Brazilian policy of universal access to AIDS treatment: sustainability challenges and perspectives

Dirceu B. Greco[a] and Mariangela Simão[b]

Introduction: The Brazilian AIDS Programme success is recognized worldwide, due to its integrated approach of prevention, respect for human rights and to free of charge universal access to state of the art antiretrovirals.

Current situation: As of 2006, 180,000 people living with AIDS are on HAART with 17 drugs available, receiving medical and laboratory care through the public health system. Costs for ART drugs reached US$ 400 million in 2006 and will increase steeply if the current trends are maintained: uptake of approximately 20,000 new patients/year and the need for more expensive, patent-protected second and third line drugs.

Discussion: We discuss the strengths and weeknesses of the programme, budgetary pressures, the need for more intense preventive efforts, for boosting local production of new drugs, for more investment in research and development and the issue of voluntary and compulsory licensing. There are many hurdles in pursuing long-term sustainability, which depends on country driven initiatives and international collaboration and participation.

Conclusion: We conclude that the Brazilian experience demonstrated the capability of a developing country to treat people with equity, independently of race, gender or economic power and that this equality ''seed'' has already spread to other countries. Internally this experience must be used to tackle other endemic diseases, such as leprosy, malaria, dengue and leishmania. The Brazilian political will has been proven but, once again, there will be the need for concerted action by civil society, researchers, health professionals, people living with HIV/AIDS and the government to convince the world that health needs should not be treated as commercial issues, and that progress in research and development must be shared throughout the world if we expect to survive as a civilization.

AIDS 2007, **21** (suppl 4):S37–S45

Keywords: Brazilian AIDS Programme, sustainability, universal access to ART

Introduction

The success of the Brazilian Ministry of Health (MoH) in confronting HIV/AIDS has gained worldwide recognition. In this paper we will discuss the current situation of the AIDS epidemic in Brazil, the impact of programmes providing universal access to treatment, and the risks, challenges and perspectives for programme sustainability. We will also touch on how Brazil might use the experience gained from the HIV/AIDS response to face other demanding health needs.

The AIDS epidemic in Brazil

With 8.5 million square kilometres and 180 million inhabitants, Brazil is the largest and most populous country in Latin America. The AIDS epidemic has reached all the 26 Brazilian states but is still more prevalent in the south-east (63% of all cases) and south regions (18% of all cases) [1]. These regions have the most populous and urbanized states of Brazil. In the 1980s HIV infection was concentrated in the south-east, affecting mostly homosexual and bisexual individuals with more

From the [a]Internal Medicine Department, School of Medicine, Federal University of Minas Gerais, Belo Horizonte, Brazil, and the [b]Brazilian AIDS Programme, Ministry of Health, Brasília, Brazil.

Correspondence to Prof. Dirceu B. Greco, Av. Alfredo Balena, 190, 30130-100 Belo Horizonte, Brazil.
E-mail: greco@medicina.ufmg.br

ISSN 0269-9370 © 2007 Lippincott Williams & Wilkins

years of schooling and who had had sexual contact outside the country (especially in the United States) [2].

Notwithstanding, sentinel studies have shown that prevalence (in individuals aged 15–49 years) has stabilized at 0.61% since 2000, the AIDS epidemic is increasing among heterosexual individuals, women and the poorer population [3]. The country is also going through different epidemics, as HIV infection is spreading gradually to the interior, affecting some regions already burdened by other infectious diseases, such as the Amazon, or with a lack of adequate healthcare [4]. The prevalence is still much higher in some vulnerable groups, such as sex workers, men who have sex with men and injecting drug users, but is clearly moving towards the general population.

The feminization, for example, was not unexpected because women may get exposed to partners who have many partners (both male and female), to injecting drug user partners or they may also use intravenous drugs themselves. Studies have also shown that women and girls are less likely to ask men to use condoms, and it is usually the men who have the decision in this matter. When asked why they do not use condoms, 29% of all girls mentioned that they trust their partners (29%), whereas only 9% of the boys gave the same reason. Sex, sociocultural dimensions, including domestic and sexual violence, add vulnerability to girls and women to HIV.

In the general population, combining all age groups there is a sex ratio of one woman to 1.4 men with AIDS, but when the data are disaggregated by age and sex the ratio for the 13–19 year age group is 1.3 women to one man.

The increase among the poorer population was expected, as the epidemic has been growing in the general population, and Brazil has a large percentage of individuals living in underprivileged conditions. Poor people have added vulnerabilities, such as difficult access to healthcare and prevention commodities. This vulnerability also affects women, as mentioned before, with the added risks related to difficulties in negotiating condom use, partner infidelity and sex for money, food or drugs [5,6].

On the prevention issue, national campaigns to promote condom use seem to be effective. Several studies on behaviour, attitudes and practices regarding AIDS, as well as a large study on sexual behaviour have shown that there is a higher level of condom use on a consistent basis, mainly among younger individuals and men who have sex with men. A survey has also shown that 96% of the population knows that a condom is the best way to prevent AIDS and other sexually transmitted diseases. The government buys large quantities of condoms for public distribution, and the goal for 2007 is the procurement of one billion condoms, and in a few months condom production is expected to start in a public plant in the Amazon region, part of a sustainable development programme, which will produce yearly up to 100 million condoms from latex extracted from native rubber trees.

There is a very open debate in the media on condom use and distribution, including in schools and work places. Bearing in mind that Brazil is a predominantly religious country, we have come a long way. These approaches may account for the increased percentage of young people who reported using condoms in their first intercourse (from less than 10% in 1986 to more than 60% in 2004).

It must also be pointed out that the role of injecting drug use in HIV transmission seems to be waning, and this may be mainly attributable to harm reduction programmes established and facilitated by the Brazilian AIDS Programme.

The experience of the Brazilian AIDS programme

The Brazilian response to the HIV/AIDS epidemic (the National STD/AIDS Programme) was established by the MoH in 1986 and since its beginning has had a balanced approach of prevention, treatment, care and protection of human rights [7,8]. The active participation of civil society organizations in different decision-making forums is key to governmental accountability. The hallmark of a 1996 federal law ensuring that all patients infected with HIV who need antiretroviral therapy (ART) should receive it free of charge is based on the Brazilian National Health System. This system was established in the Brazilian Constitution of 1988, just 3 years after the end of the military dictatorship, and it is based on the constitutional principle that health is a right of the individual and that the state has the obligation of providing it to all, universally and with equity. It was in this decentralized network of public health services that the treatment programme for HIV was established.

Current situation

The National STD/AIDS Programme has the mandate to coordinate the implementation of AIDS policy nationwide, with the participation of the states and municipalities, the universities and civil society. The distribution of zidovudine started in 1991, and it was soon produced in Brazil. It became clear that to fight HIV/AIDS effectively a multipronged approach was needed, including not only strategies to decrease stigma and discrimination, public campaigns for prevention, but also treatment and harm reduction measures. As progress in treatment was made and with the law ensuring the right of access to HAART, an expert commission was designated to define a consensus for the treatment of infected individuals, supporting the universal access to antiretroviral medicines policy.

In the early 1990s the World Bank estimated that Brazil would have more than a million people living with HIV/AIDS by the turn of the century, but the policy adopted by the Brazilian programme proved them wrong, and as of 2006 there are an estimated 600 000 individuals living with HIV/AIDS [9]. At that time a loan from the World Bank was approved aimed at boosting preventive efforts. An interesting fact was that the World Bank strongly cautioned the MoH against investing in treatment with the argument that it would be very difficult to maintain adherence to the medication, leading to high-level primary resistance. The universal access to treatment policy again proved them wrong as adherence and primary resistance is equal, if not better in Brazil, when compared with industrialized countries.

Of the estimated 600 000 individuals with HIV/AIDS, 180 000 are on ART with access to comprehensive medical care, CD4 lymphocyte counts, viral loads and genotyping. Approximately 70 000 are on follow-up but are still not meeting the criteria for treatment.

Through the public health system, a network for diagnosis, prevention, treatment and follow-up was organized, and currently includes 397 accredited hospitals, 79 day-care hospitals, 58 home-care centres and 422 outpatient facilities, 82 lymphocyte phenotyping, 71 viral load laboratories and 18 genotyping centres (Table 1). It must be emphasized that all these facilities were established and are maintained with public funds, and that all services provided are free of charge to all who need them. All patients with AIDS have access (2006) to 17 drug pharmaceutical compounds, eight of which are produced locally (Table 2).

Even with all the above-mentioned measures (prevention, non-governmental organization participation, media involvement, investment in antiretroviral drug production and distribution) the numbers in this seemingly stabilized epidemic are high: over 400 000 AIDS cases were notified to the MoH (1980–2006) [1], with approximately 32 000 new cases per year, an incidence of 18/100 000 and more than 11 000 deaths (6.0/100 000) per year.

Prevention efforts include not only mass media campaigns promoting the use of condoms, but also initiatives against prejudice and discrimination against individuals living with HIV and AIDS, and campaigns aimed at protecting the human rights of vulnerable groups. More than 10% of the MoH budget for AIDS is also decentralized to all states, and prioritizes 422 cities, allowing local planning of prevention and financing of non-governmental projects, targeting local specificities in the fight against AIDS.

Table 1. Brazilian network of public laboratories, 2005.

Facilities	Number	Examinations performed/ cost per test	Cost (million US$)
Lymphocyte phenotyping	82	542 450/14.00	7.6
Viral load	71	354 849/29.00	9.9
Genotyping centres	18	15 000/123.00	1.84

Table 2. Antiretroviral drugs universally available to people living with HIV/AIDS in Brazil, 2006.

Nucleoside reverse transcriptase inhibitors	Protease inhibitors
Zidovudine (1991)[a]	Ritonavir (1996)[a]
Stavudine (1997)[a]	Saquinavir (1996)[a]
Didanosine (1993)[a]	Indinavir (1997)[a]
Lamivudine (1996)[a]	Nelfinavir (1998)
Abacavir (2001)	Amprenavir (2001)
Tenofovir (2003)	Lopinavir/ritonavir (2002)
Didanosine ec (2005)	Atazanavir (2004)
Non-nucleoside reverse transcriptase inhibitors	Fusion inhibitor
Efavirenz (1999)	Enfuvirtide (2005)
Nevirapine (1998)[a]	

[a]Produced in Brazil.

In other words, although there is the need for improvement in HIV prevention, with a constant evaluation of the established policies such as mass media campaigns and the free distribution of condoms, there is also the need to search for and finance novel prevention mechanisms, including more effective and early sex education in schools, the facilitation of HIV diagnosis and empowerment of vulnerable groups.

Table 3 [10] shows the relevant issues of Brazilian and international ART-related policies.

Evaluation of the impact of antiretroviral therapy policy

Increasing costs

With the increasing number of patients on treatment and with longer survival rates, the need to include second and

Table 3. Relevant issues and dates of the Brazilian and international antiretroviral drug-related policies (1986–2005).

Year	Relevant issues
1986	Establishment of the Brazilian AIDS Programme
1988	Brazilian Constitution
1991	Distribution of zidovudine started
1995	Local production started
1996	Law assuring the right of access to antiretroviral therapy
2001	57th Session of the UN Human Rights Commission establishes that the access to medication during pandemics is a basic human right; Brazil produced seven of the 13 antiretroviral drugs available for treatment
2003	Presidential decree facilitates the import of generic drugs produced under compulsory licensing
2005	Brazilian law project stating that drugs for AIDS cannot be patented

Modified from Portela and Lotrowska [10].

Table 4. Investment in antiretroviral drugs and number of patients on treatment – Brazil, 1997–2005.

Year	Cost (million US$)	Patients × 1000
1997	224	36
1998	305	57
1999	336	64
2000	303	79
2001	232	90
2002	179	105
2003	181	120
2004	203	155
2005	395	180

third-line drugs, all protected by patents, budgetary needs to procure antiretroviral drugs have been rising annually (Table 4), increasing pressure on the MoH's budget. Some may reason that the government is spending too much money for one disease with a relatively small number of patients when health needs and all other Brazilian endemic diseases are taken into consideration. This is a not an uncommon discussion in Brazil, where the tendency is to level down (as other diseases do not get the same attention as HIV/AIDS) instead of levelling up (confronting the AIDS epidemic can be an example for the other more neglected diseases). The counter argument to the economic reasoning for changing this model (maybe having tiered pricing dependent on individual purchasing capacity) was an evaluation of the economic results of the investment in AIDS control. Studies have shown that the universal access to treatment policy resulted in a 40–70% reduction in mortality between 1997 and 2003, over a 60% reduction in morbidity, 360 000 hospitalizations avoided (85% reduction) and 58 000 AIDS cases avoided. These results were associated with a 10-fold increase in survival after an AIDS diagnosis (6–58 months) [11]. In this period the total cost of drugs reached over US$1.6 billion, and considering not only the invaluable social impact mentioned above, it also had a substantial economic impact, estimated at another US$2 billion reduction in costs related to hospitalization and outpatient care, in insurance and in saved productivity. Also with the local production of antiretroviral drugs and price negotiation for imported drugs, the average cost per patient decreased [12].

Costs of antiretroviral drugs

Figure 1 summarizes the evolution of the costs of providing ART in Brazil (1996–2005). Local production of quality drugs was probably one of the principal factors that initially helped curb the increase in costs even with the increasing numbers of patients on treatment. Another factor has been the continuous price negotiation with the pharmaceutical industry, a task that has been well conducted by the National AIDS Programme.

Not unexpectedly, however, the necessary change to more complex ART regimens is putting tremendous pressure on the budget. Table 5 shows the enormous price differences in the prices of six common drug combinations used in Brazil. As an example, if atazanavir/ritonavir is substituted for nevirapine (produced locally) keeping zidovudine/lamivudine as a backbone, the difference in the cost per patient reaches a staggering US$2827 per year.

Trends in the distribution of antiretroviral drugs: local and international production

Figures 2–4 show the trends in the prescription of antiretroviral drugs from 1997 to 2005, confirming the increase in the use of more expensive imported second and third-line antiretroviral agents. This is especially clear, for example, in the case of efavirenz against nevirapine, and for an increase in the prescription of atazanavir.

The proportion of the budget devoted to locally produced antiretroviral drugs has decreased as a result of the expected switch to new imported, patented, and more expensive drugs for patients on longer-term treatment programmes.

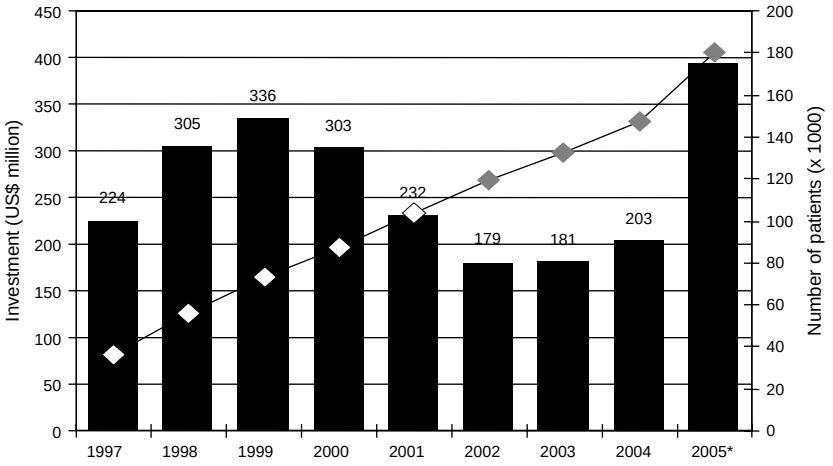

Fig. 1. Total investment (US$ million) in antiretroviral drugs and average number of patients on therapy – Brazil, 1997–2005. ■ Expenses (US$ million); ---◆--- average number of patients (× 1000); *preliminary data. Source: PN-DST/AIDS/SVS/MS.

Table 5. Cost in US$ of different antiretroviral regimens for adult formulations per patient per year – Brazil, 2006.

Antiretroviral regimen	Cost/year (US$)
Zidovudine–lamivudine–nevirapine	682.00
Zidovudine–lamivudine–efavirenz	1005.00
Zidovudine–lamivudine–lopinavir/ritonavir	1805.00
Tenofovir–lamivudine–nevirapine	1857.00
Tenofovir–lamivudine–efavirenz	2180.00
Zidovudine–lamivudine–atazanavir/ritonavir	2827.00

The proportion varied from 44.6% in 2000 to an estimated 18.4% in 2006, and this change has undoubtedly contributed to an impact on the annual drug expenditure, which was US$330 million in 1999, levelling down to approximately US$200 million between 2001 and 2004, and increasing to almost US$400 million in 2005 (Table 6). The decrease in prices in the triennium 2002–2004 has to do with price negotiations with international pharmaceutical producers coinciding with the Brazilian MoH, backed by civil society, threatening them with compulsory licensing.

Challenges

In middle-income countries such as Brazil there are specific challenges to maintaining a universal access to treatment policy, especially considering the need to move to more complex ART.

They include: (i) The burden of success: the availability of ART and the government's responsibility to provide it may decrease the political engagement of civil society, media included. (ii) As the Brazilian programme provides up to date treatment it may be possible that health providers may not pay enough attention to ART follow-up and may engage too quickly in a transition to more complex regimens. Not only is this complicated from the strict scientific point of view because a well-chosen first

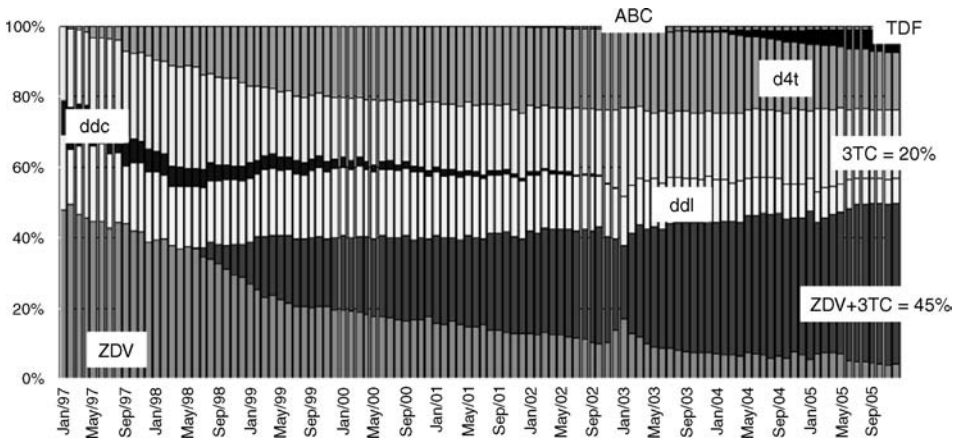

Fig. 2. Trends in prescription of nucleoside reverse transcriptase inhibitors – Brazil, 1997–2005. ABC, Abacavir; ddC, zalcitabine; ddI, didanosine; d4t, stavudine; 3TC, lamivudine; TDF, tenofovir; ZDV, zidovudine.

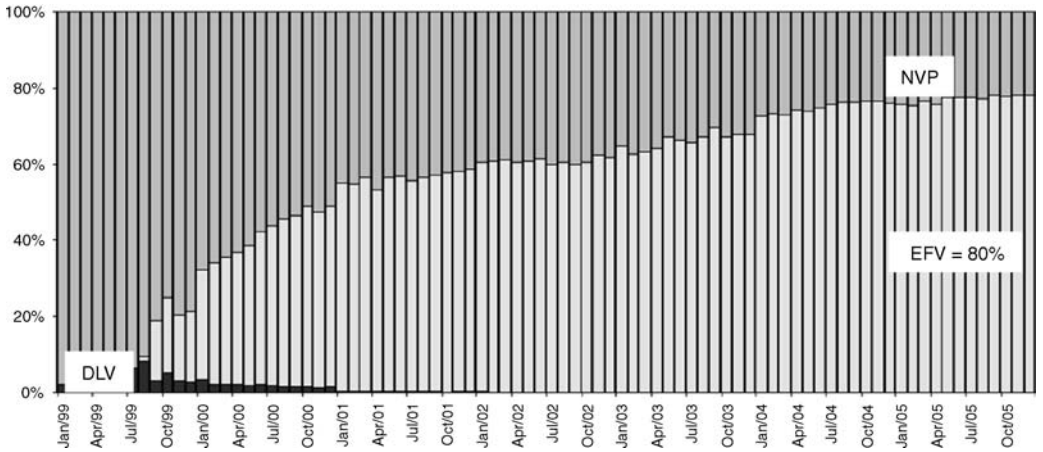

Fig. 3. Trends in prescription of non-nucleoside reverse transcriptase inhibitors – Brazil, 1997–2005. DLV, Delavirdine; EFV, efavirenz; NVP, nevirapine.

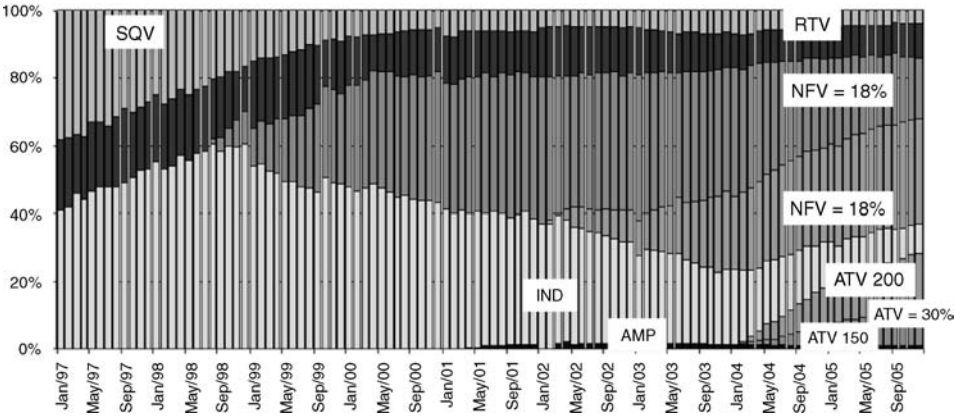

Fig. 4. Trends in prescription of protease inhibitors – Brazil, 1997–2005. AMP, Amprenavir; ATV, atazanavir; NFV, nelfinavir; IND, indinavir; RTV, ritonavir; SQV, saquinavir.

regimen is one of the markers of future success, but also economically, as the new drugs are more expensive and have usually been less well evaluated. (iii) Current mono/oligopolistic configuration of the market of active principal ingredients: even though there is local production of eight antiretroviral drugs, the active principal ingredients are all imported, usually from east Asia. This situation is very serious especially because there is a risk of a lack of these active principal ingredients as a result of the scale-up of treatment throughout the globe and also because the main producing countries may be restricted by compliance with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. (iv) The challenge of disparity or of poverty: there is a well-known relationship between poverty and the spread of epidemics of communicable disease, and at the same time epidemic disease, like any illness, has the potential to increase poverty. This bidirectional effect occurs through many different pathways. It is well known that the HIV/AIDS epidemic impoverishes individuals, their households, communities and enterprises. Households become poorer as a result of the illness and death of members, and in many cases it is the income-earning adults who are the first to succumb. Impoverishment is more than financial, however, as illness and death lead to an erosion of social capital and socially reproductive labour [13]. It is also widely recognized that poverty and inequity continue to be key issues in Latin America, Brazil included. The region faces the highest socioeconomic inequalities in the world, and changes in the distribution of income between 1990 and 2002 have been very small. Poverty in many ways increases the vulnerability to HIV infection, as it makes more difficult the access to preventive measures, to medical care, and also for destitute individuals to cope with the complexities of ART. It will thus be crucial to tackle this issue in a comprehensive way. (v) Finally, and very important for long-term sustainability, is a short-sighted perception, contributed by pharmaceutical industry propaganda, that intellectual property rights issues are not relevant. This may be a (planned) spin off of the various programmes to scale up treatment (Global Fund to Fight AIDS, Tuberculosis and Malaria, President's Emergency Plan for AIDS Relief, Bill and Melinda Gates Foundation, etc.), when the chances of getting started blur the long-term discussion of the need for local production, technical independence, and country empowerment, and may jeopardize long-term sustainability. Also, some free trade agreements are having an impact on drug prices, and that also affects sustainability on a long-term basis. The use of the TRIPS flexibilities, including compulsory licensing to buy generics or to produce locally is still incipient, although there are now many antiretroviral drug generic versions prequalified by the World Health Organization.

Crisis around the corner?

With all these challenges the Brazilian programme may be at risk with regard to its long-term sustainability [14].

Increased number of patients on treatment

Of the estimated 600 000 people living with HIV/AIDS, over 180 000 are on HAART plus approximately 70 000 are on follow-up without medication, and each year approximately 20 000 individuals start ART.

Table 6. Trends in the distribution of antiretroviral drug costs: local and multinational production.

Antiretroviral drug production	1999	2000	2001	2002	2003	2004	2005
Brazil	16.7	44.6	42.2	47.4	36.7	23.0	25.7
Multinational	83.3	55.4	57.8	52.6	64.3	77.0	74.3

2006: Local 18.4%; multinational 81.6% (estimated). Source: Brazilian STA/AIDS Programme.

Costs

In 2005 the costs of drugs alone reached US$400 million, which is an enormous amount of money even for a middle-income country. These costs will certainly increase with the expected need for new drugs that are being imported, patent-protected and that are increasingly more expensive.

Poverty issues

Even with free access to outpatient facilities, laboratories and to a fairly functional distribution pipeline, despite the continental size of the country, the expansion of the epidemic to small towns and to destitute individuals means that many patients can not access medical care at distribution points because of a lack of money for transportation.

The situation depicted may be evaluated either as a half empty or a half full glass. Undoubtedly, the AIDS programme has had a remarkable impact on the profile of the Brazilian epidemic. On the other hand, there are many factors that hold its long-term sustainability in check, such as the sheer increase in the number of individuals who need to initiate ART each year, the expected increase in the complexity of the regimens for infected individuals, who are fortunately surviving for much longer periods, and the issue of local production through technological transfer, local research and development or through compulsory licensing.

Approaches to guarantee sustainability

The role model that Brazil has assumed with its bold move in providing care and medication for all in need and its success is reason enough to pursue long-term sustainability. The approaches to maintain this goal are multipronged.

Stewardship and governance: country driven and country dependent

Many aspects are very much dependent on the country's own policies. There is an urgent need to foster the 'rational use' of ART, including a policy for more stringent scientific evidence for the addition of new drugs to the consensus treatment policy [15]. Although Brazil has had established guidelines for the treatment of individuals infected by HIV since 1996, which are reviewed yearly, there is a need for more data on the effectiveness and benefit of the rational use of ART. The strong pressures from the drug producers to introduce new drugs must be counteracted with local operational research, using the enormous amount of information collected from almost 180 000 individuals on treatment.

Increase local production plus better formulation

Investment must be made in both public and private Brazilian laboratories to increase local production at fair prices not only of the finished drugs but particularly of active principal ingredients. There is also a need for better formulation of drugs for the paediatric HIV-infected population and more fixed combinations, such as zidovudine–lamivudine–nevirapine and stavudine–lamivudine–nevirapine, which are already available elsewhere.

More investment is needed in research and development of new molecules and also of chemical supplies, including through public–private partnerships. It is also of foremost importance to increase local knowledge on the production of prevention, diagnostic and monitoring commodities. As an example, a public plant to produce condoms is being established at the Amazon region with an estimated production of 100 million condoms per year; rapid tests are being locally produced for HIV diagnosis; research into the production of both CD4 cell tests and viral loads are also in progress.

It must be remembered that even these country-driven, country-dependent initiatives are intertwined with very strong international interests, and as such international negotiations will be needed.

International collaboration: antiretroviral price reduction

Although this is a short-term policy, it is still a significant component of the maintenance of access for all. In pursuit of this aim, the amount of resources spent annually on drug procurement by the government is an unequivocally important leveller at the negotiation table. Recent publications showing the different pricing policies from different companies, including the generic producers, and other independent initiatives, such as Médecins Sans Frontières, are helping individual countries to negotiate fairer prices.

Regional initiatives in Latin America, led by the Pan American Health Organization, have also helped to reduce prices, as well as to establish an overall picture of the price situation in different countries in the Latin America–Caribbean region.

Other international initiatives, such as the Clinton Foundation HIV/AIDS Initiative, and more recently, UNITAID, are working towards expanding access to treatment, including second-line drugs, either by negotiating prices with brand and generic producers to lower costs, or by providing technical support to countries in specific areas, including the use of TRIPS flexibilities (Clinton Foundation HIV/AIDS Initiative).

Political decision plus international participation

Despite all the experience accumulated by the Brazilian National AIDS Programme over the years in dealing with all the complex aspects of HIV/AIDS control, and also despite the political and budgetary commitment, the increasing complexity and costs of new, more complex

and patent-protected medications and related tools (e.g. genotyping, cytokine receptor determination) are already straining the available health resources. The political decision to implement local production at fair prices thus becomes an unquestionable need, and the legal tools for issuing compulsory licensing are in accordance with the flexibilities allowed by TRIPS to protect public health [16]. Since 2001, Brazil has started legal proceedings on three occasions to issue compulsory licences for the most costly imported antiretroviral drugs, but backed down after the producers offered a further price reduction. Even if this had been financially advantageous at that time, it just postponed a more definite solution to the problem. These decisions were a disappointment to many activists in Brazil and throughout the world, as it was felt that a firm stand on this issue would be an example that could help many other countries. The bottom line is that the seriousness, visibility and accumulated experience of the Brazilian National AIDS Programme almost imposes an obligation to be even more vocal and act accordingly, together with international partners, in pursuing the opening of all the black boxes related to drug development and production costs aimed at establishing mechanisms for technology transfer.

In late April 2007, the Brazilian government declared the public interest in efavirenz, and issued a compulsory licence for the public and non-commercial use of the two patents registered in Brazil by Merck Co. Inc. on 4 May 2007. The public interest was based on the fact that during a 5-month negotiation process, the producer did not offer Brazil prices the government considered fair. With the compulsory licence, the government is buying prequalified generic drugs from other producers at significantly lower prices. Besides that, local production in two state-owned pharmaceutical plants is due to start soon and nationally produced efavirenz is expected to be available for the National AIDS Programme by the end of 2008.

It must be added that a substantial part of the costly research on antiretroviral drugs was and still is occurring in universities and research institutes financed mainly by the US National Institutes of Health public funds, which must also be brought to the global discussion on patents, the transfer of technology and price setting.

In conclusion, looking back at 1996 when the bold decision was taken to provide therapy to all against the prevailing common sense that developing countries should focus on prevention to curb the AIDS epidemic, and that adherence to the complex therapeutic regimens would be very hard to ensure, with the risk of spreading resistant virus, it is fair to say that the acquired experience will help us navigate through the new challenges.

The good results of this programme are recognized worldwide [17], which translates into important political support. On the other hand, and even considering the apparent stability of the AIDS epidemic in Brazil, there are currently 180 000 individuals on treatment with a conservative estimate of including approximately 20 000 per year for the foreseeable future. In 2006, the anti-retroviral drug budget increased to almost US$400 million and this is a result mainly of the switch to more expensive, imported and patent-protected drugs as a result of resistance or adverse events to first-line locally produced medication. Pressures to switch early are also often based on relatively small and short follow-up phase III clinical trials.

The challenges include: the need to expand the prevention efforts to all age groups (e.g. early sex education in the school system and also more attention to our ageing population); to increase the early diagnosis of HIV infection; to fund operational research on social, behavioural, epidemiological and clinical aspects of the AIDS epidemic; to invest in the local development and production of prevention, diagnostic and follow-up tools and also of active principal ingredients; and to boost investment to increase and diversify the national production of antiretroviral agents, including drugs under patent protection, either through voluntary licences or the use of other TRIPS flexibilities, in order to protect public health interests.

The Brazilian experience on providing universal access to AIDS treatment demonstrates that it is possible for a developing country, even with so many inequalities, to treat people with equity, independently of race, sex or economic power. The initial scepticism towards this approach has changed to how to work together not only to provide the much needed antiretroviral drugs, but bolder yet, how to provide decent healthcare to all. This equality 'seed' has already spread to other developing and also developed countries. In Brazil, the confrontation of the AIDS epidemic must expand to other important and prevalent diseases that are still rampant, such as leprosy, malaria, dengue, schistosomiasis, and leishmania. Another positive spin-off of the AIDS epidemic may thus be the possibility of levelling up our attitudes to the other needs of our population. The Brazilian political will has already been demonstrated, but now concerted action by activists, researchers, health professionals, civil society, people with HIV/AIDS and government will be needed once again really and truly to convince the world that health issues should not be treated as commercial issues, and that progress in research and development should be available to all, and must be shared throughout the world if we expect to survive as a civilization.

Acknowledgements

The authors are indebted for the contributions provided by Marco Antonio Vitoria, Pedro Chequer, Paulo Teixeira, Ronaldo Hallal and Orival Silveira.

Disclaimer: The production of this special Supplement was supported by the World Bank, the Joint United Nations Programme on HIV/AIDS and the World Health Organization. The findings, interpretations and conclusions presented in this paper do not necessarily reflect the views of these institutions or their constituent agencies or governments.

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