





# Access to anti-retroviral therapy in high middle income Latin American countries



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Caribe



Joint United Nations Programme on HIV/AIDS

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## CONTENTS

Presentation

7

Overview

*José Antonio Izazola Licea*

*Jorge Huerdo*

13

AIDS in Argentina

*Laura Astarloa*

*Fernando Silva-Nieto*

*Benigno Velez*

*Eric Calcagno*

31

Anti-retroviral therapy and public health:

A balance of the brazilian experience

*José Luciano de Mattos Dias*

*Rosa Marques*

*Marcel Guedes Leite*

*Valdiléa G. Veloso*

*Marco Antônio D'Ávila Vitória*

75

The process of access to anti-retroviral therapy in Mexico

Case study

*Jorge Saavedra*

103



# PRESENTATION



Two decades after the discovery of the Human Immune Deficiency Virus (HIV), there is a better understanding of the virus' characteristics and more information on how to limit its negative effects on health. Although the undesired result of the disease, death, has not yet been eradicated, with the new anti-retroviral treatment combinations, the appearance of the characteristic symptoms of the Acquired Immune Deficiency Syndrome (AIDS) can be delayed and life can be prolonged for those who are afflicted with this disease.

In fact, after the celebration of the Eleventh International AIDS Conference in Vancouver, Canada, in 1996, the outlook for treatment of people living with HIV or AIDS improved enormously. Even so, the cheerfulness felt at said conference on hearing the auspicious news about the discovery of highly effective treatments consisting in the combined use of anti-retroviral medicines, including protease inhibitors, declined during the following international conference, celebrated in Geneva, Switzerland, because of the presentation of more austere, albeit optimistic results.

This is how the combined use of these anti-retrovirals has become the standard prescription for people living with HIV and AIDS.

Four years later there are still many people who argue against the use of anti-retrovirals because they do not cure the disease and are apt to cause side effects. The truth is that their adequate use benefits the great majority of those who need them and the noxious effects of medical treatments are hardly new to the field of Medicine. Moreover, with the continued use of these anti-retrovirals, AIDS could one day become a controllable chronic disease. New challenges are still ahead, among these, the correct adherence to these complicated treatment regimes, the emergence of ramifications that offer resistance to drugs when treatments are incorrectly followed by patients, and other exceptional cases. However, the scientific consensus is that these medicines should be prescribe in cases when people living with HIV and AIDS (according to their viral loads and CD4+ counts) are sure to adhere to treatments without interrupting them.

In Latin America and the Caribbean, where most countries have medium income economies, the acquisition and supply of anti-retrovirals could become an important financial issue for our respective health systems.

One of the objectives of the Regional AIDS Initiative for Latin America and the Caribbean (SIDALAC) is to support the development of research projects

within the region that provide information which may be of some use for HIV/AIDS prevention strategies and help improve medical attention for people afflicted with the disease, and contribute knowledge whereby decision-makers can develop effective actions in the control and fight against this disease.

On previous occasions, SIDALAC has published and distributed reports on diverse issues, among these a collection of studies regarding the impact of the HIV/AIDS epidemic on health systems, from both the epidemiological and economic perspectives.

Access to anti-retrovirals had already been considered one of the more complex challenges for health systems due to their elevated costs, even though they also increased the survival rates of people living with HIV and AIDS and improved the quality of life of these patients.

The limited amount of funds available for health, especially in an ambit where so many compete for these meager resources, and the existence of so many old and new health problems, whose treatments are more costly because of technological advances and recurring economic crisis, make any study regarding access to anti-retroviral medicines in medium income Latin American countries extremely interesting reading material. It would indicate what lessons this region has learned with regards to its fight against AIDS, and how to apply these lessons to other possible diseases.

It is a well-known fact that universal access to anti-retrovirals is extremely difficult and only a few countries, the most developed and a few that are not, provide it. Such is the case of some Latin American countries: Argentina, Brazil, Costa Rica and Uruguay. Others, even though they have a larger per capita income than some of the aforementioned countries, have not been able to establish this type of coverage. The high cost of these medicines is undoubtedly the main reason for these limitations. However, access to high-cost and complex medical technology in our region also depends on the type of health system in each country, their financing and service mechanisms—more or less efficient—, the types of subsidies they manage—for the supply and demand of services—, the priority of each government's social agenda, and their interaction with pressure groups.

The Joint United Nations Programme on HIV/AIDS (UNAIDS), SIDALAC as well as the Brazilian National STD/AIDS Program, the Argentine National Human Retrovirus and AIDS Program, and the National Council for the Prevention and Control of AIDS in Mexico, elaborated three case studies which attempt to describe, with great detail, the procedure for access to anti-retroviral medicines, both from the public health perspectives and from a political and economic analysis with regards to health.

At the beginning of this book, the editor provides, together with a close collaborator from an AIDS organization at community level, a holistic view which attempts to outline the main contributions of each of the three case studies contained in the following pages. Moreover, since these studies were based on government AIDS programs, they review and attempt to incorporate previous studies, as well as the regional and specific prospects of each country regarding access to anti-retrovirals.

Subsequently, and in alphabetical order, the book presents studies carried out in Argentina, Brazil and Mexico.

## PRESENTATION

With these studies, SIDALAC hopes to contribute certain elements that help plan more effective health policies in the fight against HIV/AIDS, by recognizing the specific characteristics of the epidemic in each subregion, and indeed in every Latin American and Caribbean country and, most of all, the characteristics of each country's health system and their response capabilities. Finally, these studies are being published in order to analyze the lessons learned from initial procedures regarding organized social response towards the supply of combined anti-retroviral treatments which, even though they may not be the best or most curative therapy, still offer enough positive aspects in their fight against the disease to decrease mortality and improve the survival rate of people afflicted with HIV and AIDS.

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## OVERVIEW

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Most Latin American and Caribbean countries are currently or have already carried out reforms within their health systems. The number of cases and severity of HIV/AIDS have caused a significant increase in the demand for extremely complex services, putting pressure on health systems, making the distinct public health programs compete among themselves for a limited amount of funds, which in turn has provoked social tensions. As in the case of other health programs, HIV programs also have limited resources, probably less than can be justified in view of the magnitude and tendencies of the problem. Although in many cases prevention is not always as effective as treatment, in the case of HIV, the virtual absence of a 100% effective treatment makes prevention an undeniable priority.

If HIV infection is transmitted among specific groups within each country, why are the programs not focused towards high-risk groups? There are many answers to this question. The main reasons are: first, identification and recognition of high-risk groups. Second, an unjustified amount of optimism in the campaigns directed towards the general population with regards to the modification of certain sexual behaviors. These specific programs are more complex than those directed towards the general population and the capacity to design and execute them is either non-existent or still in its early stages in many countries of the region. When the demand for health services is faced with a rigid and inefficient infrastructure that offers low quality health care, the tendency is to increase philanthropic services and create more non governmental organizations to add their efforts to the medical attention dispensed by publicly funded services. However, a new effort is presently underway wherein more cost-effective and humane health care alternatives are being offered. The evolution in the coverage, benefits, financing, supply and payment systems seem to adequate themselves or indeed favor health care for HIV+ people. (1)

There are many reasons to react with alarm to the HIV epidemic in Latin America and the Caribbean. Many of these reasons have been described eloquently and with great detail in scientific, technical and economic works. Despite a deeper understanding and better ways to control the disease, it is important to remember that it has also propagated exponentially. No society in the region has the necessary resources to attend to every health care need or requirement of its inhabitants. This is sometimes forgotten when proposals to control or treat diseases are formulated. For example, if countries in Latin America and the Caribbean tried to extend social

security benefits to the entire population, the percentage of their GDP destined to public spending for health would have to be twice what it is today. On the other hand, health is a moving target. The more knowledge we acquire about physio-pathology and therapeutics, the greater the gap between what we do and what can be done to prevent and cure diseases. The greater the population with health services and the more they are offered, the greater the absolute demand for medical and public health services. The relative lack of resources cannot always be solved with more funds, the solution is to establish priorities that constitute an intrinsic part of all health systems; each containing instruments that set priorities and in which implicit criteria are established. (2)

Currently, most decision-making regarding health priorities, is carried out according to the epidemiological condition of the population. These priorities have been established by health systems that require important governmental subsidies to cover their social and public health services, which normally protect individuals within the work force and their families. The health care services that benefit from these subsidies sometimes distract our attention from national priorities towards the needs of specific sectors. (3)

Decision-making based on available epidemiological information indicates that the pattern of HIV propagation in Latin America is similar to patterns in developed countries. It is most prevalent among men who have sexual relations with other men and drug addicts who share syringes. For example, in Mexico studies suggest that up to 30% of men who have sex with other men could be infected; as for drug addicts who consume intravenous drugs in Argentina and Brazil, the rate is closer to 50%, although transmission through sexual relations is still on the rise. The heterosexual propagation of HIV is especially prominent in the Caribbean. Prevalence rates of 8% have been observed in pregnant women in Haiti, as well as at a surveillance center in the Dominican Republic.

*Statistics and regional characteristics of HIV/AIDS  
December 1998 (4)*

Region	Adults and children with HIV/AIDS	Adults and children recently HIV infected	Prevalence among HIV+adults	Percentage of HIV positive adult males	Principals forms of transmission in adults with HIV/AIDS #
Latin America	1.4 million	160 thousand	0.57%	80%	HsH and CDI
The Caribbean	330 thousand	45 thousand	1.96%	65%	HsH and Hetero

+ Adults (15 to 49 years old) living with HIV/AIDS in 1998, based on population records for 1997.

# HsH (transmission between men who have sexual relations with other men). CDI (transmission through consumption of intravenous drugs)

As we have already mentioned, the present priorities with regards to health will never be completely satisfy the needs that are constantly arising. As soon as decisions regarding the setting of priorities are made, a new epidemiological profile is born which, in turn, makes it necessary to reevaluate priorities and carry out a new selection process; these priorities cannot be established in a vacuum, they need to coincide with public health needs. It is truly necessary to revise and change current priorities with regards to the efficient assignation of resources and equity. The priority that is implemented could truly have an important impact on the community. In this context, equity means a fair distribution of health resources among the different socioeconomic groups; moreover, the efficiency with which these resources are assigned will directly affect which solutions are selected and executed to help save lives and prevent further disabilities. (5)

The institutional and legal frameworks of health systems establish the limits within which priorities can be set and carried out, unless a radical reform is intended. The institutional organization and the legal basis on which it operates constitute limits for the setting of new priorities, in which factors that are hardly ever controlled by health researchers or decision-makers exert great influence.

Budget inertia happens because of high recurring operating expenses in hospitals and the way suppliers are paid, according to the retrospective costs and size of each hospital. Moreover there are dynamic factors that determine health priorities, such as the demand for health care and political pressures. (6)

With regards to HIV/AIDS, the need for hospital beds is decreasing in some countries of the region, due mainly to access to anti-retroviral treatments (ARVs) for those afflicted with HIV/AIDS (PHIV+). There are many good examples of health systems in Latin American and Caribbean countries responding and adapting themselves to the needs of HIV+ people, while maintaining their financial status. Health systems in countries such as Argentina, Brazil and Mexico have different organizations and structures, and therefore the supply of ARV treatments and care for HIV+ people also differ.

In *Argentina* there are three different types of services within the health system: *private or pre-paid*, with a monthly quota which, according to the law, gives those who are insured the right to 100% coverage of HIV treatment, including ARVs in all their combinations. *Social or union services* where a small percentage of the worker's salary is withheld and the employer pays another part. The resources are destined to support social activities in unions or professional groups. Therefore, all employees have access to a health service that by law is obliged to cover 100% of ARV treatment costs, analysis, prophylactic medicines and, in general, all that a person afflicted with HIV or AIDS needs, at no extra charge. The State subsidizes a part of each HIV+ person's treatment. Finally, *the public health system or hospitals*, which attend to those who have no private insurance or social security benefits or have no economic resources, and by law must provide ARVs through the National AIDS Program.

In *Argentina*, where national directives on modern treatments and health care exist, all HIV+ people have access to health care through the three types of health services and the respective treatments, including the triple combinations of protease

inhibitors, without having to pay out of pocket. In the social and private services, patients have access to combinations of up to four or more anti-retrovirals and, in fact, medicines can be imported before they are legally approved, when they are necessary to guarantee the well being of the patients. As for laboratory testing, there is complete access to CD4 counts, but those who depend on public services and hospitals have difficulties gaining access to viral charges due to the amount of paperwork and delays from a lack of reactivities.

In the country's principal cities there is an abundance of doctors who specialize in HIV/AIDS, in all private, social and especially public health services. However, the quality and quantity of health care decreases in places where demand is greater and in the provinces or towns farthest from the large urban centers. Both the social and private health systems include consultation services, information and psychological treatment; in some public centers, social services are quite good (especially in the larger cities). (7)

In *Brazil*, mostly due to the fact that its health system adopted universal coverage since 1996, through law number 9313 which establishes the right to complete health care for HIV+ people, its inhabitants have complete access to free integral health care, including ARV treatments. Nowadays, the larger cities in Brazil provide ARV treatments practically without any difficulties, including most of the commercially known drugs, although access to new treatments sometimes presents some problems. Prophylactic medicines are also available and all laboratory testing, including CD4 and viral charges. However, there are still some deficiencies regarding access in some regions of the country. (8)

In *Mexico*, the structure of the National Health System engenders differences between the wage earning and non-wage earning population. It offers various types of coverage: the "insured", who have access to the Mexican Social Security Institute (IMSS), which provides health services to workers employed by private companies within the formal economy. The Institute for Security and Social Services for State Workers (ISSSTE) offers the same services to government employees. And finally, there are special health services for the armed forces, navy and petroleum workers. The "non-insured", also called "open population", depend on the Health Ministry's (SSA) assistance programs and the IMSS-Solidarity System, as well as on health services from the Federal District and the DIF, municipal or state hospitals, university hospitals, the Red Cross and both civil and religious charity organizations. The private health market, for its part, has developed without strictly adhering to official policies. Private insurance, on the other hand, still has a relatively small portion of the market.

In order for a medicine to be supplied by a social security institution (IMSS or ISSSTE), it must first appear on the official list of the Health Sector's Basic Medicine Chart. In the case of ARVs, until April 1997, only AZT appeared on this list; nowadays, most of the other medicines have been approved.

The medical services of the Health Ministry collect fees from patients, called recuperation expenses, and these vary according to their socioeconomic level. These medical services provide limited amounts of medicines, which are sold at their

own pharmacies at a discount. However, no ARVs can be found among any of these medicines. Non-insured HIV+ people, are usually sent to second and third level care units of the SSA, to specialized AIDS centers such as CONASIDA or COESIDA, to doctors in private practice or to health care units established by NGOs. However, with the exception of those who have access to protocols, most HIV+ people do not receive ARV treatments from the Health Ministry and, when they are prescribed, patients must pay for them.

At the end of 1997, as an alternative to providing ARVs for the non-insured population, a trusteeship —FONSIDA— was established through a civil association. It was to use its initial budget to provide coverage solely for minors; this decision was based on the belief that it was necessary to make benefits available for 100% of a specific sector of the population. Subsequently, in 1998, this coverage was extended to pregnant women. (9) By the end of the second half of 1999, the Health Ministry announced that another change was to take place: additional coverage for one thousand youths and adults afflicted with HIV/AIDS. It is important to point out that due to the decentralization process of the federal government, each State of the Mexican Republic must match the value of these contributions, that is to say, such specialized health care and laboratory studies as may be required.

Country	Structure of the Health System	Access to ARV Treatment
Argentina	a) Private or pre-paid b) Social Security c) Public Health or Hospitals	100% (10)
Brazil	Universal	100%
Mexico	a) Social Security (insured) b) Open Population (non-insured)	50% Social Security (11) 50% Open Population (11)

The control of HIV/AIDS is still considered high priority in Latin American and Caribbean countries, because of the high rates of prevalence and mortality and the rising tendency of infection. Public financing, totally justified by its positive results, must preferably be concentrated on high-risk groups. There are several “red focuses” of infection in many countries of the region, such as Argentina, Brazil, Honduras and Mexico, that merit intensive and focalized control programs. Treatment for HIV+ people with public funds should concentrate on prevention and treatment of concurring infections such as tuberculosis and first try to insure universal coverage for basic treatment and then the use of ARVs.

Both governments and communities, spurred on by a sense of urgency, should face HIV/AIDS by pointing out the universality and indivisibility of human rights and HIV+ people. The fulfillment of the States’ obligations as to the peoples’ right to

non discrimination, health, information, education, employment, social well-being and public participation is of the utmost importance to reduce the vulnerability to HIV infection and insure health care and support for those directly and indirectly affected by HIV/AIDS. (12)

It is important to elaborate norms directed towards public and private sectors. Norms enable us to more effectively implement the principles of human rights and better reflect the uneasiness of the community. Moreover, norms can also be more practical and are more acceptable to those they are destined to help. If they are elaborated at community level, they are apt to be more accepted, put into practice and have more immediate effects than legislation.

Both norms and the promotion of human rights vis a vis HIV, are insufficient in the case of human rights abuses committed towards people living with HIV/AIDS. It is necessary to establish efficient procedures within the countries and their communities to watch over and apply human rights. In the case of governments, protection of those afflicted with HIV/AIDS should form part of their national obligations. It is important to inform people about the existence of surveillance centers, in particular organizations for HIV+ people, so that they can benefit from their use and results. Surveillance is necessary to collect information, formulate and analyze policies and determine which changes should be undertaken first and gauge the reference points in order to ascertain their rate of success. Surveillance should also study both positive and negative aspects: on the one hand it should disseminate legitimate practices, so that others have models they can imitate, and on the other, it should help uncover abuses. The non-governmental sector could be a means to monitor abuses of HIV+ people's human rights, if it has the necessary resources, since it is closer to the affected communities. The organisms that receive reports of human rights abuses may be too bureaucratic and their procedures may be too slow. Community members must be trained to analyze each specific circumstance and report any abuse with a level of competence that is acceptable to both the States and international organisms.

In the case of HIV/AIDS, the right to have access to scientific advances and their applications is of the utmost importance, given the rapid and constant advances in treatments, ARVs and analysis. However, developing countries have grave deficiencies that not only limit access to these scientific advances but also limit the availability of prophylactics and antibiotics to treat HIV related diseases. Moreover, certain less fortunate social groups have only limited or no access whatsoever to current ARV treatments.

When making general public health policies, the States should consider the possibility of providing treatments and medicines that will prolong the life of HIV+ people and allow them to live as normal a life as possible. International support is fundamental, both in the public and private sector, for inhabitants of developing countries affected by HIV to be able to receive medical attention, treatments and proper medication. The States may have to adopt special measures so that all social groups, especially those on the fringes of society, may equally enjoy the preventive care and treatment of HIV. The obligation of the States resides in stopping discrimination and

guaranteeing medical attention and services for the entire population, and making sure that people suffering from HIV are not discriminated against in health centers.

All people have the right to an adequate standard of living that insures food and clothing, housing, health care and the necessary social services. They also have the right to insurance when faced with the loss of their normal way of life or the ability to fend for themselves due to circumstances beyond their control. An adequate standard of living is imperative if people are to reduce their vulnerability to disease. It is particularly important to attend to the needs of HIV+ people and their families who have fallen into poverty because of an increase in illness due to AIDS, or discrimination caused by unemployment, which can bring about a loss of health coverage, housing or a sudden spiral into poverty. If the States give priority to these services when they assign resources, HIV+ people will be subjected to less discrimination, which denies them an adequate standard of living or the benefit of social security services and support because of their health.

This publication presents results regarding access to ARV therapies in Argentina, Brazil and Mexico. As we have already observed, these countries' health systems are structured differently and, at the same time, all three have made important efforts to provide ARV treatment for their HIV+ populations.

For this publication the efforts of National Programs and experts in the field have been taken into consideration; also the opinion of civil society with work on AIDS has been incorporated.<sup>1</sup> Notwithstanding many of these civil organizations have good relationships and great communication with the National Programs, this not necessarily indicates that they share the same opinions, which have been also taken into account in this book in view of the pressing need to bring together points of view between authorities and civil society in order to assemble the important works which both sectors are achieving on HIV/AIDS.

In a system such as the one in Argentina, the reaction from the AIDS epidemic increased demand for health services, especially in public hospitals. It was necessary to reassign the meager resources and there was a displacement of traditional pathologies. For the Argentine health system, it meant redefining its health care model, which is not centered on the established infrastructure but on the administration of medicines (a recurring expense). Since the public health sub sector is financed with a subsidy based on supply and the system has recurring variable expenses (at least in the short term), the reassignment of these resources is blocked, unless it shuts down services and redesigns the current infrastructure. Provincial and municipal governments are currently facing this type of situation. On the other hand, the norms that oblige each institutional authority to give coverage to their patients deflects demand from the public sector and allows each sub sector to share the expenses. This means that they are trying to find a more equitable way for the health system to function through the elimination of a crossover of subsidies from the public health sector to another sub sector.

With regards to the free distribution of medicines, it is necessary to concentrate on certain fundamental aspects:

1 Based on: Jorge Belloqui, Brazil; Javier Hourcade, Argentina; and Anuar Luna, México.

The political-institutional organization in Argentina needs the collaboration and integration of its actors, especially those within the health and national education sectors, its provinces and municipalities, to face the new social problems that are arising; fundamental designs that require a change in attitude on the part of each jurisdiction.

The Health Ministry's institutionalization of a technical commission, to constantly renew the variety of medicines needed to fight the AIDS epidemic, represents an important instance regarding the legitimization of its procedures. However, given the financial restrictions and the excessive demand for ARVs, there might be a need to establish specific treatment norms, in order to improve and increase the National Program's coverage.

The legal framework obliges the entire Argentine health sector to provide assistance to HIV+ people. In order to do this, it requires each sub sector to have access to information whereby the correct treatment of those affected with the disease can be verified.

There are no integral studies on the future impact of the disease that allow an evaluation of whether or not to sustain the free distribution policy of ARVs.

The new technologies for treatments that transform the disease into one that is chronic imply that HIV+ people under treatment become a recurring variable expense, barring new patients from being admitted into the system unless there is an increase of resources.

From the perspective of resources, and given that these policies are financed with funds from the general income, budget negotiations become permanent discussions. It is important to analyze and discuss mechanisms that permit access to resources that are specifically assigned to sustain certain policies without forgetting, however, that health is a public commodity.

The 6,650 HIV+ people currently being treated with ARVs from PNLRHYS (13) have gained as many life years as there are people being treated, since with the use of any other method, they would have faced certain death. This assistance adds an important restriction to the public budget, since the discontinuation of treatments would imply condemning HIV+ people who, for the first time, are finally able to undergo a treatment that addresses their specific problems.

The new ARV treatments depend on the administration of medicines that improve the quality of life and extend the life expectancy of those affected with the disease. The impact on the economy occurs either by forcing reassignment of the resources from productive sectors towards the health system or within the system itself, where financial allotments need to be redirected towards programs that fight against the AIDS epidemic. (14)

Distribution of ARVs in Brazil raises another problem, not unlike the one in Argentina. In Brazil, as in the case of all the other political and institutional policies, the survival of the program to distribute medicines, as it is currently formulated, depends on its capacity to remain within its budget. This sustainability is closely linked to its political and administrative legitimacy and the amount of lives it manages to save.

In a universal health system there is no turning back and the current dissemination of AIDS information also makes a less active posture by government less likely vis a vis public opinion. We must therefore analyze the legal-administrative framework, in which some risks are being observed. The projection of an increase in spending allows these risks to adopt a different meaning within the ambit of a more ample political negotiation with regards to the federal budget, in the Health Ministry and the National Congress.

Since the beginning of the nineties, the State reform movement in Brazil has insisted on the need, both for fiscal and social reasons, to continue with the transition of government activities from the economic sector to the social sector. Another important sign regarding AIDS is that the National Congress is showing an interest and open-mindedness with regards to this issue. It is also important to mention that in the political-institutional domain, the level of independence attained by the Judicial Power is another positive aspect, since the courts have been prone to accept the demands that force the State to provide ARVs.

If the restrictions of the Brazilian budget policies represent a real risk of a budget reduction for the ARV distribution program, the growing relevance of social spending within the public agenda, recognized by both the government and Congress, offers new possibilities for a mobilization to support the program. On the other hand, however, the recent public debate regarding Health Ministry spending has led to another issue: whether or not the latter is sufficiently efficient. Therefore, the legitimacy of the program revolves around the legal-administrative framework, in which a great many variables influence how the program is implemented.

NGO leaders believe in the importance of the National STD/AIDS Program's ability to defend the distribution of medicines from an economic point of view. (15) If the public debate focuses on economic issues, the Program could be compared to other social programs and expenditures. A renewed emphasis on prevention programs, followed by a constant evaluation of their efficiency, costs and benefits, could be an important complement to this defense, offering the possibility of a decline in future expenditures.

It will be necessary to maintain and expand strategies that allow the National Program to improve on and overcome the restrictions imposed by the organizational realities of public administration. One of the greatest risks to be avoided is an irregularity in the distribution of medicines, since the latter lessens the effectiveness of ARV treatments and compromises the government's activities at the final consumer or service levels. The National Program has followed two parallel courses of action: cooperation with the services of the sub national offices and a computer network. Distribution is mostly in the hands of the state and municipal services, where the organizational and salary problems are more sharply felt than in the federal ambit. The National Program has followed the indications contained within the World Bank agreement: centralize the planning of activities through the liberation of funds, offer training and equipment and supervise the implementation of said activities.

Moreover, The National Program has also invested in the modernization of the medicine distribution program's logistics, through the development of a national

patient registry and a complete computer network for the distribution process of medicines through SICLOM, a system centralized in Brasilia but operating in coordination with state administrators.

A final element of legitimacy has to come directly from those who are HIV+: constant adherence to treatment, crucial to the reduction of mortality as well as hospital and ambulatory costs, must be followed religiously. With regards to this aspect, the National Program has maintained its decision to continue to invest in training doctors and other health professionals. With the growing sophistication of ARV treatments, professionals who prescribe medications and monitor their results, must necessarily be kept up to date on the latest trends. Training must always be on a par with evaluation, in order for the concrete results to be measured and transformed into an instrument of legitimacy with regards to government activity. In this field, the non-governmental organizations also play an important role and must be encouraged to participate in the efforts to increase the conscience of HIV+ people regarding the social and medical importance of following ARV treatments to the letter.

According to an analysis of the legal-administrative framework, the National STD/AIDS Program should stress the importance of the execution and evaluation of prevention programs. The latter should be closely linked to the ARV distribution program, thereby establishing a clear and explicit commitment, from the political and administrative points of view, for the correct implementation of budget resources destined to the aforementioned program. It should also maintain and increase investments earmarked for personnel training, conserve the efficiency of the administration in the distribution of ARVs and ascertain their correct prescription. Moreover, it is the responsibility of the National Program to convince NGOs to continue to encourage HIV+ people to adhere to their treatments by supporting them with consultation services, psychological treatments and other activities. The pauperization of the population and rise in the epidemic's female casualties will no doubt require greater cooperation between the government and NGOs for the ARV distribution program to continue on the same successful path it has been traveling.

The Sao Paulo Program to Improve Information on Morbidity (PROAIM) indicates a 31% decrease of total mortality rates from AIDS in the first semester of 1997, compared to the same period in previous years. The reduction was 36% in men and 13% in women. Depending on the combination of ARVs being used, the annual survival costs of patients have been estimated by several authors. Moore, in 1996 (16) projected an additional cost of US\$10 thousand per year of life saved when the triple combination therapy was used together with a protease inhibitor. Meanwhile, the annual cost of life of a patient under hemodialysis treatment was US\$50 thousand, and the life of a heart surgery patient cost US\$113 thousand. (17)

Access to ARV medicines in Mexico has been gradual, although at the beginning these medicines (initially AZT) were available to those affected with HIV through research protocols and clinical testing at the different health institutions. The first to expose the need for these new ARVs in Mexico were specialists, pharmaceutical companies and some communications media. Although groups directly affected with HIV also began to mobilize in 1996, they only did so after the three aforemen-

tioned groups; in fact, they received help from some of them and from members of some NGOs who were working on AIDS research. The structure of the Mexican Health System automatically divides the population into those who have social security benefits and those who do not, and this structure determines whether or not ARVs will be available. It is evident that the Mexican pharmaceutical companies' main ARV consumer is the federal government, through its different health institutions.

Political intervention has been a means to pressure decision-makers, especially within the social security system, to accelerate the incorporation of ARVs into the prescription medicine catalogues. It is calculated that by April 1999, approximately 55% of those with HIV/AIDS who require ARV treatments will theoretically be have access to them. Nonetheless, this has not been the case with similar mechanisms that supposedly guarantee the expedient distribution of medicines, or the availability of laboratory testing and monitoring, such as CD4 tests and viral charges, at hospitals within the social security system. These failures provoke interruptions in the consumption of ARVs with the consequent risk that viruses will develop that are more resistant to these treatments. Some HIV+ people have indeed commented that "ARV treatments are available, but there are no specialists to prescribe them".

The impact of the epidemic has caused political leaders, intellectuals and journalists to take an interest in the subject and get involved in suggesting alternative solutions or make demands and even pressure the federal and state governments. In spite of these efforts, their influence has been very limited. In fact, no new mechanisms have been developed to cover the needs of the remaining 45% of the affected population, except for the establishment of FONSIDA, which has provided ARVs to people without social security benefits since 1998, first to children, then pregnant women and recently to one thousand adults.

It is clear that because of the high cost of ARVs within the private pharmaceutical market, access to them for most people could not occur without government intervention. A new US\$73.4 millions proposal, (18) contemplating integral projects that include access to laboratories, prophylactics and other medicines that fight opportunistic infections, as well as a joint project between the federal and state governments, and a 5% co-payment of the costs by HIV+ people have apparently not received a positive response to date.

A possible solution from the government seems to have already been offered by Mexico's own President, who, during a ceremony for the presentation of the Health Ministry's 1999 Health Program, declared his commitment to defend the rights of those afflicted with HIV in Mexico. Although it has not yet become clear what these rights are, they could be derived from the concept that "the right to health", "health as a social benefit"<sup>2</sup> or "public benefit" must be provided through public funds. However, it would be necessary to spend 200 times the minimum daily wage of the country where he or she lives in order for a HIV+ person to survive and remain productive, and there is evidently no existing micro-economic rationality at the family

<sup>2</sup> Suprema Corte de Justicia de la Nación. Resolución del amparo 2231/97.

level (19) for this phenomenon to ever occur. Moreover, it is unlikely that a young adult would willingly lay down and die without putting up quite a fight.

Civil society institutions working on the AIDS epidemic are convinced that a country with Mexico's level of development should be able to procure public resources to buy ARVs. However, it is also perfectly clear that hasty decisions, because of external pressures, could cause decision-makers to forget to include essential elements necessary for their policies to be effective. They might also forget to consider certain aspects that must be included in order to obtain an integral response, and therefore put the feasibility of the decisions or even the life of patients at risk.

Some specific programs and actions should be carried out before providing free ARV treatments. This has already been mentioned in at least two proposals. The first refers to a need to train medical personnel on how to correctly prescribe ARVs and the second refers to guaranteeing access to laboratory testing (CD4 and viral charges), which will help monitor the evolution of HIV+ people, as well as the probable development of resistance to some ARVs. The latter would indicate a need to change the therapy, thereby avoiding unnecessary spending when the prescribed ARVs are failing to benefit the quality of life of HIV+ people. Moreover, it is quite clear that in order for an ARV policy to be completely effective, it should also include consultation services and other forms of support that encourage those who are HIV+ to adhere to their treatments. Most of the ARV combinations they must take throughout the day, both before and after meals, are sometimes difficult to understand or manage, especially if they lack sufficient information and/or motivation. Therefore, within the need to guarantee a systematic supply of ARVs, as opposed to other medications that are usually provided by health institutions, decision-makers should take into consideration that ARVs have at least six characteristics that render them particularly delicate. From the human rights perspective: (1) The right to survive and to a reasonable life expectancy for a young adult. From a medical perspective: (1) They can transform a death sentence into a chronic management of the disease, (2) They must be taken for the rest of the patient's life, and (3) Their interruption can lead to a resistance to the drugs. From an economical point of view: (1) They are very expensive and if patients develop a resistance to them, it would mean spending public funds and not receiving any benefits in return. Finally, from a political viewpoint: (1) A lack of these medicines is as good a reason as any to organize protest marches against health officials, and these are usually very well covered by the news media.

Mexico, because of the characteristics of its health system, needs its distinct health institutions to share information from a common data base regarding the ARVs that are being provided to their patients through public funds, since this would help avoid duplicating coverage. Other parallel programs, not necessarily prerequisites to providing ARVs, but also of some importance, are those focused towards the sensitization of health personnel who are in contact with HIV+ people. The must be taught to respect human rights, to tolerate and accept different life-styles and sexual practices, especially considering which sector of the Mexican population is most affected by this epidemic.

In order to program the resources more efficiently, it is necessary to develop projects that improve the documentation of cases and epidemiological projections regarding the propagation of the epidemic, as well as studies to help demonstrate its impact on mortality. These studies must also be documented in order to improve the projections of the fate of those who have survived so far, and plan the previously mentioned actions and programs more efficiently. The information could also support other studies that are being carried out on the cost-effectiveness of ARVs in Mexico.

We must accept that laws or new rules and norms may be required in the future. Laws that guarantee the effective operation of any type of policy, such as the modernization of the Medical Guide or Health Care Standard, or even laws to finance ARVs, like those enacted in Brazil and Argentina. We must always document procedures regarding access to these medicines in order to detect errors or avoid them in the future. Any long-term policy related to the supply of ARVs, will not work if it is not accompanied by an increase in preventive actions. To ignore this fact will engender an unending cycle of spending. (20)

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## AIDS IN ARGENTINA\*

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## **The distribution of drugs as a strategy to combat HIV/AIDS in Argentina**

### **Introduction**

To discuss the economic and social context in Argentina in the perspective of treating AIDS and to do so within a limited framework of time and space means that a series of choices must be made of the issues to be covered and their development and analysis.

We have therefore decided to present in these pages some of the features which we feel it is important to understand in order to understand the policy of free provision of drugs. In the first part, we shall discuss the general economic context and its principal characteristics, and then present the AIDS situation in Argentina. In the second part, we shall examine the current legal framework which has given rise to the National Human Retrovirus, AIDS and STD Control Programme (PNLRHS) and the free provision of drugs. We shall then look at the scope and limitations of the system in operation.

### **The economic and social context**

#### *An economic situation characterized by substantive reforms*

In 1989, Argentina embarked on a process of structural change, with the aim of reversing the prevailing stagnation and stabilizing the economy.

This process, unprecedented both in its perspectives and its instrumentation, was focused on balancing public accounts, privatizing State enterprises, deregulation of economic activity and opening to the outside world. The Government's policies thus prioritized tax collection, the sale of public assets and the reduction of employment by the State. These measures, accompanied by the liberalization of trade and the Convertibility Act—establishing parity of the peso with the dollar, with a fixed exchange rate backed by genuine reserves—brought stability to prices and growth in the gross domestic product.

Thus the consumer price index rose by 3.8% in 1994, with the lowest rate of inflation recorded in the last 40 years. Economic growth showed a sustained

upswing with an average annual rate of growth of 7.9% (for the triennium 1991-1993) in the GDP.

Nevertheless, it was already evident that the benefits of expansion demanded greater emphasis on social policies, in order to secure greater coverage and better quality in the services provided to the needy sectors.

### *The economic situation in Argentina in the last three years*

In the triennium 1995-1997 the Argentine economy suffered a period of recession followed by a process of recovery, as will be seen in table 1. Roughly speaking, this period was characterized by maintenance of exchange rate and price stability, continuing inflow of capital and the persistence of unemployment. There was also a major development in economic policy as Mercosur began to function at the beginning of 1995.

In 1995 the gross domestic product fell by 4.6, breaking a four-year process of expansion. The first months of that year were characterized by disturbances in the financial markets accompanied by a contraction of credit, demand and levels of activity. Monetary management had to cope with problems of liquidity in the financial sector and at the same time maintain the convertibility regime. There was a deterioration in fiscal collection, resulting in a fiscal deficit financed by the issue of bonds. During the crisis exchange and price stability were maintained. In earlier years, the external sector had been characterized by a heavy deficit in the goods balance, which began to move into surplus in 1995 (the balance was -4 200 million dollars in 1994 and rose to 2 200 million dollars in 1995). The worst sign of the crisis was the increase in unemployment, which rose above past average levels of 7% to 11.4% in 1994 and 18.6% in 1995. One factor of outstanding importance was the entry into operation at the beginning of 1995 of the customs union of the Common Market of the South (Mercosur).

In March 1996 a series of economic and financial measures came into force, supported by substantial financing from the International Monetary Fund and other financial agencies, directed at the public sector, and in the second half of 1996 signs of reactivation began to appear. Over the year the GDP rose by 4.3% with a dynamic performance in investment, an increase in the value of exports and a recovery in the volume of imports. Flows of direct investment, which in the previous period had gone into the buying of State-owned enterprises, now resumed and as from 1996 turned to the acquisition of large national enterprises and investment in mining and farming. Stability of exchange rates and prices was maintained; the public sector cash account deficit fell to 2% of the GDP and the Government undertook some substantial financing operations.

In 1997 GDP a growth of about 7.5% is expected in the GDP, based above all on the dynamism of investment. The general lines of the trends originating in the mid-1996 recovery have continued. Price stability has been maintained and there has been a moderate increase in the fiscal deficit and the external trade balance for goods, with a large growth in imports (30% in the first six months). The inflow of short term

foreign capital has continued and the process of direct investment in mining has intensified. There has been a slight drop in unemployment, but levels are still very high (16.1% in May 1997).

Argentina: Principal indicators of economic activity

	1995	1996	1997(1)	1997(2)
<i>National accounts</i>				
GDP	-4.6	4.3	8.2	7.8
Goods	-4.6	4.2	8.6	8.6
Services	-3	4.5	6.5	6.6
Consumption	-6.1	5.3	7	6.5
Fixed gross internal investment	-16.3	8.3	27.7	28.3
Building	-11.1	1.2	22	27
Nationally produced machinery and equipment	-24.1	6.9	2.4	7.1
Imported machinery and equipment	-20.2	20.5	46.5	39.6
Exports: real goods and services	22.7	6.5	14.6	10.5
Imports: real goods and services	-11.6	16.8	30.1	30.5
<i>External sector</i>				
Balance of payments				
Current account	-2446	-4130	-2354	-1478
Merchandise	2238	1622	-421	-49
Real services	-2175	-2495	-1253	-502
Financial services	-2941	-3591	-737	-1040
Unilateral transfers	431	334	57	113
Fluctuation in international reserves	-69	3782	-425	1514
Export of goods (fob)	20963	23811	5619	6940
Import of goods (cif)	20122	23762	6453	7451
Balance of trade in goods	841	49	-834	-511
<i>Public finances</i>				
Global result for the non-financial public sector	-1373	-5264	-1323	-924
Total resources from taxation	42562	43115	11542	12454
Public debt	87091	97105	98255	99653
<i>Unemployment</i>	17.5	17.2		16.1

Source: MEOySP, Economic Report, October 1997

*A social situation reflecting a heterogeneous reality*

Modification of the regulatory function of the State and the opening of the economy, underpinned by a substantial flow of foreign capital, has brought fragility to many parts of the productive sector, especially small and medium businesses, with logical consequences for their employees. These help to make for a strong impact from external imbalances, as was shown in the Mexican crisis.

The results of this fragility, characteristic of an economy in transition, can be observed in various orders.

In the occupational field, the indicators of employment and underemployment are alarming and in May 1995 attained 18.6% unemployment among the active population for the country as a whole. This situation has repercussions on the general social level, and, ultimately, on the health conditions of the population, when people lose the coverage provided by formal employment. At the same time, there has been an increase in informal employment, so much so that for ten jobs created, only two are in the formal sector.

The population in conditions of poverty, with their basic needs unmet, is now 19.3%, that is, nearly 6 200 000 people, according to the census taken in 1991.

At the same time, social expenditure has risen from 14.6% of the GDP in 1980/83 to 18.03% in 1994, and per capita expenditure is now 1 509 pesos.

Although this is a significant increase and does, as a rule, resolve the most urgent aspects of the social situation, the State does not always have the capacity for response or the funds available to cope with new problems, through the very fact of not having the necessary physical infrastructure and managerial capacity. In this case, AIDS raises a demand that needs to be met efficiently and effectively in the shortest possible term.

The economic crisis of the last decades has had different impacts on two groups of the population in poverty, the rural poor, whose mostly live in the northern part of the country, and the urban poor. The latter include rural migrants, as well as the unemployed and underemployed urban population living in the peripheral belts of the large conurbations. Almost half the total population in situations of critical poverty—three million people—are concentrated in the provinces of Buenos Aires, Córdoba and Santa Fe.

The consequences of economic evolution and the social situation for the problem of AIDS are reflected in a study by the University of California Center for AIDS Prevention, in which it is pointed out that “social and economic factors have played a critical role in the increase of HIV”, especially in regard to the changes taking place in the provision of health services. In so far as these changes mean reducing costs, they may not only affect the treatment of patients but may also mean the emigration of professionals, technical and managerial personnel whose posts are abolished, whose conditions of work are deteriorating and whose standard of living is going down. This situation could result in less readiness to treat a disease with a high risk for health personnel such as AIDS.

There can be no doubt that the policies pursued in structural reforms of the economy also carry a high social cost even in the case of countries like Argentina.

## AIDS in Argentina

### *The situation today*

Since the first three cases were identified in 1982, the epidemic has grown significantly in Argentina, rising to 11 244 cases by November 1997.

#### *Recorded cases of AIDS, 1982-1997*

Year	Reported cases	Estimated cases	Rate per million population
1982	3	3	0.1
1983	4	4	0.13
1984	7	7	0.23
1985	28	28	0.92
1986	37	37	1.16
1987	92	92	3.14
1988	200	207	6.9
1989	294	307	10.13
1990	488	518	15.07
1991	723	778	22.13
1992	1103	1231	33.26
1993	1417	1624	42.12
1994	2024	2400	59.77
1995	1676	2075	48.2
1996	2196	3392	60.65
1997	639	1015	54.18
Total	10889	13718	

If the delay in receiving information and the under-reporting of cases is taken into account, the number of cases is greater. If the number of notified cases is taken as the base for estimation of the number of persons infected, there are likely to be nearly 100 000 people infected in Argentina today. Projected to the end of the century, this means that there will be no less than 35 000 people with AIDS.

*Percentage structure of cases  
classified by sex and age group*

Age	Male	Female	No information	Total
1-4	344	328	6	678
5-9	33	48	0	81
10-14	17	5	1	23
15-19	160	53	2	215
20-24	1126	389	21	1536
25-29	2287	549	18	2854
30-34	1886	329	30	2245
35-39	1168	197	9	1374
40-44	776	86	9	871
45-49	422	30	5	457
50 and over	464	59	1	524
Desc.	24	5	2	31
Total	8707	2078	104	10889

Source: National Human Retrovirus and AIDS Control Programme

The reported cases show a heavy impact on the young sectors of the population. The median age of people with AIDS was found to be 31.5 years for males but 24.8 years for females. Thus, while 71% of female cases are under 30, only 48% of males with AIDS are in this age group. One of the most worrying aspects of AIDS is the extent of prevalence among women of childbearing age, as evidenced by the male/female ratio of cases.

When the male/female ratio for cumulative cases from 1982 to 1997 is classified by age group, it will be observed that this ratio increases with age. Paediatric cases in the population aged 0 to 9 years, however, as would be expected, are uniformly distributed. For the other age groups comprised in paediatric AIDS the male/female distribution is very unequal, giving rise to the figures shown in the table.

Although this disease initially struck predominantly among men (mainly homosexuals), the infection of heterosexuals and drug addicts had a decisive influence on the infection of women, making them a risk group, basically comprising the partners of intravenous drug abusers and bisexuals. From the infection of women follows the risk of vertical infection (from mother to child).

*Geographical impact and mechanisms of contagion**Percentage distribution of AIDS cases by administrative jurisdiction and by year*

Jurisdiction	1982-86	1987-90	1991	1992	1993	1994	1995	1996
Buenos Aires	69.6	28.31	28.84	33.62	41.02	44.09	44.92	46.34
Federal Capital	12.66	38.92	38.92	39.98	40.43	38.72	35.62	35.25
Córdoba	0	5.21	5.54	4.14	5.38	3.23	3.34	2.9
Santa Fe	1.27	11.55	17.9	14.07	5.38	5.53	6.14	5.52
Remainder	16.4	16	8.81	8.19	7.81	8.43	9.98	10
Total	100	100	100	100	100	100	100	100

Source: National Human Retrovirus and AIDS Control Programme

Geographical distribution shows that 90% of the reported cases are in the Federal Capital and the urban areas of the provinces of Buenos Aires, Santa Fe and Córdoba. Analysis of routes of infection (sexual, blood, mother to child) shows that 47.2% of all cases are due to sexual transmission; 46% through blood (hemophilia, transfusions and intravenous addiction); 7.2% from a seropositive mother and 2.2% due to unknown factors.

*Route of infection of AIDS cases in percentages by year*

Route of infection	1982-87	1988-90	1991	1992	1993	1994	1995	1996	1997
Haemophilia	5.88	4.46	0.14	1.45	0.22	0.22	0.05	0.09	0.15
Transfusions	0.59	1.97	2.41	2.6	1.47	1.86	0.89	1.07	0.8
IV addiction	10	31.61	41.62	45.57	44.26	44.03	54.05	42.41	36.61
Mother HIV+	1.18	5.49	6.68	5.11	7.29	4.38	7.45	6.64	13.92
Sexual	81.76	55.44	47.02	42.87	44.4	47.26	45.05	45.31	43.72
Heterosexual	4.71	6.63	8.38	15.32	15.98	20.21	19.33	23.22	23.47
Homosexual	58.24	35.54	27.27	20.13	22.09	21.41	20.52	19.52	16.5
Bisexual	18.82	13.26	11.36	7.42	6.33	5.64	5.2	2.57	3.75
No information	0.59	1.04	2.13	2.41	2.36	2.25	3.4	4.3	4.6
Total	100	100	100	100	100	100	100	100	100

Source: National Human Retrovirus and AIDS Control Programme

Although this is a sexually transmitted disease, special mention must be made of intravenous drug addition, which is responsible for 93% of cases of

bloodborne transmission. These figures have varied over the years, and the importance of the risk factors has changed. There are two phenomena that significantly affect the young: intravenous drug addiction, especially in the poorest population, and risk from heterosexual contact.

In summary, the critical nature of AIDS is enhanced by its very mode of transmission, so that new treatments that appear to alleviate the most serious consequences of the disease are needed as a matter of social urgency and a duty for the national community. The dramatic nature of the disease is finally enhanced by the fact that this epidemic does not appear to discriminate between social origins or cultural practices, although it is possible to define populations in situations of greater exposure to infection than others.

### *Women and children*

Within the overall context of the AIDS problem in Argentina, the increase in the number of cases in mothers and babies is a matter for special concern, both intrinsically and in regard to its human and social repercussions. We therefore feel that a more advanced study of this particular area is needed.

The predominance of the sexual route of infection among the first patients to appear in the country was associated with sexually transmitted disease. As the years go by, however, new risk groups are emerging more strongly and we are forced to reappraise this cause of disease. The new groups comprise intravenous drug users, and in the last few years, vertical infection giving rise to paediatric AIDS.

In this context, the problem of AIDS in young people under the age of 15 is having an increasing impact and Argentina is among the countries with the highest proportion of paediatric cases on the continent. The 782 cases of children under 15 amount to 7.2% of the total cases in the country, a figure considerably higher than in the countries of North America, where the proportion is about 1%, and also higher than Brazil.

The number of children with the disease has increased year upon year, a fact related to the increase in cases among women, vertical transmission being the causal factor in 82% of these children. It is estimated that HIV will become a significant cause of death among children under 15 by the end of the century.

The rapid increase in recent years of cases among young people (between 20 and 34 years) is particularly serious. Since the appearance of AIDS denotes earlier infection with HIV, it is obvious that initial infection must be predominantly occurring among adolescents and young adults.

Cases among people over 40 are mostly among homosexuals, so that in calculating this ratio in its pure form, these persons should be excluded due to the predominant mode of infection among women and the fact that homosexual behaviours have no impact on them. If in addition to eliminating children, we also set aside the over 40 age group, the ratio is 4.6 male cases to every female case. The ratio for the over 40 group is 15:1.

Evolution over time shows that the ratio at the start of the series was substantially higher for men, with 14 male for every female case in 1988, evolving to 3.7 in 1994 and stabilizing at this level (3.6 for 1996). There nevertheless appears to be even greater equalization in the Greater Buenos Aires conurbation, where the ratio is 2.5 men for every woman with the infection. This reveals a change in the relative weight of the population groups at risk, and their patterns of behaviour.

It is important to note that 80% of women with AIDS are of childbearing age (17% of the remainder are girls), which will aggravate the problem in children in the coming years. This risk group is therefore likely to substantially increase its relative share of the overall number of cases.

From the biological standpoint, women are more vulnerable as the receptive parties of the sexual couple and because of their sexual relations with men who have generally had a sex life with a greater number of contacts. At the same time, in our country, women also present greater vulnerability to bloodborne infection on account of transfusions, this being a common medical practice in cases of unsupervised pregnancy and childbirth.

In the light of this analysis it is important to emphasize the need to work with governmental and nongovernmental agencies specializing in gender-related problems, mothers and children, including special preventive campaigns targeting surrogate motherhood and a distinctive approach to prostitution.

### **National health policy**

In response to the situation described above, Argentina has elaborated a series of specific measures to combat HIV/AIDS that are incorporated into its general health strategy. Let us examine certain aspects.

#### ***Decree 1269/2 establishing health policy in Argentina***

Health policy, as defined in decree 1269/92, is part of the Government's overall policy and sets out to pursue the strategic orientations and programme priorities defined by it. This decree establishes substantive policies for the sector, with the objectives of ensuring full access to the right to health through a system based on equity, solidarity, efficiency, efficacy and quality. To this end the integration of health into the other sectors is being proposed. The objective is to improve the accessibility, efficiency and quality of the health services, by optimizing the use of resources, providing technical assistance to the public and private sectors, and aiming for decentralization and the formation of local networks of increasing complexity. Another substantive policy is to carry out sustained and concerted actions for the promotion and protection of health to reduce the avoidable risks of sickness and death.

### *The specific legal framework against HIV/AIDS*

The State's concern with AIDS is attested by the promulgation of law 23 798 (National AIDS Law), of 1990, and decree 1244 enacting regulations to it. These texts provide the legal framework for activities of prevention, diagnosis, treatment and rehabilitation of persons infected and also give them protection against discrimination throughout the country. The fight against AIDS is thus declared to be of national interest while implementation of policy for control is entrusted to the responsibility of the health authorities in each jurisdiction.

- Screening for the virus and antibodies of blood and blood derivatives to be used for transfusions, and of the donors of organs to be used for transplants and other human purposes, is established as compulsory;
- Notification of cases is also made compulsory and the bases for registration for statistical and epidemiological purposes, reserving the identity of those affected, are also established;
- It is established that biosafety standards will be enacted to which the use of materials which it may or may not be necessary to discard will be subject;
- In the regulatory decree, in article 1, the prevention of AIDS is included as a topic in the curricula of primary, secondary and tertiary education.

Furthermore, in the legal framework established by law 23 798 and regulatory decree 1244, Argentina has established an HIV/AIDS "coverage programme" which stipulates that social welfare agencies must take steps to care for people with HIV/AIDS. This obligation covers all aspects of curative treatment, requiring the social welfare agency to take full and integral responsibility for each person, not precluding their access to any kind of medical intervention. This avoids the usual hospital treatment, the use of day hospitals, hospitalization in the home, inter alia.

According to its own estimates, AIDS treatment accounts for 10% of the funds distributed by the Government social welfare department. 10% of the employees' and employers' contributions are paid into this Fund, together with 50% of the extraordinary funding authorized by the State. Expenditure for AIDS amounted to nearly 30 million pesos in 1997.

This new legal requirement that is binding for both social welfare agencies and medical enterprises with prepayment schemes is perhaps one of the most unusual features of the Argentine case. Establishing a compulsory obligation to care for persons with HIV/AIDS overrides the strict logic of profit to assume an ethical attitude, a moral imperative vis-à-vis the disease.

### *Operational instrumentation of the legal framework: The National Human Retrovirus, AIDS and STD Control Programme (PNLRHS)*

The need for the Argentine public authorities to have an adequate structure for response to the impact of AIDS led to the establishment of the PNLRHS in 1992. The

guidelines for the five-year period 1995-1999, drawn up as a medium term plan, are aimed at reducing infection from HIV and STD, "attenuating the biological, psychological and socioeconomic impact of the epidemic" through coordination of activities.

The specific objectives of the programme are:

1. To prevent sexual and perinatal transmission;
2. To prevent transmission through blood, blood products and invasive procedures;
3. To prevent infection among drug users;
4. To reduce the impact on individuals and families, and the socioeconomic impact;
5. To strengthen analysis of the situation and trends of the epidemic;
6. To consolidate administrative and managerial aspects, and the overall management of the programme.

In regard to these objectives, it should be pointed out that the PNLRHS consists of nine persons for a population of 34 million; that the tasks of preventing infection with HIV and STD cannot be covered operationally by the programme, since it devotes, as we shall see later, almost all its budget to the procurement and distribution of drugs to combat AIDS and opportunistic infections. Since the PNLRHS has specialized in the area of treatment and care, the Ministry of Health has set up a specific programme for prevention, the LUSIDA project, with international financing. This project is intended to address the needs of prevention, especially through articulation with nongovernmental organizations.

### *Organizational structure*

The PNLRHS is composed of a National Director, one biochemist, two psychologists, one biologist, one epidemiologist and four administrative support staff.

The executive management coordinates and directs the operational units, in liaison with the technical advisory committee, a source of reference and legal advice, and works in conjunction with international agencies such as UNAIDS, PAHO, international cooperation and international technical cooperation. It coordinates the agreements made with the provinces and other government departments, such as the Ministry of Justice and the Ministry of Education. It is responsible for relations with nongovernmental organizations.

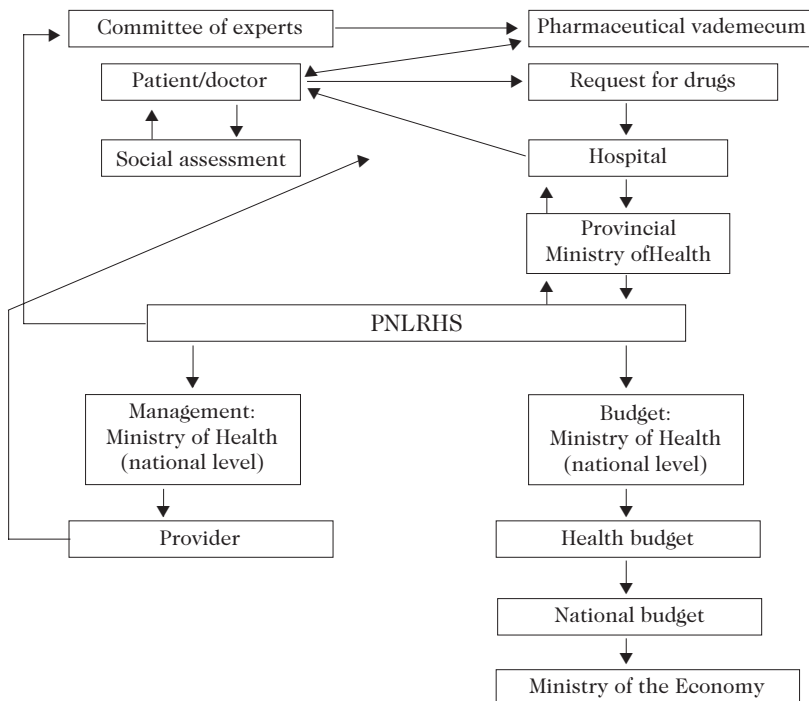
In addition to the National Directorate, there are two coordination departments, one for AIDS and the other for STD, which coordinate activities with the units of epidemiology, prevention, and technical advisory units, in particular the use of drugs and standard protocols for treatment and care. The tasks carried out are summarized in the following table:

Laboratory	Epidemiology	Prevention	Care	Administration
Standards	Sentinel surveillance	Education	Standards	Procurement
Training	Research	Training	Training	Logistics
Quality control	Notification	Information	Technical assistance	
		NGOs		

Finally, the PNLRHS is subject to evaluation in the form of internal audit by the Ministry of Health Internal Audit Unit; by the Office of the Attorney General on behalf of the National Executive; and by the Controller General of the Nation (AGN) on behalf of Congress.

***How the PNLRHS works: continuous negotiations to comply with the law and effectively maintain delivery of drugs free of charge***

*The various actors in the provision of free drugs*



*Modes of operation*

The establishment of laws, decrees and regulations to ensure free distribution of drugs to combat AIDS forms the legal basis for action. But to translate policy decisions into effective practice, an infrastructure of human and economic resources is needed. The aim of this section is to comment on the spirit and methodology used.

*The drugs cycle*

As part of the PNLRHS, Argentina has a technical committee of experts of recognized experience and standing which is there to advise on the state of the art in the treatment of AIDS. It produces a vademecum or list of drugs that can be used for the treatment of AIDS, but does not rank them any order of preference.

From the drugs available, the attendant physician selects those that are most appropriate for each patient. Since the provision of drugs is free of charge but not unrestricted, hospitals investigate the patients' social background to determine whether they are receiving any form of social support and whether they have sufficient material resources to pay the costs of their treatment themselves. These data are transmitted to ANSAL (National Social Security Administration) to corroborate that no other form of social support is being received, and to PAMI to check on receipt of disability and old age pensions.

Once this procedure is completed, the application is returned to the hospital, which submits the claim to the Ministry of Health of the Province, which in turn passes it on to the National Ministry of Health. Here the PNLRHS intervenes, arranging for the drugs specified by the doctor to be sent to Ministry of Health in the respective Province for delivery to the doctor. The time between ordering and delivery is about 30 days.

It must be pointed out that the PNLRHS specifies conditions of distribution when it invites tenders and that these are the responsibility of the supplier. Thus the Programme does not stock all the drugs required for the year - which would significantly increase maintenance costs, especially for drugs requiring a cold chain - and ensures that the drugs are effectively distributed.

Nevertheless, it must be stressed that budgetary problems sometimes mean that direct purchasing is necessary. If procurement follows its normal course, there may be times when the Ministry of the Economy is unable to advance the necessary funds, and when these funds do become available there is no time left physically for the three months normally required for government procurement, so that it is necessary to have recourse to direct purchasing to prevent any break in distribution (this was the case for direct purchases 23/97 and 30/97, made to cover shortfalls).

At the same time, the attitude of the laboratories is not always indicative of the highest level of performance. On more than one occasion companies winning tenders have not complied with delivery dates and specifications, and this is not only unprofessional, but also results in shortages of drugs. This causes a break in the

cycle. When this happens, the PNLRHS demands direct contracting, which is more flexible and ensures that the cycle is not broken, but should not become the standard procedure for procurement. It must be emphasized that the laboratories whose response makes it necessary to have recourse to direct purchasing are not eligible to bid in cases of need and emergency.

Obviously, it is necessary to devise mechanisms of procurement that comply with the norms established in the Law on the Financial Administration of the National State but are able to move more rapidly. Not only to strengthen the functioning of the system of free distribution of drugs, but also because in a continually evolving environment of technical change it may become necessary to buy other drugs that are more effective.

This was the case with protease inhibitors, which were used in Argentina after the Vancouver Conference but for which there was no budget provision in that budget year. We shall look at what happens in the budget process.

### *The budget process*

We have seen to some extent the procedure used to secure free delivery of drugs in the Ministry of Health, and in particular in the PNLRHS. It is the result of a long, and sometimes polemical negotiation by the Programme with other Government departments in Argentina. The first step is the establishment of a budget for the Programme.

In practice, the funds allocated to the PNLRHS are destined to be used in their entirety for the purchasing of drugs, either for the treatment of AIDS or to combat opportunistic infections. Financial analysis is not of interest in this section and will be discussed later. What we are trying to show here is the complex —and continuous— process of negotiation necessary to obtain funds and continue to provide drugs free of charge.

For the sake of illustration, the budget process for 1997 is summarized below.

In the framework of cost reduction and budget adjustment defined by the Ministry of the Economy, all programmes were subjected to generalized cuts across the board. Thus the budget allocated for AIDS fell from 21 million pesos in 1995 to 13 million pesos, the sum appearing in the budget. In April 1996, the Ministry of Health observed that the PNLRHS was showing a deficit of seven million pesos and would only have the operational capacity to distribute drugs until August 1996. During the months of May and June 1996, more money continued to be sought for the PNLRHS when all possibilities for internal redistribution of the budget allocated to the Ministry of Health had been exhausted. In September the need for additional budget funds as a matter of urgency was put to the executive at cabinet level, as well as to Congress. In October a one-off budget supplement of ten million pesos was approved for the Ministry of Health as a whole, so that the AIDS programme had to function throughout 1996 in a state of permanent budget emergency.

When it came to drafting the budget appropriations bill for 1997, the PNLRHS estimated its basic requirements at 34 million pesos, to take account of the introduction of new treatments, in particular the “cocktail” of drugs. On the basis of these measures, the priorities appeared to be:

- the need to ensure provision for new treatment schedules using two or three drugs;
- the incorporation of new drugs such as protease inhibitors;
- the widespread dissemination of treatments that are successful when initiated at early stages;
- the increase in the number of patients receiving treatment;
- the increase in the number of AIDS cases.

Notwithstanding efforts and although these arguments were advanced, the Ministry of the Economy set the total allocation for the PNLRHS at 21 million pesos. In Congress, due to the restrictions being placed on public spending, the figure was reduced to 19 million pesos. Finally, the Cabinet determined that 18 million pesos would be allocated to the PNLRHS for 1997. When we consider that some of the purchasing for 1996 was charged to the 1997 budget (nearly 3 million dollars), we can see that the budget actually allocated was considerably lower.

Because of the social realities of AIDS, its impact on the population and the widespread publicity in the media, it was possible to escape from this logic of cost compression, which would have meant abandoning the policy of free drugs, or else rationing of drugs for AIDS. At the present time, the credit for the PNLRHS is 54 million pesos, thanks to recovery of the initial budget and a further budget top-up of 20 million pesos.

It is obvious that in negotiating the funds to be allocated to AIDS there are other determinants of a different nature involved, whose scope is difficult to define. Nevertheless, the objective situation of the people affected, for whom the hope of remission is kindled for the first time, the weight of community organizations and other pressure groups, together with the action of the PNLRHS, have so far made it possible to obtain the assurance of fresh funds to purchase the drugs needed.

In summary, we can see that there is a clash between two different strands of logic. On the one hand, the PNLRHS is concentrating its action on the purchase and effective distribution of drugs for persons living with HIV or AIDS; while on the other hand, there is the logic of budget restriction, resulting cuts and more cuts to the budget. It is not the doctrine of the Ministry of Health, or of the PNLRHS, to argue for wastage of resources, which are, by definition, scarce. But when it is a human life that is at the end of a system supplying free drugs, it is legitimate, if not imperative, to bring all resources to bear in the framework of negotiation, be they nongovernmental organizations, public opinion, medical opinion... in support of the ultimate and incontrovertible rationale, namely, the survival of the patient.

### *Relations with the provinces*

Argentina is a federal country, with 24 autonomous provinces which, in the course of history and the building of the nation, have remained jealous guardians of their prerogatives. The PNLRHS, therefore, in accordance with the legislation currently in force, is responsible for elaborating standards for the use of drugs in treating AIDS, and is also - and this is an important feature of the Programme - responsible for the delivery of the drugs throughout the national territory.

The Programme differs from the other initiatives of the national Ministry of Health, in that it is a centralized programme with responsibilities that include the distribution of drugs. Hence the need to elaborate a system in which the provinces are able to handle the necessary information adequately, sending epidemiological data promptly and in the proper form, as well as ensuring transmission of orders for drugs, if not their distribution through hospitals.

In an apparently contradictory context, a centralized programme is being established in a federal country, because it is thought to be more cost-effective to have only one command for an epidemic of national scope. A regulatory framework is therefore needed with the provinces to ensure that drugs are distributed free of charge. This is the sense and purpose of the agreements established by the PNLRHS with each of the provinces in Argentina. Most of the provinces have accepted this agreement, but the Province of Santa Cruz in Patagonia has not yet accepted it.

#### *A model agreement: rights and obligations*

The agreements signed between the national Ministry of Health and Social Action, on the one hand, and the provincial Ministry of Health, on the other, establish the mechanisms for operation at the local level.

The Parties agree that the Province shall be responsible for dispensing drugs for patients without health insurance cover and without economic resources, as distributed by the national Programme and purchased with national budget funds. The Province also undertakes to ensure the delivery of the reagents provided by the PNLRHS for the blood banks.

In return for the distribution of drugs purchased from the national budget, the Province undertakes to prepare monthly epidemiological data (number of tests, results, number of persons infected and patients receiving treatment, and projections), together with relevant administrative information, such as data on consumption and stocks of drugs, reagents and inputs, average consumption and forecast duration.

It is important to note that the Province is made responsible for the cost of the final transport of the drugs to their destination, and for their correct and timely usage. Failure to fulfill these conditions may lead to cessation of distribution by the PNLRHS.

Failure to collect information on the social security coverage, clinical history, doctor's prescription, and in particular the perseverance of patients in taking the

drugs prescribed, is also regarded as grounds for ceasing delivery. It is important to note that throughout this process respect for the confidentiality of data, as stipulated in Law 23 798, is observed by the PNLRHS. Systems of audit are also foreseen, as a national responsibility or in conjunction with the Province.

These agreements—an example is attached in annex—define the missions and responsibilities of each of the jurisdictions involved. A system of exchange is established in which the PNLRHS, through the national Ministry of Health, ensures the distribution of drugs in the provinces through the local Ministry of Health. The local Ministry in turn must send in epidemiological data and all necessary materials for substantiation. The remaining funds, if any, revert to the national Ministry for distribution in other provinces.

Other agreements signed by the PNLRHS relate to activities carried out jointly with community organizations, which act as relays for messages of prevention and non-discrimination, through conferences, workshops or other kinds of activities. Mention may be made of the agreements signed with the Federation of War Veterans of the Argentine Republic, the Federal Programme of Social Militancy, the National People's University Front, Rotary Club International, the Boy Scouts and the Syndicate of Housewives of the Argentine Republic.

### Some observations

In this brief presentation we have tried to convey the economic and social context in which drugs for HIV/AIDS are being distributed free of charge in Argentina.

Before concluding, there are certain fundamental aspects of the process of free delivery of drugs to which we should like to refer.

- Health administration in Argentina is decentralized to the provincial and municipal levels... except in regard to AIDS. Thus different attitudes are encountered in the different jurisdictions.

- The institutionalization by the Ministry of Health of a technical commission to continuously update the vademecum of drugs for AIDS is an important instance of legitimation of the activities of the PNLRHS. It would nevertheless appear necessary to establish a typology of treatment, so that expenditure is focused on a certain number of drugs, rather than offering the whole range of drugs, as is the case, with possible situations of overlapping.

- The legal framework requires the entire health sector in Argentina to provide care to people with HIV.

- The existence of three health subsectors—public, semi-public and private—tends to adversely affect the consistency of policies.

- The increased costs arising from the introduction of the “cocktail” of drugs creates areas of uncertainty in regard to the sustainable financing of treatments.

Free distribution of drugs is thus the result of a health tradition, supported by laws, decrees and regulations stipulating that care shall be given free of charge, but it cannot be unlimited.

In practice, only patients whose socioeconomic condition makes it impossible for them to pay for treatment are entitled to free medication; access is through their attendant physician, followed by intervention of the hospital, provincial and national authorities; the cycle is completed with reporting, estimation and budgeting... in a never-ending circular process. The task of negotiation and the inclusion of the various protagonists in the public, private and community sectors in one and the same patient-centered strategy of care is perhaps the significance of the action of the PNLRHS today. Free distribution of drugs can be likened to Ariadne's thread as it tries not to get lost in the recessive labyrinth of bureaucracy.

So strong is the commitment of the national Ministry of Health, that the PNLRHS is planning to extend treatment with the "cocktail" of drugs to 9 500 adult patients and 500 children in 1998.

This will not be easy. The PNLRHS is at the crossroads of several different lines of logic, including the interest of the Ministry of the Economy in balancing the budget; relations with protagonists in the different jurisdictions and within the Ministry of Health; the behaviour of public opinion, which is not always rational; economic inertia; and ethical and moral imperatives.

## **Economic aspects of HIV/AIDS in Argentina**

### **Health coverage in Argentina**

Depending on the origin of financing for the health system, three different populations can be identified in Argentina who receive coverage from the three sub-sectors:

- The public sector;
- The social security; and
- The private sector.

A fourth component of the system can be identified, in the form of occupational health as prescribed in legislation for the protection of workers at their place of work.

### ***The health system***

The health sector in our country can be characterized as heterogeneous and fragmented, and these characteristics make for a lack of integration between and within each of these components. There have been three types of attempts to reform the system:

- In the 1970s, the State assured the right to health care of the entire population. It was attempted to set up an integrated national health system, with a project for the formation of a single State-run system to ensure egalitarian access to services.

- In the 1980s social security was strengthened with the project for national health insurance. The focus was on social welfare, and the State asserted its lead role in health policy. It was attempted to strengthen the public sector as a service provider and to incorporate it into a system in which the provision of care is shared between the parties involved. This project met with strong opponents in the trade unions.

- In this decade, reform is being promoted from changes in private insurance. Sanitarian concerns such as equity, access and healthier life-styles are being left aside to concentrate on financial flows within the sector.

The public subsystem (basically the hospital network) is being changed by a policy of decentralization which sets out to give greater autonomy of management to health facilities and of financing to provincial governments.

The national social welfare sector has begun a process of financial reorganization that consists in deregulation of the sector, promoting freedom of affiliation and with the ultimate aim of developing a competitive market in which private health insurance schemes will participate.

### *The public subsector*

This is subdivided into as many parts as there are political jurisdictions in our country. There is the national government, the provinces and municipalities. Each of these entities has different functions within the system. The State is responsible for coordination, regulation and technical and financial assistance. The provinces have most of the health service providers and the municipalities have developed their own health care networks. Within this framework, the institutional protagonists in each jurisdiction are:

- The Ministry of Health and Social Action at the national level;
- The provincial ministries and health secretariats; and
- ANSSAL (national health insurance administration), which has the function of regulating and administering a redistribution fund for social welfare.

As in most countries in Latin America, the system is subsidized on the supply side. Thus the health services are used by the population in spontaneous demand, and the costs are not reduced when infrastructure is not used to the full.

Health activities in the public sector are financed from tax and non-tax resources from public funds, together with funds from external sources (IBRD, IDB) which are used for investment.

### *Social security*

Social welfare is organized in the manner of health insurance. This subsystem is thus linked with the formal labour market and provides coverage to the employed population and their families. This compulsory social security is financed by workers' and employers' contributions and other income such as co-payments and co-insurance. Its principal characteristic is its basis of solidarity.

The social welfare funds are non-profit public legal entities subject to government regulation. These institutions may be classified into four types depending on the part of the formal labour market they serve:

- National social welfare funds: the legislation grouping these funds is the Social Welfare Act and they are registered in the National Health Insurance Register. There are approximately 310 organizations, the first 20 of which cover 80% of the total population covered (8 million people).
- Provincial social welfare funds: These comprise the health insurance funds created by the provincial government administrations and the Government of the City of Buenos Aires and they cover the civil servants employed by these governments and at lower political levels (municipalities) and their families, and retirees and pensioners from these administrations.
- Other social welfare funds: These are governed by different provisions of the Social Welfare Act. They include the national security forces, the universities, the Federal Judiciary and the National Legislative Power.
- INSSJyP: Provides coverage to the prison population in the country and prisoners' families.

The deregulation of the system allows free choice of a social welfare fund. This tends to facilitate concentration of the market. Implementation of the compulsory medical programme (PMO) is making for homogeneous welfare coverage for the whole public sector.

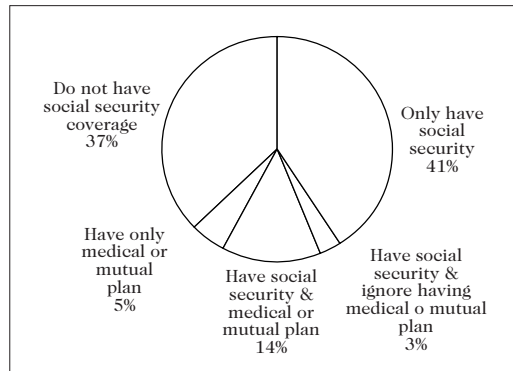
### *The private subsector*

There are two types of practice here: direct payment for services, such as private medical consultations, and recourse to private health insurance. The private sector has thus developed a network of service providers on the one hand, and, on the other hand, a whole range of insurance companies.

Insurance contracts define the scope of the risks covered, the amount of the premium contribution and the conditions in which the contract shall apply. The latter include, in most contracts, an excess period in which the insured beneficiary contributes without receiving benefits. Like all insurances, the sector takes account of the principles of adverse selection and moral risk. The services recognize different types of institutional structures:

- Institutions acting as financial administrators for their insured, restricting their activity to the management and control of funds;
- Organizations providing comprehensive services, in which the insurance companies are vertically integrated with the institutions providing services (clinics, surgeries, diagnostic services, etcetera);
- A recent and growing modality consists in private institutions acting as administrative intermediaries between social welfare or prepayment schemes and networks of service providers;
- A fourth type of undertaking is based on hospitals or groups of providers, annexing insurance activities to the normal routines of hospital management, as for example in community hospitals.

*Social Security Coverage. 1991*



***Health coverage***

The National Population and Housing Census of 1991 includes questions on health coverage for the first time. Thus it is possible to get an overall picture of coverage throughout the country in 1991. According to the census, social security coverage extended to 18.8 million people, or 58% of the country's total population. The population with only a medical or mutual (private insurance) plan was 5% and the coverage of these two subsectors was 63% of the total population, leaving 37% without any type of coverage at all.

*Population covered by social security*

	Population	%
Social security only	13.2	40.9
Social security but not aware of medical plan	1.1	3.5
Social security and medical or mutual plan	4.5	14.1
Social security coverage	18.8	58.4
Medical or mutual plan only	1.5	4.7
Population with coverage	20.3	63
No social security	11.9	36.9
Total	32.2	100

Coverage by province reveals wide variations, reflecting the uneven situation of the labour market in these jurisdictions. Thus social security coverage in relation to the total population of each province ranges from 42% in Formosa to 76% in Santa Cruz, with levels of around 60% in La Pampa, Río Negro and Entre Ríos.

The total population covered does not show great variations, except in some jurisdictions such as the Federal Capital where the social security covers 68% of the population and if the population with private insurance is added coverage rises to 80%. In the provinces of Córdoba, Santa Fe and Tucumán the situation also differs from the rest of the country.

The population with no health coverage is 20% in the Federal Capital and in the extreme cases rises to 60% in Formosa and Santiago del Estero.

*Health coverage by administrative jurisdiction, Argentina 1991*

Jurisdiction	Soc Sec	SS + med or mutual plan	SS + not aware of other plans	Soc sec	Medical plan	Soc Sec + medical plan	Neither SS nor other	Total
Federal Capital	47.8	16.4	4.1	68.3	12.0	80.3	19.7	100
Greater Buenos Aires	42.7	10.2	3.6	56.6	4.9	61.5	38.5	100
Rest of Buenos Aires	41.4	15.8	5.4	62.7	3.8	66.4	33.6	100
Catamarca	46.9	12.4	3.1	62.4	0.8	63.2	36.8	100
Córdoba	39.0	15.1	3.0	57.1	5.1	62.2	37.8	100
Corrientes	38.3	9.5	3.0	50.8	0.8	51.6	48.4	100
Chaco	33.7	10.4	2.6	46.6	1.2	47.8	52.2	100
Chubut	55.1	7.8	2.9	65.8	1.6	67.4	32.6	100

continues

## AIDS IN ARGENTINA

Jurisdiction	Soc Sec	SS + med or mutual plan	SS + not aware of other plans	Soc sec	Medical plan	Soc Sec + medical plan	Neither SS nor other	Total
Entre Ríos	43.3	12.2	3.3	58.8	2.6	61.5	38.5	100
Formosa	29.2	11.2	1.9	42.4	0.3	42.7	57.3	100
Jujuy	38.8	13.9	1.8	54.4	1.5	56.0	44.0	100
La Pampa	44.8	12.3	2.9	60.0	4.8	64.8	35.2	100
La Rioja	44.9	16.7	3.7	65.3	0.7	66.0	34.0	100
Mendoza	40.8	11.7	1.0	53.5	4.3	57.8	42.2	100
Misiones	39.4	7.5	2.7	49.7	0.5	50.2	49.8	100
Neuquén	38.1	17.6	2.3	58.0	1.7	59.7	40.3	100
Río Negro	39.2	17.2	2.5	58.8	2.4	61.2	38.8	100
Salta	31.0	16.7	2.4	50.1	1.2	51.3	48.7	100
San Juan	32.5	24.4	1.4	58.4	0.8	59.1	40.9	100
San Luís	39.9	16.0	2.8	58.8	3.6	62.4	37.6	100
Santa Cruz	62.8	11.7	2.0	76.4	0.5	77.0	23.0	100
Santa Fe	43.6	16.5	4.0	64.1	6.9	71.0	29.0	100
Santiago del Estero	23.5	16.4	2.8	42.8	1.9	44.6	55.4	100
Tucumán	28.5	26.8	3.3	58.5	6.1	64.7	35.3	100
Tierra del Fuego	58.5	7.5	1.8	67.7	1.5	69.2	30.8	100
Total	40.9	14.1	3.5	58.4	4.7	63.1	36.9	100

Source: National Population and Housing Census 1991

Coverage by age structure of the population indicates that it is the younger groups that are less well covered, as can be seen from the table. For the age groups between 0 and 29 the average level of social security coverage is 51%, rising to 58% for the age group of 30 to 49 years. For the population over 65 the level of coverage is over 88%. The population without coverage is mainly in the lower age groups, with a peak of 50% in the group aged 25 to 29 years. For the oldest group the percentage without coverage goes down to 12%. Health coverage for dependents is high due to the fact that most of the population in these age groups is within the contributory system.

*Health coverage by age group, Argentina 1991*

Age	Soc Sec	SS + medical or mutual plan	SS + not aware of others	Soc Sec	Medical plan	SS + medical plan	Neither SS nor other plan	Total
0-14	37.5	12.7	3.6	53.7	3.9	57.6	42.4	100
15-19	36.5	12.3	2.9	51.6	4.6	56.2	43.8	100
20-24	31.9	10.7	2.6	45.2	4.9	50.2	49.8	100
25-29	37.3	12.8	2.8	52.9	4.8	57.7	42.3	100
30-34	40.0	14.4	3.0	57.3	5.0	62.3	37.7	100
35-39	40.4	14.7	2.9	58.1	5.4	63.5	36.5	100
40-44	40.6	15.2	3.0	58.8	6.0	64.8	35.2	100
45-49	40.7	15.4	3.1	59.2	6.7	65.9	34.1	100
50-54	42.1	15.5	3.3	61.0	6.8	67.8	32.2	100
55-59	45.2	16.1	3.7	65.1	6.5	71.6	28.4	100
60-64	51.3	17.5	4.5	73.3	4.9	78.1	21.9	100
65+	61.2	18.8	5.8	85.8	2.2	88.0	12.0	100
Total	40.9	14.1	3.5	58.4	4.7	63.1	36.9	100

Source: National Population and Housing Census 1991

The following table presents social security coverage in 1996. The population thus covered amounts to 53%.

*Social Security health coverage*

*In millions of persons covered, by percentage structure and by total population covered. 1996*

Social Security	Population covered (millions)	Percentage share	Percentage of total population
National	8.2	43%	23%
Provincial	5.2	28%	15%
“Other (Security forces, etc)”	1.2	6%	3%
INSSJyP	4.3	23%	12%
Total	18.9	100%	53%

Source: Author, based on data from ANSES, COOSPR, MEOySP

The enterprises offering prepaid health care in 1996 provided health coverage to 2.5 million people. 40% of these people were also contributing to the social security system.<sup>1</sup>

Thus the population covered by the public sector is obtained by subtracting from the total population the population that has some kind of insurance. For 1996 this estimate was around 14.5 million people, or 41% of the country's population. The population covered by the public health system appears characteristically as being of low socioeconomic status, outside the formal labour market, with large numbers of unemployed and underemployed.

### *Public sector expenditure on health*

The consolidated total public sector (national, provincial and municipal) expenditure on health for 1996 was 80 000 million pesos.<sup>2</sup> Social expenditure accounts for 67% of these costs (54 000 million pesos). In terms of GDP they amount to 18.2%. Health expenditure is an important component of social expenditure and amounts to more than 4% of GDP, as can be seen from the following table:

#### *Health expenditure in the public sector in Argentina, as a percentage of GDP*

	1995	1996	1997
Health expenditure	4.81	4.42	4.15
Medical care	1.69	1.64	1.63
INSSJyP	1.08	0.91	0.73
Provincial + national social welfare	1.80	1.65	1.57
Drinking water + sewerage	0.25	0.22	0.22
Remaining social expenditure	14.49	13.68	13.28
Total social expenditure	19.30	18.10	17.43
Other public sector expenditure	10.35	9.66	9.07
Total public sector expenditure	29.65	27.76	26.50

Source: Author, based on data from MEOySP

As already pointed out, the health sector finances programmes of medical care (hospitals and networks of primary care in the provinces and municipalities),

<sup>1</sup> Gonzalez García, G. and Tobar, F. *More Health for the Same Money*, ISALUD-GEL Publishers, 1997.

<sup>2</sup> MEOySP.

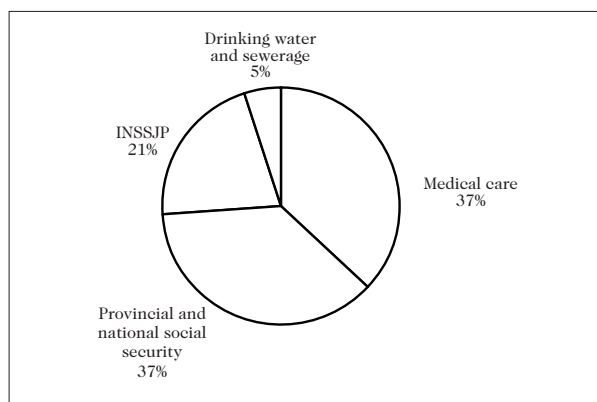
national and provincial social welfare, the INSSJyP (a social security fund), and a number of environmental sanitation programmes.

In the area of health, the State at the national level has a regulatory function and provides technical and financial assistance. It also has certain health care and prevention programmes, where the epidemiological characteristics of the problems with which they are concerned are such that central control is better to combat these diseases. Examples of this are the Chagas disease control programme, the PNLRHS and the health statistics programme.

The provinces are major providers of health services. They mostly finance programmes of services provided by their own personnel, and have their own social welfare programmes. The situation of the municipalities is similar, although the services they finance are usually less complex.

Estimated expenditure on health for the public sector as a whole in 1996 was \$ 13 141 million. Analysis by jurisdiction indicates that 52% of spending was at the national level, 43% by the provinces and the remaining 5% by the municipalities.

#### *Distribution of health expenditure*



Source: Author, based on information from MEOySP,

#### *Consolidated public sector spending on health, in millions of pesos*

Jurisdiction	1995	1996
Nation	7255	6867
Provinces and City of Buenos Aires	5553	5630
Municipalities	639	644
<b>Total</b>	<b>13447</b>	<b>13141</b>

Source: MEOySP

Per capita expenditure on health in the public sector in 1996 was \$ 373, while specific expenditure (not including sanitation) for the population with no coverage by any other subsector was \$ 320.

Estimates of expenditure in the private sector place it at about \$ 8500 million.<sup>3</sup>

In summary, our country spends more than 7% of its GDP to maintain and improve the health and quality of life of the people through expenditure on health. Per capita spending on health by society thus amounts to \$ 600.

### *The National Human Retrovirus and AIDS/STD Control Programme (PNLRHS)*

The federal system of government in our country permits the establishment of institutional responsibilities for health care. Thus, the State at the national level does not have service providers, but to cope with the problem of HIV/AIDS it has set up a national programme at the central level.

The missions and functions of this programme include prevention of the disease by all possible means, the establishment of a general regulatory framework for the implementation of practical measures for prevention, the development of a national epidemiological network and the training of health personnel in practices of protection against AIDS. This national programme is also responsible for the distribution of specific drugs to combat the disease free of charge.

To this end, it has its own budget with which to carry out these activities. The procurement of drugs is the activity that takes up the most resources, accounting for about 97% of the total budget for the programme.

#### *Budget and spending of the National AIDS Programme. In millions of pesos.*

	1994	1995	1996	1997
Initial credit	10.3	21.8	13.4	18.9
Actual credit	8.1	19.6	12.7	54.7
Expenditure	8	17.2	12.4	

Source: National Ministry of Health and Social Action

As we have seen, the AIDS Programme has a comprehensive policy of coverage consisting in the distribution of the drugs required for specific treatments and of other drugs for the treatment of opportunistic infections. With the continuing

<sup>3</sup> Gonzalez García, G. and Tobar, F. *More Health for the Same Money*, ISALUD-GEL Publishers, 1997.

and systematic incorporation of advances in technology, ever increasing resources are needed year by year to obtain new drugs and to extend coverage.

As the AIDS epidemic advances, the budget of the national programme is being increased. In 1997, the inclusion of drugs to combat retrovirus infections and the extension of coverage to more than 6600 patients resulted in an increase in the initial credit of nearly 200%.

The programme is being financed from resources from the general revenue of the nation, since there are no specific resources earmarked for the financing of these policies.

The national Ministry of Health also has a project with external funding (IBRD) —the LUSIDA, whose main objective is to develop policies of prevention throughout the community, focusing especially on the groups at risk. The budget for this project is \$ 30 million, to be spent in the next four years.

At the same time, most of the provinces and many municipalities have developed their own programmes to combat the disease. These programmes have their own budgets and in all cases they coordinate their action with the PNLRHS.

#### *Coverage of the PNLRHS*

The current legislation in Argentina establishes responsibilities for coverage by each of the subsectors in the health system. Thus, both the social security and private health insurance have a legal duty to provide comprehensive coverage to the people for whom they are responsible.

This measure brought the target population for AIDS in the public sector to about 60% of the total population. The establishment of institutional responsibilities for the care of people with HIV/AIDS was an important step forward in the provision of care.

At present the programme covers the normal drugs requirements of 6650 patients. In regard to coverage of the rest of society, the number of patients is not known, although it is thought to be substantial.

#### **Potential years of life lost (PYLL)**

For most diseases, the effect of disease on people is measured in terms of deaths. The World Bank and PAHO have developed indicators that make it possible to measure effects of diseases in terms of potential years of life lost (PYLL) and potential years of active life lost (PYALL).

The first indicator seeks to measure the effects of death at earlier than expected ages. The number of years of life that would remain at the time of a person's death, in other words, his remaining life expectancy if he did not die at that point, is estimated. This life expectancy is obtained from mortality tables published national institutes of statistics.

Potential years of active life lost (PYALL) attempt to measure the burden of morbidity and mortality from angles not hitherto taken into account such as the quality of the remaining life expectancy. This indicator attempts to measure a person's disability in terms of the capacities lost through disease, up to the point of death (morbidity). The effects of mortality are added to the effects of morbidity and the two are adjusted using a discount rate so that future years carry less weight than years past.

In 1995, there were 270 000 deaths in the country, according to the national Ministry of Health and Social Action. For purposes of analysis, these deaths were classified according to ICD-9 and divided into age groups. The following table shows the percentage structure of these deaths by cause and by age group.

Disease / age	< 1	1-4	5-14	15-49	50-64	65+	Total
Heart	3.40%	9.20%	7.50%	15.60%	27.00%	37.90%	31.10%
Malignant tumours	0.00%	0.00%	12.40%	17.40%	28.10%	17.50%	18.20%
Cerebrovascular	0.00%	0.00%	0.00%	6.20%	9.20%	10.20%	8.90%
Accidents	3.80%	21.20%	29.10%	14.00%	3.10%	1.40%	3.60%
Pneumonia and influenza	4.70%	8.00%	3.30%	1.50%	1.50%	3.90%	3.30%
Diabetes mellitus	0.00%	0.20%	0.30%	1.20%	3.10%	3.20%	2.70%
Perinatal infections	48.50%	0.00%	0.00%	0.00%	0.00%	0.00%	2.60%
Suicides and homicides	0.00%	0.80%	3.70%	7.00%	1.50%	0.40%	1.40%
Congenital anomalies	17.80%	8.80%	3.80%	0.30%	0.00%	0.00%	1.10%
Malnutrition	1.20%	3.40%	0.70%	0.20%	0.20%	0.50%	0.50%
Other	20.60%	48.30%	39.20%	36.70%	26.30%	25.00%	26.60%
Total	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

Source: Author, based on data from the MSyAS

Heart disease thus appears as the leading cause of death, but deaths are concentrated in the higher age groups. Malignant tumours show a similar pattern, although nearly 40% of cases are to be found in the 15-64 age group. Accidents, suicides and homicides are also concentrated in the middle age groups.

The purpose of calculating PYLL is to obtain indicators that can be used for the weighting of deaths by different causes so that they can be compared, and thence to make cost-benefit analyses with which to establish priorities in health policies.

Estimates of PYLL for 1995, taking life expectancy at death<sup>4</sup> obtained from mortality tables by sex and age for the period 1990-1995 as published by the

<sup>4</sup> This estimate underestimates potential life, since calculation of life expectancy at every age is based on the causes of death for that age group, so that if these causes are eliminated, life expectancy at every age should be increased.

National Statistics and Census Institute (INDEC), as the upper limit, show some 5.4 million PYLL in 1995.

*Ranking of some causes of death by numbers and by PYLL. Argentina, 1995*

By number of deaths	By PYLL
Heart	Heart
Malignant tumours	Malignant tumours
Cerebrovascular	Perinatal conditions
Accidents	Cerebrovascular
Pneumonia and influenza	Accidents
Diabetes mellitus	Pneumonia and influenza
Perinatal conditions	Diabetes mellitus
Suicides and homicides	Congenital anomalies
Congenital anomalies	Suicides and homicides
Malnutrition	Malnutrition

Source: Author, based on data from MSyAS and INDEC

Comparison of PYLL for total deaths in one year is not directly comparable with PYLL for AIDS. Comparisons of this type can be done to get an idea of the magnitude of the problem. It must be remembered that the 270 000 deaths recorded in 1995 represent a fluid magnitude, whereas in the cases of AIDS it is usual to work with a stock magnitude, that is, the number of AIDS cases are the sum of the flows occurring from year to year (from 1982 to 1997). At the same time, not all AIDS cases evolve to death.

*PYLL on account of AIDS*

The potential years of life lost through AIDS-related causes by the population registered by the AIDS Programme (10 900 cases) amount to some 450 000 years.

To calculate these PYLL, statistics from the AIDS register and deaths by sex, and ages in years up to November 1997 as recorded by the National AIDS Programme (PNLRHS), were used.

Recorded deaths account for 30% of all cases, but it is recognized that death records are not kept up to date. In our estimates, in order to simplify calculations, survival of patients in the third stage of the disease (cases) is taken to extend for five years from the date of registration. This assumption also applies to the nearly 5000 cases to whom the Programme is providing care with a permanent supply of drugs.

If we take account of under-registration and failure to report cases of AIDS, there may be estimated to be more than 13 700 cases. Estimation of PYLL for

these cases amounts to more than 560 000 years from the appearance of the epidemic in about 1982 to the present day.

One point to be remembered is that the obligation to report cases of AIDS only applies to persons receiving care in the public subsystem (hospitals), as there are no incentives for either social welfare or private insurance to report their patients. Nor are there any statistics on people who are seen privately without any form of health insurance. It must therefore be said that the number of cases registered with the PNLRHS constitutes a minimum indicator of the incidence of the diseases in the overall population.

A simplified indicator of the impact of AIDS can be obtained by measuring it in respect of recorded deaths, and thus the total number of cases recorded was 5% of deaths in 1995. If the same indicator is measured in terms of PYLL, the proportion amounts to more than 10% of PYLL in respect of deaths in 1995. This change in relative weight is due to the fact that there is a greater concentration of AIDS cases among younger people, so that per capita PYLL is 40 years whereas per capita PYLL for overall deaths does not exceed 20 years.

The reported cases that figure in the statistics of the PNLRHS correspond to the persons receiving treatment for their disease in the public hospitals. Under-reporting is not only due to erroneous diagnosis but also to the fact that people may not seek specific treatment in the public sector. These people may not receive treatment at all, or may be treated in the private sector. The latter may be covered by prepayment schemes, while others may have no health insurance.

### **The costs of HIV/AIDS**

The resources consumed by AIDS represent a substantial cost to the economy as a whole, since they are mostly derived from reallocations from the productive sector to the health services sector. Since there is no cure for the disease, treatment is aimed at improving the quality of life and prolonging the survival of patients. The high cost of these treatments call for analysis. The costs of HIV/AIDS can be divided into direct and indirect costs.

#### ***Direct costs***

These are the costs connected with personal care for individuals and their health. They include, inter alia, the specific treatment of HIV/AIDS, opportunistic infections, the costs associated with education for health, prophylaxis and research.

Although there is no single basis for calculation to permit comparisons of the disease between different countries, the importance of AIDS in terms of consumption of resources must be stressed. One possible measure for comparison between countries is the cost of treating the disease as a percentage of GDP per capita. This indicator is found in all cases above 150% when treatment is adequate. Some

estimates of the direct costs of the disease in Latin American countries are shown in the following table.

*Costs of treating AIDS in Latin America*

	Per capita GDP	Cost of treatment		As percentage of per capita GDP	
		Low	High	Low	High
Argentina (1)	9000	8000	14 000	89	156
Brazil (2)	2160	6000	12 000	278	556
Mexico (2)	2080	3286	7344	158	553

Note: (1) Pesos at current value 1997 (2) Brazil: dollars at 1988 value and Mexico: dollars at 1985 value.

Source: Author, based on data from González, E. MSyAS, MEOySP.

Variations between estimates in the same country are due to the type of treatment to which the population has access and the availability of health services and drugs for those who do not have health coverage, as well as differences in relative prices between countries. Thus in the majority of cases the real costs per patient are closer to the lower limits shown in the table.

In our country the health sector is organized on the basis of subsidized supply, so that the infrastructure in the public sector is fixed in advance and access to it is unrestricted. This system makes it possible to meet almost all the demands made by the population. Even in public sector hospitals, the fact that the infrastructure capacity of the system is nearly always saturated by the rates of utilization meant that AIDS was displacing patients with other diseases up to the beginning of the 1990s.

Drugs are provided either by the public sector hospitals (drugs in general) or by the PNLRHS (specific drugs). It must also be emphasized that the public sector is endeavouring to incorporate new forms of treatment once their efficacy has been proven. The first step along this route is the standardization of treatment schedules by the Ministry of Health and Social Action. Thus patients covered by the PNLRHS have so far had access to the latest generation of drugs, provided free of charge in accordance with a legal framework.

The organization of the health sector in Argentina is making possible greater and better access to the care required for the disease, and it may thus be considered that coverage is almost global. Thus, although the costs of the disease in Argentina do not differ noticeably from other countries, the treatment of the disease does present important differences in terms of the care and medication given to patients.

It must also be remembered that the direct costs of AIDS must be associated with the opportunistic infections that accompany the disease.

### *Indirect costs*

This type of costs is divided into costs due to loss of productivity due to morbidity and unrealized potential productivity due to mortality. Indirect costs include the value of the potential product not produced, and other losses not valued in the overall economy, such as housework, the suffering of the family, etc.

This study is concerned to evaluate the treatment of the disease, so that these types of costs are not included in the analysis. In a cost-effectiveness analysis covering all the intervening factors it is important that they should be taken into account.

### *Cost-effectiveness analysis*

Cost-effectiveness analysis is a useful tool for comparisons of alternative programmes whose effects are measured in the same type of units. Evaluation attempts to establish a measure of the cost-effectiveness of at least two alternative policies for the same problem. As in any equation, there is a dividend and a divisor. The numerator is defined depending on the material to be analyzed and the standpoint of the work to be carried out. This may be the total cost (direct + indirect costs), the net health cost (direct costs - direct benefits), or the net economic cost to society (direct + indirect costs - direct benefits - indirect benefits). The denominator is a common measurement of the relevant effect of the programme, such as the number of years of life gained, or patients treated successfully.

Thus, the costs and benefits of the programme to be evaluated are measured in monetary terms and physical units respectively. The rule of decision in analysis is to maximize the effectiveness of each alternative for a given budget. In this way, comparisons can be drawn between situations that have the same point of departure and the same objective.

The relevant direct costs in cost-effectiveness assessments are of three types:

1. Costs of treatment;
2. Reduction of extra health costs through prevention; and
3. Extra costs due to prolongation of life, but not related to the main treatment.

In our analysis with a view to simplifying our estimates we shall work with the first type of costs. With respect to years of life gained there are four possible discounting criteria:

1. Ex ante discount of the increase in life expectancy;
2. Ex post discount of the increase in life expectancy;

3. The change in the accumulated annual probabilities of survival is discounted each year in respect of maximum life expectancy; and

4. The years of life gained are discounted in accordance with a weighting for risk.

We shall use the last of these four criteria, since it involves an important factor that has not been taken into account in the other methods: the establishment of indicators of the risk of survival (probability that having survived the previous year, a patient will also survive the current year).

In summary, we define the costs (numerator) of the equation as the actual value of the total direct costs of treatment. This gives:

$$CT = S CD_t * 1/(1+i)^t$$

- where CT is the total of the direct costs discounted in t;
- $CD_t$  is the total direct costs in t;
- t defines the years for which the disease continues; and
- i is the discount rate applicable.

We define the denominator as the function:

$$Q = S(F_t * d^t * K_t)$$

· In which  $F_t = Pp_t$  are the cumulative conditional probabilities (that a person who lived through t-1 will continue to live in t);

·  $d^t = 1/(1+i)$  is the discount factor; and finally

·  $k_t$  is the term permitting adjustment for the person's quality of life from year to year. This factor takes the value of 1 when the person is in very good health and 0 upon death.

Each term is the expected value (adjusted for quality) of expected health status in the programmes to be evaluated.

### *The treatments to be compared*

This analysis works with two alternative treatments for adults.

1. Alternative 1, based on anti-retroviral treatments, at present being used in our countries and delivered through the PNLRHS.

2. Alternative 2 is defined on the basis of treatment involving the use of two drugs.

For the two alternatives to be evaluated, a system of continuous monitoring has been assumed from the moment of original infection with HIV. These con-

trols provide an adequate picture of the evolution of the disease. These controls consist in measurement of the viral load and CD4 three times a year, with continuous clinical controls and without anti-retroviral drugs.

It must be pointed out that it is assumed in all cases that the patient values life and is therefore willing to comply in time and manner with the treatment prescribed by the doctor. The main features of each treatment are described below.

### *Alternative 1*

The effectiveness of combining these drugs to arrest the progression of the disease, improve the quality of life and extend the life of patients is not questioned in medical circles.

The principal effects of these new schedules of treatment are to reduce the appearance of opportunistic diseases, and this in turn implies a change in the type of health care hitherto prevalent in the treatment of AIDS: passage from an acute care model centered on public hospitals to a model in which patients are treated as chronic sufferers.

The main items of direct cost in alternative 1 are the specific drugs, which account for more than 60% of the annual costs of treatment (\$ 14 000). Treatment in accordance with this alternative was given by the PNLRHS and its value was calculated as from the 1998 budget of this national programme.

The estimated survival of patients treated with this type of therapy can be as much 15 years from the time the individual became infected. The discounted direct costs of treatment amount to \$ 52 500. The costs of drugs are taken as their market prices and it is considered reasonable to assume an reduction in these prices of 3% annually.

With this treatment the annual mortality rate is estimated to be close to 3 % annually for the first seven years of the disease, moving to 1% a year for the rest of the period of evaluation. Although there are no completed studies on the evolution of the disease with these treatments, the improvement in the epidemiological parameters during the first three years and its estimated progression are sufficient for us to evaluate this hypothesis as adequate.

With respect to quality of life, for asymptomatic carriers the loss of capacities is marginal, corresponding to a cumulative annual conditioned probability of 2%. For the second stage in the evolution of the disease (chronic patients), this loss of capacities is evaluated at a cumulative annual rate of 3%.

### *Alternative 2*

The treatment follows the evolution of HIV/AIDS and is based strongly on the hospital care services, since the main milestones in the disease are the appearance of opportunistic infections, for which the available health infrastructures need to be used.

In preparing the AIDS Programme the Ministry of Health and Social Action undertook, with the help of the World Bank, an economic evaluation of the direct costs of the disease. This estimate of treatment with two drugs ran to \$ 63 000 per adult (for all stages of the disease). The main methodological steps in this estimate were:

- Kaplan Meier curves, with a median survival of 11 years from the moment of infection, 97% mortality at 12.5 years and 3% of cases with slow evolution.
- The disease has three distinct stages: asymptomatic carrier (7.5 years), symptomatic carrier (2.5 years), AIDS (2.5 years).
- The treatments are palliative, improving patients' quality of life but not postponing death.
- Estimates of the prices of goods and services are given as market prices.
- The treatment was validated in discussions with the managers of the PNLRHS and other specialists on AIDS.
- The loss of capacities occurs in three distinct stages. When patients are asymptomatic carriers loss is about 2% of the annual cumulative level. During each year of the second stage of the disease this loss in the quality of life is around 12% annually, while patients with AIDS suffer a more or less total loss of their capacities.

To summarize, the following table shows some considerations to be kept in mind for each of these alternatives.

Aspect to be considered	Alternative 1	Alternative 2
Treatment	Care consisting in permanent medication	Acute care in the hospital system
Stages of the disease	Asymptomatic carrier; Chronic patient	Asymptomatic carrier; Symtomatic carrier; AIDS
Patient	Based on patient as a chronic sufferer	Evolution of the disease to death
Main requirement	Appropriate medication in time and form	Available health facility
Quality of life	Gradual loss of 2% of capacities	Important changes as patient evolves to next stage of the disease
Survival (from the time at which infection occurred)	Estimated at 15 years	12.5 years

Continues

Aspect to be considered	Alternative 1	Alternative 2
Mortality	3% in the first 7 years and 1% in the following years	Median of distribution over 11 years
Direct costs of treatment	§ 52 500	§ 63 000
Indirect costs	Maintenance of productive capacity and improved quality of life	“Total loss of capacities, deterioration in the quality of life”

### *The results obtained*

The table presents the results of the analysis. It should be pointed out that both for the costs and the effects of the types of treatment compared, an annual discount rate of 6% was used.

The marginal cost per year of life gained (weighted for quality of life) was § 6 600 for the first alternative and § 11 300 for the second alternative. Treatment with anti-retroviral drugs, including protease inhibitors, is considerably more cost-effective than treatment not including these drugs. Thus, the direct costs per year of life gained are 40% more effective for alternative 1 than for alternative 2.

Programme	Total effect	Total cost	Cost-effectiveness
Alternative 1	8 years of life gained	§ 52 000	§ 6 600
Alternative 2	5.5 years of life gained	§ 63 000	§ 11 300

Source: Author

This result is obtained through two effects: on the one hand the numerator for alternative 1 is 13% less than the discounted direct cost of the second treatment. Secondly, years of life gained adjusted for quality of life with the first treatment exceed years gained with the second treatment by 44%.

The discount rate has no effect on any sensitivity analysis of the results that may be attempted, since it is used to weight both the numerator and the denominator of the indicator. Nevertheless, sensitivity tests can be carried out by reducing the costs of the package of care in alternative 2, since treatment with protease inhibitors in alternative 1 is considered as fixed.

If the practices of alternatives are reduced, a deterioration in the quality of life of the persons receiving this new treatment is to be expected, together with an increase in the mortality rate. If we maintain these two variables unchanged in

respect of the second treatment evaluated, the discounted direct cost that equalizes the results between the alternatives requires the second alternative to reduce its costs by \$ 26 500. Alternatively, measured in years of life gained, the second treatment must improve its effectiveness (years of life gained weighted for quality) by four years, without variation in the costs of treatment.

It can thus be seen that it is of value to introduce the recently developed methods of management of the disease whose effectiveness is based on the administration of drugs and which do not require the use of hospital services.

## Conclusions

For the health sector this type of treatment raises the need to redefine the pattern of care, no longer based on installed health facilities but relying instead on the administration of drugs (recurrent expenditure).

The emergence of the epidemic led to the inability of the health system at the beginning of the 1990s to cope with this new Malthusian mechanism of population control. In a system such as that of Argentina the reaction to AIDS took the form of increased demand on the health services, and especially on hospitals in the public sector. Within the hospitals scarce resources were reallocated and traditional pathologies displaced. Ultimately, the greatest effect was an excessive burden of demand on the health care services and reallocation of existing resources.

The new forms of treatment are based on the administration of drugs that improve the quality of life and prolong the life expectancy of people with AIDS. The impact on the economy is felt either in the necessary reallocation of resources from the productive sectors to the health system, or else within the system, with the reappropriation of budget lines to AIDS control programmes.

Since the supply side is subsidized in the public health subsector, the costs of the system become fixed costs (at least in the short term), preventing the reallocation of resources unless services are closed and the existing infrastructure adapted. This is the dilemma facing the provincial and municipal governments.

At the national level, since the health service does not have its own health personnel, resources for the PNLRHS are found by reallocating funds from other Ministry of Health programmes.

At the same time, the statutory requirement on institutions to provide coverage for their patients takes demand away from the public sector and enables the costs to be shared among the subsectors, so that more equitable functioning of the health system is pursued.

The 6 650 patients receiving treatment today under the PNLRHS account for the addition of that many years of life, since they would otherwise be lost through the death of these patients. The cost of this care adds a substantial new fixed cost to the public sector budget, since the discontinuation of these treatments would condemn patients who are for the first time receiving an effective palliative therapy for their condition.

In the light of this analysis, it is clear that the underlying policy on HIV/AIDS should be prevention. Until any definitive solutions for this disease emerge, AIDS continues to produce situations that call for redefinition of the health system where it is not appropriate. Thus education and promotion of health care are the most cost-effective means of combatting the disease.

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ANTI-RETROVIRAL THERAPY AND PUBLIC HEALTH:  
A BALANCE OF THE BRAZILIAN EXPERIENCE\*

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The objective of the present paper is to record and analyse the implementation process of anti-retroviral therapy in the Brazilian public health network. The final text is based on documents commissioned to consultants in the fields of public health, economics and sociology and on the suggestions of participants in a workshop held in Brasilia in March 1988. The preparation of the document was funded by UNAIDS and by the National Programme on SDT/AIDS.

The text is divided in four chapters. The first provides a general overview of public health in Brazil and of the specific problems created by the HIV/AIDS epidemic. The second chapter deals with the social and political conditions which allowed the implementation of this therapy in the public network, and the conditions for its sustainability. The third examines some hypothesis about the evolution of the cost of providing anti-retroviral drugs, and the perspectives for its continuity from a governmental budget's perspective. The last chapter summarizes the main conclusions and discusses the future challenges of anti-retroviral therapy in Brazil.

## **Public Health and Anti-retroviral Therapy in Brazil**

### ***Public Health and AIDS in Brazil***

Brazil, the largest country in Latin America, is considered the world's eight largest economy, with a Gross National Product (GNP) of approximately 810 billion dollars (1997) and an annual economic growth rate estimated between 2 and 3%. *Per capita* GNP grew from US\$ 4,625 in 1995 to US\$ 5,125 in 1997, but the income distribution continues to be very concentrated. The deep changes which took place in the country in the past 40 years were characterized by the accelerated urbanization, industrialization and, more recently, globalization of its economy.

Brazil has the world's sixth largest population, estimated in 1996 by the Brazilian Institute of Geography and Statistics (IBGE) as 158 million, corresponding to a density of 18.5 population/sq.km. (relatively low when compared to the global average of 38/sq.km.).

Life expectancy is currently 67 years, showing a progressive evolution from 60 years in 1986 and only 45 years in 1950. These are national averages; marked

regional differences still exist. The infant mortality rate shows a steady decrease, as demonstrated by comparing the rates in 1984 (81.5 per thousand live births) and in 1994 (40.0 per thousand live births), and it is higher in the North and Northeastern regions.

A survey on the composition of household budgets carried out by IBGE in the 11 largest metropolitan regions showed a true explosion of expenditures on housing, education and health between 1987 and 1996. Monthly expenditures with the last item alone increased approximately 150% in this period, a substantial amount when compared to the increase of expenditures on food (78%) or personal services (109%).

A detailed analysis of health expenditures, which accounts for almost 10% of the total household expenditures, shows a high concentration on, health insurance or maintenance plans and dental care: together, they account for approximately 73% of direct household health expenditures, and are growing. In the period 1987-1996, the increases of the average monthly expenditures were 124% for drugs, 129% for dental care and 514% for health insurance plans.

Regarding government expenditures, a preliminary survey carried out by the Ministry of Budget and Planning's Institute for Applied Economic Research (IPEA) in 1995 showed that the *per capita* expenditure in the public sector (considering the three levels, Union, States and Municipalities) would be in the neighbourhood of R\$ 140 per population/year. It is estimated that half of these monies are spent directly on care, approximately one fourth on prevention activities and the remainder on staff and administrative activities. The federal level is responsible for the largest part of the public expenditure on health (63%). In the year mentioned, the Union's expenditures on health corresponded to approximately 13% of the total revenues. On their hand, states and municipalities have invested 9.3% and 11.6% of their available revenues on health.

Compared to that in developed countries, this level of expenditure can be considered insufficient. Countries like Canada, France and the United Kingdom spend at least US\$ 2,000 *per capita* every year (adding public and private expenditures). In the US, this figure is US\$ 3,500 *per capita*/year. Even for Latin America, the Brazilian figures are low. The corresponding values of annual health expenditure *per capita* in Argentina and Chile are US\$ 400 and approximately US\$ 500, respectively.

The public sector continues to provide health care to approximately 75% of the Brazilian population, through a network made up by some 7,000 hospitals and 290,000 beds. The private sector, which serves less than a quarter of the population, has some 4,300 hospitals, most of them providing services and an additional 223,000 beds, under contract, to the Unified Health System (SUS). Nationwide, there are 2.7 beds per 1,000 population, excluding intensive care (ICU) and psychiatric beds.

One of the main reasons for the improvements in public care in the past few years has been the Ministry of Health's policy of progressive municipalization of health activities. By enabling the poorest municipalities to manage primary care funds, emphasizing preventive and primary care activities, it has fostered the improvement of health care of the poorest population groups and women's and children health.

It was in this scenario of administrative difficulties and progressive improvement of public health indicators that the country began to experience the challenge of HIV infection/AIDS.

The AIDS epidemic was first identified in Brazil in 1982 but, taking into account our knowledge about the natural history and the latency period of HIV infection, we can infer that the virus was introduced in the country at the end of the seventies, initially spreading in the main South and Southeast metropolitan areas and soon later beginning to spread to the other regions. Although currently all Units of the Federation have notified cases, the vast majority of the approximately 125 thousand cases notified to the Ministry of Health by the end of 1997 still is concentrated in the Southeast (which accounted for 89% of reported cases in 80-85 and for 69% in 94-97). By November 1997, 2,509 of the 4,974 Brazilian municipalities had reported at least one case of AIDS, and 825 municipalities had reported more than 5 cases.

Studies on the number of HIV-infected individuals in the country indicate a prevalence between 338 thousand and 448 thousand individuals between 15 and 49 years of age in 1996 (Ministry of Health, 1997). Some HIV seroprevalence studies in sentinel populations show median prevalences varying between 3.4% and 5.3% in patients seen in emergency services between 1995 and 1997; between 0.3% and 3.1% among pregnant women in 1995; between 0.3% and 13.3% in patients of STD clinics in 1995 and from 1.9% to 2.6% per thousand blood donors in 1996.

Since the beginning of the epidemic, the 20-29 year-old, which concentrate 71% of the total number of identified AIDS cases notified to the Ministry of Health by February 1997, has been the most severely attained age group. Earlier in the course of the epidemic, there was a progressive increase of the relative frequency of younger patients (20-29 y.o), which showed a trend towards stabilization after 1991.

The break down of the sexual exposure component shows that while in 1984 most reports (69%) concerned male homo/bisexuals, their proportion has progressively decreased, reaching 21% in 1997/98, as the participation of the heterosexual transmission (32% of the total number of cases) has grown. The transmission through blood and/or blood products has shown an important decline. On the other hand, there is a growing number of individuals which acquired HIV by sharing needles and syringes while using injectable drugs (21% of the total cases). These cases are concentrated in the centre-south of the country (81 % of the total cases in IDUs). In the pediatric population, perinatal transmission, which corresponded to approximately 25% in 84-87, accounts for approximately 90% of the cases diagnosed since 1994.

The fall in the sex ratio, from 16:1 in 1986, and 7:1 in 1988, to 3:1 ratio in 1997/98, has been interpreted as an indicator of the increase of heterosexual transmission to women, infected by HIV as a consequence of the high prevalence rates of HIV among male bisexuals and heterosexuals IDUs who have a stable sex relationship.

Approximately 66 thousand AIDS-related deaths had been reported to the Ministry of Health by 1995, 15 thousand in the last year mentioned, corresponding to the 11<sup>th</sup> cause of death in the general population. In that year, AIDS was the 8<sup>th</sup> cause of death among men and the 20<sup>th</sup> among women. When analysed by age, AIDS

was the second cause of death for both men and women in the 20-49 years age group, in the same year.

An overall comparison of the current situation of the AIDS epidemic in Brazil with that prevailing in the 80s reveals that it is undergoing a marked change in its geographic spread and is reaching new groups, socially considered to be more “vulnerable”. At the present time, the so-called “AIDS epidemic” is seen as rather the sum of several regional subepidemics in permanent interaction, due to the migratory flows, trade flows, manpower fluxes, tourism and other forms of population mobility.

### *Anti-retroviral Therapies and Public Health*

In 1988, the Brazilian Ministry of Health started, though rather timidly, to supply through the public network some of the drugs used to treat the main opportunistic infections affecting AIDS patients. In 1991, the MoH added anti-retroviral therapy to the public health system, beginning with zidovudine (AZT). The number of patients helped and the types of drugs offered increased progressively; by September 1998, the public network also supplied the anti-retroviral drugs didanosine (ddI), zalcitabine (ddC), injectable AZT, lamivudine (3TC), estavudine (d4T), nevirapine, delavirdine, saquinavir, indinavir, ritonavir and nelfinavir, and drugs such as amphotericin B, gancyclovir, pentamidine and human immunoglobulin, for the treatment against several opportunistic infections. Beginning in 1999, the state and municipal governments will be responsible for purchasing these drugs.

In 1997, 47,475 patients received combined anti-retroviral treatment, and 1,424 HIV-infected pregnant women received injectable AZT with the objective of reducing vertical transmission. By September 1998, the number of patients under treatment had risen to 60,000, with an estimated monthly increase between 2,000 and 3,000 new patients. 55% of the total used therapeutic regimens which included protease inhibitors.

In 1998, the amount of funds used for purchasing anti-retrovirals has increased steadily. The table below shows the amounts spent in 1996, 1997 and 1998, as well as the amount programmed for 1999.

TABLE 1  
*Expenditures in Reais (R\$) on Anti-retroviral Drugs - Ministry of Health, Brazil, 1996 -1999*

1996	1997	1998	1999*
R\$ 34,542,768.70	R\$ 241,818,653.82	R\$ 423,284,750.62	R\$ 632,446,924.48

(\*) Preliminary data

Given the broad scope of the current drug provision program and the continuously growing complexity of anti-retroviral therapy, involving a large number of drug combinations and complex tests for patient monitoring, the main new challenges faced by health teams and health managers at the different levels of the health system are:

### *Training of health professionals in the use of anti-retrovirals*

Anti-retroviral therapy has become a very dynamic field of knowledge, requiring constant update by the physicians responsible for patient care. Although the largest burden falls upon the physician, the current reality requires the contribution of the whole health team for a successful treatment, particularly regarding the increased patient compliance with anti-retrovirals.

The challenge of training health professionals has been faced in several ways. Among the strategies adopted, it is worth to highlight the partnership with universities throughout the country which, through agreements with the National Programme for STS/AIDS, have offered a great variety of training and update courses to professionals caring for HIV-infected patients. This strategy of having the university as the main axis of trainings for health professionals was consolidated in 1997, with the UNIVERSIDAIDS project. In the same year, more than 2,000 openings for training in patient care, prevention and epidemiological surveillance in the area of STD/AIDS were offered for all the health professions. The offer of trainings is in line with the needs of the region and follows priority criteria established by the State and Municipal Programmes for STS/AIDS.

### *Early diagnosis of HIV infection*

In spite of the availability of anti-retroviral drugs, a significant proportion of patients still is diagnosed in an advanced stage of the disease, with the appearance of the first opportunistic infection, thus missing the opportunity to begin the treatment in the asymptomatic stage, as well as to receive guidance on preventing the transmission of HIV infection.

To facilitate early treatment, the Ministry of Health has established Centers for Anonymous HIV Counselling and Testing (CTAs) throughout the country. Their main purpose is to ensure anonymous, confidential and free HIV serological testing to all individuals who wish to know their serological status. In these centers, the individual is assisted by a multidisciplinary technical team specially trained to provide information on the HIV test, on prevention of HIV infection and other STDs, and on the possibilities of treatment and other reference centers. By September 1998, 125 centers were functioning and 16 others were being implemented.

### ***Laboratory monitoring of the infected patient***

With the purpose of allowing the beginning of treatment still in the asymptomatic stage and a better monitoring of the efficacy of anti-retroviral treatment and thus the more rational use of these resources, a network of laboratories able to perform CD4+ and viral load counts was established in July 1997. This network comprises 33 laboratories for CD4+ and 30 laboratories for viral loads counts, with an installed capacity of 140,000 and 100,000 tests per year, respectively. Since the number of patients under treatment had reached 60,000 by September 1998, requiring an even bigger installed capacity for testing, other laboratories are being implemented to increase test coverage. The main obstacle faced in this implementation has been the scarcity of professionals in the public health network trained in the molecular biology techniques involved in this testing. This difficulty is being overcome with the support of universities, research institutions and public health laboratories.

### ***Definition of criteria for the provision of anti-retroviral drugs***

An important step in the planning of large-scale purchases by the Ministry of Health was the decision that the provision of anti-retroviral drugs would follow preestablished technical criteria. A technical advisory committee was created to establish them and support the decisions of the MoH. Annexes I and II summarize the criteria for the beginning, change and type of treatment to be instituted.

### ***Management of drug purchase and distribution***

The experience acquired by the National Programme since 1991 in the management of drug purchases, distribution and inventory control has been fundamental for successfully facing the current situation, in which a large number of different drugs needs to be purchased and distributed uninterruptedly. The staff involved had to be increased, including a pharmacist, among other professionals. The lack of this type of professionals in some states and municipalities has brought about local managerial problems.

To rationalize costs and facilitate the logistical control of the planning processes for the purchase, distribution, inventory control and dispensation of the many different anti-retroviral drugs used in Brazil, the National Programme has developed a computerized system, known as Computerized System for the Logistical Control of Drugs – SICLOM, for managing the basic information required for this type of treatment. This system will be essential for managing the funds involved in this activity and will allow, among other things, the creation of an updated national roster of patients using anti-retroviral drugs and a process of prescription criticism, as well as the rational, programmed and well-dimensioned provision of drugs, in line with the National Programme's technical recommendations.

SICLOM allows the elaboration of more than 40 different technical and managerial reports, and it is being integrated with another software devoted to data management of the laboratory tests used for monitoring the treatment of HIV/AIDS patients (counts of CD4+ cells and viral load), known as the Laboratory Exams Control and Data System - SISCEL. This system is being implemented initially in 50 reference laboratories of the CD4 and Viral Load Network. With this database it will be possible to obtain the results of the exams through the Internet, on line, with the assurance of fastness, safety and quality.

Undoubtedly, the main difficulties for the implementation of SICLOM and of SISCEL are the size of the network of interlinked services and the geographic distance between them. In addition, the team responsible for system maintenance is small and there is still a great resistance from the dispensing units to adopt this computerised system for registration and control of dispensation. Because of cultural reasons specific to the Brazilian context, the health professionals, especially physicians, are not used to this level of control and automation of the activities, a situation which the MoH proposes to change.<sup>1</sup>

### **Anti-retroviral therapy in Brazil and its socio-political context**

Throughout the eighties, we have witnessed one of the most important transitions in the field of social policy in Brazil: the affirmation of the right to health as a universal human right and the identification of the public sector as the basic responsible for its provision. It is important to examine this course and to register its specific implications on the fight against STD/AIDS and on the possibility of implementing the anti-retroviral therapies.

The first step towards the organization of a comprehensive system took place in 1975, with the creation of the National Health System (Law n° 6,229, 17 July 1975). The centralization created by this legislation would not remain untouched for long<sup>2</sup>, and it was naturally broken with the beginning of the country's redemocratization process, which was concurrent with the worsening of the Social Security financial crisis.

In the second half of the 80s, the constraints in the forms of assistance to states and municipalities, restricted to the payment for services, led to launching of the Program of Unified and Decentralized Health Systems in the States (SUDS)<sup>3</sup>, which provided more effective instruments of federal support to the expansion of the

<sup>1</sup> In May 1998, the Secretariat for Health Policy of the Ministry of Health proposed that the structure of this computerized system of logistical control be expanded to other health programmes within the MoH. Logistical control of drugs would begin by the Tuberculosis Programme and later would be expanded to the control of drugs in the National Diabetes Programme.

<sup>2</sup> José Carlos Braga and S.G. Paula, *Saúde e Previdência*. São Paulo, Cebes-Hucitec, 1981.

<sup>3</sup> Decree-Law n° 94,657, 20 July 1987.

state networks. With these measures, in 1987 most official expenditures in health were already being incurred in the public network<sup>4</sup>.

At this point of the process, the 1988 Constitution would create the deepest transition in terms of principles and would provide an organic form to the administrative evolution in course. The Constitutional text defined health care as a *social right*, no longer linked to work (Article 6). The legislation on Social Security continued to be within the private domain of the Union (Article 22), but health and the public care began to be considered as common competencies of the three governmental levels (Article 23), a point to which the legislation pertaining to health protection also concurred (Article 24, XII).

The universalization associated with the decentralization would take its final shape as the Unified Health System (SUS), created by the Organic Health Law (Law n° 8,080, 19 September 1990). Through the immense number of provisions, the spirit of the legislation indicates that the Federal Government is responsible, in practice, for the transferring of funds from the Ministry of Health and the Ministry of Social Security, the maintenance of the university hospitals and the planning and regulation activities. The states are responsible for the actual execution of services, when municipalization has not effectively taken place. Ideally, the municipalities should be fully responsible for the execution of health services, financed by the transfer of budgetary funds from the Federal Government and the States<sup>5</sup>.

The social concern for AIDS in Brazil arose within an important ideological and administrative transformation, consecrating the principles of universal health care, administrative decentralization and community participation.

### *AIDS and Democracy in Brazil*

While the process of redemocratization of the country permitted substantial advances in the definition of civil rights and government responsibilities in the health sector, it also opened up a whole new field for social action. In this context of advances in the organization of civil society, involving new social groups and new social issues, arose a social concern with HIV infection and AIDS in Brazil<sup>6</sup>.

In a short time this concern was translated into an intense activism of non-governmental organizations, closely reported on by the media. The first Brazilian NGO involved in the struggle against AIDS, (AIDS Support and Prevention Group-GAPA, in São Paulo) was created in 1985, the year of the first civil government in the country after more than two decades. The association between growing social concern, activism, and the electoral dynamics of the transition process to a civilian gov-

<sup>4</sup> Cordeiro, 1991, pp. 137-138.

<sup>5</sup> Carvalho and Santos (1995), pp. 137 *passim*.

<sup>6</sup> Concerning specific experiences, see the set of essays published in Parker et al. *AIDS no Brasil*. Rio de Janeiro, ABIA/IMS/Relume Dumará, 1994.

ernment created a favorable environment in which NGOs and governments started a whole new pattern of relations in terms of the conduct of social policies in Brazil.

In the state of São Paulo, the tradition of administrative autonomy, combined with the larger number of AIDS cases led, during the Montoro administration (1983-1987), to a pioneering and exemplary service: the AIDS Reference and Training Center (CRTA), which served as a stimulus for the creation of the first NGOs dedicated exclusively to AIDS, a pioneer action in social mobilization in Brazil<sup>7</sup>. In the state of Rio de Janeiro, this development took different paths. The state and the city did not have a professional program yet and their health infrastructure was precarious. On the other hand, the first community initiatives were led by individuals who brought to this arena their markedly reformist traditions of opposition and concerns with the so-called emerging questions of the 80s, such as ecology, gender and sexuality.

However, these two currents of activism were united in their effort of permanent criticism of government policies, heightened by the isolation of the National AIDS Programme in the Collor administration (1990-1992), after the removal of its first Director<sup>8</sup>. Even in that most critical moment, the NGO movement continued to follow an innovative course of action in the evolution of social movements in Brazil, the involvement in the elaboration of public policies.

At the end of 1991 the possibility for discussing the protocols of possible vaccine candidates, offered by the World Health Organization, promoted a re-approximation between NGOs, medical elites, and government officers. In the following year, with the change in the directorship of the National Programme, the level of these contacts became more important, as MoH staff and NGO members worked in close collaboration to prepare a letter of intention to the World Bank for a loan for a project for the control of STD/AIDS in Brazil.

The resulting agreement, signed on 16 March 1994, for the financing of projects in the areas of prevention, service delivery, institutional development and epidemiological surveillance was a decisive element for the independence and flexibility of operation of the National Programme. In addition, it provided the means for fulfilling one of the items of article 198 of the Federal Constitution concerning the organization of health services—community participation. With these funds it was possible to develop a cooperation between society and government, through the financing of NGO projects, which are a distinctive element of the Government's AIDS policy.

<sup>7</sup> With time, these organizations became increasingly independent from CRTA, and by the second half of the Quercia administration (1987-1991) its level of activity had decreased. Jose Stalin Pedrosa, former consultant to the NP STD/AIDS, personal interview, October 1997.

<sup>8</sup> Lair Guerra de Macedo Rodrigues directed the Programme from its creation in 1987, and was replaced by Eduardo Cortes in 1990. In 1992 Lair Guerra returned to the Directorship of the Programme until a serious auto accident in 1997.

### *Legal-Administrative Framework*

The new definition of social rights contained in the 1988 Constitution and its administrative translation, the Unified Health System (SUS), together with the activism of non-governmental organizations, created rare conditions of susceptibility of the State to social pressure as regards AIDS and permitted the structuring of these policies into innovative legal and administrative frameworks. In the circumstances of the 1980s it was possible, for the case of AIDS governmental programs, to partly overcome several obstacles. Firstly, the various phases of decentralization of health services made possible the active participation of sub-national government entities, with the creation of reference services, as was the case in the state of São Paulo, even before the Federal Government. Secondly, the high cost of treatment immediately created an elective affinity between the epidemic and public health care. Thirdly, the NGOs fought tirelessly against exclusion and discrimination. Finally, a series of specific circumstances permitted the maintenance of a great degree of independence and autonomy in the conduct of government policies.

From the point of view of the medical elite involved in the struggle against the epidemic, AIDS represented the emergence of a completely new field of medical research. After a brief conflict with cancer specialists, the identification of an etiologic agent brought the infectious diseases specialists into the scene, up until then relegated to the study of tropical diseases. This situation soon took on a generational character, as young physicians assumed a significant presence in the constitution of a new medical elite. These generational and technical conditions also resulted in a more open position of interaction with the other social agents involved. This was consistent with the progressive tradition of Brazilian infectious diseases medicine and public health.

From the point of view of the organization of government policies, the international dynamics of the epidemic had a natural impact on the internal context. From early on physicians, infectious diseases specialists and patients had a clear knowledge of the direction of scientific research and of government care and prevention policies in the developed countries. The international assistance to the government agencies materialized concretely in several areas and levels. In its initial phase the National Programme for STD/AIDS received funding from the Pan-American Health Organization (PAHO), directed at the critical area of training, thus helping to consolidate a national technical knowledge. From the point of view of the structuring of federal policies, a National Commission on AIDS was created in 1986.

Also of note, in the organization of federal policies, is the joint advising and support carried out by the scientific community and NGOs on research activities, vaccine studies and community activities<sup>9</sup>. In the end, all of these factors together

<sup>9</sup> Through the installation of Committees on Research (Ordinance # 348, 25 March 1993), on Vaccines (Ordinance # 336, 10 January 1994) and of Evaluation and Selection of NGO Projects (Ordinance # 843, 22 April 1994). See M. Ventura da Silva, *Legislação sobre DST/AIDS no Brasil*, Brasília, National

—the association with international agencies, the relative independence in the administration of funds, and the consistent partnerships with state and municipal administrations— guaranteed, as time went on, tangible results and the stability of the Programme's direction.

The trend towards the recognition of the specificities of treatment of persons with HIV/AIDS has also appeared at other levels of government, allowing, among other things, the creation of mechanisms which support a more active relationship between government and society, mirroring the dynamics at the federal level. Firstly, there are several examples of arrangements reserving hospital beds for AIDS patients in the state networks (Federal District, 1990) or determine the obligation to provide care for them in the public network (São Paulo, 1988; Rio Grande do Sul, 1992; Ceará, 1991, and Santa Catarina, 1993). Secondly, as a general rule the organizations providing care and assistance were granted the status of institution for public good, which allows tax exemptions, the transfer of public monies and the signing of agreements between the Executive Powers and NGOs.

At the municipal level, the initiatives take place in the area of rapports with NGOs and of organization of health services. In the first case, the concession of the status of a institution for public good, ensuring the above mentioned advantages, has been a constant characteristic. In the second case, it means the creation of municipal units for managing the transferred federal monies (Rio de Janeiro, 1993).

With its unfoldings and conditions, the provision of drugs has proved to be one of the elements of this strategy of administrative independence, openness to social activism and decentralization. This evolution begins with the authorization for marketing AZT, in 1988, as a result of very clear pressures.

On the one hand, there was already a substantial use of the drug, sustained by individual purchases in the United States or through donations from abroad. On the other hand, given the decentralized structure of health services in the country, once the medication was approved it would be difficult to stop purchase decisions on the part of hospitals and State Secretariats which managed to acquire AZT in a more or less asystematic way and promoted its distribution among patients in the public network. Probably as a way to keep the political and medical control over an already developing situation, the uncertainty regarding the action of the National Programme of STD/AIDS would be broken at precisely one of its most delicate moments. In 1991, in the beginning of the Collor administration, under its second director, the Programme decided to begin the procedures for the purchase and distribution of anti-retroviral drugs and drugs against opportunistic infections.

This decision was maintained when the previous direction returned in 1992, and here again, the agreement with the World Bank fulfilled a strategic role. By ensuring resources for training human resources, purchasing equipment and carry-

Programme on STD/AIDS, 1995, chapter 1. Similar technical commissions advising state authorities, with the participation of the scientific community and of NGOs, were created in several states, such as Mato Grosso do Sul (September 1992), Rio de Janeiro (1986), and São Paulo (1986).

ing out prevention programs, it allowed the managers to have the appropriate independence in key areas of activity and to concentrate their efforts in obtaining resources for drugs from the governmental area.<sup>10</sup> Between 1992 and 1996, the evolution of the drug provision program was marked mainly by the creation of its own logistical system, helped by the cooperation established with the state and municipal networks and by the limitation of the therapeutic possibilities.

With the new horizons opened in 1996 by the increased number of anti-retroviral and inhibitor drugs, associated with the potential of drug combinations, the National Programme and several social groups perceived that the moment required new actions.

On the part of the Programme, there was the political decision to broaden the drug provision program, and support for its funding was sought. On the part of society, the constitutional dispositions were not considered sufficient to ensure distribution, and government officers, activists and physicians lobbied in the National Congress for a specific law establishing the right to receive free medication.

Originally proposed by Senator and Former President José Sarney, the bill became Law 9,313 in November 13, 1996. Its first article explicitly states the state duty to provide HIV-positive individuals and AIDS patients, free of charge, *all the medications required to their treatment*, duly standardized and, whenever necessary, reviewed by the Ministry of Health for purposes of purchase by the managers of the Unified Health System. The second article determines that the expenditures ensuing from the law should be funded with Social Security resources from all levels of government (Union, States, Federal District and Municipalities), according to specific regulations.

According to the law's determinations, the National Programme began to prepare the medical documentation regulating access to treatment. In December 1996, several technical commissions, responsible for preparing a broad set of documents, produced the *Consensus on Anti-retroviral Therapy for HIV-Infected Adults and Adolescents* (1996-1997) and the *Consensus on Anti-retroviral Therapy for HIV-Infected Children* (1997). The directives for using anti-retroviral therapy also include the Guidelines of Therapeutic Conducts in HIV/AIDS for adults, children and for the reduction of vertical transmission (in its 1996 and 1997 editions). The regulation planned on the sharing of expenditures did not have the same fate, and it has not yet been drafted.

In the sphere of division of attributions, the Ministry of Health is responsible for funding the implementation and beginning of the operations planned, as well as by sustaining part of the permanent operations, which includes specifically the training of human resources, an important instrument for improving the quality of governmental activities, and the provision of drugs. On the other hand, states and municipalities are responsible for administrative expenditures, i.e, personnel, infrastructure, medical facilities, maintenance and other direct operational expenditures.

<sup>10</sup> José Stalin Pedrosa, former consultant to the National Program of STD/AIDS. Personal interview, October 1997.

The scenario composed by the National Programme and by these different state programmes continues to be criticized by NGO activists who have pointed out, for instance, the absence of NGO representatives in the meetings which established the national consensus, which include some points considered to be questionable<sup>11</sup>. They are ready to acknowledge the merit of the early decision of the governmental agencies regarding drug provision and their openness to the NGOs' activities. Nevertheless, they believe it is possible to say that, from the final user's perspective, the provision never ensured continuous and perfect drug availability; sometimes, the introduction of some therapeutic alternatives was delayed. The response to this situation, created by the already mentioned managerial deficiencies in the distribution, has been the multiplication of legal suits against the State by individuals having more resources and information. In the absence of these resources or information, the most common is the passive acceptance of waiting lists.

### **The funding of anti-retroviral therapy in Brazil**

The exam of the evolution of the resources allocated by the Ministry of Health to anti-retroviral drug purchases in the last two years indicates the level of priority given to this program by the Federal Government.

The funds earmarked for the purchase and distribution of AIDS medicines showed a significant increase after publication of the already mentioned Law 9,313, although the 1996 budget already reflected a clear concern with this issue. The anticipated spending for this budget item increased from R\$ 2.3 million in 1995 to R\$ 27.1 million in 1997. Considering the total spending for the purchase and distribution of medicines by the MoH's Central Agency for Medicines-CEME, the relative proportion of AIDS medicines rose from 0.5% to 4.8% over the same period.

The importance of this program in 1996 is further strengthened when considering the effectively released budget. By implementing a cut of 10.1% in the MoH budget, the Federal Government reduced significantly the funds earmarked for medicines, while maintaining practically unchanged the volume approved for AIDS. Therefore, the proportion of 4.8% increased to 9%.

In 1997 the commitment of the federal government to the struggle against AIDS became absolutely evident. The approved budget allocated to AIDS 25% of the total funding for drug purchase and distribution. In comparison with the previous year and in absolute terms, this item increased from R\$ 27 million to US\$ 137.3 million.

Analyzing the released budget, after the Ministry of Health suffered a 7.1% cut, the reduction applied to AIDS medicines was in line with that which occurred for all medicines. The budget proposal for 1998<sup>12</sup> defined an increase (to 27.3%) of the proportion of total spending on medicines earmarked for the purchase and distribu-

<sup>11</sup> Ronaldo Mussauer. President of the Grupo pela VIDDA. Personal interview, October 1997.

<sup>12</sup> Budget proposal (CMS) of September 1997.

tion of AIDS medicines. Regarding the budget approved in 1997, it is worth mentioning that, while a R\$ 50 million reduction in the total CEME expenditures on drugs is foreseen, the amount for AIDS medicines has been maintained.

The efforts of the Federal Government are complemented by actions at the state level. In the case of the state of São Paulo, for example, which accounts for 52.05% of the AIDS patients in Brazil, about 30% of the cost for the purchase of AIDS medicines is covered by state budget funds, which provided an average of R\$ 2.04 million monthly for this purpose in 1997.

### ***Resource needs for financing the anti-retroviral therapy in Brazil over the next 10 years***

The attempt to project the funding needs for anti-retroviral therapy for the next 10 years presents some difficulties. Firstly, it does not consider that, in this space of time, the therapy could benefit from the introduction of new medicines and that the current medical indication criteria could change. Secondly, the estimation of the volume of funds necessary for guaranteeing anti-retroviral therapy to all HIV-infected individuals would require a knowledge of the present HIV-infected population in Brazil, of its expected survival rate, and of its historical evolution. In addition, it would require information on what percentage of this population would fit the recommendations of the “Consensus on Anti-retroviral Therapy for HIV-infected Adults and Adolescents”, published as Ordinance 874 of the Ministry of Health and as the Guide of Therapeutic Conducts in HIV/STD. For the purposes of the projection several different hypotheses concerning the degree of coverage and the expected behavior of the drug prices were adopted.

*Concerning coverage:* the assumptions were that (1) the increase in the number of adults, children and pregnant women to receive the therapy over the next 10 years would continue to provide the present level of relative coverage; (2) anti-retroviral therapy would be provided to 50% of the estimated population of adults 15-49 years old infected with HIV; (3) anti-retroviral therapy would be provided to 75% of the estimated population of adults 15-49 years old infected with HIV; (4) anti-retroviral therapy would be provided to 100% of the estimated population of adults 15-49 years old infected with HIV.

*Concerning prices:* the assumptions were that (1) drug prices would remain constant (the data utilized were provided by the STD/AIDS National Programme); (2) drug prices would drop by 10% each year; (3) drug prices would drop by 20% each year.

The combinations of these different hypotheses permitted the construction of 12 scenarios, as presented below.

*TABLE 2*  
*Scenarios Developed from the Combination of Hypotheses Concerning the Coverage of the HIV-infected Population and the Behavior of the Drug Prices.*

Coverage	Behavior of drug prices		
	Constant	-10% / year	-20% / year
(A) Maintenance of the present coverage level	Scenario 1	Scenario 2	Scenario 3
(B) 50%	Scenario 4	Scenario 5	Scenario 6
(C) 75%	Scenario 7	Scenario 8	Scenario 9
(D) 100%	Scenario 10	Scenario 11	Scenario 12

### *Maintenance of the present coverage level*

The first three scenarios were based on the hypothesis of maintaining the present level of coverage. Three types of variables were taken into consideration: the rate of increase of the Brazilian population, the incidence rate of AIDS cases reported to the Ministry of Health per 100,000 population, and the rate of increase of case reporting to the Ministry of Health.

For population projections, we used the official IBGE estimates. For the estimation of the coefficients of incidence for the years 1998-2007 the value observed in 1996 was maintained, because the available series indicates a trend toward stabilization. The existing information on reported AIDS cases refers to the period 1980–1995. Data from 1996 and 1997 are grouped together, as the data for 1997 only covered the first 8 months of the year. Therefore, we adopted the figure of 16,500 new reported cases in 1997 used by Nunes (1997)<sup>13</sup>. For the projection of new notifications for 1997 to 2007, we applied the incidence rate (10.5) to the population estimated by IBGE.

Finally, to estimate the number of patients—adults, children and pregnant women—taking anti-retroviral therapy, starting from 1998, we used the information for 1997 (48,000; 2,500; and 2,500 respectively) and assumed that the rate of increase would accompany the number of AIDS case notifications, for all patient groups. Therefore, given a constant relation of the patient population (adults, children and pregnant women) and the number of cumulative reported cases, a (hidden) morbidity rate of 44.34% was assumed for the period. In this analysis the proportion of the population on anti-retroviral therapy is considered to be constant, in relation to the number of cumulative notifications, i.e. the present degree of coverage of the population is maintained.

<sup>13</sup> Nunes, A O impacto economico da aids/HIV no Brasil. Brasilia, 1997. Textos para discussao, Brasilia, IPEA, No. 505, 1997.

Given the hypothesis of constant anti-retroviral drugs prices, the funds required would show an annual rate of increase of 9.1%, thus yielding an estimated cost for the year 2007 that would be 139.5% higher than of 1997 (see table 3).

If the prices show an annual reduction of 10%, the estimated costs for medicines for 2007 would drop 16.5% in relation to 1997, even with an increase in the number of patients treated. This decrease in the amount of funds required would result from the difference between the annual rate of growth of the number of patients receiving the anti-retroviral therapy (9.1%) and the annual rate of price decrease assumed (10%).

If prices show an annual reduction of 20%, the estimated costs for medicines for 2007 would drop 91.0% in relation to 1997.

The assumed cost reductions of 10% and 20% per year, were applied linearly to all drugs, which would be an improbable occurrence in reality. It should be highlighted that certain drugs have already shown a significant price drop, due to an increase in the scale of production, pressure from society and governments, or, in the case of Brazil, domestic production of some of drugs by state-owned laboratories, obviating the need for imports. In addition, bulk purchases by the government have reduced the unit price. For instance, we note that over only two years (1995/1997), some drugs (AZT 100 mg capsules, AZT 10 mg/ml oral solution, Acyclovir 200 mg tablets and Immunoglobulin 1, 2.5 or 5 g IV) showed a marked drop in price of between 35% and 47 % per year, while others registered smaller and more varied decreases.

TABLE 3  
*Projection of Funding Needs for the Purchase and Distribution  
of Medicaments to AIDS Patients*

In R\$ 1.000

Year	Scenario of price behavior			Projection of the population on therapy		
	Constant	-10%aa	-20%aa	Adults	Pregnant women	Children
1997	241,029	241,029	241,029	48,000	2,500	2,500
1998	272,794	245,515	218,235	54,326	2,829	2,829
1999	304,985	247,038	195,190	60,736	3,163	3,163
2000	337,602	246,112	172,852	67,232	3,502	3,502
2001	370,629	243,169	151,809	73,809	3,844	3,844
2002	404,026	238,573	132,391	80,460	4,191	4,191
2003	437,871	232,703	114,785	87,200	4,542	4,542
2004	472,127	225,817	99,012	94,022	4,897	4,897
2005	506,792	218,157	85,026	100,925	5,257	5,257
2006	541,831	209,917	72,723	107,903	5,620	5,620
2007	577,245	201,273	61,981	114,956	5,987	5,987

*Changes in coverage*

Using the methodology of Castilho (1996), Nunes estimated the population of HIV carriers between the ages of 15 and 49 to be between 337.9 and 488.4 thousand in 1996. In his calculation he distributed the Brazilian population (male and female) estimated by IBGE into three groups according to AIDS incidence, creating six groups. These groups were then multiplied by the high and low prevalence estimate for each region, thus yielding an estimate of the number of HIV-infected individuals in the country.

Maintaining constant the proportion of the HIV-infected 15-49 years-old population, compared to the total Brazilian population in the same age group, estimated by Nunes for 1996 (for his upper and lower limits), the evolution of the infected adult population was projected until the year 2007.

It is important to highlight that the mathematical exercise used assumes that all HIV-infected individuals would be identified and would require anti-retroviral therapy at the same time. This has not happened anywhere, not even in the most developed countries. One parameter to assess the requirements for anti-retroviral drugs can be the current number of patients under treatment. After two years of wide availability of anti-retroviral drugs, by September 1998 there were approximately 60,000 patients registered throughout the country to receive anti-retroviral drugs, with no repressed demand.

Considering constant prices the projection of covering 50% of HIV-infected individuals —scenario 4— points to the need in 1997 of additional funds varying between R\$ 599 million and R\$ 973 million, representing a cost increase of 248.5% to 303.7% in relation to the expenditure foreseen for this year (table 4). Given a coverage level of 75% —scenario 7— the need for additional resources would be of the order of R\$ 1,019 million to R\$ 1,580 million in relation to the R\$ 241 million of 1997. Given a 100% coverage —scenario 10— this increase would range between R\$ 1.439 million and R\$ 2.187 million (Tables 5 and 6).

Given the methodology adopted, subsequent increases would be a function of the estimated growth (average of 1.44% in the period) of the population 15-49 years old.

In the hypothesis that drug prices would show a 10% drop per year, we see that, after a significant initial effort, the pressure caused by increased demand is more than offset by the reduction in costs. For 2007, the need of resources will always be bigger than the expenditures carried out by the MoH in 1997 with the purchase of anti-retroviral drugs (R\$ 241.0 million), with the exception of the scenario of coverage of 50% of the infected population.

In the case of a price drop of 20% per year, the effect is enhanced, leading to a substantial reduction of funding required in the year 2007, for all of the hypothetical coverage rates.

*TABLE 4*  
*Estimate of Funding Needs, 1997-2007, for the Purchase and Distribution of Medicaments, Considering a Coverage of 50% of the HIV Infected Population*

In R\$ 1.000

Year	Scenarios of price behavior						Projection of adult population in therapy	
	Constant		-10% year		-20%year		Min	Max
	Min	Max	Min	Max	Min	Max		
1997	840,024	1,214,023	840,024	1,214,023	840,024	1,214,023	172,270	248,969
1998	856,352	1,237,620	770,717	1,113,858	685,082	990,096	175,619	253,808
1999	872,700	1,261,246	706,887	1,021,609	558,528	807,198	178,971	258,654
2000	889,018	1,284,830	648,094	936,641	455,177	657,833	182,318	263,490
2001	901,307	1,302,591	591,348	854,630	369,175	533,541	184,838	267,132
2002	913,769	1,320,601	539,572	779,802	299,424	432,735	187,394	270,826
2003	925,841	1,338,047	492,030	711,093	242,704	350,761	189,869	274,404
2004	938,109	1,355,777	448,695	648,464	196,736	284,327	192,385	278,040
2005	950,377	1,373,507	409,106	591,250	159,447	230,436	194,901	281,676
2006	959,565	1,386,786	371,755	537,269	128,791	186,131	196,785	284,399
2007	968,754	1,400,066	337,783	488,173	104,019	150,331	198,670	287,122

*TABLE 5*  
*Estimate of Funding Needs, 1997-2007, for the Purchase and Distribution of Drugs, Considering a Coverage of 75% of the HIV-Infected Population*

In R\$ 1.000

Year	Scenarios of price behavior						Projection of adult population in therapy	
	Constant		-10% year		-20%year		Min	Max
	Min	Max	Min	Max	Min	Max		
1997	1,260,036	1,821,034	1,260,036	1,821,034	1,260,036	1,821,034	258,405	373,454
1998	1,284,528	1,856,431	1,156,075	1,670,788	1,027,623	1,485,145	263,428	380,713
1999	1,309,050	1,891,869	1,060,330	1,532,414	837,792	1,210,796	268,457	387,980
2000	1,333,527	1,927,244	972,141	1,404,961	682,766	986,749	273,477	395,235
2001	1,351,961	1,953,886	887,022	1,281,945	553,763	800,312	277,257	400,699
2002	1,370,654	1,980,901	809,357	1,169,703	449,136	649,102	281,091	406,239
2003	1,388,762	2,007,071	738,045	1,066,640	364,055	526,142	284,804	411,606
2004	1,407,163	2,033,666	673,042	972,696	295,104	426,491	288,578	417,060
2005	1,425,565	2,060,261	613,659	886,875	239,170	345,654	292,352	422,514
2006	1,439,348	2,080,179	557,633	805,904	193,186	279,197	295,178	426,599
2007	1,453,130	2,100,098	506,675	732,259	156,029	225,496	298,005	430,683

TABLE 6  
*Estimate of Funding Needs, 1997-2007, for the Purchase and Distribution of Medicaments, Considering a Coverage of 100% of the HIV-Infected Population*

In R\$ 1.000

Year	Scenarios of price behavior						Projection of adult population in therapy	
	Constant		-10% year		-20% year		Min	Max
	Min	Max	Min	Max	Min	Max		
1997	1,680,049	2,428,046	1,680,049	2,428,046	1,680,049	2,428,046	344,541	497,938
1998	1,712,704	2,475,241	1,541,434	2,227,717	1,370,163	1,980,193	351,238	507,617
1999	1,745,399	2,522,493	1,413,773	2,043,219	1,117,056	1,614,395	357,943	517,307
2000	1,778,036	2,569,659	1,296,188	1,873,282	910,354	1,315,666	364,636	526,980
2001	1,802,614	2,605,181	1,182,695	1,709,259	738,351	1,067,082	369,676	534,265
2002	1,827,538	2,641,202	1,079,143	1,559,603	598,848	865,469	374,787	541,652
2003	1,851,682	2,676,095	984,060	1,422,186	485,407	701,522	379,739	548,808
2004	1,876,218	2,711,554	897,389	1,296,928	393,471	568,654	384,771	556,079
2005	1,900,753	2,747,014	818,212	1,182,499	318,894	460,872	389,802	563,351
2006	1,919,130	2,773,573	743,510	1,074,539	257,581	372,263	393,571	568,798
2007	1,937,507	2,800,131	675,567	976,345	208,038	300,662	397,340	574,245

Considering the present level of commitment of the Federal Government, each of the scenarios presented implies the need for a substantial increase in the funds allocated. In order to do so, an increase of the Ministry of Health budget would be necessary so that the growth in the AIDS programme would not be offset by cutbacks in other programmes.

In other words, the demands for an increase in the funding for anti-retroviral therapy must be integrated into the larger movement to define public health as a priority of the Brazilian Government.

#### *The impact of the use of anti-retroviral therapy*

According to an estimate made by Medici and Beltrão<sup>14</sup> (1992), the total cost of treating a patient with AIDS reached US\$ 16,689 per year. Of this total US\$ 6,373 (38.2%) were spent on drugs and US\$ 10,316 (61.8%) on other costs, such as hospital admissions, fees of physicians, nurses, and support personnel, and diagnostic exams. Nunes

<sup>14</sup> Medici, AC and Beltrao, KI. *Custos da atencao medica a aids no Brasil: alguns resultados preliminares*. Rio de Janeiro, 1992. Relatorios tecnicos da ENCE/IBGE, no. 01/92.

(1997) points out that this figure is relatively close to that obtained by Petrou for the Public Health System in England<sup>15</sup>.

A recent study carried out by Foundation Institute for Economic Research (FIPE)<sup>16</sup> revealed that the average annual direct cost per patient with HIV infection in the State of São Paulo in 1996 was R\$ 5,342 (US\$ 4,862). The daily cost of the conventional hospitalization of these patients was R\$ 106 (US\$ 97), with an average length of hospitalization of 16 days. Cost analysis by type of care showed that the cost of conventional hospitalization was twice the cost of day hospital care (DH) and almost nine times higher than therapeutic home care (THC). At that time, drugs accounted for 32% of total hospital admission costs, they represented approximately 60% of the direct costs of DH and THC.

Just for comparison purposes, at the same time the Ministry of Health spent approximately R\$ 298 million in hemodialysis benefiting approximately 30,000 patients with chronic renal failure, corresponding to an average of R\$ 10,347.00 per patient/year, considering 3 hemodialysis sessions/week. It is important to highlight that this amount refers only to the use of the hemodialysis equipment, and does not include the costs of drugs and tests for the control of other medical problems frequently found in this type of patients (e.g. high blood pressure, congestive heart failure, infections, etc.). Another example of a high-complexity procedure funded by the Ministry of Health is organ transplantation. In this case, the average cost of a procedure varies from R\$ 10,000 (renal transplant) to R\$ 41,519 (heart transplant) per hospital admission. In 1997, total expenditures greater than R\$ 34 million benefited only 2,043 patients. The figures for these procedures do not include the cost of immunosuppressive drugs, chemoprophylaxis for opportunistic infections and other procedures for the medical-laboratory control required after hospital discharge (DATASUS/MoH, unpublished data).

At the 4<sup>th</sup> Conference on Retrovirus and Opportunistic Infections, held in Canada in January 1997, Stephenson (1997)<sup>17</sup> presented the following information which confirms in particular the hypothesis of a reduction in non-medicinal costs:

a) St. Vincent's hospital of New York, between 1995 and 1996: 29% increase in outpatient care; 46% decrease in the number of inpatient admissions of HIV-infected patients. This reduction more than offset the increase in ambulatory care; average 2.4 day reduction of the length of stay.

b) Tower Infectious Disease –Los Angeles, between 1994 and 1996: 57% reduction of admissions of HIV-infected patients; 65% decrease of specialized nursing

<sup>15</sup> Petrou S. et al. "The economic costs of caring for people with HIV infections and AIDS in England and Wales". *Pharmaco Economics*, April 1996.

<sup>16</sup> Cyrillo, D.C. et al. "Custos diretos do tratamento da aids no Brasil: metodologia e estimativas preliminares", June 1998, FIPE, unpublished data.

<sup>17</sup> Stephenson J. "News from the 4th Conference on Retroviruses and Opportunistic Infections", *The Journal of the American Medical Association (JAMA-aids)*, 1997.

care with day-hospital; 58% decrease in home-based care; 90% reduction of therapy for CMV; 70% decrease in the use of G-CSF; 74% decrease in the use of EPO.

c) French Federation of AIDS Reference Centers, between September 1995 and October 1996 (study done in 6 centers): 39% decrease in AIDS defining events; 36% reduction in the number of AIDS-related complications; 35% reduction in the length of hospital stay.

A drop in the number of hospital admissions, ambulatory care, emergency services and hospital-days (40% at the Reference and Training Center off São Paulo and 35% at the Hospital Emílio Ribas) has also been observed in Brazil, as well as the impact on opportunistic infections. The National Programme has recorded a drop of more than 20% in the use of gancyclovir, used for treating cytomegalovirus infection. This treatment costs, on average, R\$ 7,500 per patient-year, of which R\$ 5,258 refers to the cost of this drug.

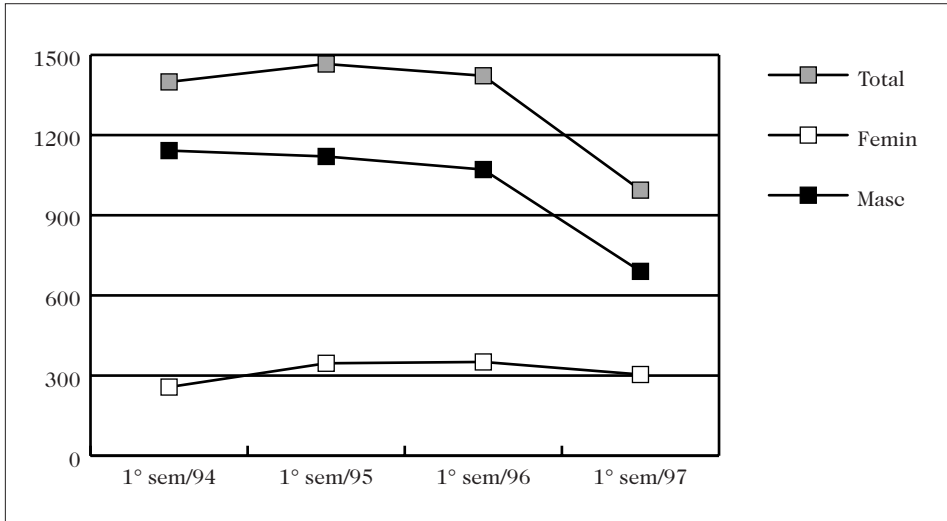
The literature provides information on the effectiveness of anti-retroviral therapy. Regarding vertical mother-to-child transmission of HIV, study 076 conducted by the *AIDS Clinical Trials Group* (ACTG 076) showed that the administration of oral AZT to the pregnant women since 14<sup>th</sup> week of gestation, followed by IV AZT during labor and by the administration of AZT syrup to the newborn reduced the rate of transmission by approximately 2/3. In addition, presentations at the 4<sup>th</sup> Conference on Retrovirus and Opportunistic Infections informed that mortality dropped 30% in the city of New York thanks to the use of these drugs, a fact corroborated by the decline of 13% in the mortality of AIDS patients observed by the Centers for Disease Control and Prevention.<sup>18</sup>

Data from the Program of Improvement of Mortality Data (PROAIM) of São Paulo City indicate a 31% drop in the overall AIDS mortality in the first semester of 1997, as compared to the same period of the previous year (see figure 1). The reduction was 36% among men and 13% among women. The calculation of the cost per year of survival has been estimated by various authors, depending on the combination of drugs used in the anti-retroviral therapy. Moore (1996)<sup>19</sup> projected an additional cost of US\$ 10,000 per year of life gained when the triple combination therapy with protease inhibitor is adopted, as opposed to monotherapy, for patients with a CD4 count between 400-500 cells/mm<sup>3</sup>. According to the same author the cost per year of life of a patient under hemodialysis is US\$ 50,000 and of a heart surgery patient it is US\$ 113,000.

<sup>18</sup> Cook, J et alii. 4th Conference on Retroviruses and Opportunistic Infections. January 1997.

<sup>19</sup> Moored Rd and Bartlett JG. *Combination Anti-retroviral Therapy in HIV Infection*. In: *Pharmaco Economics*, August 1996.

FIGURE 1  
Evolution of Number of AIDS Deaths-PROAIM/SP



In the above-mentioned Conference, Cook presented an additional cost of between US\$ 13,500 and US\$ 25,000 per year of life gained when comparing triple with double therapy. Chancellor (1996)<sup>20</sup>, at the Third International Congress of Drug Therapies in HIV Infection, held in England, suggested an incremental cost of US\$ 11,000 per year of life gained when comparing triple-therapy with monotherapy.

According to the National Programme, treatment combining three anti-retroviral drugs costs on average R\$ 8,000 per year, while the average cost of double-therapy is R\$ 3,200. It should be noted that, in relation to the estimated values given by the above-mentioned researchers, the cost of therapy in Brazil is significantly lower.

Lastly, it should be remembered that anti-retroviral therapy, beyond increasing the survival of AIDS patients, permits their continuation in the labor market, keeping them productive and reducing social security costs. Supposing that all adults currently receiving the therapy (72,000) continued to work, this would mean an annual income generation totaling R\$ 337.0 million, at December 1995 prices. The “savings” in social security costs, assuming that the benefits paid would correspond to the average values currently disbursed, would be R\$ 157.2 million (in 1997 values).

<sup>20</sup> Chancellor J et alli. Third International Congress on Drugs therapy in HIV Infection, Birmingham, England, November 1996.

In order to evaluate the true impact of anti-retroviral therapy it would be necessary to calculate its cost-benefit. However, this is hindered by the dearth of available information plus the fact of such therapy having been introduced only recently. Anyway, the above-mentioned evidence indicates that this calculation should take into account: (1) the changes seen in the total cost of AIDS patients, since the therapy costs are partially offset by the decrease of expenditures with hospital admissions and nursing care, among others; (2) the decrease in the occurrence of opportunistic infections; (3) the decrease in the number of new infections (e.g. vertical transmission); (4) the trend towards the drop of drug prices; (5) the maintenance of a productive individual; and (6) the increase in the quality of living of the AIDS patient.

One of the main conclusions of the mathematical exercise proposed above is that the funds required to extend anti-retroviral therapy to all eligible HIV-infected individuals with clinical and laboratorial indications to start treatment, as mandated by Law 9,313, would require a significant effort from the Brazilian Federal Government (at current drug prices), even if we assume the participation of the other government levels in defraying these costs. The same would happen in a scenario of 75% or 50% coverage. Under any of these conditions, this level of coverage would only be feasible if the Brazilian government made a significant increase in the funds earmarked for health, so that complying with this Law would not entail a decrease of funds to other health programmes.

If the prices will show a steady decline (10% and 20% per year, which is more consistent with the trend seen in the last few years), the coverage objectives become closer to the current expenditures on anti-retroviral therapy, but even then only in the last years of the series projected.

Under the scenario of maintenance of the current proportion of care, the need for more resources continues, albeit at a lesser degree, in the alternative of price reduction by 10% annually. If we consider the current levels of budget commitments with AIDS drugs, only by 2002 the government would be allocating a volume of funds similar to the present one. In the scenario of a 20% price reduction per year, by 1998 the volume of resources needed would be smaller than the 1997 expenditures.

From the historic and macroeconomic perspectives, there is clear evidence justifying an increase of funds earmarked for this therapy by the Brazilian Government, in spite of the difficulties met to increase the level of investments on health. International research and programme results in Brazilian cities indicate that the spending on anti-retroviral therapy simultaneously brings about a reduction of the costs associated with AIDS treatment and allows gains ensuing from keeping the HIV-infected individuals in the job market. From the macroeconomic point of view, therefore, a compensation may be possible, if all gains and expenditures derived from the therapy are taken into account.

## Constraints and Perspectives of Anti-retroviral therapy in Brazil

In the political and institutional plane, the continuity of the drug provision program, as formulated, depends on the capacity to sustain its volume of expenditures. This sustainability is closely linked to its political and administrative legitimacy and to its results in terms of human lives saved from death or from suffering.

From the perspective of the general conditions in which the policy is implemented, it is difficult to perceive any scenario of change in its basic principles. In a democratic environment, one cannot imagine any reversal in the definition of universal right to health or in the extension of the public freedoms which give vitality to the NGOs. The degree of dissemination already reached by the information on AIDS also make it unfeasible a less active position from the government vis-a-vis the public opinion. Thus, we should examine the legal-administrative framework, where some risks may be glimpsed.

The projection of a growing level of expenditures makes it possible that they will take on a different meaning in the sphere of broad political negotiation involving the Federal Budget, inside the Ministry of Health and at the National Congress. Given the characteristics of budgetary execution in Brazil, subject to the inconsistencies of the government's tax difficulties, the first of these risks has already been experienced throughout 1997, with the non-liberation (or contingency liberation) of budgeted resources. However, if the budgetary arena offers this uncertain picture, positive signs may also be registered. Since the early 1990s, the movement for the reform of the State in Brazil has insisted on the pressing need, both for fiscal and for social justice reasons, to continue the transition of government activities away from the economic and towards the social sector. Another important sign concerning AIDS is that National Congress itself shows signs of great interest and receptivity to this issue.

Still in the political-institutional level, it is important to mention that the level of independence reached by the Judiciary Power is another positive aspect, as the courts have received well suits forcing the State to provide anti-retroviral drugs.

In summary, if the constraints of the Brazilian budgetary policy represent a concrete risk to the expansion of the expenditures of the drug distribution program, the growing relevance of social expenditures in the public agenda, acknowledged both by the government and by Congress, offers new possibilities of mobilization in support of the program.

However, on the other hand, recent public debate on the MoH expenditures have given rise to another aspect: the efficiency of this expense. Thus, we are led to the other plane of the program's legitimacy, the legal-administrative framework, where a large number of variables influences the program's performance.

I) Firstly, even NGO leaders consider fundamental that the National Programme of STD/AIDS be able to formulate a defense of drug distribution based in economic terms<sup>21</sup> as the first task in the confrontation of the attempts to cut or

<sup>21</sup> Ronaldo Mussauer. President of the Grupo pela VIDDA. Personal interview, October 1997.

contingentiate funds. If the public debate focuses on economic rationality, the Programme will have to respond at this level, particularly when faced with the possibility of comparison with other social programs and expenditures. A renewed emphasis on prevention programs, followed by a constant assessment of their efficiency, costs and benefits, may be an important complement to this defense, offering a perspective of predictable or declining costs.

II) Secondly, it will be necessary to keep and broaden strategies allowing the National Programme for STD/AIDS to overcome and bypass the constraints imposed by the organizational realities of public administration (procurement mechanisms, level of human resources, etc.) on the program's execution. One of the major risks to be avoided is irregularity of drug provision, as it decreases treatment effectiveness and compromises governmental activities at the level of the final user of its services. In this case, in addition to more concrete initiatives, such as repression to fraud and theft and the maintenance of adequate facilities for drug handling and packing, the National Programme has followed two concurrent courses of action: cooperation with the services of the subnational entities and computerization.

As we saw, the executive side of the distribution is, for its most part, under the responsibility of the state and municipal services, where organizational and salary problems are felt even more sharply than in the federal sphere. In addition, there is the natural political independence of the state administrations and a tradition of coordination among the governmental levels not always without friction or problems. In this area, the Programme has followed the indications of the agreement with the World Bank: to centralize the planning of the activities through the liberation of funds, to offer training and equipment and to supervise the execution of the activities. On their hand, the state managers also feel the need for more explicit definitions of the responsibilities at each level of government.

In another direction, the National Programme has also invested in modernizing the logistics of the drug distribution program, through the development of a national register of patients and the full computerization of the drug distribution process, through SICLOM, a system centralized in Brasília, but operated in coordination with the state managers.

III) Thirdly, a last element of legitimacy must come from the patient. Treatment compliance, crucial for the success in terms of reduction of mortality and of the costs of hospital or ambulatory care, has to be constantly and transparently followed up. The growing extension of the epidemic to poorer segments of the population and its association with problems concerning women's health present serious challenges to compliance and, therefore, to the success of the anti-retroviral drug distribution program.

In this aspect, the National Program continues with the decision to invest constantly in the training of physicians and other health professionals. With the growing sophistication of treatment, the update of the professionals prescribing the medication and monitoring its results is a permanent requirement. Training should always be hand in hand with evaluation, so that the concrete results can be measured and transformed in an instrument of legitimacy of the governmental activity.

In this field, the non-governmental organizations also have their role, and they should be encouraged to participate in the efforts of increasing awareness of patients to the importance and the medical and social role of compliance. The notion so early realized by the Brazilian NGOs that the social living links were a powerful remedy against discrimination, prejudice and low esteem must be expanded as an instrument to sustain compliance. It would be worrisome if optimistic versions about the nature of the cocktail's effects encouraged the demobilization of patients, NGO members and physicians<sup>22</sup>, or that its decreasing efficacy among the poorest patients, secondary to a lower compliance, provided arguments against the program's maintenance.

### Conclusions

Given all the above-mentioned points ensuing from the exam of the legal-administrative framework, the National Programme for STD/AIDS has the responsibility to emphasize the prevention programs and the evaluation processes, which must be closely linked to the drug provision program, making a clear and explicit commitment, from the political and administrative standpoints, to the good use of the budgetary resources made available to it.

Secondly, the National Programme has to keep and increase the investment in training human resources, both to maintain the administrative efficiency in drug distribution and to ensure their correct prescription.

Finally, the National Programme is also responsible for maintaining the involvement of the NGOs in the process of ensuring patient adherence to treatment, through counselling, psychological support and other activities. The pauperization and feminization of the epidemic will certainly require the broadening of the partnerships between the State and NGOs, so that the anti-retroviral drug distribution program will continue on the same successful road it has followed so far.

<sup>22</sup> José Stalin Pedrosa, former consultant to the STD/AIDS National Program. Personal interview, October 1997.

THE PROCESS OF ACCESS TO ANTI-RETROVIRAL  
THERAPY IN MEXICO\*  
CASE STUDY

*Jorge Saavedra*

\* Paper elaborated in collaboration with the National Council for the Prevention and Control of AIDS, under contract with the United Nations AIDS Program (UNAIDS) and the Regional AIDS Initiative for Latin America and the Caribbean (SIDALAC).



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*Abbreviations and acronyms utilized in this document*

3TC	Lamivudine
AIDS	Acquire Immunodeficiency Syndrome
ARV	Anti-retroviral or Anti-retrovirals
AZT	Zidovudine
<u>Beneficiaries</u>	People with social insurance that have the right to receive care form social insurance medical services

MEXICO

COESIDA	State Level Council for Prevention and control of HIV/AIDS
CONASIDA	National Council for Prevention and Control of HIV/AIDS
D4T	Stavudine
ddC	Zalcitabine
DDF	Medical Services of the Mexico City Government, currently named Secretariat of Health of the Federal District
ddI	Didanosine
DF	Federal District (Mexico City)
DIF	System for the Comprehensive Family Development
FDA	Food and Drug Administration of the USA Government
FONSIDA	Non profit organization (Fund) for the found raising and finance of ARV for uninsured children and pregnant women
FRENPAHIV	National Front of People Affected by HIV/AIDS
GD	General Directorate
GDP	Gross Domestic Product
GNP	Gross National Product
HAART	Highly Active Anti-retroviral Therapy
HIV	Humane Immunodeficiency Virus
IMSS	Mexican Institute of Social Security
IMSS-Solidaridad	IMSS Health services provided to uninsured mostly rural and poor population
INEGI	National Institute of Geography, Statistics and Information
ISSSTE	Institute for the Security and Social Services for Government Workers
IVDU	Intravenous Drug User
MA	Metropolitan Area
mx	Mexican currency (pesos)
Open population	People that lacks of social security
PositHIVos	Organization of People living with HIV
PAC	Program to Increase Coverage of Basic Health Services
PAHO	Pan American Health Organization
PAN	National Action Party
PEMEX	National State Owned Oil Monopoly (Mexican Petroleum Company)
PLHIV	People living with HIV (Who have not developed AIDS already)
PLWA	People Living with HIV/AIDS or Person Living with AIDS
PRD	Democratic Revolution Party
PRI	Institutional Revolutionary Party. Federal Government Official Party
SH or PSH	Specialists, politicians and decision makers who participated in the Stake holders workshop
SIDALAC	Regional Initiative on HIV/AIDS for Latin America and Caribbean Countries
SSA	Ministry of Health

UNAIDS  
UNAM  
UNICEF  
USD  
WHO

United Nations Joint Program on HIV/AIDS  
National Autonomous University of Mexico  
United Nations Children Found  
U.S. dollars  
World Health Organization

## Presentation

This study was carried out at the request of the National Council for the Prevention of AIDS of Mexico (CONASIDA) and the financial support of the United Nations Program against AIDS (UNAIDS) and the Regional Initiative for HIV/AIDS in Latin America and the Caribbean (SIDALAC). It has the purpose of analyze the process of incorporation of the anti-retroviral drugs (ARV) in Mexico, as well as its availability, costs and real accessibility for the people that live with HIV/AIDS.

Within the present document there is done an initial analysis of the Mexican socioeconomic context, of its health system and types of public services that performs. In addition it also analyzes positions and opinions of political actors and decisionmakers involved in the various processes conducive to achieving the accessibility to ARV. The section referred to the costs it is based on a study previously conducted by the same author and published under the title of “Costos y Gastos de la Atención Médica del SIDA en México” (CONASIDA, 1998). (1)

In addition, files, publications and internal registries from CONASIDA, SIDALAC, and the IMSS were consulted, as well as main national newspapers that published political events related to AIDS and ARV. Another source of information were the two workshops carried out with Mexican stake holders involved in the AIDS care field, with the main objective that they could contributed with their ideas, opinions, and perceptions on this process in Mexico; some additional data were taken from public information available on the Internet, individual interviews with some other SH who did not participate in the workshop, as well as from data provided by companies of the pharmaceutical industry and drug wholesalers.

The purpose is that this publication serves not only as information and figures for national and international academic specialists on the subject, or to interested people, but basically for those who are decision makers, as well as for people of NGOs and affected by HIV/AIDS that already have been or are up to decide to be actively involved in the different areas of AIDS care policies.

## Executive Summary

The process of access to AIDS drugs (anti-retrovirals) in Mexico has been tinged by an interaction of technical & medical factors (scientific), as well as economic, and political, framed by the context of the health system that works in our country. The political factors, and the fact that the disease by itself is loaded with dosage of social stigma, causes that this process marks a great difference concerning the access to drugs for another type of diseases, which are normally regulated by taking into account health specialist opinions and budgetary/administrative considerations.

When in the 1980s, AZT began to be utilized in Mexico, it was introduced not much as a therapeutic measure of regular care to the patient, but as part of research protocols, where this product was offered free of charge to everyone that agreed to participate in these studies. Since AZT was a pharmaceutical product that already existed in the Mexican market, even before being utilized in the treatment of AIDS, the Government did not recognize its rights of patent to any single pharmaceutical company, being so far at least 8 different ones<sup>1</sup> that produce it or capsule it and market it. With the introduction of the “Generic Drugs Policy” in early 1998, zidovudine was immediately included in the classification of a low cost generic drug catalog. Therefore, the price of a box of AZT 250 mg with 30 capsules, can decline to \$22.00 USD, from an original retail price of \$85.30 USD.

The organization of the Mexican Health System that divides the population in two, the “Social Insured” (with health insurance) and those uninsured (also called “open population”); as well as the price of ARV are the principal factors that finally determine whether a person has access or not to these drugs in Mexico.

However, marginally, some parallel processes that make it possible to access ARV for uninsured people have also been developed; some of these processes have been manifested on the fringes of law and current regulations, as it is the case of the black market of ARV that originally were property of the Social Security Institutions. Another marginal way have been through affiliations of people to the social insurance scheme (IMSS or ISSSTE), still after knowing that they already have been HIV-infected. In addition, some NGOs also provide charitable or altruistic services and sell ARV at very low prices; they usually receive those drugs through grants or donations from different sources (individuals or foreign NGOs).

On the other extreme of the regulation, there are research and humanitarian protocols, from CONASIDA and of some hospitals and clinics (both institutional and private) that provide ARV free of charge, and also a publicly & private financed fund (FONSIDA) to provide these drugs to specific population groups (children and pregnant women), the later was actively promoted by the health authorities.

Finally, a very small sector of the population has economic possibilities to pay for ARV out of pocket in the private pharmacies, that to February 1999, in

<sup>1</sup> The companies that produce or capsule and market AZT in Mexico are: Glaxo-Wellcome, Novag, PISA, Fustery, Wayne, Kendrick, Protein and Seromo.

addition to the AZT had the following products: ddI, ddc, 3TC, D4T, indinavir, saquinavir, ritonavir, delavirdine, combivir (AZT + 3TC) and nevirapine.

From the estimated number of PLWA for 1999, 26,800 (graph 9), we can assume that around 55% of them, have regular access to ARV: 50% through IMSS, ISSSTE and other smaller social insurance schemes; 2% through CONASIDA, FONSIDA and local public funds (such as Michoacán); and finally around 3% by private means. This assumption does not necessarily implies that they have optimal treatment, mainly due to periodical shortages of ARV at the social security pharmacies.

Cost projections made for the year 2000 assuming no falls in the price of ARV show that the amount needed for that year in order to cover 100% of PLWA will be of \$138 million USD, this figure could drop to \$103 million USD, if ARV started falling by 10% from 1998 to 2000, which is actually closer to what has been happening in Mexico in USD terms.

Though, this later has not been properly noticed by the Mexican people since the prices in the country are set in mx pesos, and the Mexican currency has been devaluating more than 10% per year since 1998. However, from a previous study (1), we can mention that the price for buying a monthly triple combination anti-retroviral therapy that was calculated in 252 days of official minimum wages in 1997, has fallen to 213 by January 1999. Nevertheless, it still is a large amount when compared to some other countries, mainly due to the fact that the official minimum salary in Mexico still far ahead from those in the developed world or even from those in Argentina.

From another perspective we can say that in Mexico, many of the government decisions made concerning access to ARV, have not been exempted from strong political pressures, from activists, NGOs, PLWAs, the media, and even by physicians and decisions taken by other developing countries. All these pressures may have caused accelerated decisions, that have not considered other parts of an optimal ARV policy, such as access to specific lab tests, improvement of the drug procurement system, training of health personnel, etcetera.

As a summarized end, we can state that in order to achieve a policy of universal access to ARV in a permanent and timely way for all those that need them, and that it can be sustainable in the long run, it is required a conjugation of several points of view, in which all of them: science, human rights, administration, market, economic growth and politics, get to the conclusion that this policy is a beneficial one, not only for the individuals in particular, but for the society as a whole, transforming it from being a "public expenditure" into a "social investment".

## **Background**

### *Population*

Mexico is the 11<sup>th</sup> more populated country in the world, according to the most recent official count in 1995 (2), the country had 91,158,290 inhabitants (95 million esti-

mated for 1997), in the Latin American context, occupies the 2nd place, only surpassed by Brazil. The Mexican population in recent years has grown at an annual rate of 1.9%, being located mainly in urban areas, which represents 77.5% of the total, remaining 22.5% in the rural area. The large metropolitan areas (MA) of Mexico City, Guadalajara and Monterrey, concentrate 25% of the country inhabitants.

Most of the country has a temperate to warm climate throughout the entire year, the Northern region which is the most extensive is characterized by its arid and semiarid spots, but at the same time, the states of the north had been the most benefited ones with the free trade agreement with the United States and Canada (NAFTA) and jointly with Mexico City, have a greater socioeconomic development than the rest of the nation.

The Central area of the country is the more densely populated, more traditional with a strong Spanish-colonial heritage, and in general cities in this area are the best communicated between themselves and with the capital of the republic.

On the other hand, the Southern and Southeastern States, although they own an abundant vegetation, tropical climates, and fertile soil, are those of more limited development, being among them the three poorer ones of the country: Chiapas, Oaxaca, and Guerrero. However, it is also this area which absorbs most of the international tourism, since they have the tourist resorts of Acapulco, Ixtapa, Huatulco, Can-Cun, and the archeological areas of the Mayan corridor.

### *Political & Administrative Structure*

Mexico is constituted as a Federal Republic and formed by 31 states and 1 Federal District (Capital: best known as Mexico City). The power division at the national level takes shape by the Executive Branch headed by the President of the Republic and a Cabinet of Secretaries of State. The Legislative Branch is represented by the Congress of the Union, which in turn it is made up of the Chamber of 500 Representatives (population based) and a Chamber of Senators (State representatives); The country also has a Judicial Branch formed by the Supreme Court of Justice, and judges distributed in all the national territory.

The President of Mexico is elected every 6 years, and does not have possibility of being reelected, the representatives are elected every 3 years and the senators every 6. At the state level the government is headed by a Governor, which is elected every 6 years and neither has right to the reelection. The state level also has its own Chamber of Representatives elected every 3 years with a local judicial branch. The political-administrative minimum division constitutes is the municipality, which is headed by a Municipal President (Mayor) who remains 3 years in the position and can be reelected, although not for the immediate period.

### *Political Parties*

To be able to compete in Mexico in an election, it is necessary to be postulated by a political party with registry. During more than 70 years the dominant political party was the official one (the Institutional Revolutionary Party or PRI), which since then has occupied the Presidency of the Republic, and it was not but until 1990, that a triumph of a party of opposition (PAN) was recognized in a state governor post. In the federal elections of 1997 for the first time in 7 decades, the lower chamber of the congress (Representatives) no longer was controlled by the PRI, upon losing this the absolute majority; the rest of the political parties, Party of National Action (PAN, the second largest) that promotes smaller involvement of the state in the economic activity, the Party of the Democratic Revolution (PRD, the third largest), which is more for greater intervention of the government in the economic processes, and two small parties, the Ecology Green of Mexico (PVEM) and the Work Party (PT) in an unusual coalition, assumed the control of chamber, leaving for the first time the Executive Branch without the possibility of passing laws for its almost automatic approval, as it happened always before 1997.

With regard to AIDS and access to drugs against this disease, the Chamber of Representatives organized an International Forum titled "HIV-AIDS: Social and Legislative Challenge" carried out from 25 to 27 March 1998, which departed from an initiative of the President of the Health Commission, a PRD member, in this forum were presented different speeches related to AIDS and ARV (3), and also a concrete proposal in order to budget an amount for \$46.25 million dollars that would be enough to meet the needs for ARV for those which did not have social security in 1998 (4).

As a result of that forum, the so-called "Declaration of San Lázaro"<sup>2</sup> was signed, where one of the objectives would be "To prepare and to guarantee the adequate allocation of resources for the programs of AIDS prevention, comprehensive care for PLWA, and the defense of the human rights." (5) However, the involvement to support this declaration on the part of the representatives only was given by the same person-promoter of the forum, and it was more an individual position than a PRD position<sup>3</sup>.

Therefore, does not exist a very clear position of each political party with regard to the access to ARV. In a seminar-workshop carried out in September 1998, by CONASIDA and SIDALAC, as a part of this case study; "Process of Access to drugs ARV in Mexico", a representative of the PRI manifested her favorable position that ARV should be acquired with public funds<sup>4</sup>. However, this is also considered to be an individual position and not necessarily the one of her party.

<sup>2</sup>The name of "San Lázaro" was given due to the neighborhood where the Congress Building is located and not to correlate it with the "Lazarus Syndrome".

<sup>3</sup>The reason to consider it as an individual position was due to the fact that He was the only Congressman who was permanently present during the full seminar, and there was no other official declaration on behalf of the PRD.

<sup>4</sup>Congresswoman Dr. Mercedes Juan expressed it as her personal position

In November 1998, another budget proposal for ARV, was sent to representatives of the three major parties (PRI, PAN and PRD), by a new group of PLWA (PositHIVos)<sup>5</sup>, Nevertheless, except from the same representative of the PRD (President of the Health Commission) who offered an explanation on what was the fade of proposal, during a speech in a February, 1999 seminar<sup>6</sup>; none of the others stated some official position on the part of any political party.

We can assume that the official position of the PRI, as it traditionally happens, is the same than that of the Federal Government, which was expressed in a letter sent by the Ministry of the Treasury to PositHIVos regarding the budget proposal (6), where this Ministry declared that: “due to the decline in the international prices of the oil the country has received less income and as a result the public budget is insufficient... and that the solution is in the hands of the Chamber of Representatives, if they propose and authorize an alternative way of income collection in order to pay for ARV drugs.

The original proposal of PositHIVos, pointed out that these funds could come from cuts to the Secretariat of Defense, Navy, Agrarian Reform, Tourism and Estate.

In relation to the PAN, this party has not manifested a position in this regard, outside of an interview in which the Secretary of the Health Commission of the Chamber of Representatives, and also member of this party, declared that the first proposal of \$46.25 million USD presented for the previous year, was “absolutely infeasible” since it represented “10 times more than the budget with which FONSIDA was created” (7).

### *Economy*

According to the World Bank (8), in 1994 the per capita GNP of Mexico was of \$4,180 USD, and was located as the highest third of Latin America, only by below of Argentina and Uruguay, but above the corresponding to Chile, Brazil and Venezuela; however, in December 1994 the Mexican economy initiated the most severe crisis occurred since the decade of the 1930s: the growth of the GDP declined abruptly at one rate of -6.2%, annual inflation rate that was less than the 10%, amounted to 51,97% and the Mexican peso was devalued 90%, going from an annual average bid of \$3.37 pesos by dollar in 1994 to \$6.42 in 1995.

<sup>5</sup> The content of the proposal was published as a paid insertion at “Letra S” in “La Jornada” Newspaper in December the 3rd, 1998.

<sup>6</sup> Congressman Dr. Santiago Padilla, PRD member and President of the “Comission on Health” at the Chamber of Representatives gave this explanation during a seminar on AIDS prevention and the creation of Mexico City’s own AIDS program. Organized by “Letra S” and the City Authorities ( a PRD Government). During his speech he mentioned that he had asked the Secretary of Health of Mexico why there was no money for ARV in the SSA budget for 1999, and that the answer was that there was not enough money in the SSA to cover all health needs.

The political instability, the sudden interruption of the flows of capitals from abroad, and the high deficit of the balance of payments, added to the consequent devaluation of the peso, imposed on the economy and to the society a painful adjustment in its standards of living. The plan of adjustment was oriented to return the macroeconomic reorganization with stability of prices, based on a contraction of the overall public sector.

For 1996, significant progress in the process of macroeconomic adjustment was obtained. The GDP had a positive growth rate of 3.2%, rate higher than the expected and the per capita GDP was of \$3,950 dollars in 1996. The exports grew extraordinarily and the balance of trade showed an annual positive balance, the exchange rate maintained a slow slip and at the end of that year reached a bid of \$7.70 pesos by dollar. However, inflation still reached annual 27%; the reported one for April 1997 had declined to 22.3%. For February 1998, the exchange rate was located in \$8.20 MX pesos for \$1.00 USD. The Ministry of the Treasury in turn reported officially that the growth of the economy in Mexico during the year of 1997 was 7%, reaching with this a record level of growth that was not presented since 1981, time in which it grew thanks to the oil prices "Boom."

For February 1999, the bid of the Mexican peso with respect to the dollar fluctuated in 10 pesos per \$1.00 USD, being its last slip caused by influence of the financing and stock exchange instability of the markets of the Southeast Asia, as well as to the effect of the devaluation in Brazil. The last official economic announcement on the growth of the Mexican GDP, for 1998 was of 4.8%, although was lower than the one of the previous year, the federal government considered it as a great achievement considering the international financial instability of stock markets during most of 1998.

Outside of the possibility of a recovery and the complete macroeconomic stability, one of the most serious problems of the country is the social inequality, which has been strengthened by the unemployment and inflation that the crisis has taken with it. For 1994, 20% of the poorer population only had 4.2% of the income of the country, while 20% of the higher income population keeps 55.3%.

This inequality also has its geographical and ethnic manifestation, being states as Chiapas, Oaxaca, and Guerrero, states with a great concentration of indigenous population, the most left behind, not only economically, but from the standpoint of its educational levels and health indicators, such as infant and maternal mortality. It is precisely to these social inequalities, that many people attribute that it was not by accident that the indigenous guerrilla (Zapatistas) has precisely occurred in Chiapas, and that Oaxaca and Guerrero have been used to justify the appearance of another guerrilla group, the self-called "Popular Revolutionary Army" (EPR).

In the presentation of the "Social Development and Fight against Extreme Poverty Program 1999" (9), the incumbent of this Secretariat recognized the existence in Mexico of 40 million poor, 26 million of which were found in the category of extreme poverty, many of them living in rural areas of self consumption and survival crops, very far from being able to compete, take any advantage or to receive some benefit from the NAFTA or economic globalization.

In accordance with the 1998 World Development Report from the World Bank (10), for 1997, Mexico by the size of its economy, measured by its Gross Domestic Product of \$348.6 billion USD, occupied the place number 16 among the largest economies of the world, and the position number 10, if this adjusted by its purchasing power; however, from those positions it falls down to the site number 42, if measured in terms of per capita GNP, which is in fact the most common indicator to measure the level of development.

Finally the growth of the economy in the period 1996-97 (6.2%) , according with that same report was the 10th highest of the world, surpassing in that period the one of countries of high economic growth, such as Chile, Korea, Argentina or Spain.

### *Religion*

Although it is recognized that around 90% of the population in Mexico is Roman Catholic, some other protestant religions, but by far minor, have begun to gain spaces, especially in the southeastern states as Chiapas.

The high hierarchy of the Catholic church in Mexico, also has great political influence, The 3 Cardinals at the national level, and the archbishops to the level of each of their states. Unlike other countries of the world and due to the historical-political development of Mexico, the church have not developed great capacity for the operation of health services, on the other hand, whether there has succeeded in being consolidated in urban areas as an alternative to public schools.

The position of the Catholic Church with respect to official AIDS prevention programs, has been of open opposition on the part of members of the high hierarchy, especially by the Cardinal based on Mexico City, who in addition supports the group Pro-Life (PROVIDA) (11), the civil association that with more vehemence has been pronounced against the promotion of the use of the condom by the government. Concerning medical care to the PLWA, only at the local levels of the church, in parishes and convents it is that some priests and nuns, have carried out and promoted charitable actions for the care of these patients.

### **Health System**

The National Health System is made up of various public institutions that offer medical services. In 1943, the Mexican Social Security Institute (IMSS) and the Ministry of Health and Welfare (Currently Ministry of Health —SSA—) were created, subsequently, in 1959, appeared the Institute of Safety and Social Services for the State Workers (ISSSTE). All these health institutions were created as centralized entities and it was not until 1982 and later in 1995, that efforts to achieve a decentralization of the health institutions mainly the ones that provide services to uninsured population, were incorporated, that is those of the Ministry of Health, but not those of the IMSS, nor of the ISSSTE.

In the model of health in Mexico, they coexist private medical and public care. The private market, in turn, has been developed outside of the official policies, and they provide care to both, population without social security and to the insured one that prefers to utilize this private facilities. However, a great percentage of the physicians who work in the private sector come from the same ones who are at public sector, only that they work different shifts. The private insurance, in addition, still represents a minority sector of medical care.

The public system is formed by institutions of public assistance, mainly the SSA, the IMSS-Solidaridad, the Medical Services of the Government of the Federal District (DDF) and the Program for the Integral Development of the Family (DIF), the later one is traditionally headed by First Lady of Mexico, and to the state level by the wives of the governors. The Health System is also integrated by the Social Security Institutions as the IMSS, that covers workers of private enterprises, the ISSSTE, for state workers, and other minor schemes of social security that serve different sectors of workers such as the oil industry, the army, the navy, the local bureaucracy of state governments, etcetera.

The structure of the Health System finally determines the differences between salaried and non-salaried population, which gives rise to several types of access to health care. The so-called population “beneficiary”, it is the one that has access to the clinics and hospitals that directly operates the social security institutions. Beneficiaries are workers of the formal economy, both public and private, in the meantime the rest of the population not beneficiary, also called “open population”, is subject to assistance programs from the SSA, that also operates hospitals and health care centers and posts, as well as to medical services provided by IMSS-Solidaridad, and in the case of Mexico City to the health services provided by the DF government. To a lesser extent the uninsured population can also use the DIF, some civil hospitals (municipal or state), university, Red Cross, and the ones offered by charitable organizations both civilians and religious.

With official data published in the statistical annex of the 4<sup>th</sup> State of the Union Speech in 1998 (12), the population institutionally (potentially) cover by the health system in 1998 was of 99,226,249, of which 50,059,325 corresponded to uninsured population (50.4%) and 49,166,924 to beneficiaries of the social security (49.6%). The distribution is better exemplified in the following table.

*TABLE 1*  
*Public Institutions that provide medical care in Mexico, potential population covered in 1998*

Health Institution	Population Covered	Percentage
<u>Social Security</u>	<u>49,166,924</u>	<u>49.60%</u>
IMSS	39,461,964	39.80%
ISSSTE	8,465,895	8.53%
Other	11,239,065	1.25%
<u>Uninsured</u>	<u>50,059,325</u>	<u>50.40%</u>
SSA	35,463,500	35.70%
IMSS-Solidaridad	10,897,085	11.00%
DDF	3,698,740	3.70%

Source: : SSA/Statistics and Informatics General Directorate/ Sistema Nacional de Salud, Statistical annexes of the 4<sup>th</sup> State of the Union Speech of President Ernesto Zedillo, 1998.

Despite the fact that the theoretical coverage (potential) by health institutions shown with these data is of 100% of the population, the Program for Reform of the Health System (13), published by the Federal Government in 1996, recognized the existence of 10 million inhabitants who for various reasons did not have real access to these health services, being located mainly in scattered rural areas, predominantly indigenous that represent the sector of the so-called extreme poverty. That is although the health care facilities were sufficient to cover this population, the geographical conditions and the dispersion of the population, make almost impossible to have a real homogeneous coverage.

In 1995, the Mexican Government structured a loan from the World Bank for a second Basic Health Care Services project ( now called Program for the Expansion of Coverage –PAC-) by a total of \$443.4 million USD, getting 70% of the project cost from the Bank Loan, and 30% from Federal Government funds (14).

The PAC loan to be disbursed from 1995-2000, has as a central purpose to expand that coverage toward the marginalized areas described above through a package of basic health services, and in addition envisages providing support for the decentralization and modernization of the central areas of the SSA.

The institutions that form social security (IMSS, ISSSTE, Oil Industry, Army, etcetera.) for the most part they offer a broad range of medical services to its beneficiaries in units formed by three levels of care: family medicine units (first level), general or regional hospitals (second level), and specialized hospitals (third level). Only the levels second and third provide services of hospitalization. These institutions do not charge a fee for service, in addition offer to their beneficiaries the lab and image studies, as well as the drugs that require their care.

For a drug to be provided by a Social Security Institution, it should be found officially listed first in the Basic Table of Drugs of the Health Sector, which is defined periodically by specialists and health authorities. In case of the specific anti-viral drugs against HIV, until April 1997, only the 'zidovudine' (AZT) was listed in this basic table for the first level. However, currently hospitals both the IMSS and the ISSSTE have authorized also to provide zalcitabine (ddc), didanosine (ddI), and starting in May 1997, the IMSS began to include indinavir, lamivudine (3TC), and saquinavir, as a part of the anti-retrovirals that offers its beneficiaries with AIDS. In 1998, ritonavir was also officially included, and starting November of that same year they authorized D4T.

In case of the institutions of care for non beneficiaries, also called of social welfare, mainly the SSA and IMSS-Solidarity, normally provide care in health centers and rural medical units (first level), some general and regional hospitals (second level) and hospitals of high specialty (National Institutes of Health of the SSA). The units of the SSA tend to charge a small fee for service to their patients.

In 1995, begins a new effort of decentralization of the Ministry of Health, which originally had started in 1982, but stopped by the federal administration from 1988 to 1994. The services that are offered by the health centers and hospitals belonging to this institution charge a fee that goes from \$0.50 USD (50 cents of a dollar) for a visit to a general physician in a health center of first level, to \$10.00 USD for a specialized doctor visit at tertiary care hospital, however, even these charges can vary in accordance to the socioeconomic level of the patient, getting additional discounts that go from 10% up to 100%. This means that they are highly subsidized and, of course, they do not reflect the cost of the services.

These services for non beneficiaries, usually have a very limited collection of drugs, which also sell in their own pharmacies with large discounts (they do not include anti-retrovirals).

The non beneficiaries with HIV/AIDS, tend to be referred for care to health units of second and third level of the SSA, to centers of ambulatory health care operated by CONASIDA, to private physicians, or to medical care units created by nongovernmental organizations. However, except for those that enter to research protocols, the patients normally do not receive anti-retroviral drugs from the institution and, in the event that they are prescribed, they should acquire them through out of pocket payments if they can.

## Public Spending in Health

The public spending of the Federal Government for the different health institutions, showed a sustained growth from 1990 to 1994, starting in 1995, and as a consequence of the economic crisis that initiated in December 1994, registers a setback as is observed in the following table. In addition, it can be observed that these resources have devoted themselves primarily to the institutions that serve beneficiaries in a correlation of 3.5/1 over what is destined to the institutions that cover non beneficiaries, and

they were basically directed toward curative care in a correlation of 11/1 over preventive care in the last reported year (1995).

*TABLE 2*  
*Public Expenditures on Health, by type of institution and proportion of it that goes to preventive and curative care.*

Year	Total Expenses in millions USD	Open Population in millions USD	Social security in millions USD	Preventive Care	Curative care	Another programs
1990	\$5,892.70	\$1,122.60	\$4,615.60	4.89%	61.49%	33.62%
1991	\$7,546.30	\$1,408.40	\$5,957.20	4.54%	58.46%	37.00%
1992	\$9,139.70	\$1,767.40	\$7,372.30	4.70%	58.81%	36.49%
1993	\$10,207.20	\$2,084.50	\$8,122.70	6.33%	60.65%	33.02%
1994	\$11,135.20	\$2,284.60	\$8,850.60	6.28%	59.09%	34.63%
1995	\$7,108,266	\$1,503.30	\$5,203.80	5.78%	62.55%	31.67%

Source : SSA/ Statistics and Informatics Directorate General/ Sistema Nacional de Salud, Services and Resources, original data in Mexican currency mx, Boletín de Información Estadística. México, DF, No. 15, 1995 pp 11. Exchange rates: 1990: 2.65MX=\$1.00US; 1991: \$3.07MX=\$1.00US; 1992: 3.09MX=\$1.00US; 1993: \$3.12MX=\$1.00US; 1994: \$3.37MX=\$1.00US; 1995: \$6.40MX=\$1.00US; 1996: \$7.60mx=\$1.00US; 1997: \$7.85MX= \$1.00US

For 1997 and 1998, the Federal Government conveyed the general public, through the press, significant increases to the health expenditure, which can better be appreciated in the graphic 1.

In light of frequent questionings, both from political parties of opposition (PAN & PRD) and the media, as well as from health professionals, regarding the austerity and cuts to the federal budget programmed for 1999, and concerning if they would affect the programs for health of the low-income population, the SSA published in the press the following figures (originally in MX pesos), that reflect the budget authorized for 1999, compared with the one spent in 1998 by the health services for non beneficiaries (see Table 3).

GRAPH 1  
Health expenditures from the Central Government from 1990 to 1998

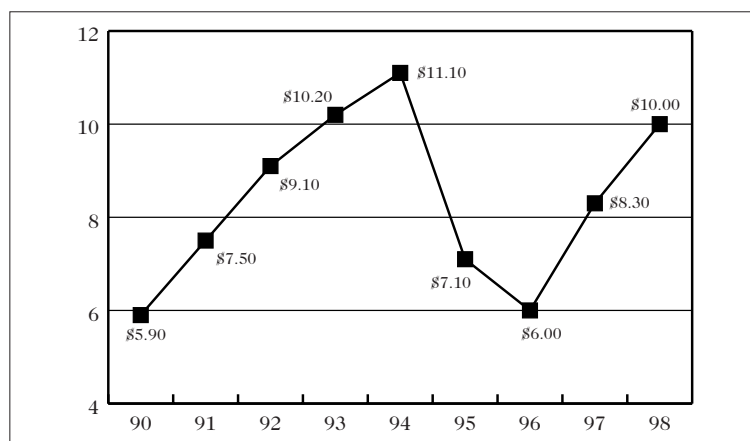


TABLE 3  
Federal budget spent in 1998 and authorized for 1999 to the institutions that provide care to the open population. In millions USD

Year	SSA	Open population*
1998	\$2,412.96	\$3,034.93
1999	\$2,708.92	\$3,321.75

\* Open population includes SSA, IMSS-Solidaridad and DIF.  
Exchange rates: 1998: \$8.89 mx = \$1.00 USD and for 1999:  
(January) \$10.17 mx = \$1.00 USD.

Whether we assume as constant the quantity of non beneficiaries (open population) conveyed in the presidential report on 1998, we would be speaking of a per capita public spending in health of \$66.40 USD by person without social security (\$3,321,750,000 USD/50,059,325 inhabitants), which is much lower than the \$197.55 per capita to be spent by the IMSS in 1999 (see graph 2).

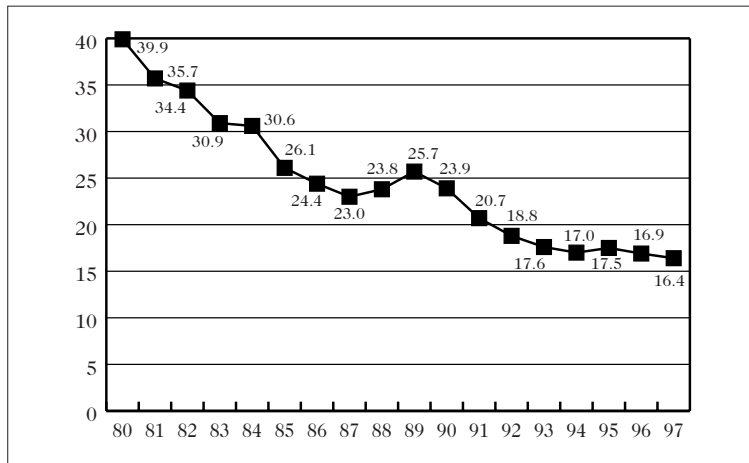
Added to the previous, is also made known the total of the resources programmed for open population in 1999, in accordance with the process of decentralization, the SSA said that these resources will be planned and spent in 70.1% directly by the state governments, compared with 66.4% that were performed in a decentralized way in 1998.

In the same press published information, the SSA pointed out that for 1999 the central objectives of the SSA will be: 1) to Support the consolidation of the decentralization in the states, 2) to Strengthen the priority public health programs, 3) to Advance in the extension of coverage of health services, 5) to Improve the quality of the medical services and 6) to Continue with the updating of the legal framework of the sanitary regulation.

### Health Indicators

In general there has been progress in Mexico, in terms of diminishing certain health indicators that are utilized at the international level to measure the degree of social development of a country; thus, concerning infant mortality in accordance with the official figures they have been lowered from 39.9 deaths of children under 1 year by 1000 live births in 1980, to 16.4 in 1997 (15), that is a reduction of 59%, during that period. This can better be observed in the following graphic.

GRAPH 2  
*Infant mortality rate<sup>7</sup> in Mexico, from 1980 to 1997*



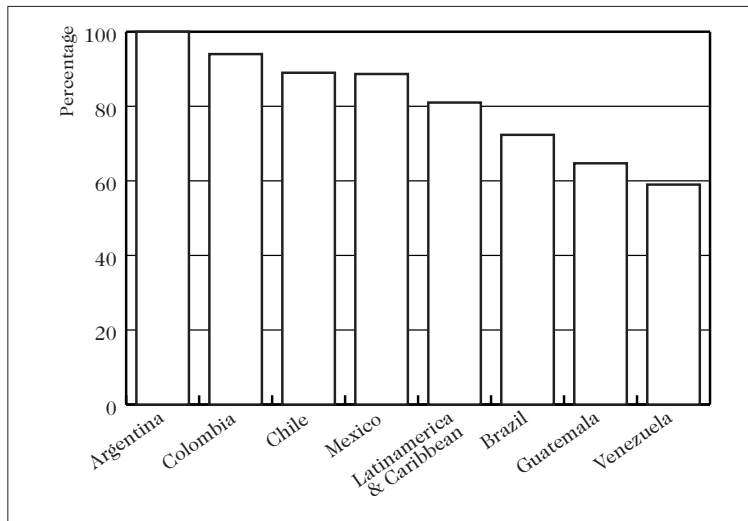
Most of the reduction of infant mortality is perhaps explained by the expansion of the health services, but especially to the broad percentages of coverage of vaccination schemes in minors reached in the last 15 years, within this it can be

<sup>7</sup>Deaths of children under 1 year of age per 1000 live births

pointed out that since 1990 there is no presented of a single case of poliomyelitis, which means that already has been considered eradicated, with regard to *dyfteria*, since 1991 a single case does not occur in minors, and concerning measles, in 1996 there were presented the last two cases. Although, it is estimated that except for polio, the other two diseases could recur if there are not expanded or maintain the current coverage of vaccination. It should be pointed out however, that actually this broad coverage of vaccination is partly being achieved in most of the countries of Latin America and the Caribbean, thanks to the strong promotion of these policies given by international agencies as PAHO and UNICEF, some coverage of selected Latin-American countries can better be appreciated in the following graphic prepared with data from PAHO (16).

GRAPH 3

*Children's measles vaccination coverage in 1996. In selected Latin-American countries*



Despite these achievements, in Mexico there is still kept the challenge of achieving greater equity concerning health, that is why the SSA has been implementing the PAC since 1995, and another one to combat the extreme poverty (PROGRESA) through the Ministry of Social Development. This inequality is manifested in a more patent way in states as Chiapas, Oaxaca and Guerrero as stated earlier.

The health status of a country, can also be shown based on the leading causes of mortality of its general population or by groups, below two tables are shown in this regard.

*TABLE 4*  
*First 15 causes of death in general population in Mexico in 1997<sup>8</sup>*

Rank	Cause	Rate
1	Heart diseases	71.8
2	Cancer	54.1
3	Diabetes Mellitus	38
4	Accidents	37.9
5	Brain vascular diseases	26.1
6	Cirrhosis and other liver diseases	24.1
7	Pneumonia and flu	21
8	Perinatal diseases	20.9
9	Homicide and criminal injuries	14.3
10	Nephritis, nephrosis and kidney diseases	10.8
11	Nutrition deficiencies	10.7
12	Birth congenital abnormalities	10.1
13	Bronchitis, emphysema and asthma	9
14	Gastrointestinal infectious diseases	7.8
15	AIDS	4.4

Rate per 100,000 inhabitants, Source: INEGI, SSA/DGEI,1998

From the previous table, it can be emphasized that for 1997, AIDS was already found as the 15<sup>th</sup> cause of mortality in the general population, but when is shown by specific age groups as is the case of productive age, then rises up to the 9<sup>th</sup> position.

*TABLE 5*  
*Main causes of mortality in productive ages*

Rank	Cause	Rate
1	Accidents	41
2	Cancer and malignant Tumors	39.6
3	Heart diseases	31.4
4	Cirrhosis and other liver diseases	27.3
5	Diabetes Mellitus	25.9

Continues

<sup>8</sup> Tables 4 and 5: 3: SSA: Estadísticas vitales 1997, Chapter on : Mortality, Main causes of death in general population, Estados Unidos Mexicanos.

Rank	Cause	Rate
6	Homicides and criminal injuries	20.8
7	Brain vascular diseases	10.7
8	Nephritis, nephrotic syndrome and kidney diseases	7.1
9	AIDS	7
10	Pneumonia and flu	5.7
11	Suicide	5.2
12	Pulmonary Tuberculosis	3.7
13	Syndrome of alcohol addiction	3.3
14	Nutrition deficiencies	2.5
15	Bronchitis, emphysema and asthma	2.1

Rate per 100,000 inhabitants of 15 to 64 years old. Source: INEGI SSA/DGEI, 1998

### The figures of the epidemic

The first case of AIDS in Mexico, was detected in 1981, to the 31st of December, 1998, had been reported 38,390 cases.

The system of report of any country is subject to multiple problems. The cases of AIDS have been reported in Mexico in accordance with international criteria that for the case definition have adapted to the evolution of knowledge of the disease and the availability of the diagnostic resources (17). The information obtained has been systematized in the National Registry of AIDS Cases, which functions since 1983 and as a electronic database since 1987.

Information on cases, is published periodically, first inside the Bulletin of AIDS whose first issue appeared in March 1987 until March 1995 (18), and currently continues to be published inside the pages of the AIDS/STD journal (Revista SIDA/ETS) and also in the Web page of the Ministry of Health (<http://www.ssa.gob.mx>).

More than fifteen years of the first report of the disease (19), the principal problem of epidemiological surveillance in Mexico has been very similar to the one reported in other countries: the under-registration of the information, mainly caused by delay in the report of the same. Since 1989 there have been published several works that analyze this problem that is necessary to take into account when notified figures are studied. (20, 21, 22)

The delay of the report is determined by the time elapsed between the onset of the disease, its diagnosis, and the report. It has been observed that the cases occurred in a year given and that are going to be subject to epidemiological report are sometimes notified until three years after its diagnosis. It is for this reason that the delay is calculated taking into account the patterns of the report in the anterior years. The first evaluation on the delay, located this in 36.7% (23) while the last published calculation indicates us that the delay amounts to 35% (23). In addition the under-registry is also determined by the number of cases that are not subject to epidemiologi-

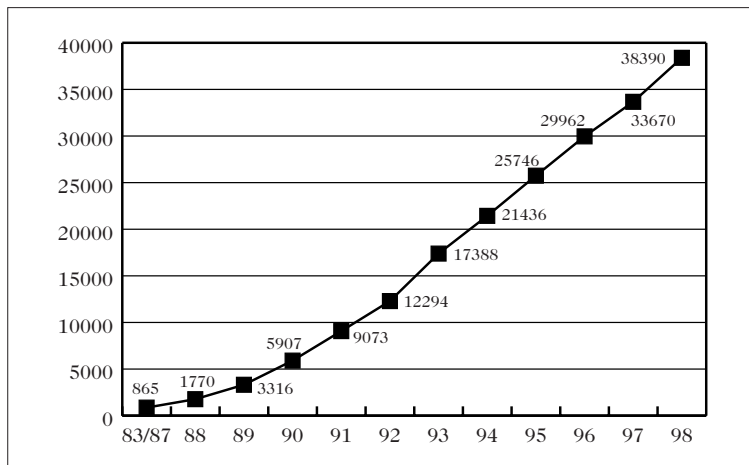
cal report. This situation has been calculated during the supervisory visits carried out to the units informants, where there were reviewed clinical files and death certificates.

The initially estimated figure of 26% (24), during the most recent probe was located in 18.5% (23). It is for this reason that to the number of cases reported in 1997 in the same publication it estimated a total of 51,000 cases (25). In summary, currently in CONASIDA they utilize the following formula: to the total number of registered cases they add 18.5% more due to under-registry and 35% by delay on the report (26).

### *Trends*

The AIDS epidemic in Mexico has presented three trends, in the first one until 1986, the increase was slow, subsequently between 1987 to 1990 the growth was exponential. Starting in 1991 the growth has been alleviated and presents doubling times of 16 months, however, this slow growth is observed mainly in the metropolitan areas of the country. The cumulative number of cases per year can be observed in the following graphic, in which the last registry is the 31<sup>st</sup> of December, 1998 (27).

GRAPH 4  
*Growth of the AIDS epidemic in Mexico.  
Cumulated registered cases from 1982 to 1998*



The epidemic in Mexico maintains a mixed pattern with predominance of the sexual transmission. The masculine homosexual unprotected practices are the

principal form of transmission, and they still present a tendency to increase, (28) also is observed a discreet increase of the heterosexual transmission. It is necessary to point out that the heterosexual transmission documented through the cases is over-estimated (29). A sign of the foregoing is that in Mexico the figure of men reported by heterosexual transmission is three times greater than that of the cases in women by the same way of transmission, while in by this mechanism in the United States there are reported two men per each woman (30).

Another indication of this of this over-registry of heterosexual transmission on men, is that in the sentinel studies conducted in Mexico on female commercial sex workers, they have had low prevalence rates of HIV.

### *Blood Cases*

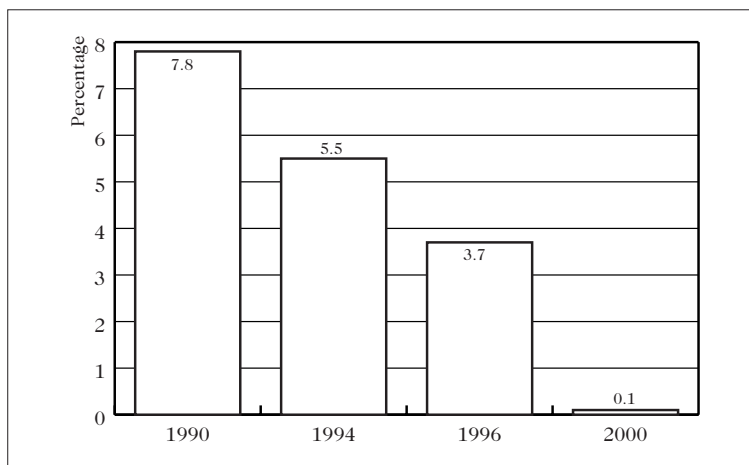
In Mexico, in addition to the legal provisions that prohibit the sale of blood and that they make it necessary to that every transfused blood has been previously analyzed for HIV, there have been carried out educational activities directed the donors with a view to avoiding that people with practices of risk donate blood. The prevalence of infection in donors has presented decline in recent years since in 1990 it was 0,06% and in 1996 it is 0,04% at the national level. The prevalence of altruistic donors varies by geographical area.

The cases of AIDS due to transmission by blood has shown a marked decline. The highest percentage of cases transmitted through blood transfusion was 17% in 1989, and declined starting in 1991 until representing 8.4% of the total for 1996. Between women the impact of post-transfusion AIDS was greater, which means that the reduction of AIDS among them was more marked, going from 100% of the cases in 1985 to 75% in 1986, 69% in 1987, 68% in 1988, 66% in 1989, 60% in 1990, and 51% in 1991, diminishing to 48% for the cases accumulated for December 1996 (31).

The success of the policy of contention of cases of AIDS due to blood transfusion it is attributed to the prohibition of the marketing of the blood decreed by the federal management of 1982-88, and continuous by the successive administrations.

Since the prohibition of that private blood trade, until the present time, all the blood transfusions are carried out in an unremunerated way, normally by relatives of the person who will be transfused. In accordance with the goal program of the Ministry of Health, the category of cases of AIDS due to blood transfusion should be practically null by the year 2000, as it is shown in the graphic utilized by this institution in its Web page. (<http://www.ssa.gob.mx>)

*GRAPH 5*  
*Percentage of AIDS cases due to blood transfusion.*  
*Selected years and goal to year 2000*



### *Children*

In case of the children, of the 1,002 cases presented in minors under 15 (2.6% of the total) to 31 December 1998 (27), the trends by category of transmission are the following ones: by blood it was presented in 43% in 1990, 26.8% in 1994, and for 1996 was 37.6%. Of these cases 55% was by perinatal transmission in 1990, and 59.1% for 1996.

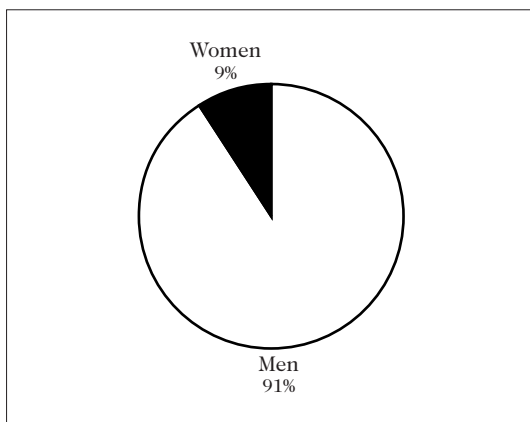
### *Intravenous drug users*

Until 1998 there registered a total of 252 cases (0.7%) whose category of transmission was related to the use of intravenous drugs (UDIV) (27).

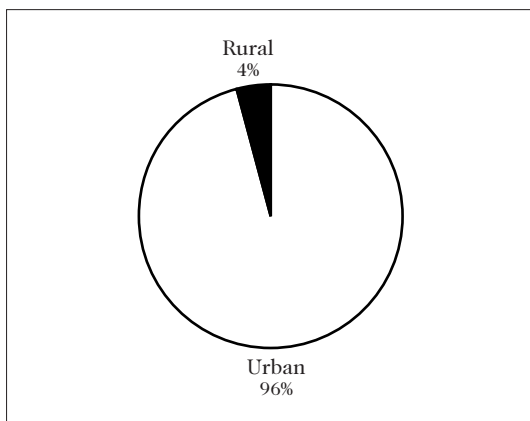
### *Rural cases*

According to the last data analyzed until 1994 there had been recorded 699 (3.7%) cases cumulative in communities of less than 2,500 inhabitants, that is in the rural area (32); although, this continuum manifested growth of rural cases, it still very far to reach 22.5% of the total, that is what the rural population represents in Mexico (2).

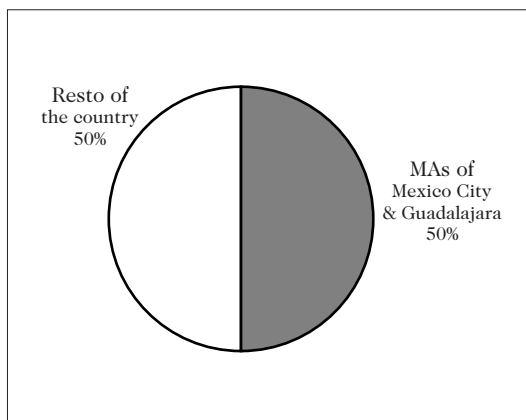
GRAPH 6  
*Percentage of masculine and feminine AIDS cases due to sexual transmission  
1998 (33)*



GRAPH 7  
*Percentage of urban and rural AIDS cases from the total cumulated  
cases in 1995 (32)*



GRAPH 8  
*Percentage of national cumulated AIDS cases concentrated  
 in the MA of Mexico City and Guadalajara in 1997 (34)*



### *Masculine and urban epidemic*

In conclusion, we can say that HIV/AIDS in Mexico, occurs predominantly by sexual transmission, 60.65% of the cumulative total and 95% of the new 1998 AIDS cases were the transmission mechanism is known (27).

We can also say that the epidemic in Mexico, still is highly dominated by males, 3,977 (86%) of the 4,625 new cases reported in 1998 were men, in fact the masculinity ratio of 6:1, increases to 11:1 (91%) when we consider only those sexually transmitted.

The epidemic in our country still affects in a more intense way the group of men who have sex with men ; it can be considered basically an urban illness, taking into account that with the last data analyzed to December 1997, in the files of CONASIDA, the metropolitan areas of only two cities: Mexico DF and Guadalajara concentrated 50% of the epidemic.

### *Mortality*

Mortality from AIDS in men from 25 to 44 years old, has risen rapidly. In 1988 in this group occurred 384 deaths from AIDS, with a rate of 34 per 100,000 population, as a cause of death in this age group, occupied the fourteenth place in that year, while for 1992 there were 1,750 deaths for this same group with a mortality of 130 and as cause of death moved up to the sixth place in the same age group (24). By the 31<sup>st</sup> of December 1998, of the total cumulative cases of all ages, 51.19% had died (27).

### *Projection of AIDS cases*

The most recent models for the prediction of the epidemic growth incorporate aspects on the transmission, natural history of the disease and behavioral variables. WHO developed a model called EPIMODEL, that permits the calculation of the number of cases of AIDS in short periods (4 to 6 years) and permits its adaptation to the conditions of every country or region (35). In Mexico this model was used for the first time in 1995 (30).

For this study, again EPIMODEL was utilized and it was calculated that by the year 2000 we will have 74,213 cases. In addition, recent estimates by another group of researchers, utilizing methods based on extrapolations and back-calculation, got to more conservative figures in the sense that for the same year in Mexico there will be 69,700 cumulative cases (36). Both estimates incorporated the under-registry.

In this section we can conclude stating that although, HIV/AIDS continues to represent an important public health problem, reflected by a large number of infected (one infected per every 1,000 population of general population and four times greater in males from 20 to 44 years).

There has been achieved a successful result in the prevention of blood transmission, the infection continues to affect mainly homosexual and bisexual males among those who the number of infected cases and deaths continuous be the highest.

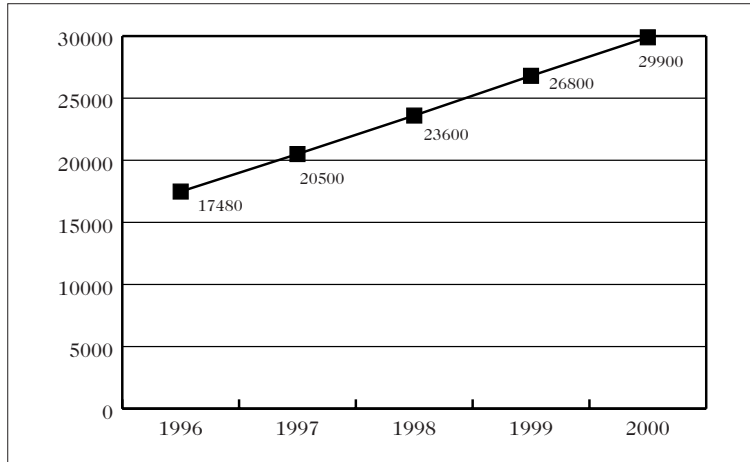
The high frequency of other STDs in some populations as among female sex workers, indicates the risk of extension of HIV to these groups. The transmission in subjects with risk of intravenous drug addiction although it is of a smaller magnitude has presented a light increase, as well as the extension of the infection to the rural areas.

For the purpose of being able to estimate the resources necessary for programs of medical care for PLWA, based on the data of recorded cases of AIDS, EPIMODEL and the number of death cases until 1997, the following estimates of live cases in Mexico were carried out for a previous study (1). These figures are better are observed in graph 9.

### **CONASIDA and the local HIV/AIDS programs**

When in 1985, in light of the growth of a disease that was already visualized as pandemic, the World Health Organization (WHO) made an appeal so that all the countries established committees of struggle against AIDS. The Mexican government that had participated in the world meeting of ministers of health, in order to establish the overall strategy for its control, strengthened the activities that were carried out, creating in February 1986 the National Committee of Prevention of AIDS (CONASIDA) that was constituted as interinstitutional group and whose objectives were to evaluate the national situation in regard to the infection by HIV/AIDS; to establish criteria for their diagnosis, treatment, prevention and control of AIDS; as well as to coordinate the implementation and evaluation of standards, guidelines, and appropriate control activities (24).

GRAPH 9  
*Estimated number of people living with AIDS 1996-2000*



In 1988, by a presidential decree published in the Official Journal of the Federation on the 24<sup>th</sup> of August of that year, the Committee adopted the character of National Board of Prevention and Control of AIDS (CONASIDA). From that moment there were allocated own resources for their operation, but the majority of its activities were carried out with international financing, mainly with funds of the Overall Program of AIDS of WHO, until 1991, in that had federal budget within the SSA.

In 1997, CONASIDA takes shape in practice as a deconcentrated organ of the SSA. The state Councils (COESIDAS) reproduce this model to organization in its area, with different success since its development has been very heterogeneous and even in some states they practically are nonexistent. However, as well as the process of decentralization that has been given in the SSA, each state it has been asked now to budget their own resources to operate their local programs.

Until 1998, two States stood out of the rest by the structure of their COESIDAS, Jalisco and Oaxaca, which, in both cases, the Governors had showed personal interest to support it. Both states have succeeded in setting up their own preventive programs, additional to those promoted by the central level. However, concerning medical care, the one which stands out is the program of the state of Michoacán, since in 1997, it decided to include within its services the free provision of ARV (except for protease inhibitors) to all those people that require them and do not have social security (see the case of Michoacán further on).

## The Nongovernmental Organizations

In 1995, for the preparation of a national directory of NGOs working in the AIDS field (37), CONASIDA succeeded in identifying the existence and operation of 112 different ones, located in 25 of the 32 states of the country. Of these, 51% were located in the MA of Mexico City.

Some of these NGOs, have been approached to activities related to direct medical care, as well as to the creation pharmaceutical banks and even to the importation of specific drugs against HIV, some of which, of another form would not be available in the country. Concrete cases can point out to saquinavir, D4T, ritonavir, indinavir and 3TC, which were available in the NGOs before in the formal market of the private pharmacies.

Although at the beginning of the epidemic, NGOs were especially full of fighting spirit upon demanding preventive programs by the government, starting in 1996, its most radical demands and of greater pressure have fallen into the category of the access to ARV and quality of medical care. This has been manifested with special emphasis on the groups of people affected by HIV.

### Health care services for PLWA

Medical care for the patient with HIV/AIDS in Mexico has been given heterogeneously, at the beginning of the epidemic, many hospitals, and health professionals refused to serve or hospitalize them, adducing reasons of space or capacity, but hiding reasons of ignorance of the problem, fear to unknown mechanisms of transmission and homophobia<sup>9</sup>.

Although, CONASIDA was created as a coordinating and normative organism, in light of the refusals of care to these patients by a large number of hospitals and health services, it began to be involved in activities of direct medical care to patients and to provide AZT through research and humanitarian protocols.

When the new drugs started to appear, the pharmaceutical companies showed interest that CONASIDA utilized their products, and tried to establish agreements based on protocols that were assumed to be finite on the one hand, and by the other CONASIDA itself began to utilize part of its budget to purchase of ARV, with the purpose of continuing with humanitarian protocols to provide free ARV, to uninsured and poor PLWA.

After the Vancouver International Conference on AIDS (1996), CONASIDA announced through the mass media the beginning of a protocol sponsored by Merck Sharp & Dome, that would include for the first time the free provision of the first inhibitor of protease that entered the Mexican market, indinavir. As criteria for access

<sup>9</sup>This information was provided by Drs. Griselda Hernández and José Antonio Izazola who were during those years members of CONASIDA.

to this drug it was established that the person had less than 60 CD4 lymphocytes count, actually it was a way to put a restriction to limit the demand since the number of available monthly doses were not higher than 90.

At the end of 1996, there was a change in the administration of CONASIDA, and the Ministry of Health pressed so that this Council reassumed its role for which it was created, that is as a normative organism, supervisory and coordinating and not as provider of assistance. At the beginning of 1997, CONASIDA decides to suspend the provision of ARV to those that were within their protocols, raising with this a reaction of disagreement from the PLWA affected with that measure, whom advised by NGOs and lawyers, interposed a judicial demand against the institution.

The Judge who took the case failed against the SSA/CONASIDA, however the institution appealed the decision and requested the revoke of the case, due to a more detailed analysis of the statutes of creation of CONASIDA, the judicial resolution was suspended.

However, the SSA and the Council itself made the announcement to the public opinion, that they would reinstate the provision of ARV to all those that were already receiving them.

As a result of this incident and taking into account its new normative and supervisory role, consonant with the policies of decentralization of the SSA, CONASIDA has not started new drug provision activities to new users, and has limited itself to continuing with the care of those that were already within its protocols.

Within the Ministry of Health, also the National Institute of Nutrition (tertiary care Hospital) in Mexico City, which was the hospital that diagnosed and provided care to the first case of AIDS in Mexico, has received grants, or financial support from pharmaceutical companies or from abroad in order to provide ARV through research protocols, which at the conclusion had not run with the same problem raised in CONASIDA.

### *Medical care to beneficiaries of the Social Security System*

Being affiliated with a Social Security Institution in Mexico is to be able to have the "hope" that not only medical care is granted, but also ARV will be received free of charge. The two largest Social Security Institutions in Mexico, the IMSS, and the ISSSTE (see table 1), since 1997, have incorporated in their drug catalogs a broad range of ARV, the drugs that currently are authorized to be prescribed by their specialized physicians are: AZT (since 1992), ddc, ddI, indinavir, saquinavir, zidovudine, 3TC, and in November, 1998, D4T was also incorporated.

Who have social security in Mexico?, the response is all those that have an employment remunerated in a private enterprise that bids at the IMSS or an employment within the government in the case of the ISSSTE.

At the national level, and in accordance with the last report of the President of the Republic in November 1998, the Mexican population that had access to social security was 49.6%, however, this distribution of coverage is not uniform through-

out the country, it varies from state to state, as well as vary the number of AIDS cases reported by each of them. This distribution can better be observed in table 6.

We can assume from the table that at least the same proportion of the population with AIDS or even the estimated living with HIV, has right to social security, however, in a report of CONASIDA it is pointed out that only 40.9% of the total of cases accumulated to 1 April 1998 had been reported by the IMSS and the ISSSTE despite the fact that the national coverage of this two institutions is of 48,33% of the general population (see Table 1).

Nevertheless, the author estimates that this percentage of coverage with social security to people with HIV/AIDS, could be higher than what is reported, and also higher than that what the figures show for the general population.

This presumption is based on that the epidemic in Mexico been manifested with a clear urban predominance, that is in cities where the Social Security Institutions have a higher percentage of beneficiaries than in national or states averages, and in addition is also the fact of the recommendation that is given to individuals when someone is detected as HIV-positive or diagnosed with AIDS: "Search for someone who affiliates you to the IMSS or ISSSTE."<sup>10</sup>

The process of looking for a person, owner or administrator of a private company or some "contact" within the government, to be able to be beneficiary of the IMSS or ISSSTE, mainly for ARV, has not been documented in any previous report, however, in an interview with a private company owner, who from an executive position decided to affiliate one PLWA to the social security, pointed out that he did it for humanitarian reasons<sup>11</sup>.

<sup>10</sup> The coordinator of this case study, has had the opportunity to talk to people who have followed this humanitarian mechanism in order to be a beneficiary of a Social Security Institution.

<sup>11</sup> The person who expressed these words, an owner of a small private company, requested that his name should not be mentioned in the report.

TABLE 6  
*Inhabitants by state<sup>13</sup> (1995), percentage of general population with social insurance (38) (1998) and share of total AIDS (1998) (27)*

State	Inhabitants	General Population with Social Insurance	Share of AIDS cases
Aguascalientes	838,791	62.90%	0.40%
Baja California	2,098,627	70.60%	3.70%
Baja California Sur	384,456	52.50%	0.60%
Campeche	629,582	45.60%	0.40%
Coahuila	2,178,785	64.60%	1.60%
Colima	472,758	45.80%	0.30%
Chiapas	3,686,209	21.30%	1.10%
Chihuahua	2,804,856	71%	1.10%
Distrito Federal	8,064,987	53.70%	27.70%
Durango	1,429,861	50.30%	0.70%
Guanajuato	4,452,581	57.70%	1.70%
Guerrero	2,878,485	34.30%	3.20%
Hidalgo	2,105,955	29.80%	0.90%
Jalisco	6,172,542	60.10%	11.20%
Mexico (State of)	12,191,867	48.70%	12.30%
Michoacán	3,852,976	36.50%	3.10%
Morelos	1,373,191	48.80%	2.30%
Nayarit	888,273	42.20%	1.30%
Nuevo León	3,457,585	62.00%	2.60%
Oaxaca	3,375,067	25.50%	1.80%
Puebla	4,806,702	38.80%	6.30%
Querétaro	1,241,860	56.50%	0.70%
Quintana Roo	672,114	53.10%	0.40%
San Luis Potosí	2,218,965	45.00%	0.90%
Sinaloa	2,383,465	60.50%	1.30%
Sonora	2,046,391	64.30%	1.30%
Tabasco	1,695,916	32.90%	0.60%
Tamaulipas	2,506,914	63.70%	1.80%
Tlaxcala	888,131	42.30%	0.80%
Veracruz	6,946,398	46.40%	4.60%
Yucatán	1,510,366	46.60%	2.10%
Zacatecas	1,351,481	36.00%	0.60%
			0.7% (Aliens)
Total National	91,606,137	49.6%	100%

<sup>13</sup>The reason to include the 1995 inhabitants per state is due that that is the last official population count, other population numbers for the following years that are shown in this document are estimates.

### *The Standard of Care*

In Mexico the health institutions are official part of the National Health System, where the Ministry of Health is the head, regulatory and normative entity. Also as a part of that regulatory role the CONASIDA was created, inside the board of the Council are representatives of the: SSA, IMSS, ISSSTE, PEMEX, Defense Ministry, Navy, Government of Mexico City, DIF, and the Indian National Institute; all of them operate clinics or hospitals that provide medical services; another non health institution, but also a member of the CONASIDA board is the Ministry of Education.

With the endorsement or involvement of all these institutions, there was created and published in 1995, in the pages of the Official Journal of the Federation<sup>13</sup>, the “Official Mexican Norm for the Prevention and Control of the Infection by Human Immunodeficiency Virus” (39).

This standard, that currently is under review, but that continues as the official one, refers to one ARV, the AZT, to be used in doses from 500 to 600 mgs daily, but it also refers to the obligation to follow the “Guide for Care of the HIV/AIDS Patient in ambulatory and Hospital care”. The norm establishes as compulsory, that this care be provided by trained staff (physicians entitled with professional certificate in effect).

The compulsory reference guide mentioned in the official norm, was updated and published in its third edition in 1997 (40), and it has a broad reference to different schemes of ARV treatment, that should be performed in accordance with the clinical status and evolution of the patient, as well as with changes in accordance with the monitoring by laboratory studies including count of lymphocytes CD4 and viral load. This Guide that is also currently under review for its updating, to 1 January 1999, continued to be in effect as compulsory follow-up reference by the health workers in accordance with the official standard, and envisages the use of double and triple therapies with ARV including inhibitors of the protease under the scheme of Table 7.

### *Physicians Sufficiency in Mexico*

At the international level, both in forums and at donor and multilateral and development agencies, tend to discuss the issue if developing countries need to train paramedical, auxiliary, community personnel or even healers, so that they can provide personal health care services to PLWA<sup>14</sup>, however many of these discussions and recommendations are based on the experience of African countries where the epidemic

<sup>13</sup> The Official Journal of the federation (Diario Oficial de la Federación) is where the government publishes all laws and standards that should be followed.

<sup>14</sup> There was an international seminar in London, UK, “Access to Treatment for HIV in Developing Countries” organized by the AIDS Consortium in June 5-6, 1998. During the seminar there was a big discussion on the issue of train non-physicians to provide health care for PLWA in Developing Countries.

TABLE 7  
*Selection of treatment by CD4 cell count and/or viral load if available, published in the Official Medical Guide for AIDS care in 1997*

CD4 cell count		Viral Load		Inicial treatment	If progression
500-350	Ó	<10 <sup>4</sup> (10,000 copies)	→	1 nucleoside (ddI)	→ 2 nucleosides
350-200	Ó	10 <sup>4</sup> - 10 <sup>5</sup>	→	2 nucleosides AZT+ddI AZT + 3TC	→ 2 nucleosides + Protease Inhibitor
<200	Ó	>10 <sup>5</sup> (>100,000 copies)	→	2 nucleosides+ Protease Inhibitor (if possible)	→ 1 nucleoside + 1 non nucleoside inhibitor of Reverse transcriptase + 1 Protease Inhibitor

reaches proportions still not observed in Mexico nor in Latin America ; and were their economies are only a fraction of those of the Latin American region (41). The Mexican Official Standard (39), makes it mandatory that the care provider, has to be a physician, professional entitled and with valid certificate.

The physician sufficiency in Mexico, seems not to be a problem since the number of physicians has been increased year after year as it is possible to observe from the graph 10, that was obtained from data contributed by the SSA in the Annex of the IV State of the Union Speech given by the President of the Republic (Nov. 1998) (Graph 10).

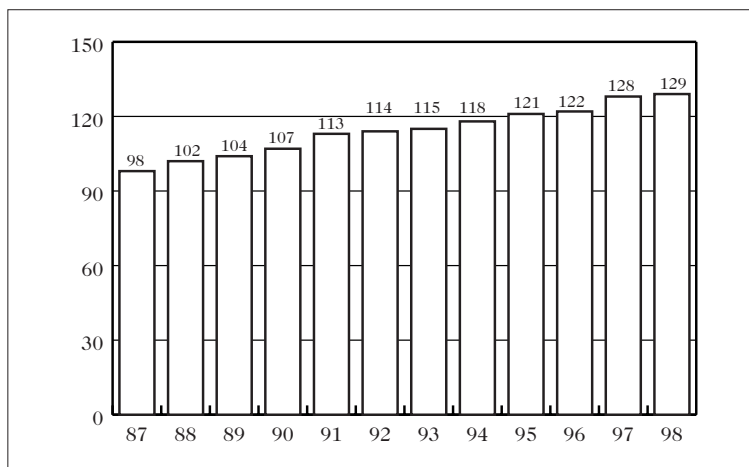
In spite of these figures, although the problem is not the number of physicians, in the case of our country the problem is the sufficiency of specialized physicians and the place where they live and work. The specialist who normally receives referrals of PLWA from general practitioners or family doctors is the Infectologist, however, the great majority of them concentrate in the three largest cities of the country: Mexico City, Guadalajara and Monterrey, that although it is where there are located little more than 50% of the cases, the problem of the sufficiency of these specialists focuses then on the remaining cities<sup>15</sup>.

In the specific case of the IMSS, patients with HIV/AIDS, normally are referred for their care with specialists localized in tertiary care hospitals or to the secondary ones that have a specialized physician, but in some cases, even in the City of Monterrey, these patients are handled in the Units of Family Medicine with primary care services.

<sup>15</sup> Concern expressed by Dr. Patricia Uribe, head of CONASIDA.

GRAPH 10 (42)

*Growth of physicians in Mexico from 1987 to 1998 (in thousands). For 1998, the estimated rate was 770 inhabitants per doctor or the equivalent to 1.3 doctors per 1,000 inhabitants.*



According with two of the most prominent clinical physicians specialists consulted in this regard<sup>16</sup>, consider that the problem to assign or train a general practitioner or family doctor in the care of an AIDS patient in a small city, is due primarily to the difficulty that he or she will have in order to be up-to-date in the subject, since the volume of PLWA to be seen in a year, would not permit him/her keep an active knowledge.

### Costs and spending on medical care of the AIDS patient

As a part of a study promoted by CONASIDA and financed by SIDALAC, and with the collaboration of the National Institute of Health Public, the author participated jointly with other researchers in the development of a project to be able to do an estimate ambulatory and hospital health care expenditures of the people with AIDS in Mexico. This study was based on interviews and questionnaires applied to 34 specialized physicians // that were providing ambulatory care to people with AIDS in 5 cities: Mexico DF (including a hospital of the metropolitan area of the State of Mexico), Guadalajara (Jalisco), Monterrey (Nuevo León), Tijuana (Baja California) and Mérida Yucatán). The

<sup>16</sup> Drs. Samuel Ponce De León and Juan Sierra from the National Institute of Nutrition

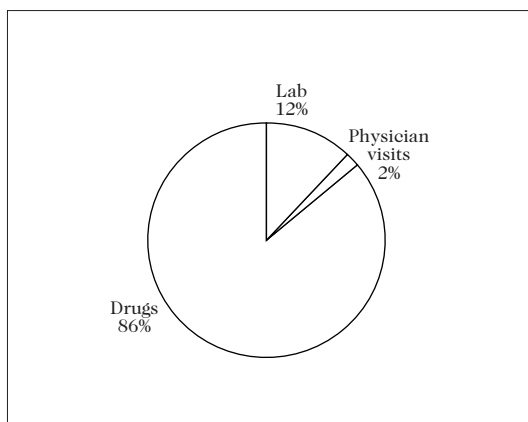
interviewed physicians worked both in public hospitals and clinics (SSA, IMSS, ISSSTE, a University Hospital and a Civil Hospital), and at the private ones. In order to determine the schemes of management of the ambulatory patient, clinical files were not utilized at the suggestion of the interviewees themselves, since they mentioned that clinical records of ambulatory patients are usually not well filled with the information to the level of detail required.

However, for the acquisition of information and data and estimate of spending on hospitalized patient care, there were consulted clinical files that contained the registries and procedures practiced during their days of internment in bed of hospitals of Mexico City, Guadalajara, and Monterrey.

A clarification is needed for this section, due to the fact that the figures, and estimate of costs and expenditures are based on data and procedures that occurred in 1996, (unless there is specified the opposite), when still the protease inhibitors were not being utilized widely and only some physicians dared to prescribe them.

Of the results obtained from the previously described study (1), it was obtained that the average total cost per year by patient for 1996, obtained with the sample of that study was of \$5,265.86 USD, the cost distribution figure is observed in the following graph, and from it can be observed clearly the high impact that ARV prices have in the total cost of ambulatory care.

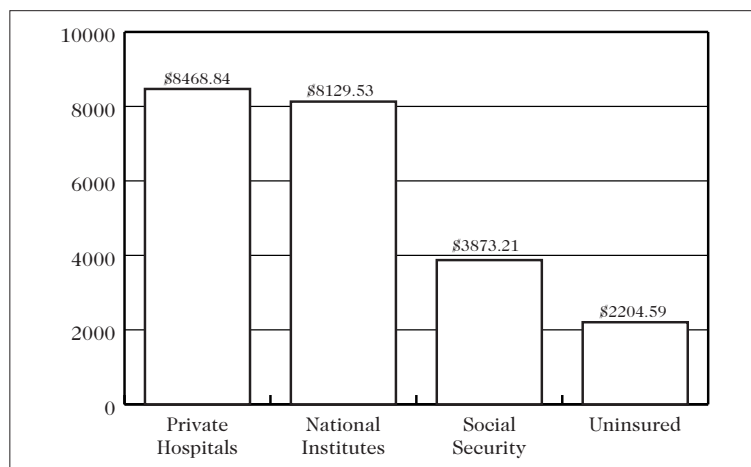
*GRAPH 11*  
*Share of the average cost of ambulatory care of an*  
*AIDS patient in Mexico in 1996*



86% of the drug component amounts \$4,542.01 USD, which in turn remains formed by \$3,222.75 (71%) corresponding to ARV and \$1,319.26 USD (29%) to other drugs commonly utilized in the care of an HIV/AIDS patient.

These figures only reflect the national average, once differentiating the costs of the drugs by type of institution, differences can better be appreciated in the graph 12.

*GRAPH 12*  
Average cost on drugs for ambulatory care per AIDS patient by institution  
(Average cost from the sample was \$4,542.01 USD)



The large difference of the two extremes: private hospitals Vs hospitals for uninsured population, is explained mainly by the purchasing power of the patient, to which, in the first case the physician feels comfortable by prescribing him ARV therapy combinations, including protease inhibitors, since the doctor knows that the patient in some way can pay for them in the retail pharmacy. The otherwise, happens in public hospitals that serve population without social security of very low resources, in which the clinician is clear, that still knowing which would be most effective therapy for the patient, they are in a practical impossibility to prescribe it, since the doctor already knows that the patient or his/her family cannot pay for it.

In the case of the National Institute of Health, included in the study, although it serves people of all the social strata, the management with drugs of the ambulatory patient, still with limited resources, is favored on many occasions by being included in research protocols that provide anti-retrovirals financed with external resources (grants, donations, etcetera).

In case of the Social Security Institutions, the yearly cost of ambulatory care for HIV/AIDS patients, is only a reflex of the use of the drugs officially authorized in their drug catalogs, or the ones that can be purchased directly with hospital funds;

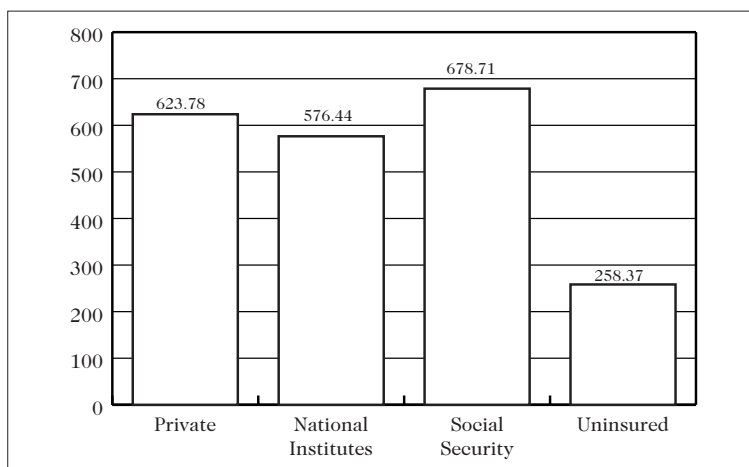
that is, for 1996 we did not find any official purchase of protease inhibitors (PI) by the IMSS or ISSSTE because they were not authorized yet. Therefore, the patients who received PI, were out of pocket expenses at Mexico City retail prices.

At the level of each hospital and physician's offices, included in the study, the extremes found for cost of annual care with ARV in ambulatory patients, were of \$9,407.39 USD in a private hospital of Mexico City, and of \$713.82 USD, in a public hospital for non beneficiaries in the metropolitan area of the same city<sup>17</sup>.

In the case of the laboratory exams, the results of yearly costs by patient, reflect a different panorama, at least with regard to social security refers, as there can be appreciated in the following graphic.

GRAPH 13

*Average annual cost of lab and other studies, per ambulatory patient in USD, 1996. (The average cost from the sample was: \$612 USD)*



As it can be observed, in this case the annual laboratory costs in the hospitals of social security show the fact that, unlike the other schemes (public assistance and private), the charge to the patient is zero in order to cover these studies, and as a result, the indications for these studies do not have economic restrictions or considerations in the part of the doctors. On the other hand, for non insured population, they seemed to be limited in order to favor that the patient has resources sufficient for the purchase of drugs.

<sup>17</sup> The Public Hospital for Non beneficiaries of the Social Security System is located in Ciudad Nezahualcóyotl, in the MA of Mexico City.

It should be pointed out that at the time of acquisition of data of the present project, the study of quantification of viral RNA (Viral Load), was not available in the social security hospitals, although, they were in the private market.

Additional analyses of the information obtained of these same 17 hospitals and physician's offices, makes it possible for us to see that the cost of care of the adult patient \$5,503.68 USD/year, is significantly higher than the care for pediatric patient \$2,550.36 USD/year, and this reflects basically the fact that during that time, physicians were very careful or afraid to use ARV in children.

With regard to the differences of costs between the metropolitan area of Mexico City and the rest of the country, they are shown in the following table.

TABLE 8  
*Annual cost of ambulatory care per AIDS patient in 1996*

Place	Drugs (USD)	Lab and other studies (USD)	Medical visits (USD)	Total (USD)
D.F.	\$4,542.73	\$681.29	\$110.41	\$5,334.43
Inner states	\$4,539.23	\$344.40	\$117.02	\$5,000.65
National	\$4,542.01	\$611.90	\$111.95	\$5,265.86

Exchange rate: 1996. \$1 USD = \$7.3 mx, (from date data was collected)

Actually, the cost of ambulatory care does not produce notable differences among the states and the capital of the country, except the laboratory category and image, which could be reflecting the least availability in province, to certain studies of greater complexity and cost.

### *Costs of Hospital Care*

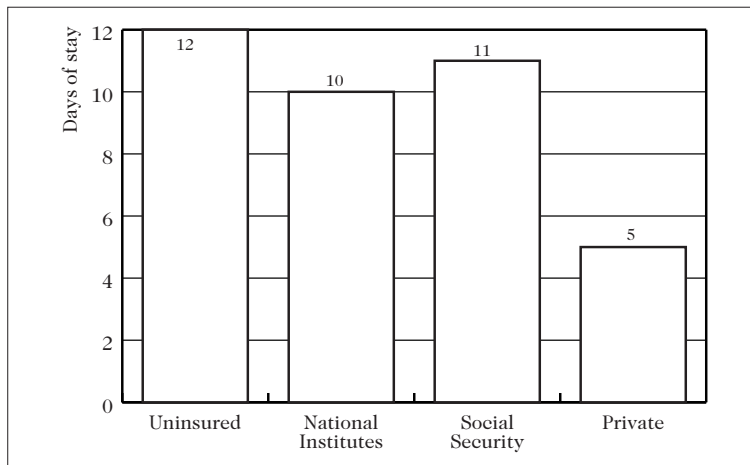
In the case of hospital care, as it was previously explained, the study was carried out through the review and analysis of patient records, that were admitted during the period of September 1995 to September 1996, with a format of capture similar to the one utilized in the ambulatory patient, but with the pertinent adjustments in accordance with the variety of procedures performed.

The collection of information on files was carried out in hospitals of three places: Mexico City and its MA, Guadalajara, and Monterrey. From a total of 12 hospitals, in 11 of them was obtained information from 782 medical records, 12% of them were female, and in one private hospital the data of 10 patients was obtained through their computerized registries.

After the analysis of the 792 patient records, we obtained that average number of hospital days by patient during his/her last hospitalization event was of 11.6 , with a median of 10. A reflex of the distribution by institutions or differences between public and private hospitals are shown in the following graph.

GRAPH 14

*Average length of stay of an AIDS patient at hospital bed (in days) during the last hospitalization event, showed by type of hospital (institution). From September 1995 to September 1996.*



As it can clearly be observed, the most relevant difference is presented between public and private hospitals. Although there could be explanations concerning the kind or quality of medical care received in some hospitals or the others, in our study is not possible to state conclusions regarding quality of care, but, indeed is possible to show that in this case, the difference between private and public hospitals could be basically given in the cost of care (see graph 12).

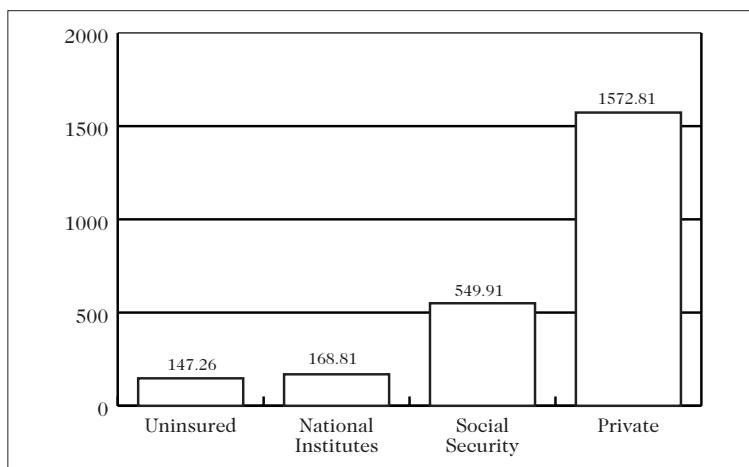
Since in the private hospital, all the expenditures are paid out of pocket of PLWA or their families, by virtue of the fact that in Mexico the private health insurance companies were not covering AIDS medical expenses.

The general average of the cost per day of hospitalization was \$186.71 USD., but as well as in the anterior case, the most notable difference is shown between private and public hospitals. However, in this case it is also significant the difference between social security hospitals and hospitals that serve uninsured population.

With regard to the annual average number of internments (sep.95-sep.96), per each patient studied, this was of 1.3 hospitalization events per patient, with a median and mode of 1.

From the total number of ambulatory patients seen in the study, the percentage of them that were hospitalized was 66% for social security hospitals, 33% for private hospitals and 30% for non beneficiaries hospitals.

*GRAPH 15*  
Average cost per day of hospitalization per AIDS patient, by type of hospital (institution). From September 1995 to September 1996<sup>18</sup>



### Drugs

The most prescribed drugs, during 1996, by the physicians interviewed, for AIDS patients care, in both public and private hospitals and Doctor's office, are the ones used in the outpatient care, which are presented in the following table. The information was gathered through interviews referring to 16 hospitals (was deleted one of the 17 originals for this analysis) and physician's offices, and they refer to the care of 1,697 patients, of which 975 were adults of social security, 172 of non beneficiaries hospitals, 240 of a National Institute of Health, 155 private; and from the children patients, 90 they were from social security and 65 from the other public hospitals.

<sup>18</sup> Exchange rate: \$7.6MX=\$1.00US

TABLE 9  
*Most frequently utilized drugs in Mexico during the care of ambulatory AIDS patients, by clinicians interviewed in 1996.*

	Patients	Percentage
<i>Anti-retrovirals</i>		
AZT	1379	80.80%
ddC	859	50.29%
ddI	396	23.20%
Indinavir	102	5.97%
3TC	100	5.83%
D4T	20	1.17%
Ritonavir	15	0.86%
Saquinavir	5	0.27%
<i>Other drugs</i>		
Bactrim	733	42.96%
Isoniazida	691	40.46%
Ranitidina	348	20.36%
Itraconazol	273	15.97%
Aciclovir	271	15.88%
Fluconazol	266	15.56%
Ganciclovir	54	3.15%

### *Price policies*

In Mexico, where we found as a result of the economic crisis a reduction of the purchasing power, it is important to study the price of drugs, especially when it is estimated that 80% of the drugs are marketed under the protection of commercial brands and at market prices. In our country there are few studies on prices of the drugs, but at different times it has been registered that the price of the essential drugs is high to international levels.

Which is the reasonable price to pay for a drug? This is a matter of a great controversy. The commercial companies collect the possible highest price based on the argument to cover the high research costs, while in case of the patient-consumers the problem is approached otherwise, since they wish to have the access to the drug without barriers of prices. The consumer organizations, some Ministries of Health and international agencies such as WHO, seek for increased access to needed drugs for patients, especially to essential drugs as a part of the strategy of "health for all".

The fair price, and a normal profitability are elements that are presented in a market of competition, but in case of the drugs, the patents, the commercial brand

names, and the differentiation of products are signs of a structure of imperfect market in which, the prices more than market delivered are management set.

The practice of price discrimination is a strategy of market that has been utilized widely in the industry, with a view to increasing the profitability, and this has been present both in drugs with overcome patent and in effect. In the case of the drugs against HIV, this practice seemed to show an imperative search of gains, by part of the industry outside of any consideration of costs. In the case of AIDS, the only relatively effective therapy that we can find are ARV drugs, which means that for the sick people there is not properly a viable alternative, in economic terms it would be said that the demand is inelastic<sup>19</sup> at the price, i.e. if patients do not consume the appropriate drugs they will die.

The problem of pharmaceutical prices in a developing country as Mexico is double. On the one hand, the case of the innovation of products is available such as in case of the new ARV, where the system of patents gives them a right of temporal exploitation in which high prices of oligopoly kind are fixed by the companies.

In addition, in the case of products with overcome patent (essential drugs or products of the basic catalog of the health System) with a well known trademark, they continue to present high prices at the retail level. In the treatment of AIDS this problem is particularly acute, given the quantity and duration of treatments, in which there are combined therapies based on new and old substances, and where the alternatives of drug procurement are very restricted and at very high prices.

### *The new policy of generic drugs*

As a result of the previous and some other considerations, in 1998, the Federal Government, through the SSA published the official norm referring to the interchangeable generic drugs, that is those salts without or overcome patent, that can be sold the public and that are similar to the original product of patent (43).

The SSA was initially approached to a strong campaign in order to promote in the media the compulsory nature from which the physicians should extend the prescriptions writing the generic name of the product and not the brand name, however, in light of the strong reaction against that policy by several big pharmaceutical companies, that were felt affected since they carry out large investments in the promotion of the brand names of their products, there was a negotiation involved, and finally an announcement of an agreement, in the sense of that the physician will have the freedom to write down in the prescription the generic or the commercial name of the product.

The promotion of consumption of generic drugs by the government, has continued in the media, and in fact in several cities there have appeared new chains of pharmacies (retailers) that specialize in selling to the public the interchangeable

<sup>19</sup> Inelastic means that the demand for a drug do not respond to the increases in the price,

drugs (“that are the same but less expensive” prays the slogan). With this measure one of the products that was included as generic was the AZT, of which, the prices that are obtained, especially in the purchases of large volumes are much smaller than with retailers, being achieved prices from \$19.50 USD to \$40.00 USD, according to the volume purchased per each box with 30 capsules of 250 mgs .

By 1998, there was available knowledge that at least 8 pharmaceutical companies were producing or importing & bottling, and marketing AZT: Glaxo-Wellcome (owner of the original patent), PISA, NOVAG, Wayne, Fustery, Protein, Kendrik, Seromo and Wayne

### *ARV approved for their use in Mexico*

Every drug that is going to be utilized in Mexico, requires a special permission (registry) of the SSA, this registry should be requested by the pharmaceutical Company that intends to market it, however, in accordance with the North American Free Trade Agreement (NAFTA), Mexico commits itself to the respect of the patents in a similar way than the United States and Canada.

Currently, except for AZT, the following drugs now available in Mexico City retailers, shown in the table, have right protection from the Mexican government, the table also shows the comparative time since the date of approval by the FDA in the United States and the date of introduction in the Mexican Market (obtained approval from the SSA), as well as the name of the pharmaceutical company that markets it.

*TABLE 10 (44)*

*Drugs approved to for use in Mexico compared with the date authorized by the FDA<sup>20</sup>*

Drugs	Company	Date of FDA approval in the USA	Date approved in Mexico by the SSA
AZT (Retrovir® and some other names)	Glaxo-Wellcome, PISA, Kendrik, NOVAG, Wayne, Fustery, Protein, Kendrik and Seromo	March 87	January 90

continues

<sup>20</sup> Data from this table was obtained by David Alberto Murillo and first published at “SIDA-Hoy” No 26, 1 of January of 1999

Drugs	Company	Date of FDA approval in the USA	Date approved in Mexico by the SSA
ddI (Videx®)	Bristol-Myers-	October 91	November 96
ddC (Hivid®)	Squibb	June 92	August 95
D4T (Zerit®)	Roche	June 94	July 98
3TC (Epivir®)	Bristol-Myers-	November 95	November 96
Saquinavir	Squibb	Dec-95	November 96
(Invirase®)	Glaxo-Wellcome	March 96	May 97
Ritonavir (Norvir®)	Roche	March 96	May 97
Indinavir (Crixivan®)	Abbott	September 97	March 98
AZT-3TC	Merk-Sharp &	June 96	June 98
(Combivir®)	Dome		
Nevirapine	Glaxo-Wellcome	May 1997	September 98
(Viramune®)	Boehringer- Ingelheim-Promeco		
Delavirdine	Pharmacia &		
(Rescriptor®)	Upjohn		

***Price of ARV in retail pharmacies***

The retail price of ARV in private pharmacies private of Mexico City are shown in the following table, those were obtained in the 4<sup>th</sup> of January, 1999 (44)

*TABLE 11*  
*Name, type of container and price of anti-retrovirals available in Mexico City.*  
*January 1999*

Drug	Unit	Retail price in Mexico City pharmacies (USD, January 1999)
AZT (Retrovir®)	Box with 30 capsules of 250 mgs.	\$85.30
AZT+3TC (Combivir®)	Bottle with 60 tablets 300/150 mgs	\$372.35
ddC (Hivid®)	Bottle with 100 tablets .75 mgs	\$209.80
ddI (Videx®)	Bottle with 60 tablets of 100 mgs	\$62.00
D4T (Zerit®)	Bottle with 60 capsules of 40mgs	\$180.00

continues

Drug	Unit	Retail price in Mexico City pharmacies (USD, January 1999)
3TC (Epivir®)	Bottle 60 capsules of 150mgs	\$189.60
lindinavir (Crixivan®)	Bottle 180 capsules of 400mgs	\$372.30
Saquinavir (Invirase®)	Bottle 270 capsules of 200mgs	\$439.40
Ritonavir (Norvir®)	Bottle 240 capsules of 100mgs	Out of the market
Nevirapine (Viramune®)	Bottle with 100 tablets of 200mgs	\$382.50
Delavirdine (Rescriptor®)	Bottle with 360 tablets 100mgs	\$251.50

Exchange rate in 1999. \$1.00 USD = \$10.00 mx

### Accessibility to laboratory studies

In order to succeed in shaping a geographical panorama on the availability of laboratory studies in Mexico, during March, 1997, a survey was carried out to be answered by the local (state level) AIDS program or health authority responsible for programs on STD/AIDS, in each of the 32 states of the country, we obtained responses from 21 of them (65.6% of total states). The results are presented in the following table.

TABLE 12  
*Availability and price of AIDS specific lab test: CD4 and viral load in 21 states of Mexico. March 1997*

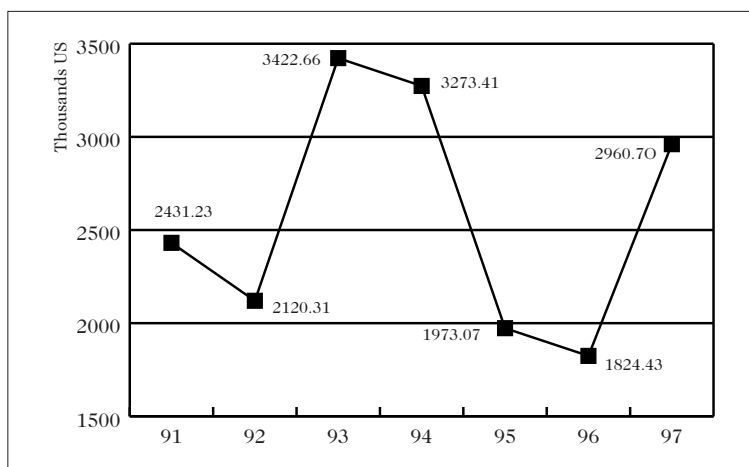
Study	Available in public labs	Available in private labs	National Average Price (USD, March 1997)
CD4 Lymphocytes count	9	8	\$65.13
Viral Load	1	5	\$136.28

States included in this table : Baja California, Baja California Sur, Chiapas, Chihuahua, Distrito Federal, Durango, Hidalgo, Jalisco, State of Mexico, Michoacán, Morelos, Nayarit, Nuevo León, Oaxaca, Querétaro, San Luis Potosí, Tabasco, Tamaulipas, Tlaxcala, Veracruz and Zacatecas.

## The CONASIDA budget

The HIV prevention programs with public resources in Mexico, had been basically carried out through the CONASIDA budget, that is, the resources of the Federal Government allocated specifically to this end are channeled to this national council, and as a result, there has been considered its annual budget as an indicator of the expenditures in HIV/AIDS prevention, this can be better appreciated in the graph.

GRAPH 16  
CONASIDA annual budget from 1991 a 1997, current prices



Exchange rates (45): 1991: \$3.07MX= \$1.00US; 1992: 3.09MX= \$1.00US; 1993: \$3.12MX= \$1.00US; 1994: \$3.37MX= \$1.00US; 1995: \$6.40MX= \$1.00US; 1996: \$7.60 mx= \$1.00US; 1997: \$7.85MX= \$1.00US. Graph source : Registries of authorized budgets for CONASIDA.

However, it should be considered that the budget of CONASIDA, is not the only public resource aimed to prevention, since an important part of the resources utilized to finance mass media campaigns, as well as the impression and reproduction of educational material and pamphlets, are traditionally budgeted inside the Directorate of Social Communication of the SSA, and some other public offices usually spend an unspecified amount in HIV prevention activities.

In addition, a previous study conducted by Saavedra and Izazola with estimates for 1995 (46), considered that the expenditure in prevention of HIV/AIDS in Mexico financed with public resources was of 16.6 millions USD, where also the spending for blood screening for HIV at the national level was also included.

It is possible to observe that the budget of the CONASIDA in current prices, as well as the budget of the Ministry of Health, and in general of the Federal Government, underwent an important decrease in the period 1995-1996, compared with the previous years, however it also is possible to observe that for 1997, it presented a new upsurge.

*TABLE 13*  
*Comparison of Central Government budget, share spent by the health system, SSA and CONASIDA in 1995*

Area	USD Millions in 1995	Percentage share from the immediate upper level
Budget spent by the Central Government	\$46,082.14	–
Budget spent by the Health (public) System	\$7,108.27	15%
Budget spent by the SSA	\$1,203.28	17%
Budget spent by CONASIDA	\$1.97	0.20%

Source: for the Central Government Budget expenditures: : Ministry of Treasury, Information in <http://www.inegi.gob.mx> public finances. For the budgets of the Health System and the SSA: : Boletín de Información Estadística del Sector Salud, in mx pesos of 1995. Budget of CONASIDA in registries of budgets at CONASIDA 1995. Exchange rate for this table: 6.40 mx = \$1.00 USD.

### *Public Spending in Medical Care of HIV/AIDS in 1996.*

In accordance with data obtained from the previous study (1), and from the 17,481 alive AIDS cases during 1996, estimated by CONASIDA, they were 39.8% from social security, 56.7% from non beneficiaries health services (including hospitals of the SSA, National Institutes of Health and other public assistance) and 3.5% that came from private origin, we obtained the following estimates of public spending on AIDS medical care.

The economic impact of HIV/AIDS on the public/institutional sector of Mexico is being given with diverse magnitude at different levels. In the level of the total public spending of the Federal Government (47) and even in the one destined to the Health Sector, it does not represent any major impact that could be considered significant, as there can be appreciated in table 13.

However it should be pointed out that in this table only there is registered the budget performed by CONASIDA, that as was mentioned in the anterior chapter, practically constitutes the only registered contribution of the federal government for preventive programs on HIV/AIDS (excluding blood banks). However, with regard to the medical care spending for HIV/AIDS for 1996, as observed in table 14,

TABLE 14  
*Estimates of total public expenditures on AIDS medical care in 1996. USD<sup>21</sup>*

Sector	Ambulatory care	Hospital care	Total
SSA and other uninsured population medical care providers	\$1,396,105.20	\$3,876,087.60	\$5,272,192.80
Social Security Institutions	\$21,887,348.13	\$25,670,607.17	\$47,557,955.30
Total	\$23,283,453.33	\$29,546,694.77	\$52,830,148.10

the total \$52.8 million USD basically consists on the contributions of the social security with 90% of total public spending on medical care for PLWA.

Of course, it should be mentioned that the estimates of expenditure are based on the costs obtained through this project and these were calculated on the basis of what is being carried out in the reality, and not necessarily reflect optimal or adequate treatments.

### Cost projections to the year 2000

In case each patient with AIDS required ambulatory basic medical treatment in one year (1997), consisting of the combination of three drugs —cocktail— (AZT, 3TC and Indinavir, \$10,197.50 USD), plus a prophylactic (Trimetropin/sulfamethoxazole, \$47.40 USD), plus an annual monitoring consisting of 2 studies of viral load ( \$272.56 US Dlls), plus 3 studies of lymphocytes CD4 cell count ( \$195.40 USD.), plus 4 hemato-logical biometrics ( \$12.23 USD), plus 1 test of liver function ( \$15.28 USD) and 4 specialized medical queries (\$153.85), the amount of this outpatient care in one year at retail prices in Mexico would be of \$10,894.20 USD.

However, as already mentioned, in wholesale purchases of AZT (48) it is possible to save up to 80% from the retail price and 45% if medical visits are granted in public hospitals, obtaining with this a reduction of 25% of the total cost of the scheme (package), remaining the new cost in \$8,180.95 USD.

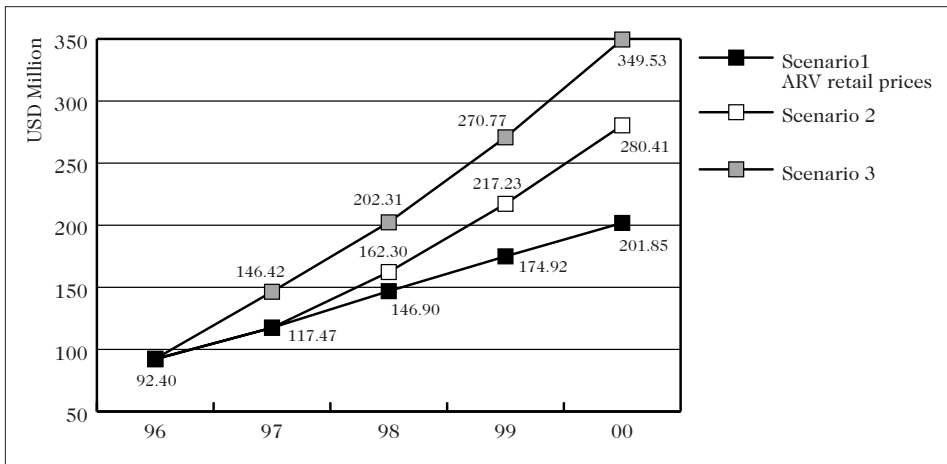
<sup>21</sup> Source : Saavedra et al “Costos y gastos en atención Médica del SIDA en México” op. Cit. Exchange rate for this table was: \$6.40mx=\$1.00USD. From the uninsured care providers the out of pocket expenditures have been taken off and they are considered as private expenditures in another table. In this specific table there are also taken off all savings that government obtains due to purchases of large amounts of drugs, and also the lower cost that represents tests in public labs when compared to private market prices.

In addition, if we take as valid an average of the prognoses from two US stockbrokers, one that estimates that by the year 2000, the protease inhibitors will down to a cost of \$4,000 USD per year, and another one that says that this cost could be in \$2,000 USD (48), if this happens will be due, of course, to a greater competition with other new drugs (50). These price reductions on PI, would take us to an average cost of \$3,000 USD per year.

In the following graphic a projection of ambulatory costs in Mexico is presented, taking as model the previously proposed basic care package, and starting 1997 with costs under three different scenarios: 1) in the first one, with costs of retail pharmacies and private medical visits are utilized; 2) in the second one, a discount is applied for wholesale purchases of AZT and physician visits in public hospitals and 3) A yearly discount rate is applied to the cost of PI in order to obtain an annual cost of \$3,000 USD for PI by the year 2000.

GRAPH 17

*Cost projections from 1996 to 2000, on the basis of essential package of medical services, including ARV and prophylactic drugs, lab tests and physician visits, in three different scenarios<sup>22</sup>*



<sup>22</sup>The first upper line has the following assumptions: 1st. a 5% of price increase and 2nd. that the access to the essential medical package in 1997 will cover 70% of all AIDS patients, 80% in 1998, 90% in 1999 and 99% by year 2000. Another set of assumptions are: 1st That the increase is given purchasing the drugs at retail pharmacies and physician visits to a private doctor. *For Scenario I*, we added: that the package includes discount prices due to large purchases of AZT and physician visits to public hospitals. *For Scenario II*, : we added to scenario A, that the price of Protease inhibitors will fall at a rate of 13% annually.

In the extreme case of projections with market prices from retail pharmacies, the total amount of 350 million USD need for the year 2000, is equivalent to 15% of the \$2,346.7 million dollars (7.85MX pesos=\$1.00USD.) authorized by the Mexican Congress (51) for health programs for non beneficiaries of the social security system in 1997 (Official budgetary branch 0012).

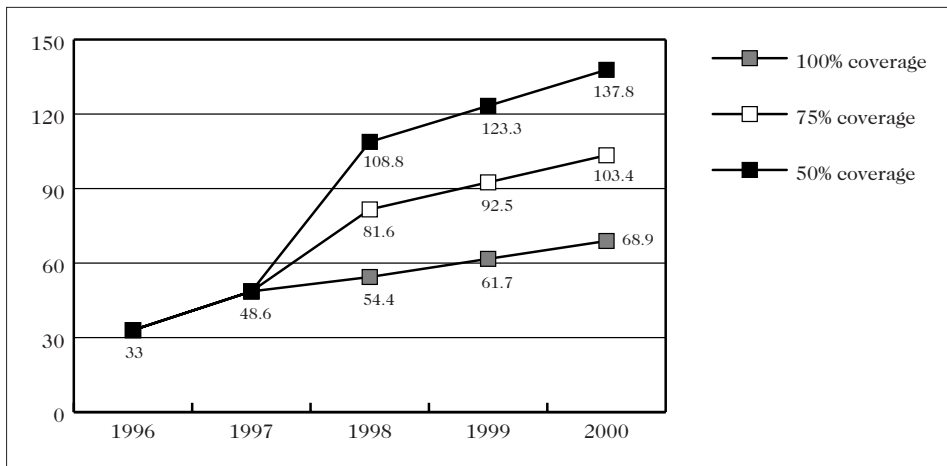
Savings on the total cost of this “Basic Health Care Package for PLWA”, obtained from scenario 1 to scenario 3, in case scenario 3 happens, would be in the order of \$150 million USD.

Finally it is necessary to point out that all of them are optimistic scenarios, with regard to the access to the package on the part of the ones affected, since it assumed reaching 70% of the patients in 1997, and 99% of them by the year 2000.

*Another type of cost projection*

A different cost projection is by only taking into account the prices of ARV can be observed in the three following graphs, showing different percentages of coverage. In this case we are going to called them Scenarios A, B and C.

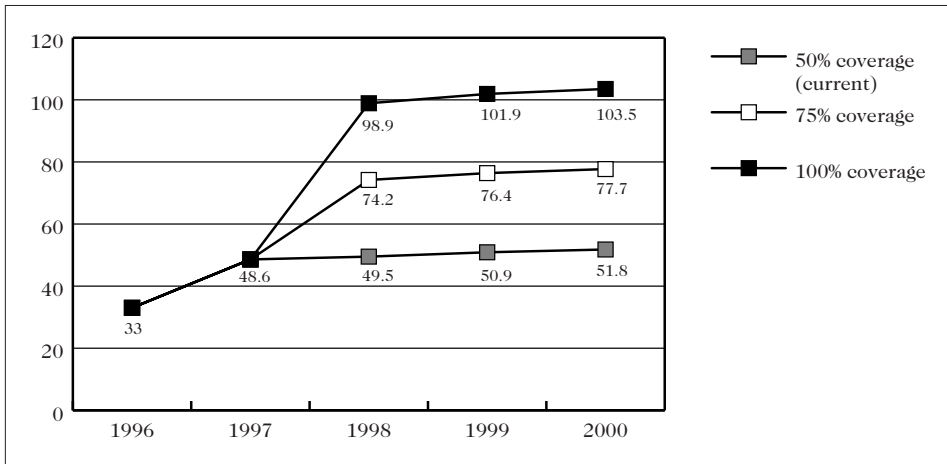
GRAPH 18  
Scenario A: Current prices fixed for the following years



In this case, scenario A, refers to the projection of costs assuming that the prices of the ARV remained constant and estimating to maintain current coverage of 50%, and an alternative 75% or 100%. In this last case the figure necessary for purchase the drugs by the year 2000, would be \$138 million USD, however, this could

be an improbable scenario, if we take into account that indeed, the prices of ARV have begun to diminish specially when acquired in large volumes

GRAPH 19  
Scenario B: Starting 1998 ARV prices fall 10% per year. USD in millions

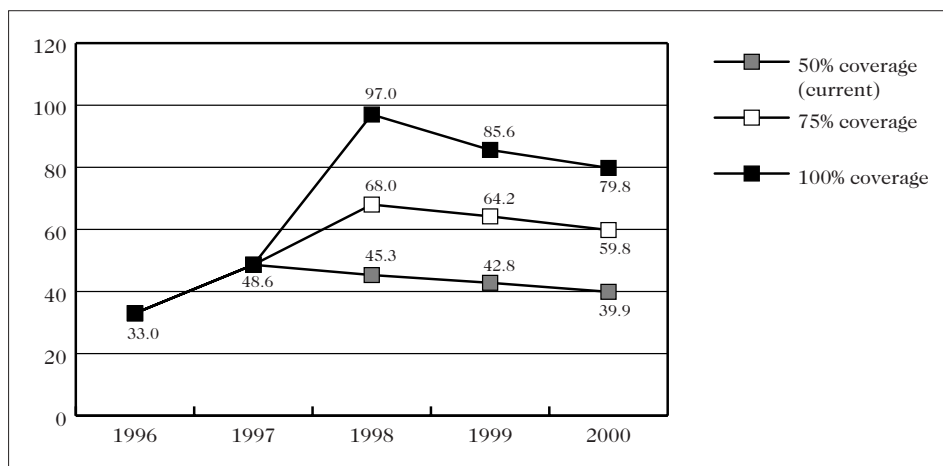


In scenario B, it is assumed that ARV would begin to lower their prices in an annual rate of 10% starting in 1998, the amount required by the year 2000 in order to cover 100% of the people that live with AIDS in that year would be of approximately \$103 million USD, and therefore it would be thought that is an amount that would resemble more the resources requested with this same purpose to the Ministry of Treasury,<sup>23</sup> by the group of people affected by HIV who requested special budget for 50% of PLWA that lack of social security.

<sup>23</sup> The budget proposal presented by PositHIVos to the Chamber of Congress, was also presented to the Ministry of Finance (Secretaría de Hacienda)

GRAPH 20

Scenario III: Starting 1998 ARV prices fall 20% per year. USD in millions



For this third, scenario C, it is assumed a fallen in the prices of ARV by a rate of 20% per year, which would cause that even with the increase of the number of cases of AIDS, by the year 2000 the total amount required for a coverage of 100% , of \$80 million USD, would be less than the amount that had been required in 1998 with the same coverage, this means that the rate of growth of the epidemic in Mexico would not compensate the fall of the prices, and therefore we obtain savings of \$58 million USD between scenario A (without reduction in prices) and scenario C, for that same year.

### Out-of-pocket expenditures

In Mexico, most of the spending on medical care of the patient without social security with HIV/AIDS, comes out-of-pocket of the patient or from his/her family, friends or private donors.

In this study and in accordance with the number of estimated private patients, as well as estimated percentages of expenditures that should carry out those that go to institutions of social welfare (open population), which collect certain fees for service, both at the ambulatory level and in hospitalization, and of course taking into account that they do not provide free drugs, it was possible to shape the following table.

*TABLE 15*  
*Estimates of total private expenditures on AIDS medical care*  
*in Mexico in 1996, in USD*

Section	Ambulatory care	Hospital care	Total
Private hospitals	\$5,709,727.44	\$1,191,167.65	\$6,900,895.09
Out of pocket expenditures with care provided by public hospital institutions	\$25,378,561.47	\$5,168,116.80	\$30,546,678.27
<b>Total</b>	<b>\$31,088,288.91</b>	<b>\$6,359,284.45</b>	<b>\$37,447,573.36</b>

Source: Saavedra et al: "Costos y gastos en atención médica del SIDA en México" CONASIDA, 1998. Exchange rate: \$6.40mx=\$1.00 USD.

From the last table, are represented the estimates of total expenditures taking into account that the number of patients looked after in private hospitals or in private doctors office, was only 3.5% of the total, while in the different schemes of social welfare (SSA, CONASIDA, National Institutes of Health, etcetera) were served 56.7% of them.

In addition to tables 14 and 15, we can release that the total expenditure (public and private) estimated in medical care for HIV/AIDS patients for 1996, was of \$90,277.721. 46 USD. Corresponding 41.5% from private origin and 58.5% public.

From this last amount (\$90.27 million USD), we can conclude that the national weighed average cost of the patient with AIDS in Mexico was \$5,164.33 USD per year, if the 17,481 alive patients with AIDS estimated for 1996 are taken as a basis.

### *Impact on the family economy*

An approximation to the purchasing power in Mexico, is the current minimum wage. The official determination of the current minimum wage at the 1<sup>st</sup> of January, 1997 (52), was established in \$3.37 USD per day<sup>24</sup>. By January 1999, with a USD being bid in 10 Mexican pesos, the minimum wage was established in \$3.44 USD per day (7 US cents more).

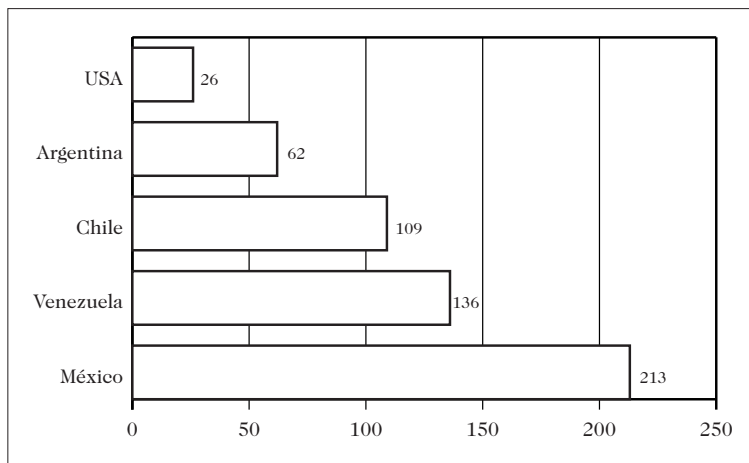
This later means that for a HIV/AIDS patient, to acquire the monthly cocktail of 3 ARV (AZT, 3TC and Indinavir), priced \$732.50 USD in a retail pharmacy in January, 1999, in Mexico, he/she will require to spend 213 days of minimum wage.

<sup>24</sup> The minimum wage is officially established by the government according to economic areas of country, for this study we utilized area A (the highest one) that includes Mexico City, Guadalajara, Monterrey and Tijuana.

However, we can say that the cost lowered in 15.5% with respect to 1997<sup>25</sup>, in terms of days of minimum wage required in order to acquire it.. Some international comparisons with data obtained in 1997, by this same study are presented in the following graph.

GRAPH 21

*Days of minimum salary needed in order to purchase a monthly dose of a triple ARV therapy in selected countries<sup>26</sup> in 1997 and 1999 in the case of Mexico.*



## The response of IMSS<sup>27</sup>

### *Regions and Budget*

The IMSS as already pointed out, is the largest health services provider in the country, covering 39.8% of the general population, this is to its members (workers of private companies) and to its family members or economic dependents who constitute

<sup>25</sup> In the previous study (Saavedra, Magis, et al: Costos y gastos.... *op cit*) it was registered that the price of this same cocktail in Mexico, was priced \$850 USD in 1997, this is a 13.8% price reduction in two years, and a light increase in the minimum daily wage.

<sup>26</sup> The Cocktail includes: AZT+3TC+Indinavir with 1997 prices in the USA was \$953 USD; in Argentina \$925 USD; in Chile \$980 USD and in Venezuela \$680 USD; for Mexico prices for 1999 are \$732.50 USD.

<sup>27</sup> This section refers mostly to the ordinary IMSS and do not to the IMSS-Solidaridad, the later which consist of medical services for rural poor population, does not provide ARV.

the vast majority of its beneficiaries<sup>28</sup>. This Institute has a national structure divided in 7 administrative regions, as it is shown in the table.

TABLE 16  
*Administrative regional division of the IMSS*

	Covers
<i><u>Siglo XXI Region</u></i> <i>based in Mexico City</i>	Mexico City South, Morelos, Querétaro, Guerrero and Chiapas
<i><u>La Raza Region</u></i> <i>based in Mexico City</i>	Mexico City North, Hidalgo and the State of Mexico (Mexico City MA)
<i><u>North Region</u></i> <i>based in Monterrey,</i> <i>Nuevo León</i>	Nuevo León, Coahuila, Chihuahua, Durango, San Luis Potosí, Tamaulipas and Zacatecas
<i><u>Occidental Region</u></i> <i>based in Guadalajara,</i> <i>Jalisco</i>	Jalisco, Aguascalientes, Colima, Guanajuato, Michoacán and Nayarit
<i><u>Northwest Region</u></i> <i>based in Hermosillo,</i> <i>Sonora</i>	Sonora, Sinaloa, Baja California and Baja California Sur
<i><u>South Region</u></i> <i>based in Puebla, Puebla</i>	Puebla, Oaxaca, Tabasco, Tlaxcala and Veracruz
<i><u>Orient Region</u></i> <i>based in Mérida, Yucatán</i>	Yucatán, Campeche and Quintana Roo

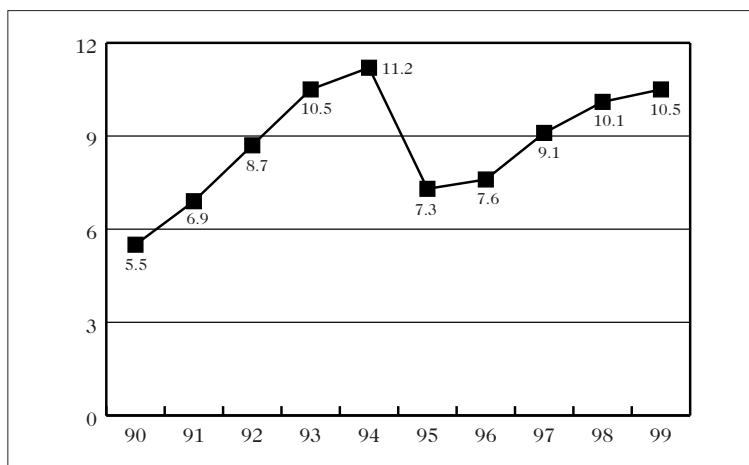
The regionalization of the IMSS is based primarily on geographical criteria and hospital infrastructure, and to a lesser extent in political criteria, as is the fact of including Chiapas in the “Siglo XXI” Region, which is the one with the greatest infrastructure, most advanced technology and largest budget. We can assume that this decision to include Chiapas in this region, although geographically was not justified, was made with the intention of benefiting more this state with the smallest socioeconomic development, and biggest political concern of the country.

The IMSS is not only the greatest institution of health services, but also the one that has the largest budget, in the following graph is shown the budget of op-

<sup>28</sup> According to the Social security General Law, IMSS has some additional ways to include people under its beneficiaries such as the migrant workers scheme, the family social insurance scheme and the facultative insurance scheme (individual or collective), of course all of them have some exclusions and prerequisites regarding previous illnesses that the person may already have.

eration of this institution from 1990 to 1997, measured in USD current prices, doing the annotation that not all its budget is performed in the category of health expenditures (medical Benefits), in this case also includes other services that IMSS also offers (social and economic benefits).

GRAPH 22  
Operation expenditures of the IMSS from 1990 to 1999 in billions.  
Current USD<sup>29, 30</sup>



As it can be observed, as well as the health budget, the fall in the resources was presented drastically from 1994 to 1995, breaking with this the trend the constant growth, and still for 1999 could not retrieve the maximum level (in current USD) reached in 1993 and 1994.

### *Purchases and supply of Drugs in 1997*

The IMSS is also the principal customer for the pharmaceutical industry, thus in 1997 carried out purchases of pharmaceuticals for a total amount of \$2,693,063,679.27 MX pesos (\$343,065,436.85 USD), from 131 different suppliers, many of which are not

<sup>29</sup> Data of this table was gathered from the registries at the IMSS Web page in February, 1999: <http://www.imss.gob.mx> at the "Finanzas Presupuesto de operación de 1997: 3.4.6" section. The figures for 1998 and 1999 were published by the IMSS in major newspapers in March the 3rd, 1999

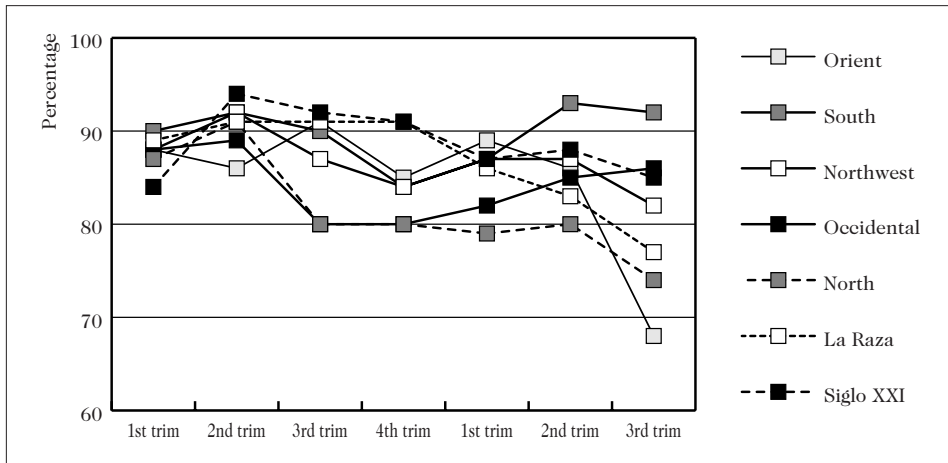
<sup>30</sup> Exchange rates in mx for \$1.00 USD utilized in this table were: 2.65 in 1990, 3.07 in 1991, 3.09 in 1992, 3.12 in 1993, 3.37 in 1994; 6.4 in 1995, 7.6 in 1996, 7.85 in 1997, 8.58 in 1998 and 10 in 1999.

exactly Pharmaceutical Companies, but intermediaries and distributors of the same companies. By law the IMSS is forced to carry out its purchases through public offerings which are open to the different interested suppliers.

Although, these purchases are currently regionalized (7 regions), the institution has a central mechanism of registry and control of supply of drugs, that nevertheless is computerized and publicly conveys the information through its electronic web page, it only shows the procurement levels of each region with 12 to 15 months behind schedule, the last data showed by this institution on the state of supply of drugs in its 7 regions, is presented in the following graph.

GRAPH 23

*Trimester procurement of drugs in each one of the 7 IMSS regions. From the 1<sup>st</sup> trimester of 1996<sup>31</sup> to the 3<sup>rd</sup> trimester of 1997<sup>32</sup>*



In general the levels of supply of drugs are high in all the regions, the average that registers the same source is 80,52% at the conclusion of the third quarter of 1997, however the Northern Region that includes the states of Coahuila, Chihuahua, Durango, Nuevo León, Tamaulipas, San Luis Potosí and Zacatecas registered the greater problems of supply during the period analyzed, but especially during 1997.

<sup>31</sup> For the 3rd and 4th trimester of 1996 the Occidental and North regions did not registered data on procurement of drugs, for that reason we assigned an arbitrary 80% in order to graph.

<sup>32</sup> Data of the percentages of drug procurement were taken from the IMSS Web page <http://www.imss.gob.mx> on the “3.5.2 Abastecimiento, 3.5.2.4 niveles de abastecimiento de medicamentos (porcentaje de claves abastecidas a nivel óptimo)” Section of the. “Dirección Administrativa/Coordinación de Abastecimiento”.

It should be pointed out that, the source does not specify which specific drugs or pharmaceutical products were those more affected during 1997, since in general the trend from 1996 to 1997, was to a greater shortage.

The following section is a textual description of the IMSS “System of Total Supply” that the IMSS is conveying through its electronic page (<http://www.imss.gob.mx>), however it does not specify dates for when this should be operating optimally.

### *Total Supply System*

The supply in the Mexican Social Security Institute represents one of the greater importance tasks in order to provide the beneficiaries, services with quality, efficiency, and opportunity.

For the purpose of bringing down costs and being timely in the supply of consumer goods, within the framework of modernism, the program for supply which is institutional, supported in the activity decentralization has been launched to the regional directions and delegations of the system.

In essence, the new supply system is based on the following aspects:

- To consider the supply comprehensively, that is as a whole system that includes from the determination of the needs up to the user satisfaction, which implies the process of procurement, the supply and the control of consumption. This cycle will be enriched with the information provided by the respective computer system, with greater reliability and opportunity.

- To decentralize faculties and functions in favor of the regions, delegations, and units of service, with a view to approaching the decisions to the points in which there are presented the needs and the problems so that those areas intervene in the determination of needs, the supply, the procurements, and the control of consumption, while the central areas strengthen their technical faculties of supervision, evaluation, standardization, and reference price policies.

- To provide in a continuous way the units, a direct service from the regional regulatory warehouse, avoiding the step by the delegational warehouse, in such a way that at the time in which the existence of a good reaches the permissible minimum, there automatically is proceeded with the provision of the item. To this end the reduction of the warehouse network is foreseen with the consequent saving, upon being deleted 38 warehouses for the supply of goods therapeutic and operating only with 7 regulatory warehouses.

- To operate a data system with management of codes of bars, that integrates the national and regional data with opportunity and reliability.

- To enter into contracts open with minimums and maximums of provision, in such a way that the suppliers supply real needs of consumption and not fixed quantities estimated.

- To cover the missing with support in alternate sources of supply, based on external wholesale suppliers, with prices previously agreed upon through public bidding, in order to fulfill the missing needs of drugs.
- To establish a permanent and special control for the 100 priority keys, in consumption and in cost.
- To set a strict control of the maximum and minimum levels of inventory, in accordance with the new frequency of supply.
- To establish the program of reasonable prescription for control of consumption, in accordance with the institutional basic catalog of drugs and with support in the already referred information system.
- To delimit the areas of national responsibility, regional, delegational, and by unit, in all the stages of the supply.

It is in process the bidding for the procurement, adaptation, installation, conversion of files, training, and setting in operation of a system of integrated computation for the institutional supply.

The system encompasses the attention to 639 medical units, same that amount to 93% of domestic consumption, as well as to the 36 delegational warehouses, 7 regulatory warehouses and one central warehouse, which represent 100% of the distribution units.

On the other hand, it should be pointed out that the system is linked with the normative and governing areas linked to the supply cycle.

Through this system there will be available the elements of control necessary in order to provide support for the operation at all levels, as well as the information necessary for the decision-making.

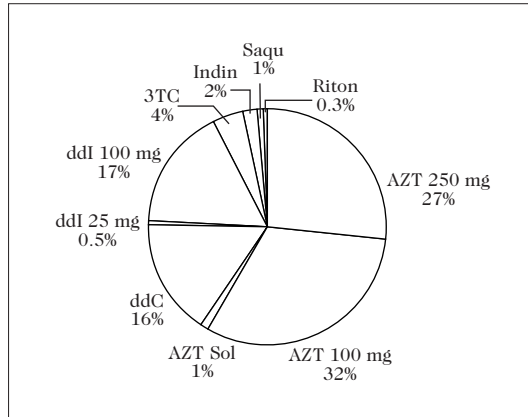
### *Purchases and Biddings of ARV*

The IMSS is also the largest buyer of ARV in the country, in 1997 it purchased a total amount of \$45,037,111 MX pesos (\$5,737,211.59 USD)<sup>33</sup> on ARV, that is 1.67% of the total pharmaceutical products purchased that year.

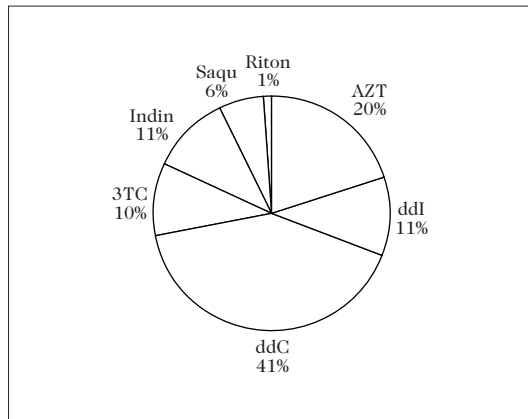
These acquisitions of ARV in 1997, had the distribution that is shown in the following graphs, in which the first shows the distribution by the number of units acquired, and the second presents the distribution of the total amount purchased in USD.

<sup>33</sup> Data provided by the marketing department of one of the IMSS supplier companies.

GRAPH 24  
 Share of the 70,226 ARV units purchased by IMSS in 1997



GRAPH 25  
 Share of the \$5,37,211.59 USD in ARV paid by IMSS in 1997

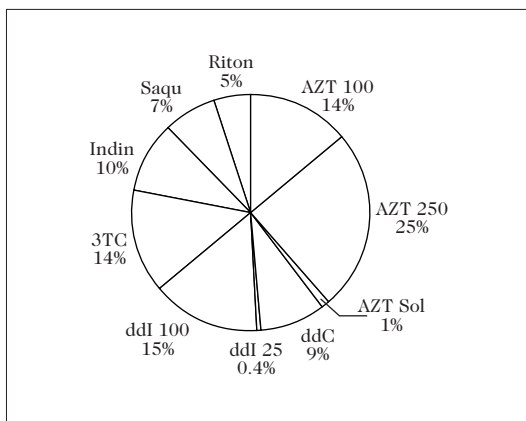


As there previously was explained, AZT is produced or imported and marketed in Mexico by more than one pharmaceutical company.

For 1998, the number of units<sup>34</sup> bid for purchase by the IMSS reached the figure of 230,952, that is an increase of 229% with regard to the previous year, the distribution for 1998 is shown in the following graph, where it is possible to note the percentage reduction of the number of units of AZT with regard to the previous year, however, this is only a reflection due to the increase on the number of units of the other ARV purchased, pointing out notably 3TC, that goes from 4% to 14%, and also the set of PI (Indinavir, Saquinavir and Ritonavir) that from being in less than the 4% jumped to 21%.

Transforming the number of units of these last drugs in annual habitual dosages, we could estimate that at least 5,076 patients received PI during 1998, 53% would receive Indinavir, 28% Saquinavir and the remaining 19% Ritonavir, however, this last product due to manufacturing problems in capsule presentation was removed from the market during that same year<sup>35</sup>.

*GRAPH 26*  
*Distribution of the number of ARV units published in the official list of public purchases by the IMSS in 1998*



<sup>34</sup>The word “units” refers to boxes or bottles containing the following amounts: AZT 250mgs box with 30 capsules; AZT 100mgs box with 100 capsules; AZT Sol bottle with 1gr in 200mls; ddI 100mgs bottle with 60 tablets; ddI 25 mgs bottle with 60 tablets; ddC .75mgs bottle with 100 tablets; Indinavir 400mgs bottle with 180 capsules; Ritonavir 100mgs bottle with 240 capsules; Saquinavir 200mgs bottle with 270 capsules; 3TC 150mgs bottle with 60 capsules. There were no units of any other ARVs purchased.

<sup>35</sup>In an Abbott laboratories Press release, the company notified that they were changing the presentation of their product Ritonavir, from capsules to liquid formula

The biddings of the IMSS during 1998, were done in regionalized way, in the following table there is a comparison of the estimated percentage of AIDS cases that every region of the IMSS has and the percentage of units of ARV that each one of them bid.

Although, it was not possible to obtain an exact number of patients that are alive and actively seen by the IMSS, if we assume that the regional representation is correct and that the amounts of the biddings were consonant with the number of people with HIV/AIDS that require ARV, from the table we could obtain that some regions would be bidding for less than what their needs indicate, and as a result having a shortage problems in ARV; this would be seen more patent in the South Region (Puebla, Oaxaca, Tabasco, Tlaxcala and Veracruz) as well as in the North (Nuevo León, Tamaulipas, Coahuila, Chihuahua, Durango, San Luis Potosí and Zacatecas). On the other hand, the regions that apparently would have a better supply of ARV would be those of Siglo XXI (South DF, Morelos, Guerrero, Querétaro and Chiapas) as well as the Orient (Yucatán, Quintana Roo and Campeche).

There should be clarified however, that it is also possible to note from the table, that there probably different patterns for the prescription of PI, between each region, since it seems that in the South Region the use of Ritonavir is given special importance, in the Orient it is preferred Indinavir, and in the Northwest (Sonora, Sinaloa, Baja California and Baja California Sur) exists more demand on Saquinavir.

In interview one of the specialists of the Occidental Region<sup>36</sup>, he points out that the volume of patients makes the difference in the probability for a hospital to undergo in a shortage of some specific ARV, since when the physician has, for some clinical cause, to change the ARV prescription, whether the number of patients is very low, the probability that the new drug is not available in the hospital warehouse or pharmacy increases.

<sup>36</sup> Dr. José Manuel Ramírez from Jalisco made that point

*Table 17 (53)*  
*Percentage of PLWA with access to IMSS covered by each region*  
*and share of the total ARV purchases in 1998<sup>37</sup> (54)*

Region	Siglo XXI	La Raza	North	Occidental	Northwest	South	Orient	Total
AIDS cases	24.1%	24.5%	8.9%	18.2%	7%	14.3%	3%	100%
AZT 100 Mgs	33.8%	36.2%	1.7%	15.7%	3.6%	8.9%	0%	31,413
AZT 250 Mgs	48.9%	13.3%	5.6%	14.8%	7.2%	4%	6.1%	60,378
AZT Sol.	4%	22.4%	3.7%	52.2%	0.7%	6.4%	10.5%	1,386
ddC	30%	16%	4.7%	30%	6.5%	10.8%	2.1%	19,832
ddI 100 mgs	35.2%	18.7%	3.7%	30.4%	3.6%	5.8%	2.7%	33,528
ddI 25 Mgs	0%	16%	4.3%	45.8%	16.9%	12.8%	4.2%	908
3TC	21.8%	30.1%	1.4%	19.5%	7.5%	13.8%	6%	32,545
Indinavir	20.9%	30%	1.8%	25.4	0%	9.8%	12%	22,596
Saquinavir	21%	30%	2.1%	20.8%	8%	6.8%	11.2%	16,978
Ritonavir	27.6%	28%	2.8%	23.2%	2.7%	15.7%	0%	11,387
Total units	33.1%	23.5%	3.3%	21.4%	5.4%	8.3%	5.1%	230,952

In addition, the differences of supply by type of ARV between every region, also could give us signs of the lack of a guide or standard treatment protocol, that although, already exists one published by CONASIDA and endorsed by the IMSS, in interviews with several physicians<sup>38</sup> have pointed out that sometimes this guide is not followed since it requires updating.

These differences in the demand or drug prescriptions, could also speak of a need for a greater training to the physicians responsible for prescribing ARV in these regions.

### From protests to proposals

After the International Conference on AIDS in Vancouver, Canada where there was given great publicity in the media on the results of the new therapeutic combinations including the protease inhibitors, motivated that seropositive people began to con-

<sup>37</sup> To estimate coverage by region the cumulated AIDS cases to December 31, 1998 provided by CONASIDA on a State by State level were used in the case of Mexico City (DF) the estimation was 60% for the Siglo XXI Region and 40% for "La Raza" Region. Taking into account a 1997 data base that shows the AIDS numbers by "Delegacion" (Neighborhood) and assigned the ones located in the North and South of the City. Taken from the Registro Nacional de casos de SAIDA SSA-CONASIDA.

<sup>38</sup> This comment was expressed by Dr. Renán Góngora from Yucatán.

cern about the access to these new drugs, and thus being known with some others through NGOs and in hospitals, decided to be grouped into an organization called Front National of People Affected by HIV (FRENPAVIH) (55). Advised by a small group of professionals lawyers and journalists, convened a press conference in order to announce the formation of the group in October, 1996; establishing as its principal objective that of the mobilization for the purpose of demanding access to the drugs ARV.

In February 1997, a group of people of the same front that participated in the humanitarian protocol of CONASIDA interposed a legal demand against the Ministry of Health and CONASIDA, because of the suspension of ARV supply to the patients involved in humanitarian protocols, and as a result to have violated the 4th constitutional article, referent to the right to health<sup>39</sup>.

The judge issued two orders to restart the supply of drugs in favor of the patients; however, the SSA and CONASIDA appealed that resolution and requested a constitutional protection, which at the end favored the health institutions, pointing out that the constitution was not violated. Nevertheless, as it was already mentioned that CONASIDA continued with the provision of ARV to the so-called “protocolary-patients”, but without expanding its treatment protocol to new PLWA.

In April 1997, the FRENPAVIH already with greater power of convocation, and taking advantage of the realization of a National Congress of Infectious Diseases, as well as the presence in the Congress of two high authorities of the health system (the Director General of the IMSS and the Health Minister), organized a rally just outside of the headquarters of the congress ( IMSS Siglo XXI Auditorium), in which they included the blockage of two large avenues of Mexico City. Within the characteristics of this rally was that the affected used white hoods, in order to cover their faces, achieving with this a greater impact on the media. Their demands were access to ARV drugs and quality of care for all PLWA, as well as regularization of the supply of ARV that already were provided by the IMSS (AZT, ddc and ddi) and to include PI.

The coverage of the mass media and the press of this event, was broad<sup>40</sup> and the political pressure raised declarations of the authorities of the IMSS in the sense of regularizing the supply of ARV as well as the inclusion in the short term of the PI (56). They even signed an agreement with FRENPAVIH in order to do that. On the other hand, The Health Minister (head of the SSA) only committed himself to looking for an alternative financing mechanism that could respond to these demands.

With this mobilization and media coverage, the FRENPAVIH achieved broad support from people affected by the virus in province, in such a way that for September 1997, they were performing mobilizations in Aguascalientes, Jalisco, and Nuevo León, and had sympathizers in 25 of the 32 states.

<sup>39</sup> The 4th Article in the constitution establishes the “right to the protection of health”, however it is not clear what this right covers.

<sup>40</sup> The news media in the 17<sup>th</sup> of April, 1997, newspapers such as Reforma and La Jornada, as well as the rest of the Mexico City newspapers and most of the ones in the States, provided wide coverage to this rally. The same way it was covered by the radio and the two main TV Networks.

The FRENPAVIH attempted to be structured at the national level similarly to the administrative division of the IMSS (by coincidental regions). In October 1997 they reached a political agreement with the SSA, with the purpose of receiving financial support for the purpose of carrying out state and regional meetings with the objective of being structured as a National Commission of Citizens with HIV, that will have national representation and to be the only speakers on behalf of PLWA with the health authorities. This commission remained finally integrated in November 1998, although they do not remain very clear about the functions and activities that will develop in the future, they have not organized rallies anymore but their new goal is not clear.

In tandem the leader of this group, received advise to present budgets proposals for public funds for ARV, to the Chamber of Representatives, which made as member of the FRENPAVIH in December 1997, before the President of the Health Commission of the Chamber of Representatives, and subsequently in March 1998 in the International forum "HIV-AIDS: Social Challenge and Legislative Challenge" organized by the Congress, which was motivated by this budget proposal, and because of the interest in the subject of AIDS on the part of some lawmakers.

In the mean time there was another budget proposal from an NGO from Yucatán, who took the figures from the previously mentioned study and added the request that the IMSS health infrastructure be used for the new ARV policy, forcing the IMSS to provide care to non beneficiaries living with HIV<sup>41</sup>.

Driven by the technical and budget proposals for access to ARV, and after being forced to leave the national leadership of FRENPAVIH, by a so-called National Coordination Committee of the same group, the former leader organized the group PositHIVos, also conformed by people affected by HIV.

PositHIVos, has the objective of developing proposals for politicians and decision makers, and to produce information for the press, as well as support activities for PLWA with low resources<sup>42</sup>. Thus, this new group, in November, 1998, presented a new budget proposal to the Ministry of the Treasury and to the Chamber of Representatives, achieving with this, once again, although by a different way, a broad coverage by the press media to this issue.

For this new proposal, and because of the appearance of an unfolded of press, was also obtained the support and signature from other AIDS NGOs and from people affected by HIV/AIDS<sup>43</sup>. This new draft budget was also presented on 14 February 1999, during the seminar "DF/AIDS: Mexico City, Capital of the Prevention" organized by the Supplement "Letra S" of the newspaper "La Jornada", and the pre-

<sup>41</sup> This proposal from Yucatan was submitted to the Presidency of Mexico by mail by Carlos Mendez of Oasis de San Juan de Dios and also a member of FRENPAVIH in Yucatan.

<sup>42</sup> This information was provided by Jorge Huerdo, Coordinator of PositHIVos and former Coordinator of FRENPAVIH.

<sup>43</sup> This press paid insertion was signed by the following organizations: PositHIVos, Mexican Network of People affected by HIV, Amigos contra el SIDA, Abrazo from Monterrey, Ave de México, AMSAVIH and Amigos Previniendo el SIDA from Guadalajara.

sentation was accompanied by support mobilization through signs and placards as well as of people with the face covered with white hood.

### *The new Proposal*

The new proposal of budget for ARV (57), delivered to the Ministry of the Treasury, and to the Congress (Chamber of Representatives) is based on the estimate that in 1999, 26,800 people with HIV/AIDS will be alive will require ARV, and takes into account that 48.7% of them will lack of social security.

The total amount of this proposal is \$73.4 million USD (\$10 MX pesos = \$1.00 USD) and it includes \$65.97 million USD for the purchase of ARV, with schemes of triple therapies for 60%, and double for 40% remaining. It also includes \$3.3 million USD in order to improve and ensure the access to laboratory, CD4 cell counts and viral load, as well as \$1.3 million USD in order to train physicians and assure quality in the attention and \$2 million USD in order to ensure the supply of drugs against opportunistic infections and prophylactic medication.

The amounts estimated, include discounts by wholesales and proposes that the amount is covered tripartitely by the federal government, the state government, and 5% of direct payment by the user once he/she receives the drug in hand.

Taking into account the unequal socioeconomic development of various states of the republic, the proposal considers that those of greater development, such as the Federal District, Baja California, and Nuevo León contribute up to 25% of the total amount required in its entity, 70% from the federal government, and 5% by patients. On the other hand, states of smaller development as Chiapas and Oaxaca will not contribute with their funds and it will be covered in 95% by the federal government and 5% by the affected people.

### **The Role of the Press**

Although, in general the media gives abundant coverage to the subject of AIDS in Mexico, it is specially the press (newspapers and journals) the one that handles more information in this regard. Practically all the diaries of the country have covered at some time the subject, although in this section we only will be referred to three of the most influential diaries of national circulation, the ones which in addition have broad prestige and credibility among the different actors involved in the struggle against AIDS in our country, as well as in the political means and with high decisionmakers.

These three diaries have been characterized since their appearance and during the years after, as pioneering means in the exercise of the freedom of the press in Mexico, and that they are handled with broad independence with regard to governmental official positions, they are: "La Jornada" and "Reforma" in Mexico City, and "El Norte" of Monterrey, Nuevo León.

*“El Norte” and “Reforma”*<sup>44</sup>

Both diaries are of the same journalistic company, in fact the second arose as a result of the success of the first one in the north of the country. Concerning political positions they enjoy great credibility upon allowing room on its pages to positions in favor and against the different areas or subjects of national life. The two newspapers have given great coverage to the subject of AIDS during the last two years, “El Norte” with 579 notes or articles that versified or referred to the subject in 1997 and 447 in 1998; in case of “Reforma” the references were even more abundant with 626 findings in 1997 and 535 in 1998.

Although they have, for obvious reasons, similarity in many notes since they share the same informative channels and news agencies both national and international, they also show differences in terms to the style and form the way they handle information on AIDS, mainly in the local articles produced by their own reporters or writers.

It is noted a more conservative tone in “El Norte”, with greater spaces than its counterpart from the DF, devoted to positions of individuals, church, and organizations that are manifested against measures such as sex education, the promotion of the use of the condom; and in addition the newspaper based on Monterrey still tends to utilize little sensitive terms as the word “Sidoso”, that in Mexico have been considered pejorative by the people who are involved in the struggle against AIDS, or that live affected by the disease. Despite the foregoing, the balance that is perceived is that the result still is positive in favor of actions of fight against AIDS recommended by international organizations and agencies.

Of the total notes and articles published by both diaries, the references to the subject of ARV range between 10% and 14% of the total of the total AIDS notes, with a light increase in the case of “Reforma” (from 10% in 1997, to 13% in 1998) and a light decline in case of “El Norte” (from 14% in 1997, to 11% in 1998). In the following graphic the monthly patterns of the notes can be observed during the two years analyzed.

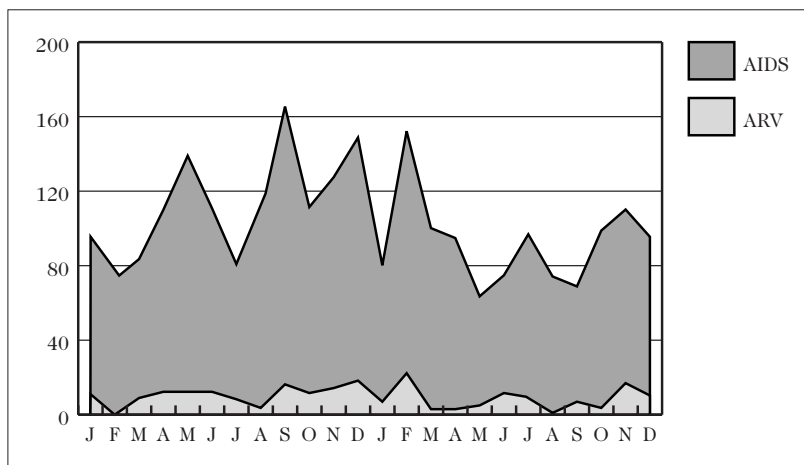
As it can be observed in the graphic 27, there are some peaks of information related to AIDS, in 1997 these were caused directly or influenced, in April-May 1997, by a National Congress of Infectious Diseases and a manifestation of people affected by HIV; in August-September 1997, by the death of Princess Diana, where the notes associated her with her activities in favor of the struggle against AIDS; in November 1997, by a National Congress of AIDS; and in December 1997, because of the international day of fight against AIDS.

During the following year, 1998, the peak of February, was related to the journalistic debate between the president of the Mexican Red Cross and CONASIDA

<sup>44</sup> For the analysis of news articles and notes referred to HIV/AIDS and ARV in both journals, it was through the subscriptions search service they have at their web page : <http://www.reforma.infosel.com.mx>.

GRAPH 27

Total monthly number of articles or references to HIV/AIDS published by "El Norte" and "Reforma" newspapers from January, 1997 to December, 1998



due to the promotional campaigns of the condom; in July, the association was the International Congress of AIDS in Geneva, and again in November-December, the world day of struggle against AIDS.

In case of the articles on ARV, although the greatest number of references to the subject influenced it during three months (April-June of the 97) was the rally of people affected by HIV, and in September of the same year, the death of the Princess Diana; in December 1997 there was a greater number of references that were associated daily world of struggle against AIDS and also related to a national press debate on the subject of ARV, between specialists and the president of the National Academy of Bioethics, being this last who was manifested against giving these treatments with public funds. During December there also was a reference upsurge due to the creation of the FONSIDA.

In 1998, in February, ARV were associated with the Red Cross-CONASIDA debate and with the resignation of a staff member of this last institution and with again with the subject of FONSIDA. Although these topics increased the number of articles and notes on ARV, in June 1998, it was the International Congress of Geneva the one which increased the percentage (21%) of citations to the ARV compared with the subject of AIDS in general; finally a proposal of special budgetary allotment for ARV drugs, presented by people affected by HIV in November 1998, caused the second largest percentage of references to ARV (20%) with regard to AIDS.

### *“La Jornada” and the Supplement “Letra S”*

The newspaper “La Jornada”, since the appearance of its first number, has been the newspaper of excellence for the Mexican left, with great penetration and sale in broad sectors of Mexico City and in the national level, it is perhaps the most influential newspaper between members, politicians or with sympathy for the PRD, and for many members of the PRI regarded as leftist. It is also the newspaper of choice for a large number of people in Mexico when they want to know about subjects such as Chiapas, social demands and positions of the PRD.

In 1995, a group of media professionals, science, humanities, and arts as well as with experience in activism of human and gay rights (58), created the Supplement “Letra S” within the newspaper “El Nacional”, this supplement subsequently came to be part of “La Jornada”, becoming thus, this last newspaper in the only one in Mexico, that has a broad and deep coverage concerning AIDS in a monthly supplement (first Thursday of every month) and it is devoted exclusively to the subject of “Health, Sexuality and AIDS.” Although the supplement already existed, it is not but up to its incorporation in “La Jornada” at the end of 1996 when it begins to be known by a much broader public<sup>45</sup>.

The Supplement has a very well defined position concerning AIDS, since its collaborators and writers are experts in the subject, they assist all the national congresses and still large number of the international ones that are carried out every year; within its Technical Council its conformed among others, by a person who it has conveyed publicly its state of seropositivity, and its Publishing Board is made up by recognized intellectual and specialists in HIV/AIDS and sexuality.

Perhaps that because of this same specialization and knowledge of the subject, it is that its journalistic position goes very consonant with the international recommendations on the matter<sup>46</sup>.

With regard to anti-retrovirals, and the access to them, their multiple articles that appear monthly support and promote the fact that the Mexican government should provide with public funds these drugs to all those which require them.

The budgetary basis of the recent proposal for special budget for the purchase of ARV, presented by a group of people affected by HIV before the Ministry of the Treasury and the Congress, first appeared published on the pages of “Letra S” (57) and subsequently as the center news of the full back cover<sup>47</sup>.

“Letra S” has become a source of monthly query for staff members and specialized decisionmakers or related to AIDS and sexuality, as well as for professionals and people involved actively in this field.

<sup>45</sup> Information provided by Alejandro Brito, Director of “Letra S”

<sup>46</sup> This conclusion is derived from interviews with Alejandro Brito, Arturo Díaz (Director and Coordinator of “Letra S”) as well as with Carlos Bonfil, Manuel Figueroa, Jorge Huerdo and Manuel Zozaya, all of the members of the Technical Council of the Supplement.

<sup>47</sup> Published in Letra S, the 3rd of December, 1998

### *The FONSIDA Case*

As a response to needs for providing with ARV to the people affected by HIV/AIDS that lack social security, and that because of their socioeconomic condition are not in possibilities of acquiring them, and in light of the scientific evidence that these drugs prolong and improve the quality of life of those who require them, the SSA through its head the Health Minister, offered to a group of people with HIV, and representatives of NGOs, in February 1997, seeking an alternative to be able to solve this problem.

Upon being known of this need, some staff members, and professionals of the Autonomous National University of Mexico (UNAM), proposed a scheme for the creation of a trust and mechanism that succeeded in attracting private and public funds for the purpose of being able to finance the provision of these ARV. Although, the proposal and original draft considered absorbing the cost of the drugs over a period of 2 to 3 years and subsequently to cover the costs of funeral; after a technical review by CONASIDA, it was decided to delete the category of funeral expenditures and to propose that it should try to cover the costs of drugs while the affected person lived.

In order to continue with the design of this mechanism, there was created a committee that incorporated not only people from the SSA, CONASIDA, and UNAM but also invited to a representative of the NGOs and to another one of the people affected by HIV. During the first meetings, it was reached the conclusion that there was a need to of an expert concerning trusts, and therefore, the SSA contracted a consulting company so that they will develop the full project proposal before being launching it, and that it will be supervised by the committee.

The proposed mechanism remained formed by a civil association, made up by the members of the committee that would operate a trust, which with the interests generated in the capital that succeeded in obtaining, from both public and private donations it could finance the purchase of ARV for those people with HIV that required it, and that previously were evaluated by CONASIDA.

Although in March 1997, in the official section of the Bulletin of "CONASIDA" published within the Supplement "Letra S" of the newspaper "La Jornada" (59), this institution reported that this trust would initially cover 5 thousand people (men, women and children) and that in the following years would increase 2,500 people more. It was until November of that same year, that it was known the amount with which would initiate its operations and which consisted in a contribution of the federal government by \$30 million pesos (\$3.75 million USD). This amount forced to reconsider its goals, of short and medium run, so during the announcement of its creation, the 1st of December, 1997, it was needed to specify that it would only cover children with AIDS.

The decision for children was based on the criterion to provide benefits for 100% of a specific population, without discriminating by other criteria<sup>48</sup>, since the resource contributed only made it possible to estimate that coverage.

<sup>48</sup> These selection criteria was expressed by Dr. Antonio Caso (UNAM), who was the person who originally proposed the creation of FONSIDA

Although artistic and cultural activities of collection of funds were carried out throughout 1998, on behalf of the children with AIDS.

In 1998, it was also announced that FONSIDA would also cover the seropositive pregnant women. As a consequence of covering Women and children first, FONSIDA started to be called “The Titanic Syndrome Found”<sup>49</sup>.

but was not until November 1998, when it was announced another important grant, one by Bristol-Myers-Squibb, consisting of \$50 million pesos (\$5 million USD), where it included contributions in kind on the basis of the drugs that the company produces (ddI and D4T), as well as some funds for training of physicians in the management of ARV. On the 1<sup>st</sup> of December 1998, there was announced another contribution from federal government by \$30 more million pesos (now \$3 million USD because of adjustment in the exchange rate).

In accordance with data published by Avila (60), by February 1999, FONSIDA had a coverage of 175 boys and girls, from a total of 192 that would be living with AIDS and lack of social security; that same source points out that in Mexico, the total of cases of children with AIDS (1,002), represented 2.6% of the total of cumulative cases of AIDS to the 1<sup>st</sup> of January 1999.

### The Michoacán Case

As a part of the policy of decentralization of the SSA, previously commented, the CONASIDA has also promoted that each of the 32 states establish their own programs for prevention and control of HIV/AIDS, some of them integrated as State Councils (COESIDAS).

CONASIDA in its document: “Program for strengthening of the prevention and control of HIV/AIDS and other sexually transmitted diseases 1997-2000”, although, it promotes actively the decentralization of the programs of HIV/AIDS and emphasizes the compulsory nature and involvement to the prevention; concerning medical care emphasizes the distribution of the Mexican official norm, of the guide of medical care, and the goal to establish three laboratories (regional) in the country in order to carry out tests of viral load.

This document also promotes the development of research protocols with new drugs for the treatment of HIV infection and includes promoting and coordinating actions in order to increase and accelerate the accessibility to the medical treatment of HIV/AIDS (26).

However, the document does not establish that the state governments have the compulsory nature to provide treatment with ARV, but neither limits it, actually leaves to the decision of every state the decision to provide them with state funds.

<sup>49</sup> Comment expressed by Dr. Alejandro Cravioto, President of FONSIDA.

Taking into account the foregoing, the Health Secretary of the State of Michoacán (in the center-west part of the country) with the approval of the Governor, requested COESIDA, the preparation of a situation diagnosis, and a follow-up of the recorded cases of AIDS. After that, they established the goal to initiate in 1997, with 50 patients which previously should be assessed in the General Hospital of the SSA of Michoacán, by an infectologist, and subsequently to go with his/her prescription to the COESIDA for a free supply of ARV, which are given after COESIDA performs a socioeconomic study, by a social worker who among other things verifies that the person is living in the state of Michoacán and that lacks of social security, then he/she is authorized to receive ARV, that includes AZT, 3TC, ddI and D4T, but do not include any protease inhibitors.

The government of the state established an agreement with a private laboratory for the purpose of guaranteeing that the patients have access, every 6 months, to the studies of CD4 cell count and viral load. The state government also provides, if necessary, two prophylactics: Bactrim<sup>a</sup> and aciclovir free of charge.

85% of the patients who are benefiting from this policy in Michoacán come from the metropolitan area of the city capital Morelia, strengthening with this the data of which AIDS epidemic in Mexico is mostly urban, even in Michoacán that is characterized by a high number of rural migrants to the United States.

By January 1999, the Michoacán COESIDA had 109 cases under ARV therapy<sup>50</sup>, the Coordinator of the COESIDA points out that the purchases of ARV carries them out the SSA every 6 months, and that they obtains discounts of 10% with Glaxo-Wellcome in the case of the 3TC and the same percentage of discount with Bristol-Myers-Squibb for ddI and D4T. They pay \$250 pesos (\$25 USD) for a unit of AZT 250 mg with 30 tablets.

The principal problems that the COESIDA have faced during this policy are: when they detected that 5 patients that were coming from a neighboring state of Guanajuato, attempted to receive these drugs free of charge, and had to be denied them, the other problem that they on occasions face, is due to the difficulty in determining if a patient is a beneficiary of the social security, since the head of the COESIDA points out, that by the frequent problems of supply of ARV in the IMSS, to the people is attractive to attempt to obtain the ARV through the COESIDA, in some occasions when the IMSS has fallen into shortage of ARV, the COESIDA has supported this institution by providing in a temporarily basis ARV to its patients.

Finally through the FONSIDA they cover the requirements of their pediatric patients (6 in total).

During the presentation of the case to Michoacán, in the workshop with stakeholders in Mexico City (as part of this case study), some participants considered that they are running the risk that the state government cannot sustain this policy of providing free ARV for a long-term, whether they will confront the need (as surely will happen) to incorporate PI which are much more expensive, or whether

<sup>50</sup> Information provided by Dr. Mario Guzmán, Head of the Michoacán COESIDA

the PLWA from the rest of the states, especially from neighboring Jalisco, will get to the idea that migrating to Michoacán could be very attractive for their health and economy. In addition, during the workshop it was recommended that Michoacán should share the costs with the federal government and wait for a broad national decision to be taken.

### Stake-Holders Workshop

For the purpose of discussing and analyzing the implications, “pro and cons” of actions directed to achieve an optimal policy of access to ARV drugs, 2 workshops were held with key actors in Mexico.

These workshops were carried out separately, the first group (14 in total) was of actors of civil society, from NGO with work in HIV/AIDS and from groups of people affected by HIV/AIDS. The second group (22 in total) was with professionals specialists in medical care of the people with AIDS, program coordinators of AIDS both of the national level and to the state level, responsible for projects of AIDS based on Mexico, health officials and politicians.

In both workshops involvement of people was available not only from Mexico City, but also from Jalisco, Nuevo León, Michoacán, and Yucatán.

In the two workshops the same methodology was followed:

1) First a slide presentation the progress of information compiled in this case “The Process of Access to ARV in Mexico”, in which there was given opportunity to all of them in order to express their opinions,

2) Subsequently there was given a presentation of responses that had been previously given in a questionnaire by the same people participating in the workshop were they addressed some statements regarding access to ARV from different standpoints, and

3) Every guest also was requested to prepare one mini-presentation (talk) that addressed one of the specific proposals that were made throughout the workshop, of course in the ones they had greater specialty or experience.

In the case of the second group, that of professionals, and staff members, they could also analyze the questionnaire answered by the civil society members, since that workshop had been carried out some days before.

After analyzing and discussing each statement, there was requested to the participants that tried to reach a consensus on an only response to the question raised, however as it can be observed later, this was frequently not achieved.

Below there is list of each statement addressed, with the response in percentage, given by each group in every option, where 0 is total disagreement with what is proposed, and 10 a total agreement with the proposal. They are identified with the acronym NGO to the responses on the part of civil society members and as FP to the staff members and professionals.

*Statement 1.* The anti-retroviral (ARV) therapy, is a procedure that in general, to individual level improves the quality of life and prolongs the same; at the level of populations it diminishes mortality from AIDS.

Group	Totally disagree	2	4	6	8	Totally agree
NGOs					21%	79%
SH					5%	95%

*Statement 2.* Taking into account the high costs of ARV, the developing countries as Mexico, still have the economic capacity to provide the ARV with public resources to all the people who need them.

Group	Totally disagree	2	4	6	8	Totally agree
NGOs						100%
SH		19%	43%	19%		19%

*Statement 3.* Thailand, provides ARV only through clinical trials as measure to guarantee that the medical staff is specialized, and it is perfectly trained in order to prescribe them, thus the patients receive therapy through research protocols that envisage standardized and controlled care. Could a recommended measure for Mexico be this?

Group	Totally disagree	2	4	6	8	Totally agree
NGOs	100%					
SH	28%	10%	10%	33%	19%	

*Statement 4.* Brazil has begun to develop a parallel and specific system of logistics and control of ARV, since its traditional public system of drug control and supply could have not been able to respond effectively to the needs for systematic and uninterrupted access of these ARV to the patients to which they are destined. Could a recommended measure in Mexico be this?

Group	Totally disagree	2	4	6	8	Totally agree
NGOs	57%					43%
SH	38%	19%	10%	14%	5%	14%

*Statement 5.* Although, we know that the criteria of the institution, physicians, the health workers and administrators, are important in the timely supply of ARV. In some countries it is considered that the monitoring of the access to drugs on the part of PLWA, is a positive element that influences fundamentally, so that the supply is systematic and timely.

Group	Totally disagree	2	4	6	8	Totally agree
NGOs						100%
SH				33%	48%	19%

*Statement 6.* Some countries have proposed to create a block of Latin American nations for the purpose of negotiating better prices in the ARV with the Pharmaceutical Companies. The prices that are obtained in some of these countries in large purchases (wholesales), are not homogeneous, in some cases they are more inexpensive than in Mexico and in others more expensive. These global purchases would benefit clearly some Latin American countries that have few people infected with HIV/AIDS; however, a probable scenario is that in case of Mexico, it would obtain better prices in some of them, but greater prices in others.

Should Mexico support the creation and participate in this strategy of a block of buyers?

Group	Totally disagree	2	4	6	8	Totally agree
NGOs					91%	9%
SH	10%		14%	24%	14%	29%

*Statement 7.* A health System that can pay for highly expensive medical treatments such as liver transplantation, renal dialysis or surgeries of some brain tumors, which are less effective than ARV, should give priority to these last before to the first ones.

Group	Totally disagree	2	4	6	8	Totally agree
NGOs	22%		7%	64%		7%
SH	24%	14%	19%	5%	10%	19%

*Statement 8.* There is a proposal that the resources necessary for the purchase of ARV for the uninsured, do not come from the budget of the Ministry of Health, but they should be obtained from reductions in other less priority sectors of the government. This proposal to you seems to be:

Group	Totally viable	2	4	6	8	Totally un-viable
NGOs						100%
SH	10%		5%	24%	24%	38%

*Statement 9.* Since the IMSS already began providing ARV to its beneficiaries, and that this process is specialized and particularly different from that of drugs for other diseases, adding that the IMSS has already developed experience in doing it. At some meeting it was proposed that instead of creating a parallel scheme in order to provide of ARV to the uninsured, there should be done the necessary legislation so there could be transfers of funds to this institution, in order that the IMSS be able to cover the whole PLWA currently uninsured.

Group	Totally disagree	2	4	6	8	Totally agree
NGOs	50%			14%	36%	
SH	52%	24%		10%	5%	10%

*Statement 10.* In counterpart with the previous point, it has also been proposed that it should be a new organism, the one which carries out the purchases and supply of drugs for 100% of the people with HIV/AIDS that require them and that should be the IMSS and the ISSSTE the ones that pay for this service to this new alternative.

Group	Totally disagree	2	4	6	8	Totally agree
NGOs	43%	57%				
SH	38%	10%	10%		24%	19%

*Statement 11.* Taking into account the new process of decentralization, some states of the Mexican Republic have decided and begun to provide ARV with public resources, to people with HIV/AIDS that do not have Social Security. In your opinion: (This statement can have more than one response)

NGOs	Opinion to this statement	SH
	The rest of the States should do the same with their own resources	38%
100%	They should share the cost with the Central Government	57%
	They should wait until a national decision is taken	24%
	Due to the high costs and to the growing of the epidemic the States have the risk of getting lack of resources and not be able to continue paying for them during the following years.	43%

For the following statements, it was asked them, that the response be given in the sense of if it was considered that the activity or program should be carried out **Before**: whether a step was considered prior to implementing a policy of access to ARV for non beneficiaries of the social security system or **During**: Whether it was considered that it was not necessary as previous step since it could start while at the same time the action of ARV provision starts. Or It is **Not Necessary**: that should be carried out as prerequisite nor during, in order to achieve an optimal ARV policy.

*Statement 12.* Allocate more resources to improve epidemiological surveillance and the registry of cases:

Group	Before	During	Not Necessary
NGOs	57%	43%	
SH	57%	33%	10%

*Statement 14.* Prepare a census of the people with HIV/AIDS for the purpose of programming resources

Group	Before	During	Not Necessary
NGOs	7%	50%	43%
SH	57%	38%	5%

*Statement 15.* Increase and improve the programs of prevention in order to avoid new infections.

Group	Before	During	Not Necessary
NGOs	7%	93%	
SH	33%	62%	5%

*Statement 16.* Achieve an agreement of discounts in prices with the pharmaceutical companies.

Group	Before	During	Not Necessary
NGOs		93%	7%
SH	67%	28%	5%

*Statement 17.* Train medical staff specialist for the management of the ARV.

Group	Before	During	Not Necessary
NGOs	100%		
SH	90%	10%	

*Statement 18.* Train and sensitize the health workers concerning human rights and tolerance toward men with different sexual orientation and female commercial sexual workers.

Group	Before	During	Not Necessary
NGOs		100%	
SH	33%	67%	

*Statement 19.* Obtain additional budgetary public resources to those of the health sector.

Group	Before	During	Not Necessary
NGOs		100%	
SH	86%	14%	

*Statement 20.* Implement programs of counseling and training in adherence to the treatment for patients with HIV/AIDS that are involved in ARV therapy

Group	Before	During	Not Necessary
NGOs	7%	93%	
SH	38%	62%	

*Statement 21.* Allocate resources and ensure access to laboratory studies (Count of lymphocytes CD4 and viral load) necessary for the monitoring of patients under ARV therapy.

Group	Before	During	Not Necessary
NGOs	100%		
SH	95%	5%	

*Statement 22.* Carry out legislative and legal reforms in the matter.

Group	Before	During	Not Necessary
NGOs		100%	
SH	85%	10%	5%

*Statement 23.* Implement a parallel and specific System of logistics and control of ARV.

Group	Before	During	Not Necessary
NGOs	14%	36%	50%
SH	62%	14%	14%

*Statement 24.* An agreement between IMSS, ISSSTE and SSA in order to avoid double coverage and diminish the risk of that the drugs paid with public resources benefit foreign people outside the country.

Group	Before	During	Not Necessary
NGOs		93%	7%
SH	90%	10%	

After this question there was requested them to identify some other activities or programs that should be considered to be carried out **Before**, from here the one that most frequently appeared on the part of the SH was the need for establishing standard criteria of treatment with ARV, that is an up-to-date national standard, moreover was proposed the need for doing an analysis of resources and services specialized in Mexico and improving the training for the timely diagnosis of AIDS and not only the training for the care of the patient.

On the part of the NGOs it was proposed the need that the agreement to which one refers in statement 24, not only includes the health institutions but also the NGOs and the people who live with HIV/AIDS.

Other activities or programs that they were considered that should be carried out **During**: were projects of research on adherence to the treatment on the part of the patients, as well as programs for continuing education of the health workers concerning care to PVVIH and creating laboratory Networks that can share test information and processing of samples.

A last request consisted in asking each one of them to point out those 5 areas in which they consider that is a need for more information, before making a decision on provision of ARV so the adopted policy be optimal. Only those 5 that had the greater number of responses are included in the first list for each group.

The group of NGOs selected the following 5 areas:

Need more information on	Percentage of people who selected the issue
Reforms needed on legal aspects in terms of access to ARV	79%
Successful ARV and drug procurement policies in other countries	71%
Sufficient numbers of specialized doctors and trained health personnel to prescribe ARV and provide health care to PLWA	64%
Access to specific lab test such as CD4 cell counts and viral load	57%
Perspectives of approval of more public funds for ARV	57%

On the other hand the group of PSH selected the following 5 areas:

Need more information on	Percentage of people who selected the issue
Adherence to HAART therapy by Mexican PLWA	57%
Successful ARV and drug procurement policies in other countries	57%
Reforms needed on legal aspects in terms of access to ARV	48%
Perspectives of financing ARV with private funds	48%
Better estimations of PLHIV and PLWA as well as the growth of the epidemic in Mexico	43%

Other areas proposed that were considered, but that received a smaller number of mentions were those which are presented in the last table.

And also more information on:

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The exact number of people who already developed AIDS and are alive

Effectiveness of current HIV prevention programs

Effectiveness of HAART

Side effects of the HAART

Current research on ARV resistance

Price discounts that the pharmaceutical industry is willing to offer

The experience developed by the IMSS and ISSSTE by providing ARV

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## Conclusions

The results of the workshops, with the two groups of stake holders, provides with elements that make it possible to arrive to conclusions in the sense of being able to address critically this process.

It is clear that in Mexico, this process has been given gradually and that although at the beginning these drugs (initially the AZT) were available for the people affected by HIV through research protocols and clinical trials from the different health institutions, such as the Hospitals “La Raza” of the IMSS, and the General Hospital of Mexico, the National Institute of Nutrition and the CONASIDA itself on the part of the SSA in Mexico City, but also by some specialists in hospitals of Jalisco, Yucatán, Nuevo León and Baja California.

In interviews with some people responsible<sup>51</sup> of those projects, they have pointed out that in those times (1987-92), the benefits of the AZT were not convincing for a large number of the people that received it, in fact a large number of them to whom was offered, preferred not to take it or even insinuated that physicians wanted them to utilize as “lab rabbits.”

When in 1992, is also granted the registry to ddI for its use in Mexico, it was also published the first medical guide for the AIDS patient care, which is used of basis to subsequently updated editions that have incorporated the new drugs.

By 1995, the principal medical service provider in Mexico, the IMSS, incorporates in its treatment protocols both ddI and ddc; however, although the specialists from IMSS and the National Institute of Nutrition were able to perceive the benefits of these two new drugs, especially when they were used in combinations with AZT, still in the public opinion and in the majority of the affected people did not remain very clear that these benefits were conclusive.

For some physicians in Mexico, that already began to review scientific literature where there was evidence of the benefits of the therapeutic combinations including the new protease inhibitors; however, it is not until the international conference of AIDS in Vancouver, when the mass media gave great echo of the benefits of

<sup>51</sup> Dr. José Izazola was one of the member of CONASIDA who started providing AZT through research protocols.

the therapeutic combinations, that the demand for the authorization of these new drugs for their use in Mexico started. The first ones to state the need of these new ARV in Mexico were the specialized physicians, the pharmaceutical companies, and specialized press as the supplement "Letra S".

The action of the groups affected directly by HIV, also began in 1996, however, it was after that response of the first three ones (physicians, laboratories and media), and in fact it was with the help of some of them and from NGOs that PLWA started to mobilize.

The structure of the Mexican health system that divides the population between beneficiaries and non beneficiaries, is what determines in a higher degree if a PLWA has access or not to ARV. Although the research and humanitarian protocols of CONASIDA helped in some measure to fulfill a part of the demand by these drugs but this only happened in Mexico City and its metropolitan area.

The availability of the new ARV drugs in the Mexican market has diminished the probability of its illegal importation, however this aspect is limited for its high costs (213 days of minimum wage for triple therapy of a month), it is evident that the Mexican market of ARV for the pharmaceutical companies, is actually formed by the sales to the government through its health institutions.

However, the illegal introduction of ARV not only has been given by people who have the economic ability to acquire them abroad (49), but also has been carried out by members of NGOs, especially those that provide some kind of medical care<sup>52</sup>. Nevertheless, this has been a mechanism that has succeeded in making accessible ARV with prices from 50% to 80% lower than in private pharmacy, doing the marginal note that the containers are not always sealed, and that on occasions the expiration date is very close to consumption, and even in some occasions this already has overcome.

Nonetheless, this has been a kind discharge valve to the pressure of the ones affected and a way of accessing these drugs. This pressure was manifested in clearer way during the avenue blockage by PLWA in April 1997.

The politization of the access to the ARV, although it has promoted that some decisionmakers, especially in the social security subsystem, had accelerated the incorporation of ARV to their therapeutic catalogs, and therefore making them susceptible of prescription. These decisions have not been equipped with similar mechanisms that guarantee access to necessary lab studies and monitoring, such as CD4 cell count and viral load, facing with this a serious risk of inducing drug resistance, or to be making an unnecessary expenditure.

It is considered that currently around 55% of the people with HIV/AIDS that require drugs have theoretical access to them; however, the problems of periodic shortages of supply in the IMSS and ISSSTE hospitals, could be causing interruptions

<sup>52</sup>These comments have been made by representatives of these organizations, they argue humanitarian reasons to do so, they establish contact persons abroad and receive donations, mainly from the United States.

in the intake of the ARV on the part of the patients with the consequent risk of creating resistant viruses.

Some PLVVA have commented that to avoid that to happen, sometimes they have their “guardadito”<sup>53</sup> (small personal storage of ARV), that is a quantity in excess of ARV kept in their houses, that is utilized when there is a shortage in his/her hospital. In some other places, but especially in hospitals of Social Security Institutions of states far from Mexico City, certain PLWA have commented that “True!, the ARV were available in their regional hospital, however there were no trained specialist that could prescribe them”<sup>54</sup>.

In some occasions, Social Security Institutions pay travel expenses for a patient traveling to tertiary care hospitals, so that the person can access to an AIDS specialist, who can prescribe him/her, and give the recommendations for proper care. For example, in the Occidental region of the IMSS based on Guadalajara, the institute provides a free bus for the people that live with HIV in Puerto Vallarta<sup>55</sup> (4 hours away).

The shortages of ARV in the Social Security Institutions, and the lack of access to them on the part of those who are not beneficiaries, has been the main fuel for rallies by PLWA in Mexico City, Guadalajara, Aguascalientes, Monterrey and Yucatán. The political impact of the epidemic has achieved in some way that political leaders, intellectual and journalists get also interested in the subject, get involved in alternative proposals of solution, or to support demands and political pressures to the federal and state governments.

Despite this, except for the creation of the FONSIDA that starting 1998, began to provide ARV to population without social security (children and pregnant women) but with very limited scope, there has not been developed a mechanism to achieve coverage to the remaining 45% of the people that do not have access to the ARV.

It is clear that due to the high prices of the ARV, in the retail market, the access to them for the majority of the affected ones cannot be achieved without the governmental involvement.

The new budgets proposals for \$73.4 million USD, presented before the Chamber of Representatives and the Ministry of the Treasury, in order to cover the uninsured, now envisage more comprehensive schemes that include access to laboratory studies, prophylactic drugs and against opportunistic infections, also conceives a three way financing method by the federal government, the state governments, and also a co-payment of 5% on the part of the PLWA at the time he/she receives the drugs.

A sign of a possible governmental response in this regard, seems to come from the President of the Republic himself, who, during the ceremony of presenta-

<sup>53</sup> Information provided by a PLWA, who mentioned that he convinces his Doctor at the IMSS to give him extra bottles of ARV, as a way of protecting himself from further shortages

<sup>54</sup> Information provided by a PLWA from Chiapas

<sup>55</sup> Information provided by Dr. José Ramírez from the Occidental Medical Center of the IMSS in Guadalajara, Jalisco

tion of the health program 1999, of the SSA, declared his involvement to defend the rights of the people that live with HIV in Mexico<sup>56</sup>.

Although, it has not been clarified which are those rights, these could be derived from the concept of “right to health” and health as a “social good” or a “public good” (61), that should be covered with public funds, especially when in order for a person to continue alive and productive requires to do a contribution that multiplies by 200 the daily minimum wage of the country of which he is a citizen. There is no micro-economic rationality at the family level (62) for that to happen, and the option of dying without complaining does not seem to be an expected behavior of a young adult, as it is the case of the vast majority of the cases of AIDS in Mexico.

## Recommendations

The majority of the recommendations that can be obtained from the present case study, are derived from the results of the workshop held with key actors, both from the civil society and from professionals, specialists, politicians, staff members and related to decisionmakers or interested in the subject; where the responses to each proposal present us guidelines of “where” should the decisions be directed in order to achieve an optimal policy of access to ARV.

Of course, it was no surprise that in some statements the two groups responded in very different ways, since the standpoints from which the problem is seen have distinct implications for both, nevertheless, from those other responses that are highly coincidental, remains clear that there is not much place for the discussion of some statements, such as the effectiveness of ARV, in terms of prolonging and improving the quality of life of those affected by HIV/AIDS.

It also is possible to observe that the representatives of civil society who participated in the workshop, are convinced that a country with the level of development of Mexico, has total economic possibilities to provide ARV with public resources. But, which also remains clear of this analysis, it is that a precipitated decision-making, motivated only by political reasons, could forget essential elements of an optimal policy, by not considering aspects of a comprehensive response, and endanger the viability of the policy, and even risking the life of the same people who are pushing for a quick response.

From the workshop is also clear that some programs and actions, should become before the provision of drugs, this is manifested fundamentally in at least two statements: the one which refers to the need that the doctors be trained to be able to prescribe ARV properly (see statement 17), and the one referent to guarantee the access to lab tests (CD4 cell count and viral load, statement 21), that will be used to

<sup>56</sup>This comment from the President of Mexico was published by most of the newspapers in Mexico on the 19th of January, 1999

monitor the evolution of the patient and the probable development of resistances to some ARV, what would give us an indicator of need for change of treatment and would avoid being making unnecessary expenditures when the ARV provided are not representing any benefits for the life of a PLWA.

It also is clear that an ARV policy, in order to approach an optimal standard, should also include in its components the programs of counseling and motivation to patients so that they fulfill the adherence to the treatment, especially taking into account that the combinations of two or three types of drugs scattered to the length of the day and with differences of schedules for their intake, including before and after meals, convert them in schemes of difficult management for a patient who does not meet himself information and basic knowledge.

From the previously analyzed statements, there is also derived the need for guaranteeing the systematic and timely supply of ARV, since unlike other drugs, usually provided by the health institutions, decisionmakers should take into account that ARV drugs have at least 6 characteristics that make them particularly delicate and different: One of human rights interpretation (1) The right to survive, specially for a young adult; three of medical criteria: (2) ARV can turn a diagnosis of death into an opportunity for chronic management of the disease, (3) ARV should be taken through life, and (4) the interruption in its intake can induce resistance. One economic criterion: (5) ARV are highly expensive and creating resistance could represent wasting resources without benefiting the patient; and finally a political criterion (6) The shortage of these drugs is the main reason for rallies against health officers, and they usually receive wide media coverage.

Within the recommendations for decisionmakers, it should also be included that in Mexico, taking into account the structure of it's health system, becomes a "must" that the different health institutions share information or create a database on ARV, that are being provided with public funds to their patients, since this would avoid double coverage, and diminish the risk that some people could market them in countries where there is no access to these same drugs.

Other parallel programs, not necessarily as prerequisites to the provision of ARV, are the ones focusing the sensitization of the health workers, that in some way are in contact with PLWA, concerning human rights, tolerance and acceptance to different life-styles, as well as to sexual diversity, especially in view of the fact that by far most of the AIDS cases in Mexico, are related to sexual transmission and taboo sexual encounters.

For the purpose of obtaining a better programming of resources, it is necessary to develop projects to improve the registry and epidemiological projections of cases, and of the growth of the epidemic, as well as studies to be able to demonstrate the impact on mortality that surely the IMSS and the ISSSTE are already achieving at the national level.

These studies are necessary to be documented for the purpose of being able to do better projections of current PLWA that will continue alive, and to fulfil a better strategic plan. The new data on mortality can also serve as support for subsequent studies on the cost-effectiveness of these therapies.

It is also necessary to explore the possibility of requirements in terms of legal amendments or new regulations and standards, in order to guarantee the optimal operation of this policy. Such as updating standard of care, official guidelines, or even new legislation relative to the financing of the ARV, as it was done in Brazil and Argentina.

Although, from the analysis of the responses to the statements of the workshop could derive a greater number of recommendations, as an end point, this author wants to quote that, at all times it is desirable to have registries of the processes or policies of access to ARV, in order to be able to identify errors and avoid them in the future. Finally, it should be said that any policy of provision of drugs, cannot be long-term successful if it is not accompanied by an increase on effective preventive programs, since by not doing so, the problem will be turned into a bottomless barrel.

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