

Access to antiretroviral treatment in Latin American countries and the Caribbean

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Objectives: To assess the access to antiretroviral therapy in the Latin America and Caribbean region and the main issues involved.

Methods: A review of National AIDS Programmes reports, published studies on HIV access to antiretroviral drugs, and personal communications from National AIDS Programmes in the region.

Results: Most countries have, or are in the process of developing, laws and regulations to ensure better access to antiretroviral drugs for people in need. However, there are still many countries that either have not implemented policies or do not have policies. There has been an important decrease in the cost of drugs, but prices are still too high for all countries to afford them. The benefits in decreased mortality and hospitalizations in the countries with high coverage are significant. The number of people receiving antiretroviral therapy has been estimated to be close to 170 000 individuals; however, this figure only represents a fraction of the people in need in the region. Some different strategies will have to be implemented in order to increase coverage.

Conclusion: Renewed efforts are needed from both governments and international community organizations to strengthen the health services and increase access to antiretroviral drugs.

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Introduction

Access to medication, in particular antiretroviral drugs, is a critical component of the treatment of people living with HIV/AIDS (PLWHA). However, access to medication should be viewed as just one part of providing appropriate management. In reality, medical care encompasses more actions than just prescribing and providing drugs. Moreover, PLWHA have a complete range of emotional, social and economic needs that also have to be addressed in the framework of comprehensive care, and that cannot be met through the use of medication.

This paper concentrates on antiretroviral drugs, while recognizing that they are not the whole answer to HIV/AIDS provision of care. The provision of antiretroviral treatments (ART) is a critical component of

the comprehensive care of PLWHA because of the dramatic impact that they have on survival, the reductions they effect in symptoms, and the improvement they cause in the overall quality of life. Because of these benefits, an increasing number of countries are working to ensure universal (or at least increased) access to ART. Most recently, one of the goals of the newly created Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) is to increase access to antiretroviral drugs in developing countries [1].

A primary concern in the design and implementation of health policies is to ensure the sustainability of the strategies and actions envisaged under such policies. In the case of antiretroviral drugs, ensuring financial sustainability requires an estimation of the future costs of the antiretroviral drugs and other related healthcare costs, plus a projection of the expected healthcare

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revenues and of costs of other programmes vis à vis the estimated number of current and future individuals who will need treatment.

This paper presents a review of the policies of anti-retroviral therapy of countries in Latin America and the Caribbean (LAC), the estimated number of people receiving antiretroviral therapy, the level of coverage of those needing antiretroviral care and the lessons learned, both negative and positive, which can benefit other countries. The main sources of information have been government reports, proceedings of conferences, workshops in the region, and personal communications from experts from the countries of the region.

Policies regarding antiretroviral treatment in the region

Of the 24 countries in the region that were surveyed, 11 have policies, regulations or laws that guarantee access to ART (see Table 1). In addition, six countries are in the process of implementing regulations to ensure access. In the remaining seven, there are no regulations regarding the provision of ART for those in need. In the Caribbean only a few countries, such as

St Kitts, Barbados and Grenada, are in the process of implementing policies.

Brazil and Argentina are the two countries in the region that most quickly ensured the availability of antiretroviral drugs for PLWHA. In Brazil, antiretroviral drugs have been provided since 1991. However, it was not until November 1996, through a presidential decree, that provision of ART was established as a right for all citizens who meet the technical criteria established by a scientific commission. This decree is unique among countries of the region, because it guarantees free and universal access to care and treatment for HIV and AIDS. The decree also defined the implementation mechanism.

In Argentina, a law was passed in 1990 that is the basis of universal access to therapy. This law declared the fight against HIV/AIDS a national priority and established the procedures for detection, diagnosis and free access to treatment (Ministry of Health and Social Security). A recent Supreme Court ruling ensures the enforcement of the law. However, with the current political and economic crisis in Argentina, there are reports about shortages in drug stocks – and not only for HIV. Uruguay has recently created a fund for financial support to provide ART via social security,

Table 1. Antiretroviral drug policies and access to care in selected Latin American and Caribbean countries, December 2001.

Country	Law/regulation	Access to care
Belize	No	No
Costa Rica	Yes	Social security 100%
El Salvador	New law	Limited coverage
Argentina	Yes (1995)	Free access
Bolivia	No	No free access
Guatemala	In process	Social security provides to affiliated. MOH in process
Nicaragua	Yes	No
Panama	In process	60% by social security. MOH covers the remaining PLWHA
Honduras	In process	MOH negotiating to cover 5000 patients
Colombia	Free access guaranteed by national law (1997)	A fund was created to provide drugs for low income people
Chile	Yes, access in process of expansion	Negotiation with several pharmaceutical companies for reducing prices is ongoing
Cuba	Very strong political decision. Economic constraints. Antiretroviral drugs production by state company and recently universal access	Triple therapy implemented State production of some antiretroviral drugs
Mexico	Yes	Free access for people covered by social security. In expansion for those not covered by social security
Paraguay	No	No specific law. Access to dual therapy and frequent interruptions on provision
Uruguay	Yes	Universal access (MOH, social security). A fund was created for financial support
Brazil	Yes	Free and universal access. High proportion of antiretroviral drugs provision by state pharmaceutical companies
Peru	Yes	Very limited coverage
Venezuela	Supreme Court decision. Political commitment	Free access
Caribbean region	In process antiretroviral drugs treatment implementation and political decision on universal coverage: St Kitts, Barbados and Granada	

Information and comments based on September–December 2001 situation. MOH, Ministry of Health; PLWHA, people living with HIV/AIDS.

and has laws and financial mechanisms in place to provide access to ART.

Other countries in the region have laws guaranteeing access, but this is limited to certain groups, or by a lack of funding. Mexico offers free access to those covered by social security under the government umbrella. In Cuba, access to ART is mandated by law, but economic issues have made true access limited in the past. Colombia issued legislation on HIV/AIDS, which dictates that comprehensive care, including ART, must be provided at every public health service or private centre affiliated to the general health and social security system. This only covers approximately 60% of the national population [2]. Other countries in the region either have laws or regulations guaranteeing access, but have not yet implemented the mechanisms needed to make ART available. Figure 1 shows the estimates of free access to ART in Brazil, as of November 2001 reported by national programmes [3].

The reported coverage of ART according to the information provided by the National AIDS Programmes varies from 15% in Peru to 100% in Argentina, Brazil and other countries. The reported level of coverage of ART may actually be lower than listed in Table 2, depending on the criteria used by the different countries for their calculation. In addition, other factors such as the actual therapy being provided (dual or triple therapy), access to testing services, and the criteria used to judge need for treatment may vary.

Table 2. Estimated number of people living with HIV/AIDS and those under antiretroviral treatment in some Latin American and Caribbean countries.

Country	Number of PLWHA under ART (September 2001) ^a	Estimated number of PLWHA (December 1999) ^b
Brazil	106 000	540 000
Paraguay	300	3000
Chile	1700	15 000
Argentina	15 000	130 000
Costa Rica	800	12 000
Cuba	472	1950
Uruguay	1500	6000
El Salvador	800	20 000
Guatemala	1600	73 000
Honduras	238	63 000
Colombia	15 000	71 000
Mexico	20 000	150 000
Panama	600	24 000
Venezuela	5300	62 000
Total	169 310	1 170 950

Sources: ^aNational AIDS Programmes/Ministry of Health; ^bUNAIDS. Report on the global HIV/AIDS epidemic, June 2000. ART, Antiretroviral treatment; PLWHA, people living with HIV/AIDS.

Access to care in Central America varies from country to country, and in a way reflects the economic resources of the country. In some, such as Belize and Nicaragua, access through public systems is negligible; whereas Costa Rica provides universal access and has a comprehensive array of health services for PLWHA via social security, which is supported by laws and a financial mechanism in place to provide access to

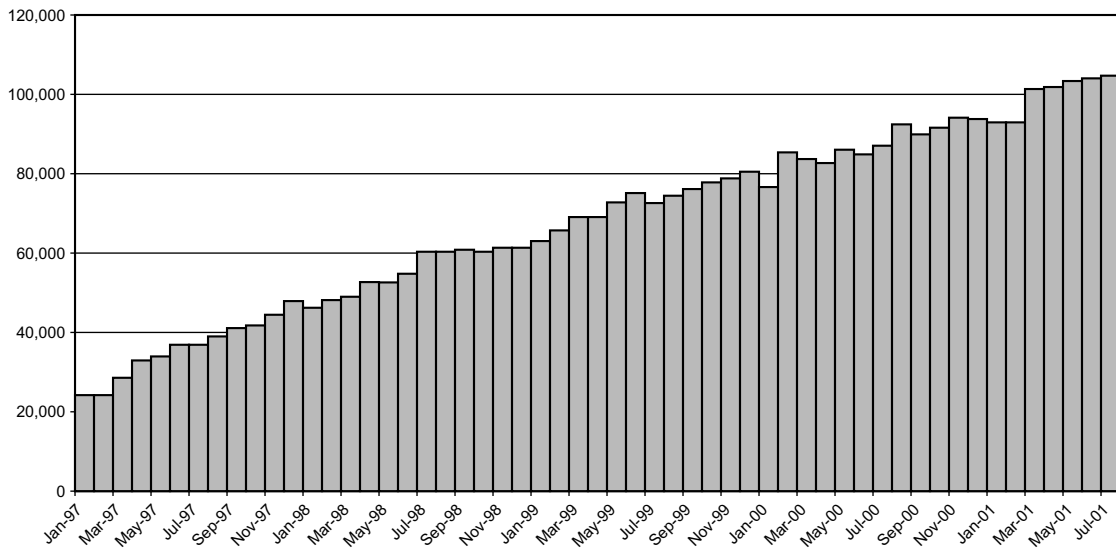


Fig. 1. Coverage of antiretroviral treatment in Brazil. Patients under antiretroviral treatment in Brazil, January 1997 to July 2001. Source: National AIDS Programme/Ministry of Health.

ART. Most countries, such as Guatemala, El Salvador, Honduras and Panama are in an intermediate stage of development, offering services to those covered by social security systems. However, most people with HIV needing treatment are not under such regimes [4].

UNAIDS and the Pan American Health Organization are providing technical and political support to countries in the region, in order to create better conditions for expanding and improving access to care and antiretroviral drugs. The role of UNAIDS/WHO on advocacy for implementation of this policy and the ongoing process of negotiation with the pharmaceutical companies, as well as the increasing production of generics, has created a very favourable environment for its sustainability and expansion in terms of coverage and adoption in some countries of the region. It has also boosted ART access negotiations and policies in the region as well as in other countries in other regions. Recently, Chile, under the umbrella of the UNAIDS Accelerating Access to Antiretroviral Drugs Project, has obtained a significant reduction in prices, and as a result, the coverage of patients under treatment with the same budget is expected to be very close to 100%. Other countries such as Jamaica are following these steps, and negotiations are currently under way that may reduce prices more than 80%.

Additional effort has been carried out by other governments in the region with support from the World Bank in the Caribbean, acting jointly with UNAIDS. For the first time ART is explicitly included within the terms of agreement for the World Bank loan. The most recent example is Barbados, where the government took the decision to adopt free and universal access to antiretroviral drugs for all citizens who meet the technical criteria. The acquisition of drugs will be financed with funds loaned by the World Bank.

Finally, the non-governmental and community-based organizations plus the strong patient advocacy as the participation of PLWHA as part of the clinics' teams bringing psychological support to other PLWHA have played a very important role in the LAC region in mobilizing the community and governments into improving treatment and access to ART for PLWHA.

Number of people receiving antiretroviral therapy and estimated coverage levels of those in need

In 2001, there were an estimated 170 000 individuals affected by HIV receiving ART in the countries of the region. As can be seen in Table 2, this number varies considerably by country, with Brazil providing ART to just over 100 000 people. These reports do not take

into account therapy that is being paid for by personal resources or private insurance schemes.

To understand the whole perspective, the information about how many people are receiving ART should be compared with the number of people in real need of ART. We have used the ratio of people receiving ART and living with HIV/AIDS in Brazil to estimate the coverage of ART for people in need of therapy in the region. In Brazil, 106 000 people received ART out of a total population of 540 000 PLWHA. (Note: Most PLWHA will not need ART until 6–8 years after becoming infected). By applying this ratio (17.5%) to the estimated number of PLWHA (1.8 million, UNAIDS, 2001) [5] we estimate that 46% of the people in the region in need of ART are receiving treatment. Of course, this estimated coverage rate is largely driven by the programmes in Brazil and Argentina, which when combined account for 70% of those covered by ART. In other countries, coverage is very poor; notably Haiti and the Dominican Republic, which together have over 250,000 PLWHA and effectively no provision for ART.

Finally, this estimate of coverage is probably too high for the region as it makes the assumption that all people who need care receive it. Even with strong outreach programmes and widespread accessibility of counselling and testing, one must assume that the actual coverage rate in Brazil is less than 100% of those PLWHA who are in need. Among other things, it is not feasible to provide treatment for those who theoretically meet the technical criteria but have not had their HIV status diagnosed.

Impact of antiretroviral drug policies

The impact and effectiveness of ART has been described widely since the introduction of antiretroviral drugs [6,7]. However, the implementation of a programme providing ART faces the problem of increasing demand for services, and therefore increasing costs. The number of people who are initially provided with ART will grow over time, as a result of both the increased demand from people who have actively sought testing because there is free therapy available, and new cohorts of people who will need ART as their CD4 cell count decreases.

In order to understand how this demand curve works, one can look at the example of Brazil. As can be seen in Figure 2, the number of people receiving ART has grown from just over 20 000 in 1997 to over 100 000 in 2001. As Brazil estimates that almost 600 000 people are living with HIV infection, the demand will continue to increase for the foreseeable future. To meet

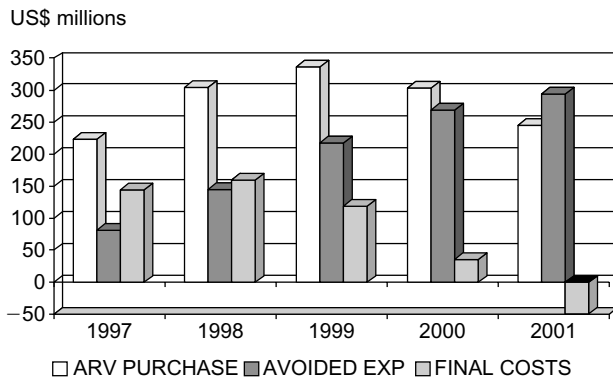


Fig. 2. Costs of antiretroviral drug purchase, avoided expenditure costs, and final cost to the Ministry of Health, Brazil, 1997–2001^a.
ARV, Antiretroviral drugs; Exp, expenditure.
^aEstimated data.
Source: Ministry of Health.

this growing demand, Brazil and other countries in the region will need financial plans that account for this increase in costs, although the cost increases because of demand may be offset somewhat by decreases in the price of drugs. On the other hand, the final cost should take into account the expenditure avoided: the reduction in the numbers of people hospitalized, fewer opportunistic infections as well as less sick leave, fewer people taking early retirement and the reduced loss of productivity.

Of course, with increases in the demand for ART also come improvements in morbidity and mortality among PLWHA. Again using Brazil, where the process has been well documented, the provision of ART has led to a large decrease in the incidence of opportunistic infections among PLWHA and a resulting 75% drop in the average time of hospitalization. Also at the national level, the AIDS mortality rate has dropped almost 50% [8]. A similar scenario has been observed in other developing countries during the same period. Argentina, for example, has reported a 20% decrease in the mortality rate as a result of HIV/AIDS, which can be linked to the wider use of ART [9]. These decreases in morbidity and mortality with the provision of ART not only have direct benefits for those people receiving treatment but also have financial benefits, with lower medical costs.

The implementation of ART policies has raised the concern among some researchers that the failure of adherence to treatment will result in the development of resistance to ART. The argument is that there may be reduced adherence to treatment as a result of the limited case management or the lack of sustainable delivery systems, including laboratory capacity. How-

ever, the available data from countries in the LAC region suggest that adherence can be high. In Brazil, where adherence has been the objective of a continuing education programme, a study carried out by the Ministry of Health/Sao Paulo State and the University of Sao Paulo shows rates very similar to those observed in developed countries [10]. This demonstrates that strong educational programmes, along with other strategies (e.g. directly observed treatment) [8] can be a successful way to ensure adherence and prevent the feared negative outcomes. Appropriate policies and resources are essential to support and keep these programmes and strategies in place. However, although Brazil has focused on adherence, strategies to ensure adherence to antiretroviral drugs may not be in place in other countries. Maintenance of the observed positive results depends on a strong official programme mobilizing healthcare workers and patients towards full adherence.

In countries where access to antiretroviral drugs is universal, very important changes have occurred in the morbidity and mortality profiles of PLWHA. This situation has been well reported in developed countries, but there is also evidence of similar results in developing countries. The best documented case is Brazil, with a huge decrease in the incidence of opportunistic infections and a reduction in the average time of hospitalization of approximately 75%. This has resulted in the average number of hospitalizations per patient dropping from 1.65 in 1996 to 0.38 in 2000. Moreover, morbidity and mortality rates have fallen over 50%. In total, over 234 000 hospitalizations have been avoided [11], and Brazil has reported net benefits from avoided hospitalizations as presented in Figure 3. The economic benefits from hospitalization may eventually increase if the number of patients receiving ART

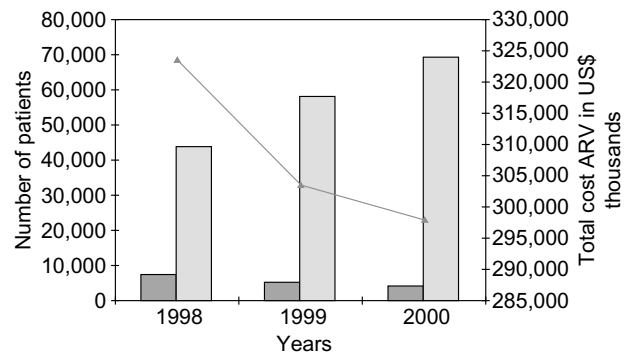


Fig. 3. Number of patients under treatment and total antiretroviral drug costs in Brazil, 1998–2000.
■ Cost of antiretroviral drugs/patient; □ estimated number of patients; —▲— total cost in US\$000s.
ARV, Antiretroviral drugs.

becomes greater and the prices of drugs remain constant. We should remember that even those patients under ART will eventually die of AIDS.

Table 3 presents the trends in hospitalizations and the mean of hospitalization in Brazil from 1996 to 2000. It shows that even with increasing number of patients there is a decreasing trend in the mean time of hospitalization.

Costs and pricing of drugs for antiretroviral therapy

A preliminary World Bank Mission Report on cost-benefits analysis showed that the antiretroviral drugs programme in Barbados could be cost effective if implemented on a universal basis. In the long run, considering that the mean survival can increase by 5 years or more with the provision of ART [11], savings can be obtained. Other Caribbean countries, namely St Kitts and Nevis, are also part of this regional approach, and most recently Granada has been under consideration.

One of the critical issues for countries in the region considering providing broad access to ART is the cost of drugs. Whereas there have been numerous initiatives announced about collective funding mechanisms being planned, the introduction of lower cost generic drugs, and a real movement on price from manufacturers, the mechanisms for making low-cost drugs available to all countries are still not in place.

For the first time in 1997, an annual survey was conducted by the Latin American and Caribbean Horizontal Cooperation Group [12]. As can be seen in Table 4, the prices paid for drugs by countries have dropped significantly between 1998 and 2001. However, the table also shows the wide disparity in pricing between countries. In 2001, Brazil spent less than US\$1500 per person-year on the drugs for a therapeutic regimen, whereas El Salvador paid more than five times that amount for the same regimen. Another

Table 3. AIDS patients hospitalizations, Brazil 1996–2000.

	1996	1997	1998	1999	2000
Number of hospitalizations	25 458	25 157	24 700	24 998	26 655
Estimated number of patients	15 390	31 140	43 823	58 362	69 446
Hospitalizations/patient (mean)	1.65	0.81	0.56	0.43	0.38

Source: Brazilian National AIDS Programmes/Ministry of Health.

Table 4. Cost (US\$) of indinavir plus zidovudine plus lamivudine in selected Latin American and Caribbean countries – government purchase 1998–2001.

Country/year	1998	1999	2000	2001
Brazil	7387	5204	4292	1424
Mexico	7745	6804	6804	...
Chile	...	8553	5928	...
Argentina	9081	9309	4730	2558
Cuba	14 607	10 435	...	2117
Uruguay	15 000	...	10 800	4314
Paraguay	11 840	4314
Panama	7000	2995
Costa Rica	7200	...	7200	...
El Salvador	7823

Source: National AIDS Programmes/Ministry of Health.

example of extreme differences is in Central American countries. Although the cost of drug cocktails has dropped to US\$1300 in Honduras in 2001, the same drug cocktails in El Salvador cost more than US\$5000. In fact, although the average price has decreased since 1998, the difference in prices paid by countries in the region has increased.

The impact of drug prices on the ability of countries to implement and finance ART programmes is illustrated with data from Brazil. The number of people receiving ART has grown dramatically since the introduction of the programme, but total costs for drugs have actually dropped in the past 2 years, as shown in Table 4.

The decreasing price of ART, even if the number of HIV patients has increased, has led to a slight decrease in the total cost of antiretroviral drug purchases as presented in Figure 3. According to the Ministry of Health, Brazil was spending over US\$325 million in 1998 treating approximately 47 000 patients, but by the year 2000, with almost 70 000 patients under ART, the cost of purchasing ART had dropped to US\$298 million.

In all countries there are many priority needs competing for limited resources (for example, development, education, work, health, etc). In the health sector alone, resources for prevention efforts compete with those of care. In search of an answer, governments, international organizations, and communities have come together to try and develop mechanisms that can provide increased access to ART to those in need, while still leaving financial resources available for other priorities. Among these approaches is the Accelerating Access initiative that has been led by UNAIDS. This initiative involves the strengthening of efforts by the UNAIDS Secretariat and its co-sponsors to assist countries in implementing comprehensive packages of

care for their citizens living with HIV/AIDS. It includes UNAIDS advocacy and policy guidance on HIV care at the global level, and also involves ‘fast track’ support for developing countries that have formally indicated that they wish to expand access to HIV care, support and treatment. This approach also calls for voluntary counselling and testing, and psycho-social support to be provided in all countries. In addition, UNAIDS is seeking to make progress on key policy issues at the global level, such as differential pricing, procurement mechanisms, and the identification of suppliers of treatments and commodities.

Figure 4 presents possible strategies that could lead to the further development of promoting equitable access ART at a low price in developing countries. Whereas patent laws and relatively low demand from countries in the region can cause prices to remain high, these factors can be overcome with strategies to purchase a high volume of drugs, to promote local production and generic drugs and to use the TRIPS safeguards from the World Trade Organization (TRIPS is the World Trade Organization agreement on trade-related aspects of intellectual property rights). [13]

There are several factors affecting the price of drugs; it seems that to have equity prices for ART, different strategies will have to be implemented at the same time in order to achieve the goal of better access to ART for PLWHA.

Conclusion

Since ART appeared ‘on the table’ the phase of the epidemic has changed, and treatment with antiretroviral

drugs is in constant evolution. The worldwide experience accumulated in the provision of treatment for PLWHA has highlighted some useful strategies to improve our capacity to provide services. Some of the critical issues on pricing are the strategies to get more affordable drugs to the people in need. Among them are: Differential pricing – also referred to as ‘equity pricing’ or ‘preferential pricing’, in which pharmaceutical companies – whether in the research and development or generics sectors of the industry – offer prices for HIV medicines that reflect the purchasing power in countries.

Voluntary licensing agreements – by which companies with patented medicines offer licences to other manufacturers based in developing countries if they are able to produce the same quality medicines at a lower cost.

Competition between suppliers to reduce prices – in which the existence of different products in the same therapeutic category allows for competition between manufacturers, or the absence of a patent or the issuance of a compulsory licence permits the use of generics.

Regional and sub-regional procurement – in which groups of countries or regions collaborate to purchase larger volumes of drugs, and thereby benefit from further discounts.

Reinforcing and using health safeguards in trade agreements – in which national authorities are aware of the flexibility provided by international agreements such as TRIPS, including the option in certain circumstances – national emergency or for public non-commercial use, for example – to issue compulsory licences for the manufacture or importation of drugs that would otherwise be protected by patent.

New funding mechanisms – in which new sources of public and private sector funding are identified and much greater resources are generated to help pay for

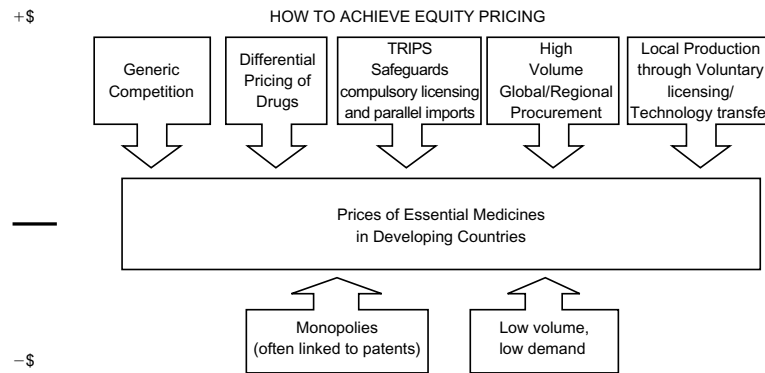


Fig. 4. Equity prices for antiretroviral drugs. TRIPS, World Trade Organization agreement on trade-related aspects of intellectual property rights. Source: UNAIDS.

treatment which, even at the lowest prices, will otherwise still be out of reach of many of the poorest PLWHA.

One strong conclusion that can be drawn from this review is that under the right circumstances and with sufficient political commitment, developing countries can provide quality care for PLWHA. Whereas coverage in the region is far from complete, Brazil and other countries in the LAC region have made the case for ART being made available to all PLWHA. The challenge remains to build on the example from these countries and make ART available to those in need, regardless of where they live.

A second conclusion from this review is that drug costs for ART have dropped considerably in the past 4 years. However, the review also identified the wide disparities that exist between countries regarding accessibility to the drugs at these reduced prices. The challenge remains to build the funding mechanisms that ensure access to drugs for ART at affordable prices for all in need.

A final conclusion is that, by working to ensure ART for those in need, countries can also benefit in their prevention efforts. By providing ART to those in need, people are more willing to be tested, links are built to vulnerable and marginalized populations, and the stigma and denial that often hinder the fight against HIV/AIDS are reduced. The challenge remains to expand these benefits, which until now have been reserved for a few, to all those in need.

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