

BRICS

Efforts to secure universal access to HIV/AIDS treatment: a comparison of BRICS countries

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Abstract

This article illustrates how the BRICS countries have been building their focused leadership, making important high level commitment and national policy changes, and improving their health systems, in addressing the HIV/AIDS epidemics in respective settings. Specific aspects are focused on efforts of creating public provisions to secure universal access to ARVs from the aspects of active responsive system and national program, health system strengthening, fostering local production of ARVs, supply chain management, and information system strengthening. Challenges in each BRICS country are analyzed respectively. The most important contributors to the success of response to HIV/AIDS include: creating legal basis for healthcare as a fundamental human right; political commitment to necessary funding for universal access and concrete actions to secure equal quality care; comprehensive system to secure demands that all people in need are capable of accessing prevention, treatment and care; active community involvement; decentralization of the management system considering the local settings; integration of treatment and prevention; taking horizontal approach to strengthen health systems; fully use of the TRIPS flexibility; and regular monitoring and evaluation to serve evidence based decision making.

Numerous clinical trials as well as observational data have demonstrated the benefits of antiretroviral (ARV) treatment for people with HIV/AIDS. ARV therapy (ART) is one good example for translating scientific advances on HIV prevention and treatment into affordable health programs that can be adopted even in resource-limited settings. However, a growing amount of evidence suggests that user-fees, even small, prevent people from accessing treatment and adhering to ART (1).

In the recent decade, considerable energy and money have been spent in achieving universal access to treatment for

HIV/AIDS. Access to free ART at the point of service is common in industrialized countries, and a growing number of developing countries are now struggling to achieve the target of expanding treatment access and providing ART to over 80% of those in need (current global treatment coverage is 54%)-an important goal for low- and middle-income countries around the world, and a new target of universal access by 2015 agreed in 2010 (2–4).

The BRICS countries (Brazil, Russia, India, China, and South Africa) represent 43% of the global population. The political and economic leadership of them in achieving

universal access to ARVs will be critically important for the developing world to achieve the above target. BRICS countries have been increasing their own domestic resources funding health, and making substantial progress in the fight against HIV/AIDS. Their positive experiences demonstrate that it is feasible to extend the access to ART to the people in need, even in a resource-poor setting, where the ideal health system infrastructure might not be in place.

The BRICS countries also look beyond their own borders and help respond to the HIV epidemic both regionally and globally. At the BRICS Health Ministers' Communiqué in Delhi in 2013, the Ministers of BRICS countries agreed to share experience and expertise in the areas of surveillance, existing and new strategies to prevent the spread of HIV and in rapid scale-up of affordable treatment. They reiterated their commitment to ensure that bilateral and regional trade agreements do not undermine TRIPS (*Agreement on Trade-related Aspects of Intellectual Property Right*) flexibilities so as to assure availability of affordable generic ARVs to developing countries (5). Experiences of BRICS countries in securing universal access to ARVs could serve as an engine of innovative health solutions for the other developing countries, and contribute in the global effort toward strengthening health systems.

Objective

This paper aims to illustrate how the BRICS countries have been building their focused leadership, making important high-level commitment and national policy changes, and improving their health systems, in addressing the HIV/AIDS epidemics in respective settings. Specific aspects will be focused on efforts of creating public provisions to secure universal access to ARVs.

General human, social, and health development

Although the BRICS countries got some similarities in terms of growth performance, human, social, and health development (as shown in Table 1). Each of them faces its own significant domestic health challenges, and each has different factors that motivated the start of public HIV/AIDS programs. No uniformed policies and institutions can be right for all countries at all times.

Brazil

The Brazilian government's management of the HIV/AIDS epidemic arose from initiatives in both civil society and the governmental sector following the democratization of the country (6, 7), the success of Brazil's response to HIV/AIDS benefited greatly from its strong government commitment to

health as a human right, providing the universal and equitable access to health care for the entire population including the treatment for HIV/AIDS by the distribution of free medicines to patients (8) and the courage and wisdom of its government in using the international norms and rules to struggle with the multinational pharmaceutical industries for achieving this commitment.

Russian Federation

The Russian governmental programs of HIV/AIDS management and prevention have always been at the core of the country's health system reforms since emergence of the epidemic. Russian economy has rebounded and clearly recovered in the 2000s mainly from the exports of oil and gas. Since then coordination of activities in responding to AIDS has been a key component of health policy of the Russian government and emerging nongovernmental organizations (NGOs) with increased governmental efforts and funds allocated to treatment and prevention of infection. The strong governmental commitment ensures free of charge access to ARV agents for all those in need despite the slowdown of the world and Russian economic development. In 2009, Russian Federation allocated new governmental funding, and strengthened its commitment to reversing the AIDS epidemic in the region (9).

India

In India, health is a state subject; however, health programs are designed and implemented both at federal level and state level based on the epidemiological pattern of infection or a disease. And as with most low- and middle-income countries, India too faces challenges in relation to poverty and malnutrition, weak infrastructure in the context of public scientific laboratories, public research facilities, equipment, and human resource.

With emergence of HIV in Indian 1992, in the initial stages, there were substantial challenges that India faces related to testing and treatment and to dealing with AIDS epidemic. In India, cultural factors that also play a significant role in the HIV/AIDS epidemic is responded mainly due to lack of discussion on safer sexual practices. Multiplicity of departments and poor coordination between various authorities and their community severely affected the ability of the Indian Government to respond to AIDS contributing to the spread of infection (10). However, the response from India has both national and international significance, as the number of people infected and affected with HIV/AIDS has a potential economic effect and the manner in which the international community achieves the Millennium Development Goals (MDGs). Thus, it became important for Indian government as well as international community to develop a strong response for prevention and care-related HIV/AIDS. In

Table 1 Basic human, social, and health indicators

Basic human, social, and health indicators	 Brazil	 Russian Federation	 India	 P. R. China	 South Africa
Population (million) ^a	196.655014	143.533	1241.49196	1344.13	50.586757
Gross national income per capita (PPP intl \$) ^a	11,500	19,940	3620	8450	10,790
Total health expenditure per capita (Intl \$) ^a	943	1038	132	309	862
Total health expenditure as% of GDP ^{a(2011)}	9.0 ^{b(2010)}	6.2	4.1 ^{b(2010)}	5.16	8.52
Life expectancy at birth m/f ^b	71/78 (74)	63/75 (69)	64/67 (65)	74/77 (76)	57/60 (58)
Under five mortality rate (per 1000 live births) ^b	21	12	66	19	62
Probability of dying 15–60 years m/f (per 1000 population) ^b	205/102	391/144	250/169	142/87	521/479
Human development index/rank ^{c(2012)}	0.730 (high)/85	0.788 (high)/ 55	0.554 (medium)/136	0.699 (medium)/101	0.629 (medium)/121

^aWorld Bank World Development Indicators (figures are for 2011 unless indicated).

^bGlobal Health Observatory (figures are for 2011 unless indicated).

^cHDRO (Human Development Report Office) United Nations Development Programme.

Source: *The 2013 Human Development Report – “The Rise of the South: Human Progress in a Diverse World”*: 144–7.

recent times, with launch of National Rural Health Mission in 2006 and announcement of National Health Mission (NHM) in 2012, there are efforts to converge the national response to HIV/AIDS within a health system framework, with creation of Department of AIDS within the Ministry of Health and Family Welfare, Government of India.

China

The 2003 SARS epidemic motivated the Chinese government to reprioritize its focus on the health of its population, including the HIV-positive population. When AIDS overtook tuberculosis as the leading cause of death from infectious diseases in 2007 (11), it gained the top political attention again, and HIV/AIDS prevention and control has been further strengthened by the government.

South Africa

Combating HIV/AIDS was made one of 22 lead projects of South Africa’s first democratic government Reconstruction and Development Program in 1994. However, HIV/AIDS was heavily politicized in 1990s. Due to the suspicious stance toward ARVs of certain principle particles, South Africa had a far lower ART coverage than it should, which has arguably left the country with the highest HIV rates in the world (12). Ignoring scientific evidence did not continue in the new administration in 2009, the government has continuously improved its HIV statistics since then.

HIV/AIDS epidemic and national response

By the end of 2011, 34.0 million (31.4 million–35.9 million) people were living with HIV/AIDS globally. An estimated 0.8% of adults aged 15–49 years worldwide are living with HIV, although the burden of the epidemic continues to vary considerably between countries and regions. More than 8 million people receive ART, and 1.7 million (1.6 million–1.9 million) people died of AIDS-related illness. Deaths have declined due in part to ART scale-up (13). The BRICS countries contribute about 30% of the global number of people living with HIV/AIDS and people receiving ART, and 52% of the global AIDS-related death.[#] Active and effective responds of the BRICS countries to HIV/AIDS will greatly help to reduce the global HIV/AIDS-related death. Detailed HIV/AIDS epidemics and national response in each of the BRICS countries are listed in Table 2.

Brazil

Brazil has a stable AIDS epidemic, which is concentrated in certain vulnerable population subgroups. Between 1980 and June 2011, 608,230 AIDS cases were reported on the national systems. The general incidence rate was 17.9/100,000 in 2010, which has been stabilized over the last 12 years. In the period between 1998 and 2010, there was a 49.1% reduction in the absolute number of cases and a 40.7% reduction in the incidence rate. There were 241,469 deaths attributed

Table 2 HIV/AIDS epidemics and national response

HIV/AIDS epidemics and national response	 Brazil	 Russian Federation	 India	 P. R. China	 South Africa
Estimated prevalence (15-49) ^a	1%	1.0%	0.3%	0.1%	17.8%
People living with HIV ^b	490,000 [430,000–570,000]	[730,000–1,300,000]	2,400,000 ^a	780,000 [620,000–940,000]	5,600,000 [5,300,000–5,900,000]
Estimated aids related deaths ^a	15,000 [12,000–20,000] ^d	88,974 ^c	320,074	26,000	310,000
Reported no. of people receiving ART ^a (2010)	201,279	79,430	424,802	86,122	1,389,865
Estimated no. of people needing ART based on WHO2010 guideline ^{a(2010)}	290,000 [270,000–310,000]	[270,000–380,000]	[1,100,000–1,400,000]	270,000 [230,000–330,000]	2,500,000 [2,400,000–2,700,000]
DALYs ('000), HIV/AIDS ^a	485	533	3852	671	8545

^aGlobal Fund Portfolio (figures are updated as of 2 November 2012).

^bGlobal Health Observatory Data Repository (2011).

^cFederal Scientific and Methodological Center for Prevention and Control of AIDS.

Source: Available: <http://www.hivruussia.ru/stat/2012-2.shtml>. Accessed 16 September 2013.

primarily to AIDS in Brazil between 1980 and 2010, and 11,965 deaths in Brazil in 2010. The gross AIDS mortality coefficient in Brazil in 2010 was 6.3/100,000 inhabitants. The standardized mortality coefficient for 2010 was 5.6/100,000 inhabitants, corresponding to an 11.1% reduction in the last 10 years. In 2010, 200,000 people received ART via the Public Health system (SUS), and 93.0% of adults and children with HIV were known to be on treatment 12 months after initiating ART in 2011 (14).

Russian Federation

The HIV/AIDS epidemic in Russia peaked in 2001. Since 2004, the number of infected people has been increasing steadily. In 2009, there were 58,448 new cases of infection, which was an 8% increase as compared to 2008. There were 617,018 HIV-positive residents in November 2012. A total of 62,865 people were found HIV-positive in the first 10 months of 2012, which was more than the last year by 12.5%. WHO estimates that the number of people living with HIV/AIDS in Russia ranges from between 700,000 and 1.3 million. Nearly 100% (95.6%) of people with HIV/AIDS receive ART (15).

India

In India, the national response against HIV/AIDS is federally supported with National AIDS Control Organization (NACO), through different phases of National AIDS Control Program (NACP), currently being NACP IV. Over a period of time, it has implemented various interventions on prevention and care that has shown effect on prevalence rates of HIV

infection as well as the number of people accessing ART. According to latest annual report by NACO (16), based on the recent serological HIV estimates in India in 2012, there has been an overall reduction of 57% in the annual new HIV infections (among adult population) from 2.74 lakhs in 2000 to 1.16 lakhs in 2011, with decrease of adult HIV prevalence rates from 0.41% in 2001 to 0.27% in 2011. Wider access to ART has resulted in 29% reduction in estimated annual deaths due to AIDS-related causes between 2007 and 2011. It is estimated that around 1.5 lakhs lives have been saved due to ART. Till the end of 2011, the proportion of eligible people receiving ART was <60%. There has been considerable decrease over a period of a decade in HIV infection in most high-risk population of female sex workers, male having sex with male, and intravenous drug users as well.

China

At the end of 2011, the estimated number of people living with HIV (PLHIV) in China stood at 780,000 people. There were 154,000 cases of AIDS. The overall prevalence stood at 0.058%. HIV incidence among people on treatment fell from 0.54% in 2009 to 0.31% in 2011 (17). The total number of people ever receiving and currently receiving treatment increased from 81,739 and 65,481 in 2009 to 155,530 and 126,448 in 2011. Currently, 18,703 adults and 216 children are receiving second-line treatment. The proportion of reported adults and children meeting treatment criteria who were receiving ART increased from 67.2% in 2010 to 76.1% in 2011, and the proportion remaining alive and on treatment

after 12 months increased from 82.3% in 2009 to 86.9% in 2011 (18).

South Africa

South Africa's general HIV epidemic has stabilized over the past four years at a national antenatal prevalence of around 30% (19). There is a wide variation in HIV prevalence by age, race, gender, socioeconomic status, and geographical location. Although HIV prevalence has increased, the absolute number of PLHIV is on a steep increase of approximately 100,000 additional PLHIV each year. The estimated number of PLHIV in 2009 was 5.63 million. There is a substantial downturn in AIDS-related mortality in recent years, with the annual number of AIDS deaths reduced from about 257,000 in 2005 to about 194,000 in 2010 (20). Reaching 2 million people with ART in 2012, South Africa has surpassed its target of universal access by that was to be reached in 2015 (21).

National HIV/AIDS program

Brazil

With the newly adopted constitution in 1988, Brazil began campaigns for Sanitary Reform, which attempted to democratize health policies and establish healthcare as a human right for all Brazilians (22). When Zidovudine became available in the late 1980s, the state of São Paulo made small quantities available at no cost.

The promise of treatment motivated individuals more at-risk to be tested and gave physicians an incentive to report AIDS cases, thus improving surveillance and prevention programs. The success of the São Paulo free drug program led to its adoption by other states and ultimately by the federal government (23, 24). In 1996, once ARVs were available, the Brazilian government approved a law about providing anti-AIDS therapies at no cost to all patients in need.

The first government HIV/AIDS initiative was the creation of the National STD/AIDS in 1986, now called Department of STD, AIDS and Viral Hepatitis, Ministry of Health (MoH). In the early 1990s, the networks for diagnosis, counseling, and treatment of HIV/AIDS were set up and structured different care modalities—Counseling and Testing Centers (ATC), Services for Specialized Assistance in HIV (SAE), Units for Antiretroviral dispensing (UDM), Hospitals-Day (HD) services, and Home Care Therapy (ADT) (25). Since the approval of Law 9.313/96, Brazil started to guarantee access to ARVs to everyone in need (26), so Brazil was the first developing country to distribute free ARVs to people. The country has a National Drug Policy, with guaranteed budget for purchasing and distributing ARVs. From February 2003, it was implemented an incentive policy for HIV/AIDS and other STDs (27), which provides, among other provisions,

transferring of resources directly to the Civil Society Organizations (CSOs).

Brazil also provides free of charge female and male condoms. The national HIV/AIDS program was praised as the best of its kind in the developing world by the United Nations and has served as a model for 31 other developing countries as well as for the global HIV/AIDS policy adopted by the World Health Organization (WHO) since 2003. By 2010, about 200,000 patients in the country benefited from these therapies. By providing universal treatment, the country proved that it was possible for developing countries to offer efficient AIDS treatment. Moreover, Brazil has demonstrated that a strategy that combines prevention and treatment is far more effective than concentrating on prevention alone.

Russian Federation

In April 2006, the State Council met with the Russian President to set goals for developing a strategy for responding to AIDS; improving coordination, through the creation of a high-level multi-sector governmental commission on AIDS; and establishing a unified monitoring and evaluation (M&E) system. A new Federal AIDS Program for 2007–2011 was developed to meet the maximum satisfaction of the needs of the population in high-quality and affordable medicines. The program was developed based on a rational system of drug supply, a balanced budget with the financial resources at all levels. On 21st April 2006, at a special session of the Presidium of State Council on HIV and AIDS, President Putin announced goals for developing a long-term AIDS strategy, improving coordination through the creation of a high-level multi-sector Coordinating Commission and a unified M&E system. The government committed at the highest levels to the “*Three Ones*” principles. The 2006 Russian State Budget for AIDS was increased 20-fold to approximately 3 billion Rubles (\$58 million) and funding was allocated to the National Priority Project for Health to develop HIV and AIDS protocols and normative documents and other national-scale efforts to improve coordination and ensure universal access to HIV prevention, treatment, care, and support.

Nowadays, public prevention and treatment of HIV-infected people in Russia are conducted in compliance with the priority national project Health and the Federal Law “*On Prevention of Spread of the disease caused by the human immunodeficiency virus (HIV)*” (No. 38-FZ) and other programs, laws and orders of the Russian Federation. There are also different projects of various scales implemented by the UN agencies, international, and local NGOs.

The Governmental decree “*On the financial support for procurement of diagnostic and antiviral drugs for the prevention, detection, treatment monitoring, and treatment of persons infected with human immunodeficiency virus and hepatitis B and C*” (No. 1438, from 27th December 2012,

the latest one) defines the list of diagnostic tools and ARVs and determines the allocation of funding and subsidies of the federal budget to the subjects of the Russian Federation (regions), as well as the procedure for procurement of medicines. This document is approved annually.

India

NACP is more than two decades old started after the detection of the first AIDS case in India. The first phase of NACP was started with the support of development partner United States of America's Aid for International Development (USAID), after initial stages being addressed by task force comprising of Indian Council for Medical Research (ICMR) and National AIDS Committee under the leadership of secretary, the Ministry of Health and Family Welfare. By 2002, HIV/AIDS became widely prevalent with a need of more coherent and comprehensive response, which was addressed through World Bank credit in form of NACP II, 1999–2006. It was the time when many programmatic innovations were done and implemented, including targeted interventions for high-risk groups. It was during this phase that the national free ART program for general public was launched. Prior to this, through the support of Global Fund for HIV/AIDS Tuberculosis and Malaria (GFATM) comprehensive program for Prevention of Parent to Child Transmission (PPTCT), the access of free ART was provided to pregnant mothers. The initial launch of free ART program, in April 2004, focused on the six high prevailing states, which was later on scaled up universally, with access to second-line ART as well. It was in the second phase of the national program, implemented till early 2007, the government stepped up its advocacy, prevention, care, support, and treatment program. Political advocacy as an activity gained importance. In order to increase outreach to rural populations, the program was decentralized and District AIDS Prevention and Control Units (DAPCU) were set up, which became the centers for implementing NACP considering the need for a holistic, multi-sector approach to the problem has been recognized (28). NACP III, 2007–2012, build on the gains of NACP, further strengthening national response to HIV/AIDS and converging service delivery with existing health systems.

China

The Chinese government began providing free ART in March of 2003 to selected counties through the China CARES pilot program. China's key HIV/AIDS treatment care policy was firstly developed and implemented in 2004, named "Four Frees, One Care":

- i. For the rural residents and the urban poor who are not covered by the basic health insurance program, and meanwhile who are qualified for the inclusion criteria for ART,

ARVs procured and distributed by the government could be freely provided; for those who are not eligible for free ARVs, the ARV cost could be covered by the basic health insurance program.

- ii. For the poor HIV positives and the AIDS patients, the government provides them medicines subsidies for opportunity infection treatment.
- iii. Health facilities are designated by the local health authorities to conduct free consultation and voluntary initial screening test.
- iv. For the HIV-positive pregnant women, the government provides free consultation and treatment to prevent mother-to-child transmissions.
- v. Textbook and miscellaneous fees for the HIV-positive nonadults and the orphans of AIDS patients are exempt, and tuition fees for primary school and high school education are remitted. The focus of free ART has been on patients infected through plasma donations in China's central provinces; however, treatment is being expanded to other populations, such as intravenous drug users, commercial sex workers (CSW), and children with AIDS.

During 2010–2011, while continuing to implement the "Four Frees, One Care" policy, further efforts were made to implement the "Five Expands, Six Strengthens" approach, resulted in important achievements. "Five Expands" means to expand Information Education and Communication (IEC) activities, surveillance and testing, prevention of mother-to-child transmission program (PMTCT), comprehensive interventions, and coverage of ART. "Six Strengthens" means to strengthen blood safety management, health insurance, care and support, rights protections, organizational leadership, and strengthening of response teams (15).

South Africa

In 1982, the first case of AIDS in South Africa was reported. The first deaths from AIDS in South Africa occurred in 1985. The government subsequently held a conference to address the potential threat the disease posed for the country. The scope of these early efforts by the apartheid administration remained minimal. The first democratic government made combating HIV/AIDS one of 22 lead projects of the new government's Reconstruction and Development Program (RDP), and had South Africa actively involved in the international community in combating the pandemic. At the beginning of 1998, a battle for the provision of ARVs by the South African government that would last for much of the following decade began. On 19th April 2001, the South African government successfully protected a law to allow the domestic production of cheaper, generic brand medicines – including ARVs. However, government provision of ARVs through public health structures after this victory remained remarkably low. Partly due to this increased pressure from civil society, the South

African cabinet approved a plan for universal ART in August 2003. By late 2005, more than 5 million South Africans were HIV-positive, making South Africa the country with the highest HIV rates in the world. In 2006, the National Department of Health initiated the development of a 5-year National Strategic Plan that called for a multi-sector response to the epidemic and included prevention and treatment as priority areas in the national response. On 22nd April 2009, the election of President Jacob Zuma completely turned the previous poor policy around. However, by the end of 2010, only 55% of people who needed ART were receiving it, falling significantly short of the government’s goal of 80% coverage. The government maintained its commitment to rectifying these statistics over the next several years. There has been steady progress since 2009.

Health systems

All BRICS countries established national ART system based on their respective unique health system. There have been increased domestic public spending on HIV in BRICS countries. They contribute together to more than half of all domestic spending on AIDS in low- and middle-income countries. Their domestic public spendings increased by more than 122% between 2006 and 2011 (29). Percentage of HIV funding coming from international sources in BRICS countries was all less than 3% in recent years (as shown in Table 3). BRICS countries now fund, on average, more than 75% of their domestic AIDS responses. Domestic sources already account for more than 80% of resources spent on AIDS in South Africa and China – and the Chinese government has pledged to fully fund its response in the coming years. India, too, has committed to increase domestic funding to more than 90% in its next phase of the AIDS response. Brazil and Russia have already fully funded their AIDS response with domestic resources (30).

Brazil

The healthcare system in Brazil has been steadily evolving since the creation of SUS in 1988 and the subsequent introduction of the Family Health Program in 1994. SUS was created by the 1988 Constitution and regulated by Law No. 8080 and No. 8.142/90 (31), in order to change the situation of inequality in healthcare population. SUS is ruled by a set of principles and guidelines that include universal access, equality in care, comprehensiveness, community participation, and administrative decentralization policy. Thus, every citizen can be seen at SUS for free. In Brazil, there is also the private sector in which individuals can contract health services by payment, and the health services are delivered by both public and private sectors.

Table 3 External resources for health as a percentage of total expenditure on health 1995–2011 (%)

Country	Year																
	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Brazil	0.2	0.1	0.2	0.3	0.5	0.5	0.5	0.4	0.1	0	0	0.1	0.1	0.1	0.1	0.3	0.3
Russian Federation	0.1	0.5	0.4	0.6	0.8	0.2	0.2	0.2	0.2	0.1	0	0.1	0	0	0	0	0
India	1.3	1.6	1.6	1.7	1.3	0.6	2.4	0.3	0.6	0.5	0.4	0.7	1.4	1.7	1.1	1.3	1
P.R. China	0.2	0.1	0.1	0.1	0.1	0.1	0	0	0.1	0.1	0.1	0.1	0.1	0.2	0.1	0.1	0.1
South Africa	0.1	0.1	0.1	0.2	0.1	0.3	0.2	0.4	0.4	0.5	0.5	0.7	0.8	1.2	1.9	2.2	2.1

Source: World Health Organization National Health Account database (<http://apps.who.int/wha/database/DataExplorerRegime.aspx>); World Bank World Development Indicators.

Created in 1994, the Family Health Program – Brazil’s main primary healthcare strategy – seeks to provide a full range of quality health care to families in their homes, at clinics, and in hospitals. All three levels of government in Brazil – federal, state, and municipal – have worked hard to encourage the poor to use and benefit from the health system through initiatives, such as the Family Health Program and through the deployment of auxiliary health workers (Community-based health workers) working with the poor.

Since 1996, the Brazilian government has guaranteed universal access to ARV treatment at no cost. ATRs are procured by the MoH and distributed exclusively in the Drug Dispensing Units (UDM) in the public health, also supplying the needs of patients in the private network. Purchase of ARVs accounts for approximately 70% of the total budget for STD/AIDS and Viral Hepatitis actions.

An important contributor to the success of Brazil’s response to the HIV/AIDS epidemic is SUS, which has strengthened its public health system. Brazil has adopted the following strategies to universal access to diagnosis:

- Decentralization of testing actions;
- structuring laboratory networks for the purposes of patient testing and monitoring;
- political incentives for testing;
- social mobilization to encourage the population to seek early diagnosis;
- preparation of national norms and protocols;
- articulations with the organized civil society;
- guaranteeing financial resources through agreements with the different service management levels for the purchase of tests for diagnosis;
- increased funding for specific commitments, such as the reduction of mother-to-child transmission.

Russian Federation

Russia funded almost all of their national AIDS programs from domestic sources. After the break of the Soviet Union in 1991, the Russian health system continued to develop as an extensive, centralized system. Health financing in the Russian Federation is a relatively even mix of financing from two compulsory sources: general taxation and payroll contributions from the mandatory health insurance (MHI) and out-of-pocket payments. The coverage of the population is universal, free, and guaranteed as a constitutional right. However, the responsibility for enforcing this is, in practice, shared between the central, regional, and local authorities, and determined by the state medical benefit package. The state guarantees are determined by government decrees issued each year. The state medical benefit package consists of the basic MHI package and the package of care to be financed by budgetary funds. The basic MHI package covers the everyday health needs of the population, while the bud-

get package covers specialized and high-technology medical care, outpatient pharmaceutical costs for certain groups as well as emergency care.

The two main sources of compulsory financing for the Russian health system are general government revenues, and a payroll contribution to the MHI scheme, in the form of an earmarked share of the unified social tax. The MHI Funds pool contributions and transfer them to insurance companies on the basis of a weighted capitation formula, although the actual reimbursement methodology varies widely. The third-party insurer ideally engages in selective contracting with providers, so as to encourage competition between facilities as well as lower costs, higher quality care, and better primary care and prevention services. The insurance companies enter into contracts with providers based on case payments, which were expected to create pressures for efficiency. For payments from the regional or local budgets, the organizational relationship is integrated as the providers are directly owned by the relevant tier of government. The activities of providers are therefore largely controlled through hierarchical management structures at the local and regional levels.

The Russian Federation inherited a large network of primary care facilities, which covers the whole territory of the country. There is a hierarchy of clinics and hospitals at the municipal, regional, and federal levels to which complex cases can be referred. The network of secondary and tertiary facilities combines hospitals, hospital outpatient clinics, and specialist outpatient centers based in polyclinics. All state-owned health facilities belong to a unified form of legal incorporation: a state or municipal budget health facility. Most of the health facilities within the state and municipal health systems are financed from two public sources: the budgets of the corresponding level and the MHI system. Institutions providing care for socially significant diseases (such as HIV/AIDS, etc) and epidemiological surveillance institutions are financed only from the budget. Resources are allocated “historically” on the basis of previous budgets, which are based on capacity measures such as the number of beds, although there has been an increased use of activity volume indicators in budget allocation to health facilities.

There have been a number of recent reform initiatives at the federal level, which have focused on the delivery of services, increasing funding for priority areas, such as the federal reimbursement program for pharmaceuticals, with the aim of improving access to pharmaceuticals for particular vulnerable groups as part of wider changes to the benefits system. According to the current legislation, pharmaceutical coverage is free for inpatients, and medicines for outpatient treatment are paid for in full out of pocket. Some special groups (veterans, disabled, having certain chronic diseases, such as diabetes mellitus, tuberculosis, HIV/AIDS, hepatitis, psychiatric diseases, rare diseases, etc) who are eligible for benefits get prescription medications for outpatient care

either free or with a discount. Citizens also receive prescription medications for certain conditions free of charge, including AIDS, HIV infection, diabetes, cancers, leprosy, TB, etc. Subsidized pharmaceuticals are provided through the federally funded channels, which have consisted of two subprograms – the provision of necessary medicines and high-cost conditions. Patients do not have to pay anything out of pocket for the covered medicines; regional or federal governments reimburse special pharmacies, which supply the medicines. Pharmaceuticals prescribed in hospitals are free of charge for patients (32).

Health care for people with HIV/AIDS was in Russia's network of regional AIDS centers. Although staffing varies from region to region, most centers boast an infectious disease specialist; pediatrician; ear, nose, and throat specialist; ophthalmologist; neurologist; dentist; physiologist; social worker; nurses; and laboratory personnel – each of whom receives a significant salary supplement to work with HIV/AIDS patients.

More recently, two Federal programs have been established to supplement the existing system: "Development of Health 2020" and "Pharmaceuticals 2020." The Federal Program "Development of Health 2020" aims to extend basic healthcare coverage to include the reimbursement of outpatient medicines, and the unification of EDL and DLO lists to form part of a system of universal healthcare coverage. Pilot schemes are being rolled out from 2013, with full implementation expected by 2020. Analysts believe this to be optimistic. The Federal Program "Pharmaceuticals 2020" aims to substitute 50% of all generics with domestic alternatives by 2017, and domestically manufacture half of all innovative medicines by 2020. The policy, which received government funding of \$4 billion in March 2011, has provided a catalyst for major domestic and international investment in the Russian pharmaceutical industry (33).

India

India has a mixed healthcare system, where 25% of its population accesses health care through public health system, while 75% of its health care is accessed through private health care, paid through out of pocket (34). Government expenditure on health is only 1.4% of its GDP (35), and the public health system is composed with multiple levels: at national, state, district, community, primary healthcare center, and subcenter levels. Public health infrastructure in rural areas consists of a three-tier system: a subcenter for every 5000 population with a male and female worker; a primary healthcare center for every 30,000 population with a medical doctor and other paramedical staff, and a Community Health Center (CHC) for every 100,000 population with 30 beds and basic specialists. In urban areas, it is two-tier systems with the Urban Health Center (UHC)/Urban Family Welfare Center

(UFWC) for every 100,000 population followed by general hospital.

Even though there is wide network of health care service delivery points, many institutions are underperforming due to health system challenges of staff shortage and nonavailability of medicines and consumables and essential equipment (24) in a scenario of low spending by the government on public health in general and increased spending on vertical programs like AIDS, a new initiative by the government, to increase access to ARVs through the public health system has become the subject of a major debate in India (16). The policy-making environment in relation is also fragmented. The availability and prices of medicine are regulated by the Ministry of Chemical and Fertilizer, whereas quality of medicine and medical devices is regulated by the Ministry of Health and Family Welfare. Similarly, the accreditation of medical doctors is done by the Medical Council of India (MCI), which is an independent autonomous body, not under government's regulation.

China

The national AIDS program of China is still a vertical communicable disease control, prevention, treatment, and care program, although the government has been exploring the approach to integrate these vertical programs (including HIV, TB, etc) into the overall health systems. The national AIDS system is managed by the National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention, which is a subordinate technical advising body of the National Health and Family Planning Commission (former MoH), who formulates the national policies for HIV/AIDS prevention, control, treatment, and care. Due to the significant social and political impact of HIV/AIDS issues, the government also established a high-level coordination body – The State Council AIDS Working Committee Office, established in February 2004 to strengthen the previous AIDS coordinating mechanism that had been in place since 1996. The national AIDS program is funded by both the central and local government budget. Central resources are transferred to the underdeveloped areas and areas with serious epidemics to compensate the weak local financing.

Under the current national government ART program, eligible population are provided with free ARVs through the local Disease Control System under China Center for Disease Control and Prevention (CDC), who locally manage the procurement. AIDS patients are treated. Public health facilities are also designated by the local disease control authorities to provide free ART. There has been an ongoing exploration of integrating the national AIDS program into the overall health system, to achieve more efficient treatment and care (reduce coordination between disease control authorities and medical service deliveries), and to provide universal health security to

the people in need of the care and treatment (shift the vertical financing mechanism into the national basic health insurance system, and list all free ARVs in the reimbursed medicines list of the insurance programs).

In 2011, 14,571 medical treatment facilities at various levels, across China, carried out HIV tests and found new cases of HIV. At the end of 2011, a total of 3142 ART providers were in place nationwide, located in 2082 counties (or districts) within 31 provinces (and autonomous regions, municipalities). Central and local government continuously increased investments to prevention and control of HIV/AIDS. According to incomplete statistics, investment from various sources during 2010–2011 amounted to approximately CNY 7.8 billion, of which CNY 970 million came from international cooperation programs (15).

South Africa

South Africa represents one of the most diverse medical markets in existence. On the one hand, there are wealthy urban areas that enjoy access to high-quality medical facilities, highly specialized, hi-tech health services available in both the public and private sector; while, on the other hand, the rural areas and townships lack basic health facilities, although the government committed to offer the most basic primary health care free of charge through the public sector. The state government contributes about 50% of total health expenditure; the public health sector is under pressure to deliver services to about 80% of the population. Health institutions in the public sector have suffered poor management, underfunding and deteriorating infrastructure. The private sector, on the other hand, is run largely on commercial lines and caters to middle- and high-income earners who tend to be members of medical schemes. It also attracts most of the country's health professionals. This two-tier system is further challenged by the scourge of the HIV/AIDS pandemic that is most prevalent in areas of low socioeconomic development. The government has been trying to fast-track the implementation of a National Health Insurance (NHI) scheme, which will eventually help to achieve universal health coverage.

The health sector is mainly funded by the South Africa's National Treasury. The Department of Health holds overall responsibility for health care, with a specific responsibility for the public sector. South Africa has more than 90 registered medical schemes, with around 3.8 million principal members (and 8.6 million beneficiaries in 2012). Health facilities – such as nursing colleges and tertiary hospitals – are being upgraded and rebuilt to lay the way for the implementation of the NHI scheme, which intendeds to bring about reform that will improve service provision and healthcare delivery. It will promote equity and efficiency to ensure that all South Africans have access to affordable, quality healthcare services regardless of their employment status and ability to

make a direct monetary contribution to the NHI Fund. There are 4200 public health facilities in South Africa. Hundreds of NGOs make an essential contribution to HIV/AIDS and TB, mental health, cancer, disability, and the development of public health systems (36).

Local production of ARVs

The BRICS countries have come to acquire an unprecedented influence in the World Trade Organization (WTO). Their rise offers several new opportunities for the trading system. They have captured large shares of global trade; and politically, their growing voice in the WTO is reshaping at least some of the rules of the game. BRICS countries all have large local markets and capacity to produce pharmaceutical and biopharmaceutical products. The economies of scale and required technology for domestic pharmaceutical industry development in the BRICS countries have enabled them with the capacity of local production of essential medicines, and concentrated on producing assured quality, low-cost generics as a matter of health policy.

Brazil

The presence of multinational pharmaceutical companies in Brazil has grown in recent years, largely due to an increase in the acquisition of local generics companies. Pfizer, GSK, Sanofi, and Amgen are among the high-profile pharmaceutical companies to invest in, or partner with, Brazilian generics manufacturers. While generics account for around a quarter of all medicines sold in Brazil – making it the largest generics market in Latin America.

AIDS treatment in Brazil has relied heavily on the local production of generic ARVs as a strategy to contain treatment costs. This strategy has not only reduced imports of unpatented anti-AIDS medicines but also forced price cut of brand patented medicines in order to avoid having their patents' monopoly rights overrun by compulsory licensing. Since the MoH began substituting expensive imports with local generic equivalents in 1996, the prices of unpatented ARVs fell by an average of 80.9% in Brazil until 2001. By 2011, 11 of the 19 anti-AIDS drugs offered in Brazil were locally supplied. ARVs available in Brazil comprised 19 active ingredients and one fixed-dose combination, which are available in 38 pharmaceutical formulations for adult and pediatric use. Ten ARVs are currently produced in Brazil by several public laboratories and one private laboratory.

Brazil has proven to be the most successful challenger of the current transnational system governing intellectual property rights and a necessary opponent in protecting the rights of developing nations. Specifically, it is the leader in promoting access to HIV/AIDS medicines and, in spite of TRIPS, continues to pursue “development as freedom” by

championing the human right to health. Given that Article 1 in the legislation establishes TRIPS as a set of obligations rather than a model, nations are allowed to create sovereign laws as long as they are above minimum standards. Brazil used this freedom in order to protect their interests in Article 68 of Brazilian IP law (Lei 9.279), which stipulates that the owner of a patent must satisfy a local-working requirement (planalto.gov.br). If the product is not manufactured in Brazil three years after its registration, then Brazil has the right to issue a compulsory license for domestic production or buy a foreign generic version through parallel importing.

In doing so, Brazil was protecting its healthcare system, by assuring access to necessary medications and also protecting the emerging biotech industry, which has been a national priority in the past 20 years. The state-owned pharmaceutical company *Farmanguinhos* has continually grown since its development in the 1970s and from 2001, has produced 56% of the ART consumed nationally (37). “For the Brazilian government, seeking convergence and avoiding isolation did not mean accepting a subordinate position; however, on the contrary, it was the path toward strengthening Brazil’s relative position in international the society” (38). Rather than seeing enactment of TRIPS legislation as a defeat, Brazil used it as an opportunity to put pressure on the system in an area that remained (and still remains) somewhat ambiguous. Brazil’s use of the DSB, especially against the United States, shows that they will not collapse under pressure exerted from developed nations in the IP area.

Although Brazil is considered a middle-income country, its government provides ARVs to its constituents free of charge. To make such a policy viable, the government has limited the high cost of medicines by producing some ARVs domestically and by negotiating with international pharmaceutical companies to import other ARVs. Increased local production of ARVs has been integral to the Brazilian strategy.

The Brazilian experience has played a key role in changing expectations in the interpretation of the World Trade Organization’s TRIPS Agreement. When the Doha Ministerial Meeting of the World Trade Organization at the end of 2001 declared that the TRIPS Agreement should not stand in the way of AIDS responses, it in effect acknowledged the ethical and practical imperatives represented by Brazil’s generic ARV industry.

Russian Federation

The Russian pharmaceutical market consists of two major sectors: commercial and public. The public segment of the pharmaceutical market comprises pharmacy’s sales of medicines under the Federal Fund Subsidy, as well as purchasing medications for inpatient settings where patients are entitled to free medicines. After the break of the Soviet Union, Russian Federation inherited a limited medicines

production capacity oriented toward less-expensive generic, and the country relies heavily on imports to meet its pharmaceutical needs, much driven by unregulated medicines promotion.

As pointed out earlier, Russian Federal Program “Pharmaceuticals 2020” was developed to substitute 50% of all generics with domestically produced alternatives by 2017. The goal is to ensure domestic manufacture of half of all innovative medicines by 2020. Unfortunately, these goals were set mostly by global multinational pharmas, rather than health needs of the Russian population. The policy, which received government funding of \$4bn in March 2011, has provided a catalyst for major domestic and international investment in the Russian pharmaceutical industry. Locally produced medicines may gain preferential access to state reimbursement lists. This provided an added incentive for international manufacturers to invest in Russian infrastructure. In 2011, The Association of International Pharmaceutical Manufacturers pledged a minimum of \$1 billion in investment in Russian manufacturing, packaging, and R&D. Novartis – which is investing \$500 million over the course of five years – Nycomed (Takeda), Novo Nordisk, and Sanofi have all developed operations in Russia since 2010. Others, such as Roche, are partnering with local manufacturers under out-licensing agreements (39).

India

Availability and accessibility of ART in India is interplay of various departments and ministries and even though there is a national free ART access program, fully funded by Government of India, there is a sizable population in India that access ART from private market. Currently, in India, there are 323 brands of ART available in the private healthcare market, which is showing a growth of 14% for past four years, with only 15 of them are multinational companies, while rest of all are domestic Indian companies, producing and supplying ARV to national and international community for access to ART. Prices of ARVs in India also have an international significance as India is the biggest supplier of low-cost ART to global ART support programs.

The patent regimes, pricing mechanism, and regulatory structure of India as well international conventions affect the availability and accessibility of ARV. Indian patent regimes have consistently evolved in this context, with shift from product patent to pathway patent in early 1970s in wake of high medicine prices and going back to product patent in 2005, after being signatory of WTO. However, its applicability is only on those pharmaceutical products invented after this date that are patentable, giving a pipeline protection until the country started giving patent protection on those products. India also does not support inventions that were minor modifications and thus prevented undue monopoly

during the extended period of patent protection by the inventor/company. The generics industry in India has become a booming industry and Indian generics have become the cheapest medicines in the world, which made the Indian generics manufacturers the major global suppliers of safe, effective, and affordable AIDS medicines, which facilitated the rapid scale-up of HIV/AIDS treatment in the developing world. However, in recent times, the complexity of policy environment is an area that needs an immediate attention in India, as it can have an effect on India's access to ARV as well as global communities.

China

China has a large generics industry with many local manufacturers who have the capacity to produce formulations of most of the first-line ARVs. Appreciated to its strong chemical industry in terms of production capacity and low price, China is also the largest API supplier for ARVs, both first line and second line. However, very few of them can produce formulations of the second-line ARVs under the patent system. The government has to allocate government funding to procure those expensive patented second-line ARVs (some of them already shifted to the first line according to the newly updated national treatment guideline) from the multinational pharma, although local manufacturers are able and eager to supply these products to both domestic market and international market. There is yet a formal discussion by the government to use the flexibility of TRIPS agreement, like Brazil and South Africa, as well as India to issue compulsory license, and to enable either local production or exportation of these products.

South Africa

South Africa has the largest pharmaceutical industry in Africa, comprising a complex network of pharmaceuticals manufacturers, distributors, and dispensers. Given the HIV/AIDS challenge the country faces, the pharmaceutical industry has been with a view to provide medicines as efficiently and cost effectively as possible. When the government disregarded the doubts about AIDS science and ARVs, and initiated concrete actions, the budget shortfalls prevented them from providing HIV-positive women with ARVs. To lower the cost of treatment in order to move forward to expanded provision of ARVs, South Africa allowed in its legislation for the importation of generics or compulsory licensing. The Pharmaceutical Manufacturers' Association of South Africa (PMA) immediately challenged the act as contravening South Africa's obligations as a WTO member committed to TRIPS. The government was particularly resistant to trade pressure on Medicines Act; The PMA case came to court in 2001. The PMA eventually settled out of court, an outcome hailed as a victory for the South Africa

government and a sign that cheap generic imports or domestically produced medicines were on the way. The government finally did not issue compulsory licenses, but rather negotiated with originator companies into providing voluntary license agreements to generic manufacturers to produce and import generic versions of patented medicines. The government has subsequently used the act as a tool to negotiate the price of ARVs.

Procurement policy

Brazil

ARVs are purchased by the MoH and distributed exclusively via the public health system Medication Dispensing Units (MDUs), also meeting the needs of private health service patients. Medicines for the treatment of opportunistic infections and other STDs are purchased by the state-level governments, in accordance with agreements between the three levels of government that form the National Health Service (NHS). The MoH has various committees that advise the Department of STD, AIDS, and Viral Hepatitis on procedural norms in relation to ART for HIV-positive adults, children and adolescents, and pregnant women. The care network includes 720 MDUs, 80 laboratories for viral load count, 90 for CD4/CD8 counts, and 23 for genotyping, in addition to reference hospitals and day-hospitals. ARV dispensing has been managed by the Medication Logistics Control System (*Sistema de Controle Logístico de Medicamentos – SICLOM*), permanently deployed since 2006. Apart from controlling the distribution, dispensing, and stock levels, the system assists the analysis of the medical prescriptions in accordance with MoH technical recommendations. The National Network of Genotyping Laboratories (*Rede Nacional de Laboratórios de Genotipagem – RENAGENO*) was created in 2002 and helps physicians to choose the best treatment regimen. All the complex issues of patient management are guided by clinical protocols prepared by expert committees and based on available scientific evidence. The recommendations are updated annually. The committees also advise on decisions as to the incorporation of new ARVs by the NHS. This indication is assessed by the National Commission on Technology Incorporation (CONITEC) which, if approved, recommends its incorporation to the MoH (40). ARVs of STD/AIDS program are exempt from prior authorization for shipment abroad (41).

Russian Federation

Medicines purchased for healthcare facilities in Russia are mostly nonbranded generics. Hospitals use a bidding system for purchasing pharmaceuticals but their funding remains within the limits of the committed pharmaceutical budget. Locally made medicines account for 30% of inpatient

purchases in cost volume (their share increased in 2009; in 2008, it was about 22%). In terms of packages, however, domestic medicines predominate, being as high as 67% (32).

The MoH has been procuring ARVs at the federal level since 2010. The main procedures include the formation of a commission, the publication of a notice on open bidding, the review of the first section of bids received, the timely conducting of the auction, the review of the second section of bids, followed by the distribution and publication of the final protocol as well as the signing of the contract by the winner. The auction winner (as a rule, the supplier with the lowest offered price) has to supply medicines to AIDS centers in due time according to the contract. There are clearly stipulated time frames for the majority of these procedures. The federal procurement of ARVs is financed with funding from the National Priority Project Health (NPP Health). There are likewise regional and local programs for counteracting HIV infection, within which procurement of medicines also takes place.

India

Access to ART is free in India. NACO procures and sends ARVs directly to the ART Centers. Rites Ltd., a national procurement agency, is nominated for NACO for supported purchase and for Externally Aided Component. The procurement is dependent on the conditions laid by the donor, and in certain medicines, it needs to procure through Green Line Committee. National or International tendering process is used for finalization of the rates of ARV procurement, to which Indian companies also participate. NACO supplies the ARTs to all State AIDS Prevention and Control Societies (SACS) and SACS store the medicines. SACS distributes the ARVs to the centers (355 centers throughout the country) three times in a year and also on urgent requirement basis. A buffer stock is maintained at SACS. Most of the financing for ARV procurement is done through global health initiative or development partners.

China

The AIDS center of China CDC is responsible for ARV procurement to be freely provided to the eligible people, while the local Health Bureaus are responsible for administrative matters. Annual bidding process is managed by the AIDS center of China CDC, and local disease control authorities deal with distributions. Supplies forecasts are collected from the provinces. These forecasts are used by the National Center for AIDS/STD Prevention and Control (NCAIDS), on behalf of the MoH, to bid for medicines. The winning bidder, which should offer the lowest priced. The tendering open to the local suppliers and the negotiation with the importers are conducted annually.

South Africa

The South African government ARV tender is the largest in the world, and it is gradually being scaled up to meet the growing number of HIV/AIDS patients that are being enrolled in the government's AIDS treatment program. It constitutes the highest number of people initiated on ART for any country. The higher volumes and generic entry and a more competitive climate attributed the reduction of ARV price. The contracts awarded in the 2013/2014 national tender were awarded to 13 suppliers, 11 of them generics manufacturers. Many of the tender awards were split between different suppliers in an attempt to ensure security of supply.

Information Systems

Brazil

Brazil has the Information System for Notifiable Diseases (SINAN), which is fed mainly by the reporting and investigation of cases of diseases and conditions listed on the national list of reportable diseases (including AIDS) (42). This system allows for the dynamic diagnosis of the occurrence of an event in the population, and may provide support for causal explanations of compulsory notification of infectious diseases, and come to indicate risks to which people are subjected to, thus contributing to the identification of epidemiological reality in a specific geographic area. Since 1975, the information system on mortality (SIM) allows, from the cause of death build indicators epidemiological that contribute to the efficiency of health management.

Specifically on HIV/AIDS, The Brazilian government set up a national public medicines distribution database covering the whole supply chain (Figure 1) and ARVs are incorporated into this system.

The subsystem for HIV/AIDS monitoring includes a computer-based system for logistic management, SICLOM, of ARVs in order to ensure rational supply and consumption all dispensary units. The major objectives of this logistic control system are: (i) to control medicine stocks at national, state, and municipal levels; (ii) to ensure efficiency and safety of medicine supply; (iii) to adequately plan for medicine purchases; and (iv) to assure optimal medicine management. There are also a CD4 & viral load measurement system (SIS-CEL), and a System Information and Network Genotyping (SISGENO), these systems store information generated from the tests performed for further analysis and serve as a tool for physician and other health professionals to monitor these examinations. Among actions to prevent HIV/AIDS and other sexually transmitted diseases, there is also the Monitoring System Inputs Prevention (Previni) to control the distribution of male and female condoms, lubricant gel, kit for harm reduction, and materials education (39).

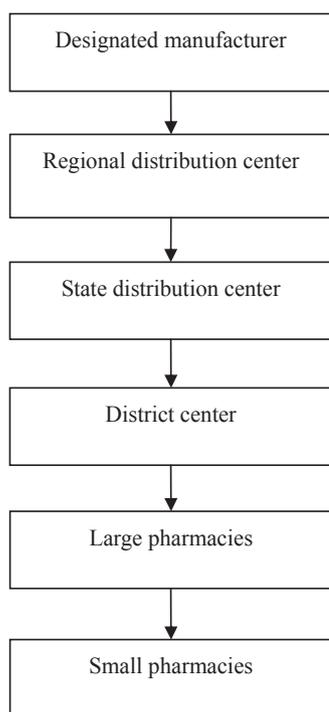


Figure 1 Supply chain.

Russian Federation

Record of the persons infected with human immunodeficiency virus is carried out according to the guidelines of the Ministry of Health of the Russian Federation “On the Organization of data acquisition on HIV and AIDS cases,” No. 5962 from 6th August 2007. The guidelines describe procedures of data acquisition on HIV-antibodies-tested patients, and revealed seropositive and HIV-infected patients, AIDS patients, the procedures for providing information on the diagnostics of HIV-infected patients by the request of the regulatory authorities, but there is no unified system of patients database, which successfully could be used for control of implementation of standard medical care and serve as the evidence base in case.

A public electronic auctions system was set up to record list of goods (work, services) that must be purchased by means of an electronic auction is provided in Decree No 236-r of the Government of the RF dated 17th February 2008. Since 2010, public auctions at the federal level are only held electronically via specific electronic trading platforms. All document interchange occurs in the form of electronic documents.

India

Health management information system (HMIS) is very crucial for decision-making processes in India. India has a national disease surveillance system, for polio and HIV/AIDS

and in more recent times added for noncommunicable diseases as well. The NRHM, with an objective of health systems improvement, has its monitoring cell, which is updated frequently and guides decision-making process, based on performance monitoring. Apart from that India has Central Bureau of Health Intelligence (CBHI), Sample Registration System (SRS), and Statistic Division of Department of Health and Family Welfare, at the federal level that helps in monitoring the health systems as well as health outcome indicators (43). Along with this, there are also state-specific HMISs developed as well as disease-specific. However, there is a need for a strong disease surveillance network in the whole country for better information on diseases and better health initiatives.

China

The monitoring and evaluation system on treatment and care based on the “*China free ART manual*” was established in 2004 in China. Detailed information on each patient on ART is collected at county level using uniformed templates, which contain details on initial patient assessment, treatment follow-up, treatment (follow-up) termination, and change of treatment. The system, when fully implemented, will provide valuable data for forecasting. It also provides information on frequency of side effects. It will also reflect problems of adherence so that corrective interventions can be initiated.

The NCAIDS ARV/diagnostics database is a tool for the administration division. It consists of three modules: procurement, inventory, and storage. The system is focusing more on financial accounting and not on supply management issues. It provides information for each product from where it was supplied, at what price and to where it has been distributed. However, it does not provide information on stock levels for each item. Expiry dates of products are being logged, but not covers batch numbers. Products can be traced only to province level, distribution of a product (or a batch) to prefecture level and below is not recorded.

South Africa

Since January 2000, the Africa Center for Health and Population has built up an extensive longitudinal database of demographic, social, medical, and economic information about the members of its Demographic Surveillance Area, which is situated in a rural area of northern KwaZulu Natal where HIV prevalence is extremely high. It has developed from this database, a web-based Unified Report, as a management tool to provide a consolidated real-time database-linked tracking and progress report for surveillance activities from printing, document distribution and control, data collection, fieldwork quality control, data entry, and archiving (both physical and digitally). The MEDUNSA Campus of the University of Limpopo is responsible for ARV

pharmacovigilance reports and surveillance. Each province also has its own information systems collating information on new and current patients on their ARV programs to feed into national and donor reporting systems.

Challenges

One of the major challenges faced by all the BRICS countries is the limited-resource setting, especially since they are facing the durable threats of both the communicable and noncommunicable diseases.

Brazil

Brazil helped shape global AIDS treatment norms and donor policies in several important ways:

- Strong civil society and public policy responses are critical for improving treatment access: using media strategies and public protests to demand responses to the AIDS crisis, NGOs formed and demanded that the government adopts antidiscrimination policies, implements prevention and education programs, and provides AIDS treatment and care (44–46).
- Innovative strategies to promote access to medicines can lower AIDS treatment costs: threatening to issue compulsory licenses is a unique strategy to reduce the price of ARVs.
- Using global channels can help normalize AIDS treatment in resource-limited settings: Brazil has made great efforts in changing international norms concerning access to essential medicines, and helped to make AIDS treatment more available around the world. By encouraging public discussions on AIDS treatment costs and engaging the media and activist groups about price negotiations, Brazil promoted transparency about medicines prices in developing countries.
- Production of generics, price negotiations with pharmaceutical companies, and amendment of national legislation relating to compulsory licensing are measures that promote and ensure universal access to ART and that can serve as a model for other countries (44, 47, 48).
- The Brazilian experience shows that centralized procurement in the health sector can be effectively used to significantly reduce medicines prices by increasing the bargaining power of the MoH in price negotiation. To stimulate innovation, closer interaction between the MoH and the public laboratories is necessary to align the Ministry's main priorities to the production activities, in order to improve production capacity and the quality of healthcare delivery to the population (46, 49).
- Challenges remain in several areas in relation to commitments taken on how: halve cut by half sexual transmission of HIV, reduce transmission of HIV among people who

inject drugs by 50%, reduce tuberculosis deaths in people living with HIV by 50%, ensure that no children are born with HIV and substantially reduce AIDS related to maternal deaths, increase access to ART to get 15 million people on life saving treatment, and close the global resource gap for AIDS and work towards increasing funding to between US\$22 billion and US\$24 billion per year and recognized that investments in the AIDS response is a shared responsibility (14).

Russian Federation

Until very recently, the Russian government's response to the epidemic was silent. Officials at the highest levels of government did not see HIV/AIDS as a prevalent disease or as a priority. Significant steps forward happened in the fall of 2005, with Putin's announcement of dramatic increases in the federal budget allocation for the fight against the virus. At the 2010 International AIDS Conference in Vienna, a representative of the Andrei Rylkov Foundation for Health and Social Justice criticized Russian authorities for their harsh line on injecting drug users, which makes people in this high-risk group afraid of seeking out the health services they need, causing HIV rates to rise (50). The Norwegian Institute for Urban and Regional Research conducted a research in 2010 and revealed that despite Federal authorities' increased efforts, there remains a systemic reluctance to fund programs targeted at risk groups, with big regional differences in level of commitment to and way of organizing campaigns and treatment. Influence of individuals at the local level and personal relations between key stakeholders in concrete regions seem to be of core importance.

Significant challenges include co-infections with tuberculosis and hepatitis, treatment adherence, and overall capacity building. In general, the Russian system of health care is vertically oriented, with extreme specialization of personnel and facilities treating specific diseases or patient groups. This rigid system has kept information about HIV out of the hands of general practitioners, who do not see it as their responsibility. Prevention and detection is therefore virtually absent at most regular polyclinics. Doctors and nurses outside the confines of the AIDS centers remain ignorant of even the most basic facts about HIV. The lack of communication between different specialists lets patients co-infected with HIV and TB, for example, or HIV and hepatitis, fall through the cracks.

India

UNAIDS' 2008 Report on the Global AIDS Epidemic reports that there are up to 3.2 million people living with HIV in India, although the government places this figure at 2.3 million. The International Labor Organization (ILO) reports that 70% of persons living with HIV face discrimination in

India. According to Human Rights Watch (HRW), many doctors refuse to treat HIV-positive children. HRW also claims that some orphanages refuse HIV-positive children and that some children are expelled from school on the grounds that their parents are infected with HIV. Inadequate procurement of medicines is the main reason for the inadequate intake of the ART program. Several factors increase Indian vulnerability to a devastating AIDS epidemic widespread poverty, illiteracy, poor nutritional and health status, social inequalities based on caste and gender, inadequate health infrastructure, taboos about sex, lack of political commitment, and a persistent denial of the AIDS epidemic in many states. Interdepartmental coordination and strengthening community response is also something that needs improvement for a holistic response against HIV/AIDS in India.

China

In February 2009, China's MoH announced that, HIV/AIDS was the leading cause of death in 2008 compared with other infectious diseases (51). The state media reported 7000 deaths as a result of HIV/AIDS in the first nine months of 2008. China's MoH claimed that until three years ago, fewer than 8000 people altogether had died from HIV/AIDS. By 2008, the number had risen to around 40,000. However, data on HIV/AIDS remain unreliable in China, although official reporting appears to have improved. The current "*China HIV/AIDS Response Monitoring & Evaluation Framework (trial version)*" requires updating. Although there is now a greater degree of commitment to M&E at the national level, it is still much less than is necessary. There is also a lack of integration and comprehensive analysis of M&E data between different systems and different departments, which means that M&E results are not sufficiently utilized in practice. Finally, the grassroots-level M&E staff are lack requisite technical skills. There is limitation on information collection about HIV transmission behaviors among populations. M&E on community-based organization's (CBO) participating in AIDS response is not sufficient, and the capacity of M&E at primary level needs to be strengthened.

China also has the similar problem with its health system to response HIV/AIDS like in Russia. Both of them have a vertical health system. Disease control programs including HIV/AIDS are parallel programs, and are isolated from the overall health system, which is not preferable for efficient resource allocation and information sharing. Although the central government has realized this and considered to integrate HIV/AIDS treatment and care with the general healthcare delivery system, there are many changes in ahead in terms of linking such integration with the national health system reform, especially the reform of the public hospitals.

Although the present system has resulted in the decline in HIV infections caused by blood transfusion, the following activities should be intensified further:

- HIV/AIDS awareness and education, particularly among the youth and the students.
- Involvement of the private sector and building up public-private partnerships.
- More support services for those living with HIV/AIDS.
- Stronger political commitment.
- Collaboration of the health sector with various stakeholders such as other government departments, NGOs, and CBOs for expanded response.
- Transform HIV/AIDS from the image of a private problem to a public problem through information, education, and communication.

South Africa

In South Africa, integrating HIV and TB at the primary healthcare level has shown improved case-finding and better outcomes (52), as well as reducing half the delay in starting ART for people newly diagnosed with TB (53). Optimizing ART delivery also requires providing treatment within settings where people can have their broader healthcare needs addressed at the same time, in one location, and from the same health worker. With the continuing shift away from specialized clinic HIV care, ART has been increasingly be ideal to be managed as a chronic disease (54). This means addressing health needs beyond HIV, and integrating the vertical disease control programs (including HIV) into the regular health systems, and managing HIV at community healthcare level. Recently, South Africa has also moved to Nurse Initiated and Management of Antiretroviral Therapy (NIMART). It remains to be seen as to how successful this policy is in improving access and care to patients.

Policy Lessons

Right-based approach

Health care is recognized in the Brazilian constitution as a fundamental right of all citizens and a fundamental responsibility of the government. This creates an obligation on the government to take all reasonable steps to actualize that right. The Brazilian constitution created both a moral and a legal basis for the demand for comprehensive treatment for people living with HIV/AIDS (PLWHA). Many countries recognize health care as a human right, but in relatively, few instances have legal strategies been as fruitful as in Brazil, which is the most important contributor to the success of Brazil in response to HIV/AIDS.

Political commitment

Political commitment to necessary funding for universal access and concrete actions to secure equality care are the core and decisive factors for the successful response to

HIV/AIDS. This is tested in all BRICS countries, either in country such as Brazil who achieved this in the early stage, or in countries such as Russia and South Africa where the political commitment finally prevailed the prejudice and misjudgement, or in countries such as India and China where critical epidemics played as a facilitator of achieving these essential factors.

Universal access

A comprehensive system to secure demands that all people in need be capable of accessing prevention, treatment, and care are needed. Obstacles to scaling up HIV treatment persist in most countries, including funding shortages, limited human resources, and weak procurement and supply management systems for HIV medicines and diagnostics and other health systems bottlenecks. But BRICS countries all demonstrated that universal access is achievable even in resource-limited settings. By starting treatment earlier and improving adherence within the first year, many more lives can be saved.

Brazil's treatment program is free, which has received considerable attention, but less publicized is the fact that it is universal. Universal distribution, in contrast to free medication solely in the public health sector, created many more points of access to treatment and allowed more rapid scale-up. Universal access encompasses the principles of equity, equality, nondiscrimination, comprehensiveness, accessibility, and sustainability, which guided the development of interventions with comprehensive approach. It should be physically accessible, affordable, equitable, and nondiscriminatory. Supply should be determined by need but not limited by cost or other considerations. Access to the interventions should *not* be restricted by sociodemographic or other criteria.

Community participation

Community participation is the advantages of countries such as Brazil, India, and South Africa, where miscellaneous NGOs and civil societies played a very important role in raising both the public and the political awareness, and pushing forward positive actions toward HIV/AIDS responses. Even in countries where NGOs had ever been not very vigorous, worldwide experiences of good involvement of community and civil society led demonstrative effects in these two countries. Where NGOs exercised at all levels of government, in many cases working productively to educate government officials about the need to respond to the epidemic.

Centralization versus decentralization

The balance between centralized and decentralized functions is a problem all national health systems confront. In most of the BRICS countries, there is a quite clear hierarchy be-

tween the central and local governments. The MoH initiates HIV/AIDS program, formulates directive policies, standards, and budgets to state or provincial health departments responsible for regional planning. These regional health authorities then direct local health departments to implement the HIV/AIDS program. Centralization is dominant in most health ministries, and it is not uncommon for regional and municipal departments to be responsible for implementing programs without receiving funding to deliver the services.

While in Brazil, treatment and surveillance remained governmental functions, NGOs increasingly took the lead in the prevention of HIV and the promotion of human rights. The Brazilian response to AIDS thus emerged from the bottom up. It has been characterized by an active collaboration between government and NGOs, as well as by mobilization of activist political support and commitment, particularly on the part of local service providers in the public health system.

The Chinese national AIDS program shifted its ARV procurement and management function between centralization and decentralization several times, explored, and finally worked out a mechanism of centralized planning and tendering, mixed with decentralized management system including inventory control.

Integration of treatment and prevention

HIV/AIDS has been challenging health systems in resource-limited settings to provide lifelong treatment and care. This requires a shift from acute care only to acute and chronic care. Based on this approach, in many settings, tasks can be shifted from more specialized (and scarce) to less specialized health workers to general doctors and/or medical or clinical officers, from doctors to nurses, from nurses to ART AIDS and other lay providers. The most important task shift is to the patient themselves (self-management). The community can be progressively involved in managing HIV care and ART (eg, for treatment support, medicines refills, and simple monitoring). The integration of care and treatment was fundamental to the HIV/AIDS program even before the development of effective ART. The successful free medicines program of one state of Brazil San Paulo gave incentive for more at-risk individuals to be tested and for doctors to report AIDS cases, which improved surveillance and preventions of HIV/AIDS. South Africa is still looking for indicators of the success of the Nurse-Initiation and Management of ART (NIMART) approach to managing HIV/AIDS in the country.

Horizontal approach and strengthened health system

Response to HIV/AIDS helped BRICS countries to strengthen their national health systems by attracting new financial resources for health, building systemic capacity,

and introducing chronic disease management approaches for the first time in resource-limited settings. Brazil successfully integrated its health services, strategies, and plans. South Africa's HIV program implemented within a primary health-care framework and provides integrated services, which included services for maternal and child health, harm reduction, and the management of tuberculosis, sexually transmitted infections, and viral hepatitis. Horizontal approach led to strengthened health system and improved not only equity, access, and coverage, but might also enhance the quality and efficiency of care.

Russian's lessons demonstrated that, to successfully address HIV where injecting drug use occurs, countries should prioritize implementing evidence-based medicines dependence treatment. Countries should also ensure that people who inject drugs are successfully reached by comprehensive interventions within the overall health systems.

Fully use of the TRIPS flexibility

Using price negotiation mechanisms and TRIPS flexibilities has been important strategy for the sustainability of universal access to treatment, as well as, to stimulate national production of ARVs in BRICS countries. This is especially successful in Brazil and South Africa. India also fully took the opportunity of being exempted from implementing WTO's intellectual property rights agreement, fostered a prospering generic pharmaceutical industry, and contributed to the affordable ART in the developing countries, and helped to save huge amount of funding for donors to provide aid in those least developed poor countries. The Brazilian experiences show that, centralized procurement in the health sector can be effectively used to significantly reduce the medicines prices by increasing the bargaining price negotiation power of the MoH. Such centralization can also promote a closer interaction between the MoH and the public laboratories, and their alignment on prioritizing production activities (44, 55).

Monitoring and evaluation to serve evidence-based decision making

Monitoring national progress requires data collection at the service delivery level and analyzed centrally. For data collected from different services to be aggregated, data collection systems must be consistent across services. Tools are needed to be introduced for analyzing the impact on public health, economic evaluation, and evidence-based practices, with the aim of establishing more precise parameters, thereby strengthening the sustainability of universal access to treatment.

Note

#Total number of people living with HIV/AIDS and people receiving ART in BRICS countries were between 9.64–9.95 and 2.2 million, respectively, by the end of 2011, which accounted for about 30% of the global number. The estimated AIDS-related death in the BRICS countries was about 0.89 million by the end of 2011, which accounted for about 52% of the global number.

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