: China, drug price reduction, diabetes, interrupted time series

#### Changes in Use of Antidiabetic Medications Following Price Regulations in China (1999-2009)

Christine Y Lu<sup>1</sup>, Peter Stephens<sup>2</sup>, Bao Liu<sup>3</sup>, Dennis Ross-Degnan<sup>1</sup>, Anita Wagner<sup>1</sup>

<sup>1</sup>Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute; <sup>2</sup>IMS Health;

<sup>3</sup>Fudan University

Problem statement: Pharmaceutical expenditures are a major burden in China. In 2005, pharmaceuticals accounted for 44% of health care expenditures. Between 1997 and 2007, the National Development and Reform Commission implemented 24 rounds of reductions (by between 5% and 40%) in maximum retail prices of medicines, covering 87% of medicines listed in the National Drug Catalogue of Basic Medical Insurance and Worker Medical Insurance. Each regulation was intended to reduce pharmaceutical expenditures by between 12 and 700 million yuan.

Objectives: To examine the effects of price regulations on use of insulin and oral hypoglycemic medications in Chinese hospitals

Setting: We used longitudinal purchasing data collected by IMS Health from about 15% of Chinese hospitals (810 general and 208 specialty) with at least 100 beds.

Design: Interrupted time series design

Outcome measure(s): Quarterly market volume (standard units sold per 1000 population) and market share of price-regulated products (percentage of the total market) in each category from Q1, 1999 through Q4, 2009.

Results: After the first price regulation in December 2001, there was a significant increase in market volume trend of insulin products (0.06 standard units per 1000 population per quarter; 95% CI, 0.04-0.08) but utilization of oral hypoglycemic products remained stable. After the subsequent price regulation in December 2006, there were significant increases in market volume trend of insulin products (0.18 standard units per 1000 population per quarter; 95% CI, 0.12-0.23) and oral hypoglycemic products (10.31 standard units per 1000 population per quarter; 95% CI, 5.65-14.98). Market share of price regulated insulins (a small portion of total insulin market) or oral hypoglycemic products (the majority of total oral hypoglycemics market) did not change significantly after either price regulation.

Conclusions: China's pharmaceutical price regulations targeted specific products within individual chemical entities of various therapeutic classes. Our results suggest that lowering the prices of specific antidiabetic products was associated with increases in the overall utilization of antidiabetic medications, suggesting improved access to essential medications or increased prescribing quantities after price reductions on some products. Further investigations on the impact of these drug price regulations on drug prices and pharmaceutical expenditures are warranted. This study creates baseline data on patterns in medication use against which policy changes under China's current health care reform can be evaluated.

Funding source(s): IMS Health provided data in kind. Drs. Wagner and Ross-Degnan were supported by a grant from WHO for the development of the ICIUM2011 scientific program.

## 879

### Policy, Regulation, and Governance

Keywords: Medication reconciliation, compliance

#### Compliance of Multidisciplinary Team on Medication Reconciliation Policy at Siriraj Hospital

Theeraya Mayakul, Kulabusaya B., Promraj R., Thammatinno V., and Yoobang U.

Siriraj Hospital, Thailand

**Problem Statement:** Medication errors frequently occurred in surgical wards due to several transitions in hospital care. Medication reconciliation (MR) was an effective tool to reduce and prevent errors. MR process consisted of verification, clarification and reconciliation patients' medication. These processes were successful by co-operation of multidisciplinary team including physicians, nurses and pharmacists.

**Objective:** To assess the compliance of multidisciplinary team on MR policy implementation.

**Design:** Retrospective descriptive study

**Setting:** Twelve surgical wards, Siriraj Hospital, Mahidol University

**Study population:** Medical Records of Patients admitted in 12 surgical wards during Oct.1st, 2009 to Sep. 30th, 2010

**Interventions:** On admission, nurses and pharmacists interviewed patient's current medications including OTC medications, herbs and other supplements then recorded on MR form. Pharmacists reviewed medication history and completed list of medications. These medication lists would be considered by physicians before the first order. During hospitalization, pharmacists reconciled, identified medication discrepancies and also searched for drug related problems. Nurses could also compare medication lists to medication orders and identify discrepancies. They rechecked all medications before patients were discharged.

**Policy:** Medication reconciliation should be done for all patients

**Outcome measures:** The compliance of multidisciplinary team was assessed by nurse records, pharmacist reviews and physician signatures on MR form. Incompleteness of nurses' interview and pharmacists' interventions were measured.

**Results:** There were 8,882 cases admitted which 5,893 cases (66.35%) were conducted MR, by nurses alone 224 cases (4.1%), nurses and pharmacist 1,622 cases (24.5%) and pharmacists alone 4,027 cases (68.1%). There were few (0.12%) physicians signed on MR form. From 1,622 cases of nurses MR with pharmacist double checks, there were 507 cases (31.3%) found incomplete lists which incomplete in item was 65.5%, regimen was 17.5% and both item and regimen was 17.0%. Of those 1,581 medication errors found, there were omission (68.2%), commission (3.5%), difference of dose frequency (22.4%), and medication change within the same class (5.9%). Of 1,043 pharmacist interventions 83.2% were completely accepted, 8.0% partial accepted and 8.8% not accepted.

**Conclusion:** MR process could prevent medication errors. Pharmacists had major role on MR. The main problems of non-compliance of nurses and physicians on MR policy were a lot of work load and limited access to sources of medication information. These problems led us to develop a computerized program which will support patient's medication profile, and also improve compliance of multidisciplinary team on medication reconciliation.

880

#### Access

*Keywords:* Monitoring and Evaluation, Pharmaceutical Policies, Primary Healthcare

### **Pharmaceutical Situation in Barbados: WHO Level II Health Facilities Survey, 2010**

**Maryam Hinds<sup>1</sup>, Cheryl Ann Yearwood<sup>1</sup>, Catherine Vialle-Valentin<sup>2</sup>, Dennis Ross-Degnan<sup>2</sup>, Adriana Mitsue Ivama<sup>3</sup>, Jenifer Nunes<sup>4</sup>, Gabriel Vivas<sup>5</sup>**

<sup>1</sup>Barbados Drug Service, Ministry of Health of Barbados; <sup>2</sup>Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, MA, USA.; <sup>3</sup>Pan-American Health Organization/World Health Organization (PAHO/WHO), Office of Caribbean Programme Coordination (OCPC); <sup>4</sup>University of West Indies (UWI); <sup>5</sup>Pan-American Health Organization/World Health Organization (PAHO/WHO), Office of Eastern Caribbean Countries (ECC)

**Problem statement:** In Barbados, the key contributors of morbidity and mortality are heart disease, cerebrovascular disease, diabetes mellitus, cancer, hypertension, and HIV/AIDS among adults. Medicines from the Barbados National Drug Formulary (BNDF) are provided free at pharmacies of the public health facilities (PHFs) and with payment of a dispensing fee at private pharmacies (PPs) to patients 65 years old (yo) and over, children under 16, yo and persons prescribed for hypertension, diabetes, cancer, asthma, and epilepsy. Patients from 16 to 64 can receive the same medicines at subsidized prices.

**Objective:** Assess the pharmaceutical situation in Barbados related to access, quality and rational use of medicines

**Design:** A cross sectional study was undertaken from October 2009 to July 2010 using WHO Level II Health Facilities survey. Analysis was done with Epidata and Excel.

**Setting:** Barbados is a middle-income country with a population of 275,700 (2009).

**Study population:** All 18 public health facilities (PHFs) which dispense medicines to outpatients and 30 private pharmacies (PPs) randomly selected were surveyed and 1026 outpatients interviewed.

**Results:** Key essential medicines were available in 100% of PHFs and 94% of PPs; 99% of prescribed medicines were dispensed in the PHFs. No expired medicines were found and adequacy rates of storage conditions were 85% in PHFs and 90% in PPs. The BNDF was found in 92% of PHFs. Standard treatment guidelines (STGs) for diabetes, hypertension, and asthma were found in 55% of PHFs; 23 % of patients were prescribed antibiotics and 7 % were given injections. All patients interviewed in the PHFs and PPs knew how to take their medicines; 97% of patients travel less than an hour to reach a PHF. The international non-proprietary name (INN) in PHF was used for only 36 % of prescription medicines; 38% of private pharmacies sold at least 1 prescription medicine without prescription at the time of visits. Based on STGs, the survey found that there was underuse of antibiotics to treat pneumonia in children under 5 and overuse to treat non-bacterial upper respiratory infections. Also, some children under 5 with diarrhoea were not prescribed the appropriate treatment of oral rehydration salts.

Conclusions: Even though the availability of medicines in public pharmacies was excellent at the time of the survey, only the data from current stock was available. The software used needs to be improved for retrieving historical data. It is also necessary to expand availability of STG. Use of INN for prescribing should be encouraged, as part of the promotion strategy of generics. Dispensing of prescription medicines without a prescription should be discouraged and addressed regarding legal and ethical aspects. Managerial policies related to pharmaceuticals need to be improved. The development of Good Practices through the distribution chain is recommended. These findings were used as evidence for updating the National Pharmaceutical Policy, discussed with stakeholders in early 2011, and submitted to Cabinet for approval.

Funding source: EU/ACP/WHO Project Partnership on Pharmaceutical Policies funded by the European Union

**882**

**Access**

*Keywords:* Monitoring and Evaluation, Caribbean Cooperation Health, Pharmaceutical Policy, Good Governance

### **Proposal for a Baseline Assessment for the Caribbean Pharmaceutical Policy**

**Adriana Mitsue Ivama<sup>1</sup>, Nelly Marin<sup>2</sup>, Vera Lucia Luiza<sup>3</sup>, Catherine Vialle-Valentin<sup>4</sup>, Maryam Hinds<sup>5</sup>, Princess Thomas-Osborne<sup>6</sup>, Miriam Naarendorp<sup>7</sup>, John Hasrat<sup>7</sup>, Enrico Cinnella<sup>8</sup>**

<sup>1</sup>Pan-American Health Organization/World Health Organization (PAHO/WHO), Office of Caribbean Programme Coordination (OCPC); <sup>2</sup>Pan American Health Organization/World Health Organization (PAHO/WHO), Medicines and Technologies; <sup>3</sup>Nucleo de Assistencia Farmaceutica/National School of Public Health/Fiocruz, Brazil; <sup>4</sup>Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, MA, USA.; <sup>5</sup>Ministry of Health Barbados; <sup>6</sup>Ministry of Health Jamaica; <sup>7</sup>Ministry of Health Suriname; <sup>8</sup>World Health Organization (WHO), Medicine Programme Coordination (MPC)

**Problem Statement:** The Caribbean Cooperation in Health, Phase 3, is the health agenda adopted by the Caribbean Community Ministries of Health in 2009. One of the areas for collaboration on Health Systems Strengthening is "Design and implementation of a Caribbean Pharmaceutical Policy (CPP) and mechanisms to enhance access, quality, and rational use of medicines." The challenge is to develop mechanisms for monitoring implementation of the policy. It is proposed to use the WHO indicators for the pharmaceutical situation, including the WHO Level II surveys on access and rational medicine use (RMU) at health facilities and households.

**Objective:** The objective of this work is to propose a baseline assessment for the CPP based on the two to three selected indicators for each priority area based in the WHO Level II survey.

**Design:** This is a descriptive study. The WHO questionnaires on pharmaceutical outcomes at health facilities and households were adapted to the small island states and administered. Data was analysed using EpiData and Excel.

**Setting:** The study was conducted in 3 countries that were randomly tagged A, B, and C (Jamaica, Suriname, and Barbados). In each country, access, quality and RMU were assessed within the public and private health sector and in households.

**Study Population:** The three countries are middle income countries. The populations of Barbados and Suriname are below one million while Jamaica has 2.7 million inhabitants. On average, 27 public and private facilities were visited, 803 outpatients, and 694 households were interviewed per country.

**Outcome Measures:** For most selected indicators, results are presented by country as % of total facilities or households surveyed.

**Results:** For access to medicines, availability of essential medicines in both public and private pharmacies was good and varied from 93% to 100%. The average cost varied considerably for a prescription for an acute illness, from 4.00 US dollars (USD) in A to USD 33.00 in B. For medicine quality, no expired medicines were found and a good number of pharmacists were present in dispensing facilities in all countries. Adequacy of storage conditions was lowest in country A.

**Rational use—**The use of non-proprietary name for prescriptions in public facilities varied from 36% in country C to 45.5% in country A. The percentage of persons with a chronic disease that were told to take medicines and took them as recommended varied from 68% in B to 78% in A. With regards to adequate labeling of medicines at home, this varied between 62% of all medicines in country A to 82% in country C.

**Conclusions:** The CPP will provide the framework for strengthening the pharmaceutical sector both at subregional and national levels, continuing the work initiated within the current partnership. The indicators presented will certainly contribute to follow up and to assess progress.

Funding source: EU/ACP/WHO Project Partnership on Pharmaceutical Policies funded by European Union

**883**

**Economics, Financing, and Insurance Systems**

*Keywords:* medicine prices, procurement, public sector, transparency

### **Price Information Exchange for Selected Medicines in the World Health Organization Western Pacific Region**

**Dardane Arifaj-Blumi**

World Health Organization Western Pacific Regional Office

**Problem Statement:** Prices of medicines procured in the public sector vary greatly between countries in the Western Pacific region and the prices are often not publicly available. Countries in the region have expressed the need for establishing a transparent mechanism for information exchange which will help them to assess procurement efficiency and provide leverage when negotiating prices with suppliers.

**Objectives:** To establish a platform for information exchange on procurement prices of medicines in the Western Pacific region which will enable countries to assess their procurement prices against other countries in the region and the international median prices; use the information to influence policy and managerial decisions on reducing prices that appear high; and to provide leverage for in-country negotiations with suppliers.

**Setting:** Regional level involving member states and focusing only on public sector. **Study Population:** Member countries of the WHO Western Pacific region were invited to participate of which 18 countries responded between May and October 2009 and 14 countries between June and November 2010, respectively.

**Intervention:** Participating countries shared procurement prices for 31 (in 2009) and 40 (in 2010) common medicines obtained in the most recent procurement cycle using structured questionnaires. Information on countries' procurement systems was collected using semi-structured questionnaires. Gathered information was processed, screened for quality, and displayed in a customized website.

**Outcome Measure:** Establish a publicly accessible website where users can view comparatively details on procurement prices for selected medicines. Increase transparency and information sharing between countries in the region. Update prices annually.

**Results:** The website Price Information Exchange for Selected Medicines ([www.piameds.com](http://www.piameds.com)) allows users to browse by medicine's name where details on prices can be found on product name, pack size, price per pack and unit, manufacturer, supplier, and quantity procured. These data represent the public procurement prices at the time of data collection. In addition, charts can be generated to allow comparison between prices of 2009 and 2010. International and regional median prices are presented in vertical lines for use as benchmarks. When browsing by country, a brief description of countries' medicines procurement system complements interpretation of charts. Links are also provided to the countries' health information profiles. Other features include a description of the website, glossary, links to resources on prices and procurement systems, forum, and a data collection form that can be downloaded for countries that wish to participate.

**Conclusions:** The new, user-friendly website [www.piameds.com](http://www.piameds.com) enables countries in the region to share information on the prices of selected medicines procured in the public sector. Countries can use it primarily for assessing their procurement efficiency and as a tool to get leverage when negotiating with suppliers. Presentation through comparative bar diagrams makes information on prices transparent and easy to use.

**Funding:** WPRO

**884**

#### **Access**

**Keywords:** essential medicines, right to health, judicial decisions, National Medicines Policy, Brazilian Health System

### **Characterization of Lawsuits for the Supply of Essential Medicines in the State of Rio De Janeiro, Brazil**

**Vera Lucia Edais Pepe<sup>1</sup>, Miriam Ventura<sup>2</sup>, João Maurício Brambati Sant'ana<sup>1</sup>, Tatiana Aragão Figueiredo<sup>1</sup>, Vanessa dos Reis Souza<sup>1</sup>, Luciana Simas<sup>1</sup>, Claudia Garcia Serpa Osorio-de-Castro<sup>1</sup>**

<sup>1</sup>ENSP-Fiocruz, Brazil; <sup>2</sup>IESC- Universidade Federal do Rio de Janeiro. Brasil

**Problem Statement:** Recognition of the right to health in Brazil raises a practical issue: the government's ethical and legal duty to ensure comprehensive health care and citizens' recourse to legal action to guarantee this right.

**Objectives:** This study focused on lawsuits to demand essential medicines, filed at the State Court of Appeals in Rio de Janeiro, Brazil, in 2006.

**Design and Setting:** Descriptive retrospective study of lawsuits brought by citizens against the government (federal, state, municipal). The source of information was the data bank of the Courts of the State of Rio de Janeiro (TJ/RJ) where judicial decisions on lawsuits demanding medicines and which had already followed an appeal were researched for the terms "medicines" and "essential." Relevant information was collected through a structured questionnaire, including sanitary, medical, and scientific elements, as well as elements of the judicial process.

**Results:** One hundred and eighty-five suits were examined, and the claims were granted in all but three cases. In 36.8% of suits, defendants included more than one government entity. Median times between filing the suit, the injunction, first ruling, and appellate ruling were 7, 239 and 478 days respectively. Of the 316 identified medicines, 35.8% were present in the Brazilian National Essential Medicines List. In 80.6% of the 98 suits in which the specific medicines could be identified, at least one medicine did not belong to any publicly funded list of medicines. This could indicate that lawsuits demanding essential medicines were motivated not only by problems in procurement, distribution, and dispensing but also by non-inclusion of medicines in official lists. Most of the medicines demanded through lawsuits were for conditions involving the cardiovascular and nervous systems ailments.

**Conclusions:** Almost all petitions were granted. In the perspective of the health sector, "essential" expresses the meaning in the essential medicines concept, while for the judicial sector, "essential" is related to the plaintiff's need of the medicine. Not considering the concept of essential medicine adopted by public health, the judge is guided solely by the opinion of the prescriber; therefore the effectiveness of the right to medicines can be mistaken for the supply of any of the medicines on the Brazilian market.

**Funding Source:** Fundação de Amparo à Pesquisa do Estado do Rio de Janeiro

885

**Access***Keywords:* generic medicines, pharmaceutical policy, pharmacists, New Zealand**Evaluating Pharmacists' Views, Knowledge, and Perception Regarding Generic Medicines in New Zealand****Zaheer-Ud-Din Babar, Piyush Grover, Joanna Stewart, Michele Hogg, Leanne Short, Hee Gyung Seo, Anne Rew**  
University of Auckland, New Zealand

**Problem Statement:** Generic medicines are commonly used in New Zealand; however, the Pharmaceutical Management Agency of New Zealand (PHARMAC) has indicated a need for better information for the public. Studies on consumers' perceptions suggest that pharmacists play an important role in consumers' choice; hence, "quality use of generic medicines" can be promoted with a better understanding of pharmacists'

views, knowledge, and perception.

**Objectives:** (1) To evaluate pharmacists' perceptions, views, and knowledge of and willingness to recommend generic medicines; (2) to explore pharmacists' perceptions of the safety, quality, and efficacy of generic medicines; and (3) to assess pharmacists' views on current policy with respect to substitution of generic medicines.

**Design:** Descriptive study

**Setting:** National-level study, assessing individual pharmacists' responses

**Study Population:** A cross-sectional survey using a postal questionnaire was conducted, and questionnaires were sent to 625 randomly selected pharmacists from a list of 1,594 pharmacists who had agreed to release their information for research purposes.

**Results:** Three-hundred and sixty pharmacists responded to the questionnaire (a response rate of 58%). Seventy percent of pharmacists stated there is no difference in safety between original brand and generic medicines. However, 65% stated that original brand medicines were of higher quality than their generic counterparts, and half stated that generic medicines and original brand medicines are equally effective. A large number of pharmacists reported concerns regarding brand substitution and offered suggestions, such as the need for advertising campaigns, patient pamphlets, updating prescribers' software, and distinct packaging for generic medicines. It was found that pharmacists' perceptions of generic medicines are primarily driven by PHARMAC's policies and their experiences with consumers.

**Conclusions:** About one-third of pharmacists correctly defined the term "generic medicines," suggesting discrepancies in pharmacists' knowledge and perceptions of generic medicines. Concerns were raised regarding quality, safety, and effectiveness; however, most of the pharmacists acknowledged the economic benefits to the health care system.

**Funding Sources:** School of Pharmacy, University of Auckland

888

**Policy, Regulation, and Governance***Keywords:* Essential Medicines, Pharmaceutical Services, National Medicines Policy, Right to Health, legislation & jurisprudence**Pharmaceutical Services and Essential Medicines: Considerations on Access to Medicines and Judicial Demands in Brazil****João Maurício Brambati Sant'Ana<sup>1</sup>, Vera Lúcia Edais Pepe<sup>1</sup>, Claudia Garcia Serpa Osorio de Castro<sup>1</sup>, Miriam Ventura Ventura<sup>2</sup>**<sup>1</sup>ENSP-Fiocruz, Brazil; <sup>2</sup>IESC- Universidade Federal do Rio de Janeiro, Brasil

**Problem Statement:** The right to pharmaceutical services established as an aftermath of the 1988 Brazilian Constitution provided grounds for the use of the judicial pathway to guarantee access to medicines. This phenomenon has been branded judicialization of pharmaceutical services.

**Objectives:** To discuss the judicialization phenomenon, considering the National Medicines Policy's (NMP) conceptual framework, especially aspects concerning essential medicines versus the need to allocate scarce health funds.

**Design and Setting:** A search of the literature uncovered conceptual, normative, and institutional aspects of the Brazilian NMP. The focus emphasized access to essential medicines. A discussion of judicial demands for medicines in light of the concept of essential medicines and of allocation of funds ensued.

**Results:** Two directives of the NMP are (1) re-orientation of pharmaceutical services— from a product-centered to a patient-oriented outlook; and (2) adoption of the essential medicines list (EML). Pharmaceutical services managers realize the need to promote structured services based on the Brazilian Health Policy principles of universal access, comprehensiveness, and equality. The federal EML must guide the medicine lists of other levels of government (state and municipal). However, the scarcity of funds must force the adoption of criteria, jointly agreed upon by all levels of the health system, and expressed in the country's legislative framework. The criteria should favor all individuals equally, without bias. Without these directives, arbitrary decisions may become routine, an application of a different set of requisites on a case-to-case basis, exercised by those who are invested with the power to decide. The presence of these criteria nevertheless should not hamper or eliminate the possibility of litigation when called for in extraordinary situations. The health sector and the judicial sector have both contributed to judicialization. Health managers may have failed to guarantee access to medicines, while the judicial system tends to ignore health sector policy and priorities as legitimate instruments for decision making and for resource allocation. The system may also give little consideration to

the essential medicines concept when faced with the medical prescription, by perceiving it as the only source of necessary information on the needs of the patient, and when providing any medicine that is demanded regardless of evidence to the contrary.

Conclusions: There are deficiencies that surpass the health system and the judicial system in regard to access to medicines in the Brazilian Health System. There seems to be no other way than to bring these two sectors together to agree upon a common agenda and mutual responsibilities.

Funding Source: Fundação de Amparo à Pesquisa do Estado do Rio de Janeiro

889

#### HIV/AIDS and TB

*Keywords:* financing, HIV/AIDS, technology, access to medicines, adherence

### **WeTel Kenya: Business Case for Using Mobile Phones as a Cost-Effective Health Intervention to Provide Care and Support HIV/AIDS Patients**

**Bella Hwang<sup>1</sup>, Jesse Coleman<sup>2</sup>, Richard Lester<sup>3</sup>**

<sup>1</sup>Simon Fraser University; <sup>2</sup>British Columbia Centre Disease Columbia; <sup>3</sup>University of British Columbia

**Problem:** The high prevalence of transmittable diseases coupled with limited resources hinders developing world countries' ability to effectively treat their patients. The use of mobile phones and text (SMS) messages is proposed to be a cost-effective method for patients, health clinics, and entire health systems to provide patient-centered care. We recently reported in a multisite, randomized clinical trial that use of a simple cell phone patient-support intervention in Kenya improved adherence to ART and successful suppression of HIV viral load (The Lancet, 2010).

**Objectives:** We examined the resources, costs, and costs savings models required to scale-up WeTel Kenya's SMS intervention from the original 538 patients to a national and global example. The two examples used include: (1) 500,000 cohort of patients on ART in Kenya; (2) 2,485 million cohort of patients on ART in globally funded PEPFAR programs.

**Design:** To estimate and analyze costs associated with scaling up SMS interventions to manage ARV patients. We developed both cost expenditures and cost savings models.

**Setting:** We looked at implementing the purposed program throughout Kenya and globally.

**Study Population:** Patients on ART who have access to a mobile phone.

**Intervention:** Analysis of programmatic implementation using a protocol of weekly SMS inquiries from a health provider to patients on ART. Patients are required to respond within 48 hours. Those indicating a problem or nonresponsive are followed up with a phone call to triage the problem and provided support as appropriate.

**Policy:** Enabling routine, structured cell phone communication with ART patients and provision of care via mobile phones are not currently the standard of care. As policy makers consider bringing mobile phone interventions to scale, these estimates provide insight into cost implications and costs savings.

**Outcome Measures:** Cost benefits analysis

**Results:** To estimate and analyze costs associated with scaling up SMS interventions to manage ARV patients, we looked at both cost expenditures and cost savings models. Cost expenditure models took several costs into account including: (1) cost of airtime for SMS and call-backs; (2) technological requirements (including computer, software, SMS gateway) at each health clinic or group of health clinics; and (3) human resources. Through a three-year strategy, SMS intervention costs between 10.21 to 11 US dollars (USD)/year. Cost saving models were used to predict health systems savings due to improvements in HIV treatment outcomes observed in WeTel Kenya<sup>1</sup> (viral suppression and adherence). The following factors were taken into consideration: (1) preventing the need for second-line therapy; (2) preventing opportunistic infections; and (3) savings in health provider time. The potential costs savings for the Kenya cohort range from USD 1.6 to 19.4 million, and in the PEPFAR cohort range from USD 8.2 to 48.3 million from year 1 to 3. Costs saved do not take into account quality of life improvement factors to patients.

**Conclusions:** Using a weekly SMS protocol to deliver health services and provide support to ART patients provides both qualitative benefits and is anticipated to be a cost-effective way for a health system with limited resources to reach a large number of patients.

Funding Source: MBA thesis

890

#### Economics, Financing, and Insurance Systems

*Keywords:* pharmaceutical policy, prescriber behaviour, cancer

### **The Impact of Evidence-Based Subsidy Restrictions on Prescriber Behaviour and Patient Outcomes: A Case Study of Lapatinib for the Treatment of HER2+ Metastatic Breast Cancer**

**Sallie-Anne Pearson, Preeyaporn Srasuebku, Christine Lu, Timothy Dobbins, Robyn Ward**

Lowy Cancer Research Centre and Prince of Wales Clinical School, University of New South Wales, Australia

**Problem Statement and Policy:** Third-party payers often impose restrictions on the way in which subsidised drugs are prescribed. Lapatinib is an oral agent targeting the HER2+ receptor in metastatic breast cancer. It has been subsidised in Australia since 2008. Prescribing restrictions specify patients are only eligible for lapatinib after progressing on

trastuzumab, an IV HER2+ therapy subsidised publically since 2001. Once treated with lapatinib, patients are ineligible for subsequent publically funded trastuzumab therapy.

Objective: To describe the prescribing patterns, predictors of treatment, and overall survival (OS) of patients treated with lapatinib since its subsidy in May 2008.

Design and Methods: A population-based longitudinal cohort study (February 2008-March 2010) of women alive and on trastuzumab in May 2008 (or ceased trastuzumab within the preceding 3 months). We used pharmaceutical claims to define courses of treatment (first to last dispensing +28 days for trastuzumab or +14 days for lapatinib), concomitant chemotherapy ( $\geq 2$  dispensings for the same chemotherapy  $\geq 7$  days apart) and switches in chemotherapeutic partners. Logistic regression determined the predictors of lapatinib therapy and Kaplan-Meier analysis estimated median OS since commencing lapatinib treatment.

Results: Of the 1,770 women (median age 56: range 21–92 yrs) meeting our inclusion criteria, 13% were prescribed lapatinib and another 21% had switched chemotherapeutic partners on trastuzumab (indicative of disease progression, and thus lapatinib treatment eligibility). The likelihood of receiving lapatinib treatment increased with younger age ( $p < 0.001$ ), use of multiple (three or more) chemotherapeutic partners with trastuzumab ( $p < 0.001$ ), and trastuzumab treatment durations of 6–12 months ( $p = 0.003$ ). Median OS was 11.9 months (95% CI: 9.4–15.3), 3.7 months shorter than RCT estimates.

Conclusions: Our study demonstrates the negative impact of prescribing restrictions on treatment practices for HER2+ metastatic breast cancer. A substantial proportion of patients who were likely to benefit did not proceed to lapatinib therapy. It is not surprising our OS estimates were shorter than RCT results as lapatinib appears to be used as the last resort. Australian oncologists tended to switch chemotherapeutic partners with trastuzumab (for which there is little to no evidence of efficacy) than prescribe lapatinib, an evidence-based treatment. What is the rationale for such behavior? Financial incentives may be a driver as Australian oncologists are remunerated for the administration of IV but not oral therapy. Our study outcomes should be reassessed after Dec 2010 when the restriction that lapatinib-treated patients are ineligible for trastuzumab therapy is removed.

Funding: Cancer Institute NSW and Cancer Australia

**891**

#### **Policy, Regulation, and Governance**

*Keywords:* health litigation, right to health, pharmaceutical services, medicines, Brazilian Health System

#### **Health Litigation and New Challenges in the Management of Pharmaceutical Services**

**Vera Lucia Edais Pepe<sup>1</sup>, Tatiana de Araújo Figueiredo<sup>1</sup>, Luciana Simas<sup>1</sup>, Claudia Garcia Serpa Osorio-de-Castro<sup>1</sup>, Míriam Ventura<sup>2</sup>**

<sup>1</sup>ENSP-Fiocruz, Brazil; <sup>2</sup>IESC- Universidade Federal do Rio de Janeiro. Brazil

Problem Statement: Health litigation spurs many challenges in the management of pharmaceutical services. Performance of health managers and decision-makers must be adjusted to new administrative and legal boundaries. Their actions must also be efficient in responding to ongoing lawsuits, as well as in avoiding additional litigation and in upholding principles and directives of the Brazilian Health System (SUS).

Objectives: This paper proposes to better understand one of the aspects of health litigation, namely the growing use of lawsuits demanding medicines, and the relationship between this phenomenon and pharmaceutical services management in SUS.

Design and Setting: A review of management and technical procedures related to health litigation of medicines in Brazil was carried out. Through the analysis of available published research on the subject the main elements of "medicines litigation" are presented and examined in light of their interference on the activities of the pharmaceutical services cycle.

Results: Three possible negative effects of judicialization were found: problems with the principles of universal access and equity, difficulties in the management of pharmaceutical services and risks to patient safety, due to misguided prescribing of listed and public-funded medicines, and also of new, innovative medicines without solid established evidence. Moreover, unregistered, unauthorized medicines as well as off label uses may be the target of demands. All technical and operational phases of the pharmaceutical services cycle may suffer disruption by judicial demands. Injunctions can press health system to select medicines in order to adjust the AF cycle to judicial demands, increase the acquisition costs and contribute to the non-rational use of medicines. It is important to develop tools to update information about lawsuits; increase ethical, legal and technical actions and stimulate future innovative actions in different fields of knowledge. A model flow for the analysis of judicial demands in light of the need for evidence-based decision-making was obtained.

Conclusions: The analysis points to possible mechanisms to be adopted by decision-makers in management and in the Judicial System, since the right to health can only be effectively established when management and Justice are predominantly aware and committed to the safety and the protection of patients and users.

Funding Source: National Council for Scientific and Technological Development (CNPq) and Carlos Chagas Filho Research Support Foundation of Rio de Janeiro (FAPERJ)

**895**

#### **Policy, Regulation, and Governance**

*Keywords:* National Medicines Policy, indicators, components, implementation, strategies

## **The Role of Malaysian National Medicines Policy (MNMP) in Improving Overall Use of Medicines**

**Othman, Nour Hanah; Hasan, Hasnizan; Nagalingam, Sarah; Ong, Woon May; Zolkopri, Nor Yati**

Pharmaceutical Services Division, Ministry of Health (MOH) Malaysia

**Problem Statement:** The Malaysian National Medicines Policy (MNMP) which was approved and endorsed by the Malaysian Cabinet in 2006 is a way forward of the Pharmaceutical Services Division, MOH Malaysia in ensuring good drug management in improving health outcomes for all Malaysians. The implementation of the policy's Master Action Plan over a 5-year period is to ensure equitable access to, and rational use of, safe, effective and affordable essential drugs of good quality to improve health outcomes of the people.

**Objective:** To evaluate the implementation and effect of MNMP for overall use of medicines in Malaysia.

**Setting:** Several indicators were measured for background (23), structure (47), process (17) and outcome (3) of pharmaceutical system as part of the monitoring indicators of the MNMP, in primary and secondary care, public and private settings.

**Outcome Measure(s) :** Indicators measured include average number of drugs per prescription; number of advertisements in violation of regulations on the ethical promotion of drugs, out of total number of advertisements monitored; and number of drug samples tested, out of drug samples collected. New country-specific indicators which have been identified during the MNMP mid-term review are currently being finalized. These include Number of Continuous Professional Development (CPD) programme conducted, out of total number of CPD programmes planned; Number of educational tools on drugs/issues on drugs disseminated, out of total number of educational tools planned in a year; Number of drug awareness programmes organized, out of total number of drug awareness programmes planned; Number of products detected with fake security labels (hologram), out of total number of products with security labels (hologram) inspected; and Number of adverse drug reaction reported, out of 1 million populations.

**Results:** From year 2006 to 2009, it was found that the average number of drugs per prescription is four (4). Comparing 2006 data with that of 2009 showed an increment in the average number of drugs per prescription (3.6 to 3.9). There was a decreasing trend in the advertisements monitored which do not comply with the regulations on the ethical promotion of drugs from year 2006 to 2008, but there was an increase in 2009 which could be caused by the increased total number of advertisements monitored. All drug samples which have been routinely collected were tested in year 2007 (compared to 99% in 2006). Subsequently, there was a decreasing trend from year 2007 to 2009 (100% to 90.2%).

**Conclusions:** The results showed that there are improvements and fluctuations in some indicators in achieving the respective targets. These data are useful in demonstrating the successes and limitations in policy development and implementation; and suggest change and enhancement of the strategies to ensure the overall improvement in the use of medicines through MNMP.

**Funding Source(s):** MOH Malaysia

**896**

### **Child Health**

*Keywords:* drug-related problems, readmission rate, patient safety, pediatric cardiac patient, pharmacist's role

## **Impact of Pharmacist's Roles on Reducing Readmission Rate and Promoting Patient Safety in Pediatric Cardiac Patients**

**Manita Suriyarangsee, Monwarat Laohajeeraphan, Vimonkarn Sirisuksan**

Siriraj Hospital, Mahidol University, Thailand, Thailand

**Problem Statement:** In the year 2008, there were two serious cases of medication errors in a hospital's pediatric cardiac patients—one of them was readmitted. A multidisciplinary team suggested pharmacists perform discharge counseling and medication reconciliation program for these vulnerable patients.

**Objectives:** To study the characteristics of drug-related problems (DRPs) throughout discharge counseling and medication reconciliation process and its impacts on readmission rate and patient safety.

**Design:** Observational descriptive study

**Setting:** Pediatric cardiac ward in Siriraj Hospital, the 2,300 beds tertiary-care teaching hospital of Mahidol University, Thailand.

**Study population:** Every patient who was admitted during October, 2009 to October, 2010 was screened by ward nurses. Only 9 high risk patients were enrolled to the study from one of the inclusion criteria

: (1) first time received cardiovascular drugs as home medication; (2) received new item(s) of high alert drugs as home medication; (3) prone to have drug-related problems (DRPs) from limitations of age, race, and illiteracy; or (4) had previous DRPs that attributed to a current readmission.

**Intervention:** The pharmacists identified DRPs by chart reviews and patient or caregiver interviews. Discharge counseling was planned and done by several educational materials. All DRPs were resolved based on patients' needs. The pharmacist made the first phone call one week after discharge and every 2 weeks or more. At a visit date, pharmacist reassessed DRPs and reconciled the medication lists.

**Policy:** Pharmaceutical cares by pharmacists were provided for vulnerable chronic disease patients.

**Outcome measures:** Number of the pharmacist's activities, identified DRPs and readmission rate

**Results:** From 9 enrolled patients, average of 8.3 home medication items per patient, there were 258 pharmacist activities and 99 DRPs were identified. All detected DRPs were resolved before resulting in harm to patients. DRPs

were mostly found by patient chart reviews and patient or caregiver interviews (43.4%) and by phone calls (35.4%). The top three identified DRPs were non-adherences (52.5%), medication errors (18.2%) and inappropriate administration skills (17.2%). Only one patient (11.1%) was readmitted from her depressive disorder.

Conclusion: The pharmacist's activities could prevent readmission from non-adherences and medication errors. Early DRPs detection and resolving could generate more patient safety in vulnerable chronic disease patients.

Funding Source: ICIUM scholarship

903

**Access**

*Keywords:* Safe use of Medicines, Antimicrobials, community

**Impact of Community Education Programme on Safe Use Oo Medicines in Two States of India**

**Usha Gupta Gupta<sup>1</sup>, Neera Agnimitra<sup>3</sup>, Sangeeta Sharma<sup>1</sup>, Dayanand Tondon<sup>2</sup>, Ranjitha Parameswar<sup>1</sup>**

<sup>1</sup>Delhi Society for Promotion of Rational Use of Drugs, India; <sup>2</sup>CREATE; <sup>3</sup>Delhi University

Problem Statement: Irrational use of medicines amongst community is a global problem more so in developing countries. Several surveys conducted in different states of India have shown that inappropriate use of medicines is due to lack of awareness and knowledge about medicine use amongst the community.

Objectives: To educate community on medicine use, using the educational material and observe the impact

Design: Pre-post educational intervention study

Setting: The educational programme was conducted in 4 districts each in 2 states of India—Uttar Pradesh and Bihar.

Study Population: 400 households were included for assessing the knowledge and behavior about the use of medicines. A predesigned and pretested proforma was used for interview.

Interventions: Education material included 4 clusters; (1) advice seeking behavior during general ailments; (2) use of medicines as prescribed by the doctors including antimicrobials; (3) storing of medicines, and (4) care to be taken while purchasing the medicines. The programme was carried out for 6 months followed by assessment.

Outcome Measures: Primary outcome measures included self medication, probing about the prescription while consulting the doctor, awareness about expiry date while purchasing medicine, storage of medicine, knowledge of antimicrobials, and adherence to prescription containing antimicrobials.

Results: In Uttar Pradesh, 66% of respondents and in Bihar, 46% of respondents informed that they do not self-medicate. After the educational programme, the percentages increased to 77% and 86% who reported that they do not self medicate. In Uttar Pradesh, 80% respondents probed the prescription while consulting the doctor. It increased to 99% after educational programme. In Bihar, it increased from 63% to 72%. In Bihar, 56% respondents were aware of checking the expiry date and matching the medicines with prescription. This increased to 78% after the educational programme. Similar changes were seen in Uttar Pradesh. In both Uttar Pradesh and Bihar, the percentage of respondents having any knowledge about antimicrobials was quite low— 26% in Uttar Pradesh and 38% in Bihar; the majority of households believed that antimicrobials acted quickly to help heal. There was an improvement in the knowledge of respondents after educational programme (53% in Uttar Pradesh and 62% in Bihar). Since the knowledge about the antimicrobials was quite low, very small percent of respondents—26% in Uttar Pradesh. and 27% in Bihar—demanded antimicrobials. The change after educational programme was very low.

Conclusion: it was observed that all activities that involved one-to-one interactions were successful, and to achieve sustainability, reinforcement on continuous basis is required.

Funding Source: CORDAID

904

**Economics, Financing, and Insurance Systems**

*Keywords:* access to medicines

**Cost Plus Price Setting of Medicines**

**Amanullah Saif**

Ministry of Health, Government of Pakistan, Pakistan

Problem statement: Medicine prices in the low- to middle-level income countries deprive the poor population of access to essential medicines.

Objectives: To draft a policy paper describing, analyzing, and discussing cost plus price setting to assist countries which are using or intend to use the method.

Design, Setting, and Study Population: To carry out global search on use of cost plus pricing method, a questionnaire was sent to 67 persons (mostly WHO/HAI survey managers) in 46 countries to identify the countries currently using or had ever used cost plus method. A web search was carried out and published and gray literatures were reviewed to find studies and literature available on use of cost plus pricing method to fix prices of medicines. It was found that 13 countries were using this method and three countries had discontinued it. It was also found that Clinton Foundation uses a template for production cost information that the manufacturer needs to fill in as part of their submission if they want to take part in the price negotiation for procurement of medicines under Clinton Health Access Initiative. A detailed questionnaire (requesting information for details on cost components, pharmaceutical market size, share of locally manufactured drugs, etc.) was sent to eight countries using the cost plus method to study how this method worked in

those countries. A short questionnaire was sent to countries which had discontinued this method to study why they did so but no replies were received. Based on responses to questionnaires and published/gray literature, six case studies on countries (Bangladesh, China, India, Iran, Pakistan, and Slovakia) currently using this method were included in the paper. Evidence was found that Australia is using this method where the drug is unique in its category or when a benchmark price is being calculated for a therapeutic group.

Policy : Regulation of medicines prices

Results: Three billion people live in countries that use the cost plus method which makes it one of the methods worth studying though evidence on its effectiveness is limited. Its utility or effectiveness depends on the circumstances and overall health care delivery system. This method is not about patent protected medicines. It may also not be a viable option for countries with small populations or countries primarily dependent on imported medicines.

Conclusions: Cost plus method is comparatively complex. Its application in conjunction with other pricing methods (such as Reference Pricing, Value Based Pricing) may provide better results. Maintenance of database on prices of raw and packing materials and other cost components will help better estimation of prices. Since regulation of medicine prices requires dynamic skills to analyze market and fair return, capacity building of the regulatory agency is critical for success of this or any other pricing method.

Funding Source: WHO/Health Action International.

**905**

#### **Economics, Financing, and Insurance Systems**

*Keywords:* pharmaceutical policy, pharmaceutical expenditure, medicine prices, access to medicines, pharmacoconomics

### **The Impact of the 2008 Economic Recession on the Pharmaceutical Sector in the Baltic Countries**

**Joel Hernandez Buenaventura<sup>1</sup>, Richard Ogilvie Laing<sup>2</sup>, Kees de Joncheere<sup>3</sup>, Carandang Edelisa<sup>2</sup>**

<sup>1</sup>Boston University School of Public Health, United States of America; <sup>2</sup>World Health Organization Department of Essential Medicines and Pharmaceutical Policies; <sup>3</sup>World Health Organization Regional Office for Europe

Problem Statement: The global financial crisis of September 2008 severely affected the economies of many countries. The World Health Organization, in line with its agenda to build global health security, is concerned with the assessment of the possible health consequences of the economic recession. An important area of interest is gauging how an economic recession can impact the access to health care of the population, particularly access to essential medicines.

Objectives: To investigate the impact of the 2008 economic recession on the pharmaceutical sector of two Baltic countries (Estonia and Latvia), which was shown to have the most substantial declines in pharmaceutical consumption and explore qualitatively what policies could have caused this decline to possibly provide a framework for policy making in times of economic recession.

Design: Descriptive study. Data were gathered through comprehensive literature review to identify possible contributory factors that led to the substantial decrease in pharmaceutical consumption in Estonia and Latvia. Country specific quarterly data from IMS Health and Economic Intelligence Unit (EIU) from 2007 to 2009 were also generated. Teleconference interviews with a focal person from Estonia and from Latvia each was done to validate findings.

Setting: International/Regional (Baltic). Examines public sectors in Estonia and Latvia.

Policy: Policies enacted in Estonia and Latvia during the 2008 economic recession.

Outcome Measure: Pharmaceutical expenditure, consumption, pricing index

Results: EIU data showed that the economies of Estonia and Latvia had been contracting even before the global economic crisis hit them and other countries. Because of their determination to fulfil the Maastricht Criteria for the adoption of the euro, they had limited flexibility in terms of policy changes in response to the economic crisis. While the economic crisis has led to reduced public expenditures in most countries with health budgets spared and medicine consumption remaining stable, Baltic countries gave mixed picture. IMS data showed that there was a substantial decline in the pharmaceutical expenditure and consumption, and an increase in pharmaceutical prices. Estonia had increase in public expenditure; Latvia had 10% decline in public sector budgets on medicines, but patients were protected from co-payments through social compensation funds. Decline in total market was mostly in therapeutically less relevant groups.

Conclusion: IMS data indicate that pharmaceutical consumption substantially declined in the Baltic countries among other European countries. Many individual patients were likely to have either reduced their consumption or increased their out-of-pocket expenditure as the prices of pharmaceuticals went up. However, the impact of the decline in pharmaceutical consumption during the economic recession on the health status of these populations remains to be seen.

Funding Source: WHO

**906**

#### **HIV/AIDS and TB**

*Keywords:* antiretrovirals, pharmacovigilance, patient safety, surveillance

### **Pharmacovigilance Reporting in Kwazulu-Natal—Evaluation of a Solicited System of Reporting**

**Viloshinie Krishna Manickum<sup>1</sup>, Fatima Suleman<sup>2</sup>**

<sup>1</sup>Strengthening Pharmaceutical Systems/Management Sciences for Health; <sup>2</sup>University of KwaZulu-Natal, South Africa

**Problem Statement:** The high burden of HIV in KwaZulu-Natal resulted in an increase in the numbers of patients being initiated on HAART. However, very little information on adverse events was forthcoming from facilities. Therefore a solicited system of reporting was established to facilitate the reporting of adverse drug reactions (ADRs) from all accredited sites.

**Objectives:** To evaluate the effect of the solicited reporting system on ADRs reported.

**Design:** A retrospective audit was performed on forms that were received from 1 May 2007 to 31 May 2008 for all patients on HAART who experienced ADRs.

**Setting:** The study was conducted at provincial level. All public sector facilities that were issuing antiretrovirals were included in this study.

**Study Population:** The following patients were included in this study: (1) patients that were on HAART and experienced ADRs for which regimen changes were requested (n=3,534); (2) patients who required non-standard regimens (n=216); and (3) high-risk patients who were survivors of sexual assault and required post-exposure prophylaxis (n=173). Non-serious (Grade 1 and 2) adverse drug reactions that did not require a change of regimen were not considered in this study.

**Intervention(s):** The completion of the ADR form by clinicians, when they requested a change in antiretroviral/regimen. This form was then evaluated by a pharmacist at pharmaceutical policy and systems development in collaboration with consultants. Specific forms and guidelines were developed for the reporting process, and health care workers were trained with respect to the guidelines and the completion of the forms.

**Policy(ies):** Results generated by the solicited reporting system were disseminated to the National and Provincial Authorities resulting in the recommended adult dose of stavudine being decreased from 40 mg twice daily to 30 mg twice daily; and amending the South African National Guidelines in April 2010 to include newer antiretrovirals such as tenofovir.

**Outcome Measure(s):** Increase in number of reports submitted to the province; increase in the number of adverse events reported

**Results:** The total numbers of reports received from 77 hospitals were 3,923. Of the 3,322 reports that indicated patients were on stavudine, lamivudine and efavirenz/ nevirapine, 2,946 (88.7%) reports documented stavudine as the possible cause of the ADR. The proposed new regimen in 73.6% of the reports was zidovudine, lamivudine, and efavirenz/nevirapine.

**Conclusions:** The system of centralized system of solicited reporting looks intensively at the reporting of adverse drug reactions, and provides results rapidly. It can be incorporated into a systematic, continuous risk assessment system in a resource constrained setting for the monitoring and evaluating of adverse drug reactions.

**Funding Source(s):** SPS, Department of Health (KZN)

909

#### HIV/AIDS and TB

*Keywords:* antiretrovirals, HIV/AIDS, pharmacovigilance, adverse drug reactions,

### **A Prospective Study of Prevalence, Severity and Preventability of Adverse Drug Reactions in Hospitalized Human Immunodeficiency Virus (HIV) Positive Patients**

**Parthasarathi Gurumurthy<sup>1,2</sup>, Sumathi Devaraj<sup>1</sup>, Anand Haruger<sup>1</sup>, Madhan Ramesh<sup>1,2</sup>, Rajendra Prasad Shivaswamy<sup>3</sup>, Atiqulla Shariff<sup>1,2</sup>**

<sup>1</sup>JSS College of Pharmacy, JSS University, Mysore, India; <sup>2</sup>JSS Medical College Hospital, JSS University, Mysore, India; <sup>3</sup>Vivekananda Youth Movement Hospital, Saragur, H D Kote Taluk, India

**Problem statement:** It is estimated that free antiretroviral therapy (ART) will be provided to 300,000 adults and 40,000 children by 2012 in India by National AIDS Control Organisation (NACO). Safety information for ART amongst the Indian population is lacking. There is a need to integrate pharmacovigilance in the ART program of NACO.

**Aims:** To determine the frequency and nature of adverse drug reactions (ADRs) in hospitalised human immunodeficiency virus (HIV) positive patients.

**Design:** Prospective observational study

**Setting:** Community Care Centre located at a secondary care hospital in southern India.

**Study population:** HIV-positive patients admitted to the study site.

**Outcome measures:** Prevalence, severity, preventability, and risk factors for development of ADRs in hospitalised HIV-positive patients.

**Results:** Total of 529 consecutive patient episodes from 463 patients (354 [66.9%] male) were followed throughout the hospital stay. Prevalence of ADRs was found to be 60.86% (439). ADR was the cause for hospital admission in 179 (33.83%) admission episodes, while 260 (49.14%) ADRs were observed during hospital stay. The majority of ADRs (243 [76.2%]) were due to ART and were moderate in severity (285 [64.92%]). Medications used to treat opportunistic infections were implicated in 196 (35.1%) ADRs. The gastrointestinal system (131 [29.82%]) was the organ system frequently affected by ADRs. The majority of ADRs 371 (84.51%) were probably preventable. Tuberculosis (OR: 3.6 [CI: 2.2-6.0], p<0.001), patients on ART treatment (OR: 4.0 [CI: 2.8-5.9], p< 0.001) length of hospital stay (>10 days) (OR: 3.64 [CI: 1.97-6.71], p< 0.001) and number of concomitant medications with ART (>10) (OR: 5.4 [CI: 2.9-10.0p< 0.001]) were identified as risk factors for developing ADRs.

Conclusion: ADRs were observed in 60.86% of the admission episodes in hospitalized HIV patients with majority (64.92%) being moderately severe. Interventions to reduce the risk of ADRs in hospitalized HIV-positive patients should focus on the identified risk factors. Creation of a registry for ADRs to ART linking all ART centres across India would prove very useful.

Funding Sources: No funding was available for this project.

**910**

### **Policy, Regulation, and Governance**

*Keywords:* generic (multisource) medicines, pharmaceutical policy, regulatory authority, retail market

#### **The Volume Share of Generic Medicines in the Retail Market between 1999 and 2009: a Comparison between Brazil and Mexico**

**Rene Soria-Saucedo<sup>1</sup>, Veronika J Wirtz<sup>1</sup>, Warren A Kaplan<sup>2</sup>**

<sup>1</sup>Center for Health Systems Research, National Institute of Public Health, Mexico; <sup>2</sup>Center for Global Health and Development, Boston University, USA

**Problem Statement:** Most Latin American countries have implemented some pharmaceutical policies that encourage the use of generic medicines to increase access to pharmaceutical products. Mexico and Brazil are two Latin American countries that decided early on to introduce the concept of bioequivalence to increase confidence in the quality of generic medicines, and hence, promote its uptake. Little comparative analysis has been carried out to study the way policies were implemented.

**Objectives:** To analyze the relationship between public policies to promote the use of generic medicines and their volume share in the retail market between 1999 and 2009.

**Design:** Time series analysis of the retail pharmaceutical market volume and analysis of policies to promote the use of generic medicines

**Setting:** Brazil and Mexico retail sectors

**Study Population:** Innovator and generic medicines retail sales volume between 1999 and 2009

**Intervention:** Public policies introduced to promote the use of generic medicines

**Outcome:** Percentage change in volume share of generic medicines out of total retail market volume between 1999 and 2009

**Results:** From 1999 to 2009, the percentage volume share of generic medicines increased by more than five fold for Brazil (5% to 27.5%) and nearly four-fold for Mexico (1.8% to 8.5%). In Brazil, the annual increase in generic volume share was relatively constant over the 10 years (annual increase of 2.13%). In Mexico from 1999 to 2004, the annual increase in volume share was minimal (0.16% mean annual increase) and this changed after 2005 when the generic medicines volume increased about 1.31% per year.

Even though the policy objectives in Brazil and Mexico are similar in promoting generic medicines use, they differ largely in strategies and focus of implementation: Brazil enacted a law in 1999 which provided the framework for an explicit pharmaceutical policy largely based on WHO recommendations as well as a norm defining the requirements that generic medicines have to comply with before market authorization (among other bioequivalence tests). A key player in Brazil's efforts to promote generic medicines was the Medicines Regulatory Agency (ANVISA). In contrast, Mexico lacked a coherent explicit pharmaceutical policy. Even though since 1998, regulations included a list of interchangeable generics, the Mexico's Medicines Regulatory Authority (COFEPRIS) did not play an active part to promote generic medicine uptake in the private sector. In 2005, it was announced that all generic medicines will require a bioequivalence test similar to standards in Europe and the United States.

**Conclusions:** The Brazilian pharmaceutical policies were placed high on the political agenda, and ensured the technical, logistical, and financial preconditions for the medium- and long-term implementation since 1999. Mexican policies were targeted more effectively at the public market than the retail market.

Funding Sources: National Institute of Public Health, Mexico.

**912**

### **Access**

*Keywords:* availability, supply management, essential medicines

#### **Using a Rapid Results Approach to Improve Supply Chain Efficiency and Increase Availability of Essential Medicines and Supplies**

**Rosalind Wanjugu Kirika<sup>1</sup>, Jackson Omondi<sup>2</sup>, John Odondi<sup>2</sup>, Mary Wangai<sup>1</sup>**

<sup>1</sup>Management Sciences for Health, Kenya; <sup>2</sup>Ministry of Public Health & Sanitation

**Problem Statement:** Delivery of essential medicines and supplies (EMMS) to health facilities from the Kenya Medical Supplies Agency (KEMSA) is sometimes delayed, resulting in medicine stock-outs.

**Objectives:** Reduce delivery time of EMMS to health facilities in Kenya's North Eastern Province from KEMSA by 40% (from 10 to 6 days) in 100 days.

**Design:** Intervention with before/after evaluation, no control

**Setting and Study Population:** The North Eastern Province was selected because of its poor infrastructure. It has 134 public sector facilities: 9 hospitals, 3 health centers, and 122 dispensaries, all which were included in the study. The intervention team comprised selected supply chain stakeholders including Ministry of Public Health and Sanitation, KEMSA, and SPS.

**Intervention(s):** The Rapid Results Initiative is a results-focused methodology to jump-start system changes by implementing bite-sized, high-visibility, and momentum-building projects in 100 days. The Rapid Results Initiative's commodity management team developed an action plan and clearly defined milestones with a goal of reducing KEMSA's delivery time. The team undertook a survey to establish the baseline delivery time. The team sensitized stakeholders (KEMSA management, contracted transporters) and engaged them in analyzing the gaps in delivery. The team then developed appropriate interventions, namely to re-map the distribution route by geographic proximity of facilities; develop a real-time distribution schedule and communicate it to the lowest level (manually and electronically); and "containerize" each facility's consignment, so that the transporter can deliver directly to the facility without needing to search and sort en route. The intervention was planned, implemented, and reported in 100 days.

**Outcome Measure:** The number of days for KEMSA to deliver EMMS to all North Eastern Province facilities.

**Results:** The 134 facilities received their EMMS within 4 days from dispatch at KEMSA. In addition, none of the consignments were returned because staff was available at each destination to receive the shipments. The activity was well documented and will be rolled out to the other provinces. The delivery in the second dispatch followed the same pattern and was accomplished in the same number of days. This may mean that the process is viable.

**Conclusions:** The rapid results initiative reduced delivery times, which improves supply chain efficiency and availability of health commodities. This method can be used in other settings to address a variety of supply chain and medicine use issues.

**Funding Sources:** Government of Kenya, U.S. Agency for International Development, Kenya.

913

#### Access

*Keywords:* appropriate use, dispensing, pharmacist, pharmacy practice, emergency contraceptive pills

### **The Practice of Community Pharmacists on Emergency Contraceptive Pills Dispensing in a Contraindicated Situation**

**Surarong Chinwong, Napatsawan Akemane, Piyanan Pothakieng, Pimploy Lertwanich**

Faculty of Pharmacy, Chiang Mai University, Thailand

**Problem Statement:** Unintended pregnancies rate in Thailand is quite high and with most unintended pregnancies, women decide to have induced abortions. Emergency contraceptive pills (ECPs) are effective in preventing pregnancy when it is correctly used. ECPs are more effective the sooner they are taken but are contraindicated in pregnancy. In Thailand, ECPs can be dispensed in pharmacies without prescription; therefore, community pharmacists play a significant role to ensure the most effective and safest use of ECPs.

**Objectives:** To investigate the practice of community pharmacists on emergency contraceptive pills dispensing in a contraindicated situation

**Design:** Cross-sectional study

**Setting and Study Population:** The population was community pharmacists working in pharmacies located in Amphur Muang, Chiang Mai Province, Thailand. The study aimed to target 48 community pharmacists (working at 48 pharmacies) using the quota sampling technique.

**Method:** The secret shopping technique was used in this study. During June to August 2010, two well-trained secret shoppers visited each community pharmacy to assess practices of pharmacists by informing them that their periods were absent for 2 months and asking for ECPs. This study was approved by the Human Ethic Committee of the Faculty of Pharmacy, Chiang Mai University.

**Outcome Measures:** Appropriateness of screening and medical history-taking, advice-giving on how to use ECPs efficiently, pregnancy testing, other methods for pregnancy prevention, and ECPs dispensing were measured.

**Results:** Forty-one community pharmacists were included for data analysis. Seven pharmacies were excluded because of absence of pharmacist on duty during the secret shopping. The result showed that the majority of pharmacists did not identify the clients and did not ask about the history of contraceptive use. Twenty-six pharmacists (63%) asked the clients about the pregnancy testing history and 35 (85%) advised the clients to do the pregnancy test. Only 6 pharmacists (15%) inquired about other possible causes of absent periods. About half of the pharmacists gave the correct information about indication and efficacy of the ECPs. However, none of the pharmacist asked the clients about underlying diseases, drug allergies, or current medication used. Four pharmacists (10%) dispensed the ECPs in this contraindicated situation.

**Conclusions:** Most of the community pharmacists disregarded the importance of screening and medical history-taking before dispensing ECPs. These practices might be causing not only ineffective protection against pregnancy leading to the social problem but also danger from using it. The study has identified opportunities for improving quality of providing ECPs. The training of community pharmacists about ECPs should be supported to ensure that women who have unprotected intercourse will be provided with the most effective and safest contraceptive method.

**Funding Source:** Faculty of Pharmacy, Chiang Mai University, Thailand

918

**Access**

*Keywords:* Accreditation, access to medicines, dispensing practise

**Increasing Access to Quality Essential Medicines and Services Provided by Drug Shops in Uganda Through Accreditation and Regulation**

**Aziz Maija<sup>1</sup>, Saul Kidde<sup>1</sup>, Kate Kikule<sup>2</sup>, Dennis Mwesigwa<sup>2</sup>, Nasser Lubowa<sup>2</sup>, Martha Embrey<sup>1</sup>, Keith Johnson<sup>1</sup>**

<sup>1</sup>Management Sciences for Health, Uganda; <sup>2</sup>National Drug Authority

**Problem Statement:** Most people in rural areas of Uganda often turn to local drug shops for their medicines and health care advice. These shops may be unlicensed, have staff that are untrained, and sell medicines that may be of uncertain quality or that they are not allowed to dispense. Regulatory inspection and supportive supervision are infrequent.

**Objectives:** To transform existing Class C drug shops into well regulated Accredited Drug Shops (ADS), so that people living in rural communities have access to quality medicines and pharmaceutical services.

**Design:** A quantitative and qualitative pre- and post-intervention design in Kibaale district, with Mpigi district as the control. We collected baseline (2008) and endline data (2010) using drug shop audits and interviews with owners and shop attendants and measured quality of pharmaceutical services using a mystery shopper scenario (malaria in a 5-year-old child).

**Setting and Study Population:** 45 Class C Drug Shops in Kibaale district; 43 in Mpigi district

**Intervention:** NDA developed standards for premises, personnel, record keeping, and dispensing practices; and established a list of prescription medicines that can be legally dispensed by ADS. Local monitors and supportive supervision teams from the district were trained and empowered to supplement NDA's routine inspections. Drug shop attendants received training in good dispensing practices and how to handle common medical problems, patient communication, and referrals. Owners also received business skills training and guidance on obtaining loans from microfinance institutions.

**Outcome measures:** Percentages related to indicators of medicines availability, price change, and service quality.

**Results:** Endline results from Kibaale indicate improvement in service quality and dispensing practices. For example, availability of injectables, which are illegal in all drug shops, dropped from 61% to 0% in ADS compared to the control district, where availability remained unchanged at 35% ( $p < 0.05$ ). In addition, the percentage of mystery shopper encounters where the drug seller enquired about prior medicines given to the child rose from 31% to 64% in Kibaale compared to a much smaller increase (from 40% to 43%) in Mpigi ( $p = 0.136$ ). The legal availability of essential prescription-only medicines has also improved (e.g., availability of essential antibiotics in Kibaale increased from 57% to 84% compared to Mpigi where their illegal availability remained unchanged at 64% [ $p < 0.05$ ]). Medicine prices have not changed on average, despite concerns that costs might rise in ADS because of the expenses associated with meeting new regulatory standards.

**Conclusions:** Results indicate that the accreditation of Class C drug shops has improved access to legally available products and quality services in retail drug outlets that serve populations living in rural areas in Uganda.

**Study Funding:** Management Sciences for Health/East African Drug Seller Initiative, funded by a grant from the Bill & Melinda Gates Foundation

919

**Drug Resistance**

*Keywords:* Antibiotic prophylaxis, Drug Use Evaluation, appropriate use, Antimicrobial

**Application of Drug Use Evaluation and Feedback to Promote Rational Antibiotic Prophylaxis in C-Sections in Kenya**

**Nath Winston Opiyo Arwa<sup>1</sup>, Ahmed Tawaka<sup>1</sup>, Patrick Boruett<sup>2</sup>**

<sup>1</sup>The Mater Hospital ,Kenya, Kenya; <sup>2</sup>Management Sciences for Health/Strengthening Health Systems

**Problem Statement:** Antibiotic prophylaxis is beneficial to both elective and non-elective cesarean section surgery patients. However, the use of surgical antibiotic prophylaxis is characterized by inappropriate practices including inappropriate selection of antibiotic, wrong dosage and time of administration, and long duration of use.

**Objectives:** To evaluate the impact of the systematic, criteria-based program of drug use evaluations (DUE) with feedback on prescribing trends in antimicrobial prophylaxis for cesarean section at the Mater Hospital, a leading private hospital in Nairobi, Kenya.

**Design:** This is a retrospective review of medical records of C-sections done between January 2006 and June 2009. It consists of a baseline DUE and subsequent DUEs with feedback conducted every six months. Prescribing trends were compared with the set criteria based on antibiotic choice, dose, duration, and timing of first dose.

**Setting:** The study was conducted by the Mater Hospital Pharmacy and Therapeutic Committee (MHPTC) in conjunction with the obstetrics and gynecology division at the hospital.

**Study Population:** The hospital performs an average of 600 C-sections annually. The records reviewed were randomly sampled from the medical records. HIV sero-positive patients were automatically excluded because their immunological status merited longer-term antibiotic therapy.

**Intervention:** This was an ongoing, systematic, criteria-based program of drug use evaluations with feedback through MHPTC to registrars, consultants, pharmacists, nursing staff and Hospital anesthetists to improve rational use of

antibiotics. Managerial and educational strategies were used to improve antibiotic prophylaxis in C-section at the hospital. Regular dissemination of findings at division meetings sensitized members on DUE results and hospital guidelines.

Outcome measures: Percentage of antibiotic prophylaxis prescribed as per guideline

Results: Overall adherence to all aspects of criteria of DUE is only achieved when all criteria are met including that on duration of prophylaxis. The proportion of prescription adhering to all criteria was 5% at baseline. Subsequent DUEs show an increase in cases that fully adhered to the criteria from 5% at baseline, 10.3% (DUE-1), 23.5 (DUE-4), 46.1% (DUE-5, and 52.3% (DUE-9). Overconsumption of antibiotics, especially the use of additional oral antibiotics post-operatively, was the main challenge according to our findings.

Conclusions: Application of structured DUE is a useful strategy to identify, monitor, and help correct challenges encountered during antibiotic prophylaxis in C-section surgeries at health facilities. This should be augmented by other strategies implemented through multidisciplinary hospital teams such as pharmaceutical therapy committees.

Funding source: No funding source

921

### Malaria

Keywords: Accreditation, Malaria case management, dispensing practise

#### Improving Quality of Malaria Case Management Provided by Drug Shops in Uganda Through Accreditation and Regulation

**Aziz Maija<sup>1</sup>, Saul Kidde<sup>1</sup>, Kate Kikule<sup>2</sup>, Dennis Mwesigwa<sup>2</sup>, Nasser Lubowa<sup>2</sup>, Martha Embrey<sup>1</sup>, Keith Johnson<sup>1</sup>**

<sup>1</sup>Management Sciences for Health, Uganda; <sup>2</sup>National Drug Authority

Problem Statement: In Uganda, most people in rural areas buy medicines from drug shops, which are often the only place nearby to do so. These shops may not be legally licensed or have staff that are trained or supervised. Drug shop customers typically do not receive instructions for medicine use, and often attendants sell the wrong medicines or the wrong dosages to treat common ailments, including malaria.

Objectives: To improve quality of uncomplicated malaria case management in the retail drug outlets through training, accreditation, and supportive supervision of drug sellers.

Design: A quantitative pre- and post-intervention design in two Ugandan districts: Kibaale as the intervention district and Mpigi as the control district. The baseline (2008) and endline (2010) studies measured quality of uncomplicated malaria case management using a mystery shopper scenario (malaria in a 5-year-old child).

Setting and Study Population: 45 Class C Drug Shops in Kibaale district; 43 in Mpigi district

Intervention: Attendants in existing Class C drug shops in Kibaale underwent training in good dispensing practices, uncomplicated malaria case management, record keeping, and patient communication as part of the transformation of the drug shops into Accredited Drug Shops. Training was supplemented by regular supportive supervision.

Outcome measures: Quality of uncomplicated malaria case management in a five year aged child as measured by (1) percentages of malaria encounters with appropriate malaria treatment (correct choice of treatment, dose, and treatment duration); (2) drug sellers stocking the recommended first-line antimalarials; (3) drug sellers asking about symptoms; and (4) drug sellers asking about prior medication given to the child and instructions for taking medicines.

Results: The percentage of malaria encounters with appropriate malaria treatment in Kibaale rose from 6% at baseline to 68% at endline. Mpigi drug shops also experienced increases from 5% to 47%. Availability of artemether-lumefantrine (AL) increased from 5-6% in both districts to over 85% ( $p = 0.291$ ). However, there was a dramatic fall in the availability of chloroquine (from 80% to 2%) in Kibaale compared to a decrease from 73% to 32% in Mpigi ( $p < 0.05$ ). SP availability decreased from 100% to 7% in Kibaale while in Mpigi, it declined slightly from 100% to 85% ( $p < 0.05$ ). The percentage of mystery shopper encounters where the drug seller (1) asked about symptoms rose from 56% to 64% in Kibaale and declined from 75% to 43% in Mpigi ( $p = 0.136$ ); (2) asked about other medicines the child took—increased from 31% to 64% in Kibaale and remained unchanged in Mpigi; 40% at baseline and 43% at endline ( $p = 0.136$ ); and (3) gave instructions for taking medicines—decreased slightly from 75% to 68% in Kibaale and also declined from 70% to 52% in Mpigi ( $p = 0.243$ ).

Conclusions: Drug sellers play a complimentary public health role. Equipping these drug sellers with the necessary knowledge and skills as part of a government accreditation program can improve malaria case management.

Funding Source: Management Sciences for Health/East African Drug Seller Initiative, funded by a grant from the Bill & Melinda Gates Foundation

922

### HIV/AIDS and TB

Keywords: Anemia, zidovudine, pharmacovigilance, Namibia, antiretroviral therapy

#### Risk of Anemia Associated with Zidovudine (AZT)-based HAART in Namibia

**Assegid Tassew Mengistu<sup>1</sup>, Ishmael Katjitae<sup>1</sup>, Catherine Corbell<sup>3</sup>, Johannes Gaeseb<sup>1</sup>, Jennie Lates<sup>1</sup>, Evans Sagwa<sup>2</sup>, David Mbirizi<sup>2</sup>, Jude Nwokike<sup>2</sup>, Francis Kalemeera<sup>1</sup>, Andy Stergachis<sup>3</sup>**

<sup>1</sup>Ministry of Health and Social Services; <sup>2</sup>Management Sciences for Health/ Strengthening Pharmaceutical Systems;

<sup>3</sup>University of Washington

**Problem Statement:** Anemia among AZT-based antiretroviral therapy users was the most commonly reported adverse event to Namibia's Therapeutics Information and Pharmacovigilance Center (TIPC), accounting for 41% (106/256) of total adverse events reported in 2009. This generated a safety signal, which led to conduct of a pharmacoepidemiologic study to establish the incidence rate and risk factors of anemia among AZT users.

**Objectives:** To determine the incidence of and risk factors for anemia in adults on AZT-based HAART and to demonstrate the feasibility of using linked automated databases as a sustainable platform for assessing the safety and use of HAART to support evidence-based decision making in Namibia.

**Design:** A cohort of HIV adult patients newly initiated on AZT and d4T-based HAART from January 2007 to June 2008 were followed retrospectively using linked data from three automated data sources: (1) the ART electronic dispensing tool (EDT), a pharmacy-based database; (2) the electronic Patient Management System (ePMS), a clinical database; and (3) MEDITECH, a laboratory database from the Namibia Institute of Pathology. The paper-based clinical records stored at health facilities was used to validate the linked electronic data and to obtain additional information on risk factors of anemia for the nested case-control study.

**Study Population:** A total of 12,365 persons aged 19 to 65 years started on HAART between January 2007 and June 2008 whose unique person-records were identified from EDT and matched to ePMS and MEDITECH database.

**Outcome Measure:** Anemia, hemoglobin (Hb) value < 7.0 g/dl, diagnosed at least 30 days after starting HAART

**Results:** The adjusted relative risk (ARR) of severe anemia 29.76 (95% CI: 2.87,308.86) was highest during the first three months of AZT use compared to non-use. The risk dropped after the first three months of AZT use (ARR: 1.09 ) (95% CI: 0.17, 7.05) compared to non-use. In persons with baseline Hb values available, the incidence rate of developing severe anemia was 2.28 per 100 PY in the AZT cohort (95% CI: 1.81, 2.87). There was no significant difference in the incidence rate of severe anemia between the AZT and d4T cohorts during the entire period of follow-up among this subset of persons with baseline Hb values available. The incidence rate of severe anemia was similar to the incidence rate reported in South Africa and in Haiti but lower than the incidence rate reported in the Ivory Coast. The median number of Hb measurements during the first year was 2 for both AZT and d4T cohorts. Furthermore, the median time to a first Hb measurement was 37 days in the AZT cohort and 146 days in the d4T cohort.

**Conclusions:** Risk of severe anemia associated with AZT-based HAART was highest during first three months of AZT use and diminished thereafter. This study successfully demonstrated the benefit of records linkage in the examination of incidence rate and risk factors of adverse events and compliance with treatment guidelines.

**Funding Source:** USAID-funded Strengthening Pharmaceutical Systems

## 923

### Drug Resistance

*Keywords:* Antibiotic/antibacterial drugs, interventions, misuse, systematic review, developing countries

### **Effect of Interventions on Misuse of Antibiotics/Antibacterial Drugs in Developing Countries: a Systematic Review**

**Godfrey Sande Bbosa<sup>1</sup>, Geoff Wong<sup>2</sup>, David B Kyegombe<sup>3</sup>, Jasper Ogwal-Okeng<sup>1</sup>**

<sup>1</sup>Makerere University College of Health Sciences, Uganda; <sup>2</sup>University of London, United Kingdom; <sup>3</sup>Kampala International University Medical School, Ishaka Campus, Uganda

**Problem Statement:** Misuse of antibiotics/antibacterial (AB) drugs is global problem, especially in developing countries. This results in an increased emergence of resistance to most common bacteria, higher cost of treatment, and adverse drug reactions.

**Objective:** Review to determine effect of various intervention studies on AB misuse in developing countries.

**Methods:** A systematic review was conducted to determine the effect of different interventions on misuse of AB drugs in developing countries. A search strategy was developed to retrieve relevant articles from various databases like Medline/PubMed, Embase, INRUD, Management Sciences for Health, WHO, and Cochrane. Google scholar search engine was used to retrieve more studies and gray literature.

**Results:** A total of 722 articles were retrieved and 55 were reviewed—10.9% were from African, 63.6% from Asia, 9.1% from Latin America, and 16.4% from Southeastern Europe. A total of 52.7% were hospital settings, 5.5% outpatient departments, 21.8 public health care facilities, 12.7% private pharmacies/drug stores, and 7.3% communities. Education intervention was 27.3% with group discussion having 19.2% mean reduction in AB use, 27.6% in AB prescription, and 41% belief of no AB use. Community training had 30.5% reduction in AB use, 23.8% mean reduction in AB prescription, and 36% belief of no AB use. Managerial was 20% with 8% improvement in AB dose, 8–100% AB use adherence and 31.8% mean reduction of AB receipt, 29.1% change of AB in resistance cases and 9.8-100% reduction in prophylactic AB use. Managerial/education was 3.6% with 4.7% reduction in AB prescription. Regulatory was 9.1% with 60.5% improvement in AB use in restriction unlike 16.4% in non-restriction. Education/regulation were 9.1% with 8% reduction in nonindicated AB, 24% improved AB use rate, 14% mean appropriate AB use improvement, 11.1% reduction of incidence of bacterial resistance, 75.1% reduction in AB use in diarrhea, 42.4% reduction in scabies, 13.8–33.6% reduction in AB use in acute respiratory infection, and overall 60% reduction in AB use. Diagnostic was 3.6% with 68% reduction in AB use after test as compared to 100% control. There was 73% likelihood of AB use in positive results as compared to 87% in negative. Multifaceted were 27.3% with 63% improvement in appropriate doses prescribed, 2.6 mean number of AB encounter reduction, 23% AB prescription reduction, 18.3% generic prescribing improvement, 32.1% reduction in AB use, 89% reduction in AB use in acute respiratory infection, 82% in surgery, 62.7% mean reduction in deliveries, 39% in STDs, 36.3% mean reduction in diarrhea, 14.6% mean reduction in

malaria, and 6–11% in the cost of treating bacteria-resistant organisms. Also noted was 6.3 reductions in mean AB encounters after 1 month of intervention, then increased to 7.7 after 3 months, lacking sustainability.

Conclusion: Multifaceted interventions are effective in reducing misuse and inappropriate use of AB drugs and emergence of resistance to the commonest bacteria in the developing countries though they lack sustainability.

Funding Source: Information not provided

**924**

### **Policy, Regulation, and Governance**

*Keywords:* ethics, good governance, legislation, pharmaceutical policy, promotion

#### **Draft South African Marketing Code—A New Model for Marketing Ethics**

**Kirti Narsai**

PIASA, South Africa

**Problem Statement:** Pharmaceutical marketing has long been criticised both in the media and in medical communities in many countries, and developing countries are no exception. The pharmaceutical industry has responded by focusing on ethical marketing practices and making this core to the way they do business. This has resulted in the development of marketing codes both at industry and company levels. In South Africa, a broader focus has emerged bringing together stakeholders from different parts of the health sector, not only pharmaceuticals.

**Objective:** To share South Africa's model, as proposed, in the draft South African Code, which has a broader focus than just pharmaceuticals. The development of the Code has been driven by industry associations in South Africa representing pharmaceuticals (prescription, OTC and generics), medical devices, diagnostics and animal health products. Logistics service providers and pharmaceutical professionals society have endorsed the Code.

**Design:** The SA Code consists of the following parts: Part A—Marketing and promotion of health products to healthcare professional; Part B—Marketing and Promotion of health products directly to the consumer; Part C—Medical Devices; and Part D—Provision for the enforcement of the Code.

**Policy:** The Medicines Act, which regulates medicines in South Africa, makes provision for a marketing code. The industry was tasked with developing the code as well as establishing a Marketing Code Authority for the enforcement of the Code. Sanctions have been developed after careful analysis of international best practice, in both developed and developing markets. The sanctions will be applied for breaches of the Code by the Marketing Code Authority.

**Methods:** The methodology used in establishing the code and sanctions has been through detailed analysis of existing codes of practice in approximately 13 countries, both developing and developed. The task team then extracted the most appropriate aspects to developing the standards. This was debated extensively to gain consensus amongst all stakeholders.

**Outcome Measure:** It is expected that initially there might be an increase in the number of complaints, though not all valid, with companies testing the new system followed by a decline in complaints, once a code use has been embedded in the industry. A pilot phase of implementation, including intensive training of relevant staff across organisations, has already begun. The Marketing Code Authority, managed by an executive officer, has also been established after an memorandum of understanding was signed by all associations.

**Conclusion:** The health products industry has an important role to play in both business and society. In countries like South Africa, where the target audience for marketing activities is small, it is important that common standards of practice are used because of overlap in marketing and promotional activities. Therefore, collaboration amongst different industry stakeholders is important in establishing standards, even though the time to gain consensus might be significantly longer. The benefits of collaboration outweigh the increase in implementation time.

Funding Source: PIASA

**926**

### **Drug Resistance**

*Keywords:* drug resistance, policy analysis, Thailand, comprehensive networking campaign

#### **Antibiotic Resistance Policy in Thailand: Role of Comprehensive Networking Campaign**

**Niyada Kiatying-Angsulee<sup>1,2</sup>, Yupadee Sirisinsuk<sup>2,3</sup>**

<sup>1</sup>Social Research Institute, Chulalongkorn University, Thailand; <sup>2</sup>Drug System Monitoring and Development Program, Chulalongkorn University, Thailand; <sup>3</sup>Social Pharmacy Research Unit, Chulalongkorn University, Thailand

**Problem Statement:** Antibiotic resistance (ABR) has reached alarming levels as the consequence of many factors. Overuse and irrational use were observed at institutional and community levels. Antibiotics were available freely in the villages. While consumers perceived antibiotics as a magic bullet and health care providers seemed unaware of ABR, there has not been a real national antibiotic policy to combat the problem. Recently, however, there has been a comprehensive movement to lift an ABR policy to the national agenda.

**Objectives:** To elaborate roles of a comprehensive networking campaign as a model in analyzing ABR policy process.

**Design:** Analytical qualitative policy study

**Setting:** All levels of areas involving in an ABR policy

**Study Population:** All stakeholders within the ABR policy arena in Thailand

**Policy Change:** National ABR policy

Outcome measures: Policy formulation and implementation process and campaign strategy analyses

Results: The first and second National Drug Policy announced in 1981 and 1993, respectively, did not contain any phrase regarding ABR which emphasized unawareness of developing an ABR policy. The first ABR policy, seen in 1987, was drafted by academia without any direct implications. Different organizations implemented selected policies such as drug use evaluation of certain classes of essential drug list including antibiotics and the pay for performance policy of national health security office (NHSO) to include rational use of antibiotics in hospital. The latest ABR policy was included in the overall seven strategies on rational use of medicines, which aims to tackle ABR both in human and animals. The policy climate was encouraging because of a comprehensive networking campaign during these years. Activities ranged from meeting with key policy makers, academic workshops at different levels, scale-up of activities in health care institutions, a public awareness campaign, and education in schools. Positive support for the policy was shown by dedicated professional groups, national health insurance payers, accrediting bodies, nongovernmental organizations, the media, and international support. The Drug System Monitoring and Development Program is one catalyst of the process with clear focus, good networking, and resources. ABR policy efforts, however, were hindered by industry, distributors, regulatory enforcement, and pharmacists at drugstores. Next step is to monitor the implementation process and evaluate the impact on ABR and rational use to maintain sustainability.

Conclusions: Comprehensive campaign and academic activities via networking among all relevant stakeholders can bring success to policy formulation against antibiotic resistance. Still, more needs to be done on policy implementation at different levels.

Funding source: Thai Health Promotion Foundation, ReAct, and World Health Organization

**929**

#### Access

*Keywords:* appropriate use, essential medicines, standard treatment guidelines, primary health care, health workers

### **The Use of Medicines and Standard Treatment Guidelines in Rural Timor-Leste**

**Michiyo Higuchi<sup>1,2</sup>, Junko Okumura<sup>3</sup>, Asuko Aoyama<sup>2</sup>, Sri Suryawati<sup>4</sup>, John Porter<sup>1</sup>**

<sup>1</sup>London School of Hygiene & Tropical Medicine, UK; <sup>2</sup>Nagoya University School of Medicine, Japan; <sup>3</sup>Institute of Tropical Medicine, Nagasaki University, Japan; <sup>4</sup>Faculty of Medicine, Gadjah Mada University, Indonesia

Problem Statement: Appropriate use of medicines and treatment of common diseases are critical in resource-limited settings.

Objectives: The aim of this study was to investigate the use of medicines and adherence to standard treatment guidelines (STGs) in community health centres (CHCs) in Timor-Leste. Factors that influence the utilisation of the STGs were then analysed.

Design: Mixed methods research was employed.

Setting: Targeted CHCs are categorized as subdistrict CHCs under the Ministry of Health (MoH). Those in the enclave and the capital were excluded. When the data were collected from February to August 2006, there were no inpatient facilities and no laboratory equipment in these CHCs, and the majority of the posted health professionals were nurses and midwives who had graduated from a nursing high school with/without 1-year midwifery education.

Study Population: In 20 randomly sampled CHCs, 1,799 cases were collected from patient registration books in 2005 and 583 cases were directly observed for quantitative analysis. Furthermore, individual interviews for qualitative analysis were conducted with 55 nurses/midwives identified in the 20 selected CHCs.

Outcome Measures: (1) The INRUD/WHO indicators were used to assess the use of medicines. (2) Adherence to STGs was examined on the basis of selected guidelines published by the MoH. (3) Nurses'/midwives' knowledge of and attitudes toward STGs were qualitatively analysed based on in-depth interviews.

Results: Very few injections, 0.4% or 0.3% of all encounters, were used in the CHCs. Of 32 prescribers, those with clinical nurse training prescribed significantly fewer antibiotics than those without such training ( $P < 0.01$ ). The adjusted odds ratio of prescribing adherence for clinical nurse training, after accounting for confounders and prescriber clustering, was 6.6 (95% CI: 2.5–17.6;  $P < 0.01$ ). Qualitative analysis revealed that the respondents believed that they "should" follow the STGs. This feeling arose from their self-awareness as frontline health professionals and as local government workers. Self-confidence was more clearly identified in the clinical nurse interviews. The changes brought about by the introduction of STGs were positively perceived by respondents and few difficulties in using STGs were indicated.

Conclusions: Clinical nurse training positively influenced prescribing attitudes and practice. The STGs' understandable and manageable contents led to the nurses'/midwives' acceptance of the policy changes which introduced the STGs and consequent changes in daily practice, and further, resulted in their positive perception of these changes. Development of STGs in a health policy framework was considered a key factor to interconnect related policies and programmes. When appropriately developed and introduced, comprehensive STGs for non-physician health professionals at the PHC level have potential value in delivering basic health care in resource-limited communities.

Funding Source: The Takagi Fund for Citizen Science, the Dr. Gordon Smith Travelling Scholarship, and the Toyota Foundation

**930**

#### HIV/AIDS and TB

*Keywords:* ART, Treatment literacy, Adherence, Audiovisual materials, Namibia

## The Namibia Treatment Literacy Approach: Empowering Patients with Knowledge on Antiretroviral Therapy through Audiovisual Materials

**Francis Kalemeera<sup>1</sup>, Jennie Lates<sup>1</sup>, Johannes Gaeseb<sup>1</sup>, Evans Sagwa<sup>2</sup>, David Mbirizi<sup>2</sup>, Assegid Mengistu<sup>1</sup>, Elena Moreno<sup>1</sup>, Emmy-Else Hango<sup>3</sup>, Francina Tjituka<sup>1</sup>, Meghan Majorowski<sup>4</sup>, Rebecca Oser<sup>4</sup>**

<sup>1</sup>Ministry of Health and Social Services; <sup>2</sup>Management Sciences for Health; <sup>3</sup>Catholic Health Services; <sup>4</sup>Broad Reach Health Care

**Problem Statement:** Namibia's rapid scale-up of antiretroviral therapy (ART) that began in 2004 led to a steep rise in the number of HIV infected patients being initiated on ART. By early 2008, there was no standardized approach for empowering patients on their lifelong ART. As an intervention, the Treatment Literacy Approach (TLA) was proposed, since ART-educated patients are more likely to adhere to long-term treatment.

**Objectives:** Evaluate the effectiveness of the TLA in empowering patients on ART knowledge and the efficiency of the TLA in terms of time spent on educating HIV infected patients on ongoing ART

**Design:** Post-test with control group

**Setting:** Public sector ART facilities (6 pilot and 5 control)

**Study Population:** Patients who started ART from October 2009 to May 2010 at the selected sites

**Intervention:** Health worker-facilitated counseling sessions using the TLA. The TLA consists of a pictorial story-telling flip chart, videos featuring selected ART-experienced patients, and posters. The flipchart covers key areas such as disclosure, starting ART, adherence, and alcohol use. The videos are recordings of patients' testimonies on (1) preparing to start ART, (2) starting ART, (3) alcohol and ART, and (4) long-term adherence to ART. The posters are images used to emphasize the messages in the flip chart and videos. Patients responded to a structured questionnaire: 181 patients from pilot sites and 93 from control sites. The questionnaire was used to get information from leader(s) at the sites. Information on number of patients starting ART; time spent counseling patients per month, etc., was abstracted.

**Outcome Measures:** (1) Patient knowledge, (2) time spent per patient counseling new and ongoing ART patients, and (3) patient-reported adherence

**Results:** Pilot site patients scored higher than the control site patients in 27 out of 36 knowledge questions. The mean knowledge score was higher for patients at pilot sites than for patients at the control sites: 85% (30.4/36) vs. 79% (28.4/36), P value = 0.0002. Further, the pilot sites spent less time on pre-ART education than control sites per ongoing ART patient (2.3 minutes vs. 9.7 minutes). A lower proportion of patients (11.7% vs. 20.7%, P value = 0.251) missed doses at pilot sites than at control sites. While the majority of patients at the pilot and control sites cited staff friendliness as reason for their happiness with the ART services; patients at the pilot sites also cited good education materials. The staff at the pilot sites said that the TLA had broader coverage of key themes than the tools they used prior to the TLA.

**Conclusions:** The TLA is effective in empowering patients with knowledge and it improves efficiency in time spent on educating patients. The TLA may be associated with a lower proportion of patients missing doses of ARVs. The TLA needs strengthening especially in the areas where the control sites outperformed the pilot sites.

**Funding Source:** Information not available

932

### Chronic Care

*Keywords:* pharmaceutical policy, access to medicines, adherence to treatment, provision of medicines

## Remedies at Home: Evaluating an Innovative Medicines Provision Program

**Vera Lucia Luiza<sup>1</sup>, Rondinelli Mendes Silva<sup>2</sup>, Angela Esher<sup>1</sup>, Fernando Avelar<sup>1</sup>, Samara Ramalho Matta<sup>1</sup>, Rocha Claudia Rocha<sup>2</sup>, Ranieri Camuzi<sup>3</sup>, Egléubia Oliveira<sup>4</sup>**

<sup>1</sup>NAF/ENSP/Fiocruz, Brazil; <sup>2</sup>SMS DC- RJ; <sup>3</sup>FF/UFRJ; <sup>4</sup>UFRJ

**Problem Statement:** Aiming to improve access to hypertension (HT) and diabetes (DM) treatment, and improve health care and enhance the information system, the municipality of Rio de Janeiro, Brazil, in 2002, implemented a public medicines provision program for HT and DM patients that delivered, free of charge, medicines directly to the patients' homes. This program is named "Remedies at home" (Remédio em Casa or RECASA)

**Objectives:** Evaluate the RECASA program by considering aspects of structure, activities, and results.

**Design:** A cross-sectional survey was conducted. Data collection methods included interviews with managers and health professionals, observation of storage conditions, and medical records review. A household survey was also conducted. Indicators were related to financing, human resources, health care, dispensation, adherence to treatment, and patient satisfaction.

**Setting:** Municipality of Rio de Janeiro, Brazil (about 6 million inhabitants)

**Study Population:** All 88 health facilities operating the program were visited. A representative (10%) random sample of 580 patients were surveyed at household level.

**Outcome Measure(s):** Adequacy of structure and process. Outcome approach included patient satisfaction and adherence to treatment.

**Results:** The program was structured to establish a specific central distribution facility where prescriptions were prepared for delivery. RECASA was given a specific budget, access to an information system, and limited human resources. Not all procedures were adequately standardized and clearly communicated to professionals involved.

There were also inconsistencies between information entered in the computerized system and medical records. Most of patients (91.6%) declared to be satisfied with RECASA but only 1% were found to be totally adherent according to Martín-Bayarre-Grau scale.

Conclusions: Some good results were achieved as a structure was established to operate the program and to provide patient satisfaction. However, the program implementation was not successful due to the major challenge of operating the program in a city with 6.2 million inhabitants; in addition, city violence caused problems with the program's outreach.

Funding Source: Rio de Janeiro Foundation for Supporting Research (FAPERJ)

933

### **Economics, Financing, and Insurance Systems**

*Keywords:* Access to medicines, availability, affordability, medicine prices, policy

#### **Monitoring Medicine Prices and Availability in Kenya Using WHO/HAI Methodology 2009–2010**

**Christina Anna Cepuch<sup>1</sup>, Regina Mbindyo<sup>2</sup>, Fred Moin Siyoi<sup>3</sup>, Njeri Mucheru<sup>4</sup>, Joanne Wakori<sup>5</sup>**

<sup>1</sup>HAI Africa, Kenya; <sup>2</sup>WHO Kenya Country Office; <sup>3</sup>Pharmacy and Poisons Board, Kenya; <sup>4</sup>Ministry of Medical Services, Kenya; <sup>5</sup>Kenya Medical Supplies Agency

**Problem Statement:** Access to essential medicines (EMs) is a goal for Kenya's health system. Price is a barrier to access especially in developing countries and where significant out-of-pocket spending occurs. Monitoring EM prices and availability (MMePA) gives evidence for policy development and strategic planning on pricing. Collaborative MMePA is carried out quarterly in Kenya.

**Objectives:** To document availability and price of EMs in the public, private, and faith-based health (FBH) sectors. To monitor affordability of treatment for ordinary Kenyans. To monitor procurement prices in public sector and compare them to international reference prices.

**Design:** Time series study; adapted WHO/HAI medicine price survey methodology

**Setting:** National monitoring in public, private, and FBH sectors in four provinces. Monitoring sites: hospitals, health centers, dispensaries, central warehouses, retail pharmacies

**Study Population:** 96 facilities (32 per sector) and 26 EMs in 2009/2010.

**Policy Change:** MMePA results used in the ongoing review of National Drug Policy 1994. Health SWAp implemented within the second Health Sector Strategic Plan. Some increase in medicines financing from government and donors. MMePA results are basis of innovative civil society Stop Stock-Outs campaign.

**Outcome Measures:** Availability, price, medicines for free, affordability

**Results:** Selected results for public, private, and FBH sectors: (1) median availability of EMs—69, 69, 80; (2) median price ratios for centralized procurement (public, FBH sector) —0.44, 0.61; (3) Percentage medicines issued for free—89, 15, 0; and (4) affordability of selected individual treatments: <1day's reference wage.

**Conclusions:** Low and fluctuant availability of EMs especially in public and FBH sector facilities. Price efficient public and FBH sector centralized procurement. Low or no price barriers to accessing EMs in public sector. MMePA not integrated within health sector monitoring and evaluation framework.

**Funding Sources:** DFID-supported WHO/HAI Collaboration Project on Access to Essential Medicines and Directorate-General for International Cooperation, Netherlands through HAI Global

934

### **Policy, Regulation, and Governance**

*Keywords:* Transparency assessment, Governance, framework, policies, evaluation

#### **Active Enforcement to Code of Conduct and Conflict of Interest Policies Based on Transparency Assessment Study in Jordan**

**Sana Naffa, Adi Nseirat**

World Health Organization, Jordan

**Problem Statement:** Transparency assessment survey showed that there are different levels of vulnerability to corruption, these levels are classified into; minimally vulnerable, marginal, moderate, very and extremely vulnerable, in six key functions in the pharmaceutical sector.

**Objectives:** To assess the level of transparency and potential vulnerability to corruption of six essential functions in the pharmaceutical sector; and to develop a framework for improving the good governance in medicine practices within pharmaceutical sector.

**Study Design:** The assessment instrument contains three questionnaires, one for each function. Each questionnaire is used with key informants selected according to explicit criteria. Sixty-one key informants were selected.

**Results:** (1) Registration: 7.52—marginally; (2) promotion 1.88 —extremely; (3) inspection 5.79—moderately; (4) selection 7.71—marginally; (5) procurement 8.59—minimally; distribution 8.41—minimally. The total was 6.65—marginally.

**Interventions:** A national workshop was conducted. Two committees have been formed by ministerial decree—a task force to follow up on study findings and recommendations leading to developing a framework for implementing and socializing the framework; and a steering committee to approve and set policies for reform in the pharmaceutical sector.

A national Framework for Good Governance in Medicine was developed to activate the integrity system, which includes a code of conduct, policies on conflict of interest, whistle blowing mechanisms, sanctions, and reprehensible acts. Information on the framework was distributed through a national workshop. The Code of Ethics and conduct was enforced in the civil servants practice. Conflict of interest policy and contest was enforced in all committees working at Jordan Food and Drug Administration. Guidelines regarding medicine promotion control have been issued. Other laws and guidelines are now under revision.

Outcome Measures: Improve performance in transparency in six functional areas in the ph. sector. In medicine registration, the clear written criteria for selecting members of the committee scored 0.6 in the baseline assessment but was raised to 0.83; in the terms of reference for the committee was raised from 0.62 to 0.88. In inspection and market control, the baseline was 0.83 in 2007 and increased to 1.0 in 2010. In promotion control, the provision on medicine promotion and advertising included explicit mention of the different forms of promotion increased from 0.4 in 2007 to 0.9 in 2010 and the provision foresaw an enforcement mechanism stating sanctions, increased from 0.2 in 2007 to 1.0 in 2010. In selection of medicines, use of clear criteria for selection of members of the selection committee increased from 0.53 in 2007 to 0.86 in 2010.

Conclusions: The transparency assessment survey set the guidelines and a baseline for measuring six key functions in the pharmaceutical sector. Sector. Follow up on these measurable indicators in the assessment tool showed remarkable improvement in performance; setting the stage for new guidelines, policies, and reform.

Funding source: WHO

941

#### Chronic Care

*Keywords:* affordability, chronic disease, retail pharmacy, medicine prices, essential medicines

### Prices of Antihypertensive Medicines in Sub-Saharan Africa and Alignment to World Health Organization's Model List of Essential Medicines

**Marc Twagirimukiza<sup>1</sup>, Lieven Annemans<sup>2</sup>, Jan Kips<sup>3</sup>, Emile Bienvenu<sup>4</sup>, Luc M. Van Bortel<sup>5</sup>**

<sup>1</sup>Heymans Institute of Pharmacology and Department of Family Medicine and Primary Health Care, Ghent University, Belgium; <sup>2</sup>Center for Health Economics, Department of Public Health, Ghent University, Belgium; <sup>3</sup>Heymans Institute of Pharmacology, Ghent University, Belgium; <sup>4</sup>Department of Pharmacy, Faculty of Medicine, National University of Rwanda and PhD Fellow - Department of Pharmacology Sahlgrenska Academy at the University of Gothenburg; <sup>5</sup>Heymans Institute of Pharmacology, Ghent University, Belgium

**Problem Statement:** Based on the World Health Organization (WHO) Model List of Essential Medicines (EML), most sub-Saharan Africa (SSA) countries have nowadays elaborated a National List of Essential Medicines. Those national lists standardizes hypertension management and aims to increase accessibility of care in most of sub-Saharan African countries, where drugs are not subsidized through social insurance.

**Objective:** To investigate compliance of existing (15th edition, March 2007) National EML with the WHO/EML and to compare prices of antihypertensive drugs in and between 13 SSA countries.

**Methodology:** All hypertension medicines advocated by the WHO/EML 15th edition 26 were surveyed: amlodipine, atenolol, enalapril, hydralazine, hydrochlorothiazide, and methyldopa. In addition, this survey included also advocated use of captopril and nifedipine—drugs from previous editions (12th-14th WHO/EML) which were still used in more than half of the sampled countries. Data on NEMs and drug prices were collected from the Ministry of Health or National Pharmaceutical Office of 13 SSAs: Rwanda, Burundi, Tanzania, Uganda, DRC, Kenya, Cameroon, Congo, Gabon, Ivory Coast, Senegal, Niger, and Mozambique. Prices were compared with the International Drug Price Indicator Guide (IDPIG, 2007). The cost of drug treatment within a country was calculated using defined daily doses (DDD) and between countries using DDD prices adjusted for purchasing power parity-based gross domestic product per capita.

**Results:** The WHO/EML advises four antihypertensive drugs from a different class: hydrochlorothiazide, atenolol, enalapril, and amlodipine. However, no one has the 4 advocated drugs, but 11/13 have a drug in all 4 drug classes. All surveyed countries had a national EML. However, none of these lists was in complete alignment with the 2007 WHO/EML, and 38% had not been updated in the last 5 years. Surveyed medicines were cheaper when on the national EMLs; they were also cheaper in public than in private pharmacies. Prices varied greatly per medicine. A large majority of the public prices were higher than those indicated by the IDPIG. Overall, hydrochlorothiazide is the cheapest drug.

**Conclusion:** There are substantial differences in national EML composition between the 13 SSA countries. The proportion of national EMLs not regularly updated was double the global UN estimates. Prices of WHO/EML advised drugs differ largely between drugs and for each drug within and between countries. In general, the use of drugs on the national EML improves financial accessibility and these drugs should be prescribed preferentially. Since hydrochlorothiazide is the cheapest drug, it should be the first drug to be considered.

**Funding Source:** This study was sponsored by (1) the Flemish Interuniversity Council (VLIR-Vlaamse Interuniversitaire Raad) through Own Initiative Project; (2) Laboratory of Pharmaceutical Technology (of the faculty of pharmaceutical sciences at Ghent University; and (3) the Heymans institute of pharmacology, Ghent University.

942

#### HIV/AIDS and TB

*Keywords:* HIV, antiretroviral therapy, adherence, mobile phones, India

### Supporting Adherence to Antiretroviral Therapy Using Mobile Phone Reminders In South India

**Rashmi Rodrigues<sup>1,2</sup>, Jimmy Antony<sup>1</sup>, Kristy Sydney<sup>2</sup>, Karthika Arumugam<sup>1</sup>, K Shuba<sup>1</sup>, George D'Souza<sup>1</sup>, Ayesha DeCosta<sup>1,2</sup>, Anita Shet<sup>1,2</sup>**

<sup>1</sup>St Johns National Academy of Health Sciences, India; <sup>2</sup>Division of Global Health, Karolinska Institutet, Stockholm, Sweden

**Problem statement:** The success of antiretroviral therapy (ART) is compromised by poor adherence leading to resistance and treatment failure. In India, 0.3 million HIV-positive patients are on ART and up to 40% are reported not to be optimally adherent to treatment. Therefore, interventions that are contextually feasible to promote adherence are necessary to prevent resistance and prolong life. Given the ubiquity of mobile phones in India, mobile phone based interventions for improving adherence hold promise.

**Objective:** (1) To test the hypothesis that mobile phone reminders improve adherence to medication in HIV-positive patients on ART, (2) To assess participant experiences with the intervention over a period of 6 months.

**Study Design and Sample:** Quasi-experimental time series design involving 150 HIV positive patients aged 18–60years who have been on ART for at least one month and have a mobile phone.

**Study Setting:** The infectious disease clinic, St. John's National Academy of Health Sciences from April to November 2010.

**Intervention:** All participants received two types of adherence reminders on their mobile phones, i.e., an automated interactive voice call (IVR) and a non-interactive neutral picture short message service (SMS) once a week for 6months. Participants adherence was assessed at baseline followed by months 1, 3, 6, 9, and 12 using the pill count. All participants were trained to receive the IVRs and SMS. Adequate adherence was defined as an adherence rate  $\geq$ 95%. An interviewer administered questionnaire assessed participant experiences at week 24.

**Outcome Measure:** Change in adherence over time during the intervention, sustainability of this effect for 6months post intervention and participant experiences at the end of the intervention period. Statistical analysis involved frequencies, measures of central tendency and dispersion, Wilcoxon signed rank test, and Cochran's Q.

**Results:** The mean age of the participants was  $39\pm 7.7$  yrs, 27% were female and 90% urban. The median duration of ART was 65 weeks. Over the 24-week period, 4,103 IVRs and 3,073 SMSs were sent to the 150 participants. Of the IVRs, 87% were accessed by the participants while 59% of the participants reported viewing the SMSs at least once in the 6th month of the intervention. The proportion of participants adequately adherent to medication was 86%, 93%, 94%, 92%, 95%, 94% at baseline, months 1, 3, 6, 9, and 12, respectively ( $p=0.001$ ). At the end of 6 months, 74% of the participants preferred voice calls with or without the SMS, 10% preferred only the SMS and 16% preferred neither. The IVR was considered more helpful than the SMS ( $p<0.001$ ). Both components of the intervention were not perceived as intrusive by the participants ( $p>0.05$ ).

**Conclusion:** Mobile phone reminders were found acceptable for adherence support in the context of HIV in South India. Interactive voice calls were preferred over SMSs. The proportion of participants adherent to medication increased during the study. Improvement in adherence persisted even after the cessation of the intervention.

**Funding Source:** EU-FP 7, HIVIND grant

944

#### **Economics, Financing, and Insurance Systems**

*Keywords:* access to medicines, financing, health economics

#### **East African Health Budgets 2010/2011: An Analysis on Financing for Essential Medicines**

**Christina Anna Cepuch<sup>1</sup>, Thomas Maina<sup>2</sup>**

<sup>1</sup>HAI Africa, Kenya; <sup>2</sup>Health Economist, Kenya

**Problem Statement:** Access to essential medicines (EMs) is a goal for all the health systems in the East Africa Community (EAC). Insufficient financing is a barrier to access. Monitoring and tracking of national budget allocations to health and EMs provides evidence for advocacy surrounding government prioritization, expenditure tracking, and participation in the budget-making process.

**Objectives:** To analyze the national budgets of four East African countries to identify and determine the overall budget allocations to the public health sector. To understand the broad and specific budget lines where the allocations on health relate to current and development spending. To examine the allocations to EMs and to treating specific diseases. To identify other resources outside the budget that relate to the health sector such as health-related economic stimulus packages and complimentary donor resources.

**Design:** Economic analysis

**Setting:** Four EAC countries—Kenya, Rwanda, Tanzania, Uganda. Health policy strategic plans and priorities. Macroeconomic settings. 2010/11 budget estimates reviewed and compared with 2009/10 estimates. Analyses of budgets by recurrence and development and by economic categories with a focus on EMs.

**Study Population:** National health budgets of Kenya, Rwanda, Tanzania, Uganda.

**Policy Change:** Budgetary allocations for health and medicines were evaluated based on the same stated priorities in national budgets, future vision documents (e.g., Vision 2030), and strategic plans.

**Outcome Measure:** Budget allocations to health and essential medicines.

**Results:** For Kenya: from 2009/10 to 2010/11, total government budget for health increased by 19.3% but decreased (by 0.6%) in terms of percentage to health from total government budget. Expenditure on medicines remains low (8.8% of total MOH recurrent budget) and is decreasing over time. Significant shift of resources from recurrent budget to

development budget. Rising share for primary health. Significant development partner funds are off-budget. Medicines dropped from economic stimulus package funding. Per capita expenditure on medicines 1.37 US dollars. We found similar findings for Rwanda, Tanzania, and Uganda.

Conclusions: Insufficient (and decreasing) budgetary allocations for essential medicines from national and health budget. Decreasing expenditure on health as a percentage of government budgets. Low financing for EMs is a major barrier to access.

Funding Source: Children's Investment Fund Foundation (CIFF) through the Campaign to End Paediatric AIDS (CEPA) and Open Society Institute (OSI) through the Stop Stock-outs Campaign (SSO)

**946**

#### **HIV/AIDS and TB**

*Keywords:* TB suspects, private pharmacies, Egypt

#### **Role of Private Pharmacies in TB Control in Egypt**

**Sherry Victor Michael, Magdy Fawzy Boktor**

Ministry of Health, National TB Control Program, Egypt

**Problem Statement:** Egypt has a significant private health care sector with over 50% of all utilization and expenditure on health care occurring in the private sector. This study is aiming at investigating the current pattern of anti-tuberculosis drug use in the private pharmacies in Egypt, the prescribing practices of the physicians referring their cases to the private pharmacies for purchasing the drugs, and the feasibility of engaging the private pharmacists in identifying TB suspects and their referral to the nearest TB medical unit (MU) for diagnosis. A cross-sectional survey was conducted whereby pharmacists/pharmacists assistants in a representative sample of private pharmacies were interviewed using a questionnaire.

**Objectives:** (1) To describe the current pattern of anti-TB drug use in the private pharmacies in Egypt; (2) to determine the proportion of private pharmacies those have anti-TB treatment (ATT) in different geographical areas; (3) to evaluate the prescribing practices of the physicians referring their cases to the private pharmacies for purchasing the drugs; (4) to evaluate the knowledge, attitudes and practices of the private pharmacists towards TB; (5) to evaluate the case load of TB suspects and patients that purchase ATT from the private pharmacies; (6) to evaluate the feasibility of engaging the private pharmacists in identifying TB suspects and their referral to the nearest TB MU for diagnosis.

**Setting and Study Population:** The study was carried out in a representative sample of all Egyptian governorates. A representative sample of private pharmacies in the country was included in the study. The estimated sample size  $n$  is calculated, using simple Gaussian theory eligibility criteria. Private pharmacists and/or other personnel working in the pharmacies were enrolled according to the following inclusion criteria—pharmacies that have been open for at least three months whether registered or not which consented to participate in the study. Exclusion criteria was those pharmacies that had been open for at least three months but did not consent to participate in the study.

Funding Source: Global Fund to Fight Against AIDS, Tuberculosis and Malaria

**947**

#### **Economics, Financing, and Insurance Systems**

*Keywords:* cost containment, health reform, pharmaceutical expenditure, pharmaceutical policy, prescribing

#### **Study on the Effect of Zero Mark-up Policy on Medicines in Beijing Community Health Facilities**

**WEI CHENG<sup>1</sup>, YUNYUN FANG<sup>1</sup>, DEHUI FAN<sup>1</sup>, JING SUN<sup>2</sup>, XUEFENG SHI<sup>1</sup>, JIAO LI<sup>1</sup>**

<sup>1</sup>Beijing University of Chinese Medicine, P.R.China; <sup>2</sup>National Institute of Hospital Administration, MoH, P.R.China

**Problem Statement:** A mark-up policy on medicines in Chinese public health facilities was originally set to supplement government subsidies, however, has evolved into a perverse incentive for preference of expensive medicines and over prescribing, and a driver for the soaring medicine costs. The government decided to remove the mark-up on medicines in public facilities (starting with community health centers [CHC]) to contain medicine costs. A zero mark-up policy (ZMP) was firstly implemented in Beijing, associated with different government subsidy approaches (GSA).

**Objectives:** This study analyzes the effects of the policy, expects to see if it contained the medicines cost, and how it affected the operation of the CHCs and staff moral. The study also explores which GSA is more effective in helping achieve the objective.

**Design:** The effect is measured in time series before and three years after the reform, and compared with different GSAs.

**Setting:** The study was conducted in the public CHCs in Beijing.

**Study Population:** All 351 public CHCs in 18 districts were divided into 3 groups according to GSA. 20% of the total number of CHCs with the same GSA in each district were randomly selected as sample CHC. A total of 70 CHCs was sampled and distributed in three GSA groups: 17, 42, 11 CHCs in fixed subsidy (FS), income-linked subsidy (IS), and government purchase services of providing "zero mark-up medicines (ZMMs) (GPS) groups respectively.

**Policy:** The government developed a list of medicines based on the national essential medicines list and required CHCs to procure these medicines via government pooled tendering and to dispense them at the procurement price. Government subsidy was allocated based on FS, IS, and GPS approaches.

**Outcome Measure:** The effect is measured with the changes of proportion of ZMMs to total medicines cost per visit, medicines cost per visit, government subsidy, medicines and medical income as a proportion to the total revenue; and

annual staff salary. Data were directly obtained from the clinical database of the 70 sample CHCs. Statistical analysis was done using the SPSS<sup>®</sup>17.0 software.

Results: Until the end of 2009, the proportion of ZMMs to total medicines cost per visit achieved 75.4%, 57.8%, and 52.6% in FS, IS, and GPS facilities. The medicines cost per visit in FS and IS facilities reduced 18.7% and 1.9% by the end of 2007 ( $P=0.001$ ,  $\alpha=0.05$ , t test), and rebounded in 2008 and 2009. There was a significant difference between the reductions ( $P=0.016$ ,  $\alpha=0.05$ , t test). The medicines cost per visit in GPS facilities increased 25.2% by the end of 2007, and kept growing in 2008 and 2009. The proportion of government subsidy to the total revenue grew the fastest in FS facilities. GPS facilities grew the slowest. IS facilities were in the middle. In 2006, total revenue in GPS facilities was more than twice of that in FS facilities and continued growth during 2006-09. FS and IS facilities generated less total revenue than GPS facilities by the end of 2007, and was only about 20% and 30% of that in GPS facilities in 2009. The annual staff salary in all CHCs kept rising during 2006-09. In 2006, GPS facility salaries were the lowest; IS facility salaries were the highest; and FS facility salaries were in the middle. By the end of 2007, FS facility salaries achieved the highest; GPS facility salaries were always at the lowest level; IS facility salaries were in the middle.

Conclusions: The ZMP dose help in containing the rapid growing of medicines costs. The FS approach is more effective in reducing the financial burden of the patients than IS and GPS; it offers security for facility operation and salary scale but faces the challenges of financial sustainability, budget justifiability, and regulation capacity. The GPS approach causes lower willingness to use ZMMs. It also raises a question for other GSAs in keeping work enthusiasm high under more or less secured government subsidies. The IS approach has a mixed effect.

Funding Source: WHO

950

#### Access

Keywords: Education, Drug Utilization, Training, Adherence, Standard treatment guidelines, Primary health care

### **Use of Brief Educational Intervention and Academic Detailing to Improve Use of Antidotes for Acute Poisoned Patients in Rural Hospitals in Sri Lanka—A Cluster Randomised Controlled Trial**

**D Lalith Priyasantha Senarathna<sup>1,2</sup>, Michael Dibley<sup>1</sup>, Andrew Dawson<sup>2</sup>**

<sup>1</sup>Sydney School of Public Health, University of Sydney, Australia; <sup>2</sup>South Asian Clinical Toxicology Research Collaboration, Faculty of Medicine, University of Peradeniya, Sri Lanka

Problem statement: Improving use of evidence-based treatment guidelines for acute poisoning in rural hospitals of developing countries where poisoning is a major medical emergency is a challenge. So it is essential to find sustainable way to educate staff on clinical guidelines to promote proper use of antidotes.

Objective: The objective of this trial is to assess the effect of an outreach education program to improve treatments including proper antidote utilisation for acute poisoning patients and to improve antidote management including appropriate storage in primary care hospitals in North Central Province of Sri Lanka.

Study Design: This study was planned to deliver an educational intervention using cluster randomised controlled design. Rural primary care hospitals in the study area were considered as clusters and randomly allocated to either intervention or controlled groups.

Setting: The study setting was North Central Province of Sri Lanka with 46 primary care hospitals.

Participants: 46 primary care rural hospitals in the province were considered as clusters. All staff members in 23 intervention hospitals including doctors, nurses, and pharmacists/dispensers were participants. Following invitations, more than 75% of the staff from each hospital took part in the intervention.

Intervention: A single 2-hour interactive workshop was conducted in intervention hospitals to discuss key messages on poisoning treatments, antidote utilisation, and management based on national poisoning treatment guidelines. Wall charts and promotional items such as pens and notice boards with printed messages that referred back to the guidelines were distributed. Both interventional and controlled hospital received printed copies of the guideline.

Outcome Measures: Data was collected from patient records to assess treatments including antidote use. Antidote availability and ordering pattern details were collected using hospital records. The number of patients who received antidotes—activated charcoal, atropine, and pralidoxime—were compared between intervention and controlled hospitals.

Results: Both interventional and controlled hospitals received approximately similar number of poisoned patients during a 12-month period, 1,362 and 1,287 respectively. After 10 months, 293 (40%) of patients from intervention group had received activated charcoal comparing to 161 (25%) from control group ( $P$  value  $<0.01$ ). Further observations revealed that this pattern continued after 12 and 16 months. And also the availability of activated charcoal and pralidoxime showed an increase in interventional hospitals.

Conclusion: This study reveals that a single brief intervention supported by promotional prompts delivered within a rural hospital was effective in increasing compliance with clinical guideline and improves antidote utilisation and management. Such interventions are low cost and accessible to rural hospitals staff members.

Funding Source: This study was supported by the South Asian Clinical Toxicology Research Collaboration which is funded by the Wellcome Trust/National Health and Medical Research Council International Collaborative Research Grant GR071669MA.

953

**HIV/AIDS and TB***Keywords:* DR-TB, Egypt, anti-TB drugs**Management of Drug-Resistant Tuberculosis Patients, Egypt Experience****Magdy Fawzy Boktor, Sherry Victor Michael, Alaa Mokhtar Morsy**

Ministry of Health, National TB control program, Egypt

**Problem Statement:** Multidrug resistant tuberculosis (MDR-TB) is a global important problem represents , and among all cases (4.8%) , new (2.9%), and previously treated (15.3%). In Egypt, MDR-TB was 2.2% and 38.4% among new and retreated cases respectively.

**Objective:** To evaluate treatment outcome of the first treatment cohort and to identify factors affecting it.

**Methods:** One hundred sixty-eight MDR-TB patients were admitted to Abbassia Chest Hospital through the end of September 2008. Of these patients, , 65 completed their treatment course on an individualized regimen.

**Results:** Forty-four patients achieved successful treatment (67.7%). The proportion of failures, defaulters. and deaths were 6 (9.2%), 4 (6.2%), and 11 (16.9%) respectively. Successful treatment was associated with young age, nonsmoking, no regimen of second-line anti-TB drugs, sputum culture conversion before 3 months, and less extensive lung destruction. On multivariate analysis, independent factors were age, time to culture conversion, and extension of lung destruction.

**Conclusions:** The rate of successful treatment (67.7 %) is comparable with the average reached in other countries. The relatively high mortality rate (16.9%) mandates rapid diagnosis, treatment, and application of direct observation throughout the whole course. Age, time to culture conversion, and extension of lung lesion were independent predictors of successful treatment.

**Funding Source:** Information not available

954

**Access***Keywords:* access to medicines, drug utilization, equity**Gender and Access to Medicines in 15 Low- and Middle-Income Countries: Does Physician Prescribing for Men and Women Differ?****Peter Neil Stephens<sup>1</sup>, Dennis Ross-Degnan<sup>2</sup>, Anita Wagner<sup>2</sup>**<sup>1</sup>IMS HEALTH, United Kingdom; <sup>2</sup>Harvard Medical School and Harvard Pilgrim Health Care Institute

**Problem Statement:** Hypotheses of gender differences in access to medicines exist but information about these is lacking.

**Objectives:** To assess whether gender differences exist in access to medicines for acute (Upper respiratory infections [URI]) and chronic (diabetes, depression) diseases.

**Setting:** Private sector physicians recruited by IMS HEALTH who recorded patient age, sex, diagnoses, and medicines prescribed.

**Study Population:** Fifteen countries—1 low-income and 14 middle- income—from six regions: Americas (6); East Mediterranean (3); Europe (2); South East Asia (2); Africa (1) and Western Pacific (1). Between 2007 and 2010, 92,969 consultations for depression (median across countries: 1,758), 143,087 for diabetes (median 6,747), and 251,785 (median 17,224) for URI were included. Diabetes and depression consultations were defined by drug prescribed and physician's diagnosis, URI consultations by diagnosis only.

**Outcomes:** Gender differences by age group defined as (1) a statistical difference in the observed number of consultations for men and women for each disease compared to the expected number (estimated based on WHO estimated disability adjusted life years by cause tables); and (2) statistical differences in the observed number of prescriptions for new oral drugs used in diabetes or for medicines in URI compared to that expected from the observed visit numbers.

**Results:** A significant difference between the observed number of visits for depression and that expected was detected on 36% of 45 comparisons across countries and age groups, for diabetes on 58%, and for URI on 87%. Where a statistical difference was found, the observed number of visits was higher than expected for women on 75% of occasions for depression, on 18% occasions for diabetes, and on 44% of occasions for URIs. A statistical difference between the expected and observed number and type of prescriptions was found in fewer than 26% of comparisons made in URI and diabetes. Where a statistical difference was found in URI, the observed number was higher than expected for women twice as often as for men.

**Conclusions:** The present results suggest gender differences in access to medicines. Depending on country, disease, and age group, both women and men may have preferential access. These analyses may provide an important basis for addressing equity concerns in medicines policy decision making.

**Funding Sources:** IMS HEALTH, UK Government

955

**Policy, Regulation, and Governance***Keywords:* Governance, corruption, pharmaceutical sector, anti-corruption agency, India

## **Improving Governance in the Pharmaceutical Sector of Karnataka—the Role of an Anti-Corruption Agency and its Limitations**

**Reinhard Huss<sup>1</sup>, Hanumatappa Sudarshan<sup>2</sup>, Andrew T Green<sup>1</sup>, Sylvia S Karpagam<sup>2</sup>, Goeran Tomson<sup>3</sup>, K V Ramani<sup>4</sup>, Nancy Gerein<sup>1</sup>**

<sup>1</sup>University of Leeds, United Kingdom; <sup>2</sup>Karuna Trust, Bangalore, India; <sup>3</sup>Karolinska Institutet, Public Health Sciences, Stockholm, Sweden; <sup>4</sup>Indian Institute of Management, Centre for Management of Health Services, Ahmedabad, India

**Problem statement:** Governance is defined as the system of institutions by which a society manages its economic, political, and social affairs within the public sector and between the public and private sector. Poor governance includes misjudgement, mismanagement, and corruption. Corruption is defined as the deliberate betrayal of public trust and the undermining of the public good. During the period 2001 to 2006, the Karnataka Lokayukta (KLA), a public complaint institution for maladministration, has been effective in the detection of governance problems in the pharmaceutical sector.

**Objectives:** (1) To describe the scope of corruption, (2) examine the role of the KLA, and (3) analyse the effectiveness of KLA governance interventions in the pharmaceutical sector of Karnataka

**Design:** A participatory and opportunistic case study evaluation was chosen

**Setting:** The evaluation was conducted during a four-week period in 2006. Data was obtained by reviewing KLA documentation and case records and by semi-structured interviews with key informants, health professionals, and citizens at 3 sites of the health care sector. Study sites were selected based on accessibility and interviewees based on willingness to participate. The questionnaire was based on a typology of corruption and a modified McKinsey 7S value-based organizational framework. Transcripts of interviews were analysed by using a thematic approach.

**Study population:** The main study unit was the KLA. We conducted 2 key informant, 44 completed semi-structured, and 13 partial interviews and 4 group discussions.

**Interventions:** The evaluation included data from key informants, KLA documents, media articles, and semi-structured interviews of public servants, citizens, and representatives of stakeholder organizations.

**Outcome measures:** Perceived and reported governance changes; sanctions of key pharmaceutical personnel and public servants; and personnel and structural changes in pharmaceutical sector.

**Results:** Poor pharmaceutical governance had a broad scope, presented in different ways and at all levels of the health care system with the private sector as the corruptor. Most interviewees were aware of the situation. Two key determinants were the financial demands of the political system and the limitations of the judicial system. A change of personnel in the Drug Regulatory Authority had only limited impact, whereas a structural change of the supply system improved governance.

**Conclusions:** The KLA only became effective after a change of leadership because of its technical expertise and the power of its leaders. Governance improvement was limited because of constraints in the political and judicial system. Civil society organizations became co-producers of governance because of structural changes in pharmaceutical supply and the strengthened role of a state agency.

**Funding Source:** University of Leeds

**957**

### **Economics, Financing, and Insurance Systems**

*Keywords:* Health care financing, Out-of-pocket payment, Access to medicines, Asia

## **Challenges of Health Care Financing and Access to Medicines in Low-income Countries of Asia**

**Soonman Kwon**

Seoul National University, Korea, South (Republic of)

**Problem Statement:** This conceptual paper examines the key policy issues and challenges of health care financing related to access to medicines in low-income countries of Asia. Health care financing in low-income countries of Asia can be examined in terms of resource generation, resource pooling and purchasing/payment. Limited funding to health care has been a chronic problem, resulting in high out-of-pocket payment and limited financial protection especially for the poor. Expenditure on medicines has been a major source of out-of-pocket payment in many low-income countries of Asia.

**Objectives:** Introducing a separate financing mechanism for medicines is not efficient. Instead, health care financing needs to expand the benefit package to include medicines. This paper compares the tax and SHI (Social Health Insurance) approach in minimizing out-of-pocket payment for better access to medicines and health care. Without government subsidy, social health insurance tends to have a limited effect on the population coverage in the informal sector and the poor, who have a limited capacity to pay contribution. Traditional approaches of covering the formal sector first through social health insurance and incrementally extending it to the informal sector has not been successful in Asia, with the exception of the countries with very rapid economic development. Furthermore, fragmented health insurance system with multiple payers cannot have a financial leverage and bargaining power with respect to medical providers and pharmaceutical suppliers.

**Conclusions:** Access to medicines can be also enhanced by improving the efficiency in purchasing and payment systems for health care providers, but the role of price regulation of pharmaceuticals and the incentivizing/regulation of provider behavior in the prescribing of pharmaceuticals is very limited.

**Funding Source:** Not applicable

959

**Economics, Financing, and Insurance Systems***Keywords:* appropriate use, cost containment, health reform, pharmaceutical expenditure, pharmaceutical policy**Evaluation of the New Rural Cooperative Medical Scheme Outpatient Capitation Payment Reform in Qianjiang****Qian Qu<sup>1</sup>, Jing Sun<sup>2</sup>, Jun Kang<sup>3</sup>, Weibin Zhang<sup>1</sup>, Yongqian Tan<sup>4</sup>, Wenxian Xiang<sup>4</sup>**<sup>1</sup>Chongqing Health Bureau, P.R.China; <sup>2</sup>National Institute of Hospital Administration, MoH, P.R.China; <sup>3</sup>Chongqing Medical University, P.R.China; <sup>4</sup>Qianjiang District Health Bureau, Chongqing, P.R.China

**Problem Statement:** The funding level of New Rural Cooperative Medical Scheme (NRCMS) is low, there has been an increasing cost containment pressure for NRCMS. The fee-for-service payment and other factors created perverse incentives, which drive the irrational provider behaviours. Capitation payment reform was piloted in Qianjiang district of Chongqing (Qianjiang) with the expectations of containing the cost and rationalizing provider behaviours.

**Objectives:** To evaluate if the reform contained the cost, and rationalized the providers' behaviour, and if such changes caused health workers and facilities to lose income.

**Design:** The effect of the policy is measured with changes of cost per visit, quality of care, and income of facilities and health workers before and after the reform in Qianjiang. 4 prescription indicators help to show if medicines are rationally used; referral and hospitalization rates, and proportions of appropriate referrals show if patients are selected and shifted from outpatient to inpatient. The cost and hospitalization data of Qianjiang are compared with that of Southeast Chongqing (SEC) with similar social and economical development situations.

**Setting:** In 2009, there are 30 township/community health centers (THC/CHC) and 169 village clinics (VC) in Qianjiang. SEC covers Qianjiang and other 5 neighbour counties/districts, comprises 200 THC/CHC and 1,431 VC.

**Study Population:** The cost and hospitalization data of Qianjiang and SEC are obtained from the NRCMS management database of Chongqing and Qianjiang; the quality of care and income data in Qianjiang are collected from sample facilities (6 VC and 3 THC/CHC). The qualitative data are obtained from the key informants interviews and group discussions.

**Policy:** The capitation payment reform for NRCMS designated primary outpatient services started from two VC in July 2007 and expanded to all facilities by Jan. 2009. A performance assessment was developed as a base for payment within the annual limit, which was set to appropriately reflect the ongoing situation. No compensation to overruns and the balance could be kept by facilities.

**Outcome Measure:** Cost is measured with annual average value of all facilities of Qianjiang and compared with SEC during 2006-9. Annual median costs of all and sample facilities in Qianjiang during 2007-9 are also calculated. Both compare with the prescription caps. Quality of care and income data are collected from sample facilities. Interviews provided complementary information.

**Results:** The average costs per visit of all THC/CHC and VC in Qianjiang are at the same level with that in SEC in 2006, but much lower in 2009. The median cost per visit of all THC/CHC and sample THC/CHC in Qianjiang are both with an increasing trend during 2007-9, which are statistically significant ( $\chi^2 = 851.7614$ ,  $P < 0.0001$  and  $\chi^2 = 1078.8001$ ,  $P < 0.0001$ ). Both average and median cost of Qianjiang kept within the prescription caps during 2007-9, when costs of SEC far exceed. There are no significant changes of referral and prescription data in Qianjiang during 2007-9 ( $\chi^2$  test,  $P > 0.05$ ), except that of the proportion of essential medicines used in THC/CHC ( $\chi^2$  test,  $P < 0.05$ ). The qualitative interviews and group discussions show, doctors are more likely to adopt less costly alternative treatments, and are more willing to provide outreach services for preventive care. There are no significant differences between the average hospitalization rates of sample THC/CHC of Qianjiang and SEC in 2006 and 2009 ( $\chi^2$  test,  $P > 0.05$ ). The monthly income of the health workers and the outpatient revenue of facilities in Qianjiang keep growing during 2007-9. There are no overruns in all the sample facilities in Qianjiang.

**Conclusions:** The cost containment objective is achieved. Provider behaviours are partially improved but with limited affect on prescriptions. Careful consideration of supporting policies is critical to address the unexpected side effects of the reform. The reform does not bring financial loss to both the facilities and the individuals, but creates incentive for less costly alternative treatments and more attention to prevention.

**Funding Source:** WHO

961

**Policy, Regulation, and Governance***Keywords:* prescribing, health insurance, health workers**Rational Drug Use Policy in Turkey****Burcak Deniz Dedeoglu, Hatice Demet Celik, Akif Akbulat, Halil Akar, Saim Kerman**

Ministry of Health of TURKEY, Turkey

**Problem Statement:** Studies were conducted by Ministry of Health and many different associations on the issue about rational drug use in Turkey. Institutional activities regarding this issue were initiated on October 10, 2010, by the Ministry of Health of Turkey with the establishment of rational drug use department under the department of pharmacoconomics.

**Objectives:** Among the main purposes of the Rational Drug Use Department is to use various methods to disseminate the accepted principles of rational drug use throughout Turkey and stress their importance.

Interventions: (1) To make suggestions to Social Security Institution (SSI) about the issues of considering the principles of rational drug use while developing the repayment (reimbursement) plans, (2) to educate health staff on principles of rational drug use, (3) to evaluate prescriptions according to principles of rational drug use, (4) to coordinate the publishing the national guidelines for diagnosis and treatment with updating and publishing the medicines guideline on a regular basis, and (5) to measure the awareness level of society and health care workers about rational drug use.

Outcome Measures: Based on the data taken from SSI, excluding the primary health care services, the number of patients who applied to a health care service and invoices for their care were sent to SSI in 2008, 2009, and 2010 were 216.930.000, 247.142.000, and 230.112.000 (for first ten months of 2010) respectively. These numbers were classified as "outpatients", "inpatients," "others," and "daily." In monthly distribution perspective, the applications were higher in summer than winter.

Results: Total prescription numbers for workers, civil servants, and green card owners in 2009 and 2010 (for first ten months of 2010) were 327.000.000 and 250.138.000 respectively and total prescription invoice number was 16.000 billion TL and 12.259 billion Turkey lira (TRY). while the average costs per prescription were TRY48.95 . and 49.01, respectively.

Conclusion:- The expectation is that the rational drug use policy will reduce the total drug cost and increase the awareness of society and health staff about rational drug use.

Funding Source: Information not available

964

#### Access

*Keywords:* access to medicines, indicators, affordability, consumers, health insurance

### Measuring Access to Essential Medicines in Kenya Using the Standardized WHO Level II Household Survey

**Regina M Mbindyo<sup>1</sup>, Fred M Siyoi<sup>2</sup>, Christa Cepuch<sup>3</sup>, Njeri Mucheru<sup>4</sup>, Joan Wakori<sup>5</sup>**

<sup>1</sup>WHO, Kenya; <sup>2</sup>Pharmacy & Poisons Board; <sup>3</sup>Health Action International-Africa; <sup>4</sup>Ministry of Medical Services; <sup>5</sup>Kenya Medical Supplies Agency

Problem Statement: Access to essential medicines (EMs) is a stated goal for Kenya's health system. There is little evidence on access to and use of medicines in households (HHs) in Kenya. This is critical in determining the extent to which existing policies are contributing to access for policy development and strategic planning. A household survey was undertaken in Kenya in October 2008.

Objectives: To investigate household situations with regard to (1) how they access the medicines they need (where they obtain medicines and how much they pay for them), (2) barriers to medicines affordability, and (3) examine access and use of medicines in specific situations of acute and chronic diseases.

Design: Cross-sectional study; adapted WHO Level II Household Assessment tool

Setting: National survey covering households in 18 districts from 6 of the 8 provinces.

Study Population: 1,069 HHs with 5,955 household members. HHs purposively sampled with reference to 6 public facilities in each province, 30 HHs per facility, selecting 3 clusters of 10 HH within 5, 10, and 15 kilometers respectively of each of 6 public facilities per region. Analysis of HHs within 5 self-selected socioeconomic categories, with A=lowest and E=highest.

Policy Change: National Drug Policy 1994 under review. Health sector-wide approach implemented within the second National Health Sector Strategic Plan. Public supply of EMs being integrated centrally, with partial roll-out of the inventory-based ordering (pull) system. Some increase in public and donor medicines financing.

Outcome Measure(s): Access, use, affordability

Results: Percentage of health expenditures spent on medicines: A-95%, E-50%. Prevalence of chronic conditions in HHs: A-38%, E-13%; in women: >50% except diabetes and tuberculosis. Of medicines in HH: analgesics, antipyretics, non-opioids and nonsteroidal anti-inflammatory medicines, and disease modifying anti-rheumatic medicines: 31%; anti-infectives-28%. Percentage of HHs taking longer than 1hour to reach nearest public facility: A-67, E -47. HHs with medicines at home: A-41, E-74. Percentage of HHs obtaining medicines from public facilities for acute illness: A-54, E-18. Percentage of medicines for chronic illness obtained from public facilities: A-45, E-2.8. Percentage of HHs that disclosed at least one chronic illness: A-23%, E-35%. Percentage of HHs with chronic illness and medicines for chronic illness at home: overall 75%. Percentage of HHs that experienced catastrophic expenditure on medicines: A-2%, E-0%. Percentage of HHs that borrowed money to buy medicines: A-70%, E-2%. Percentage of HH with full insurance coverage for medicines: A-1%, E-1%.

Conclusions: Public facilities are a major source of medicines for poor HH

Poor HH spend more time travelling to a public hospital than wealthy HH

Chronic conditions are more likely found in wealthier HHs and in women. The wealthiest HHs are more likely to keep medicines at home. Medicines are a significant part of HH health expenditure; and they take up virtually all HH health expenditure for the poorest HH. Overall, non-public sources were the most frequent medicines sources in HHs. The majority of HHs took medicines as prescribed for chronic illnesses but the poorest HHs were more likely to fail to take prescribed medicines for chronic illness because they could not afford them. Insurance coverage for medicines is practically nonexistent for poorest HHs.

Funding Source: The survey was conducted with financial support through WHO from the UK Department for International Development (DFID) project on Access to Essential Medicines; and the European Commission's

EC/ACP/WHO Partnership on Pharmaceutical Policies. WHO provided technical support in collaboration with HAI-Africa, in the context of the DFID-supported WHO/HAI Collaboration project on Access to Essential Medicines.

965

### Economics, Financing, and Insurance Systems

*Keywords:* access to medicines, financing, pharmacoeconomics, pharmaceutical expenditure,

#### Introducing a Revised Model for Pricing and Reimbursement of Medicines in Macedonia

**Marija Gulija<sup>1</sup>, Tonci Buble<sup>2</sup>, Neda Milevska-Kostova<sup>3</sup>**

<sup>1</sup>AD "Dr Panovski", Skopje, Macedonia, Republic of.; <sup>2</sup>Belupo d.d, Zagreb, Croatia; <sup>3</sup>Centre for Regional Policy Research and Cooperation "Studiorum", Skopje, Macedonia

**Problem Statement:** Pricing and reimbursement policy of medicines (P&R) in Macedonia is defined by Ministry of Health (MOH) and implemented through Drug Bureau (DB) and Health Insurance Fund (HIF). MOH/DB regulates all registered drugs by defining "unified price" as ceiling price. Reference price system was complementarily introduced by HIF only for drugs financially covered by HIF through an health insurance scheme. The two mechanisms failed in improving P&R system for lacking of systematized methodology and transparency. A serious gap existed in relevant information on drug consumption. Revision of the model for P&R was needed.

**Objective:** To present and evaluate the impact of revised reference pricing model in improving access to drugs for primary health care (PHC). Improved access is described as reducing the copayment from patients and enabling more drugs to be available without payment. The financial aspect for the HIF is seen as paying "the same price" for more drugs by adjusting the prices of primary health care drugs financially covered by the HIF. Thus, HIF improves access to essential drugs for the population at the lowest cost and copayment.

**Design:** Study describes model development, its implementation, and evaluates the effects of P&R policy. All drugs for PHC from the national drug list were included (383 generics). This study uses public data from Consultancy on P&R Policy as a part of the World Bank's Health Sector Management Project in Macedonia.

**Methods:** Unified methodology was used in several consecutive steps. Countries for comparison were defined (external reference system). Selected publications/sources of information on drug prices to be used as basis for comparison were defined. Three coefficients for price adjustment were defined as ratio gross domestic product/ purchasing power parity in percentages: maximum 100% comparative price for innovative drugs, adjustment up to 79%, 23% comparative price for generics and adjustment up to the minimum level of 51%, 46% comparative price.

**Outcome Measure(s):** Adjustment calculation of reference prices was implemented to all drugs with exceptions for specific drugs/population groups. Five pharmaco-therapeutic groups were identified (internal reference system) according to anatomic therapeutic chemical (ATC) and daily defined dose (DDD) classification system and reference price for each level of DDD within the group was determined. Methodology used was similar to the one implemented in Croatia (2006), having been adjusted to the needs and conditions of Macedonian pharmaceutical market. Implementation of the revised model started in May 2010.

**Results:** Implementing revised model for reference prices of drugs from PHC resulted in adjusting the prices of drugs. The previous model provided for 77 drugs to be available without copayment. Some drugs were above calculated maximum coefficient of 100% comparative price, other were below minimum coefficient of 51%, 46% comparative price.

**Conclusion:** Revised model enabled 209 generics (55%) to be available to the patients without copayment, since extremely low prices of locally produced generics were appropriately adjusted. Also, HIF can contain over expenditures on expensive drugs.

**Funding Source:** Funds used for this consultancy mission were part of a World Bank health sector management project (HSMP) component for assistance to the Macedonia MOH for improving the pharmaceutical sector.

967

### Policy, Regulation, and Governance

*Keywords:* Access to medicines, MeTA, country comparison, disclosure, baseline

#### Country Comparison of MeTA Baseline Pharmaceutical Sector Scan Data

**Birgit Kerstens<sup>1</sup>, Samia Saad<sup>2</sup>, WJ Bannenberg<sup>1,3</sup>**

<sup>1</sup>Health Research for Action (HERA), Belgium; <sup>2</sup>Independent Consultant, United Kingdom, <sup>3</sup>Medicines Transparency Alliance (MeTA),

**Problem Statement:** Information about medicines is often lacking and not publicly disclosed.

**Objectives:** Improving transparency in the pharmaceutical sector through collection, disclosure, and analysis of information by a multi-stakeholder group (MSG).

**Design:** The MeTA Pharmaceutical Sector Scan (Component 1a) captures yes/no and quantitative responses to implicit questions and asks for sources on quality, availability, price, and promotion of medicines. Based on the pharmaceutical sector scan tool, developed with support from the WHO Harvard Collaborating Centre in Pharmaceutical Policy, the MeTA pilot countries collected and reported pharmaceutical sector data for more than 250 indicators. Forty-seven core indicators relating to medicine prices, quality, availability, promotion, transparency and accountability were selected for a cross-country analysis.

**Setting:** All seven MeTA pilot countries (low-middle income): Ghana, Jordan, Kyrgyzstan, Peru, Philippines, Uganda, and Zambia. Assessments were made at national level covering both public and private sectors.

**Study Population:** In each MeTA pilot country, the pharmaceutical sector scan was conducted with input and validation from a MSG, representing key national institutions from the public and private sector, civil society, and academia.

**Interventions:** The pharmaceutical sector scans were conducted between November 2009 and June 2010. Duration of the data collection was ~ 2 months. Technical validation by country MSG took a further 4–6 months. Cross-country summary tables were developed for comparison purposes.

**Outcome Measures:** Data on national medicines policy, regulatory framework, price control, promotion, and use of medicines were extracted from individual country reports and entered in a cross-country comparison table. Consumer and procurement prices in the public and private sectors were compared for both originator brand medicines and lowest price generics. A traffic light analysis was added to the multi-country comparative table to show the degree of availability and disclosure of the data. Individual country pharmaceutical sector scans and the cross-country analysis have been placed in the public domain.

**Results:** The cross-country analysis of data on price, quality, availability, and promotion of medicines not only shows in which areas the countries are similar or different and how they compare in terms of the degree of data disclosure, but also reveals some methodological interpretation differences as well.

**Conclusions:** The cross-country analysis enables comparison of the pharmaceutical sectors in seven diverse countries, highlights similarities and differences and assesses where there is room for improvement in terms of data collection and disclosure.

**Funding Source:** UK Department for International Development.

**969**

### **Economics, Financing, and Insurance Systems**

*Keywords:* donations, differential pricing, industrial organisation in health, health technologies, market dynamics, theoretical economic modelling, dynamic access to medicines

#### **Modelling the Potential for Market Impact and Supply Security Risks: Focus on Donations with Applications for Differential Pricing**

**Cheri L Grace<sup>1</sup>, Padmashree Gehl Sampath<sup>2</sup>**

<sup>1</sup>HLSP Institute, United Kingdom; <sup>2</sup>UNCTAD

**Problem statement:** In-kind product donations and differential pricing are strategies credited with improving access to medicines and, undoubtedly, they have improved static access to medicines in certain circumstances. This work considers the appropriateness of differential pricing and in-kind donations in the current supply environment, from the perspective of competition policy and market dynamics.

**Objectives:** To analyse the potential market impact of differential pricing and in-kind donations from the perspective of longer term dynamic access to medicines.

**Design:** Through an iterative process of market analysis, hypotheses generation, industry validation of these hypotheses, and economic modelling, we developed a risk framework which reveals the primary market characteristics which predispose a commodity sector to experiencing negative market impact from a donation or differential pricing offer. We constructed a theoretical, mathematical model to demonstrate how these risks would be experienced at the level of a single generic firm which is competing with a donation, including a sensitivity analysis to provide insight into how the results would differ according to varying assumptions, e.g., size of market share taken up by the donation or the differentially priced product, and degree of operating leverage of the competing firm.

**Setting:** The work is adapted from earlier research and analyses of the authors, commissioned to inform the Global Fund's in-kind donations policy. The adapted work focuses not only on donations but also on differential pricing and is relevant to the World Health Organisation's normative work, and to donors and international agencies who are interested in shaping markets towards enhanced consumer welfare and donor value for money.

**Study scope:** A recent paper provided a comprehensive summary of challenges experienced with donations. We focused only on market impact of donations and also transferred the analysis to encompass the risks of differential pricing as well.

**Results:** The risk framework revealed a key paradox—those health commodity product categories where there is most to gain in terms of resource mobilisation are those where market impact risk would be the highest (i.e., short-term gains could risk longer-term access). This paradox is demonstrated through economic modelling of the loss of margin suffered by a firm competing with a donation:  $m^* = m - RS^*F/((1 - RS)^*R)$

(new margin = old margin minus reduction in market share multiplied by fixed cost, divided by new revenue [equivalent to old revenue multiplied by 1 minus percent reduction in market share]). Sensitivity analysis confirmed that volume dependent firms will be more severely affected by even small donations. Other factors which will affect whether the non-donor competitor will remain in the market are the size and time length of the donation, as well as ability to raise prices or recoup the lost volume through other markets or growth in the market with the donation.

**Conclusions:** The economic effect of differential pricing or donations (a differential price with price set at zero) may be akin to predatory pricing. Firms competing with donations and differentially priced products may respond by reducing output, raising prices, exiting the product line or deciding not to enter the product line in the first place. The degree to which a product or service sector can be negatively affected by donation (or differential pricing) offers depends partly on the market characteristics of that sector and partly on the size, duration and structure of the offer itself. Policies and guidance on donations and differential pricing need to account for possible negative effects on competition and risk to dynamic supply and access. Competition policies need to be developed, implemented, and monitored for global health product markets. WHO Guidelines on donations should also incorporate this perspective.

Funding source: (for original work only on donations) The Global Fund to Fight AIDS, Tuberculosis and Malaria

970

#### Access

*Keywords:* Access to medicines, household survey, low income countries

### Access to Medicines For Treating Acute Condition in Three Low- Income Countries In Central America

**Isabel Cristina Martins Emmerick<sup>1</sup>, Dennis Ross-Degnan<sup>2</sup>, Vera Lucia Luiza<sup>1</sup>, Luiz Antonio Bastos Camacho<sup>1</sup>**

<sup>1</sup>Oswaldo Cruz Foundation, Brazil; <sup>2</sup>Departament of Medicine and Population - Harvard Medical School

**Problem Statement:** Access to medicines is a complex subject, linked to many economic, social, and demographic aspects. Different barriers from inside and outside of health system may affect access.

**Objectives:** Identify the main predictors of access to medicines for persons who had an acute health condition in the two preceding weeks in household surveys in Nicaragua (Nic), Honduras (Hon), and Guatemala (Gut).

**Design:** Cross-sectional analytic study based on data from a household (HH) survey implemented using methods developed by the World Health Organization, adapted to study exclusion from health care in Latin America. Data were analyzed using descriptive statistics and logistic regression.

**Setting:** 2,761 HH located in Nic, Hon, and Gut.

**Study Population:** One case of acute illness per household occurring during the two weeks preceding the survey was considered. If the household reported more than one case, the youngest person experiencing an illness was selected.

**Outcome Measure(s):** Two dependent variables were considered: "seeking care in the formal health system" and "having full access to medicines" (all medicines sought for the acute condition were obtained). Multivariate models included all independent variables related to the study outcomes with  $p < 0.20$  in bivariate analyses. All variables with  $p < 0.10$  were kept in the final model.

**Results:** Overall, 59.0%, 56.2%, and 30.9% of households experienced an acute illness in Nic, Hon, and Gut respectively. The proportion of persons who sought care in the formal health system for the acute condition varied from 41.3% in Hon to 47.1% in Nic, while full access to medicines ranged from 60.3% in Gut to 86.5% in Hon. The significant predictors of seeking care in at least one country included: urban geographic location, higher education level, age under 15 years, and treating an illness perceived to be severe. The strongest predictors of full access to medicines inside the health system were seeking care in the private sector, household head retired, higher education level, and more positive perceptions about quality of health care and medicines. For patients receiving care outside of the formal health system, the predictors of full access to medicines were urban geographic location, higher economic status, son or daughter of household head, female gender, and the duration of working hours in the public health facility.

**Conclusions:** Prevalence of acute health condition was different across countries. Around half people with acute conditions sought care in the formal health system. Predictors of full access to medicines inside and outside the health system were different.

**Funding Source:** Pan American Health Organization, Coordination for the Improvement of Higher Education People

971

#### Policy, Regulation, and Governance

*Keywords:* counterfeit drugs, mobile communications

### Digital authentication of pharmaceutical products

**Justin Picard**

Advanced Track & Trace, France

While holograms, security inks and RFID chips are costly solutions and increasingly copied or imitated by counterfeiters, digital technologies based on strong security principles offer an attractive alternative to protect pharmaceutical products and their packaging from counterfeiting. STAMPS, which stands for Secure Tracking and Authentication through Matrix Printing and Scanning, is a new form of digital authentication that is particularly well suited to industrial production, with a high security and an extremely low incremental cost on large productions. This paper will present a case study with a pharmaceutical company, where the technology is integrated on a range of pharmaceutical products.

The pharmaceutical company is affected by significant rates of counterfeits on its drugs sold in emerging markets. Production of packaging components is decentralized and is done in Europe, Russia and China as well as several other geographical regions, again using a range of printing technologies including rotogravure for large volumes. Precise protocols have to be elaborated to handle communication and data exchange between the authentication provider, the company, its local subsidiaries and subcontractors. Authenticators are integrated on blisters, leaflets and external packaging, with the data contained in the authenticators being correlated. Large scale investigations are done in pharmacies in Russia and China, using a web application and flatbed scanner or mobile device to automate scanning of packaging components and receive immediate feedback; previously, the suspected samples had to be sent to the company's R&D lab and it would take weeks before analysis could be concluded. Thanks to this more efficient technique of monitoring markets, decreased rates of counterfeits are already being observed.

The paper also presents an initiative to provide, under a non-profit model, authenticators on life saving medications such as artesunate. Artesunate is the only affordable and effective medication that can heal *parcifarum* malaria, a

particularly deadly form of malaria that is found in South East Asia. However, a large survey in the region by the WHO, Interpol and a coalition of scientists and health practitioners has found that 49.9% of analyzed samples were counterfeit, and there are significant worries that fakes with sub therapeutic dosage are promoting resistant forms of the disease that cannot be healed. Digital authentication technologies such as STAMPS can be used to streamline verification of pharmaceuticals for a negligible cost that can be afforded even in low income countries. This paper will explain why and how the initiative can be implemented.

972

Access

Keywords: incentivising innovation

### **Assessing Global Health Financing and Policy: Potential Contribution of Pooled Funds**

---

**Cheri L Grace, Mark Pearson**

HLSPI Institute, United Kingdom

**Problem statement:** There is growing interest in methods to accelerate the development of technologies for neglected diseases. Public and private groups have come together to conduct research and development (R&D) in these areas. However, some argue that funding flows inefficiently resulting in insufficient resources, funding volatility, poor resource allocation, and duplicated efforts. Also some believe that the current architecture could be reconfigured to better meet the needs of new donors who might prefer to fund a diversified “package” of product R&D efforts. In response, several pooled funding mechanisms have been proposed to address what proponents see as the key problem(s) in the current system: the Industry R&D Facilitation Fund (IRFF) originally proposed by the George Institute, the Fund for Research in Neglected Diseases (FRIND) proposed by Novartis, and the Product Development Partnership Financing Facility (PDP-FF) proposed by the International AIDS Vaccine Initiative (IAVI).

**Objectives:** We explored how these proposals would be expected to perform against two principal objectives—their capacity to raise additional money for neglected disease R&D and their capacity to improve the efficient allocation of the funding.

**Design:** We identified 7 avenues through which the proposals might be expected to deliver under the two principal objectives; these avenues became our criteria for assessing the proposals. For each criteria, we discuss the evidence for the extent of the problem, identify alternative options for resolving problems, and evaluate whether the proposal would be a superior method to resolve the problem, relative to the alternatives identified.

**Results:** (1) New Resource Generation? PDP-FF offers government donors a wider choice of funding modalities and could theoretically attract new government donors who are interested in innovative financing options. FRIND and IRFF would not be restricted to government donors and would theoretically have the best potential for attracting new donors. Interviews with donors who already support neglected disease R&D revealed limited interest in pooled funding participation; most of these donors want to maintain a direct line of sight and control over their funds. Others were hesitant because of current financial pressures and/or lack of certainty over which problems are the most critical to solve. (2) Improved Resource Allocation? The PDP-FF model could provide more predictable funding to PDPs, although this would not necessarily result in a more predictable disbursement process or improve resource allocation decision-making. The PDP-FF would frontload R&D resources and may allow donors to recoup their investments, FRIND would be useful if one believes that milestone-based payments increase the overall performance of neglected disease research, there is potential for more research groups to participate in neglected disease outside of PDPs, and current resource allocation process across PDPs is suboptimal. FRIND’s overall complexity is reduced and effective portfolio management becomes more feasible if the fund focuses on late stage candidates only. There is also a theoretical fit between risk averse donors and a Phase III focused fund. IRFF could improve funding if current system problems relate to predictability of funding for PDPs and if the current portfolio management process pursued by PDPs is already sound. IRFF could allocate resources to PDPs in a predictable manner and with low transaction costs, keeping the PDP and funder interests aligned through partial reimbursement of expenditures.

**Conclusions:** Each proposal is designed to address a particular perceived problem(s) in the current system. This begs the question: which problems, if solved, would give us the highest leverage to accelerate R&D for neglected diseases? Through our interviews with over 50 experts, we found little consensus on the nature of the core problems or the relative importance of the problems.

**Funding source:** Bill & Melinda Gates Foundation through the Center for Global Health R&D Policy Assessment at the Results for Development Institute

975

**Policy, Regulation, and Governance**

Keywords: civil society, government, partnership, policy dialogue, transparency

### **Government, Civil Society, and WHO Partnership: a Catalyst for Better Access to Medicines In Countries**

---

**Nel Druce<sup>1</sup>, Gilles Forte<sup>2</sup>, Patrick Mubangizi<sup>3</sup>, Philippa Saunders<sup>4</sup>, Helen Tata<sup>2</sup>, Jean-Marie Trapsida<sup>2</sup>, Saul Walker<sup>5</sup>**

<sup>1</sup>HLSPI Institute; <sup>2</sup>World Health Organization; <sup>3</sup>HAI Africa (at time of study); <sup>4</sup>Independent consultant; <sup>5</sup>DFID

**Problem statement:** Evidence is limited that civil society and government can work in complementary ways to improve access to medicines, while retaining independent functions in the health system and governance structures. Information

is needed on added value of government, WHO, civil society partnership for improving policies and practices for access to medicines.

**Objectives:** The 2009 evaluation of the WHO-HAI Africa Regional Collaboration (2002-2008) assessed its achievements against the WHO Medicines Strategy (WMS) 2004–2007 (policy, access, quality and safety, and rational use), and the added value of a civil society network (HAI Africa), WHO and government partnership in countries.

**Design:** The evaluation methodology comprised a review of programme documents, country policy guidelines, and tools produced; WHO surveys (Level 1 study on structures and processes, 2003 and 2007, n=14), WHO/HAI availability and affordability surveys in 14 countries, structured interviews (160); surveys of 15 WHO Medicines Advisers (Essential Drugs and Medicines Policy National Professional Officers, EDM/NPOs); WHO Representatives (WRs); and national counterparts (n = 45).

**Setting:** Case studies in 4 countries with EDM/NPOs (Republic of Congo, Ethiopia, Senegal, Tanzania); in 1 country without EDM/NPOs (Malawi), and in Kenya, Uganda and Ghana (focus of civil society activities), plus HAI Africa headquarter office and WHO regional and headquarter offices.

**Study population:** Government officials, civil society, and other regional and national stakeholders

**Interventions:** The evaluation reviewed inputs (staff and technical resources), outputs, and results for countries (improved policy, good practices, and access to medicines) for network of WHO Country Medicines Advisers (EDM/NPO); for WHO Geneva and AFRO; and HAI Africa and its regional network members.

**Policies:** Policies and programmatic strategies in WMS objectives.

**Outcome measures:** Progress against WMS 2004-2007 indicators (qualitatively and quantitatively assessed)

**Results:** Revised medicines policies that included consumer perspectives and mechanisms for involvement; robust, credible, and independent data on prices and availability across all market sectors; protection of public health safeguards in new trade laws; removal of taxes and tariffs; medicines higher on policy agenda; countries capacity strengthened.

**Conclusions:** The WHO-HAI Africa Regional Collaboration (2002-2008) provided a new and unique space for dialogue and collaborative activities. It helped to change attitudes and introduce new working approaches for civil society, government, and WHO in the pharmaceutical subsector. This was achieved through a complementary mix of approaches: use of methodology for generating quality information; collaborative research and policy advise; civil society advocacy and campaigning; and policy dialogue with government ministries including health, trade, and justice. Through its facilitatory role, WHO has helped to broker civil society's contribution as a respected and strategic partner in policy fora.

**Funding Source:** DFID, WHO.

## 976

### Policy, Regulation, and Governance

*Keywords:* drug promotion, ethics, regulation

### Pharmaceutical Advertising and Promotion: Advertising Components Analysis in Five Latin American Countries

**Claudia Vacca**<sup>1,2</sup>, **Claudia Vargas**<sup>1,2</sup>, **Martín Cañas**<sup>3,4</sup>

<sup>1</sup>IFARMA, Colombia; <sup>2</sup>CIMUN, (Centro de Información de Medicamentos Universidad Nacional de Colombia);

<sup>3</sup>Federación Médica de la Provincia de Buenos Aires (FEMEBA) Argentina; <sup>4</sup>Grupo Argentino Para el Uso Racional de los Medicamentos (GAPURMED)

**Problem Statement:** Unethical and inappropriate drug promotion has been a continuing concern of both nongovernmental organizations (NGOs) and the World Health Organization (WHO). Several studies had shown that students and health professionals do not know WHO ethical guidelines for drug promotion, so the WHO and Health Action International have shown the importance of research and interventions to promote the developing educational methods on the subject, strengthening regulatory agencies, and fostering transparency in promotional information.

**Objectives:** To analyze advertising materials available to the public and health personnel in five Latin American countries, to make an approach to the evaluation of monitoring and enforcement capabilities of national authorities to the promotional information available.

**Design:** Descriptive study

**Setting:** Peru, Ecuador, Colombia, Nicaragua, and Argentina

**Methodology:** For one month, drug promotional pieces available in health facilities, pharmacies and public roads were collected in 5 Latin American countries. Of the material collected, 30 promotional pieces by country were randomly selected and tested against WHO ethical criteria for drug promotion, independent technical information, and national regulations.

**Results:** 683 advertising pieces were collected and 133 were analyzed; 69.2% were about prescription drugs. Half of the pieces were collected in pharmacies. The most frequently omitted information was that related to drug safety, over 80% of cases were included indications. 50% of over the counter medicines advertising collected from pharmacies included non-approved indications. The risk of lack of information on dosage was twice as high in promotions distributed in pharmacies compared with distributed promotional institutions (RR 2.80, 95% CI 1.32-3.39).

**Conclusions:** Advertising messages continue to violate WHO ethical standards, technical information, and national regulations, particularly the omission of or inaccurate information which implies a high risk of inducing drug misuse.

There is an urgent need to strengthen the monitoring and control of advertising so as to ensure the reliability, accuracy, and ethics of the promotional material, as well as the impact of promotional messages about consumption and its affect on the population's health.

Funding Source: Acción Internacional para la Salud (AIS LAC)

With the support of AIS Peru, AIS Ecuador, AIS Bolivia, AIS Nicaragua, and the Argentine Group for the Rational Use of Drugs (GAPURMED).

977

### Policy, Regulation, and Governance

*Keywords:* access to medicines, disclosure, Medicines Transparency Alliance (MeTA), country comparison, baseline

#### Country Comparison of MeTA Baseline Data Disclosure Surveys

---

**Samia Saad<sup>1</sup>, Birgit Kerstens<sup>2</sup>, WJ Bannenberg<sup>2,3</sup>**

<sup>1</sup>Independent Consultant, <sup>2</sup>Medicines Transparency Alliance (MeTA), United Kingdom; <sup>3</sup>Health Action for Research (HERA)

**Problem Statement:** The pharmaceutical sector is complex and information about medicines is often not disclosed or not easily available to stakeholders.

**Objectives:** To improve transparency in the pharmaceutical sector through information disclosure and analysis by a multi-stakeholder group (MSG). The MeTA Data Disclosure Survey (DDS) collates and describes the disclosure status of information on medicines quality, availability, price, and promotion.

**Design:** The DDS tool was designed with support from WHO Harvard Collaborating Center in Pharmaceutical Policy. A list of 37 indicators was developed out of recommended "key types of data to disclose" listed in the tool. Data was then extracted from qualitative information on practices supplied in the MeTA pilot country surveys into a cross-country summary table.

**Setting:** All 7 MeTA pilot countries (low to middle income): Ghana, Jordan, Kyrgyzstan, Peru, Philippines, Uganda, and Zambia. The survey assesses the national situation in both public and private sectors.

**Study Population:** The DDS was conducted with input and validation from a MSG, representing key national institutions from public, private and civil society sectors and academia.

**Intervention:** Surveys were conducted by countries between Aug 2009 and Jan 2010. Duration of data collection was ~2 months. Technical validation by country MSGs took a further 4-6 months. Cross-country summary tables were developed for comparison purposes.

**Outcome Measure(s):** Data covering policies—the laws and regulations that are in place; practices—suggested procedures to follow and actual practices; and results—achievements in the core areas of medicines' registration and quality, availability, price, and promotion. Practices were extracted into a cross-country table to which a traffic light analysis was then applied. Individual country data disclosure surveys and cross-country analysis have been placed in the public domain.

**Results:** Cross-country analysis of data disclosure on medicines' price, quality, availability, and promotion highlights similarities and differences in disclosure status across countries, whether disclosure is proactive or reactive, and whether information is out of date, unreliable, or simply unavailable.

**Conclusions:** The DDS enables national stakeholders to prioritize activities, supports progressive disclosure, and creates a baseline against which changes in transparency and disclosure can be measured. It also facilitates multi-stakeholder engagement since it requires that the stakeholders disclose relevant information they and the institutions they represent hold. Cross-country analysis of DDS data is possible and useful.

Funding Source: UK Department for International Development (DFID)

978

### Chronic Care

*Keywords:* Community pharmacists, Home health care, Medication Therapy Management (MTM), Drug related problems (DRPs), Patient adherence

#### Effectiveness of Pharmacist Home Health Care for Type 2 Diabetes in Bangkok Metropolitan: A Community Based Study

---

**Sirirat Tunpichart<sup>1</sup>, Ratana Somrongthong<sup>1</sup>, Rungpetch Sakulbumrungsil<sup>2</sup>**

<sup>1</sup>College of Public Health Sciences, Chulalongkorn University, Thailand; <sup>2</sup>Faculty of Pharmaceutical Sciences, Chulalongkorn University, Thailand

**Problem Statement:** Community pharmacy services have not been a part of universal health coverage. However, if Medication Therapy Management (MTM) for chronic conditions provided by pharmacists, improved quality of patient medication utilization, it should be included as a part of benefit package for patients.

**Objectives:** To assess the effectiveness of community pharmacist home health care for diabetic patients in community-based Bangkok urban area.

**Design:** This study was one group before-and-after quasi-experimental design.

**Setting:** Thirty-three communities out of 68 Bangkok Metropolitan Health Centers were participating in referring uncontrolled diabetic patients to 3 community pharmacy settings for home health care visits.

**Study Population:** The 288 uncontrolled diabetic patients with high prevalence of drug-related problems were purposively identified by nurses from primary care units during their regular home health visits and referred to community pharmacists.

**Intervention:** Three pharmacist home health care interventions using MTM process were planned over the 6-month period. Two additional pharmacist home visits were also conducted for outcome assessment. The average time spent by the pharmacist on each patient was approximately 60 minutes of which 20 minutes were spent on patient and/or caregiver interview and medication review, and 40 minutes on intervention, patient medication record, documentation, and referral, if needed.

**Policy:** Integrating community pharmacy services as a part of health benefit scheme would improve patient medication utilization and in turn improving patient medication therapy.

**Outcome Measure:** The blood glucose level, blood pressure, and medication adherence were major indicators for program effectiveness.

**Results:** The mean (SD) age was 66.0 (9.4) years and 75.3% were female. Hypertension was the main co-morbidity found in 82.6% of patients. They were taking on the average (SD) of 7.1 (3) medications and 89.3% of patients had 4 or more medications. A total of 771 drug related problems or 2.7 problems per patient were addressed by registered community pharmacist. Among these, 738 or 95% were non-adherence. The peripheral neuropathy was the major clinical symptoms detected in 20% of patients. Inappropriate eating behavior and lack of exercise were life-style problems. After 3 interventions, non-adherence was reduced by 17.6%. Fasting blood glucose level was improved in 45.5% of patients, while blood pressure was improved in 28.8% of patients. Out of 34 cases referred to physicians, 55% or 19 cases had their medications altered as recommended by community pharmacists.

**Conclusion:** This study concluded that community pharmacist home health care could alleviate patients' medication utilization problems and would thus improve overall quality of patient care. The integrated care among primary care units and community pharmacists would be recommended to extend to other provinces and at a larger scale.

**Funding Source:** Information not available

## 979

### Chronic Care

*Keywords:* standard treatment guidelines, pharmaceutical policy, adherence of prescribers, prescription

#### **Adherence of Prescribers to High Cost Medicines Standard Treatment Guidelines in Rio De Janeiro**

**Daniela Moulin Maciel Vasconcelos<sup>1</sup>, Vera Lucia Luiza<sup>2</sup>, Marismary Horsth De Seta<sup>3</sup>**

<sup>1</sup>SESDEC RJ - Brazil; <sup>2</sup>NAF/ENSP/Fiocruz; <sup>3</sup>DAPS/ENSP

**Problem Statement:** Implementing the National Medicines Policy NMP, the Brazilian MoH defined criteria and policies to select, finance, and prescribe high cost medicines (MDCE). As part of these efforts, a standard treatment guideline (PDCT) was developed by a high-qualified working group through an open and consultative process. Free dispensation is linked to the adherence of prescribers to the PDCT.

**Objectives:** To analyze adherence of prescribers to the high cost medicines (MDCE) official standard treatment guideline (PDCT)

**Design:** Medical record review. A checklist was built to guide the review considered clinical procedures and laboratory tests recommended by the PCDT. Scores were created to rank adherence level. The study was approved by the ENSP Ethical Committee.

**Setting:** Three main health facilities (number of patients under this treatment) in each group were studied—public, teaching, and private hospitals located in the municipality of Rio de Janeiro.

**Study Population:** Erythropoietin (EPO) to test for chronic kidney impairment was elected as tracer condition because of the highest number of patients involved among high cost treatments under public financing. Representative random sampling of 202 patients cared from December 2004 to December 2005 for IDC-10 N18.0 or N18.8

**Outcome Measure(s):** Adherence of prescribers level to the PDCT considering inclusion patient monitoring and maintenance treatment criteria.

**Results:** Adherence to PDCT was ranked as completely adequate for 38.1% and totally inadequate for 3% of patients. The PDCT recommendations most followed were haematocrit results and realization of complete blood cells count to include patients under treatment, and complete blood cells count and platelet count each three months for monitoring. Less followed recommendations were the initial dose of EPO, interruption according to blood cells count results, and transferrin and ferritin blood test each three months.

**Conclusions:** Prescribers did not adhere to all recommendations of the PDCT, including the ones implying increased risk of death according to the literature. Dispensation occurred even so. Pharmacists and other professional involved in dispensing medicines need better training to verify compliance with PDCT. Audit mechanisms need to be enforced.

**Funding Source:** No specific financing

## 981

### Policy, Regulation, and Governance

*Keywords:* good governance, transparency, disclosure, conflict of interest, medicines management

## **Implementation of Good Governance in Medicine (GGM) Programme in Malaysia to Strengthen Medicines Management**

**Nour Hanah Othman, Eisah Abdul Rahman, Rosminah Mohd Din, Wan Norashikin Wan A. Kadir, Mariam Bintarty Rushdy (presented by Abida Haq)**

Ministry of Health, Malaysia, Malaysia

**Problem Statement :**Malaysia participated in the Good Governance for Medicines (GGM) programme since 2004. Since then, Malaysia is currently in phase III of its implementation.

**Objectives :** To examine the level of implementation of good governance for medicines in Malaysia.

**Design :** Transparency assessment survey and observational report.

**Setting :** Pharmacy facilities in the Ministry of Health Malaysia.

**Outcome Measure(s) :**The vulnerability scale scores in registration, selection and procurement from the transparency assessment survey and observational findings from field visit.

**Results :** The level of implementation of good governance for medicines can be shown by the constant enhancement of administrative procedures throughout the medicines management system, which include online registration of medicines, dissemination of information on the Division or Ministry's website, disclosure of medicines contracts awarded and implementation of conflict of interest policy for various committee members.

**Conclusions:** Malaysia has succeeded in adopting and institutionalizing the GGM programme by establishment of the national GGM framework, GGM Steering Committee and GGM Task Force Committee. The Government Transformation Programme has enhanced the implementation of the GGM programme in Malaysia

**984**

### **Access**

*Keywords:* access to medicines, affordability, drug utilization, consumers, pharmaceutical policy,

## **Priority Policy Research Questions in the Area of Access to Medicines in Cameroon, Chad, Congo, and Gabon**

**NTSAMA ESSOMBA CLAUDINE<sup>1</sup>, BIGDELI MARYAM<sup>2</sup>, TIWODA CHRISTIE<sup>3</sup>**

<sup>1</sup>University of Yaoundé 1, CAMEROON; <sup>2</sup>Alliance HPSR, WHO; <sup>3</sup>Ministry of Public health, Cameroon

**Problem statement:** Access to medicines is often poor in low- and middle-income countries (LMICs). WHO estimates that the average availability of essential drugs in LMICs is 35% in public sector facilities and 66% in the private sector. Medicines account for a high proportion, between 20%–60%, of health spending in LMICs (developed country spending is around 18%). Moreover, between 50% to 90% of expenditure on medicines in LMICs is out-of-pocket. This inequitable mode of financing creates significant access barriers for the poor and may lead to catastrophic household expenditures. Despite progress in some areas, such as price and availability, data on access to and use of medicines is often weak. Even where data are available, there is limited contextual evidence and minimal capacity for analysis and interpretation to develop sound policy options. The present study lies with the framework of the Access to Medicines Policy Research project developed by WHO's Alliance for Health Policy and System Research for which the aim is to increase the use of evidence in policies to improve access to medicines in LMICs.

**Objectives:** (1) Identify and rank, to the extent possible, policy concerns related to access to medicines as perceived by policy makers, civil society organizations, communities, and patients in Cameroon, Congo, Gabon, and Chad; and (2) identify and rank, to the extent possible, related policy research questions in the field of access to medicines in these countries.

**Design:** The study is divided in two parts : a literature review and a survey of key informants through structured interviews. **Setting :** This study is conducted at national level in Cameroon, Chad, Congo, and Gabon. It examines the public and private sector.

**Study population:** For the review, national and regional published and grey literature, policy documents, relevant reports, and prior priority setting exercises in accordance with the selection criteria were inventoried. The policy statements and concerns are recorded. For the survey, the keys informants were selected according to their significant involvement at different levels in medicines issues, especially high ranking officials of Ministry of Health, public and private sector pharmacists, and a convenience sample of patients recruited.

**Outcome measure:** Specific constraints related to access to medicines are identified according to the four areas of WHO Framework for Equitable Access to Essential Medicines at the four different levels of health systems described in the WHO Framework for Developing a Health Systems Research Agenda. The research priorities are set according the checklist for priority setting in health research developed by WHO.

**Results and conclusions:** Concerning the literature review; 82 documents were selected. 27 were included. 20 barriers and 23 research questions to access to medicines were identified and ranked. For the survey, 411 people agreed to participate. From their perceptions, 29 barriers and 24 research questions to access to medicines were identified and ranked. Minimal health services responsiveness to patients needs was ranked as the first barrier, followed by the low quality of human resources. Financial issues generally presented as the main barrier to access to medicines were ranked at the third place. The reliability of the health systems appeared as the weak point in all the four countries.

**Funding source:** Alliance for Health Policy and System Research (WHO)

985

**HIV/AIDS and TB***Keywords:* Antiretroviral treatment, electronic dispensing tool, patient tracking**Tracking of Inter-Facility Patient Transfers and Retention on Antiretroviral Treatment in Namibia****Dawn Pereko<sup>1</sup>, Greatjoy Mazibuko<sup>1</sup>, David Mbirizi<sup>1</sup>, Sandya Wellwood<sup>3</sup>, Laura Brandt<sup>3</sup>, Jennie Lates<sup>2</sup>, Mbayi Kangudie<sup>4</sup>, Victor Sumbi<sup>1</sup>**<sup>1</sup>Management Sciences for Health/Strengthening Pharmaceutical Systems (SPS)/Namibia; <sup>2</sup>Ministry of Health and Social Services (MoHSS); <sup>3</sup>I-TECH, Namibia; <sup>4</sup>United States Agency for International Development (USAID)

**Problem Statement:** The public sector in Namibia started to provide and roll out antiretroviral therapy (ART) services in 2003. By September 2009, a total of 70,496 patients representing more than 80 percent of those in need were on record at public sector pharmacies as receiving antiretroviral (ARV) medicines through 101 ART sites, including outreach (35 main and 66 outreach sites). Namibia has reported an average of 99% availability of ARVs in district and referral hospitals since October 2007. With larger numbers of patients on medications, an increasing level of attention is being focused on adherence to treatment. The Electronic Dispensing Tool (EDT) is one of two computerized systems used to manage and monitor patients receiving ARVs and can be found at all ART sites in Namibia. EDT data from the individual ART sites are aggregated at the national level onto the pharmacy ART National Database (NDB). A report from October 2009 from the NDB showed that 2,290 patients were recorded as having transferred out since 2005.

**Objective:** The aims of the study were to determine the level of patient retention on therapy and the outcome of patients who transferred out from any facility in Namibia that uses EDT.

**Study design and population:** A retrospective cohort analysis of patients who started treatment in 2008 and who were recorded as transferred out was done. Data from EDT and NDB was used to determine the percentage of patients who were readmitted into any facility after transferring out from any public facility in Namibia. The data was also used to determine the status of all those patients readmitted as of September 2009 and determine any treatment gaps. between transfer out and readmission.

**Results:** 456 (2.2%) patients were on record as transferring out in 2008 from public health facilities providing ART services countrywide out of 20,576 initiated. . Only 202 (45%) of these 456 patients were readmitted back into the system: 77% of these readmitted patients were still active on treatment, 1.5% had died, and 12% were lost to follow up. The treatment gap between transfer out and readmission ranged from 0 months (62%) to 8 months (3%). There was no significant difference between male and female patients in terms of readmission after transferring out.

**Conclusions:** An electronic patient record system in conjunction with a national data repository system was found to be useful in tracking patients between ART sites in a country with high patient mobility. The transfer of patients between facilities should be accompanied by appropriate monitoring in order to track the patient that are not re-absorbed into the system). Appropriate patient tracking and referral measures ensure that the referring and receiving facilities are aware of the arrival of the patient through a feedback loop and will decrease the interval between transfer out and re-uptake, thereby increasing patient retention on treatment.

**Funding Sources:** US Agency for International Development/Namibia

986

**Access***Keywords:* self medication, appropriate use, drug utilization**Self Medication in a Kerala District, India - Prevalence and Analysis****Habeeb Ibrahim Abdul Razack<sup>1</sup>, Jegan RS<sup>2</sup>**<sup>1</sup>Accenture Services Pvt Ltd, India; <sup>2</sup>Semlar Research, India

English philosopher-physician Sir William Osler (1849-1919) said, "One of the first duties of the physician is to educate the masses when not to take medicines".

Self medication is a positive change that provides a number of benefits to the individual as well as the society. But, it is also important to draw a line somewhere while choosing for a remedy appropriate for the condition.

The present work aimed to assess the prevalence of self-medication with analgesic and anti-pyretic drugs in Kollam district, Kerala and to identify the determination of self-medication. 100 families were selected, which contributed to a total sample population of 369 subjects. A structural and pre-tested questionnaire was used for collecting information from the participants.

The prevalence of self-medication with analgesic and anti-pyretic was found to be 41.7%, 95% CI, p<0.05. The prevalence was more among women (48.1%) than men (31.1%). Higher the educational status, higher was the prevalence (49.7%). Higher the socioeconomic status, higher was the prevalence (39.5%). Many (79%) was using these drugs for the treatment of fever, followed by headache (63.2%). Paracetamol was the choice of drug for the majority (93.2%) of the sample population. 68.0% were aware of the name of the drug. About 40% of those who were unaware of it identified the drug by its physical appearance. Previous prescription remained as the major source (37.5%) of self-medication. Only 27.5% obtained counseling from the concerned pharmacist. A majority of 51.0% of the subjects were advising their family member, friend and colleagues about the drugs to be administered in certain ailments.

World Self Medication Industry (WSMI) aims to convey the social and economic value of responsible self-medication to health professionals, health authorities, consumers and others. Better Patient-Pharmacist-Physician relationship can lead to responsible self-medication

The most common reasons for choosing to self-medicate among the southern parts of India were mainly could be: (1) Inability to afford physician's fees; (2) Relatives/Friends' advice/insistence to buy a particular medicine based on their experience; (3) Increased awareness of availability of medicines (especially among the higher class) and use for appropriate conditions through various advertisements. (4) Also the tendency to momentarily suppress the minor symptom/condition rather than wanting to go to the root cause of it because of hidden fears, cost factor, busy schedule etc.,

990

#### HIV/AIDS and TB

*Keywords:* Mobile technology, antiretroviral therapy, electronic dispensing tool

#### **Using Mobile Technology to Strengthen HIV/AIDS Management in Remote Areas**

---

**Mwape Kunda<sup>2</sup>, Dawn Pereko<sup>1</sup>, Abraham Blom<sup>2</sup>, Samson Mwinga<sup>1</sup>, David Mbirizi<sup>1</sup>, Victor Sumbi<sup>1</sup>**

<sup>1</sup>Management Sciences for Health/Strengthening Pharmaceutical Systems (MSH/SPS).; <sup>2</sup>Ministry of Health and Social Services (MoHSS)

**Problem Statement:** Namibia is the second most sparsely inhabited country in the world. Vast distances have to be travelled to district hospitals which can greatly compromise quality of care and services resulting in patients being non-adherent in attending clinic appointments and medicine collection. To improve access to antiretroviral therapy (ART) services, the MoHSS has decentralized ART services to clinics and health centers in remote areas of Namibia. Data capturing and management at outreach sites was a challenge resulting in duplication of work. The staff at the outreach site had to use paper records and then use those records to update the Electronic Dispensing Tool (EDT) upon return to the main antiretroviral therapy (ART) facility site. Furthermore, data for outreach sites would often be missing or incomplete and therefore monitoring patients and quantifying medicines presented challenges.

**Intervention:** SPS supported the MoHSS in developing the EDT mobile using a hand-held scanner. The device has the same functionality of the EDT in that it enables dispensing, monitoring adherence through pill counts, setting patient appointments, and managing stock. Data from the EDT is uploaded onto the scanner at the main site before an outreach visit is done. The scanner is then used to dispense medicines at the outreach site, and upon return to the main site, the primary EDT is updated with information from the scanner. At this stage, patient and stock records are updated.

**Results:** (1) 14 % (12,320) of all ART patients are serviced at outreach sites through the EDT-mobile; (2) Speed and accuracy of dispensing at outreach sites increased as dispensing is automated and labels printed. The need for double recording was eliminated thus freeing staff to perform other critical tasks. (3) Improved stock control at outreach sites due to accurate data on quantities of each antiretroviral (ARV) dispensed at the outreach site; (4) Improved patient and data management at outreach sites allowed for patient monitoring, stock management, and quantification of ARVs; (5) The need to computerize smaller outreach sites as had been envisaged was eliminated, thus saving on costs; and (6) Pill counts could be recorded which helps to objectively assess patient adherence as well as the facility average adherence.

**Conclusion:** The EDT mobile scanner is a fast, cost-effective and efficient way to manage ART records in remote settings. Because it uses batteries, the scanner can be employed in areas where there is no electricity. The record holding capacity of the scanner enables use for multiple outreach sites and eliminates the need to update the EDT daily (updates can be done monthly or quarterly). EDT mobile is effective to use where record management is essential, but installation of a desktop computer is not feasible. This novel concept is recommended for data management in sparsely populated and resource limited countries like Namibia.

**Funding Source:** US Agency for International Development/Namibia

997

#### Access

*Keywords:* monitoring and supervision; drug supply management; support supervision; harmonized supervision

#### **Monitoring and Supervision as Tool for Improving Drug Supply Management**

---

**Oudam Roath Or, Sokhan Chroeng, William Mfuko**

Ministry of Health, Cambodia

**Problem statement:** Since 1995 the management of pharmacy stores of most health facilities in Cambodia, as ascertained from a set of selected indicators, performed unsatisfactorily, among other factors, due to irregular, uncoordinated and often fewer monitoring and support supervision visits to health facilities. In 2007, in addition to the regularization, harmonization and increased the number of support supervision agreed upon with other partners, indicators were reviewed and monitored since then accordingly. Based on harmonized schedules, regular and increased numbers of monitoring and supervision visits were conducted by the central, provincial and district level staff and relevant partners.

**Objectives:** the objective of the program and change in strategy was to ensure improved drug management in all its aspects, including improving their availability by implementing measures that would minimize stock outs. This paper presents a consolidated summary of results based on the selected indicators used to evaluate the overall impact of the decision to implement this intervention in a more systematic manner.

**Setting:** increased and regularized monitoring and supervision visits to selected provincial and district health facilities. **Study population:** pharmaceutical staff working in pharmacy stores located in provincial and district hospitals. **Outcome measures:** proportion of facilities:- monitored and provided support supervision; that used correctly stock management tools; with accurate inventory; with adequate stocks; overstocks; under stocks; that experienced stock out and stock out levels; with expired medicines; and that stocked medicines that are not in the National Essential Medicines List (NEML).

Results: In 2010 a total of 92% (or 398/435) facilities were monitored and provided support supervision in about 91% visits (or 64/70 of the planned visits); the correct use of stock management tools was 96% in 2010 than in 2008 at 91%; facilities with adequate/satisfactory stock levels were higher in 2010 (at 75%) than in 2008 (at 62%); facilities that experienced overstocking declined from 9% in 2008 to 7% in 2010; facilities that were likely to experience (potential) stock out declined from 16% in 2008 to 12% in 2010; overall stock out rate declined from 13% in 2008 to 5% in 2010; the level of expired medicines declined to nearly 0.0% in 2010 from 0.9% in 2008; and the proportion of medicines stocked that are not in the NEML declined to 0.02% in 2010 from 0.09% in 2008.

Conclusions: Clearly results from this intervention demonstrate that adequate and timely monitoring and support supervision visits to health facilities pharmacy store has the potential of improving drug supply management and reducing, most important, the level of stock out at health facilities.

Funding sources: UNICEF, WHO, AEDES, KfW, HSSP, GFR5

**998**

### Policy, Regulation, and Governance

*Keywords:* pharmaceutical policy, generic (multisource) medicines, regulation, antimicrobials, private sector

### Evolution of the Generic Medicines Market in Brazil, 1998-2010: Antihypertensives, Antidiabetics, and Antibiotics

**Andréa Dâmaso Bertoldi<sup>1</sup>, Peter Stephens<sup>2</sup>, Anita K. Wagner<sup>3</sup>, Dennis Ross-Degnan<sup>3</sup>**

<sup>1</sup>Universidade Federal de Pelotas, Pelotas, RS, Brazil; <sup>2</sup>IMS Health, London, UK; <sup>3</sup>Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, US

**Problem Statement:** Generic medicines were launched in Brazil in February 2000 after implementation of the Generic Medicines Policy in 1999. Since then, three types of medicines have been available in the market: originator brands, unbranded generics, and similares (non-originator brands). In Brazil, all generic medicines must be commercialized with no brand and they are the only group of medicines which are considered interchangeable with the originator brand; similares are all the other brand medicines available in the market.

**Objectives:** To describe changes in market share of selected originator products, similares' and generics over time, following the 1999 Brazilian generics law.

**Design:** Interrupted time series.

**Setting:** Longitudinal data on sales by wholesalers to retail pharmacies in Brazil of antihypertensives, antidiabetics, and antibiotics collected by IMS Health between 1998 and 2010.

**Policies:** Generics policy (February 1999).

**Outcome Measures:** Proportion, by originator, similares, and generic products within three therapeutic classes (antihypertensives, antidiabetics, and antibiotics), of the total volume sold by quarter (unit sales volume divided by the total volume of units sold in the market) from the second quarter of 1998 (period 1) through the first quarter of 2010 (period 48).

**Results:** We analyzed 8,559 products marketed in Brazil between 1998 and 2010; 448 medicines used in diabetes, 2,113 medicines used to treat hypertension and 2,825 systemic antibacterials. Antidiabetics—Starting in period 1, the number of manufacturers producing similares rose rapidly, but this changed at period 30. From the introduction of generics in the market (period 14), the number of manufacturers producing them constantly increased. At period 1, originator brands corresponded to around 85% of the volume of sales. From period 1 to period 14, the volume of similares sales rose and originator brands sales declined. The sales volume of originator brands continued to decline, and the sales volume of similares no longer increased. At the end of the period, generics made up half of the sales, similares accounted for just over 30%, and originator brands to just below 20%. Antibiotics—At any point in time, there were more manufacturers producing similares than any other type of medicine. The number of manufacturers producing generics, on the other hand, rose during the whole period under study. The volume of sales changed very rapidly after the introduction of generics in the market. In period 9, the first generic antibiotics became available in the market. In about one year, generics overtook originator brands and similares in terms of market share. The market share of originator brands declined over time. The market shares of generics and similares in period 48 were about 60% and 35%, respectively. Antihypertensives—In period 9, the first generics were launched in the market, and the number of manufacturers producing generics increased over time. However, the number of manufacturers producing 'similares' was consistently higher than that of generics. The volume of sales of both similares and generics tended to increase until period 32. From that period onwards, volume of generics sales continued to increase while similares sales tended to stabilize.

**Conclusions:** Using data from IMS Health, it is possible to evaluate the impact of the Generic Medicines policy in the Brazilian market share. Sales of similares and particularly originator brands decreased substantially following the launch of generics in the Brazilian market.

**Funding Source:**

IMS Health provided data in kind. Drs. Wagner and Ross-Degnan were supported by a grant from the World Health Organization for the development of the ICIUM2011 scientific program.

**999**

### Access

*Keywords:* Stress-ulcer prophylaxis, cost, guidelines, clinical pharmacy

## **An Evaluation of A Clinical Pharmacist Directed-Intervention to Rationalize Overuse of Stress Ulcer Prophylaxis in Intensive Care Unit.**

**Ibrahim Labouta, Akram Fayed, Ghada Abu Shesha, Mohamed Mosly, Nahla Kandil, Abeer Hassan, Muhammad Zaitoun**

Andalusia group (Dr.Hazem Darweesh Zagzoug) - Al-Salama hospital, Egypt

**Problem Statement:** Routine pharmacologic stress ulcer prophylaxis (SUP) among critically ill patients has been questioned. Guidelines have proposed limiting the use of prophylaxis to ICU patients who are at high risk of developing stress-related hemorrhage.

**Objectives:** The purpose of this study is to compare prescription patterns according to whether stress ulcer prophylaxis is indicated or not, and the estimated cost savings pre and post the intervention of the clinical pharmacists to implement the guidelines of the (ASHP) for use of stress ulcer prophylaxis (1999) and International guidelines for management of severe sepsis and septic shock (2008) in critically ill patients.

**Design:** The current study is an intervention pretest-posttest study (without control group).

**Setting:** The study was conducted at the Intensive Care Unit of Al Salama Hospital, Alexandria; Egypt.

**Study Population:** Fifty four patients were identified for inclusion and evaluated in terms of adherence to the guidelines for two month. Then, the SUP guidelines were presented to the intensivists. Subsequently, 48 ICU patients were assessed prospectively for 6 weeks for proper indication of SUP.

**Intervention(s):** The study was conducted by the clinical pharmacists, it consisted of sending an educative email to the intensivists with a list of risk factors that predispose patients to stress ulcer so as to limit prescription of SUP to these patients; this list was also posted on the ICU board, and then followed by individual verbal communication.

**Outcome Measure(s):** The Number and percentage of ICU patients with and without correct prescription of SUP according to indication pre and post intervention were compared. The resulting costs pre and post intervention were also compared as the secondary measurement outcome.

**Results:** The clinical pharmacy intervention reduced the inappropriate prescription of overall stress ulcer prophylaxis by 6.3 percent (2 cases) (Fisher's Exact test,  $p = .219$ ). The improvement of inappropriate prescription according to indication did not differ significantly; however it was less frequent. No patients developed clinically significant gastrointestinal bleeding in the post-intervention phase. The estimated annual savings of (to be calculated) in patient charges and (to be calculated) in actual drug costs in our intensive care unit were decreased.

**Conclusions:** The interventions made by the Clinical Pharmacy Department in the form of sending an educative email and hanging posters as well as individual verbal communication were not effective in changing the prescription habits of SUP of the intensivists to meet the guidelines criteria. Limiting use of SUP to high risk patients can significantly reduce patient charges.

**Funding Source(s):** Al Salama Hospital, Andalusia Group for Medical Services

**1002**

**Access**

*Keywords:* Proton pump inhibitors, H2-blockers, gastritis, emergency department, clinical pharmacy

## **Evaluation of Pharmacist Clinical Intervention to Optimize Treatment of Gastritis in the Emergency Department**

**Hazem Zagzoug, Nahla Kandil, Ghada Abu Sheasha, Abd El Naser Khalef, Ibrahim Labouta**

Al Salama Hospital, Andalusia Group for Medical Services

**Problem statement:** Proton pump inhibitors (PPIs) are one of the most frequently prescribed classes of drug in the world because they combine a high level of efficacy with low toxicity. Yet studies consistently show that proton pump inhibitors are being overprescribed worldwide in both primary and secondary care. Emergency department physicians generally prefer prescribing PPIs over H2-blockers to relieve acute pain of patients with gastritis with no evidence of gastrointestinal bleeding, although H2-blockers are considered a more suitable alternative for the quick onset of action according to its pharmacological and therapeutic properties.

**Objectives:** The purpose of the current study is to decrease the overuse of PPIs in the emergency department (ED) and to encourage the usage of H2-blockers instead to relieve acute pain of patients admitted to ED with gastritis with no evidence of gastrointestinal bleeding.

**Design:** The current study is an intervention pretest-posttest study (without control group).

**Setting:** The study was conducted at the ED of Al Salama Hospital, Andalusia Group for Medical Services.

**Study population:** All patients admitted to the ED complaining of gastritis during 1 month pre- and post-intervention.

**Intervention:** An educative email was sent by the clinical pharmacy department concerning the pharmacological and therapeutic differences between PPIs and H2-blockers based on the fact that "PPIs are prodrugs and require an acidic environment for conversion to the active sulfonamide. This conversion requires an actively secreting proton pump." It was made clear that H2-blockers are considered more suitable for relief of acute pain for patients with gastritis. The email was followed by personal contact to assure that the message was received.

**Outcome measure(s):** The primary study outcome measurement are the consumption rates of PPIs and H2-blockers prescribed for patients admitted to the ED complaining of gastritis before and after the intervention was made.

Results: In the pre-intervention phase, 28% of drugs prescribed for gastritis among patients admitted to the ED were PPIs. After the intervention, this rate was significantly reduced to 12%; ( $\chi^2_1 = 39.715$ ,  $p < .0001$ ).

Conclusions: Clinical pharmacists can influence the attitudes and priorities of prescribers in their choice of correct treatments. This is demonstrated in this study as a significant decrease in the use of PPIs, and thus reflected in a reduction of expenditures and a reduction in medication errors.

Funding source(s): Al Salama Hospital, Andalusia Group for Medical Services

#### 1004

##### Economics, Financing, and Insurance Systems

Keywords: chronic disease, cost containment, drug utilization, pharmaceutical expenditure, health insurance

#### Impacts of Direct Fee-For-Service Payment Insurance on Access and Use of Drug: An Interrupted Time Series Study on Diabetic Care

Inthira Kanchanaphibool<sup>1</sup>, Sanita Hirunrassamee<sup>2</sup>

<sup>1</sup>Faculty of Pharmacy, Silpakorn University, Thailand; <sup>2</sup>Pharmacy division, Phramongkutklao Hospital, Thailand.

Problem Statement: Instead of advance payment by patients, the direct fee-for-service payment from the Thailand Ministry of Finance to hospitals for outpatient care has been implemented for beneficiaries of the Civil Servant Medical Benefit Scheme (CSMBS) since 2006. Consequently, the provision of care might be affected.

Objectives: To determine access and use of antidiabetic drugs before and after the implementation of direct fee-for-service payment for CSMBS beneficiaries to the hospital and to compare them with other health insurance.

Design: Longitudinal quasi-experimental analysis with an interrupted time series design.

Setting: A 1,200-bed public hospital with tertiary care services

Study Population: All diabetic outpatients with CSMBS who obtained antidiabetic drugs at the hospital between 2005 and 2009 were extracted from the hospital electronic prescription database.

Policy: The expenditure on health care for CSMBS beneficiaries had been dramatically and steadily increased every year. Many strategies were implemented for inpatient care but few for outpatient care. Health care utilization data is important for new policy formulation and development for cost-containment of outpatient care. This direct payment policy was implemented to reduce a burden of advance payment on beneficiaries and to obtain electronic health care utilization data submitted from hospitals for reimbursement. Diabetes was selected as a tracer chronic disease that could indicate the lifelong burden of outpatient healthcare costs. However, the more convenience for reimbursement might increase consumption of healthcare resources. This policy was implemented in the studied hospital in July 2006.

Outcome Measures: Levels and trends of number of patients accessed to antidiabetic drugs and average charge of antidiabetic drugs per patient per month before and after the direct payment policy implementation were examined by segmented regression analysis.

Results: The level and trend of number of diabetic outpatients with CSMBS who had access to antidiabetic drugs were not significantly changed from the baseline trend before the policy implementation ( $p > .05$ ). The same findings were found for the beneficiary patients of Social Security Scheme (SSS) and out-of-pocket (OOP) patients, except for the patients in Universal Coverage (UC) project. For the average charge of antidiabetic drugs per patient per month after the policy changed, both the level and the trend were significantly higher than the baseline trend for CSMBS and OOP patients ( $p < .05$ ). There was no change for SSS patients while the average charge was significantly decreased in level and trend for UC patients.

Conclusions: The direct fee-for-service payment to hospitals for CSMBS patients seems to extensively increase health care expenditure while the access to care was not changed.

Funding Source: No financial support.

#### 1009

##### Policy, Regulation, and Governance

Keywords: Therapeutics Committees, rabies

#### The Effectiveness of Therapeutics Committees (TCs) in Addressing Key Public Health Problems

Mary Katongo<sup>1</sup>, Victor Sumbi<sup>2</sup>, Dawn Pereko<sup>3</sup>, David Mabirizi<sup>4</sup>

<sup>1</sup>Ministry of Health and Social Services (MoHSS); <sup>2</sup>Management Sciences for Health/Strengthening Pharmaceutical Systems (MSH/SPS); <sup>3</sup>Management Sciences for Health/Strengthening Pharmaceutical Systems (MSH/SPS);

<sup>4</sup>Management Sciences for Health/Strengthening Pharmaceutical Systems (MSH/SPS)

Problem statement: During the April 2008–March 2009 fiscal year, an average of 82 dog bites per month were reported in the Kavango Region. Throughout this period, the rabies vaccine was among the top 10 expenditure items in all four districts of the region.

Objectives: To reduce the expenditure of anti-rabies vaccine in Kavango Region by addressing underlying factors which are responsible for high expenditure.

Design: Rabies, caused by bites from rabies-infected animals, is a preventable disease. The Therapeutics Committees' (TCs) interventions were designed to reduce the number of bites from infected domestic animals.

**Setting:** As part of the intervention, district TCs held meetings in four districts at the Regional Health Directorate in Rundu with the Village Development Committees and traditional leaders in their localities. The regional TC invited the Chief Executive Officer of the Rundu Town Council, Regional Veterinary Officer, and the Head of the Society for the Prevention of Cruelty to Animals (SPCA) to attend two regional TC meetings to map out interventions.

**Interventions:** (1) The Regional Council mandated Constituency Councillors to sensitise their communities on the danger of rabies and the importance of having their pets and their farm animals vaccinated against rabies. (2) The Rundu Regional veterinary team embarked on a mass vaccination campaign for pets and farm animals against rabies. (3) The Rundu Town Council committed itself to expedite the allocation of land to the SPCA for the construction of larger kennels to accommodate stray dogs. The application had been pending for the last five years. (4) The Rundu Town Council began the process of developing bylaws to control the movement of domestic animals in the community. To date, no bylaws were in place. (5) The Rundu Town Council, together with the three other local councils in the region, improved the safe disposal of domestic waste, which was the major attraction for stray domestic animals. (6) The four regional hospitals had their perimeter fences mended and instructed security officers operating main entrances not to allow dogs into the premises.

**Results:** In Kavango region, for the period April 2008 to March 2009, the average number of dog bites per month decreased from 82 to 39 and annual expenditure on anti-rabies vaccine reduced from 56,600 to 29,600 US dollars. The position of anti-rabies vaccine in the top expenditure items list dropped as follows in the four districts: 8th to 47th in Andara, 1st to 4th in Nankudu, 5th to 20th in Nyangana, and 3rd to 27th in Rundu.

**Conclusion:** TCs working in a collaborative way can be drivers for implementing effective interventions to address critical medicine use problems in their jurisdictions. TC interventions can additionally lead to significant cost savings thus facilitating use of scarce resources for priority health problems.

**Funding sources:** Operations of the TCs were fully funded by the Kavango Regional Health Directorate, Namibia.

## 1011

### Access

*Keywords:* access to medicines, equity, financing, intellectual property, pharmaceutical innovation

### **Jumping into the Pool: Is It the Shallow or the Deep End?**

---

**Anthony D. So<sup>1</sup>, Cecilia Oh<sup>1</sup>, Pascale Boulet<sup>2</sup>**

<sup>1</sup>Duke University, United States of America; <sup>2</sup>Drugs for Neglected Diseases Initiative, Switzerland

**Problem Statement:** Pooling can lower the transaction costs of accessing building blocks of knowledge, thereby facilitating and accelerating R&D for new health products. But for neglected diseases, benefits from such pooling may be restricted by tiering policies that place limits on such access for specific market segments defined by disease or geography.

**Objectives:** This study examines how the design of such pooling arrangements affects access to those in need, from bench to bedside. Specifically, what are the implications of tiering criteria on access to a pool's resources?

**Design:** The study contrasts the approaches taken to design various pooling arrangements, from compound libraries and preclinical data upstream in the R&D pipeline to journal articles, clinical trial data, and patented drugs further downstream.

**Setting:** Pooling arrangements initiated in industrialized countries have significant implications on access in low- and middle-income countries.

**Study Population:** Examples of pooling arrangements were selected to illustrate the range of upstream and downstream R&D inputs that might be assembled to accelerate innovation for neglected diseases.

**Intervention or Policy Change:** Using publicly available data on pool criteria and components, the burden of selected neglected diseases, and intellectual property arrangements, the analysis examines the implications of pool tiering design on access.

**Outcome Measures:** Disability adjusted life-years (DALYs) and deaths for selected neglected diseases

**Results:** Various pools apply different eligibility criteria for accessing the R&D inputs assembled. For example, the Pool for Open Innovation for Neglected Tropical Diseases sets initial licensing to 16 diseases and to least developed countries (LDCs). By contrast, the Medicines Patent Pool strives to include both low- and middle-income countries. Looking at three neglected diseases, tiering limited to countries classified as least developed countries has significant coverage implications. By deaths and DALYs, nearly three-quarters of the burden of disease from trypanosomiasis falls in LDCs. For leishmaniasis, the reverse is true, and 80 percent or more of the DALYs or deaths occur in non-LDCs. For Chagas disease, the burden of disease almost exclusively falls outside of LDCs. Considered another way, those living under \$2 a day in India exceed the entire populations of the 49 least developed countries combined.

**Conclusions:** Such tiering in pools has different implications for upstream or downstream R&D inputs. Upstream, noncommercial research fueled with public sector investment might go forward regardless of such tiering, but where private sector investment for scale-up is needed, the market of middle-income countries matters, and so does tiered access to these R&D inputs. Downstream, large segments of populations in need of the product may go without access. This calls for a more ambitious framework for neglected diseases R&D that ensures both innovation and access.

**Funding Source:** Drugs for Neglected Diseases Initiatives, the Open Society Institute, and the National Human Genome Research Institute

1012

**Policy, Regulation, and Governance***Keywords:* pharmaceutical policy, quality assurance, procurement, access to medicines**Experience with the Global Fund's Revised Quality Assurance Policy for Pharmaceutical Products****Sophie Logez, Joelle Daviaud, Monika Zweggarth, Carmen Perez Casas, Thuy Huong Ha**

The Global Fund to Fight AIDS, Tuberculosis and Malaria, Switzerland

**Problem Statement:** As a major financing organization in the fight against AIDS, malaria and tuberculosis, the Global Fund is committed to ensure that patients in grant-funded programmes receive quality medicines. In 2007, stakeholders raised concerns about quality criteria for key medicines such as antimalarials and anti-TB medicines which are vulnerable to emerging resistance.

In 2008, the Global Fund reviewed its Quality Assurance (QA) Policy for pharmaceuticals, using a consultative approach. Since July 2009, all funded antiretrovirals, antimalarial and anti-TB medicines must be WHO-prequalified or authorized by a regulatory authority belonging to ICH, or - if fewer than two such finished products are available on the market - have a time-limited recommendation by a WHO-hosted expert review panel. Requirements for quality monitoring in recipient countries were strengthened.

**Objective:** To monitor the impact of the revised quality policy for ARVs, antimalarial and anti-TB medicines (ATM medicines) procured with Global Fund resources.

**Design:** Policy implementation is monitored through the Global Fund's procedures for purchasing ATM medicines with grant funds: recipients must obtain the Global Fund's approval to procure products which have been reviewed by the Expert Review Panel, and must report all purchases in the online price and quality reporting (PQR) system.

**Setting:** The Global Fund finances over 600 public and private sector programs in 145 countries. Recipients procure directly from manufacturers or through national or international organizations.

**Study Population:** Since the implementation of the revised policy, Global Fund grant recipients have reported over 2500 purchases of ATM medicines worth approximately 400 million USD.

**Results:** PQR reporting indicates that grant recipients have procured exclusively WHO-prequalified or stringently authorized antiretrovirals since July 2009, but challenges remain for anti-TB products and some products for severe malaria. With the implementation of the new criteria prices have increased for some products, while qualified sources are lacking for some antimalarial and anti-TB products. The policy was fine-tuned to ensure the continued supply of products. QA policy harmonization has started with key partners; the Global Drug Facility of the Stop TB Partnership now shares the Global Fund's standards and assessment procedures.

**Conclusion:** The revised policy has created incentives for manufacturers of ATM products to meet the required standards for products of which the Global Fund is a major funder. It thus supports procurement of quality-assured medicines at competitive prices in the long term. Harmonization among donors and capacity-building in recipient countries are essential to shape the market and to facilitate implementation by countries. Consultations are under way to strengthen quality requirements for other essential medicines.

**Funding Source:** The Global Fund to Fight AIDS, Tuberculosis and Malaria

1013

**Policy, Regulation, and Governance***Keywords:* access to medicines, disclosure, Medicines Transparency Alliance (MeTA), baseline, quality information**MeTA Baseline Assessments: Experiences and Results****Samia Saad<sup>1</sup>, Wilbert Bannenberg<sup>2,3</sup>, Dennis Ross-Degnan<sup>4</sup>, Catherine Vialle-Valentin<sup>3</sup>, Anita Wagner<sup>4</sup>, Nick Perkins<sup>5</sup>, Kate Hawkins<sup>5</sup>, Gavin Stedman-Bryce<sup>6</sup>, Gilles Forte<sup>7</sup>, Saul Walker<sup>8</sup>**

<sup>1</sup>Independent Consultant, <sup>2</sup>Medicines Transparency Alliance (MeTA); <sup>3</sup>Health Action for Research (HERA); <sup>4</sup>WHO Collaborating Centre in Pharmaceutical Policy; <sup>5</sup>Institute of Development Studies (IDS); <sup>6</sup>Pamoja Consulting, <sup>7</sup>WHO; <sup>8</sup>UK DFID

**Problem Statement:** Medicines supply chains are complex and often inefficient—these issues add to patients' difficulties in accessing good quality, affordable essential medicines. Reliable pharmaceutical data is hard to find.

**Objectives:** To improve transparency in the pharmaceutical sector through data disclosure and analysis by a multi-stakeholder group (MSG), with the ultimate aim of improving access to essential medicines.

**Design:** Cross-sectional study. The MeTA baseline assessment consisted of three components: (1) An inventory of existing pharmaceutical sector data that is made publicly available; (2) An indication of the degree of community access to essential medicines through health care facilities and household surveys; and (3) An indication of quality of multi-stakeholder process, including an assessment of existing levels of engagement. MeTA and WHO worked with the WHO Collaborating Centre in Pharmaceutical Policy at Harvard and the Institute of Development Studies to develop baseline tools and provide technical assistance to countries.

**Setting:** MeTA pilot countries (Ghana, Jordan, Kyrgyzstan, Peru, Philippines, Uganda, and Zambia). National level, covering both public and private sectors.

**Study Population:** All seven MeTA pilot countries undertook component 1—a pharmaceutical sector scan and a data disclosure survey. Four countries undertook component 2—based on WHO level II methodology which surveys warehouse, health centre, hospital, and retail pharmacy facilities, while the household survey investigated medicines use in 1,080 households at community level in six regions. Five countries undertook component 3.

**Intervention(s):** All assessments were conducted between August 2009 to September 2010 with input and validation from key national institutions from public, private, civil society sectors, and academia. Results were analysed and validated by MSGs and disseminated to wider stakeholders at national fora.

**Outcome Measures:** Standardized country reports with a composite picture of the pharmaceutical market, highlighting strengths and weaknesses, with recommendations for possible policy interventions to Ministries of Health, which have been placed in the public domain.

**Results:** All seven MeTA pilot countries obtained a core set of reliable baseline data on price, quality, availability, and promotion of medicines for comparison in the next MeTA phase.

**Conclusions:** Pharmaceutical baseline surveys are an essential tool for generating good quality information and for shaping practices and policies that affect access to essential medicines. They enable tracking of progress and cross-country analysis.

**Funding Source:** UK Department for International Development (DFID).

#### 1014

##### HIV/AIDS and TB

*Keywords:* Tracking, retention, ART, resource-limited setting, loss-to-follow-up

### **Experiences and Challenges of An Accelerated Tracking Approach To Enhance Client Retention in Rural HIV clinics in North East Nigeria**

**Olukunle Omotoso, Ndulue Nwokedi, Johnson Fagbamigbe, Longjo Yusuf, Ekundayo Aigbomian, Iyaji-Ochanya Paul**

Management Sciences for Health (MSH), Nigeria

**Problem Statement:** Recent concern has been raised regarding poor retention of patients enrolled in care and treatment programs in developing nations such as Nigeria. With inadequate access, identifying innovative approaches for improving client retention is critical to the long-term sustainability of treatment efforts in resource-limited settings.

**Objective:** To examine an accelerated approach in enhancing client retention in rural HIV clinics in North East Nigeria.

**Design:** An intervention was carried out using the time series with comparison. Mapping of clients according to residential locations and communities closest to the sites were done with tracking activities. Data clerks, referral coordinators, community volunteers, and people living with HIV/AIDS were then mobilized to conduct tracking.

**Setting:** The study was carried out in five rural clinics in Adamawa State, north east Nigeria

**Study Population:** A clinical quality audit in March 2010 indicated that 380 patients out of 2,350 enrolled were lost to follow-up.

**Intervention:** Lost to follow-up was defined as not keeping to clinic appointment for more than three months from the last scheduled visit. To address this, we reorganized the defaulters tracking unit.

**Outcome Measures:** Figures showed that majority of lost clients returned to care after the intervention.

**Results:** Out of 185 patients tracked in the first phase, 102 (55%) were successfully tracked back to care, had repeat CD4 tests and were restarted on antiretroviral therapy, 34 (24%) provided incorrect addresses and could not be tracked, 10 (5.4%) had self transferred to other treatment sites. Fourteen (7.6%) denied their status, 19 (10.3%) patients were confirmed dead, while 13 (7%) tracked are still expected to restart ART.

**Conclusion:** Three major challenges were identified which leads to lack of continuity in patient-facility and patient-provider relationships; distance to clinic sites, lack of street addresses, and clients' self stigma. Development of a community-based HIV education and support program with decentralization of services to hard-to-reach communities may improve retention of clients in HIV care and treatment programs in resource-limited settings.

**Funding Source:** Management Sciences for Health

#### 1015

##### HIV/AIDS and TB

*Keywords:* Antiretroviral Therapy (ART), Integrated Management of Adult Illness (IMAI), Decentralization

### **Improving Access to ART Services in Namibia through Decentralization**

**Victor Sumbi<sup>1</sup>, Dawn Pereko<sup>2</sup>, David Mabirizi<sup>3</sup>, Jennie Lates<sup>4</sup>, Bona Nashilongo<sup>4</sup>**

<sup>1</sup>Management Sciences for Health/Strengthening Pharmaceutical Systems (MSH/SPS); <sup>2</sup>Management Sciences for Health/Strengthening Pharmaceutical Systems (MSH/SPS); <sup>3</sup>Management Sciences for Health/Strengthening Pharmaceutical Systems (MSH/SPS); <sup>4</sup>Ministry of Health and Social Services (MoHSS)

**Problem statement:** Namibia is said to be the second most sparsely inhabited country in the world. Long distances that patients have to travel to district hospitals can result in patients being non-adherent to attending clinic appointments and thus experience treatment interruptions. To improve access and ensure that services are brought closer to the people, the Ministry of Health and Social Services (MoHSS) has started providing antiretroviral therapy (ART) through outreach services and Integrated Management of Adult Illnesses (IMAI). These approaches allow districts to roll out ART services to clinics and health centres nearest to the patients. The challenges to these approaches were that they are not coordinated centrally, making it difficult for the national level to provide support to the districts and outreach sites. In addition, lack of central coordination meant that the impact and coverage of outreach services was not known.

**Objective:** To assess the extent of ART services provided through outreach and determine characteristics of clients managed through outreach to be able to support this important mechanism of ART provision throughout Namibia.

**Intervention:** Annual surveys to monitor the decentralization of ART services were introduced in 2008. Additionally, the mobile version of the electronic dispensing tool (EDT) was developed to support patient, medicines, and data management at outreach ART sites. Through the EDT-mobile, data from the outreach sites was incorporated onto the main EDT and could be analysed as part of the main site or separately for outreach sites. Thirty main ART sites were provided with the EDT mobile to support outreach services.

**Results:** (1) Number of outreach sites in Namibia increased from 66 in 2008 to 106 in 2010. (2) Fourteen facilities that were previously outreach sites have been upgraded to full ART sites through provision of full-time ART staff to manage patients. These are the sites that had high volume or were a great distance from the main ART sites. (3) Survey reports are used centrally in coordinating allocation of resources, e.g., dispensing equipment, human resources, and medicine storage infrastructure. (4) 14% (12,040) of all patients on ART are seen at outreach sites. (5) More paediatric patients (under 13 years) are seen at outreach sites than adult patients. (6) Districts, which were previously not conducting outreach services, have now planned to take services closer to the people through outreach services.

**Conclusions:** One of the barriers to accessing treatment is the distances patients have to travel to service delivery points. Outreach services in Namibia have proved to be an effective way of reaching patients in remotes areas. Annual surveys and the EDT mobile are effective ways of monitoring outreach services for both the districts and the central level.

**Funding sources:** US Agency for International Development/Namibia

## 1016

### Policy, Regulation, and Governance

*Keywords:* drug promotion, regulation

#### Pharmaceutical Advertising and Promotion Regulation of Seven Latin American Countries

**Claudia Vacca<sup>1,2</sup>, Claudia Vargas<sup>1,2</sup>, Martín Cañás<sup>3,4</sup>**

<sup>1</sup>IFARMA, Colombia; <sup>2</sup>CIMUN, (Centro de Información de Medicamentos Universidad Nacional de Colombia);

<sup>3</sup>Federación Médica de la Provincia de Buenos Aires (FEMEBA) Argentina; <sup>4</sup>Grupo Argentino Para el Uso Racional de los Medicamentos (GAPURMED)

**Problem Statement:** Pharmaceutical advertising and promotion (PA&P) refers to activities that pharmaceutical companies use to release and promote sales of their products, depending on creative initiatives in the marketing areas, national legal restrictions, surveillance capabilities of the regulatory authority, and harmonization trends.

**Objectives:** To analyze the regulation of PA&P in 7 Latin American countries based on the WHO ethical criteria.

**Design:** Descriptive study

**Setting:** Argentina, Bolivia, Brazil, Colombia, Ecuador, Nicaragua, and Peru

**Methodology:** Between November and December 2007, and an update query in September 2008, information was collected about laws and regulations about PA&P from Argentina, Bolivia, Brazil, Colombia, Ecuador, Nicaragua, and Peru. The analysis identified the gaps between the WHO ethical criteria and the contents for the rules and the degree of restriction (detailed appearance and expanded WHO ethical criteria) and/or flexibility (absence or less detail from the WHO ethical criteria) in each country.

**Results:** The regulation of PA&P for over-the-counter medicines in Argentina, Bolivia, and Ecuador are more flexible in relation to other countries. The outcomes assessed include permitted broadcast media, requirements for public information, restrictions information, promotional activities, free samples, sponsorship of events, prohibited promotional activities, and penalties. While all tested regulations for prescription drug seem restricted in relation to these variables, in addition to the requirements of information for professionals.

**Conclusions:** The comparison suggests a tendency to exclude some key criteria for risk prevention and consumer protection and streamline some of WHO criteria, through strategies of ambiguity and the use of vague terms. For example, the vague definitions of promotion, advertising, and medical information included in the legislation enable the mass dissemination of disguised promotion. There is poor information on surveillance and punishment. The mass dissemination of disguised promotion should be monitored, reported, and its impact documented so it can be prevented through penalties. We recommend that this subject be actively researched, with special emphasis on the impact of regulation, the procedures for approval of advertising (prior approval or not), and the impact on population use and health, as well as the effects of the international trend allow direct to consumer advertising and the adoption of codes of self-regulation by the industry for its overall impact and potential negative consequences for health and health spending.

**Funding Source:** Acción Internacional para la Salud

## 1018

### Drug Resistance

*Keywords:* Hospital, antimicrobials, medicine use indicators, antimicrobial resistance, rational medicine use

#### Development and Application of Selected Indicators to Investigate Antimicrobial Use in Hospitals

**Terry L. Green<sup>1</sup>, Mohan P. Joshi<sup>1</sup>, Aisha Noorzaee<sup>2</sup>, Zahir Siddiqui<sup>3</sup>, Zafar Omari<sup>3</sup>**

<sup>1</sup>Strengthening Pharmaceutical Systems (SPS) Program, Management Sciences for Health (MSH), Arlington, VA, USA; <sup>2</sup>Ministry of Public Health, Afghanistan; <sup>3</sup>MSH/SPS Afghanistan

**Problem Statement:** Detecting problems in antimicrobial use in hospitals is the first step in evaluating the underlying causes and taking remedial action. The World Health Organization (WHO) published "How to Investigate Drug Use in Health Facilities" in 1993, which focused mainly on ambulatory departments of primary care settings. Participants at ICIUM 1997 and 2004 identified the need for indicators and methodology suitable for use in hospital settings. To fill this need, the Strengthening Pharmaceutical Systems Program (SPS), and its predecessor Rational Pharmaceutical Management (RPM) Plus, developed a set of indicators to investigate antimicrobial use in hospitals.

**Objective:** To field test and finalize the hospital antimicrobial indicators and implement them in a low-resource country

**Setting and Intervention:** Field test of the draft indicators in 3 public Ugandan hospitals in 2008 and application of the validated indicators in 14 public and private hospitals in Afghanistan in 2009

**Outcome Measures:** A set of antimicrobial indicators and data collection methodology validated, finalized, and used in low-resource setting hospitals

**Results:** The field test in Ugandan hospitals validated the indicators and led to their finalization. The resulting manual, "How to Investigate Antimicrobial Use in Hospitals: Selected Indicators" has five hospital indicators, nine prescribing indicators, and two patient care indicators along with detailed instructions and data collection forms for use in resource-constrained settings. The field test generated data on antimicrobial misuse, overuse, and underuse in Ugandan hospitals. The application of the finalized indicators in Afghanistan as a part of a medicine use study revealed problems in the availability and use of antimicrobials in hospitals. For example, 92% of patients received one or more antimicrobials in multiple doses over multiple days for surgical prophylaxis; half of the patients received a third-generation cephalosporin (100% in one private hospital); no hospital performed culture and sensitivity tests; and the average number of days out-of-stock per month for a set of key antimicrobials was 8.7. This study, along with the WHO health facility indicator study, led to recommendations to the Ministry of Public Health to develop standard treatment guidelines, establish drug and therapeutics committees (DTCs), and revise rational medicine use training programs for professional staff.

**Conclusions:** DTCs, physicians, pharmacists, managers, and researchers can use this indicator manual to assess and monitor antimicrobial use in their hospitals. Its application in Afghanistan generated local hospital data and recommendations to improve antimicrobial use and contain antimicrobial resistance.

**Funding Sources:** SPS and RPM Plus through US Agency for International Development

## 1022

### HIV/AIDS and TB

*Keywords:* drug resistance, tuberculosis, supply management, gender perspective, pediatric medicines

### **MMDR-TB Among Children in Moldova**

**Natalia Cebotarencu, Manoj Kurian, Maria Cetulean, Sofia Alexandru**

CoRSUM - Coalition for Rational and Safe Use of Medicines, Moldova, Republic of

**Problem Statement:** As the 21st century begins, tuberculosis (TB) remains a major public health threat and the world's leading cause of death from a curable infectious disease. Pediatric TB did not have a high priority in many developing countries including Moldova as fewer children than adults have the disease and children are not usually infectious. A vast number of infected children remain undiagnosed—creating a reservoir of future adult disease. There are a limited number of pediatric TB departments in Moldova, and families with a child with TB have to pay for travelling to a clinic. The next problem is the lack of pediatric dosages which can lead to increasing rate of resistance forms of tuberculosis among children.

**Objectives:** To investigate the situation in TB, and multidrug-resistant (MDR) –TB among children in Moldova. To identify obstacles in accelerating progress in the achievement of the Millennium Development Goals (MDG).

**Design:** Epidemiological study, pharmaceutical policy analysis, time series study

**Setting:** Children with TB in Moldova. Municipal tuberculosis hospital, pediatrics department, Chisinau, Moldova.

**Study Population:** All TB cases among children registered in Chisinau, Moldova, from 2000 to 2009

**Interventions:** Studied medical cards of children treated in municipal TB hospital, Chisinau; annual reports of anti-Tb medicines supply during 2000–2010 focusing on availability of pediatric forms.

**Policy:** Implementation of the MDG Target 4 and Target 6; and Resolution WHA 60\_R20.

**Outcome Measures:** Number of TB and MDR-TB cases in children TB; availability of pediatrics forms and strengths of anti-TB medicines.

**Results:** In Moldova, the total number of children with TB was 85 in 2000. A DOTS program was implemented in Moldova in 2001. The number of new case notification of TB in children increased during four years to 217 cases in 2004. Since 2005, the total number of children with TB started to decrease; children received the treatment in Chisinau TB hospital and in two more settings— Balt and Bender. In 2005, 50% of all children with TB (86 of 170 total) in Chisinau municipal hospital were treated; in 2006–85 children out of 162 were treated; in 2007–70 children out of 162. In 2008 and 2009, about 30% were treated—51 (141) and 59 (150). Among all children with TB, the % of girls with TB increased: in 2005–43%, 2006– 48%; 200 – 47%; 2008–47% and in 2009– 53%. Patterns of drug resistance were registered among children since 2006: in 2006, there were 9 cases of MDR-TB in children (6 girls), in 2007, 3 cases (3

girls); 2008, 9 cases (5 girls), and in 2010, 14 cases (10 girls). Despite pediatric formulation being included in Essential Drug List of Moldova, at present no pediatric forms and strengths are available in Moldova.

Conclusions: MDR-TB among children is increasing during last few years, mainly among girls. There is the urgent need of procuring children's dosage forms of anti-TB drugs.

Funding Sources: WCC, CoRSUM.

**1024**

**Policy, Regulation, and Governance**

*Keywords:* quality assurance, essential medicines, pharmaceutical policy, procurement

**Study on Quality Assurance for Essential Medicines other than ARVs, Antimalarial and Antituberculosis Medicines**

**Joëlle Daviaud<sup>1</sup>, Jean-Michel Caudron<sup>1</sup>, Corinne Pouget<sup>2</sup>, Monika Zweggarth<sup>2</sup>, Abu Saleh<sup>1</sup>, Carmen Perez Casas<sup>1</sup>, Sophie Logez<sup>1</sup>**

<sup>1</sup>The Global Fund to Fight HIV, Tuberculosis and Malaria, Switzerland; <sup>2</sup>Quamed, Institute of Tropical Medicine, Antwerp, Belgium

**Problem Statement:** The Global Fund's quality assurance policy for pharmaceutical products requires that ARVs, antituberculosis, and antimalarial medicines procured with grant funds meet internationally recognized quality norms and standards. However, less stringent requirements are in place for other essential medicines, which include life-saving medicines, such as anti-infectives.

**Objectives:** The study aimed to determine the current quality assurance status of essential medicines other than ARVs, antimalarial, and anti-TB medicines, and to identify areas for improvement to inform policy development.

**Design:** This descriptive study entailed a questionnaire survey and visits to five recipient countries (Armenia, Burkina Faso, Cambodia, Nepal, and Nicaragua).

**Setting:** The questionnaire survey was conducted among key donors, grant implementers and organizations with procurement activities. Relevant stakeholders were interviewed during the country visits, including representatives of facilities across levels of health care, regulatory authorities, local manufacturers, recipients of Global Fund grants, WHO country offices, and disease programmes.

**Study Population:** The questionnaire survey was completed by 27 of 53 organisations contacted. Key informants were interviewed during each of the five one-week country visits.

**Results:** Based on the outcomes of the study, national regulatory authorization of essential medicines does not by itself give reasonable assurance that pharmaceutical products used in grant-funded programmes meet internationally recognized quality standards. Procurement agencies assume responsibility for quality assurance of the products that they deliver, but many lack the specific pharmaceutical capacity, insight and/or access to information required for this purpose. Quality control testing is overemphasized in relation to more proactive measures such as qualification of sources based on evaluation of product documentation and production sites assessment. Key stakeholders recognize the need for a more stringent approach to quality assurance for essential medicines; however they expressed concerns about possible price increases, reduced access to medicines if the market were to be limited, the impact on local pharmaceutical industries, and the creation of multiple quality standards for these widely-used medicines.

**Conclusions:** A global harmonized approach is needed to promote adherence to internationally recognized quality norms and standards for essential medicines. Major donors should work together to develop a policy approach and to phase in quality assurance requirements on a risk basis. These donor-driven measures should benefit the wider national health and medicines regulatory systems of recipient countries.

**Funding Source:** The Global Fund to Fight AIDS, Tuberculosis and Malaria

**1025**

**Policy, Regulation, and Governance**

*Keywords:* MeTA, multi-stakeholder groups, transparency, disclosure, good governance

**Multi-Stakeholder Collaboration: Can It Improve Transparency, Disclosure**

**WJ {Wilbert} Bannenberg<sup>1,6</sup>, Samia Saad<sup>2</sup>, Christine Kalume<sup>3</sup>, Carolyn Green<sup>1</sup>, Claire Innes<sup>3</sup>, Saul Walker<sup>3</sup>, Gilles Forte<sup>4</sup>, Andreas Seiter<sup>5</sup>**

<sup>1</sup>Medicines Transparency Alliance (MeTA); <sup>2</sup>Independent Consultant, <sup>3</sup>DFID; <sup>4</sup>WHO; <sup>5</sup>World Bank; <sup>6</sup>Health Research for Action (HERA)

**Problem Statement:** After 30 years of a valid essential medicines concept, 2 billion people are still without access to essential medicines (ATM). Efforts to promote ATM have largely focused on interventions by governments; they have not yet seriously involved the private (for profit, nonprofit) sector or civil society.

**Objectives:** The MeTA pilot phase aimed to test the hypothesis that multi-stakeholder collaboration between government, private sector, and civil society improves disclosure, transparency, accountability, policies; and ultimately improves ATM.

**Design:** Review, qualitative study.

**Setting:** Global and national level, involving public and private sector, and civil society

**Study Population:** Seven countries (Ghana, Jordan, Kyrgyzstan, Peru, Philippines, Uganda, and Zambia), who accepted an invitation by DFID to pilot MeTA.

**Intervention:** In collaboration with stakeholders, MeTA established multi-stakeholder groups (MSGs) willing to perform a pilot of the MeTA hypothesis. These transformed into 7 national MeTA councils, establishing work plans, budgets, and national secretariats. Stakeholders were asked to transparently disclose key data about the overall medicines supply chain, analyse the information, seek country-specific solutions, and advocate for policies to improve access to medicines. Baseline studies were undertaken on the pharmaceutical sector and disclosure practices in all 7 countries. Four countries undertook WHO level II household and facility surveys. Five countries assessed the multi-stakeholder collaboration using a new tool. Civil society coalitions were formed and assisted with capacity building in all 7 countries. All 7 countries organised national fora to discuss MeTA data and reports. Establishing MSGs took more than 12 months; the pilot phase lasted 2.5 years. A second phase of MeTA started in 2012.

**Policies:** Several MeTA countries also discussed national medicines policies, and contributed to changes in legislation, drug regulatory transparency, price surveys/ monitoring, generic policies, and evidence-based treatment guidelines.

**Outcome Measures:** Baseline and country reports. MeTA review of the pilot phase. An independent evaluation of MeTA in February 2010 concluded that time was too short to reject or confirm the MeTA hypothesis, or to expect impact on ATM, but there were promising signs.

**Results:** All 7 countries established active MSGs, performed baseline studies, disclosed and analysed data, advocated for better policies, and presented results to national fora and through Internet.

**Conclusions:** Structured multi-stakeholder dialogue at country level can increase transparency and disclosure. The MeTA pilot phase was too short to prove whether or not it increases access to medicines.

**Funding Source:** DFID (with technical support by WHO, World Bank)

**1033**

### **Policy, Regulation, and Governance**

*Keywords:* Pharmacovigilance; Indicators, Performance indicators; Monitoring and Evaluation

#### **Proposed Set of Indicators for Monitoring and Evaluation of Pharmacovigilance Activities**

**Ambrose Ohumagho ISAH<sup>1</sup>, Shanthi PAL<sup>2</sup>, Sten OLSSON<sup>3</sup>**

<sup>1</sup>University of Benin, Benin City, Nigeria (INRUD Nigeria), Nigeria; <sup>2</sup>World Health Organization, Geneva; <sup>3</sup>International Collaborating Centre, Uppsala, Sweden

**Problem Statement:** The thalidomide tragedy triggered global consciousness regarding the safety of medicines. The need to monitor safety issues regarding the intake of medicines has resulted in the tremendous growth of pharmacovigilance (PV) structures and activities. However, there are no acceptable standard set of indicators to measure and monitor these activities. Furthermore, there are no indices for comparison of measures in relation to baseline periods or inter- and intra-country, region, and facility comparisons.

**Objectives:** To outline a set of indicators for monitoring PV activities

**Design:** A qualitative study with the identification of a set of candidate indicators.

**Setting:** The envisaged setting for use will include country, regional, and health facilities, and public health programmes.

**Methods:** The set of indicators were identified from several sources—initially from a detailed review of the established pharmacovigilance process/routine, contributions from pharmacovigilance experts, national pharmacovigilance centres, and groups including Pharmacovigilance sans Frontiers (PVSF), the World Health Organization (WHO) Advisory Committee on Safety of Medicinal Products (ACSoMP), WHO/Uppsala Medical Centre, and literature sources.

**Results:** A total of 64 candidate indicators were identified. The indicators were categorized into structural (19) which assesses the existence of key PV structures, systems, and mechanisms in the setting; process (26) which assesses the entire mechanisms and degree of PV activities; and outcome/impact (19) which measures the effects (results and changes) of PV activities indicators. A set of background information parameters (10) to put into perspective the PV milieu (demographics, economics, health care system, and pharmaceutical scenario) generating the indicator data was also noted. This will also serve to provide the denominator for measuring the indicators. A further categorization into core and complementary indicators were made. A further subset for use in public health programmes is also highlighted

**Conclusions:** The set of indicators provide a useful robust tool to monitor and evaluate PV activities at various levels of the health care system as well as to provide indices for comparison of PV activities at country, regional, and facility levels, and within public health programmes.

**Funding:** WHO

**1034**

### **Economics, Financing, and Insurance Systems**

*Keywords:* Drug utilization, Health insurance, Health policy evaluation, Cost-effective use, Thailand, Market share data

#### **The Impact of Universal Coverage on Use of Medicines in Thailand: An Evaluation Using Market Share Data**

**Laura Faden Garabedian<sup>1</sup>, Dennis Ross-Degnan<sup>1</sup>, Sauwakon Ratanawijitrasin,<sup>2</sup> Peter Stephens<sup>3</sup>, Anita Wagner<sup>1</sup>**

<sup>1</sup>Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, MA, United States of America; <sup>2</sup> Mahidol University, Nakhonprathom, Thailand and the Pharmaceutical System Research and Intelligence Center; PhaReD Foundation, Bangkok, Thailand <sup>3</sup>IMS Health, London, UK

**Background:** In 2001, Thailand implemented the 30 Baht Scheme, a public insurance scheme covering the poor and uninsured. Goals of the capitated payment scheme were to achieve universal access to health care, including medicines on the National List of Essential Medicines (NLEM), and to influence provider behavior to use resources efficiently. Under the policy, patients paid a flat fee of 30 Baht for every encounter, including prescription medicines, at the area hospital to which they were assigned. After implementation of the 30 Baht Scheme, the percentage of the Thai population covered by public insurance jumped from 40% in 2001 to 95.5% in 2004, with 75.2% of the population insured through the 30 Baht Scheme.

**Objectives:** To evaluate the immediate (first year) and long-term (five year) impacts of the 30 Baht scheme on pharmaceutical consumption in Thailand for medicines in three non-communicable disease areas: cancer, cardiovascular disease, and diabetes.

**Design:** Interrupted time series design without control and with unequal comparison group

**Setting:** Thailand (a lower-middle income country) from 1998-2006

**Study Population:** Quarterly purchases of medicines used for cancer (antineoplastics, cytostatic hormones, and immunostimulating agents), cardiovascular disease (antihypertensives, cardiac therapy, and lipid regulating agents), and diabetes (oral antidiabetics and insulins) from hospital and retail pharmacies collected by IMS Health between 1998 and 2006.

**Interventions/Policies:** Thailand's 30 Baht Scheme (also known as the Universal Coverage Scheme) implemented in 2001.

**Outcome Measures:** There are two outcome measures:

(1) Total Volume is the number of units of medicines purchased. We examine total volume per 1,000 people by sector (i.e., retail and hospital) and by inclusion on the Thai NLEM.

(2) Market share is the percent of total volume within therapeutic category by licensing status (i.e., originator products, branded generics, generics and GPO-produced products).

**Results:** Volume: In Thailand, the majority of sales for cancer, cardiovascular disease and diabetes medicines between 1998-2006 occurred in the hospital sector, as opposed to the retail sector, and were for medicines on the NLEM. The 30 Baht Scheme was associated with long-term increases (i.e., increased post-policy trend and absolute increase after 5 years) in hospital sector sales of medicines for conditions that can be adequately treated in outpatient and primary care settings, such as diabetes, high cholesterol and high blood pressure. The policy was associated with no change, or a decrease, in sales of medicines for more life-threatening diseases, such as myocardial infarction, stroke and cancer, which are more appropriately treated in secondary or tertiary settings. While the majority of sales were for medicines on the NLEM, there were also significant post-policy increases in non-NLEM medicines for most therapeutic classes.

**Market Share:** Immediately following the reform, there was a significant shift (i.e., level change) in hospital sector market share by licensing status for most classes of medicines. For antidiabetics and cardiac therapy medicines - the two therapeutic classes that experienced the largest shifts - we observed significant increases in government-produced products, primarily at the expense of branded generics. Two classes - lipid regulating and immunostimulating agents - experienced a significant shift from originator products to branded generics.

**Conclusions:** Our results suggest that expanding health insurance coverage with a medicines benefit to the entire Thai population increased the volume of medicine sales in primary care hospitals. However, our study also suggests that implementation of the 30 Baht Scheme may have been associated with possibly undesirable effects: increased use of non-NLEM medicines and decreased use of less expensive generics and medicines in secondary and tertiary settings. Thorough evaluation of desired and undesired effects of universal health insurance programs are urgently needed.

**Funding Source:** IMS Health (data provided in kind), Harvard Medical School Fellowship in Pharmaceutical Policy Research

## 1035

### Access

**Keywords:** Household, Access, Ghana, Medicines, Rational Use

### Household Access to and Use of Medicines in Ghana

**Daniel Kojo ARHINFUL<sup>1</sup>, Edith Andrews Annan<sup>2</sup>, Martha Gyansa-Lutterodt<sup>3</sup>, Anthony Kusi<sup>1</sup>, Augustina Koduah<sup>3</sup>**

<sup>1</sup>Noguchi Memorial Institute for Medical Research, University of Ghana, Legon, Accra, Ghana; <sup>2</sup>WHO Country Office, Accra, Ghana; <sup>3</sup>Ghana National Drugs Programme, Ministry of Health, Accra, Ghana

**Problem statement:** As part of the first Five-Year Medium Term Strategic Framework (1997–2001) for health development, starting in 1997, Ghana implemented a set of interventions in the pharmaceutical sector to improve access to essential medicines and their rational use. This field study to measure access to and use of medicines in households was undertaken in May–June 2008.

**Objectives:** The main goal of the survey was to document access to and use of medicines in the population and across socioeconomic levels.

**Design:** A population-based survey using the standardized methodology developed by the World Health Organization (WHO) and the proposed Medicines Transparency Alliance (MeTA) sampling approach for Level II facility and household surveys.

**Setting:** It was conducted in six of the ten regions of Ghana systematically selected to represent varied socioeconomic profile and agro-ecological zones based on a combination of purposive and random sampling.

**Study population:** In each survey region, households were systematically chosen by purposive cluster sampling according to their distance from a reference facility: a third of sampled households were within 5 km, a third between 5 and 10 km, and a third farther than 10 km from the reference facility. A total of 1,065 household respondents were interviewed by means of a structured paper questionnaire and data entry was performed with EpiData software and analysis with Excel.

**Outcome measure(s):** The primary outcomes assessed information on socioeconomic level of households, access to and use of medicines for acute and chronic conditions, and opinions and perceptions about medicines including geographic access, affordability, and quality of medicines.

**Results:** The results show that geographical access to health facilities by households was high. The majority (80%) were close (less than 15 minutes travel time) to a health care facility, and have easy access to medicines in case of acute illness and for chronic diseases. The penetration of medicines insurance coverage in Ghana was fairly high (46% and 47% of households for acute and chronic conditions respectively). About a third of household respondents, however, believe that medicines are not affordable with the majority of them being in the lowest socio-economic status (SES) group (spending less than GhC16 (US\$10) per person per month). Some 53% of households had medicines at home suggesting good access to medicines. Two monotherapies, chloroquine and quinine together, accounted for 1 in 4 of antimalarials kept at home.

**Conclusions:** Results of the survey show that while access to medicines in Ghana is fairly good, their appropriate use by households leaves much to be desired. To ensure appropriate and rational use, therefore, there is need to step up consumer education through providers and other community structures.

**Funding source(s):** Financial support was provided by the European Union and the World Health Organization (WHO) country office, Accra.

1037

#### Child Health

*Keywords:* public-private partnerships, access to medicines, pharmacoepidemiology, surveillance, vaccines

### **Evaluating the Impact of a Public-Private Partnership for the National Introduction of a New Rotavirus Vaccine: Evidence from a Case-Control Study in Nicaragua (2006–2009)**

**T. Christopher Mast<sup>1</sup>, Felix Espinoza<sup>2</sup>, Leonel Palacio del Carmen<sup>3</sup>, Shazia Khawaja<sup>1</sup>, Anna Cardellino<sup>1</sup>, Edmundo Sanchez<sup>4</sup>**

<sup>1</sup>Merck Research Laboratories, United States of America; <sup>2</sup>Leon University, Leon, Nicaragua; <sup>3</sup>Manuel de Jesús Rivera Hospital, Managua, Nicaragua; <sup>4</sup>Ministry of Health, Managua, Nicaragua

**Problem Statement:** Rotavirus causes over 500,000 annual deaths globally among children aged <5 years; 80% of deaths are in the developing world. In 2006, a highly efficacious rotavirus vaccine (RV5; RotaTeq™ [rotavirus vaccine, live, oral pentavalent] ) was licensed in the United States and Europe but its effectiveness in low-income countries was unknown. In addition, it has historically taken up to 20 years for a new vaccine to be available in developing countries.

**Objectives:** The Merck and Nicaragua RotaTeq™ Partnership was established in 2006 to provide: (1) free vaccinations against rotavirus gastroenteritis to all eligible infants born in Nicaragua; (2) a scientific evaluation to measure the public health impact of the three-year partnership; and (3) planned programmatic sustainability.

**Design:** A matched case-control design evaluated vaccine effectiveness (VE) between February 2007–October 2009. A surveillance program assessed vaccination coverage.

**Setting:** Six hospitals in Nicaragua and the surrounding communities

**Study Population:** The surveillance program enrolled 6,174 children with acute gastroenteritis (GE). Of these, 1,082 children had rotavirus RGE and 300 met the protocol definition of RGE for inclusion in the VE analysis. Cases were age-matched with 1,685 community controls and 1,894 hospital controls.

**Intervention:** The partnership provided over 1.3 million RV5 doses to infants in Nicaragua. Vaccine introduction and administration was implemented by the Ministry of Health through its routine vaccination program.

**Policy:** The study evaluated the policy impact of adopting a new vaccine into the routine national immunization delivery system.

**Outcome Measures:** (1) Extent of vaccination coverage, (2) public health impact assessment of the partnership, and (3) sustained national vaccination with RV5 after completion of the partnership.

**Results:** The partnership resulted in a three-dose RV5 vaccine coverage rate of 92% among age-eligible children within the study period. Using conditional logistic regression, the adjusted VE against severe rotavirus disease in children receiving three doses was 87% (95% confidence interval [CI]:74,93) using community controls; 64% (95% CI:44,78) using hospital controls; and 76% (95% CI:63, 84) using combined control groups. In children at highest risk (<12 months old at the time of RGE onset), VE was 85% (95% CI:66,93) for the combined groups (all results p<0.05). After the completion of the partnership, Nicaragua continues vaccination with RV5 in 2011 and the sustainability of rotavirus vaccination has been ensured by a commitment from the GAVI Alliance.

Conclusions: The partnership demonstrated a feasible and sustainable model to reduce the delay in introducing a measurably effective new health intervention into a GAVI-eligible country.

Funding Source: Merck Research Laboratories.

**1039**

#### HIV/AIDS and TB

*Keywords:* Availability, TB, Policy, Medicines, Private Market, Legislations

### Restricting the Availability of Anti-TB Medicines in the Private Market of Eastern Mediterranean Region Countries: A Call for Policy Intervention

**Mohamed Abdelhakim<sup>1</sup>, Khaled Khalil<sup>1</sup>, Zafar Mirza<sup>2</sup>, Nada Ramy<sup>3</sup>, Akihiro SEITA<sup>4</sup>, Mohamed Binshahna<sup>1</sup>, Mohamed Ismail<sup>1</sup>**

<sup>1</sup>WHO/EMRO, Egypt; <sup>2</sup>WHO, Geneva; <sup>3</sup>London School of Hygiene and Tropical Medicine; <sup>4</sup>UNRWA

**Problem Statement:** Tuberculosis (TB) medicines should be dispensed only under control or supervision (according to DOTS principles), yet very few countries in the Eastern Mediterranean Region (EMR) have seriously considered the subject or issued any regulatory/legislative intervention to limit the presence of these medicines in the private market.

**Objectives:** Collecting evidence on the availability of TB medicines in the private market in EMR countries and mapping current legislative arrangements of countries from the region in relation to regulating the availability and dispensing of TB medicines.

**Design:** Questionnaires were sent to National Medicines Regulatory Authorities, requesting (1) A list of all registered TB medicines in the country (registered—got market authorization not necessarily circulating in the market); (2) whether there was existing legislation on selling these medicines in the private market (pharmacies/other licensed vendors). If so, we asked for a copy of the legislation, law, or provision on that issue. In addition, managers at Ministries of Health (MOH) and National Tuberculosis Programme (NTP) managers were interviewed by phone. In addition, data from field visits to 140 private pharmacies in 14 of the 22 EMR countries were used from during the regular WHO/ Global Drug Facility travel missions.

**Setting:** The study was conducted in the 22 WHO EMR countries.

**Intervention:** One pilot intervention

**Policy:** No policy intervention took place yet, as the synthesis of the study is still on going

**Outcome Measures:** (1) Number of responses from countries; (2) number of laws and legal provisions received from countries; and (3) lists of anti-TB medicines registered in countries.

**Results:** Among the 22 EMR countries, 8 of them (36%) did not respond; in the remaining 14 countries (64%), the results were anti-TB medicines were present in all pharmacies visited for the survey in 9 (64%) of them. The type of medicines present varied between rifampicin, isoniazid, pyrazinamide, and ethambutol and their combination of different strengths and dosage forms. Prescribing anti-TB medicines was usually targeted towards treating TB and not other conditions requiring antibacterials. Over-the-counter dispensing of these medicines by pharmacists is practiced but not frequently. The level of education about anti-TB medicines is generally low.

**Conclusions:** There is an indispensable need to have a policy intervention on the issue of anti TB medicines availability in private market. Among the suggested recommendations are (1) facilitate further systematic operational research to be executed by the governments to provide evidence for a proper regulatory intervention; (2) mobilize policy makers for a favorable decision on deregistration of medicines that are present in the market and not complying with the global clinical and WHO recommendations; and (3) limiting the presence of anti-TB medicines to primary health care clinics in rural areas and primary health care hospitals in urban areas.

Funding Source: Global Drug Facility

**1040**

#### Policy, Regulation, and Governance

*Keywords:* Procurement, Transparency, Accountability, Benchmarking, Regional collaboration

### Transparency, Governance and Regional Collaboration in Pharmaceutical Procurement in Kenya, Tanzania, and Uganda

**YK {Yvonne} Nkrumah<sup>1</sup>, WJ {Wilbert} Bannenberg<sup>2</sup>, EM {Marianne} Schuermann<sup>2</sup>, AC {Ed} Vreeke<sup>2</sup>, VS {Tina} Patel<sup>3</sup>, J {Joseph} Mhando<sup>3</sup>, JW {James} Tamale<sup>3</sup>**

<sup>1</sup>World Bank Institute (WBI); <sup>2</sup>Health Research for Action (HERA); <sup>3</sup>Independent consultant

**Problem Statement:** Poor governance in pharmaceutical procurement undermines access to medicines of good quality that are reasonable priced and supplied in sufficient quantities for those most in need. Poor governance can result in product specifications that limit competition, biased quantification and supplier selection decisions, manipulation of orders to increase quantities of certain items, skewed award of contracts or other circumventions of tenders, and poor knowledge of end-user needs. Ultimately, poor governance contributes to the inability of service providers to fulfill the demand for essential medicines.

**Objective:** To strengthen and institutionalize accountability and transparency in government pharmaceutical procurement and supply chain management policies, practices and procedures.

**Design:** Literature review, institutional assessment, capacity building events, use of information and communication technology (ICT) for data collection, and public feedback.

**Setting:** Regional multiple stakeholders initiative being piloted in Kenya, Tanzania, and Uganda

**Study Population:** Public sector and non-profit private sector procurement agencies, ministries of health, and civil society organizations (CSO) in Kenya, Tanzania, and Uganda

**Interventions:** Literature review, followed by interviews of procurement agencies and their stakeholders on issues around procurement and transparency. An assessment tool was applied to benchmark the performance of the procurement agencies. Draft country reports were discussed at national validation workshops and a national coalition made up of multiple stakeholders has been established in each country to drive procurement reforms. Three priority areas have been identified by countries and translated into action plans to address poor governance: CSO empowerment, improved access to procurement and supply chain information, and use of ICT to generate and analyze data to inform policy reform. The coalitions are linked at the regional level through a regional online platform ([www.enepp.net](http://www.enepp.net)) where they share information on the implementation of their action plans. Members also exchange information on essential medicines selection, quantification, prices and quality obtained, and supplier performance.

**Policy:** The initiative seeks to determine whether a multi-stakeholder group working together to facilitate information sharing, leverage technical expertise, and monitor procurement and supply chain functions could improve the systems for procuring and supplying medicines, as well as contribute to increased access to medicines.

**Outcome Measures:** benchmark assessments, capacity development, country multi-stakeholder coalitions, country action plans, regional comparative data on prices, use of ICT tools, and efficiency and transparency of procurement agencies.

**Results and Conclusions:** (1) Creation of active country multiple stakeholder coalitions in Kenya, Tanzania, and Uganda that focus on pharmaceutical procurement and supply chain management; (2) development and implementation of country action plans with a focus on CSO empowerment, use of ICT, and improved access to information on procurement; (3) design and establishment of an online social networking platform ([www.enepp.net](http://www.enepp.net)) to facilitate and sustain peer-to-peer learning and problem solving, and provide access to comparative medicine price data for the three countries; and (4) developed a regional training of trainers manual to enhance capacity and credibility of CSOs.

**Funding Sources:** World Bank Institute, Irish Aid Trust Fund

## 1042

### HIV/AIDS and TB

*Keywords:* antiretrovirals, health facilities, information technology, pi

### **Demonstrating the Potential Role of Information and Communication Technologies in Improving Management and Use of Antiretroviral Medicines in Resource-Limited Settings**

#### **Sarah Akoth Chuchu**

Ministry of Medical Services, Kenya

**Problem statement:** Rapid scale up of antiretroviral therapy (ART) in Nairobi faces several challenges including inadequate human resources. These health care personnel are charged with tedious manual tasks that prevent effective pharmaceutical and patient records management.

**Objectives:** The pilot project aimed to demonstrate that use of appropriate information and communication technologies (ICTs) can significantly improve ART pharmaceutical and patient management in resource-limited and disadvantaged settings. Specifically, it sought to facilitate live data entry, increase accuracy and timeliness of reports, hasten access to patient records, enable patient tracking, facilitate prompt feedback, and eliminate time wastage.

**Intervention(s):** The intervention was carried out in 16 public health centers in Nairobi Province, selected according to the following criteria: offering ART, sourcing ART supplies exclusively from Kenya Medical Supply Agency, well-kept manual ART records, secured buildings, uninterrupted power supply, and strong wireless connectivity signal. A public/private partnership was formed to strengthen ART pharmaceutical management system through use of appropriate ICTs—deploying new computer software and broadband wireless connectivity to replace manual ART pharmaceutical management system. An integrated ART patient and pharmaceutical supply management system called zCore was developed based on the manual daily activity register and staff were trained on its use. Unique software features enable live data entry, automated reports, quick review of patient medication history, alerts, and identification of defaulters among others. The software is based on open source software platform, eliminating recurrent software licensing fees.

**Outcome measure(s):** Key outcomes include timeliness of ART reports improving from 50% to 100%; decrease in time spent on updating daily ART records from 7.5 to 2.8 minutes per patient; decrease in time spent on generating 3 required ART reports from 11.6 hours to 29 minutes; decrease in time spent on delivering ART reports from 8 hours to 5 minutes; increase in access of reports by the provincial pharmacist from 0 to 100%; increase in percentage of facilities completing ART records at time of dispensing from 30 to 100%, and total elimination of hand delivery and transport costs. Non measurable outcomes include ability of site staff to communicate quickly with managers, and ability of the latter to update, monitor, and supervise.

**Conclusions:** The project has increased efficiency and strengthened pharmaceutical and patient management practices. Improved communication has enabled quality assurance of processes and timely feedback. The intervention is modular allowing for easy replication.

**Funding source(s):** Qualcomm (Wireless Reach); Telkom Kenya Ltd; Communications Commission of Kenya, Dell (USA); Research Triangle International, USA; and Provincial Medical Office

1044

**HIV/AIDS and TB***Keywords:* access to medicines, antiretrovirals, public private partnerships, resource limited settings**Enabling Continuity of a Public Health ARV Treatment Program in a Resource-Limited Setting: The Case of the Transition of the African Comprehensive HIV/AIDS Partnerships (ACHAP) Support to the National ART Program to the Government of Botswana****Innocent Chingombe<sup>1</sup>, Charles Olenja<sup>1</sup>, Godfrey Musuka<sup>1</sup>, Lesego Busang<sup>1</sup>, Themba Lebogang Moeti<sup>1</sup>, Thabo Phologolo<sup>2</sup>, Ava Avalos<sup>2,1</sup>**<sup>1</sup>African Comprehensive HIV/AIDS Partnerships, Botswana; <sup>2</sup>Department of HIV/AIDS Prevention and Care, Ministry of Health, Botswana

**Problem Statement:** The African Comprehensive HIV/AIDS Partnerships (ACHAP), a public-private partnership between the Government of Botswana, Merck & Co., Inc./The Merck Company Foundation, and the Bill & Melinda Gates Foundation, was formed in 2000 to provide comprehensive support to Botswana's HIV/AIDS response. HIV prevalence among pregnant women aged 15–49 years was about 36.2% and hospitals were overburdened with 60% of medical beds occupied by patients with HIV-related illnesses. Adult mortality increased almost fourfold between 1990 and 2000 and antiretroviral therapy (ART) was available to only 5% of the estimated 110,000 patients in need.

**Design:** With funding and technical support from ACHAP, leveraging the Government's own significant resource input, Botswana initiated its national ART program in 2002, the first in sub-Saharan Africa. ACHAP support included infrastructure, laboratory, and human resource development through training and recruitment, generation of strategic HIV and AIDS information, as well as donation of ARV medicines by Merck. Long-term challenges with provision of support across such a wide spectrum include sustainability and maintenance of program quality following transition.

**Outcomes:** With ACHAP as one of its key partners, Botswana's ART program has achieved significant results in preventing deaths among adults and children. The public sector antiretroviral (ARV) program covers all districts in the country, treating almost 92% (156,581) of patients in need by end of July 2011, 61.9% being females and 38.2% males. It is estimated that between 2002 and 2007, the national ART programme with support from ACHAP and other partners has prevented deaths of about 53,000 Botswana living with HIV, helping them return to productive life, supporting their families, and contributing to the economy. The number of new childhood infections declined by 80% between 1999 and 2009 due to nearly complete coverage of an effective program to prevent mother-to-child transmission.

**Results:** Following the end in 2009 of ACHAP's first phase, which focused on treatment, the partnership shifted to greater investment in the support of HIV prevention in its second phase from 2010 to 2014. To safeguard the gains of the national ART programme as well as enabling continued delivery of quality services beyond the second phase, ACHAP is transitioning programmatic support to the Government of Botswana by end of 2011, with the medicines donation continuing until December 2014. ACHAP has supported expansion of government treatment capacity by filling close to 200 positions, constructing 35 treatment facilities, and extending treatment capacity to primary clinic level through nurse training. The Botswana Government has absorbed over 90% of the ACHAP supported positions.

**Conclusions:** Joint management of this transition, effective monitoring of progress, continued government investment in cost-effective treatment, and prevention approaches will enhance capability to maintain programme quality, coverage, and access beyond the period of ACHAP support.

**Funding Source:** ACHAP.

1047

**Economics, Financing, and Insurance Systems***Keywords:* Health Insurance, Access to medicines, Household, insured, non-insured**The National Health Insurance Programme in Ghana and Household Access to Medicines****Daniel Kojo Arhinful<sup>1</sup>, Selassi A d'Almeida<sup>2</sup>, Edith Andrews Annan<sup>2</sup>**<sup>1</sup>Noguchi Memorial Institute for Medical Research, University of Ghana, Legon, Accra, Ghana; <sup>2</sup>WHO Country Office, Accra, Ghana

**Problem Statement:** Lack of access to essential medicines in developing countries is one of the most pressing health issues. Health insurance is increasingly seen as an important alternative financing mechanism for health care. In Ghana, a National Health Insurance Scheme (NHIS) became operational in 2004 through an Act of Parliament. All people living in Ghana can become members through the payment of premiums, which cover 90% of medicines. Has health insurance in Ghana led to increased access to health? How does it affect utilization of medicines in general?

**Objectives:** Collect data on household expenditure on health for subscribers and non-subscribers of insurance schemes. Examine differences in health services utilization between insured and non-insured households and between subscribers to the national insurance and private health insurance.

**Design:** Policy evaluation to examine differences in household health care utilization and expenditure including medicines for the insured and non-insured of the NHIS and private insurance schemes.

**Setting:** A national population based survey using the standardized World Health Organization and the Medicines Transparency Alliance (MeTA) sampling approach for household surveys. The survey was conducted in six of the ten regions in Ghana systematically selected to represent varied socioeconomic profile and agro-ecological zones based on combination of purposive and random sampling.

**Study Population:** Data was collected from 30 households located in the vicinity of a reference public health facility. A third of sampled households were within 5 km, a third between 5 and 10 km, and another third farther than 10 km. Altogether, 1,020 households were interviewed by means of a questionnaire. Data entry was done with EpiData software and analysis with SPSS and Excel.

**Policy evaluation:** Survey explored the increase in access to health care following the introduction of health insurance in Ghana.

**Outcome Measure(s):** Health insurance coverage; household expenditure on health insurance, where household members sought outpatient treatment, admissions to a health facility, and expenditures for health services including medicines.

**Results:** Some 72% of households had at least one member covered by health insurance in the past 12 months of the study. 51.8% made an expenditure of 20 Ghana cedi (GHC) on administrative cost and premium for NHIS. Of insured households, 1.9% reported a median of GHC 12 for private health insurance premium. 10.78% reported some spending on insecticide treated nets (ITNs) and 37.16% utilized various sources of treatments. 53.56% sought complementary treatments and drug outlets were popular sources for the non-insured.

**Conclusions:** Introduction of health insurance has led to greater access to health care and health security. Proximity or geographical access to health facility is a likely key determinant to household enrollment but additional analysis need to be carried out to determine that.

**Funding Source(s):** WHO, Accra, Ghana, MoH, Ghana

## 1049

### Access

*Keywords:* Ghana, Level 2, Essential Medicines, Indicator based, Access

### Health Facility Pharmaceutical Situation Assessment in Ghana

**Daniel Kojo Arhinful<sup>1</sup>, Edith Andrews Annan<sup>2</sup>, Martha Gyansa-Lutterodt<sup>3</sup>, Augustina Koduah<sup>3</sup>, Anthony Kusi<sup>1</sup>**

<sup>1</sup>Noguchi Memorial Institute for Medical Research, University of Ghana, Legon, Accra, Ghana; <sup>2</sup>WHO Country Office, Accra, Ghana; <sup>3</sup>Ghana National Drugs Programme, Ministry of Health, Accra, Ghana

**Problem statement:** Periodic monitoring, evaluating, and assessing country pharmaceutical status is important in determining existing capacity to measure if people have access to essential medicines that are safe, efficacious, of good quality, and used appropriately. This survey was carried out in May–June 2008 to assess the situation at health facility level.

**Objectives:** Provide systematic data on access to medicines availability, affordability, geographical accessibility, quality, and rational use, among other issues.

**Methods:** An indicator-based approach using the standardized World Health Organization (WHO) methodology was used to assess country pharmaceutical situations and the proposed MeTA sampling approach through a facility-based survey.

**Setting:** Nationwide survey conducted in six of the ten administrative regions of Ghana. Public, mission, private health care facilities, regional medical stores, and private pharmacies were surveyed.

**Study population:** In each region, 6 public health care facilities, 6 private not-for-profit and private for profit health care facilities, 12 private pharmaceutical retail outlets, and the regional medical stores were targeted. Altogether, 36 public, 19 mission/NGO, and 17 private health facilities; 68 private medicines outlets and 6 warehouses; and 4,061 outpatients/records were studied, of which the majority (57.12%) were female.

**Outcome measure(s):** Measures included availability of key medicines, average stock-out duration in public health facility dispensaries, and warehouses; drug prices and affordability in the public sector outlets and private sector outlets, and geographical accessibility to public health dispensaries and private drug outlets.

**Results:** Just about one in ten patients took more than one hour to reach a public dispensing facility; but all clients took less than an hour to reach private pharmacies. The key essential medicines selected for the country were to a greater extent available in public health facilities (80%) and mission health facilities (98%), but slightly less available at private pharmacies (73.3%). In the public sector, the procurement agency is purchasing medicines at 1.50 times higher than international reference prices. Final patient prices for generic medicines in the public sector were about 3.48 times their international reference prices. Public sector patient prices for generic medicines were 139.6% more than those for public procurement. Quite a high level of injection use (13.3%) and excessive levels of antibiotic (43.3%) prescribing were observed.

**Conclusions and recommendations:** The results of the survey show that access components such as pricing, affordability, and rational medicines use should be improved. The strategies should include price regulation backed by an effective enforcement and sustained rational drug use education.

**Funding source(s):** Financial support was provided by European Union and WHO country office, Accra.

## 1050

### HIV/AIDS and TB

*Keywords:* Quality assurance, tuberculosis, pharmaceutical policy, quality standards

## Impact of policy revision on harmonization and transparency of quality assurance criteria for anti-Tuberculosis medicines

Joëlle Daviaud<sup>1</sup>, Paloma Marroquín Lerga<sup>2</sup>, Carmen Perez Casas<sup>1</sup>, Sophie Logez<sup>1</sup>, Rachel Bauquerez<sup>1</sup>, Mohamed Abdel Aziz<sup>1</sup>, Ha Thuy Huong<sup>1</sup>

<sup>1</sup>The Global Fund to Fight HIV, Tuberculosis and Malaria, Switzerland; <sup>2</sup>Global Drug Facility of the Stop TB Partnership

Problem statement: Global Fund-financed programmes have provided 7.7 million of anti-tuberculosis treatment, and the Global Fund is the major contributor for the costly treatment of multi-drug resistant TB (MDR-TB).

With the introduction of the Global Fund's revised Quality Assurance Policy for pharmaceuticals in July 2009, anti-TB medicines became subject to strict quality criteria for procurement. As few anti-TB products fulfilled the preferred criteria (WHO-prequalification or authorization by a stringent regulatory authority), there was significant reliance on the alternative criteria of the revised policy (review by a WHO-hosted expert panel). These criteria were similar but not identical with those of the Global Drug Facility procuring anti-TB medicines for grant-funded programmes, including all second-line TB products. There was thus a need for full policy alignment.

Objectives: To describe the implications of the Global Fund's policy revision for procurement of anti-TB medicines in grant-funded programmes and outcomes of harmonization with partners.

Design: Descriptive, qualitative review of policy implementation and harmonization.

Setting and study population: Developing countries, international and national organizations involved in procurement of anti-TB medicines in the public sector through procurement entities or GDF.

Results: GDF was actively involved in the Global Fund's policy review and in the subsequent one-year process to align the GDF criteria and procedures with the new Global Fund requirements. Since July 2010, the two organizations are sharing their invitations for expression of interest, process and outcomes of product questionnaire dossier assessment by a WHO-hosted expert panel, and of randomized pre-shipment quality control testing. This avoids duplication of work and reduces costs for manufacturers, the Global Fund, GDF and the expert review panel. Criteria, process and outcomes of these activities, and reports on purchasing transactions, are publicly available online. At country level, procurement of quality-assured anti-TB products has become simpler and quicker, reducing the risk of procurement delays. On the other hand prices for some products have increased, and challenges remain to ensure a sustainable supply e.g. for paediatric and second-line anti-TB formulations.

Conclusion: While a number of donors, implementers and procurement agencies have been working to harmonize their procurement practice for some time, this is the first time that common transparent quality criteria and processes are being fully shared by two organizations, conveying a single message to manufacturers and buyer countries. Based on first experiences, it is expected that this will incentivize manufacturers to produce medicines meeting these standards. Similar harmonized policy approach is under way with UNITAID for antiretrovirals, and with the World Bank and other stakeholders for other types of medicines.

1053

HIV/AIDS and TB

Keywords: tuberculosis, drug resistance, surveillance, pharmacovigilance, public sector

## Monitoring Drug Resistant Tuberculosis Treatment in Brazil through an Innovative Web-Based Information System

Joel Keravec<sup>1</sup>, Margareth Dalcolmo<sup>2</sup>, Luis Gustavo Valle Bastos<sup>1</sup>, Jorge Luiz Rocha<sup>1</sup>

<sup>1</sup>Projeto MSH (Management Sciences for Health), SPS (Strengthening Pharmaceutical Systems), Brazil; <sup>2</sup>Centro de Referência Professor Hélio Fraga, Fiocruz, Ministry of Health, Brazil

Setting: All patients with multidrug-resistant tuberculosis (MDR-TB) cases treated in Brazil have been notified and followed-up through the web-based management information system (e-TB Manager) accessed by all references health facilities and TB coordinations countrywide. Since 1999, all MDR-TB patients have been treated for a 18-24-months duration by a standardized regimen of quality-assured amikacin, ofloxacin (changed to levofloxacin in 2009), ethambutol, terizidone, and clofazimine (changed to pyrazinamide in 2004) provided free of charge by the Ministry of Health.

Methods: The e-TB Manager was developed and implemented by the partnership between Projeto MSH and Centro de Referência Prof. Hélio Fraga since 2004, allowing online extraction of epidemiological reports, such as incidence, prior treatment history, treatments outcomes, adverse reactions, co-morbidities, and clinical and radiological presentation, among others.

Results: From January 2000 to December 2010, 4,049 new MDR-TB cases (and 437 retreatment cases) were notified in Brazil. Among them, 15% referred one previous TB treatment, 34% referred two, 47% referred three or more, and only 4% referred no previous TB treatment. Of these cases, 98% were pulmonary; 65% bilateral cavitary, and 17% unilateral cavitary. Related adverse reactions were experienced by 43.5% of registered patients, with the following frequency: 60% skin hyperpigmentation, 38% joint pain, 22% gastrointestinal intolerance, 18% hearing disorders, 17% insomnia, 14% headache, and 14% psyche disorder; 33% related comorbidities were recorded, among them, 15% alcoholism, 8% diabetes, 7% AIDS, and 6% use of illicit drugs; 99% were tested for HIV with 8% positive results. Treatments outcomes registered from 2000 to 2008 for 3,053 cases show a significant increase of cure rate from 47 to 62%, while the death rate was reduced from 24 to 11%. The failure rate was reduced from 20 to 10%, but the default rate remains around 9%—probably related to adverse drug effects, diverse co-morbidities, and other risk factors. Based on survival analysis, MDR-TB patients not treated with directly observed therapy (DOT) presented almost 3 times more treatment default than those treated with DOT.

Conclusions: The e-TB Manager is an innovative tool that provides a rapid extraction of key data and epidemiologic reports so action can be rapidly taken and resources strategically allocated. Data collected show the severity of the pulmonary disorders after many irregular previous treatments for TB. Regular monitoring of adverse reactions, such as hearing and psyche disorders were crossed with data recorded by physician for adequate drug substitutions. Alcoholism and use of illicit drugs contributed to lower patients' adherence. Treatments outcomes are improving progressively, a consequence of permanent assistance network strengthening for better diagnosis, clinical practices, and information sharing at all levels. DOT could reduce substantially the treatment default, and appears as a crucial element to increase treatment efficacy in MDR-TB.

Funding source: Information not provided

**1054**

#### **Drug Resistance**

*Keywords:* education, consumers, health economics,

### **School-Based Education Program Can Favorably Impact National Public Health Budget**

---

**Natalia Cebotarenco, Patricia Bush, Anaida Aivazyan, Svetlana Shetinina**

CoRSUM - Coalition for Rational and Safe Use of Medicines, Moldova, Republic of

Problem Statement: One reason antimicrobial drug resistance is of concern is its economic impact on the public health system. Few programs designed to decrease inappropriate antibiotic use have demonstrated economic benefits relative to their cost.

Objectives: Estimate savings from decreasing antibiotic use for colds and flu by a student-taught program.

Design: Pre-post design with well-matched control.

Setting and Study Population: 3,586 sixth-level students and 2,716 of their primary caregivers in Chisinau, Moldova, in 2003–04.

Intervention: Parents and students in 21 schools (20 schools served as controls) were taught by classmates not to take antibiotics for colds and flu. Pre-intervention survey results indicated that during the winter, 73% of students and 57% of adults had 1+ cold and/or flu; 79% of students and 91% of adults believed that it is always or sometimes useful to take antibiotics for colds or flu. Of those with 1+ cold and/or flu, 51% of students and 71% of adults treated them with antibiotics; however, 32% of students didn't know if they had taken an antibiotic or not. Post-intervention survey results adjusted for controls indicated that students who reported they did not treat colds or flu with antibiotics increased 34%; the comparable increase for adults was 38%. Logistic regression modeling indicated that intervention students were 3.7 times more likely than control students to indicate they had not taken an antibiotic and for adults, 5.5 times more. A conservative estimate of cost was based on these assumptions: (1) if antibiotic was used, it was used for only one cold/flu episode; (2) the average antibiotic prescription cost was 9 U.S. dollars (USD); (3) patient pays for prescription but not for physician visit to obtain prescription; and (5) student "do not know" response rate equals that of adults.

Policy: Implementation of ICIUM 2004 recommendation, "Children can be effective change agents to improve community medicine use. Countries should consider school-based education programs that involve children as a way for key messages to reach parents."

Outcome Measures: Cost savings from reduced antibiotic use in target population and estimated savings if intervention implemented throughout Moldova.

Results: The cost savings in the reduction of antibiotic use for colds and flu from pre-intervention to post-intervention was estimated to be USD 1.94 per student and USD 2.01 per adult primary caregiver. Imputing this savings to the national population of seventh-form students (56,090 in 2004–2005) and their primary caregivers resulted in a national estimated savings of USD 221,556. This underestimates the actual savings as the cost of reducing physician visits to obtain the antibiotic prescriptions is not included nor is the probable reduction in antibiotic use by other family members.

Conclusion: School-based program is cost-effective and should be extended to national level.

Funding Source: CoRSUM.

**1057**

#### **Drug Resistance**

*Keywords:* antimicrobial resistance, surveillance, extended spectrum beta-lactamase, drug resistance, gram-negative

### **Monitoring Antimicrobial Resistance Trends: How the Private Sector Can Contribute to Improved Understanding of Global Trends in Antimicrobial Resistance**

---

**Walter Lee Straus**

Merck, United States of America

Problem statement: Lack of a robust and comprehensive surveillance system for antimicrobial resistance (AMR) represents a major hurdle in guiding selection of appropriate antimicrobial use and is one of many barriers in stimulating new drug development. For this reason, in its 2010 report on drug resistance, the Center for Global Development called for development of a multi-disease surveillance network to make pathogen-specific information available for use by global policy makers and donor agencies. An incremental step toward this goal is reviewing and assessing information available from ongoing surveillance efforts. The private sector is often overlooked as a resource for AMR surveillance information. This paper provides an overview of a multinational surveillance program sponsored by a large pharmaceutical company (Merck).

**Design:** International prospective (2002–present) laboratory-based surveillance program of temporal and regional trends in vitro susceptibility of aerobic and facultative anaerobic gram-negative bacilli isolated from intra-abdominal infections (IAIs).

**Setting:** As of 2009, the Study for Monitoring Antimicrobial Resistance Trends (SMART) studied collected data from 44 countries (147 sites).

**Study population:** Hospitalized patients in surveillance hospitals with IAIs due to gram-negative pathogens.

**Intervention:** Each site collects up to 100 consecutive aerobic and facultative anaerobic gram-negative bacterial isolates from intra-abdominal sites (and, as of 2009, 50 consecutive gram-negative isolates from urinary tract infections); identifies specimens per local protocol, then ships isolates for confirmation and susceptibility testing at a central laboratory setting. Results are stratified based on whether the organism produces extended spectrum beta-lactamases (ESBLs) and time since hospitalization.

**Policy:** Results allow for country, region, and global assessment of AMR trends to commonly used drugs for these potentially life-threatening infections. Data are made available through presentations and publications and supplemented with online information resources.

**Outcome measure:** The primary outcome measure is in vitro susceptibility to 12 antibiotics, based on central laboratory confirmation and testing.

**Results:** One analysis evaluated 3,093 *E. coli* isolates collected (116 sites, 44 countries, in 2008). Of these, the proportions of ESBL+ isolates ranged from 30.6% (Latin America) to 2.7% (North America). The ESBL- isolates were generally susceptible to the drugs in the antimicrobial panel. In contrast, only two carbapenems retained >90% activity against ESBL+ isolates. Susceptibility rates for ESBL+ isolates to ampicillin/sulbactam were <60% in all but one region, and less than 60% to levofloxacin in three of the six regions.

**Conclusions:** The SMART study demonstrates the potential value of a private sector- supported specialized surveillance program to monitor global trends in AMR.

**Funding source:** Merck & Co., Inc.

## 1058

### Access

*Keywords:* access to medicines, pharmaceutical policy, health reform,

### **Increasing Access To Medicines—Taking a Multifaceted Approach**

**Saul Sebastian Walker, Claire Innes**

Department for International Development, United Kingdom

**Problem Statement:** Access to medicines in developing countries is determined by a complex mix of international and local factors, public and private sector interactions and economic, political and social drivers. Analytical frameworks are needed to support strategic and multidisciplinary approaches to policy development and implementation to improve access to medicines in developing countries.

**Objectives:** To outline the analytical framework used to prioritise investments in access to medicines policy and programming by the DFID. To also discuss progress and challenges in implementation.

**Design:** A descriptive study drawing on literature review, project documentation, and project evaluations across a range of UK/DFID interventions to support increased access to medicines in developing countries.

**Setting:** Examples of work at international, regional, and country levels that illustrate and explore how interventions overlap and support (or conflict) with each other to support increased access to medicines.

**Study Population:** People living in developing countries, with particular focus on the poor and countries where the UK supports bilateral programmes in the health sector.

**Interventions:** Interventions include: (1) influencing policy; (2) project funding to improve the quality and availability of information relating to medicines at international, company, and country levels; (3) investments in policy research; and (4) direct investments and engagement in activities to shape international commodity markets for pharmaceuticals.

**Policy(ies):** Development of and contributions to a number of UK strategies and policy positions including (1) access to medicines; (2) working with the international pharmaceutical industry; (3) UK government strategies on HIV; malaria; and reproductive, maternal, and newborn health; (4) DFID research strategy, including investments in new health product development; and (5) UK government positions on intellectual property, innovation, and public health.

**Outcome Measure(s):** These include (1) changes in international policy, (2) prices of medicines on international markets, (3) quality and availability of information on pharmaceutical markets, (4) availability and affordability of selected medicines in developing countries, and (5) size of research pipeline for new prevention, diagnostic, and treatment technologies.

**Results:** These include a reductions in the price of key HIV medicines, improved transparency in pharmaceutical sectors in MeTA countries, and increased investment in R&D for new health technologies for developing country use.

**Conclusions:** Access to medicines policy development and implementation requires a multifaceted approach that links interventions along the pharmaceutical value chain, and that locates this value chain within the contexts of broader health, political, economic, and social drivers.

**Funding Source:** The UK Department for International Development.

1059

**Policy, Regulation, and Governance**

*Keywords:* Key word: FORMULARY, MEDICINE USE, GLAUCOMA

**Use of Hospital Formulary to Improve Medicine Use at Alexandria Ophthalmology Hospital. Egypt.**

---

**Hager Abd Elkhalek Elkazaz**

Ministry of Health, Egypt

**Problem Statement:** Hospital formularies have been used in several health institutions to improve medicine use. Hospital pharmacists play important role in the development of hospital formularies, WHO published an important technical document on Drug Use and Therapeutic Committee. However, many of the hospitals in Egypt don't have medicine formulary and irrational prescribing is commonly practiced.

**Objective:** To assess the short term impact of Formulary development at Alexandria hospital of ophthalmology on improving medication use and prescribing habits of glaucoma therapy.

**Design:** The formulary developed in this study was based on, evaluation of samples of glaucoma patient prescriptions and development of standard treatment guidelines, cost effectiveness analysis for glaucoma therapy, and analysis of the available budget. The formulary was developed as collaborative efforts between pharmacists and clinician.

Prescriptions of glaucoma out-patients were evaluated using a specially designed form and analyzed the following criteria: Quantity of medications dispensed and cost of each item, The most expensive drugs, The most frequently or infrequently used drugs, Average number of drugs per prescription, Percentage of drugs prescribed by generic name, percentage of drugs prescribed from essential drugs list or formulary, Average drug cost per prescription and Frequency of administration (recorded or not).

**Setting:** Ministry of health, Alexandria hospital of ophthalmology.

**Study Population:** Ophthalmologists in glaucoma outpatient clinic

**Intervention:** The Formulary was developed in 9/2010 and its impact was studied over a period of 6 month, 3month before and 3month after the use of formulary.

**Results:** Financial analysis indicated that most of the hospital budget was directed toward glaucoma therapy, Prostaglandin analogues were found to be the costliest among various drug groups. The most frequently prescribed drug for glaucoma was one of the brand medicines containing latanoprost constituting 38.4% of total prescriptions, followed by another brand medicine containing dorzolamide & timolol constituted 27.5% the consumption of which decreased after the use of the formulary to 18.6 %. Both the prescription volume of glaucoma drugs and the average cost per prescription was high due to an 'add-on' prescribing effect of the more expensive carbonic anhydrase inhibitors. Changes in drug costs can result from changes in prescription volumes. Quantity per prescription changed from 1.4 to 1.3 and the average cost per prescription decreased from 87 L.E. to 72 L.E with total cost saving of 1762 L.E. over three months. Prescribing by generic name increased from zero to 12.5%, prescribing outside formulary decreased by 12.8% and no. of prescription without instructions decreased by 11.4%.

**Conclusions:** following the development of a formulary for the hospital, ophthalmologists prescribed from narrower range of drugs and the study suggests that formulary in Alexandria hospital of ophthalmology may favorably improve prescribing pattern and medication use.

1061

**Access**

*Keywords:* community, consumers, appropriate use, availability, medicines supply

**Characteristics of Medicines Found in the Households of the District of Chimbote – Ancash (Peru), December 2007**

---

**Raul Cruzado**

Universidad Catolica Los Angeles de Chimbote, Peru

**Problem statement:** In Peru, some problems have been identified related to polypharmacy, drugs without effectiveness or safety, self-medication, lack of adherence to treatment, presence of counterfeit medicines, and inadequate conditions of drug storage in health services. In July 2007, the government through DIGEMID (e.g., FDA) started the first "National Campaign for the Dissemination of the Good Storing Practices of Medicines at Households". There is no research about this topic in the country.

**Objectives:** Determine the characteristics of the drugs that are found in the households from the district of Chimbote – Ancash (Peru).

**Design:** It is a descriptive and cross-sectional study, based on the design established in the document of WHO: How to investigate the use of medicines by consumers.

**Setting:** This study was conducted at the district level. The households were visited and people older than 18 were interviewed.

**Study population:** The sample was taken from the district of Chimbote. The design of the study was probabilistic, multi-stage sampling, and systematic sampling. A sample of 796 dwellings with a level of significance of 5 % and an error of 0.03252.

**Intervention(s):** The study took about 3 months and 25 ULADECH university students were trained to implement the survey.

**Policy(ies):** This research was exposed at a national meeting in the DIGEMID in 2010. There were public health workers of Ministry of Health from all regions of the country.

Outcome measure(s): Percentage of more commonly used pharmaceutical forms, pharmacotherapeutic groups, generic drugs, combinations drugs, where medicines were obtained/who gave advice, households who received information given by the health worker, and drug storage

Results: The tablets represented 53% and the pharmacotherapeutic groups were the apparatus skeletal muscle (27%) and anti-infectives (17%). The generic drugs represented 44% and fixed dose combinations 21%. The medicines were obtained from pharmacies (40%). The physicians and the pharmacists indicated the medicines in 57% and 29% respectively. Also, 96% stated they never received education about medicines in the community by any health workers. They store the medicines in the room (62%), bathroom (9%), kitchen (8%), and backyard (7%). The drugs not fit for human consumption represented 10%.

Conclusions: It was determined the characteristics of drugs were found in the households of people who lives at the district of Chimbote which need be improved in relation to the education for becoming better both the storage and the use of medicines principally.

Funding source(s): ULADECH

## 1062

### HIV/AIDS and TB

Keywords: PMTCT, Nevirapine, Malawi

#### Assessing How Health Care Providers Use Nevirapine in Malawi

**Edmund R Rutta<sup>1</sup>, Cynthia Kamtengeni<sup>1</sup>, Judy Wang<sup>1</sup>, Michael Eliya<sup>2</sup>**

<sup>1</sup>Management Sciences for Health, United States of America; <sup>2</sup>Ministry of Health, PMTCT Unit Malawi

Problem Statement: In 2006, the Ministry of Health in Malawi started to scale up prevention of mother-to-child-transmission (PMTCT) services. By 2009, about 500 health facilities were providing PMTCT services. However, anecdotal reports indicated that lack of skills in how to administer nevirapine (NVP) syrup and the complexity of administering the combination regimen for PMTCT clients were key challenges.

Objective: To assess NVP dispensing practices and management of NVP suspension.

Design: Descriptive study using interviews with health care providers and facility assessments in November 2009

Setting: 84 government and faith-based health facilities providing PMTCT services were selected. This included all 28 central and district hospitals and 56 randomly selected health centers (at least two per district) and 140 health care providers (PMTCT coordinator, nurses, and pharmacy staff) in all 27 districts in Malawi were interviewed.

Outcome measures: Percentages of responses measuring NVP use indicators

Results: Although treatment adherence counseling and monitoring are not part of Malawi's PMTCT guidelines, 82% of the providers indicated that they monitor adherence. However, 42% of the facilities had NVP suspension bottles without labels that included the opened or expiry dates, making it difficult for the providers to know if the NVP suspension was still usable; and 43% of the providers interviewed did not know how to calculate the new expiry date of opened NVP suspension bottles. Of those who knew how to calculate the new expiry date, 52% indicated that they learned the method in a training session.

Conclusions: Using these findings, SPS supported the MOH's PMTCT unit design interventions to improve NVP suspension management. This included training providers on how to calculate the new shelf life of NVP suspension once it is opened. In addition, job aids on shelf life management of NVP suspensions, PMTCT combination regimens, and general dispensing procedures were developed. PMTCT service provider training should include pharmaceutical management to improve the rational use of PMTCT medicines.

Funding source: Strengthening Pharmaceutical System funded by USAID

## 1064

### Policy, Regulation, and Governance

Keywords: access to medicine, transparency, communication channels, multistakeholder process, access to information

#### Data Disclosure: An Ongoing Process Towards Transparency

**Abeer Ahmad Al Rabayah**

The Jordanian Pharmaceutical Manufacturing Company, Jordan

Problem statement: Lacking a systematic process to collect pharmaceutical data on a regular basis in the Jordanian pharmaceutical sector minimizes the opportunity of evidence-based decision making regarding pharmaceutical policy issues which leads to an inefficient system.

It is important to collect data in order to set the countries' priorities based on what the pharmaceutical sector needs to improve access for Jordanian citizens. Establishing a culture of more applied research that leads to useful intervention that can be used locally to improve the efficiency and effectiveness of the sector should be a priority in any reform in the future. On the other hand, the public domain in Jordan is still not aware of the availability of data regarding the medicines supply chain, and more effort is needed to create awareness among the public and the different stakeholders; also the communication channels between different stakeholders (public, private, CSOs) are still limited and each sector is moving forward without knowing the needs and capabilities of the others that might be of mutual benefit for all of them.

**Research design:** One of the most important areas of the Medicines Transparency Alliance is the baseline assessment's 3 components, which are the tools that MeTA is using in all countries to generate data and help the national councils in setting their priorities in an evidence-based way. The MeTA data disclosure survey is a descriptive, qualitative survey that used secondary data sources and conducted meetings and in-depth interviews to assess the data disclosure status in the Jordanian pharmaceutical sector. It was also an opportunity for the council member to understand each other perspectives.

**Results:** The data disclosure process helped the MeTA Council in highlighting some challenges that they have to work jointly to overcome such as limited contribution from CSO members, limited access to some data (requirement of fees), and engaging the private sector in disclosing data. Data disclosure should lead to more transparency and accountability about the pharmaceutical supply chain.

**Conclusions:** One of the most important impacts of the data disclosure survey in Jordan is that the council found that more work should be devoted to their organizations' websites in terms of accessibility and awareness. The data disclosure report highlighted some gaps regarding publicly available data and created a debate for discussion between stakeholders (public, private, CSO). This debate can be considered as an ongoing exercise to assess the pharmaceutical data disclosure status on a regular basis in order for MeTA Jordan to track changes, improvements or drawbacks in data disclosure.

**References:** The Medicines Transparency Alliance Council in Jordan, Data Disclosure Survey Report, final version, 2010; <http://www.medicinetransparency.org/meta-countries/jordan/>

**Funding sources:** Information not provided

**1067**

#### **Child Health**

*Keywords:* HIV/AIDS, pediatric medicines, adherence, appropriate use, pharmacy

### **Encourage Appropriate Use of Pediatric Antiretrovirals With a Demonstration Kit in Pharmacies: Results 18 Months after Kit Was Made Available in 2 HIV/AIDS Pediatric Treatment Centers in Niamey, Niger**

**Sophie Ouvrard<sup>1</sup>, Mariama Idrissa Also<sup>2</sup>, Zaliqa Oumarou<sup>2</sup>, Etienne Guillard<sup>3</sup>**

<sup>1</sup>Solthis, Niger; <sup>2</sup>Hôpital National, Niamey, Niger; <sup>3</sup>Solthis, France

**Problem statement:** For correct use of pediatric drugs and regular adaptation of doses to the child's weight, one of the parents must fully understand the situation, particularly in antiretroviral therapy (ART) management because of the risk of developing resistances if dosage is not respected. Moreover, in resource-limited countries where school enrollment rate is low, comprehension aids are necessary. Therefore, Solthis, an international medical association dedicated to people living with HIV/AIDS in developing countries, provided pediatric demonstration kits to health care centers that it supports in Niger

**Objective:** Evaluate the availability and use of these pediatric demonstration kits in 2 pediatric care hospitals after 18 months and identify possible improvements that could be made.

**Design:** Intervention descriptive study

**Setting:** This study took place in pharmacies of 2 health care centers from the Public Sector which manage children: one national and one provincial: HNN, CHR Poudrière

**Intervention(s):** The demonstration kits included empty bottles of several common antiretrovirals (ARVs) and a chart of pediatric dosages. These were made available to pharmacies in April 2009 and dispensers were trained on how to use them. During ARV dispensing, instructions on the kit use, targeted at parents or tutors with comprehension difficulties, was presented in two steps. The pharmacist showed the mother how to use the kit. Then, the mother used it herself to make sure that she had understood.

**Outcome measure(s):** Survey questionnaire: evaluation of kit availability, understanding of kit by concerned health care providers, actual use, and analysis of the problems encountered during use.

**Results:** Both of the centers had a demonstration kit, and most of the dispensing pharmacists in these centers knew that it existed. However, although dispensing pharmacists provided some explanation about correct treatment use to the tutor/parent present, the kits were very rarely used. Analysis of why the kit was not used showed that lack of time by users was the primary cause. Moreover, certain people felt that a demonstration was not useful and that providing an explanation was enough. For others, the kit would have been more appropriate in the pediatric unit than in the pharmacy. Also, the kit was not used to let the parent practice and learn.

**Conclusions:** This study shows that the actors in the centers we evaluated were sensitive to the question of correct use of pediatric treatment but don't used the kit. Therefore, like any learning situation, practice is necessary ensuring correct use implies that dispensing pharmacists must take the time necessary to make sure that the person accompanying the child has acquired the necessary know-how. Besides demonstrating the use of medicine, this kit should be part of an integrated therapeutic education approach by adding, for example, some pictures. The use of this kit could be extended to nurses, doctors, educators. Finally, these problems are changing as pills become available for pediatric use and attention should be paid to rational use of these forms.

**Funding source:** Information not provided

1068

**HIV/AIDS and TB***Keywords:* Anti Microbial Resistance (AMR), Daily defined dose (DDD), ABC analysis**Application of an ABC Analysis in the Prevention of Antimicrobial Resistance in Tuberculosis Treatment****Gavin Steel<sup>1</sup>, Andy Parrish<sup>2</sup>, Bada Pharasi<sup>3</sup>, Jean-Pierre Sallet<sup>4</sup>**<sup>1</sup>Management Sciences for Health, Strengthening Pharmaceutical systems (SPS) Program, South Africa; <sup>2</sup>3Rhodes University, South Africa; <sup>3</sup>Walter Sisulu University; <sup>4</sup>Management Sciences for Health, Strengthening Pharmaceutical systems (SPS) Program, South Africa; <sup>5</sup>Management Sciences for Health, Strengthening Pharmaceutical systems (SPS) Program, South Africa

**Problem statement:** Medication consumption measurements using ABC analysis leave unexplored the reasons for particular items' comparative rank. Further insights into utilisation may be provided by adding daily defined dose (DDD) information.

**Objectives:** The aim was to explore whether the addition of DDD information would provide insights into the use of antituberculous medication and provide opportunities to develop strategies to limit the development of multidrug-resistant tuberculosis (MDR-TB).

**Design:** Case study modelling the addition of DDD information to a basic ABC analysis.

**Setting:** Public service medication supply chain in the Eastern Cape province of South Africa.

**Study population:** Patient medication consumption in a government-run TB treatment programme

**Intervention:** The addition of DDD information to an ABC analysis.

**Policy issues:** Review of the potential impact of correction of supply side challenges on the development of MDR-TB

**Outcome measure(s):** Discrepancies between medication supplied and that anticipated according to programmatic requirements using ethambutol and streptomycin consumption as key determinants.

**Results:** The South African national TB retreatment standard treatment guidelines (STGs) combines rifampicin, isoniazid, pyrazinamide, and ethambutol with streptomycin for the first two months of the initial phase, followed by a 5-month continuation phase of ethambutol with rifampicin and isoniazid. During the review period, 407,409 DDDs of ethambutol were issued compared to 515,060 DDDs of streptomycin. According to the STG and streptomycin DDD consumption, this suggests that there were approximately 9, 198 retreatment cases. The corresponding figure for ethambutol would be 2,910, leaving 6,288 streptomycin cases unaccounted for. Based on packs issued, the retreatment to new treatment ratio reveals that 42,467 patients received the initial phase of treatment and roughly 31,813 the continuation phase. In MDR-TB, ofloxacin offers a potential indicator. During the review period, 40,547 DDDs were issued which would cover 1,843 cases, hence MDR may account for as much as half of the ethambutol DDDs. Although ethambutol can be used to treat *Mycobacterium avium* complex, the consumption of co-prescribed clarithromycin was negligible. Adherence may have contributed to the low use of ethambutol. Streptomycin, being parenteral, is administered under supervision. A high retreatment rate coupled with discrepancies between the initiation and continuation phases support this. Follow up data revealed erratic medicines supply for 7 months of the year and that there were no suppliers for a full month due to nonperformance of a manufacturer awarded the national tender.

**Conclusions:** The addition of DDD information to an ABC analysis provides further insights which may yield the potential for programmatic improvements in supply chain management.

**Funding source:** US Agency for International Development/South Africa

1069

**Child Health***Keywords:* ADDOs, Tanzania, Diarrhea**Can the Management of Uncomplicated Diarrhea at the ADDOs in Tanzania be Further Improved?****Edmund R Rutta<sup>1</sup>, Suleiman Kimatta<sup>1</sup>, Jafary Liana<sup>1</sup>, Amani Philip<sup>2</sup>, Keith Johnson<sup>1</sup>**<sup>1</sup>Management Sciences for Health, United States of America; <sup>2</sup>Tanzania Food and Drug Authority, Tanzania

**Problem statement:** The accredited drug dispensing outlet (ADDO) program has increased access to affordable quality medicines and pharmaceutical services in retail drug outlets in underserved areas of Tanzania. Program monitoring and evaluation have showed improved medicine availability and dispensing; however, anecdotal evidence suggested continuing problems with diarrhea management.

**Objective:** To determine how ADDO dispensers manage uncomplicated diarrhea in children under age five

**Design:** Quantitative data collection was performed in 2010 using a mystery shopper scenario in the Ruvuma region, where the program had operated for seven years, in the Singida region with one year of ADDO operations, and in the Mara region, which had no ADDOs (control). Ruvuma data from 2004 came from a retrospective record review.

**Setting:** 30 randomly selected ADDOs from Ruvuma, 60 each in Singida and in Mara

**Intervention:** Ruvuma and Singida dispensers received training in 2003 and 2009, respectively, on how to manage uncomplicated diarrhea in children under five as part of ADDO accreditation. ADDO dispensers in both regions received supportive supervision on diarrhea management. Drug shop workers in Mara received no training or supervision.

**Outcome measures:** Percentage of uncomplicated diarrhea encounters in which either antibiotics or appropriate treatment using oral rehydration solution were dispensed.

**Results:** In Ruvuma in 2010, cases managed according to treatment guidelines did not change from the 2004 levels of 29%; in Singida, the percentage of encounters in which uncomplicated diarrhea was managed appropriately rose from 20% at baseline in 2009 to 42% at end-line; no change was observed in Mara (25% at baseline compared with 27% at end-line). The percentage of uncomplicated diarrhea encounters that included dispensing of an antibiotic declined from 98% at baseline to 76% at endline in Singida, while it remained constant in Mara (87% at baseline and 84% at endline). The percentage of diarrhea cases in which metronidazole was dispensed by ADDOs in Ruvuma declined from 53% in 2004 to 42% in 2010.

**Conclusions:** Managing uncomplicated diarrhea with oral rehydration solution increased and antibiotic dispensing decreased after the ADDO intervention in Ruvuma and Singida; however, practices still fall well short of the recommended national treatment guidelines. Qualitative research suggests that other factors beyond ADDO dispensing skills and knowledge may fuel these practices, such as the prescribing practices at public and private health facilities, consumer pressure and preference for metronidazole, and profit motive. Stakeholders recommended further assessments to understand the ADDO dispenser/health facility prescribers and consumer dynamics and its impact on antibiotics use in diarrhea management.

**Funding source:** Management Sciences for Health/East African Drug Seller Initiative, funded by a grant from the Bill & Melinda Gates Foundation

## 1071

### Access

*Keywords:* ADDOs, Tanzania, Sustainability

### Can ADDO Accomplishments Be Sustained? The Tanzania Experience Six Years Later

**Edmund R Rutta<sup>1</sup>, Jafary Liana<sup>1</sup>, Elizabeth Shekilaghe<sup>2</sup>, Martha Embrey<sup>1</sup>, Keith Johnson<sup>1</sup>**

<sup>1</sup>Management Sciences for Health, United States of America; <sup>2</sup>Tanzania Food and Drug Authority (TFDA), Tanzania

**Problem Statement:** In 2003–2004, the accredited drug dispensing outlet (ADDO) program was piloted in Tanzania's rural Ruvuma region, which had few pharmaceutical services. The program focused on training and supervision to improve dispensing practices at retail outlets and regulatory enforcement to assure quality. The pilot evaluation showed improved access to affordable quality medicines and pharmaceutical services, particularly related to managing common conditions, such as malaria. However, a major question has been the sustainability of these improvements.

**Objective:** To determine if ADDOs in Ruvuma have maintained the availability of quality products and services and profitability seven years after implementation.

**Design:** A quantitative data collection through a price and availability survey and a mystery shopper exercise (five-year-old child with simple uncomplicated malaria). The results were compared with the ADDO pilot results from 2002 and 2004.

**Setting:** 30 randomly selected ADDOs from Ruvuma that had opened during the original pilot and were still operating in 2010.

**Outcome measures:** Percentage availability and median prices of tracer products, percentage of unregistered products available, and indicators on dispensing services for malaria.

**Results:** Average availability of select antibiotics in Ruvuma in 2010 was 70% compared with 77% at endline in 2004 and 45% in 2002. No unregistered products were found in 2010 compared to 2% in 2004. The average median price for a market basket of antibiotics compared with the International Price Guide showed virtually no difference between 2004 and 2010 (+15% compared with +16%). The percent of encounters where malaria cases were treated according to national standard treatment guideline rose to 63% in 2010 compared to 24% in 2004 and 6% in 2002. In terms of dispensing practices, the percentage of mystery shopper encounters where the drug seller: (1) asked about symptoms—rose from 48% in 2004 to 53% in 2010; (2) asked about other medicines the child took—decreased from 54% in 2004 to 43% in 2010; gave instructions for taking medicines—increased from 60% in 2004 to 77% in 2010; and recommended a referral to a doctor or clinic—decreased from 52% in 2004 to 27% in 2010.

**Conclusions:** With minimal additional training and supportive supervision since the pilot, the 2010 assessment showed that overall, the quality of dispensing services in Ruvuma ADDOs has actually improved since 2004. Declines in referral for simple malaria indicate ADDO dispensers' increased ability and confidence to manage simple malaria. Median prices compared to the International Price Guide increased 1% between 2002 and 2010.

**Funding Source:** Management Sciences for Health/East African Drug Seller Initiative funded by a grant from the Bill & Melinda Gates Foundation

## 1074

### Chronic Care

*Keywords:* Drug Utilization Evaluation, second generation antipsychotics, metabolic abnormalities, monitoring, intervention.

### Improved Safety Monitoring of Second Generation Antipsychotics Following a Rational Prescribing Intervention

**Renier Coetzee<sup>1</sup>, Ruth Lancaster<sup>1</sup>, Jane Riddin<sup>1</sup>, Janine Munsamy<sup>1</sup>, Christine Njuguna<sup>1</sup>, Betty Patterson<sup>2</sup>, Sandi Willows<sup>3</sup>**

<sup>1</sup>Rhodes University, South Africa, South Africa; <sup>2</sup>North Dakota State University, United States of America; <sup>3</sup>Fort England Psychiatric Hospital, South Africa

**Problem Statement:** Second generation antipsychotics (SGAs) pose increased metabolic adverse effects which may pose a health risk for mental health patients. There is consensus that these metabolic abnormalities associated with SGAs require regular screening so as to facilitate early intervention when required. There is, however, generally reluctance to perform these tests in resource-constrained environments for various reasons.

**Objectives:** To determine the impact of a rational prescribing intervention to improve the safety of SGAs through appropriate monitoring.

**Design:** A retrospective drug use evaluation was used to measure compliance with recommended safety monitoring of SGAs before and after a rational prescribing intervention. The baseline assessment and design of the intervention took place in March 2008 with a follow-up drug use review (DUR) in November 2009 to assess the impact.

**Setting:** Public health sector psychiatric hospital in South Africa.

**Study Population:** All admitted patients receiving SGAs were identified for possible inclusion; 48 patients' SGA prescriptions were evaluated in the post-intervention DUE. Patients were included if they received an SGA for more than 1 month. Patients initiated on an SGA prior to the intervention in 2008 were excluded as well as those who were already receiving an SGA when referred to the institution.

**Intervention(s):** The baseline DUE identified that inadequate safety monitoring put patients at risk. The local Pharmacy and Therapeutics Committee approved a safety screening protocol, which formed the basis of the intervention. The final intervention comprised three aspects: (1) a paper monitoring tool that contained all the relevant baseline and follow-up safety tests; (2) in-service training of all levels of health care workers, which highlighted the importance of metabolic monitoring in patients on SGAs, to support the monitoring tool; and (3) educational posters to guide clinicians on appropriate monitoring recommendations.

**Outcome Measure:** Improved patient safety through increased monitoring of SGAs.

**Results:** Post-intervention monitoring improved overall. Fasting glucose and cholesterol monitoring at baseline increased by 40% and 36% respectively. There has been an increase in the annual cholesterol monitoring of 25%. A concerning finding was a reduction in monitoring of blood pressure and weight by nursing staff from baseline. Monthly weight monitoring was also reduced by 54%.

**Conclusions:** These data confirm that multiple interventions have improved compliance with safety monitoring of SGAs as judged by DUR findings. Follow-up data is planned for 2011 to confirm the durability of this finding; however, these data confirm that safety monitoring in a resource-constrained environment can indeed be achieved through appropriate support measures.

**Funding Source:** No funding

## 1076

### Economics, Financing, and Insurance Systems

*Keywords:* EML, cost minimization, oncology, selection

#### Improving Access to Oncology Treatments in a Resource-Constrained Setting Using Pharmacoeconomic Analysis

Gavin Steel<sup>1</sup>, Paul Ruff<sup>2</sup>, Lydia Dreosti<sup>3</sup>

<sup>1</sup>Management Sciences for Health, Strengthening Pharmaceutical systems (SPS) Program, South Africa; Rhodes University, South Africa; <sup>2</sup>University of the Witwatersrand, South Africa; <sup>3</sup>University of Pretoria, South Africa

**Problem statement:** Cost consideration of medicine during the selection process is biased toward acquisition price. To date, pharmacoeconomic analysis is not considered practical in a resource constrained environment. In the South African public sector, FOLFOX, a schedule of infusional and bolus 5-fluorouracil (5FU) plus folinic acid (FA) plus oxaliplatin every second week has been established as a standard of care for first-line treatment of metastatic colorectal cancer (mCRC). Despite the potential benefits for the patient, the price of capecitabine was considered unfavourable relative to 5FU/FA.

**Objectives:** The aim was to explore whether the application of cost minimization to the selection of capecitabine would favour it listing on the formulary.

**Design:** A literature review established XELOX to be noninferior to FOLFOX, justifying the use of cost minimization was the appropriate pharmacoeconomic method to inform the selection decision. Public sector tender prices were used to cost out equieffective courses of chemotherapy and equipment used for the administration of treatment. Prices of laboratory tests were determined using National Health Laboratory Services' codes. Standardized public sector budgeting costs were used to estimate the cost of theatre time required for the insertion of an intravenous port. An estimated rate of complications was also applied to standardized antibiotic treatment regimens.

**Outcome measure:** These findings contributed toward the listing of capecitabine for the treatment of mCRC.

**Results:** The 2008 state tender price of 5FU plus FA was only 48% of that of capecitabine. Costing out the medicines costs for FOLFOX and XELOX provided a ratio of 0.82 in favour of FOLFOX. Taking into consideration all administration costs, FOLFOX increased to 0.97 of the cost of XELOX. Finally, adding in the cost of monitoring and complications marginally brought XELOX to cost parity. A sensitivity analysis of assumptions and variables suggested that this ratio may reside between 0.83 and 1.01 with the regulated private sector pricing of capecitabine having the greatest possible impact. The cost minimization did not take into consideration nursing time, hospital stays, or loss of productivity, as reliable cost estimates for these factors in our environment were not available. However, as services are currently oversubscribed; potentially more patients could be enrolled for treatment, thereby increasing treatment access.

Conclusions: These findings were submitted to the EML process as supporting documentation for inclusion which was subsequently approved. This case study reveals that limiting consideration of cost to acquisition prices may prevent access to otherwise more favourable treatments and establishes cost minimization as an acceptable medicines selection tool.

Funding source: US Agency for International Development/South Africa

1077

Access

Keywords: drug promotion, education, critical appraisal

### Teaching Critical Appraisal of Medicinal Drug Promotion (CADP) in 3 Latin American Countries: A Network Initiative

**Benoit Marchand<sup>1</sup>, Carlos Fuentes<sup>1</sup>, Martín Cañas<sup>2,3</sup>, Claudia Vacca<sup>4,5</sup>**

<sup>1</sup>Acción Internacional Para la Salud (AIS) Nicaragua; <sup>2</sup>Federación Médica de la Provincia de Buenos Aires (FEMEBA), Argentina; <sup>3</sup>Grupo Argentino Para el Uso Racional de los Medicamentos (GAPURMED); <sup>4</sup>Red para el uso Adecuado de Medicamentos (RAM), Colombia; <sup>5</sup>Universidad Nacional de Colombia

Problem statement: Health workers utilize drug promotional materials from pharmaceutical companies as a major source of information, which can induce unnecessary drug consumption and/or misuse. WHO and HAI have identified this risk and have developed documents and material to make this problem known. Such documents were used as a reference by HAI-Nicaragua to develop and implement a CADP teaching module, which was presented as a network initiative to the Drug Utilization Research Group (DURGLA) and implemented in Argentina in 2006-2010 and Colombia in 2008-2010.

Objectives: To promote a critical attitude towards medicinal drug promotion, implementing CADP teaching module with health workers and medicine and pharmacy students

Design: Intervention to improve critical appraisal of medicinal drug promotion cross-sectional study

Setting: Medicine and pharmacy schools from Nicaragua, Argentina, and Colombia

Study population: Students from these universities

Intervention(s): Application of a CADP teaching module with doctors and pharmacy and medicine students that contained introductory material (PowerPoint and paper) about relevance of independent information and critical appraisal of drug information, pharmaceutical advertising pieces from each country, tools to evaluate advertising pieces against the WHO Ethical Criteria, workshop support material (videos especially in Colombia and Nicaragua), and workshop evaluation. In Nicaragua, the impact was evaluated through a pre – post workshop survey.

Results: The CADP module was applied to 1,762 medicine students, 213 pharmacy students, and 30 doctors and pharmacists from Nicaragua, Argentina (3 universities of 3 great cities), and Colombia (biggest university in the capital). In Argentina and Colombia, the activities were developed in medicine and pharmacy degree courses, respectively. The participants and students considered the inclusion of CADP teaching module important and useful in their education. The module was considered pertinent by the majority of professionals and they would recommend it to their colleagues. When the module was evaluated for Nicaragua, knowledge and critical perceptions about industry/health professionals' interactions, pharmaceutical sale representatives, and printed advertising material showed improvement.

Conclusions: The CADP teaching module is pertinent and useful for developing a critical attitude towards medicinal drug promotion. The contents could be incorporated into a degree curriculum of health professionals (Rosario University in Argentina will do it with a formal, 80-hour course at medical school) including impact studies, standardized materials, and experiences. These results are a concrete output of the complementarity of different networks in the region (DURG-LA, HAI/AIS-LAC, ISDB) and experiences of groups at the national level (GAPURMED, RAM). In 2009, the HAI/WHO guide Understand Pharmaceutical Promotion and Respond to it was published and it is now proposed to validate and evaluate the manual in the different universities of Latin America.

Funding source(s): Acción Internacional para la Salud /Drug Utilization Research Group

1078

HIV/AIDS and TB

Keywords: tuberculosis, adherence, appropriate use, dispensing, medication errors

### Drugs Identification and Interaction Checker to Reduce Tuberculosis Drug Compliance and Improve Treatment Adherence

**Antonio J. Jara<sup>1</sup>, Madeleine de Rosas-Valera<sup>2</sup>, Mona Alsaedy<sup>3</sup>, Miguel Zamora<sup>1</sup>, Antonio G. Skarmeta<sup>1</sup>**

<sup>1</sup>University of Murcia, Spain; <sup>2</sup>World Health Organization, Western Pacific Region; <sup>3</sup>Kingston University London, UK

Problem statement: Tuberculosis treatment is a combinational therapy of antibiotic over a period of six months, subject to clinicians' discretions and diagnosis. Unsuccessful treatment may have various reasons including compliance. Poor compliance is due to prolonged treatment time and side effects such as nausea, itching, and rashes. WHO DOT's (directly observed therapy) recommendations are applicable for recommended candidates. It is a form of a medical treatment supervision that has shown to successfully enhance patients' compliance and treatment efficacy. However, this service is quite limited and inaccessible in the third world because of the high cost and the intensive human resources required for such supervised treatment.

**Objectives:** This solution aims to develop a new technology to increase drug compliance electronically. For this purpose, a novel hand-held personal device has been developed to assist the patient through different ways including an inbuilt alarming system to remind the patient of the next dose; informing about encountered adverse drug reactions and side-effects; confirming that the right drug has been taken; and finally a warning system in case of consumption of additional pills. A previous solution was defined, SMS Pill (short message service reminders for treatment), but it is not feasible for the third world because of cost limitations of the required GSM infrastructure. We have defined a solution based on infrared communications (IrDA). This presents a low-cost communication channel based on light, which is suitable for the requirements of the solution and is more feasible and cheaper than other solutions. This presents additional functionality to SMS Pill by embedding an intelligent system to detect common adverse drug reactions.

**Design:** Design issues have been focused on reaching a low-cost solution and with a high battery autonomy because in some places access to an electrical grid infrastructure is not easy. The cost solution reached is around \$20 (\$200-800 for other solutions), and the battery lifetime of the device has been optimized to 12 years.

**Study population:** The study population will be patients from the Philippines. Trials out of our labs have not yet been defined, but we are pending to carry it out with the support from WHO Western Pacific and Department of Health Philippines. We hope to get results similar to SMS Pill, with treatment adherence among 155 tuberculosis patients at 86-92% with a treatment success rate of 94% in a trial at three clinics in Cape Town after 10 months.

**Conclusion:** As a conclusion, TB is a disease that requires new solutions and strategies to supervise the treatment, increase its efficacy and compliance, and reduce costs. For that reason, it has been defined as a flexible, low cost, and preventive solution to assist patients during their treatment and allow a more specific supervision for health care professionals.

**Funding sources:** Foundation Séneca; Spanish Ministry for Industry, Tourism and Infrastructure; and University of Murcia

## 1079

### Economics, Financing, and Insurance Systems

*Keywords:* Cost, ATC, Formulary, EML

#### Application of the Antacid {A02} ATC Review to Achieve Formulary Cost Efficiencies

Gavin Steel<sup>1</sup>, Jane Ridding<sup>2</sup>, Janine Munsamy<sup>3</sup>

<sup>1</sup>Management Sciences for Health, Strengthening Pharmaceutical Systems (SPS) Program, South Africa; Rhodes University, Grahamstown, South Africa.; <sup>2</sup>Rhodes University, Grahamstown, South Africa.; <sup>3</sup>Rhodes University, Grahamstown, South Africa.

**Problem statement:** Public health programs achieve cost efficiencies through economies of scale and competition. Economies of scale are achieved by pooling demand, restricted formularies and generic use policies. Competition is largely driven through the bid process of tenders although the judicious use of therapeutic classes holds the potential to improve competition. In 2009 the South African government had announced that antiretroviral (ARV) treatment would be initiated at the primary health care level and the H2 antagonists of choice, cimetidine, holds considerable potential for clinically relevant drug interactions.

**Objectives:** To determine whether the current A02 class (Antacids) of the Essential Medicines List (EML) offered the optimal treatment for gastroesophageal reflux disease (GERD) based on current tender prices.

**Design:** Medicines were classified according to their Anatomical Therapeutic Chemical Classification System (ATC) and the cost per daily defined dose (DDD) was calculated. A sensitivity analysis of tender prices was performed using the international pricing guide and approved single exit price for the private sector.

**Setting:** South African national EML

**Outcome measure(s):** These findings were presented to the national essential medicines committee and an amendment was published to replace cimetidine with ranitidine.

**Results:** The EML regularly makes use of therapeutic classes to improve competition by increasing the number of products eligible for procurement. The 2008 primary health care EML, however, did not list H2 antagonists as a class and only cimetidine had been included. This ATC review identified that the competitor within this class, ranitidine, had a lower cost per DDD. An age analysis of the tenders over the past 5 years showed that the cimetidine price had increased by 66% whilst ranitidine's price had been relatively stable over this period. To confirm that price reduction had not been used to gain market share only to increase at the next tender cycle, the South African tender price was compared with those of the international pricing guide. International tender prices were consistent with those offered on the local tender. Strengthening the argument was the finding that the ratio of costs between the H2 antagonists in the private sector was consistent with that observed in the tender. Finally, competition for market share is likely to be supported by the fact that at least 6 suppliers were able to service the need. In addition to offering a competitive price, ranitidine presented a safer drug interaction profile when compared with cimetidine.

**Conclusions:** This case study reflects the utility and importance of using therapeutic classes to stimulate competition, regularly reviewing ATC in formulary management, and applying international benchmarking principles to achieve cost efficiencies in an EML program.

**Funding source:** US Agency for International Development/South Africa

1081

**Malaria**

*Keywords:* antimalarials, availability, access to medicines, private sector, retail drug outlet

**Improving Access to ACTs Through Licensed Chemical Sellers in Ghana**

---

**David Ofori-Adjei<sup>1</sup>, Sylvester Segbaya<sup>2</sup>, Kwadwo Koram<sup>1</sup>, Kwame Adogboba<sup>3</sup>, Nana Enyimayew<sup>3</sup>**

<sup>1</sup>Noguchi Memorial Institute for Medical Research, University of Ghana, Accra, Ghana; <sup>2</sup>National Malaria Control Programme, Ghana Health Service, Accra, Ghana; <sup>3</sup>Health Partners Ghana, PO Box AC 649, Accra, Ghana

**Problem Statement:** Artemisinin-based combination therapies (ACTs) are recommended for the treatment of malaria. In many endemic countries, ACTs are not readily available especially in rural communities where they are needed most. In Ghana, Licensed Chemical Sellers (LCS) are usually the first port of call for people seeking health care. LCS operate shops licensed to sell over-the-counter medicines as well as antimalarials. The Mobilize Against Malaria (MAM) project started in Ghana in 2008 to improve access to ACTs through LCS. The intervention involved training of LCS in treating malaria in children under age 5 and pregnant women, stock management, and referral of patients. The monitoring and evaluation component of the project involved regular annual surveys of LCS practices from 2008 to 2011.

**Objectives:** To measure the availability of antimalarial medicines stocked by LCS, knowledge of treatment of malaria, and referral practices.

**Design:** A questionnaire-based comparative descriptive study

**Setting:** LCS shops in selected communities

**Study Population:** LCS selected from six randomly selected districts in the Ashanti Region of Ghana for each annual survey in 2008(baseline), 2009, 2010 and 2011 by cluster sampling based on census enumeration areas.

**Intervention(s):** Monitoring the effect of an educational intervention delivered by a third party.

**Policy:** Change in first-line treatment of malaria from chloroquine (CQ) to artesunate/amodiaquine(ASAQ) in 2005 and the introduction of intermittent preventive therapy in pregnancy using sulfadoxine/pyrimethamine (SP).

**Outcome Measure:** Effect of training on treatment knowledge; stocking and selling of SP and CQ; and referral patterns

**Results:** The number of LCS surveyed in 2008, 2009, 2010, and 2011 were 161, 160, 157 and 160, respectively. There was no difference in the number that had received training in general but there was a significant difference in the number that has received the project intervention between 2009 and 2010 (32.7% and 53.6%,  $p < 0.001$ ). The proportion of LCS stocking ACTs rose from 41% to 92.5% between 2008 and 2011. Knowledge of national treatment policy increased from 41.6% to 84.7% in the study period. The proportion of LCS recommending ACT for malaria rose from 0% in 2008 to 70.6% in 2011. The most commonly sold malaria medicine by LCSs were ACTs by 79.4%. The variables studied were better ( $p < 0.001$ ) in the trained LCS. There was no change in the stocking of SP and sales increased from 2.5% to 14.7% between 2009 and 2010. Stocking of chloroquine dropped from 45.3% in 2008 to 15% in 2011. The stocking and sale of SP and CQ was not influenced by training. There was no change in the pattern of referral for children under age 5, 72.5% in 2009 and 64.3% in 2010 ( $p = 0.1$ ); and a fall to 48% in 2011. Referral forms were readily available in trained LCS in 2009, 2010, and 2011 (65.4%; 47.4%; 42.9% respectively).

**Conclusion:** There is increased availability and use of ACTs as a result of the MAM training. There was no change in the referral of children under age 5. LCS still stocked CQ and SP which was against national policy but the use of CQ had been significantly reduced.

**Funding Source:** Pfizer MAM Project

1083

**HIV/AIDS and TB**

*Keywords:* Tuberculosis, drug consumption, procurement

**Calculation of Tuberculosis Patients' Drug Consumption Using Electronic Nominal Recording–Reporting System at District Level**

---

**Amal Galal Kaboh**

Ministry of Health, Egypt

**Problem statement:** An uninterrupted supply of good quality anti-tuberculosis (TB) drugs is one of the five components of the DOTS strategy. The design and implementation of a Drug Logistics Management Information System is an important technical intervention in supply chain management. A well-implemented system reduces the likelihood of stock-outs, which is crucial to the success of any program. It also minimizes overstocking that can waste scarce resources and lead to drug expiry. Egypt has implemented an Electronic Nominal Recording–Reporting System (ENRS) for TB patients. It is the electronic version of the main four registers in the TB recording–reporting system, where data entry is done on nominal bases at district level using Excel. Nominal data are then processed to produce the routine reports in the NTP. Calculating indicators using Excel and Access, registers are linked to produce patient profiles. One of the ENRS packages is the electronic district (DR) file for the first- and second-line of treatment, which contain the demographic data, all investigations which may confirm the diagnosis, patient follow-up data, and the outcome of the treatment. The file is supported by built-in equations to facilitate the work and to calculate the patient's actual TB drug consumption using the average amount needed of each drug. This amount is based on the actual duration of treatment which is calculated by the total number of treatment days using another built-in equation based on the start date of treatment and the end date of treatment.

**Results:** During 2009, more than 7,000 district patient record were obtained from about 157 TB management units in 28 provinces. By analysis of these records, the average number of treatment days for category one treatment line is about

187 days/patient and the average consumption is 374 tablets for 4 fixed-dose combination (4FDC), 561 for isoniazid , ethambutol , and pyrazinamide .

Conclusion: By using this system, the TB drugs procurement planning now is based on the evidence of the actual consumption and actual needs of the TB patient.

Funding source: Information not provided

#### 1084

##### Drug Resistance

*Keywords:* Accredited Drug Dispensing Outlets, community, antimicrobial resistance, IEC, private sector

### Engaging Private Sector Drug Dispensers to Improve Antimicrobial Use in the Community: Experience from the Tanzania Accredited Drug Dispensing Outlets

Richard Valimba<sup>1</sup>, Jafary Liana<sup>1</sup>, Mohan P. Joshi<sup>2</sup>, Michael Gabra<sup>1</sup>, Edmund Rutta<sup>2</sup>, Maganga Bundala<sup>3</sup>, Brycesson Kibassa<sup>3</sup>

<sup>1</sup>Strengthening Pharmaceutical Systems (SPS) Program, Management Sciences for Health (MSH), Tanzania;

<sup>2</sup>MSH/SPS, Arlington, VA, USA; <sup>3</sup>Tanzania Food & Drugs Authority (TFDA), Tanzania

**Problem statement:** The accredited drug dispensing outlet (ADDO) program uses regulation, training, and supervision to increase access to quality pharmaceutical products and services in underserved areas of Tanzania. The private sector is an important, yet often neglected, community resource that can be tapped to educate consumers on antimicrobial resistance (AMR) and rational antimicrobial use.

**Objectives:** To improve antimicrobial dispensing and counseling practices of private sector ADDO dispensers through use of job aids, educational materials, training, and regular supervision.

**Design:** Intervention with evaluation at 3 and 10 months post-intervention without a control group; evaluation based on retrospective review of ADDO dispensing records and 80 exit interviews with ADDO clients at 3 months and 58 exit interviews at 10 months.

**Setting and Study Population:** 126 dispensers from 120 ADDOs in the Kilosa district of Morogoro Region in Tanzania

**Intervention:** The Tanzania Food and Drugs Authority (TFDA) and the Strengthening Pharmaceutical Systems (SPS) Program of Management Sciences for Health (MSH) developed, pretested, and finalized job aids for ADDO dispensers (antimicrobial dispensing guide, table tent cards, and rubber stamps for labeling medicine envelopes) and a poster with AMR messages for display in ADDOs and at public sites in the community. We trained 126 dispensers on the use of these materials in December 2009. Three on-site supportive supervision visits were conducted in March, June, and October 2010 for 93, 101, and 110 ADDO dispensers, respectively.

**Outcome measures:** Percentages of indicators related to ADDO dispensers' management of cough/cold and acute, watery diarrhea; percentage of ADDO clients who had correctly labeled medicines and who understood how to take the medicines dispensed.

**Results:** Comparison of data collected during supervision visits showed that antibiotic dispensing for acute, watery diarrhea decreased from 37% in March to 12% in October; similarly, antibiotics dispensed for cases of cough and cold decreased from 27% to 11%. Exit interviews to assess dispensers' labeling of antimicrobials on medicine envelopes with medication name and strength and instructions for use showed an improvement from 88% to 96%, while clients' understanding of how to take their dispensed medicines rose from 77% to 98%. Availability of job aids in the ADDOs improved from 20% before the intervention to 86% in October (10 months post-intervention), while the availability of educational materials with AMR messages improved from 3% to 98%.

**Conclusions:** The Kilosa results suggest that using a package of job aids, educational materials, trainings, and supportive supervision visits improves dispensing and counseling practices of private sector drug dispensers and supports awareness of AMR and rational use of antimicrobials in the community.

**Funding Sources:** MSH/SPS through U.S. Agency for International Development

#### 1086

##### Economics, Financing, and Insurance Systems

*Keywords:* pharmacoconomics, cost containment, price regulation

### Role of Pharmacoconomics in a Developing Country Context

#### Anban Pillay

National Department of Health, South Africa

**Problem statement:** There are various measures that countries can apply to contain the costs of medicines. Developing countries have limited resources; therefore, it is important that they identify the interventions that would have the greatest effect.

**Objectives:** The objectives are to (1) identify the role of pharmacoconomics relative to other interventions as a cost-containment measure, and (2) propose a pharmacoconomics implementation plan in a developing country context.

**Design:** This is a policy evaluation based on a literature review.

**Setting:** Developing country context

**Interventions:** There are various measures to control the costs of medicines. These include a pro-generics policy (fast track registration, substitution), regulation of manufacturer prices (control rebates/discounts, internal and external reference pricing), regulation of supply chain costs (wholesaler fees, dispensing fees, tariffs, and taxes), price transparency, application of TRIPS flexibilities, and pharmacoeconomics.

**Results:** The application of pharmacoeconomics as a cost-containment measure would have a margin impact on cost containment relative to other interventions—progenerics policy, price regulation and price transparency. The implementation of pharmacoeconomics requires specific expertise (pharmacoepidemiology, biostatistics, evidence-based medicine) and resources which is not abundantly available in a developing country. The requirements to submit a pharmacoeconomics analysis is usually for the purposes of reimbursement and is stipulated in legislation. Economic analyses are usually required where the manufacturer claims that there is a clinical benefit/lower adverse event incidence with a new chemical entity. Economic analyses are rarely required for generic drugs since reference pricing is the more effective policy instrument. Economic analyses are prepared by the manufacturer with a view to convince the purchaser (usually government) that the price premium for the new drug offers value for money when the benefits are considered. The application process includes a detailed guideline of how to prepare an economic analysis submission and the criteria that are used in decision making. A positive evaluation of an economic analysis usually results in a recommendation that the drug should be reimbursed for a specific disease stage which is linked to a treatment guideline.

**Conclusion:** Pharmacoeconomic analyses are not the most effective cost-containment tool relative to other interventions that should be first implemented in a developing country setting. The implementation of a pro-generics policy and price regulation are more effective in containing costs. When pharmacoeconomic analyses is considered as a policy option, its use to be restricted to specific high cost new chemical entities that claim a significant price premium due to a “clinical benefit.”

**Funding source:** Information not provided

**1089**

**Access**

*Keywords:* access to medicines, chronic disease, community, appropriate use

### **Access to and Use of Medicines in Barbados: Evidence from a Household Survey**

**Maryam Hinds<sup>1</sup>, Adriana M. Ivama<sup>2</sup>, Carol Mulder<sup>3</sup>, Dennis Ross-Degnan<sup>4</sup>, Catherine E. Vialle-Valentin<sup>4</sup>**

<sup>1</sup>Barbados Drug Services, Ministry of Health, Bridgetown, Barbados; <sup>2</sup>Office of Caribbean Program Coordination (CPC), Pan American Health Organization/ World Health Organization (PAHO/WHO), Bridgetown, Barbados; <sup>3</sup>University of the West Indies, Cave Hill, Barbados; <sup>4</sup>Harvard Medical School, United States of America

**Problem Statement:** Barbados is a middle-income country with high prevalence of diabetes and hypertension. Medicines are free at all public and private points of service for persons over age 65 or under age 16, and for those receiving prescribed medicines listed on the National Drug Formulary (NDF) for diabetes, hypertension, cancer, asthma, and epilepsy. At all dispensing facilities, all citizens and permanent residents, that are eligible, do not pay for prescribed medicines that are in the BNDF. Since April 1, 2011, at private pharmacies, a dispensing fee has been re-introduced. Monitoring the effects of this policy is critical to ensure that it meets the objective of adequate cost-effective access to medicines and appropriate use for all Barbadians.

**Objective:** To generate reliable evidence for policy makers in Barbados about current medicines access and use at the community level.

**Design:** Descriptive analysis of survey data with technical support from PAHO/WHO and Harvard Medical School.

**Setting:** Household survey conducted in Barbados in 2010 with a questionnaire developed by WHO.

**Study Population:** Surveyed households were selected by random stratified sampling (n = 317). Those with asset and expenditure data (n = 272) were classified into “higher” (n = 160) or “lower” (n=112) Socio-Economic Status (SES) groups according to their total monthly expenditure (predefined threshold at BBD800) and reported ownership of preselected assets. The percentage of households reporting at least one chronic disease in the higher and lower groups was 53% and 67% respectively.

**Outcome Measures:** Indicators of medicines access and use.

**Results:** Most households (99%) could reach a public health care facility within 1 hour; 4% in the higher group lived at over 1 hour from a public hospital vs. 11% in the lower group. The percentage of households keeping medicines at home in the higher and lower groups was 76% and 71% respectively. The percentage of persons who obtained medicines free for their chronic disease was 74% in the higher group vs. 98% in the lower group; for those who paid, the average monthly medicines cost was 177 Barbados dollars (BBD) in the higher vs. BBD 9 in the lower group. In the higher group, 6% of persons with a chronic disease had not been told to take medicines vs. 15% in the lower group. Respondents in the lower group had a better opinion of care and access to medicines in public facilities than those in the higher group. In both groups, a high percentage of persons with chronic disease did not take the medicines prescribed (23% in higher and 17% in lower group) most often because they felt symptoms had improved.

**Conclusions:** Overall, our results indicate good community access to medicines in Barbados with notable differences in access between lower and higher SES groups for people with chronic disease. They draw attention to misconceptions about treatment of chronic diseases and point to the need for interventions convincing people with chronic disease to continue treatment even if symptoms improve.

**Funding:** The study was part of the EU/WHO ACP Partnership on Pharmaceutical Policies Project funded by the European Union.

1090

**Access***Keywords:* gender perspective, reproductive health, drug utilization, women**Literature Review of Gender and Drugs in Eastern Mediterranean Region Index Medicus****yomna mohamed Abd el-fatah, yomna tarek Abo-shadi**

faculty of pharmacy, Alexandria university, Egypt

**Problem statement:** In recent years, concerted efforts have been taken by international and regional health organizations to promote women's health and emphasize gender-related issues. One of the important concerns is shortage of scientific studies on areas related to women's health. This study was carried out to review the research studies available in the database of Index Medicus for the WHO Eastern Mediterranean Region (IMEMR).

**Objectives:** To search the IMEMR on available studies on women and drugs, and encourage academic institutions to carry out scientific studies on important issues related to women and health.

**Design:** This study was carried out by searching the IMEMR using key words relevant to women and medicine. IMEMR provides free access to the prestigious health and biomedical sciences literature published in the eastern Mediterranean Region. It contains more than 107,500 citations of peer-reviewed health and biomedical literature published in 483 journals from the region's 19 countries.

**Results:** A search of the IMEMR database using the key words women and drugs and gender and drugs resulted in 144 and 40 research articles, respectively. The main topics covered by these articles are (1) ovarian induction and related issues emphasizing that clomifene citrate may be correlated to increasing the risk of ovarian cancer; (2) pregnancy disorders and drugs indicating that irrational use of drugs and herbs can decrease pregnancy outcomes; (3) labour-related issues providing suggestions to manage complications related to cesarean section and anaesthesia; and (4) hormonal replacement therapy studying the effect of this therapy on bone mineral density and on insulin resistance in diabetic postmenopausal women. There were fewer reports found on the important topics of self-medication, contraceptives, mental health of women, dysmenorrhea, breast diseases, and suicide and self harm. When searching the database with key words related to women and different disease conditions, several articles were found related to women and cancer, women and infection, women and mental health, women and trauma, and women and sexual health. A few reports were also found related to women and musculoskeletal problems, sensory impairment, and psychosocial considerations of menopause.

**Outcomes:** A review report on research studies published in the Index Medicus concerning women and medicine in EMR countries.

**Conclusion:** IMEMR provides an important database for research studies on women health. The database search indicated that many topics are well studied while other important areas related to women and medicines need more attention and research by academic community in EMR.

**Funding source:** Information not provided

1092

**HIV/AIDS and TB***Keywords:* prescribing pattern, treatment guidelines, antiretroviral therapy, regimen**Trends in Antiretroviral Drugs Prescribing at Public Health Facilities in Ethiopia: Compliance to Treatment Guidelines****Hailu Tadeq Meteleya<sup>1</sup>, Negussu Mekonnen Woldemaskal<sup>2</sup>**<sup>1</sup>Management Sciences for Health/Strengthening Pharmaceutical Systems, Ethiopia; <sup>2</sup>Management Sciences for Health/Strengthening Pharmaceutical Systems, Ethiopia

**Problem statement:** Treatment guidelines provide a standardized and simplified guide and are designed to help practitioners make appropriate therapeutic decisions specific to the clinical circumstances. In Ethiopia, the treatment guideline for antiretroviral therapy (ART) was revised in March 2008. Since then, there has not been a systematic assessment of antiretroviral (ARV) prescribing patterns and compliance of prescribers to the new treatment guideline.

**Objectives:** To determine trends in the prescribing of ARV drugs in public health facilities and the level of compliance to treatment guidelines

**Design:** A retrospective descriptive study based on reports received from ART health facilities in the past 3 years

**Setting:** ART pharmacies of selected public hospitals and health centers providing free ART services in different regions of Ethiopia

**Study population:** 154 health facilities comprising 70 hospitals and 84 health centers

**Intervention(s):** Following development of the revised antiretroviral treatment guidelines, health care providers were given training on the new guidelines followed by mentoring support to reinforce ART prescribing as per the new protocol.

**Outcome measure(s):** Trends in ARV drug prescribing, percentage of patients on the preferred first-line regimen, percentage of patients on tenofovir versus stavudine-based regimens, percentage of patients on a regimen that is not in the guideline

Results: Analysis of the regimen profiles over the 3-year period indicated that the proportion of patients on preferred first-line regimen increased from 32% in 2008 to 49% in 2010. Conversely, patients on an alternative first-line regimen decreased from 66% in 2008 to 48% in 2010. Proportion of patients on TDF-based regimen increased from 0.68% in 2008 to 12% in 2010, whereas those on D4T-based regimen decreased from 65% in 2008 to 48% in 2010. Although the new treatment guidelines recommend TDF-based regimen as the preferred first option, the proportion of patients on this regimen is still very low (12%). The rate of increase of patients on TDF-based regimens appears to be faster in health centers (0.03% to 2.48% to 8.15%) compared to hospitals (0.95% to 12% to 14%) in 2008, 2009, and 2010, respectively. The percentage of patients on regimens that are not recommended by the guidelines increased more than 5-fold between 2008 and 2010 (0.02% and 0.11%, respectively).

Conclusions: The findings of this study indicate that compliance to ART treatment guidelines is quite low. A significant number of patients are still on alternative first-line regimens, although this finding has shown improvement over the study period. The proportion of patients on D4T-based regimen is of particular concern because these patients could develop toxicity, thereby compromising adherence to treatment and outcome of therapy. Therefore, additional interventions are required to improve ARV drug prescribing practice.

Funding source(s): PEPFAR/USAID

### 1093

#### Access

*Keywords:* Access, medicines, health system research, priority setting

#### **Priority Policy Research Questions in the Area of Access to Medicines in Latin America, Middle East, and Asia**

**Maryam Bigdeli<sup>1</sup>, Vera Luiza Lucia<sup>2</sup>, Arash Rashidian<sup>3</sup>, Shakti Selvaraj<sup>4</sup>, Rithy Men Chen<sup>5</sup>**

<sup>1</sup>World Health Organization, Switzerland; <sup>2</sup>National Institute of Public, Oswaldo Cruz Foundation, Rio de Janeiro, Brazil;

<sup>3</sup>National Institute of Health Research, Tehran University of Medical Sciences, Iran; <sup>4</sup>Public Health Foundation of India;

<sup>5</sup>Centre for Advanced Studies, Phnom Penh, Cambodia

**Problem Statement:** Access to Medicines (ATM) is weak in low- and middle-income countries (LMICs). WHO estimates that the average availability of essential drugs in LMICs is 35% in public sector facilities and 66% in the private sector. Medicines account for a high proportion of health spending in LMICs, where 50–90% of expenditure on medicines is out-of-pocket. This inequitable mode of financing creates significant access barriers for the poor and leads to catastrophic household expenditures. Despite some progress in areas such as price and availability, data on ATM is weak. Even where data are available, there is limited contextual evidence and weak capacity for translation of evidence to policy. There is therefore an urgent need to identify relevant policy research questions related to ATM, and support generation and synthesis of evidence to inform medicines policies.

**Objectives:** The current work is being done to (1) identify and rank policy concerns related to ATM as perceived by policy makers, civil society organizations, communities, and patients in several countries in Latin America, Asia, and the Middle East; (2) identify and rank related policy research questions in the field of ATM.

**Design:** Published and grey literature search and analysis complemented by key informant interviews at country and regional level

**Setting:** Latin America, Asia, and the Middle East

**Interventions:** The following steps have been followed in the priority setting process—(1) definition of context and scope of ATM for the current exercise; (2) definition of a bottom-up country-driven approach; (3) mapping of stakeholders; (4) information gathering through published and grey literature search complemented by key informant interviews; (5) definition of criteria for selecting priorities; and (6) selecting priority policy research questions in the field of ATM.

**Outcome Measure:** Policy concerns, issues, and barriers around access to medicines in the Latin American, Asian, and Eastern Mediterranean Regions will be presented according to the 4 dimensions of the World Health Organization Framework for Equitable Access to Essential Medicines—rational selection and use, affordability, sustainable financing, and reliable health systems. The exercise will further identify at which level of the health system barriers occur: individuals and communities, health services and facilities, health sectors and beyond the health sector. Health system research questions will be formulated to answer identified policy concerns. These questions will be prioritized according to predefined criteria.

**Results and conclusions:** Will be available at the time of the conference

**Funding Source:** UK Department for International Development

### 1094

#### HIV/AIDS and TB

*Keywords:* tuberculosis, drug resistant strains, TB in Egypt

#### **The Risk of Getting Anti-TB Drugs as OTC Drugs**

**Karim Maged EL-Ghazouly<sup>1</sup>, Tarek Gamal El-Sawaf<sup>2</sup>, Nehal Mohamed Magdy Daebis<sup>1</sup>**

<sup>1</sup>Pharos University in Alexandria (PUA); <sup>2</sup>Faculty of Pharmacy, Alexandria University.

**Background:** Tuberculosis control efforts are often ineffective in controlling tuberculosis among patients who use illicit drugs<sup>1</sup>. The occurrence of multidrug-resistant tuberculosis is increasing in many parts of the world. Resistance of *Mycobacterium tuberculosis* (*M. Tuberculosis*) to Anti-tuberculosis drugs is man-made. In Egypt, private pharmacies

constitute an important part of the private healthcare sector where some Anti-tuberculosis drugs dispensed without prescriptions. With such malpractice emergence of serious types of *M. tuberculosis*-resistant strains is highly likely to occur.

**Methods:** Surveys of a random sample of 78 pharmacies in Alexandria and Behira for Anti-tuberculosis drugs were included in our study. These pharmacies were divided into hospital pharmacies, pharmacies in rural areas and pharmacies in urban areas. Questionnaires were given to these pharmacies, and interviews were carried out based on a structured questionnaire.

**Results:** It was found that 90.8% of the pharmacies enrolled in this study hold in their inventory Anti-tuberculosis drugs; however, 77% of them dispense these drugs without prescription, while 15.4% advise the patient about their risks. Nevertheless, 20% only ask the patient why they take these drugs

**Conclusion:** Awareness to patient taking Anti-tuberculosis drugs about their risk is of paramount importance, meanwhile; awareness to pharmacists dispensing these drugs about their risk. Imposing a penalty on pharmacists dispensing Anti-tuberculosis drugs without prescription. Limiting the dispensing of these drugs to hospitals curing tuberculosis. Encouraging pharmacists to counsel the patient asking for these drugs, are all viable options.

## 1095

### Malaria

**Keywords:** Cost effectiveness, diagnostic tests, Artemether-lumefantrine

### **Cost-Effectiveness of Treating Malaria Following Three Methods of Diagnosis: Implications for Scaling-Up Use of Rapid Diagnostic Tests in Uganda**

**Vincent Batwala<sup>1</sup>, Pascal Magnussen<sup>2</sup>, Fred Nuwaha<sup>3</sup>**

<sup>1</sup>Mbarara University of Science & Technology, P. O. Box 1410, Mbarara, Uganda; <sup>2</sup>Centre for Health Research and Development, Faculty of Life Sciences, Copenhagen University, Thorvaldsensvej 57, DK1871 Frederiksberg C, Denmark; <sup>3</sup>Disease Control and Environmental Health, Makerere University School of Public Health, P. O. Box 7072, Kampala, Uganda

**Problem statement:** The use of high-cost artemisinin-based combination therapy (ACT) as first-line treatment for uncomplicated malaria stimulated the interest in reassessing the diagnostic practices in sub-Saharan Africa. Clinical (presumptive) diagnosis of malaria as it is now performed in remote settings leads to considerable drug expenditure on inappropriate treatment of patients free of parasitaemia.

**Objectives:** To compare the cost-effectiveness of treating malaria with artemether-lumefantrine based on microscopy, rapid diagnostic test (RDT), and presumptive diagnosis in different transmission settings.

**Design:** A cost-effectiveness trial with two intervention arms and one control arm.

**Setting:** Three public primary health care centers (HCs) located in a district of low transmission intensity in western Uganda and three in a high transmission setting in the eastern part of the country were involved.

**Study population:** Some 22,052 consenting outpatients weighing  $\geq 5$ kg, with suspected uncomplicated malaria were consecutively enrolled from March 2010 to February 2011. Of these, a random sample of 1,627 was selected to measure additional socioeconomic characteristics.

**Intervention:** Three HCs were randomized to three diagnostic arms (microscopy, RDT and presumptive diagnosis) in each study district. In intervention arms (microscopy and RDT), finger-prick blood was examined before receiving treatment. Patients were treated basing on test results and clinician judgement. Socio-demographics, symptoms, and cost data were directly collected from patients and service providers. Costing was performed following both the standard step-down cost allocation method and the ingredients approach. Essential features of policy change that were evaluated included cost-effectiveness of the diagnostic strategies to appropriately target antimalarial drugs in peripheral government HCs and to improve the management of non-malarial febrile illness.

**Outcome measures:** Proportion of outpatients correctly diagnosed and treated; average cost-effectiveness ratios (ACERs) and incremental cost-effectiveness ratios (ICERs).

**Results:** RDT was more effective (87.7%) than microscopy (79.7%) and presumptive diagnosis (64.3%). The superior effectiveness of RDT was maintained when data was stratified by transmission intensity. Overall RDT was cost-effective with lowest ACER 5.95 US dollars (USD) and ICER USD5.0 compared to microscopy ACER 6.94 and ICER USD 9.61 per case correctly diagnosed and treated. The difference in ICERs between RDT and microscopy was greater in the high transmission area (USD 8.90) than in low transmission setting (USD 1.78).

**Conclusion:** RDT was cost-effective in both low and high transmission settings. Adherence to test results is essential to benefit from use of RDTs and with a global campaign to reduce the cost of artemether-lumefantrine, the Malaria Control Program and stakeholders need a strategy for malaria diagnosis because as the cost of the drug decreases, presumptive treatment is likely to become attractive.

**Funding Source:** TARGETS Makerere University School of Public Health/ Department for International Development project; Center for Health Research and Development, Copenhagen University, Denmark; and the Belgian Technical Cooperation local grant.

## 1097

### Chronic Care

**Keywords:** polypharmacy, elderly, drugs consumption

## **Polypharmacy Among Older Adults in Tehran**

**Batoul Ahmadi, masoumeh Alimohamadian, mahmood mahmoodi**

Tehran university of medical sciences/school of public health, Iran, Islamic Republic of

**Problem statement:** Multiple drug use is frequently considered to be hazardous for the elderly because of their greater vulnerability to the complications. The older population in Iran is increasing and they likely use more drugs than any other age groups. The older adults often suffer from chronic conditions that may require long-term medical treatment, and likely involve multiple drug therapies. These patients may consume up to four times as many defined daily doses as the rest of the population.

**Objectives:** The purpose of this study was to determine the prevalence of polypharmacy in Tehran and to assess the relative medical and demographic characteristics of patients.

**Design and setting:** In a cross-sectional descriptive study, the selective patients were interviewed to answer a questionnaire at home and their current medications were reviewed. The information on all medications used was collected. The questionnaire also contained questions regarding personal, social, and medical factors. Polypharmacy was defined as daily intake of three or more drugs. Chi-square and Fisher's exact tests and determination of odds ratios were used to analyze data.

**Study population:** Four hundred cases of patients aged 55 and older by cluster sampling were randomly selected from community residents in Tehran.

**Results:** Median number of drugs used was  $3.4 \pm 1.9$  in studied cases and 39.6% of cases were exposed to polypharmacy. The prevalence of physician prescribed drug usage was observed to be increased by increasing number of total used drugs in each case ( $P < 0.002$ ). The most commonly used drugs were acetylsalicylic acid, atenolol, and propranolol; these drugs were prescribed by physician in over 90% of cases. There were positive correlations between polypharmacy and referring multiple physicians ( $OR = 1.96$ ,  $CI$  95%, 1.28- 2.98) ( $P < 0.002$ ) and adverse drug reactions ( $OR = 2.44$ ,  $CI$  95%, 1.47-4.05) ( $P < 0.001$ ). Polypharmacy was more prevalent in the age group of 65–75 years ( $P < 0.04$ ) and lower levels of education ( $P < 0.004$ ), and less prevalent in the group with moderate income ( $P < 0.001$ ).

**Conclusion:** Polypharmacy is common among adults aged 55 years and older in Tehran and is affected by age, education level, and economic status. Polypharmacy should be reduced as it has many potential adverse effects.

**Funding source:** This study was granted by Tehran University of Medical Sciences in Tehran, Iran.

**1098**

### **Policy, Regulation, and Governance**

*Keywords:* Monitoring and Evaluation, Pharmaceutical Policies, Pharmaceutical Situation

## **Pharmaceutical Situation in the Caribbean as Background for Policy Development**

**Adriana Mitsue Ivama<sup>1</sup>, Enrico Cinnella<sup>2</sup>, Edelise Carandang<sup>2</sup>, Nelly Marin<sup>3</sup>, James Fitzgerald<sup>3</sup>, Christophe Rerat<sup>4</sup>**

<sup>1</sup>Pan-American Health Organization/World Health Organization (PAHO/WHO), Office of Caribbean Programme Coordination (OCPC); <sup>2</sup>World Health Organization (WHO), Medicine Programme Coordination (MPC);; <sup>3</sup>Pan American Health Organization/World Health Organization (PAHO/WHO), Medicines and Technologies; <sup>4</sup>Pan American Health Organization/World Health Organization (PAHO/WHO), Brazil

**Problem statement:** Promoting access to safe affordable and efficacious medicines will certainly contribute to the implementation of the CARICOM single market and economy (CSME), the Port of Spain Declaration, the Caribbean Cooperation in Health Phase III, among other mandates. In the Caribbean, technical cooperation was provided from 2004 to 2010 in the framework of the EU/ACP/WHO Partnership on Pharmaceutical Policies.

**Objective:** Assess the pharmaceutical situation in the Caribbean

**Design:** A descriptive study, comparing results from the WHO level I survey in Caribbean countries in 2003 and 2007, was conducted in 2009. Analysis was done with Excel.

**Setting:** 12 CARICOM countries and the Dominican Republic.

**Results:** Progress was observed in all areas. The number of countries with a National Medicines Policy increased from 3 (27%) in 2003 to 7 (54%) in 2007, of which 2 were officially adopted in 2003 and 4 (57.1%) in 2007. In 2003, only 4 countries had legal provisions for a Medicines Regulatory Authority (MRA) and had a MRA established; in 2007, there were 11 (85%) countries. All the participating Caribbean countries mentioned having public sector procurement pooled at the national level. In 2003, the Ministry of Health performed the procurement function in all 7 countries that responded, and in 2007, in 12 countries (92%). The distribution function was performed by the Ministry of Health in 5 countries (100%) in 2003 and in 7 countries (88%) in 2007. The median public expenditure per capita/year was higher in the participating Caribbean countries (USD 20.9) than the median of whole region of the Americas (USD 11.5). In 2003, TRIPS flexibilities were under discussion. In 2007, only a few countries had implemented them. The availability and utilization of essential medicines lists (EML) and standard treatment guidelines (STG) increased between 2003 and 2007. On the other hand, not much progress has been achieved as regards the introduction of concepts related to RMU in the curricula of health in the Caribbean.

**Conclusions:** Special attention must be paid to implementation with monitoring and evaluation of pharmaceutical policies. Gaps were identified on regulatory functions with needs to strengthen the institutional and technical capacity with the need of joint collaboration. The results suggest the need to strengthen the medicines procurement and supply system thereby ensuring its sustainability and cost containment. It is necessary to strengthen the use of TRIPS flexibilities by member states. It would be useful to strengthen the development of human resources in the different

areas. Taking into account limitations of the survey and the need of more specific information in some areas, the findings contribute to identify strengths and gaps that, combined with other subregional surveys, were used as evidence to support decision making informing the development of a Caribbean Pharmaceutical Policy.

Funding source: EU/ACP/WHO Project Partnership on Pharmaceutical Policies funded by the European Union

## 1101

### Policy, Regulation, and Governance

*Keywords:* Conflict of interest, pharmaceutical policy

#### **Conflict of Interest Policies: Do Academic Medical Centers Make the Grade?**

**Christopher Manz**<sup>1,3</sup>, **Timothy Anderson**<sup>2,3</sup>

<sup>1</sup>Duke University, United States of America; <sup>2</sup>Case Western School of Medicine, United States of America; <sup>3</sup>American Medical Student Association, United States of America

**Problem:** Conflicts of interest can distort physician prescribing practices, resulting in inappropriate prescribing, increased reliance on expensive brand name drugs and increased utilization of healthcare resources. Appropriate institutional policies can mitigate the negative impact of conflicts of interest on prescribing practices and patient care in industrialized and non-industrialized countries.

**Objective:** This survey examined the quality of conflict of interest policies at all academic medical centers in the United States, with the intent of promoting policy transparency and encouraging schools to implement stronger policies.

**Design/Intervention/Policies:** The American Medical Student Association administers an annual PharmFree Scorecard survey. The survey evaluates academic medical centers on 11 metrics related to conflict of interest: gifts, consulting relationships, industry-funded speaking relationships, disclosure, pharmaceutical samples, purchasing and formularies, industry sales representatives, on and off site educational activities, industry support for scholarships and funds for trainees, and medical school curriculum. Each policy is evaluated on a 3 point scale according to standards widely used and established by literature, and schools are assigned a letter grade of A through F.

**Setting/Population:** The Scorecard surveys all 152 allopathic and osteopathic medical schools in the US.

**Outcome Measure:** The quantity and quality of conflict of interest policies at academic medical centers.

**Results:** From 2008 to 2010, the Scorecard has documented a large increase in the number of schools with strong conflict of interest policies (rated A or B), from 19% of schools in 2008 (29 out of 149 schools) to 52% of schools in 2010 (78 out of 152). The Scorecard has seen a consistent rise in strength of policies across all 11 metrics and a participation rate of 92%.

**Conclusions:** Since the Scorecard was instituted in 2007, the number and quality of conflict of interest policies at medical schools has increased substantially. That the Scorecard campaign has played an active role in this process is evidenced by coverage from major media outlets, including CNN, Fox News, the New York Times and the Wall Street Journal. In 2009, when 18 schools refused to respond to the survey, US Senator Grassley required that they submit policies to the US Senate instead, highlighting the importance of the Scorecard in promoting conflict of interest policies. The Scorecard has empowered medical students at institutions across the country (most visibly at Harvard Medical School) to push their institutions to improve their policies, underscoring the utility of the survey to drive policy change at an institutional level. Strong policies may reduce the negative impact of conflicts of interest, improve prescribing practices and lower cost of care in both developed and developing countries.

**Funding:** The Scorecard is supported by funding from Pew Charitable Trusts.

## 1102

### HIV/AIDS and TB

*Keywords:* Anti-TB medicines (ATBM), Drug supply system, Global Fund (GFATM), Global Drug Facility (GDF), drug shortage,

#### **Causes of ATBM Shortages in GFATM and GDF-Supported Countries in the Eastern Mediterranean Region and How to Avoid Them in the Future**

**Khaled Khalil**

WHO/EMRO, Egypt

**Problem Statement:** The regional office has received many complaints. (1) country A—stock-out of rifampicin (R), isoniazid (H), Pyrazinamide (Z), ethambutol (E) due to delay in funding transfer; (2) country B—stock-out of RH due to mismanagement of the treatment regimens; (3) country C—stock-out of streptomycin due to misdistribution; and (4) country D— stock-out of RHZ 150/60/30 due to port clearance delay. The stock out may be due to (1) inadequate funding; (2) poor selection and quantification of medicines and lack of prioritization; (3) delay in procurement; (4) extensive expiration of medicines; (5) port clearance delay (in some cases, as long as 6 months); (6) countries that do not follow Good Manufacturing Practices and good laboratory practices often experience product failure; and (7) programs that do not follow push or pull system of distribution.

**Methods:** A regional survey was done during Global Drug Facility (GDF)/World Health Organization (WHO) field visits in 15 GDF-supported countries, 12 of which are supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria. Interviews were conducted with 76 directors of the pharmacy departments at the Ministries of Health as well as NTP staff. The questionnaire endorsed GDF/WHO questionnaires about the availability of ATBM at central/district levels. It also included questions on possible causes of shortage of ATBM at all country health care levels, how countries were

managing their ATBM supply system, how shortages occur despite the era of these high- quality initiatives, how WHO and countries have tried to manage the shortage, and what is the possibility for having no future shortages.

Results: Usable responses were received. Among 15 GDF-supported countries, 20% of them, the shortage was due to noticeable decrease in the political commitment towards ATBM funding; 13.3 % was due to unplanned switching to 6-month regimens in countries which were working on the 8-month regimens; 26.6 % was due to a delay of funding of ATBM; in the 33.3% of the 12 GF-supported countries. Significant increase in the GDF leadtime of ATBM orders was noticed as a result of the above reasons in 20% of the surveyed countries. The last 20.1% was due to different reasons, such as delay in port clearance and lab analysis. However, the background of why the shortages occurred raises questions. None of the countries appears to have faced a real stock-out. The shortages of TB medicines only affected the buffer stock (safety stock ) at different levels. And all countries have faced mismanagement of the drug management components.

Conclusion: To prevent future shortages of ATBM, we suggest that transparency is maintained and increased in the drug procurement and supply mechanism at national level and that health sector funding gap be addressed by partners working together to establish a revolving fund at the regional level. In addition, work should continue on the rational use of ATBM and WHO pre-qualification for more GDF/WHO pre-qualified suppliers from the region. GDF has established the system for stockpiling second-line drugs (first-line is in process).

Funding source: Information not provided

**1104**

### **Economics, Financing, and Insurance Systems**

*Keywords:* Health Insurance, Medicines, MeTA, Access

#### **Tackling Medicine Related Issues Affecting the National Health Insurance Scheme in Ghana**

**Daniel Kojo ARHINFUL<sup>1</sup>, Alexander Dodoo<sup>2</sup>, Daniel Ankras<sup>3</sup>, Edith Andrews Annan<sup>4</sup>, Brian Asare<sup>5</sup>, David Ofori-Adjei<sup>1</sup>**

<sup>1</sup>Noguchi Memorial Institute for Medical Research, University of Ghana, Ghana; <sup>2</sup>Centre for Tropical Clinical Pharmacol. & Therapeutics, University of Ghana Medical School, Korle-Bu Teaching Hospital, Accra, Ghana;

<sup>3</sup>Pharmacy Department, Korle Bu Teaching Hospital, Accra, Ghana; <sup>4</sup>WHO Country Office, Accra, Ghana; <sup>5</sup>Ghana National Drugs Programme, Ministry of Health, Accra, Ghana

Problem statement: Ghana is one of seven pilot countries implementing the Medicines Transparency Alliance (MeTA) to make information available to the public on the quality, availability, pricing and promotion of medicines. MeTA seeks to provide an opportunity to develop a transparent and accountable pricing and quality monitoring mechanism to inform the National Health Insurance Scheme (NHIS) through systematic data analysis, and thereby provide decision support for management for the financial sustainability of the scheme.

Objectives: The main aim is to assess medicine prices, availability, and quality to inform and provide regular decision support for the programme and management activities of the NHIA and other relevant stakeholders.

Design: Periodic data extraction and analysis of the NHIS electronic data system and validation survey through primary data collection using the standardized methodology of World Health Organization (WHO) Level II Facility Survey and tracer medicines list developed with the NHIA.

Setting: Both electronic database and validation surveys utilize the proposed MeTA sampling approach and involve selected schemes and regions in the country. The pilot validation survey reported here was a two-stage facility-based survey conducted in four of Ghana's ten regions.

Study population: At stage one, three regions were selected from the three ecological zones of Ghana. In each region, six public health care facilities, two mission facilities, and one private facility were selected and studied per survey area. All facilities were NHIS accredited. At the second stage, 10 private health facilities were selected in two regions and studied.

Outcome measure(s): Included availability of key medicines, drug prices and affordability, and rational use.

Results: The availability of key essential medicines selected for the country were higher in public health facilities (87.5%) than private facilities (83.3%). In the public sector, the procurement agency is purchasing medicines at 1.49 times higher than international reference prices compared to 1.67 in the private sector. Final patient prices for generic medicines in the public sector were 2.63 times higher the international reference prices and compared to 2.22 in the private sector. Quite a high level of injection use (10% and 18.3% for public and private, respectively) and antibiotic use (50% and 46.7% for public and private, respectively) are observed in both the public and private sectors.

Conclusions: Further analysis and comparison with data from the NHIA electronic platform is required to obtain a more in-depth understanding of the consequences of the findings.

Funding source: Financial support was provided by DfID with technical support from WHO

**1106**

### **Access**

*Keywords:* access to medicines, financing, TRIPS, legislation, medicine supply

#### **Developing Interdisciplinary Methods for Research to Explain and Enhance Access to Medicines in Africa and South Asia**

**Marc Twagirimukiza<sup>1</sup>, Ashwin Budden<sup>2</sup>, Mitchell Weiss<sup>2</sup>, Paul Waako<sup>3</sup>, Rogers Bariyo<sup>4</sup>, David Sanders<sup>5</sup>, Sachin Atre<sup>6</sup>, Shilpa R Maiya<sup>6</sup>, Jan De Maeseneer<sup>1</sup>, Allyson Pollock<sup>7</sup>, Roger Jeffery<sup>7</sup>, AMASA Consortium Investigators<sup>7</sup>**

<sup>1</sup>Department of Family Medicine and Primary Health Care, Ghent University, Belgium; <sup>2</sup>Department of Public Health and Epidemiology, Swiss Tropical and Public Health Institute, Switzerland; <sup>3</sup>Department of Pharmacology and Therapeutics, Makerere University College of Health Sciences, Uganda; <sup>4</sup>Faculty of Development Studies, Mbarara University of Science & Technology, Uganda; <sup>5</sup>School of Public Health, University of the Western Cape, South Africa; <sup>6</sup>Foundation for Research in Community Health, India; <sup>7</sup>School of Social and Political Science, University of Edinburgh, UK

**Problem statement:** Public health and disease control rely on effective policy and action to ensure the availability of quality medicines and their appropriate use. A focus on tracer medicines provides a means of considering the effectiveness of policy and health systems in low- and middle-income settings where industrial, social and cultural features of African and South Asian societies pose unique challenges for disease control and public health.

**Objectives:** A European Union FP7-supported project, Accessing Medicines in Africa and South Asia (AMASA), has been established as a North-South partnership to study the production, distribution, supply, and consumption of selected medicines in Uganda, South Africa, and India, and to consider implications for these countries and their respective regions. Studying the selected tracer medicines and the health problems they control should clarify the public health priorities for the three selected countries and guide policy to improve public health. The tracer medicines include rifampicin for tuberculosis and leprosy control, artemisinin for malaria, lamivudine for HIV/AIDS, fluoxetine for unipolar depression, metformin for diabetes, oxytocin for reproductive health, and fentanyl for pain control.

**Design:** Questions concerning access to medicines are best answered with an interdisciplinary research agenda integrating systems, biomedical, social, and cultural research perspectives. Seven working groups are developing and employing interdisciplinary methods in literature reviews and field research to address key questions concerning production and acquisition of these medicines, regulatory systems and policies, patents and trade, donor funding of medicines for health systems, supply chains and distribution, consumer and community patterns of use, and the evidence-based recommendations for use of the tracer medicines. The project team engaged in this research is led by the University of Edinburgh with European partners at the Swiss Tropical and Public Health Institute and the University of Ghent. Research partners include teams at field study sites at Makerere University and Mbarara University of Science and Technology in Uganda, University of Western Cape in South Africa and the Foundation for Research in Community Health in India.

**Results, interventions, and policies:** Involving additional national and international stakeholders to develop and implement the project and to disseminate its findings will ensure appropriate consideration of implications of the project to improve access and appropriate use of medicines required for major public health challenges in low- and middle-income countries.

**Conclusions:** This presentation introduces the project and its interdisciplinary methods, and it reviews key questions, findings, and implications from the experience of implementing the project.

**Funding sources:** This paper forms part of research funded by the European Union 7th Framework Programme Theme: Health-2009-4.3.2-2 (Grant no. 242262) under the title "Access to Medicines in Africa and South Asia."

## 1108

### Policy, Regulation, and Governance

*Keywords:* Medicines Transparency Alliance (MeTA), country comparison, multi-stakeholder collaboration, baseline, access to medicines

### Country Comparison of Multi-Stakeholder Process Assessments in the MeTA Baseline

**Birgit Kerstens<sup>1</sup>, Samia Saad<sup>2</sup>, Wilbert Bannenberg<sup>1,3</sup>**

<sup>1</sup>Health Action for Research (HERA); <sup>2</sup>Independent Consultant, <sup>3</sup>Medicines Transparency Alliance (MeTA)

**Problem statement:** No suitable tool existed to measure multi-stakeholder collaboration in MeTA countries. The concept was also new to in-country stakeholders, and led to substantial confusion and barriers in pilot countries at the start of MeTA.

**Objectives:** To assess the multi-stakeholder process in (MeTA) pilot countries and suggest ways to overcome barriers and challenges, with the ultimate aim of improving access to medicines.

**Design:** Cross-country study, desk-based review

**Setting:** Five MeTA pilot countries (Jordan, Peru, Philippines, Uganda, and Zambia) and an assessment of the multi-stakeholder process involving public, private, and civil society sectors.

**Study population:** A high level multi-stakeholder group (MSG), representing key national institutions from public, private, and civil society sectors; and from academia.

**Intervention:** MeTA partnered with the Institute of Development Studies (IDS) to create a set of tools for the assessment. The multi-stakeholder process assessments were conducted between February and August 2010 through face-to-face interviews using standardised questionnaires, as well as two workshops with stakeholders involved in the MeTA multi-stakeholder alliances. Data collected for ~2 months. Findings were presented in country reports. Cross-country summary tables were developed for comparison purposes, and analyzed by a MeTA consultant.

**Outcome measures:** The cross-country study compares the governance and structure of each MeTA pilot country MSG, the in-country multi-stakeholder process, the barriers and levers to multi-stakeholder engagement and lists all recommended changes for future working.

Results: Report with a cross-country analysis of the multi-stakeholder assessments, showing in which areas the countries are similar or different, and how they compare in terms of governance, structures, communication, and data sharing. Lessons learned about the multi-stakeholder process: these can be used in the future by countries applying the MeTA concepts. Individual country assessment reports and the cross-country analysis have been placed in the public domain.

Conclusion: Analysis of the cross-country table of baseline component 3 can provide a quick overview of which country has built the best multi-stakeholder alliance through MeTA, whether there is balanced representation in the MSG, and whether communication and information sharing has improved.

Funding source: UK Department for International Development (DFID)

## 1109

### **Economics, Financing, and Insurance Systems**

*Keywords:* medicine prices, quality assurance, pharmaceutical expenditure, corruption, cost containment,

#### **An Analysis of the Global Fund's Price and Quality Reporting Database**

---

**Thomas Patrick Aylward, Sophie Logez, Thuy Huong Ha, Monika Zweggarth, Carmen Perez Casas**

The Global Fund to Fight AIDS, Malaria and Tuberculosis, Switzerland

Problem Statement: The Global Fund believes that the disclosure of information on prices paid for purchases is a matter of principle and facilitates a process leading to lower prices. The procurement of pharmaceutical and health products accounts for approximately 35% of all funds disbursed and as a result the Global Fund has tracked and made publicly available transaction level procurement information since 2005 which is stored in a database called the Price and Quality Reporting System (PQR). The information contained in the PQR has been a valuable tool for the Global Fund, other organizations, and researchers. However, data quality issues and a lack of effective operational reports have limited the use of PQR information amongst procurement practitioners.

Objectives: To describe the data quality challenges and solutions associated with collecting procurement information from several hundred users in 114 countries. To illustrate how procurement data is informing decision makers at the Global Fund and at the country-level. To provide some high level insights on the procurement of key medicines by Global Fund recipients.

Design: Descriptive review of policy implementation.

Setting and Study Population: International and national organizations involved in procurement of pharmaceutical and health products using Global Fund financing. From February 2009 to September 2011, the Global Fund collected information on 10,544 procurement transactions costing more than US\$ 1.8 billion.

Intervention: The PQR has recently been overhauled to (1) improve data quality, (2) increase the completeness of reporting, (3) produce useful reports for procurement practitioners, and (4) facilitate benchmarking of prices against international references.

Results: By standardizing data, improving user interface design, and increasing data governance efforts, the Global Fund has significantly improved the quality of procurement data collected from its recipients. These improvements have enabled the Global Fund to create automated reports that provide recent price indicators, facilitate cross-country comparisons, and track compliance with the Global Fund's Quality Assurance policies. The PQR has also enabled the Global Fund to evaluate price differentials across countries and to benchmark prices against international references.

Conclusions: The Global Fund's PQR is a key source of data on procurement by developing countries around the world. With its improvements the PQR is becoming a more useful and informative tool for procurement practitioners. Additionally, the improved PQR can contribute to improving transparency in the market for pharmaceutical and health products.

Funding Source: The Global Fund

## 1110

### **HIV/AIDS and TB**

*Keywords:* Tuberculosis, Global Drug facility, anti-TB medicines, patient survey, clinical trial

#### **Patients' Compliance and Adherence to 4-FDCs that are Provided by Global Drug Facility to 15 Countries in the Eastern Mediterranean Region**

---

**Khaled Khalil**

WHO/EMRO, Egypt

Background: Tuberculosis still represents one of the main public health problem in the world. The World Health Organization (WHO) recommended the use of fixed-dose combination (FDCs) formulations as one step to ensure enough and adequate treatment of patients. The main advantage of using FDCs is simplified treatment which may bring about a possible increase in patient's compliance and adherence to such medicines. Since 2001, GDF took the lead of introduction of FDCs medication to different countries in the world.

Method: A comparative study was done to compare the efficacy, safety, and acceptability of the 4FDCs and 2FDCs during the intensive continuation phase of treatment as compared to regimens using single formulations. The method was applied to 1,000 new +ve cases (male and female, adolescent and adults'  $\geq 15$  years). The daily dose of four tablets of 4-FDCs was given to every patient in the FDCs group (weight bands 55-70 kg, average 65 kg); and 3 tablets of the 4FDCs were given to patients (45-54 kg, average 52 kg). Sputum microscopy was done after 2 months of

therapy, after the continuation phase. At the end of treatment, a chest X-ray was required to ensure full recovery from the disease. The study components included treatment satisfaction and regimen acceptability on the number and size of tablets taken. Patient compliance and adherence to the treatment were monitored during and after the treatment. The above steps were applied to the same number of cases but using single component tablets of rifampicin (R), isoniazid (H), pyrazinamide (Z), and ethambutol (E); and RH.

Results: So far, there was clear progress in 490 (98%) out of 500 cases in the FDCs group in 12 out of 15 countries (80%) of the efficacy of the 4FDCs compared to the given single formulations. Sputum conversion rates at the end of treatment by 4FDCs (RHZE) and 2FDCs (RH150/75) were 98.99 % and 98%, respectively, compared to 96.17 % and 97.27% for single tablets, respectively. After 2-months treatment, 88.25% of the 4DCS group have addressed their fully satisfaction to the number and size of the 4FDCs compared to 85% of the single formulations group who complained about swallowing the single formulations of RHZE. After 6-months treatment, 90.25% of the 2DCS (RH) group have addressed their fully satisfaction to the number and size of the 2FDCs they received during the continuation phase compared to 89.98% of the single formulations group. Thirteen cases out of 500 (FDCs group) were registered under default group compared to 89 out of 500 cases (single formulations group).

Conclusion: The results concluded the effectiveness and efficacy of and accessibility to the 4FDC tablets compared to the single tablets treatment regimens. Moreover, patients were more likely to be completely adherent to the FDCs compared to the single one. The results suggest that the countries should establish a policy for a sustainable using of FDCs other than single formulations.

Funding source: Information not provided

**1113**

**HIV/AIDS and TB**

*Keywords:* medicines, supply, availability, tuberculosis, indicators

### **Evaluating the Effectiveness of TB Medicine Supply Management Training in Western Cape, South Africa**

**Fathima Fyzoo<sup>1</sup>, Margaret Von Zeil<sup>2</sup>**

<sup>1</sup>Management Sciences for Health, SPS, South Africa; <sup>2</sup>Department of City Health, Western Cape

Problem Statement: South Africa (SA) has the second highest tuberculosis (TB) incidence in the world at 971 per 100,000 population. (WHO 2009) The SA National TB programme targets for 2011 are to achieve a cure rate of 85% and treatment success rate of >85%. A major key to achieve these targets is to strengthen the implementation of the DOTS strategy. To achieve this objective, it is important to have an effective medicine supply management (MSM) system to ensure an uninterrupted supply of TB medicines. In SA, TB is managed mainly at a primary health care (PHC) level. MSM at most PHC facilities presents a huge challenge. Nurses perform this function in addition to their clinical functions, often resulting in poor stock management practices. As a consequence, stock-outs of essential medicines, including those for TB, is a common occurrence. The USAID-funded Strengthening Pharmaceutical Systems project decided to provide support for MSM with a specific focus on TB.

Objectives: To determine the effectiveness of TB MSM training for PHC facilities in Western Cape, SA, using TB medicine supply monitoring indicators.

Design: Intervention with a before and after assessment and no control group

Setting: The intervention was undertaken provincially at primary health care facilities within the public sector in the Western Cape.

Intervention/Methods: A TB medicine supply facility assessment tool was developed and a two-day training workshop on TB MSM was conducted for nurses from 28 PHC facilities. A baseline assessment of TB stock management was undertaken by facilities followed by monthly facility assessments for three consecutive months after training. Effectiveness of training was monitored using key TB MSM indicators.

Outcome measures: Improvement in TB medicine management

Results: At baseline, 21% of facilities did not have stock cards for all TB medicines, stock cards were not updated in 50% of facilities, 71% of facilities did not have correct average and reorder levels, 18% facilities had expired TB medicines, and TB medicines were out of stock at 46% of facilities. Post-training assessment at 3 months showed a 29% increase in the number of facilities with updated TB stock cards. The number of facilities with correct average/reorder levels of TB medicines increased by 32%. There was 21% improvement in the number of facilities experiencing no stock-out of TB medicines. The number of facilities where expired TB medicines was found declined by 11%.

Conclusions: Use of TB MSM indicators was effective in measuring the outcome of training in a primary health care setting. Nurse training in TB medicine supply management resulted in improved TB stock management at PHC facilities. This method of evaluation did not follow-up on longer-term sustainability of good medicine management practices. It is recommended that future evaluations be designed as quarterly assessments over a longer period.

Funding Source: Information not provided

**1115**

**HIV/AIDS and TB**

*Keywords:* Adherence, ART, Multi method, measurement

## **Development and Implementation of a Multi-Method Medication Adherence Assessment Tool Suitable for Antiretroviral Therapy Facilities in Resource-Constrained Settings**

**Gavin Steel<sup>1</sup>, Jude Nwokike<sup>2</sup>, Mohan P. Joshi<sup>3</sup>, Mupela Ntengu<sup>4</sup>**

<sup>1</sup>Management Sciences for Health's Strengthening Pharmaceutical Systems; Rhodes University, South Africa;

<sup>2</sup>Management Sciences for Health's Strengthening Pharmaceutical Systems; <sup>3</sup>Management Sciences for Health's Strengthening Pharmaceutical Systems; <sup>4</sup>Management Sciences for Health's Strengthening Pharmaceutical Systems

**Problem Statement:** Optimal outcomes for antiretroviral therapy (ART) require near perfect levels of adherence. Successful adherence support and improvement interventions require information regarding the patient's adherence levels. Currently, no gold standard for measurement of adherence exists and there is a consensus that calls for multi-method approach should be used. A few studies have reported the resulted on concurrent findings using different methods but none have consolidated the findings into a single assessment.

**Objectives:** To develop and implement an adherence assessment strategy for patient care in resource constrained settings.

**Design:** Observational study to validate a multi-method for adherence in adult patients on ART treatment against the objective measures of viral load, CD4 count, and Medication Event Monitoring System. In addition, data was collected regarding the clinical feasibility of the assessment tool.

**Setting:** South African public sector ART at the national level

**Study Population:** For the validation study, a convenient sample was used to enroll adult patients who had been stabilised on ART.

**Intervention:** A multi-method adherence assessment tool was developed based on previously validated elements including self-report, visual analogue scale, pill identification test, and pill count. To assess the tool's feasibility, we analyzed the administration time, demographic data believed to impact administration, and the subjective evaluations of the administering pharmacists. The tool was validated against viral load and MEMS adherence measurements for lamivudine. Once the tool had been validated, training workshops were conducted in all the provinces and the findings presented to key stake holders at the national level.

**Outcome Measure:**

A validated multi-method tool for assessing adherence to ART in adult patients that was adopted into national treatment guidelines.

**Results:** Clinical utility was demonstrated in a sample of 440 participants irrespective of level of education, age, and literacy. The median time taken to administer the tool was 5 minutes with a 9% CI of 3-15 min. A total of 40 patients who had given informed consent were enrolled and their lamivudine dispensed in a MEMS device according to the randomization schedule. The MEMS data was used to model a composite adherence assessment tool and a scoring system modelled to identify patients as having high, moderate, or low level of adherence, or nonadherence. The multi-method approach provided the best estimate of adherence relative to MEMS with  $r = 0.73$ , 95% CI 0.5 – 0.85. The tool was included in the 2010 national ART guidelines as standard of care for assessing adherence in all the 9 provinces of South Africa. Training workshops including training of trainers were held and 635 health care workers were trained in the use of the tool.

**Conclusions:** A validated multi method tool was developed and found to be suitable for national implementation.

**Funding Source:** SPS and Rational Pharmaceutical Management Plus through USAID

1116

### **Drug Resistance**

*Keywords:* Antimicrobial resistance, infection control, quality improvement

## **Implementing a Self-Assessment and Continuous Quality Improvement Approach to Improve Hospital Infection Control Practices in Africa and Latin America**

**Wonder Goredema<sup>1</sup>, Mupela Ntengu<sup>2</sup>, Jane Briggs<sup>1</sup>, Chris Ntege<sup>3</sup>, Terry Green<sup>1</sup>, Jacqueline Sekgothe<sup>4</sup>, Christine Gordon<sup>5</sup>, Thabsile Dlamini<sup>6</sup>, Silvia Palma de Ruiz<sup>7</sup>, Jean-Pierre Sallet<sup>2</sup>, David Mbirizi<sup>3</sup>, Jude Nwokike<sup>1</sup>, Mohan P Joshi<sup>1</sup>**

<sup>1</sup>Strengthening Pharmaceutical Systems (SPS) Program, Management Sciences for Health (MSH), Arlington, VA, USA; <sup>2</sup>MSH/SPS, South Africa; <sup>3</sup>MSH/SPS, Namibia; <sup>4</sup>Formerly with the National Department of Health, South Africa; <sup>5</sup>Ministry of Health and Social Services, Namibia; <sup>6</sup>Ministry of Health and Social Welfare, Swaziland; <sup>7</sup>Vice-Minister of Health and Social Assistance, Guatemala

**Problem Statement:** Infection control (IC) is a fundamental intervention to prevent the emergence and spread of antimicrobial resistance in hospitals. However, developing effective IC programs in resource-constrained countries remains a challenge.

**Objective:** The intervention was designed to improve hospital IC practices in resource-constrained settings using the SPS infection control self-assessment tool (ICAT) and continuous quality improvement (CQI) approach.

**Design:** Pre- and post-intervention surveys without control groups

**Setting and Population:** Eighteen hospital IC committees comprised mainly of nurses, pharmacists, physicians and environmental health staff in four countries: Guatemala, Namibia, South Africa, and Swaziland.

**Intervention:** The SPS Program and its predecessor, Rational Pharmaceutical Management (RPM) Plus, collaborated with ministries of health (MOH) to implement and evaluate the use of ICAT and CQI to improve IC practices in

hospitals. IC teams conducted baseline surveys to assess their respective hospital adherence to recommended IC standards and practices from approved national or World Health Organization guidelines. Committees then developed and implemented IC improvement plans. National partners and RPM Plus/SPS staff supported IC teams through site visits and telephone or e-mail follow-up. The teams conducted post-intervention assessments, reviewed progress, shared experiences, and developed plans to scale up the approach.

Outcome Measures: Percentage improvement in: adherence to infection control standards and practices and availability of IC supplies.

Results: Pilot hospitals experienced measurable improvements over their initial 6–9 months of implementation. Guatemala—Percentage of staff who washed hands according to procedures improved on average from 23% for 5 pilot hospitals to 77% three months post-intervention. Availability of hand washing supplies rose from 36% at baseline to 84%. MOH expanded the approach to the national network of 43 hospitals. South Africa—One hospital improved adherence to hand hygiene policies by 29 percentage points from a baseline of 57% to 86%; a second hospital increased its compliance with contaminated waste policies from 38% to 73%. Swaziland—One hospital doubled its hand hygiene assessment score from 33% vs. 66%, and a second hospital's waste management score increased from 12% to 83%. Namibia—Percentage of staff who washed hands according to internationally recognized procedures improved from 27% to 61% in one hospital. Supplies and equipment for hand washing improved from 78% to 94%.

Conclusions: The application of the ICAT tool coupled with CQI demonstrated improvement in IC practices. It is simple to apply and is a sustainable approach that builds teamwork and yields quantifiable improvements.

Funding Sources: RPM Plus and SPS through U.S. Agency for International Development; MOH (Guatemala, Namibia, South Africa, Swaziland)

1118

### Chronic Care

Keywords: Chronic disease, primary health care, quality of care, information technology

#### Evaluating the Quality of Care for Patients with Type 2 Diabetes Using Electronic Medical Record Information in Mexico

**Ricardo Perez-Cuevas<sup>1,4</sup>, Svetlana Doubova<sup>1</sup>, Michael Law<sup>2</sup>, Aakanksha Pande<sup>3</sup>, Magdalena Suarez<sup>1</sup>, Dennis Ross-Degnan<sup>3</sup>, Anita Wagner<sup>3</sup>**

<sup>1</sup>Epidemiology and Health Services Research Unit at Instituto Mexicano del Seguro Social, Mexico; <sup>2</sup>Centre for Health Services and Policy Research The University of British Columbia, Canada; <sup>3</sup>Department of Population Medicine at Harvard Medical School and Harvard Pilgrim Health Care Institute, USA; <sup>4</sup>Hospital Infantil de México Federico Gómez, Mexico.

Problem Statement: Affecting 10.6% of the Mexican population, type 2 diabetes (T2D) is the most common chronic condition seen at Mexican Institute of Social Security (IMSS) family medicine clinics (FMC), and among the top causes of hospital admissions and death. In 2003, IMSS introduced an electronic medical record (EMR) system in its 1,400 FMC that serve 48 million people. This is the first study to evaluate quality of care (QC) using data from the IMSS EMR and associated electronic pharmacy and laboratory databases.

Objectives: (1) To validate data in the IMSS EMR and to test the feasibility of structuring extracted medical records and other electronic data according to data specifications used for large health system research collaborations in the United States; and (2) to develop indicators and evaluate the quality of diabetes care provided in IMSS clinics based on electronic EMR and other data.

Design: The study used a mixed method approach consisting of development of quality of care indicators for T2D using the RAND-UCLA method; evaluation of the feasibility to extract and process EMR data and construct QC indicators; and evaluation of QC for T2D.

Setting: 39 FMCs in Mexico City

Study Population: Patients with T2D who received care in 2009

Outcome Measures: We developed and tested 12 QC indicators including prescription drug use (metformin, statins, angiotensin converting enzyme inhibitors [ACEI] and acetylsalicylic acid [ASA]); nutritional counselling; foot evaluation; orders of blood glucose and total cholesterol measurements; outcome indicators were blood glucose, blood pressure, and total cholesterol control and body weight.

Results: Among 7,152 patients in a pilot FMC, 57.5% of overweight or obese (BMI  $\geq$  25 kg/m<sup>2</sup>) patients received metformin; 58.9% with known cardiovascular disease and total cholesterol >200 mg/dl were prescribed statins; 46.0% of patients with arterial hypertension received ACEI; and 45.8% of patients over 40 years of age with one or more risk factors (smoking, hypertension, dyslipidemia) received ASA in doses of 75–150 mg/day.

Conclusion: This pilot study demonstrated that it is feasible to evaluate QC using the IMSS EMR data. It highlighted needs for improvement of both QC and the completion of information in the EMR at the IMSS.

Funding Source: Information not available

1120

### Drug Resistance

Keywords: Antibiotics; Drug utilization; Fees, medical; Hospitalization

#### The Impact of Abuse of Antibiotic Therapies on Inpatient Cost in China

**Li Yang<sup>1</sup>, Yong-hong Xiao<sup>2</sup>, Yao Nie<sup>3</sup>**

<sup>1</sup>School of Public Health, Peking University, China, Peoples Republic of; <sup>2</sup>The first Hospital of Zhejiang University, Hangzhou, China; <sup>3</sup>Nanjing Medical University, Nanjing, China

**Problem statement:** In the 1980s, China launched market-oriented reforms. Public hospitals were encouraged to make their own incomes with the aim of mobilizing medical workers and improving hospital efficiency. Less government funding resulted in deficits for public health institutions, which forced hospitals to generate their own revenue by aggressively selling drugs, especially antibiotics.

**Objectives:** This study was designed to discover how serious a problem inappropriate antibiotic use is and evaluate the impact of inappropriate antibiotic use on inpatients' costs in ten hospitals from five provinces in China.

**Design:** Retrospective cohort analysis of medical records databases of hospital drug use and inpatients cost

**Setting and study population:** First, in 2005, 6,000 cases (average 50 cases per month per hospital) were randomly selected in five secondary public hospitals and five tertiary public hospitals from five provinces (Beijing, Shandong, Hubei, Sichuan, and Ningxia) in China. Second, 964 cases where antibiotics were used in treatment were randomly selected from all cases receiving antibiotic therapies. These cases were divided into the rational use group and the irrational use group by trained senior doctors according to Guideline for Antimicrobial Therapy published by the Ministry of Health in 2004.

**Outcome measure(s):** Percentage of patients being treated rationally or irrationally with antibiotics; average inpatient cost per case in yuan (1 yuan = 0.12 US dollar) with or without rational antibiotics use; and adjusted odds ratio (OR) for receiving irrational antibiotics.

**Results:** Rate of antibiotic use was 70% and rate of inappropriate antibiotic use was 58.4% in ten hospitals in China. Average cost of inpatients with inappropriate antibiotic use (19,145.43 yuan) was 1.55 times higher than the ones with appropriate use (10,155.21 yuan). Adjusted for the differences in length of stay and patient demographics, antibiotic prophylaxis (OR=2.929, P<0.001) and medication for surgery (OR=2.44, P<0.001) had a higher propensity to receive irrational antibiotic use. Patients in tertiary hospital were 49% less likely to receive irrational antibiotic use than secondary hospital (OR=0.510, P<0.001).

**Conclusions:** Inappropriate antibiotic use could increase by 55% unnecessary inpatients cost. Efforts to control misuse of antibiotics such as regulating antibiotic prophylaxis and medication for surgery should be pursued.

**Funding source:** Supported by the major policy research program of the China Association for Science and Technology

1121

**HIV/AIDS and TB**

*Keywords:* Adherence, antiretrovirals, patients

**Intervention Strategy in Improving ART Adherence in Tanzania**

**Salama Jacob Mwakisu<sup>1</sup>, David Sando<sup>2</sup>, Rainalds Malele<sup>3</sup>, Candida Moshire<sup>3</sup>, Bernard Rabiel<sup>2</sup>, John Chalker<sup>1</sup>, Dennis Ross-Degnan<sup>4</sup>, Amos Masseur<sup>3</sup>, Rowland Swai<sup>2</sup>, Geoffrey Somi<sup>2</sup>**

<sup>1</sup>Management Sciences for Health, Tanzania, United Republic of; <sup>2</sup>Ministry of Health and Social Welfare; <sup>3</sup>Muhimbili University of Health and Allied Sciences; <sup>4</sup>Harvard University

**Problem Statement:** For a successful patient outcome, a high level of adherence to antiretrovirals (ART) is needed. A 2008 report in Tanzania indicated poor clinic attendance and high rate of lost to follow up.

**Objectives:** To measure the effects of strengthening appointment and tracking systems in improving attendance in ART clinics.

**Design:** A multifaceted intervention study with staggered implementation. An interrupted time series analysis was applied and comparisons were made with a control group.

**Setting:** The study was conducted in Coast and Morogoro regions involving three district ART sites from both public and faith based organizations as intervention sites in each region, and one facility as control. Selection of the regions and districts based on feasibility and the existence of strong community outreach programs.

**Study Population:** Facilities that had at least 150 patients on ART and accessible by the study team were selected. At each facility, 2 cohorts of patients were recruited: (1) 100 patients on treatment for at least 9 months at baseline, and (2) up to 20 patients initiating ART each month from 6 months before baseline.

**Interventions:** A one-year intervention study involved introduction of an appointment diary, negotiated appointments with patients, and strengthening linkage with communities to trace missing patients.

**Outcome Measures:** Percentage of patients with missed visits by more than 3 days, time until newly treated patients miss visits by more >3 days or >14 days and lost to follow-up.

**Results:** In both regions, between 15% and 20% of experienced patients miss visits by >3 days each month prior to the interventions. After intervention, the rate declined to about 11% in Coast facilities but not in Morogoro and Control facilities. In Coast, the intervention had no apparent effect in increasing the time until newly treated patients missed visits compared to the comparison facilities while for Morogoro, newly treated patients had much smaller increases in the rates of missed visits compared to the control facilities. There was also a substantial reduction in rates of loss to follow-up over time in Morogoro region compared to comparison facilities.

**Conclusions:** The interventions show some impact on improving appointment keeping and adherence to ART among patients in Tanzania. The success of the interventions depend on number of staff, supervision reliability of transport to the clinic, and good documentation.

Funding Sources: Swedish International Development Cooperation Agency

1122

HIV/AIDS and TB

Keywords: tuberculosis, medicine supply, drug distribution, availability

### Investigating Medicine Supply as a Rate Limiting Step in the Scale-Up of Isoniazid Preventive Therapy in Kwazulu-Natal, South Africa

**Fathima Fyzoo<sup>1</sup>, Nirupa Misra<sup>2</sup>**

<sup>1</sup>Management Sciences for Health, SPS, South Africa; <sup>2</sup>Department of Health, KwaZulu-Natal

**Problem Statement:** Tuberculosis (TB) is the commonest cause of morbidity and mortality amongst HIV-infected persons in South Africa (SA). In April 2010, SA published guidelines for TB preventive therapy among HIV-infected individuals and embarked on massive scale-up programme of isoniazid preventive therapy (IPT). In terms of the National Service Delivery Plan, 600,000 HIV-positive patients were to be initiated on IPT by June 2011. The SA province of KwaZulu-Natal (KZN) set a target of initiating 70,238 patients on IPT by September 2010. One of the initial challenges to this rapid scale-up was the unavailability of isoniazid (INH) 300 mg, so the implementation strategy included an accelerated plan for the procurement and supply of INH 300 mg. The uptake of IPT patients has been slow and by September 2010, only 21% of the provincial target had been achieved. One of the constant factors cited for the low uptake of IPT has been perceived problems with the supply of isoniazid to health facilities in the districts. An investigation into the supply of INH 300 mg to districts was needed.

**Objective:** To conduct an analysis of the INH 300 mg tablets supply with the actual number of patients initiated on IPT for the period April to September 2010. The specific aim was to identify medicine supply problems and propose possible solutions.

**Design:** Comparative analysis

**Methods:** A desktop review was undertaken using medicine consumption data extracted from the provincial medicine supply depot for the period April to September 2010. Data on the actual number of patients initiated on treatment was extracted from KZN District Health Information System (DHIS). Actual medicine requirements based on cumulative uptake of patients was calculated.

**Results:** The data was manipulated to show drug distribution patterns of INH to the 11 districts from April to September 2010. The analysis identified several important issues. Supply of INH appeared to be a challenge in some districts only during the initial phases of the rollout. Since inception of the programme, 9 out of 11 districts in KZN had more than the required amount of stock of INH 300 mg to initiate patients treatment. In most districts, overstocking seemed to be the major problem with many districts having >6 times the quantity required. Only the medicine supply in Umkhanyakude district was lower than the number of patients initiated on treatment. It is possible that INH 100 mg was being to treat adult patients or there was incorrect reporting of patient enrollment into the programme.

**Conclusions:** The review showed that medicine supply of INH 300 mg was not a rate limiting step in the scale-up of IPT in KZN. With the exception of Umkhanyakude, all other districts had more than adequate stock of INH 300 mg. The recommendations included redistribution of excess stock in overstocked districts and further analysis into INH 300 mg stock levels and patient numbers per facility as well as an analysis of INH 100 mg use in districts.

**Funding Source:** Information not available

1123

HIV/AIDS and TB

Keywords: resource-limited, HIV, AIDS, community, support, quality of life, adherence

### The Effect of Community-Based Support Services on Clinical Efficacy and Health-Related Quality of Life in HIV/AIDS Patients in Resource-Limited Settings in Sub-Saharan Africa

**Inoussa Kabore, Gina Etheredge**

FHI, United States of America

**Problem:** Data on the efficacy of ART in developing countries are limited. The paper reports an investigation of the delivery of medical care combined with community-based supportive services for patients with HIV/AIDS in four resource-limited settings in sub-Saharan Africa, carried out between 2005 and 2007.

**Objectives:** To document changes over time in patients' clinical outcome as measured by CD4 cell count, health-related quality of life (HRQOL), and adherence to ART and to correlate these changes with exposure to community support programs.

**Design:** The clinical and HRQOL efficacy of ART combined with community support services was studied in a cohort of 377 HIV-infected patients followed for 18 months, in community-based clinics through patient interviews, clinical evaluations, and questionnaires.

**Setting:** Four treatment sites in Maseru, Lesotho; Ladysmith, Kwa Zulu Natal, South Africa; Katima-Mulilo, Namibia; and Bobonong, Botswana.

**Study Population:** Consented HIV-infected adult patients who initiated ART beginning August 2005 at selected sites participated in an Enhanced Patients Evaluation observational cohort study; and followed-up for 18 months.

**Intervention:** The intervention consisted of community-based support services including community mobilization, prevention education and outreach, counseling and testing, home-based health care, tracing of defaulting patients, support groups, positive-living workshops, food security, nutritional support, financial and income generating support, and buddy services

**Policy:** The article was recently published (September 2010) in The Journal of AIDS Patient Care and STDs. The findings contributed to scaled-up of interventions with government ownership.

**Outcome Measures:** Changes over time in patients' clinical outcome as measured by CD4 cell count, HRQOL, and adherence to ART and correlation of changes with exposure to community support programs.

**Results:** Patients exposed to community-based supportive services experienced a more rapid and greater overall increase in CD4 cell counts at 18 months than unexposed patients (increase of 51 cells/mm<sup>3</sup> greater for exposed versus unexposed,  $p=0.016$ ). They also had higher levels of adherence attributed primarily to exposure to home-based care services (80% in the exposed group with 90% or higher adherence versus 65.8% in the unexposed,  $p=0.049$ ), as measured by multiple regression analysis. Patients receiving home-based care and/or food support services showed greater improvements in selected health-related QOL indicators and notably in overall HQOL (57.3% for the exposed versus 56.0% for the unexposed,  $p=0.010$ ).

**Conclusions:** HBC and other community services, including food support, have a positive effect on HIV patients' overall health, QOL, treatment adherence, and clinical outcomes. The association is still strong even when age, education, gender, and baseline CD4 counts are taken into account. A potential limitation includes a relatively high rate of lost to follow-up (LTFU). However, LTFU was taken into account in the design at the level of 20%, which does not significantly affect the magnitude of changes and the level of power desired for the analysis

**Funding Source(s):** Bristol Myers Squibb

## 1125

### HIV/AIDS and TB

*Keywords:* Antiretrovirals, Availability, patients, appropriate use of medicine

#### **Promoting Rational Use of ARVs in HIV/AIDS Clinic in Tanzania**

---

**Michael Gabra, Salama Mwakisu, Vicent Manyilizu, Rose Marwa, Charles Wanga, Edmund Rutta Rutta**

Management Sciences for Health, Tanzania, United Republic of

**Problem statement:** Tanzania has made significant progress in scaling up antiretroviral therapy (ART) to eligible people living with HIV/AIDS. However, little is known about current medicines use practices in ART clinics.

**Objectives:** To assess current medicines use practices in ART clinics and identify areas needing improvement

**Design:** This was just a rapid assessment conducted to explore current medicines use practices related to ART from February to April 2010. Data was collected through document review, dispensing encounters, retrospective prescriptions review, and qualitative interviews with dispensers and prescribers to understand factors influencing medicines use practices.

**Setting and study population:** The assessment involved 51 public and private ART facilities at the district and primary health care levels. The selection of district was based on the HIV prevalence rate and on the needs identified by National AIDS Control program and other partners supporting the ART program.

**Intervention(s):** The assessment was meant to identify gaps and help in selection of appropriate interventions to promote rational use of HIV/AIDS related medicines.

**Outcome measure(s):** Percentages of availability of key medicines, of facilities with selected guidelines available, and of dispensers providing adequate information to patients on how to use medicines

**Results:** Availability of pediatric ARVs was found to be low compared to adult formulations. Of the 141 dispensers involved in handling ARVs, only 18% had pharmaceutical training; guidelines for the management of HIV/AIDS were available in 82% of the sites visited. However, many dispensers were not up to date with the current recommended ART default first-line regimen, or criteria for Co-trimoxazole prophylaxis; 80% of visited facilities did not have SOPs for good dispensing practices or for patient medication use counseling. Generally, dispensers did not provide adequate information to patients on how to use ART medicines; 75% of facilities had forums that meet regularly to monitor patient treatment progress, but few reported having a DTC in place. Only 16% of facilities indicated that their staffs are trained on adverse drug reaction (ADR) reporting. ADR forms were available in 22% of visited sites and underreporting of ADR was observed.

**Conclusion:** Regular training and on-site support is crucial with emphasize on rational use of medicines. DTCs need to be strengthened and used in promoting appropriate use of ART medicines. The assessment highlights the need to strengthen the pharmacovigilance system for ART by ensuring the availability of ADR reporting forms and ensuring that staff are well trained on ADR reporting.

**Funding source:** USAID through Strengthening Pharmaceutical Systems (SPS) Program

## 1126

### Policy, Regulation, and Governance

*Keywords:* Cost containment; Standard Treatment Guidelines, Essential Medicines List, efficiency gains

#### **Containing Health Care Costs in Ghana: Role of Evidence-Based Selection of Medicines**

---

**Martha Gyansa-Lutterodt<sup>1</sup>, Edith Andrews Annan<sup>2</sup>, Augustina Koduah<sup>1</sup>, Brian Adu Asare<sup>1</sup>, Francis Ofei<sup>3</sup>**

<sup>1</sup>Ghana National Drugs Programme; <sup>2</sup>WHO, Ghana; <sup>3</sup>University of Ghana Medical School

**Problem statement:** Standard treatment guidelines (STGs), if properly developed, usually reflect the consensus among health practitioners on the optimal treatment options within a health system and aim at beneficially influencing prescribing behavior at all levels of care. In Ghana, prescribing according to national STGs, initiated from 1998 to 2010, is high and could potentially influence health outcomes positively in the long term. At the implementation of national health insurance, a 2007 Ministry of Health report on a nationwide survey indicated that, on average, 90.5% of children and 87.5% of adults with pneumonia received 1 of the first-line antibiotics recommended in the STGs. For hypertension in adults, recommended first-line anti-hypertensive agents were prescribed in 96.4% of patients on average across the country.

**Objectives:** To select cost-effective treatments based on the strength of current evidence and to provide evidence-based selection of medicines for disease conditions

**Setting:** Various experts with practical knowledge in internal medicine (adults and children), the surgical disciplines, clinical pharmacy, pharmacology, and pharmaceutical policy are selected from leading health care facilities in the country by the Ministry for Health. The experts disclosed conflicts of interest. The experts peer-reviewed each other's work and this was later subjected to stakeholder analyses in the public and private health sectors. An editorial group of physicians and pharmacy experts reviewed the draft document, using clearly set out procedures, after which the document and selected treatments were presented to a stakeholder forum for further inputs, comments, clarifications, and recommendations.

**Study population:** A sample of experts in several medical disciplines purposely selected

**Intervention(s):** Updated selection of medicines for procurement and reimbursements; levels of use based on various evidence ratings with built-in trigger mechanisms for referral to the higher levels of care

**Policy:** Evaluate cost effectiveness of medicines selected for use in Ghana

**Outcome measure:** Evidence-based selection of medicines; prescribing guidelines based on current evidence and levels of use; medicines status with respect to national health insurance authority benefits package

**Results:** A regularly updated evidence-based treatment guideline for various common disease conditions and an essential medicines list 2010 with levels of use outlined. Average percentage of patients receiving antibiotics has improved from 54.0% in 1998 to 42.8% in 2002 and 47.7% in 2006. The 2008 median value was 43.3%. Average percentage of patients receiving injections has improved from 42.0% in 1998 to 34.9% in 2002 and 30.59% in 2006. The 2008 median value was 13.3%. Likewise, the average percentage of prescribed medicines on the EML reveals the following trend: 96.1% in both 1998 and 2002 and 78.92% in 2006; the 2008 median value was 87.5%, which indicates the long-term effect of STGs on medicines use.

**Conclusions:** Treatment guidelines development and use are critical cost-containment tools for reducing wastage and gaining efficiency for the Ghana National Social Health Insurance Scheme.

**Funding Sources:** The Kingdom of the Royal Netherlands Embassy, WHO, and MSH

**1127**

### **Drug Resistance**

*Keywords:* report cards, public disclosure, antibiotic prescribing, prescribing behavior

### **Report Cards and Prescribing Behavior: Assessing the Impacts of Public Disclosure on Antibiotic Prescribing Rates in South Korea**

**Seemoon Choi, Michael Reich**

Harvard School of Public Health, United States of America

**Problem statement:** In Korea, a policy to separate dispensing and prescribing was introduced in 2000, followed by a policy to provide feedback on individual prescribing patterns in 2001. Yet the antibiotic prescribing rate (APR) for acute upper respiratory tract infection (AURI) was still very high at about 65% in 2005. Antibiotic overuse contributes to escalating pharmaceutical expenditures and high antibiotic resistance in the country.

**Policy:** Since February 2006, the APR for AURI of all health care providers has been publicly disclosed on the website of the Health Insurance Review Agency in the form of report cards for each facility.

**Objectives:** To assess the impacts of the public disclosure of health care providers' APRs for AURIs and whether public disclosure changed antibiotic prescribing behavior in Korea.

**Design:** Time-series without comparison series

**Setting:** Public and private care providers in Korea who contract with the National Health Insurance (NHI)

**Study population:** All health care providers that had more than 100 AURI patient visits for 3 months based on NHI claims data from the first quarter of 2004 to the fourth quarter of 2009. The study included 15,669 health care providers from 249 districts in 16 metropolitan areas or states.

**Outcome measures:** APR for AURI, defined as the total number of antibiotic prescriptions for patients diagnosed with AURI, divided by the total number of patients diagnosed with AURI, for all health care providers at a specific facility

**Results:** Nationwide, the disclosure policy successfully reduced the APR for AURI in all types of health care providers by 8.9%. Restricted to primary care clinics, the response to public disclosure varied across specialties. Pediatricians were the most sensitive specialty group to public disclosure. We found a heterogeneous impact of report cards on antibiotic use for AURI among quartile groups of providers based on the mean APR prior to the introduction of report

cards. Although primary clinics in the fourth quartile (highest use of antibiotics) reduced their APR for AURI by 16.93 percentage points (19%), primary clinics in the first quartile increased their APR for AURI by 1.6 percentage points (8%). (All estimates are statistically significant at 5%.)

Conclusions: Public disclosure of APR for health care providers through report cards available on the Internet can be an effective intervention to reduce the use of antibiotics. The heterogeneous impacts of public disclosure suggest that more-tailored interventions are necessary to maximize the intended impacts of public disclosure.

Funding source: None to declare

1129

### Policy, Regulation, and Governance

*Keywords:* essential medicine, essential drug, National Essential Medicine List, healthcare reform, China

### Provincial Essential Medicine List Comparison among 12 Provinces in China

**Bin Jiang<sup>1,2,3</sup>, Anita Wagner<sup>3</sup>, Dennis Ross-Degnan<sup>3</sup>, Luwen Shi<sup>1,2</sup>**

<sup>1</sup>Department of Administrative and Clinical Pharmacy, School of Pharmaceutical Sciences, Peking University, No. 38, Rd. Xueyuan, District Haidian, Beijing, 100191, P.R. China; <sup>2</sup>International Research Center for Medicinal Administration, Peking University, No. 38, Rd. Xueyuan, District Haidian, Beijing, 100191, P.R. China; <sup>3</sup>Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, 133 Brookline Avenue, Boston, MA 02215, USA

**Background:** China introduced the concept of essential medicine in 1979 and issued its first *National Essential Medicine List* in 1982. But an integrated and systematic national essential drug policy hasn't been established until the issuance of "the CPC Central Committee and State Council on Deepening the views of the medical and health system" (new healthcare reform for short) in April 2009. In the current new healthcare reform, the Chinese government emphasized to set up a national essential medicine system and listed it as one of the five top priorities of the reform in the coming years. On August 17, 2009, Chinese Ministry of Health (MOH) released the National Essential Medicine List (NEML) for the primary care institutions (PCI). Till the end of September, 2009, totally 12 provinces in China have announced the related provincial essential medicine list (PEML). A scientific EML is the basis for access and rational use of quality essential medicines. Therefore the article analyzed and compared the available 12 PEMLs, aiming to prepare a foundation for the selection and modification of EMLs in future.

**Result:** (1) Provincial location: among the 12 provinces with PEMLs, 7 are located in the east China, 2 in the middle and 3 in the west. (2) Economy status: The 7 eastern provinces are among Top 10 in GDP ranking in China, the 2 middle provinces are famous for pioneers in new healthcare reform, the 3 western provinces rank at the bottom of GDP and can enjoy special financial support from central government. (3) Amount: the amount of essential medicines in PEMLs is quite different, ranging from 31 to 305. The average amount of essential medicines in eastern PEMLs is 214 (among which there are 128 western medicines and 86 traditional Chinese essential medicines), in middle province is 212 (among which there are 166 western medicines and 46 traditional Chinese essential medicines), and in western is 57 (among which there are 25 western medicines and 32 traditional Chinese essential medicines). (4) Category: in the 12 PEMLs, there are totally 1025 medicines, among which 533 (52%) are western medicines and 492 TCMs (48%). TCM enjoys a larger proportion in PEMLs compared with NEMLs. Seventy-one percent of the medicines in PEMLs belongs to Reimbursement Medicine List (RML), with 24% going to type A and 47% to type B

**Conclusion:** (1) More developed provinces or provinces with financial support are more likely to implement NEML. (2) In PEMLs, there're more local medicines for the sake of local medication habit, disease pattern and the development of local pharmaceutical industry. (3) except for EML, supporting policies such as education for medical professionals and patients, pricing, reimbursement, etc., are both urgent and important in order to achieve the goal of access to and rational use of quality essential medicines.

1133

### Malaria

*Keywords:* access to medicine, corruption, equity, financing, pharmacoeconomics

### Informal Payments for Health Care: Differences in Expenditures from Consumers and Providers Perspectives for Treatment of Malaria in Nigeria

**Obinna Emmanuel Onwujekwe<sup>1,4</sup>, Nkem Dike<sup>2</sup>, Benjamin Uzochukwu<sup>1,3,4</sup>, Ogochukwu Ezeoke<sup>4</sup>**

<sup>1</sup>University of Nigeria, Nigeria; <sup>2</sup>Northwestern University; <sup>3</sup>Dept of Community Medicine, University of Nigeria Enugu-Campus; <sup>4</sup>Health Policy Research Group, University of Nigeria

**Problem statement:** Knowledge is limited about the disparity between the official fees that should be paid compared with the fees that consumers actually pay for the treatment of malaria in Nigeria. Unapproved/illegal collection of fees from consumers in public facilities with better trained health care providers may deter people from consuming appropriate malaria treatment services from these facilities.

**Objectives:** To examine differences in malaria treatment expenditures from the perspectives of consumers and providers in southeast Nigeria

**Design:** Cross-sectional study conducted with a household and provider surveys and exit poll interviews

**Setting:** 6 communities in Anambra state, southeast Nigeria

**Study population:** The population was public providers and consumers of malaria treatment services.

Policy context: The need to decrease the financial burden to consumers and increase access to malaria treatment services.

Outcome measure: The amount of money that the providers claimed to charge their patients for different items for malaria treatment services was compared with the expenditures that the respondents actually incurred for malaria treatment services from the same providers.

Results: Most expenditure items differed significantly from providers' and consumers' perspectives. The costs from the providers' perspectives were generally much lower than what consumers reported to have paid, especially in the public hospitals. The widest gaps between expenditures for consumers and amounts purportedly charged by providers were found in public health care facilities. The average expenditure to treat malaria from the consumers' perspectives was very similar at \$6.30 and \$6.40 from exit poll and household surveys, respectively, which were very different samples. However, they differed significantly from providers' prices, which was only \$2.20 per treatment for malaria. The magnitude of possible informal payment ranged from \$4.10 to \$4.20 per episode of malaria. All socioeconomic status groups and residents of urban and rural areas were exposed to informal payments.

Conclusion: The differences in malaria treatment expenditures from consumers' and providers' perspectives point to high levels of informal payments, which worsen the economic burden of the disease and may predispose to catastrophic health spending and people seeking inappropriate treatment. The informal payments are personal gains to the individual providers but represent a loss to society in terms of higher health care costs. Such payments should be addressed by policy makers so as to make treatment of malaria less costly to patients.

Funding sources: Gates Malaria Partnership

1134

#### Chronic Care

Keywords: antidepressants, benzodiazepines, depression, combined use

### Rational Use of Antidepressants Combined with Benzodiazepines

**Izabela Fulone, Luciane Cruz Lopes, Silvio Barberato-Filho**

University of Sorocaba, Brazil

Problem statement: Combinations of antidepressants and benzodiazepines are often used to treat major depression and evidence suggests that combination is more effective than monotherapy with antidepressants. However, the benefits of such combination only occur in the beginning of the treatment (up to 4 weeks), reducing by 50% or more depression symptoms and the dropout rate. The prolonged use of combined therapy should be balanced because there is a significant increase in addiction risks, tolerance, propensity to accidents, teratogenicity, and costs.

Objectives: Evaluating the rational use of antidepressants/benzodiazepines combinations in major depression patients who were attended in the public health care system of Porto Feliz, São Paulo State, Brazil, and relating it to risk factors in the development of adverse drug reactions.

Design: Observational, transversal, retrospective, analytical study

Study population: Patients under treatment with antidepressants, whether combined with benzodiazepines or not, from January 2008 to December 2009

Outcome measure: Users' profile as far as gender, age, comorbidities, and the use of other drugs are concerned and the relationship to the rational use of antidepressants (indication, dose, frequency, duration of use, and safety)

Results: 265 patients were analyzed, namely 86.4% women, 60.7% married, 70.6% between 21 and 59 years of age, 62.3% diagnosed with depression for at least 5 years, 52.8% presenting comorbidities, and 50.6% using other medicines chronically; 1601 prescriptions were made for such patients, namely 53.7% for combined therapy and 42.3% for monotherapy. In monotherapy, fluoxetine at 65.4% and amitriptyline at 17.8% were the most prescribed drugs, and 68.8% of the patients remained under treatment for at least 180 days. In combined therapy, the biggest prevalence was for fluoxetine plus diazepam at 23.7%, fluoxetine plus clonazepam at 14.4% and sertraline plus clonazepam at 11.2%. Only 22.9% of the prescriptions presented a duration of up to 4 weeks. Approximately 64.4% of patients remained under combined treatment for at least 360 days. Psychotropic polypharmacy was found in 91.4% of prescriptions. Associations prevailed with benzodiazepines at 58.8%, antipsychotics at 19.4%, which resulted in 9% of severe interactions. In 98.8% of cases, the clinical indication justified the prescription and 98% of dosages and frequency were recommended.

Conclusions: Most depressed patients treated by the public health care system usually receive a long, combined therapy treatment. Such a pattern is irrational and inconsistent with recommendations based on evidence, which exposes patients to significant and possibly unnecessary risks.

Funding sources: No funding

1135

#### Policy, Regulation, and Governance

Keywords: pharmacovigilance, patient safety

### Pharmacovigilance and Risk Management in Thailand

**Wimon Suwankesawong**

Health Product Vigilance Center, Food and Drug Administration, Thailand

**Problem statement:** Risk management has been described as the overall and continuing process of minimizing risk throughout the life cycle of a product to optimize its benefit/risk balance. The process is related to pharmacovigilance (PV) activities. These activities could result in several measures to minimize risk of medicinal product in many countries, not only risk communication, but also regulatory action. As PV has been established in Thailand for more than 2 decades, whereas various risk management tools have been used to minimize risk. The association of PV and risk management should be explored.

**Objective:** Ascertain the impact of PV activities in risk management system in Thailand.

**Design:** Documentary research was used for studying the perform of various risk minimization tools.

**Setting:** The National Health Product Vigilance Centre at Food and Drug Administration, Ministry of Public Health, Thailand

**Results:** Up to 2009, overall risk management measures related to PV activities in Thailand have included provision of information and control the use of medicine. The modification of product information and legal warning of drugs of anti-TB drug, paracoxib, fluoroquinolone drug group, bupivacaine spinal block medicine were performed due to the serious adverse effects such as hepatitis, severe skin reaction (SJS/TEN) and fatal outcome. The risk of QT prolongation because of the inappropriate use of cisapride, with potential interaction drugs and high risk patient, were led to limited indication to specific indication (GERD) and restricted used in hospitals only. An unexpected hepatitis in patient exposed to herbal products containing Cassia Simea (leaf) was increased awareness of herbal safety and registration cancelled. The high frequent of Pure Red Cell Aplasia (PRCA) was associated with Erythropoiesis Stimulating Agent (ESA) in chronic renal failure patients was resulted in conducting of Thai ESA Registry Project.

**Conclusion:** The appropriate and effective risk management could be performed with a good practice of PV. Therefore, strengthening PV system is needed to ensure to the safety of medicines.

**Funding source:** There is no funding source and the authors have no conflict of interest in this study.

1137

Malaria

*Keywords:* antimalarials, treatment quality, appropriate use,

### **Improving Quality of Malaria Treatment Services: Assessing Inequities in Consumers' Perceptions and Providers' Behaviour in Nigeria**

**Obinna Emmanuel Onwujekwe<sup>1,2</sup>, Eric Obikeze<sup>2</sup>, Benjamin Uzochukwu<sup>2,3</sup>, Ijeoma Okoronkwo<sup>4</sup>, Ogochukwu Onwujekwe<sup>5</sup>**

<sup>1</sup>Department of Pharmacology and Therapeutics, University of Nigeria, Nigeria; <sup>2</sup>Health Policy Research Group, College of Medicine, University of Nigeria; <sup>3</sup>Department of Community Medicine, University of Nigeria; <sup>4</sup>Department of Nursing Sciences, University of Nigeria; <sup>5</sup>Department of Pharmacy, University of Nigeria Teaching Hospital, Enugu

**Problem statement:** Information about the quality of malaria treatment services of different health care providers is needed to know how to improve the treatment of malaria because inappropriate service provision leads to increased burden of malaria.

**Objective:** To determine the technical and perceived quality of malaria treatment services of different types of providers in different geographic settings

**Design:** A questionnaire was used to interview randomly selected health care providers about the technical quality of their malaria treatment services. Exit polls were used to obtain information about perceived quality from consumers. A socioeconomic status (SES) index and comparison of data between urban and rural areas were used to examine SES and geographic differences in quality of services.

**Setting:** The study was undertaken in 6 communities (3 urban and 3 rural areas) from Anambra state, southeast Nigeria.

**Study population:** The population was a broad range of public providers and consumers of malaria treatment services. A minimum sample size of 500 consumers and 25 providers was selected from each community.

**Policy context:** The need to improve the quality of malaria treatment services in public and private facilities, especially with the change of the first-line regimen to the expensive artemisinin-based combination therapy (ACT).

**Outcome measure:** These were the providers' technical and consumers' perceived quality of malaria treatment services.

**Results:** History taking was used to diagnose 2098 patients (90.4%), a blood test for 155 patients (19.6%), and other modes for 14 (5.8%) patients. Blood tests were used least in primary health care (PHC) centres ( $p < 0.0001$ ). Artemisinin-monotherapy (AMT) was more prescribed and procured compared to ACTs. However, higher proportions of ACTs were prescribed in public hospitals compared to private hospitals and other providers ( $p < 0.0001$ ). The lowest technical quality of services was found in patent medicine dealers. Conversely, public and private hospitals as well as primary health care centres had the highest quality of services. Consumers were least satisfied with the quality of services of patent medicine dealers and pharmacy shops and were mostly satisfied with services rendered by public and private hospitals. The better-off SES groups perceived higher quality of services compared to the worse-off SES groups. The urbanites were more satisfied with the overall quality of services than the rural dwellers.

**Conclusion:** These findings provide areas for interventions to equitably improve the quality of malaria treatment services, especially for patent medicine dealers and pharmacy shops, which are 2 of the most common providers of malaria treatment, especially with the change from relatively inexpensive drugs to the expensive ACTs. The goal is to decrease inappropriate drug prescribing and use, costs, and resistance to ACTs.

**Funding sources:** Gates Malaria Partnership

1138

Access

*Keywords:* appropriate use, drug utilization

### Use of Medicines with Unknown Fetal Risk among Pregnant Women from the Pelotas Birth Cohort 2004, Brazil

Andréa Dâmaso Bertoldi<sup>1</sup>, Aline Lins Camargo<sup>2</sup>, Tatiane da Silva Dal Pizzol<sup>3</sup>, Aluísio J D Barros<sup>1</sup>, Alicia Matijasevich Manitto<sup>1</sup>, Iná S Santos<sup>1</sup>

<sup>1</sup>Universidade Federal de Pelotas, Brazil; <sup>2</sup>Universidade Federal de Ciências da Saúde de Porto Alegre, Brazil;

<sup>3</sup>Universidade Federal do Rio Grande do Sul, Brazil

**Problem statement:** Prenatal exposure to medicines may represent potential risks to fetal development, with minor or major consequences to child health. It is possible to minimize the fetal risks with the rational use of medicines, based on previous knowledge about teratogenic and other fetal risks. The Food and Drug Administration (FDA) classification, one of the most used, is based on studies carried out in animals and humans to classify medicines into 5 risk categories (A, B, C, D e X).

**Objectives:** To estimate the exposure to medicines with unknown fetal risk during pregnancy and to analyze the maternal characteristics associated with it

**Design:** Cross-sectional study; an interview with the mother was carried out within 24 hours of delivery

**Study population:** All mothers of children belonging to the 2004 Pelotas (Brazil) birth cohort study

**Outcome measures:** A standardized and precoded questionnaire was administered to mothers about the use of any medicine during the gestation period, as well as the month in which the mother started and stopped taking each medicine. We used the FDA teratogenic risk categories. **Results:** Out of the 4,189 women, 92.7% reported using at least 1 medicine during pregnancy. The mean number of medicines reported was 2.4 (SD 1.5), ranging from 1 to 10. We identified 38.9% category C (unknown fetal risk) medicines and around 5% from the D and X categories (positive evidence for fetal risk). Multivitamins and the association between butylscopolamine and dipyron were responsible for 40% of the category C medicines used in each trimester. In the adjusted analyses (logistic regression models), use of category C medicines was associated with white skin color, high school education, high income, 6 or more antenatal care consultations, hospital admission during pregnancy, morbidity during gestation (depression, anemia, threatened abortion, pre-term labor threat, and urinary infection).

**Conclusions:** The use of medicines with unknown fetal risks must be addressed with caution with the aim of restricting its use to cases in which the benefits of the use are greater than the potential threats.

**Funding sources:** Supported by WHO, the National Council for Scientific and Technologic Development (CNPq), the Fundação Nacional de Saúde, and the Pastoral da Criança

1141

Access

*Keywords:* ADDO, Tanzania, Policy

### How the Accredited Drug Dispensing Outlet Program Has Influenced Medicine Access Policies in Tanzania?

Edmund R Rutta<sup>1</sup>, Hiiti Sillo<sup>2</sup>, Jafary Liana<sup>1</sup>, Keith Johnson<sup>1</sup>

<sup>1</sup>Management Sciences for Health, United States of America; <sup>2</sup>Tanzania Food and Drug Authority, Tanzania

**Problem statement:** The successful pilot of the accredited drug dispensing outlets (ADDO) program in Tanzania's Ruvuma region provided the proof of concept that innovative regulatory and accreditation interventions can improve access, availability, and quality of pharmaceutical products and services. The challenge to the government was how to scale up Ruvuma's pilot experience into a sustainable national program.

**Objective:** To document how the policy changes related to the ADDO program contributed to a new approach to public-private partnership in health

**Design:** Qualitative data collection through interviews and document review

**Setting:** Tanzania

**Policy:** The launch of the ADDO program in 2003 in Ruvuma required changes in the law, which led to the Tanzania Food Drugs and Cosmetics Act of 2003, a regulatory framework that governed the ADDO pilot. The Act included standards and regulations governing the establishment of ADDOs and dispensers, inclusion of a limited list of prescription-only medicines that ADDOs could sell legally, and creation of a cadre of local inspectors to monitor regulatory compliance. These major policy milestones led to the creation of a new cadre of accredited health service providers. In 2005, the government decided to roll out the program country wide.

**Outcome measures:** The number of new national policies that were created to support scale up and sustainability after the ADDO pilot

**Results:** In 2009, the Ministry of Health and Social Welfare (MOHSW) issued a notice to phase out all unaccredited drug shops by 2011. To ensure coordination, the Medicine Access Steering Committee was formed under MOHSW stewardship. In 2006, Tanzania's National Malaria Control Programme adopted the ADDO platform as part of its national strategy to increase access to malaria treatment in the private sector, paving the way for distribution of

subsidized artemisinin-based combination therapy through ADDOs and a Global Fund grant (2007) to scale up the program in 8 additional regions. Other significant new policies include the incorporation of child health services (2006); the National Health Insurance Fund decision to allow members to fill prescriptions at ADDOs (2007); revision of the model to decentralized implementation at the district level (2008); a mandate requiring local government incorporation of ADDO implementation and maintenance in planning and budgeting (2008); and the development of a strategy for ADDOs in urban areas (2009).

Conclusions: The ADDO pilot, which required changes to pharmaceutical sector policies, has acted as a catalyst and resulted in completely new policies that improve access to medicines in the private sector. These new policies, which relate to public-private partnership in the pharmaceutical sector, place Tanzania in a stronger position to meet the health needs of both rural and urban communities.

Funding sources: Management Sciences for Health/East African Drug Sellers Initiatives (EADSI) funded by Bill & Mellinda Gates Foundation

1142

### Drug Resistance

*Keywords:* antimicrobials, drug resistance, drug utilization, hospital, pharmaceutical policy

### Antibiotic Policy, Antibiotic Consumption, and Antibiotic Resistance: Situation of Hospitals Participating in the National Antimicrobial Resistance Surveillance Thailand Program

**Siritree Suttajit<sup>1,2</sup>, Jutharat Srisupharangkul<sup>2</sup>, Naruemon Boonsan<sup>2</sup>, Bulan Udomsri<sup>2</sup>, Surang Dejsirilert<sup>3</sup>**

<sup>1</sup>Faculty of Pharmacy, Chiang Mai University, Thailand; <sup>2</sup>Faculty of Pharmacy, Mahasarakham University, Thailand;

<sup>3</sup>The National Antimicrobial Resistance Surveillance Center, Thailand (NARST)

Problem statement: Previous studies in developed countries have shown relationship between implementation of antibiotic (AB) policy and the reduction of restricted AB and the resistance rate. Little is known about the situation in Thailand.

Objectives: To explore the AB policy and its relationship to AB consumption and resistance in Thai hospitals

Design: Cross-sectional study

Setting: Questionnaires on AB policy and consumption in 2005-2009 were sent out to all 33 hospitals in the network of the NARST program. The AB resistance rates of MRSA, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, *Escherichia coli*, and *Streptococcus pneumoniae* of each hospital were retrieved from NARST's WHONET database.

Study population: 16 hospitals (48.5%), 14 public (50%) and 2 private (40%), from all 5 regions of Thailand returned the questionnaire and AB consumption data. All were secondary or tertiary care hospitals. The low response-rate was due to incomplete hospital databases and the inconvenience of participating.

Outcome measures: Structure of AB and infection control (IC) policies (structure and organization of related committees, policy measures, treatment guideline, surveillance system, and databases); AB consumption (DDD/1000 patient-days); resistance rate

Results: Although all hospitals had IC policy and a pharmacy and therapeutic committee, only 38% had an AB committee. There were 61–1,447 items (median 79) of AB in the hospital formulary, most in the National Essential Drug List (2008) and 1-13 (median 8) items are in the hospital restricted list. Over 88% had a drug use evaluation (DUE) program and 63% had their own AB prescribing criteria. There were increasing trends of most AB consumption, expenditure, and resistance rates. AB consumption was 1.1–2 times higher within 5 years; the top prescribed medicines were penicillin and penicillins and enzyme inhibitors, quinolones, cephalosporin, and sulfonamides and trimethoprim. Special concern is needed on costly consumed ABs, i.e., carbapenems, cephalosporin, and penicillins and enzyme inhibitors; *A.baumannii* has become increasingly resistant to imipenem. Internal (hospital size, AB items) and external factors (hospital accreditation and NHSO's rational drug use criteria) seemed to have no impact on consumption. However, possible effective policies observed in hospitals with low AB consumption include a restricted AB list; requiring microorganism sensitivity testing before prescribing high alert AB together with DUE program; strength of the related committees; coordination of multidisciplinary teams; resistance surveillance; and promotion of awareness.

Conclusions: Despite several reported hospital policies, AB consumption, its expenditure, and resistance rates still increased. This suggests rooms for improvement in developing more effective strategies for Thai hospitals. And as policy and practice gaps among hospitals exist from the benchmarking, hospitals have opportunities to share and learn from the best practice hospital that had better control of AB use and a lower rate of drug resistance.

Funding source: Drug System Monitoring and Development Program

1143

### Policy, Regulation, and Governance

*Keywords:* access to medicine, policy, earch priority setting, health system, health financing

### Priority Policy Research Agenda to Achieve Access and Rational Use of Medicines in Thailand

**Niyada Kiatying-Angsulee<sup>1,2</sup>, Nussaraporn Kessomboon<sup>3</sup>, Usawadee Maleewong<sup>2</sup>, Vithaya Kulsomboon<sup>2</sup>, Jiraporn Limpananont<sup>2</sup>**

<sup>1</sup>Social Research Institute, Chulalongkorn University, Thailand; <sup>2</sup>Social Pharmacy Research Unit, Faculty of Pharmaceutical Sciences, Chulalongkorn University; <sup>3</sup>Faculty of Pharmacy, Khon Kaen University

Problem statement: Access to medicine is an issue of concern in developing countries. Thailand, as a low- and middle-income country, despite many attempts, still faces such problems. Public health strengthening and health system

research were promoted but there has been no study in Thailand to elaborate the research priorities in health systems and health financing systems.

Objectives: To identify research priorities relevant to access to medicine by using health system approach

Design: Qualitative participatory study using WHO template of analysis

Setting: Community, health sector, and beyond health sectors

Study population: All relevant stakeholders within access to medicine arena

Outcome measures: Policy research priorities

Results: The first phase comprised of analyzing different sources; research questions were drawn up to identify which ones were known and which were needed for future study. The matrix of checklist was developed by means of existing documents review and experts consultation. Four core issues in health systems were rational selection and use, affordability, sustainability financing, and reliable health system. The second phase of analysis was based on 3 levels of perspectives as individual, health sector, and beyond health sectors. Priorities were performed through 3 steps: systematic and grey review, interview of key informants, and workshops among stakeholders. The Thai Ministry of Public Health has established 5 strategies for access to medicine after the resolution of the first National Health Assembly in 2008. The 5 strategies were drafted as (1) encourage patient group to get access to medicines and to take part in health promotion, (2) promote affordable prices of medicines, (3) make use of TRIPS flexibilities in patent law to reduce legal hurdles, (4) develop local pharmaceutical production, and (5) develop traditional medicines. Other priorities for research were identified as sustainable funding, human resources development, information, political commitment, governance, and monitoring and evaluation. Process of gathering data is on going to get the final result of research priorities and rank.

Conclusions: Policy priorities research to achieve access to medicine were drawn up using health system approach analysis via qualitative participatory method. These will be used as input for policy formation and implementation in the future.

Funding source: World Health Organization

#### 1144

##### Access

Keywords: Monitoring and Evaluation, Pharmaceutical Situation, Pharmaceutical Policies, Primary Healthcare

#### Assessment of Pharmaceutical Situation in Suriname

**John Hasrat<sup>1</sup>, Thiago Botelho Azeredo<sup>2</sup>, Vera Lucia Luiza<sup>2</sup>, Adriana Mitsue Ivama<sup>3</sup>, Primnath Ritoe<sup>1</sup>, Miriam Naarendorp<sup>4</sup>**

<sup>1</sup>Ministry of Health of Suriname; <sup>2</sup>Nucleo de Assistencia Farmaceutica/National School of Public Health/Fiocruz, Brazil;

<sup>3</sup>Pan-American Health Organization/World Health Organization (PAHO/WHO), Office of Caribbean Programme Coordination (OCPC); <sup>4</sup>Pan-American Health Organization/World Health Organization (PAHO/WHO), Suriname

Problem statement: In Suriname, the Ministry of Health is responsible for assuring a functioning health care system. Prevalence and incidence of chronic diseases are increasing and cardiovascular disorders top the mortality list.

Objective: Assess the pharmaceutical situation in Suriname related to access, quality, and rational use of medicines

Design: A cross-sectional study was undertaken from October 2009 to April 2010 using WHO Level II methodology of health facilities and household surveys. Analysis was done with Epidata and Excel.

Setting: Suriname is located in the north of South America and is part of the Amazonian tropical rainforest with a population of 492,829 (2004) with several ethnic groups.

Study population: 38 public health facilities (PHFs), which dispense medicines to outpatients, 22 private pharmacies (PFs), and 3 warehouses were surveyed; 656 outpatients and 960 households were interviewed

Outcome measures: Indicators of medicines access and use

Results: Access to medicines: availability of key essential medicines was 93% in PHF and 100% in warehouses and PFs. The average cost for prescription for an acute illness was USD 4.00 and a monthly treatment of a chronic disease was USD 6.16. Quality: no expired medicines were found in any of surveyed facilities. Presence of pharmacists was 100% in all facilities and PFs. Storage conditions were adequate in 60% of storerooms of PHFs, in 90% of public warehouses, and in 70% of PFs. Rational use: the percentage of prescriptions by non-proprietary name (INN) in PHFs was very low (45.5%); 78% of people with chronic diseases reported taking medicines recommended in the prescription; 62% of the medicines found at home was adequately labeled.

Conclusions: There is very good access to medicines, nevertheless, quality and rational use are areas with room for improvement. It can be addressed through the updating of the National Medicines Policy. It is recommended to develop and adopt Good Practices in the medicines supply chain, centred on the patient, community, and families. Special attention can be paid to the promotion of rational use of medicines, such as promoting prescribing by the INN, as well as the development of a National Therapeutic Formulary and active development and dissemination of standard treatment guidelines for the main conditions.

Funding source: The study was part of the Partnership on Pharmaceutical Policies Project funded by the European Union and PAHO/WHO.

1145

### **Economics, Financing, and Insurance Systems**

*Keywords:* medicine prices, availability, access to medicines, retail pharmacy, chronic disease,

#### **Medicine Prices in Peru: Validation of the Sampling Approach Used in WHO/HAI Surveys**

**Jeanne Marie Madden, Edson Meza, Margaret Ewen, Richard O. Laing, Peter Stephens, Dennis Ross-Degnan**

Harvard University & Harvard Pilgrim Health Care, United States of America

**Problem statement:** WHO/HAI medicine price surveys describe pharmaceutical prices and pricing problems in support of policy reforms to increase access to essential medicines. The survey methodology relies on data collectors to obtain prices for a defined basket of medicines (up to 50) from a sample of 30 outlets per sector (e.g., public clinics, private retailers). The sampling of medicines, outlets, and geographic regions is designed to balance representativeness and pragmatic concerns. However, such rapid sample methodologies involving only a small numbers of selected facilities and case types may mask potential biases.

**Objectives:** In a special validation activity, we sought to determine if: WHO/HAI survey results differed in the more remote areas typically excluded from sampling; medicines on the core target list reflected overall medicine availability and prices; limiting data to the originator brand and the lowest price generic version accurately captured a medicine's price range; and WHO/HAI survey prices agreed with independent estimates.

**Design:** To investigate the extent of potential sampling biases, a survey was carried out that expanded the sampling frame of outlets and medicines in specific ways. Remote regions of the country and remote outlets within catchment areas were added. Comprehensive data were gathered on medicines within 3 therapeutic classes. WHO/HAI median retail prices were compared with average wholesale prices from global pharmaceutical sales data supplier IMS Health.

**Setting:** 6 regions in Peru, South America, in 2005

**Study population:** Analyses were conducted at the level of outlets (N = 52 public sector facilities and 96 private pharmacies) and medicines (N = 38 using standard outcomes, plus detailed investigations within 3 therapeutic classes: 6 ACE inhibitors, 7 anti-ulcerants, and 8 oral anti-diabetic agents).

**Outcome measures:** Study measures included product availability, price distributions, retail and wholesale price medians, brand premiums, and treatment costs.

**Results:** No significant differences were found in overall availability or prices of target list medicines by retail location. The comprehensive survey of ACE inhibitor, anti-diabetic, and anti-ulcer products revealed that some treatments not on the target list were costlier for patients and more likely to be unavailable, particularly in remote areas. WHO/HAI retail prices and IMS wholesale prices were strongly correlated for higher-priced products, and weakly correlated for lower-priced products (which had higher estimated retailer markups).

**Conclusions:** The WHO/HAI survey approach strikes an appropriate balance between modest research costs and optimal information for policy. Focusing on commonly used medicines yields sufficient and valid results. Surveyors elsewhere should consider the limits of the survey data as well as any local circumstances, such as scarcity, that may call for extra field efforts.

**Funding sources:** WHO and Health Action International

1146

### **Malaria**

*Keywords:* antimalarials, appropriate use, drug utilization, dispensing, prescribing

#### **Inappropriate Provision and Treatment of Malaria in Public and Private Sectors in Nigeria: Threat to Malaria Elimination Efforts**

**Obinna Emmanuel Onwujekwe<sup>1</sup>, Lindsay Mangham<sup>2</sup>, Bonnie Cundhill<sup>2</sup>, Ogochukwu Ezeoke<sup>1</sup>, Benjamin Uzochukwu<sup>1</sup>, Virginia Wiseman<sup>2</sup>**

<sup>1</sup>University of Nigeria, Nigeria; <sup>2</sup>London School of Hygiene and Tropical Medicine

**Problem statement:** Since June 2006, many brands of artemisinin-based combination therapies (ACTs) have been deployed unsystematically in Nigeria by both the government and pharmaceutical companies through a broad spectrum of public and private providers. There is lack of information about the extent that the drugs have been appropriately used and whether providers are adhering to treatment guidelines.

**Objective:** The study examined the current malaria treatment provision and utilization practices and patterns in Nigeria, especially the pattern of diagnosis, prescribing, and dispensing of malaria treatment of febrile patients for whom treatment was sought at the different types of health facilities.

**Design:** A cluster survey was conducted with 2089 patients (or caregivers) exiting public and private health facilities. Data was also collected from providers at 20 public primary health care centres, 25 pharmacies, and 55 patent medicine dealers.

**Study setting:** The study was undertaken at 2 local government areas (LGA) in Enugu state, southeast Nigeria. These were Enugu LGA (urban) and Udi LGA (rural).

**Study population:** All eligible health workers at public primary health centres and dispensaries plus public health posts and private pharmacies and patent medicine dealers (PMD) were interviewed. The study population for the patient exit surveys was individuals seeking treatment for fever and/or malaria or individuals receiving an ACT. This included individuals seeking treatment for themselves or for someone else.

**Data collection:** Data was collected using a provider survey questionnaire and a patient exit questionnaire.

Policy context: The need to ensure that ACTs that are the new first-line drugs and other antimalarials are used appropriately so as to improve treatment outcomes and decrease treatment failures and the burden of malaria.

Outcome measure: Appropriate provision and use of ACTs and other antimalarials by a broad spectrum of providers and consumers at the primary health care level.

Results: 78.4% of facilities had first-line ACT (AL) in stock, 88.3% had any ACT in stock; many facilities had artemisinin monotherapy (AMT) and sulfadoxine-pyrimethamine (SP) in stock; 65.4% of health workers reported that the nationally recommended treatment for uncomplicated malaria was an ACT. Very little laboratory diagnosis of malaria (3%) was done in public facilities). There were low levels of use of ACTs among febrile patients (28.8% of patients visiting pharmacies compared to 22.8% in public facilities and 19.0% of patients attending PMDs). Also, 14.8% of patients at pharmacies received an ACT in the correct dose, and for patients attending a public facility, it was 11.1% and attending a PMD, 9.0%. Many febrile patients received SP and AMT.

Conclusion: There are still very high levels of inappropriate provision and consumption of malaria treatment, even with the ready availability of ACTs.

Funding sources: ACT consortium, LHSTM, through a grant from Bill & Melinda Gates Foundation

1147

#### Access

Keywords: Keywords: Monitoring and Evaluation, Pharmaceutical Situation, Pharmaceutical Policies, Primary Healthcare

### Assessment of Pharmaceutical Situation in Jamaica

Princess Thomas-Osborne<sup>1</sup>, Cyntia Lewis-Graham<sup>1</sup>, Adriana Mitsue Ivama<sup>2</sup>, Vera Lucia Luiza<sup>3</sup>, Paula Pimenta Souza<sup>3</sup>, Andre Dennis<sup>1</sup>

<sup>1</sup>Bureau of Standards and Regulations, Ministry of Health of Jamaica; <sup>2</sup>Pan-American Health Organization/World Health Organization (PAHO/WHO), Office of Caribbean Programme Coordination (OCPC); <sup>3</sup>Nucleo de Assistencia Farmaceutica/National School of Public Health/Fiocruz, Brazil

Problem statement: Jamaica, the largest of the English-speaking Commonwealth Caribbean Islands, is divided into three counties that are subdivided into 14 parishes. The average population density was estimated at 660 per square mile. Health care in Jamaica is provided by the Ministry of Health (MoH), the private sector, and other nongovernmental organizations.

Objectives: Assess the pharmaceutical situation in Jamaica related to access, quality, and rational use of medicines.

Design: A cross-sectional study was undertaken from July 2009 to May 2010 using WHO Level II methodology of Health Facilities and Household Surveys. Analysis was done with EpiData and Excel.

Setting: Jamaica, a middle-income country with a population of 2.6 million

Study population: 30 public health facilities (PHFs), which dispense medicines to outpatients; 30 private pharmacies (PFs), randomly selected; and the central public warehouse were surveyed; 726 outpatients and 805 households were interviewed

Outcome measures: For most selected indicators, results are presented as a percentage of total surveyed facilities or households.

Results: Access to medicines: availability of the key essential medicines in PHFs was 100% and in PFs, 93%. The average cost for prescription for an acute illness was USD 33.00, and a monthly treatment of a chronic disease averaged USD 21.00. Quality: no expired medicines were found in any of surveyed facilities. The presence of pharmacists was lower in PHFs (62.1%) than in PFs (96.2%). Storage conditions were adequate in 70% of the storerooms in PHFs, in 90% of the public warehouse, and in 80% of PFs. Rational use: The percentage of prescriptions by non-proprietary name (INN) in PHFs was very low (41%); 20% of people who had a chronic disease and who had been told to take medicines mentioned that they did not take them, and the main reason given was that they were not following the prescription; 76% of the medicines found at home had adequate labeling.

Conclusions: It is highly recommended that the National Pharmaceutical Policy be developed to address the main challenges and constraints identified, such as quality of medicines and services with adoption of Good Pharmacy Practices. Even though the availability was high, the stock-out and storage conditions need to be addressed. The results also show that managerial and economic policies concerning pharmaceuticals should be improved. Promotion of rational use of medicines is necessary, including improving prescribing by the INN and updating the VEN list, the therapeutical formulary, and the STGs based on the concepts of essential medicines; evidence-based decision making is also needed.

Funding source(s): EU/ACP/WHO Project "Partnership on Pharmaceutical Policies," funded by European Union.

1148

#### Economics, Financing, and Insurance Systems

Keywords: medicine prices, availability, access to medicines, retail pharmacy, public sector

### Monitoring Medicine Prices with WHO/HAI Surveys: Upsides, Downsides, and Forward-Thinking Strategies

Jeanne Marie Madden

Harvard University & Harvard Pilgrim Health Care, United States of America

**Problem statement:** In the past decade, WHO/HAI medicine price surveys have been conducted in dozens of countries. The surveys represent snapshots of pharmaceutical prices and availability, based on limited samples, which can support policy reforms to increase patient access. The value of this information has great potential to multiply if surveys are conducted at regular intervals, such as quarterly. Several countries have implemented monitoring of medicine prices and availability using the WHO/HAI approach, including Kenya where monitoring continued for 4 years. Longitudinal monitoring poses both opportunities and pitfalls for local teams, but accumulated experiences and various tools are on hand to assist.

**Objectives:** To review the utility of medicine price surveys, particularly as part of a longitudinal activity; to explore design options for price monitoring and the consequences of design choices; to describe data patterns from actual practice in the field, trouble spots to be aware of, and analytic approaches that will get the most out of monitoring

**Design:** Price monitoring in general will be reviewed, with particular reference to the Kenyan experience, in which data was collected quarterly on the price and availability of targeted medicines (lowest priced version, regardless of manufacturer).

**Setting:** Examples will be drawn especially from monitoring in Kenya from 2006 to 2009.

**Study population:** Analyses for the Kenya monitoring were conducted at the level of medicines (N = up to 36 per survey round) and survey round (N =12 rounds representing calendar quarters). Approximately 15 rural and 15 urban outlets were covered in each survey round and sector (public, private retail, and mission).

**Outcome measures:** The presentation will cover the key WHO/HAI measures of percentage availability across outlets and median medicine price. An array of analyses were undertaken to aggregate data across medicines and assess changes over time. Price distribution and outlier observations were assessed, and results compared to an earlier snapshot survey.

**Results:** In the Kenya monitoring activity, several scheduled rounds were skipped, the targeted medicines list was updated twice, and the public sector exhibited a rapid shift toward zero-priced medicines, posing substantial challenges for comprehensive analysis. Nevertheless, the data were of generally good quality and a clear picture of changes in Kenya emerged, both at the aggregate level and in finer detail.

**Conclusions:** Price monitoring can be extremely useful in terms of enhancing our confidence around survey results, tracking important trends over time, and evaluating effects that may be attributable to specific policy changes. Attention must be paid particularly to the consistency of methods over time, so that data are comparable among rounds. Techniques are available to adjust for inconsistent data and to quantify both gradual and sudden changes over time.

**Funding sources:** WHO and Health Action International

1150

### **Policy, Regulation, and Governance**

*Keywords:* Rational use of medicines, Regional strategy

### **Regional Strategy for Implementing the Rational Use of Medicines at the National Level in Latin American Countries**

**José Luis Castro<sup>1</sup>, Perla M. de Buschiazzo<sup>2</sup>, Héctor Buschiazzo<sup>2</sup>, Lennita Wanmaher<sup>4</sup>, Benito Marchand<sup>3</sup>, José Orozco<sup>6</sup>, Albin Chávez<sup>5</sup>, Martín Cañas<sup>2</sup>, Lilly Gordillo<sup>7</sup>, Victoria de Urioste<sup>1</sup>, James Fitzgerald<sup>1</sup>**

<sup>1</sup>PAHO/WHO; <sup>2</sup>CUFAR; <sup>3</sup>HAI; <sup>4</sup>URGS; <sup>5</sup>CCSS; <sup>6</sup>UNC; <sup>7</sup>Ministerio de Salud, Guatemala

**Problem statement:** The irrational use of medicines remains a widespread problem in developed and developing countries, with serious consequences for patients' therapeutic outcomes and the wastage of resources. In 2007, the World Health Assembly adopted the Resolution WHA 60.16 about "Progress in the rational use of medicines" (RUM) committing WHO and governments to lead the promotion of RUM. Isolated actions on different levels have been developing to improve medicines utilization in the countries of Latin America; however there is a need integrate and articulate these actions under 1 single plan of action. In the Americas, PAHO/WHO coordinated the development of an integral strategy to implement the RUM at country level.

**Objectives:** To support the country implementation of an integrated and participatory strategy of RUM with defined lines of actions, tools, and evaluation mechanisms

**Design:** Adaptation of a regional proposal with the development and management of a national working plan with mission, values, objectives, 5 main axes, cross-cutting axes, lines of action and activities

**Setting:** The proposal was designed for countries of the region of the Americas and a pilot was developed in Nicaragua and Bolivia.

**Study population:** The population included in the pilot phase is that in 1 of the countries.

**Intervention(s):** A first draft document was enriched and complemented in 3 meetings of a group of experts of the region. Three countries presented a note expressing the intention of piloting the proposal. In 2 of them, a national working group developed a national proposal of the strategy. Each country adapted the lines of actions within the 5 axes proposed in the regional document: policy and structure, regulation and legislation, education and culture, management, and research. A requisite for the strategy development was the establishment of a structure in the Ministry of Health for coordinating the strategy.

**Policy(ies):** The proposal is focused on improving patients' health through better use of medicines in the context of primary health care. The strategy is inserted in the medicines policies and the health services.

Outcome measure(s): National proposals developed and approved by the health authority. Coordinating group settled at the national level. Pilot countries implemented the proposal.

Results: Nicaragua and Bolivia performed a SWOT analysis of the medicines management that was shared and discussed with health representatives from the different regions of each country developed a national adaptation of the proposal that was agreed in a national meeting and approved by the Ministry of Health. The final proposal included a working plan with prioritization of activities in each of the axes to be followed up by a national group that was established to that purpose.

Conclusions: This initiative allows placing the RUM in the governments' agenda with a ministerial structure to follow up the plan implementation, with a horizontal approach, connecting the disease programs and prioritizing and coordinating the different actions in the field.

Funding source: PAHO/WHO, national governments, Spanish Agency for International Cooperation (AECID)

**1152**

**Policy, Regulation, and Governance**

*Keywords:* Access, medicines, research questions, barriers

**Access to Medicines in India: Setting Priorities in Policy Research Issues**

**Sakthivel Selvaraj, Habib Hasan, Preeti Kumar, Maulik Chokshi**

Public Health Foundation of India, India

Problem statement: Access to medicines is critical to the provision of equitable, affordable, and quality health care in low- and middle-income countries (LMICs). According to the WHO estimates, the mean availability of essential drugs in LMICs is 35% in public sector facilities and 66% in the private sector. And in India it differs between states. On the other hand, medicines account for a high proportion of households out-of-pocket (OOP) expenses, accounting for as much as 70% of all households' spending on health care. Despite improvements in terms of price and availability, data on access to and use of medicines is often weak. Even where data are available, there is limited contextual evidence and weak capacity for analysis and interpretation for development of sound policy options. This study uses the framework of the Access to Medicines Policy Research project developed by the Alliance for Health Policy and System Research (WHO). The aim is to enhance the use of evidence in policy formulation to improve access to medicines in LMICs.

Objectives: (1) Identify and rank policy concerns in respect to access to medicines, as perceived by multiple stakeholders, such as health planners, policy makers, civil society organizations, communities, and patient groups in India and its states; (2) identify and rank the related policy research questions in the field of access to medicines in India

Design: The study has two components: a literature review followed by a survey of key informants through structured interviews.

Setting: This study is conducted at national and state levels in India, covering both private and government institutions.

Study population: As part of the review exercise, national- and state-level published and grey literature, policy documents, relevant reports, and prior priority setting exercises in accordance with the selection criteria were inventoried. In addition, we have registered the policy statements and concerns of various stakeholders. As far as the survey is concerned, the key informants were selected according to their significant involvement at different levels in medicines issues, especially high-ranking officials of the central and state governments (including Ministry of Health, Department of Pharmaceuticals), civil societies, academic researchers, private pharmaceutical companies and industry confederations, etc.

Outcome measure: Specific constraints related to access to medicines are identified according to the 4 areas of WHO Framework for Equitable Access to Essential Medicines at different levels of health systems.

Results and conclusions: Our evidence highlighted wide disparities in drug expenditures across states in terms of per capita resource allocation. Except for the Drugs Price Control Order (DPCO), there are no other policy instruments to manage drug prices, especially for the innovator drugs and for those not under DPCO. Lack of communication, coordination, cohesion, and coherence among various institutions/ministries has been observed, which has significant implications for access to medicines.

Funding source: Alliance for Health Policy and System Research (WHO)

**1153**

**HIV/AIDS and TB**

*Keywords:* dispensing, antiretrovirals, HIV/AIDS, evaluation, patient satisfaction

**National Evaluation of Medicines Dispensing within Brazilian AIDS Program**

**Thiago Botelho Azeredo, Vera Lucia Luiza, Angela Esher, Isabel Cristina Martins Emmerick, Samara Ramalho Matta, Fernando Genovez Avelar**

ENSP/Fiocruz, Brazil

Problem statement: Pharmaceutical services concerning for People Living with HIV and AIDS (PLWHA) are fundamental for the Brazilian response to the epidemic. However, little is known about service performance and user satisfaction in pharmacies that dispense medicines necessary for this treatment.

Objectives: To evaluate the quality of pharmacies that dispense medicines for opportunistic infections and antiretrovirals in Brazil, focusing on aspects of service performance and user satisfaction within the public sector

**Design:** Cross-sectional study; a pharmacy services (PS) sample was selected according to a proportional probability based on the number of patients usually attended. Data from direct observation (based on check lists, document consultation) and interviews of professionals and users were collected. The entire process involved interactions with main stakeholders, as civil society, national and local health managers, and policy makers.

**Setting:** PS within the public sector distributed in 19 municipal districts, in 10 Brazilian states; a probabilistic sample of patients was calculated so as to be an estimate of the target states and the set of states.

**Study population:** 29 PS were visited and 101 health professionals and 1412 patients were interviewed

**Outcome measure(s):** Performance and satisfaction indicators were organized in 3 dimensions: accessibility, availability, and adequacy to technical standards. Satisfaction scores ranged from 0 to 100, based on a psychometric instrument.

**Results:** In relation to accessibility, the average time spent (from home to PS) was 68.4 min, and the average waiting time was 10.9 min; 81.1% of the checked list of medicines was available. No expired medicine was found. In terms of adequacy to technical standards, 61.9% of the stock register was confirmed by counting; 60% of the items checked for environmental quality were adequate; 20.5% of users were oriented by the pharmacy attendant and 50.8% of attended prescriptions were complete. In terms of patient satisfaction, the worst evaluated dimension was accessibility, 67.2 (SE  $\pm$  0.9). Within this dimension, choice of care provider and time spent received the lower scores, 39.7 ( $\pm$  2.2) and 58.4 ( $\pm$  1.6), respectively. Service organization was the best evaluated component, 90.0 ( $\pm$  0.7). The best estimated dimension was ARV availability, 77.4 ( $\pm$  1.5). The adequacy average score was 73.4 ( $\pm$  0.8). Within this dimension, the component interpersonal aspects showed the worst result, 70.8 ( $\pm$  1.0).

**Conclusions:** Strengths and weaknesses of the Brazilian AIDS Program were identified, allowing feedback to stakeholders in many ways (meetings, publications, and Internet). As 1 of the results of this process, a working group was established at the national level, including representatives from state-level programs, civil society, and the evaluators group, aiming to set strategies related to problems identified.

**Funding source:** Information not provided

## 1154

### **Policy, Regulation, and Governance**

*Keywords:* good governance, transparency, regulation

### **Transparency in the Armenian Pharmaceutical Sector**

**Irina Kazaryan (Ghazaryan)<sup>1</sup>, Anaid Sevikyan<sup>1</sup>, Lusine Vardanyan<sup>1</sup>, Anaid Amirkhanyan<sup>2</sup>, Margarita Melikyan<sup>2</sup>**

<sup>1</sup>National Institute of Health, Armenia; <sup>2</sup>Drug Utilization Research Group PO, Armenia

**Problem statement:** Many factors contribute to Armenia's problems with access to medicines, irrational prescribing, and use. As successful and efficient use of still very restricted resources depends very much on behavior of persons involved at all the stages of "medicines chain", a lack of transparency should also be an issue of concern, especially the health sector which is considered to be one of the most corrupt sectors in Armenia.

**Objectives:** To assess the current situation on transparency and accountability in the pharmaceutical sector, as well as to define perception of health care professionals concerning the current situation on and importance of transparency and accountability for the Armenian pharmaceutical sector

**Design:** Pharmaceutical situation analysis, stakeholders surveys, qualitative study

**Setting:** Yerevan, the capital of Armenia

**Study population:** 72 health care professionals completed the questionnaire A being asked to estimate using 5-mark scale the current situation on transparency/accountability in 13 main areas and to determine importance of providing them; 12 key informants filled a draft assessment instrument for measuring transparency to improve good governance in the public pharmaceutical sector (WHO, 2006); 136 health and pharmacy professionals were asked about necessity of wide use of transparency and accountability for the spheres of management and regulation of medicines.

**Outcome measure(s):** The set of indicators was developed for questionnaire A (13 areas). Scoring for the assessment instrument was implemented according to the methods described in the WHO tool. The percentage of professionals who believe that wide use of transparency and accountability for the spheres of management and regulation of medicines is necessary was calculated in the third survey.

**Results:** Armenian legislation and regulation documents related to medicines do not cover issues of accountability and transparency. Mark "5" was very rarely selected (6.9% and less) by professionals who completed the first questionnaire. No one component has been marked "3" or higher by even half of respondents; 82% of 72 respondents noted high importance of providing transparency/accountability for the sphere of counterfeit medicines. Analysis of the key informants' responses revealed that the majority of important mechanisms necessary for providing transparency are still not introduced; 61% of 136 professionals consider that wide use of transparency and accountability is necessary for area of medicines supply.

**Conclusions:** According to opinion of local experts and professionals, transparency and accountability are not enough in the local pharmaceutical sector, and wide use of these tools is important for managing medicines supply. Draft of paragraph covering transparency issues was developed for a draft of a new law on medicines and submitted to the National Assembly of Armenia.

**Funding source(s):** None

1155

**Access***Keywords:* Medicine supply, supply management, education, access to medicines, availability**Improving Access to Medical Supplies in Emergency Settings by Preparing Humanitarian Responders with Online Medicine Supply Management Training****Libby Levison<sup>1</sup>, Monica Onyango<sup>2</sup>, Leilani Johnson<sup>3</sup>**<sup>1</sup>Independent consultant, United States of America; <sup>2</sup>Boston University School of Public Health; <sup>3</sup>Circle of Health International

**Problem statement:** When organizations respond to an emergency, one significant determinant of their ability to deliver effective medical care is the robustness of the medicine supply management system. Many relief organizations may not have the time or resources to develop specific training materials. Additionally, responders to humanitarian emergencies are often required to depart immediately, with minimal time for training before departure and limited resources upon arrival. To address this problem, we are developing a set of training modules on medical supply management to be made available online to academic and not-for-profit organizations.

**Objectives:** To test the feasibility of using an online course to teach medical supply management to potential responders to humanitarian emergencies

**Design:** Descriptive; before-after study with no control group. Participants were given a written quiz on the management of medical supplies. Participants then followed 4 online modules on medical supplies, quantification, stores management, and the analysis of morbidity and consumption data. After completing the online modules, participants retook the original quiz.

**Setting:** Online

**Study population:** Graduate students in public health enrolled in a course on humanitarian emergencies and volunteers preparing to travel to Circle of Health International's project in Haiti

**Outcome measures:** Increased scores as measured by comparing the results of the pre- and post-training quizzes.

**Results:** After taking online lectures, 100% of students increased their knowledge of medical supply management; 64% showed significant increase.

**Conclusions:** Findings from this study will facilitate the development of additional online training materials on medical supply management in emergency settings. These materials will allow organizations to standardize the management of supplies in their projects and to train responders as part of their preparation to go to the field. Strengthening the management of medical supplies will lead to improved health delivery and more rational use of medicines by guaranteeing that the right medical supplies are available when and where they are needed.

**Funding sources:** None

1156

**Access***Keywords:* Monitoring and Evaluation, Pharmaceutical Policies, Pharmaceutical Situation**Caribbean Network on Pharmaceutical Education****Adriana Mitsue Ivama<sup>1</sup>, Eugenie Brown-Myrie<sup>2</sup>, Rian Extavour<sup>3</sup>, Sureshwar Panday<sup>4</sup>, Sandeep Maharaj<sup>4</sup>, Lesia Proverbs<sup>5</sup>, Evelyn Davis<sup>6</sup>, Bridget Hogg<sup>7</sup>, Janet Campbell-Shelly<sup>2</sup>, Rudolph Cummings<sup>8</sup>, Lydia Harris-Thurton<sup>9</sup>, Juana Castillo<sup>10</sup>, Emmanuel Cummings<sup>11</sup>**

<sup>1</sup>Pan-American Health Organization/World Health Organization (PAHO/WHO), Office of Caribbean Programme Coordination (OCPC); <sup>2</sup>University of Technology, Jamaica; <sup>3</sup>Caribbean Association of Pharmacists, University of West Indies, Trinidad and Tobago; <sup>4</sup>School of Pharmacy, University of West Indies, Trinidad and Tobago; <sup>5</sup>Barbados Community College; <sup>6</sup>T. A. Marryshow Community College; <sup>7</sup>College of the Bahamas; <sup>8</sup>Health Desk, CARICOM Secretariat; <sup>9</sup>University of Belize; <sup>10</sup>Escuela de Farmacia, Universidad Autonoma de Santo Domingo.; <sup>11</sup>Faculty of Health Sciences, University of Guyana

**Problem statement:** In the Caribbean Community (CARICOM), health reform is on the agenda of many governments, with associated challenges of access and rational use of efficacious, quality, and safe medicines and health technologies. Another influence is the CARICOM Single Market and Economy (CSME), which includes free movement of labor, harmonization of social services, transfer of social security benefits, and establishment of common standards and measures for accreditation and equivalency. In this context, strengthening and harmonizing pharmacy education is a priority as part of the Caribbean Pharmaceutical Policy, supported by PAHO/WHO, CARICOM and the Caribbean Association of Pharmacists.

**Objective:** Establish the Caribbean Network on Pharmacy Education (CNPE)

**Design:** A descriptive study was conducted in December 2010 about the process of establishing the network from May 2009 until December 2010.

**Setting:** CARICOM countries and the Dominican Republic

**Study population:** 7 institutions with the Pharmacy Program in the Caribbean

**Interventions:** Identification of the existing pharmacy programs in the Caribbean (2008), 2 workshops (2009, 2010), several virtual meetings using "illuminate"®, and a telephone survey with 11 interviews (2010)

**Results:** Six schools offering pharmacy programmes were identified in the English-speaking Caribbean and were invited for the workshop conducted in May 2009 with the technical advisory group of medicines of CARICOM. The background

information and each program were presented. We identified 3 different degrees, namely, diploma and associate's and bachelor's degrees, with no difference in professional recognition or levels of responsibility. A decision for establishing the network was made, and each school nominated a focal point. Afterward, 2 schools were incorporated from the Dominican Republic and Belize. The survey's findings with the main challenges and possible barriers for collaboration and harmonization were presented in the second workshop in October 2010. Based on the results, the proposal of network was validated with the mission to "promote strengthening and harmonization of pharmaceutical education and to contribute to strengthening of pharmaceutical policies and other initiatives for the achievement of the highest level of health in the Caribbean." Working groups were established to address the identified priorities, namely, (1) develop a proposal for a harmonization, (2) study the requirements and standards for registration and the practice of pharmacists, and (3) develop a proposal for addressing pharmaceutical policy issues in the pharmacy curricula. A biennial work plan was prepared and its progress continued to be monitored with monthly virtual meetings, where results are reported and discussed.

Conclusions: The schools recognize their limited capacity and consider the network to be one alternative for improving pharmacy education both in the Caribbean and individually, with possibilities of sharing personnel and resources in the future.

Acknowledgement: The support of Prof. Dorothea Rudolf from Massachusetts University in collaboration with the WHO Collaborating Centre on Pharmaceutical Policies of Harvard University is acknowledged.

Funding sources: EU/ACP/WHO Project Partnership on Pharmaceutical Policies funded by the European Union

1157

#### **Policy, Regulation, and Governance**

*Keywords:* Medicines Safety, Pharmacovigilance, performance monitoring tool, guided interventions, capacity building

### **Strengthening Pharmacovigilance at the National Level: Development of an Indicator-Based Pharmacovigilance Assessment Tool to Assess Medicines Safety System at the Level of the Pharmaceutical Industry in Developing Countries**

---

**Jude Nwokike<sup>1</sup>, Caroline Adam<sup>2</sup>**

<sup>1</sup>Management Sciences for Health, Strengthening Pharmaceutical Systems (SPS) Program, South Africa; <sup>2</sup>Management Sciences for Health, Strengthening Pharmaceutical Systems (SPS) Program, South Africa

Problem statement: There are no universally accepted performance metrics for determining optimally functioning pharmacovigilance (PV) and medicines safety systems in the pharmaceutical industries in developing countries. PV activities required by regulations and routinely adhered to by pharmaceutical companies operating in stringent, regulatory environments are rarely implemented in developing countries where the burden of adverse reactions may be more and regulatory systems are often weak.

Objectives: To develop a performance monitoring and diagnostic assessment tool for monitoring PV activities within the pharmaceutical industry in developing countries

Design: We adapted the indicator-based pharmacovigilance assessment tool (IPAT) earlier developed by the MSH/SPS program. These indicators were reviewed and compared with post-authorization safety responsibilities from the pharmaceutical regulations of selected countries. Forty four indicators (32 core and 12 supplementary) were developed that address 5 PV and medicine safety systems components that represent the elements of a functional PV system and are applicable to medicinal products under development and drugs during all life-cycle management. The IPAT is modular and the evaluation is conducted through a series of assessment questions reflecting on structures, processes, and outcomes of medicines safety systems. We pilot-tested the pharmaceutical industry IPAT on 4 companies: 2 multinational, 1 generic, and 1 local-owned agency in South Africa. The tool was subsequently used for a comprehensive assessment of selected pharmaceutical companies.

Outcome measure(s): Performance assessment tool; reliable assessment and diagnosis of status of PV systems within a pharmaceutical company

Results: The post-pilot assessment showed that the pharmaceutical industry IPAT was a useful and reliable tool for assessing PV systems across different levels and types of pharmaceutical companies including branded, multisource, contract research organizations. The tool is able to generate both quantitative and qualitative data on medicines safety systems and practices.

Conclusions: The pharmaceutical industry IPAT provides reliable baseline data and informs the development of interventions for improving PV in the industry setting. The use of the pharmaceutical industry IPAT is feasible in a developing country. The tool can also be used for longitudinal measurement of progress after the recommended interventions are implemented.

Funding source(s): United States Agency for International Development

1158

#### **Economics, Financing, and Insurance Systems**

*Keywords:* health insurance, affordability, drug utilization, chronic disease, equity

### **2006 Medicare Part D Benefit: Evaluating a Major Expansion of Medicines Insurance for Vulnerable Americans**

---

**Jeanne Marie Madden**

Harvard University & Harvard Pilgrim Health Care, United States of America

**Problem statement:** In the US, health care and its access via insurance has been notoriously uneven and reliant on the private marketplace. With health spending at 17% of GDP, reforms are slow and contentious, despite widely acknowledged problems. National health insurance established in 1965 for elderly and disabled Americans did not include medication insurance. In 2006, a medicines benefit finally became available, Medicare Part D. A balanced evaluation of this major policy shift requires application of multiple, carefully selected approaches.

**Objectives:** To evaluate the impact of Medicare Part D for elderly and disabled persons in the United States, with focus on medicines affordability from the patient perspective, particularly for those burdened with chronic illness and for the poor

**Design:** Interrupted time series analysis

**Setting:** National samples from the United States, including (1) a representative panel survey of Medicare beneficiaries, and (2) insurance claims and enrollment data on 5% sample of persons dually enrolled in Medicare (for the elderly and disabled) and Medicaid (for the poor)

**Study population:** (1) approximately 15,000 survey participants per year (2000 to 2007), stratified by income, with subgroups defined by hypertension and diabetes diagnoses; (2) approximately 10,000 continuously dually enrolled individuals (2004 to 2007) with severe mental illness (schizophrenia or bipolar disorder)

**Outcome measures:** Study outcomes include type and generosity of medication insurance if any; annual prescription fills; annual out-of-pocket spending; costs of disease treatment; cost-related medication nonadherence; and adverse events (psychiatric hospital and ER admissions).

**Results:** After implementation of the new benefit in 2006, among the overall beneficiary population, we saw increases in total annual fills (+1.8 fills in 2006, +3.4 by 2007) and modest decreases in self-reports of cost-related nonadherence (relative decline about 15%). Decreases in annual out-of-pocket spending on medications were substantial (overall, 23% in first year), especially for those with no prior source of medicines insurance who enrolled in the new benefit (-37%). The new benefit reduced disparities among income subgroups, as intended. However, because of the benefit structure, chronic disease sufferers still faced large cost-sharing burdens and saw fewer improvements as compared with healthier beneficiaries.

**Conclusions:** These interrelated studies demonstrate the power of insurance reform to effect major changes for patients, even in the context of relative wealth. Moreover, these studies demonstrate the necessity of longitudinal data to accurately measure change and the importance of multiple measures and subgroup analyses in constructing a complete story. The presentation will focus on methods messages applicable in other settings with a broad range of developmental levels.

**Funding sources:** US National Institute on Aging and US Agency for Healthcare Research and Quality

**1159**

**HIV/AIDS and TB**

*Keywords:* Antiretrovirals, cost reduction, international reference lists

### **Application of an International Reference Price List to National Medicines Procurement Tenders**

**Gavin Steele<sup>1</sup>, Bada Pharasi<sup>2</sup>, JP Sallet<sup>3</sup>**

<sup>1</sup>Management Sciences for Health, Strengthening Pharmaceutical Systems (SPS); <sup>2</sup>Management Sciences for Health, Strengthening Pharmaceutical Systems (SPS); <sup>3</sup>Management Sciences for Health, Strengthening Pharmaceutical Systems (SPS)

**Problem statement:** The success of antiretroviral (ARV) scale-up in developing countries requires access to affordable prices. Large public health programs rely on economies of scale and competitive tendering to achieve optimum prices. Previously South Africa, the largest ARV program in the world, has purchased ARVs at prices much higher than the average international ones for most ARVs. The South African Government has recently embarked on a massive HIV testing campaign with the objective of enrolling 500,000 new patients on the ARV treatment program every year. This campaign will result in a significant increase in funding requirements. If prices of ARVs remain at such high levels, the ART program might become unsustainable overtime.

**Objectives:** Cost reduction by improving competition among bidders through international benchmarking and publication of international reference price lists during tender process for ARVs; a study commissioned by the Minister of Health and tasked with improving medicines procurement in the country's public sector conducted a comparison of national prices with international prices.

**Design:** Analysis of tender prices was performed to evaluate the potential impact of this intervention. Confounders were controlled for by analysing the impact of the number of bidders and exchange rates.

**Setting:** National South Africa ART program

**Intervention:** A reference price list was compiled based on international transactional prices and introduced as a stimulus for competition amongst local suppliers during the national ARV procurement.

**Policy issues:** International reference lists increase competition in national tenders through vicariously projecting competition prevalent in international markets.

**Outcome measure:** Reductions in ARV prices and improved access within a finite budget

**Results:** For key ARVs, price reductions of up to 65% were obtained. In nearly all cases, the awarded tender price was below that of the reference price list. The data suggests that international benchmarking contributed towards this price

reduction and subsequent savings. Furthermore, the price reductions are larger than those projected based on volumes alone. It is estimated that these price reductions will result in ARV procurement costs saving of roughly 50%, allowing for a doubling of the number of patients accessing treatment.

Conclusion: The application of international reference lists during national tenders is a valuable tool in achieving optimal pricing. Although South Africa has traditionally sourced virtually all of its pharmaceutical requirements from local and international pharmaceutical companies represented in the country, recent experiences have demonstrated that resorting to international benchmarking and opening the market to international prices and suppliers has increased competition and allowed for reduced local prices. Through this strategy, the country has cut expenditures on ARVs by 50%.

Funding source: USAID/SPS program

1161

### **Policy, Regulation, and Governance**

*Keywords:* Policy process analysis, governance, medicines system, transparency assessment, Thailand

#### **Good Governance of Medicines System in Thailand: From Assessment to National Policy Agenda**

**Niyada Kiatying-Angsulee<sup>1,2</sup>, Suntharee T.Chaisumritchoke<sup>2</sup>, Yaowalak Amrumpai<sup>3</sup>**

<sup>1</sup>Social Research Institute, Chulalongkorn University, Thailand; <sup>2</sup>Social Pharmacy Research Unit, Faculty of Pharmaceutical Sciences, Chulalongkorn University; <sup>3</sup>Faculty of Pharmacy, Silpakorn University

Problem statement: The pharmaceutical or medicine sector is perceived as vulnerable to corruption and unethical practices, due in part to failure market and the high value of pharmaceutical products as one health technology in the prevention and treatment of diseases. Furthermore there are wide ranges of stakeholders with sometime different objectives or goal. There has been a move from WHO to alleviate such situation by introducing Good Governance in Medicine System (GGM) into all regions. Thailand is one country that started the project from the very beginning. Experience from Thailand can be learnt and shared.

Objectives: To assess transparency situation in medicines system and to elaborate process of bringing GGM to national policy agenda

Design: Mixed-method study

Setting: National and regional levels of medicine system

Study population: Stakeholders within medicines system

Outcome measures: Transparency situation in medicine system and policy agenda process

Results: Assessment of transparency situation of medicine system was performed in five areas out of ten areas according to WHO assessment tools. The first three areas were performed by using the previous version and will be updated later. Registration scored 7.0 out of 10. Selection scored 8.0 and procurement scored 7.1. All meant marginally vulnerable to corruption. Inspection and promotion were the next two under studying. From the results of first phase assessment, attempt has been done by introducing onto agenda as resolution of the second National Health Assembly in 2009 as entitle 'Stop unethical drug promotion: to reduce risk of patient health and economic of the nation'. The process of putting this topic onto policy agenda required multifaceted approaches as technical study, assessing the situation, public communication, participation from concerned and relevant groups. Media was major channels for communication to the public which received good attention. More work is needed for further implement the policy agenda and the performance of monitoring system.

Conclusions: Assessment of transparency situation can help setting policy agenda on good governance in medicine system. Other components were technical study, public communication.

Funding source: World Health Organization, Thai Health Promotion Foundation

1162

### **HIV/AIDS and TB**

*Keywords:* CVD, HIV, high blood pressure, cholesterol, risk assessment

#### **Findings from Integrating CVD risk factors screening and services among HIV clients in resources constrained setting**

**Inoussa Kabore<sup>1</sup>, Frank Mwangemi<sup>2</sup>, John Adungosi<sup>2</sup>, Peter Mwarogo<sup>2</sup>, Peter Lamptey<sup>3</sup>, Rebecca Dirks<sup>1</sup>**

<sup>1</sup>FHI/Arlington; <sup>2</sup>FHI/Kenya; <sup>3</sup>FHI/Ghana

Problem Statement: There is mounting evidence demonstrating that 1) People Living with HIV (PLWHA) - whether or not on antiretroviral treatment (ART) - have an increased vulnerability to cardiovascular (CVD), certain cancers, diabetes, and depression; and 2) ART itself can increase risk factors for CVD and diabetes. As HIV treatment programs continue to scale up, people infected with HIV will be living longer and be at an increased risk of acquiring CVD.

Objectives: To pilot-test the feasibility of integrating the screening of CVD/diabetes risk factors with HIV services in a resource-limited setting; to describe the prevalence of CVD/diabetes risk factors among patients in existing HIV sites, and to provide patients indentified with CVD/diabetes risks with services or referrals.

Design: Adults accessing HIV counseling and testing (HCT), HIV care and/or treatment at the pilot sites were screened for CVD/diabetes risk factors using a behavioral risk assessment tool and measurement of body-mass index (BMI) and blood pressure. Those patients in HIV care and/or treatment were additionally screened for lipid and blood sugar levels.

Setting: The intervention, in collaboration with the Kenyan Ministry of Health and Kenya Cardiac Society, took place in five public health facilities providing HIV services in Kenya.

Study Population: The population included adult patients accessing HCT, care and/or treatment in the selected pilot sites. A total of 4,027 individuals were screened for CVD/diabetes between September 2009 to September 2010: 1023 HCT clients, 952 HIV + clients in care (not on ART), and 2052 HIV+ clients on ART.

Intervention: CVD/diabetes screening, referral and limited treatment services were integrated into HIV services in 5 public health facilities. The service providers were trained in behavioral and biological CVD/diabetes risk assessment. The sites were equipped with materials to screen patients for blood sugar, blood pressure, and lipid levels. Appropriate behavioral and biomedical interventions and referrals were provided to patients at risk or suffering from CVD/diabetes.

Policy: The government of Kenya will use results from this CVD/HIV integration pilot to inform the national HIV strategy.

Outcome Measure: Blood sugar; Cholesterol; Blood pressure; Body-mass index (BMI)

Results: The integration of CVD risk assessment in existing HIV services is feasible, and perceived positively by service providers, clients, and the government of Kenya. Among patients on ART, 20% on a first line treatment regimen had high blood pressure (HBP), versus 98% of those on second line ART. Blood pressure among was higher among patients who were on ART for three years or more. The prevalence of diabetes and high cholesterol was low among all patients.

Conclusions: Integration of CVD/diabetes to HIV service is feasible. The finding corroborates recent studies demonstrating the association between HIV and CVD; and CVD and ART.

Funding Source: FHI

1163

HIV/AIDS and TB

Keywords: ART, electronic dispensing tool (EDT), adherence

### Strengthening Patient Adherence Monitoring through the Electronic Dispensing Tool (EDT)

Dawn Pereko<sup>1</sup>, Victor Sumbi<sup>2</sup>, David Mbirizi<sup>3</sup>

<sup>1</sup>Management Sciences for Health/ Strengthening Pharmaceutical Systems; <sup>2</sup>Management Sciences for Health/ Strengthening Pharmaceutical Systems; <sup>3</sup>Management Sciences for Health/ Strengthening Pharmaceutical Systems

Problem statement: Namibia reported an average of 99.9% availability of antiretrovirals (ARVs) in public hospitals in October 2007-September 2010. As obstacles to access are overcome, attention is being increasingly focused on adherence to treatment.

Challenge: Self-report was the main standard measure of ART adherence at public health facilities in Namibia. Some ART sites in Namibia were using pill counts as a measure for monitoring adherence; however, pill count results were entered on patient-held records and thus there were no records of adherence kept at facilities. It was not possible for facilities to monitor patients' adherence over time.

Intervention: The MoHSS with support from MSH/SPS program developed an adherence-monitoring module on the electronic dispensing tool (EDT) widely used in Namibia. The adherence module is able to provide patient data for a proxy adherence measure of on-time ARV pick up. This is easily monitored as the EDT automatically checks whether a patient on ART was on time (i.e., on or before their ARV refill appointment date) for each pharmacy visit.

Results: Analysis of ARV on-time pick up results from 33 selected health facilities for June 2011 shows that an average of 88% of patients collected their ARVs within 4 days of their appointment date. For these facilities, between 1% and 18.8% of patients were 4-10 days late; between 0.6% and 18.8% were 11-19 days late while the percentage of those late by 20-29 days was 0%-12%. All hospitals can generate monthly reports of on-time ARV pick up. At the facility level, an individual's on-time ARV pick-up history can be tracked and appropriate remedial measures taken where necessary. At managerial level, comparison of results for different facilities and for the same facility over time help district-, regional- and national-level managers identify facilities where the proportion of patients picking up their ARV refills on time is lower and thus initiate or support corrective measures.

Conclusion: Electronic data management tools like the EDT can serve as useful tools for effective monitoring of patients' ARV refill data and thus identifying patients with adherence-related problems for appropriate follow-up.

Funding sources: United States Agency for International Development/Namibia

1164

Policy, Regulation, and Governance

Keywords: Drug Information Center, Latin America network

### Development of a Regional Network of Medicines Information Centres

José Julián López<sup>1</sup>, Martín Cañas<sup>2</sup>, Claudia Vaca<sup>1</sup>, Mónica Nova<sup>1</sup>, Mariana Caffarati<sup>4</sup>, Zully Vera<sup>4</sup>, Victoria Hall<sup>4</sup>, Carlos Fuentes<sup>4</sup>, Dulce Calvo<sup>4</sup>, Lorena Cerna<sup>4</sup>, Wendy Flores<sup>4</sup>, Susy Machicado<sup>4</sup>, Amelia Villar<sup>3</sup>, José Luis Castro<sup>3</sup>, James Fitzgerald<sup>3</sup>

<sup>1</sup>Universidad Nacional de Colombia; <sup>2</sup>FEMEBA; <sup>3</sup>PAHO/WHO; <sup>4</sup>Centro de Información de país

Problem statement: Health services', professionals', and communities' access to independent information about medicines is a challenge that requires strategies to develop sustainable initiatives in the field. Members of the Drug

Utilization Research Group (DURG-LA) and PAHO/WHO agreed to develop a proposal presented by a team of the University of Colombia and the FEMEBA foundation.

**Objectives:** To establish a regional network of medicine information centers (MICs) of Latin America and the Caribbean beginning with the evaluation of their characteristics and the development of a draft document containing the objectives and rules for the network operation and sharing of resources

**Design:** Intervention consisting of gathering MICs of the region, conducting a survey to establish a diagnostic, and developing a draft operational document

**Setting:** MICs of the countries of the region

**Study population:** 16 countries and 22 MICs of the region of the Americas

**Intervention:** We sent a survey to 30 Latin American MICs, and 22 answered. The survey included questions about human and bibliographic resources, funding sources, queries classifications, and other criteria. The confirmation of the centers' participation in the network was addressed through an official PAHO/WHO note. Virtual meetings were made to reach an agreement on the operating network rules.

**Results:** Most MICs that agreed to participate in the network belong to public universities (13) or governmental entities (5). Pharmacists are part of the staff in most MICs (18), and university students collaborate in 21 centers. Most MICs (13) do not have SOPs, and 14 produce some type of bulletin. The possibility of exchanging staff for training experiences is present in 11 countries. The centers agreed to develop the network activities through the coordination of 1 main center and another 1 acting as secretariat and to develop the activities through 4 working groups. A pilot experience of the network functioning has already been performed.

**Conclusions:** This initiative will allow MICs of the region of the Americas to better perform their activities potentiating their work through the sharing of bibliographic resources; discussing of particular topics; and exchanging of personnel, information analysis, and new ideas in accordance with their strengths and weaknesses.

**Funding source(s):** PAHO/WHO, National University of Colombia

## 1165

### **Economics, Financing, and Insurance Systems**

*Keywords:* access to medicines; affordability; Cardiovascular diseases; Insurance scheme; rural area

### **Access to Pharmaceuticals among Adults with Cardiovascular Diseases: An Impact of the Free Medicine Policy in Beijing, China**

**Li Yang<sup>1</sup>, Jianjiang Liu<sup>2</sup>, Yonghua Hu<sup>1</sup>, Xun Tang<sup>1</sup>, Liping Yu<sup>2</sup>, Haitao Xu<sup>2</sup>, Wujun Liu<sup>2</sup>, Sushen Wen<sup>2</sup>**

<sup>1</sup>School of Public Health, Peking University, China, Peoples Republic of; <sup>2</sup>Health Bureau of Fangshan District, Beijing, China

**Problem statement:** The implementation of the New Cooperative Medical Scheme (NCMS) has made considerable progress. By the end of 2009, 833 million farmers from 2716 counties are covered by NCMS, accounting for 94.19%. However, existing evidence shows that so far NCMS falls short of achieving the stated goal of assuring affordable access to basic health care, increasing financial-risk protection, and improving health status.

**Objectives:** To determine the availability of pharmaceuticals related to the free-medicine policy among adults with cardiovascular diseases (CVDs) from a gender point of view and evaluate the impacts of this policy on health care utilization and medical spending in Fangshan district, Beijing.

**Design:** Intervention time series (ITS) analysis of NCMS databases of drug use, outpatient visits and costs, patient admissions, and inpatients costs

**Setting and population:** 98,371 rural residents at least 40 years old have been screened for CVDs and 56,363 adults have received drugs for 3 consecutive years in Fangshan district of Beijing, China

**Interventions:** From 2008 to 2010, the rural residents covered by the NCMS have been screened for CVD and those were diagnosed with hypertension, diabetes, coronary heart disease, and stroke have received up to 17 free essential drugs in Fangshan district of Beijing, China.

**Policy:** The screening fees and 17 essential medicine treatments for above 4 diseases were fully covered by the NCMS. The procurement of 17 essential medicines was directly implemented by the NCMS office of the health bureau and delivered by township hospitals and village clinics.

**Outcome measures:** % of patients receiving essential medicine treatments for 4 chronic diseases and outpatient visits, inpatient admission, and total costs before and after the policy. The NCMS data from adults with CVDs were selected in 2 counties where the policy was implemented in 2009 and 2010, separately. The segmented time series regression model was used to assess the impacts of the policy on drug use, outpatient visits and costs, admissions, and inpatients costs.

**Results:** 45.3% rural residents aged at least 40 years have been screened and 85.2% of those with 4 chronic diseases have received free drugs from 2008 to 2010; the NCMS has spent RMB 7.618 million yuan on 17 medicines in the past 3 years. The results of the segmented time series regression model showed that the outpatient visits increased dramatically and the hospital admissions dropped slightly after the free-medicine policy in the intervention county, compared to the control county. There were no significant changes for the outpatient cost and inpatient cost between these 2 counties, but males spent more on health care costs than females.

Conclusions: The need for treatment for 4 chronic diseases was met among most of rural residents with CVDs by the free medicine policy under the NCMS. The accessibility and affordability has improved dramatically and the total medical spending and out of pocket per case hasn't increased yet.

Funding source: Ministry of Education, China

**1168**

### **Economics, Financing, and Insurance Systems**

*Keywords:* Zambia, user fees, drugs, primary health care

#### **Impact of User Fee Removal on Utilisation of Public Health Services in Zambia**

**Felix Masive**

University of Zambia, Zambia

**Problem statement:** Poor access to health care is one of the biggest impediments to improved health in Africa. In Zambia, user fees are considered to be partly responsible for substantial disparities in access to health services. When the Government introduced user fees in 1993, explicit concern was expressed about the adverse effects on utilisation and access. A national exemption policy was designed to protect the poorest sections of the population. However, this was largely ineffective in reaching the majority of the eligible population. On January 13, 2006, the President of Zambia announced a policy to abolish user fees on primary health care in designated rural districts. A number of observers in the Zambian health policy arena were skeptical about the impact of this policy on utilisation and, more importantly, quality of care.

**Objectives:** Evaluate the performance of free primary health care policy in rural Zambia

**Study setting:** This study was based on 54 rural districts of Zambia. Secondary data on the number of visits and availability of drugs were obtained from a national information system that covers all primary health centres in the 54 districts. Within the 54 districts, 2 districts were surveyed for primary data collection on perceptions of quality of care. Only private sector facilities were included in this study.

**Design:** We reviewed data on utilisation of health services at public health facilities, including patient exit polls to determine the quality of services following user fee removal. Availability of basic drugs was a key variable used in assessing quality. Local health stakeholders, health workers, and community health volunteers were interviewed regarding their perceptions of quality and service utilisation.

**Policy:** Zambia reviewed its health care financing policy by abolishing fees on primary health care in designated rural areas of the country.

**Results:** We found that utilization (i.e., visits at public health facilities) increased among the rural population aged at least 5 years by 55%. The poorest districts accounted for the greatest share of the increase in health care utilisation. Further, our patient survey reveals that perceptions of quality of health care remained largely positive. Proportion of patients receiving prescribed drugs for various ailments did not decline. This is in contrast to the experience in other countries. Finally, 2 significant policy actions accompanied user fee removal; first, the government used public funding to compensate districts on loss of user fee revenue; second, the Ministry procured drugs to ensure that anticipated increase in utilisation was matched with availability of drugs.

**Conclusion:** The Zambian example demonstrates how utilisation of health services by the poor can be enhanced using public funding.

Funding source: Network of Equity in Health in Southern Africa

**1172**

### **HIV/AIDS and TB**

*Keywords:* adherence, appropriate use, antiretrovirals, HIV/AIDS, indicators

#### **Adherence to Antiretroviral Medicines Not Emphasized in Global Fund Grants**

**Klara Tisocki, Douglas Ball, Maaïke Esselink, Aryanti Radyowijati, Hilbrand Haak**

Consultants for Health and Development, The Netherlands

**Problem statement:** Grants provided through the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) have significantly increased access to antiretroviral (ARV) therapy (ART) in low- and middle-income countries (LMIC). However, ART requires a high degree of adherence to ensure that it is effective and to minimise development of resistance. Although access to and impact of ART are commonly monitored for GFATM grants, it is unclear whether sufficient attention is paid to monitoring adherence to ART.

**Objectives:** To determine whether indicators for patient adherence to ART are included in monitoring of GFATM grants

**Design:** Descriptive study of adherence indicators from GFATM grants for HIV/AIDS

**Setting:** National and regional GFATM HIV/AIDS grants to LMICs from 2002 to 2009

**Study population:** Recipients of GFATM grants for HIV/AIDS in LMICs

**Intervention/policy:** GFATM grants are monitored through process/output indicators in various service delivery areas (SDAs) and evaluated through outcome/impact indicators. Indicators in the 'treatment: antiretroviral treatment and monitoring' SDA and evaluation indicators relevant to adherence were extracted and assessed.

**Outcome measures:** Number/proportion of adherence indicators, quality of adherence indicators, changes over time

Results: 230 HIV/AIDS grants were identified; based on preliminary analysis of 117 grants containing 247 indicators under the ART treatment SDA, only 1 indicator of actual adherence was used. On average, less than 4% of indicators were related at all to adherence, with the majority of these being measures of persistence on therapy rather than true adherence, e.g., “percent of adults and children with HIV known to be on treatment 12 months after initiation of antiretroviral therapy”.

Conclusion: Adherence to ART is not sufficiently monitored in GFATM HIV grants. Indicators related to true adherence should be included in grants which aim to expand ART access.

Funding source: Information not provided

**1173**

### **Economics, Financing, and Insurance Systems**

*Keywords:* procurement, public sector, medicine prices, good governance, medicine supply

#### **Efficiency of Public Procurement of Medicines in the Philippines**

---

**Klara Tisocki, Douglas Ball**

Health Action International, Consultants for Health and Development, Netherlands

Problem statement: Medicine prices in the Philippines have been relatively high compared to other countries with similar wealth in the region for last 2 decades. In addition, there are long-standing concerns about prices and availability of essential medicines procured by public sector hospitals and local government units (cities, provinces, municipalities).

Objectives: To assess the efficiency of public procurement systems used at various levels of the health care system in the Philippines through evaluation of the procurement prices of a selected basket of essential medicines

Design: Procurement price data for a basket of 50 medicines was collected December 2008 through February 2009 from objectively verifiable document sources (contracts, invoices etc).

Setting: DOH-retained, provincial, and municipal hospitals in 6 different regions of the Philippines

Study population: Total of 5 DOH, 6 provincial, and 5 municipal facilities

Outcome measures: The unit prices were converted to a median price ratio (MPR) by dividing by the unit price from an international reference price (Management Sciences for Health 2007).

Results: DOH-retained hospitals had greater procurement efficiency than provincial and municipal hospitals (summary MPRs 2.2, 3.2, and 3.9, respectively). Although some facilities procured generic essential medicines at prices comparable to international markets, most procurement entities were procuring medicines at levels much higher than the reference prices, e.g., doxycycline, diazepam, and fluoxetine procured at 13–40 times international prices. Extreme variability in the efficiency of public procurement was observed, e.g., ciprofloxacin and doxycycline had maximum procurement prices more than 40 times the minimum observed. Variations were unrelated to procurement volume. Health facilities operating revolving funds had higher availability of medicines but also higher prices.

Conclusion: There is an urgent need to improve efficiency of public sector procurement of medicines through improved transparency and good governance, more efficient management, and enhanced financing in the Philippines.

Funding source: Information not provided

**1175**

### **Policy, Regulation, and Governance**

*Keywords:* pharmacovigilance, resource-poor countries, WHO collaborating centres

#### **Role of the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance on the Establishment of National Centres in Africa**

---

**Alexander Nii Oto Dodoo<sup>1</sup>, Shanthi N. Pal<sup>2</sup>, Sten Olsson<sup>3</sup>, Marie Lindquist<sup>3</sup>, I. Ralph Edwards<sup>3</sup>**

<sup>1</sup>University of Ghana Medical School, Accra, Ghana; <sup>2</sup>World Health Organisation, Geneva, Switzerland; <sup>3</sup>Uppsala Monitoring Centre, Uppsala, Sweden

Problem statement: Very few functional national pharmacovigilance (PV) centres exist in sub-Saharan Africa. This is due to several factors, including shortage of skilled personnel, financial limitations, weak health systems, and low priority for PV in the face of competing priorities. The need for PV systems in all countries is obvious however, especially in the current era in which access to medicines is improving as a result of huge donor inflows to support management of key diseases like HIV/AIDS, tuberculosis, and malaria and also to help in the attainment of the Millennium Development Goals.

Objectives: To examine the influence of a dedicated WHO Collaborating Centre on the establishment of national pharmacovigilance centres in sub-Saharan Africa

Method: In 2009, WHO designated the University of Ghana Medical School as a WHO Collaborating Centre for Advocacy and Research in Pharmacovigilance. The technical arm of the WHO PV programme, the Uppsala Monitoring Centre (UMC), also established an office in Accra (UMC-Africa) with both organisations having the prime objective of providing dedicated support for the establishment of pharmacovigilance centres in Africa. The main interventions undertaken were training and capacity building in pharmacovigilance, drug safety data management, and communication.

Results: A year after the establishment of the Collaborating Centre, the number of countries in sub-Saharan Africa with national PV centres participating as full members of the WHO Programme increased 40% from 15 to 21. Attainment of

technical competence and full WHO PV Programme membership by 5 of these 6 countries was as an immediate and direct result of training and support by the WHO Collaborating Centre and UMC-Africa.

Discussion: Multinational organisations, donor agencies, and global normative bodies can stimulate the setting up of essential health systems and structures, such as national pharmacovigilance centres, by establishing regional centres to provide local support. Such regional centres, by their proximity to countries and understanding of regional problems, would be able to mobilise funds and provide long-term support to ensure sustainability of these centres. The need for earmarked funding for such regional coordinating centres is important to ensure that their activities are not stalled.

Conclusions: Focused interventions and regional support can yield remarkable results in the establishment of pharmacovigilance centres in resource-limited settings.

Funding sources: WHO

**1178**

### **Policy, Regulation, and Governance**

*Keywords:* access to medicines, affordability, essential medicines, pharmaceutical policy, pharmacovigilance

### **Improving Access and Quality Use of Medicines in Palliative Care within National Drug Policy, Regulatory, and Funding Frameworks**

**Debra Rowett<sup>1</sup>, Tania Shelby-James<sup>2</sup>, Simon Eckerman<sup>2</sup>, Janet Hardy<sup>3</sup>, Lynn Weekes<sup>4</sup>, David Currow<sup>2</sup>**

<sup>1</sup>Drug and Therapeutics Information Service, Australia; <sup>2</sup>Discipline, Palliative and Supportive Services, Flinders University, South Australia; <sup>3</sup>Mater Health Services and Centre for Palliative Care Research and Education, Queensland; <sup>4</sup>NPS: Better Choices - Better Health.

Problem statement: There is a growing need for palliative care throughout the world with an ageing world population, an increasing incidence and prevalence of cancer and HIV/AIDS, and progressive advanced chronic illness. However, improving equity of access and quality use of medicines in palliative care is impeded by the limited evidence for efficacy, cost effectiveness, and safety data for medicines commonly used for symptom control.

Objective: Improve access to affordable priority medicines to relieve suffering and symptom burden in palliative care

Methods: Australia has both a National Medicines Policy and a Palliative Care Strategy which provide a policy framework for implementing improved access to and quality use of medicines in palliative care. The work was coordinated by a government auspiced committee, the Palliative Care Medications Working Group. This committee provided a forum for medicines regulators, the pharmaceutical industry, government, policy makers, and clinicians to address the issues of access and quality use of medicines.

Results: A process to support the listing of medicines to manage symptom burden in palliative care through the national public drug reimbursement programme has been established and continues to be expanded where efficacy, safety, and cost-effectiveness criteria are met. Funding has been provided for a national multi-site collaborative clinical study network, the Palliative Care Clinical Studies Collaborative (PaCCSC), to improve the availability of evidence of clinical interventions in the palliative care setting with rigorously designed and performed phase III and IV studies to inform registration and subsidy applications. Symptoms being studied include delirium, complex pain, bowel obstruction, anorexia, breathlessness, constipation, and nausea. The improvement in access has been complemented by strategies to improve quality use through effective industry partnerships, education programs for practitioners (through NPS: Better Choices-Better Health, an independent, not-for-profit organisation), and a broader communication network for the health workforce and community. A rapid reporting pharmacovigilance programme that builds on the work of the PaCCSC has been developed and is being extended into South East Asia and New Zealand.

Conclusion: Regional and global public health programs struggle with the reality of funding disease-modifying therapies and prevention measures while trying to relieve suffering and provide optimal end of life care. This programme of work is contributing to the evidence base to inform policy decisions concerning access and quality use of medicines.

Funding source: Australian Government, Department of Health and Ageing

**1184**

### **Access**

*Keywords:* essential medicine use, primary health care institutions, Beijing

### **Analysis of essential medicine use in primary health care institutions of Beijing**

**Yugin Wang**

Xuanwu Hospital of Capital Medical University, China, Peoples Republic of

Problem Statement: Developing community health care and establish essential medicine system are important methods relieving situation of "difficult to see a doctor and high medical cost" in China. It is also a part of Chinese health care reforms. Pilot policy such as separating revenue from expenditures and drug zero price difference strategy has been implemented in Beijing as early as 2006. China announced a series of health care reform policy in 2009. How about the current situation on drug use in primary health care institutions of Beijing? There are no data now.

Objectives: The objective is to understand the impact of health care reform and national essential medicine policy on drug use in primary health care institutions of Beijing.

Design: The type of study design is policy evaluation. The data from literatures were used as historical control. The historical data refer to drug use information before health care reform in primary health care institutions.

Intervention(s): No interventions were implemented in this study.

Policy(ies): In 2009, China announced several national health care reform policies including essential medicine policy and essential medicine list. Outcome Measure(s): WHO rational drug use indicators were used for prescription evaluation. The key indicators include the proportion of antibiotic, the proportion of injection and the proportion of the essential medicines.

Results: Now 42 sample institutions data and 8400 prescriptions are obtained. 22 samples are urban institutions and 20 samples are rural institutions. The average number of outpatients and emergency patients is 5668 person-time/month. The average prescriptions is 6298 / month. Each institution has 57 staffs on average. The percentage of pharmacy staff is 9.3%. Outpatient drug income accounts for 84.9% of the total outpatient income. The ratio of western medicine to Chinese medicine is 1.34.

8400 prescriptions analysis showed that the average cost per prescription is RMB 156. The proportion of antibiotic is 28.8%, the proportion of the injection is 17.9%, the proportion of the essential medicine is 78.7%. For the 3 indicators (antibiotic, injection and essential medicine proportion), the data from urban institutions are 20.4%, 11.7% and 75.1% and the data from rural institutions are 38.0%, 24.6% and 81.5%.

A 2007 data from literature showed antibiotic indicator and injection indicator are 51.5% and 39.0% in primary health care institutions in some area of China, which is higher than those of this study.

Conclusions: This study indicates that the pilot policy "separating revenue from expenditures" and national essential medicine policy under health care reform is effective in promoting rational drug use in primary health care institutions in China.

**1186**

### **Policy, Regulation, and Governance**

*Keywords:* Medication Errors, intravenous medication, multiple causes, multiple opportunities, reduce the incidence

#### **Medication Errors of Intravenous Medication in Teaching Hospital in China**

---

**Yanqi Chu, Yuqin Wang, Suying Yan**

Xuan Wu Hospital of Capital Medical University, Peoples Republic of China

Problem statement: Intravenous infusion, widely used in hospitals, is an important method for disease treatment and complementary nutrition. It was reported that the usage rate of drugs added during infusion in abroad hospitals is 45–76%, while it is up to 80% or more in China. Application of intravenous infusion is important for patient safety because infusion is a direct way for the liquid entering to blood circulation and reach vital organs in the human body. Although the process of infusion has become standardized gradually with the efforts of medical workers especially nursing staff, it still needs to be further researched for potential risks in the process of drug preparation and infusion. Any unreasonable phenomenon should be avoided and forewarning and prevention measures should be taken. Currently, there is limited literature on systematic observation of safety for application of intravenous medication at home and abroad.

Objective: To find potential risks existing in the process of preparation and infusion of intravenous medication, analyze influencing factors to put forward feasible measures or warning methods to avoid errors during preparation and infusion processes and increase intravenous medication safety

Design: Observations of intravenous medication administration in 5 intensive care units—general surgical ICU, coronary surgical ICU, vascular ICU, neurosurgery ICU, and neurology ICU.

Setting: Observe status of intravenous medication application in Beijing Xuanwu Hospital at the Capital Medical University

Study population: ICU patients

Intervention(s): Intravenous drugs with high usage frequency, high occurrence of errors, and relatively high risk were selected for observation; observed nursing staff in the process of preparation and infusion of intravenous medications

Policy(ies): Describe the essential features of any policy change evaluated, including content and implementation details.

Outcome measure(s): The medication error rate varies from 1% (or even less) to 20%, needed to collect at least 20 findings for each error, so the sample size would be 2000 cases (20/1%).

Results: 748 records of medication administration were collected. The most frequent classification of drugs given in all the intensive care units were anti-infectives. The percentage of medication errors was 13.39%. The most frequently reported error was wrong dose, wrong drug, wrong route, and wrong time. No errors were reported that involved giving medications to the wrong patient.

Conclusion: These data show that there are both multiple causes for medication administration errors and multiple opportunities for system checks that may help reduce the incidence of these errors.

Funding sources: Information not provided

**1189**

### **Policy, Regulation, and Governance**

*Keywords:* corruption, ethics, legislation, pharmaceutical policy, regulation

## WHO Good Governance for Medicines Programme: Innovative Approach to Curb Corruption in the Pharmaceutical Sector

Guitelle Baghdadi-Sabeti<sup>1</sup>, Mohamed Ramzy Ismail<sup>2</sup>

<sup>1</sup>WHO-HQ, Geneva, Switzerland; <sup>2</sup>WHO-EMRO, Cairo, Egypt

**Problem statement:** Corruption is increasingly recognized as a major impediment to reaching the Millennium Development Goals and to strengthening health systems. The health sector is an attractive target for corruption, with USD 5.3 trillion spent on health services each year and a global pharmaceutical market value of USD 750 billion. Corruption negatively affects access and quality of health care. It endangers the health of entire communities, wastes resources, and destroys public trust.

**Objectives:** To address this challenge, WHO launched the Good Governance for Medicines (GGM) programme. Its goal is to contribute to health systems strengthening and to prevent corruption by promoting good governance in the pharmaceutical sector.

**Design and interventions:** The programme assists countries through a 3-step process of assessing their vulnerabilities to corruption and developing and implementing specific programmes to maintain efficient health care systems that are not undermined by the abuse of corruption. The first step involves a nationwide study on transparency and vulnerability to corruption in the pharmaceutical sector using WHO methodology. The national assessment emphasizes the system's actual structures, particularly the mechanisms to prevent unethical practices and the administrative procedures to measure transparency and accountability. It also looks at how different procedures and mechanisms are known by those involved in the pharmaceutical sector. Elements targeted include country regulations and official documents; written procedures and decision-making processes; committees, criteria for membership, and declaration of conflict of interest policy; and appeals mechanisms and other monitoring systems.

**Setting:** The willingness of governments to implement the GGM has exceeded initial expectations. Starting in 2004 as a pilot project in 4 Asian countries, the GGM rapidly became a global programme operating in 31 countries.

**Results:** After 6 years of implementation, successes are visible in countries. Medicine procurement practices have been enhanced, leading to lower costs for medicines and pharmaceutical services; information is publicly available on Ministry of Health websites; management of conflicts of interest has been implemented; legislation has been updated to ensure more transparency and accountability; and a culture of transparency is emerging.

**Conclusions:** Momentum for change is increasing and good governance often becomes one of the top priority items on Ministries' agendas. Many challenges remain, but availability of evidence on areas of national pharmaceutical systems that are more vulnerable to corruption has led to positive change in several participating countries. More information and references can be found at <http://www.who.int/medicines/ggm>.

**Funding source(s):** AusAID, BMZ, DFID, European Commission, State of Kuwait, and WHO

1190

### Chronic Care

**Keywords:** potentially inappropriate medication, elderly, high-risk medication, drug utilization

## Prevalence of and Factors Associated with Potentially Inappropriate Medications Use in the Elderly Population in Thailand

Rosarin Srumsiri<sup>1</sup>, Nathorn Chaiyakunapruk<sup>1,2,3</sup>, Napawan Jeanpeerapong<sup>4</sup>

<sup>1</sup>Center of Pharmaceutical Outcomes Research, Department of Pharmacy Practice, Faculty of Pharmaceutical Sciences, Naresuan University, Phitsanulok, Thailand; <sup>2</sup>School of Population Health, University of Queensland, Brisbane, Australia; <sup>3</sup>School of Pharmacy, University of Wisconsin-Madison, Madison, WI, USA; <sup>4</sup>Department of Pharmacy, Buddhachinaraj Hospital, Muang, Phitsanulok,

**Problem statement:** The elderly population are vulnerable to medical misadventures, as they change in both pharmacokinetics and pharmacodynamics and become disabled and dependent. Older people are more likely to take several medications to treat concomitant diseases and therefore may have an increased risk of adverse drug reactions (drug-drug and drug-disease interactions). Improving prescribing quality in the elderly means reducing inappropriate prescribing, thereby resulting in better health outcomes. It is important to examine the magnitude of potentially inappropriate medication (PIMs) use among elderly and identify factors associated with inappropriate use.

**Objective:** To determine the prevalence and factors associated with PIMs in the elderly population in Thailand

**Design:** Retrospective descriptive study

**Setting:** We retrospectively examined an electronic patient database in a provincial hospital.

**Study population:** Patients aged 65 years or older who visited the outpatient department in 2008 were included. The outpatient pharmacy database, patient demographic database, and diagnosis database containing ICD-10 were linked using a hospital number.

**Intervention:** We adopted the criteria for high-risk medication use that was developed by Winit-Watjana and colleagues. The criteria identify PIMs in the Thai context using delphi technique and geriatric medicine expert consensus.

**Outcomes measure:** Descriptive statistics were used to describe patients' demographic and determine the prevalence of PIMs among them. Factors associated with the use of PIMs were evaluated using generalized estimating equations.

**Results:** Of 14,994 elderly patients included in this study, 58% were prescribed at least 1 PIM. The most common PIMs, which are rarely appropriate for elderly patients, were NSAIDs (17%). NSAIDs prescribing with peptic ulcer patients (5%) and NSAIDs prescribing with aspirin (8%) were the most prescribed pairs of drug-disease and drug-drug

interaction in elderly Thai patients. The adjusted odd ratio of receiving PIMs was more than triple in elderly patients taking 6-9 medications compared with taking < 5 medications; for more than 10, the value was 6 times. There was an increasing trend of PIMs in patients with higher morbidities (adjusted OR, 5.04; 95% CI, 4.69 – 5.51 for Charlson's co-morbidities index [CCI] score of 2-3 and adjusted OR, 8.78; 95% CI, 8.86 – 8.90) for CCI > 4, compared to CCI 0-1. PIMs are also a problem for patients with universal coverage (adjusted OR, 1.77; 95% CI, 1.72 – 1.82) and those under the care of prescribers in training (residents or interns; adjusted OR, 1.95; 95% CI, 1.81-2.11).

Conclusions: The prevalence of PIMs in the elderly population was high. Both individual and system factors were associated with PIMs. Careful management is needed especially among those with co-morbidities. Future research is needed to target extended, clinical practice and policy implementation to reduce PIMs.

Funding source: No funding

1191

### **Economics, Financing, and Insurance Systems**

*Keywords:* health insurance, access to medicine, pharmaceutical policy, pricing

#### **Pharmaceutical Policies Used by Private Health Insurance Companies in Saudi Arabia**

**Saleh Abdullah Bawazir, Abdullah S. AlHumaidan, Larry Sasich, Mohammed Alkudsi, Maher Aljaser**

Saudi Food and Drug Authority, Saudi Arabia

**Problem statement:** During the last decade, the health care system in the Kingdom of Saudi Arabia (KSA) has undergone the process of restructuring in order to develop a for-profit, private sector of health insurance for all citizens. The extent to which this restructuring has impacted the accessibility and price of pharmaceuticals now and in the future remains unknown. Under existing Saudi law, Saudi citizens have free access to health care. A national debate continues with regard to the advisability of changing from a totally public system to a system that includes participation by private, for-profit health insurance companies. Currently, the Council of Cooperative Health Insurance (CCHI) is the body responsible for regulating health insurance in the KSA. Although the cooperative health insurance schedule (i.e., model policy for health insurance) is available on the CCHI Web site, policies related to pharmaceuticals are ambiguous.

**Objectives:** The primary objective of this study was to assess the impact of health insurance policies provided by health insurance companies in KSA on access to medication and its use.

**Design:** This study was descriptive in design and used a survey, which was administered through face-to-face interviews with the medical managers of health insurance companies.

**Setting:** This study was national in scope. The interview process was conducted at the insurance company site or at the Saudi Food and Drug Authority (SFDA).

**Study population:** All 25 insurance companies accredited by CCHI were eligible for the study. Out of these 25 companies, 3 were excluded from this survey as no response was received. A third-party administrator represented 7 out of the 22 companies, and these 7 companies used identical insurance policies. As result, the total number of the companies counted and enrolled in the survey was 16.

**Results:** All 16 companies responded "yes" that they have a prior authorization policy; however, the reasons were varied; 8 (50%) of the companies were concerned with the duration of treatment. The result showed that 10 (62.5%) of the companies do not offer additional coverage beyond what the CCHI model policy offers; however, the other 6 (37.5%) companies reported that they can reconcile certain conditions. The survey also demonstrated that 10 of the companies allowed refilling of medication, but with some limitations. In other words, 6 out of the 10 restrict refilling to 3 months as a maximum time and the other 4 companies have no limits on refills. The other 6 companies rejected allowing refills without a prescription.

**Conclusion:** Although this paper was primarily descriptive, the findings revealed a substantial scope for improvement in terms of pharmaceutical policy standards and regulation in health insurance companies in the KSA. Additionally, the study highlighted other areas that affect the overall quality use of medication, such as overprescribing and irrational use of medication. Further research, thus, is definitely reasonable and needed.

Funding source: Saudi Food and Drug Authority, Riyadh, Saudi Arabia

1193

### **Policy, Regulation, and Governance**

*Keywords:* WHO-GGM, Macedonia, development, current status

#### **Development and Current Status of the National Good Governance for Medicines Initiative in Macedonia**

**Renata Slaveska Raichki<sup>1</sup>, Arta Kuli<sup>2</sup>**

<sup>1</sup>Faculty of Pharmacy, Macedonia, Republic of; <sup>2</sup>WHO Regional office, R.Macedonia

**Problem statement:** International professional analysis and evidence have revealed that the pharmaceutical sector is particularly vulnerable to corruption and unethical practices, which manifests itself in various forms. In response to these challenges, WHO initiated Good Governance for Medicines (GGM) in line with the recent WHO Global Medicines Strategy. The core goal of the GGM is to support countries in maintaining efficient health care systems through the implementation of transparent, accountable administrative procedures in medicines regulatory systems and supply chains, supported by the promotion of ethical practices among health professionals.

**Objectives:** Macedonia, recognizing the concept of the GGM as one of the priorities of the Medicines Strategy joined the project at the end of 2007. This study describes how the recommended 3-step structured approach has been carried out as a model to establish GGM at the national level.

**Design and settings:** Within the first-stage of a 3-step structured GGM, an assessment measuring the transparency of national medicines regulatory agencies and public procurement systems was conducted. The transparency assessment report served as an entry point for phase II. In phase II, the focus was placed on the development of a national GGM framework document. Phase III aims to implement the national GGM through a set of officially adopted long term, strategic activities that will ensure sustainability of the developed GGM.

**Study population:** The choice of key informants from both public and private sectors were carefully selected according to explicitly defined criteria.

**Policies:** Considerable progress has been achieved in endorsing new regulations, policies, and procedures after the acceptance of the national assessment report on measuring transparency in medicines registration, promotion, selection, procurement, inspection, and distribution.

**Outcome measures:** To improve transparency of the national pharmaceutical sector, a range of topics within each pharmaceutical function were identified as worthy of development and building for the future. **Results:** The transparency assessments presented the evidence for the country to revise and adjust its laws and policies and its administrative structures and processes to ensure transparency in medicines regulation and public procurement processes. The assessment also provided a platform for discussion at the national level on developing an ethical framework and for implementing strategy promoting GGM.

**Conclusions:** The GGM has been undoubtedly identified as indispensable for preventing corruption in the pharmaceutical sector. Its main aims are to establish transparent procedures related to the whole spectrum of the pharmaceutical sector, minimize corruption, and promote access to safe and good quality medicines.

**Funding source:** WHO

**1197**

#### **Policy, Regulation, and Governance**

*Keywords:* Pharmacotherapy committees. Capacity building.

#### **Regional Strengthening of Pharmacotherapeutic Committees**

**Perla M. de Buschiazzo<sup>2</sup>, Héctor Buschiazzo<sup>2</sup>, Gustavo Marín<sup>2</sup>, Soledad Carlson<sup>2</sup>, Martín Cañas<sup>2</sup>, Christian Doratti<sup>2</sup>, Adriana Ivama<sup>1</sup>, James Fitzgerald<sup>1</sup>, José Luis Castro<sup>1</sup>**

<sup>1</sup>PAHO/WHO, United States of America; <sup>2</sup>CUFAR (PAHO/WHO collaborating Centre)

**Problem statement:** Though many countries in the region of the Americas have developed an Essential Medicines List (EML) or National Formulary (NF) there is a need of improving the quality and strengthening capacities for applying evidence based criteria and operational procedures for the selection process. Along the last 2 years PAHO/WHO with the collaboration of the CUFAR center supported countries to achieve this goal through an online/workshops combination strategy.

**Objectives:** To support the countries of the Region of the Americas in building capacities for the evidence based selection of medicines, update or design of EML and NF.

**Design:** Two types of workshops with different complexity levels, a distance learning course with five modules and a follow up phase were implemented as agreed with the countries according to their needs.

**Setting:** The activities involved members of the national and local pharmacotherapy committees. The online course was regionally implemented and the workshops took place at each country.

**Study population:** The participants were selected in agreement with the country health authorities.

**Intervention(s):** A flexible approach to country needs included two workshops and whenever possible the participation in an online training. The first workshop had basic contents about criteria for information and medicines selection and was aimed at professionals dealing with the topic and representatives of health institutions of the country. The online training was developed during 5 months and among the contents a manual of procedures for the pharmacotherapy committees was discussed. A second workshop was aimed at members of the pharmacotherapy committees to develop the selection process including an example of their own list were available. As an optional step the collaborating center (CUFAR) proposed in many cases a draft Formulary to be evaluated and discussed by the committee.

**Policy(ies):** These activities had increase awareness about the role of pharmacotherapy committees among Health authorities. The need for changes in the policies for the lists and formularies implementation is also discussed as part of the activities in participating countries.

**Outcome measure(s):** Countries and professionals participating in the activities; lists/formularies updated or designed with the proposed criteria.

**Results:** More than 200 professionals from twelve countries participated in the workshops and 6 countries and 124 professionals participated in the online training. Through this cooperation 6 countries updated the national EML. The systematic approach with the online workshops training will be continued next year and will be complemented with a performance evaluation of the committees.

**Conclusions:** The offer of a flexible and comprehensive combined online-workshops strategy has shown to be a good approach for building capacity or strengthening the available human resources of pharmacotherapy committees.

**Funding source:** PAHO/WHO, National governments, USAID deliver

1198

### Drug Resistance

*Keywords:* Antibiotic utilization, survey.

#### **Estimation of Antibiotic Utilization Patterns in 4 Latin-American Countries**

**Gabriel Levy Hara<sup>2</sup>, Sergio Muñoz<sup>3</sup>, Mauro Silveira de Castro<sup>4</sup>, Azucena Montenegro<sup>5</sup>, María Elena Berríos<sup>1</sup>, Georgina Nazar<sup>6</sup>, Isabel Seaman<sup>1</sup>, Zully Vera<sup>7</sup>, Javier Uribe<sup>1</sup>, María Oyola<sup>8</sup>, Julio Maycas<sup>9</sup>, José Luis Castro<sup>1</sup>**

<sup>1</sup>PAHO/WHO; <sup>2</sup>Universidad Maimónides, Argentina; <sup>3</sup>Universidad de la Frontera, Chile; <sup>4</sup>Universidad Federal de Río Grande do Sul, Brazil; <sup>5</sup>Universidad de León, Nicaragua; <sup>6</sup>Consultora; <sup>7</sup>Universidad Nacional de Asunción, Paraguay; <sup>8</sup>DIGEMID, Perú; <sup>9</sup>Consultor

**Problem statement:** The misuse of antibiotics (ATB) is a well-known problem and potential solutions are complex. It is important to know the amount, pattern and characteristics of the antibiotic utilization in a country to better address policies to improve it.

**Objectives:** To estimate the prevalence of ATB consumption, the different patterns of its use, and the main reasons for misuse and its proportion

**Design:** We performed 2 surveys – 1 at household (HS) and another at point of sales (PS)- and a study using ATC/DDD methodology in Nicaragua, Honduras, Paraguay and Peru.

The study was carried out sequentially in the 4 countries between August 2005 and April 2008. In each country both HS and PS surveys were performed in parallel stages. The sample consisted in 64 conglomerates made up of 20 HSs. The study was conducted at national level with more than 3,100 interviews at PSs and 1,200 HS interviews. The DDD study was performed by extracting data from the International Marketing Services.

**Setting:** HSs and PSs of medicines of representative regions of Nicaragua, Honduras, Paraguay and Peru.

**Study population:** The universe studied consisted in representative areas grouped according to health indicators that included 70% of the population of each country.

**Intervention(s):** To determine the proportions of ATB that were misused, an algorithm was designed taking as reference regional and international guidelines. Based on this algorithm, reasons for inadequate use of ATB were grouped in 3 categories: lack of indication (the reason described by the interviewed didn't merit its use), incorrect indication (the drug selected was inadequate to treat the described reason) and incorrect length of treatment.

**Outcome measure(s):** Countries and professionals participating in the activities; lists/formularies updated or designed with the proposed criteria

**Results:** The HS involved 5,557 persons in Nicaragua, 5,381 in Honduras, 5,724 in Paraguay and 5,305 in Peru. Both surveys and the DDD study showed similar results regarding prevalence of consumption among the interviewed people. The prevalence was: Nicaragua 21.5%, Honduras 16.7%, Paraguay 14.9% and Peru 27.3%. Amoxicillin was by far the most used ATB in the four countries (HS: between 46.6% in Honduras and 67% in Paraguay; PS: between 26.7% in Nicaragua and 52.5% in Paraguay; IMS: between 1.51 DDD/1,000 habitants/day in Honduras and 3.77 DDD/1,000 habitants/day in Peru). The total ATB sales according to IMS were between 4.5 DDD/1,000 habitants/day in Honduras and 9.2 DDD/1,000 habitants/day in Peru. According to the applied algorithm in the HS survey the proportions of ATB misused was: 58.7% in Nicaragua, 67% in Honduras, 59.2% in Paraguay and 71.9% in Peru while in the PS survey: 54.5% in Nicaragua, 55.7% in Honduras, 55.8% in Paraguay and 71.7% in Peru. The main general cause of estimated misuse was the lack of need of antibiotic indication (Over 40% in the HS survey in the four countries) and in the PS sore throat was the leading cause (between 19.5% in Paraguay and 34.1% in Honduras).

**Conclusions:** The identification through these complementary interventions of the estimated patterns of misuse of antibiotics including prescription factors allows focusing in alternatives for improving the situation. A first step was the development of an on-line free access course about rational use of antibiotics at the first level of care. Other interventions have been proposed and are under discussion with Health authorities.

**Funding source:** PAHO/WHO, USAID

1199

### Child Health

*Keywords:* appropriate use, consumers, education, patient safety, quality assurance

#### **Impact of IT based Promotion of Rational Use of Medicine in Indonesia**

**Purnamawati Sujud Pujiarto, Arifianto Arifianto, Yulianto Santoso Kurniawan, Windhi Kresnawati**

Concern & Caring Parent Foundation, Indonesia

**Problem statement:** Doctors routinely prescribe mixtures of potent antibiotics and medicines with potentially serious side effects for common viral illnesses. Parents lack access to health information and support.

**Objectives:** To evaluate the impact of IT-based health education on parents' knowledge and behavior related to use of drugs for fever, URI, and acute GE

**Design:** Data of illness-prescriptions collected before-after intervention (written materials, recommended links, and discussion boosters on the mailing list, e.g., QA and discussion articles); we evaluate changes in knowledge related to the 3 conditions, use of drugs, and patient-doctor interactions and changes in behavior in managing those 3 conditions; using pre-post questionnaires, prescriptions and consumed medicines

Setting: Jakarta 2010

Study population: Members of our mailing list from Indonesia

Results: Sample (197); Internet access: 52.3% (office), 34.5% (cell phones); membership: 22.8% < 6 months, 43.6% for 6-24 months, 19.8% for 2-3 years, 6.6% >5 years; knowledge (before-after): understanding: fever 6.6% vs 53.8%; URI 18.3% vs 100%; GE 14.2% vs 98.5%; ORS 3% vs 70%; antibiotics 3% vs 97%; the meaning of medical consultation: 23.7% vs 76.2%.

Changes (improvement) of knowledge: fever: importance of fluid 2.5% vs 98.5%; proper use of anti-fever 21.3% vs 93.9%; URI: expectorant anti-tussive use 75.6% vs 0%; bronchodilator 67.3% vs 2.3%; acute GE: anti-diarrhea 48.7% vs 0.5%; anti-emetic 20.2% vs 0%; ORS 8.6% vs 94.4%; seeking info about the diagnosis 19.3% vs 97.9%. Changes of behavior related to use of drugs: decreased consumption of pooier during 3 conditions: fever 76.8% vs 2.1%; URI 79.7% vs 1.5%; GE 41.0% vs 1.6%; antibiotic: URI 64% vs 3%, GE 40% vs 1%, fever 87% vs 6%; Changes of behavior related to doctor consultation: asking diagnosis-treatment 19.8% vs 92.4%; consultation: 95.4% are <10-20 minutes (35.0% < 5 minutes); after intervention, 59% of 10–30 minutes, 14% of > 30 minutes; annual visit: none 10% vs 47%; 3–6 visits 34% vs 5%; 7 – 12x 14% vs 1%; changes of behavior related to drug in formation: seeking info: from doctors 17% vs 24%; Internet 6% vs 64%, did not seek 34% vs 8%; asking indication-contraindication 14.7% vs 87.8%; giving medicine without seeking information 61.4 vs 15%

Conclusions: Promoting RUM through active interaction in a health based mailing list can be used as a new approach.

Funding sources: This is an independent study. This study is also part of our operational activities; therefore, any expenses are covered by our budget.

## 1202

### Policy, Regulation, and Governance

*Keywords:* Pharmacy Management Information System (PMIS), service provision, performance tracking

#### **Use of an Indicator-Based System for Assessing, Monitoring, and Improving Pharmacy Practice**

**Jennie Lates<sup>1</sup>, Victor Sumbi<sup>2</sup>, Dawn Pereko<sup>3</sup>**

<sup>1</sup>Ministry of Health and Social Services (MoHSS); <sup>2</sup>Management Sciences for Health/Strengthening Pharmaceutical Systems (MSH/SPS); <sup>3</sup>Management Sciences for Health/Strengthening Pharmaceutical Systems (MSH/SPS)

Problem statement: An assessment by the Ministry of Health and Social Services (MoHSS) in 2004 identified the unavailability of routine data to monitor and improve pharmaceutical services as well as inform decision making and planning at all levels of the health system. The assessment identified a need to empower district and regional management teams to identify and address their shortcomings in the delivery of pharmaceutical services.

Objectives: To implement a Pharmacy Management Information System (PMIS) that can provide data for planning and decision making at hospital, regional, and national levels.

Setting: Following a comprehensive consultative process, the PMIS was introduced at all public hospitals in Namibia in October 2007 with the intention of rolling out at a future date to primary health care facilities.

Interventions: The main activities carried out to set up the PMIS were (1) development of the system through an all-inclusive consultative process; data collection tools, data collection and reporting schedules and systems for upward reporting and provision of feedback were established; (2) training regional pharmacists who then trained their pharmacy staff on the PMIS; (3) strengthening therapeutics committees to implement interventions to address gaps identified through PMIS; (4) implementation of the system through on-going data collection, analysis, and use at district, regional, and national levels; and (5) provision of feedback through quarterly PMIS reports at the national level.

Results: The PMIS was formally launched in July 2007; accomplishments to date include (1) all 35 hospitals in the public sector have been producing timely PMIS reports submitted through the 13 regional directorates; (2) a national database has been developed for tracking performance by all hospitals in the various areas of pharmacy service provision since October 2007; (3) PMIS data and results are discussed at district and regional therapeutic committees, and interventions aimed at improving services are designed and implemented. Notable results include development and use of a medicine list that shows brand and generic names of essential medicines has improved generic prescribing in Ohangwena region; rational medicine use trainings carried out in Kunene region to address prescribing problems identified using PMIS data (polypharmacy, inappropriate antibiotic prescribing); improved inventory management across the country as reflected by the increased percentage of stock cards with a balance that is equal to the physical stock (75.6% in December 2007 to 94.5% in April 2010); use of PMIS workload data to successfully advocate for additional pharmacy staff in the Hardap region as well as to guide allocation of dispensing equipment to hospitals.

Conclusions: Implementation of a PMIS leads to availability of critical information that can be used to guide decision making and to improve various aspects of pharmacy service provision including rational medicine use and inventory management.

Funding sources: USAID Namibia and MoHSS, Government of Republic of Namibia

## 1203

### Economics, Financing, and Insurance Systems

*Keywords:* health insurance, antiretrovirals, medicine prices, private sector

#### **Cost of ARV Medicines in the Namibian Private Sector: Limitation to Increased Access**

**Jennie Lates<sup>2</sup>, Dawn Pereko<sup>3</sup>, Tiaan Serfontein<sup>4</sup>, Els Bindels<sup>5</sup>, Frank Feeley<sup>1</sup>, Wessels Afrikaner<sup>6</sup>**

<sup>1</sup>Boston University School of Public Health, United States of America; <sup>2</sup>Namibia Ministry of Health and Social Services; <sup>3</sup>Management Sciences for Health; <sup>4</sup>Medscheme Namibia; <sup>5</sup>Pharmaccess Namibia; <sup>6</sup>Namibian Association of Medical Aid Funds

**Problem statement:** Namibia has a substantial health insurance industry (covering about 18% of the population) as well as a major HIV epidemic (estimated adult prevalence ~18.8%). Insurers in the country have experimented with low-cost primary care health policies that include coverage for antiretroviral therapy, but uptake has been relatively low, increasing the proportion of the population insured by less than 1%. Almost half of formal sector workers still have no health insurance. Medicine costs are rising rapidly for insurers—from 20% of medical claims in 2008 to 35% in 2009. Costs for antiretroviral medicines in the private sector in Namibia are relatively high, raising the costs of the ART benefit in these low-cost policies. Treatment of HIV and AIDS is a national priority. The majority of clients receiving ART do so through the public health sector. Currently, over 95,000 clients receive ART at public health facilities, and this puts a huge strain on the public health sector. As a result Namibia is looking at ways that private health sector resources can be utilised in the fight against HIV/AIDS.

**Objectives:** The overall objective is to determine ways in which Namibia can increase the involvement of the private health sector in management of the HIV/AIDS epidemic. The specific objective of this study is to determine whether reducing the cost of ARVs in the private sector may have a significant effect on cost of ART provision in the private sector.

**Methods:** Using claims data from 1 private health insurer, we determined the normal cost at wholesale and retail levels for standard ART regimens within the national guidelines. These costs were then compared to the costs paid by the Ministry of Health and Social Services for similar regimens. Data from 1 low-cost private insurance plan was also reviewed from all clients on ART to assess the medicine costs as a proportion of total annual ART costs in a private insurance plan.

**Results:** Public sector costs for typical regimens were 35% to 72 % below costs at the wholesale level in the private sector. With the addition of the current retail markup, the annual cost of ART paid by private insurers is USD 202 to USD 1,510 per year, 54 % to 257% higher than costs for the same regimens in the public sector. In the low-cost private insurance plan studied, medicines accounted for 42% of the total annual cost of treatment for patients on ART.

**Conclusions:** The cost of ARVs in the private sector is much higher than in the public sector, and this cost contributes a large proportion of the cost of providing ART in the private sector. Therefore, providing ARVs at lower cost in the private sector has clear potential to make health insurance more affordable and thus increase the accessibility of low cost health insurance.

**Funding sources:** United States Agency for International Development (USAID)/Namibia

## 1204

### Child Health

*Keywords:* appropriate use, medication errors, patient safety, prescribing, community

### Compounding Polypharmacy Prescription in Indonesia

**Purnamawati Sujud Pujiarto, Arifianto Arifianto, Farian Sakinah, Yulianto Santoso Kurniawan**

Concern & Caring Parent Foundation, Indonesia

**Problem statement:** The WHO-EML stated that “the custom in some places is to treat sick children with a mixture of several medicines (‘puyer’), not necessarily all appropriate to their needs. Adult solid dosages forms are mixed together, ground to a powder, and the powder divided into assumed pediatric doses then dispensed for administration to the child. The Committee recommended that this irrational practice should not be used.” However, resistance to change is very strong.

**Objective:** To study the “puyer” prescribing for children diagnosed with 4 viral infections (antibiotic not needed)—URI, fever, acute cough (without fever and signs of URI), and acute GE; and to see the change of “puyer” and types of medicine consumed after being educated

**Method:** Intervention (done by doctors-trainers): written materials, focus discussion groups[Cmnt:1] (6 months, 3 weekly meetings), “boosters” through the mailing list; pre-intervention, participants submit prescriptions, data of illness-consumption of puyer, questioner

**Setting:** Jakarta, 2004-2006

**Study population:** Members of our mailing list from Indonesia

**Result:** 160 eligible e-mails; pre-post intervention, puyer prescribed 67.4%-24.7% and consumed 65.4% vs 4%, respectively; the most prescribed were antibiotic, steroid, antipyretic, and antihistamines, which changed significantly post intervention. URI: median of medicines was 5, maximum 8, puyer 77.4%; fever: median 4, maximum 8 medicines, puyer 72.6%; diarrhea: median 3, maximum 7 medicines, puyer 55.4%; cough: median 4, maximum 11 medicines, puyer 87.0%; generic for URI, fever, acute GE, and acute cough 16.9%, 9.7%, 3.6%, and 18.4%, respectively; pre-post intervention, types of medicine: (1) antibiotic for URI 64.6% vs 3.8%; GE 40.9% vs 1.7%; fever 87.3% vs 6.4%; coughs 46.3% vs 5.2%; (2) ORS for GE 4.6% vs 68.7%; (3) antitussive-mucolytic 86.9% vs 21.2%; knowledge 7.4% vs 96.2%; seeking information 23.2% vs 96.4%

**Conclusion:** Puyer opens a window toward irrational polypharmacy that is potentially harmful and costly. Consumer education is important to reduce irrational polypharmacy puyer and to improve patient safety.

**Funding source:** This study was part of our daily operation; therefore, expenses were covered by our foundation's own budget. This study is independent and has no connection with other parties which may cause a conflict of interest.

1206

**Drug Resistance***Keywords:* Rational medicines use, Outcome, education, AMR, Ethiopia, Telephone interview**Outcome of the Live ETV Education on Rational Use of Medicines****TENAW Andualem Tadege<sup>1</sup>, Mengistab W Aregay<sup>2</sup>, Habtamu Birhanu<sup>3</sup>**<sup>1</sup>SPS/MSH Ethiopia; <sup>2</sup>FMHACA Ethiopia; <sup>3</sup>ERTA Ethiopia

**Problem statement:** Irrational medicines use leads to increased morbidity and mortality, costs, and antimicrobial resistance (AMR). Knowledge on and appropriate use of medicines are far from being achieved. WHO recommends using the media to promote RMU.

**Objective:** To assess the outcome (recall and understanding) of the live RMU intervention

**Design:** Qualitative outcome evaluation of the live RMU education

**Setting:** Evaluation of the outcome of the Ethiopian television audience education on RMU

**Intervention:** A one-hour live RMU intervention was transmitted through Ethiopian television (ETV) on Saturday, October 30, 2010 and repeated later. The journalist and the audiences asked questions to which the speakers responded to help the public grasp RMU in general and antimicrobials in particular. This was followed by a rapid assessment a few weeks later. A random sample of mobile telephone numbers selected and interviewed the audiences.

**Outcome measure:** Respondents' recall and correct understanding of the message from the live RMU education transmitted through ETV

**Results:** A total of 40 respondents were interviewed through their mobile telephones. Of the total, 35/40 (87.5%) had watched the live rational medicines use education. Among those who watched the live transmission, 32/35 (91.4%) were non-health care professionals and 3/35 were (8.6%) health care professionals. All of the respondents recalled and correctly understood 2 or more RMU messages from the education program including the type, magnitude, and impact of irrational medicines use; role of the public/patients in promoting rational medicines use; the importance of consumers telling their medicines use history to health care providers; information that consumers should receive with their medicines; drug interactions; that antimicrobials are not to be used for tekmat (watery diarrhea) and gunfan (common cold); that infection prevention and proper antimicrobial use reduces AMR; and that some illnesses may not require medicines.

**Conclusion:** A large proportion of randomly chosen people had viewed the RMU educational show on live television. The education program was successful and resulted in respondents recalling and understanding at least 2 relevant messages. This finding has paved the way for new approaches in promoting RMU. Audiences suggested using television to address more specific topics to educate and empower the population about RMU.

**Funding source:** No fund is involved

1208

**Chronic Care***Keywords:* Chronic diseases, Access to Medicines**Evidence on the Use of Medicines to Treat Chronic Diseases from Household Surveys in Seven Low- and Middle-Income Countries****Brian Serumaga<sup>1</sup>, Dennis Ross-Degnan<sup>2</sup>, Maryam Bigdeli<sup>3</sup>, Robert LeCates<sup>2</sup>, Anita Wagner<sup>2</sup>, Catherine Vialle-Valentin<sup>2</sup>**<sup>1</sup>University of Nottingham, United Kingdom; <sup>2</sup>Department of Population Medicine, Harvard Medical School/Harvard Pilgrim Healthcare Institute, USA; <sup>3</sup>Alliance for Health Policy and Systems Research, World Health Organization, Switzerland

**Problem statement:** Evidence about treatment of chronic diseases in the community is lacking in most low- and middle-income countries.

**Objectives:** To generate reliable and standardized evidence about the use of medicines for chronic diseases at the community level. Specific aims are to describe patterns of use and costs of medicines for chronic diseases in households and to identify key predictors of adherence to treatment. A secondary objective is to compare the age-specific prevalence of chronic diseases reported by households with published rates.

**Design:** Descriptive, cross-sectional analysis of survey data

**Setting:** Household surveys conducted in Gambia, Ghana, Jordan, Kenya, Nigeria, Philippines, and Uganda between 2007 and 2009 using a survey instrument developed by the World Health Organization (WHO) to monitor country pharmaceutical situations at the community level.

**Study population:** Households were selected by multistage cluster sampling (900 to 1,080 households per country). Study population consisted of 2,457 household members reporting a chronic disease; data were collected on all members in the household reporting a chronic illness in five surveys (Ghana, Jordan, Kenya, Philippines, Uganda) and only on the oldest sick member in two surveys (Nigeria and Gambia).

**Outcome measure(s):** Prescription of medicines for chronic diseases (overall, and for subgroups reporting hypertension and diabetes), use of medicines as recommended.

Results: 2,457 households reported at least one chronic disease; 40.5% of persons with chronic disease had hypertension, 18.1% diabetes, 12.4% asthma or chronic respiratory disease, and 15.3% arthritis or chronic body pain. The percentage of households keeping some medicines at home was higher for households reporting a chronic disease (66.5% vs. 30.3%). 43.6% of individuals with hypertension and 59.8% of individuals with diabetes had been told to take medicines, but only 31.1% and 45.1% took them as directed. The median number of medications received by chronically ill individuals was 2 (interquartile range 1). The most frequently prescribed medicines were bendrofluazide for hypertension and glibenclamide for diabetes. Monthly out-of-pocket cost to treat hypertension and diabetes varied widely across countries (from \$1.50 to \$116.60 for hypertension and \$4.00 to \$204.60 for diabetes). Adjusted multivariate analyses are under way to identify predictors of adherence to treatment for hypertension and diabetes.

Conclusions: Our results provide direct evidence about use of medicines for chronic diseases in the community in low- and middle-income countries.

Funding source(s): The WHO Department of Essential Medicines in Geneva organized and funded data collection, with support from the Medicines Transparency Alliance. The Alliance for Health Policy and Systems funded the analysis.

1209

### **Economics, Financing, and Insurance Systems**

*Keywords:* access to medicines, affordability, generic (multisource) medicines, intellectual property, medicine prices

### **A Win-Win Solution? Critical Analysis of Tiered Pricing to Improve Access to Medicines in Developing Countries**

**Suerie Moon<sup>1,2</sup>, Elodie Jambert<sup>1</sup>, Michelle Childs<sup>1</sup>, Tido von Schoen-Angerer<sup>1</sup>**

<sup>1</sup>Medecins Sans Frontieres, Campaign for Access to Essential Medicines, Switzerland; <sup>2</sup>Kennedy School of Government & School of Public Health, Harvard University

Problem statement: Ensuring the affordability of medicines in developing countries is a critical policy challenge, particularly for newer medicines under patent. At the same time, establishing an equitable system for global contributions to medicines R&D has remained elusive. Policy proposals to improve access to medicines, such as tiered pricing, should be critically assessed to gauge how well they achieve these joint goals.

Objectives: Tiered pricing – the selling of health technologies in developing countries at prices systematically lower than those in industrialized countries – has received support in situations where the seller exerts significant power over pricing (limited or no competition because of patents, small markets, or other barriers to market entry). We reviewed recent policy discussions on tiered pricing for HIV/AIDS, TB, malaria, kala azar, and vaccines.

Design: We conducted a policy evaluation using 3 questions central to international debates: (1) How can medicines be made affordable in developing countries? (2) Who should pay for R&D and how much? (3) Who decides and how? We carried out case studies based on a review of international drug price developments for antiretrovirals, artemisinin combination therapies, drug-resistant TB drugs, liposomal amphotericin B (for kala azar), and pneumococcal vaccines to examine the impact of tiered pricing and competition.

Setting: Developing countries, including low- and middle-income countries

Outcome measures: Price trends in the public sector of developing countries

Results: Tiered pricing may meet short-term needs for access to a product in special cases such as when market volumes are very small or multi-source production capacity is lacking. However, tiered-pricing suffers from a number of critical shortcomings: it is inferior to competition as a way to achieve the lowest sustainable prices; it often involves arbitrary divisions between markets and/or countries, which can lead to perverse outcomes such as very high prices for middle-income markets; and it leaves a disproportionate amount of decision-making power in the hands of sellers vis-à-vis consumers (i.e., governments or patients). In many developing country contexts, resources are often stretched such that affordability can only be approached by selling medicines at or near the cost of production.

Conclusions: In general, competition should be the default option for improving the affordability of important medicines for use in developing countries, as it has proven superior to tiered pricing to achieve the lowest sustainable prices. In special cases where tiered pricing is justified, steps should be taken to ensure affordability and availability in the longer term, including auditing production costs, improving production efficiency, and/or transferring technology to transition as quickly as possible to competitive multi-source supply. Alternate strategies should be explored that harness the power of competition, avoid arbitrary market segmentation, and recognize government responsibilities for ensuring access to medicines for their populations. In particular, policies that “de-link” the financing of R&D from the price of medicines merit further attention, because they can reward innovation while exploiting robust competition in production to generate the lowest sustainable prices.

Funding source: Médecins Sans Frontières

1210

### **Child Health**

*Keywords:* Drug toxicity, Child, Hospitalization, Economic burden, Nigeria

### **Incidence and Cost Estimate of Treating Paediatric Adverse Drug Reactions in Lagos, Nigeria**

**Kazeem Adeola Oshikoya<sup>1,2</sup>, Henry Chukwura<sup>3</sup>, Olisamedua Fidelis Njokanma<sup>2</sup>, Idowu Odunayo Senbanjo<sup>2</sup>, Iyabo Ojo<sup>3</sup>**

<sup>1</sup>Pharmacology Department, Lagos State University College of Medicine, Ikeja, Lagos, Nigeria, Nigeria; <sup>2</sup>Paediatrics Department, Lagos State University Teaching Hospital, Ikeja, Lagos, Nigeria; <sup>3</sup>Pharmacy Department, Lagos State University Teaching Hospital, Ikeja, Lagos, Nigeria

**Problem statement:** Adverse drug reactions (ADRs) may cause prolonged hospital admissions with a staggering cost of treatment. The burden of ADRs in children has never been evaluated in Nigeria.

**Objectives:** To determine the incidence of paediatric ADRs and the estimated cost of treatment over an 18-month period

**Design:** This is a prospective observational study of children admitted to the paediatric wards of LASUTH in Nigeria, between July 2006 and December 2007.

**Setting:** LASUTH, a tertiary health centre situated in the capital of Lagos State, is funded by the Lagos State Government. The available facilities and standard of care obtainable from this hospital is comparable to the international standard. Paediatric health care is partly free at LASUTH; the cost of treating paediatric inpatients is partly borne by the Lagos State Government and by the parents.

**Study population:** During the study period, a research team comprising a paediatric clinical pharmacologist, paediatricians, and two hospital pharmacists prospectively assessed all admissions to the paediatric wards to determine whether patients were admitted as a result of a suspected ADR or whether an ADR had occurred during admission.

**Method:** ADRs were defined in accordance with Edwards and Aronson (2000) and identified on the basis that they were well recognized as shown by their inclusion in the summary of product characteristics, the Nigerian National Drug Formulary and the paediatric British National Formulary, or in previously published case reports.

**Outcome measure(s):** Numbers of ADR cases, their severity, and the suspected medicines were recorded. Medical and nonmedical costs to the hospital and patient were estimated for each ADR. Cost estimates were performed from the perspectives of the hospital (government), service users (patients), and the society (sufferers of the total costs accrued to treating ADRs).

**Results:** 2,400 children were admitted during the study; 12 (0.6%) were admitted because of ADRs and 23 (1.2%) developed ADR(s) during admission. 40 ADRs (severe: 23 cases, moderate: 15 cases, and fatal: 2 cases) were suspected in 35 patients and involved 53 medicines. An average of 4.2 to 4.5 medicines was used per patient with ADRs. Self-medication contributed to 7 cases of admission because of ADRs. Antibiotics (50%) were the most suspected medicines. All but 7 of the ADRs were type A (dystonia due to amodiaquine, artesunate, or cefixime; hypothermia due to amodiaquine, artesunate, or cefixime; macular and morbilliform rash due to albendazole; anemia due to carbamazepine; angioneurotic edema due to amodiaquine; seizure due to cefixime; and transient loss of vision due to quinine) that were idiosyncratic. Cutaneous (17; 43%) was the most common manifestation and presented mostly as erythema multiforme rash (7) and pustular rash (4); 8 ADRs were judged to be avoidable (electrolyte disturbance and hyperglycemia due to prolonged use of prednisolone; erythema multiforme due to prolonged use of phenobarbitone; electrolyte disturbance and ileus due to prolonged use of frusemide; hemolysis due to the use of cotrimoxazole in a glucose-6-phosphatase dehydrogenase deficient patient; and red man syndrome due to rapid administration of intravenous vancomycin). Approximately 1.83 million naira (USD 15, 466:60) was expended to manage all the patients admitted due to ADRs.

**Conclusions:** Treating paediatric ADRs was substantially expensive. Paediatric drug use policy in Nigeria needs to be reviewed to discourage self-medication, polypharmacy prescribing, and sales of prescription medicines without prescription.

**Funding source:** Self-funded

**1211**

**Access**

*Keywords:* access prices rational use quality medicine

### **Pharmaceutical Situation Assessment: Level II Health Facilities Survey in Syria**

**Hazar Faroun**

MOH /Syria, Syrian Arab Republic

**Problem statement:** A field study to assess the pharmaceutical situation was undertaken in Syria in October 2009 using a standardized methodology developed by WHO.

**Objectives:** To answer questions related to availability, affordability, and access of medicines

**Method:** A descriptive study used a structured questionnaire as the main tool. In addition, patient records and medicines records were reviewed in the health facilities; 5 provinces were selected as "survey areas" representing different development levels. In each survey area, 6 public health facilities were identified. An additional 4 public medicine outlets per survey area were then selected randomly from all middle-level PH care facilities. For each public facility, the nearest private pharmacy was visited. Additionally, 1 warehouse that supplies the public sector was visited in each area, resulting in 30 public health facilities with their dispensaries, 30 private pharmacies, and 5 warehouses being visited. The number of outpatient interviews was 1787. The field team consisted of 15 data collectors and 5 supervisors. Data were typed into summary forms 1–4 and the workbook, both in Excel. For data on drug prices and affordability, the WHO-HAI workbook was used.

**Results:** Overall indicators of access show that key essential medicines selected for the country are partially available in public health centers (57%), warehouses that supply public health system (81.1%), and private pharmacies (96.3%).

The length of stock out duration does not indicate a recurrent logistic problem. Few patients (5.2%) had to drive more than an hour to public and private dispensing facilities. Medicine prices at public facilities are lower than in private pharmacies. About 1/3 of final patient prices for generic medicines in the public sector are close to MSH prices and the rest of the products (18 products) are between 2-6 times more than MSH prices. When originator brand medicines are prescribed/dispensed in the private sector, patients pay about 1.4-7.7 times more than they would for generics. The percentage of expired medicines and adequate storage practices are indications of the adequate quality of medicines. An excessive level of antibiotics and a reasonable level of injectable medicines are prescribed. The national EML was found in only 26.7% and STGs in only 13.3% of surveyed health facilities. Physicians rarely consult STGs. The selling of prescribed medicines without prescription seems to be a widespread practice.

Recommendations: The access components such as strategies to improve availability and enhance affordability of medicines should be maintained. Appropriate use of drugs should be promoted.

Funding sources: Information not provided

1214

**Malaria**

*Keywords:* malaria, access to medicines, household survey

### **Treating Acute Fever with Artemisinin-Based Combination Therapy: Prevalence and Predictors in Five African Household Surveys**

**Catherine E. Vialle-Valentin, Robert F. LeCates, Fang Zhang, Dennis Ross-Degnan**

Harvard Medical School, United States of America

Problem statement: In recent years, national policies have endorsed artemisinin-based combination therapy (ACT) in countries at high risk of malaria.

Objectives: To generate reliable evidence on the adoption of ACT by the community. Specific aims are to describe how households treat acute fever and to identify predictors of ACT at the consumer level

Design: Descriptive, cross-sectional analysis of household survey data

Setting: Surveys conducted in five African countries (2007–08) with an instrument developed by WHO to monitor country pharmaceutical situations at the community level

Study population: Households were selected by multistage cluster sampling (900 to 1,080 households per country). Study population consisted of 2,000 household members experiencing fever in the two weeks preceding the survey: data were collected on all sick members in three surveys (Ghana, Kenya, Uganda) or only on the youngest sick member in two surveys (Nigeria, Gambia).

Outcome measure(s): Treatment of acute fever (ACT vs. other therapy); public vs. private sector location of care

Results: The percentage of fevers treated in the public sector ranged from 44.8% in Ghana to 72.6% in Gambia. The percentage of fevers treated with ACT varied from none in Gambia to 28.8% in Uganda. Artemisinin derivatives were the most used antimalarial category in Ghana, Kenya, and Uganda. Product combinations were consistent with national policies in Kenya and Uganda. In Ghana and Nigeria, 13% of antimalarials were artemisinin monotherapy. In adjusted multivariate analyses, determinants of seeking care in the public sector varied across countries. The likelihood was significantly ( $p < 0.05$ ) higher when the public facility was close by (Kenya, Nigeria, Uganda), when respondents had a favorable opinion of the facility (Kenya, Nigeria), when respondents could not get credit in a private pharmacy (Ghana, Kenya), when the closest retail medicines outlet was far away (Kenya), and when medicines were obtained free-of-charge (Uganda). Public sector treatment was also significantly higher when the household was poor (Ghana), when respondents were male (Nigeria), and when patients were under 5 (Nigeria) or had severe fever (Ghana). Seeking care in the public sector was a strong predictor of ACT use in all four countries ( $p < 0.05$  in Ghana, Kenya, Uganda,  $p = 0.053$  in Nigeria). Other determinants of ACT use varied across countries; the likelihood was significantly higher when respondents were more educated (Ghana, Kenya, Nigeria), when households were not poor (Ghana), and if the fever was not considered severe ( $p < 0.05$  in Nigeria).

Conclusions: Our results highlight the critical importance of the public sector in the treatment of fever in general, and especially in the diffusion of ACT. They indicate that individuals treated with ACT soon after the implementation of ACT national policies tended to belong to a more educated, wealthier, and less sick subset of those seeking care for fever.

Funding source(s): WHO Department of Essential Medicines in Geneva organized and funded data collection with support from the Medicines Transparency Alliance. Harvard Pilgrim Health Care Institute funded the study.

1216

**Policy, Regulation, and Governance**

*Keywords:* off-label, endocrinology

### **Off-Label and Non-Licensed Endocrinology Medicine Use in Turkey: A Retrospective Analysis of Computer Records in the Turkish Ministry of Health**

**Guvenc Kockaya, Pelin Tanyeri, İsmail Mert Vural, Akif Akbulat, Halil Akar, Mahmut Tokaç, Saim Kerman**

General Directorate of Pharmaceuticals and Pharmacy, Turkey

Objectives: Off-label is defined by the Turkish Ministry of Health (MoHT) as the use of licensed pharmaceutical products in doses outside of or exceeding the scope of the registered indication, and the use of non-licensed, but imported medicinal products for the purpose of individual treatment.

**Methods:** The use of off-label or non-licensed endocrinology medicines was evaluated to provide an understanding of Turkey's perspective within this area of health care provision. A computer search was performed of IEGM's database. A patient base using off-label endocrinology medicine applications from 19 June 2009 to 19 June 2010 were searched. The key word "endocrinology" was used in the search. Outcomes were evaluated in the light of indications for use.

**Results:** The computer search showed that 357 applications were submitted for off-label endocrinology medicine use. It was concluded that the highest application percentage was established by "osteoporosis" in all of the applications (43%, 155/357). The highest application was established by Ankara province (28%, 44/155). University hospitals had the highest off-label osteoporosis medicine use applications within the given timeline (65%, 102/155). Specialized physicians in the fields of endocrinology and metabolism (adult and paediatric) had the highest number of off-label osteoporosis applications (71%, 111/155). It was concluded that the highest application percentage was established by "teriparatide use in osteoporosis" (87%, 136/155) in all of the osteoporosis applications; 92 of 136 applications were approved. There was a significant difference between the T score (L1-4) of rejected and approved applications for patients ( $3,07 \pm 1,85$  and  $3,23 \pm 1,63$ , respectively;  $p < 0.001$ ).

**Discussion and conclusion:** Yet, there was not a significant difference between ages of patients for whom applications were rejected or approved. In addition, it could be said that off-label use can lead to reimbursement restrictions in endocrinology, especially for teriparatide-like oncology medicines. In Turkey, physicians who want to prescribe an off-label or non-licensed pharmaceutical or a medicine that has a different use from reimbursement indications needs to apply through the off-label medicine use process.

**Funding sources:** There was not any funding source or conflict of interest for the manuscript.

1217

### Economics, Financing, and Insurance Systems

*Keywords:* cost of treatment, pharmacoeconomy, colon cancer,

#### Treatment Cost of Metastatic Colon Cancer in Turkey

**Guvenc Kockaya<sup>1</sup>, Mine Polat<sup>2</sup>, Ahmet Özet<sup>3</sup>, Tanyeri, Pelin<sup>1</sup> İsmail Mert Vural<sup>1</sup>, Akif Akbulat<sup>1</sup>, Halil Akar<sup>1</sup>, Saim Kerman<sup>1</sup>**

<sup>1</sup>General Directorate of Pharmaceuticals and Pharmacy, Turkey; <sup>2</sup>Baskent University, Turkey; <sup>3</sup>Gazi University, Turkey

**Problem statement:** Colon cancer is the third most common in the top cancer incidence list—212,000 patients die in Europe per year because of colon cancer. In Turkey 150,000-180,000 new cancer patients are diagnosed every year, 13% of whom have colon cancer. Metastasis will occur among 50% of the patients who are newly diagnosed and operated on. It is believed that metastasis will occur in 9,000-10,000 colon cancer patients every year in Turkey.

**Objective:** Survival appears to be prolonged to more than 20 months with the new pharmaceuticals; however, these new pharmaceuticals increase the total cost. The aim of our study is to calculate colon cancer treatment options for Turkey.

**Method:** Gazi University Hospital treatment protocols for colon cancer treatment were used. The cost of Irinotekan-Erbutix, B-IFL, Bevacizumab-FUFA, XELOX, XELIRI, IFL-Cetuximab, Irinotekan, FOLFIRI-Doillard, FOLFOX-4, FOLFIRI-Tornigard, Raltrexed, FUFA, and Inf-5 FU (Degramount) protocols were calculated. The cost of pharmaceuticals and medical treatment used in the protocols were taken from the Social Security Institution's website. The exchange rate was USD 1 for TL 1.5.

**Results:** Inf-5 FU (Degramount) (USD 220) had the lowest cost for 1 cycle, followed by FUFA (USD 342), FOLFIRI-Tornigard (USD 390), Raltrexed (USD 504), FOLFIRI-Doillard (USD 521), Irinotekan (USD 619), FOLFOX-4 (USD 704), XELOX (USD 880), XELIRI (USD 947), IFL (USD 1785), Bevacizumab-FUFA (USD 2730), B-IFL (USD 5203), and Irinotekan-Cetixumab (USD 11625).

**Conclusion:** Every treatment protocol is administered for 6 cycles for each patient depending on the disease's stage. If a treatment protocol is not successful, the patient will be given a different protocol. Different combinations of cycles can be administered, depending on the responses of the patients. Although Irinotekan-Cetixumab had the highest cycle cost, further analysis is needed to compare the cost and effectiveness of different protocols and combinations.

**Funding source:** There was no funding source or conflict of interest for the manuscript.

1218

### Child Health

*Keywords:* Cost effectiveness; neonatal resuscitation; neonatal sepsis; traditional birth attendant; community intervention

#### Cost and Cost-Effectiveness of Training Zambian Traditional Birth Attendants in Interventions Targeting Common Causes of Neonatal Mortality

**Lora Sabin, Christopher Gill, Anna Knapp, Davidson Hamer**

Boston University School of Public Health, United States of America

**Problem statement:** The Lufwanyama Neonatal Survival Project was a randomized controlled effectiveness trial that showed that training traditional birth attendants (TBAs) to perform interventions targeting birth asphyxia, hypothermia and neonatal sepsis reduced all causes of neonatal mortality by 45% (relative risk 0.55, 95% confidence interval 0.33 to 0.90). The interventions consisted of (1) training TBAs in a simplified neonatal resuscitation protocol algorithm and (2) identification of sepsis, initiation of amoxicillin, and facilitated referral to a health center.

**Objective:** This companion analysis was conducted to assess the costs and cost-effectiveness of this package of interventions.

**Methods:** We calculated the intervention's financial and economic costs, the economic cost of implementing a modified model of the intervention over a future 10-year period (2011–20), and the incremental cost-effectiveness of deaths avoided and disability-adjusted life years (DALYs) saved for both the 2.5 years of the actual program and the projected 10-year scenario to model the interventions if used programmatically. Sensitivity analysis was conducted for the economic cost-effectiveness outcomes of the 10-year program.

**Results:** Total financial and economic costs of the intervention were \$106,271 and \$114,998, respectively, in real 2006 US dollars, or \$47,232 and \$51,110 on an annualized basis. Fixed costs were responsible for close to 90% of total costs. Total and annualized costs in 2011 US dollars of the 10-year program were \$258,076 and \$25,808, respectively. For the 10-year program, the estimated cost per DALY saved was \$29.52, and the cost to have a trained TBA at each delivery was \$11.30. Sensitivity analysis indicated that outcomes were most sensitive to variations in the effectiveness of the interventions, the extent to which expensive foreign consultants were used, the average number of births conducted per TBA per year, and the number of program TBAs per training workshop.

**Conclusions:** This simple package of interventions was highly cost-effective. We believe that this is a highly generalizable model for reducing neonatal mortality for populations with limited access to health care.

**Funding source(s):** Information not provided

**1219**

### **Policy, Regulation, and Governance**

*Keywords:* counterfeit drugs, drug distribution, drug information

#### **Overview of Drug Tracking System (ITS) in the Pharmacies of Ankara: Preliminary Research**

**Fikri Yildirim<sup>1</sup>, Guvenc Kockaya<sup>1</sup>, Julide Yildirim Ocal<sup>2</sup>, Melek Yildirim<sup>1</sup>, Akif Akbulat<sup>1</sup>, Hanefi Ozbek<sup>1</sup>, Saim Kerman<sup>1</sup>**

<sup>1</sup>General Directorate of Pharmaceuticals and Pharmacy, Turkey; <sup>2</sup>Gazi University, Turkey

**Problem statement:** WHO has reported that fake drugs are involved in 6-10% of all the drug sales. The use of counterfeit drugs has reached 50% in undeveloped countries. Although the percentage of counterfeit drugs in Turkey is unknown, police often find fake labels and counterfeit drugs during raids. Gangs use fake labels to get reimbursement without selling real drugs. The Drug Tracking System (ITS) is a unique system based on a cubic code; the Turkish Ministry of Health, General Directorate of Pharmaceuticals and Pharmacy, gives each box of medicine a cubic code to lessen the chances of counterfeit medicines being sold. This way it is easy to know and follow any box of medicine at any pharmacy in the country.

**Objective:** The aims of our preliminary study are to show the possible problems with ITS, to obtain pharmacists' opinions about ITS, and to provide a basis for further studies.

**Methods:** From April 24 to May 5, 2010, 20 pharmacists who are running pharmacies in Ankara were surveyed and the results were evaluated with the programme 'SPSS 16' for Windows and Windows Excel.

**Results:** Although 65% of participants confirmed that ITS can work in Turkey, nearly all mentioned that ITS increased the workload in pharmacies; 75% and 100% of participants mentioned that they already have the equipment for ITS and cubic coded pharmaceuticals, respectively; 90% of participants mentioned that the authorities haven't given enough education about ITS to pharmacists. It was reported that ITS may prevent fake labels and fake drugs by the 75% and 60% of participants, respectively, and may be useful for pharmacists, patients, and society. In addition, 95% of the participants mentioned that ITS will also be used for controlling and tracking pharmacy revenues.

**Conclusion:** Although most of the participants believe that ITS will be effective for preventing counterfeit drugs, there are several misunderstandings caused by a lack of sufficient information about ITS and the lack of education. It was concluded that education is needed for all stakeholders of ITS, especially for pharmacists because they are the main users of ITS. The lack of infrastructure for ITS and the longer processing times are the most common complaints. There will be resistance to ITS unless processing times are shortened and the necessary education is provided.

**Funding source:** There was not any funding source or conflict of interest for the manuscript

**1220**

### **Chronic Care**

*Keywords:* chronic disease, clinical guidelines, surveillance, performance assessment

#### **Glycemic and Non-glycemic Control in Diabetic Outpatients Receiving Oral Antidiabetic Drugs at Sultan Qaboos University Hospital**

**R Vaishnav, Israa Nather Ahmed Al Metwali, Nicholas Woodhouse**

Department of Pharmacology and Clinical Pharmacy, College of Medicine & Health Sciences, Sultan Qaboos University

**Problem Statement:** Type 2 diabetes mellitus is a progressive disorder and Oman ranks among top 10 countries worldwide with the highest prevalence. Lifestyle changes, weight loss, pharmacotherapy and good control of glycemic and non-glycemic parameters lead to successful management.

**Objectives:** To provide a descriptive report of the glycemic parameter glycosylated hemoglobin and non-glycemic parameters blood pressure, body mass index, lipid profile, urine albumin creatinine ratio and glomerular filtration rate in Type 2 diabetics at Sultan Qaboos University Hospital. To determine the predictors (oral antidiabetic drugs, body mass

index, age, sex, diabetes duration) of good glycemic control in these patients and to determine the predictors (sex, age, glycosylated hemoglobin, hypertension, log serum creatinine, diabetes duration, and body mass index) of microalbuminuria.

**Design and study population:** A retrospective observational study of Type 2 diabetic outpatients on one or more oral antidiabetic drugs aged  $\geq 20$  years who attended and were followed up in the diabetes and other clinics of the Outpatient Department from January 2009 to December 2009. Also all Type 2 diabetes outpatients who attended the Family and Community Medicine Clinic were included. Demographic information, and glycemic and non-glycemic parameters were recorded and data analysis was done by using (SPSS) version 17.0.

**Results:** 376 Type 2 diabetic patients were included in the study of which 295(78.4%) were Omanis and 81(21.5%) were Non-Omanis. The mean age of the cohort was 54.7 years, and male to female ratio was 194(51.6%):182(48.4%). The mean of disease duration for 268 participants was 8.0 years and 332(88.3%) of the study cohort received metformin therapy. By using multi-variable logistic regression model and after adjusting for other factors in the model there was a significant association between good glycemic control (Hb A1C $\leq 7\%$ ) and oral antidiabetic drugs. Of the study cohort 131 (35.3%) patients had good glycemic control (Hb A1C $\leq 7\%$ ), 119(31.8%) had good blood pressure control ( $<130/80$  mmHg), 62(19.8%) patients had normal BMI ( $\leq 24.9$  kg/m<sup>2</sup>) and 46(15.3%) had optimal lipid profile control. Nineteen (6.64%) participants achieved the targets of Hb A1C, BP and LDL-C. By using adjusted multi-variable logistic regression model, microalbuminuria correlated significantly with Hb A1C, diabetes duration, and BMI.

**Conclusions:** Good glycemic control was associated with utilization of oral antidiabetic drugs, but not with age, sex, BMI, and diabetes duration. Also, appropriate utilization of metformin was observed as initial antidiabetic therapy. The significant predictors of microalbuminuria were Hb A1C, DM duration, and BMI, while age, sex, hypertension and log serum creatinine were not associated.

**Funding source :** partial funding

**1221**

### **Policy, Regulation, and Governance**

*Keywords:* quality assurance

## **The Plague of Substandard Medicines in Developing Countries: Evidence for Policy Change**

**Christophe Luyckx, Jean-Michel Caudron, Raffaella Ravinetto**

Institute of Tropical Medicine, Belgium

**Problem statement:** The global pharmaceutical market is characterized by multiple qualitative standards. Although the quality of medicines is generally assured in wealthy, strictly regulated countries, many resource-limited countries are still permeable to poor quality medicines. This North-South gap is caused by multiple factors, including the lack of awareness of key-actors, the increasing complexity of the global market, the lack of public information on the quality of essential medicines, the insufficient regulatory safeguards, the ever-increasing pressure on prices, and the insufficient political will to address the problem. Various international initiatives have been created to fight counterfeit medicines, whereas the problem of substandard medicines, which has an at least equally deleterious impact to the health of populations in resource-poor countries, is insufficiently addressed.

**Objectives:** To document the extent of the problem of substandard medicines in resource-poor countries and to develop guidance for corrective measures, with the ultimate objective of fostering universal access to quality medicines. Since most current initiatives aiming at strengthening pharmaceutical quality assessment focus solely on HIV/AIDS, malaria, and tuberculosis, we will look especially at medicines for other infective and chronic diseases.

**Design, setting, and methods:** The QUAMED Network, created at the end of 2010, brings together partners from Belgium, the Democratic Republic of Congo, France, Kenya, Madagascar, Togo, and the UK to develop operational, policy research, and advocacy activities. The core operational activities consist of technical assessments of finished pharmaceutical products, manufacturers, and procurement agencies, whose findings will be used through an innovative database for improving the procurement strategies of the partners in sub-Saharan African and for developing evidence-based policies to improve the quality of medicines in public health programs worldwide.

**Results and policy:** We will present the preliminary findings from the first year of activities of QUAMED, and we will discuss their possible short- and long-term implications, with special focus on the impact of quality of medicines on the performance of health systems. Policy changes could be envisaged both at the procurement level (for operational actors, such as procurement agencies, NGOs, and donors) and at regulatory level.

**Funding source(s):** QUAMED core activities are funded by the Belgian Directorate General for Development Cooperation (DGDC).

**1222**

### **Malaria**

*Keywords:* Adherence, artemisinin-combination therapies, AMFm, anti-malarials, private sector

## **Adherence to Artemisinin Combination Therapies (ACTs) Purchased in the Informal Private Sector: Evidence from Soroti District, Eastern Uganda**

**Jessica Cohen<sup>1,2</sup>, Elif Yavuz<sup>1,2</sup>, Alexandra Morris<sup>1</sup>, Jean Arkedis<sup>1</sup>, Oliver Sabot<sup>1</sup>**

<sup>1</sup>Clinton Foundation Health Access Initiative; <sup>2</sup>Harvard School of Public Health

**Problem Statement:** Patient non-adherence has contributed to the emergence of drug-resistant malaria strains, prompting increasing failure rates to the most common antimalarial medications. Numerous studies have documented

adherence to antimalarials obtained in the public sector; however, this is one of the first studies to estimate adherence rates among patients purchasing artemisinin combination therapies (ACTs), currently the most effective treatment for malaria, in the private retail sector.

**Objectives:** The study seeks to determine adherence rates to ACTs purchased in private drug shops in Eastern Uganda.

**Design:** Study participants were recruited in four licensed private drug shops in Eastern Uganda in December 2009. Participants were eligible to enroll if they elected to purchase subsidized artemether-lumefantrine (AL) made available through the project. Enrolled participants (n=395) were randomly assigned to one of three study arms: no follow up (10%; n=39), follow up after two days (40%; n=159), and follow up after three days (50%; n=197). The two-day follow-up arm captured whether participants completed the full course before the recommended treatment period concluded, while the three-day arm measured failure to complete the full course by the end of the treatment period.

**Study Population:** The study population consists of 359 patients or caregivers who purchased ACTs at privately owned drug shops in Soroti District, Eastern Uganda

**Outcome Measure(s):** The primary outcome is completion of the full treatment course, as assessed by blister pack observation.

**Results:** Loss to follow up was balanced in the follow up groups at approximately 17%. For the two-day group, the maximum time to follow up was 55 hours, whereas for the three-day group, participants were included in the main analysis if they were found within 96 hours after medicine purchase; 67% (n=106) and 77% (n=152) of these groups, respectively, were followed up within the specified time frame. Approximately 56% of participants had finished their medication as prescribed when followed up with after three days, indicating lack of treatment compliance is significant. More than a quarter of patients in this group (26%) had at least a full day of treatment (2 doses) left. There was limited evidence of participants finishing the treatment course early: about 9% of patients completed the treatment on the second day. *Multivariate analysis to assess determinants of adherence is ongoing.*

**Conclusions:** This study is one of the first to quantify adherence rate to ACTs obtained through the private sector, where between 60-80% of malaria patients seek treatment in sub-Saharan Africa. The results suggest that non-adherence to subsidized ACTs is substantial and notably lower than adherence in the public sector. Low levels of ACT adherence could lead to resistance to the only remaining effective antimalarial.

**Funding:** UK Department for International Development.

1223

**Access**

*Keywords:* household, perceptions, access to medicines, affordability, equity

### **Consumer Knowledge and Perceptions about Medicines: Evidence from Household Surveys in Five Low- and Middle-Income Countries**

**Brian Serumaga<sup>1</sup>, Dennis Ross-Degnan<sup>2</sup>, Robert LeCates<sup>2</sup>, Gilles Forte<sup>3</sup>, Catherine Vialle-Valentin<sup>2</sup>**

<sup>1</sup>University of Nottingham, United Kingdom; <sup>2</sup>Harvard Medical School and Harvard Pilgrim Health Care Institute, USA;

<sup>3</sup>World Health Organization, Switzerland

**Objective:** To generate reliable evidence on community knowledge and perceptions about medicines that can serve as baseline for interventions aimed at educating the public about medicines and at increasing transparency in the pharmaceutical sector. Specific aims are to describe the opinions prevailing in the community about quality, affordability and access to medicines and to identify how socioeconomic and geographic disparities shape community beliefs and awareness about issues related to pharmaceutical products.

**Design:** Descriptive, cross-sectional analysis of survey data

**Setting:** Household surveys conducted in Ghana, Jordan, Kenya, Philippines, and Uganda between 2007 and 2009 using a survey instrument developed by the World Health Organization (WHO) to monitor country pharmaceutical situations at the community level.

**Study population:** Households were selected by multistage cluster sampling (900 to 1,080 households per country).

**Outcome measure(s):** Selected indicators of attitudes, experiences, and beliefs about obtaining and using medicines

**Results:** 3,133 (59.7% of total sample) of households kept at least one medicine at home: most frequent classes of medicines found in households were analgesics, antibiotics, and antacids. 43.2% of households reporting a recent acute illness and 30.8% reporting a chronic disease had obtained medicines free of charge in a public health care facility.

61.6% of respondents agreed that they can easily find out how much medicines cost; 57.3% knew that two identical medicines may be sold at different prices; 47.3% knew where to find medicines at the lowest price; and 38.7% were comfortable asking for the least expensive product when buying a medicine. 36.4% of respondents agreed that health providers in private health care facilities take into account their ability to pay when prescribing medicines, 67.2% trusted their pharmacists to recommend good-quality medicines, and 58.8% trusted them to recommend medicines that offer best value for money. 68.02% of respondents believed that medicines of better quality are more expensive. 59.6% of respondents knew that the same medicine may have different names, and 44.5% had heard the term generic to describe medicines; of these, 60.7% thought generic medicines are usually lower in quality than brand medicines, and 77.7% thought generics were lower in price than brand medicines. Multivariate analyses are under way to characterize socioeconomic and geographic disparities and the key determinants of perceptions about medicines.

Conclusions: Our results provide evidence about community knowledge and perceptions about medicines in low- and middle-income countries.

Funding source(s): The WHO Department of Essential Medicines in Geneva organized and funded data collection, with support from the Medicines Transparency Alliance.

**1225**

#### Chronic Care

*Keywords:* psychiatric disorder, psychotropic drugs, prescribing pattern, polypharmacy, neuropsychiatric hospital

### **Prescribing Pattern of Psychotropic Substances in a Nigerian Neuropsychiatric Hospital**

**Mohammed Saheed Lawal, Ibrahim Oreagba, Olufunsho Awodele, Sunday Olayemi, Ishola Ismail**

College of Medicine, University of Lagos, Nigeria

Background: Psychiatric disorder accounts for more morbidity than is often recognised. In developing countries, experience has shown that there are diverse patterns of psychotropic drug prescription, the commonest being polypharmacy.

Objective: To determine the prescription pattern of psychotropic drugs and to assess rational prescribing of these drugs in Neuro-psychiatric Hospital Yaba.

Methods: The study was carried out at the pharmacy department in the Federal Neuro-psychiatry Hospital, Yaba, Lagos. The hospital is a Federal Government owned specialist Hospital. Fifty prescriptions were systematically sampled for each month for a period of one year (January to December 2007), giving a total of six hundred prescriptions. Data was collected using standard prescription encounter sheets

Results: About 35.49% prescriptions contained at least an injection. 86.50% prescriptions contained antipsychotic drugs, other psychotropic drugs included antidepressants (27.50%), mood stabilizers (22.83%) and sedative/hypnotics (8.50%). Other drugs included anticholinergics (67.33%), analgesics (3.67%), antibiotics (3.67%), antihypertensive (11.67%), antihistamine (0.08%), antimalarials (4.50%), and haematinics (36.67%); 46.62% of prescriptions contained only 1 antipsychotic drug and 16.38% contained at least 3 antipsychotic drug combinations Chlorpromazine (49.32%), Fluphenazine (32.18%), Trifluoperazine (32.76%), were the 3 most frequently prescribed typical antipsychotic while Clozapine (1.15%), Olanzapine (0.96%) and Risperidone (5.97%) were the most frequently prescribed atypical antipsychotics.

Funding source: Information not provided

**1228**

#### HIV/AIDS and TB

*Keywords:* CQI, HIV, Training, health facilities, education, promotion

### **The Science of Quality Improvement (QI) Through Small Tests of Change (STOC) and Modeling of QI Teams to Improve Health Systems in Resource Limited Settings**

**Peter Memiah<sup>1</sup>, Martine Etienne<sup>1</sup>, Kristen Stafford<sup>1</sup>, Eva Karorero<sup>1</sup>, Mwansa Mulenga<sup>1</sup>, Francesca Odhiambo<sup>1</sup>, Ruth Atukunda<sup>1</sup>, Solomon Agbor<sup>1</sup>, Ian Wanyeki<sup>2</sup>**

<sup>1</sup>University of Maryland,; <sup>2</sup>Futures Group

Problem Statement: Quality improvement measures have been proven to be highly effective in the poorest health systems, but they often are not applied appropriately. There is therefore need to focus on building the capacity of health care workers to deliver quality services at primary health care facilities through the promotion of data use for decision making, building QI teams and carrying out STOCs'

Objectives: To create site ownership and build sustainable teams that focus on data to improve processes and outcomes

Design: A descriptive before-after study with no control group was used to evaluate the impact of the interventions. Time series designs were used for comparing trends

Setting: 40 rural health Facilities in Kenya, Uganda, Tanzania and Rwanda

Study Population: The sample included 40 rural health facilities with 160 health care workers providing HIV care and treatment to approximately 12,000 patients.

Intervention: Through CQI training, each HF is represented by a 3 - 4 person team, members learn improvement techniques, exchange insights and advice, and have a shared sense of commitment to achieving common improvement goals and outcomes. Back at the HF level they conduct repeated cycles of interpreting data, problem diagnosis, development and implementation of small-scale improvement efforts, assessment of effects, and refinement and expansion of effective actions until desired outcomes are achieved.

Policy : Advocacy for health facilities to form functional CQI teams to focus on data to improve processes and outcomes.

Outcome Measures: Mortality rates, Lost to Follow up rates, Reduction in missed appointments and increase in pediatric enrollment

Results: Four participants each came from the 40 facilities and went through a comprehensive quality improvement training package for 3 days. Topics discussed included (1) problem/issue identification from collected data (2) interpreting data trends (3) developing a small scale improvement effort (STOC) (4) How to engage other providers in

the intended small change (5) Refining and expanding effective actions (6) providing effective feedback to the rest of the team. Individuals were asked to form QI teams at their various facilities and implement STOC

Conclusion: To achieve continuous quality improvement a new culture of quality has to be established at all levels of the health system whereby all staff are engaged in and take responsibility for maintaining and improving the quality of care that they deliver; where clients are equal decision-makers in the care process; and where the focus of the entire system is on problem resolution, rewarding good performance, and improving health outcomes.

Funding Sources: PEPFAR

**1229**

**HIV/AIDS and TB**

*Keywords:* adherence, HIV/AIDS, antiretrovirals

### **How Far is too Far? Does Distance to Clinic Matter for HIV/AIDS Treatment Adherence?**

---

**Peter Memiah, Martine Etienne, Mian Hossain, Kristen Stafford, Mercy Niyang, Patience Mnjala, Anthony Amoroso, Solomon Agbor, Robert Redfield**

University of Maryland, United States of America

Problem Statement:

Several indicators have been identified as impacting adherence to antiretroviral therapy (ART) in resource limited settings. Distance to clinic has been often cited as an important factor; however this indicator has not been thoroughly investigated in the rural African setting.

Objectives: The objective of this analysis is to examine the relationship between distance from patients' home to clinic and adherence to ART

Design: A cross-sectional analysis. The dependent variable is adherence to ART. Adherence is measured using three questions from the validated Institute of Human Virology Adult Adherence Survey—doses missed in last week, last month and appointment missed in past three months. Age, gender, baseline CD4, opportunistic infections, ARV knowledge, and total months on therapy are used as controls in the multivariate analysis. Crude and adjusted logistic regression models are used to estimate the relationship between distance to clinic and adherence to ART treatment.

Setting: Rural health Facilities in Nigeria, Uganda and Tanzania

Study Population: The sample included 1258 HIV AIDS patients in Nigeria, Uganda and Tanzania.

Intervention: A cross-sectional retrospective review of patient health information documented in patient medical charts is conducted annually in AIDSRelief supported sites as part of the quality improvement program. Nigeria, Uganda and Tanzania conducted this on-treatment review on its adult population in 2008.

Policy : Advocacy for health facilities to form satellite sites ; and community-based organizations have emerged to provide essential services in HIV-related prevention, care and treatment.

Outcome Measures: The primary variable of interest is patients' reported distance to clinic

Results: Crude logistic regression results show that the odds of adherence to ART respectively is 1% ( $p < 0.960$ ), 20% ( $p < 0.199$ ) and 45% ( $p < 0.001$ ) less when a patient comes from 5-10km, 11-20km and more than 20km compared to a patient who comes from 5km or less. The trend in odds of adherence to ART remains consistent when the effect of other covariates in the model including baseline CD4 and number of months on ART are controlled for. Adherence to ART does not show any significant difference between males and females.

Conclusion: Simulation analysis show adherence to ART could be improved if distance to clinic could be minimized. Findings suggest that bringing care closer to patients and their communities through mobile or satellite clinics should be increased in order to improve the adherence to ART

Funding Sources: PEPFAR

**1263**

**Policy, Regulation, and Governance**

*Keywords:*

### **Drugs for Anemia**

---

**Gopal Dabade**

Drug Action Forum - Karnataka, India

Problem Statement: Anaemia is an extremely common problem and a major public health problem in India and several developing countries. More than 50% of population is affected with anaemia and in several pockets of population around 95% of adolescents are suffering from it. Anaemia particularly strikes women and children. As per Essential Drug List of India and World Health Organisation, the drugs needed to treat anaemia are a combination of iron with Folic acid or just iron preparation in proper doses. Internationally renowned standard text books of medicine have also advocated the same.

Objectives: To look for availability of medicines to treat anaemia both in public and private health care systems.

Design: Popular drug guides used by doctors were chosen and drugs to treat anaemia were culled from it. Totally 338 drugs were listed. These drugs that were listed were compared to the WHO Essential Drugs and also reference was taken from standard pharmacology text books to see if they matched with rationality etc.

**Setting:** The study was situated in the South Indian state of Karnataka.

**Results:** After screening 338 drugs to treat anaemia from a popular doctors' reference drug guide book, it revealed that there is just one drug that fits into the standards prescribed by the Essential Drug List of India and World Health Organisation. Many of the drugs listed, to treat anaemia; in the doctors' popular publication contained substances never advocated in any standard text books. Some even contained alcohol, liver extract and haemoglobin. The one drug that fits into standards prescribed by WHO is NOT easily available at most chemists' outlets, for the simple reason that it does not offer much profit margin.

The study observed that the cost of medicines to treat anaemia ranges from a low of Rupees 0.13 per tablet to Rupees 6.97 per tablet, which works out for 30 days treatment from a low Rupees 11.70 to as much as Rupees 660. It was also observed that anaemia patients spend anywhere from a minimum of 2 to 56 times than what they ought to.

The Indian drug industry has become a major global power in drug production it has not grown to meet the needs of this country, as a vast majority of the population does not have access to essential medicines. This situation holds good for drugs to treat anaemia as well. As per the Government of India figures, the Indian drug manufacturers had a turnover of Rupees 500,000 million during the year 2003-2004. The above estimates show that we need approximately Rupees 5,850 million to treat 50% of the Indian population of nearly 1,000 million for a treatment period of 30 days.

**Conclusions:** From the findings of the study it is clear that making available Essential Medicines is an important public health issue and needs urgent policy intervention.

**Funding:** Drug Action Forum – Karnataka independent, not for profit, registered organization with support from Health Action International AsiaPacific (<http://www.haiap.org/>).

**1264**

#### **Economics, Financing, and Insurance Systems**

*Keywords:* Rheumatoid Arthritis (RA), Ankylosing Spondylitis (AS), cost of illness

### **Cost of Care of Rheumatoid Arthritis and Ankylosing Spondylitis Patients in Tertiary Care Rheumatology Units in Turkey**

**Simten Malhan**

Baskent University, Turkey

**Problem statement:** Rheumatoid Arthritis (RA) and Ankylosing Spondylitis (AS) are the prototypical chronic MSDs which are associated with morbidity, long-term disability, and high costs of care, but mortality rate is low compared to that of other disease groups.

**Objective:** To conduct cost of illness study for RA and AS in Turkey

**Design:** Cost-of-illness (COI) study

**Setting:** National rheumatology healthcare centers

**Study population:** Turkish RA and SA populations evaluated by an expert panel convened from members of 20 of 53 rheumatology healthcare centers nationwide, 28 of which are teaching hospitals.

**Interventions:** An expert panel composed of 22 experts chosen from all national tertiary care rheumatology units (n=53) was convened to estimate the direct and indirect costs of care of patients with RA and AS in Turkey, using "cost-of-illness" methodology. To measure indirect costs, the number of days of sick leave, the extent of disability, and the levels of early retirement and early death were also evaluated. Lost productivity costs were calculated using the "human capital approach", based on the minimum wage.

**Outcome measures:** Mean annual direct and indirect cost per patient with RA and AS (in Euro), cost of illness of an RA and AS (in Euro)

**Results:** The total annual direct costs per RA and AS patient were determined to be 2.917,03 Euro and 3.565,9 Euro, respectively. The direct costs were thus substantial, but the indirect costs were much higher because of extensive morbidity and mortality rates. The total annual indirect costs per RA and AS patient were 7.058,99 Euro and 6.989,81 Euro, respectively. Accordingly, the total cost for each RA and AS patient in Turkey was 9.976,01 Euro and 10.555,72 Euro, respectively.

**Conclusions:** From the societal perspective, both RA and AS has become a burden in Turkey. The costs attributed to loss of productivity were higher than the medical costs due to RA and AS diseases. Second important conclusion is that indirect costs constitute 70% and 66% of total costs related to RA and AS, respectively. The annual costs of RA and AS for whole Turkish population are 2,130,424,680 Euro and 2,209,201,904 Euro, respectively. This amount contributes to 0.37% of the GDP in Turkey for RA 0.38% of the GDP for AS. To conclude, both diseases have a high burden in Turkey having an impact of 4,339,626,584 Euro that contributes to 0.75% of the Turkish GDP.

**Funding sources:** This study was supported by grants from the Abbott Company.

## ABSTRACTS INDEXED BY PRESENTING AUTHOR

Presenting Author	ID	Title
Abdelhakim, Mohamed	1039	Restricting the Availability of Anti-TB Medicines in the Private Market of Eastern Mediterranean Region Countries: A Call for Policy Intervention
Abdulla, Ahmed Abdo-Rabbo	810	Consultation and Dispensing Time at Primary Health Care Facilities in Oman
Abdulla, Ahmed Abdo-Rabbo	813	Medicines Use in Oman: Public Knowledge, Attitudes, and Practices
Abdulla, Ahmed Abdo-Rabbo	301	Household Survey on Medicine Use in Oman
Abegunde, Dele Olawale	353	Does Antimicrobial Use Granger-Cause Community-Based Antimicrobial Resistance?
Abegunde, Dele Olawale	354	Behavioural Model for Community-Based Antimicrobial Resistance, Vellore, India
Abegunde, Dele Olawale	343	Inefficiencies Due to Poor Access to and Irrational Use of Medicines to Treat Acute Respiratory Tract Infections in Children
Abegunde, Dele Olawale	358	In Scaling Up Health Related MDGs, How Much More Will It Cost to Procure Essential Medicines for 49 Low-Income Countries?
Abegunde, Dele Olawale	819	Universal Health Insurance Coverage and Reimbursement for Medicines in Countries
Abo Shady, Yomna Tarek	1090	Literature Review of Gender and Drugs in Eastern Mediterranean Region Index Medicus
Abu-Youssef, Randa Mahmoud	766	Awareness and Adherence to Methicillin-Resistant S. Aureus Guidelines, as per WHO, at Alexandria University Hospitals
Acuna, Maria Cecilia	760	Social Determinants of Access to Medicines in 3 Central American Countries
Adams, Lisa Virginia	488	Parents' and Caretakers' Administration Practices and Formulation Preferences of Children's Medicine in Tanzania
Agomo, Chimere Obiora	264	Parasitological Assessment of Two-Dose and Monthly Intermittent Preventive Treatment of Malaria During Pregnancy with Sulphadoxine-Pyrimethamine (IPTp-SP) in Lagos, Nigeria
Ahmad Hassali, Mohamed Azmi	114	Facilitators and Barriers for Generic Drug Use Among General Practitioners in Northern State of Malaysia: Findings from a Cross-Sectional Mail Survey
Ahmad Hassali, Mohamed Azmi	115	Public Knowledge and Attitudes Toward Antibiotic Usage: Findings from a Cross-Sectional Survey in the State of Penang, Malaysia
Ahmad Hassali, Mohamed Azmi	800	Consumer behavior toward counterfeit drugs: scale development in a developing country setting
Ahmadi, Batoul	682	The Assessment of Relation between Inappropriate Medication and Health Status Among Elderly Discharged from Hospitals Affiliated with Tehran University of Medical Sciences, through Beers Criteria
Ahmadi, Batoul	1097	Polypharmacy Among Older Adults in Tehran
Ajuba, Miriam, Obinwanne	714	Pharmacovigilance of Antimalaria Drug Treatment in Enugu State, Nigeria: Community and Health Workers' Perceptions and Suggestions for Reporting Adverse Drug Events
Akaleephan, Chutima	164	Extension of market exclusivity and its impact on the accessibility to essential medicines, and drug expense in Thailand: Analysis of the effect of TRIPs-Plus proposal
Akhideno, Ehizokhale Peter	780	Pattern of Medicine Use Among In-Patients in a Tertiary Health Care Setting Using the WHO Prescribing Indicators
Akinkunmi, Ezekiel Olugbenga	848	Susceptibility of Methicillin Resistant Coagulase-Negative Staphylococci Isolated from Faecal Samples of Children to Commonly Used Antiseptic Agents
Al Rabayah, Abeer Ahmad	1064	Data Disclosure: An Ongoing Process Towards Transparency
Al shizawi, Mona Mohammed Ali	563	Unit Dose System – Implementation in a Secondary, Multispecialty Referral Hospital: Sohar Hospital, Ministry of Health, Sultanate of Oman

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
Alabbadi, Ibrahim Ali	537	Piloting the Development of a Cost-Effective, Evidence-Informed Clinical Pathway: Managing Hypertension in Jordanian Primary Care
Alabbadi, Ibrahim Ali	414	A Comparison of Generic and Originator Brand Drug Prices between Jordan and the United Kingdom
Alabbadi, Ibrahim Ali	411	Direct-to-Consumer Advertising for Pharmaceuticals in Jordan from a Gender Perspective
Alabbadi, Ibrahim Ali	413	Cost Impact of Purchasing Pharmaceuticals Jointly in the Public Health Sector in Jordan
Alabbadi, Ibrahim Ali	415	One-Year Assessment of Joint Pharmaceutical Procurement in the Jordanian Public Health Sector
Al-Rashdi, Issa Sulaiman	843	Quality of Dispensing in Outpatient Pharmacy at Sultan Qaboos University Hospital: Peer Review Audit
Aly Mostafa, Noha Shawky	591	Medication Adherence: Comparative Study between Institutionalized and Community-Dwelling Elderly
Al-Zadjali, Badriya Ali	627	Analysis of Clinical Pharmacists' Interventions on Discharged Patients' Prescription in a Tertiary Care Teaching Hospital in Oman
Al-Zadjali, Badriya Ali	632	Caution! Look Alike, Sound Alike Medication
Anansakunwatt, Wimon	870	Interventions to Improve Medication Safety in a University Hospital in Thailand
Anggriani, Yusi	478	Generic Medicine Pricing Policies Evaluation in Indonesia and the Impact on Availability and Medicine Price in Private Sectors
Annan, Edith Asaabah	404	Assessing Local Manufacturing Capacity for Child-Specific Dosage Formulations: The Case of Ghana
Ansah, Evelyn Korkor	307	Effect of Removing Direct Payment for Health Care on Utilization and Health Outcomes in Ghanaian Children: A Randomized Controlled Trial
Arhinful, Daniel Kojo	1035	Household Access to and Use of Medicines in Ghana
Arhinful, Daniel Kojo	1049	Health Facility Pharmaceutical Situation Assessment in Ghana
Arhinful, Daniel Kojo	1047	The National Health Insurance Programme in Ghana and Household Access to Medicines
Arhinful, Daniel Kojo	1104	Tackling Medicine Related Issues Affecting the National Health Insurance Scheme in Ghana
Arifaj-Blumi, Dardane	883	Price Information Exchange for Selected Medicines in the World Health Organization Western Pacific Region
Ashigbie, Paul Gamelie	557	Pharmaceutical Regulation in 12 Countries
Assaad-Khalil, Samir Helmy	637	Trends of Current Treatment and Outcomes of the Management of Type 2 Diabetic (T2DM) Patients in Egypt: Results from the International Diabetes Management Practices Study (IDMPS)
Athuraliya, Theresa Nimal	527	Access and Use of Medicines in Kandy District, Sri Lanka
Atta ElMannan Ali, Abeer Abuzeid	126	Antimalarial Prescribing and Dispensing Practices in Health Centres of Khartoum State, 2003–04
Ayinbuomwan, Stephen, Airmunwonsa	754	Effects of the 2005 Change in National Antimalarial Treatment Policy on Prescribing Practices in Two Referral Hospitals in Benin City, Nigeria
Ayinbuomwan, Stephen, Airmunwonsa	822	Safety and Tolerability Profile of Artemisinin-Based Antimalarial Combination Therapy (ACT) in Adult Nigerians
Aylward, Thomas Patrick	1109	An Analysis of the Global Fund's Price and Quality Reporting Database
Azeredo, Thiago Botelho	1153	National Evaluation of Medicines Dispensing within Brazilian AIDS Program
Babar, Zaheer-Ud-Din	885	Evaluating Pharmacists' Views, Knowledge, and Perception Regarding Generic Medicines in New Zealand
Bahri, Salmah	602	Survey on the Use of Medicines by Consumers in Federal Territories of Kuala Lumpur and Putrajaya

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
Bahri, Salmah	604	Survey on the Use of Medicines by Malaysian Consumers
Balasubramaniam, Ramasamy	608	Availability, Price, and Affordability of Key Essential Medicines for Children in a Resource-Limited Country
Ball, Douglas	287	Regulating Supply Chain Mark-Ups to Control Medicine Prices—A Review of the Literature in Low- and Middle-Income Countries
Bankar, Mangesh Anandrao	659	Promoting Proper Use of Medicines in School Children: An Interventional Study
Bannenberg, Wilbert	1025	Multi-Stakeholder Collaboration: Can It Improve Transparency, Disclosure
Bapna, Jawahar Singh	324	Effects of an Intervention on the Use of Medicines in Herat Province of Afghanistan
Barasa, Edwine	678	Costs and Effects of a Multifaceted Intervention to Improve the Quality of Care of Children in District Hospitals in Kenya
Bassi, Peter Usman	580	Pilot study of cohort event monitoring (CEM) on patients treated for malaria with Artemisinin Based Combination Therapies (ACTs) in Nigeria
Batmanabane, Gitanjali	612	Facilitating the Preparation of Essential Medicines List for Children in India: Lessons Learned
Batmanabane, Gitanjali	615	Better Medicines for Children in India: A Project to Improve Access to Essential Medicines
Batmanabane, Gitanjali	671	Analysis of Clinical Trials in Children Registered in the Clinical Trials Registry of India
Batmanabane, Gitanjali	647	Comparison of the National List of Essential Medicines (India) with the WHO Model Lists of Essential Medicines and Essential Medicines for Children
Batra, Suntheep	705	Clinical Impact of Adherence to Pharmacotherapeutic Guidelines on the Outcome in Patients with Chronic Heart Failure
Batwala, Vincent	1095	Cost-Effectiveness of Treating Malaria Following Three Methods of Diagnosis: Implications for Scaling-Up Use of Rapid Diagnostic Tests in Uganda
Bawazir, Saleh Abdullah	1191	Pharmaceutical Policies Used by Private Health Insurance Companies in Saudi Arabia
Bbosa, Godfrey Sande	923	Effect of Interventions on Misuse of Antibiotics/Antibacterial Drugs in Developing Countries: a Systematic Review
Beran, David	144	A Rapid Assessment Protocol for Improving Access (RAPIA) to Medicine and Care for Children living with a Chronic Condition (Congenital Adrenal Hyperplasia) in Vietnam
Beran, David	152	Irrational Use of Diabetes Medicines in Resource-Poor Settings
Bergstrom, Richard	860	Exploring a Global Compact to Preserve Novel Antibiotics
Bergstrom, Richard	788	Role of Pharmaceutical Industry Marketing Codes in Securing Good Governance
Beshir, Hatem Ahmed Ibrahim Ahmed	528	Patient Behavior When Prescribed Non-Affordable Drugs in University Hospitals of Alexandria, Egypt
Bhanbhro, Muhammad Sadique	395	Balancing Gender-Based Inequities to Improve Access and Uptake of TB Treatment
Bigdeli, Maryam	832	A Conceptual Framework for a System-Wide Definition of Access to Medicines
Bigdeli, Maryam	833	Bibliometric Study of Publication Patterns in Access to Medicines in Low- and Middle-Income Countries
Bigdeli, Maryam	1093	Priority Policy Research Questions in the Area of Access to Medicines in Latin America, Middle East, and Asia
Bisalinkumi, Ezechiel	866	Prescribing Pattern of Antibiotics in Health Facilities in Baghdad, Iraq
Boing, Alexandra	651	Gender Inequalities in Medicine Expenditure and Family Budget Allocated to Medicines in a Southern Brazilian City: Population-Based Study
Boruett, Patrick Kibiwott	542	Improving Adherence and Clinic Attendance Among Patients on Antiretroviral Treatment in Kenya: A System Level Intervention
Brantuo, Mary Nana Ama	416	An Audit of Case Management of Common Childhood Illnesses in Hospitals in Ghana

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
Bruneton, Carinne	374	Study on National Essential Medicines Lists from 8 Countries of the Western African Economic and Monetary Union
Buabeng, Kwame Ohene	113	Medicine Outlets and Their Practitioners in Malaria Control in Ghana
Buenaventura, Joel Hernandez	905	The Impact of the 2008 Economic Recession on the Pharmaceutical Sector in the Baltic Countries
Cameron, Alexandra Meagan	204	Differences in the Availability of Medicines Used for Noncommunicable and Communicable Conditions in the Public and Private Sectors of Developing Countries
Cameron, Alexandra Meagan	357	Availability, Price, and Affordability of Cardiovascular Medicines: A Comparison across 36 Countries Using WHO/HAI Data
Carapinha, Joao	640	Gender and Medicines In HIV/AIDS, Tuberculosis, and Malaria in Low- and Middle-Income Countries: A Systematic Review
Carapinha, Joao	213	Health Insurance Systems in Five Sub-Saharan African Countries: Medicines Benefits and Data for Decision-Making
Cassimjee, Mariam	128	The Evaluation of Compliance to an Essential Medicine Programme: Use of Standard Treatment Guidelines in South Africa's State Health Facilities of eThekweni
Castro, José Luis	1198	Estimation of Antibiotic Utilization Patterns in 4 Latin-American Countries
Castro, José Luis	1150	Regional Strategy for Implementing the Rational Use of Medicines at the National Level in Latin American Countries
Castro, José Luis	1164	Development of a Regional Network of Medicines Information Centres
Castro, José Luis	1197	Regional Strengthening of Pharmacotherapeutic Committees
Cebotarenco, Natalia	553	Community Learns Appropriate Antibiotic Use Through Kindergarten Performances
Cebotarenco, Natalia	1054	School-Based Education Program Can Favorably Impact National Public Health Budget
Cebotarenco, Natalia	1022	MMDR–TB Among Children in Moldova
Cepuch, Christina Anna	933	Monitoring Medicine Prices and Availability in Kenya Using WHO/HAI Methodology 2009–2010
Cepuch, Christina Anna	944	East African Health Budgets 2010/2011: An Analysis on Financing for Essential Medicines
Chalwe, Victor	748	Influence of Mefloquine Malaria Prophylaxis on HIV Disease Progression: A Randomized Placebo-Controlled Trial
Chalwe, Victor	746	Effectiveness of Using RDTs and ACTs for Home Management of Malaria in Children Under 5 Years Old in Zambia
Chandy, Sujith John	538	Economic Burden and Health Consequences of Antibiotic Resistance in Patients at a Tertiary Care Hospital, Vellore, South India
Chandy, Sujith John	539	Effectiveness of an Antibiotic Policy in Containing Antibiotic Use at a Tertiary Care Hospital, Vellore, South India
Chimedtseren, Munkhdelger	741	Pharmaceutical Situation Analysis of Mongolia
Chindove, Stanley	127	Impact of Strategies to Improve Collection and Reporting of Logistics Information for Managing Essential Medicines in Developing Countries
Chinwong, Surarong	816	Practice of Community Pharmacists Dispensing Emergency Contraceptive Pills in Chiang Mai, Thailand
Chinwong, Surarong	913	The Practice of Community Pharmacists on Emergency Contraceptive Pills Dispensing in a Contraindicated Situation
Choi, Seemoon	1127	Report Cards and Prescribing Behavior: Assessing the Impacts of Public Disclosure on Antibiotic Prescribing Rates in South Korea
Chu, Yanqi	1186	Medication Errors of Intravenous Medication in Teaching Hospital in China
Chuchu, Sarah Akoth	1042	Demonstrating the Potential Role of Information and Communication Technologies in Improving Management and Use of Antiretroviral Medicines in Resource-Limited Settings

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
Cinnella, Enrico	535	Baseline Assessment of Pharmaceutical Situation in Southern African Development Community
Cinnella, Enrico	975	Government, Civil Society, and WHO Partnership: a Catalyst for Better Access to Medicines In Countries
Claudine, Essomba Ntsama	984	Priority Policy Research Questions in the Area of Access to Medicines in Cameroon, Chad, Congo, and Gabon
Coetzee, Renier	1074	Improved Safety Monitoring of Second Generation Antipsychotics Following a Rational Prescribing Intervention
Coignez, Veerle	219	The Good, the Bad, and the Ugly: A System-Based Three-Pronged Strategy to Combat Substandard and Counterfeit Medicines in Low-Resource Countries
Cruzado, Raul	1061	Characteristics of Medicines Found in the Households of the District of Chimbote – Ancash (Peru), December 2007
Dabade, Gopal	1263	Drugs for Anemia
Dâmaso, Andréa Homsí	1138	Use of Medicines with Unknown Fetal Risk among Pregnant Women from the Pelotas Birth Cohort 2004, Brazil
Dâmaso, Andréa Homsí	407	Medicine Use from Birth to Two Years of Age: The 2004 Pelotas (Brazil) Birth Cohort Study
Dâmaso, Andréa Homsí	408	Factors Associated to Medicine Use Among Children from the 2004 Pelotas Birth Cohort (Brazil)
Dâmaso, Andréa Homsí	409	Medicine Utilization in Adolescents Aged 11 from the Pelotas (Brazil) 1993 Birth Cohort Study
Dâmaso, Andréa Homsí	775	Affordability of Medicines for Treating Chronic Diseases in Southern Brazil
Dâmaso, Andréa Homsí	560	Role of Free Provision on Household Expenditures for Medicines in Brazil
Dâmaso, Andréa Homsí	706	Medicine Prices and Availability in Southern Brazil
Dâmaso, Andréa Homsí	998	Evolution of the Generic Medicines Market in Brazil, 1998-2010: Antihypertensives, Antidiabetics, and Antibiotics
Dartnell, Jonathan	468	Improving Diabetes Management in Primary Care
Dartnell, Jonathan	467	Establishing a Nationally Consistent Approach to Implementing the Principles of Good Prescribing in Health Practitioner Education
Daviaud, Joëlle	1012	Experience with the Global Fund's Revised Quality Assurance Policy for Pharmaceutical Products
Daviaud, Joëlle	1024	Study on Quality Assurance for Essential Medicines other than ARVs, Antimalarial and Antituberculosis Medicines
Daviaud, Joëlle	1050	Impact of Policy Revision on Harmonization and Transparency of Quality Assurance Criteria for Anti-Tuberculosis Medicines
Dedeoglu, Burcak Deniz	961	Rational Drug Use Policy in Turkey
Diwan, Vishal	526	Antibiotic Prescription by Informal Health Providers in Ujjain District, India
Djanun, Zunilda	793	Antibiotic Surveillance in Intensive Care Unit: Quality Assurance of Antibiotic Usage
do Valle Bastos, Luis Gustavo	1053	Monitoring Drug Resistant Tuberculosis Treatment in Brazil through an Innovative Web-Based Information System
Doodoo, Alexander Nii Oto	1175	Role of the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance on the Establishment of National Centres in Africa
Doubova, Svetlana Vladislavovna	235	Effects of Two Educational Programs Aimed at Improving the Utilization of Non-opioid Analgesics in Family Medicine Clinics in Mexico
Dreser, Anahi	509	Impact of Implementing Antibiotic Sales Restrictions: Reactions of Key Stakeholders and Citizens in Mexico
Edwards, Suzanne Elizabeth	270	Health Care Payments in the Asia Pacific: Validation of Five Survey Measures of Economic Burden
Edwards, Suzanne Elizabeth	600	Anecdotal Evidence for Ways in which the Originator Pharmaceutical Industry Has Contributed to Improving the Appropriateness of Medicine Use in Low-Income Countries through Product and Packaging Adaptations

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
Edwards, Suzanne Elizabeth	599	Marketing and Promotion of the Pharmaceutical Industry: Snapshot of Current Practice Within, or With Possible Implications In, Low- and Medium-Income Countries
Eghan, Emmanuel Kwesi	834	Impact of Training, Monitoring, and Mentoring on Drug and Therapeutic Committees in Ghana
EL-Ghazouly, Karim Maged	1094	The Risk of Getting Anti-TB Drugs as OTC Drugs
Elkazaz, Hagar Abd Elkhalek	1059	Use of Hospital Formulary to Improve Medicine Use at Alexandria Ophthalmology Hospital, Egypt
El-Sayed, Hesham Ahmed Fathey Mohamed	708	Assessment of the Effectiveness and Safety of Outpatient Treatment of Severe Pneumonia Among Egyptian Children with Oral Amoxicillin
El-Sayed, Hesham Ahmed Fathey Mohamed	709	Effectiveness of Oral Zinc Supplementation in the Treatment of Acute, Watery Diarrhea
Emmerick, Isabel Cristina Martins	733	Pharmaceutical Situation Assessment: Methodological Challenges for Different Contexts
Emmerick, Isabel Cristina Martins	970	Access to Medicines For Treating Acute Condition in Three Low- Income Countries In Central America
Espin, Jaime	747	External Reference Pricing (ERP): Existing Evidence and Lessons for Developing Countries
Ewen, Margaret Anne	285	Out of Pocket and Out of Reach: The Unaffordability and Unavailability of Medicines in Low- and Middle-Income Countries
Ewen, Margaret Anne	498	Taxes on Medicines
Eze, Soludo Bartholomew	367	Health Systems Barriers that Determine Access to Antiretroviral Drugs in Southeast Nigeria
Ezenduka, Charles C	704	Retail Drug Market and the Price of Malaria Medicines in Enugu Urban, Southeast Nigeria: Implications for Affordability and Access to Artemisinin-Based Combination Therapy
Garabedian, Laura Faden	236	Active Pharmaceutical Management Strategies of Health Insurance Systems to Improve Cost-Effective Use of Medicines in Low- and Middle-Income Countries: A Systematic Review of Current Evidence
Garabedian, Laura Faden	1034	Impact of the 30-Baht Scheme on Access to and Use of Medicines in Thailand: A Policy Evaluation Using Market Share Data
Faroun, Hazar	1211	Pharmaceutical Situation Assessment: Level II Health Facilities Survey in Syria
Fernandopulle, Rohini	773	Tsunami Drug Donations in Sri Lanka: Have the WHO Guidelines on Drug Donations been Effective in Meeting Public Health Pharmaceutical Needs in Times of Disaster?
Fort, Marie-antide	825	Working Together for Mental Health: The Nouadhibou Pilot Experience
Fort, Marie-antide	634	Access to Antimalarial Medicines: The Impact Malaria Approach
Fracalossi Redigueri, Carolina	828	New warnings for medicines labeling and packaging in Brazil
Fulone, Izabela	1134	Rational Use of Antidepressants Combined with Benzodiazepines
Fyzoo, Fathima	1113	Evaluating the Effectiveness of TB Medicine Supply Management Training in Western Cape, South Africa
Fyzoo, Fathima	1122	Investigating Medicine Supply as a Rate Limiting Step in the Scale-Up of Isoniazid Preventive Therapy in Kwazulu-Natal, South Africa
Galang, Rainier	519	Educational Intervention to Combat Counterfeit Medicines in Selected Areas in the Philippines
Gaparayi, Patrick	621	Assessment of Generic Antimicrobial Unit Retail Price Mark-Ups Applied in Public Hospitals in Rwanda
Garcia Serpa Osorio-de-Castro, Claudia	217	Planning for Sustainability of ARV Provision: A Study in Peru, Bolivia, and Mozambique
Garcia Serpa	211	Pharmaceutical Services for Uncomplicated Malaria by P. vivax and P.

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
Osorio-de-Castro, Claudia		falciparum in High-Risk Municipalities of the Brazilian Amazon: Organization of Services, Prescribing, Dispensing, and Adherence to Treatment
Garcia Serpa Osorio-de-Castro, Claudia	460	An Action Plan for the Selection of Essential Medicines
Garcia Serpa Osorio-de-Castro, Claudia	461	What Do Managers and Prescribers of the Brazilian Health System Think of Essential Medicines? Preliminary Results of a Nationwide Qualitative Study
Garcia Serpa Osorio-de-Castro, Claudia	683	Analysis of NMP Documents of the Region of the Americas
Geer, Mohammad Ishaq	814	Intensive Hospital-Based Adverse Drug Reactions Monitoring Studies on 5482 Patients of Kashmiri Origin in a Tertiary Care Hospital
Ghandour, Rula Abdelakrim	804	Variation in Service-Providers' Prescribing Behaviour and Policy Implications for Women with Genitourinary Tract Infections in Ramallah, Occupied Palestinian Territory (oPt)
Gharpure, Kunda Jayant	176	Effect of IEC Intervention on Awareness about Rational Pharmacy Practice in Pharmacy Students
Gill, Christopher John	758	Antibiotics with Facilitated Referral to a Rural Health Center Using Zambian Trained Traditional Birth Attendants as a Strategy for Reducing Neonatal Mortality
Gill, Christopher John	1218	Cost and Cost-Effectiveness of Training Zambian Traditional Birth Attendants in Interventions Targeting Common Causes of Neonatal Mortality
Gitau, Lilian Nyambura	543	Routine Assessment of Patients' Attendance and Adherence to Antiretroviral Treatment In Kenya – Providers' Views on Usefulness to Improve Performance
Godman, Brian Barr	278	Trends in Pricing Policy of Generics: Global Implications
Godman, Brian Barr	279	Intensity of Reforms Resulting in Considerable Differences in Generic Utilisation across Europe; Implications for Others
Godman, Brian Barr	281	Risk-Sharing Arrangements—Opportunity or Threat to Fund New Medicines?
Godman, Brian Barr	282	Care Needed When Comparing IMS and Administrative Databases in Cross National Comparative Studies?
Godman, Brian Barr	283	Intensity of Individual Reforms Results in Considerable Differences in Subsequent Utilisation; Implications for Countries When Contemplating Future Initiatives
Godman, Brian Barr	359	Challenges When Introducing Generic Policies to Enhance Their Utilisation: Impact and Next Steps
Godman, Brian Barr	360	Care Needed When Introducing Generic Policies to Reduce Costs: Experiences From Abu Dhabi
Goredema, Wonder	1116	Implementing a Self-Assessment and Continuous Quality Improvement Approach to Improve Hospital Infection Control Practices in Africa and Latin America
Grace, Cheri L	972	Assessing Global Health Financing and Policy: Potential Contribution of Pooled Funds
Grace, Cheri L	873	Value for Money Perspective on Global Health Initiative Market-Shaping Impact
Grace, Cheri L	969	Modelling the Potential for Market Impact and Supply Security Risks: Focus on Donations with Applications for Differential Pricing
Green, Terry L.	690	Drug and Therapeutics Committees in Africa and Asia: From Training to Implementation
Green, Terry L.	1018	Development and Application of Selected Indicators to Investigate Antimicrobial Use in Hospitals
Guillard, Etienne	1067	Encourage Appropriate Use of Pediatric Antiretrovirals With a Demonstration Kit in Pharmacies: Results 18 Months after Kit Was Made Available in 2 HIV/AIDS Pediatric Treatment Centers in Niamey, Niger
Guillard, Etienne	850	Development of a Tool for Simple Visualisation of Periods of ARV Therapy Availability in a Context of Expanding Treatment Coverage
Gulija, Marija	965	Introducing a Revised Model for Pricing and Reimbursement of Medicines in

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
		Macedonia
Gunn, Brian Conroy	585	Importance of Monitoring Patients on Atypical Antipsychotics
Gunn, Brian Conroy	587	Reasons for Rejection of Medications by Patients in Oman
Gunn, Brian Conroy	796	Prophylactic Use of Antimicrobials During Surgery
Gunn, Brian Conroy	807	Using Defined Daily Doses, Pivot Tables, and Charts as a means of Measuring Medicine Utilisation Trends
Gupta, Usha Gupta	903	Impact of Community Education Programme on Safe Use Of Medicines in Two States of India
Gurumurthy, Parthasarathi	812	Prevalence and Predictors of Potentially Inappropriate Medication Use in Elderly Patients in Two Indian Teaching Hospitals
Gurumurthy, Parthasarathi	596	Integrating Pharmacovigilance in Revised National Tuberculosis Control Programme of India: A Pilot Study
Gurumurthy, Parthasarathi	909	A Prospective Study of Prevalence, Severity and Preventability of Adverse Drug Reactions in Hospitalized Human Immunodeficiency Virus (HIV) Positive Patients
Gyansa-Lutterodt, Martha	421	Assessment of Availability, Price, and Affordability of Medicines for Children In Ghana
Gyansa-Lutterodt, Martha	1126	Containing Health Care Costs in Ghana: Role of Evidence-Based Selection of Medicines
Hadiyono, Johana E. P.	790	Empathic Caring Consultation (ECC): Will It Be Able to Reduce the Unnecessary Use of Analgesics?
Hamra, Rasha Saadi	711	Transparency Monitoring Study: A Rapid Assessment of Transparency in Key Functions of Pharmaceutical Services in 15 Countries
Hansen, Ebba Holme	831	Medication Among Children in Africa South of Sahara: Qualitative Systematic Review
Haq, Abida	981	Implementation of Good Governance in Medicine (GGM) Programme in Malaysia to Strengthen Medicines Management
Harbarth, Stephan	246	Characteristics and Outcomes of Public Campaigns with the Aim to Improve Outpatient Antibiotic Use in High Income Countries
Hartayu, Titien Siwi	148	Improving Diabetic Patients' Adherence to Treatment Program by Using CBIA-DM Strategy in Hospital- Based Patient Community
Haustein, Thomas	406	Can the Application of the International Health Regulations to Antimicrobial Resistance Events Help to Preserve Antimicrobials?
Hawkins, Loraine	847	Can Competition Law or Other Competition-Promoting Policies Reduce Medicine Prices in Developing Countries?
Hegab, Nahla Maher	779	People Living with HIV/AIDS : Role of Community Pharmacist
Helali, Abdelkader	294	Impact of the WHO Guide to Good Prescribing on Medical Students
Hemming, Mary	449	Up-to-Date, Evidence-Based Advice for Busy Clinicians
Hensen, Bernadette	241	Taking Stock: Provider Prescribing Practices in the Presence and Absence of ACT Stock
Hidayati, Sri	143	CBIA-Pregnancy to Improve Skills of Pregnant Mothers in Selecting OTC Common Cold Preparations
Higuchi, Michiyo	929	The Use of Medicines and Standard Treatment Guidelines in Rural Timor-Leste
Hirunrassamee, Sanita	718	Does Your Health Care Depend on How Your Insurer Pays Providers? Variation in Utilization and Outcomes in Thailand
Hirunrassamee, Sanita	811	Effects of Listing and Delisting in National Essential Medicine List on Utilization Patterns
Hoebert, Joelle Martine	826	How Sustainable is the EU Regulatory Network in the Context of the Uptake of New Medicines?
Hoebert, Joelle Martine	257	Do European Rheumatoid Arthritis Patients Have Equal Access to Treatment with New Medicines?
Hogerzeil, Hans V.	555	Access to Essential Medicines as Part of the Right to Health in National Constitutions of 186 Countries

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
Holloway, Kathleen Anne	337	Progress in Standard Indicators of Medicines Use Over 20 Years
Holloway, Kathleen Anne	338	Medicine Use in Children Under 5: 20 Years of Practice Patterns and Intervention Effects
Holloway, Kathleen Anne	340	Surveillance of Antimicrobial Use in Resource-Constrained Community Settings
Holloway, Kathleen Anne	341	Surveillance of Antimicrobial Resistance in Resource-Constrained Community Settings
Holloway, Kathleen Anne	339	Do Countries with Pharmaceutical Policies Have Better Medicines Use Than Those without?
Holloway, Kathleen Anne	611	Health Systems Approach to Improving the Use of Medicines in the S.E. Asian Region (SEAR)
Hosseini, Seyed Ali Reza	320	Prescribing Pattern of Physicians in Rural Health Insurance Program in Primary Health Care Facilities in Iran
Hosseini, Seyed Ali Reza	323	Development and Implementation of an Evidence-Based Drug List for Rural Health Insurance Program in Iran
Hsu, Chih-Sheng	507	The Evolution of Taiwan's National Health Insurance Drug Policy—Review and Analysis
Huss, Reinhard	955	Improving Governance in the Pharmaceutical Sector of Karnataka—the Role of an Anti-Corruption Agency and its Limitations
Hwang, Bella	744	Effects of a Mobile Phone Short Message Service (SMS) on Antiretroviral Treatment Adherence in Kenya (WeTel Kenya1): A Randomized Trial
Hwang, Bella	889	WeTel Kenya: Business Case for Using Mobile Phones as a Cost-Effective Health Intervention to Provide Care and Support HIV/AIDS Patients
Ibrahim, Samaa Zenhom	377	Assessment of Patient Knowledge Regarding Drugs Prescribed and Dispensed in Some Health Insurance Outpatient Clinics in Alexandria
Ibrahim, Samaa Zenhom	376	Assessment of Drug Utilization Patterns in Some Health Insurance Outpatient Clinics in Alexandria
Ibrahim, Ahmed Mustafa	559	Pattern of Use of Complementary and Alternative Medicine (CAM) Among Patients with Type 2 Diabetes Mellitus (T2DM) in Alexandria, Egypt
Isah, Ambrose Ohumagho	1033	Proposed Set of Indicators for Monitoring and Evaluation of Pharmacovigilance Activities
Islam, Qazi Shafayetul	111	Availability and Rational Use of Essential Drugs in the PHC Facilities in Bangladesh: Are We on the Right Track?
Ismail, Mohamed Ramzy	1189	WHO Good Governance for Medicines Programme: Innovative Approach to Curb Corruption in the Pharmaceutical Sector
Ivama, Adriana Mitsue	880	Pharmaceutical Situation in Barbados: WHO Level II Health Facilities Survey, 2010
Ivama, Adriana Mitsue	882	Proposal for a Baseline Assessment for the Caribbean Pharmaceutical Policy
Ivama, Adriana Mitsue	1144	Assessment of Pharmaceutical Situation in Suriname
Ivama, Adriana Mitsue	1147	Assessment of Pharmaceutical Situation in Jamaica
Ivama, Adriana Mitsue	1156	Caribbean Network on Pharmaceutical Education
Ivama, Adriana Mitsue	856	Partnership on Pharmaceutical Policies in the Caribbean: 2006-2009
Ivama, Adriana Mitsue	867	Development of the Caribbean Pharmaceutical Policy
Ivama, Adriana Mitsue	1098	Pharmaceutical Situation in the Caribbean as Background for Policy Development
Jara, Antonio J.	1078	Drugs Identification and Interaction Checker to Reduce Tuberculosis Drug Compliance and Improve Treatment Adherence
Jelastopulu, Eleni	423	The Rational Use and Access to Medicines by the Citizens: The Greek Experience
Jelastopulu, Eleni	691	Attitudes, Beliefs, and Prescription Habits of Greek Physicians Regarding Generic Drugs

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
Jiang, Bin	1129	Provincial Essential Medicine List Comparison among 12 Provinces in China
Joshi, Mohan P.	694	Indicator-Based Survey Tool to Determine the Use of Antimicrobials and Knowledge about Drug Resistance in the Community
Joshi, Mohan P.	699	Capacity-Building for Country and Regional Level Advocacy and Interventions to Contain Antimicrobial Resistance in Africa
Juban, Noel Reyes	502	Process and Lessons from the Philippine Pharmaceutical Sector Scan
Kaboh, Amal Galal	1083	Calculation of Tuberculosis Patients' Drug Consumption Using Electronic Nominal Recording–Reporting System at District Level
Kabore, Inoussa	1123	The Effect of Community-Based Support Services on Clinical Efficacy and Health-Related Quality of Life in HIV/AIDS Patients in Resource-Limited Settings in Sub-Saharan Africa
Kabore, Inoussa	1162	Findings from Integrating CVD risk factors screening and services among HIV clients in resources constrained setting
Kafle, Kumud Kumar	473	Implementation of a Policy for Monitoring Prescribing Practices in Public Health Care Outlets in Nepal
Kakai, Rose	267	Low Reliability of Home-Based Diagnosis of Malaria in a Rural Community in Western Kenya
Kalemeera, Francis	922	Risk of Anemia Associated with Zidovudine (AZT)-based HAART in Namibia
Kalemeera, Francis	930	The Namibia Treatment Literacy Approach: Empowering Patients with Knowledge on Antiretroviral Therapy through Audiovisual Materials
Kanchanaphibool, Inthira	1004	Impacts of Direct Fee-For-Service Payment Insurance on Access and Use of Drug: An Interrupted Time Series Study on Diabetic Care
Kandil, Nahla Hesham	391	Medication Administration Management: Assessment of Critical Care Nurses' Baseline Knowledge and Strategies for Building Awareness
Kanjanasilp, Juntip	764	Outcomes of Pharmaceutical Care in Schizophrenic Patients
Kaplan, Warren	716	Evolution of Generic Medicine Market Share in the Pharmaceutical Retail Sector of 21 Low- and Middle-Income Countries Between 1999 and 2009: Time-Series Analysis
Kaplan, Warren	490	Policies to Increase Use of Generic Medicines in Low- and Middle-Income Countries: A Literature Review of Implementation Research
Karga-Hinds, Maryam Jamila	1089	Access to and Use of Medicines in Barbados: Evidence from a Household Survey
Kasparas, Gustavo Guillermo	876	Computer Alert System and Telephone Support to Improve Antiretroviral Therapy Adherence
Kayiwa, Joshua	532	Decongesting Public Health Facilities is Associated with Better Clinical Outcomes Among Patients Initiating Antiretroviral Therapy in Uganda
Kazaryan (Ghazaryan), Irina	697	Access to and Use of Medicines by Households in Armenia: Impact of Current Policy on Reimbursement of Medicines
Kazaryan (Ghazaryan), Irina	1154	Transparency in the Armenian Pharmaceutical Sector
Kedenge, Sarah Vutagwa	712	Evaluating the Impact of Subsidized Artemether-Lumefantrine in the Retail Sector on Coverage of Prompt Effective Treatment of Children Under Five in Kenya- A Cluster Randomized Controlled Trial
Kerstens, Birgit	967	Country Comparison of MeTA Baseline Pharmaceutical Sector Scan Data
Khalil, Khaled	1102	Causes of ATBM Shortages in GFATM and GDF-Supported Countries in the Eastern Mediterranean Region and How to Avoid Them in the Future
Khalil, Khaled	1110	Patients' Compliance and Adherence to 4-FDCs that are Provided by Global Drug Facility to 15 Countries in the Eastern Mediterranean Region
Kiatying-Angsulee, Niyada	926	Antibiotic Resistance Policy in Thailand: Role of Comprehensive Networking Campaign
Kiatying-Angsulee, Niyada	795	Drug System Monitoring and Development Project, Funded by Sin Tax, and the Roles in Promoting Rational Drug Use in Thailand
Kiatying-Angsulee, Niyada	1143	Priority Policy Research Agenda to Achieve Access and Rational Use of Medicines in Thailand
Kiatying-Angsulee,	1161	Good Governance of Medicines System in Thailand: From Assessment to

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
Niyada		National Policy Agenda
KIRIKA, Rosalind Wanjugu	912	Using a Rapid Results Approach to Improve Supply Chain Efficiency and Increase Availability of Essential Medicines and Supplies
Kittisopee, Tanattha	664	Knowledges and Attitudes toward Emergency Contraceptive Pill among Thai Men in Bangkok and Its Utilization
Km, Mandavi	262	Comparison of Different Inappropriate Prescribing Screening Tools Used for Assessment of Inappropriate Drug Prescription in the Elderly
Kockaya, Guvenc	1217	Treatment Cost of Metastatic Colon Cancer in Turkey
Kockaya, Guvenc	1216	Off-Label and Non-Licensed Endocrinology Medicine Use in Turkey: A Retrospective Analysis of Computer Records in the Turkish Ministry of Health
Kockaya, Guvenc	1219	Overview of Drug Tracking System (ITS) in the Pharmacies of Ankara: Preliminary Research
Kollannur, Antony	771	Survey of the Availability and Prices of Children's Medicine in Chhattisgarh State
Konradsen, Dorthe	727	Is a Standard Kit an Effective Way to Optimise Use of Limited Resources and Increase Availability of Medicine? Experiences from Reintroducing Standard Kits in Resource-Poor Settings in Uganda
Kotwani, Anita	642	Can the Indian Government Improve Access to Medicines Through Generic Drug Stores?
Kotwani, Anita	673	Impact of Standard Treatment Guidelines and Patient Education on Asthma Control and Knowledge in Asthmatic Patients: A Controlled Trial
Kotwani, Anita	556	Trends in Antimicrobial Use Among Outpatients in New Delhi, India
Kotwani, Anita	582	Antibiotic Prescribing Practices of Primary Care Prescribers for Acute Respiratory Tract Infections and Diarrhoea in New Delhi, India
Kotwani, Anita	584	Factors Influencing Antibiotic Prescribing by Primary Care Doctors in Delhi, India: Qualitative Study
Kounnavong, Sengchanh	107	Effect of Multiple Micronutrient Supplements for Improving Anaemia of Preschool Age Children in Rural, Lao People's Democratic Republic: A Randomized Trial
Kusu, Ndinda	770	Human Resources for Health: Preservice Training of Pharmacy Students on Effective Management of Antiretroviral Therapy Commodities in Kenya
Kusu, Ndinda	769	Strengthening Pharmacovigilance Systems: Experiences from Kenya
Kwon, Soonman	254	International Comparison of Generic Medicine Prices
Kwon, Soonman	298	Reimbursement Price, Market Structure, and Pharmaceutical Firm Behavior in Korea
Kwon, Soonman	957	Challenges of Health Care Financing and Access to Medicines in Low-income Countries of Asia
Ladd, Elissa	510	"Under the Radar": Nurse Prescribers and Pharmaceutical Industry Promotions
Lal, Vivek	378	Nonadherence to HAART: A Cross-Sectional Two-Site Hospital-Based Study
Lal, Vivek	496	Reasons for Nonadherence to Antiretroviral Therapy among Adult Patients Receiving Free Treatment at a Tertiary Care Hospital in Delhi
Lates, Jennifer Ann	1203	Cost of ARV Medicines in the Namibian Private Sector: Limitation to Increased Access
Lates, Jennifer Ann	1163	Strengthening Patient Adherence Monitoring through the Electronic Dispensing Tool (EDT)
Lates, Jennifer Ann	1202	Use of an Indicator-Based System for Assessing, Monitoring, and Improving Pharmacy Practice
Lawal, Mohammed Saheed	1225	Prescribing Pattern of Psychotropic Substances in a Nigerian Neuropsychiatric Hospital
Leonardo Alves, Teresa	593	Unbranded Advertising of Prescription Medicines—A Systematic Literature Review
Leopold, Christine	483	Differences in External Price Referencing in Europe—A Descriptive Overview
Leopold, Christine	484	How Much of the Price Variance of Medicines Can Be Explained by External Price Referencing?—A price Comparison among 15 European Countries

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
Levison, Libby	1155	Improving Access to Medical Supplies in Emergency Settings by Preparing Humanitarian Responders with Online Medicine Supply Management Training
Li, Xiaoling	1184	Analysis of essential medicine use in primary health care institutions of Beijing
Liana, Jafary Hassan	1071	Can ADDO Accomplishments Be Sustained? The Tanzania Experience Six Years Later
Liana, Jafary Hassan	1084	Engaging Private Sector Drug Dispensers to Improve Antimicrobial Use in the Community: Experience from the Tanzania Accredited Drug Dispensing Outlets
Lu, Christine Y	514	Spillover Effects of Prescribing Restrictions for Trastuzumab in Australia
Lu, Christine Y	878	Changes in Use of Antidiabetic Medications Following Price Regulations in China (1999-2009)
Luiza, Vera Lucia	932	Remedies at Home: Evaluating an Innovative Medicines Provision Program
Luiza, Vera Lucia	979	Adherence of Prescribers to High Cost Medicines Standard Treatment Guidelines in Rio De Janeiro
Lukulay, Patrick	248	A Risk-Based Cost-Effective Approach to Medicines Quality Monitoring in Resource-Limited Countries
Luyckx, Christophe	1221	The Plague of Substandard Medicines in Developing Countries: Evidence for Policy Change
Lyimo, Ramsey A	667	Electronic Monitoring to Assess Adherence and Validate Alternative Adherence Measures in Tuberculosis Patients on Community-Based Directly Observed Treatment
Mabugu, Travor	189	Cost Analysis of Management of Malaria Using ACT in the Private Sector of Zimbabwe: A Regulatory Implication
Madden, Jeanne Marie	1145	Medicine Prices in Peru: Validation of the Sampling Approach Used in WHO/HAI Surveys
Madden, Jeanne Marie	1148	Monitoring Medicine Prices with WHO/HAI Surveys: Upsides, Downsides, and Forward-Thinking Strategies
Madden, Jeanne Marie	1158	2006 Medicare Part D Benefit: Evaluating a Major Expansion of Medicines Insurance for Vulnerable Americans
Maiga, Diadie	326	Assessment of the Impact of Market Regulation in Mali on the Price of Essential Medicines Provided through the Private Sector
Maija, Aziz	918	Increasing Access to Quality Essential Medicines and Services Provided by Drug Shops in Uganda Through Accreditation and Regulation
Maija, Aziz	921	Improving Quality of Malaria Case Management Provided by Drug Shops in Uganda Through Accreditation and Regulation
Malhan, Simten	1264	Cost of Care of Rheumatoid Arthritis and Ankylosing Spondylitis Patients in Tertiary Care Rheumatology Units in Turkey
Mantel-Teeuwisse, Aukje Kaija	397	Comparative Analysis of the Medicines Financing System of 11 Countries Included in the Pilot of the "WHO Country Profiles" Project
Mantel-Teeuwisse, Aukje Kaija	499	Selection of Essential Medicines
Manz, Christopher	1101	Conflict of Interest Policies: Do Academic Medical Centers Make the Grade?
Mao, Ngeav	371	Improving Access to Routine Medication from a Revolving Drug Fund for Chronic Patients in Rural Cambodia
Marin, Nelly	700	Access to Medicines in Guatemala, Honduras, and Nicaragua: The Challenge of Adapting Methodologies
Masiye, Felix	1168	Impact of User Fee Removal on Utilisation of Public Health Services in Zambia
Masoud, Abdullah	778	Using Routine Information for Improving Rational Prescribing
Mast, T. Christopher	1037	Evaluating the Impact of a Public-Private Partnership for the National Introduction of a New Rotavirus Vaccine: Evidence from a Case-Control Study in Nicaragua (2006–2009)
Mathai, Elizabeth	384	Examples of Interventions to Contain AMR based on International Consultations
Maundu, Josephine Thitu	721	Assessing the Readiness of Pharmacy Outlets to Support Chronic Care: Results from a National Assessment in Kenya

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
Mayakul, Theeraya	879	Compliance of Multidisciplinary Team on Medication Reconciliation Policy at Siriraj Hospital
Mayakul, Theeraya	895	Compliance of Multidisciplinary Team on Medication Reconciliation Policy at Siriraj Hospital
Mbindyo, Regina M	497	Measuring Access to Essential Medicines in Kenya Using the Standardized WHO Level II Health Facility Assessment
Mbindyo, Regina M	964	Measuring Access to Essential Medicines in Kenya Using the Standardized WHO Level II Household Survey
Meiburg, Anke	865	Availability of Paediatric Medicines and Factors Impacting Availability in Faith-Based Health Facilities in Chad
Meiburg, Anke	713	Knowledge, Attitudes, and Perceptions on Antimicrobial Resistance and Antibiotic Use Among Hospital Staff in Kenya
Memiah, Peter	1228	The Science of Quality Improvement (QI) Through Small Tests of Change (STOC) and Modeling of QI Teams to Improve Health Systems in Resource Limited Settings
Memiah, Peter	1229	How Far is Too Far? Does Distance to Clinic Matter for HIV/AIDS Treatment Adherence?
Men, Chean	300	"I Wish I Had AIDS": Qualitative Study on Access to Health Care Services for HIV/AIDS and Diabetic Patients in Cambodia
Metelaya, Hailu Tadeq	1092	Trends in Antiretroviral Drugs Prescribing at Public Health Facilities in Ethiopia: Compliance to Treatment Guidelines
Michael, Sherry Victor	946	Role of Private Pharmacies in TB Control in Egypt
Michael, Sherry Victor	953	Management of Drug-Resistant Tuberculosis Patients, Egypt Experience
Mino, Dolores	266	Pharmacoepidemiologic Study of Potential Drug Interactions in Hospital Inpatients
Mirembe, Justine	786	Predictors of Switching Antiretroviral Regimen Among Clients Attending TASO Jinja, Uganda
Moeti, Themba Lebogang	1044	Enabling Continuity of a Public Health ARV Treatment Program in a Resource-Limited Setting: The Case of the Transition of the African Comprehensive HIV/AIDS Partnerships (ACHAP) Support to the National ART Program to the Government of Botswana
Mohamed Ali, Gamal Khalafalla	220	Controlling Medicine Prices in Sudan: The Challenge of a Recently Established Medicines Regulatory Agency
Mohamed, Aida mohey	344	Adherence to and Outcome of Isoniazid Preventive Chemotherapy in Household Children Contact with Adults Having Pulmonary Tuberculosis: A Prospective Facility-Based Study in Alexandria, Egypt
Mohammednur, Mohammedsied Nuru	293	Cost as a Barrier to Access: Availability, Affordability, and Identifying Component Cost of Essential Medicines
Mohanta, Guru Prasad	346	Newspaper Column for Consumer Education on Medicine Use—An Indian Columnist's Experience
Moldoisaeva, Saltanat	806	Monitoring the Safety of Medicines in Kyrgyzstan
Moon, Suerie	1209	A Win-Win Solution? Critical Analysis of Tiered Pricing to Improve Access to Medicines in Developing Countries
Mori, Amani Thomas	256	Priority Setting for Implementation of Artemisinin-Based Combination Therapy Policy in Tanzania: Evaluation against Accountability for Reasonableness Framework
Mosly, Mohamed Metwally	999	An Evaluation of A Clinical Pharmacist Directed-Intervention to Rationalize Overuse of Stress Ulcer Prophylaxis in Intensive Care Unit.
Movahed, Moslem	787	Standardization of Prescribing and Using Oral Liquid Dosage Forms (OLDFs)
Mwakisu, Salama Jacob	1121	Intervention Strategy in Improving Art Adherence In Tanzania
Mwakisu, Salama Jacob	1125	Promoting Rational Use of ARVs in HIV/AIDS Clinic in Tanzania

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
Naffa, Sana	934	Active Enforcement to Code of Conduct and Conflict of Interest Policies Based on Transparency Assessment Study in Jordan
Narsai, Kirti	622	Impact of Regulatory Requirements on Medicine Access in African Countries: Perceptions and Experiences of Pharma Companies in South Africa
Narsai, Kirti	924	Draft South African Marketing Code—A New Model for Marketing Ethics
Nashilongo, Bona Naita	985	Tracking of Inter-Facility Patient Transfers and Retention on Antiretroviral Treatment in Namibia
Nashilongo, Bona Naita	990	Using Mobile Technology to Strengthen HIV/AIDS Management in Remote Areas
Nashilongo, Bona Naita	1015	Improving Access to ART Services in Namibia through Decentralization
Nashilongo, Bona Naita	1009	The Effectiveness of Therapeutics Committees (TCs) in Addressing Key Public Health Problems
Ndagije, Helen Byomire	313	Regionalisation of Pharmacovigilance in Uganda
Ndekwe, Morris	763	Assessing the Extent of Pharmaceutical Care Provision in Kigali Community Pharmacies
Nguhiu, Peter	722	Piloting the Use of Mobile Short Messaging Systems (SMSs) to Improve Access to Medicines: Experiences from Kenya
Nguyen, Chuc Thi Kim	129	Unnecessary Antibiotic Use for Mild Acute Respiratory Infections in a 28-Day Follow-Up of 823 Children under Five in Rural Vietnam
Nguyen, Chuc Thi Kim	199	Antibiotics and Pediatric Acute Respiratory Infections in Rural Vietnam: Health Care Providers' Knowledge, Practical Competence, and Reported Practice
Nguyen, Connie	185	Use of Prophylactic Oxytocin by Health Care Providers in Northeast Argentina as Part of Active Management of the Third Stage of Labor
Nguyen, Tuan Anh	192	Medicine Prices, Availability, and Affordability in Vietnam
Nguyen, Tuan Anh	193	Corruption and High Medicine Prices in Vietnam: A Qualitative Study
Niëns, Laurens Mathieu	173	Quantifying the Impoverishing Effects of Purchasing Medicines: A Cross-Country Comparison of the Affordability of Medicines in the Developing World
Njogo, Susan Muthoni	544	Improving Appointment Keeping and Adherence Monitoring In HIV Facilities in Kenya: Views of Providers and Patients
Nkrumah, Yvonne Korkoi	1040	Transparency, Governance and Regional Collaboration in Pharmaceutical Procurement in Kenya, Tanzania, and Uganda
Norquay, Carol Ann	330	Editor Training Program
Nwokike, Jude	513	Actions of the National Regulatory Authorities in Developing Countries Following US FDA and EMA Safety Alerts on Rosiglitazone
Nwokike, Jude	1157	Strengthening Pharmacovigilance at the National Level: Development of an Indicator-Based Pharmacovigilance Assessment Tool to Assess Medicines Safety System at the Level of the Pharmaceutical Industry in Developing Countries
Nyamusore, Jose	817	Effects of Patient Tracking Systems and Providers Incentives on Patient Appointment Keeping in Rwanda
Obua, Celestino	505	Improving Adherence to Antiretroviral Treatment in Uganda: Facility-Based Minimal-Input Intervention
Obua, Celestino	859	Plasma Drug Level Validation of Self-Reported Adherence Predicts Limited Specificity for Intrinsic Poor Adherence in Resource-Limited Settings
Ofori-Adjei, David	1081	Improving Access to ACTs Through Licensed Chemical Sellers in Ghana
Okafor, Ukamaka Gladys	638	Access to Medicines in Nigeria – Gender Perspective
Okumura, Junko	195	A Survey on the Quality of Anthelmintic Medicines in Cambodia
Okwen, Mbah Patrick	658	Piloting a Medical Injection Safety Assessment Protocol in Cameroon: Indirect Reuse Represents Risk of Blood-Borne Virus Transmission
Olowofela, Abimbola	740	Antihypertensive Medicines Prescriptions Before and After the Nigeria Hypertension Society Guidelines and Prescriber's Awareness of the Guideline

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
Omotoso, Olukunle	1014	Experiences and Challenges of An Accelerated Tracking Approach To Enhance Client Retention in Rural HIV clinics in North East Nigeria
Onwujekwe, Obinna Emmanuel	439	Role of Patient Demand in the Treatment of Uncomplicated Malaria at Public and Private Health Facilities in Southeastern Nigeria
Onwujekwe, Obinna Emmanuel	1133	Informal Payments for Health Care: Differences in Expenditures from Consumers and Providers Perspectives for Treatment of Malaria in Nigeria
Onwujekwe, Obinna Emmanuel	1137	Improving Quality of Malaria Treatment Services: Assessing Inequities in Consumers' Perceptions and Providers' Behaviour in Nigeria
Onwujekwe, Obinna Emmanuel	1146	Inappropriate Provision and Treatment of Malaria in Public and Private Sectors in Nigeria: Threat to Malaria Elimination Efforts
Opiyo Arwa, Nath Winston	919	Application of Drug Use Evaluation and Feedback to Promote Rational Antibiotic Prophylaxis in C-Sections in Kenya
Or, Oudam Roath	997	Monitoring and Supervision as Tool for Improving Drug Supply Management
Oreagba, Ibrahim Adekunle	517	The Knowledge, Perceptions, and Practice of Pharmacovigilance among Community Pharmacists in Lagos State, Southwest Nigeria
Orwa, Jennifer Akinyi	466	Quality of Some Pharmaceutical Products Manufactured in Kenya
Oshikoya, Kazeem Adeola	1210	Incidence and Cost Estimate of Treating Paediatric Adverse Drug Reactions in Lagos, Nigeria
Ottiglio, Mario	541	R&D Pharmaceutical Industry's Partnerships to Improve Developing World Health
Ouédraogo, Alphonse	745	Different Approaches for Delivery of Intermittent Preventive Treatment (IPT) to Pregnant Women in Burkina Faso
Oyetunde, Olubukola Olusola	275	Impact of Generic Substitution Practice on Care of Diabetic Patients
Ozgulcu, Senay	676	Evaluation of Prescribing Pattern of Physicians in Various Health Care Facilities in Turkey with Respect to the Rational Use of Medicines Principles
Palafox, Benjamin	312	Mapping the Private Sector Distribution Chain to Understand Barriers and Opportunities for Improved Access to Antimalarials in Six Low-income Countries in Africa and South-East Asia
Pasrija, Anuj	385	Commercial Innovation to Improve Health Care Access at the Bottom of the Pyramid in Rural India
Patel, Aarti	210	Quality of Medicines in South Africa: Perceptions vs. Reality
Pathak, Ashish	772	Adherence to Treatment Guidelines for Acute Diarrhoea in Children up to 12 Years in Ujjain, India
Pearson, Sallie-Anne	890	The Impact of Evidence-Based Subsidy Restrictions on Prescriber Behaviour and Patient Outcomes: A Case Study of Lapatinib for the Treatment of HER2+ Metastatic Breast Cancer
Pepe, Vera Lucia Edais	677	Analysis of Medicines Dispensed by Court Order in the Court of Rio de Janeiro: The Application of Scientific Evidence in Decision-Making Process
Pepe, Vera Lucia Edais	884	Characterization of Lawsuits for the Supply of Essential Medicines in the State of Rio De Janeiro, Brazil
Pepe, Vera Lucia Edais	888	Pharmaceutical Services and Essential Medicines: Considerations on Access to Medicines and Judicial Demands in Brazil
Pepe, Vera Lucia Edais	891	Health Litigation and New Challenges in the Management of Pharmaceutical Services
Perez-Cuevas, Ricardo	1118	Evaluating the Quality of Care for Patients with Type 2 Diabetes Using Electronic Medical Record Information in Mexico
Pharasi, Olehile Bada	1159	Application of an International Reference Price List to National Medicines Procurement Tenders
Picard, Justin	971	Digital authentication of pharmaceutical products
Pillay, Anban	1086	Role of Pharmacoeconomics in a Developing Country Context
Pinheiro, Rafael Mota	830	Successful Intervention to Improve the Pharmaceutical Services in a Region of Brazil
Ploylearmsang, Chanuttha	566	Cost Effectiveness of Simvastatin Compared with Atorvastatin for Low-Density Lipoprotein Cholesterol (LDL-C) in Diabetes Patients with Dyslipidemia at a

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
		General Hospital, Northeast of Thailand
Provin, Mércia Pandolfo	679	Brazilian Courts as a Pathway to Medicines which Represent Pharmacotherapeutic Gaps
Pudjiarto Purnamawati	703	Irrational Prescribing Pattern for Children with Upper Respiratory Tract Infection (URTI) in Indonesia
Pujiarto, Purnamawati Sujud	1199	Impact of IT based Promotion of Rational Use of Medicine in Indonesia
Pujiarto, Purnamawati Sujud	1204	Compounding Polypharmacy Prescription in Indonesia
Pumtong, Somying	734	Two-Year Experience of Antibiotics Smart Use Pilot Project in Saraburi, Thailand
Qato, Danya M.	794	Social Disparities in the Use of Prescription Medications: A Population-Based Approach
Quesada-Morúa, Maria Soledad	286	Measuring Transparency in the Public Pharmaceutical Sector. National Assessment for Costa Rica
Quiza, Ma. Fidelis Espiritu	318	Household Drug-Storing Practices Among Community Residents in Paknaan, Mandaue City, Philippines, 2010
Razack, Habeeb Ibrahim Abdul	986	Self Medication in a Kerala District, India - Prevalence and Analysis
Reda, Hailemariam Lemma	314	Feasibility and Impact of Deploying Artemether-Lumefantrine (AL) At Community Level with the Introduction of Rapid Diagnostic Test (RDT)
Reyes-Morales, Hortensia	448	Effectiveness of a Medical Education Intervention to Treat Hypertension in Primary Care
Reyes-Morales, Hortensia	696	Evaluation of a Continuing Medical Education Program for Primary Care Services in the Hypoglycemic Agent's Prescription in Diabetes Mellitus Type 2
Reyes-Morales, Hortensia	489	Antibiotic Knowledge and Self-Care for Acute Respiratory Tract Infections in Mexico
Robertson, Jane	524	Availability of Children's Medicines in Africa, 2007
Rodrigues, Rashmi Josephine	942	Supporting Adherence to Antiretroviral Therapy Using Mobile Phone Reminders In South India
Roughead, Elizabeth E	200	Rapid Assessment Methods for Monitoring Pharmaceutical Policy
Rowe, Alexander	445	Preliminary Results of a Systematic Review of the Effectiveness and Costs of Strategies to Improve Health Care Provider Performance in Low- and Middle- Income Countries
Rowe, Alexander	633	The Rise and Fall of Supervision in a Project Designed to Strengthen Supervision on the Integrated Management of Childhood Illness (IMCI) Strategy in Benin
Rowe, Alexander	635	Multifaceted Intervention to Improve Health Worker Adherence to Integrated Management of Childhood Illness Guidelines in Benin
Rowett, Debra	1178	Improving Access and Quality Use of Medicines in Palliative Care within National Drug Policy, Regulatory, and Funding Frameworks
Roy, Vandana	203	Essential Medicine Concept as a Core of Drug Policy: Impact on Costs, Availability of Quality Medicines, and Their Rational Use in Delhi (India)
Rustemova, Kulsara Rustemovna	120	The role of pharmaco-economics in the decision tasks to improve the quality of medical care in Kazakhstan Republic
Rutta, Edmund R	1141	How the Accredited Drug Dispensing Outlet Program Has Influenced Medicine Access Policies in Tanzania?
Rutta, Edmund R	1069	Can the Management of Uncomplicated Diarrhea at the ADDOs in Tanzania be Further Improved?
Rutta, Edmund R	1062	Assessing How Health Care Providers Use Nevirapine in Malawi
Saad, Amr Abdel Moneim Abdel Rahman	759	Implementing an Egyptian Pharmacovigilance System: University and Public Hospitals' Experience
Saad, Samia	977	Country Comparison of MeTA Baseline Data Disclosure Surveys

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
Saad, Samia	1013	MeTA Baseline Assessments: Experiences and Results
Saad, Samia	1108	Country Comparison of Multi-Stakeholder Process Assessments in the MeTA Baseline
Sabde, Yogesh Damodar	797	Mapping Private Sector Pharmacies and their Characteristics in Ujjain District, Central India
Sagwa, Evans Luvaha	486	Prevalence and Risk Factors of Adverse Effects of Second Line Anti-Tuberculous Medicines in a Treatment Facility in Namibia: 2009-10
Sahoo, Krushna Chandra	729	Infectious Diseases, Antibiotic Use, and Antibiotic Resistance in Context of Environmental Changes: Study Among Community Members in Orissa, India
Saif, Amanullah	624	Relationship Between Tariffs, Prices, and Consumption of Interferon
Saif, Amanullah	904	Cost Plus Price Setting of Medicines
Salifu, Monday	839	Partnership with State Government to Strengthen HIV/AIDS Commodities Logistics Management System
Sallet, Jean-Pierre	1068	Application of an ABC Analysis in the Prevention of Antimicrobial Resistance in Tuberculosis Treatment
Sanjjav, Tsetsegmaa	751	Case Study of the Implementation of Good Governance for Medicines Programme in Mongolia
Saranza, Gerard Raimon Makinano	334	Factors Affecting Patients' Incomplete Understanding of Prescriptions
Sato, Azusa	265	Exploring Traditional Medicines Use by Ghanaian Households
Sau, Sokunna	471	Improving the Rational Medicine Use through the MTP Approach in Cambodia
Selvaraj, Sakthivel	783	Evidence on Availability and Stock-Outs of Essential Medicines: A Study of Two Diverse Government Drug Procurement and Distribution Systems in India
Selvaraj, Sakthivel	1152	Access to Medicines in India: Setting Priorities in Policy Research Issues
Senarathna, D Lalith Priyasantha	950	Use of Brief Educational Intervention and Academic Detailing to Improve Use of Antidotes for Acute Poisoned Patients in Rural Hospitals in Sri Lanka—A Cluster Randomised Controlled Trial
Serour, Sawsan Mahfouz	668	Use of Antibiotics in the Alexandria Community Setting: Magnitude and Pattern
Serumaga, Brian	1223	Consumer Knowledge and Perceptions about Medicines: Evidence from Household Surveys in Five Low- and Middle-Income Countries
Serumaga, Brian	1208	Evidence on the Use of Medicines to Treat Chronic Diseases from Household Surveys in Seven Low- and Middle-Income Countries
Shafiq, Samreen	366	Prescribing Pattern and Therapeutic Drug Monitoring of Vancomycin at a Tertiary Hospital in Oman
Shah, Sital Amit	695	Steady Persistence While Chasing the Elusive: When Guidelines and Policies for Antimicrobial Use Clash with the 800-Pound Gorilla
Sharma, Megha	702	Antibiotic Prescribing in a Teaching and a Non-Teaching Private, Non-Computerized, Tertiary Care Hospital in Ujjain District, India
Sia, Isidro Cabuyao	493	Policy for Rational Regulation and Quality Use of Natural Health Products in the Philippines
Siddiqui, Abdul Zahir	849	Pharmaceutical Management Interventions through a Drug and Therapeutics Committee (DTC) in Kabul, Afghanistan: Initial Experience after Decades of Neglect
Simba, Daudi Omari	434	Does Artemether-Lumefantrine Subsidy to Private Sector Improve Prompt Access to Antimalarials to Febrile Children in Rural Areas?
Simba, Daudi Omari	474	High adherence to artemether-lumefantrine treatment in children under real-life situation in rural Tanzania
Singal, Girdhari Lal	730	Comparative Evaluation of Quality of Some Generic Versus Branded Medicines Using Compendia Standard Tests In India
Singh, Angel Dillip	132	Improvements in Access to Malaria Treatment in Tanzania Following Community, Retail Sector and Health Facility Interventions—A User Perspective
Singh, Jatinder	781	Teaching Rational Prescribing to Medical Undergraduates: Impact of the Introduction of a Specialized Module

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
Singh, Jyotika	306	Prophylactic Antimicrobials: Triumph Over Cancer Chemotherapy Complications?
Slaveska Raichki, Renata	1193	Development and Current Status of the National Good Governance for Medicines Initiative in Macedonia
Snell, Beverley Frances	269	Where There Are No Pharmacists
So, Anthony D.	1011	Jumping into the Pool: Is It the Shallow or the Deep End?
Soleymani, Fatemeh	405	Management Information System in Promoting Rational Drug Use in Iran
Sontakke, Smita dipak	180	Interventional Study on Self Medication in Commonly Occurring Illnesses in Nonmedical Staff of a Tertiary Care Teaching Hospital
Soria, Rene	910	The Volume Share of Generic Medicines in the Retail Market between 1999 and 2009: a Comparison between Brazil and Mexico
Srinivas, Sunitha Chandrasekhar	453	Evaluation of Prices and Availability of Essential Medicines in Grahamstown, South Africa
Srinivas, Sunitha Chandrasekhar	420	Field Testing WHO's Rational Use of Medicines Rapid Assessment Tool in Grahamstown, South Africa
Sruamsiri, Rosarin	1190	Prevalence of and Factors Associated with Potentially Inappropriate Medications Use in the Elderly Population in Thailand
Steel, Gavin Stewart	1076	Improving Access to Oncology Treatments in a Resource-Constrained Setting Using Pharmacoeconomic Analysis
Steel, Gavin Stewart	1079	Application of the Antacid {A02} ATC Review to Achieve Formulary Cost Efficiencies
Steel, Gavin Stewart	1115	Development and Implementation of a Multi-Method Medication Adherence Assessment Tool Suitable for Antiretroviral Therapy Facilities in Resource-Constrained Settings
Stephens, Peter Neil	954	Gender and Access to Medicines in 15 Low- and Middle-Income Countries: Does Physician Prescribing for Men and Women Differ?
Stergachis, Andy S	508	Genital Ulcer Disease Treatment Policies and Access to Acyclovir in Eight Sub-Saharan African Countries
Straus, Walter Lee	1057	Monitoring Antimicrobial Resistance Trends: How the Private Sector Can Contribute to Improved Understanding of Global Trends in Antimicrobial Resistance
Suleman, Fatima	906	Pharmacovigilance Reporting in Kwazulu-Natal—Evaluation of a Solicited System of Reporting
Suleman, Fatima	186	Overview of Systematic Reviews on Pharmaceutical Policy and Their Relevance to Low- and Middle-Income Countries
Summers, Beverley	852	Non-Uptake of Antiretroviral Therapy (ART) at a Primary Care Antiretroviral (ARV) Clinic in South Africa
Sumpradit, Nithima	572	Antibiotics Smart Use Program: A Mixed Model to Promote Rational Use of Medicines
Sun, Jing	243	Comparison of the Public Procurement Prices of Essential Medicines in China with Other Western Pacific Developing Countries and Its Implication
Sun, Jing	947	Study on the Effect of Zero Mark-up Policy on Medicines in Beijing Community Health Facilities
Sun, Jing	959	Evaluation of the New Rural Cooperative Medical Scheme Outpatient Capitation Payment Reform in Qianjiang
Sun, Qiang	356	The Dilemma of Price Regulation and Pharmaceutical Centralized Bidding in China
Sun, Qiang	345	The Irrational Use of Drugs in Rural China: Evidences from Two Provinces
Suriyarangsee, Manita	896	Impact of Pharmacist's Roles on Reducing Readmission Rate and Promoting Patient Safety in Pediatric Cardiac Patients
Suryawati, Sri	146	CEMA-Community to Improve Knowledge and Skills in Evaluating Medicine Advertisements
Suttajit, Siritree	777	"A Healthy Box Project" for Improving Self-Administration of Medicines among the Pre-elderly and Elderly with Chronic Diseases: A Case Study in Horathep Subdistrict, Saraburi Province, Thailand

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
Suttajit, Siritree	978	Effectiveness of Pharmacist Home Health Care for Type 2 Diabetes in Bangkok Metropolitan: A Community Based Study
Suttajit, Siritree	1142	Antibiotic Policy, Antibiotic Consumption, and Antibiotic Resistance: Situation of Hospitals Participating in the National Antimicrobial Resistance Surveillance Thailand Program
Suwankesawong, Wimon	792	Use of Thai Vigibase to Assess the Safety of Antituberculosis Drugs for Thai Patients: Application from Thai Vigibase
Suwankesawong, Wimon	1135	Pharmacovigilance and Risk Management in Thailand
Tadege, Tenaw Andualem	309	Magnitude of and Contributing Factors to Antibacterial Resistance in Ethiopia
Tadege, Tenaw Andualem	1206	Outcome of the Live ETV Education on Rational Use of Medicines
Taur, Santosh Ramesh	840	Drug Approvals and Medicine Pricing In India
Thamlikitkul, Visanu	291	Randomized Controlled Study of Antibiotic Approval Program on Patients' Clinical Outcomes and Antibiotic Expenditures
Tharathep, Chanvit	818	How GGM Program Enhanced National Drug Policy, Thailand Experience
Theodorou, Mamas	271	Factors Influencing Prescribing Behaviour of Physicians in Greece and Cyprus
Tisocki, Klara	1173	Efficiency of Public Procurement of Medicines in the Philippines
Tisocki, Klara	1172	Adherence to Antiretroviral Medicines Not Emphasized in Global Fund Grants
Tomson, Göran Bengt	864	Exploring the Development, Design, and Implementation of a Pharmacotherapy Knowledge Center – A Qualitative Study
Trap, Birna	728	Impact of Visualizing Performance in Improving Medicines Management in Public Health Sector Facilities in Uganda
Trap, Birna	731	New Performance-Based Reward Strategy to Improve Pharmacy Practices, Financial Management, and Appropriate Medicines Use in the Public Sector in Uganda
Trap, Rete	477	Is Performance-Based Reward the Strategy of the Future for Strengthening the Quality of Reporting and Immunization Systems?—Experiences from GAVI
Twagirumukiza, Marc	1106	Developing Interdisciplinary Methods for Research to Explain and Enhance Access to Medicines in Africa and South Asia
Twagirumukiza, Marc	941	Prices of Antihypertensive Medicines in Sub-Saharan Africa and Alignment to World Health Organization's Model List Of Essential Medicines
Umoh, Mary Emem	365	Peer-to-Peer Counseling: A Model for Improving Male Involvement in ARV Treatment Access and Adherence among PLWHA in Kwara State, Nigeria
Vaishnav, R	1220	Glycemic and Non-glycemic Control in Diabetic Outpatients Receiving Oral Antidiabetic Drugs at Sultan Qaboos University Hospital
van der Velden, Alike W.	863	Physician as Primary Target in Improving Antibiotic Use in Primary Care: Review of Behavioural Interventions (CHAMP)
van der Velden, Alike W.	868	Understanding and Optimising Antibiotic Prescription in Primary Care: Guidelines, Education, and Audit/Feedback in a Multiple Intervention
Vanpelt, Maurits	363	Managing a continuum-of-care with Revolving Drug Fund for People with Diabetes (DM) and Hypertension (HBP) through a Peer Educator Network in rural Cambodia
Vargas Peláez, Claudia Marcela	1077	Teaching Critical Appraisal of Medicinal Drug Promotion (CADP) in 3 Latin American Countries: A Network Initiative
Vargas Peláez, Claudia Marcela	976	Pharmaceutical Advertising and Promotion: Advertising Components Analysis in Five Latin American Countries
Vargas Peláez, Claudia Marcela	1016	Pharmaceutical Advertising and Promotion Regulation of Seven Latin American Countries
Varughese, Shirly Samson	450	Impact of Comprehensive Efforts on the Performance of a Pharmacovigilance System in Oman
Vialle-Valentin, Catherine E.	851	Is Pediatric Diarrhea Treated Correctly in African Communities? Evidence from Household Surveys in Five African Countries

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
Vialle-Valentin, Catherine E.	386	Predictors of Antibiotic Use in African Communities: Evidence from Household Surveys in Five African Countries
Vialle-Valentin, Catherine E.	1214	Treating Acute Fever with Artemisinin-Based Combination Therapy: Prevalence and Predictors in Five African Household Surveys
Vogler, Sabine	393	Prices of Medicines, Including High-Cost Cancer Medicines, in a Hospital Setting Compared to Outpatient Use
Vogler, Sabine	400	Policy Making Support by Sharing of Information and Experiences among the PPRI Network
Vogler, Sabine	429	Perspectives of Rational Use of Medicines in the EU
Vogler, Sabine	617	Role of Tendering of Medicines in European Countries
Waako, Paul John	545	Existing Capacity to Manage Pharmaceuticals and Related Commodities in East Africa: An Assessment with Specific Reference to Antiretroviral Therapy
Waako, Paul John	546	Challenges of Building Effective Pharmacovigilance Systems in Resource Limited Settings: A Case Study of Kampala Region, Uganda
Wagner, Anita Katharina	854	Are There Gender Differences in Access to Medicines In Africa? Results from 5 Sub-Saharan African Countries
Wagner, Anita Katharina	276	Health Care Payments in the Asia Pacific: Validation of Five Survey Measures of Economic Burden
Walker, Saul Sebastian	1058	Increasing Access To Medicines—Taking a Multifaceted Approach
Weekes, Lynn	426	What Is Needed to Sustain a National Academic Detailing Workforce?
Weekes, Lynn	427	Building Confidence in Generic Medicines
Widayati, Aris	319	Identifying Key Beliefs of Self Medication with Antibiotics in Yogyakarta City, Indonesia
Wiedenmayer, Karin Anne	492	A Blended e-Learning Course—“Management of Medicines in International Health”—Contributes to Knowledge Transfer and Improving Medicines Use
Wiedenmayer, Karin Anne	433	Simplifying Vaccine Delivery with Combination Vaccines—Evidence from a Time-Motion Study in India
Wijesinghe, Pushpa Ranjan	762	Practice and Predictors of Self-Medication Among Urban and Rural Adults in Sri Lanka Three Decades after Market Economic Reforms
Wirtz, Veronika J.	379	Consumption of Antibiotics Before and After Sales Regulations in Chile and Venezuela
Wirtz, Veronika J.	875	Framework Proposal to Improve Access to Medicines and Routine Care for Patients Living with Chronic Conditions in Low and Middle Income Countries
Wuliji, Tana	531	Pharmaceutical Human Workforce for Access to and Use of Medicines in Countries: Estimate Gaps and Identify Relevant Strategies for Human Resources Development
Yabila, Nadia Djenebou	643	Ethical Issues Raised by the Inclusion of Gender in the Implementation of Prevention of Mother-to-Child Transmission of HIV (PMTCT) Program in Burkina Faso
Yang, Li	1120	The Impact of Abuse of Antibiotic Therapies on Inpatient Cost in China
Yang, Li	1165	Access to Pharmaceuticals among Adults with Cardiovascular Diseases: An Impact of the Free Medicine Policy in Beijing, China
Yavuz, Elif	1222	Adherence to Artemisinin Combination Therapies (ACTs) Purchased in the Informal Private Sector: Evidence from Soroti District, Eastern Uganda
Yeboah-Antwi, Kojo	835	Improving the Use of Artemisinin-Based Combination Therapy in Rural Zambia
Yee, Siew Mei	125	Evaluation of Prescribing Practices by Assistant Medical Officers at Malaysian Public Health Care Facilities
Zagzoug, Hazem	1002	Evaluation of Pharmacist Clinical Intervention to Optimize Treatment of Gastritis in the Emergency Department
Zaman, Muhammad Hamid	511	Developing Superior Screening Technology for Monitoring Medicine Quality in Low-Resource Countries
Zhou, Ying	194	Promoting Rational Antibiotic Prophylaxis in Clean Surgeries in China

<b>Presenting Author</b>	<b>ID</b>	<b>Title</b>
Ziegler, Rene	516	SMS for Life: A Pilot Project to Reduce or Eliminate Stock-outs and Improve Access to Malaria Medicine at the Remote Health Facility Level, Using Innovative SMS, Internet, and Mapping Technologies
Ziganshina, Liliya Eugenevna	606	In-Service, Problem-Based, Pharmacotherapy Teaching and Clinical Pharmacology Services Contribute to Improved Medicine Use in Children
Ziganshina, Liliya Eugenevna	607	Medicines Lists as Policy Instruments in Tatarstan and Russian Federation in the 21st Century
Zorzet, Anna	639	New Method for Identification and Antibiotic Resistance Screening of Bacteria
Zuo, Yejin	592	Financial Impact of Judicious Use of Medicine in Primary Care

## ABSTRACTS INDEXED BY TRACK

### Access

---

ID	Title
114	Facilitators and Barriers for Generic Drug Use Among General Practitioners in Northern State of Malaysia: Findings from a Cross-Sectional Mail Survey
125	Evaluation of Prescribing Practices by Assistant Medical Officers at Malaysian Public Health Care Facilities
127	Impact of Strategies to Improve Collection and Reporting of Logistics Information for Managing Essential Medicines in Developing Countries
143	CBIA-Pregnancy to Improve Skills of Pregnant Mothers in Selecting OTC Common Cold Preparations
176	Effect of IEC Intervention on Awareness about Rational Pharmacy Practice in Pharmacy Students
180	Interventional Study on Self Medication in Commonly Occurring Illnesses in Nonmedical Staff of a Tertiary Care Teaching Hospital
185	Use of Prophylactic Oxytocin by Health Care Providers in Northeast Argentina as Part of Active Management of the Third Stage of Labor
204	Differences in the Availability of Medicines Used for Noncommunicable and Communicable Conditions in the Public and Private Sectors of Developing Countries
265	Exploring Traditional Medicines Use by Ghanaian Households
269	Where There Are No Pharmacists
270	Health Care Payments in the Asia Pacific: Validation of Five Survey Measures of Economic Burden
271	Factors Influencing Prescribing Behaviour of Physicians in Greece and Cyprus
294	Impact of the WHO Guide to Good Prescribing on Medical Students
318	Household Drug-Storing Practices Among Community Residents in Paknaan, Mandaue City, Philippines, 2010
324	Effects of an Intervention on the Use of Medicines in Herat Province of Afghanistan
334	Factors Affecting Patients' Incomplete Understanding of Prescriptions
337	Progress in Standard Indicators of Medicines Use Over 20 Years
385	Commercial Innovation to Improve Health Care Access at the Bottom of the Pyramid in Rural India
391	Medication Administration Management: Assessment of Critical Care Nurses' Baseline Knowledge and Strategies for Building Awareness
423	The Rational Use and Access to Medicines by the Citizens: The Greek Experience
445	Preliminary Results of a Systematic Review of the Effectiveness and Costs of Strategies to Improve Health Care Provider Performance in Low- and Middle-Income Countries
473	Implementation of a Policy for Monitoring Prescribing Practices in Public Health Care Outlets in Nepal
492	A Blended e-Learning Course—"Management of Medicines in International Health"—Contributes to Knowledge Transfer and Improving Medicines Use
497	Measuring Access to Essential Medicines in Kenya Using the Standardized WHO Level II Health Facility Assessment
516	SMS for Life: A Pilot Project to Reduce or Eliminate Stock-outs and Improve Access to Malaria Medicine at the Remote Health Facility Level, Using Innovative SMS, Internet, and Mapping Technologies
519	Educational Intervention to Combat Counterfeit Medicines in Selected Areas in the Philippines
527	Access and Use of Medicines in Kandy District, Sri Lanka
531	Pharmaceutical Human Workforce for Access to and Use of Medicines in Countries: Estimate Gaps and Identify Relevant Strategies for Human Resources Development
541	R&D Pharmaceutical Industry's Partnerships to Improve Developing World Health
555	Access to Essential Medicines as Part of the Right to Health in National Constitutions of 186 Countries
563	Unit Dose System – Implementation in a Secondary, Multispecialty Referral Hospital: Sohar Hospital, Ministry of Health, Sultanate of Oman
600	Anecdotal Evidence for Ways in which the Originator Pharmaceutical Industry Has Contributed to Improving the Appropriateness of Medicine Use in Low-Income Countries through Product and Packaging Adaptations
602	Survey on the Use of Medicines by Consumers in Federal Territories of Kuala Lumpur and Putrajaya

<b>ID</b>	<b>Title</b>
604	Survey on the Use of Medicines by Malaysian Consumers
627	Analysis of Clinical Pharmacists' Interventions on Discharged Patients' Prescription in a Tertiary Care Teaching Hospital in Oman
638	Access to Medicines in Nigeria – Gender Perspective
640	Gender and Medicines In HIV/AIDS, Tuberculosis, and Malaria in Low- and Middle-Income Countries: A Systematic Review
642	Can the Indian Government Improve Access to Medicines Through Generic Drug Stores?
651	Gender Inequalities in Medicine Expenditure and Family Budget Allocated to Medicines in a Southern Brazilian City: Population-Based Study
658	Piloting a Medical Injection Safety Assessment Protocol in Cameroon: Indirect Reuse Represents Risk of Blood-Borne Virus Transmission
664	Knowledges and Attitudes toward Emergency Contraceptive Pill among Thai Men in Bangkok and Its Utilization
676	Evaluation of Prescribing Pattern of Physicians in Various Health Care Facilities in Turkey with Respect to the Rational Use of Medicines Principles
690	Drug and Therapeutics Committees in Africa and Asia: From Training to Implementation
691	Attitudes, Beliefs, and Prescription Habits of Greek Physicians Regarding Generic Drugs
697	Access to and Use of Medicines by Households in Armenia: Impact of Current Policy on Reimbursement of Medicines
700	Access to Medicines in Guatemala, Honduras, and Nicaragua: The Challenge of Adapting Methodologies
722	Piloting the Use of Mobile Short Messaging Systems (SMSs) to Improve Access to Medicines: Experiences from Kenya
727	Is a Standard Kit an Effective Way to Optimise Use of Limited Resources and Increase Availability of Medicine? Experiences from Reintroducing Standard Kits in Resource-Poor Settings in Uganda
728	Impact of Visualizing Performance in Improving Medicines Management in Public Health Sector Facilities in Uganda
730	Comparative Evaluation of Quality of Some Generic Versus Branded Medicines Using Compendia Standard Tests In India
760	Social Determinants of Access to Medicines in 3 Central American Countries
762	Practice and Predictors of Self-Medication Among Urban and Rural Adults in Sri Lanka Three Decades after Market Economic Reforms
763	Assessing the Extent of Pharmaceutical Care Provision in Kigali Community Pharmacies
780	Pattern of Medicine Use Among In-Patients in a Tertiary Health Care Setting Using the WHO Prescribing Indicators
781	Teaching Rational Prescribing to Medical Undergraduates: Impact of the Introduction of a Specialized Module
783	Evidence on Availability and Stock-Outs of Essential Medicines: A Study of Two Diverse Government Drug Procurement and Distribution Systems in India
794	Social Disparities in the Use of Prescription Medications: A Population-Based Approach
797	Mapping Private Sector Pharmacies and their Characteristics in Ujjain District, Central India
810	Consultation and Dispensing Time at Primary Health Care Facilities in Oman
813	Medicines Use in Oman: Public Knowledge, Attitudes, and Practices
816	Practice of Community Pharmacists Dispensing Emergency Contraceptive Pills in Chiang Mai, Thailand
826	How Sustainable is the EU Regulatory Network in the Context of the Uptake of New Medicines?
830	Successful Intervention to Improve the Pharmaceutical Services in a Region of Brazil
832	A Conceptual Framework for a System-Wide Definition of Access to Medicines
833	Bibliometric Study of Publication Patterns in Access to Medicines in Low- and Middle-Income Countries
854	Are There Gender Differences in Access to Medicines In Africa? Results from 5 Sub-Saharan African Countries
880	Pharmaceutical Situation in Barbados: WHO Level II Health Facilities Survey, 2010
882	Proposal for a Baseline Assessment for the Caribbean Pharmaceutical Policy
884	Characterization of Lawsuits for the Supply of Essential Medicines in the State of Rio De Janeiro, Brazil
885	Evaluating Pharmacists' Views, Knowledge, and Perception Regarding Generic Medicines in New Zealand
903	Impact of Community Education Programme on Safe Use Oo Medicines in Two States of India

<b>ID</b>	<b>Title</b>
912	Using a Rapid Results Approach to Improve Supply Chain Efficiency and Increase Availability of Essential Medicines and Supplies
913	The Practice of Community Pharmacists on Emergency Contraceptive Pills Dispensing in a Contraindicated Situation
918	Increasing Access to Quality Essential Medicines and Services Provided by Drug Shops in Uganda Through Accreditation and Regulation
929	The Use of Medicines and Standard Treatment Guidelines in Rural Timor-Leste
950	Use of Brief Educational Intervention and Academic Detailing to Improve Use of Antidotes for Acute Poisoned Patients in Rural Hospitals in Sri Lanka—A Cluster Randomised Controlled Trial
954	Gender and Access to Medicines in 15 Low- and Middle-Income Countries: Does Physician Prescribing for Men and Women Differ?
964	Measuring Access to Essential Medicines in Kenya Using the Standardized WHO Level II Household Survey
970	Access to Medicines For Treating Acute Condition in Three Low- Income Countries In Central America
972	Assessing Global Health Financing and Policy: Potential Contribution of Pooled Funds
984	Priority Policy Research Questions in the Area of Access to Medicines in Cameroon, Chad, Congo, and Gabon
986	Self Medication in a Kerala District, India - Prevalence and Analysis
997	Monitoring and Supervision as Tool for Improving Drug Supply Management
999	An Evaluation of A Clinical Pharmacist Directed-Intervention to Rationalize Overuse of Stress Ulcer Prophylaxis in Intensive Care Unit.
1002	Evaluation of Pharmacist Clinical Intervention to Optimize Treatment of Gastritis in the Emergency Department
1011	Jumping into the Pool: Is It the Shallow or the Deep End?
1035	Household Access to and Use of Medicines in Ghana
1049	Health Facility Pharmaceutical Situation Assessment in Ghana
1058	Increasing Access To Medicines—Taking a Multifaceted Approach
1061	Characteristics of Medicines Found in the Households of the District of Chimbote – Ancash (Peru), December 2007
1071	Can ADDO Accomplishments Be Sustained? The Tanzania Experience Six Years Later
1077	Teaching Critical Appraisal of Medicinal Drug Promotion (CADP) in 3 Latin American Countries: A Network Initiative
1078	Drugs Identification and Interaction Checker to Reduce Tuberculosis Drug Compliance and Improve Treatment Adherence
1089	Access to and Use of Medicines in Barbados: Evidence from a Household Survey
1090	Literature Review of Gender and Drugs in Eastern Mediterranean Region Index Medicus
1093	Priority Policy Research Questions in the Area of Access to Medicines in Latin America, Middle East, and Asia
1106	Developing Interdisciplinary Methods for Research to Explain and Enhance Access to Medicines in Africa and South Asia
1138	Use of Medicines with Unknown Fetal Risk among Pregnant Women from the Pelotas Birth Cohort 2004, Brazil
1141	How the Accredited Drug Dispensing Outlet Program Has Influenced Medicine Access Policies in Tanzania?
1144	Assessment of Pharmaceutical Situation in Suriname
1147	Assessment of Pharmaceutical Situation in Jamaica
1155	Improving Access to Medical Supplies in Emergency Settings by Preparing Humanitarian Responders with Online Medicine Supply Management Training
1156	Caribbean Network on Pharmaceutical Education
1184	Analysis of essential medicine use in primary health care institutions of Beijing
1211	Pharmaceutical Situation Assessment: Level II Health Facilities Survey in Syria
1223	Consumer Knowledge and Perceptions about Medicines: Evidence from Household Surveys in Five Low- and Middle-Income Countries

## Child Health

---

ID	Title
107	Effect of Multiple Micronutrient Supplements for Improving Anaemia of Preschool Age Children in Rural, Lao People's Democratic Republic: A Randomized Trial
129	Unnecessary Antibiotic Use for Mild Acute Respiratory Infections in a 28-Day Follow-Up of 823 Children under Five in Rural Vietnam
144	A Rapid Assessment Protocol for Improving Access (RAPIA) to Medicine and Care for Children living with a Chronic Condition (Congenital Adrenal Hyperplasia) in Vietnam
199	Antibiotics and Pediatric Acute Respiratory Infections in Rural Vietnam: Health Care Providers' Knowledge, Practical Competence, and Reported Practice
338	Medicine Use in Children Under 5: 20 Years of Practice Patterns and Intervention Effects
404	Assessing Local Manufacturing Capacity for Child-Specific Dosage Formulations: The Case of Ghana
407	Medicine Use from Birth to Two Years of Age: The 2004 Pelotas (Brazil) Birth Cohort Study
408	Factors Associated to Medicine Use Among Children from the 2004 Pelotas Birth Cohort (Brazil)
409	Medicine Utilization in Adolescents Aged 11 from the Pelotas (Brazil) 1993 Birth Cohort Study
416	An Audit of Case Management of Common Childhood Illnesses in Hospitals in Ghana
421	Assessment of Availability, Price, and Affordability of Medicines for Children In Ghana
433	Simplifying Vaccine Delivery with Combination Vaccines—Evidence from a Time-Motion Study in India
477	Is Performance-Based Reward the Strategy of the Future for Strengthening the Quality of Reporting and Immunization Systems?—Experiences from GAVI
488	Parents' and Caretakers' Administration Practices and Formulation Preferences of Children's Medicine in Tanzania
524	Availability of Children's Medicines in Africa, 2007
606	In-Service, Problem-Based, Pharmacotherapy Teaching and Clinical Pharmacology Services Contribute to Improved Medicine Use in Children
608	Availability, Price, and Affordability of Key Essential Medicines for Children in a Resource-Limited Country
612	Facilitating the Preparation of Essential Medicines List for Children in India: Lessons Learned
615	Better Medicines for Children in India: A Project to Improve Access to Essential Medicines
633	The Rise and Fall of Supervision in a Project Designed to Strengthen Supervision on the Integrated Management of Childhood Illness (IMCI) Strategy in Benin
635	Multifaceted Intervention to Improve Health Worker Adherence to Integrated Management of Childhood Illness Guidelines in Benin
659	Promoting Proper Use of Medicines in School Children: An Interventional Study
671	Analysis of Clinical Trials in Children Registered in the Clinical Trials Registry of India
678	Costs and Effects of a Multifaceted Intervention to Improve the Quality of Care of Children in District Hospitals in Kenya
703	Irrational Prescribing Pattern for Children with Upper Respiratory Tract Infection (URTI) in Indonesia
708	Assessment of the Effectiveness and Safety of Outpatient Treatment of Severe Pneumonia Among Egyptian Children with Oral Amoxicillin
709	Effectiveness of Oral Zinc Supplementation in the Treatment of Acute, Watery Diarrhea
758	Antibiotics with Facilitated Referral to a Rural Health Center Using Zambian Trained Traditional Birth Attendants as a Strategy for Reducing Neonatal Mortality
771	Survey of the Availability and Prices of Children's Medicine in Chhattisgarh State
772	Adherence to Treatment Guidelines for Acute Diarrhoea in Children up to 12 Years in Ujjain, India
787	Standardization of Prescribing and Using Oral Liquid Dosage Forms (OLDFs)
831	Medication Among Children in Africa South of Sahara: Qualitative Systematic Review
851	Is Pediatric Diarrhea Treated Correctly in African Communities? Evidence from Household Surveys in Five African Countries
865	Availability of Paediatric Medicines and Factors Impacting Availability in Faith-Based Health Facilities in Chad
896	Impact of Pharmacist's Roles on Reducing Readmission Rate and Promoting Patient Safety in Pediatric Cardiac Patients
1037	Evaluating the Impact of a Public-Private Partnership for the National Introduction of a New Rotavirus Vaccine: Evidence from a Case-Control Study in Nicaragua (2006–2009)
1067	Encourage Appropriate Use of Pediatric Antiretrovirals With a Demonstration Kit in Pharmacies: Results

<b>ID</b>	<b>Title</b>
	18 Months after Kit Was Made Available in 2 HIV/AIDS Pediatric Treatment Centers in Niamey, Niger
1069	Can the Management of Uncomplicated Diarrhea at the ADDOs in Tanzania be Further Improved?
1199	Impact of IT based Promotion of Rational Use of Medicine in Indonesia
1204	Compounding Polypharmacy Prescription in Indonesia
1210	Incidence and Cost Estimate of Treating Paediatric Adverse Drug Reactions in Lagos, Nigeria
1218	Cost and Cost-Effectiveness of Training Zambian Traditional Birth Attendants in Interventions Targeting Common Causes of Neonatal Mortality

## **Chronic Care**

---

<b>ID</b>	<b>Title</b>
128	The Evaluation of Compliance to an Essential Medicine Programme: Use of Standard Treatment Guidelines in South Africa's State Health Facilities of eThekweni
148	Improving Diabetic Patients' Adherence to Treatment Program by Using CBIA-DM Strategy in Hospital-Based Patient Community
152	Irrational Use of Diabetes Medicines in Resource-Poor Settings
235	Effects of Two Educational Programs Aimed at Improving the Utilization of Non-opioid Analgesics in Family Medicine Clinics in Mexico
257	Do European Rheumatoid Arthritis Patients Have Equal Access to Treatment with New Medicines?
262	Comparison of Different Inappropriate Prescribing Screening Tools Used for Assessment of Inappropriate Drug Prescription in the Elderly
266	Pharmacoepidemiologic Study of Potential Drug Interactions in Hospital Inpatients
275	Impact of Generic Substitution Practice on Care of Diabetic Patients
300	"I Wish I Had AIDS": Qualitative Study on Access to Health Care Services for HIV/AIDS and Diabetic Patients in Cambodia
301	Household Survey on Medicine Use in Oman
306	Prophylactic Antimicrobials: Triumph Over Cancer Chemotherapy Complications?
330	Editor Training Program
357	Availability, Price, and Affordability of Cardiovascular Medicines: A Comparison across 36 Countries Using WHO/HAI Data
363	Managing a continuum-of-care with Revolving Drug Fund for People with Diabetes (DM) and Hypertension (HBP) through a Peer Educator Network in rural Cambodia
371	Improving Access to Routine Medication from a Revolving Drug Fund for Chronic Patients in Rural Cambodia
377	Assessment of Patient Knowledge Regarding Drugs Prescribed and Dispensed in Some Health Insurance Outpatient Clinics in Alexandria
448	Effectiveness of a Medical Education Intervention to Treat Hypertension in Primary Care
468	Improving Diabetes Management in Primary Care
508	Genital Ulcer Disease Treatment Policies and Access to Acyclovir in Eight Sub-Saharan African Countries
514	Spillover Effects of Prescribing Restrictions for Trastuzumab in Australia
528	Patient Behavior When Prescribed Non-Affordable Drugs in University Hospitals of Alexandria, Egypt
537	Piloting the Development of a Cost-Effective, Evidence-Informed Clinical Pathway: Managing Hypertension in Jordanian Primary Care
559	Pattern of Use of Complementary and Alternative Medicine (CAM) Among Patients with Type 2 Diabetes Mellitus (T2DM) in Alexandria, Egypt
585	Importance of Monitoring Patients on Atypical Antipsychotics
587	Reasons for Rejection of Medications by Patients in Oman
591	Medication Adherence: Comparative Study between Institutionalized and Community-Dwelling Elderly
637	Trends of Current Treatment and Outcomes of the Management of Type 2 Diabetic (T2DM) Patients in Egypt: Results from the International Diabetes Management Practices Study (IDMPS)
673	Impact of Standard Treatment Guidelines and Patient Education on Asthma Control and Knowledge in Asthmatic Patients: A Controlled Trial
682	The Assessment of Relation between Inappropriate Medication and Health Status Among Elderly

ID	Title
696	Discharged from Hospitals Affiliated with Tehran University of Medical Sciences, through Beers Criteria Evaluation of a Continuing Medical Education Program for Primary Care Services in the Hypoglycemic Agent's Prescription in Diabetes Mellitus Type 2
705	Clinical Impact of Adherence to Pharmacotherapeutic Guidelines on the Outcome in Patients with Chronic Heart Failure
721	Assessing the Readiness of Pharmacy Outlets to Support Chronic Care: Results from a National Assessment in Kenya
740	Antihypertensive Medicines Prescriptions Before and After the Nigeria Hypertension Society Guidelines and Prescriber's Awareness of the Guideline
764	Outcomes of Pharmaceutical Care in Schizophrenic Patients
775	Affordability of Medicines for Treating Chronic Diseases in Southern Brazil
777	"A Healthy Box Project" for Improving Self-Administration of Medicines among the Pre-elderly and Elderly with Chronic Diseases: A Case Study in Horathep Subdistrict, Saraburi Province, Thailand
790	Empathic Caring Consultation (ECC): Will It Be Able to Reduce the Unnecessary Use of Analgesics?
804	Variation in Service-Providers' Prescribing Behaviour and Policy Implications for Women with Genitourinary Tract Infections in Ramallah, Occupied Palestinian Territory (oPt)
812	Prevalence and Predictors of Potentially Inappropriate Medication Use in Elderly Patients in Two Indian Teaching Hospitals
825	Working Together for Mental Health: The Nouadhibou Pilot Experience
875	Framework Proposal to Improve Access to Medicines and Routine Care for Patients Living with Chronic Conditions in Low and Middle Income Countries
932	Remedies at Home: Evaluating an Innovative Medicines Provision Program
941	Prices of Antihypertensive Medicines in Sub-Saharan Africa and Alignment to World Health Organization's Model List Of Essential Medicines
978	Effectiveness of Pharmacist Home Health Care for Type 2 Diabetes in Bangkok Metropolitan: A Community Based Study
979	Adherence of Prescribers to High Cost Medicines Standard Treatment Guidelines in Rio De Janeiro
1074	Improved Safety Monitoring of Second Generation Antipsychotics Following a Rational Prescribing Intervention
1097	Polypharmacy Among Older Adults in Tehran
1118	Evaluating the Quality of Care for Patients with Type 2 Diabetes Using Electronic Medical Record Information in Mexico
1134	Rational Use of Antidepressants Combined with Benzodiazepines
1190	Prevalence of and Factors Associated with Potentially Inappropriate Medications Use in the Elderly Population in Thailand
1208	Evidence on the Use of Medicines to Treat Chronic Diseases from Household Surveys in Seven Low- and Middle-Income Countries
1220	Glycemic and Non-glycemic Control in Diabetic Outpatients Receiving Oral Antidiabetic Drugs at Sultan Qaboos University Hospita
1225	Prescribing Pattern of Psychotropic Substances in a Nigerian Neuropsychiatric Hospital

## Drug Resistance

---

ID	Title
115	Public Knowledge and Attitudes Toward Antibiotic Usage: Findings from a Cross-Sectional Survey in the State of Penang, Malaysia
194	Promoting Rational Antibiotic Prophylaxis in Clean Surgeries in China
246	Characteristics and Outcomes of Public Campaigns with the Aim to Improve Outpatient Antibiotic Use in High Income Countries
291	Randomized Controlled Study of Antibiotic Approval Program on Patients' Clinical Outcomes and Antibiotic Expenditures
309	Magnitude of and Contributing Factors to Antibacterial Resistance in Ethiopia
319	Identifying Key Beliefs of Self Medication with Antibiotics in Yogyakarta City, Indonesia
340	Surveillance of Antimicrobial Use in Resource-Constrained Community Settings

<b>ID</b>	<b>Title</b>
341	Surveillance of Antimicrobial Resistance in Resource-Constrained Community Settings
353	Does Antimicrobial Use Granger-Cause Community-Based Antimicrobial Resistance?
354	Behavioural Model for Community-Based Antimicrobial Resistance, Vellore, India
366	Prescribing Pattern and Therapeutic Drug Monitoring of Vancomycin at a Tertiary Hospital in Oman
379	Consumption of Antibiotics Before and After Sales Regulations in Chile and Venezuela
384	Examples of Interventions to Contain AMR based on International Consultations
386	Predictors of Antibiotic Use in African Communities: Evidence from Household Surveys in Five African Countries
406	Can the Application of the International Health Regulations to Antimicrobial Resistance Events Help to Preserve Antimicrobials?
471	Improving the Rational Medicine Use through the MTP Approach in Cambodia
489	Antibiotic Knowledge and Self-Care for Acute Respiratory Tract Infections in Mexico
509	Impact of Implementing Antibiotic Sales Restrictions: Reactions of Key Stakeholders and Citizens in Mexico
526	Antibiotic Prescription by Informal Health Providers in Ujjain District, India
538	Economic Burden and Health Consequences of Antibiotic Resistance in Patients at a Tertiary Care Hospital, Vellore, South India
539	Effectiveness of an Antibiotic Policy in Containing Antibiotic Use at a Tertiary Care Hospital, Vellore, South India
553	Community Learns Appropriate Antibiotic Use Through Kindergarten Performances
556	Trends in Antimicrobial Use Among Outpatients in New Delhi, India
572	Antibiotics Smart Use Program: A Mixed Model to Promote Rational Use of Medicines
582	Antibiotic Prescribing Practices of Primary Care Prescribers for Acute Respiratory Tract Infections and Diarrhoea in New Delhi, India
584	Factors Influencing Antibiotic Prescribing by Primary Care Doctors in Delhi, India: Qualitative Study
621	Assessment of Generic Antimicrobial Unit Retail Price Mark-Ups Applied in Public Hospitals in Rwanda
639	New Method for Identification and Antibiotic Resistance Screening of Bacteria
668	Use of Antibiotics in the Alexandria Community Setting: Magnitude and Pattern
694	Indicator-Based Survey Tool to Determine the Use of Antimicrobials and Knowledge about Drug Resistance in the Community
695	Steady Persistence While Chasing the Elusive: When Guidelines and Policies for Antimicrobial Use Clash with the 800-Pound Gorilla
699	Capacity-Building for Country and Regional Level Advocacy and Interventions to Contain Antimicrobial Resistance in Africa
702	Antibiotic Prescribing in a Teaching and a Non-Teaching Private, Non-Computerized, Tertiary Care Hospital in Ujjain District, India
713	Knowledge, Attitudes, and Perceptions on Antimicrobial Resistance and Antibiotic Use Among Hospital Staff in Kenya
729	Infectious Diseases, Antibiotic Use, and Antibiotic Resistance in Context of Environmental Changes: Study Among Community Members in Orissa, India
734	Two-Year Experience of Antibiotics Smart Use Pilot Project in Saraburi, Thailand
766	Awareness and Adherence to Methicillin-Resistant <i>S. Aureus</i> Guidelines, as per WHO, at Alexandria University Hospitals
778	Using Routine Information for Improving Rational Prescribing
793	Antibiotic Surveillance in Intensive Care Unit: Quality Assurance of Antibiotic Usage
796	Prophylactic Use of Antimicrobials During Surgery
848	Susceptibility of Methicillin Resistant Coagulase-Negative Staphylococci Isolated from Faecal Samples of Children to Commonly Used Antiseptic Agents
860	Exploring a Global Compact to Preserve Novel Antibiotics
863	Physician as Primary Target in Improving Antibiotic Use in Primary Care: Review of Behavioural Interventions (CHAMP)
866	Prescribing Pattern of Antibiotics in Health Facilities in Baghdad, Iraq
868	Understanding and Optimising Antibiotic Prescription in Primary Care: Guidelines, Education, and Audit/Feedback in a Multiple Intervention
919	Application of Drug Use Evaluation and Feedback to Promote Rational Antibiotic Prophylaxis in C-

<b>ID</b>	<b>Title</b>
	Sections in Kenya
923	Effect of Interventions on Misuse of Antibiotics/Antibacterial Drugs in Developing Countries: a Systematic Review
926	Antibiotic Resistance Policy in Thailand: Role of Comprehensive Networking Campaign
1018	Development and Application of Selected Indicators to Investigate Antimicrobial Use in Hospitals
1054	School-Based Education Program Can Favorably Impact National Public Health Budget
1057	Monitoring Antimicrobial Resistance Trends: How the Private Sector Can Contribute to Improved Understanding of Global Trends in Antimicrobial Resistance
1084	Engaging Private Sector Drug Dispensers to Improve Antimicrobial Use in the Community: Experience from the Tanzania Accredited Drug Dispensing Outlets
1116	Implementing a Self-Assessment and Continuous Quality Improvement Approach to Improve Hospital Infection Control Practices in Africa and Latin America
1120	The Impact of Abuse of Antibiotic Therapies on Inpatient Cost in China
1127	Report Cards and Prescribing Behavior: Assessing the Impacts of Public Disclosure on Antibiotic Prescribing Rates in South Korea
1142	Antibiotic Policy, Antibiotic Consumption, and Antibiotic Resistance: Situation of Hospitals Participating in the National Antimicrobial Resistance Surveillance Thailand Program
1198	Estimation of Antibiotic Utilization Patterns in 4 Latin-American Countries
1206	Outcome of the Live ETV Education on Rational Use of Medicines

### **Economics, Financing, and Insurance Systems**

---

<b>ID</b>	<b>Title</b>
120	The Role of Pharmaco-Economics in the Decision Tasks to Improve the Quality of Medical Care in Kazakhstan Republic
173	Quantifying the Impoverishing Effects of Purchasing Medicines: A Cross-Country Comparison of the Affordability of Medicines in the Developing World
192	Medicine Prices, Availability, and Affordability in Vietnam
213	Health Insurance Systems in Five Sub-Saharan African Countries: Medicines Benefits and Data for Decision-Making
220	Controlling Medicine Prices in Sudan: The Challenge of a Recently Established Medicines Regulatory Agency
236	Active Pharmaceutical Management Strategies of Health Insurance Systems to Improve Cost-Effective Use of Medicines in Low- and Middle-Income Countries: A Systematic Review of Current Evidence
243	Comparison of the Public Procurement Prices of Essential Medicines in China with Other Western Pacific Developing Countries and Its Implication
254	International Comparison of Generic Medicine Prices
276	Health Care Payments in the Asia Pacific: Validation of Five Survey Measures of Economic Burden
278	Trends in Pricing Policy of Generics: Global Implications
279	Intensity of Reforms Resulting in Considerable Differences in Generic Utilisation across Europe; Implications for Others
281	Risk-Sharing Arrangements—Opportunity or Threat to Fund New Medicines?
282	Care Needed When Comparing IMS and Administrative Databases in Cross National Comparative Studies?
283	Intensity of Individual Reforms Results in Considerable Differences in Subsequent Utilisation; Implications for Countries When Contemplating Future Initiatives
285	Out of Pocket and Out of Reach: The Unaffordability and Unavailability of Medicines in Low- and Middle-Income Countries
287	Regulating Supply Chain Mark-Ups to Control Medicine Prices—A Review of the Literature in Low- and Middle-Income Countries
293	Cost as a Barrier to Access: Availability, Affordability, and Identifying Component Cost of Essential Medicines
298	Reimbursement Price, Market Structure, and Pharmaceutical Firm Behavior in Korea
307	Effect of Removing Direct Payment for Health Care on Utilization and Health Outcomes in Ghanaian Children: A Randomized Controlled Trial

<b>ID</b>	<b>Title</b>
320	Prescribing Pattern of Physicians in Rural Health Insurance Program in Primary Health Care Facilities in Iran
343	Inefficiencies Due to Poor Access to and Irrational Use of Medicines to Treat Acute Respiratory Tract Infections in Children
356	The Dilemma of Price Regulation and Pharmaceutical Centralized Bidding in China
358	In Scaling Up Health Related MDGs, How Much More Will It Cost to Procure Essential Medicines for 49 Low-Income Countries?
393	Prices of Medicines, Including High-Cost Cancer Medicines, in a Hospital Setting Compared to Outpatient Use
397	Comparative Analysis of the Medicines Financing System of 11 Countries Included in the Pilot of the “WHO Country Profiles” Project
400	Policy Making Support by Sharing of Information and Experiences among the PPRI Network
414	A Comparison of Generic and Originator Brand Drug Prices between Jordan and the United Kingdom
453	Evaluation of Prices and Availability of Essential Medicines in Grahamstown, South Africa
478	Generic Medicine Pricing Policies Evaluation in Indonesia and the Impact on Availability and Medicine Price in Private Sectors
483	Differences in External Price Referencing in Europe—A Descriptive Overview
484	How Much of the Price Variance of Medicines Can Be Explained by External Price Referencing?—A price Comparison among 15 European Countries
498	Taxes on Medicines
507	The Evolution of Taiwan’s National Health Insurance Drug Policy—Review and Analysis
560	Role of Free Provision on Household Expenditures for Medicines in Brazil
566	Cost Effectiveness of Simvastatin Compared with Atorvastatin for Low-Density Lipoprotein Cholesterol (LDL-C) in Diabetes Patients with Dyslipidemia at a General Hospital, Northeast of Thailand
624	Relationship Between Tariffs, Prices, and Consumption of Interferon
706	Medicine Prices and Availability in Southern Brazil
716	Evolution of Generic Medicine Market Share in the Pharmaceutical Retail Sector of 21 Low- and Middle-Income Countries Between 1999 and 2009: Time-Series Analysis
718	Does Your Health Care Depend on How Your Insurer Pays Providers? Variation in Utilization and Outcomes in Thailand
747	External Reference Pricing (ERP): Existing Evidence and Lessons for Developing Countries
819	Universal Health Insurance Coverage and Reimbursement for Medicines in Countries
840	Drug Approvals and Medicine Pricing in India
847	Can Competition Law or Other Competition-Promoting Policies Reduce Medicine Prices in Developing Countries?
873	Value for Money Perspective on Global Health Initiative Market-Shaping Impact
878	Changes in Use of Antidiabetic Medications Following Price Regulations in China (1999-2009)
883	Price Information Exchange for Selected Medicines in the World Health Organization Western Pacific Region
890	The Impact of Evidence-Based Subsidy Restrictions on Prescriber Behaviour and Patient Outcomes: A Case Study of Lapatinib for the Treatment of HER2+ Metastatic Breast Cancer
904	Cost Plus Price Setting of Medicines
905	The Impact of the 2008 Economic Recession on the Pharmaceutical Sector in the Baltic Countries
933	Monitoring Medicine Prices and Availability in Kenya Using WHO/HAI Methodology 2009–2010
944	East African Health Budgets 2010/2011: An Analysis on Financing for Essential Medicines
947	Study on the Effect of Zero Mark-up Policy on Medicines in Beijing Community Health Facilities
957	Challenges of Health Care Financing and Access to Medicines in Low-income Countries of Asia
959	Evaluation of the New Rural Cooperative Medical Scheme Outpatient Capitation Payment Reform in Qianjiang
965	Introducing a Revised Model for Pricing and Reimbursement of Medicines in Macedonia
969	Modelling the Potential for Market Impact and Supply Security Risks: Focus on Donations with Applications for Differential Pricing
1004	Impacts of Direct Fee-For-Service Payment Insurance on Access and Use of Drug: An Interrupted Time Series Study on Diabetic Care
1034	The Impact of Universal Coverage on Use of Medicines in Thailand: An Evaluation Using Market Share

<b>ID</b>	<b>Title</b>
	Data
1047	The National Health Insurance Programme in Ghana and Household Access to Medicines
1076	Improving Access to Oncology Treatments in a Resource-Constrained Setting Using Pharmacoeconomic Analysis
1079	Application of the Antacid {A02} ATC Review to Achieve Formulary Cost Efficiencies
1086	Role of Pharmacoeconomics in a Developing Country Context
1104	Tackling Medicine Related Issues Affecting the National Health Insurance Scheme in Ghana
1109	An Analysis of the Global Fund's Price and Quality Reporting Database
1145	Medicine Prices in Peru: Validation of the Sampling Approach Used in WHO/HAI Surveys
1148	Monitoring Medicine Prices with WHO/HAI Surveys: Upsides, Downsides, and Forward-Thinking Strategies
1158	2006 Medicare Part D Benefit: Evaluating a Major Expansion of Medicines Insurance for Vulnerable Americans
1165	Access to Pharmaceuticals among Adults with Cardiovascular Diseases: An Impact of the Free Medicine Policy in Beijing, China
1168	Impact of User Fee Removal on Utilisation of Public Health Services in Zambia
1173	Efficiency of Public Procurement of Medicines in the Philippines
1191	Pharmaceutical Policies Used by Private Health Insurance Companies in Saudi Arabia
1203	Cost of ARV Medicines in the Namibian Private Sector: Limitation to Increased Access
1209	A Win-Win Solution? Critical Analysis of Tiered Pricing to Improve Access to Medicines in Developing Countries
1217	Treatment Cost of Metastatic Colon Cancer in Turkey
1264	Cost of Care of Rheumatoid Arthritis and Ankylosing Spondylitis Patients in Tertiary Care Rheumatology Units in Turkey

## **HIV/AIDS and TB**

---

<b>ID</b>	<b>Title</b>
217	Planning for Sustainability of ARV Provision: A Study in Peru, Bolivia, and Mozambique
344	Adherence to and Outcome of Isoniazid Preventive Chemotherapy in Household Children Contact with Adults Having Pulmonary Tuberculosis: A Prospective Facility-Based Study in Alexandria, Egypt
365	Peer-to-Peer Counseling: A Model for Improving Male Involvement in ARV Treatment Access and Adherence among PLWHA in Kwara State, Nigeria
367	Health Systems Barriers that Determine Access to Antiretroviral Drugs in Southeast Nigeria
378	Nonadherence to HAART: A Cross-Sectional Two-Site Hospital-Based Study
395	Balancing Gender-Based Inequities to Improve Access and Uptake of TB Treatment
486	Prevalence and Risk Factors of Adverse Effects of Second Line Anti-Tuberculous Medicines in a Treatment Facility in Namibia: 2009-10
496	Reasons for Nonadherence to Antiretroviral Therapy among Adult Patients Receiving Free Treatment at a Tertiary Care Hospital in Delhi
505	Improving Adherence to Antiretroviral Treatment in Uganda: Facility-Based Minimal-Input Intervention
532	Decongesting Public Health Facilities is Associated with Better Clinical Outcomes Among Patients Initiating Antiretroviral Therapy in Uganda
542	Improving Adherence and Clinic Attendance Among Patients on Antiretroviral Treatment in Kenya: A System Level Intervention
543	Routine Assessment of Patients' Attendance and Adherence to Antiretroviral Treatment In Kenya – Providers' Views on Usefulness to Improve Performance
544	Improving Appointment Keeping and Adherence Monitoring In HIV Facilities in Kenya: Views of Providers and Patients
545	Existing Capacity to Manage Pharmaceuticals and Related Commodities in East Africa: An Assessment with Specific Reference to Antiretroviral Therapy
596	Integrating Pharmacovigilance in Revised National Tuberculosis Control Programme of India: A Pilot Study
643	Ethical Issues Raised by the Inclusion of Gender in the Implementation of Prevention of Mother-to-Child

<b>ID</b>	<b>Title</b>
	Transmission of HIV (PMTCT) Program in Burkina Faso
667	Electronic Monitoring to Assess Adherence and Validate Alternative Adherence Measures in Tuberculosis Patients on Community-Based Directly Observed Treatment
744	Effects of a Mobile Phone Short Message Service (SMS) on Antiretroviral Treatment Adherence in Kenya (WelTel Kenya1): A Randomized Trial
748	Influence of Mefloquine Malaria Prophylaxis on HIV Disease Progression: A Randomized Placebo-Controlled Trial
770	Human Resources for Health: Preservice Training of Pharmacy Students on Effective Management of Antiretroviral Therapy Commodities in Kenya
779	People Living with HIV/AIDS : Role of Community Pharmacist
786	Predictors of Switching Antiretroviral Regimen Among Clients Attending TASO Jinja, Uganda
792	Use of Thai Vigibase to Assess the Safety of Antituberculosis Drugs for Thai Patients: Application from Thai Vigibase
817	Effects of Patient Tracking Systems and Providers Incentives on Patient Appointment Keeping in Rwanda
839	Partnership with State Government to Strengthen HIV/AIDS Commodities Logistics Management System
850	Development of a Tool for Simple Visualisation of Periods of ARV Therapy Availability in a Context of Expanding Treatment Coverage
852	Non-Uptake of Antiretroviral Therapy (ART) at a Primary Care Antiretroviral (ARV) Clinic in South Africa
859	Plasma Drug Level Validation of Self-Reported Adherence Predicts Limited Specificity for Intrinsic Poor Adherence in Resource-Limited Settings
876	Computer Alert System and Telephone Support to Improve Antiretroviral Therapy Adherence
889	WelTel Kenya: Business Case for Using Mobile Phones as a Cost-Effective Health Intervention to Provide Care and Support HIV/AIDS Patients
906	Pharmacovigilance Reporting in Kwazulu-Natal—Evaluation of a Solicited System of Reporting
909	A Prospective Study of Prevalence, Severity and Preventability of Adverse Drug Reactions in Hospitalized Human Immunodeficiency Virus (HIV) Positive Patients
922	Risk of Anemia Associated with Zidovudine (AZT)-based HAART in Namibia
930	The Namibia Treatment Literacy Approach: Empowering Patients with Knowledge on Antiretroviral Therapy through Audiovisual Materials
942	Supporting Adherence to Antiretroviral Therapy Using Mobile Phone Reminders In South India
946	Role of Private Pharmacies in TB Control in Egypt
953	Management of Drug-Resistant Tuberculosis Patients, Egypt Experience
985	Tracking of Inter-Facility Patient Transfers and Retention on Antiretroviral Treatment in Namibia
990	Using Mobile Technology to Strengthen HIV/AIDS Management in Remote Areas
1014	Experiences and Challenges of An Accelerated Tracking Approach To Enhance Client Retention in Rural HIV clinics in North East Nigeria
1015	Improving Access to ART Services in Namibia through Decentralization
1022	MMDR–TB Among Children in Moldova
1039	Restricting the Availability of Anti-TB Medicines in the Private Market of Eastern Mediterranean Region Countries: A Call for Policy Intervention
1042	Demonstrating the Potential Role of Information and Communication Technologies in Improving Management and Use of Antiretroviral Medicines in Resource-Limited Settings
1044	Enabling Continuity of a Public Health ARV Treatment Program in a Resource-Limited Setting: The Case of the Transition of the African Comprehensive HIV/AIDS Partnerships (ACHAP) Support to the National ART Program to the Government of Botswana
1050	Impact of Policy Revision on Harmonization and Transparency of Quality Assurance Criteria for Anti-Tuberculosis Medicines
1053	Monitoring Drug Resistant Tuberculosis Treatment in Brazil through an Innovative Web-Based Information System
1062	Assessing How Health Care Providers Use Nevirapine in Malawi
1068	Application of an ABC Analysis in the Prevention of Antimicrobial Resistance in Tuberculosis Treatment
1083	Calculation of Tuberculosis Patients' Drug Consumption Using Electronic Nominal Recording–Reporting System at District Level
1092	Trends in Antiretroviral Drugs Prescribing at Public Health Facilities in Ethiopia: Compliance to Treatment Guidelines

<b>ID</b>	<b>Title</b>
1094	The Risk of Getting Anti-TB Drugs as OTC Drugs
1102	Causes of ATBM Shortages in GFATM and GDF-Supported Countries in the Eastern Mediterranean Region and How to Avoid Them in the Future
1110	Patients' Compliance and Adherence to 4-FDCs that are Provided by Global Drug Facility to 15 Countries in the Eastern Mediterranean Region
1113	Evaluating the Effectiveness of TB Medicine Supply Management Training in Western Cape, South Africa
1115	Development and Implementation of a Multi-Method Medication Adherence Assessment Tool Suitable for Antiretroviral Therapy Facilities in Resource-Constrained Settings
1121	Intervention Strategy in Improving Art Adherence In Tanzania
1122	Investigating Medicine Supply as a Rate Limiting Step in the Scale-Up of Isoniazid Preventive Therapy in Kwazulu-Natal, South Africa
1123	The Effect of Community-Based Support Services on Clinical Efficacy and Health-Related Quality of Life in HIV/AIDS Patients in Resource-Limited Settings in Sub-Saharan Africa
1125	Promoting Rational Use of ARVs in HIV/AIDS Clinic in Tanzania
1153	National Evaluation of Medicines Dispensing within Brazilian AIDS Program
1159	Application of an International Reference Price List to National Medicines Procurement Tenders
1162	Findings from Integrating CVD risk factors screening and services among HIV clients in resources constrained setting
1163	Strengthening Patient Adherence Monitoring through the Electronic Dispensing Tool (EDT)
1172	Adherence to Antiretroviral Medicines Not Emphasized in Global Fund Grants
1228	The Science of Quality Improvement (QI) Through Small Tests of Change (STOC) and Modeling of QI Teams to Improve Health Systems in Resource Limited Settings
1229	How Far is Too Far? Does Distance to Clinic Matter for HIV/AIDS Treatment Adherence?

## **Malaria**

---

<b>ID</b>	<b>Title</b>
113	Medicine Outlets and Their Practitioners in Malaria Control in Ghana
126	Antimalarial Prescribing and Dispensing Practices in Health Centres of Khartoum State, 2003–04
132	Improvements in Access to Malaria Treatment in Tanzania Following Community, Retail Sector and Health Facility Interventions—A User Perspective
189	Cost Analysis of Management of Malaria Using ACT in the Private Sector of Zimbabwe: A Regulatory Implication
211	Pharmaceutical Services for Uncomplicated Malaria by <i>P. vivax</i> and <i>P. falciparum</i> in High-Risk Municipalities of the Brazilian Amazon: Organization of Services, Prescribing, Dispensing, and Adherence to Treatment
241	Taking Stock: Provider Prescribing Practices in the Presence and Absence of ACT Stock
256	Priority Setting for Implementation of Artemisinin-Based Combination Therapy Policy in Tanzania: Evaluation against Accountability for Reasonableness Framework
264	Parasitological Assessment of Two-Dose and Monthly Intermittent Preventive Treatment of Malaria During Pregnancy with Sulphadoxine-Pyrimethamine (IPTp-SP) in Lagos, Nigeria
267	Low Reliability of Home-Based Diagnosis of Malaria in a Rural Community in Western Kenya
312	Mapping the Private Sector Distribution Chain to Understand Barriers and Opportunities for Improved Access to Antimalarials in Six Low-income Countries in Africa and South-East Asia
314	Feasibility and Impact of Deploying Artemether-Lumefantrine (AL) At Community Level with the Introduction of Rapid Diagnostic Test (RDT)
434	Does Artemether-Lumefantrine Subsidy to Private Sector Improve Prompt Access to Antimalarials to Febrile Children in Rural Areas?
439	Role of Patient Demand in the Treatment of Uncomplicated Malaria at Public and Private Health Facilities in Southeastern Nigeria
474	High adherence to artemether-lumefantrine treatment in children under real-life situation in rural Tanzania
580	Pilot study of cohort event monitoring (CEM) on patients treated for malaria with Artemisinin Based Combination Therapies (ACTs) in Nigeria
634	Access to Antimalarial Medicines: The Impact Malaria Approach

<b>ID</b>	<b>Title</b>
704	Retail Drug Market and the Price of Malaria Medicines in Enugu Urban, Southeast Nigeria: Implications for Affordability and Access to Artemisinin-Based Combination Therapy
712	Evaluating the Impact of Subsidized Artemether-Lumefantrine in the Retail Sector on Coverage of Prompt Effective Treatment of Children Under Five in Kenya- A Cluster Randomized Controlled Trial
714	Pharmacovigilance of Antimalaria Drug Treatment in Enugu State, Nigeria: Community and Health Workers' Perceptions and Suggestions for Reporting Adverse Drug Events
745	Different Approaches for Delivery of Intermittent Preventive Treatment (IPT) to Pregnant Women in Burkina Faso
746	Effectiveness of Using RDTs and ACTs for Home Management of Malaria in Children Under 5 Years Old in Zambia
754	Effects of the 2005 Change in National Antimalarial Treatment Policy on Prescribing Practices in Two Referral Hospitals in Benin City, Nigeria
822	Safety and Tolerability Profile of Artemisinin-Based Antimalarial Combination Therapy (ACT) in Adult Nigerians
834	Impact of Training, Monitoring, and Mentoring on Drug and Therapeutic Committees in Ghana
835	Improving the Use of Artemisinin-Based Combination Therapy in Rural Zambia
921	Improving Quality of Malaria Case Management Provided by Drug Shops in Uganda Through Accreditation and Regulation
1081	Improving Access to ACTs Through Licensed Chemical Sellers in Ghana
1095	Cost-Effectiveness of Treating Malaria Following Three Methods of Diagnosis: Implications for Scaling-Up Use of Rapid Diagnostic Tests in Uganda
1133	Informal Payments for Health Care: Differences in Expenditures from Consumers and Providers Perspectives for Treatment of Malaria in Nigeria
1137	Improving Quality of Malaria Treatment Services: Assessing Inequities in Consumers' Perceptions and Providers' Behaviour in Nigeria
1146	Inappropriate Provision and Treatment of Malaria in Public and Private Sectors in Nigeria: Threat to Malaria Elimination Efforts
1214	Treating Acute Fever with Artemisinin-Based Combination Therapy: Prevalence and Predictors in Five African Household Surveys
1222	Adherence to Artemisinin Combination Therapies (ACTs) Purchased in the Informal Private Sector: Evidence from Soroti District, Eastern Uganda

## **Policy, Regulation, and Governance**

---

<b>ID</b>	<b>Title</b>
111	Availability and Rational Use of Essential Drugs in the PHC Facilities in Bangladesh: Are We on the Right Track?
146	CEMA-Community to Improve Knowledge and Skills in Evaluating Medicine Advertisements
164	Extension of market exclusivity and its impact on the accessibility to essential medicines, and drug expense in Thailand: Analysis of the effect of TRIPs-Plus proposal
186	Overview of Systematic Reviews on Pharmaceutical Policy and Their Relevance to Low- and Middle-Income Countries
193	Corruption and High Medicine Prices in Vietnam: A Qualitative Study
195	A Survey on the Quality of Anthelmintic Medicines in Cambodia
200	Rapid Assessment Methods for Monitoring Pharmaceutical Policy
203	Essential Medicine Concept as a Core of Drug Policy: Impact on Costs, Availability of Quality Medicines, and Their Rational Use in Delhi (India)
210	Quality of Medicines in South Africa: Perceptions vs. Reality
219	The Good, the Bad, and the Ugly: A System-Based Three-Pronged Strategy to Combat Substandard and Counterfeit Medicines in Low-Resource Countries
248	A Risk-Based Cost-Effective Approach to Medicines Quality Monitoring in Resource-Limited Countries
286	Measuring Transparency in the Public Pharmaceutical Sector. National Assessment for Costa Rica
313	Regionalisation of Pharmacovigilance in Uganda
323	Development and Implementation of an Evidence-Based Drug List for Rural Health Insurance Program in Iran

<b>ID</b>	<b>Title</b>
326	Assessment of the Impact of Market Regulation in Mali on the Price of Essential Medicines Provided through the Private Sector
339	Do Countries with Pharmaceutical Policies Have Better Medicines Use Than Those without?
345	The Irrational Use of Drugs in Rural China: Evidences from Two Provinces
346	Newspaper Column for Consumer Education on Medicine Use—An Indian Columnist’s Experience
359	Challenges When Introducing Generic Policies to Enhance Their Utilisation: Impact and Next Steps
360	Care Needed When Introducing Generic Policies to Reduce Costs: Experiences From Abu Dhabi
374	Study on National Essential Medicines Lists from 8 Countries of the Western African Economic and Monetary Union
376	Assessment of Drug Utilization Patterns in Some Health Insurance Outpatient Clinics in Alexandria
405	Management Information System in Promoting Rational Drug Use in Iran
411	Direct-to-Consumer Advertising for Pharmaceuticals in Jordan from a Gender Perspective
413	Cost Impact of Purchasing Pharmaceuticals Jointly in the Public Health Sector in Jordan
415	One-Year Assessment of Joint Pharmaceutical Procurement in the Jordanian Public Health Sector
420	Field Testing WHO’s Rational Use of Medicines Rapid Assessment Tool in Grahamstown, South Africa
426	What Is Needed to Sustain a National Academic Detailing Workforce?
427	Building Confidence in Generic Medicines
429	Perspectives of Rational Use of Medicines in the EU
449	Up-to-Date, Evidence-Based Advice for Busy Clinicians
450	Impact of Comprehensive Efforts on the Performance of a Pharmacovigilance System in Oman
460	An Action Plan for the Selection of Essential Medicines
461	What Do Managers and Prescribers of the Brazilian Health System Think of Essential Medicines? Preliminary Results of a Nationwide Qualitative Study
466	Quality of Some Pharmaceutical Products Manufactured in Kenya
467	Establishing a Nationally Consistent Approach to Implementing the Principles of Good Prescribing in Health Practitioner Education
490	Policies to Increase Use of Generic Medicines in Low- and Middle-Income Countries: A Literature Review of Implementation Research
493	Policy for Rational Regulation and Quality Use of Natural Health Products in the Philippines
499	Selection of Essential Medicines
502	Process and Lessons from the Philippine Pharmaceutical Sector Scan
510	“Under the Radar”: Nurse Prescribers and Pharmaceutical Industry Promotions
511	Developing Superior Screening Technology for Monitoring Medicine Quality in Low-Resource Countries
513	Actions of the National Regulatory Authorities in Developing Countries Following US FDA and EMA Safety Alerts on Rosiglitazone
517	The Knowledge, Perceptions, and Practice of Pharmacovigilance among Community Pharmacists in Lagos State, Southwest Nigeria
535	Baseline Assessment of Pharmaceutical Situation in Southern African Development Community
546	Challenges of Building Effective Pharmacovigilance Systems in Resource Limited Settings: A Case Study of Kampala Region, Uganda
557	Pharmaceutical Regulation in 12 Countries
592	Financial Impact of Judicious Use of Medicine in Primary Care
593	Unbranded Advertising of Prescription Medicines—A Systematic Literature Review
599	Marketing and Promotion of the Pharmaceutical Industry: Snapshot of Current Practice Within, or With Possible Implications In, Low- and Medium-Income Countries
607	Medicines Lists as Policy Instruments in Tatarstan and Russian Federation in the 21st Century
611	Health Systems Approach to Improving the Use of Medicines in the S.E. Asian Region (SEAR)
617	Role of Tendering of Medicines in European Countries
622	Impact of Regulatory Requirements on Medicine Access in African Countries: Perceptions and Experiences of Pharma Companies in South Africa
632	Caution! Look Alike, Sound Alike Medication
647	Comparison of the National List of Essential Medicines (India) with the WHO Model Lists of Essential Medicines and Essential Medicines for Children
677	Analysis of Medicines Dispensed by Court Order in the Court of Rio de Janeiro: The Application of

<b>ID</b>	<b>Title</b>
	Scientific Evidence in Decision-Making Process
679	Brazilian Courts as a Pathway to Medicines which Represent Pharmacotherapeutic Gaps
683	Analysis of NMP Documents of the Region of the Americas
711	Transparency Monitoring Study: A Rapid Assessment of Transparency in Key Functions of Pharmaceutical Services in 15 Countries
731	New Performance-Based Reward Strategy to Improve Pharmacy Practices, Financial Management, and Appropriate Medicines Use in the Public Sector in Uganda
733	Pharmaceutical Situation Assessment: Methodological Challenges for Different Contexts
741	Pharmaceutical Situation Analysis of Mongolia
751	Case Study of the Implementation of Good Governance for Medicines Programme in Mongolia
759	Implementing an Egyptian Pharmacovigilance System: University and Public Hospitals' Experience
769	Strengthening Pharmacovigilance Systems: Experiences from Kenya
773	Tsunami Drug Donations in Sri Lanka: Have the WHO Guidelines on Drug Donations been Effective in Meeting Public Health Pharmaceutical Needs in Times of Disaster?
788	Role of Pharmaceutical Industry Marketing Codes in Securing Good Governance
795	Drug System Monitoring and Development Project, Funded by Sin Tax, and the Roles in Promoting Rational Drug Use in Thailand
800	Consumer behavior toward counterfeit drugs: scale development in a developing country setting
806	Monitoring the Safety of Medicines in Kyrgyzstan
807	Using Defined Daily Doses, Pivot Tables, and Charts as a means of Measuring Medicine Utilisation Trends
811	Effects of Listing and Delisting in National Essential Medicine List on Utilization Patterns
814	Intensive Hospital-Based Adverse Drug Reactions Monitoring Studies on 5482 Patients of Kashmiri Origin in a Tertiary Care Hospital
818	How GGM Program Enhanced National Drug Policy, Thailand Experience
828	New warnings for medicines labeling and packaging in Brazil
843	Quality of Dispensing in Outpatient Pharmacy at Sultan Qaboos University Hospital: Peer Review Audit
849	Pharmaceutical Management Interventions through a Drug and Therapeutics Committee (DTC) in Kabul, Afghanistan: Initial Experience after Decades of Neglect
856	Partnership on Pharmaceutical Policies in the Caribbean: 2006-2009
864	Exploring the Development, Design, and Implementation of a Pharmacotherapy Knowledge Center – A Qualitative Study
867	Development of the Caribbean Pharmaceutical Policy
870	Interventions to Improve Medication Safety in a University Hospital in Thailand
879	Compliance of Multidisciplinary Team on Medication Reconciliation Policy at Siriraj Hospital
888	Pharmaceutical Services and Essential Medicines: Considerations on Access to Medicines and Judicial Demands in Brazil
891	Health Litigation and New Challenges in the Management of Pharmaceutical Services
895	Compliance of Multidisciplinary Team on Medication Reconciliation Policy at Siriraj Hospital
910	The Volume Share of Generic Medicines in the Retail Market between 1999 and 2009: a Comparison between Brazil and Mexico
924	Draft South African Marketing Code—A New Model for Marketing Ethics
934	Active Enforcement to Code of Conduct and Conflict of Interest Policies Based on Transparency Assessment Study in Jordan
955	Improving Governance in the Pharmaceutical Sector of Karnataka—the Role of an Anti-Corruption Agency and its Limitations
961	Rational Drug Use Policy in Turkey
967	Country Comparison of MeTA Baseline Pharmaceutical Sector Scan Data
971	Digital authentication of pharmaceutical products
975	Government, Civil Society, and WHO Partnership: a Catalyst for Better Access to Medicines In Countries
976	Pharmaceutical Advertising and Promotion: Advertising Components Analysis in Five Latin American Countries
977	Country Comparison of MeTA Baseline Data Disclosure Surveys
981	Implementation of Good Governance in Medicine (GGM) Programme in Malaysia to Strengthen

<b>ID</b>	<b>Title</b>
	Medicines Management
998	Evolution of the Generic Medicines Market in Brazil, 1998-2010: Antihypertensives, Antidiabetics, and Antibiotics
1009	The Effectiveness of Therapeutics Committees (TCs) in Addressing Key Public Health Problems
1012	Experience with the Global Fund's Revised Quality Assurance Policy for Pharmaceutical Products
1013	MeTA Baseline Assessments: Experiences and Results
1016	Pharmaceutical Advertising and Promotion Regulation of Seven Latin American Countries
1024	Study on Quality Assurance for Essential Medicines other than ARVs, Antimalarial and Antituberculosis Medicines
1025	Multi-Stakeholder Collaboration: Can It Improve Transparency, Disclosure
1033	Proposed Set of Indicators for Monitoring and Evaluation of Pharmacovigilance Activities
1040	Transparency, Governance and Regional Collaboration in Pharmaceutical Procurement in Kenya, Tanzania, and Uganda
1059	Use of Hospital Formulary to Improve Medicine Use at Alexandria Ophthalmology Hospital, Egypt
1064	Data Disclosure: An Ongoing Process Towards Transparency
1098	Pharmaceutical Situation in the Caribbean as Background for Policy Development
1101	Conflict of Interest Policies: Do Academic Medical Centers Make the Grade?
1108	Country Comparison of Multi-Stakeholder Process Assessments in the MeTA Baseline
1126	Containing Health Care Costs in Ghana: Role of Evidence-Based Selection of Medicines
1129	Provincial Essential Medicine List Comparison among 12 Provinces in China
1135	Pharmacovigilance and Risk Management in Thailand
1143	Priority Policy Research Agenda to Achieve Access and Rational Use of Medicines in Thailand
1150	Regional Strategy for Implementing the Rational Use of Medicines at the National Level in Latin American Countries
1152	Access to Medicines in India: Setting Priorities in Policy Research Issues
1154	Transparency in the Armenian Pharmaceutical Sector
1157	Strengthening Pharmacovigilance at the National Level: Development of an Indicator-Based Pharmacovigilance Assessment Tool to Assess Medicines Safety System at the Level of the Pharmaceutical Industry in Developing Countries
1161	Good Governance of Medicines System in Thailand: From Assessment to National Policy Agenda
1164	Development of a Regional Network of Medicines Information Centres
1175	Role of the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance on the Establishment of National Centres in Africa
1178	Improving Access and Quality Use of Medicines in Palliative Care within National Drug Policy, Regulatory, and Funding Frameworks
1186	Medication Errors of Intravenous Medication in Teaching Hospital in China
1189	WHO Good Governance for Medicines Programme: Innovative Approach to Curb Corruption in the Pharmaceutical Sector
1193	Development and Current Status of the National Good Governance for Medicines Initiative in Macedonia
1197	Regional Strengthening of Pharmacotherapeutic Committees
1202	Use of an Indicator-Based System for Assessing, Monitoring, and Improving Pharmacy Practice
1216	Off-Label and Non-Licensed Endocrinology Medicine Use in Turkey: A Retrospective Analysis of Computer Records in the Turkish Ministry of Health
1219	Overview of Drug Tracking System (ITS) in the Pharmacies of Ankara: Preliminary Research
1221	The Plague of Substandard Medicines in Developing Countries: Evidence for Policy Change
1263	Drugs for Anemia