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Health care to HIV/AIDS patients in Brazil

ABSTRACT

This study was intended to assess care provided to those living with HIV/AIDS in Brazil and the Brazilian Unified Health System (SUS) capacity of delivering interventions to cope with the epidemic as well as to discuss the sustainability of the Brazilian initiative of providing universal free access to antiretrovirals (ARVs). Original data from a study comprising 119 respondents on the potential capacity of delivering a prospective HIV vaccine in Brazil was used. Inpatient and pharmaceutical care was based on data from the SUS Hospital Information System and Drug Logistics Management Systems of the National Program for STD/AIDS. The study results indicate good performance of the Brazilian ARV Access Program but access to treatment of opportunistic infections was, however, unsatisfactory. The rates covered by SUS for AIDS hospital admissions remained very low, on average around R\$700 in 2004. Health care to HIV/AIDS patients has been considered a citizen's right strongly supported by an effective joint action of the Brazilian government and civil society. The current challenges are fine monitoring of processes and program results and ensuring sustainability of universal free ARV access.

KEYWORDS: Acquired immunodeficiency syndrome, prevention & control. Acquired immunodeficiency syndrome, therapy. AIDS-related opportunistic infections, prevention & control. AIDS-related opportunistic infections, therapy. Anti-HIV agents, supply & distribution. Anti-HIV agents, economics. HIV long-term survivors. SUS (BR). Delivery of health care, organization & administration. Health services administration.

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INTRODUCTION

The Care, Support and Treatment principle of the United Nations Declaration of Commitment on HIV/AIDS* addresses two main points. First, strengthening health care systems for safely and effectively providing antiretroviral (ARV) therapy and best care recommended for prevention and treatment of opportunistic infections, including actions on drug practices and policies that would allow a sustainable ARV provision. Second, developing and progressively implementing comprehensive strategies for care and support, including psychosocial support, to those individuals, families and communities living with HIV/AIDS, on a family or community basis or at the level of health care services.

The commitment agreements endorsed for 2003 and 2005 have already been incorporated to the guidelines developed by the Brazilian government. The Brazilian Health System first provided drug for opportunistic infection treatment in 1988, and zidovudine became available in 1991.^{3,4} In 1996, the government took a groundbreaking step and pioneered passing a law establishing as the State's responsibility to provide universal free drugs for the treatment of HIV/AIDS patients.* In addition, the National Program for STD/HIV/AIDS (PN-DST/AIDS) has been historically characterized by taking thorough care measures and incorporating comprehensive strategies to fight against the epidemic and having a central role in promoting joined action with civil society.^{2,7}

Measuring the achievement of the established targets goes beyond the simple formal verification of their attainment. It poses challenges that indicate the need for finer monitoring of processes and results of care provided to those living with HIV/AIDS concerning drug therapy, and health services utilization as well as attention at the community level. It also raises questions on quality of care provided through actions of a distinctive National Program, unique in many aspects but still relying on the Brazilian care system undermined by serious operational problems. Ultimately, it brings about issues on the government agenda on how to assure sustainable drug access programs to those living with HIV/AIDS given their rising costs.

While most issues outlined above still need to be further explored and appraised, some have already been studied. HIV/AIDS outpatient care was assessed

in a study conducted in seven Brazilian states – Pará, Maranhão, Ceará, Rio de Janeiro, São Paulo, Rio Grande do Sul and Mato Grosso do Sul –, in 2001 and 2002 and recently published by the QualiAids Project group.^{9,10}

The present study intended to further address other aspects of care provided to those living with HIV/AIDS in Brazil, including an overall assessment of the health system capacity to fight the epidemic; a descriptive outlook on hospital admission rates in the Brazilian Unified Health System (SUS) in recent years; and an input on the impact and sustainability of universal free access to ARVs.

SOURCE OF DATA ANALYZED

Data were collected from several sources, and unpublished results are presented as well as previously published results from other studies and documents.

The overall assessment of the capacity for implementing interventions on HIV/AIDS is based on original data from a 2005 research study on the potential capacity for providing a prospective anti-HIV vaccine in Brazil, as proposed by the World Health Organization (WHO).¹ Data were collected from interviews with 119 subjects, including managers of the PN-DST/AIDS, local and state representatives of STD/AIDS program, representatives of non-governmental organization (NGOs), investigators, and HIV/AIDS health providers. A total of 12 HIV interventions were evaluated and their scores ranged from 0 to 10 and comprised items such as prophylactic treatment to HIV exposed health providers, access to primary and secondary prophylactic treatment to opportunistic infections, access to opportunistic infection treatment and effective population-based HIV/AIDS treatment programs.

Hospital and drug care aspects included in the Brazilian ARV access program intertwine when analyzing data from SUS Hospital Information System (SIH)** and the PN-DST/AIDS Drug Logistics Management System (SICLOM).⁶ HIS data comprise all admissions in public and private (contracted and philanthropic) hospitals covered by SUS at national level and include variables such as demographic (age and gender), clinical diagnosis and those related to health services utilization (length of hospital stay, intensive care unit admission, procedures).

When SUS costs, hospital admission rates and patients

*Brasil. Lei nº 9.313, de 13 de novembro de 1996. Dispõe sobre a distribuição gratuita de medicamentos aos portadores de HIV e doentes de Aids. Disponível em <http://www6.senado.gov.br/legislacao/ListaPublicacoes.action?id=144779> [acesso em 1 mar 2006]

**Sistema de Informações Hospitalares do Sistema Único de Saúde. Disponível em <http://www.datasus.gov.br> [acesso em 1 mar 2006]

Table 1 - Assessment of the capacity of implementing HIV interventions. Brazil, 2005.

Intervention	N	Mean	Standard deviation	Min.	Median	Max.
Public efforts for HIV knowledge	119	7.6	1.8	3	8	10
Promotion/distribution of condoms	119	7.0	1.9	1	7	10
Promotion of safe injecting drug use	114	4.8	2.0	0	5	10
Access to HIV counseling/voluntary testing	119	6.6	1.7	2	7	10
Access to STD testing and treatment	118	5.8	1.8	2	6	10
Access to prevention of vertical transmission	118	6.6	1.9	2	7	10
Access to patient-based behavioral counseling	117	5.8	2.0	1	6	10
Campaigns for promoting safe sex targeting adolescents, women, etc.	119	6.3	1.9	0	7	10
Prophylaxis to HIV exposure for health providers	116	6.5	2.0	0	7	10
Access to primary and secondary opportunistic disease prophylaxis	119	6.4	2.1	0	7	10
Access to opportunistic infection treatment	118	6.4	2.1	0	6.5	10
Effective wide scale HIV/AIDS treatment programs	118	7.1	2.0	0	8	10

receiving ARVs were addressed, some results presented here are from joined historical series data from the above mentioned sources, obtained from the PN-DST/AIDS Indicator Monitoring System (MONITORAIDS).^{*} However, hospital admission approvals (AIH), which are the SIH observation units, do not allow for differentiating inpatients from day hospital patients. Also, it was not possible to identify duplicated registries of ARV patients in SICLOM.

There were also used SIH data from AIDS AIH issued between January and December 2004, selected based on the variable "procedure performed": AIDS treatment; AIDS patients receiving long-term care; and AIDS care in day hospital. Inpatients were differentiated from those receiving day hospital care in these analyses. When SICLOM database was used directly, there were analyzed data on the longitudinal follow-up of 42,058 patients during the period between January 1998 and March 5, 2003, enrolled in 54 of 485 HIV/AIDS drug provision units available at that time. After controlling for multiple registries, SICLOM included 102,582 patients enrolled dur-

ing this study period, but only 42,058 patients had data on drug provision.

CAPACITY TO FIGHT THE EPIDEMIC

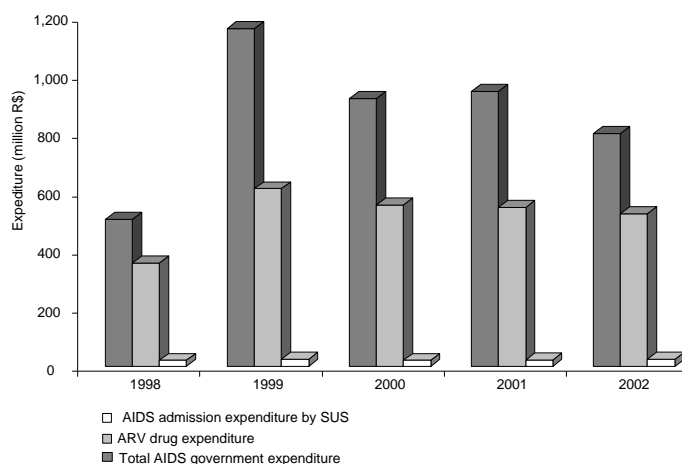
Table 1 shows the results of the assessment of the capacity for implementing interventions on HIV/AIDS. Specifically, the last items are focused in the aforementioned principle of the UN Declaration of Commitment on HIV/AIDS: prophylaxis and HIV exposure of health providers; access to primary and secondary prophylaxis to opportunistic infections; access to opportunistic infection treatment; and implementation of effective HIV/AIDS treatment national programs. Although means are slightly low because of several very negative evaluations, medians indicate relatively favorable evaluations, especially concerning the implementation of effective HIV/AIDS treatment national programs (median = 8). Of the four aspects highlighted, access to opportunistic infection treatment had the poorest evaluation.

Though ARVs are provided by SUS services, SICLOM includes treatment registry data from both public and private sectors, which allowed to estimating that 90.5% of patients actually receive care in SUS. This finding puts into context the counterpoint between hospital admission rates and costs covered by SUS and ARV provision, which pervades the following results.

Figure 1 shows the heavy burden of ARVs to the total public AIDS costs, where as it shows a relative stability of, at least overall, hospital care expenditures.

HOSPITAL ADMISSION RATES IN THE SUS

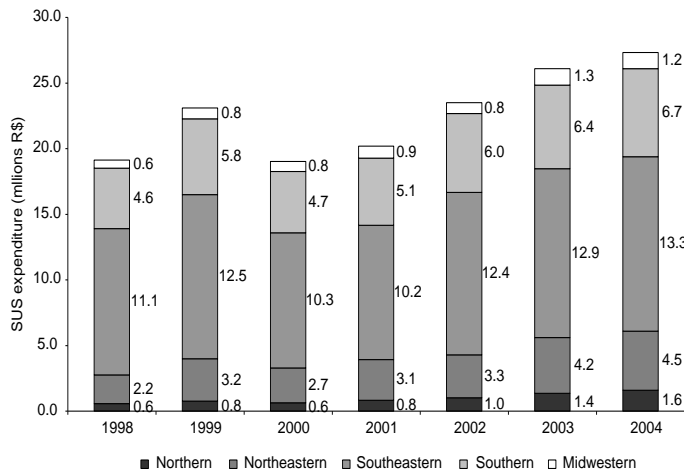
Figure 2 illustrates detailed expenditures by SUS for HIV/AIDS hospital care, including hospital admissions as such and day hospi-



Sources: Programa Nacional de DST/Aids e Datusus; Sistema de Monitoramento de Indicadores do Programa Nacional de DST/Aids - MONITORAIDS. Disponível em <http://www.aids.gov.br> [acesso em 1 mar 2006]

Figure 1 - Total expenditures by SUS with ARV drugs and AIDS hospital admissions as part of government HIV/AIDS care. Brazil, 1998-2002.

^{*}Sistema de Monitoramento de Indicadores do Programa Nacional de DST/Aids - MONITORAIDS. Disponível em <http://www.aids.gov.br> [acesso em 1 mar 2006]



Sources: Datasus; Sistema de Monitoramento de Indicadores do Programa Nacional de DST/Aids - MONITORAIDS. Disponível em <http://www.aids.gov.br> [acesso em 1 mar 2006]

Figure 2 - SUS expenditure with AIDS hospital admission by regions (million R\$). Brazil, 1998-2004.

tal care, ranging from slightly less than R\$20 million in 1998 to about R\$27.3 million* in 2004. The Southeastern region had the largest share which, rather consistently, showed the lowest mean cost per hospital admission in this period (Figure 3). Nationwide, the mean AIDS admission cost ranged from approximately R\$550 in 1998 to R\$700 in 2004. The highest mean costs were seen in the Northern and Southern regions.

Figure 4 displays the number of AIH for AIDS care issued between 1998 and 2004, by regions. There was a non-significant growth of total admissions countrywide, which is translated by a difference of less than 5,000 hospital admissions between 1998 and 2004. In regard to regions, Figure 4 shows relatively significant growth in the Northern, Northeastern and Midwestern regions, which contrasts with declining rates in the Southeastern region.

The ratio estimate between the number of AIDS hospital admission and total admissions covered by SUS could be slightly masked by AIH for day hospital care. Figure 5 indicates high hospital admission rates in the Southeastern and Southern regions, however declining in the former and still growing in the latter. In the Northern, Northeastern and Midwestern regions, the observed rates are dramatically lower with mostly increasing trends in 2004, showing two AIDS admissions per 1,000 SUS admissions.

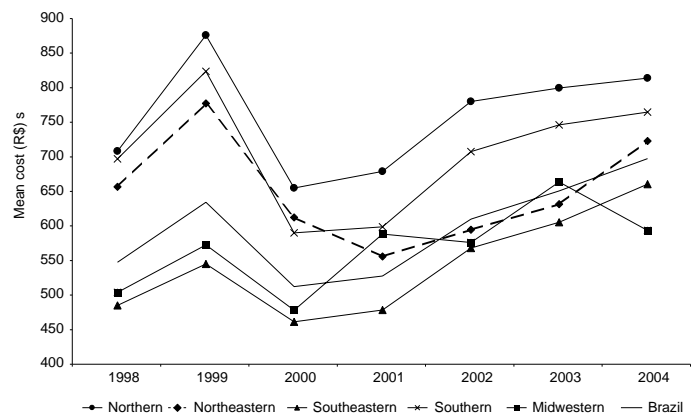
Figure 6 depicts a direct analysis of HIV/AIDS admission distribution (N=28,163), by re-

gions and SUS hospital categories in 2004, make a distinction between inpatients and day hospital care. It is noted the high share of state (44.2%) and philanthropic hospitals (25.0%). In contrast, the fact that there are no registries of university hospital admissions could be explained by a set financial ceiling on SUS payment to hospitals. It also suggests a reversal of the trend seen in the last decade when university hospitals were the main providers of AIDS care.

Figure 7 shows the nationwide distribution of the total amount covered by SUS for day hospital care (R\$ 1,515,656.00) in 2004, by regions and hospital categories. Attention is drawn to the fact that SUS day hospital care is not provided in the Northern region as well as to the majority of government hospitals.

Still based on data from hospital admissions covered by SUS in 2004, Table 2 displays the distribution of the variables "costs and length of stay according to main diagnosis," defined by the International Classification of Diseases – 10th revision (ICD-10) for regular hospital admissions.¹¹ Basically descriptive, data on Table substantiate low payment of HIV/AIDS hospital admissions by SUS.

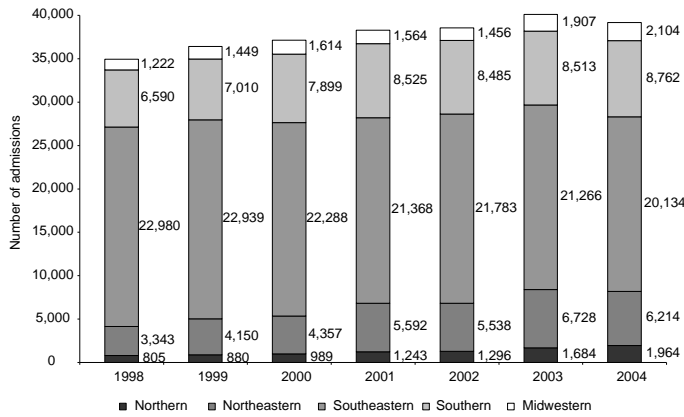
Based on data on provision of drugs registered in SICLOM between 1998 and 2003, there has been a gradual increase in adequate ARV therapeutic regimens according to the recommendations (Figure 8). SICLOM data provides longitudinal monitoring of ARV provision and dynamic as well as a registry of all patients receiving ARVs. This system has not yet



Sources: Datasus; Sistema de Monitoramento de Indicadores do Programa Nacional de DST/Aids - MONITORAIDS. Disponível em <http://www.aids.gov.br> [acesso em 1 mar 2006]

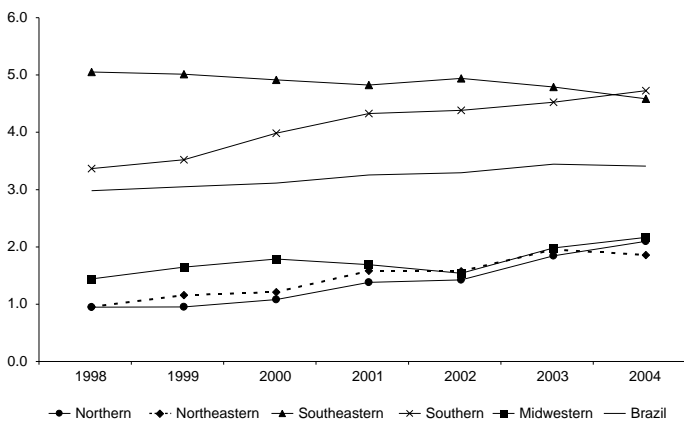
Figure 3 - Mean AIDS admission costs to SUS by regions and nationwide. Brazil, 1998-2004.

*In May 2006, US\$1 = R\$2,10



Sources: Datasus; Sistema de Monitoramento de Indicadores do Programa Nacional de DST/Aids - MONITORAIDS. Disponível em <http://www.aids.gov.br> [acesso em 1 mar 2006]

Figure 4 - Distribution of AIDS admissions in SUS by regions. Brazil, 1998-2004.



Sources: Datasus; Sistema de Monitoramento de Indicadores do Programa Nacional de DST/Aids - MONITORAIDS. Disponível em <http://www.aids.gov.br> [acesso em 1 mar 2006]

Figure 5 - Number of AIDS admissions per 1,000 admissions covered by SUS by regions and nationwide. Brazil, 1998-2004.

been fully implemented to allow for following up all patients on therapy.

Figures 9 and 10 show AIDS hospital admission rates and social security benefits to those patients receiving ARVs in the period between 1998 and 2004 and between 1997 and 2001, respectively. The clearly declining rates are suggestive of the effectiveness of ARV access programs.

UNIVERSAL FREE ACCESS TO ARVS

Table 3 summarizes some relevant facts on universal free ARV access program in Brazil.

The groundbreaking policy on HIV/AIDS in Brazil raises questions that now go beyond

the simple achievement of the targets established in the 26th Special Session of the United Nations General Assembly. Having achieved these goals beforehand, challenges are posed for finer monitoring of processes and results of care provided to those living with HIV/AIDS. Differences in these processes and results should be further explored and understood in order to identify strategies that could effectively increase the existing gains. There is also a need to further knowledge on adverse effects of ARVs for providing timely effective responses.

The interiorization and pauperization of AIDS epidemic in Brazil represents a challenge and calls for the results attained in main urban centers to be extensive to all other regions and social segments. Brazil should be involved in discussions on the utilization of intervention models based on more practical and less complex technologies that will ensure satisfactory results in health settings with less developed infrastructure that are not easily accessible to different populations.

While compliance to ARV therapy is 75%,* which is consistent with that seen in developed countries, it is imperative to find new ways of scaling up actions for compliance promotion through improving health services, building up capacity of multidisciplinary teams and supporting joined activities of health services with local community.

Improving quality of care provided by a distinctive National Program for STD/AIDS, unique in many aspects, but that relies on the strengthening of Brazilian care system in all levels, should be a concern. The Brazilian health care system is undermined by serious operational problems and several different local realities, many of them below the desired care standards.

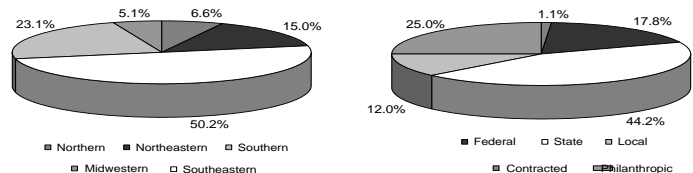


Figure 6 - HIV/AIDS hospital admissions covered by SUS (N=28,163) by regions and hospital categories. Brazil, 2004.

*Sistema de Monitoramento de Indicadores do Programa Nacional de DST/Aids - MONITORAIDS. Disponível em <http://www.aids.gov.br> [acesso em 1 mar 2006]

HIV/AIDS outpatient care comprises services with heterogeneous settings and infrastructures that mostly are in easily accessible areas and have the minimum required resources. In their study, Melchior et al.⁹ reported that 74% of all outpatient care units had at least one infectious disease specialist available and 90.4% had at least one non-medical provider, and 76% of health teams consisted of a social worker, a nurse, a psychologist and a pharmacist. The majority of health units had in place referral mechanisms to direct patients to other specialties within the SUS. However, some specialty services require long waiting hours, and referrals to pneumologists, neurologists, eye specialists and general surgeons are the most troublesome. CD4 and CD8 counts and viral load tests as well as regular laboratory tests and X-rays were available in more than 95% of services but there was increased difficulty in having access to more complex testing, especially imaging tests. ARVs were consistently highly available, contrasting with low access to other drugs for opportunistic infection prophylaxis and treatment, which are distributed by local and state governments. In regard to health care organization,

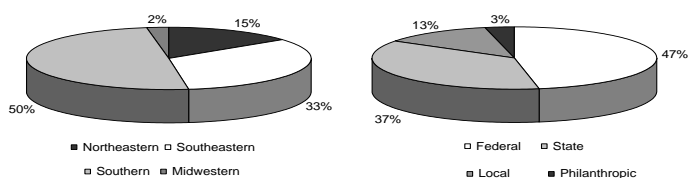


Figure 7 - Costs covered by SUS for day hospital services to HIV/AIDS patients (R\$ 1,515,656) by region and hospital categories. Brazil 2004.

Melchior et al⁹ stressed below desired levels of professionalization in service management, inadequate operation with limited service hours, limited use of care protocols, inexistent systematic evaluations of processes and results, lacking meetings of health care team, and poor control of visit no-shows and patient withdrawal, either due death, dropouts or others. On the other hand, these authors emphasize as positive widespread pre- and post-testing counseling, strongly supported by the PN-DST/AIDS.

The Brazilian drug program for HIV/AIDS is characterized by universal free access to ARV therapy and a consensus among Brazilian experts to recommend the use of ARV therapy and opportunistic infection prophylaxis.

Table 2 - Costs and length of hospital stay for HIV/AIDS patients covered by SUS according to main diagnosis. Brazil, 2004.

ICD-10	Description	N	%		Mean	Standard deviation	Minimum	Median	Maximum
B20.0	HIV disease resulting in mycobacterial infection	3,358	11.9	Costs (R\$)	902	620	87	743	10,158
				Length of stay (days)	19	20	0	13	256
B20.1	HIV disease resulting in other bacterial infections	2,486	8.8	Costs (R\$)	751	741	272	531	13,037
				Length of stay (days)	14	13	0	10	137
B20.2	HIV disease resulting in cytomegaloviral disease	101	0.4	Costs (R\$)	778	435	272	634	2,595
				Length of stay (days)	21	18	0	15	92
B20.3	HIV disease resulting in other viral infections	564	2.0	Costs (R\$)	800	677	272	558	7,343
				Length of stay (days)	17	26	0	11	368
B20.4	HIV disease resulting in candidiasis	502	1.8	Costs (R\$)	576	439	272	470	5,734
				Length of stay (days)	14	13	0	6	104
B20.5	HIV disease resulting in other mycoses	192	0.7	Costs (R\$)	908	906	136	660	7,969
				Length of stay (days)	18	17	1	13	110
B20.6	HIV disease resulting in Pneumocystis carinii pneumonia	1,900	6.8	Costs (R\$)	992	957	83	724	14,900
				Length of stay (days)	18	16	0	14	119
B20.7	HIV disease resulting in multiple infections	2,837	10.1	Costs (R\$)	1,065	839	272	803	8,630
				Length of stay (days)	21	22	0	14	371
B20.8	HIV disease resulting in other infectious and parasitic diseases	2,444	8.7	Costs (R\$)	866	947	27	531	9,865
				Length of stay (days)	18	55	0	11	1,485
B20.9	HIV disease resulting in unspecified infectious or parasitic disease	1,331	4.7	Costs (R\$)	887	915	272	602	14,766
				Length of stay (days)	19	22	0	13	380
B21.2	HIV disease resulting in other types of non-Hodgkin's lymphoma	36	0.1	Costs (R\$)	1,001	837	470	767	4,265
				Length of stay (days)	18	13	1	17	60
				Length of stay (days)	20	15	2	17	48
B22.0	HIV disease resulting in encephalopathy	2,153	7.6	Costs (R\$)	1,110	947	87	834	13,561
				Length of stay (days)	19	17	0	14	127
B22.1	HIV disease resulting in lymphoid interstitial pneumonitis	525	1.9	Costs (R\$)	878	949	272	607	11,726
				Length of stay (days)	18	16	0	13	130
B22.2	HIV disease resulting in wasting syndrome	30	0.1	Costs (R\$)	630	305	258	513	1,919
				Length of stay (days)	15	15	1	9	63
B23.0	Acute HIV infection syndrome	311	1.1	Costs (R\$)	795	529	271	616	4,588
				Length of stay (days)	18	16	0	14	138
B23.2	HIV disease resulting in haematological and immunological abnormalities, not elsewhere classified	114	0.4	Costs (R\$)	719	299	272	741	2,900
				Length of stay (days)	17	17	1	13	125
B23.8	HIV disease resulting in other specified conditions	1,935	6.9	Costs (R\$)	523	571	87	365	12,238
				Length of stay (days)	13	14	0	8	117
B24.0	Unspecified HIV disease	7,159	25.4	Costs (R\$)	936	816	27	667	12,984
				Length of stay (days)	19	46	0	12	1,469
J70.9	Respiratory conditions due to unspecified external agent	75	0.3	Costs (R\$)	1,150	1,551	272	582	9,167
				Length of stay (days)	16	19	1	9	99

This Table includes only diagnoses reported in at least 30 hospital admissions covered by SUS in 2004.

laxis and treatment. This practice follows current internationally recommended evidence-based clinical guidelines and these recommendations are periodically updated and disseminated nationwide.*

The positive impact of a comprehensive health care program to those living with HIV/AIDS in Brazil is patent. Studies reported significantly improved survival rates of those living with HIV/AIDS.^{8,12} On the other hand, where as the absolute rates of HIV/AIDS hospital admissions remained stable in the period between 1998 and 2004, the number of those receiving ARVs was significantly reduced, indicating an increase in patients on therapy, early diagnosis, higher survival rates and, ultimately, improved general health condition of these patient.

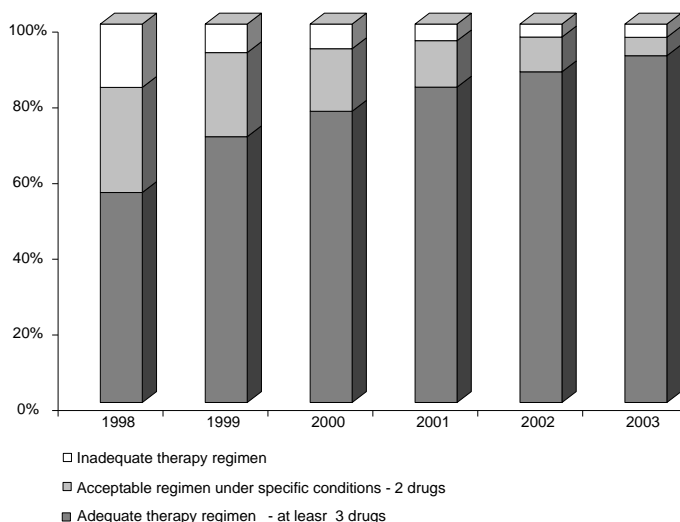
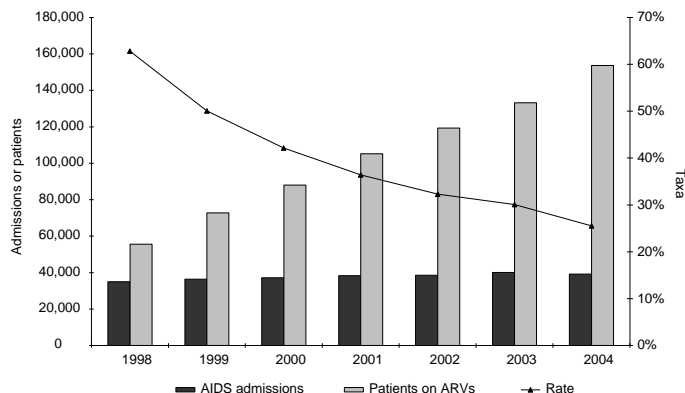


Figure 8 - Distribution of drug dispensing reported in the Drug Logistic Control System (SICLOM) by therapy regimens. Brazil, 1998-2003.



Source: Programa Nacional de DST/Aids e Datasus; Sistema de Monitoramento de Indicadores do Programa Nacional de DST/Aids - MONITORAIDS. Disponível em <http://www.aids.gov.br> [acesso em 1 mar 2006]

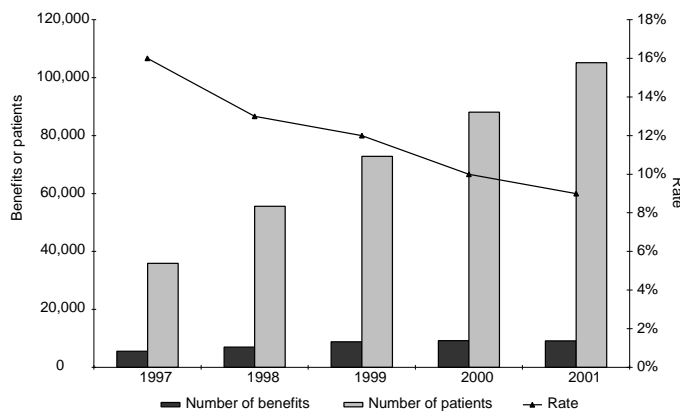
Figure 9 - AIDS hospital admission rates among patients receiving ARVs. Brazil, 1998-2004.

ment such program was essentially political, grounded on the perception of it as a human and legal right of Brazilian population, strongly supported by the joined action of the PN-DST/AIDS with local and state authorities and the organized civil society.^{2,7}

As for sustainable access to ARV therapy, the UN Declaration of Commitment on HIV/AIDS recognized the need for reducing ARV costs and the impact of free trade agreements on local essential drug manufacturing on the development of new drugs.

The Brazilian government has been making efforts to ensure sustainable universal access to ARVs now provided to around 170,000

Translating reduced hospital admission rates in economic terms is strongly appealing but this is prevented by the very low SUS coverage. Assuming in 2004 the same hospital admission rates of ARV patients as in 1998 and mean cost of R\$ 700 per admission, it can be roughly estimated that, in 2004, more than 57,000 admissions were prevented, a saving of approximately R\$ 40 million to SUS. It should be noted, however, that these figures do not provide a measurement of efficiency of ARV access program in Brazil, to be determined through a careful economic evaluation. Effectiveness data, translated into increased survival and quality of life, are much more compelling. Moreover, it should be emphasized, no demerit, the decision to imple-



Source: Ministério da Previdência, Programa Nacional de DST/Aids; Sistema de Monitoramento de Indicadores do Programa Nacional de DST/Aids - MONITORAIDS. Disponível em <http://www.aids.gov.br> [acesso em 1 mar 2006]

Figure 10 - Social security benefit rates to HIV/AIDS patients on ARVs. Brazil, 1997-2001.

*Programa Nacional de DST e Aids. Disponível em <http://www.aids.gov.br> [acesso em 20 abr 2006]

Table 3 - Relevant facts on universal free ARV Access Program to HIV/AIDS patients in Brazil.

Year	Relevant facts
1988	The new Brazilian Constitution creates the Unified National Health System (SUS) recognizing health care as a basic citizen right. The guiding SUS principles are: universal access, comprehensive care, social control and public financing.*
1991	The Brazilian government begins providing free zidovudine (AZT).
1995	Brazil starts to produce ARVs.
1996	Law establishing free provision of ARVs to those living with AIDS.** TRIPS Agreement.
2001	Brazil threatens to break ARV patents employing compulsory licensing, a provision established by the Brazilian Intellectual Property Law. ³ The World Trade Organization (WTO) accepts a claim from the United States questioning the compatibility of the Brazilian law on patents with TRIPS Agreement. The United Nations 57th Session of Human Rights Commission establishes access to drugs during pandemics as a basic human right. The United States withdraws its claim to WTO against Brazil. The United Nations 26 th Special Session of the General Assembly on HIV/AIDS is held. By the end of the year Brazil is already producing seven of 13 ARVs used in AIDS treatment.
2003	Decree facilitating import of generic drugs produced under compulsory licensing. ⁴
2004	Negotiations between the Brazilian government and multinational pharmaceutical companies.
2005	Bill establishing AIDS drugs as non-patentable.***

*Brasil. Lei nº 8.080, de 19 de setembro de 1990. Dispõe sobre as condições para a promoção, proteção e recuperação de saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências. Disponível em <http://www6.senado.gov.br/legislacao/ListaPublicacoes.action?id=134238> [acesso em 1 mar 2006]

**Brasil. Lei nº 9.313, de 13 de novembro de 1996. Dispõe sobre a distribuição gratuita de medicamentos aos portadores de HIV e doentes de AIDS. Disponível em <http://www6.senado.gov.br/legislacao/ListaPublicacoes.action?id=144779> [acesso em 1 mar 2006]

***Brasil. Comissão de Constituição e Justiça e de Redação. Projeto de Lei nº 22, de 2003. Altera a Lei nº 9.279, de 14 de maio de 1996 incluindo os medicamentos e respectivos processos de obtenção destinados à prevenção e ao tratamento da Síndrome da Imunodeficiência Adquirida - SIDA-AIDS, entre as invenções não-patenteáveis. Disponível em <http://www.camara.gov.br/sileg/integras/188522.htm> [acesso em 1 mar 2006]

people at an annual cost of about US\$450 million. This program comprises strategies of national manufacturing of non-patented drugs, negotiating prices with drug companies and playing a role internationally for changing regulations on intellectual property and access to drugs.* Between 1997 and 2004, there was a 4.6 time reduction in the mean ARV treatment cost, from US\$6,2 to 1,300.

However, since 2005, the declining cost trend has changed. The Brazilian Ministry of Health estimates significantly increasing mean treatment costs due to a proportional reduction of first line drug use, which are locally manufactured and have an average cost of about US\$600 per year per patient, and increased second line therapies, all imported and patent protected. ARV import currently accounts for 80% of government ARV budget and this situation tends to be aggravated if TRIPS (Trade-Related Aspects of Intellectual Property Rights) flexibilities will not be put into practice and compulsory licensing will not be granted.

An agreement signed by the Brazilian government and Abbott Laboratory by the end of 2005 further aggravates the current situation, setting Kaletra[®] price for the next six years and committing the Brazilian government not to apply for compulsory licensing of any ingredients of this drug. The annual drug cost of US\$1,380 per patient is too high, and even higher than US\$500 paid by other countries, such as South Africa. In short, while ARVs are freely provided, their costs are becoming

unsustainable and threatening the PN-DST/AIDS.

In addition, the generic AIDS drug program adopted by Brazil is based on strengthening public laboratories for allowing them to develop other drugs essential to public health. But uncoordination between national public drug manufacturers' efforts, development of new technologies and research promotion have aggravated in recent years despite considerable investments by the Ministry of Health on infrastructure and equipment. Consequently, combined to slow rigid administrative and legal bureaucratic bidding processes, in 2004 and 2005, there was ARV undersupplying, projects for new drug development were delayed, including those drugs associated at fixed doses, and the sustainability of the PN-DST/AIDS and quality of care provided to those living with HIV/AIDS were jeopardized.

In conclusion, International Trade Agreements are not compatible with public health needs of Southern hemisphere countries for research promotion, technological development, strengthening of national industries and universal free access to health services. In Brazil, in addition to the fact that there is no properly defined strategy for research and development, international laws have deterred reverse engineering for developing second line drugs and, hence, the national drug industry. Local governments have not taken any actions to guarantee compliance with Article 68 of the Industrial Property Law, which determines that drugs can be locally manufactured three

*Ministério da Saúde. A sustentabilidade do acesso universal a anti-retrovirais no Brasil. Disponível em <http://www.aids.gov.br/main.asp> [acesso em 14 nov 2005]

years after they have been registered.³ The government has not either applied TRIPS flexibilities favoring the local industry. All ARV cost negotiations conducted by the Ministry of Health with patent holder multinational drug companies produced lower price agreements. However, these agreements did not include provisions concerning technology transfer and voluntary licensing and thus have not been an actual encouragement to local public and private drug manufacturers. Brazil has actively been involved advocating that free trade agreements under negotiation should not include restrictive provisions concerning intellectual property, referring to TRIPS agreement and Doha Declaration as the highest commitment with intellectual property issues. Internationally, Brazil has also headed a so-called movement "Friends for Development," questioning the impact of patents on drug research and development and access to drugs in the World Intellectual Property Organization (WIPO). Brazilian and Argentine leader-

ship contend to prevent the implementation of patent agreements under negotiation as they would jeopardize the sovereignty of developing nations.

In 2003, the Brazilian government changed the legislation to allow generic drug imports under compulsory licensing nationwide⁴. In 2005, the Lower House passed a bill establishing all AIDS drugs as non-patentable therapies.* This bill is now under scrutiny in the Brazilian Senate for approval.

Efforts are expected to be made to overcome the difficulty created by the Bidding Law 8.666,⁵ which determines rotation of producers providing raw material to government laboratories and hinders the registry of drugs as generic. This is so despite adequate bioequivalence evaluations and proper local regulations for registry and control of locally manufactured drugs, including an actively involved National Agency of Health Surveillance (ANVISA).

REFERENCES

1. Barth-Jones DC, Cheng H, Kang LY, Kenya PR, Odera D, Mosqueira NR et al. Cost effectiveness and delivery study for future HIV vaccines. *AIDS*. 2005;19:W1-W6.
2. Berkman A, Garcia J, Munõz-Laboy M, Paiva V, Parker R. A critical analysis of the Brazilian response to HIV/AIDS: lessons learned for controlling and mitigating the epidemic in developing countries. *Am J Public Health*. 2005;95:1162-72.
3. Brasil. Lei da Propriedade Industrial nº 9.279, de 14 de maio de 1996. Regula direitos e obrigações relativos à propriedade industrial. Código Comercial. In: ALT Pinto, MCVS Windt, L Céspedes. 50ª ed. São Paulo: Saraiva; 2005. p. 757.
4. Brasil. Decreto nº 4.830, de 4 de setembro de 2003. Dá nova redação aos arts. 1º, 2º, 5º e 10º do Decreto nº 3.201, de 6 de outubro de 1999, que dispõe sobre a concessão, de ofício, de licença compulsória nos casos de emergência nacional e de interesse público de que trata o artigo 71 da Lei nº 9.279, de 14 de maio de 1996. Código Comercial. In: ALT Pinto, MCVS Windt, L Céspedes. 50ª ed. São Paulo: Saraiva; 2005. p. 757.
5. Brasil. Lei nº 8.666, de 21 de junho de 1993. Regulamenta o artigo 37, inciso XXI da Constituição Federal, institui normas para licitações e contratos da Administração Pública e dá outras providências. Constituição Federal, Coletânea de legislação administrativa. In: O Medauar, organizador. São Paulo: Revista dos Tribunais; 2002. p. 579.
6. Galvão J. Access to antiretroviral drugs in Brazil. *Lancet*. 2002;360:1862-5.
7. Galvão J. Brazil and access to HIV/AIDS drugs: a question of human rights and Public Health. *Am J Public Health*. 2005;95:1110-6.
8. Marins JRP, Jamal LF, Chen SY, Barros MB, Hudes ES, Barbosa AA et al. Dramatic improvement in survival among adult Brazilian AIDS patients. *AIDS*. 2003;17:1675-82.
9. Melchior R, Nemes MIB, Basso CR, Castanheira ERL, Alves MTSB, Buchalla CM et al. Evaluation of the organizational structure of HIV/AIDS outpatient care in Brazil. *Rev Saúde Pública*. 2006;40:1-9.
10. Nemes MIB, Castanheira ERL, Melchior R, Alves MTSB, Basso CR. Avaliação da qualidade da assistência no programa de Aids: questões para a investigação em serviços de saúde no Brasil. *Cad Saúde Pública*. 2004;20:S310-S21.
11. Organização Mundial de Saúde - OMS. In: Centro Colaborador da OMS para a Classificação de Doenças em Português, tradução. Classificação estatística internacional de doenças e problemas relacionados à saúde, décima revisão (CID-10). São Paulo: Editora da Universidade de São Paulo; 1999.
12. Saraceni V, Cruz MM, Lauria LM, Durovni B. Trends and characteristics of AIDS mortality in the Rio de Janeiro City after the introduction of highly active antiretroviral therapy. *BJID*. 2005;9:209-15.
13. United Nations. General Assembly. Declaration of commitment on HIV/AIDS. Disponível em <http://www.un.org/ga/aids/docs/aress262.pdf> [acesso em 1 mar 2006]

*Brasil. Comissão de Constituição e Justiça e de Redação. Projeto de Lei nº 22, de 2003. Altera a Lei nº 9.279, de 14 de maio de 1996 incluindo os medicamentos e respectivos processos de obtenção destinados à prevenção e ao tratamento da Síndrome da Imunodeficiência Adquirida - SIDA-AIDS, entre as invenções não-patenteáveis. Disponível em <http://www.camara.gov.br/sileg/integras/188522.htm> [acesso em 4 mar 2006]