

Invoking Rights and Ethics in Research and Practice

Brazil and Access to HIV/AIDS Drugs: A Question of Human Rights and Public Health

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I explore the relationship between public health and human rights by examining the Brazilian government's policy of free and universal access to antiretroviral medicines for people with HIV/AIDS.

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. The dismantling of authoritarian rule in Brazil was accompanied by a strong orientation toward human rights, which formed the sociopolitical framework of Brazil's response to the HIV/AIDS epidemic.

Even if the Brazilian experience cannot be easily transferred to other countries, the model of the Brazilian government's response may nonetheless serve as inspiration for finding appropriate and lifesaving solutions in other national contexts. (*Am J Public Health*. 2005;95:1110–1116. doi: 10.2105/AJPH.2004.044313)

FOR SEVERAL YEARS I HAVE

studied Brazil's management of the HIV/AIDS epidemic and the ways in which Brazil's policies have contributed to the global fight against the HIV/AIDS epidemic.^{1–7} In this article, I analyze the links between public health and human rights, using the Brazilian government's policy of free and universal access to antiretroviral medicines (ARVs) for people with HIV/AIDS as an example. Although I refer to the production of generic versions of AIDS drugs as well as the role of international pharmaceutical companies, both topics are explored in greater detail elsewhere.^{8–15}

Globally, ARVs remain beyond the reach of the majority of people with HIV/AIDS. 16-18 Of the 6 million people worldwide who needed ARVs in 2003, fewer than 8% were receiving them.¹⁸ Although Brazil is considered a middle-income country, 19 its government provides ARVs to its constituents free of charge. To make such a policy viable, the government has limited the drugs' high cost by producing some ARVs domestically and by negotiating with international pharmaceutical companies to import other ARVs^{2,20}; of the 15 ARVs utilized in the country in 2002, 7 were produced in local laboratories, either public or private, and the remainder were purchased on the international market.2,21

The relative success of the ARV program in Brazil reflects a somewhat privileged position compared to lower-income countries, some of which have higher levels of HIV infection. In turn, using the Brazilian government's management of HIV/AIDS as a model may not transfer easily to other nations.²² However, Brazil's experience offers inspiration for finding appropriate and life-saving solutions in other contexts.²³ To gain a wider perspective on Brazil's HIV/AIDS policy-and in particular the synergy between health and human rights-I solicited comments from several individuals, quoted in this article, who work for Brazilian and international organizations that are currently at the forefront of the struggle against HIV/AIDS. By reviewing Brazil's policies and relating other people's experiences, I hope to demonstrate the importance of community mobilization, political will, international solidarity, and financial commitment in the fight against HIV/AIDS.

HIV/AIDS IN BRAZIL

In 1980, the first case of AIDS in Brazil was registered. By December 2003, 310 310 cases had

been reported in the country, comprising 220783 men and 89 527 women²⁴; of this total, approximately 48% have died.24 The epidemic is spreading, particularly among the poor, women, and those living outside the urban centers.²⁵ In people aged 15 to 49 years, the estimated prevalence of HIV is 0.65%, with approximately 600000 people infected with HIV.21 Of this total, approximately 200000 know their HIV status, 26,27 the majority of which are registered in the public health system and are receiving treatment. According to figures from 2003, of those individuals in the public health system, 135 000 were undergoing highly active antiretroviral therapy.²⁸

LIMITING THE COSTS OF ARV THERAPY

Although other countries in Latin America have established programs to improve access to treatment for people with HIV/AIDS, ²⁹ Brazil's program is the most far reaching. ³⁰ The program provides state-of-the-art ARV treatment to people in need, free of charge, through the public health system, and the govern-



ment controls the costs of the program by encouraging local laboratories to produce ARVs, which decreases Brazil's need to import vital drugs from foreign countries. During his tenure as director of Brazil's National AIDS Program, Paulo Teixeira understood that the success and sustainability of Brazil's policy of access to ARVs depended on effective strategies to control costs. He believes that maintaining political will while fostering new international alliances for more favorable regulations on pharmaceutical-related trade and intellectual property will continue to be central. According to Teixeira,

The biggest challenge for the future of the Brazilian National AIDS Program is the maintenance and the sustainability of the policy of free and universal access to ARVs. This is directly linked to a change in the world economic order with regard to medicines. It will depend not only on a firm position by Brazil, in the defense of its policy of production and distribution of ARVs, but also on the strengthening of international alliances that are beginning to form with the World Health Organization, the World Trade Organization, the United Nations Special Session on HIV/ AIDS, and the Global Fund to Fight AIDS. Tuberculosis and Malaria. It is extremely important that these alliances are maintained and intensified to guarantee the conquests already achieved.

Increased local production of ARVs has been integral to the Brazilian strategy. According to Eloan Pinheiro, former director of Far-Manguinhos, a Brazilian Ministry of Health (MOH) laboratory that produces ARVs, "the local production of AIDS drugs

made access to ARV therapy possible for the Brazilian population. Without it, the price of the drugs would be beyond Brazil's reach."

The Brazilian government's strategy for controlling the costs of AIDS medicines has not been without challenges and obstacles. In 2001, the country was involved in international disputes about its program of access to AIDS medicines.2 In that year, the World Trade Organization (WTO) accepted a request for a panel by the United States, which was challenging Brazil's patent laws, laws that permit the compulsory license of patents under special conditions. At its heart, the US challenge questioned Brazil's commitment to producing ARVs nationally; explicitly, however, the United States was challenging the prospective patent violations that would occur as a result of Brazil's program. In June 2001, the United States withdrew its complaint before the WTO. To date, Brazil has not produced any of its medicines under compulsory licensing, and the ARVs that are currently produced are those medications whose introduction predated Brazil's signing of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. In September 2003, a presidential decree was issued that facilitated the importation of generic medicines.31 At the time, according to Brazil's MOH, 3 imported name-brand ARVs-nelfinavir, lopinavir, and efavirenz-were consuming 63% of the budget for acquiring ARVs.^{28,32} The possibility of importing generic medicines improved Brazil's bargaining position with the patent-holding companies that manufacture those medicines. As a result, in January 2004, the National AIDS Program announced that it had successfully negotiated reduced prices for those drugs and other related medicines, thereby anticipating savings of almost US\$100 million for 2004.33,34 Because of these price reductions, the estimated costs of ARV treatment in 2004 were around US\$170 million.33

Concern for human rights combined with the urgent need for access to treatment by people with HIV/AIDS has bolstered wider efforts to lower the costs of ARVs. Peter Piot, executive director of the Joint United Nations Programme on HIV/AIDS (UNAIDS), recognized the role of Brazil's HIV/AIDS policies in facilitating this development, saying,

The Brazilian experience has played a key part in changing expectations in the interpretation of the World Trade Organization's TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement. When the Doha Ministerial Meeting of the World Trade Organization at the end of 2001 declared that the TRIPS Agreement ought not stand in the way of AIDS responses, it in effect acknowledged the ethical and practical imperatives represented by Brazil's generic antiretroviral industry.

AIDS AND HUMAN RIGHTS

Globally, violating the human rights of people with HIV/AIDSthrough stigmatization, discrimination, and violence-is increasingly recognized as a central problem that is impeding the fight against AIDS. 35-38 AIDS

NGOs and human rights advocates have linked HIV/AIDS to human rights and have demonstrated that human rights violations increase the spread of HIV.^{39–42} For example, people affected by HIV/AIDS who are living in areas where discrimination, stigmatization, and threats against individuals with HIV/ AIDS are high are less inclined to seek testing, thereby postponing treatment if available, which means that opportunities to decrease HIV transmission are lost.

Gruskin et al. described 3 stages through which the relationship between HIV/AIDS and human rights has proceeded.⁴² In the first stage, 1981–1986, human rights advocates pitted themselves against public health officials who proposed measures such as mandatory testing and quarantine to counter the emerging epidemic. In the second stage, beginning around 1987, officials openly acknowledged that mandatory testing and quarantine undermined the efficacy of prevention programs. In the third phase, which started in the late 1980s, research developed from the idea that vulnerability was a key to infection. This research was then developed and disseminated by human rights activists such as the late Jonathan Mann, a central figure for and staunch defender of human rights for people living with HIV/AIDS, and by groups such as the Global AIDS Policy Coalition, which was founded and led by Mann. During this phase, Gruskin et al. argued, "it became clear that a lack of respect for human rights and dignity was a



major contributor to the HIV/AIDS problem." 42(p326) With the advent of more effective treatments for controlling the effects of AIDS, a fourth phase in the relation between human rights and HIV/AIDS began: the promotion of access to treatment.

Today, access to treatment increasingly is being advocated as a human right, a viewpoint that is playing a prominent role in developments to counter the HIV/ AIDS pandemic. 43-48 For example, at the April 2001 57th Session of the Commission on Human Rights, the United Nations High Commissioner for Human Rights approved a resolution that makes access to medical drugs in cases of pandemics such as HIV/AIDS a basic human right.49 Although this resolution did not have the power of law, it was nonetheless an important step toward establishing the right of people living with HIV/AIDS to receive the medicine and treatment they need. Also in 2001, a declaration was approved at the Fourth World Trade Organization Ministerial Conference⁵⁰ that allowed countries to apply for compulsory licensing in order to produce necessary medicines in cases of national public health emergencies.51 In 2003, UNAIDS reaffirmed the relevance of human rights to HIV/AIDS by establishing a Global Reference Group on HIV/AIDS and Human Rights.⁵²

HIV/AIDS AND HUMAN RIGHTS IN BRAZIL

In the early 1980s, after a military dictatorship that lasted

almost 20 years, Brazil went through a process of democratization, gradually reconstructing civil society⁵³ and formulating a new social agenda for areas such as education and health. During this period, campaigns such as the Movement for Sanitary Reform, which sought to democratize health policy and establish health care as a right for all Brazilians, began.^{20,54} At this time, Brazilian newspapers also began describing the emergence of a new disease, as the first AIDS cases in the country were being reported.^{3,6}

In Brazil, the early HIV/AIDS movement relied on experienced activists who had organized against the military regime; some of these individuals helped create the first nongovernmental organizations (NGOs) and some came to assume roles in local, state, and federal government. Not surprisingly, this first generation of Brazilian activists approached the government about the new disease using strategies they had implemented against the dictatorship, strategies that included the demand for the democratization of access to information and the defense of human rights.4 In Brazil, the response to the HIV/AIDS pandemic arose from initiatives in both civil society and the government and followed the process of democratization^{4,55}—a context with a strong orientation toward human rights.

In 1988, with the reorganization of Brazil's public health system⁵⁶ and the adoption of Brazil's new constitution, access

to health care, including access to medicines, improved in the country. At that time, the Unified Health System (Sistema Único de Saúde [SUS]) was established. 54,56,57 The SUS offered free comprehensive health care to the entire population, regardless of employment status or access to other forms of health insurance.2 However, prior to the establishment of the SUS, the national agenda had included local production of some medicines by state laboratories and free distribution of certain medicines by the public health system.⁵⁸

People with HIV/AIDS were among those who benefited from the new health system; they began to receive drugs for opportunistic infections, and in 1991 began to receive zidovudine (AZT).^{3,4,59} In November 1996, the access to medicines policy became firmly established when the president of the republic signed a law60 that guaranteed free distribution of medicines to people with HIV/AIDS throughout the public health system.^{2,3,21,29,59} ARVs, along with medicine for malaria, Hansen disease, cholera, hemophilia, diabetes, schistosomiasis, trachoma, leishmaniasis, and filariasis, form the category of medicines the MOH has deemed "strategic" for treating endemic diseases; these medicines in turn are purchased by the federal government.^{5,61}

The government's commitment to provide AIDS medicines resulted, in part, from pressure from civil society, where people with HIV/AIDS sought to force the health system to provide

them with the needed medications by suing state or municipal governments. 62,63 In these struggles, the judiciary proved to be an important ally. The judges often ruled favorably, citing Brazil's constitution, which guaranteed that every citizen had a right to health and the state had a duty to ensure every citizen's health. Brazilian lawyer Miriam Ventura pointed to the codification of the policy as the "successful result of a model of action adopted by organized civil society." This mobilization, she continued, "utilized the language of human rights and the strategic application of national laws . . . [and] succeeded in placing on the political agenda questions that affect the life of people living with HIV/AIDS, and in so doing altered public and state policies regarding health care."

In 1989, Ventura helped to establish Pela VIDDA-which means "For the Valorization, Integration and Dignity of People with AIDS"-the legal AIDS service for the first group of Brazilian people with HIV/AIDS. Herbert Daniel, founder and first president of the group, denounced the denial of the rights of people with HIV/AIDS, which he termed "civil death." 64 Daniel was a writer and a militant of the gay movement who also fought against the dictatorship in Brazil before being forced into exile; he died of AIDS in 1992.

In Brazil, the participation of civil society had a key role in bringing about and sustaining the Brazilian government's ARV distribution policy. ^{1,7,62,63} The importance of this contribution was



highlighted by Veriano Terto, Jr, executive director of the Brazilian Interdisciplinary AIDS Association (ABIA), an NGO founded in 1986 in Rio de Janeiro:

> The participation of organized civil society in access to AIDS treatment goes back to the eighties, when popular pressure and progressive political forces were fundamental in creating a unified public health system based on the principles of universal access, comprehensiveness, and participatory decision making. If currently we have a system for the distribution of medicines in the public health network, and legislation that guarantees this system, this is based in the values of universality and equality in access to treatment for all epidemics contemplated in the health system, and in public participation, which underlies and accompanies the Brazilian public health policies.

Terto continued, saying,

The participation of civil society also was fundamental for including solidarity, respect for human rights, and the struggle against prejudice and discrimination to the response against AIDS. These points were fundamental for amplifying the notion of health beyond the search for physical wellbeing, and technical measures focused only on the treatment of individuals. In this sense, the demand for universal and free access to medicines should be seen as a question of making real the right to life, and respect of the basic human rights of people living with HIV/ AIDS in Brazil.

Piot made a similar observation:

The HIV epidemic is aided by social exclusion-marginalized populations are the most vulnerable to HIV infection, whether through sex or needle sharing, and people living with HIV/AIDS, however they ac-

quired infection, are tarred with the same brush of stigma. Breaking the vicious cycle of social exclusion is therefore crucial both to interrupting transmission and to maximizing the care and support available to people living with HIV/AIDS. This is perhaps the key to the tremendous impact of Brazil's 1996 decision to guarantee constitutionally access to ARV therapy. Not only has this decision led to the quadrupling of the number of Brazilians accessing these drugs, it also sent the signal that people living with HIV/AIDS were valued citizens, whose care was a matter of entitlement, not of privilege.

ABIA was the first Brazilian AIDS NGO to have as its president and founder someone who disclosed his HIV positive status. Herbert de Souza-known by the nickname Betinho-was a former political exile. He was a hemophiliac, as were his 2 brothers; all 3 became infected with HIV through blood transfusions in the mid 1980s. One of the first important struggles carried out by ABIA was the promotion of blood safety, a tremendous problem at that time in Brazil. After the approval of the Brazilian constitution in 1988, it was forbidden to sell blood in Brazil. Betinho's brothers died in the mid 1980s, and Betinho died in 1997.4,7

LINKING TREATMENT AND PREVENTION

In Brazil, there are at least 2 important arguments from an economic perspective for maintaining free access to AIDS medicines: the impact of ARVs in reducing deaths and the significant reduction in hospitalization and treatment costs associated with opportunistic infections.^{2,21,29} However. beyond the biomedical and economic arguments for treatment, a rights-based approach focused on the inequality that fueled the virus's spread. 65,66 Current ABIA president Richard Parker, chair of the Department of Sociomedical Sciences in the Mailman School of Public Health at Columbia University, stated

By affirming universal access to treatment for all those infected with HIV, Brazilian policy has simultaneously reaffirmed the rights and citizenship of those who otherwise would be defined primarily by their broader exclusion in Brazilian society. Because of this, prevention becomes possible, not just as a technical exercise in public health, but as itself the right to health of all citizens. While the broader social inequalities that shape the epidemic have only become more extreme over time, the strategic approach to AIDS in Brazil has thus been able, in a targeted way, to mitigate their worst effects, to respond to the stigma and discrimination so often generated by the epidemic, and to recover the simple idea of human dignity, guaranteed by civil rights, as the most powerful way of responding to the reality of AIDS-related vulnerability.

Providing better access to HIV/AIDS therapy in resourcepoor countries is not only a humanitarian imperative⁶⁷ but also a viable and financially justified course of action in terms of economic costs and social benefits. This is apparent when considering the Brazilian initiative of distributing ARVs-with savings in both lives and financial resources-along with studies elsewhere that suggest socioeconomic levels of patients do not

interfere with adherence to $treatment.^{68-71}$

Providing better access to HIV/AIDS therapy has become a global initiative as well. In 2003, the World Health Organization launched its "3 by 5" strategy, 18, 43,47,72 which aims to extend access to ARV therapy to an additional 3 million people with HIV/AIDS living in developing countries by the end of $2005.^{72}$ The theme for the XV International AIDS Conference, held in Bangkok, Thailand, in July 2004 was "Access for all," an assertion that it is time to deliver the message, the medicine, the help, and the hope to all.⁷³ In this manner, Brazil, whose human rights advocates lobbied for health rights and whose government placed human rights at the center of its HIV/AIDS policy, has been a vital role model.

Resources allocated to disease treatment are often seen as competing with resources available for disease prevention, a dichotomy leading to a debate regarding priorities in the fight against the HIV/AIDS pandemic.⁷⁴ In the 1990s, The World Bank, for example, did not favor a policy of providing AIDS medicines to developing countries, 75 including Brazil.⁷⁶ At the time, the World Bank believed that, with limited resources, funds should be directed to prevention in order to limit new infections. More recently, however, the World Bank has come to emphasize the importance of combining prevention and treatment.77,78 According to Piot, "[there is an] inextricable link between prevention and care, which operate together as twin



pillars of a comprehensive AIDS response." He added that "Brazil is perhaps the world's leading example of the synergies available between prevention and care." But even with Brazil's success at offering treatment to people with HIV/AIDS, an assessment is needed to determine how the nation—which is devoting financial and human resources to both prevention and treatment—is or is not succeeding in preventing new infections.

In order to adequately analyze the public health system in Brazil^{54,56,57} and explain how Brazil's AIDS program was developed, I would need to write another entire article. However, even in Brazil, when deciding how to first proceed against the HIV/AIDS pandemic, there was great internal conflict within Brazil's government, as sectors that wanted to prioritize HIV/ AIDS were opposed by sectors that wanted money and resources allocated elsewhere.⁷⁹ Even today, despite international recognition and growing internal support, the Brazilian government's HIV/AIDS policy occasionally receives criticism at home from those who believe Brazil should spend more money in other areas and less money on HIV/AIDS.80

There are 3 points to consider regarding Brazil's HIV/AIDS policy, lest the positive lessons described herein give a simplistic image of a genuinely complex reality. First, the Brazilian program in response to the HIV/AIDS epidemic has been successful even though the country is still marked by profound socioeco-

nomic inequalities.81 Second, the Brazilian policy regarding access to ARVs needs to be analyzed in terms of the program's sustainability and potential transferability to other countries. 2,22,82 Third, Brazil must continue to strive for positive results. The experience of other countries such as Thailand demonstrates that it is not easy to sustain a successful response against the HIV/AIDS pandemic.83-85 In Thailand, severe police repression against injection drug users has threatened prevention measures directed at that particular population. In any national program, it is essential to prevent past success from turning into complacency and inaction and to remain vigilant in regard to human rights, particularly for the rights of those people who are made most vulnerable.85

New developments linking HIV to national, international, and human security, 86-89 together with a growing human rights orientation toward people with HIV/AIDS, have contributed to new recommendations from organizations such as the World Health Organization90 and others⁹¹ to combine prevention, support, treatment, and care in responding to the HIV/AIDS pandemic. Although the Brazilian experience has helped move access to treatment as a basic human right beyond abstract discussion, this approach still poses immediate and practical challenges, particularly in terms of maintaining political will and sustaining financial support. To respond to some of these challenges, UNAIDS recently announced the establishment of an International Centre for Technical Cooperation on AIDS in Brazil to help developing countries strengthen their responses to HIV/AIDS. Placing this center in Brazil is not likely coincidental—UNAIDS hopes to draw from Brazil's rich experience in responding to the HIV/AIDS pandemic.

Brazil's experience and related initiatives will merit continued attention as the world confronts the growing HIV/AIDS pandemic. Providing access to lifesaving medicines and transferring technologies will be challenges, not only for those involved with HIV/AIDS but also for the field of public health as a whole, posing practical and theoretical questions that will need to be answered in the years to come. ⁹³

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