Accelerating Access Initiative

Widening access to care and support for people living with HIV/AIDS

PROGRESS REPORT, JUNE 2002

WORLD HEALTH ORGANIZATION

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Acronyms and Abbreviations

Acronyms

AIDS	acquired immunodeficiency syndrome
ARV	antiretroviral
CARICOM	Caribbean Community
ECOWAS	Economic Community of Western African States
HAART	highly active antiretroviral therapy
HIV	human immunodeficiency virus
MAP	Multi-Country HIV/AIDS Programme for Africa
MTCT	mother-to-child transmission (of HIV)
NGO	nongovernmental organization
TB	tuberculosis
UN	United Nations
UNAIDS	United Nations Joint Cosponsored Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNGASS	United Nations General Assembly Special Session on HIV/AIDS
UNICEF	United Nations Children's Fund
WHO	World Health Organization

Drug abbreviations

ABC	abacavir
APV	amprenavir
d4T	stavudine
ddC	zalcitabine
ddI	delavirdine
EFZ	efavirenz (also abbreviated as EFV)
IDV	indinavir
LPV	lopinavir
NFV	nevirapine
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor
NRTI	Nucleoside Reverse Transcriptase Inhibitor
PI	protease inhibitor
RTV, r	ritonavir
RTV-PI	ritonavir boosted protease inhibitor
SQV	saquinavir
TDF	tenofovir disoproxil fumarate
ZDV	zidovudine (also known as AZT)

Executive Summary

The World Health Organization (WHO) and Joint United Nations Programme on HIV/AIDS (UNAIDS) estimate that in 2001 about 3 million people died from AIDS, with the vast majority of these deaths occurring in developing countries. While the availability of antiretroviral (ARV) therapy has significantly reduced AIDS morbidity and mortality in the industrialized world, in developing countries, where 95% of HIV-positive people live, the overwhelming majority of HIV-positive people do not have access to these life-sustaining medications.

WHO conservatively estimates that in 2002, around 6 million people in developing countries are in need of ARV therapy. Yet only about 230,000 people living with HIV in those countries have such access today. Half of these live in one country, Brazil.

Access to medicines is dependent on their rational selection and use, the availability of financial resources, the strength of the health infrastructure and their affordability. As the high cost of medicines is a major factor limiting access to ARVs in developing countries, in May 2000 five UN organizations (the United Nations Population Fund [UNFPA], United Nations Children's Fund [UNICEF], World Health Organization [WHO], World Bank and UNAIDS Secretariat) entered into a partnership offered by five pharmaceutical companies (Boehringer Ingelheim GmbH; Bristol-Myers Squibb; GlaxoSmithKline; Merck & Co., Inc.; and F. Hoffmann-La Roche Ltd. – later joined by Abbott Laboratories) to address the lack of affordability of HIV medicines and to work together to increase access to HIV/AIDS care and treatment in developing countries.

Since the launch of Accelerating Access in May 2000, 80 countries have expressed their interest in the Initiative. In 39 of these countries, national plans to improve access to care have been or are being developed. These plans have been used as a framework for dialogue with the pharmaceutical companies, and as a consequence, 19 countries (Barbados, Benin, Burkina Faso, Burundi, Cameroon, Chile, Republic of the Congo, Côte d'Ivoire, Gabon, Honduras, Jamaica, Mali, Morocco, Romania, Rwanda, Senegal, Trinidad and Tobago, Uganda, and Ukraine) have concluded agreements for the supply of their ARV drugs with individual companies participating in the Initiative. In each of these countries the pharmaceutical companies involved, acting independently, have significantly reduced the cost of their drugs. In addition, several companies have also made their drugs available at reduced cost to governments, nongovernmental organizations (NGOs), private sector employers and health care organizations outside the framework of the Accelerating Access Initiative. In May 2002, two major groups of countries coalesced to engage in negotiation with the individual pharmaceutical companies, with WHO and UNAIDS support, through the Accelerating Access Initiative. These are the Economic Community of Western African States (ECOWAS) and the Caribbean Community (CARICOM). Formal statements of intent between ECOWAS and CARICOM, respectively, and the companies, are expected to be signed in July 2002.

The 19 countries that have concluded supply agreements within the Accelerating

Since the launch of Accelerating Access in May 2000, 80 countries have expressed their interest in the Initiative.

Access Initiative have all moved to waive import taxes and duties on drugs used in HIV/AIDS treatment, and some countries introduced generic ARV drugs in the treatment of HIV infection at competitive prices – in one instance for as low as US$295 for a year's treatment with a first line triple ARV therapy regimen.

As of December 2001, the cost of ARV drugs offered individually by the pharmaceutical partners in the Accelerating Access Initiative for the least developed countries had decreased significantly, in some cases to 10–20% of their price in industrialized countries. About 27 000 people had gained access to ARV therapy in the 19 countries in Africa, Eastern Europe, and Latin America and the Caribbean that had concluded supply agreements within the Accelerating Access Initiative framework. This represents a nearly 10-fold increase in the number of patients treated in those countries.

In addition, the public offer of lower prices led to an increased uptake of ARVs in Africa outside the Accelerating Access Initiative framework. In Africa, the six companies involved in the Initiative had supplied treatment to more than 35 500 people as at the end of March 2002, part within and part outside the Accelerating Access Initiative countries. Their data also show that in Africa the proportion of patients on triple combination therapy up to that time increased from one third to nearly two thirds, which indicates a concomitant increase in the quality of ARV treatment.

While this is significant progress, these numbers represent only a fraction of those in need of ARVs. The failure to reach more people with ARV therapy in resource limited settings reflects the persisting limited availability of funding for medicines, diagnostics and infrastructure, as well as continued lack of affordability in many countries. Despite the major reductions in ARV prices, the annual cost of ARV treatment for a person living with HIV still exceeds the annual per capita gross domestic product of many least developed countries. Thus, procurement of ARVs solely through domestic financing remains almost impossible in many countries. While far greater investments in health and social services infrastructure are needed to expand access to treatment on a massive scale, many countries have underutilized health system capacity that, but for lack of financing and affordability, could be used to expand treatment today.

Despite the major reductions in ARV prices, the annual cost of ARV treatment for a person living with HIV still exceeds the annual per capita gross domestic product of many least developed countries.

In spite of the limited number of patients treated to date, however, the Initiative has contributed significantly to overcoming the inertia surrounding treatment access in developing countries. A marked shift has occurred in perceptions of how the HIV epidemic can be tackled. The Declaration of Commitment by the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS reflects this shift, recognizing that care for people living with HIV/AIDS is an integral part of the fight against AIDS, and making specific mention of ARV therapy as an important element of comprehensive care.

This increased recognition of care as an important element of the fight against AIDS is reflected in several recent important developments. Supporting access to treatment is a central part of the agenda of the recently established Global Fund to Fight AIDS, TB and Malaria (the Global Fund). HIV/AIDS accounted for more than 60% of the funding committed following the first round of proposal submissions in April 2002. Total funding committed over two years in this round of proposals, for AIDS, TB and malaria prevention and treatment programmes, amounts to US$616 million. Of the 28 countries that will receive funds to fight HIV/AIDS, 21 have grants that specifically include funding to purchase ARV treatments for people living with HIV/AIDS. In addition, the World Bank's Multi-Country HIV/AIDS Programme for Africa (MAP), initiated in 2001, recently decided to re-emphasize support for HIV/AIDS care and treatment as part of its eligible activities.

Introduction

The World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) estimated that at the end of 2001, more than 40 million people were living with HIV/AIDS worldwide. More than 28.1 million were in sub-Saharan Africa, a region that accounts for about 2.3 million of the estimated 3 million adult and child deaths related to AIDS in 2001. In addition, more than 20 million lives have been lost to AIDS since the start of the epidemic in the early 1980s.

This death toll could have been lower if highly active antiretroviral therapy (HAART), which was introduced for the treatment of HIV in 1996, had been available more widely. Everywhere HAART was introduced, spectacular improvements in the treatment of HIV patients ensued, dramatically reducing mortality among treated patients by about 70% and improving their quality of life. Where HAART was introduced, it changed the perception of HIV/AIDS from a death sentence to that of a manageable chronic illness.

However, in many developing countries, people living with HIV/AIDS do not have access even to basic treatment for opportunistic infections, or to palliative care. The injustice of this treatment gap led to a wide movement for treatment access, led by people living with HIV and by civil society.

In 1998, the UNAIDS Secretariat, with several pharmaceutical partners, introduced the Drug Access Initiative which explored the feasibility of a structured introduction of price-reduced ARV therapy in a range of developing countries. The Drug Access Initiative which established that antiretroviral (ARV) therapy could be safely and effectively used, even in the least developed countries, led to the first differential pricing for ARVs in developing countries, and demonstrated that diversion of price-reduced drugs could be limited. A first evaluation of its activities published in March 2000 found, however, that in the pilot projects the price of the drugs was the main obstacle to expanding drug access up to the maximum capacity of the pilot centres. This led the UNAIDS Secretariat and the managers of the Drug Access Initiative in Uganda and Côte d'Ivoire to explore whether the drugs could be obtained more cheaply, first from the research-based companies that were partners in the initiative, and later from generic manufacturers. Further action was also prompted by public information about prices of locally produced ARVs in Brazil and Thailand.

Building on this experience, five UN organizations (the United Nations Population Fund [UNFPA], United Nations Children's Fund [UNICEF], World Health Organization [WHO], World Bank and UNAIDS Secretariat) entered in a partnership offered by five pharmaceutical companies (Boehringer Ingelheim GmbH; Bristol-Myers Squibb; GlaxoSmithKline; Merck & Co., Inc.; and F. Hoffmann-La Roche Ltd.) in May 2000, joined later by Abbott Laboratories Inc. The present paper reports on the progress achieved through this partnership.

Where HAART was introduced, it changed the perception of HIV/AIDS from a death sentence to that of a manageable chronic illness.

Aims of Accelerating Access

The objective of the Accelerating Access Initiative is to make HIV/AIDS drugs more affordable and accessible in developing countries...

The Accelerating Access Initiative was set up to explore practical and specific ways of working together more closely to accelerate access to HIV/AIDS-related care and treatment in developing countries.

The objective of the Accelerating Access Initiative is to make HIV/AIDS drugs more affordable and accessible in developing countries and to improve technical collaboration in the development of national programme capacities to deliver care, treatment and support.

The partners in the Initiative agreed to a Joint Statement of Intent (see Annex 1), which sets out the expected benefits of the Initiative, as follows:

- for people in developing countries, to accelerate their sustained access to, and increase their use of, appropriate, good quality interventions for the prevention, treatment and care of HIV/AIDS-related illnesses, and the prevention of perinatal transmission of HIV;
- to ensure that care and treatment reach significantly greater numbers of people in need, through new alliances involving committed governments, private industry, the UN system, development assistance agencies, non-governmental organizations (NGOs) and people living with HIV/AIDS; and
- to implement public-private co-operation in ways that respond to the specific needs and requests of individual countries, with respect for human rights, equity, transparency and accountability.

The following fundamental principles underlie the Initiative:

(i) unequivocal and ongoing political commitment by national governments is essential for success;
(ii) strengthened national capacity is crucial for delivering care and treatment on an equitable basis;
(iii) engagement of all sectors of national society and the global community is essential in facilitating access to treatment;
(iv) efficient, reliable and secure distribution systems are necessary to ensure that medical supplies and other consumables are made available to people who need them;
(v) significant additional funding from new national and international sources is necessary for long-term success; and
(vi) continued investment in research and development by the pharmaceutical industry on innovative new treatments for HIV/AIDS is critical to expanding the global response to HIV/AIDS. Therefore, intellectual property rights should be protected, in compliance with international agreements, since society depends on them to stimulate innovation.

How the Initiative Works

At global level, the Accelerating Access Initiative was structured in three working groups: (i) country support (in which, in addition to the pharmaceutical companies, the UNAIDS Secretariat, UNICEF and WHO participated); (ii) communications (in which all partners participated); and (iii) procurement (in which the UNAIDS Secretariat, UNFPA, UNICEF and WHO participated).

Following the announcement of the Accelerating Access Initiative, governments were informed about the Initiative through the UN Theme groups on HIV/AIDS, which is the co-ordinating mechanism in countries for UN action on AIDS at the national level. Governments were offered UN input in their planning of care and support for people living with HIV/AIDS and requested to signify their possible interest in the Accelerating Access Initiative to the Executive Director of UNAIDS, who then ensured that the country was approached by UN staff participating in the country support working group. The latter explored the intent of the government, and then organized support to the government for the development of a plan for access to ARV drugs while promoting comprehensive care and informing the government about all procurement options, including information on the availability and cost of generic ARVs. After finalization, with approval of the government, the plan for access to ARV drugs was transmitted by the UN to those pharmaceutical companies with which the government wished to open discussions on prices and transactions. The discussions involved representatives of the government and individual pharmaceutical companies, and were facilitated by the UN staff in the country support working group. As regional and sub-regional collaborations developed, at the initiative of governments, the same procedure was used to ensure they were technically supported.

At global level, there was regular consultation with the stakeholders in the Accelerating Access Initiative, including governments and NGOs, through the establishment of the Contact Group on Accelerating Access to HIV/AIDS-related Care. The Contact Group provided a forum for consultation and exchange of views on the Initiative, as well for a regular update on progress (Box 1).

Box 1 **Contact Group — Accelerating Access to HIV/AIDS related care**

The Contact Group provides a forum for representatives of governments, people living with and affected by HIV/AIDS, NGOs and other parties, including the pharmaceutical industry. Through this, they can exchange information and views, engage in consultation and articulate needs and expectations, especially those emanating from governments, and provide advice and guidance to the UNAIDS Secretariat, WHO, UNICEF, UNFPA and the World Bank on principles, policy and practice that will apply to the Accelerating Access Initiative.

The discussions in the Contact Group are intended to ensure a well-informed co-ordinated, participatory and transparent approach to the Initiative.

The Contact Group is convened by the UNAIDS Secretariat and Co-sponsors and established by the Chair of the UNAIDS Programme Coordinating Board (PCB), in consultation with the UNAIDS Secretariat and members of the PCB.

The procurement working group defined various options for procurement[1] for pharmaceuticals that the Initiative might pursue. Unfortunately, the partners were unable to agree initially on an option other than individual country-by-country negotiation, which proved a labour-intensive and time-consuming process.

[1] Such options included procurement by individual countries or organizations within countries, pooled procurement by countries or organizations, including on a regional basis, and procurement through a central global agent.

Achievements

Increasing access

At present, of the 80 countries that have expressed interest in the Accelerating Access Initiative, 39 countries have developed plans of action for HIV/AIDS care. These plans have been used as a framework for dialogue with pharmaceutical companies and have led to successful UN-brokered supply agreements for ARVs in 19 out of the 22 countries that initiated and finalized such discussions. The countries where UN-brokered supply agreements were concluded and are now in effect include Barbados, Benin, Burkina Faso, Burundi, Cameroon, Chile, Republic of the Congo, Côte d'Ivoire, Gabon, Honduras, Jamaica, Mali, Morocco, Romania, Rwanda, Senegal, Trinidad and Tobago, Uganda, and Ukraine. The governments of three countries (Ethiopia, Kenya, and Swaziland) opted for a care agenda that does not include ARVs after a first planning round with the UN, and, while price reductions are available in their private sectors, have so far not initiated discussions with the pharmaceutical companies themselves (Annex 2).

In addition, in May 2002, two major groups of countries coalesced to engage in negotiation with the individual pharmaceutical companies, with WHO and UNAIDS support, through the Accelerating Access Initiative. These are the Economic Community of Western African States (ECOWAS) and the Caribbean Community (CARICOM). Formal statements of intent between ECOWAS and CARICOM, respectively, and the industry companies are expected to be signed in July 2002. Fifteen Caribbean countries and 15 West African countries are involved in these regional discussions.

In the first 19 countries in Africa, Eastern Europe, and Latin America and the Caribbean to conclude supply agreements, as of December 2001, about 27 000 people had gained access to ARV therapy, representing an almost 10-fold rise in the number of patients treated.

Reduced prices

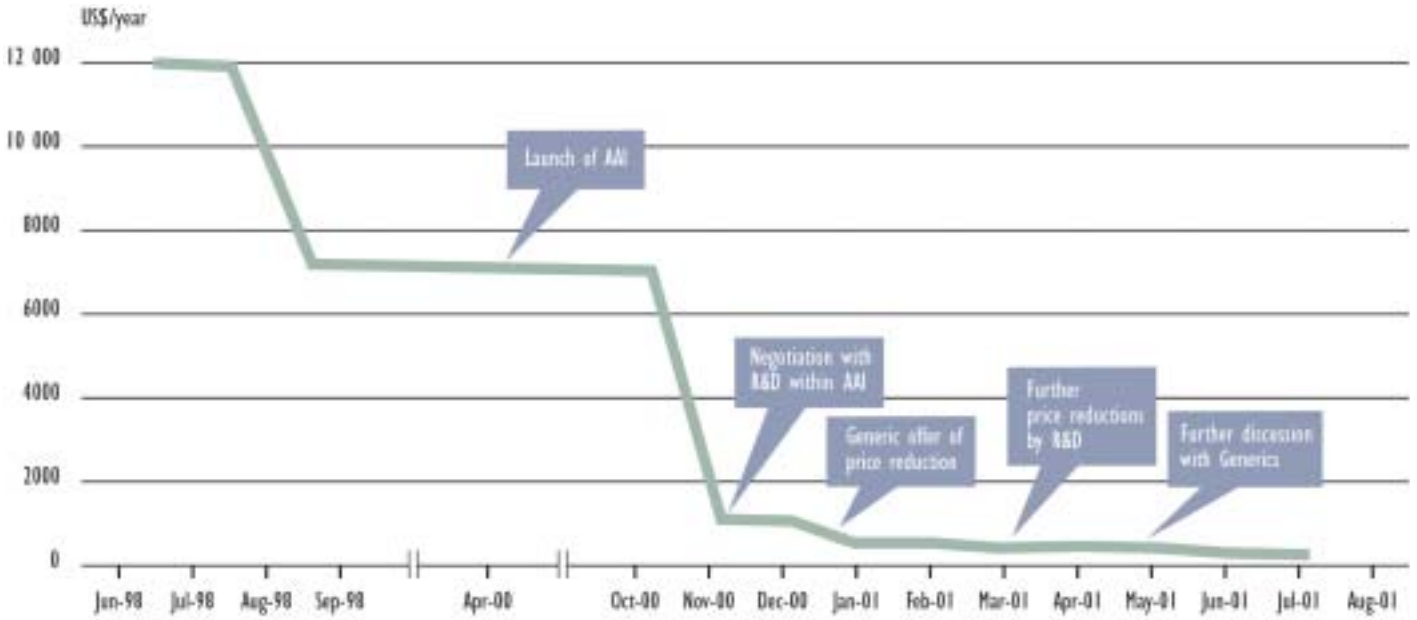
Achieving lower prices for ARVs has been a significant achievement of the Accelerating Access Initiative, as affordability is a fundamental starting point for increasing access.

When HAART was introduced in 1996, conventional wisdom held that it would remain financially and logistically beyond the reach of most HIV-positive people in developing countries for the foreseeable future. The Accelerating Access Initiative changed this perception: within months the cost of ARV drugs offered individually by the pharmaceutical partners in the Accelerating Access Initiative for the least developed countries decreased, in some cases to 10–20% of their price in industrialized countries. Emerging competition from generic manufacturers for some drugs also was a critical factor, in particular on the cost of first line regimens that do not include protease inhibitors, as illustrated by the evolution of the price of a first line ARV regimen in Uganda (Figure 1 overleaf).

However, the Accelerating Access Initiative for the first time brought about transparent differential pricing for ARVs

Achieving lower prices for ARVs has been a significant achievement of the Accelerating Access Initiative.

Figure 1 **Price reductions of a first line ARV regimen in Uganda**



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in the least developed countries, and led to the first significant move in transacted prices in its target countries and beyond, on the African continent. Mainly as a consequence of this transparent pricing policy, Africa was able to significantly increase the number of people treated, both within and outside the framework of UN brokered supply agreements within the Accelerating Access Initiative. According to estimates compiled on behalf of the six companies involved in the Accelerating Access Initiative, about 35 500 people in Africa were being treated with ARVs supplied by the six companies by the end of March 2002, a four-fold increase in 18 months. In addition, the data show that the proportion of patients on triple combination therapy over that period increased from one third to nearly two thirds, which indicates a concomitant increase in the quality of ARV treatment.

Annex 3 gives an overview of sales in Africa by the companies that participate in the Accelerating Access Initiative. The cost of ARV drugs supplied by the research-based companies in agreements brokered under the Accelerating Access Initiative, is given in full in Annex 4. It should be noted that none of these supply agreements contain undue restrictions. They are typically concluded for a period of one year, but leave the buyer the option to buy from other (i.e., generic) supply sources, consistent with regulatory requirements and international agreements.

Announcements of price reductions continue to be made, the most recent being Abbott Laboratories' announcement of 19 June 2002 of additional price reductions for its anti-HIV drugs lopinavir / ritonavir and ritonavir. The UN will continue to press for further decreases where possible, while recognizing that the policy of most companies is to cover the costs of production. The UN will also continue to press for increased transparency and access to a wider formulary. While prices in Africa are transparent now, in countries outside Africa lack of transparency continues to hamper price comparisons, which holds up the ability of those in charge of treatment programmes to agree on some of the proposed supply agreements. Also, as is evident from the table in Annex 4, supply agreements concluded under the Accelerating Access Initiative between

countries and the individual pharmaceutical companies outside Africa cover only 11 drugs out of the 17 offered by the companies participating in the initiative, as country dialogues do not yet involve all companies.

Mobilization for care

The demands of treatment activists and civil society for equitable access to HIV care have been a major factor in drawing world attention to the gap in treatment accessibility. With reduced prices, perceptions about the feasibility of providing care to all those who need it have dramatically changed. The inertia surrounding action on HIV/AIDS care could be rationalized when prices were far beyond the reach of people in developing countries.

But when the price of a first line regimen fell from US$10 000 to around US$350 a year during the course of two years, people living with HIV/AIDS in developing countries could see that the medicines and drugs they needed were almost within their reach. As is evident from the UNGASS commitments on care, the international community has responded to this convergence of forces, committing to provide care including ARV therapy to those in need.

Without the greatly reduced prices of ARVs in the least developed countries brought about through the Accelerating Access Initiative, and the significant media coverage that ensued, the unwavering resolve of civil society to address the disparity between treated and untreated might have continued to meet resistance from the international development community. Instead, the perception that care is now possible changed the direction of major international commitments, as reflected, for example, in The Plan of Action that came out of the African Development Forum organized by the Economic Commission for Africa (ECA) in Addis Ababa, in December 2000; in the Abuja Declaration on HIV/AIDS, Tuberculosis and other related Infectious Diseases issued by Organization of African Unity (OAU) Heads of State in April 2001; and in the Declaration of Commitment on HIV/AIDS adopted at the UN Special Session on HIV/AIDS (UNGASS) in June 2001. The inclusion of the possibility of purchasing ARV drugs within the scope of the Global Fund to Fight AIDS, TB and Malaria, included in the Framework Agreement of the Fund and demonstrated in concrete terms in the first round of grants, and the availability of World Bank financing for care and treatment, is further evidence of the changed attitude of donors to financing the purchase of ARVs.

Taxes and duties

All 19 countries that entered supply agreements for ARVs in the Accelerating Access Initiative have moved to eliminate or waive import taxes and duties on drugs used in HIV/AIDS treatment.

Other results

In addition to offering reduced-price medicines, several companies have continued or expanded their support for the training for health care professionals, strengthening health infrastructure and capacity.

Boehringer Ingelheim GmbH has offered nevirapine free of charge to developing countries for the prevention of mother-to-child transmission (MTCT) of HIV, and Abbott Laboratories joined this effort in June 2002 with an offer of free rapid tests for MTCT programmes.

With reduced prices, perceptions about the feasibility of providing care to all those who need it have dramatically changed.

Limitations

Too few patients benefit

WHO estimates that, overall, only about 230 000 people have access to ARV therapy in low- and middle-income countries (half of them in Brazil alone), while about 6 million are estimated to be in need. Building on the commitments made at UNGASS in June 2001, WHO advocates that at least 3 million people in need should be on ARV drugs by 2005.

Measured against this scale of need, the number of beneficiaries of the Accelerating Access Initiative remains disappointingly low. The reasons for this are many. The failure to reach more people with ARV therapy in resource limited settings reflects the persisting limited availability of funding for medicines, diagnostics and infra-structure, as well as continued lack of affordability in many countries.

Despite the major reductions in ARV prices, the annual cost of ARV treatment for a person living with HIV still exceeds the annual per capita gross domestic product of many least developed countries.

Thus, procurement of ARVs solely through domestic financing remains almost impossible in many countries. However, the weakness of health systems in developing countries is also a major constraint. Voluntary counselling and testing for HIV infection is, for example, not widely available, and staff to prescribe and supervise treatments are in short supply in most developing countries.

WHO estimates that, overall, only about 230 000 people have access to ARV therapy in low- and middle-income countries.

Lack of funding and resources

Various financial mechanisms have been utilized by countries with supply agreements under the Accelerating Access Initiative framework. These range from out-of-pocket payment by individual patients to full government subsidy involving national subsidy schemes, revolving funds, work-based schemes, private insurance, debt relief, and bilateral and multilateral aid. So far only a few countries, including Barbados, Chile, Gabon, Morocco, Romania, and Trinidad and Tobago, have been able to commit to fully subsidize the cost of ARV therapy. The other 13 countries with supply agreements in place could not do so for lack of funding.

A number of recent global resource mobilization developments opens the way for greater progress in funding increased access to care. In particular, the establishment in January 2002 of the Global Fund to Fight AIDS, TB and Malaria as a result of concerted action by a wide range of stakeholders, including bilateral donors, the UN system, civil society and the private sector offers a major opportunity to scale up HIV/AIDS care and support treatment. The Fund explicitly includes provision for drugs and medicines, including ARVs, within its scope. The first round of grants announced by the Global Fund in April 2002 commits a total of US$616 million in grants (for all

three diseases) for two years for programmes in more than 30 countries. About 60% of the first two years of funding will go to HIV/AIDS programmes, and 21 countries will use part of these funds to purchase ARVs.

The World Bank's Multi-Country HIV/AIDS Programme for Africa (MAP), initiated in 2001, is providing support for HIV/AIDS prevention, care and treatment programmes, with an emphasis on vulnerable groups, by assisting governments, communities and civil society organizations in Africa as they implement national multi-sectoral HIV/AIDS strategies. About US$400 million a year in concessional lending, with a corresponding grant value of US$275 million–300 million, is projected through 2005. A similar initiative is under way in the Caribbean. Totalling US$155 million, the Multi-Country HIV/AIDS Prevention and Control Project for the Caribbean works as a five-year loan programme that allows countries to obtain separate loans or credits to finance their national HIV/AIDS prevention and control projects. By April 2002, about US$40 million had been allocated to projects, including treatment access, in Barbados and the Dominican Republic. Several Caribbean countries have agreed that parts of these loans may be assigned to the purchase of ARV drugs. Barbados is the first country that has met the required criteria and drawn on these funds to finance ARV access. The second phase of MAP will more directly address treatment access.

Mobilizing more resources to scale up access to HIV care is a major priority for the UN system. It is estimated that about US$2 billion a year is needed to reach the WHO target of treating 3 million people with ARVs by 2005.

UN capacity

One of the disadvantages of the country-by-country approach adopted by the Accelerating Access Initiative is that it has been relatively slow and labour intensive. The resources of the UN system have consequently been stretched to respond to the demands for assistance from countries to participate in the Accelerating Access Initiative. In some cases, the UN has not been able to respond positively to requests from countries in a timely manner, and resources have not been available to provide technical support once supply agreements had been reached.

In order to increase the human resource base serving the Initiative, 60 consultants were briefed on the Initiative and used to assist countries with their planning. The transfer of the responsibility for technical assistance for the Initiative from the UNAIDS Secretariat to WHO, in November 2001, will also increase capacity. At the time of writing, four regional offices of WHO (AFRO, PAHO, SEARO and WPRO) have assigned full-time staff to access to care, and two regional offices (EMRO and EURO) are building up networks of experts to support planning at country level. National professional officers dealing with essential drugs in the offices of WHO representatives in anglophone and francophone Africa have also been trained and will help out in the future, and similar training is foreseen in collaboration with PAHO. National HIV focal points in WHO offices in Africa will be the next group of trainees.

Box 2 **Funding mechanisms**

A variety of financial mechanisms has been put in place to provide care and support to a larger number of people living with HIV/AIDS in the countries where the Accelerating Access Initiative led to supply agreements. Some governments are devoting increased public funds towards prevention and care. For example:

- Côte d'Ivoire, Cameroon, Gabon, Mali, Morocco and Senegal are allocating funds to subsidize access to ARVs to people who are unable to afford the drugs.
- Burundi and Rwanda have established a revolving fund dedicated to the procurement of HIV medicines to allow continuous purchasing of drugs.
- Cameroon and Mali have converted part of their debt relief proceeds into a fund for care and treatment.
- Some governments have invited private companies to subsidize access to drugs for their employees and families.

Through the Accelerating Access Initiative, various public and private health providers in developing countries have accessed ARV drugs and gained some experience with their use.

Regional approaches offer an opportunity to decrease the demand for technical support and increase its efficiency. Recently, progress has been marked in developing regional approaches in the Caribbean and in Western Africa. During the last World Health Assembly in May 2002, CARICOM and ECOWAS met representatives of the pharmaceutical industry, and agreed to work on further reduction of prices within regional approaches. Such regional initiatives offer the possibility of bulk purchasing, shared technical assistance and joint resourcing, and thus can significantly expand the benefits of increased access to care.

Capacity building

Through the Accelerating Access Initiative, various public and private health providers in developing countries have accessed ARV drugs and gained some experience with their use. Generally, however, this experience was not supported by nationally-developed ARV management guidelines.

The Initiative aims to support capacity, but places the responsibility for it with countries, as there are no funds in the Initiative for this purpose.

The constraints on capacity building, parallel to those for access to drugs, have meant that little capacity building has occurred.

Monitoring

Reports on progress with Accelerating Access Initiative have been presented regularly, at the Contact Group and at other relevant consultations, by key partners in the Initiative. A structured framework for systematically collecting and presenting data on the Initiative's performance has not yet been developed. WHO and the UNAIDS Secretariat have developed indicators for a wide range of care activities, with a large number of institutional partners. These indicators are now being pilot tested in Cambodia, Ethiopia and Kenya. They will be used within the framework of second generation surveillance of the HIV epidemic, and could also be applied in the evaluation of the Initiative.

Focus on governments

A limitation of the Accelerating Access Initiative has been the tendency to work mainly with ministries of health in countries. The intention to engage other important partners has not always been met. NGOs and large employers are key points of entry for ARVs. In the interests of inclusiveness and efficiency, all people and organizations at country level need to feel empowered to support treatment access. This shortcoming will be tackled increasingly in the future, mainly through wider partnerships.

Lack of promotion of generic pharmaceutical partners

During the course of the past two years, the collaboration in the Accelerating Access Initiative has been focused largely on the six research-based pharmaceutical companies and the UN. While the Initiative has been open to generics companies, with some countries accessing generic ARVs, and while a representative of the generics industry recently joined the Contact Group, greater efforts must be made to support generic competition (consistent with international agreements) and to engage generic producers.

Related Activities

The Accelerating Access Initiative is not the only UN activity supporting access to care for people living with HIV/AIDS.

The potential impact of patents and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) on access to medicines has been a continuing concern for the WHO and the UNAIDS Secretariat. WHO and UNAIDS have played pivotal roles in raising awareness about the potential impact of the TRIPS Agreement on access to medicines. For an overview of these concerns the reader is referred to the document *Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement* published in 1998, and one of the 128 publications on this topic by the WHO since 1998, as well as the statements of WHO and UNAIDS at the World Trade Organization (WTO) Ministerial Conference in Seattle (1999) and Doha (2001), available on their respective websites.

As access to HIV drugs has been one of the main concerns in the debate around the interpretation of the TRIPS Agreement, WHO published, supported by the UNAIDS Secretariat, a study on the patent situation of HIV-related drugs in 80 countries in 1999, which will be updated in 2002–2003. This document provides important information for the procurement of the drugs considered in the study.

In December 2000, the UN system released a call for expressions of interest from manufacturers committed to providing HIV/AIDS products at differential prices to developing countries. This call has been repeated twice since then. The data collected through this process have been used for two purposes: first, to document the existence of supply sources of medicines of interest to people living with HIV/AIDS that are difficult to find on the international market; and second, in an effort to improve the quality of the drugs considered. The annual survey of *Sources and Prices of Selected Medicines and Diagnostics for People Living with HIV/AIDS*, produced by UNICEF, WHO, the UNAIDS Secretariat and Médecins-Sans-Frontières, which provides market information to help procurement agencies make decisions on the source of drugs and to help them negotiate better prices, is one of the outputs of this effort. The 2002 edition of this survey was due to be launched during the International Conference on AIDS in Barcelona in July 2002.

A second output is prequalification of those manufactures that provided detailed information on the quality of their products and whose production facilities successfully pass an inspection site visit. A first list of prequalified products and suppliers was published in April 2002.

A further output is the production of generic quality standards for ARVs. For most ARVs, such standards are not available in the public domain, and this impedes the ability of quality assurance laboratories to provide independent certification of the quality of the products they test.

An important step towards reversing common misperceptions about the complexity of ARV treatment was the publication by WHO in April 2002 of *Guidelines for Scaling Up Antiretroviral Therapy in Resource Limited Settings*. This guidance on the rational selection and use of ARV drugs in resource limited settings acknowledges the relative

WHO and UNAIDS have played pivotal roles in raising awareness about the potential impact of the TRIPS Agreement on access to medicines.

complexity of HIV treatment but addresses the need to scale up treatment by presenting a framework for selecting the most potent and feasible ARV regimens as part of an expanded national response. The framework aims to standardize and simplify ARV therapy, without compromising the quality and outcomes of the treatment offered, presenting options for first and second line regimens that bear in mind that health systems in resource poor settings often lack sophisticated personnel and monitoring facilities. WHO is promoting the wide acceptance of these guidelines and adapting them for different regions. This regional adaptation is ongoing — in South East Asia, the adaptation process by SEARO has been completed; in the Americas, the process by PAHO is almost complete.

The preparation of these guidelines provided an important impetus for the inclusion of 12 ARVs in WHO's Model List of Essential Medicines. The Model List provides an example from which countries can develop their own essential medicines lists, according to their priority health needs. The inclusion of ARVs in the list will facilitate their registration in countries by all producers and their procurement by major distributors of essential medicines. The list is based on a careful analysis of current evidence of ARV efficacy in developing countries, which shows that these medicines can be used effectively and safely in poor settings.

Lessons Learned

After some two years of work on the Accelerating Access Initiative in countries, it has become clear to all partners that increasing access to treatment is a daunting task that has only just begun. Millions of people will need to gain access to ARV therapy in the coming years. WHO advocates that, by 2005, 3 million people should have access to ARVs. A number of lessons have been learned that can further support efforts to scale up access.

First and foremost, access to ARV therapy is possible in resource poor settings. Building on the results of the UNAIDS/WHO Drug Access Initiative, the experience of the Accelerating Access Initiative has further reinforced the feasibility of delivering ARV treatment in developing countries. A number of developing countries have committed themselves to universal access.

Advocacy for access to ARVs facilitates efforts to introduce comprehensive care for people living with HIV/AIDS. For example, Uganda, Côte d'Ivoire and Senegal have introduced national policies for prevention of opportunistic infections along with the introduction of ARVs. National authorities often favour access to ARVs because of their dramatic impact on survival and often link other important care interventions to ARVs.

Clear and transparent information about drug pricing facilitates the development of plans for access to care, fostering predictability of implementation costs and, in turn, greater specificity in fundraising efforts.

Countries are committed to scaling up treatment urgently. At the UNGASS, all UN Member States committed themselves to expanding access to comprehensive care, including ARVs. Within the Accelerating Access Initiative, governments have waived import tariffs and taxes on HIV medicines and mobilized domestic resources to increase procurement.

Although they have decreased significantly in many cases, the prices of ARVs in developing countries remain too high in relation to local purchasing power. Despite the major reductions in ARV prices, the annual cost of ARV treatment for a person living with HIV still exceeds the annual per capita gross domestic product of many least developed countries. Thus, procurement of ARVs solely through domestic financing remains almost impossible in many countries. A massive increase in international financial support for HIV/AIDS care is crucial. While far greater investments in health and social services infrastructure are needed to expand access to treatment on a massive scale, many countries have underutilized health system capacity that, but for lack of financing and affordability, could be used to expand treatment today.

Broader partnerships are essential to scale up access to care. For example, when NGOs dealing with HIV/AIDS were involved in the Accelerating Access Initiative to support treatment preparedness, such as in Morocco, the level of knowledge about and interest in accessing treatment improved considerably. In many countries, NGO advocacy has advanced political commitment to treatment. In some countries, such as Burundi, Côte d'Ivoire, Rwanda and South Africa, employers have supported treatment access among their workforces.

The experience of the Accelerating Access Initiative has further reinforced the feasibility of delivering ARV treatment in developing countries.

Conclusion

We have seen encouraging progress in the past two years and a steady increase in patients receiving ARV treatment through Accelerating Access and related initiatives.

The Accelerating Access Initiative was established in May 2000 to help increase access to HIV/AIDS care and treatment in developing countries.

The Initiative, building on the political commitment of governments, intense treatment advocacy of civil society and earlier UN initiatives, has helped the world to move from inertia to action in working on improving access to HIV care and treatment in developing countries. It has encouraged many countries to think about and plan for expanded efforts in HIV care and support. It has helped all stakeholders concerned with access to HIV/AIDS care and treatment to learn about new possibilities. It has also catalyzed new efforts – by the countries themselves, international donors, private sector enterprises, NGOs, and others – to extend care to more of those living with HIV infection in the developing world.

As a result of Accelerating Access and related efforts, with companies independently entering into discussions with countries and other purchasers, the prices of ARV medicines have declined significantly in developing countries in the past two years. In some cases the prices of these medicines have decreased by more than 90% during this time. These price reductions have acted as a catalyst in stimulating efforts to increase access to ARVs in developing countries. Nevertheless, to date few people have been able to benefit from these price reductions.

While further price reductions will lead to an increase in the number of people on ARV therapy, it is clear that significantly expanding such access will require work on the other barriers to care and treatment too.

This will require two main approaches: unequivocal and ongoing political commitment from national governments; and greater financial resources from national resources and the international community (including the new Global Fund to Fight AIDS, TB and Malaria) to fund the drugs and diagnostics needed, and to strengthen health infrastructure and delivery systems in developing countries. In addition, greater engagement of all stakeholders (including people living with HIV/AIDS and the private sector), guidance on the rational use of treatment, and continued investment in the development of improved medicines will be needed.

Clearly, there is still much more work to be done, given the scope of the challenge. While in absolute terms the numbers are still small, we have seen encouraging progress in the past two years and a steady increase in patients receiving ARV treatment through Accelerating Access and related initiatives.

This experience offers strong hope for the future.

Further Reading

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ANNEX 1

Accelerating access to HIV/AIDS care and treatment in developing countries

A Joint Statement of Intent

Building on the work undertaken by the Joint United Nations Programme on HIV/AIDS (UNAIDS), its Cosponsors and other partners worldwide in responding to the growing demand for care and treatment of HIV/AIDS-related illnesses in developing countries, a new effort is being undertaken to enhance progressively the capacity of countries to increase access to, and use of, sustainable, comprehensive and quality HIV/AIDS interventions across the entire spectrum of prevention, treatment, patient care and support (including prevention of perinatal transmission).

Five pharmaceutical companies — Boehringer Ingelheim GmbH, Bristol-Myers Squibb; Glaxo Wellcome; Merck & Co., Inc.; and F. Hoffmann-La Roche Ltd. — are responding to calls from UN Secretary-General Kofi Annan (in launching the International Partnership against AIDS in Africa, in December 1999); Dr Gro Harlem Brundtland, Director-General of the World Health Organization (in her address to the WHO Executive Board in January 2000), where she invited the pharmaceutical companies to 'take a fresh and constructive look at how we can increase access to relevant drugs', and to the invitations of Dr Peter Piot, Executive Director of UNAIDS, James D. Wolfensohn, President of the World Bank, Carol Bellamy, Executive Director of the United Nations Children's Fund, and Nafis Sadik, Executive Director, United Nations Population Fund, to the private sector to engage in partnerships for expanding the global response to HIV/AIDS.

The five companies have begun constructive discussions with UNAIDS, WHO, the World Bank, the United Nations Children's Fund (UNICEF), and the United Nations Population Fund (UNFPA) to explore practical and specific ways of working together more closely to accelerate access to HIV/AIDS-related care and treatment in developing countries. This endeavour is expected to expand to include other partners from all sectors.

Participants acknowledge that affordability of HIV/AIDS-related care and treatment is an issue in developing countries — though only one among many obstacles to access including social/political/structural and economic issues, healthcare financing, physical barriers, and information gaps — and are willing to work with committed governments, international organizations and other stakeholders to find ways to broaden access while ensuring rational, affordable, safe and effective use of drugs for HIV/AIDS-related illnesses. The companies, individually, are offering to improve significantly access to and availability of a range of medicines.

Intended to benefit people in developing countries, this public/private co-operation

- is designed to accelerate their sustained access to, and increase their use of, appropriate, good quality interventions for the prevention, treatment and care of HIV/AIDS-related illnesses, and the prevention of perinatal transmission of HIV.
- strives to ensure that care and treatment reach significantly greater numbers of people in need, through new alliances involving committed

governments, private industry, the UN system, development assistance agencies, non-governmental organizations (NGOs) and people living with HIV/AIDS.

- will be implemented in ways that respond to the specific needs and requests of individual countries, with respect for human rights, equity, transparency and accountability.

The following principles reflect a common vision of how the HIV/AIDS epidemic can more effectively be tackled in developing countries:

(i) *Unequivocal and ongoing political commitment by national governments* is essential for successful efforts to reduce the impact of HIV/AIDS in line with poverty reduction and broader development strategies.

(ii) *Strengthened national capacity,* including well-designed HIV/AIDS prevention and care strategies and a strengthened health-care infrastructure, is crucial for delivering care and treatment to people with HIV/AIDS on an equitable basis.

(iii) *Engagement of all sectors of national society and the global community* – including governments of developing and industrialized donor countries, international NGOs, industry, other segments of civil society (particularly people living with HIV) and multilateral organizations – is essential in facilitating access to treatment of HIV/AIDS-related illnesses.

(iv) *Efficient, reliable and secure distribution systems* are necessary to ensure that medical supplies and other consumables procured by the public sector or NGOs are made available to people who need them at the appropriate contact points within health systems.

(v) *Significant additional funding from new national and international sources,* commensurate with the health challenges posed by the HIV epidemic, is necessary for long-term success, so that current health and social sector priorities can be maintained.

(vi) *Continued investment in research and development by the pharmaceutical industry* on innovative new treatments for HIV/AIDS and other diseases affecting the developing world – the best hope for new and better future medicines and vaccines – is critical to expanding the global response to HIV/AIDS and to advancing world health. Therefore, intellectual property rights should be protected, in compliance with international agreements, since society depends on them to stimulate innovation.

This public/private co-operation is intended to increase the proportion of people living with HIV/AIDS in the developing world who have safe, equitable, sustained and affordable access to care and treatment. As a practical response to the call for multi-sectoral action in the face of this global health challenge, it is an important step in a longer-term process of increasing the access to care of women, men and children in developing countries. It aims to contribute to the International Partnership against AIDS in Africa, as well as efforts to curb the spread of HIV and mitigate its impact in other continents and, more broadly, to support the international development agenda.

ANNEX 2

Countries that have expressed interest in Accelerating Access (as of March 2002)

Continent	Country	Status
Africa	Algeria	Mission being planned
	Angola	No follow-up yet
	Benin	Plan completed and supply agreements in place
	Botswana	Planning completed, discussions on supply agreements finalized outside the AAI framework
	Burkina Faso	Plan completed and supply agreements in place
	Burundi	Plan completed and supply agreements in place
	Cameroon	Plan completed and supply agreements in place
	Cap Vert	Planning ongoing supported by ECOWAS
	Central African Republic	Plan completed, no supply agreements sought by government at this stage
	Chad	Plan completed, supply agreements partly in place
	Congo	Plan completed and supply agreements in place
	Côte d'Ivoire	Plan completed and supply agreements in place
	Ethiopia	Plan completed, no supply agreements sought by government at this stage
	Gabon	Plan completed and supply agreements in place
	Gambia	Plan completed and discussions on supply agreements awaited
	Ghana	Planning ongoing supported by ECOWAS
	Guinea	Plan completed and discussions on supply agreements awaited
	Guinea-Bissau	Planning ongoing supported by ECOWAS
	Kenya	Plan completed, no supply agreements sought by government at this stage.
	Liberia	Planning ongoing supported by ECOWAS
	Malawi	Plan completed. Discussions on supply agreements ongoing outside the AAI framework
	Mali	Plan completed and supply agreements in place
	Mauritius	No follow-up yet
	Morocco	Plan completed and supply agreements in place
	Niger	Planning ongoing supported by ECOWAS
	Nigeria	Plan completed and discussions on supply agreements awaited
	Rwanda	Plan completed and supply agreements in place
	Sierra Leone	Planning ongoing supported by ECOWAS
	Senegal	Plan completed and supply agreements in place
	Seychelles	No follow-up yet
	Swaziland	Plan completed, no supply agreements sought by government at this stage
	Togo	Planning ongoing supported by ECOWAS
	Tunisia	Plan completed and discussions on supply agreements awaited
	Uganda	Plan completed and supply agreements in place
Mozambique, Namibia, Lesotho, South Africa United Replublic of Tanzania, Zambia, Zimbabwe		These countries are members of SADC and have so far not decided whether to start collaboration with AAI. In some of these countries there is important use of ARVs in the private sector.

Cont'd

Continent	Country	Status
Latin America and Caribbean	Bahamas	Plan completed and supply agreements in place
	Barbados	Plan completed and supply agreements in place
	Belize	No follow-up yet
	Chile	Plan completed and supply agreements in place
	Costa Rica	No follow-up yet
	Guatemala	No follow-up yet
	El Salvador	Plan completed and discussions on supply agreements ongoing
	Honduras	Plan completed and supply agreements in place
	Jamaica	Plan completed and supply agreements in place
	Mexico	Plan completed and discussions on supplies progressing with some companies
	Nicaragua	No follow-up yet
	Panama	No follow-up yet
	Trinidad and Tobago	Plan completed and supply agreements in place
	Venezuela	Plan completed and discussions on supply agreements awaited
Antigua and Barbuda, Dominica, Grenada, Guyana, Haiti, Montserrat, St Kitts and Nevis, St Lucia, St Vincent/Grenadines, Suriname		These countries are members of CARICOM and are planning for access to ARVs on a regional basis
Europe	Georgia	Planning ongoing
	Belarus	No follow-up yet
	Moldavia	Plan completed and opening of discussion on supply agreement awaited
	Romania	Plan completed and supply agreements in place
	Ukraine	Plan completed and discussions on supply agreements ongoing
Asia	China	Planning ongoing
	Indonesia	A final decision whether to pursue improving access to ARVs through AAI is pending
	Malaysia	A final decision whether to pursue improving access to ARVs through AAI is pending
	Thailand	The Thai government opted to continue its planning outside the AAI framework
	Viet Nam	Plan completed, no supply agreements sought by government at this stage
Middle East	Jordan	Follow-up by EMRO started
	Egypt	Follow-up by EMRO started
	Oman	Follow-up by EMRO started
	Lebanon	Plan completed and discussions on supply agreements awaited
	Syria	Follow-up by EMRO started

AAI = Accelerating Access Initiative

ANNEX 3

Estimated numbers of African patients on antiretroviral therapy

Introduction

The Accelerating Access Initiative was established in May 2000 to help increase access to HIV/AIDS care and treatment in developing countries. The Initiative is the first broad-based public / private partnership of its kind. It is a partnership of five United Nations organizations (UNAIDS Secretariat, WHO, UNICEF, the UN Population Fund and the World Bank) and six research-based pharmaceutical companies (Abbott Laboratories; Boehringer-Ingelheim; Bristol-Myers Squibb; GlaxoSmithKline; F. Hoffmann – La Roche; and Merck & Co., Inc.).

In April 2001, the original five Accelerating Access companies, now joined by Abbott Laboratories, announced additional steps to improve access to HIV and HIV-related medicines and diagnostics for poor countries.

The purpose of this interim report is to estimate the number of patients who have been treated with ARVs supplied by the six companies in the countries of Africa, the geographic region most affected by the HIV/AIDS epidemic and the region in which early efforts by the Initiative were concentrated.

Currently, the only available systematic and reliable data for the companies to use to estimate the number of patients treated are the quantity of drug units supplied to the countries. These data, however, are confidential and cannot be shared between companies. For this reason, Axios International, as a third party with experience in the area of HIV/AIDS care in the developing world and operating under an agreement of confidentiality, received and analyzed the data from the companies and compiled results across companies.

Method of analysis

The data provided are either in packs, tablets or grams of active substances supplied each quarter. In addition, many products exist as multiple dosages or pack sizes. For the sake of consistency, a single formula relying on the weight of active drug is applied to convert the figures into an estimated patient number for each quarter.

Once these data are converted into the estimated number of patients for each product per quarter, the data are pooled as follows:

- It is assumed that all patients take at least two Nucleoside Reverse Transcriptase Inhibitors (NRTI) and all patients follow the standard daily dosages. It is further assumed that no patients are taking monotherapy. A proportion of the patients are taking, in addition to their two NRTI's, one Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI) or one Protease Inhibitor (PI). As it is a common practice to combine Norvir® (ritonavir) with Crixivan® (indinavir sulfate) or with Invirase® / Fortovase® (saquinavir) the analysis took this aspect into consideration. The combination of Norvir as a booster to another PI was considered as one PI.
- All NRTI figures for data units (per product and per quarter) were added and pooled and divided by two to

obtain the number of patients on 2 NRTI. Countries are divided by regions. For Africa, four regions are categorized, i.e. North Africa, West Africa, Southern Africa and East Africa. The assumption is that all patients are on at least 2 NRTI. Some are on double combinations with 2 NRTI only and the others are on triple combination 2 NRTI + 1 PI or NNRTI. Hence the final figures of pooled NRTI obtained represent the total estimated number of patients on ARVs.

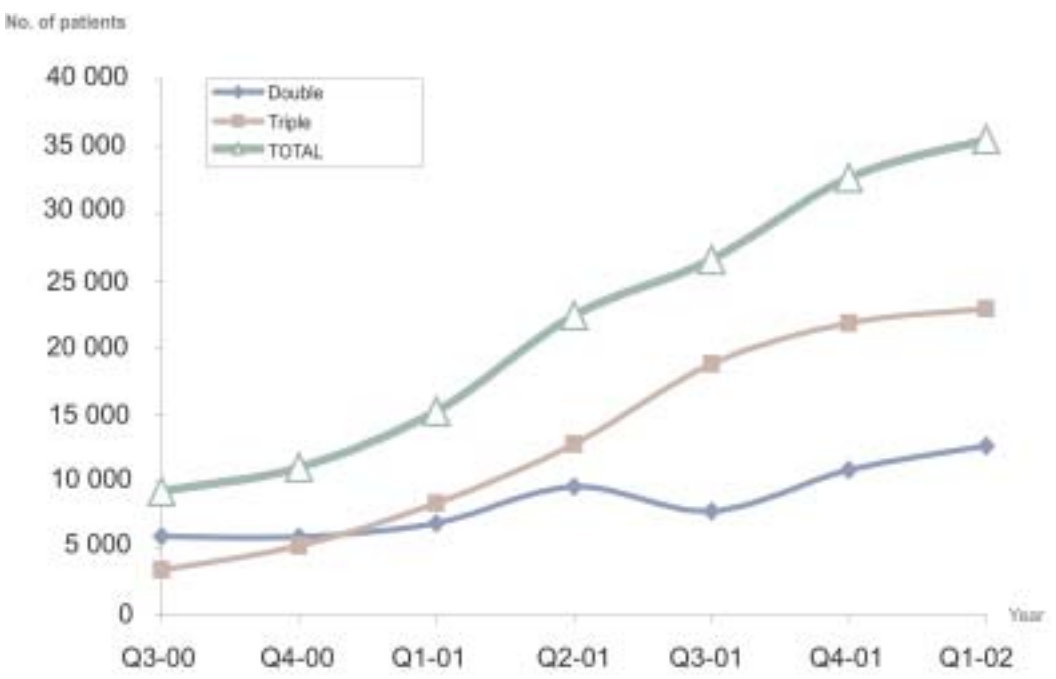
- NNRTI and PI data are then pooled and matched with the NRTI figures. The results are therefore presented per quarter and for the whole of Africa and by region as follows:

  – Total estimated number of patients on ARVs = patients on at least 2 NRTI.
  – Estimated number of patients on double combination of 2 NRTI.
  – Estimated number of patients on triple combination including 2 NRTI+1 NNRTI; 2 NRTI+1 PI.

Table A3.1 **Africa double and triple combination**

Breakdown	Q3-00	Q4-00	Q1-01	Q2-01	Q3-01	Q4-01	Q1-02
Double combination	5887	5866	6863	9616	7792	10 864	12 669
Triple combination	3377	5174	8371	12 788	18 751	21 790	22 882
Estimated number of patients	**9264**	**11 040**	**15 234**	**22 404**	**26 543**	**32 654**	**35 551**

Figure A3.1 **Africa: Estimated number of patients on at least 2NRTI Double and Triple Combination Therapies Breakdown**

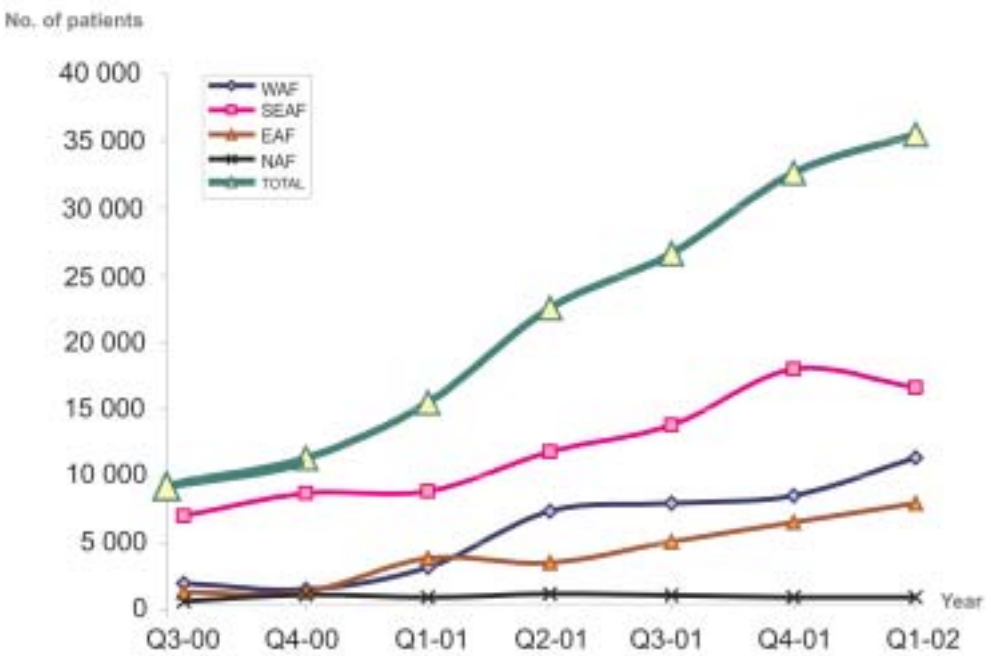


At the end of March 2002, Axios estimates that the six companies involved in Accelerating Access supplied treatment to more than 35 500 people in Africa, a four-fold increase over the past 18 months. In addition, the data show that the proportion of patients on triple combination therapy over that period increased from one third to nearly two thirds, which indicates a concomitant increase in the quality of ARV treatment.

Table A3.2 **Africa by region**

Regions	Q3-00	Q4-00	Q1-01	Q2-01	Q3-01	Q4-01	Q1-02
West Africa	1554	1094	2778	7032	7632	8189	11 064
Southern Africa	6670	8367	8530	11 512	13 549	17 789	16 396
East Africa	866	895	3438	3093	4714	6195	7614
North Africa	174	684	488	767	648	481	477
Estimated number of patients	**9264**	**11 040**	**15 234**	**22 404**	**26 543**	**32 654**	**35 551**

Figure A3.2 **Africa by region**
Estimated number of patients on at least 2NRTI



The figures above show that the East and West Africa regions had the greatest increase in the rate of numbers of patients accessing ARVs. In addition, results for Southern Africa reveal an anomalous observation that the number of patients treated actually decreased between Q4 '01 and Q1 '02. Whether this is due to normal wholesaler/distributor buying patterns (see the similar observation between Q4 '00 and Q1 '01) or to other factors will require further investigation.

Q2 '02 results will be important additions to these trend lines.

Definition of the regions

WAF = West Africa	SAF = Southern Africa	NAF = Northern Africa	EAF = East Africa
Benin	Angola	Algeria	Burundi
Burkina Faso	Botswana	Chad	Djibouti
Cameroon	Lesotho	Egypt	Ethiopia
Central African Republic	Mozambique	Libyan Arab Jamahiriya	Kenya
Congo	Namibia	Morocco	Madagascar
Gabon	South Africa	Tunisia	Malawi
Gambia	Swaziland		Mauritius
Ghana	Zambia		Rwanda
Guinea	Zimbabwe		Seychelles
Ivory Coast			United Republic of Tanzania
Mali			Uganda
Niger			
Nigeria			
Senegal			
Sierra Leone			
Togo			

Limitations

The fact that this analysis was based on drug units supplied and converted into estimated patient numbers implies a number of advantages and limitations compared to formal country surveys.

- The data are collected precisely and consistently as they represent units supplied and data sales. The analysis is therefore underpinned by reliable data.
- The calculated number of patients represents only an estimate of the number of patients treated by ARVs supplied by the six companies in the Accelerating Access Initiative. It does not represent an estimate of the total number of patients treated in Africa as it does not take into account the patients treated with ARVs supplied by other companies.
- It is unlikely that all patients took the exact recommended daily dosages. It is equally unlikely that patients took higher doses than those recommended. Usually the problem is incomplete daily dosage. This means that the actual number of patients is likely to be higher than that calculated.
- It is possible that a number of patients are taking one ARV as monotherapy or a combination of 1 NRTI and 1 PI or other combinations. It is estimated that this number is limited. However, this also implies that the actual number of patients is likely to be higher than the calculated one.
- Paediatric use has not been included in the analysis given the difficulty in estimating infant dosages. Usually, these dosages are by the child's body weight, which requires knowledge of the age of the child. The absence of paediatric treatment from the analysis does contribute to the underestimation of the actual number of patients.

- It is widely admitted that a substantial proportion of patients (20–40%) does not regularly take the medications due to a variety of factors (e.g. drug "holidays", structured therapy interruptions, non-adherence to prescribed drug regimens). This implies that the actual number of patients is possibly substantially higher than the calculated one.
- Commonly, a proportion of the drugs supplied does not actually get to the patients and is wasted either during distribution or when the patients switch to another combination therapy. The estimated number of patients does not take into account this fact and tends to overestimate the actual number of patients.
- It is also assumed that a proportion of the amount of drugs sold into a country simply acts to fill the distribution pipeline in that country. It is further assumed that this proportion is roughly equal from quarter to quarter and, therefore, the increases seen in estimated numbers of patients on therapy from quarter to quarter are due to actual increases in the estimated numbers of patients accessing therapy.

Conclusion

More than half of the countries involved in the Accelerating Access Initiative are in Africa, which provides an important example of how this Initiative has catalyzed efforts to extend HIV care, treatment and support. According to the data in this interim report – compiled on behalf of the six companies involved in Accelerating Access – which are consistent with UN figures, more than 35 500 people in Africa were being treated with ARVs supplied by the six companies by the end of March 2002, a four-fold increase in 18 months. In addition, the data show that the proportion of patients on triple combination therapy over that period increased from one third to nearly two thirds, which indicates a concomitant increase in the quality of ARV treatment.

Even if the estimated numbers in this interim report do not exactly represent the total number of patients treated with ARVs in Africa, they do provide relevant information on:

- the trends in the quality of treatment provided, and
- the substantial increase in the patient numbers since the Accelerating Access Initiative was launched.

Given that most of the limitations imply that the actual number of patients is higher than the number calculated in this analysis, it is safe to consider that the numbers constitute a conservative estimate of the patients actually treated with ARVs supplied by the six companies in the Accelerating Access Initiative. A 20–50% increase in the calculated number would likely be closer to the real figure

Clearly, there is still much more work to be done, given the scope of the challenge. While in absolute terms the numbers are still small, we have seen encouraging progress in the past 18 months and a steady increase in patients receiving ARV treatment in Africa through Accelerating Access and related initiatives.

ANNEX 4

Prices of ARVs (US$/day) in the Accelerating Access Initiative

This table contains information about adult formulations and dosages only

	ZDV—600 mg/d	3TC—300 mg/d	ZDV/3TC—2/d	ABC—600 mg/d	ZDV/3TC/ABC—2/d	AMP—2400mg/d	ddI—400 mg/d	d4T—80 mg/d	ddC (1)—2.25 mg/d	EFV—600 mg/d	NVP—200 mg/d	RTV—200 mg/d	LPV/R—6/d	IND—2400 mg/d (3)	SQV Hard Gel (1)—2000mg/d (with RTV) (2)	SQV Soft Gel (1)—3600mg/d (4)	NFV (1)—2500mg/d
Sub-Saharan Africa	1.60 CIF	0.64 CIF	2.00 CIF	3.80 CIF	6.60 CIF	8.70 CIF	0.85 (2) DDU	0.15 (2) DDU	0.44 CIF	1.37 CIF	1.20 CIF	0.23 (8) FOB	1.37 FOB	1.64 CIF	2.35 CIF	6.62 CIF	6.47 (5) CIF
Chile	1.60	0.64	2.00	6.60	9.30	9.60	2.37	3.29		5.18	2.47			4.6			
Morocco	1.60	0.64	2.00	ND (6)	ND (6)	ND (6)	0.85 DDU	0.75 DDU		2.52	1.20			2.82			
Barbados	1.60	0.64	2.00	3.96	ND	ND	1.25 DDU	1.00 DDU		IP	1.20			IP			
Jamaica	1.60	0.64	2.00	ND	ND	ND	0.85 DDU	0.75 DDU		IP	1.20			IP			
Trinidad and Tobago	1.60	0.64	2.00	3.96	ND	ND	0.85 DDU	0.75 DDU		IP	1.20			IP			
Honduras		1.66	2.60	ND	ND	ND	0.85 DDU	0.75 DDU		IP	1.20			IP			
Romania	7.30	S	S	6.80	15.0	14.8	4.8 (5)	5.2 (5)		1.37	1.58			1.64			
Ukraine	2.22	3.20	2.00 (5)	ND	ND	ND	IP	IP		IP	IP			IP			
Median price offered by generic industry (FOB)*	0.9	0.46	1.38	NA	NA	NA	1.12	0.20	NA	1.55	0.54	NA	NA	2.40	4.80	NA	8.2

ND: no discussion; S: syrup formulation discussed; no adult formulation supplied; IP: in progress; NA: no price available; Blank cell: no supply agreement under the Accelerating Access Initiative for this drug in this country on record. (1) These drugs are billed in Swiss Francs. In this table the exchange rate used is 1.7 Swiss Francs to the US$; (2) The hard gel formulation of SQV should be used only in combination with ritonavir as booster drug (1000mg/100 mg BID). The price of ritonavir is not included in the price quoted; (3) Clinical studies indicate that, when used with ritonavir as booster drug, the dose of indinavir can be decreased to 2*800 mg; (4) When used with ritonavir as booster drug the dose of saquinavir can be reduced to 2*1000 mg or 1*1600 mg; (5) This price includes a volume-driven discount; (6) Not yet registered — registration ongoing; (7) Source: Sources and prices of selected drugs and diagnostics for people living with HIV/AIDS. UNICEF, UNAIDS secretariat, WHO, MSF, Geneva, May 2002. While some drugs included in this row have been pre-qualified by WHO, the quality of the products mentioned here has not necessarily been evaluated; (8) Price for 2*100 mg ritonavir, as booster of other protease inhibitors.

ANNEX 5

Offers for antiretroviral drugs by proprietary companies for developing countries

Company	Products	Countries targeted	Price per day in US$ (FOB/CIF/DDU) (DDD)	Eligible organizations	Comment
Abbott	ritonavir lopinavir/ritonavir	Africa plus Afghanistan, Bangladesh, Bhutan, Cambodia, Cape Verde, Haiti, Kiribati, Lao People's Democratic Republic, Maldives, Myanmar, Nepal, Samoa, Solomon Islands, Tuvalu, Vanuatu, Yemen	0.23 (FOB) (2*100mg) 1.37 (FOB) (2*3 caps)	Governments, NGOs, UN system organizations, and other national and international health institutions	The price of ritonavir is given for its use as booster drug to be used with another protease inhibitor. No adjustment to the dose and cost of other protease inhibitors has been made. As of 3 May 2002 organizations in the following countries have accessed lopinavir and ritonavir at reduced prices: Algeria, Benin, Botswana, Burundi, Cambodia, Cameroon, Côte d'Ivoire, Djitouti, Gabon, Haiti, Kenya, Mauritius, Namibia, Rwanda, Senegal, Sierra Leone, South Africa, Tunisia, Uganda, Zimbabwe
Boehringer Ingelheim	nevirapine	Sub-Saharan Africa plus other countries identified as low-income in the World Bank Classification of Economies. For countries identified as lower-middle and upper-middle income in the World Bank Classification of Economies, public sector prices are negotiated on a case-by case basis, bilaterally or through the AAI	1.20 (CIF) (2*200 mg)	In sub-Saharan African countries and other countries identified as low-income in the World Bank Classification of Economies, both private and public sector organisations that are able to provide effective, sustainable and medically sound care and treatment of HIV/AIDS are eligible	Nevirapine is available also free of charge specifically for use in the prevention of mother-to-child transmission through the Viramune Donation Programme (www.viramune-donation-program.org)
Bristol-Myers Squibb	didanosine stavudine	Lowest price for sub-Saharan Africa Developing countries outside of sub-Saharan Africa need to discuss prices on a case-by-care basis	0.85 (DDU) (4*100 mg) 0.15 (DDU) (2*40 mg)	Both private and public sector organisations that are able to provide effective, sustainable and medically sound care and treatment of HIV/AIDS are eligible	As of May 15, 2002, the public sector in Senegal, Benin, Ivory Coast, Rwanda, Gabon, Chad, Republic of Congo, Mali, Cameroon, Togo, Burundi, Guinea and Burkina Faso have availed themselves of this offer. Numerous organizations in the private sector (including NGOs, communities of faith, private employers, retail pharmacies) in Botswana, Kenya, Lesotho, Malawi, Mozambique, Namibia, South Africa, Swaziland, Uganda, United Republic of Tanzania, Zambia and Zimbabwe have also availed themselves of this offer
GlaxoSmith-Kline	abacavir lamivudine zidovudine lamivudine/zidovudine abacavir/lamivudine/zidovudine	Least Developed Countries (LDCs) plus sub-Saharan Africa For middle income developing countries public sector prices are negotiated on a case-by-case basis, bilaterally or through the AAI	3.80 (CIF) (2*300 mg) 0.64 (CIF) (2*150 mg) 1.60 (CIF) (2*300 mg) 2.00 (CIF) (2*1 tabl) 6.60 (CIF) (2*1 tabl)	Governments, aid organizations, charities, international and UN agencies and international purchase funds. In sub-Saharan Africa, the offer is only available to employers who can deliver care and treatment directly to their staff. All organizations must supply the preferentially priced products on a not for profit basis	As of June 2002, some 95 arrangements have been concluded covering 31 countries for the supply of preferentially priced ARVs. The countries are Barbados, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Congo (Brazzaville), Chile, Eritrea, Gabon, Guinea (Conakry), Haiti, Honduras, Ivory Coast, Jamaica, Kenya, Mali, Morocco, Namibia, Nigeria, Romania, Rwanda, Senegal, South Africa, Tanzania, Togo, Trinidad and Tobago, Uganda, Ukraine and United Republic of Tanzania

Cont'd

Company	Products	Countries targeted	Price per day in US$ (FOB/CIF/DDU) (DDD)	Eligible organizations	Comment
Merck	indinavir	Low HDI countries plus medium HDI countries with adult HIV prevalence of 1% or greater	1.64 (CIF) (6*400 mg)	Governments, international organizations, NGOs, private sector organizations (e.g., employers, hospitals and insurers).	Clinical studies suggest that when used with ritonavir as booster drug, the dose of indinavir can be decreased to 2*800 mg
		Medium HDI countries with adult HIV prevalence less than 1%	2.82 (CIF) (6*400 mg)	Merck & Co., Inc. does not rule out supplying ARVs to patients through retail pharmacies	Romania also benefits from the low HDI prices as an exception, in response to the Government's commitment to provide universal coverage to all patients (mostly children) who require ARV therapy
	efavirenz	Low Human Development Index (HDI) countries plus medium HDI countries with adult HIV prevalence of 1% or greater	1.37 (CIF) (3*200 mg)		
		Medium HDI countries with adult HIV prevalence less than 1%	2.52 (CIF) (3*200 mg)		
Roche	saquinavir (hard gel caps)	LDCs plus sub-Saharan Africa	2.35 (CIF) (2*1000 mg to be combined with 2*100 mg RTV))	Governments, NGOs, private sector employers	Prices are in Swiss Francs (CHF) and were converted in US$ using an exchange rate of 1.7 CHF to the US$. When used with ritonavir as booster drug the dose of saquinavir (soft gel caps) can be reduced to 2*1000 mg or 1*1600 mg The nelfinavir tablet price includes a volume driven discount
	saquinavir (soft gel caps)		6.62 (CIF) (3*1200 mg)		
	nelfinavir		6.47 (CIF) (2*1250 mg)		Nelfinavir tablet price includes volume driven discount
	zalcitabine		0.44 (CIF) (3*0.75 mg)		

AAI: Accelerating Access Initiative
FOB: Free on Board (supplied in ship or aircraft), price does not include transport or insurance or clearance charges to and in the country of destination
CIF: Cost, Insurance, Freight. Price includes transport and insurance to country of buyer, but excludes clearance charges, import tax, VAT or sales tax, and transport within the country of the buyer
DDU: Delivered to Door of User: price includes all costs of goods, freight, insurance, clearance charges and taxes
HDI: Human Development Index, in scale published in the annual *Human Development Report* by the United Nations Development Program (UNDP) to assess the development status of countries
LDCs: Least developed countries, according to UNCTAD
NGO: Nongovernmental organization