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The Potential Demand for an HIV/AIDS Vaccine in Brazil

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Abstract

This study assesses the potential demand by the public sector for a preventive HIV/AIDS vaccine in Brazil and the costs of alternative strategies for a vaccination program. Brazil has a mature AIDS epidemic: the percent of the population living with HIV or AIDS (about 0.6 percent of adults) is not as high as in other severely affected developing countries, but infection rates in specific risk groups in the population are very high and HIV has spread beyond these groups into the general population of low-risk individuals.

Preventive HIV/AIDS vaccines are still in the testing stage. The characteristics of the first vaccines developed, in terms of their efficacy, duration of effectiveness, ease of administration, and price, are still unknown. But the potential benefits of such a vaccine in Brazil would be high. The study reviews the cost and impact of HIV/AIDS in Brazil, in terms of disease and economic burden, as a proxy for the benefits of an HIV/AIDS vaccine. The

epidemiology of AIDS and Brazil's experience with immunization coverage with other vaccines are used to assess the number of vaccines, delivery strategies, and possible costs of an HIV/AIDS immunization program in Brazil, assuming the availability of a 100 percent effective AIDS vaccine that lasts a lifetime under different pricing and dosing assumptions.

A low-cost, highly effective vaccine would likely be affordable to an upper-middle-income country like Brazil and yield large benefits from a policy of universal, publicly subsidized immunization. But if prices are higher and the impact less favorable, the costs and effects would have to be compared with other AIDS prevention programs or other health interventions. Both political and economic considerations will likely figure into public policy on HIV/AIDS vaccination, when such a vaccine is developed.

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Acronyms

AIDS Acquired immune deficiency syndrome

ARV Anti-retroviral

GDP Gross domestic product

HIV Human immunodeficiency virus

HAART Highly active anti-retroviral therapy

IAVI International AIDS Vaccine Initiative

IDU Intravenous drug user

LC Local currency

MSM Men who have sex with men

NGO Non-governmental organization

OI Opportunistic infections

PAHO Pan American Health Organization

PNI National Immunization Program

PPP Purchasing power parity

SINAN Sistema de Informação de Agravos de Notificação

STD Sexually transmitted disease

STI Sexually transmitted infection

SUS Sistema Único de Saúde

WAP Working age population

I. Introduction

The AIDS Vaccine Task Force of The World Bank has commissioned individual case studies of the potential demand and delivery strategies for an AIDS vaccine in developing countries, representing both low- and middle-income countries and different degrees of severity of the epidemic, and Brazil was included in this project. The objectives of the study were to assess the cost and impact of HIV/AIDS in terms of disease and economic burden, as a proxy for the benefits of prevention and of an AIDS vaccine, and the ability to pay of the public and private sector and individuals, as a proxy for their willingness to pay for an HIV/AIDS vaccine. These estimates and the AIDS vaccine R&D scenario should be the basis for a discussion about potential costs and benefits of alternative vaccination strategies and thus provide inputs for follow-up studies.

Although the availability of this vaccine as a marketing product is still years ahead, and by that time epidemiologic and social and political conditions may be different in these countries, this type of study is very useful to increase awareness and preparedness for when this happens. The study is based on existing data, research and policy documents, and the estimates used have been considered adequate by the National Aids Program. Vaccination strategies are referenced by studies developed in other countries, especially Thailand (Tangcharoensathien and others 2001), but take into account health and immunization policies and economic and social conditions in Brazil.

In this type of study, based on the interpretation of the existing elements to develop future scenarios, general concepts about health, society and science and technology in and for health contribute to the analysis on a specific subject, but often are not recognized as participating elements. We introduce in this first section some of the elements considered important as a context for our study. In the second section we present a synthesis of HIV/AIDS epidemiology in Brazil, and in the third a synthesis of health and AIDS expenditures in Brazil. The fourth section discusses alternative vaccination strategies based on epidemiological, economic and health policy estimates and includes the concluding remarks.

The identification and measurement of population health problems and diseases depends on the articulation of different disciplinary fields, concepts, and data. Among these fields, epidemiology occupies an important space, through the use of largely accepted and systematic technical procedures and analytical methodologies. But it does not in itself define which will be the health priorities in a given context, for other factors besides epidemiological magnitude and transcendence contribute to make priorities effectively so.

The AIDS epidemic worldwide is a clear example. On the one hand, never before have so many resources been used for one disease in such a relatively short time interval, with impressive scientific results and very positive impacts on the clinical treatment of the disease.

On the other hand, the African pandemic and the situation in several other countries, point out that from a population perspective epidemiological knowledge alone has not been powerful enough to guarantee that resources for health care (health care facilities and professionals, preventive, diagnostic and therapeutic procedures) are equitably distributed (Grassly and others 2001).

It is also significant to observe that the strongest investment, from an industrial point of view, has been in the development of new drugs, a very successful accomplishment by the pharmaceutical companies. Particularly in the last five years, many drugs have been marketed and combination drug therapies have succeeded in reducing AIDS mortality and HIV infectiveness and enhancing patient quality of life (Jordan and others 2002). For a decade, efforts for the development of a vaccine were very limited, and special movements like the creation of the International AIDS Vaccine Initiative (IAVI) were necessary to strengthen the vaccine agenda (Esparza 2001).

This is not very different from what has happened with other diseases. Vaccines have commonly been slower to develop and disseminate than drugs, and the involvement of the public sector is always essential (IAVI 2001; WHO-UNAIDS 2001; Makgoba, Solomon, and Tucker 2002). To provide access to an AIDS vaccine some commitments have to be made involving the public sector of rich and poor countries. As a first step, governments must be aware of the vital importance of such a vaccine and countries with higher income must recognize the urgency in controlling the AIDS pandemic and offer financial support. Their involvement should not be limited to the research and development of an efficient vaccine, but also with the implementation of an adequate delivery system. It is clear that in order to raise the levels of private research and development for an AIDS vaccine a combination of push strategies, to reduce the cost and scientific risk of investment for the companies, and pull strategies, to guarantee a market, will be necessary (Batson and Ainsworth 2001).

The development of safe and effective vaccines against HIV/AIDS faces several challenges. The ideal vaccine should stimulate the production of antibodies capable of neutralizing free viral particles and also the cellular immunity needed to destroy infected cells. Another challenge is that there is still a lack of understanding of which immune responses are necessary to confer protective immunity. In other words, there is no knowledge of the correlates of immunity that would be necessary to evaluate the response to an AIDS vaccine. Further complications include the fact that there is not an ideal animal model for HIV/AIDS. Additional challenges are that HIV has multiple subtypes and different infection routes. It is possible that several vaccines (or vaccine "cocktails") will be required to overcome these challenges.

In spite of the problems, there are some signs of optimism. Trials of vaccines for simian immunodeficiency virus (SIV) on monkeys have provided important information

about immune mechanisms. Studies about people who have been exposed to HIV and are resistant have also contributed to the understanding on human immunity to HIV. Besides that, the majority of currently used vaccines have been developed before the precise knowledge on the immune mechanisms and correlates were fully understood.

Vaccine research is a long process that begins with basic science to design immunogens or vaccine concepts, identification of correlates of immunity, and experimental trials in animal models. The next step is to translate basic research into candidate vaccines for evaluation in human volunteers. Vaccine trials in human volunteers involve three phases. Phase I and II trials provide data on the safety and immunogenicity of the product. Depending on the results, the candidate may be moved to Phase III trials, to obtain data on its efficacy.

Since the first human trial of an HIV 1 candidate vaccine was carried out in the United States in 1987, a great number of candidate products have been tested. Several approaches to the development of an HIV vaccine have been attempted. Initially the majority of the products focused the virus envelope proteins, which seemed obvious, once the envelope is the primary target to neutralizing antibodies. At least 13 different candidate products targeting gp 120 and gp 160 envelope proteins have been submitted to Phase I/II trials. They have been shown to be safe and immunogenic, having induced neutralizing antibodies in nearly all subjects, but failed to induce CD8+ cytotoxic T lymphocytes (CTL). In spite of the limits posed by low level neutralizing antibodies in providing protection from viral infection, one product developed using this approach has been moved to Phase III trials. The VaxGen bivalent preparation of gp 120 using one lab isolate (subtype B) and one primary isolate (subtype B or E) is currently being evaluated in trials in the United States and Thailand. Efficacy results are not yet available. Besides the recombinant proteins subunits, other approaches are also being attempted, such as DNA vaccines, poxvirus vector based vaccines and whole killed virus vaccines. A candidate product using the canarypox virus vector is currently being evaluated in a multicentric trial, which is being carried out also in Brazil (IAVI 2002; NIH 2000; HVTN 2001).

In summary, these results so far have shown that: (1) Several doses of the candidate products are necessary to induce antibody response; (2) short duration of antibody's titers; (3) it is not clear whether these products have any effect in stimulating cellular immunity; (4) antibody response is subtype specific, and (5) vaccine trials usually evaluate the candidate product combined with behavioral risk reduction interventions, whose effectiveness in HIV infection risk is variable, depending on the epidemiological context, making it difficult to separate the candidate product and the intervention effects; 6) to accelerate the development of an HIV vaccine, additional candidate vaccines must be evaluated in parallel in both industrialized and developing countries, and this requires international collaboration and facing critical ethical considerations (Esparza and Bhamarapravati 2000; Esparza 2001). At

this stage, these important scientific uncertainties contribute to the fact that most pharmaceutical companies consider the development of an AIDS vaccine to be risky and expensive, and no reasonably valid cost estimates are available.

To make this vaccine available for the rest of the world high-income countries will have to adopt special price policies and lower-income countries must be aware of their responsibility in creating the conditions for an effective and efficient allocation of resources, while joining the global efforts for the development of a vaccine (Collins and Morin 2001). Besides epidemiology, diverse conditions of income, educational level, culture and access to the health system determine the specific strategies that will maximize vaccine impact.

The social construction of demands in health care are complex processes involving scientific knowledge, health practices, and social, economical and cultural dimensions, as has progressively been recognized by all those responsible for the definition and implementation of science and technology (S&T) and health policies. This implies considerable difficulties in health impact assessments, for they depend on adequate definition of possible impacts and ways of measuring them, on the quality of existing information, on advocacy capabilities of those responsible for implementing the policy under analysis, and on the present and future economic and political context (Parry and Stevens 2001; Buck, Eastwood, and Smith 1999; Bunker 2001; Chapman 2001).

II. HIV/AIDS Epidemiology in Brazil

The AIDS epidemic in Brazil constitutes a very special and vivid example of the complex articulation between epidemiological knowledge, public health policies and economic, social and political dimensions indicating that the discussion about the potential impact of an AIDS vaccine needs to take into account an ample range of elements.

Brazil, the largest country in Latin America, had a population of 166 million people in 1998. The working age population (WAP) between 15 and 64 years old, 108 million, represented 65 percent of the total population. With a relatively recent and intense urbanization process (81 percent of the population, ranging from 69 to 90 percent in the different regions, Census 2000), there is a significant concentration of the population in the more industrialized areas, the South and Southeast regions of the country.

The Brazilian gross domestic product (GDP) in 1998 was US\$ 4,673.69 per capita and US\$ 7,186.51 per WAP, and **Table** 1 presents the Brazilian 1998 GDP expressed also in Reais, the national currency, and in Purchasing Power Parity and the conversion factors. ¹

^{1.} Although American dollars are an international reference in substitution for local currencies (*Real* in Brazil, R\$), the purchasing power of American dollars is different in each country and also varies through the years (Summers and Heston 1991). Therefore, the GDP per capita of each country is better expressed in

Poverty did not decline during the nineties, and about 34 percent of the population was classified as below the poverty level at the end of the decade. Brazil continues to have one of the most unequal income distributions in the world. The 10 percent of the population with the highest income controlled 50 percent of the national income, while the 50 percent with the lowest income controlled only 10 percent of the national income (Brazil 2001).

Table 1. GDP per working age population - Brazil

Current	GDP	GDP	GDP
values	(billion)	per capita	per WAP
R\$ (LC)	900	5426.62	8344.25
US\$	775	4673.69	7186.51
I\$ (PPP)	1145	6907.56	10621.41
Total populat	ion		166
WAP - 15 to	64 years old		108
R\$ per US\$			1.16
R\$ per I\$			0.79
R\$/I\$ per			0.68
Cauragi Mari	d Book		

Source: World Bank.

According to The World Bank methodology,² which divides the economies in four categories: low-income, lower middle-income, upper middle-income and high-income, Brazil is classified as an upper middle-income economy. Other countries also classified as upper middle-income are Venezuela, Argentina, South Africa, Turkey and Poland.

One of the most important differences with other countries in this category is the educational level of the population, which improved in the last decade but is still lower than could be expected. Although in the year 2000, 95 percent of the children aged 7-14 years were

Purchasing Power Parity (PPP), also known as International dollars (I\$). Table 1 presents the Brazilian 1998 conversion factors: R\$ 1.16 per US\$, R\$ 0.79 per I\$ and R\$/I\$ 0.68 per R\$/US\$.

The Brazilian 1998 PPP per exchange rate (R\$/I\$ 0.68 per R\$/US\$) indicates that, in 1998, US\$ 68.00 could buy in Brazil the same basket of goods as US\$ 100.00 in the United States. In 1999, however, due to the Brazilian Real devaluation, US\$ 45.00 was enough to buy in Brazil the same basket of goods as US\$ 100.00 in the United States. The Brazilian 1999 conversion factors were R\$ 1.81 per US\$, R\$ 0.81 per I\$ and R\$/I\$ 0.45 per R\$/US\$ (World Bank 2001). Almost all domestic good prices in Brazil (non-tradable and even exportable goods) decreased in current US\$ from 1998 to 1999 due to the local currency devaluation (from R\$ 1.16 per US\$ in 1998 to R\$ 1.81 per US\$ in 1999). The variation of the Brazilian conversion factors explains why the Brazilian GDP per WAP decreased in current American dollars (from US\$ 7,186.51 in 1998 to US\$ 4,808.82 in 1999) at the same time that increased in current International dollars (from I\$ 10,621.41 in 1998 to I\$ 10,773.73 in 1999).

2. For an explanation about this method see: http://www.worldbank.org/data/databytopic/class.htm#Definitions of groups

attending school, only 78 percent of those aged 15-17 and 31 percent of those aged 18 to 25 did so. Tables 2 and 3 indicate the existing significant regional differences. Educational level is considered to be an important element in intervention policies for AIDS, as shown in preventive behavior and adherence to ARV therapy, and in immunization policies in general.

Table 2. Distribution of Brazilian adults 15 years and older by the highest level of schooling attained, by gender and region, 1998 (percent)

	Region						
Gender and schooling level	North	Northeast	Southeast	South	West	Total	
Men	100	100	100	100	100	100	
Elementary*	75	83	69	73	74	74	
High school	20	13	20	18	18	18	
College	5	4	10	8	8	8	
Women	100	100	100	100	100	100	
Elementary*	71	78	67	71	69	71	
High school	24	17	22	20	23	20	
College	5	5	11	9	8	9	

Source: FIBGE, 2000.
* illiterates included.

Table 3. Number of high school and college students in Brazil, by gender and region, 1998

(thousands)	Region						
	North	Northeast	Southeast	South	West	Total	
High school	417	1,457	3,595	1135	532	7,136	
Men	171	588	1,631	509	219	3,117	
Women	247	869	1,965	626	313	4,020	
College	87	356	1,281	488	185	2,398	
Men	40	138	590	204	77	1,048	
Women	48	219	692	284	108	1,350	

Source: FIBGE, 2000.

Macro level political will is essential for the development of effective and efficient HIV/AIDS policies. The perception by both government and civil society of the significance of an even wider AIDS dissemination can contribute to the political basis for an adequate distribution of resources. Brazil has been internationally recognized for its positive policies in AIDS treatment and prevention. Free distribution of AZT started, very slowly, in 1988, with drugs for treatment of some opportunistic infections. Anti-retroviral therapy was introduced in the public health services in 1991.

The strengthening of the democratic political system in the late eighties and beginning of the nineties made it possible for society to express a growing demand for political actions

concerning AIDS. In response to these social demands in 1990 a STI/AIDS National Program was created in the Ministry of Health, in order to centralize the decisions and policies involving AIDS prevention and treatment. This National Program was, and still is, financially supported not only by the Brazilian government, but by loans from international organizations, like the World Bank and Panamerican Health Organization.

In 1996, with the promulgation of a Federal Law³ the Brazilian government decided to supply all AIDS cases with the necessary treatment drugs, based on a medical consensus, and the budget expenses related to AIDS started to increase considerably. Just the expenditures for anti-retroviral drugs grew approximately 17 times (Brazil 1999b) between 1996 and 1999.

Brazil is considered to have reasonable to good quality health information, but of irregular distribution, with some regions still with very deficient health information systems, but existing information is easily accessible through several official databanks. The mortality information system has an increasing reliability and credibility and nowadays information from the state capitals, with a big share of the population, have an adequate standard, especially in the South and Southeast regions.

Hospital morbidity information is provided by the Autorizações de Internação Hospitalar information system which registers all hospitalizations financed by the public health care system, the Sistema Único de Saúde (SUS). Although essentially of an administrative and financial nature, it provides useful information about government funded hospitalizations and since most AIDS cases are treated in SUS hospitals, it constitutes a good information source for this study.

The information concerning the mandatory notification list of diseases is registered in the Sistema de Informação de Agravos de Notificação (SINAN), and includes AIDS. This information system is coordinated by the epidemiological surveillance system and can be considered a reasonably consolidated system, allowing the follow up of these diseases on a national level. One of the problems, and this affects AIDS notification very much, is the time it takes the local and regional authorities to clear the technical elements involved with correct notification, before registering the information in the SINAN. Although statistical methods have been developed to minimize this underestimation of recent numbers, data are more precise with two to three year interval (Luiz and Costa 2001), which is the reason why in this study we will be using 1998 as our year of reference. Data for more recent years seem to indicate a tendency for a decrease in AIDS incidence, but in this study it seems preferable to incur in overestimation rather than underestimation of the number of cases.

^{3.} Law n° 9313, 13/11/1996.

Besides these national health information systems, there are other systems, at both the federal and state levels, that give access to social and demographic information obtained in the Census and several other official surveys, which enable the identification of the social, political and economic situation of the Brazilian population.

The scientific community in Brazil has increased its volume of research and publications in the last decade, and in the health area particularly so. Epidemiological and public health investigations frequently articulate the universities with the public health sector, and the Ministry of Health and State Secretaries of Health contribute with the dissemination of these studies through their websites. The National AIDS Program has been especially active in the dissemination of research results concerning HTV/AIDS and sexually transmitted infections (STI).

Brazil's population health situation shows as its first cause of death the circulatory diseases (158/100,000), with cancer and external causes in second (68/100,000 and 72/100,000, respectively). Deaths from infectious diseases, dominated by diarrhea, which went down significantly in the 1970s and 1980s with the improvement of sanitary conditions, have now TB and AIDS as important causes. The specific death rate for AIDS was 6.65/100,000 in 1998 (IDB 2001: www.saude.gov.br).

In the period between 1987 and 1996 the pattern of AIDS changed from one concentrated in specific regions and social groups to a national scale affecting all social groups (Szwarcwald and others 2000a). In recent years the dissemination apparently slowed down, which may possibly be explained by the "exhaustion" of susceptibles, changes in population behavior and the introduction of ARV therapy on a large scale (PAHO 2001). This was partly due also to the widely disseminated official educational and preventive measures, through its coordinating centers, and the activities of non-governmental organizations, present all over the country, and with high capacity of action and intervention. Nevertheless, an important concentration of number of cases continues to be observed in the States of São Paulo and Rio de Janeiro, in the more developed Southeast region.

Recent publications point out a tendency of stabilization of the disease. While, in 1991, incidence was circa 8 cases for 100,000 inhabitants, it rose to 13,7 cases for 10⁵ in 1998 and fell to 11,2 for 10⁵ in 1999 (Teixeira and others 2001). **Table 4** shows the number of notified AIDS cases for the period between 1995–1998 for Brazil and its regions. There is a continuous growth of notifications in the period of 1995–1998, except for the southeast region, where in 1997 a declining tendency is already clear, and the west region, where new cases declined in 1998.

Table 4. Newly reported AIDS cases by year and region, Brazil 1995-1998

Region	1995	1996	1997	1998
North	362	435	501	519
Northeast	1,596	1,984	2,224	2,628
West	1,184	1,260	1,430	1,195
Southeast	14,112	15,618	15,251	14,572
South	3,103	3,646	4,139	5,101
Brazil	20,357	22,943	23,545	24,015

Source: Boletim Epidemiológico Aids 14(2), 2001.

Besides the dissemination on a national scale, AIDS cases changed their social-economic profile. While first affecting predominantly individuals from the middle and upper classes, in the 1990s the epidemic went through what has been called a pauperization process (Szwarcwald and others 2000b; Fonseca and others 2000; Parker and Camargo 2000) This has been partially explained by the increase of cases among intravenous drug users (IDU), by changes in the exposition and transmission categories and the substantial variation in knowledge about HIV infection according to educational level (Medeiros, Barbosa, and Aguiar 2001).

As for the exposure categories, described initially among men who have sex with men, and hemophiliacs, later on they expanded to other groups like IDU, and finally to heterosexuals, with a very important increase among women, and some other categories, like the so-called marginal or "forgotten" groups, prisoners, homeless, and ethnic minorities, among others. Heterosexual transmission in 1998 occurred in 42 percent of the cases, men who have sex with men (MSM) in 19 percent and IDU in 16 percent (3 percent perinatal, 20 percent unknown).

An estimated 155,590 AIDS cases had been diagnosed by the end of 1998, with about 50 percent still alive and about 80 percent of these were under treatment. New cases continue to be included. In recent years methodologies using sentinel surveillance have been introduced and the estimates of HIV infection prevalence have become more reliable. Adult (15-49) prevalence rates for 1999/2000 range from 0.57 percent (UNAIDS) to 0.65 percent (AIDS/STD NC/Ministry of Health), with men at 0.84 percent and women at 0.47 percent, with an estimated 550,000 infected adults alive at the end of 1999 (UNAIDS). HIV seroprevalence among antenatal attendees in 1998, part of the sentinel surveillance program, was less than 1 percent in five sites outside of the major urban sites and data for the regions range from 0.189 percent (North) and 0.149 percent (Northeast), to 0.555 percent for the South and Southeast regions (Szwarcwald and Castilho 2002).

In 1998 pregnancies an estimated 14,222 were HIV positive, with 1,943 infected newborns, indicating a transmission rate of 14 percent. In 18 percent of the infected pregnancies adequate therapeutic interventions occurred in 1998, and this number is estimated to have been 30 percent in 2000 (Szwarcwald, Barbosa, and Fonseca 2001).

The impact caused by the introduction of therapeutic measures, like the antiretrovirals in their different compositions and associations and/or health promotion and protection measures, though evident, has not been completely explored yet. Data published by Teixeira and others (2001) show that "the decline of AIDS-related deaths since 1995 coincides with the adoption of antiretroviral therapies and the free disposition of treatment for all AIDS cases". While in 1994-95 there was a 13.0 percent increase of deaths, between 1996-99 a decline of 31.5 percent has been observed. Impact on life expectancy, although estimated by international agencies at a 5.3 years loss in the years before treatment, were considered to be much less in a recent national study, and were estimated at 0.3 for Brazil, with a maximum of 0.7 to 0.8 for Rio de Janeiro and São Paulo (Gotlieb, Castilho, and Buchalla 2000).

Temporal trends in AIDS-associated opportunistic infections also indicate a significant decrease since 1995, including TB, especially for the higher educational level groups (Guimarães 2000). These data indicate an effectiveness of antiretroviral therapies, with an estimated 80 percent level of adherence to treatment in the State of São Paulo, probably the highest level in the country (Nemes 2000).

These results must be associated with prevention and promotion measures, like condom distribution program, educational programs and syringe distribution and exchange but the precise weight of each element for different social contexts still remains unknown. The long average incubation period between HIV infection and clinical AIDS disease constitutes an additional element in making impact analysis more difficult.

As for preventive behavior, the percentage of condom users in the first sexual intercourse increased 12 times between 1986 and 1999 (form 4 to 48 percent). Regular condom use among sexually active individuals increased substantially, in particular among the younger ages, and this has been a consistent finding in several different studies. Some recent studies seem to indicate that this relatively high condom use persists even with decreasing knowledge about the disease (Szwarcwald and others 2002).

Although incomplete, the existing numbers for the public and private distribution of condoms also indicate a growing utilization (UNAIDS 2002). Approximately 200 million male condoms were purchased in the year 2000 in order to supply projects, campaigns and public health services, and recently 2 million female condoms were made available for use in specific activities (Teixeira and others 2001).

Non-governmental organizations promoted contact with 31,000 intravenous drugs users between 1999-2000, organizing the exchange of more than 1,500,000 syringes. Despite the efforts of the National AIDS Program and NGOs, population coverage of IDU targeted interventions remains low (around 5 percent). A sharp decline in HIV prevalence has been observed in some major Brazilian cities in recent years among drug users, due to the increasing use of crack (Bastos, Telles, and Hacker 2001).

Brazil's efforts in implementing its priorities for HIV/AIDS control have been considered as very positive, although more successful in some areas than in others, but they have depended also, as all other health policies, on the availability of public resources, and even with an increasing fiscal burden, these have not been stable in the last decade (Ainsworth and Teokul 2000; Nandy and Scott 2000; Reis, Ribeiro, and Piola 2001).

III. Health and AIDS expenditures

Aids cases, income and private health expenditures

The 1988 Brazilian Constitution guarantees universal public health care for the population but the implementation of the public Sistema Único de Saúde (SUS) in the 1990s also allowed market segmentation and an expansion of private insurance coverage among wealthy people (Almeida 1998). Only 7 percent of the families with the lowest income per capita (Group 1) had private health insurance, and the coverage grows to 31.2 percent for Group 2, 63.1 percent for Group 3 and 83.2 percent for Group 4, with the highest income per capita (Table 5). Poor people in Brazil represent the largest part of the population and 76 percent of the Brazilian population does not have private health insurance coverage.

In 1998, 53 percent of the Brazilian population received up to the equivalent of the monthly minimum wage per capita (Group 1, **Table 5**). The annual family income for this group was I\$ 972.97 per capita and their family private health expenditure was only I\$ 81.46 per capita/year. For people in households earning nine or more times the minimum wages per capita (Group 4), the annual family income was I\$ 32,953.92 per capita and their family private health expenditure was I\$ 2,021.28 per capita/year.

Table 5. Income distribution and family private health expenditures in Brazil, 1998

		Groups of t	amily income	per capi <u>ta</u>	
	Group 1	Group 2	Group 3	Group 4	Total
	until 1mw*	+1 to 3mw*	+3 to 9mw*	+9mw*	
Population (%)	53	32	13	3	100
Income (%)	13	28	32	27	100
, ,					(Current I\$)
Annual income per capita	972.97	3,426.60	9,659.25	32,953.92	•
Annual expenditures per capita	81.46	287.40	778.94	2021.28	296.12
Health insurance	7.23	73.11	325.06	937.81	97.67
Physicians	3.96	11.91	27.34	75.40	11.69
Other health professionals	0.31	1.74	5.16	34.74	2.46
Medical exams	2.67	7.88	12.79	34.98	6.62
Drugs	52.63	131.84	232.79	415.62	111.95
Orthopedic/medical durables	0.11	0.89	2.72	7.66	0.92
Vision products	2.97	12.50	32.38	81.52	12.19
Dental services	5.38	31.39	100.17	309.56	35.21
Hospital care	3.54	10.90	24.53	87.00	11.16
Nursing home care	0.47	0.90	5.58	11.42	1.60
Others	2.19	4.34	10.43	25.56	4.65
% of population with private health	insurance 7	7 31	63	83	24

Source: Kilsztajn, Camara, and Carmo, 2001.

Brazil's statistical system collects the highest level of completed schooling of reported AIDS cases and this information can be used as a proxy for income (Ramos and Vieira 1996). The variation in the proportion of cases and the incident AIDS cases in all regions of the country for both genders indicate that the AIDS epidemic in Brazil started among social groups with a high education level and progressively disseminated to social groups with lower education levels (Bastos and Szwarcwald 2000).

Brazil registered 23,632 new AIDS cases in 1998 and 97 percent were 15 years or older. The school degree structure of AIDS cases (recorded for 81 percent of the new cases in 1998) is very similar to the total adult population of Brazil in 1998 (**Table 6**).

Table 6. Completed schooling of new AIDS cases compared with that of the adult population* in Brazil, 1998 (percent)

	Elementary**	High school	College	Total
New AIDS cases	74	18	8	100
Total Brazilian population	73	19	8	100

Source: Brazil. Ministry of Health, 2001b (AIDS); FIBGE, 2000 (population).

Considering the similarity of the schooling of adult AIDS cases with the Brazilian population and the correlation of schooling with income, family income and private health expenditures data from the 1998 Brazilian Household Sample Survey (FIBGE 2000) can be used to infer other characteristics of AIDS patients.

^{*}mw = monthly minimum wage per capita (R \$130.00 or US \$ 112.02 or I \$ 164.56).

^{*0} to 14 years old excluded; **illiterate included.

AIDS expenditures and economic loss

The introduction of highly active antiretroviral therapy (HAART) in 1996 decreased the frequency of opportunistic infections (OI) and prolonged life in AIDS patients, reducing social security costs in Brazil (Brazil 1999b). Expenditures with antiretroviral drugs (ARV), I\$ 382 million in 1998, represented 53 percent of the total public AIDS expenditures in Brazil (I\$ 727 million in 1998). Other public treatment expenditures, including OI drugs, laboratory tests for management of HIV infection and hospitalization, represented I\$ 127 million. Blood screening, laboratory tests for diagnosis of HIV infection, condoms and other preventive public expenditures were responsible for I\$ 157 million. Public expenditures (federal, 85 percent, state and municipal, 15 percent) for AIDS represented around 3 percent of the Ministry of Health budget in 1998 (around I\$ 24 billion).

Private AIDS expenditures in 1998 were estimated in I\$ 234 million, 63 percent for condoms. There is no available information about how much is spent on blood screening in the private sector, and no amount could be introduced in Table 6, but it may not be negligible, especially in those regions (South and Southeast) where the private health care system is stronger (covering up to 50 percent of the population, but leaving ARV treatment and other costly procedures – transplants, hemodialysis, etc., for the public sector).

National public and private AIDS expenditures reached I\$ 961 million in 1998 (**Table** 7), and were 28 percent higher than in 1997, even with a 1 percent budget reduction in the Ministry of Health. In recent years Brazil has been able to pay less than other countries for ARV drugs and is producing quite a few of them as generics, but new drugs are continuously being discovered and introduced in the therapeutic consensus. On the other hand, less is being spent on hospitalizations and OI treatment, and officials of the AIDS Program consider ARV treatment already cost-effective.

Nevertheless, the socioeconomic impact of the epidemic is very important. Considering that in 1998: (a) 95 percent of AIDS deaths occurred in the working age population (10,204 deaths); (b) the average age of those deaths was 36 years; and (c) the GDP per WAP was I\$ 10,621.41 - the total GDP loss to the country on account of AIDS premature death in 1998 was I\$ 3,035 million. This concept takes into account that the economic loss from AIDS deaths in a specific year will be distributed over 28 years (36-64) but the GDP of that year is already affected by AIDS deaths from previous years. Medici (1994), applying an alternative method, estimated the Brazilian annual economic loss in US\$ 2,700 million.

Table 7. AIDS expenditures and economic loss due to AIDS in Brazil, 1998 (Current values)

(Current values)						
AIDS expenditures	Public		Private		Total	
	(I\$ million)	(%)	(I\$ million)	(%)	(I\$ million)	(%)
Prevention	157	22	198	84	355	37
Blood screening	37	5	-	-	37	4
HIV tests	88	12	_	_	88	9
Condoms	7	1	147	63	154	16
Other	25	4	51	22	76	8
Treatment	509	70	36	16	545	57
ARV	382	53	-	-	382	40
Other	127	17	36	16	163	17
Institutional development	61	8	-	-	61	6
Total	727	100	234	100	[a] 961	100
AIDS economic loss						
AIDS deaths - 1998					10767 de	eaths
AIDS deaths 15 to 64 years	old - 1998 [b]				10204 de	eaths
Average age of AIDS deaths	5				36 year	s old
Average years to 64 per per	son [c]				28	years
GDP per WAP (I\$) [d]					1062	21.41
Economic loss per year (I\$ r	nillion) [e=b.c.c	1]				3035
AIDS expenditures and ecor	nomic loss (I\$ r	nillion)	[a+e]			3996
per capita (I\$)					2	24.10
% of GDP						0.35

Source: Brazil. Ministry of Health, 2000 (expenditures), 2001a (AIDS deaths); 2001e (distribution of laboratory tests between prevention and treatment); Table 1.

Together, AIDS expenditures (public and private) in 1998 and economic loss due to AIDS deaths in 1998 were responsible for I\$ 3,996 million (I\$ 24.10 per capita, 0.35 percent of the 1998 Brazilian GDP). Besides AIDS expenditures and economic loss, AIDS morbidity and mortality increase the social security costs and also cause other serious economic impacts, tangible and intangible, to family members. Increased life expectancy and less morbidity in treated AIDS patients may have an impact on these estimates in the next years, but are presently difficult to measure.

AIDS cost per patient/year

International AIDS cost comparison is very problematic due to differences in data quality, clinical records, responses to treatment, disease severity, use of public versus private services etc (Cameron 1992). It is also very difficult to compare AIDS cost per patient in

different countries and years without a purchasing power parity strictly designed for AIDS cost comparison (that takes into account the structure and prices of AIDS cost in different countries and time).

In many countries the same ARV drug and other AIDS related goods prices differ in American dollars as well as in International dollars. Also, the price of a specific drug can be reduced and new drugs introduced, and the total cost per patient can vary in different proportions or even directions in terms of local currency, American dollars or International dollars: ARV therapy in a particular country can decrease in constant US\$ while increasing in constant local currency (and the Ministry of Health budget is always enacted in local currency).

The first cost estimate for treating AIDS in Brazil was US\$ 16,689.00 per patient in 1989 (Medici and Beltrão 1992). For 1996, AIDS cost was estimated in US\$ 5,597.49 per patient/year: US\$ 2,786.71 for services and drugs (direct costs) and US\$ 2,810.78 related to the AIDS share of general hospital costs (FIPE 1998).

In 1998, there were 73,580 reported patients living with AIDS and 55,600 patients on ARV therapy (Table 8). The Brazilian public health system registered 34,940 AIDS hospitalizations in 1998, with an average of 18 days per hospitalization (Brazil 2001d), and very few AIDS patients are hospitalized outside the public health system.

Table 8. AIDS treatment expenditures per patient/year, Brazil, 1998

	ARV	Ol drugs L	aboratory tests	Hospital	Other	Total
Total (million)	382	35	9	34	85	545
(%)	70	6	2	6	16	100
Per patient living with AIDS						
(average: 73,580 patients)	5,195.64	475.82	122.27	460.55	1,159.28	7,413.54
Per patient on ARV therapy						
(average: 55,600 patients)	6,875.81	629.69	161.80	609.48	1,534.16	9,810.95

2001c (on ARV therapy).

According to Table 8, the total public and private AIDS expenditures with treatment was I\$ 545 million in 1998. ARV therapy corresponds to 70 percent of the total expenditures with treatment, I\$ 5,195.64 per patient living with AIDS and I\$ 6,875.81 per patient on ARV therapy. The estimate per patient on ARV therapy is consistent with the recent National AIDS Drug Policy value, US\$ 4,860.00 (I\$ 7,139.38) in 1998 (Brazil 2001c).

OI drugs, laboratory tests for management of HIV infection, hospital and other treatments in 1998 were estimated, respectively, in I\$ 629.69, I\$ 161.80, I\$ 609.48 and I\$ 1,534.16 per patient on ARV therapy. Total AIDS treatment expenditures in 1998 were I\$ 7,413.54 per patient living with AIDS and I\$ 9,810.95 per patient on ARV therapy.

Good quality cost-effectiveness studies of HIV/AIDS interventions are rare in Brazil (as in most developing countries) (Creese and others 2002) and there are no available data to be used in this study.

IV. Vaccination strategies for an HIV/AIDS vaccine

To develop vaccination strategy scenarios, information about HIV prevalence and incidence in the adult population and for specific high risk social groups, the utilization of preventive measures (condom use in particular) for these same groups, STI prevalence and estimates of infectivity in treated AIDS patients constitute the nuclear epidemiologic information (Barbosa and Struchiner 2002). With the utilization of mathematical models, these data, together with estimates of vaccine effectiveness, have shown that high-efficacy vaccines manage to impact on HIV prevalence, in spite increased risk behavior, but that tradeoffs increasingly get worse the more imperfect the vaccine (Massad 2001).

A recent World Bank paper, with data from Zimbabwe, Uganda and Thailand and computer simulation models, investigated the epidemiological impact of an HIV/AIDS vaccine, and indicated that even with a vaccine effectiveness as low as 50 percent it could be useful in controlling the epidemic, with high coverage (65 percent or more of the adults). If efforts to maintain safe sex behavior are not successful, behavioral reversals could eliminate most of the benefits of the vaccine. Vaccination programs targeted to high-risk groups would forcefully have better cost-effectiveness than vaccinating all adults, but total impact might be less and politically difficult to justify in countries with generalized epidemics (Stover and others 2002).

Immunization policies in Brazil and an HIV/AIDS vaccine: The National Immunization Program

The Brazilian version of the Expanded Program of Immunization, named Programa Nacional de Imunizações (PNI), was established in 1973. It gained public visibility with the poliomyelitis eradication campaigns, which began in 1980. Poliomyelitis transmission was interrupted in Brazil in 1989. Since then PNI has expanded itself, in the numbers of vaccine delivery sites, doses delivered, as well as with the incorporation of new vaccines targeted at different population groups.

Routine childhood vaccines include OPV, DTP, BCG, HIB, MMR and hepatitis B. Vaccine coverage for routine vaccines increased to more than 90 percent among one-year-old

children in recent years. Vaccine preventable disease incidence has decreased to record low levels among young children.

The vaccine delivery system includes more than 26,000 vaccination delivery sites (capable of administering all official vaccines) and a well established refrigeration network, with a national storage and distribution center located in Rio de Janeiro and 27 state centers, in each of Brazil's states. Vaccines are purchased centrally by the Ministry of Health and distributed to states and local health departments. In 2000, the budget for vaccine purchase was I\$ 296 million. In the same year 179 million vaccine doses were delivered.

Several initiatives are currently being undertaken to expand PNI beyond childhood vaccines. Yellow fever vaccination has been intensified especially in sylvatic yellow fever endemic areas, such as the Amazon region and Central-Western Brazil. More than 40 million people above 1 year of age were vaccinated since 1998. Since 1999 the country has begun national annual campaigns of influenza vaccination, targeting the over-60 age group, and the goal of vaccinating 70 percent of that age group was accomplished in 2000 and 2001. A national campaign to reduce the incidence of congenital rubella was also undertaken in 2001; its goal was to vaccinate 95 percent of non-pregnant women from 12 to 29 years of age. Preliminary figures point to a coverage of 92.7 percent, for a population of 15.3 million women. Although short of the goal, the numbers show the capacity of the PNI in mobilizing resources to vaccinate more than 14 million adults in one month. Vaccines are also administered in private clinics, and although there are no good numbers to estimate their participation in the national immunization coverage, it is considered to be small and restricted to larger cities.

Brazil also has three large vaccine research and development institutes and production plants, Instituto Butantan, in São Paulo, FIOCRUZ, in Rio de Janeiro, and TECPAR, in Curitiba. Their production accounts for a large share of the country's vaccines' needs. In 2001, their production reached 193 million vaccine doses. They are modernizing their facilities and are also participating with foreign pharmaceutical industries in programs of technological transfer for the production of newly introduced vaccines, such as HIB and influenza (Brazil 2002).

Epidemiological and policy estimates for potential target groups

The estimates by this study of the size of potential target groups for HIV/AIDS vaccination in Brazil by relative riskiness of behavior and accessibility (**Table 9**), are based on several large studies supported by the National AIDS Program. They can be found at the site www.aids.gov.br/final/biblioteca and are referred at the end of the text. References and explanations of the calculations are in Annexes 1a and 1b.

Table 9. Classification of potential target groups for vaccination by relative riskiness of behavior and ease of access

Group	HIV	Beh	avior	IInfections prevented		Relative	How group
(and partners)	prevalence	Partners	Condom	With con-	Without	access	reached
	а	b	С	doms d*	e=(ab)+a	************	
1 Sex workers	0.1300	2401.00		31.434	312.260	low	health services
(customer)		2400.00	0.90				NGO
(regular sex)		1.00	0.20				associations
2 IDU	0.1500	64.00		7.890	9.750	low	health services
(needle share)		42.00					NGO
(casual sex)		20.00	0.60				
(regular sex)		2.00	0.20				
3 Prisoners	0.1500	13.30		1.575	2.145	high	prisons
(needle share)		6.30					
(casual sex)		6.00	0.60				
(regular sex)		1.00	0.20				
4 MSM	0.1000	126.00		1.540	12.700	low	health services
(casual sex)		120.00	0.90				NGO
(regular sex)		6.00	0.60				
5 STI: men	0.0465	61.00		1.195	2.883	low	health services
(casual sex)		60.00	0.60				
(regular sex)		1.00	0.30				
6 Transport workers	0.0130	21.40		0.116	0.291	medium	associations
(casual sex)		20.00	0.66				road facilities
(regular sex)		1.40	0.20				
7 STI: women	0.0225	3.00		0.056	0.090	łow	health services
(casual sex)		2.00	0.60				
(regular sex)		1.00	0.30				
8 Military	0.0084	2.77	0.34	0.024	0.032	high	army facilities
9 Police	0.0084	1.49	0.34	0.017	0.021	high	police facilities
10 Health workers	0.0065	1.30	0.35	0.012	0.015	high	health services
11 Pregnant women	0.0047	1.22	0.35	800.0	0.010	high	health services
12 HS and univ.students	0.0013	3.00	0.48	0.003	0.005	high	schools
13 Conscripts	0.0013	2.77	0.48	0.003	0.005	high	army facilities
1 Men: 15-49	0.0084	1.49	0.34	0.017	0.021	medium	health services
2 Women: 15-49	0.0047	1.22	0.35	0.008	0.010	medium	health services

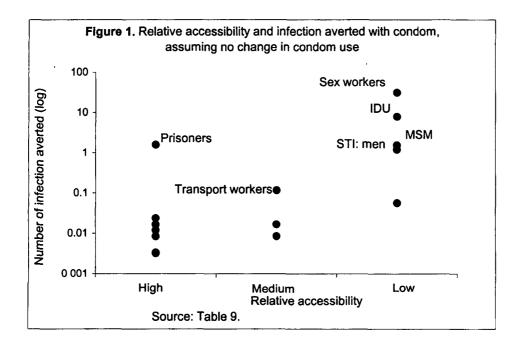
Source: See table 12.

HIV prevalence data for specific population groups, such as MSM, IDU, prisoners, commercial sex workers and transport workers were estimated from several surveys and epidemiological studies. The HIV national sentinel survey network routinely collects prevalence data in specific groups (pregnant women, military conscripts, newborns and STI patients). Sentinel surveillance data for pregnant women and conscripts have been used by the National STI/AIDS Program to estimate HIV prevalence in the general population. In the present study these data were used as prevalence estimates for the military, police and health workers, once it was assumed that in the Brazilian context these groups are not exposed to different risks than the general adult population. Data on specific risk behaviors were also collected from published surveys, from estimates of the National STI/AIDS Program, and by direct information form professionals working on STI/AIDS prevention initiatives aimed at specific groups.

^{*} d=(ab_i(1-c_i))+a, where i is the group or sub-group (e.g., client of sex workers).

The potential target groups included in Table 9 can be grouped in three categories: those at high risk, due to relative riskiness of behavior, and low accessibility (1-7); those with high accessibility, due to institutional access, and at medium to lower risk (8-13); and the sexually active population (15-49), with a potential although lower risk for HIV/AIDS, and medium accessibility. These groups are plotted according to their ease of access and the number of infections averted by an AIDS vaccine in **Figure 1**.

The number of infections caused by each member of these groups (for as long as they belong to them), assuming no change in condom utilization, that would be prevented with a 100 percent effective vaccine (100 percent efficacy and coverage), go from a maximum of 31 for sex workers to 0.003 for conscripts. If vaccine recipients discontinue condom use, then the number of infections prevented by a vaccine would be even higher.



Relative accessibility to the potential target groups was classified in three large categories, high, medium and low. Sex workers, IDU, MSM and STI men and women were considered to be of low accessibility. These assumptions were based on existing information in the National AIDS Program and personal communications of professionals working with these groups. As indicated before in this text, population coverage of IDU targeted interventions is low. Although there is over-the-counter syringe availability in pharmacies, they are too expensive for most IDUs, and pharmacies (to be found in expanding numbers in most cities) are not allowed to sell vaccines by the health authorities.

We considered MSM of low accessibility for although a considerable number participate actively in NGOs with strong media and political presence, this is true only in the bigger cities in the Southeast and South. In other regions of the country homosexuality and bisexuality is still stigmatized and strategies that imply exposure would be difficult to implement.

STI patients were considered of low access because a large number of them are poor and cared for in the public health system. The public sector STI treatment is known to be relatively ineffective and has low coverage of poor adults. In these low accessibility groups some double counting certainly occurs, but this has not been contemplated in our calculations.

Immunization policies depend almost exclusively on the public sector and immunization sites are almost always based in community health services. Routine immunization (on a daily basis) is practiced almost exclusively in these health services. Mass campaigns include some other sites, but they distinguish themselves mainly by happening on special "national vaccination days", always Saturdays. The other sites mentioned as places where specific groups can be reached are self-evident.

Table 10 shows the number of vaccinations required for "catch up" and "maintenance" vaccination for the potential target groups. "Catch up" means the total population in each group at the time the vaccine is first introduced, and "maintenance" is the number of new individuals estimated to be added annually in each group. Maintenance estimates vary according to "turnover" characteristics in each group. For example, we considered pregnant women as having a 100 percent maintenance size (in relation to catch up), which implies considering that each year all pregnancies are first-pregnancies. This is of course not true but plausible enough to be used in this scenario, when we take into consideration the fast lowering Brazilian mean fertility rate. We also assume that men and women with STIs have a 100 percent maintenance size in relation to catch-up. We estimated 3 million new students joining each year high school and university, in accordance with existing data. After some years of immunization this number should be smaller, as all students entering university would have already been vaccinated.

⁴ The number of male and female STI clients are the number officially reported. However, as STIs are not subject to mandatory reporting in Brazil, these are likely underestimates. There is very little information on which to base assumptions on the size of the 'maintenance' group of STI patients relative to 'catch-up' size for a potential AIDS vaccine, and the estimates below on the costs of alternative strategies are quite sensitive to these assumptions. Better estimates of the extent of repeat STI clients would improve the reliability of estimates of the costs of alternative vaccination strategies.

Table 10. Size of population groups for catch-up and maintenance vaccination programs and HIV incidence

Group	Size	HIV		
•	Catch up	Maintenance	(b/a)	incidence
	а	b	(%)	
1 Sex workers	354	6	1.7	0.01000
2 IDU	800	13	1.6	0.01000
3 Prisoners	234	20	8.5	0.01000
4 MSM	3040	50	1.6	0.00500
5 STI: men	3930	3930	100.0	
6 Transport workers	700	35	5.0	0.00025
7 STI: women	4800	4800	100.0	
8 Military	150	6	4.0	0.00025
9 Police	473	30	6.3	0.00025
10 Health workers	600	27	4.5	0.00019
11 Pregnant women	3500	3500	100.0	0.00017
12 HS and univ.students	9543	3000	31.4	0.00025
13 Conscripts	800	800	100.0	0.00025
1 Men: 15-49	45534	1750	3.8	0.00025
2 Women: 15-49	46955	1750	3.7	0.00017

Source: See table 12.

Incidence estimates were obtained from existing research in specific and smaller contexts and expanded to the population group as a whole (Bastos, Telles, and Hacker 2001; Medeiros, Barbosa, and Aguiar 2001; Szwarcwald and others 1998 and 2000).

Table 11 presents the budget requirements in international dollars (I \$) for two vaccines, one costing closer to what most vaccines cost today (I \$1), and the other with a maximum affordable price for governments (I \$10), even in developed countries (Bishai, Lin, and Kiyonga 2000). We introduced in our estimates a delivery cost ranging from 0.20 to 0.40 of the vaccine cost taking into account the increase in delivery cost with lower accessibility.

These price estimates, and the decision to consider the number of doses to be bought as at least equal to the size of the population are conservative. Depending on the technical characteristics of the vaccine and campaign strategy, quite frequently immunization officials buy up to 20 percent more doses than the population size, even when desired coverage is 90 percent.

When comparing costs for different groups it is important to consider both catch up and maintenance costs, for some groups are smaller but have high maintenance numbers (STI, pregnant women) and others are large but have low maintenance numbers (men and women 15-49), and total costs after some years are a better measure for comparison.

Table 11. Budget requirement in \$I

Group	Delivery	Catch-up (\$I 1000.00)		Annual maintenance (\$I 1000 00)					
·	cost per	Vaccine: \$I 1.00 Vacc		Vaccine:	ne: \$I 10.00	Vaccine: \$I 1.00		Vaccine: \$I 10.00	
		1 dose	2 doses	1 dose	2 doses	1 dose	2 doses	1 dose	2 doses
1 Sex workers	0.40	496	991	3682	7363	8	17	62	125
2 IDU	0.40	1120	2240	8320	16640	18	36	135	270
3 Prisoners	0.20	281	562	2387	4774	24	48	204	408
4 MSM	0.40	4256	8512	31616	63232	70	140	520	1040
5 STI: men	0.40	5502	11004	40872	81744	5502	11004	40872	81744
6 Transport workers	0.30	910	1820	7210	14420	46	91	361	721
Total: 6 groups		12564	25129	94086	188173	5668	11336	42154	84308
7 STI: women	0.40	6720	13440	49920	99840	6720	13440	49920	99840
8 Military	0.20	180	360	1530	3060	7	14	61	122
9 Police	0.20	568	1135	4825	9649	36	72	306	612
10 Health workers	0.20	720	1440	6120	12240	32	65	275	551
11 Pregnant women	0.20	4200	8400	35700	71400	4200	8400	35700	71400
12 HS and univ.students	0.20	11452	22903	97339	194677	3600	7200	30600	61200
13 Conscripts	0.20	960	1920	8160	16320	960	1920	8160	16320
Total: 13 groups		37364	74727	297680	595359	21224	42447	167177	334353
1 Men: 15-49	0.30	59195	118389	469004	938008	2275	4550	18025	36050
2 Women: 15-49	0.30	61042	122084	483640	967279	2275	4550	18025	36050
Total population. 15-49		120237	240473	952644	1905288	4550	9100	36050	72100

Source: See table 12

In this study we considered this vaccine with a 100 percent efficacy and coverage and life time duration, calculating costs only for one or two doses, those necessary to achieve these conditions. This is not realistic at all, when comparing with existing vaccines and especially when taking into account the present probability that an AIDS vaccine will be able to achieve this (Kribs-Zaleta and Velasco-Hernández, 2000), but we considered this exercise a good starting point for these values represent the minimum cost of these vaccination strategies to achieve maximum impact.

With lower efficacy and coverage, potential changes in preventive behavior have to be taken into account, for a sense of false security may eventually contribute to increased risk behavior, and result in an unfavorable cost-effectiveness ratio. A large national study with highly-active anti-retroviral therapy (HAART) patients is under way, which will be able to indicate if these patients have changed their preventive behavior but at this moment there is no good information available on this subject. To further deepen the analysis, and in order to arrive at results that take into consideration all necessary elements, computer mathematical modeling is essential. This was not contemplated in this study, but should be a next step.

Although intuitive, when calculating the cost of each infection prevented through vaccination, for two "extreme" potential target groups, sex workers and the total population, it

is possible to confirm that the cost of preventing an infection is much different, being more cost-effective for sex workers, and this argument is frequently used to recommend focused vaccination strategies.

Nevertheless, an economic rationale based only on epidemiological evidence frequently underestimates the real effectiveness obtained when vaccinating these groups with very low accessibility and does not take into account the very important political implications that exist when a potentially beneficial product is denied to the general population. Although HIV prevalence in low-risk groups in Brazil is lower than in other countries with mature AIDS epidemics, it has spread into the general population and there are important differentials by region, social status, and specific groups. Brazil, with a tradition of strong health and HIV/AIDS policy, would find it very difficult to implement a limited vaccination program.

Public health resources are already intensively used in AIDS treatment, and as the impact of the vaccination programs on reducing these costs would be on a long time frame, resources for vaccination would have to be "new money". Simple calculations with our numbers reveal that immunization of all adults 15-49 would cost, at the lowest price and two doses, I \$240 million (1/4 of annual public expenditures on AIDS) for catch up, and another I \$45 million for five-year maintenance, totaling I \$285 million. Immunization for all 13 target groups would cost I \$75 million for catch-up and I \$210 million for maintenance, for a total of I \$285 million PPP, the same amount.

Of course, this is the most favorable scenario, in all aspects, and represents an important but achievable financial investment for the country, indicating that a population immunization policy would be viable from an economic point of view also. If prices are higher and impact is less favorable opportunity costs considerations, and comparisons with other AIDS programs or other health problems, would influence prioritizing.

Although private payment would be possible for a small proportion of the population, it is very important to maintain this immunization policy a public policy, for in this way considerable health impacts in this area have been made possible and equity in access has been guaranteed. The Brazilian STI/AIDS Program in a document distributed at the AIDS Conference in Barcelona, July 2002, declared that "if an effective product is successfully developed, as expected, at prices compatible with the coverage needs for the control of the epidemic, the National HIV Vaccine Committee should participate actively in the debate on the availability of vaccines for the entire Brazilian population" (Brazil, Ministry of Health, STI/AIDS Program, 2002, pg. 29).

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Annex 1a. Sources of HIV incidence and prevalence (population and behavioral data by group)

Group	Data sources				
Group	Data sources				
Men who have	Harrison et al (1999); Kerr-Pontes and others (1999); Luna (1998)				
sex with men (MSM)	National STD/AIDS Program. 2000. "Bela Vista & Horizonte: estudos comportamentais e epidemiológicos entre homens que fazem sexo com homens", Ministry of Health, Brasília.				
	National STD/AIDS Program. 2002. "Comportamento Sexual da População Brasileira e Percepções HIV/Aids", www.aids.gov.br/final/biblioteca/avalia4/equipe.htm .				
Intravenous Drug	National STD/AIDS Program Home Page (www.aids.gov.br/final/udi.htm):				
Users (IDU)	Caiaffa and others (2001).				
	www.aids.gov.br/final/biblioteca/avalia8/equipe.htm: "Contribuição dos estudos multicêntricos frente à epidemia de HIV/AIDS entre UDI no Brasil"				
	Bastos, F.I. and M. Hacker. 2002. "Uma década de pesquisas sobre usuários de drogas injetáveis e HIV/aids no Rio de Janeiro".				
	Mesquita, F. et al. 2002. "AIDS entre usuários de drogas injetáveis na Região Metropolitana de Santos na década de noventa".				
Commercial sex workers (CSW)	National STD/AIDS Program Home Page (www.aids.gov.br/final/prevencao/p-sexo.htm) Luppi, C.G. and Campagnoli; personal communication, 2002				
Prisoners	National STD/AIDS Program Home Page (www.aids.gov.br/final/prevencao/presidios.htm) Marins (1997)				
Transport	National STD/AIDS Program Home Page, 2002				
workers	(www.aids.gov.br/final/prevencao/trabalho.htm)				
	Lacerda and others (1997)				
Armed forces &	National STD/AIDS Program Home Page, 2002				
police	(www.aids.gov.br/final/prevencao/armed.htm)				
	Szwarcwald and Castilho (2000); Szwarcwald and Carvalho (2001)				
Pregnant women	National STD/AIDS Program Home Page (www.aids.gov.br)				
	Szwarcwald and Castilho (2000); Szwarcwald and Carvalho (2001); Szwarcwald and others (2001)				
Newborns	National STD/AIDS Program Home Page (www.aids.gov.br)				
	Szwarcwald and Castilho (2000); Szwarcwald and Carvalho (2001); Szwarcwald and others (2001)				
STD patients	National STD/AIDS Program Home Page (www.aids.gov.br)				
(Men & Women)	"Comportamento Sexual da População Brasileira e Percepções HIV/Aids", 2002. www.aids.gov.br/final/biblioteca/avalia4/equipe.htm				
Health workers	National STD/AIDS Program Home Page (www.aids.gov.br)				
	Szwarcwald and Castilho (2000); Szwarcwald and Carvalho (2001)				
	"Comportamento Sexual da População Brasileira e Percepções HIV/Aids", 2002. www.aids.gov.br/final/biblioteca/avalia4/equipe.htm.				
High school &	National STD/AIDS Program Home Page (www.aids.gov.br)				
college students	Szwarcwald and Castilho (2000); Szwarcwald and Carvalho (2001)				
	Comportamento Sexual da População Brasileira e Percepções HIV/Aids. www.aids.gov.br/final/biblioteca/avalia4/equipe.htm, 2002				
	National STD/AIDS Program Home Page (www.aids.gov.br)				
49 (Men &	Szwarcwald and Castilho (2000); Szwarcwald and Carvalho (2001)				
Women)	Comportamento Sexual da População Brasileira e Percepções HIV/Aids. 2002. www.aids.gov.br/final/biblioteca/avalia4/equipe.htm.				
	Instituto Brasileiro de Geografia e Estatística – IBGE, Home page (www.ibge.gov.br)				

Annex 1b. Size, prevalence, and number of secondary infections prevented

(by selected groups, explanations)

Group	HIV prevalence	Lifetime secondary infections without condom h	Condom use rate c	Lifetime secondary infections with condom use d	Total infections prevented without condom e
Sex	0.1300	Customers: 2 cust/day X 20 days/month	Customers: 90%	31.434	312.260
workers		X 12 months X 5 ys = 2,400 + 1 regular partner = 2,401	Regular partner: 20%		
IDU	0.1500	Frequency of use = 10 days/month Duration of use = 10 ys Needle share = 70% No. new partners/ use = 0.05 (10 X 12 X 10 X 0.7 X 0.05) = 42 Sexual partners: Steady: 2 in 10 ys. Casual: 2 year X 10 = 20 Total. 42 + 20 + 2 = 64	Steady: 20% Casual [.] 60%	7 890	9.750
Prisoners	0.1500	IDU (70% of HIV positive prisoners) Mean prison time = 3 ys. Frequency of use: 5 days/month Needle share = 70% No. new partners/ use = 0.05 (3 X 5 X 12 X 0 7 X 0.05) = 6 3 Sexual partners: Steady: 1 Casual: 2/year X 3 = 6 Total: 6.3 + 1 + 6 3 = 13.3	Steady: 20% Casual: 60%	1.575	2.145
MSM	0.1000	Steady: 1/5 ys/30 ys = 6 Casual: 4/ year/30 ys = 120 Total: 126	Steady [·] 60% Casual: 90%	1.540	12.700
STD patients – men	0.0465	Steady: 1/life Casual: 2/year/ 30 years = 60 Total = 61	Steady. 30% Casual: 60%	1.195	2 883
Transport workers	0.0130	Steady: 1.4/ life Casual: 20/life Total: 21.4	Steady: 20% Casual: 66%	0 116	0.291
SDT patients women	0 0225	Steady: 1/ life Casual· 2/ life Total: 3	Steady: 30% Casual: 60%	0.056	0 090
Military	0.0084	2.77	34%	0.024	0.032
Police	0.0084	1.49	34%	0.017	0.021
Health workers	0.0065	30% male & 70% female 1.486 X 0 3 = 0.4458 1.221 X 0.7 = 0.8547 Total: 1.30	35%	0.012	0 015
Pregnant women	0.0047	1.22	35%	0.008	0.010
HS & college students	0 0013	3.00	48%	0.003	0.005
Conscripts	0.0013	2.77	48%	0.003	0 005
Men 15 – 49	0.0084	1.49	34%	0.017	0.021
Women 15 – 49	0.0047	1.22	35%	0.008	0.10

Note: $d = \Sigma$ ab (1 - c) + a, e = (ab) + a. Rationale of the model: Model used was developed by the Thai group working with the same subject. It considers that all sexual or intravenous drug partners would be infected by contact with the index case. So, column b represents the lifetime secondary infections when condom was not used (model does not take into account the probability of transmission per contact, therefore represents the maximum infectivity possible). Column c presents the estimates of condom use for each group. Columns d and e present the total number of infections that would be prevented with and without condoms.

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