

RESEARCH ARTICLE

Evolution of HIV/AIDS response in Brazil: Policy innovations and challenges in the fourth decade of the epidemic

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Funding information

Fundação de Amparo à Pesquisa do Estado de São Paulo, Grant/Award Number: 2015/18604-5

Summary

Brazil was the first low- and middle-income country to provide universal treatment access to people living with the acquired immunodeficiency syndrome (AIDS), becoming a widely acclaimed model for best practice to managing this epidemic. However, we know little about important challenges to the key pillars of Brazil's response. This article discusses how the evolution of the country's health system institutions and international advancements in AIDS treatment and prevention affected the national response. Decentralization of health system resources and policy making brought fresh challenges to the centralized governance of the national AIDS program and to civil society, weakening their coordination and advocacy capacity. Regardless, AIDS treatment and prevention strategies in Brazil remain aligned with the current international protocols, but unfortunately have been restricted in some geographic areas and/or populations.

KEYWORDS

Brazil, global health, HIV/AIDS policy

1 | INTRODUCTION

Brazil was the first low- and middle-income country to provide universal treatment access to individuals living with the acquired immunodeficiency syndrome (AIDS). The manner by which Brazil dealt with the looming AIDS crisis remains one of most successful public policy interventions in the global health's recent history. The impact of these policies was evident, as the quality of life for people living with AIDS improved, followed by a decline in overall mortality and morbidity.^{1,2} Brazil's policy implications spanned beyond the country's borders and provided crucial evidence for exhibiting a strong global response to the epidemic.³

This study was conducted in compliance with Brazil's ethical guidelines for social science research and excepted of ethics review board according to the National Council for Scientific and Technological Development (CNPq) Resolution 510/2016.

Because of its remarkable policy decisions, the country received tremendous attention from the public policy, health, and international relations scholars. A great majority of these studies focused on key components of the national policy including the integration of prevention and treatment, partnerships with civil society, and local medicine production.^{4,5} Other scholars focused more on Brazil's controversial decisions to negotiate the price of patent antiretroviral (ARV) medications through threatening to override intellectual property (IP) protection and produce these drugs in public laboratories. This decision resulted in impressive cost savings.⁶⁻⁸ To a lesser extent, other studies analyzed the incremental policy process and the political economy of AIDS in Brazil.^{9,10} This literature examined the period between the 1990s and the mid-2000s, when the epidemic became a crisis and the policy decisions to build a national response, threaten pharmaceutical companies, and dispute international trade/health norms occurred. However, recent developments of AIDS response in Brazil have been largely underresearched.

The fourth decade after the epidemic launched renewed challenges for policymakers. These challenges encompassed, among others, issues associated with harmonizing the relatively autonomous and centralized National AIDS Program (now Department of Sexual Transmitted Disease, AIDS, and Viral Hepatitis [DDAHV]) with the formal structures and norms of the national health system (Sistema Único de Saúde [SUS]) and the deep impact of the ongoing economic and political crisis on the infrastructure and working force of the SUS as a whole. Paradoxically, although integrating HIV/AIDS policies within the national health system perpetuates and legitimizes the response to the epidemic in the country, the process also reproduces inequalities and flaws within the health system, leading to the potential weakening of AIDS policies. The situation became much more complicated in recent years, with successive cuts to the health budget and other constraints from the broad fiscal crisis. It is one thing to try to integrate a successful treatment program into a robust health system; it is another thing to, at the same time, prioritize the management and care of uncomplicated cases of AIDS at the level of primary health care units, which are often overburdened by several different problems. These issues have included a shortage of funds, limited manpower, and successive national emergencies such as the recent challenges posed by the spread of Zika virus and the reemergence of peri-urban (affecting a very large network of small- and middle-sized municipalities, besides the rural area) yellow fever after more than half a century.¹¹

This article does not intend to evaluate the AIDS response, but it expects to contribute to a better understanding of the evolution of AIDS policy in Brazil, a country that has provided important lessons to the global health community although there is a need to understand its current challenges and developments. We focus here on exploring key pillars of the AIDS policy in the country: centralized governance, civil society, and integrated treatment and prevention. Above all, we intend to explore how these elements have evolved in the context of local development of Brazil's health system institutions and international advancements of AIDS care and prevention. Thus, study can also contribute to our understanding of what is happening to countries with mature AIDS policy responses.

This paper is divided into 4 sections. The first section discusses basic data on the country epidemiological profile and dynamics over time, which includes a warning that cannot be ignored. The second section discusses the evolution and challenges to the public management of HIV/AIDS care response. The third and fourth parts explore the trajectory of civil society engagement along with current treatment and prevention interventions.

2 | AN EPIDEMIOLOGICAL WARNING

The current epidemiological profile of the epidemic in Brazil sends a warning message and invites us to revisit Brazil's AIDS policies. Although AIDS incidence has been stable in the last several years in Brazil, with a detection rate of around 20 cases per 100 000 inhabitants between 2010 and 2015, there are some regions of the country with an increasing number of new cases,^{12,13} as well as unacceptably high prevalence of HIV and syphilis among some vulnerable populations, such as transsexuals, young gay men, and drug-dependent people.^{14,15}

Some deep contrasts have been observed in logically interrelated issues, yet to be minimally integrated, such as the prevention of the vertical transmission of HIV and the proper prophylaxis of congenital syphilis. Whereas the

former has been considered a major achievement, the deep failures and gaps of the latter are nothing but a disgrace for a middle-income country, considering the simple, low-cost options that might curb the latter. This initiative has not progressed but worsened.¹⁶

Around 734 000 people are estimated to be living with HIV/AIDS in Brazil, corresponding to an overall point prevalence rate of 0.4% in the general population. Responding to these geographical disparities and the increasing heterogeneities between different subgroups of people (relatively low vs very high infection rates) is one of the core challenges for contemporary AIDS policy in Brazil.

There has been a marked reduction in incidence in large metropolitan areas, but there has been a continuous, though relatively modest, spread of the epidemic to less industrialized regions of the country, as well as to municipalities of small and medium size,¹ due to the less than optimal implementation of measures successfully adopted in major metropolitan areas and populations prioritized by most interventions.¹⁷ A similar reasoning applies to the undeniable failures respecting some vulnerable populations, such as the very low enrollment and adherence of drug-dependent people, such as female crack users.¹⁸

Briefly, the HIV epidemic remains largely concentrated in vulnerable populations. For instance, among men who have sex with men, the prevalence was 14.8% in 2015, forty times higher than in the general population (0.4% in 2012). Among other key populations, the prevalence is about 5% (female commercial sex workers 4.9% in 2009; drug users 5.0% in 2013). There is also a concern with increasing incidence among youth, individuals born during the 1990s, and who initiated sexual relations after the AIDS crisis. In an editorial, the former coordinator of AIDS response in Brazil warned that the epidemic is evolving to a similar epidemiological profile of the 1980s, that is, highly concentrated among specific populations, with high mortality rates, in clear dissonance with the auspicious prospects of the late potent ARVs era, worldwide.¹⁹

AIDS mortality is worrisome. Overall, there has been a decrease in AIDS mortality, with a reduction of more than 10% between 2003 and 2015. However, the north and northeast have seen the largest increase in the mortality rate. Studies suggest that mortality is less associated with failure of ARV therapy than the gaps of service provision and proper care and management over time.²⁰

Civil society demands a prompt response from the Ministry of Health on the alarming profile of the epidemic. Nongovernmental organizations (NGOs), who once partnered with the government, began speaking out about ARV stock outs, shortage in funding for civil society prevention activities, and the evolution of the epidemic. But, why and how Brazil, a country with one of the most successful AIDS policies worldwide, can be experiencing such an alarming epidemic profile? The following sections explore this dilemma.

3 | GOVERNING AIDS POLICY IN THE FOURTH DECADE

Much of the success of Brazil's response to AIDS is related to the centralized governance of the National AIDS Program (nowadays a department known under the acronym DDAHV) and to its autonomy within the Ministry of Health.¹⁰ Both of these key elements have been reformed during the past years to integrate the AIDS response within the formal structures of the national health system.

AIDS policy in Brazil was launched in São Paulo state in the late 1980s, but quickly reached the federal level when patients with AIDS groups demanded a national response to the looming epidemic. In its initial years, the National AIDS Program suffered from a limited budget, but eventually, it successfully guaranteed funding to expand AIDS care. In 1993, the Ministry of Health acquired a loan agreement with the World Bank (WB) to develop a comprehensive response to AIDS. Brazil was first of many countries to contract loan agreements with the WB to respond to AIDS epidemic, which was spreading quickly among low- and middle-income countries. The WB loan, which has been renewed 3 times (and lasted from 1993 to 2014), was crucial for several reasons: First, with the expansion of health care in Brazil in 1988, public spending on health increased; therefore, it would have been very unlikely that the Ministry of Health could have provided comprehensive care for AIDS under these circumstances. Second, it guaranteed

autonomy to the National AIDS Program to design and implement its policies in a timely fashion. During the 1990s, the Ministry of Health was still formulating their rules and mechanisms for decentralizing resources and policies to subnational government; the WB loan created stability during this uncertain period. Third, the loan agreement stimulated the collaboration with NGOs to focus on preventing AIDS among vulnerable population, foster epidemiological surveillance, create a monitoring and evaluation culture, and develop institutional cooperation. Given these exceptionalities, the National AIDS Program was described by many scholars as a "para-state" agency within the Ministry of Health.

However, the dissociation of the AIDS program from the formal structures of the health system became uncomfortable, particularly with the acceleration of decentralization process in early 2000, when a great majority of states and municipalities had already assumed considerable autonomy in organizing and managing the health system and resources. For this reason, several adjustments were applied to the National AIDS Program.

One of the most important changes in the governance of the AIDS policy was the decision to decentralize the resources among the 27 states and municipalities affected by the epidemic. Although resources of the WB were transferred to subnational governments, planning mechanisms and contract agreements were done outside the formal structure of the health system. It was necessary to devolve management of resources and policy formulation to local governments not only to increase efficiency and strengthen their institutional capacity to respond to the AIDS epidemic but also to integrate AIDS into the guidelines of the National Health Policy. Decentralization would also increase efficiency of the National AIDS Program, as it would allow the federal government to focus on other crucial initiatives such as international cooperation agreements while monitoring and evaluating the national AIDS response that was, until then, highly deficient.

Therefore, in 2004, parallel to the process of decentralization, and with the support of the United States Centers for Disease Control and Prevention and the WB, Brazil created a comprehensive monitoring system.⁴ Until then, there was an insufficient mechanism for monitoring the epidemic. Indicators were developed as to inform monitoring of the profile of AIDS and sexually transmitted diseases (STDs) and to assess the policy responses.

Besides these crucial adjustments, three other important organizational changes occurred during the 2000s. First, in 2009, the National AIDS Program was officially included within the National Health Surveillance Office (second echelon of the Ministry of Health) and renamed the Department of STD and HIV/AIDS. This was an old demand from AIDS staff as the "program" structure was fragile, based on a ministerial decree, and was not formally included in the organizational chart of the Ministry of Health.²¹ Second, the Ministry of Health merged the hepatitis program with the AIDS department, naming the new office as Department of STD, HIV/AIDS, and Viral Hepatitis aiming at strengthening the response on viral hepatitis in the country.²² Third, the Ministry of Health acquired a new loan agreement (2010-2014) with the WB to improve the institutional capacity of the department and the decentralized governance, among others.²³ The coordinator of the DDAHV, Mariangela Simão, explained that the crucial relevance of the fourth international agreement was not due to resource limitation, but to take advantage of the control and monitoring mechanisms from the WB that assisted in maintaining Brazil's accountability.²⁴ p.14

Although these were crucial decisions to crystalize the AIDS policy within the Health Ministry and guarantee institutional stability, merging the DDAHV with formal health system structures brought fresh challenges. Decentralization of resources was transferred through earmarked transfers ("incentive mechanisms"), conditional to the subnational government's continued adherence to the National AIDS policy guidelines and to providing an Annual Target Plan approved by the local councils and intergovernmental commissions. This mechanism would allow for a better monitoring and evaluation but also ensure coordination between different levels of government and the federal response. In 2014, almost R\$200 million earmarked resources were transferred to states to implement AIDS policies (see Figure 1).

Despite these mechanisms aiming to foster continuous monitoring and accountability, studies suggest that the AIDS policy is actually reproducing the inequalities prevailing within the health system. For instance, municipalities with increasing rates of AIDS incidence are also those with a lower capacity to respond to the epidemic and less

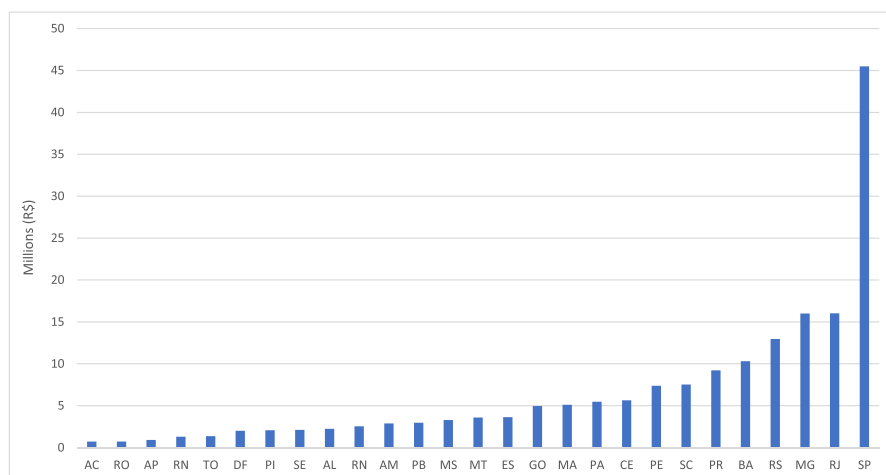


FIGURE 1 Earmarked acquired immunodeficiency syndrome transfers according to federative unit (R\$), 2014† | source: Department of Sexual Transmitted Disease, AIDS, and Viral Hepatitis

institutionalized responses to the epidemic (mostly in the north and northeast regions).¹⁷ On the other hand, cities with a higher magnitude and incidence of AIDS, mostly in the south and southeast, with a more stable epidemic, tend to have a consistent institutionalized and historical record of response to AIDS. In addition, although ARV drugs are purchased at the national level, states have autonomy to organize their distribution centers. States with less organized and inefficient systems have a record of unstable supply of ARV medicines.

The adoption of an incentive mechanism was in accordance with the rules of the health system to ensure coordination of the national health policy. In 2013, the Ministry of Health issued new regulations for transferring resources to subnational governments, which increased the autonomy of subnational governments. It revoked conditional transfers and the Annual Target Plan that was a core instrument for monitoring and coordinating the AIDS response. Therefore, it increased liquidity of resources transferred from federal to local governments to states and municipalities. The problem with this decision is that HIV/AIDS has always been a highly political issue,²⁵ especially in a context of mounting conservative political coalitions and policies.²⁶ As Brazilian governors and mayors are elected, they could be unwilling to engage with sensitive issues such as HIV prevention among drug users and the gay community.

The state of São Paulo, for instance, was the oldest and one of the most successful regions to respond to the epidemic but is now facing challenges to coordinate policy implementation in municipalities that have been mostly affected by AIDS. A staff of the São Paulo State AIDS Program, in a personal communication with the authors of this study, reports that decentralization of resources attached to conditionality was crucial to organize a response among the 145 municipalities in São Paulo. In addition, it solidified intergovernmental coordination by negotiating AIDS policy implementation within the bipartite commissions (a collegiate decision-making body composed of representatives from municipalities and the state government to define health priorities and policy implementation). She warns that the new rules of transferring resources have made it much more difficult to engage municipal health departments in AIDS care and prevention. We do not yet understand the long-term impact of these decisions, but we could expect that more freedom to municipalities might deepen the inequalities. Also, a revision of the process (and concept) of health decentralization is urgent. The needs and context of the contemporary health care system are different from the one faced by health reformists. “Tutelary” decentralization has proven important to policy coordination, especially in a country marked by deep inequalities and different administrative capacities such as Brazil.

4 | EVOLUTION OF CIVIL SOCIETY ACTIVISM IN THE CONTEXT OF DECENTRALIZED RESOURCES

Civil society organizations (CSOs) and gay activism played a key role in shaping the Brazilian response to the HIV/AIDS epidemic. Their activism has evolved over the years.²⁷ The first cycle of AIDS advocacy began in the 1980s. At that moment, as in many countries, the Brazilian federal government largely ignored the AIDS crisis. The epidemic was viewed as a problem of gay men and other marginalized groups, rather than a general public health threat. Newly formed AIDS CSOs played a key role in the development and implementation of many prevention programs targeting hard-hit populations (eg, sex workers). The second cycle of activism happened in mid-1990s with a productive collaboration between CSOs and the government (alternated with periods of dissent and eventual conflict), when Brazil received their first WB loan. Representatives from civil society and health professionals helped in the design of the WB loan agreement, and later on, many were invited to join the National Coordination of HIV/AIDS as staff members.^{10: 61} This gave them an advantageous position to participate in the ongoing development of Brazil's response. The loan agreement included funding for CSOs projects ranging from capacity building, advocacy events (eg, the annual gay parade in São Paulo), and preventive interventions with vulnerable population (cf Fonseca & Bastos²⁸)

A third cycle of AIDS activism in Brazil happened after 2004 when 2 important phenomena happened. First, Brazil participated in many international forums and discussion to ameliorate the regulation of IP and public health while developing international norms on access to medicines and human rights. This process also influenced the direction of AIDS activism, as CSOs started a new avenue of advocacy focusing on IP rules. Until then, AIDS activism was concerned, almost exclusively, on demanding better care for people living with HIV/AIDS. The Working Group on Intellectual Property, formed by a group of NGOs interested in this issue and coordinated by the Brazilian Interdisciplinary AIDS Association, has been the most active group within civil society in articulating the IP debates. Important decisions on pharmaceutical patents regulation in Brazil has been affected by the positions and demands of the Working Group on Intellectual Property.²⁸ For instance, this network of NGOs was crucial in the decision to oppose the patent request of Tenofovir, a core medication used for pre-exposure prophylaxis; lobbying against the pipeline patent mechanism (the validation in Brazil of a patent issued abroad, ratifying the examination conducted by a foreign patent office); they have also served as consultants in IP matters in courts (*amicus curia*), as consultants in public hearings in Congress, and provided feedback in many public consultations at the Patent Office (Instituto Nacional de Propriedade Intelectual [INPI]), the Brazilian Food and Drug Regulatory Agency (Agência Nacional de Vigilância Sanitária), among others. AIDS activists have shown remarkable ability and expertise with which to bargain for patent rights. Their advocacy initiatives have resulted in more balanced and democratic decisions regarding controversial regulatory decisions in the country.

A second issue affecting the CSO after 2004 was the decision by the Ministry of Health to decentralize resources and planning of AIDS policy to subnational government, including funding for HIV/AIDS CSO (which was until then centralized at the federal level). Decentralization deeply harmed funding for regional and local CSO for different reasons. (1) Some controversial initiatives such as needle exchange program did not receive support at the local level as it had at the Ministry of Health²⁹; (2) bureaucratic mechanisms of transferring resources from government to CSOs and inexperience of local governments in working with civil society also influenced the lack of funding; (3) and finally, many CSO were ill-equipped to monitor the process of planning and implementation of AIDS plans at the subnational level, this includes pressuring for funding for civil society.³⁰ We have yet to identify a comprehensive study about the influence of decentralization of resources on the activities and advocacy of AIDS CSOs. However, there has been records of a decrease in the number of organizations providing advocacy on AIDS.³¹ In response to this crisis in long-term sustainability of civil society advocacy, new forms of funding have been developed such as the Positive Fund that represents a trust of private sector funding to be applied to NGOs. This initiative launches a new era for funding AIDS advocacy that historically refused support from pharmaceutical industries, relying only on funding from governmental and international agencies.

5 | AIDS TREATMENT AND PREVENTION IN THE 21ST CENTURY

Brazil has one of the most comprehensive AIDS programs worldwide, as it combines mass prevention strategies with universal, free access to AIDS medication. Despite the challenges of governance from the DDAHV, treatment and prevention protocols have been recently revised to incorporate the most recent developments in HIV/AIDS research. The main challenge here does not refer to the lack of innovation or expertise but rather the need to scale-up initiatives that have been basically limited to the reach of a few research centers, primarily located in the industrialized southeast/south axis.

5.1 | Treatment

All people living with HIV/AIDS are entitled to receive ARV medication in Brazil. In 1996, congress passed a law guaranteeing free, universal access to drugs for AIDS. However, 2 events constrained the capacity of the federal government to fulfill this commitment. First, in 1996, Brazil modernized its Intellectual Property Law, complying with the World Trade Organization Trade-Related Aspects of Intellectual Property Rights. This guarantees pharmaceutical industries exclusive market rights for their products. Second, during that same year, a new protocol was proposed to treat patients with AIDS, the triple therapy (or highly active antiretroviral therapy). New medications were developed and protected by the recently approved patent law. Together with the raising numbers of patients entering into care, the costs of treatment peaked in the late 1990s. This crisis exposed vulnerabilities of the health system in providing access to ARVs and prompted the government to explore strategies to comply with its obligations.

In response, Brazil has adopted 2 initiatives. First, in 2000, to induce price discounts, the Ministry of Health invested in generic drug production of ARV medicines introduced prior to 1997 and used this production capacity along with a threat of compulsory license. This strategy induced deep discounts from innovative pharmaceutical companies and is widely documented in the literature.^{7,8} Price negotiations saved the Brazilian Ministry of Health \$US1.2 billion in AIDS treatment costs between 2001 and 2005.⁶ In 2007, Brazil issued its first compulsory license to import Efavirenz, a drug that was under patent in Brazil and was the most commonly prescribed ARV in Brazil's AIDS treatment guidelines at that time. Two years later, after a partnership between 2 local pharmachemical companies and a public laboratory, Brazil began producing its generic version of Efavirenz.³²

The second strategy to be adopted by the Ministry of Health launched a new era for health policy in Brazil. The relationship between the Ministry of Health and private health suppliers (drug companies, medical device industries, etc) evolved. Through using the experience of collaboration to produce Efavirenz, the government developed a comprehensive strategy of technology transfer and voluntary licenses to supply medicines that were strategic to the health system, including ARVs.³³

To encourage multinational companies into licensing its products, the Ministry of Health committed to purchase their medicines for a period of 5 years when knowledge about product manufacturing would be transferred. Local pharmaceutical companies and public laboratories would receive this technology and supply drugs for the government afterwards. Through using its purchasing power, the Ministry of Health promoted 86 technology transfer agreements. Currently, there are 3 ARVs being developed in Brazil under this agreement (Tenofovir, Atazanavir, and Tenofovir + Lamivudine). This strategy has received strong support from representatives of drug companies and the public health community more broadly. However, civil society has monitored this policy and raised concerns about transparency. Representatives from the DDAHV interviewed for this study have expressed concerns with this strategy, as some contracts might increase the costs of providing ARVs, instead of purchasing in the international market.

Finally, the guidelines to treat AIDS in Brazil have gone through 2 important adjustments. (1) In 2013, Brazil made a bold decision to expand ARV treatment to all patients diagnosed with HIV, regardless of immunological status (treatment as prevention). Until then, only the US, France, and the United Kingdom used the treatment as prevention

strategy. Between 2009 and 2015, the number of patients in treatment increased almost 97% in Brazil, from 231 000 to 455 000 people, and 90% of these patients³⁴ have been virally suppressed (Figure 2). This is an important hallmark as low levels of HIV represents decreased risk of passing the disease on to others. Also, new drugs were included in the salvage therapy protocol, Maraviroc and Tipranavir, for patients that are not responding to other treatments. The Ministry of Health included 2 combination therapies into the first-line protocol: Tenofovir, Lamivudine, and Efavirenz (produced by the federal laboratory Farmanguinhos; a branch of the Oswaldo Cruz Foundation) and Tenofovir and Lamivudine (produced by Farmanguinhos and the local drug company, Blanver). Both products are being developed within public-private partnerships in Brazil. Combination therapy is important to reduce the number of pills taken, helping patients comply with treatment protocols more easily.

It is important to note that the revision of the 2013 treatment protocol, for the first time, was conducted by the National Committee for Health Technology Incorporation (Conitec). Before that, it was the responsibility of an ad hoc clinical committee of the DDAHV to decide how to incorporate new technologies for AIDS treatment. Conitec is a relatively new department within the Ministry of Health, created in 2011 to assess all technologies introduced in national health system. It increased and organized the criteria for technology assessment and made the process more democratic, as it includes open public consultancies. Therefore, bringing the decisions on AIDS clinical protocols to Conitec limits lobbying the members of the AIDS Clinical Committee, increases transparency, and opens the process to different stakeholders (civil society, patients, health professionals, and drug companies) who now can participate in this process.

(2) In 2016, new protocols were developed suggesting a new class of medicines to be provided as first-line treatment, the integrase inhibitors. This strategy reduces the changes of viral resistance and has fewer side effects than the combination treatment with Efavirenz. HIV/AIDS activists strongly voiced against the outdated protocol used in Brazil, demanding an urgent revision to the guidelines.³⁵ As a response, the Ministry of Health revised the AIDS clinical protocol in August 2016, including 2 integrase inhibitors, Raltegravir and Dolutegravir. The later was in process of approval at the regulatory agency. The combination of Dolutegravir and Tenofovir + Lamivudina was defined as first-line treatment for new patients and second line for those with resistance to the medication. The DDAHV announced a price discount of 70% with Glaxo-SmithKlein of Dolutegravir.³⁶ This decision gives people living with AIDS in Brazil the most up-to-date clinical protocol to treat AIDS. The total cost of ARV treatment in Brazil is more than R\$1 billion, representing 7% of total of pharmaceutical care expenditure in Brazil (Figure 3)

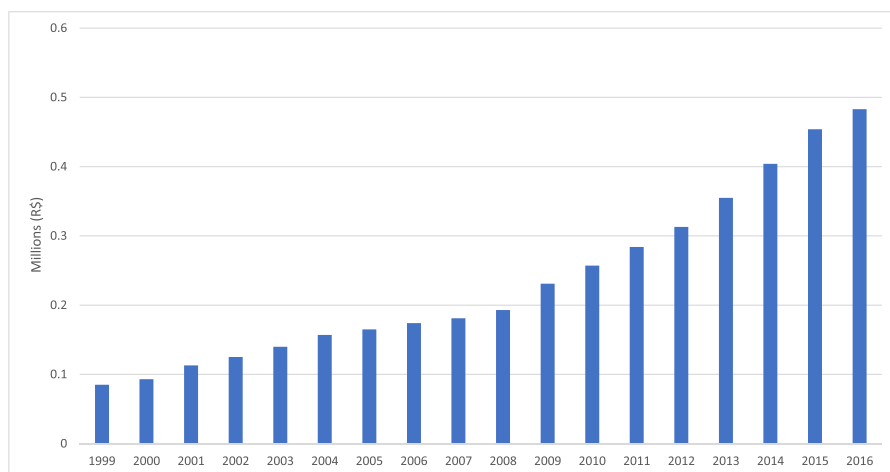


FIGURE 2 Total number of patients in antiretroviral treatment in Brazil, 1999 to 2016 | source: Department of Sexual Transmitted Disease, AIDS, and Viral Hepatitis, 2016

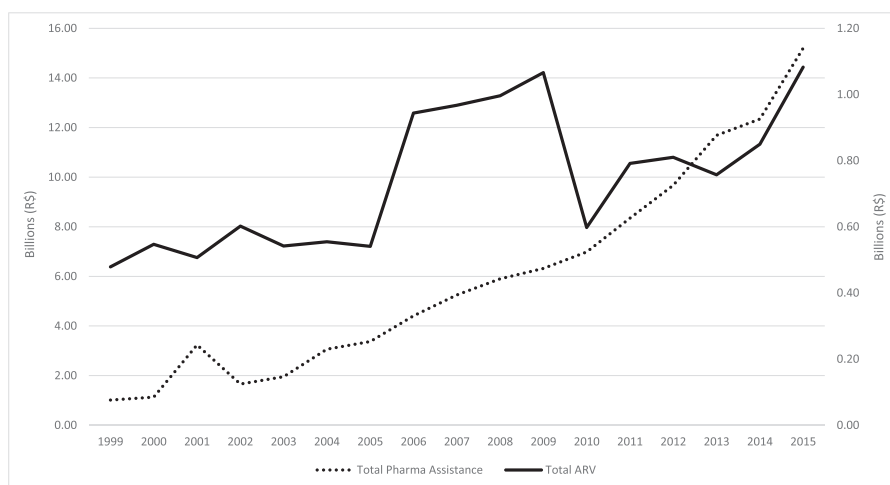


FIGURE 3 Cost with antiretroviral (ARV) and pharmaceutical care in Brazil (R\$), 1999 to 2015 | source: Department of Pharmaceutical Assistance, Ministry of Health, 2015

5.2 | Prevention

A milestone for HIV prevention worldwide was the development of new technologies that may control the AIDS epidemic, the postexposure prophylaxis (PEP) and the pre-exposure prophylaxis (PrEP) combined with other traditional prevention strategies. The former was not technically a new development, as PEP has been suggested as a protocol to avoid HIV infection among health care workers exposed to blood and body fluids and victims of sexual violence since the 1990s. Brazil slowly introduced PEP in 2006, as the DDAHV expanded this prevention protocol to serodiscordant couples, while in 2010, the prevention guidelines expanded this strategy to all those exposed to risk, including unsafe sexual relations with an unknown serological status.³⁷

Pre-exposure prophylaxis is a protocol for people at high risk for HIV, those using a combination of 2 ARV, Truvada® (Tenofovir and Emtricitabine), daily to lower their chances of becoming infected. In Brazil, initial discussion of PrEP happened in 2015 and a multicentric study is still being conducted in the country to assess the safety and efficacy of this protocol.

In 2016, the National Commission for Technology Assessment initiated a public consultancy to discuss the PrEP protocol as Truvada® was not already approved by the Health Regulatory Agency (Agência Nacional de Vigilância Sanitária) to be used for prevention. Some important considerations are worth mentioning. (1) One of the components of Truvada®, Tenofovir, has been under dispute in the National Patent Office (INPI) for more than a decade.²⁸ In January 2017, after strong advocacy by CSO, including technical, legal, and public health arguments, INPI declined to give Gilead the rights of patent, arguing the combination was not a novel product.³⁸ (2) Truvada® is currently under development through a public-private partnership between Blanver and Farmanguinhos. The consortium has already performed all stages of product development, including a bioequivalence test. Therefore, it is expected that the drug will be locally produced, reducing the cost from \$400/day treatment to \$100/day treatment.³⁹ (3) PrEP implementation will require a reorganization of AIDS care services to accommodate at risk, but seronegative patients.

The use of ARVs requires constant monitoring of patients beyond medication dosing. At the moment, health professionals and decision makers are still discussing the framework of this initiative.⁴⁰ The international literature only recently began to address issues of adherence to PrEP as the intervention moves from clinical trials to effective implementation of long-term prevention therapies.⁴¹

Besides these new technologies, Brazil also continued to invest in traditional prevention and testing strategies. One core adjustment in the AIDS response over the past 10 years was to introduce prevention practices within

primary care. The Family Health Program is the main model for primary care in Brazil and is also renowned for its successful health outcomes. In mid-2000s, as part of the decision to merge AIDS policies with the formal structures of SUS, the Ministry of Health recommended that STDs/AIDS should be integrated to Family Health Program. Until then, many interventions for vulnerable population and at risk groups were developed by CSO. However, several challenges have been reported with this process, including lack of adequate training and staff to deal with STDs and AIDS testing and awareness campaigns, high health professional turnover, health professional difficulty at sharing HIV-positive results, problems in distribution of condoms, and others.^{42,43}

In addition, Brazil has gone through a wave of political conservatism, which impacts well-succeed strategies such as mass media campaigns during carnival festivals and others. Because of disagreements between the DDAHV, the Ministry of Health, and conservative politicians, the director of the DDAHV resigned after a controversial campaign to prevent HIV among sex workers.⁴⁴ Historically, although many countries in Latin America have records of disagreement between the Catholic Church and AIDS response, Brazil took a different direction and built ties between the church and the national AIDS program.⁴⁵ Although there are no formal studies on this, anecdotal information suggests that these conservative religious groups are mainly related to evangelical/protestants politicians (who represent an important political ally to the government coalition). During the political crisis in mid-2010s, these religious groups were crucial to ensure governability, and the Ministry of Health had to make concessions to ensure governability; these included backing on prevention campaigns during carnival festivals and to commercial sex-workers, for instance.⁴⁴ For more information on the evolution and influence of religious groups and beliefs on democratic politics in Brazil, see the study of Smith.⁴⁶

6 | CONCLUSION

As extensive as the literature on the successful case of AIDS policy in Brazil is, authors have largely ignored the current developments and challenges of providing a response to the epidemic today. Formally including the infra-structure, funds and trained staff of the DDAHV into the national health system solidifies the policy path, but it has come with a cost. Decentralization of resources to states and municipalities has at the same time induced subnational governments to take ownership of the epidemic within their jurisdictions, but not all of them were prepared to deal with innovative mechanisms of prevention among vulnerable populations (such as partnering with NGOs) and did not have local capacity to provide AIDS care. Civil society, which was historically empowered by the DDAHV, is now struggling to survive, as subnational governments are not willing to include them in their programs or are not as effective in consorting with NGOs as the national government was. As a result, many NGOs have now vanished. Consequently, the AIDS epidemic has emerged as a public health crisis in some regions of the country, such as in the north and south, where rates of AIDS-related deaths are similar to some African countries.

Despite these worrisome results, the national AIDS policy has been resilient. Although there was a fear in the early 2000s that Brazil would not be able to keep up with its comprehensive AIDS care, given the increasing costs of patent medicines, the country still provides novel drugs and has one of the most advanced clinical protocols in the world. In addition, Brazil is now preparing to introduce PREP, a new prevention technology, into the national health system. Policy instruments have evolved; for instance, aggressive price negotiations were replaced by technology transfer agreements, and AIDS prevention initiatives have been shifted from NGOs to primary care institutions. Issues such as delays in transferring funds to NGOs and medicines stock outs, a side effect of decentralization, have revived the old AIDS activism from initial years of the epidemic. Remaining CSO, particularly those in large cities such as Rio and Sao Paulo, have been particularly active in holding the DDAHV accountable to its commitments and have expanded their advocacy agenda to issues related to pharmaceutical regulation.

Ironically, it was not the imposing agenda of multinational pharmaceutical companies or only the lack of resources that threatens the sustainability of the AIDS response in Brazil, but the challenges of the health system itself. At the moment, Brazil is facing a severe political and economic crisis, one of the most severe in its history. Conservative

groups, such as evangelical/protestants politicians ("bancada evangelica") that are vital to ensure the president's governability, now have a say in health policy, which deeply harms AIDS prevention campaigns. Also, while the incentive mechanism was crucial to expand AIDS care and increase the democratic channels of agreement between health service users and the three levels of government, the recent decision to radically decentralize health policy-making and implementation to municipalities will reduce the coordination capacity of the DDAHV and, possibly, deepen inequalities in responding to the epidemic. Facing these threats will require a broad mobilization of the health community to ensure that rights gained in the 1988 Health Reform are not revoked by opportunistic interests that mushroom in any political crisis.

ACKNOWLEDGEMENTS

We thank our interviewees for their valuable comments on the AIDS policy in Brazil. Their names were not mentioned here to guarantee anonymity. This study was funded by the (2015/18604-5).

CONFLICT OF INTEREST

The authors have no competing interests.

AUTHOR CONTRIBUTION

EMF and FIB contributed equally to data collection and analysis and writing up of this manuscript.

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How to cite this article: da Fonseca EM, Bastos FI. Evolution of HIV/AIDS response in Brazil: Policy innovations and challenges in the fourth decade of the epidemic. *Int J Health Plann Mgmt*. 2018;33:e238-e250. <https://doi.org/10.1002/hpm.2452>