

Improving access to care in developing countries: lessons from practice, research, resources and partnerships



MINISTÈRE DES AFFAIRES
ÉTRANGÈRES



**Report from a meeting:
Advocating for access to
care and sharing experiences
29 November – 1 December 2001, Paris, France
Convened at the invitation of the French Ministry of Foreign Affairs**

With support from:



**World Health
Organization**



Joint United Nations Programme on HIV/AIDS

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An enlarged version of this booklet, including over 60 papers from experts contributing to the development of the Declaration for a Framework for Action, is published on the UNAIDS website and is available on CD-ROM.

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Foreword

This publication reflects the mobilisation of a group of experts in the fields of medicine, science, economics, social services and care, in sharing their experiences and advocating for accelerating access to care for people living with HIV/AIDS in developing countries.

It includes papers developed by members of this group during the year 2001, collating lessons learnt and analysing key issues in the implementation of the care agenda, and a Declaration for a Framework for Action (*Appendix 1*), which was adopted at a meeting of these experts held in Paris from 29 November – 1 December 2001, at the invitation of the French Ministry of Foreign Affairs.

This publication is neither a technical update nor guidelines for care and treatment. Instead, readers should refer to the recent WHO publication *Scaling up antiretroviral therapy in resource limited settings: guidelines for a public health approach* published in April 2002.

The UNAIDS Secretariat and WHO welcome and encourage the involvement of all actors of society to respond to the epidemic in a coordinated and multisectoral effort. The mobilisation of these experts from all over the world has reinforced the advocacy efforts of many other groups fighting for equitable and sustainable access to care and treatment in developing countries. The papers in this publication echo the commitments taken by all nations during the UN General Assembly's Special Session on AIDS of June 2001.

Article 27 "...recognizing the importance of sharing and building on our collective and diverse experiences, through regional and international cooperation including North-South, South-South and triangular cooperation."

Article 56 "By 2005, develop and make significant progress in implementing comprehensive care strategies to: strengthen family and community-based care, including that provided by the informal sector, and health-care systems to provide and monitor treatment to People Living with HIV/AIDS, including infected children, and to support individuals, households, families and communities affected by HIV/AIDS; and improve the capacity and working conditions of health-care personnel, and the effectiveness of supply systems, financing plans and referral mechanisms required to provide access to affordable medicines, including anti-retroviral drugs, diagnostics and related technologies, as well as quality medical, palliative and psychosocial care:"

Declaration of Commitment on HIV/AIDS
United Nations General Assembly
Special Session on HIV/AIDS
25-27 June 2001



Executive summary

In the development of the papers presented in this publication, experts from Africa, Asia, Europe, North America and South America were consulted during the year 2001. They are members of a Technical Network on Access to Care comprised of 155 experts from 27 countries and 57 national and international organizations.

This publication reflects their mobilisation in sharing their experiences and advocating for accelerating access to care to people living with HIV/AIDS in developing countries. It features papers developed by the experts, collating lessons learnt and analysing key issues in the implementation of the care agenda, and a Declaration for a Framework for Action (*Appendix 1*), which was adopted at a meeting of these experts held in Paris from 29 November – 1 December 2001, at the invitation of the French Ministry of Foreign Affairs.

The following key points are emphasized in these collected papers and in the *Framework for Action*:

- A real opportunity to alter the course of the HIV/AIDS epidemic now exists to the extent that it is recognized that care, treatment and prevention of HIV/AIDS are strongly linked. It is estimated that less than 5% of people living in urgent need of antiretroviral treatment currently use these treatments in the developing world.
- Care constitutes an effective entry point and a key element for effective prevention. It is estimated that nine out of ten HIV-infected people in sub-Saharan Africa do not know their serostatus. Limited participation in voluntary counselling and testing programmes is unlikely to change unless access to adequate care in case of a positive test result is offered.
- Several nationwide or smaller pilot programmes in middle-income (Argentina, Brazil, Chile, Thailand, etc.) and low-income (Côte d'Ivoire, Senegal, Uganda, etc.) countries have shown adherence levels and efficacy outcomes with antiretroviral treatment that are similar to those obtained in high-income countries.
- The sharp drop in the prices of antiretroviral drugs in developing countries has dramatically improved the cost-effectiveness of antiretroviral treatment. In low- and middle-income countries, providing access to a wide array of life-prolonging care services, including antiretroviral treatment, is feasible and cost-effective today.
- Governments, the private and not-for-profit sectors, and the international community must now commit the required financial resources commensurate with the need as identified by the United Nations General Assembly Special Session on HIV/AIDS of June 2001.
- Failure to seize this opportunity to expand access to care and antiretroviral treatment will perpetuate untold human suffering and increase poverty and inequity on a worldwide scale.



**Contributions of experts
to the development of the
declaration**





Chapter 1

Managing care: lessons from practice

Chapter editors: Pedro Cahn, Jeffrey O'Malley

Chapter researchers: Mandeep Dhaliwal, Vinh Kim Nguyen, Carlos Zala

Access to health care for people living with HIV/AIDS is a moral imperative, directly related to human rights. The ultimate goal is to guarantee universal access to care for all HIV/AIDS patients, and regional diversity regarding the ability to provide therapies should be recognized in different areas around the world. Therefore, locally developed treatment programmes based on epidemiological, economic and political factors should not be further delayed. It is also important to stress that these programmes should not compromise best clinical practices.

The true impact of the HIV/AIDS epidemic can only be known if infected people come forward. However, by the time many patients seek care, their HIV has already developed into AIDS. Hence, awareness of the disease among the general population needs to be enhanced. In this context, governments should be encouraged to improve systems for HIV/AIDS diagnosis.

Scaling up of voluntary counselling and testing (VCT) services is urgently needed in order to reduce high-risk behaviour, improve safety of blood transfusions, reduce the rate of mother-to-child transmission (MTCT) and facilitate timely access to prophylaxis for opportunistic infections and to antiretroviral (ARV) therapy.

Early diagnosis of HIV infection can encourage individuals to seek treatment and, theoretically, can also help to reduce HIV transmission by dissuading people from high-risk behaviours. Rapid and simple HIV tests, with proven specificity and sensibility, are needed.

Provision of clinical care as a continuum

ARV therapy cannot be considered in isolation from a comprehensive AIDS strategy, including prevention, diagnosis, treatment and prevention of opportunistic infections. Furthermore, care has to be considered as a continuum, including, but not limited to, medical care. Therefore, together with clinical management (early diagnosis, including testing, rational treatment and follow-up care) we must consider nursing care (including promoting hygiene and nutrition), palliative care, home care (including education for care providers and patients' relatives, promoting universal precautions), counselling and social support.

Last but not least, parallel programmes devoted to confronting stigma and discrimination are essential in order to remove these barriers to accessing care.

- Universal access to HIV care is the main goal. Some developing countries have achieved it to some extent, most are still struggling, and others have not yet taken any steps towards it. Thus, progressive steps aimed at scaling up access should be taken in all countries urgently.
- Prevention of perinatal transmission and treatment of symptomatic patients

must be considered essential priorities in any HIV/AIDS care programme. Additional important priorities are prophylaxis and treatment of opportunistic infections and post-exposure prophylaxis for health care providers.

Prevention programmes for HIV infection have started in many countries. To accelerate the process, the theoretical potential of ARVs for preventing HIV transmission by encouraging people to come forward for testing should be stressed to decision-makers.

To achieve the goal of universal access to HIV care, ARV drugs must be available. Supply needs to be continuous and reliable. Any eventual discontinuation in drug supply will not only increase the risk of treatment failure, but also facilitate the emergence of resistance.

Symptomatic patients should be treated with the best option that can be given, i.e. highly active ARV therapy (HAART). Extensive clinical and epidemiological evidence has shown that HAART is the best regimen for AIDS. It is often understood as a triple combination containing a protease inhibitor (PI). Nevertheless, non nucleoside reverse transcriptase inhibitor (NNRTI) based combinations have shown similar benefits. Also, abacavir-based triple nuke combos result in similar virologic outcomes, when compared to PI-containing regimens.

Based on data gathered in developed countries, most experts recommend delaying the onset of treatment in asymptomatic patients with relatively preserved immune function (> 200 CD4 cells/mm³) as a reasonable decision.

Once a decision about therapy has been taken, care of HIV/AIDS patients should ideally be implemented through a multidisciplinary team, including physicians, nurses, pharmacists, social workers, psychologists and, last but not least, people living with HIV/AIDS (PLWHA). The increasing complexity of treatment for HIV/AIDS disease demands that trained physicians administer it. In several areas, distance hinders access to reference centres for many patients. A useful strategy to cope with this problem is for reference centres in peripheral institutions to coordinate training for physicians. Trained primary-care physicians could be in charge of the initial management of uncomplicated HIV/AIDS patients in rural centres. Patients with complicated disease would be referred to tertiary centres. These strategies should be assessed on a regular basis to allow for timely adjustments.

Adequate laboratory facilities for diagnosing HIV disease or monitoring ARV therapy are lacking in many countries. However, while initiation of ARV therapy can be decided on a clinical and/or immunological basis, ideally CD4 counts are required for adequate monitoring. Rapid, simple tests that do not require specific technical expertise are needed, particularly in very poor regions.

Viral load testing is useful but not necessary for clinical monitoring. Resistance testing is expensive and its use cannot be recommended for routine clinical care. It has a role for surveillance purposes.

Adherence is known to have a great impact on the outcome of ARV therapy and is also a major problem for many patients. Strategies to enhance adherence, including up-to-date information for patients, social and psychological support, thorough knowledge of their environment, etc., should be part of any comprehensive health care programme. Withholding treatment based on presumptions of non-adherence due to a particular lifestyle is unacceptable.

A major moral issue is discrimination and stigmatization of HIV-infected persons. Though extended worldwide, this attitude should be opposed through political and economic pressure. To some extent, it may be the cause of failure to identify and treat people living with

HIV/AIDS. Fear of losing their jobs, or even their family bonds, can deter people from seeking testing and medical care.

Community groups have often taken the lead in the establishment of HIV/AIDS health care policies in developed and some developing countries. Community group involvement should be extended throughout the rest of the world.

Community members can also play a role in a number of efforts, including political pressure to induce governments to improve access to health care, cooperation with care providers in the development of specific educational (and even therapeutic) programmes, and the establishment of a network of social support for people living with HIV/AIDS.

Several studies show that the savings resulting from a reduced incidence of opportunistic infections and hospitalizations may offset the costs of ARV therapy. Enhancing the efficiency of ARV therapy will contribute significantly to improve the cost-effectiveness equation. Control of HIV viral load and replication has been one of the major contributions of triple ARV therapy. As a result of therapy, infectivity might decrease, thus facilitating the control of the epidemic via a reduced risk of HIV transmission. This will be beneficial for society as a whole, and not only for individual patients. In addition, consumer education and protection, setting up efficient systems for clinical diagnosis and referral, timely interventions directed at prevention and treatment of opportunistic infections and high-impact MTCT interventions are all desirable components of a comprehensive care system. Last but not least, nutritional and complementary therapies and end-of-life issues are important contributions to a comprehensive approach to care.

Getting people into care

Voluntary counselling and testing (VCT)

Background

VCT is the process by which an individual undergoes counselling to enable him or her to make an informed choice about being tested for HIV. This decision must be entirely the choice of the individual and he or she must be assured that the process will be confidential. It is an important and cost-effective HIV prevention measure, which also improves access to care and support. VCT services are now being more widely promoted in countries that are gradually instituting VCT as part of their primary health care package. Recent developments in prophylaxis of tuberculosis and other infections for people with HIV, prevention of mother-to-child transmission (MTCT) and antiretroviral (ARV) therapy have focused attention on the need to expand access to VCT to allow timely use of these interventions.

Key issues and challenges

Expanded access to VCT is necessary to reach the UNGASS goals¹ of:

- 25% reduction of HIV prevalence among people of 15-24 years in the most affected areas by 2005 and 25% globally by 2010.
- 20% reduction in numbers of infants infected with HIV by 2005 and 50% by 2010.

The benefits of VCT include:

- Better health through earlier access to treatment/prevention of HIV-related illness.
- Emotional support and better ability to cope with HIV-related anxiety.
- Awareness of options for prevention of MTCT.
- Motivation to initiate or maintain safer sexual and drug-related behaviours.
- Reduction of stigma and secrecy surrounding HIV/AIDS.
- Safer blood donation.

Compulsory testing for HIV is not supported by UNAIDS and mandatory screening plays a role only for blood donation. The International Guidelines on HIV/AIDS and Human Rights advise against compulsory testing on both public health and human rights grounds. People should have the right to opt out or refuse testing if they do not think that it is in their best interest.

Models of VCT

- *Individual pre- and post-test counselling and testing* (“classic” model, most free-standing VCT sites). Allows all people offered an HIV test to have in-depth individual discussion of personal risks of infection and explore the implications of HIV testing. Shown to be cost-effective but time-consuming when dealing with large numbers of people.
- *Group information, opt-in individual pre-test counselling, individual post-test counselling*. Widely used in high-prevalence settings, workplaces and outreach counselling. After group pre-test information/education, people can “opt in” for short pre-test counselling, followed by post-test counselling for everyone who accepts testing.
- *Group information, opt-out individual testing, individual post-test counselling for seropositives, seronegatives are informed of their negative status*. Used in low-prevalence countries during routine medical screening, e.g. antenatal clinics. Attendees can opt out. Seronegatives are informed of test result, with little/no post-test or preventive counselling. Seropositives receive post-test and ongoing counselling. This depends on availability of treatment and support for seropositive people. If inadequate services are available, seropositives may be disadvantaged following testing.
- *Group information, opt-in couple/family pre-test counselling, individual/couple/family post-test counselling*. Shown to be highly effective in promoting sexual behaviour change to prevent HIV transmission. Overcomes problem of sharing test results, enables couples to be counselled together to avoid blame and make risk reduction plans together before testing.
- *No pre-test information, testing with an option to opt-out, individual post-test counselling for those found HIV positive*. Used for screening in some antenatal, sexually transmitted infection (STI) and drug clinics in

some low-prevalence countries. In practice, very few people opt out and testing cannot be considered truly voluntary due to lack of informed consent. Of little benefit for seronegative people who are at risk from HIV infection.

Recommendations

We recommend rapid scaling up of VCT within a global framework for VCT services outlining key strategies including:

- Clear goals and targets supported by technical, ethical and operational guidelines.
- Multisectoral linkages and mobilization of adequate human and capital resources.
- Reorganization of health services to better respond to the needs of VCT clients.
- Advocacy for increased resource mobilization for VCT.
- Development of centres of excellence and identification of models of best practice.

Scaling up VCT services may bring a number of important gains including:

- Equitable coverage, extending beyond major urban areas to remote and rural areas.
- Cost reduction. VCT may be less expensive per person receiving VCT with larger services that are more efficient, and when larger numbers of people attend VCT.
- Effective and acceptable provision of services using lessons learnt from pilot projects for planning and development of more effective and beneficial services.
- More comprehensive interventions from larger VCT services offering a broader range of services. However, smaller services may have developed a wide network of support services, which may not be easily replicated on a larger scale.

National VCT policy should ideally include the following components:

- Legal protection and anti-discrimination legislation.
- Issues of equity (e.g. costs and access for different groups in the population).
- Development of acceptable standards of service provision (e.g. acceptable content and quality of counselling and testing, ensuring confidentiality).
- Harmonization of VCT policy with existing national policies for HIV and health education (e.g. around harm reduction activities).

Consumer education and protection

Background

There is increasing need for consumer education and protection for people with HIV as and when the necessary health technologies and skills are made available to them. People need to understand clearly what their health rights are and how to ensure that they are respected. Respect for rights will only be possible within a sufficient framework of legal and other sanctions to provide consumer protection that is sensitive to the needs of people with HIV.

People with HIV often find that some health rights are denied them at individual and social levels simply because they are HIV positive. The question of rights is thus very closely associated with the problems of stigma and discrimination for people with HIV.

Key issues and challenges

Health rights include such things as²:

- Access to reasonable and acceptable standards of health care.
- Access to information that allows a patient to play an active role in his or her health care.
- Participation in health care, not only about choice of treatment for the individual but also through consumer representation in evaluating, planning and delivery of health services.
- Dignity and humane care – every patient has the right to be treated with care, consideration, respect and dignity without discrimination of any kind.
- Confidentiality – personal information about a patient should only be released if the patient authorizes it, or there are compelling medical/legal reasons to share it with others.
- Complaints and redress for patients when availability and/or quality of health care is unacceptable or causes harm.

Against this background, the increasing quantity and variety of treatments centred on pharmaceuticals poses a number of issues for people with HIV:

- Emphasis on drug treatment for HIV and related health problems without emphasizing the necessity for also addressing issues of poverty, food security, healthy living and the social, economic and political background in which health needs arise constitutes a narrow focus.
- People's desire for "magic bullets" and miracle cures for HIV provide fertile fields for sellers to make money from harmful or inappropriate treatments, putting people at risk from dangerous treatments or wastage of hard-earned funds.
- Marketing of medical products to health workers and consumers, frustrating efforts to encourage rational prescribing and use of treatment. Direct-to-consumer advertising of prescription medicines and indirect marketing through support for patient groups are key concerns.
- Media news presentation of new or spurious treatments, biased by sensationalism or lack of balanced information, particularly about ARVs or "quack" treatments. Lack of monitoring and correction of popular reporting of HIV-related news with an eye to consumer protection and education.
- Drug quality and dangers from substandard or fake drugs produced in poorly regulated environments or marketed in deliberate attempts at fraud. People with HIV are vulnerable to substandard anti-infective drugs. As more treatments become available, greater vigilance will be necessary to ensure only good quality drugs are used.
- Overuse and misuse of anti-infective drugs in the general population, creating major difficulties for treatment of several infections relevant to

people with HIV – acute respiratory infections, diarrhoeal disease, STIs, tuberculosis (TB) and malaria. Drug resistance is encouraged by under-treatment and inadequate access to anti-infective drugs or when these drugs are too readily prescribed and accessible.

- Resistance to ARV drugs already exists and this will increase as they are used for more people with HIV infection if effective adherence counselling is not a basic care component.
- Involvement of HIV patients in research, particularly clinical trials of new drugs and vaccines or new methods of using existing treatments. Researchers must conduct research that is scientifically sound and in the patient's best interests. In poorly resourced countries, these criteria require special efforts to ensure justice and equity, especially where effective treatments are unaffordable, and where trial participants may not be able to make use of treatments developed from the trials³.

Recommendations

Consumer education

- Education for consumers about treatments for HIV-related conditions and their relationship to other means of promoting well-being and prolonging life for persons with HIV, such as healthy living, income generation, family and community support.
- Education about health rights and the need to combat discrimination against the rights of people with HIV, including access to health care and treatment and involvement in clinical research.
- Fostering the role of the media in the education of consumers and educating journalists to provide balanced, non-stigmatizing reporting about HIV infection, care and treatment.
- Ensuring availability and accessibility of independent, objective sources of advice and information for people with HIV and those responsible for their treatment and care.

Consumer protection

- Development and support of mechanisms for regulating pharmaceutical quality, promotion and prescribing.
- Mechanisms for regulating media reporting and advertising of health-related products.
- Development of local and national consumer representation to ensure that measures are taken to protect health rights, prevent harm and ensure consumer-friendly policy-making.
- Enforcing ethical behaviour by researchers and drug companies in the development of new treatments. The special constraints of living with HIV should be incorporated into codes of ethics through involvement of people with HIV in their development.

Clinical diagnosis and referral

Background

People will continue, as at present, to have their HIV diagnosis identified mainly at clinical sites until VCT programmes become widespread. Many people who suspect they may have HIV consult health workers in hospitals, dispensaries or private clinics only after they have exhausted other options such as traditional healers. Since they are already symptomatic with HIV-related illnesses, these individuals can benefit most from treatment. Thus, clinical sites are a crucial front line for getting people into treatment and linking them with support systems, both public and those led by nongovernmental organizations (NGOs).

Key issues and challenges

- HIV diagnosis and referral has been difficult because busy clinicians in general health settings often do not have time, facilities or skill. Perceptions that treatment cannot help people with HIV contribute to a culture of silence, despite efforts to raise awareness and train clinicians, and to a failure to establish links with other disease control programmes, for TB, malaria or sexually transmitted infections (STIs), or with diagnostic facilities or support programmes for people with HIV.
- Rapid tests for HIV are available that can reliably deliver a result with minimal laboratory facilities within 15-20 minutes of a simple pinprick. This is advantageous but the danger is that testing may occur without appropriate counselling and referral.
- Before the advent of ARVs, prevention and treatment of opportunistic infections were shown to have a significant impact on morbidity and mortality of people with HIV, however patients had increasing difficulty recovering from the physiological setback of each opportunistic infection, even if cured. Preventive treatments exist for a number of diseases that are known to cause the bulk of morbidity and mortality in people with HIV.

Recommendations

Programmes must be developed to facilitate diagnosis of HIV and referral in front-line clinical settings such as dispensaries and hospitals as well as in specialized clinics such as STI, TB and antenatal clinics.

While clinical criteria permit a diagnosis to be made when HIV tests are not available, it is not advisable to rely solely on them for treatment decisions. Front-line clinical settings must establish links with diagnostic laboratories, e.g. through established VCT sites with access to HIV tests. Patients can be sent to VCT sites or to hospitals with diagnostic facilities. Clinicians should be encouraged to counsel and test patients appropriately, and additional resources such as counsellors should be provided to support this.

Links with other programmes are key to effective use of resources. VCT sites are a logical entry point into HIV treatment programmes. As demand for testing grows, they can be drawn upon as centres of excellence for training in counselling and testing and to set up satellite programmes in other clinical sites. Initially, linking VCT sites with clinical sites represents an effective strategy for recruiting patients into treatment programmes without committing significant resources to providing counselling and testing across a large number of clinical

sites. It may be useful to develop counselling and testing in specialized clinics such as STI and TB clinics where HIV prevalence may be high, and in antenatal clinics so that prophylaxis of mother-to-child transmission can be offered to infected women.

Linkages must be established between HIV treatment and other programmes, specifically:

- Establish two-way referral systems for TB patients to be tested and treated for HIV, and vice versa.
- Establish referral systems between front-line clinics, VCT centres and treatment programmes.
- Consider using VCT centres as gatekeepers to HIV treatment programmes initially.
- Use operations research in VCT programmes to develop models that can be reproduced or scaled up.

Linking prevention and care

Background

It is widely agreed that prevention of new HIV infections is the most effective way of reducing the long-term threat posed by the epidemic, but this is not sustainable without addressing the care and treatment needs of those already infected. Practical, naturally occurring linkages between prevention and care can generate synergies in HIV/AIDS programmes.

Key issues and challenges

- Prevention activities raise awareness of HIV, increasing demand for testing and treatment.
- Counselling and testing are thought to reinforce behaviour that prevents HIV transmission.
- Increased availability of treatment encourages people with HIV to accept their condition in a more positive light and, eventually, be more visible.
- Increased visibility of HIV sustains behaviour changes that help prevent transmission.
- Increased visibility works to lessen stigma.

Applying expertise acquired in prevention work to care and treatment programmes is a prime example of this synergy. Several mechanisms exist for transferring technical expertise and organizational capacity used in prevention to care and treatment programmes. Individuals and organizations experienced in prevention provide a key resource for developing care and treatment programmes.

Prevention relies on creating and meeting demands, whether for general information about HIV/AIDS or for specific information on ways to protect oneself against infection. Care work, however, responds to an already existing demand for treatment. Further, treatment and care are usually delivered by stable institutions such as the state and churches, which are often better equipped to deliver services than smaller programmes oriented to advocacy and

self-help, which may lack resources to offer support to those on the front line of treatment and care. Using prevention resources to meet needs for care and treatment risks weakening prevention efforts through diversion of human resources to more demanding work in response to the pressing needs of already afflicted individuals. Thus capacity to remain effective advocates of prevention may be undermined by involvement as service providers of care and treatment.

Furthermore, mobilization of prevention workers into care and treatment offers the potential for conflict between community and public health approaches and those of clinicians, who may be reluctant to share therapeutic authority with lay people. Patient activists and community workers may resent clinicians' authority, especially if they have led the fight for access to care and treatment, resulting in conflict over resources. Strategies to reinforce links between prevention and care must therefore balance these opportunities for synergy, reducing the risks to prevention programmes and preventing conflict over control of resources.

Once developed, care, support and treatment programmes provide invaluable opportunities for prevention work. When people with HIV receive meaningful services that prolong and improve their lives, they become particularly receptive to prevention messages. This must be used to advantage – improving the adoption of safer sex practices by people with HIV has potential for significant impact on HIV transmission. This is of particular importance in serodiscordant couples, where the partner of the infected person is HIV negative. Increasing interest is focusing on strategies for linking adherence to treatment and adherence to safer sex.

Personal experience with treatment makes beneficiaries of HIV care and treatment programmes ideally suited to take a leadership role in these programmes, as well as in the development of new services to meet ongoing needs posed by care and treatment. The potential of these programmes to effect social and behavioural change cannot be underestimated, and should be harnessed in order to sustain prevention work.

Groups of people living with HIV/AIDS (PLWHAs) play an increasingly important role as advocates for persons living with HIV. Many of these groups in resource-poor situations were created by funding opportunities, the result of donors' desire to push for greater involvement of people with HIV in the response to the epidemic. Donor efforts have been sometimes generous and often inconsistent, resulting in competition within and between PLWHA groups. Justifiably, these groups are increasingly serving as resources for the development of care and treatment programmes, providing benefits such as additional legitimacy and access to scarce resources. However, a tension exists between the dynamic of self-help and the institutionalization implied by professionalization. It is important therefore to protect the dynamic of self-help, which stimulates true community-based responses and advocacy, while encouraging leadership by those most affected by HIV.

Care and treatment programmes are also inevitably confronted with the issue of widows and orphans, although it can be expected that this problem will be helped if and when effective ARV treatment becomes available. Orphans are vulnerable to HIV infection because of socioeconomic instability. As a result, care and treatment programmes that develop interventions to support orphans and those that care for them must address underlying socioeconomic vulnerability to prevent future HIV infections.

Recommendations

- Involvement of prevention programmes in care activities:
 - development of links between VCT centres and treatment programmes
 - introduction of effective prevention organizations into pilot care and treatment programmes.
- Reinforcement and scaling up of VCT and other prevention programmes that employ counselling and peer-to-peer strategies, through training-of-trainers methods.
- Seeking out and developing training programmes that encourage inter- and trans-disciplinary and participatory approaches to the delivery of health care services.
- Enhancing the potential of care and treatment programmes to sustain prevention through:
 - mechanisms to recruit, train and employ people with HIV as peer counsellors to support adherence to treatment and safer sex
 - involvement of people with HIV in developing programmes and policies in government and nongovernmental organizations (NGOs)
 - developing programmes to support people affected by HIV, including family members, widows and orphans.
- Instituting care and treatment programmes as health care delivery mechanisms, in order to take the burden of care delivery away from PLWHA groups. Care and treatment programmes can be developed within:
 - public health systems, such as STI and TB control programmes
 - private health systems, such as church and NGO health programmes
 - civil society/government partnerships, such as an NGO developing a programme housed within a public health facility.

Links to stigma reduction, self-help groups

Background

Stigmatizing perceptions of HIV see it as a life-threatening disease, associated with sex or stigmatized behaviours such as drug use, and conflicting with moral beliefs about choice and responsibility for disease. Stigma generates denial and secrecy about HIV/AIDS, which in turn lead to discrimination – people are treated unfairly because of their serostatus. Thus, people are blamed and victimized, social exclusion and divisions are reinforced and HIV infections continue to emerge. The greater the silence surrounding HIV, the more the stigma and discrimination directed towards people with HIV.

Key issues and challenges

HIV/AIDS-related stigma, denial and discrimination have many effects, such as:

- People are afraid to be tested, posing a major challenge to HIV prevention work.
- People who know they are HIV positive are afraid to disclose their serostatus.
- People known to be HIV positive lose jobs, are expelled from education, are evicted from home, lose custody of children or face other discrimination from their communities.
- People with HIV are denied the right to marry, or are banned from worship

by their religious communities.

People with HIV suffer discrimination in the health care setting through:

- Being tested for HIV without knowledge or consent.
- Encountering trained health workers who refuse to treat them.
- Being denied access to even simple medication such as pain relievers or antibiotics.
- Having health staff refuse to bathe or physically examine them when they are hospitalized.
- Health workers informing the media of their personal details.

Stigma and discrimination decrease access to care and support. At the same time, provision of care and support can in themselves effectively help to reduce stigma and discrimination, leading in turn to greater uptake of testing, care and support. The visibility of home-based care and support, especially when it actively involves people with HIV, is a powerful challenge to stigma and discrimination, and enhances community responses to HIV.

Recommendations

Encouraging openness and decreasing stigma and discrimination against individuals with HIV will lead to people being able to discuss HIV/AIDS more openly, identify more personally with infection risks and play active roles in prevention, care and support, specifically through:

- Sensitizing communities to the epidemic and making HIV/AIDS more visible.
- Training and sensitizing health workers to improve access to care and support.
- Improving the availability and quality of services as keys to improving access to care and support and reducing stigma, denial and discrimination.
- Encouraging and facilitating greater involvement of people with HIV in care, support and prevention – as educators of health workers and communities, as peer supporters and as providers of first-hand experiences of living with HIV.

End-of-life issues

Background

End-of-life issues include a range of medical and other challenges to people with chronic or life-threatening illness. Advanced HIV illness is associated with severe pain, discomfort and anxiety, which can be alleviated through palliative care when life-prolonging treatment is not available or no longer effective. Palliative care is also appropriate at earlier stages when symptom control can restore well-being and optimism while curative care is given for opportunistic illnesses. Non-clinical end-of-life issues also face PLWHA with social, legal, psychological and spiritual challenges. Decisions may need to be made about care and support for the dying person, funeral arrangements and inheritance, and support for family members before and after the person dies, all within a context of stigma and discrimination, lack of resources and prevalence of sickness due to HIV infection in the community.

Key issues and challenges

Palliative care is still poorly understood and there are insufficient resources and training to deliver it. Medical professionals too often see it as an admission of failure or “giving up the fight”. This combines with political, financial and logistical problems to prevent many people from receiving the care they need in the late stages of HIV/AIDS. The philosophy of palliative care is one that:

- Affirms life and regards death as a normal process.
- Affirms individual and family rights to participate in informed discussions and treatment.
- Does not hasten or postpone death.
- Provides relief from pain and other symptoms.
- Offers a support system to help patients live as actively as possible until their death.
- Integrates psychological and spiritual care.
- Provides support to help the family cope during the patient’s illness and after death.

Pain control is central to palliative care. Pain and other symptoms are important causes of distress in HIV infection, causing anxiety and depression. Freedom from pain and discomfort allows a person to attend to their lives and to come to terms with their approaching death. The World Health Organization (WHO) provides a simple hierarchy for pain control, the three-step “analgesic ladder”:

Step 1: non-opioid analgesics such as acetylsalicylic acid, and paracetamol.

Step 2: opioids for mild to moderate pain, such as codeine with or without non-opioids.

Step 3: opioids for moderate to severe pain, e.g. morphine with or without non-opioids.

Effective palliative care includes access to these and other symptom control drugs and access to staff authorized and competent to use them. Access to opioids is restricted by law and, in practice, many people do not receive the analgesia that they need.

Delivery of palliative care takes place both in specialized centres such as hospices and in home settings. Hospitals and hospices, especially in high-prevalence areas, cannot admit every HIV patient needing palliative care. Home care helps many in the late stages of life with end-of-life issues and support from families and caregivers. However, they can often provide only mild pain relief and simple treatment of symptoms due to a combination of limited resources and legal restrictions on pain control. In many countries, palliative care is provided by small community-based organizations (CBOs) and NGOs with limited resources. Many have the potential to provide a platform from which provision of palliative care can be extended through partnerships and collaboration with governments. Some provide training as well as care, increasing local capacity and improving understanding of HIV issues in palliative care. Good referral systems for different aspects of care are essential, and it is important that palliative care complements, rather than competes with, other HIV home care for people and families affected by HIV.

Family relationships: Caring for people in the terminal stages of AIDS puts great strain on all involved. Care for the dying at home is traditionally provided by family and community members who may themselves be struggling with illness and poverty. Sometimes, family members who are unable to cope may abandon the sick person. Care must therefore address these difficulties as well as medical needs in order to support carers and preserve family

structures.

Grief and mourning are natural effects of serious loss, giving rise to a range of reactions such as anger, sadness, depression or avoidance. The death of someone through HIV/AIDS is preceded by other losses as the person loses ability to maintain normal life and relationships. Family members and friends of the dying person also experience loss at a time when they wish to communicate care and optimism. Support is therefore needed for those involved both before and after a death. Families often support each other before and after bereavement, but help may also be needed from carers or counsellors.

Children's bereavement experiences and needs are often misunderstood, but they merit special attention. They have limited understanding and capacity to express grief, and their concerns about who will look after them when a parent or other carer is dead are often neglected by adults who wish to shield children from death, or assume that they are less affected by bereavement and more able to adapt. Failure to attend to children's needs at this time can lay foundations for mental health difficulties later in life. Traditional methods of child care and rituals around death are often helpful but, in communities eroded by HIV-related disease and economic circumstances, there is need to take special care of bereaved children.

Inheritance problems resulting from the death of a family member are well recognized, especially for wives and their children when a husband dies. Will-writing is becoming more widespread, but traditional practices still prevail in many situations. Inheritance problems can seriously compound the effects of grief and loss, particularly if possessions vital to daily living are taken away from the newly bereaved or custody of children is disputed.

Recommendations

- Development of national policies on palliative care within government health plans, based on WHO's recommendations for palliative care services.
- Appropriate budget allocations by governments for palliative care as part of health care for those with chronic and terminal illnesses.
- Provision of training for health workers and public education to build understanding of HIV palliative care. This must link to policy change and training on other HIV-specific areas, such as preventing transmission, stigma and discrimination and ensuring confidentiality.
- Urgent steps should be taken to ensure that national drug legislation allows for appropriate use of opioids for pain control.
- Lessons learned from experiences of assisting children with cancer should be adapted for palliative care of children with HIV.
- Inheritance rights and legal issues must be addressed through legislation and care programmes for people with HIV.
- Palliative care workers should receive training and supervision for bereavement support to patients and families, especially in multiple or untimely bereavements and for children; experiences that have proved helpful should be more widely shared.
- Experiences of bereavement support projects should be studied and adapted to address HIV bereavement needs with respect to differing cultures and beliefs.

Reduction of mother-to-child transmission

Background

HIV transmission from mother to child varies from 15-30% in Europe and North America to 30-40% in Africa. HIV may be transmitted during gestation, labour and delivery or breastfeeding. Better understanding has resulted in successful interventions and, in areas of the developed world, the rate of mother-to-child transmission has been dramatically reduced. Failure to implement interventions in other countries results in unacceptable rates of infant HIV infection. Optimization of current interventions and research into new preventive strategies remain a challenge for scientists, communities and governments committed to improving the health of people affected by the AIDS epidemic.

Key issues and challenges

Primary prevention of HIV infection in women

The first step in any plan aiming to reduce paediatric HIV is to target women of reproductive age with education, prevention, counselling and testing programmes, addressing sexual health issues, including abstinence, delay in initiation of sexual activity, and female-controlled barrier methods and contraception.

Reproductive choice for HIV-positive women

Health workers in high-risk areas should be fully aware of contraceptive options that provide the best balance of effectiveness and safety. Choices surrounding unplanned/unwanted pregnancy should be addressed. Strengthening sexual and reproductive care systems for women, together with early sexual education, are essential steps in primary prevention of MTCT of HIV.

Prenatal care and HIV testing

- Mothers with no or incomplete prenatal care remain at high risk of transmitting HIV. HIV infection may be unnoticed in asymptomatic pregnant women unless a systematic offer of testing is in place. Detection of infection during early pregnancy allows:
 - timely initiation of prophylaxis to prevent AIDS-related opportunistic infections
 - evaluation of the need for ARVs to treat maternal HIV disease
 - planning ARV prophylaxis to reduce the risk of MTCT.

Although the performance of rapid HIV tests has been extensively evaluated, women and health care workers should be aware of the possibility of false positive or false negative results. Nevertheless, a rapid test with high sensitivity and specificity, with concurrent or even later confirmatory testing, is an optimal strategy for identifying and treating mothers at risk of risk transmitting HIV.

Therapeutic interventions

- Maternal risk factors: A number of observational studies have identified the level of plasma HIV RNA as the factor with the highest predictive value for mother-to-child transmission of HIV. There is now clear and compelling evidence indicating that ARV prophylaxis can save infant lives when available to HIV-infected pregnant women and their newborns. Demonstration that

women with low plasma viral load at delivery have a low rate of HIV transmission provides a rational basis for designing strategies aimed at suppressing viral replication, but the risk that such strategies may select resistant strains warrants careful observation. Available data indicate that simple therapeutic strategies have the potential for reducing the number of HIV-infected newborns. Monitoring for toxic effects in women and newborns exposed to ARVs is of critical importance. Behavioural factors such as cigarette smoking, drug use and unprotected sex are possible cofactors for MTCT. Sexually transmitted and other genital infections increase the chance of transmission and short courses of antibiotics in this setting deserve further evaluation in clinical trials.

- Obstetric factors: Prematurity, prolonged duration of membrane rupture, use of instruments and vaginal delivery have all been shown to enhance mother-to-child transmission of HIV. It should be noted, however, that the benefit of elective caesarean has not been evaluated in resource-poor areas where health systems are not able to routinely implement this intervention, or where this intervention may have a higher morbidity than in developed countries. Morbidity associated with surgical infections could outweigh its potential benefits and add significant hospitalization and antibiotic costs.
- Postnatal factors: Breastfeeding women with established HIV infection show increased risk of transmitting HIV-1. Risk factors include a clear relationship between duration of breastfeeding and HIV transmission to the newborn, viral load in breastmilk and subclinical mastitis. In one South African study, exclusive breastfeeding or exclusive formula feeding was associated with reduced risk of transmission compared with early mixed feeding. Strategies suggested to prevent transmission have included replacement feeding, exclusive breastfeeding followed by early weaning, and newborn infant and maternal ARV prophylaxis during breastfeeding.

Recommendations

Primary prevention

- Set up sexual education programmes for teenagers and young women.
- Promote and provide condoms for free distribution.
- Link HIV prevention with reproductive health programmes.

Prenatal care

- Prioritize overall prenatal medical care.
- Promote and facilitate HIV testing during pregnancy.
- Provide rapid HIV testing for pregnant women showing up in late pregnancy or in labour.

Maternal risk factors

- ARV therapy can improve maternal health, but special caution should be taken with drugs associated with birth defects, such as efavirenz or indinavir.
- Priority should be given to ARV prophylaxis. The ACTG 076 protocol is

poorly adapted to resource-constrained settings. Shorter interventions described above will have immediate impact on the current situation.

- Nevirapine (one dose during labour, one dose for the newborn) should be considered if zidovudine has not been provided in a timely fashion.
- Research is needed in order to establish the potential value of adding post-natal zidovudine to nevirapine.
- The nutritional status of pregnant women is crucial regardless of their HIV status, underlining the importance of linkage with maternal health care programmes.
- Counselling to modify behaviours must be part of prevention programmes.

Obstetric factors

- Set up educational programmes for obstetric care providers, highlighting the importance of shortening the gap between rupture of membranes and delivery.
- Encourage timely diagnosis and treatment of placental inflammation.
- Set up educational programmes on the prevention of mother-to-child transmission targeted to people with HIV.
- Promote timely detection and treatment of STIs.

Breastfeeding

- Promote exclusive formula feeding where feasible, including assurance of water safety.
- Promote early weaning if safe formula provision is not assured.
- Educate care providers and mothers to avoid mixed feeding.
- Consider research and advocacy for ARV prophylaxis during breastfeeding.
- Referral of exposed/infected children should be an essential component of the programme.

Mother-to-child transmission of HIV is a multifactorial process that must be tackled at multiple points. Behavioural interventions, contraceptive counselling, prenatal care, ARV therapy during pregnancy and safe feeding are critical issues to be discussed. Last, but not least, providing an enabling environment and preventing discrimination of HIV-positive women are essential.

Preventing and managing opportunistic infections

Prophylaxis, diagnosis, treatment – TB, fungal infections

Background

In endemic countries up to 70% of TB patients are HIV positive, and up to 50% of HIV patients will develop TB. Other serious infections are also a significant problem in people with HIV. Bacteraemia, pneumonia and bacterial meningitis caused over 50% of deaths in one study.

Key issues and challenges

Improving diagnosis and treatment of TB can have a significant impact on length and quality of life, even in the absence of ARVs. Treatment of TB requires a combination of at least three drugs strictly adhered to for several months. Anything less results in the emergence of multi-drug-resistant strains (MDR-TB) which are very difficult and expensive to treat. In the absence of TB diagnosis and treatment, many people with HIV are unlikely to live long enough to benefit from ARVs.

Treatments are available that either prevent an initial episode of TB (primary prophylaxis), or prevent recurrence in a patient who has already had TB (secondary prophylaxis). These reduce the risk of TB by 40-60% in HIV-positive individuals. However, people with HIV tend to have false negative results to TB skin tests, and wide-scale preventive treatment carries a risk that active tuberculosis will mistakenly be treated with a preventive regimen, potentially resulting in epidemics of MDR-TB. Implementation of TB prophylaxis requires strict protocols for treatment and strong linkage with TB control programmes.

Preventive treatment with cotrimoxazole, a common low-cost generic antibiotic, has been shown to result in significant reduction in morbidity in two important studies, irrespective of CD4 counts. Cotrimoxazole prophylaxis can prevent serious infections such as typhoid and toxoplasmosis and may have an antimalarial effect.

Cryptococcus causes sub-acute meningitis, usually fatal if untreated in people with HIV. It is a serious cause of mortality in Africa but its epidemiology in Africa is poorly understood. Regular antifungals, used to treat oral or oesophageal thrush in people with HIV, may be prophylactic although this is not proven.

Recommendations

- Determine protocols for identifying those who can benefit from TB prophylaxis.
- Monitor TB resistance patterns.
- Implement generalized use of cotrimoxazole prophylaxis.
- Monitor impact of cotrimoxazole prophylaxis on clinical outcomes and antibiotic resistance.
- Study antifungal drugs to ascertain optimal timing and dosage for prophylactic use; treatment of thrush may affect cryptococcal meningitis morbidity and mortality.
- Study antimalarial prophylaxis in malaria-endemic countries for people with HIV who may suffer greater malarial morbidity due to a weakened immune system.
- Deworming with agents such as mebendazole or albendazole decreases parasitic morbidity, including anaemia, and decreases the strain on the immune system.

Monitoring HIV infection and ARVs

Background

Care and prevention are two sides of the same coin – better care for people with HIV will have little impact if not linked with prevention programmes, including counselling and testing. Initial evaluation of newly diagnosed patients should include assessment of prognosis and the need for prophylaxis of HIV-related opportunistic infections and/or ARV therapy. In

resource-limited settings, the majority of patients have no access to ARVs, have symptomatic HIV disease at diagnosis and are more likely to have coexisting morbidity⁴. Laboratory tools have been developed and validated to guide clinicians in the care of people with HIV, but in high-prevalence, low-resource areas there is very limited access to these tests, in a context of inadequate health services, lack of consistent laboratory supplies and quality assurance, and scarcity of trained health workers.

Key issues and challenges

Nevertheless, HIV/AIDS care and support is actually being delivered, though it is uncoordinated in some areas, and benefits a limited number of patients. These efforts could be improved, strengthened and widened to include other people in need. A stepwise approach, based on concrete goals, may be a way to break the inertia that condemns millions of human beings to remain in their current situation.

In 1990, a proposal for a staging system for HIV infection and disease was published⁵. This system is based on clinical and biological parameters, using total lymphocyte count as a marker where CD4 counts are unavailable. The WHO staging system has been validated and, according to current therapeutic guidelines, patients who belong to stage 3 or 4 would be eligible to start ARV therapy. Field evaluation of the use of the WHO staging system for initiation of ARV therapy could be an area for research planning in the short term.

The WHO staging system identifies four stages, with a laboratory axis of three categories of CD4+ T-cell counts, replaced by lymphocyte counts when the former are not available:

1. Asymptomatic, with normal performance status.
2. Early disease – mild symptoms/signs, weight loss <10%, oral ulcers, seborrheic dermatitis, herpes zoster, etc. Performance status: symptomatic, normal daily activity.
3. Intermediate stage – ongoing symptoms, unexplained weight loss, chronic diarrhoea, oral thrush, etc. Performance status: in bed <50% of the day for the last month.
4. Late disease – AIDS. Performance status: in bed >50% of the day for the last month.

Plasma viral load is the most sensitive marker of treatment effect. The goal of ARV therapy is to reduce plasma viraemia below the limit of detection to preserve/restore immune functions, preventing disease progression and death. In resource-rich settings it is no longer acceptable to treat HIV with ARVs without knowing baseline and subsequent responses of plasma viral load to therapy. Viral load determinations are expensive and restricted to reference laboratories with their use being limited in developing countries. Efforts to develop reference laboratories in high-prevalence areas have to move in tandem with making ARV therapy available; however, when necessary ARV therapy can be introduced on the basis of clinical criteria and monitored on the basis of clinical responses. In planning treatment interventions in resource-poor areas, the cost of ARV therapy should include the associated cost of monitoring via CD4 count determinations or, failing these, total lymphocyte counts.

Management of opportunistic infections is one of the most cost-effective interventions in HIV medicine. Several studies have shown striking effects on morbidity and mortality through wide use of cotrimoxazole for *Pneumocystis carinii* pneumonia (PCP) prophylaxis, with

secondary impact on bacterial diseases, toxoplasmosis and *Isospora belli* infection.

Recommendations

Care must not be limited to ARV therapy – it should include at least the following:

- Prevention of opportunistic infections
- Treatment of opportunistic infections
- Tuberculosis programmes
- Palliative care.

ARV therapy for people in resource-constrained settings using the highest standards of care through pilot programmes would allow training of health care workers and demonstrate that ARVs can save lives. Pilot programmes could be scaled up or reproduced, resulting in well monitored therapies for increasing numbers of people living with HIV. This process requires coordinated initiatives to improve health worker education, public confidence and health care infrastructure in order to provide concrete help to patients. The first step would involve identification of centres that are already providing ARV therapy in order to start training programmes and develop referral networks.

If and when drugs become available to communities, treatment programmes must be in place for supervised delivery of ARV therapy. It will be essential to centralize information regarding the number of people on treatment, adherence to therapy and toxicity monitoring. Systems should be built simultaneously for safe distribution and use of ARVs, including drug quality, procurement, distribution, dispensing and support. Surveillance of viral resistance for newly infected individuals would be highly desirable, based on ongoing research programmes of the International AIDS Society (IAS), WHO and UNAIDS.

Selection of appropriate antiviral regimens

Guidelines and clinical practice for ARV therapy in industrialized countries are moving towards later initiation of treatment, replacing the previous model of “hit hard and hit early”. This is based on assumptions that eradication is not currently feasible, and that long-term HAART requires almost perfect adherence to drug combination regimens, with associated side-effects, pill burden, food restrictions, drug interactions and interference with patients’ daily life. There is enough evidence now that cheaper and simpler regimens (monotherapy or double nucleoside therapy) are a low-standard approach, which jeopardizes future options and selects for resistance.

The standard of care for HIV-infected individuals eligible to start ARV therapy requires the use of triple combination therapy with at least one protease inhibitor or a non nucleoside reverse transcriptase inhibitor in addition to two analogue nucleosides. Triple nucleoside therapy has also shown similar efficacy to PI-containing regimes. Clinical trials in industrialized countries have shown that both are equally effective in reducing plasma viraemia and that CD4 cell counts increase over a 48-week period. Patients and physicians should decide together about the initial regime after considering the potential for adverse effects and difficulties in adhering to a complex regimen. Simpler regimes with lower pill burdens and less risk of side-effects may be considered. Dosing for populations with different anthropometric characteristics should to be explored urgently in clinical research, since it may provide both cost savings and a reduction in short and long-term toxicities.

Nutrition and complementary therapies

Background

Nutrition for people with HIV and the effects of HIV on nutrition have been key issues since the first discovery of HIV infection in humans. Given that the majority of people with HIV live in countries where many communities are under-nourished, nutrition must be addressed as an integral part of any strategy to ensure adequate treatment and care for people with HIV. Poorly nourished people get sick from HIV-related infections and other health problems sooner than if they had enough of the right food to eat. They also find it harder to fight infections and recover from health problems, thus further shortening their lives.

Complementary therapies, including exercise, massage and promotion of well-being through diet, touch, meditation and related therapies are used by many patients alongside medical treatment. “Alternative” systems of treatment, so named because they may be chosen instead of conventional “Western” health care, would include Chinese, Tibetan, Ayurvedic and other systems of medicine, although when they are routinely used by a population they become mainstream rather than alternative.

Key issues and challenges

Nutritional problems affecting people with HIV include:

- Loss of appetite, nausea and digestive problems, which prevent people eating and absorbing what they need from their food.
- Diarrhoea, causing dehydration and poor absorption of food.
- Increased energy requirements due to fever from illnesses such as malaria or TB.
- Anaemia due to inadequate iron intake or diseases such as malaria or hookworm, causing lack of energy, reducing appetite and ability to cook, work, buy food, etc.
- Infections in the mouth or lips making it difficult to chew and swallow food.
- Poverty and insufficient supplies of food, further compounded when a person with HIV is sick and not able to earn enough (or at all) to purchase necessary supplies of food.
- Environmental circumstances limiting food supplies, such as displacement or crop failure.

Access to food cannot always be taken for granted, even when it appears to be available. Home-grown supplies might be available but not in sufficient quantities, or food may be available at low prices from farms but families may not be able to afford the money and time to get them, making them reliant on nearby retailers where prices are high. People with HIV, family members, carers and assistance programmes need advice and training about food supplies and the nutrients most needed by a person with HIV, including⁶:

Macronutrients

- Energy-providing carbohydrates and fats: an adult with HIV needs 10-15% more energy than an uninfected adult.
- Proteins: an adult with HIV needs 50-100% more protein than an uninfected adult.

Micronutrients (vitamins and minerals)

- Vitamins A, B6, B12, C, iron, selenium and zinc are required to fight infections.
- Vitamin B6 supplements are necessary for people treated for TB with isoniazid.

Food supply planning for people with HIV should therefore favour foods containing these nutrients. Sufficient calorie intake is easier to achieve than increased protein in poorer communities, particularly where the available protein is from bulky foods such as beans and lentils. People also need to understand how to ensure that sick people can eat when they are weak or disabled.

Complementary therapies are used by many people with HIV who find them comforting or stress reducing and supportive of their attempts to live positively with the virus. Physical therapies such as gentle exercise, massage and yoga have an important effect on the functioning of the lymphatic system and can be encouraged in moderation, although they may also result in increased energy requirements from food. Any exercise should be tailored to the abilities of the person involved. Herbal or “home” remedies can also be helpful, providing useful first-aid and costing little. Peer support groups and home care programmes often use complementary therapies alongside encouragement of healthy living and care for sick people.

Traditional healers are available to people with HIV in many regions and countries, either as the main source of health care or as alternatives to medical treatment. They may offer a wide range of treatments, some of them quite complex and involving a spiritual element which makes them different from medical treatment. In some countries, traditional healers are licensed and well organized. They can work alongside Western medical workers or make referrals when someone needs treatment that they cannot provide. They are potentially an important group of people to involve in HIV prevention work. Differences between the work of traditional healers and science-based medicine make it hard to evaluate their effectiveness but also make them attractive when people are dissatisfied with conventional medicine. The costs of traditional treatment may be as high as those of “Western” treatment, but alternative methods of payment are often possible.

Other medical systems have a long history in some parts of the world, particularly in Asia. Millions of people, including people with HIV, use Chinese, Tibetan and Indian systems and some form of them can be found in most parts of the world. Use of alternative medicine may be an alternative to “Western” medicine or a supplement to it. The safety and efficacy of doing either is not well understood and further research is needed about the comparative advantages and disadvantages with regard to HIV.

Recommendations

- Nutritional needs must be addressed as integral to any care and treatment programme.
- High priority must be given to security and safety of food and water supplies for all people with HIV. If whole communities lack these supplies, the needs of people with HIV must not be addressed in isolation – supplies must be made available to all who need them.
- Attention must be paid in care programmes to the special nutritional needs of people with HIV. Advice and training should be given about increased energy and protein needs and about foods that provide key micronutrients. Support must be given to food-growing efforts by and for

- people with HIV and for their families and communities.
- Complementary and alternative therapies that are proven supports for positive living in people with HIV should be included where possible in treatment and care programmes.
 - Qualitative methods to test acceptability and changes in well-being should be applied alongside quantitative studies to test the efficacy and safety of traditional remedies and therapies and to check for interactions with pharmaceutical treatments.
 - Efforts must be continued and experiences shared on the involvement of traditional healers in HIV prevention and care for people with HIV.
 - Research must continue into the effects and safety of alternative medical treatments with regard to HIV and potential interactions with pharmaceutical medicines.
 - People with HIV must be informed of, and protected from, the use of treatments where evidence shows that they are harmful, interact adversely with pharmaceutical treatments, or are of doubtful efficacy, so as to prevent harm and avoid waste of resources.

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Expert contribution

The Benin Initiative on Access to Antiretrovirals

Jean Sehonou

According to the estimate of the National AIDS Control Programme, seroprevalence of HIV/AIDS infection in Benin was 4% in 1999¹. Beyond this figure, which may appear modest compared to rates prevailing in other countries of the sub-region, the issue of concern is the ten-fold multiplication of this seroprevalence over the past ten years. Several (one short-term and two medium-term) plans have been put in place and, in 2000, a national AIDS control strategy was developed.

If the emphasis has been placed on prevention, counselling and testing, psychosocial, economic and medical care, it is also true that treatment, particularly with antiretrovirals (ARVs), also occupies an important place. The Benin Initiative on Access to Antiretrovirals (BIA ARV) falls within this framework.

Establishment of the institutional framework

The initiative, which is the outcome of the collaboration between France, represented by the International Therapeutic Solidarity Fund (ITSF), the nongovernmental organization (NGO) Action Plus AIDS Health and the Government of Benin, proposes to offer ARV treatment to 400 patients over a period of two years at a cost of about US\$ 1000 per patient per annum.

An Eligibility Committee was set up by Ministerial Decree No 7345/MSP/DC/SGM/PNLS/SA of 5 November 2001. It is composed of about 20 pluri-disciplinary and pluri-professional members: 11 doctors, two pharmacists from the public and private sectors, two representatives of NGOs involved in the fight against HIV/AIDS, one representative of people living with HIV/AIDS (PLWHA), one representative of the employers' association and two representatives of civil society. The mission of the committee is to select PLWHA to whom tritherapy will be administered on the basis of specific scientific criteria, and also to determine the level of financial participation of the selected patients.

The Eligibility Committee meets once a month to analyse and take a decision on applications submitted to it by the technical coordinator. The initiative is managed by a Steering Committee. The Eligibility and Steering Committees are both headed by the coordinator of the National Aids Control Programme.

Three sites in the economic capital, Cotonou (National Teaching Hospital, Ambulatory Treatment Centre and Medico-Social Centre of GUEZO Camp), and two sites in Porto Novo, the political capital (Departmental Hospital and a private clinic, the Louis Pasteur Clinic) have been identified and retained.

Training of the members of the initiative

Concurrent to the establishment of the committees, three training sessions were organized for about 30 health professionals (hospital doctors and private doctors) who would provide care to

the patients. The course content gradually moved from general knowledge on HIV/AIDS and sexually transmitted infections (STIs) to manipulation of ARVs (surveillance and prescription of treatment, prevention and management of side-effects, etc.). The training courses, organized in the form of workshops, were also held on the three sites in Cotonou for paramedical and perimedical staff.

Recruitment of patients

After testing positive, the patient is invited to report for a biological check up, comprising tests to confirm the diagnosis, count the CD4/CD8 lymphocyte sub-types, as well as haemogram, transaminases, glycaemia, creatinaemia, and amylasaemia. The patient bears the cost of these initial tests. However, the costs of the CD4 test – about CFAF 15 000 (US\$ 15.4) may be refunded if the patient is considered eligible. This examination, which is expensive (60% of the minimum monthly wage in our country), constitutes a major limiting factor for some patients.

Dosage of the plasmatic viral load is not yet a routine test. Serotheques are constituted for their eventual dosage.

A synthesis sheet containing all the data of the biological clinical examination, together with the social survey, are sent by the doctors of the site to the Eligibility Committee, which makes a final decision. The cost of the monthly biological follow-up is borne by the programme.

Eligibility is based mainly on clinico-biological and socioeconomic criteria. At the clinical level, a CD4 rate below 200 per mm³ is a major criterion of inclusion, whether the patient is symptomatic or not.

The psychological and social criteria include, among others, the socioeconomic situation of the patient, his/her commitment to strictly comply with the constraints of the programme (frequency of consultations, biological tests, taking of drugs), and his/her living conditions (declared income, number of dependants, accommodation, place of abode). The personal and environmental capacities of adherence to the treatment are evaluated by both the doctor and social worker. To that end, a social worker is recruited and attached to each site. An informed agreement is signed by the patient.

Patients are requested to make a monthly contribution of CFAF 1000, 5000 or 20 000 depending on the data of the social survey.

On average, the Eligibility Committee meets once a month to take a decision on applications submitted anonymously.

Results

Since September 2001, 120 applications from adults² (12 of which cannot be examined because they are incomplete), have been submitted to the Eligibility Committee. The remaining 108 were subjected to in-depth examination and decisions taken on them. Out of these initial applications submitted to the committee:

- 54 concerned female patients (50%).
- The average age was 36 years with the extremes ranging from 17 to 62 years.
- Most of them were married couples of monogamous (42.6%) or polygamous (11.2%) families, single (16.7%) or widowed (10.2%).
- 82% have a CD4 rate of below 200 per mm³ according to CDC classification, 40.7% belong to the B3 stage and 36.1% to stage C3.

- 42% present a hepatic cytolysis.
- 98 patients (90%) were declared eligible. A CD4 rate of well above 200 per mm³ among patients not yet treated is one of the major reasons for non-eligibility.

Since the beginning of March 2002, about 50 patients are effectively on ARVs. First (3TC + ddI +IP, d4T+ ddI + IP) and second intention protocols have been established and indications given to the referral doctor, taking into account not only the stock available but also the clinical state and biological parameters. For example, zidovudine, which is relatively expensive and anaemiant, is not proposed in first intention protocols in our first-line schemes. The addition of ritonavir to indinavir helps, with the same efficacy, to reduce the number of capsules and the frequency of taking antiproteases; this could contribute to promoting adherence to treatment.

At the socioeconomic level, the social survey was not done in 30% of the cases. In the other cases, the financial participation proposed by the social worker, and most often approved by the Eligibility Committee, was CFAF 1000 (21.3% of cases) and CFAF 5000 (11.1% of cases). It was in just one instance that a financial participation of CFAF 20 000 was proposed.

Lessons learnt

- Knowledge of the biological and immunological profile of HIV patients in Benin is increasingly getting better.
- Education of patients and counselling in the area of ARVs need to be intensified in order to avoid encouraging false beliefs. Patients did not deem it necessary to announce their HIV-positive status to their spouse, as they believed that ARV treatment was going to free them from the use of condoms.
- The financial difficulties of the patients are considerable and may have a negative impact on adherence. In fact, despite the low financial participation proposed, the patients are incapable of meeting their primary needs (food, travel, etc.). These difficulties are all the more important since the people concerned are most often physically affected, and consequently impoverished by the increase in their health expenditures and the fact that they are not engaged in any professional activity. Some had already, at cost price, started the ARV treatment (in the hope of being supported by the initiative) but this has ruined them financially.
- Additional psychosocial care programmes are being developed to make up for the financial difficulties of the patients, without developing the chronic assistance phenomenon.

Prospects

New paths are opening up for the programme:

- Partnership with the Global Fund to Fight AIDS, Tuberculosis and Malaria, which plans to provide care to 2000 patients over a three-year period for the country with an amount of US\$ 6 428 571.

- Negotiations are underway between national authorities and laboratories producing generic drugs (with Indian Laboratories CIPLA) to facilitate access of the greatest number of PLWHA to ARVs.
- Inter-hospital partnership is also being initiated: it is proposed to establish a partnership between the National Teaching Hospital and Paris hospitals.
- Prevention of vertical transmission through the use of nevirapine during childbirth, which was the subject of a pilot study on 15 000 pregnant women in Cotonou in 2000, will be intensified in all major towns of the country.

Despite the start-up difficulties, the interest of putting in place the Benin Initiative on Access to Antiretrovirals has confirmed that it is possible for a poor country to have access to ARVs: it changes the paradigms and improves prevention.

In that respect, we can say that it is already an achievement, although a lot remains to be done.

NOTES

- 1 It is estimated that 169 500 people are living with HIV in Benin.
- 2 The recruitment of children into the programme has not yet begun.

Chapter 2

Access to care and research

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The objectives of this chapter are: 1) to propose research themes that could contribute, in the short term, to the scaling up of care and treatment of people living with HIV in developing countries, at the bio-medical, sociobehavioural and economic levels; and 2) to envisage the conditions under which the research on these themes should be conducted.

The experts unanimously considered that research development should not be a pretext to slow down the efforts of the international community to extend access to antiretrovirals (ARVs). On the contrary, research is considered as an indispensable complement to this extension, or as one of its engines. Hence, it was strongly recommended to integrate a research and evaluation component into programmes on access to treatments: concurrent to the establishment of research protocols or specific therapeutic tests, the collection of virological, immunological and behavioural data on patients participating in these programmes should facilitate the evaluation of their impact and help to improve the care and treatment.

Biomedical research priorities in developing countries

Initiation to ARV therapies

Without challenging the consensus on optimal anti-HIV treatment, it is necessary to define the therapeutic care and treatment that is most adaptable to low-income countries.

What is the most appropriate time to initiate an ARV treatment? In developed countries, the answer to this question has constantly evolved through research and the resulting recommendations are always based on virological, immunological and clinical judgement criteria. In low-income countries, where availability of immuno-virological tests is limited, care providers often rely on clinical science alone to decide to put their patients on treatment. Although this contextual approach cannot be criticized, research verifying the relationship between clinical science and biological reference data would be beneficial. Besides, in the framework of this research, it is necessary to take into consideration certain regional epidemiological specificities such as lymphocytoses, which are frequently found in Africa and the Caribbean Basin.

Biological monitoring

Obviously, alternative techniques for biological monitoring of people living with HIV should be researched and/or evaluated actively (types of sample, laboratory techniques, stability, preservation). As in the case of the participants of the World Health Organization (WHO) Meeting in May 2001, it was recommended to reserve the use of the viral burden for research

purposes only, by comparing it, for example, to the monitoring based solely on the association of CD4 and clinical signs.

Therapeutic strategies

Beyond the initiation of the treatment and biological monitoring, it is essential to evaluate the best possible therapeutic strategies for patients in developing countries, including:

- Simplification of the therapeutic regimens (reduction of doses, three molecules in a single tablet, etc.).
- Accompanying patients in order to improve adherence (comparison of different models of directly observed therapy (DOT), psychosocial follow-up, home care, involvement of communities of infected people).
- Personalized monitoring of side-effects of the drugs (dosages adapted to weight, plasma concentrations, where possible).
- Observation of interactions with traditional medicine.
- Addressing nutritional problems.
- Personalized monitoring of drug resistance, at least for patients participating in research.
- Specific surveillance of tuberculosis.
- Programmed therapeutic interruptions.

Research on all these aspects of treatments, in the broadest sense, should ultimately help to optimize the meeting of ARV needs in an equitable and efficient manner.

Specific populations and situations

Special attention should be paid to specific populations and situations. Concerning pregnant women, it was recommended to put in place pilot interventions and observation cohorts for the prevention of mother-to-child transmission (MTCT). In fact, it seems essential to study, within this population, the acceptability of treatments, adherence to treatments, appearance of viral resistance, the risk of HIV transmission by women receiving prophylaxis while breastfeeding, supplementary interventions to prophylaxes, efficacy of new molecules in this field and, an equally important theme, different feeding options for children.

Breastfeeding should be the subject of in-depth studies because of the correlation between risk of HIV transmission, ARVs and breastfeeding; mechanisms and determinants of HIV transmission through breastmilk; improving knowledge of the different breastfeeding practices. Newborns and children should be included in research aimed at evaluating the consequences of the different methods of infant feeding, whether the milk is contaminated or not, and on morbidity and mortality. Moreover, studies on paediatric formulations of ARVs and therapeutic strategies adapted to their situation (dosages, etc.) should be launched. This recommendation is not specific to developing countries. Finally, the passage of ARV molecules into genital secretions should be subjected to more advanced exploration.

Optimizing treatment of opportunistic infections

Optimization of ARV treatments also goes hand in hand with that of treatment of opportunistic infections. Since the latter concerns the entire population of people living with HIV or exposed to HIV, it was proposed to develop an algorithm of diagnostics and treatments adapted to low-

income countries. Special attention should be paid to the consequences of diarrhoea (often accompanied by dehydration and severe undernutrition), as well as kidney infections. Furthermore, attention should also be given to potentially effective treatments, absorption of drugs against these pathologies, and the effects of ARV toxicity on hepatic diseases.

Among the opportunistic infections, tuberculosis continues to cause great concern. The impact of ARVs on its secondary incidence should also be analysed.

Post-exposure prophylaxis

Care providers benefiting from post-exposure prophylaxis following occupational accidents should be included in epidemiological studies on the risk of transmission, side-effects of treatments (*a fortiori* acceptability of the treatments) and viral resistance.

Viral resistance

Research on viral resistance should be conducted at the level of both individual monitoring of patients, among the entire population and at the level of the epidemiological and observational studies to be conducted:

- Study of risks of emergence of resistant HIV-1 and HIV-2 variants: rapid creation of a sentinel network of surveillance of the circulation of these variants, for example, at the regional level, in collaboration with reference laboratories in the North and South.
- More advanced studies on individuals subjected to viral invasion and those included in the therapeutic cohorts (MTCT, etc.).
- Evaluation of the risks of selecting resistant variants according to the viral sub-type.
- Incidence of resistant variants among the patients treated.

Public health research priorities in scaling up access to ARVs

Integration of ARVs into health care systems

The feasibility of programmes on access to ARVs was demonstrated in the framework of pilot experiments conducted on a limited number of patients. Scaling up access to ARVs raises many questions related to the capacity of health care systems, often seriously limited, to develop a new complex activity that demands human and financial resources and the optimum conditions of implementation. The process should be backed with the development of operational research in order to identify the major obstacles and contribute to the search for solutions.

Scaling up access to ARVs in developing countries goes hand in hand with that of access to HIV testing. Counselling should also be intensified, not only in the testing centres, but also in all centres where clinical diagnostics are practised, thanks notably to the training of the medical teams locally. Before transforming testing and counselling centres into units providing diagnostic and care services, it would be necessary to evaluate their capacities to do so.

More generally, scaling up access to ARVs cannot rely on existing mechanisms for HIV care and treatment alone. It should also rely on health programmes in other areas (e.g.

maternal health, reproductive health, control of tuberculosis, diarrhoea and malnutrition) and related infrastructures (e.g. perinatal consultation centres, dispensaries, the Centre de Récupération et Education Nutritionnelle), be they peripheral or not. Indeed, those programmes that are not doing so already should be made to encourage HIV testing and provide the therapeutic care to people infected with HIV. To that end, three strategies are proposed: 1) training of care providers (e.g. basic medical issues, stigmatization); 2) linking of HIV programmes with other programmes; and 3) standardization of protocols and tools for HIV testing and therapeutic care. These strategies should be evaluated.

The same approach is recommended for family planning centres, on condition that their accessibility is extended, particularly to breastfeeding mothers.

Ultimately, and still in the perspective of improving care and treatment of people living with HIV, the evaluation of the application of these strategies by centres not dealing specifically with HIV should provide answers to many practical issues, particularly:

- Which “entry points” of the care system are more efficient, acceptable and applicable for providing care and treatment with ARVs (clinics for MTCT, voluntary counselling and testing (VCT), sexually transmitted diseases (STDs) or tuberculosis, or general outpatient clinics)?
- What equilibrium should be found between comprehensive care and treatment and specialization (e.g. quality and continuity of care, acceptability)?
- What impact can the management of ARVs have on that of other essential drugs (e.g. tuberculosis, STDs, etc.) in health care centres?
- How will the workload and time of care providers be distributed among the different units? How many consultations per doctor? What kind of training? What kind of access to laboratory tests?
- What are the implications for community-based organizations (CBOs) in the centres?
- How can medical care services be coordinated with those of centres for psychosocial and legal care?
- What nutritional care should be developed?
- How can the management of medical information be optimized (e.g. use of medical files, referral and counter-referral modalities)?
- How can the teams in place ensure efficient management of confidentiality?

To perpetuate access to ARVs, the research should be focused on systems of supply and distribution of drugs in order to avoid theft, excessive use of unprescribed drugs and loss of drugs due to storage problems. It should at the same time pay attention to the circulation of all anti-HIV drugs (including “traditional” drugs), and in particular on: 1) diversion of indications, use of expired drugs, imitation drugs; 2) places and circumstances in which drugs are prescribed and sold; and 3) consultants and users of these drugs.

To ensure greater involvement of families and communities, it is necessary to identify the best forms of home care. Furthermore, the role of CBOs in accompanying and improving adherence should also be evaluated (with particular emphasis on their availability, their acceptability by patients and care providers, and the consequences of an eventual acknowledgement of their status on the subject).

Adherence and DOT

This reflection naturally leads us to envisage the monitoring of the treatments from a perspective of large-scale access to ARVs.

The issue of determinants of adherence to treatments and continuity of care, among all the populations concerned, should be studied. This analysis cannot be limited to the sole behaviour of the patient. The conditions of care and treatment, the relationship with the service provider and the organization of the health care system, and the distribution of treatments are all factors to be taken into consideration. Similarly, it is important to evaluate the amount of expense that a family can effectively devote to anti-HIV treatments and ARVs.

The different methods of intervention concerning patients and health professionals should also be evaluated. Hence, the different models of DOTs that can provide support to adherence should be evaluated, compared to one another, as well as to other types of monitoring of patients in this field. For example, will the idea of “making responsible” the patient who chooses his own “companion”, when DOT is prescribed, be more beneficial than another type of DOT in terms of adherence to treatment?

Such interventions should be adapted to the sociocultural context of the patient. The research should contribute to the study of these contexts in order to ensure greater coherence between actions implemented and the context.

Finally, the impact of ARVs on the quality of life should be analysed.

Economic evaluation

In the area of economic evaluation of enhanced access to ARVs, cost-efficiency analyses, based on data from clinical cohorts, should help to better define the criteria of access to treatments. It should also facilitate in-depth comparisons between the different therapeutic strategies at the economic level.

These analyses should integrate the “indirect” costs associated with the disease (including production losses through morbidity and mortality) and the reduction of these costs with treatment. The impact on national budgets should also be evaluated. Similarly, an exhaustive study on the funding mechanisms (private sector, social security and assistance schemes) that could ensure the perpetuation of the enhanced access should be carried out.

Linking care and prevention

Scaling up access to ARVs arouses a debate on its relationship to prevention. Research should be conducted in order to document this debate in a rigorous manner. The priority themes are as follows:

- Changes in the attitudes and behaviours regarding risks associated with HIV, among people living with HIV and among HIV-negative people, and access to testing (this issue should be examined particularly among HIV-discordant couples).
- Attitudes and behaviours of care providers towards people living with HIV, behaviour of care providers, and evaluation of the knowledge of professionals in the areas of prevention, recommendation for testing and counselling, treatment of opportunistic diseases, and HIV itself.
- Prevention behaviour of care providers in relation to occupational exposure.
- Identification and evaluation of the interventions, based on the supply of ARVs

resulting in a reduction of stigmatization, within the family and the couple, as well as in the health care units.

- Evaluation and modelling of the long-term impact of ARVs on the epidemic (these analyses should simultaneously address the reduction of transmissibility of HIV, the changes in behaviour and life expectancy after putting the patient on treatment).

Conditions for developing research

Beyond the legal and institutional aspect regarding the respect of the individual, it is imperative that the research should be conducted under the following conditions:

- Ensuring, first of all, the availability of a “package” of care (including, where possible, ARVs for patients who have to leave the studies) for their participants.
- Facilitating equitable recruitment of women and men.
- Ensuring accessibility to anti-tuberculosis drugs for their participants, and where necessary, to DOT models specific to this pathology.
- Integrating education programmes on basic hygiene into all programmes focused on pregnant women.

Research should be conducted under a mutual partnership agreement between researchers of the host countries and those of the financing countries. Such partnerships should ensure that the development of research is in line with the public health priorities of the host countries.

The communities should become the real partners of the research. They should be consulted at the various stages of the research projects in order to solicit their views on the nature and definition of the research, the benefits expected and the potential risks, the informed consent and “package” of care.

Expert contribution

Prevention and care of HIV infection in pregnant women, mothers and children

Phillipe Van de Perre

Significant progress has been achieved recently in access to HIV antiretroviral (ARV) therapy in developing countries. In spite of these efforts, UNAIDS and WHO estimate that at the end of 2001 around 40 million people were living with HIV infection, 95% of them in the developing world. UNAIDS and WHO also estimate that at least 5 million became infected and 3 million died of HIV infection during the year 2001 alone¹.

Mother-to-child transmission (MTCT) of HIV-1 represents a particularly dramatic aspect of the HIV epidemic with an estimated 600 000 newborns infected yearly, 90% of them living in sub-Saharan Africa. As mother and child health is a key factor for any sustainable development, prevention of MTCT of HIV-1 must be a priority and become achievable in many countries as well as mothers' accessibility to ARV therapy when indicated. In many parts of the world, HIV/AIDS is already the leading cause of adult and child mortality. The HIV pandemic compromises the gains made in recent decades in terms of quality of life and life expectancy².

Opportunities

Important prerequisites for access to care implementation involve the whole health system and structure (e.g. accessibility, social acceptability, structures and competence for voluntary counselling and testing (VCT), education of health professionals), as well as economic and political commitment. A new comprehensive and socially acceptable concept of taking care of households instead of individuals is emerging in some countries such as South Africa³, Botswana⁴ and India⁵. This concept could decrease the economic fragility of affected households and mitigate the impact of HIV/AIDS on vulnerable children and orphans.

Innovative and appropriate technologies are developed or are already available, such as plasma and salivary rapid test for HIV diagnosis in adults, as well as CD4+ T-cell counts by alternatives to flow cytometry⁶ and modified p24 antigen measurement technologies for monitoring of therapeutic efficacy⁷. These techniques could render monitoring and diagnosis more accessible and affordable in resource-limited settings.

New drugs that may be active against HIV, including new ARV families (integrase inhibitors, inhibitors of viral assembly, cytokine as adjuvants, etc.) and drugs from the traditional pharmacopoeia (China, India and some African countries) are currently under evaluation⁸. These compounds may improve the efficacy of current ARV regimens.

Challenges

The success of HIV/AIDS prevention and care programmes depends on good access to and performance of the primary health care system. However, in resource-limited countries, the human, financial and logistic resources needed for programmes of HIV/AIDS care may compete

with other sectors of the health care systems. The strengthening of the necessary infrastructure and human resources to deliver HIV/AIDS prevention and care is of the utmost priority.

Access to care/ARV drugs should not be restricted to ARV therapy alone but should be considered as a continuum of medical and psychosocial support. Antenatal care and VCT are entry points for prevention and care but are presently frequently lacking or not fully operational. Voluntary counselling, testing and care should be regarded as components of a comprehensive package of prevention and care. ARVs and drugs for prophylaxis and treatment of opportunistic infections should be made available, affordable and sustainable, and be distributed in an equitable way. On no account should an HIV-infected pregnant woman eligible for ARV therapy be deprived of adequate ARV therapy for herself, where available. HIV/AIDS prevention and care programmes should also include availability of reliable and inexpensive tests to diagnose and monitor the treatment of HIV infection and associated conditions, as well as appropriate training for health care workers in management. Urgent recommendations are needed for criteria for initiation of therapy, scheduling, switching, interrupting and monitoring regimens. In order to ensure the success of such programmes, joint decision-making involving the whole therapeutic team and the household/family is mandatory. Health care workers should be provided with training on occupational hazards, appropriate equipment and management of all accidental exposures.

Disclosure of the HIV test results to the husband/partner and significant others varies considerably from one area to another (50-80% in Soweto, South Africa; 17% in Dar es Salaam, Tanzania; 15% in Namakkal, India; and less than 10% in Abidjan, Côte d'Ivoire and Bobo-Dioulasso, Burkina Faso) and is a frequent limiting factor for maternal interventions (ARV therapy, feeding practices, etc.)^{3-5, 9}.

The efficacy of a short regimen of perinatal prophylactic ARV drugs in reducing the rate of MTCT of HIV-1 decreases over time and may even be lost if breastfeeding is prolonged⁹⁻¹¹.

The maternal CD4+ T-cell count is a strong predictor of the efficacy of perinatal prophylactic ARV treatment. Indeed, in a combined analysis of two clinical trials evaluating short zidovudine regimens given during the perinatal period, no efficacy on MTCT was demonstrable at any time of the follow-up in women who had less than 500 CD4+ T cells per mm³ at delivery^{9, 11}. However, in women with more than 500 CD4+ T cells per mm³ at delivery, breastfeeding had only a minimal impact on transmission.

Interruption of maternal ARV administration around the time of lactation may increase the short-term viral load in breastmilk and, putatively, transmission to the infant⁹. Breastfeeding by HIV-infected women has been reported to be associated with excess maternal mortality in a clinical trial performed in Nairobi, Kenya¹².

A framework for research actions

How to improve existing pilot interventions aimed at reducing mother-to-child transmission of HIV?

Of particular interest is operational research on primary prevention of HIV acquisition in young women of reproductive age, in addition to the provision of adequate family planning services for HIV-infected women who wish to avoid undesired pregnancy.

As research questions are mainly operational in many settings, research priorities may not be on assessing improvement of existing short ARV perinatal regimens efficacy by means of controlled clinical trials. In these settings, emphasis should be put on prophylactic cohorts and

pilot interventions. Questions of operational research that should be addressed in therapeutic/prophylactic cohort studies should focus on social acceptability and observance of prophylactic and therapeutic ARV regimens, monitoring of drug resistance, infant feeding options, shared confidentiality, social stigma and social/familial consequences of HIV result disclosure. Ideally, in order to improve MTCT intervention programme coverage, the disclosure by women of their HIV test result to husband/partner and significant others should be encouraged by learning from successful experiences (such as in South Africa and India), with respect to local sociocultural mores. Disclosure of HIV status may further encourage the husband/partner to get tested and improve the overall efficacy of prevention programmes. The social consequences of disclosure should be carefully elucidated in all settings prior to implementation.

In programmes for the prevention of MTCT of HIV-1, CD4+ T-cell count as well as other surrogate markers still to be validated, may become a critical criterion for adapting prophylaxis, maternal treatment and appropriate infant feeding options (see Figure 1).

Mass prophylaxis of pregnant women (regardless of their HIV serostatus) with a single dose of non-nucleosidic reverse transcriptase inhibitor, such as NVP, has been advocated in areas of high HIV prevalence¹³. Although probably cost-effective, this procedure is of unknown efficacy and has the disadvantage of depriving women, couples and families of VCT benefits and of exposing women and children to needless ARV monoprophyllaxis. In no instance should prevention of MTCT be regarded as solely delivering ARV, as VCT by itself may have a clear positive impact on HIV prevention and care (safer sex, nutritional counselling, etc.)¹⁴.

Evaluation of efficacy and tolerance of preventive interventions complementary to ARV prophylaxis such as HIV perinatal vaccine, passive immunoprophyllaxis, micronutrient supplementation and vaginal-cervical disinfection by means of microbicides should be actively continued and encouraged.

Is there a place for evaluation of new ARV molecules particularly suitable for prevention of MTCT in developing countries?

The characteristics of some new molecules may make them less satisfactory for the treatment of patients infected with HIV but particularly suitable for prophylaxis of MTCT in developing countries. In order to ensure access to these new drugs for developing countries, these molecules, which may not be commercially attractive for industrial companies, may be further developed and scientifically evaluated by the public sector or nongovernmental organizations (NGOs). Good safety profiles, ability to rapidly decrease viral load, low cost, and potential for production in large amounts, are all characteristics that render some of these molecules (such as new non nucleosidic reverse transcriptase inhibitors) particularly interesting to develop and evaluate.

How to reduce the risk of transmission by breastfeeding?

The mechanisms and determinants of HIV transmission by breastfeeding are still poorly understood and should be the scope of explanatory research, including through the use of animal simian immunodeficiency virus (SIV) models. More research is urgently needed on differential transmission risks associated with breastfeeding practices, patho-physiology of breastmilk transmission and viral/host relationships related to MTCT. Social sciences should contribute considerably to our understanding of HIV transmission by breastfeeding.

Although perinatal prophylaxis using short ARV regimens has been shown to be remarkably effective, more research is required for ensuring a maintained reduction of the

transmission risk in mothers who benefited from a perinatal prophylactic ARV treatment but have no acceptable alternative to breastfeeding. Maternal and/or infant ARV prophylaxis prolonged during the whole duration of lactation or deferred at the introduction of a weaning food is of unknown efficacy, although theoretically appealing. However, efficacy may be difficult to assess (due to ethical and methodological issues such as the number of study participants needed for assessing efficacy in a controlled clinical trial). The application of UN Agencies' recommendations is expected to be more effective in reducing postnatal transmission of HIV-1 than any new ARV treatment administered to mothers and/or infants if mixed feeding is applied for prolonged periods; this also applies to those mothers who choose to practise exclusive breastfeeding for 4-6 weeks followed by rapid weaning.

A possible association between an excess of maternal mortality in HIV-infected mothers and breastfeeding should be urgently scrutinized in existing data sets (retrospectively) and in new research projects.

Considerable efforts are still needed to optimize the safety of all potential feeding practices by appropriate education of both health professionals and mothers and to identify adequate standardized indicators to assess infant feeding practices (formula feeding, animal milk, exclusive breastfeeding, early cessation of breastfeeding, etc.). Similarly, the consequences of each infant feeding option in terms of infant morbidity and mortality should be urgently studied both in HIV-infected and uninfected infants.

How to link prevention and care?

It is tremendously important to link prophylaxis of MTCT with maternal and child care, using new tools to help decisions to treat and to monitor HIV treatments, such as cheap, alternative techniques to perform CD4 cell counts (immunomagnetic or immunochemistic methods, ELISA, etc.). An example of a preventive/therapeutic scheme in which feasibility, acceptability, efficacy and tolerance should be evaluated is given in Figure 1.

How to improve maternal/child morbidity and mortality?

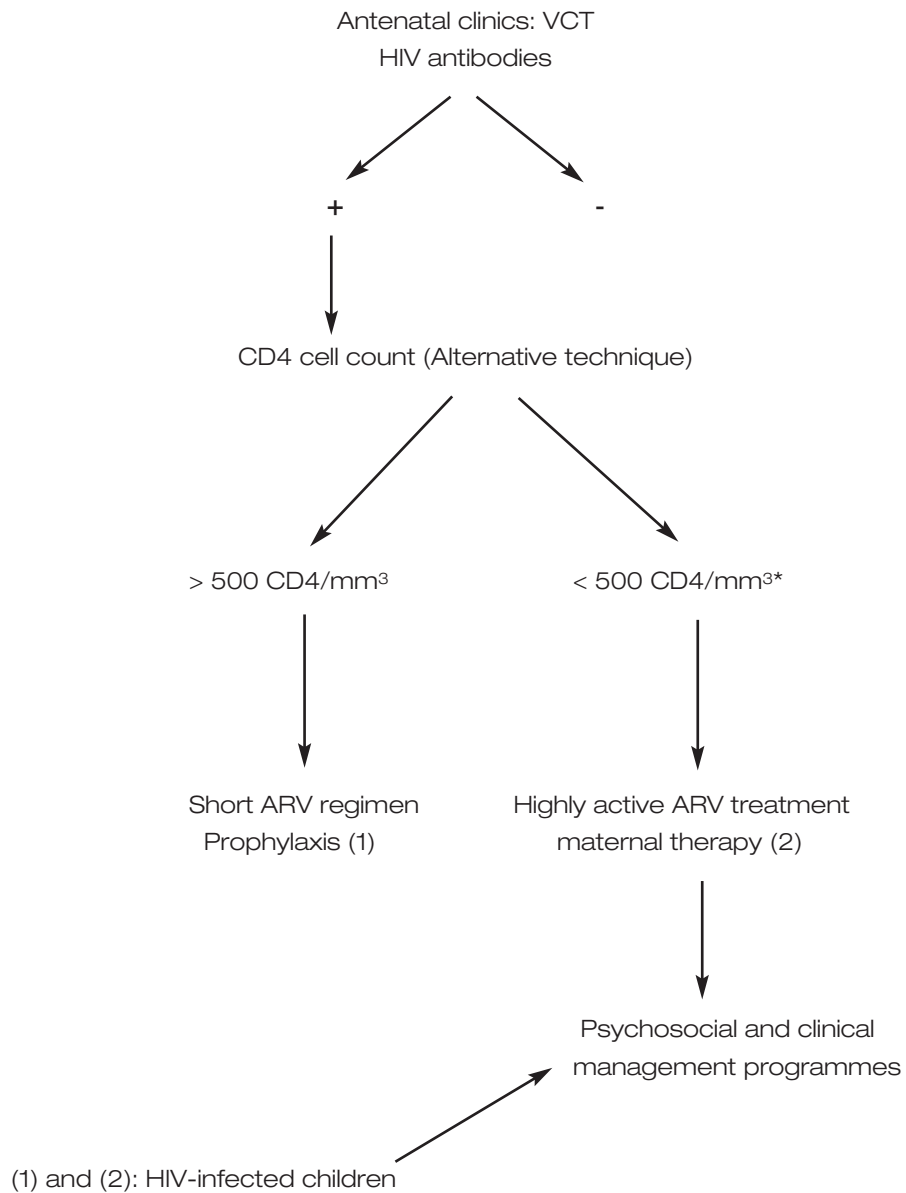
In order to ensure the integration and synergism of innovative interventions to prevent MTCT of HIV with existing antenatal/obstetric perinatal care activities, comprehensive packages of antenatal and obstetric care that could be administered to both HIV-infected and uninfected women should be urgently evaluated. The overall efficacy of the administration of these packages (including micronutrients supplementation, malaria treatment and prophylaxis, use of vaginal microbicides, correction/prevention of pregnancy anaemia, diagnosis and treatment of sexually transmitted infections (STIs) and fulfilment of emergency obstetric needs) should be evaluated in terms of maternal and child morbidity and mortality. Improved access to appropriate family planning services should also be studied (also for those who are breastfeeding their child).

Framework for partnership

Universities, national and international research centres, associations of people living with HIV, NGOs, other non-profit organizations and the pharmaceutical and biotechnology industries, are all potentially synergistic contributors. In particular, the creation of a common supranational body for the ethical review of new research initiatives is timely and appropriate and should be articulated with national ethical committees.

FIGURE 1:

Example of an intervention associating prevention of MTCT and maternal treatment of mothers and children (to be evaluated for feasibility, social acceptability, compliance, tolerance and efficacy)



* Due to physiological lymphocytosis in many African patients, 500 CD4/mm³ is equivalent to 350 CD4/mm³ in European patients¹⁵

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AUTHOR'S NOTE

This document largely covers and extends a meeting report entitled "Mother-to child transmission of HIV-1 and antiretroviral therapy: A scientific and community challenge", Meeting of World Federation of Scientists in Erice, Italy, August 2001. Joint Working Group Report of AIDS and Infectious Diseases PMP, and Mother and Child Health PMP.

Group members included: G Biberfeld (Solna, Sweden), P Biberfeld (Stockholm, Sweden), F Buonaguro (Naples, Italy), N Charpak (Bogota, Colombia), G de Thé (Paris, France), MF Rea (Sao Paulo, Brazil), G Gray (Soweto, South Africa), Ch Huraux (Paris, France), A Lindberg (Marcy l'Etoile, France), NM Samuel (Guindy-Chennai, India), G Scarlatti (Milan, Italy), S Tlou (Gaborone, Botswana), Ph Van de Perre (Montpellier, France), Zeng Yi (Beijing, China), R Zetterström (Stockholm, Sweden).

Expert contribution

Planning the incorporation of antiretroviral therapy into comprehensive care programmes

Eric van Praag

Preliminary findings from the introduction of antiretroviral (ARV) therapy in district-based comprehensive HIV care services in highly affected countries in Africa suggest that such an approach is both acceptable and feasible. Results in adherence rates, for example, are comparable to what is found in Asia/Pacific, the Americas and Europe¹. To date, ARV therapy interventions have been small scale, because only a very few people could afford the ARV drugs, because the particular project was targeted for a pre-determined catchment area of a health unit and was heavily subsidized, or because it was implemented in a low-prevalence country¹.

With the price of ARV drugs decreasing, thus making the drugs more affordable for programmes and clients, programme managers and health planners need to consider a number of planning questions in order to design scaled up services while ensuring sustainability and feasibility within current health systems. This paper responds to the following four questions:

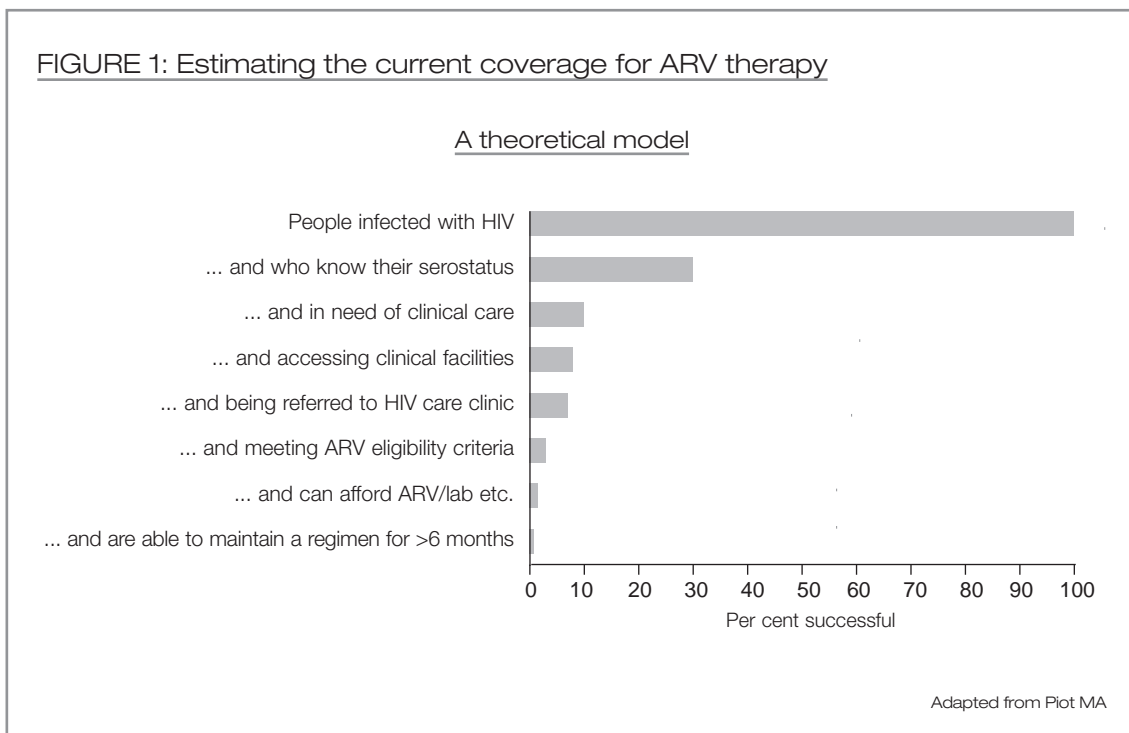
- 1 What are the expected numbers of patients to benefit from the interventions?
- 2 Will standardization of the interventions be able to obtain the minimally required resources (financial/technical/human) to meet current and expected demands?
- 3 What can be done to involve communities in the expansion and replication process?
- 4 How would a simple and sound monitoring and evaluation framework allow rapid learning from the interventions?

Question 1

What are the expected numbers of patients to benefit from the interventions?

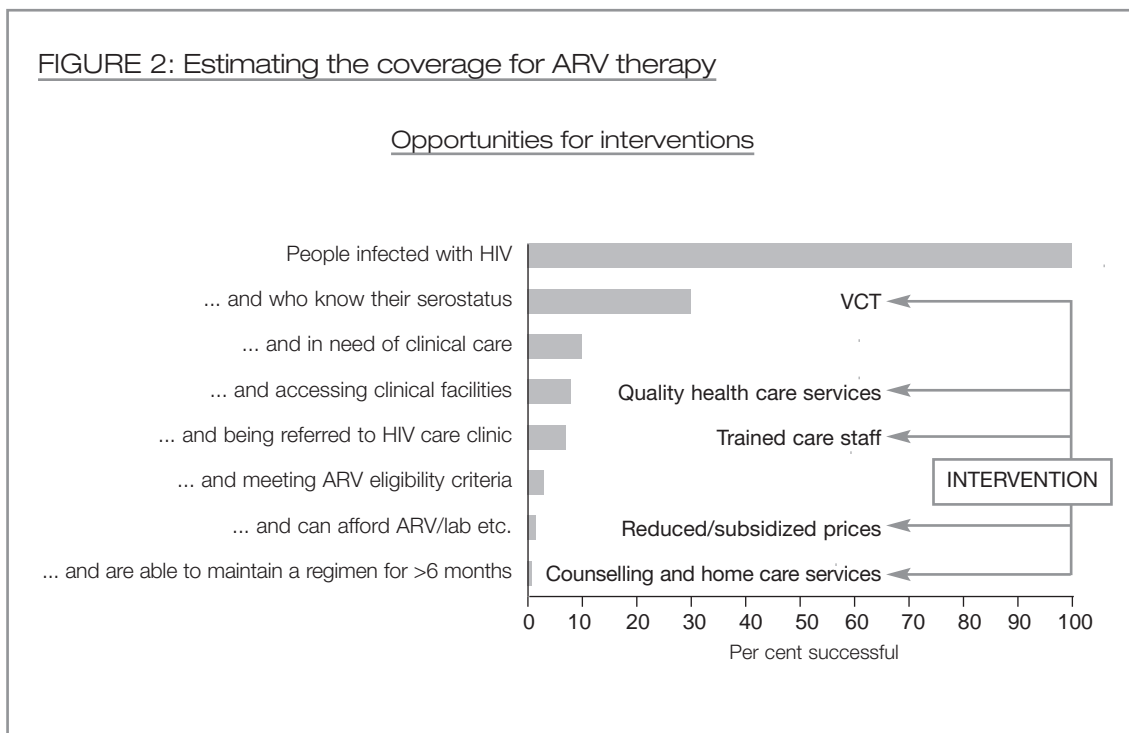
In order to plan adequately for the demands for HIV care when introducing ARV therapy (e.g. drug quantities, personnel, space, laboratory and other support services), the current and expected HIV care-seeking behaviour of the communities and the capacity and quality of current health care facilities must be considered. The following operational access-benefit model developed by MA Piot for tuberculosis (TB) in the 1980s (more recently it was also used extensively in regard to sexually transmitted infections (STIs)) looks at the cascade of coverage levels at the various stages of interaction between HIV-positive clients and the health system (Figure 1). Planning quality services will require addressing the barriers hindering access including stigma, costs and the current fragile state of public and not-for-profit health service provision. Other barriers are tied to public perceptions and require communication and education efforts at community levels. Finally, there are factors limiting coverage inherent to

FIGURE 1: Estimating the current coverage for ARV therapy



the natural history of HIV infection and to the pharmacological profile of the currently available drugs. For example, few HIV-infected people have access to services where they can learn their serostatus, and an estimated one third of those infected are symptomatic in countries with advanced epidemics². A proportion of them have access to medical care and a smaller proportion to HIV skilled care. Only a small proportion of HIV-infected persons will meet clinical and laboratory eligibility criteria for ARV therapy³, and only some of the “eligible” HIV-infected will be able to afford the current prices of drugs and laboratory services. Of those, a proportion will be able to tolerate and adhere to a given regimen during a minimum period of drug-taking to fully benefit from the intervention.

To address the decreasing access between the different functional stages of the model, effective and feasible interventions within HIV care programmes have been developed over the last ten years in Africa (Figure 2). Comprehensive HIV care and support services are essential to enhance access to ARV therapy and ensure that those eligible and those non-eligible for whatever reason can benefit from care and support. For example, those not fulfilling eligibility criteria for ARV therapy, such as those with concurrent opportunistic infections requiring treatment for opportunistic infections prior to ARV therapy (e.g. TB and meningitis), those who cannot tolerate or are not able to maintain ARV therapy, those with terminal illness or those who no longer respond to the available regimen, will all need HIV care and support. ARV therapy thus can only complement ongoing HIV care and support services and will not replace the need to prevent and manage opportunistic infections or provide home care. The package of these comprehensive HIV care elements (voluntary testing and counselling (VCT), strengthened HIV medical and nursing management, preventive therapies, TB prevention and control, nutritional support, follow-up psychological and social support, palliative care, home care) has been recognized as essential by many national HIV strategies in Africa. Nonetheless,



there is still a long way to go to reach all those in need. For example, service coverage and access at all stages of the model are much lower for women and children⁴. There remains an urgent need to implement a comprehensive strategy and HIV care programmes that ensure benefits to all those in need.

Question 2

Will standardization of the interventions be able to obtain the minimally required resources (financial/technical/human) to meet current and expected demands?

Meeting current demands and scaling up for a nationwide coverage require a systematic planning approach where as many care providers as possible can rapidly and safely acquire the skills to implement these interventions in a safe and effective way. Lessons have been learned from effective implementation of nationwide TB control programmes using standardized approaches. For ARV therapy this will require that some national standards should be set on what a first- or second-line regimen should be, on the eligibility criteria for starting ARV therapy and on what criteria to use for patient monitoring. Only through the setting of national standards, can public or institutional health planners and administrators negotiate better price deals through, for example, bulk purchases, more rapid training of mid-level clinical personnel using standard clinical management protocols, and a more consistent and easier monitoring and evaluation system to quickly learn from what is being practised, so as to effectively plan for the future.

Setting norms and national standards for HIV care are also necessary for testing and counselling, for good clinical practices, standard operational procedures for infection control, for home care and for the safe and effective use of ARV therapy. This may involve the creation of regulations which may not be immediately accepted, in particular by the private sector

where the bulk of ARV prescriptions currently take place. Hence the need for continuous advocacy and explanation of the benefits that will result from such implementation still exists. At the institutional level, standardizing clinical and nursing practices is also essential to assist in planning the mobilization of local resources as well as for coordination between different partners involved in HIV care and ARV therapy.

The following interventions benefit from such standardization and need to be operational in order to allow rapid scaling up to ensure optimal benefits for clients in need of HIV care and ARV therapy.

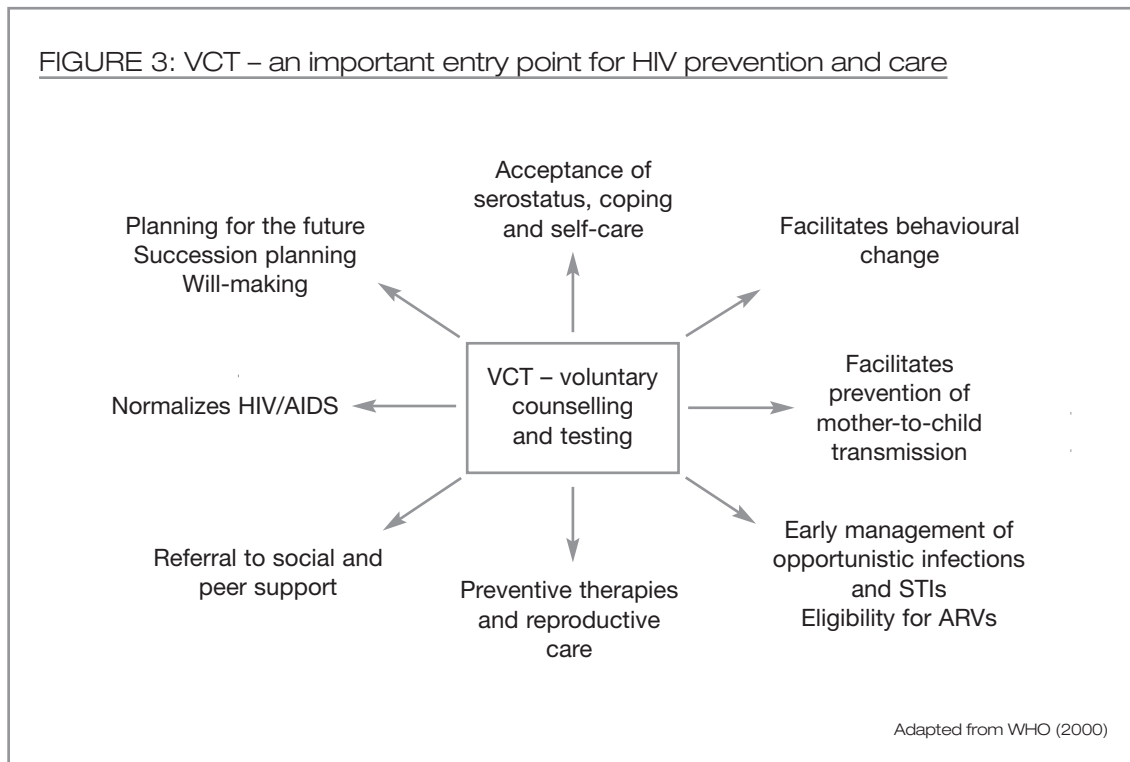
- VCT, including for diagnostic purposes.
- Primary care and home care services with functional referral networks.
- Comprehensive HIV care, including opportunistic infections management (prevention and treatment), TB directly observed therapies (DOTs), palliation and nursing care (e.g. nutrition, universal precautions, support).
- Capacity for ARV therapy management: trained staff, drugs and commodity management, space and appropriate laboratory support.
- Client follow-up systems and other adherence-enhancing measures (e.g. counselling, DOTs, family members, etc.)

This does not mean that all of these interventions are prerequisites before starting ARV therapy, as this would be both unrealistic and lead to unacceptable delays. Indeed, it simply means that these interventions need to be strengthened, or developed at the same time as ARV drugs are introduced. As Jonathan Mann said while establishing the Global Programme on AIDS in the World Health Organization (WHO) in 1986, “One builds the ship while sailing”.

VCT for HIV and follow-up counselling for coping, disclosure and drug adherence

Counselling and testing is not only an effective prevention, care and support intervention aimed at the public in general, but an essential first step in the diagnostic process for people with suspected HIV-related illness (Figure 3). Therefore, collaboration is needed between those who diagnose and manage HIV-related illnesses and those who manage VCT services. Patient consent and involvement as part of the diagnostic process ensures better coping and results in increased HIV clinic attendance in both sophisticated and non-sophisticated settings⁵. Good collaboration between counsellors and clinicians creates efficiency and enables diagnosis at an earlier stage of disease, allowing more people living with HIV/AIDS to access screening for eligibility to start ARV therapy. Follow-up counselling to address coping and the client/patient’s readiness to disclose serostatus to a significant other is crucial in order to enhance adherence. It is here where the lessons learned from the directly observed therapy model for TB could be adapted and made applicable to the specific challenges of ARV therapy drug adherence. The extensive demands of the regimen, more than once a day treatment for life, will also need to be addressed by client, pharmacist and care provider. Observed treatment at intervals and/or support by a relative or a community member chosen by the client are suggestions of modalities to be examined.

A small but increasing number of countries now have national VCT programmes and standardized HIV testing regimens. The number of sites where VCT services are available either as stand-alone centres, or integrated into health and clinical services, is rapidly growing.



For example, in Kenya in 1998 there were only four established VCT sites, yet in mid-2002, 49 sites are operating, both in the public and not-for-profit sectors⁶. Manuals and guidelines on how to plan and scale up VCT services are available from numerous organizations including WHO, the Centers for Disease Control and Prevention (CDC) and Family Health International (FHI).

Strengthen primary care services to recognize and manage early HIV-related illnesses

Late recognition of HIV-related illness by clinicians at peripheral care levels is a very common complaint made by district health managers in many countries. Lack of clinical skills in HIV management, the reluctance of clinicians to go through the diagnostic process, and the late care-seeking and initial unpreparedness of patients to cope with an HIV diagnosis, are all issues that need to be addressed. Stigmatization is particularly pervasive and needs to be explicitly addressed in both health institutions and communities in order to maximize the scaling up of services. Addressing stigma has proven to be difficult even in areas with readily available and free ARV drugs⁵. Attitudes and practices of health care providers in general care need to be improved through appropriate policies, peer pressure, peer example-setting, support for staff burn-out, training and addressing fears among providers. In-service training as well as basic training at the current medical, nursing and paramedical schools is an intervention that should be considered immediately. Furthermore, adhering to infectious control principles, regular supplies of protective materials and provision of post-exposure prophylaxis can be organized and managed relatively easily. Providing psychosocial support for people with chronic illnesses as a routine service in an institution is another way to normalize HIV. So far these approaches are still relatively rare.

Training staff and organizing the health and laboratory services for ARV therapy management: standard procedures, drug management and regulation

HIV management with ARV drugs is not simple but is feasible at mid-level district hospitals in resource-poor settings, as has been shown in South Africa, Kenya, Uganda and Senegal. The rapidly evolving research and expertise in ARV therapy, clinical and laboratory monitoring require continuous learning. Ease of administration, drug tolerance, side-effects and the development of antiviral resistance are issues well known in the use of antibiotics in general, but are more complex for the currently available ARV drugs. Training materials are rapidly becoming available for resource-constrained settings⁷. National ARV therapy specific guidelines, or HIV clinical management guidelines including ARV therapy, are being developed rapidly in most countries in sub-Saharan Africa, although these guidelines often reflect the individual and non-standardized clinical use of ARV drug regimens in the United States or Europe. Since they cannot be directly applied to resource-limited settings and situations with different clinical presentation and health care management of HIV disease, attention should be given to their appropriate adaptation in the local circumstances of developing countries.

Reliable laboratory support to diagnose HIV and common opportunistic infections, to determine biological eligibility for ARV therapy, to monitor side-effects and effectiveness, is another essential function of an HIV clinic. Building the necessary laboratory infrastructure and capacity will require substantial financial and technical resources. This may be based on the example of Brazil's experience of rapidly building a capacity of 44 laboratories nationwide to provide additional virological monitoring. Furthermore, alternatives do exist which focus on more cost-effective approaches that may speed scaling up without losing effectiveness. For example, restricting viral load testing to national academic sites for research purposes and implementing CD4 alternatives using light microscopy will allow many more eligible patients to afford ARV therapy. Many experts in HIV research and care are now supporting simplified monitoring procedures and developing mechanisms to rapidly avail these techniques to resource-poor settings⁸.

Presently, the management of drug selection, supplies, storage and distribution, together with the development of necessary regulations to avoid stock-outs, spoilage and unauthorized use, is being pinpointed as critical by health care managers in considering the incorporation of ARV therapy in HIV care. Guidance in drug management in these areas has been developed⁹ but experiences in applying and scaling up these particular activities in resource-poor settings is still limited.

Question 3

What can be done to involve communities in the expansion and replication process?

The growing availability of affordable ARV drugs raises public expectations of a cure far beyond the current ability to substantially reduce morbidity and mortality. A quick look through the common daily newspapers in Anglophone and Francophone Africa makes the reader believe that a cure is nearby for all those infected. This perception will affect any HIV care site offering ARV therapy, as inevitably the clinics will have to refuse this treatment to patients who do not meet ARV therapy eligibility criteria. Addressing a sense of realism is required, while at the same time ensuring a steady increase in the safe and effective use of ARV therapy, as well as joint decision-making at the individual (i.e. the care team, including the patient) and community levels. Providers of traditional health care (e.g. healers, herbalists and

others) have a key role in community care-seeking behaviour and also need to be involved in information programmes. Similarly, the private clinics and laboratories often already involved in prescribing ARV therapy need to be involved in communicating to communities realistic expectations of ARV therapy. Here the role of people living with HIV/AIDS (PLWHA) becomes paramount. In Uganda, PLWHA involvement has guided and assisted ARV therapy projects, which has been well appreciated. PLWHA groups have worked with individuals seeking diagnosis or disclosing their serostatus, have provided clients with referral to numerous support groups, and have worked on advocating and educating PLWHA and the public in setting realistic expectations about what comprehensive care and ARV therapy can achieve. Furthermore, working with the media, in particular local radio stations and daily newspapers, and working in national and local languages is an essential element in any programme where ARVs are being introduced or scaled up. Mechanisms for this exist within National AIDS Control Programmes and Councils insofar as media training is incorporated in most national HIV/AIDS strategies.

Question 4

How would a simple and sound monitoring and evaluation framework allow rapid learning from the interventions?

Moving from small to larger-scale programmes can only be successful if lessons are learnt quickly from the immediate results of such an implementation. Hence, there is a crucial need for careful monitoring and evaluation to identify and correct inefficiencies, obstacles and adverse effects from programmes in the field. Monitoring and evaluation should also address feasibility, costs and the role the programme has within a comprehensive care approach, while operational studies could address various modalities in implementing drug adherence approaches. Specific studies may be needed to provide a greater insight about the effects and impact on prevention and on the health services in general. The primary aim of this kind of operational or intervention development research is to assist programme implementers and care teams (carers and patients) to do a more efficient job in a more cost-effective way. Therefore, there is a need to involve programme managers, clinicians and clients, combined with rapid data analysis, in order to develop specific plans to use evaluation results in modifying the programme implementation.

Checklists for monitoring, tabulation and rapid analysis, as well as indicators to determine trends over time, need to be developed to measure progress. Complementary quantitative and qualitative operational studies also need to be put in place to fully understand what is happening and why. There is a challenge for ARV therapy programmes to balance monitoring through a strengthened ongoing health information management system and meeting the need for careful and specific monitoring and evaluation of the ARV therapy intervention in order to learn quickly and scale up HIV-related care activities.

Intervention-linked research

Following the planning process by addressing the above questions, some important operational research questions will evolve which need to be incorporated in the design of a scaled up ARV therapy programme. These questions may include the following:

- 1 What will the trends in demand be over time for the different infection/disease stages in accessing testing, VCT and care services?

- 2 How will an ARV therapy programme affect stigmatization?
- 3 What will the effect of HIV care with ARV therapy be on the health institutions and community in regard to prevention practices and programmes?
- 4 What are the determinants of adherence to ARV therapy and what is necessary to develop sustainable adherence practices?
- 5 What community and home care models are relevant in order to support HIV care/ARV therapy programmes?
- 6 Which entry points (or combination of) for HIV care/ARV therapy are most efficient, acceptable, effective and feasible (e.g. mother-to-child transmission, VCT, STI, TB, general outpatient and HIV clinics, etc.)?
- 7 What models of VCT for accessing ARV therapy will ensure normalization and respect confidentiality, while being feasible within current health systems?
- 8 How will ARV drug management affect essential TB, STI and other drug management programmes at site level?
- 9 How will workload and time flows be affected at various clinical service points?
- 10 What is the balance between integrated and vertical ARV therapy services vis-à-vis quality, sustainability, ownership and acceptance?
- 11 How can national standards evolve as new drugs, diagnostics and other information become available?
- 12 What is an affordable household expenditure for HIV care with ARV therapy?
- 13 How can HIV care/ARV therapy programmes be made accessible to children given the various specific requirements: drug formulations, eligibility, adherence and disclosure, clinical monitoring, etc.?

NOTES AND REFERENCES

- 1 This has been shown in Médecins Sans Frontières (MSF) projects in seven countries, including Homa Bay, Kenya and Khayelitsha, South Africa; the national ARV programme in Senegal and the UNAIDS access to ARV pilot projects in Uganda and Côte d'Ivoire.
- 2 WHO/UNAIDS (2001) AIDS epidemic update, December 2001. Geneva.
- 3 See the MSF eligibility social criteria for Homa Bay, Kenya and Khayelitsha, South Africa in MSF Guidelines for ART, access@geneva.msf.org and the US and European criteria in "Panel on clinical practice for treatment of HIV infection, US Department of Health and Human Services" and the Henry J Kaiser Foundation (2000) www.hivatis.org; Recommendations of the International AIDS Society (IAS) (2000) *Journal of the American Medical Association*, 283, no.3.
- 4 To illustrate the possible uptake for ARV therapy at antenatal clinic sites in heavily affected Rakai district in Uganda, it was found that among the HIV-positive pregnant women only 14.6% had more than 55 000 viral RNA cps/ul and would have met the US standard viral load criteria to be eligible for ARV therapy (Rosenfield, Columbia University, personal communication).

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- 7 WHO (2002) *Guidelines for a public health approach*. April 2002, Geneva. [www.who.int/HIV/AIDS/HIV/AIDS Care](http://www.who.int/HIV/AIDS/HIV/AIDS_Care); WHO (1998) Guidance modules on antiretroviral treatments, 9 modules. WHO/ASD/98.1 www.who.int; Guide FSTI by Jean-Elie Malkin, fsti97@hotmail.com; Harvard-Botswana training package; IAPAC GALEN training modules, www.iapac.org and SHARE educational programme, International AIDS Society, www.ias-share.org
- 8 Forum for Collaborative HIV Research (2002) Proceedings of workshop: Transfer of diagnostic & monitoring technologies into resource poor settings. Washington DC, 22 April 2002, www.HIVForum.org
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Chapter 3

Human, material and financial resources

Chapter editors: Hans Binswanger, Somsak Supawitkul, Jorge Bermudez
Chapter researcher: Lisa Mbele-Mbong

Introduction

The objective of the working group of experts entitled “Human, Material and Financial Resources” was to analyse and disseminate information on promising, or already proven, mechanisms by which care and treatment of HIV/AIDS patients can be sharply scaled up. This entailed examining programmes which had already been put in place as well as current working models which could be adapted to suit new circumstances.

The urgency that it is required to put constructive programmes into place, particularly in countries of high prevalence, cannot be underestimated. Yet the ability of countries to respond will often be dependent upon their financial and technical resources, as well as the level of training of health care workers. Despite constraints to the development of programmes, the identification of potential interventions is the first step in offering opportunities to respond to the epidemic.

The experts who have contributed to this section, “Human, Material and Financial Resources”, include many who are currently working in the field alongside people living with HIV/AIDS, or organizing the response at local and national levels, as well as technical, medical and financial experts. The contributions include discussions of methods by which the patients may be assisted to finance their health care needs and observations on the importance for programmes of increasing capacity while simultaneously developing sustainable models.

The overriding theme concerns the means by which antiretroviral drugs (ARVs) can bring relief to patients and benefits to families, communities and countries. Access to ARVs reflects, in part, the complexity of the fight against HIV/AIDS. Lowered prices have made access to ARVs possible although they remain out of reach for many people living in countries with high prevalence. Among the subjects that must be considered in increasing the availability of ARVs are procurement and distribution, adherence, resistance, side-effects and laboratory monitoring.

In the current environment of limited access, major questions remain concerning how these drugs and services will be paid for and how intellectual property issues can be addressed.

The need for training of health care staff, for establishing how to provide drugs for opportunistic infections and basic monitoring of programmes, are but a few more of the areas which this working group has considered.

In recognizing HIV/AIDS as a global concern, international donors have begun to contribute financially to the endeavours of the many partners who are responding to the devastating effects of this disease. The ability to link forces that have already been mobilized, both locally and globally, will be fundamental in increasing the capacity and maximizing the effectiveness of these programmes.

It is the objective of this group to discuss the most appropriate and cost-effective means

of instituting practical programmes. Through the results of these analyses it is intended to assist countries to build thorough and sustainable financial, human and material resources for care and support programmes.

Expert contribution

Antiretroviral drugs: financing the patient

Peter Mugenyi

Uganda experience

To date, the costs of antiretroviral drugs (ARVs) as well as diagnostic and monitoring tests are paid by the patient, or by personal sponsors. ARVs are not available in the public health sector, and the few private centres managing ARVs are based in the capital city Kampala.

The main constraint on the use of ARVs in Uganda is the unaffordably high costs of the drugs made worse by the equally high cost of diagnostic and monitoring tests. This has confined access to ARVs to a tiny wealthy minority, although the recent decrease in the cost of ARV drugs has resulted in a modest increase in the number of patients. The cost of the drugs has been as follows in Uganda:

TABLE 1: The cost of drugs in Uganda

Dates	Cost of 3 drugs combination	No. of patients at Kampala clinic
1997 to 1998	US\$ 800 per month	Less than 200
1998 to 1999	US\$ 450 – 500 per month	Approximately 600
2000	US\$ 350 – 450 per month	Approximately 1000
2001	US\$ 100 per month US\$ 50 (generic)	Less than 3000

The effect of lowered costs has been an increase in the number of patients accessing ARVs, currently estimated at about 8000 patients in Uganda. However, these costs remain way above the means of the vast majority of patients who desperately need this therapy in Uganda.

Recommendation for financing patients in resource-poor settings

Cost reduction

Cost reduction of ARVs is the most effective way to increase access to life-saving ARVs. The methods to achieve this include the following:

- Continuing advocacy, negotiation and activism for drugs cost reduction.
- National and international policies to amend the World Trade Organization Agreement on Trade Related Aspects of Intellectual

Property Rights (WTO TRIPS Agreement) so as to address the needs of the poor and of national health.

- Encouragement of competition among international pharmaceuticals, including generics manufacturers.
- Elimination of taxes on life-saving drugs.
- Improvement in logistics for drugs purchase, storage and distribution, while minimizing costs added by middlemen.
- Consideration of bulk purchases to achieve lower individual costs.
- Setting up of national/regional non-profit distribution centres to minimize overhead costs.

Laboratory monitoring costs

The current international recommended monitoring tests, especially PCR – viral load and CD4 tests, have remained very expensive and have not been reduced as the costs of ARVs came down. Measures which may help reduce these monitoring costs include the same methods as those used for advocating reductions in the cost of ARVs, in addition to:

- Use of low-priced alternative monitoring tests or methods.
- Development of simpler and more cost-effective tests.
- A programme of specimen referral to regional referral centres to maximize the available infrastructure.

Graduated cost sharing

Patients may participate in a cost-sharing programme designed on the principle of equity so that those able to pay a higher proportion of the cost do so, while those with a lower income pay a lower rate and those not able to pay get treatment free.

National subsidies

Countries should be encouraged to allocate a higher proportion of the national budget to HIV/AIDS activities, according to the countries' wealth. A subsidy should be made to AIDS care treatment.

Employer treatment schemes

Employers should be made aware of the advantages and cost-saving benefits of providing ARVs for their staff/employees. Other examples of constructive employer actions may include:

- Industries may come up with ARV treatment schemes designed as incentives to workers, or be encouraged to incorporate services on site (e.g. prevention education, possible counselling, etc.).
- Governments, nongovernmental organizations (NGOs) and parastatal organizations, both national and international, should have an ARV treatment policy for their workers.
- Unions, as representatives of the workers themselves, should be encouraged to participate in programmes and represent employees in negotiations, as well as incorporate a contribution from funds for workers' HIV treatment.

Insurance

Health insurance companies should be encouraged to offer insurance irrespective of serostatus to pay for ARVs if needed.

National and international donors and funders

Donors and funders should ensure that funding of ARV treatment is cost-effective and needs to be prioritized.

Global AIDS Fund

The Global Fund to Fight AIDS, Tuberculosis and Malaria should dedicate a considerable percentage, at least 40%, to funding ARV drugs or at least offer a subsidy that helps make these drugs accessible to resource-poor countries.

Expert contribution

Human capacity development: sustaining local responses through the long term

Lisa Mbele-Mbong

In order to be accessible and effective, care and treatment for HIV/AIDS should be provided within an organized continuum. A continuum of care involves a network of resources and services that provide holistic and comprehensive support for the patient and family caregivers. The goal is an affordable range of services in various settings, from home to clinic to hospital, and vice versa. Comprehensive care involves care, treatment, support and prevention. Many issues need to be addressed before comprehensive care can be provided. In particular, there need to be resources (financial, supplies, services, staff, volunteers, government and community support) with effective connections between them.

In its *World health report 2000*, the World Health Organization (WHO) recognized that “human resources, the different kinds of medical and non-medical staff who make each clinical and public health intervention happen, are the most important resource in the public health system. The performance of the health care system ultimately depends on the knowledge, skills, motivation and utilization of the people responsible for the delivery of services.”

In this paper, therefore, we will focus on the issue of human resources, albeit not in isolation from other resource needs. We will look at what human resources are needed for which services. We will identify the forms of competence they require. We will then explore the ways in which education, training, environments, work or operating methods, and other health and social system resources, combine to achieve that competence.

Human resources for the continuum of care

Direct care and service providers

Table 1 illustrates the wide array of human resources and services required for effective care and treatment for HIV/AIDS infection. It also lists the settings in which human resources deliver these services.

Human resources in the health system

Medical and paramedical personnel are the main actors in formal care and treatment delivery. These professionals provide a broad range of complementary services, from voluntary counselling and testing (VCT), mother-to-child transmission (MTCT) interventions, treatment of opportunistic infections, palliative care and antiretroviral (ARV) treatment, to nutritional counselling, psychosocial support and comprehensive pharmaceutical services. These services all require specific and well-trained human resources, including physicians (generalists and specialists), nurses, laboratory technicians, physiotherapists, psychologists, nutritionists and pharmacists. They are provided in the context of rapidly evolving “best practices” and changing medical technologies. Medical and paramedical personnel should therefore continue their learning and apprenticeship even after they complete formal education and training for

their initial qualifications. Ongoing training and learning from action ensure that practitioners will retain the technical knowledge and skills to deliver adequate services over time; it can also help sustain their sense of motivation.

Over the course of the illness, medical and paramedical services will be provided in a number of contexts ranging from the hospital and the primary health clinic to the home or community. As with other long-term or chronic illnesses, the continuum of care between these different venues or the various phases of the disease will need thoughtful management. Medical and paramedical staff intervening at any point in the continuum will need information, skills and processes to understand the various contexts through which the patient moves. They will also have to coordinate with colleagues rendering the complementary

TABLE 1: Direct service providers for HIV/AIDS care and treatment

Direct service providers	Services provided	Settings for provision of services
Physicians, nurses, Physiotherapists Psychologists Nutritionists Pharmacists	<ul style="list-style-type: none"> ○ Voluntary counselling and testing ○ Psychosocial support ○ Prevention of mother-to-child transmission ○ Treatment of opportunistic infections 	Hospital Clinic Home Day care or respite care venues Community
Traditional healers	<ul style="list-style-type: none"> ○ Palliative care ○ Antiretroviral treatment 	
Social workers	<ul style="list-style-type: none"> ○ Nutritional counselling ○ Pharmaceutical services 	
Family members	<ul style="list-style-type: none"> ○ “Caring” (e.g. activities of daily living management, emotional and spiritual support) 	
Community actors (i.e. individuals from local solidarity networks, traditional community structures, faith-based organizations)	<ul style="list-style-type: none"> ○ Direct assistance with managing psychological, social and economic impacts of the illness on people living with HIV/AIDS and their families 	
Transportation system Sanitary system Food security policies and programmes Legal system	<ul style="list-style-type: none"> ○ Other social services and safety nets (e.g. food, transportation, and education) ○ Legal protection and assistance 	

services that allow or facilitate people living with HIV/AIDS (PLWHAs) to move through its different stages and address the various impacts of the disease.

Traditional healers

In many countries, particularly in Africa and the Caribbean, traditional healers frequently intervene in HIV/AIDS infection. While traditional healers and their patients often share common cultural representations of life, disease and death, other characteristics of traditional healer interventions are perhaps more determinant in explaining their pervasive role in care for HIV/AIDS. These characteristics include:

- 1 They are accessible where formal health care is not. Their accessibility is explained as much by geographic proximity as by their integration into the community. In some cases, they are also more affordable than some medical services or interventions.
- 2 Traditional healers are often the only ones who will regularly alleviate pain and other symptoms caused by opportunistic infections, particularly once the HIV status of a patient is known. Furthermore, they tend to provide more direct and intimate physical care. From the patient's perspective, the accepting attitude they often display towards the body and infection can make traditional healers appear less intimidating and more responsive than many formal medical practitioners.
- 3 In addition, the overall approach or philosophy of traditional healer interventions tends to be more holistic than that adopted or implemented by formal health services so far. Traditional healers tend to place a greater importance on welcome, they spend considerable amounts of time listening to their patients and, most importantly, they respond to social, relational and psychological aspects of the patients' illness hand-in-hand with the medical or curative interventions.

For these reasons, much can be learned from traditional healers despite widespread problems. However, traditional healers' reputations are often hurt by the wide variations in competence, credibility and attitudes that exist amongst them. In most places, there are no formal accreditation processes for traditional healers and few, if any, practise norms, regulations or controls. The informal context in which they practise makes it difficult to ensure standards and accountability for care. It also makes it difficult to differentiate between practitioners respected and valued for their expertise and those that prey on the vulnerability of patients and families while providing sub-standard, and sometimes dangerous, care.

Another important problem is the lack of education on HIV/AIDS. Traditional healers are increasingly aware of the disease, are able to diagnose it and generally understand modes of transmission. Nonetheless, the problem lies in their feeling challenged by formal health care systems that do not recognize their role and expertise and call into question their belief systems, their influence and/or market. Further education on HIV/AIDS and the benefits of referring patients to the formal health care system is therefore required. Ultimately, providing traditional healers some formal status and integrating them into the health system or continuum of care could be ways of increasing the quality, scope and accessibility of care for HIV/AIDS.

Family caregivers

Family caregivers are the human resources who spend the most time providing care and treatment for HIV/AIDS. In places where medical care is inaccessible or non-responsive, PLWHAs rely entirely on family (or other informal caregivers such as friends, servants, community members) for care. Even where professional care and treatment are provided, family caregivers remain the ones responsible for “caring”, meaning that they are responsible for the daily physical and emotional support that goes beyond what formal health and social care services can offer. Family caregivers are thus key “human resources” in the continuum of care.

Family caregivers are also the ones most personally involved in their caregiving. The main difference between family caregivers and professional caregivers lies in the level of personal impact the disease and their caregiving role have. They are directly affected emotionally, psychologically, socially, economically and physically.

In order to ensure efficient and quality care for PLWHAs, family and other informal caregivers, as key care providers, should receive thorough training in nutrition, drug management, daily living management, universal precautions and basic nursing techniques. In addition, a number of services listed in Table 1, such as psychosocial support and improved social services and safety nets, should target caregivers as well as PLWHAs in order for them to continue providing care over time. (Ultimately, counselling and respite care are considered to be highly beneficial to family and community caregivers, as well as other medical professionals.)

People living with HIV/AIDS

PLWHAs themselves are invaluable to the process and quality of care and treatment. Their role is addressed in some depth in the UNAIDS Technical Note, *Greater involvement of people living with AIDS*.

Members of community groups and movements

Community volunteers are often the backbone of viable community home-based care programmes, working in coordination with medical and paramedical personnel. Local volunteers live in communities and know the population well. Ultimately, they help ensure the sustained presence, the credibility and the responsiveness of the care programme. With proper training and support, their skills and competencies can include providing basic nursing, palliative care, the use and promotion of universal precautions, basic psychosocial support and counselling, nutritional advice, patient/family referral and patient/family education.

In addition to direct care, community members and their representatives are instrumental in addressing stigma, in changing the attitudes and behaviours of the community towards patients and families, in advocating for policies and programmes (at local, regional or national levels) and in initiating and/or consolidating local responses. Generally, expressions of support and solidarity from community members from faith-based organizations, neighbourhoods or other social groups, women’s associations, etc., greatly increase the quality of life of patients and families.

The expert contribution, *The role of associations in care and treatment of HIV/AIDS*, further addresses issues pertaining to civil society organizations in the HIV/AIDS care delivery.

Social workers

Social workers can play an essential role in supporting public health and medical interventions by helping to build the conditions that facilitate compliance. In dealing with HIV/AIDS, patients and families are often overwhelmed by socioeconomic constraints, including dramatic losses in socioeconomic status, loss or changes of sources of revenue, undernourishment or malnutrition, social isolation, stigmatization, family and/or community conflicts, etc.

The socioeconomic impact of HIV/AIDS limits the ability of PLWHAs to seek or follow through with medical interventions. It also places further emotional and psychological stress on patients and families, thereby increasing their physical vulnerability. By helping manage, solve or respond to these problems or simply by offering links to other service providers, social workers give the crucial support that makes medical interventions affordable, as well as physically, materially and psychologically manageable.

While the need for their services is enormous, there is a shortage of trained social workers in most resource-limited settings. Even where social workers are trained and integrated into public health interventions such as community home-based care, they are often operating outside any formal structure and support network due to the lack or absence of wide-scale social policies and services in many developing countries.

Legal service providers

Experience has shown that patients and families are often in need of legal service providers at some point during or after the illness. HIV/AIDS often causes or exacerbates conflict within couples, nuclear and extended families, as well as employer/employee relations and other social constructs. The more a society is “AIDS competent”, the more it is likely to avoid HIV/AIDS-related conflicts or to resolve them at early stages and through more informal means of social mediation than formal dispute mediation or court litigation. Nonetheless, clear and binding laws regulating labour and civil rights as well as inheritance, child support and divorce or separation on the one hand, and accessible and adequate legal services on the other, will remain essential in helping achieve just and equitable treatment of all those affected by the disease.

Transportation system

Comprehensive care involves patients and families being able to travel to and from health facilities, and for service providers to travel to patients’ communities or homes when necessary. In resource-poor settings, transportation is expensive, unreliable and sometimes inappropriate, thereby compromising access and compliance to care (both in health facilities and in the home). Providing transportation may not be a direct health action; however, it is a social service that is crucial to ensuring the accessibility and efficacy of care for HIV/AIDS.

What human resources support the service providers?

Direct service providers are not the only human resources with a role in ensuring access to care and treatment. Equally important are the persons responsible for defending, designing, planning and financing care and treatment. Table 2 lists a number of the human resources involved in making care and treatment possible.

TABLE 2: Human resources supporting home-based care

Human resources	Roles to be played
<ul style="list-style-type: none"> ○ Community and civil society leaders (e.g. traditional leaders, religious leaders, youth role models) 	<ul style="list-style-type: none"> Advocacy Policy-making Management Financing
<ul style="list-style-type: none"> ○ Advocacy groups/NGOs/associations 	<ul style="list-style-type: none"> Technical assistance Leadership and role modeling
<ul style="list-style-type: none"> ○ People living with HIV/AIDS 	
<ul style="list-style-type: none"> ○ Developing country governments <ul style="list-style-type: none"> - National policy-makers and legislators - National regulators - Local policy-makers and representatives 	
<ul style="list-style-type: none"> ○ Developed country governments and international organizations 	
<ul style="list-style-type: none"> ○ Private sector 	

Challenges for the health care system

Health care systems face a number of problems producing, maintaining, managing and financing human resources. Many of these problems are general and not specific to care and treatment services for HIV/AIDS. Nonetheless, HIV/AIDS has considerably increased demands on the type, quantity, scope and aims of health services, forcing health systems to readdress the following issues:

Imbalances in human resources for health

Imbalances in human resources for health are commonly divided into three categories:

- a Imbalances in overall numbers, meaning differences between the number of health care providers of various categories and the numbers a country or community needs (and can afford).
- b Imbalances in skills and skill-mix, meaning a mismatch between the type or level of training and the skills required for adequate service delivery.
- c Imbalances in distribution, meaning a mismatch in the geographical, occupational, public/private, institutional or specialty mix.

Redressing shortages

Health care systems suffer from varying degrees of shortages of qualified health personnel. “Numerical imbalances” in health personnel can be explained by: a) a country’s limited educational and training capacity, and b) poor retention of personnel (due to low pay, low morale, distribution imbalances or excessive professional mobility).

Access to care for HIV/AIDS infection is limited by the lack of qualified personnel. In most resource-poor settings, lack of qualified personnel exists at both ends of the care spectrum, limiting access to preventive and community-oriented care on the one hand, and medical interventions (more or less advanced technologically) on the other.

Balancing the skills mix

Health care systems must ensure the composition or skills of its workforce are adequately balanced. Skill-mix imbalances may stem from low educational standards, lack of specialist training, a mismatch between the skills of the health workers and the needs or priorities of the health care system. Skill-mix is the key to the continuum of care for HIV/AIDS. For HIV/AIDS care and treatment to be accessible and comprehensive, not only will a broad array of personnel categories be needed but the right balance for each given population and socioeconomic context will also be crucial.

Ensuring adequate distribution

In most resource-poor settings, two key distributional imbalances occur. The first is geographic distribution or the gaps in the distribution of providers between urban and rural areas. The second imbalance is in the distribution of providers or categories of providers between the public and private sectors. The categories of providers (medical specialists, paramedical staff, psychosocial service providers) are particularly unevenly distributed between the two sectors. Similarly, comparable quality of providers in the public and private sectors has been difficult to achieve or maintain (see reasons below). These imbalances have obvious repercussions on the accessibility of care and treatment for HIV/AIDS.

Responding to compensation and management needs

Public sector personnel compensation and management issues include inadequate pay and benefits, poor working conditions (including poor facilities; inadequate facilities, equipment and essential drugs; and lack of basic amenities, such as electricity, water and schools). As a result, recruitment and retention of health personnel in public sector facilities remain difficult at a time when important numbers of health care personnel have been lost to HIV/AIDS infection and the demands of the public health system are increasing.

Many countries also face personnel management problems. These include inadequate job descriptions, personnel supervision and involvement in decision-making, continuing education opportunities, incentives for improvement of performance and basic financial and management skills at various levels of the health system. While these problems are not specifically tied to the AIDS epidemic, they will need to be addressed in order for activities implemented in the context of national AIDS strategies to be effective. (National AIDS strategies often call for expanded supply of quality services for basic care, VCT, ARV treatment and massive-scale training interventions).

Challenges to professional behaviour

While AIDS challenges private individual behaviour, it also challenges the professional behaviour of health care workers and managers. Traditional education and training teaches nurses and doctors to think that they are in control. HIV/AIDS is forcing them to recognize limitations. Health workers are starting to let individuals, communities and non-traditional counterparts (such

as traditional healers and local nongovernmental organizations (NGOs) participate in their health programmes. They are beginning to recognize the validity of non-traditional or “soft” programmes, such as counselling and psychosocial support, and thereby accept them as legitimate use of staff and other resources. Finally, they are having to accept that their patients may not make “rational” health choices or decisions, but will continue to need care and support.

Policy-makers will have to make similar adjustments when considering or reconsidering policy content and strengthening collaboration with other social and economic sectors.

Ensuring the continuum of care

HIV/AIDS is a long-term illness. It also remains both terminal and stigmatized, causing “irrational” patient behaviour. Finally, care and treatments are often difficult to access and/or expensive. For these reasons, HIV/AIDS patients, particularly in developing nations, often seek a multiplicity of interventions (more or less avowed) from a broad array of service providers. Complicated care trajectories and lack of coordination between services and between service providers make it difficult to follow interventions through and hamper their effectiveness. The challenge to health care systems is, therefore, to establish mechanisms to ensure the continuum of care. The technical components of the health system that deserve particular attention and make the continuum of care possible include: a) case finding, b) record keeping, c) case management, d) discharge planning, e) referral systems, f) the functions of various service providers within the referral systems, and g) information, networking and coordination between service providers. Many of these technical components require specific, well-trained and supported human resources.

Defining priorities for the health care system

The scope and impact of HIV/AIDS have begun to call into question the very priorities of health care systems. Fundamental questions include:

- What care needs to be provided for PLWHAs? What services need to be developed and made available? On what scale?
- What importance should be given to prevention? How are services aiming at prevention and care linked?
- Is equity in care for HIV/AIDS (or health) a goal?
- Is the health care system structured to meet stated priorities and policies?

How is human capacity-building achieved?

Knowledge and technical capacity: part of a whole

Technical capacity is an essential dimension of human capacity-building, particularly in the context of access to care and treatment for HIV/AIDS. However, technical capacity must be viewed as part of a whole. Without the proper attitudes, values, incentives and material and financial means, technical capacity will not be utilized. These complementary dimensions of capacity-building should be integrated in planning, designing and implementing professional/technical education and training. They should be reflected in the pedagogical methods used, should inform the selection of the target populations and the professional categories developed, and should be addressed explicitly in the content of the education and training.

The discussion of education and training below tries to be consistent with the holistic approach to human capacity-building.

Education and curricula reform: addressing long-term needs

General levels of education or knowledge, as well as technical training and skills, are essential to producing qualified health personnel. Education is also one of the basic building blocks for effective health responses and governance at the local and national levels. Development data and analyses have long shown the correlation between education and health indicators, and between levels of general education and overall economic and political development.

The importance of education has been made increasingly clear in the wake of the HIV/AIDS epidemic. Implicitly or explicitly, national and international public health strategies, and HIV/AIDS advocates in particular, recognize the need for identifying and/or producing human resources able to deliver increasingly multifaceted and technologically advanced health interventions through effective local responses and governance. Scaling up training programmes is clearly an urgent need, particularly in the short term. However, no matter how much training approaches broaden as international and local trainers and training programmes learn from action, efforts that ultimately aim at “compensating” for lack or gaps in the production of knowledge in a society are unlikely to ever yield the scope and quality of results required to effectively combat the HIV/AIDS epidemic.

Relying solely on training for the production of qualified human resources ultimately suggests lowering the quality of overall results. The content and standards of *ad hoc*, specialized and even continued training must be tailored to the level of general knowledge and skills of the target audiences. For example, depending on the levels of general and professional education in a given community, the content of training (for community home-based care or management of district or local health services or management of specific HIV/AIDS treatments, for example) will change. In addition, the amount of training and follow-up required is likely to be higher. And finally, the result indicators or standards are likely to be fewer or lower.

Furthermore, communities and societies are likely to pay dearly for opportunities lost in responses to HIV/AIDS. While training and other efforts at technical capacity-building are relied on in lieu of or because of sub-standard levels of general and professional education, communities lose from a human and a development perspective. Local human resources are under-utilized and thereby suffer from a lack of motivation and assurance that has profound long-term consequences. As mentioned above, equally valid and important services and processes are placed in competition by increasing demands on limited numbers of educated human resources, thereby limiting overall community development. At a national level, services and coverage remain sub-standard to the detriment of larger numbers of individual patients and families and leaving communities with long periods for which they need to catch up. And financial resources are spent on approaches that help but do not fully address long-term needs.

General and professional education is therefore an urgent priority. As in health system reform, the education sector requires profound commitment. It also produces results for the medium and long term. However, delays in systematic and planned human resource production are only lengthened by the reform of education being pushed back.

The contribution of *Curricula reform* addressed the priorities for professional education for health personnel, including the necessary changes in medical school curricula. While curricula reform should be national in scope, many of the recommendations made in this paper can be implemented at the level of individual private or public initiatives

and programmes. In other words, education can, and will, need to be addressed in manageable segments.

Education for human resources for health can also be addressed at the local level. Bringing local schools and education professionals into HIV/AIDS responses and ensuring that they are targeted for technical and human competence training is an important means to multiply the training of the trainers and integrate the broader education system.

Rethinking approaches to training: who, why and how?

In response to the devastation caused by the AIDS epidemic and the urgent need for trained human resources, considerable efforts have been placed in training both through international technical assistance programmes and through local NGOs or community-based organizations (CBOs). These activities and institutions have yielded important results and equally important lessons learnt:

- 1 *Taking into account the local environment.* In order for training to be truly responsive and applicable, it should take full account of the contexts in which trainees are operating. One-size-fits-all modules and training approaches should be avoided in favour of training content consciously adapted to local realities. This requires developing some knowledge of the context in which target audiences operate before selecting content and designing (or finalizing) modules. It requires that trainers talk to (a sample of) individual trainees about needs and constraints, but also that they have some experience operating in similar contexts themselves.
- 2 *Ensuring follow-up.* Training programmes and mechanisms should allow for trainees to come back to trainers for technical questions and moral support. Training programmes can be extremely empowering after they are delivered. They teach new skills, they allow necessary breaks for ongoing work and they allow beneficiaries to network. All of these factors increase confidence, reflection and motivation, while also reducing the sense of isolation and fatigue. However, when the means of communications with trainers and peers is cut, the benefits of training quickly dwindle. Technical and support follow-up is, therefore, extremely important for ensuring that the benefits of training are sustained.
- 3 *Consistency of pedagogical methods and programme design.* Pedagogical methods and programme design should be both appropriate to cultural learning styles and consistent with the objectives and values of AIDS competence (see below).

Learning from action and continued education: maintaining knowledge and adapting to the disease

Continued education and established organizational processes and cultures of “learning from action” are essential to effective human capacity-building for HIV/AIDS. Because care and treatment for HIV/AIDS needs to be so comprehensive and take into account evolving social and local dynamics, best practices and lessons-learnt in care and treatment delivery should be

constantly fed back to health staff and community human resource development. Similarly, continued education should also allow human resources to stay abreast of and adapt to new technologies.

Human capacity or AIDS competence

As mentioned above, the attitudes, values and behavioural patterns (i.e. human capacity or HIV/AIDS competence) of individual human beings with regard to HIV/AIDS is crucial to health actions. Human capacity requires focus, learning and support in order to take advantage of technical capacity, to resolve issues of stigma, to preserve efforts of individual, family and community solidarity, to raise expectations in terms of health, social, political policies and actions, and ultimately, therefore, to ensure the quality and access to care and treatment for HIV/AIDS.

Human capacity will not be developed “by the course of things”; sustained efforts and resources have to be committed to making it happen. We have discussed how human capacity should be taught in medical and other professional curricula and training. It should also be integrated into:

- Programme design and implementation.
- Health system structures (such as skill-mix, technical components of the continuum of care).
- Health system functions (health systems should not see themselves simply as health care providers but indeed as health care and social “facilitators”).
- Systems and processes of participatory, representative and accountable governance from the local to the national level, etc.

The expert contribution, *Discrimination and stigma in care and treatment for HIV/AIDS*, illustrates the need for overall AIDS competence to be consciously integrated into human capacity-building efforts.

Policy recommendations, implementation strategies and activities

All actors involved should commit to a holistic approach to human capacity-building

Wherever possible, policies, approaches, programmes and financing should seek to develop:

- 1 Education, training and continued learning from actions.
- 2 The material, infrastructural and institutional means to put knowledge, skills and attitudes into action.
- 3 General attitudes, values and behaviour towards HIV/AIDS.

Activities and implementation strategies

- Advocacy for human capacity-building at policies and programme levels.
- Revision of training modules and approaches to include all aspects of human capacity-building.
- Discussion and pilot programmes for medical school curricula to take into account all aspects of human capacity-building; pilot programmes can be implemented through the creation and public and/or private funding of research institutes (see Uganda, South Africa), distance learning technologies, etc.

- Creation of networks of organizations and people doing training, education and/or learning action; networks should be given funding and political support, and should be geared towards education and training of health and community human resources.
- Criteria, objectives and/or mechanisms for funding should be broadened to ensure that financial support to governments, NGOs, or projects cover not only programmatic activities, but also human capacity-building and material and infrastructure support.

Human capacity-building efforts should build on existing strengths, structures and programmes at the local level

Activities and implementation strategies

- Identify, develop and fund locally available team approaches to home and day care.
- Identify and reinforce community-driven processes of acknowledgement and response.
- Identify local human resources (community volunteers, entrepreneurs, leaders, role models); it is important to recognize the work these individuals are already doing, and to avoid monopolizing local capacity to the detriment of existing processes and initiatives. Nonetheless, it is important to learn from respected human resources and engage them as much as possible or beneficial in local responses to HIV/AIDS.
- Provide training in programme design and management, including learning from the experience of those local initiatives, processes and persons previously identified.
- Primary and district-level health care systems (facilities, staffing, equipment, funding, coordination mechanisms, and other technical components of the continuum of care) should be reinforced.

Human capacity-building should be made an explicit priority of the international and regional partnership and initiative agenda

Activities and implementation strategies

- Identify international and regional initiatives, partnerships and agreements on HIV/AIDS.
- Ensure that human capacity-building components are integrated into their principles, programmes and funding arrangements.
- Use international partnerships and initiatives to advocate with governments, international organizations and NGOs for urgent attention to human capacity-building.
- Create networks in support of international and regional initiatives, partnerships and agreements.

Human capacity-building should be integrated into all levels of national strategic planning, financing schemes, formulation of procedures and regulations, timetables, and assessments of performance of individual personnel and entire health systems

Human capacity-building must involve all sectors of society

Activities and implementation strategies

- Support of existing federations, unions, networks, and other partnerships whose membership, structures, activities, reputations and audiences or beneficiaries can be used to lobby and support human capacity-building for HIV/AIDS, as well as develop AIDS competence and cultures of learning from action.
- Lobby the private sector (corporations, business councils, federations) for funding and support for education, professional schools (medical, nursing, social work, etc.), curricula development, and learning from action.
- Training for national and local policy-makers and leadership on HIV/AIDS and its impacts on patients and families. Policy-makers include parliamentarians, government representatives, regulators, local representatives, local leadership, etc.
- Establishment of ethics and jurists' committees.
- Advocacy training for various actors (including PLWHA and family associations, NGOs, and health personnel).
- Support for day care and respite care programmes.
- Support for community home-based care.

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Several of these documents are available on the UNAIDS website, or from UNAIDS on the CD-ROM: "Improving access to care in developing countries: Lessons from practice, research, resources and partnerships".

Essential medicines and AIDS care in Brazil: recent lessons learnt

Jorge Bermudez, Maria Auxiliadora Oliveira

Initial settings and steps forward

Access to medicines must be addressed as a priority within each individual country, according to the development of their national health systems and the procurement practices that are currently implemented. According to Management Sciences for Health¹, medicines are important for the following reasons:

- Drugs save lives and improve health.
- Drugs promote trust and participation in health services.
- Drugs are costly.
- Drugs are different from other consumer products.
- Substantive improvements in the supply and use of drugs are possible.

The recommendations and guidelines that the World Health Organization (WHO) is strongly advocating rely on four fundamental objectives: (i) supporting country efforts to formulate, implement and monitor national drug policies; (ii) securing access to essential drugs; (iii) ensuring global standards for drug quality and safety; and (iv) promoting rational use of medicines²⁻⁶.

Further to simply addressing access to medicines, access to care (including medicines that are necessary for people living with HIV/AIDS) may be considered as one of the major and most difficult challenges facing governments and public policies, especially when we are speaking about developing countries. Besides the dramatic figures related to the AIDS pandemic, the worldwide scenario is heavily impacted by the unequal geographic and social spread of the infection. Aside from the scarce resources that are usually available at the national levels for public or health policies, globalization has other perverse consequences. These include: limitations to local or domestic production, patent protection bearing 20-year monopolies, in addition to other implications of trade agreements, especially the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights (WTO TRIPS Agreement) that the totality of nations in the world will have to agree to by the year 2005.

Brazil is a continental country of 8.5 million square kilometres in South America, with an estimated population of nearly 170 million inhabitants, an annual growth rate of 1.6%, and more than 80% of its population settled in urban areas. Brazil is organized as a Federal Republic, with 26 States and the Federal District that include 5508 municipalities. Its legislative, executive and judiciary branches are totally independent. Brazil may be characterized as five absolutely different geopolitical regions, and has been considered as a country of enormous contrasts, with one of the highest economic growth rates coexisting with one of the worst income distributions in the world^{7, 8}.

Nevertheless, despite this adverse context, advances have been pursued in Brazil, since

the discussion that led to the approval of the new Constitution in 1988. It includes a chapter dealing with social security that has progressively established a very broad social protection system, which merges health, social security and social care, guaranteeing the universal right to health⁹⁻¹¹.

Most recent debates have included a broad scope of initiatives that are being implemented by Brazil, which are leading the way on the possible potential approaches for expanding access to medicines in developing countries. Of special interest is the universal access to antiretroviral (ARV) drugs that the Ministry of Health has established during recent years.

These initiatives cannot be discussed as isolated actions, but rather as a sequence of steps that have made it possible to make advances on this issue within our National Health System, as we have described in previous papers^{10, 12, 13}. The Brazilian health system consists of the public, private not-for-profit and private-for-profit health units under a single command, with a trend to decentralization and evaluation of activities within the system.

Even considering the peculiarities of the pharmaceutical sector, the health system is responsible for procurement and distribution of a great number of medicines countrywide by diverse modalities, so that pharmaceutical care also has to be considered within the recent trends in our health care system.

As discussed in previous papers^{10, 14-18}, the recent performances, the conflicts arising and the consequent decommissioning of a governmental enterprise (Central de Medicamentos (CEME)) in 1997 led to the necessity of having an explicit National Drug Policy establishing the guidelines for priorities regarding access to medicines. This was formulated by the Ministry of Health in 1998.

Following a one-year national debate, based mainly on WHO guidelines but also considering other national and international experiences, the Ministry of Health issued Ruling No 3.916/98 approving the National Drug Policy, with the guidelines and priorities for activities to be implemented linking intersectoral actions^{19, 20}. Following that debate, the National List of Essential Drugs (RENAME), was reviewed (the previous update had been in 1982). This revision was strongly based upon the WHO Model List for Essential Drugs and on evidence-based background information. It was officially adopted as Ministry of Health Ruling No 597/99, and has been distributed throughout the health system. A National Commission was nominated in 2001 by the Ministry of Health, as responsible for the continuous revision of the National List of Essential Drugs.

A strengthened Brazilian Regulatory Agency (ANVISA) was created, highlighting administrative and financial autonomy with tenure for its department heads. This was enacted by law in 1999 (Law 9.782/99), replacing the former body that was responsible for those actions within the Ministry of Health.

An additional law was enacted in late October 1999 (Law 9.787/99), with corresponding supplementary measures, establishing the basic framework and concepts that introduced generic drugs into the Brazilian market. This enabled the implementation of a generic drug policy in Brazil, establishing technical standards and norms, as well as defining the concepts of bio-availability and bioequivalence, and those of generic, innovative, reference and similar drugs. Previous attempts to issue generic medicines policies in Brazil had never been successful.

This regulation has led to domestic manufacturers replacing branded products from transnational companies, thus provoking mass media campaigns sponsored by the transnational companies trying not to loose hegemony of brand names of drugs in our market.

Additionally, it has been prohibited to use generic denomination for marketed medicines, which has been a common recent practice in Brazil, unless the manufacturers prove that there is compliance with bioequivalence regulation, and therefore they have to apply for registration as generic products.

Nearly all pharmacological groups of drugs have had generic products licensed in Brazil, including those for hospital and outpatient use. No strict control as to what products are being licensed is being implemented, but the Brazilian Ministry of Health has proposed two reference lists of products based on the WHO Model List for Essential Drugs (the Brazilian Essential Drugs List, and the Basic Health Care lists of drugs), that would be strongly encouraged to have generic drugs, and considerations on market share of medicines. These two lists have had a positive reaction from manufacturers and requests for licensing of generic drugs within them have been enforced^{10, 12, 13}.

Specific additional aspects of economic regulation related to the pharmaceutical sector in Brazil, that have been addressed recently, have previously been discussed by us^{12, 13}.

Trade rules, and especially the WTO TRIPS Agreement, have been severely criticized, worldwide, as being rules that do not effectively benefit the poor populations of developing countries, but instead are considered as heavily biased in favour of the industrialized economies. Besides introducing a minimum 20-year patent term for all products, therefore delaying the availability of cheaper generic products and determining monopolies, the pressure from developed countries is forcing developing countries to enact laws which are based on a very restrictive interpretation of the TRIPS Agreement, jeopardizing the implementation of public health safeguards²¹. Of specific interest in increasing access to medicines, patent law legal exceptions like compulsory licensing, the Bolar provision and parallel importing, are TRIPS Agreement safeguards that are recognized as necessary to allow low-cost versions of patented medicines to be legally approved^{6, 22}.

Parameters analysed in a previous report^{10, 11} have demonstrated clearly that the greatest beneficiaries of recent changes in the Brazilian legislation and the implementation of the WTO TRIPS Agreement have not been Brazilian companies, but transnational corporations that hold hegemony in our market. Therefore, the implications of these agreements for developing countries must be more thoroughly explored and corrective measures recommended and addressed, not only by the governments, but strongly supported by the United Nations international agencies.

Key issues regarding the Brazilian HIV/AIDS programme

The Brazilian model of universal access to ARV medicines cannot be analysed in isolation, but must be considered as one of the key elements for a global programme that has been implemented on a step-by-step basis over the years. Indeed, the programme was set up as early as 1985 and the National Commission began work in 1986, so there have been more than 15 years of struggle and discussion up to now. The environment that has been set up for pharmaceutical care within health care, as described previously, is stimulating and allows measures that undoubtedly have an incisive impact on the health conditions of people living with HIV/AIDS.

Between 1980 and December 2000, 203 353 cases of AIDS were reported to the Ministry of Health, leading to an estimated total of 536 000 people infected with HIV. The Ministry of Health policy and guidelines for care of people living with HIV/AIDS has the necessary legal

support. Besides the Brazilian Constitution and the health system regulation (organized upon the principles of universality, equity, integrality and community participation), there is a Congressional Bill that was passed in 1996 (Law 9.113/96) that guarantees every patient free access to all medication required for treatment. Standard Treatment Guidelines, by means of a Consensus on Recommendations, are set forth and reviewed at least once a year under the sponsorship of the Ministry of Health²³.

The Brazilian programme includes not only a massive distribution of low-cost locally produced medicines, mainly ARVs, but also a responsible system to sustain it. The infrastructure of the system is composed of 362 accredited hospitals, 148 specialized care services, 69 day hospitals and 52 home therapeutic care projects. Additionally, there is a network of 70 laboratories with the capacity to perform CD4+ T lymphocytes counts and 63 laboratories for viral load quantification²³⁻²⁵.

Brazilian epidemiological surveillance of HIV/AIDS is a broad programme that includes HIV infection monitoring and not only notification of cases. Research and studies are conducted with the clients of sexually transmitted disease (STD) health facilities, emergency hospitals and public maternity facilities. HIV seroprevalence among recruits to the Brazilian Army and surveillance of infected pregnant women and children are also part of the monitoring programmes²³.

Having begun in 1991 with the distribution of zidovudine as a single medicine, by 1996 the progress achieved included the available new technologies, availability of new efficacy-proven protease inhibitors and the proposal of combined use of medicines. Intense media coverage of activities certainly contributed to a more comprehensive approach and compliance with Ministry of Health guidelines.

The initial launching of the access to treatment in Brazil (mainly during 1991 to 1995) had a limited range because of insufficient availability and supply of medicines within the public health network. From 1996 on, enhanced supply was ensured by the Ministry of Health. By this time the first Brazilian consensus on the use of ARV therapy and Technical Advisory Groups was settled, and a logistical system was developed for the purchase, storage, distribution and availability of medicines, at the same time as the passing of Law 9.313/96, establishing the right to receive free medication²⁴.

According to the Brazilian Ministry of Health²⁵, the principles of universality and equity are behind the main objective of ensuring that 100% of the people with HIV/AIDS receive the necessary treatment. The results have been dramatic. They include a reduction of 48% and 49%, respectively, in the mortality rates of patients in two studies carried out in São Paulo and Rio de Janeiro. The reduction of hospital admissions has been considerable since 1997, as well as the reduction in the length of hospitalization. These reductions have been estimated to represent savings of nearly US\$ 421 774 297 in the two-year period 1997-1998^{23, 24}.

The Brazilian Ministry of Health is responsible for the supply of 13 ARV, including 5 nucleoside analog reverse transcriptase inhibitors (NRTI), 3 non-nucleoside analog reverse transcriptase inhibitors (NNRTI), and 5 protease inhibitors (PI), comprising 27 pharmaceutical presentations. The medicines are distributed through 424 pharmacies of HIV/AIDS outpatient services²³. Complementing this, the state level is responsible for the provision of medicines for HIV-associated opportunistic infections (with the exception of those that are also provided at the federal level), as are the medicines for strategic programmes, which

include tuberculosis.

National manufacturing of ARV in Brazil includes one Federal manufacturer and five state-owned manufacturers, as of the year 2000. The Federal manufacturer (Far-Manguinhos), besides developing the manufacturing process of the final products, supplies nearly 30% of the medicines used in AIDS in the country, and is responsible for the reverse-engineering of the technology for developing the raw materials and the medicines as a strategic support to the Ministry of Health policy. All of the products that are being produced by the public manufacturers undergo bioequivalence tests, in accordance with the Generics Law. Quality control includes compliance with good manufacturing practices (GMP), certified by inspection by the National Regulatory Authority, with monitoring of the first batches, as well as double-checking with university laboratories accredited by the Ministry of Health²³.

Prices of ARVs in Brazil have been reduced over the past years, due to negotiation and centralized procurement with international companies, as well as promoting public manufacturing. Recent patent protection law includes the safeguard of compulsory licensing on behalf of public health interest, in compliance with the WTO TRIPS Agreement.

Domestic production has reduced prices by 78%, negotiation based on differentiated prices has reduced prices by 70%, and imported products have been reduced by 25%. A cost-benefit ratio, taking into account the resources that are being spent in ARV therapy, the saving in hospitalization, welfare and years of life gained are clearly positive. Government support has been sustained by a combination of the pressure of social forces, a well-built programme and the worldwide importance that is being attributed to AIDS^{23, 24}.

Recent negotiations by the Ministry of Health with transnational companies have reduced the prices of ARV. In March 2001, Merck Sharp & Dohme agreed to reduce indinavir from US\$ 1.34 to US\$ 0.47 per unit, representing a 64.8% reduction. For efavirenz, the price was reduced from US\$ 2.05 to US\$ 0.84, a reduction of 59%. Roche has also recently agreed to reduce the price of nelfinavir by 40%, from US\$ 1.07 to US\$ 0.64. These reductions have been negotiated with the idea of implementing a compulsory licence for local production by a state manufacturer. Additionally, the Ministry of Health has announced that Glaxo Wellcome has discussed potential partnership for manufacturing abacavir and amprenavir, which are being included in the AIDS treatment consensus in 2002²⁶.

A decrease in the frequency of the most common opportunistic infections has also been reported in Brazil, and new cases of tuberculosis in HIV-positive patients have likewise been reported as decreasing²³.

Further evidence of the positive aspects of the Brazilian policy of providing universal access to ARVs can be related to the phenomenon of partial immunological reconstruction that is being promoted by treatment. This has been described as related to the demonstration of a progressive rise in the main CD4+ T count after 18 months of treatment. Apparently, this improvement seems to reduce the frequency and severity of opportunistic infections, resulting in a better quality of life²³. Additionally, we would state that these observations are a response to the criticisms that have been posted regarding the domestic production of ARVs in Brazil.

Cooperation is being sought by other developing countries, mainly from Africa. Brazil has stated that it can promote the transfer of technology for the establishment of production facilities, as well as enter discussions aiming to establish comprehensive AIDS programmes, and has agreed to an exchange with several countries on different approaches.

Recent lessons learnt on a critical approach

It is interesting to note that the history of the AIDS epidemic or pandemic in Brazil is coincident with a nationwide process of returning to democracy, following the 20-year period of military governments initiated by the *coup d'état* in 1964. An intense mobilization preceded this decade, with broad movements, as well as specific debates, many of them related to minority groups, e.g. racial and ethnic groups^{27, 28}.

Furthermore, during the 1970s, nongovernmental organizations (NGOs) were developed in Brazil, most of them committed to social movements, having been created for very specific reasons. At the same time, another social movement present and active in Brazil was the Health Reform Movement, which aimed to reform the health system with a care approach. This would include a unique command, involving administrative decentralization of health services and activities, different levels of complexity, but above all, universal and equitable access, and popular or social participation.

In spite of the profound economic recession that was a characteristic of that period, not only in Brazil, it is nevertheless considered that the pledge for democracy, including the development of a new approach in the health system, was a positive step.

When considering the different countries' approaches regarding care, it is worth recalling the considerations that were proposed in 1987 at the United Nations by Jonathan Mann, as mentioned by Daniel and Parker²⁹. Three different phases of the AIDS epidemic may be distinguished, the first one being a silent infection within a community; then the second epidemic only arises some years later and is related to the suffering of cases of opportunistic infections related to immune deficiency caused by HIV. The so-called third epidemic is that related to social, cultural, economic and political reactions to AIDS, and is considered by far the most potentially explosive, yet at the same time the most fundamental for the global challenge²⁹.

It is not unlike Brazil's experience. In the first years of the HIV/AIDS epidemic in Brazil it was not considered a priority issue, neither by Brazilian society as a whole nor by the public sector, and especially not by the Ministry of Health. The only body that gave it priority in that period was the mass media. Therefore, the first years yielded to an imported model in order to address the measures needed regarding the disease.

The discovery of the etiology of AIDS, from 1984 on, substantially changed the approach worldwide. In that era, research was addressed towards developing more diagnostic procedures, aiming to identify the disease during the asymptomatic phases, as well as searching for more effective medicines.

Social perception and organization of responses to the epidemics also suffered significant changes after the discovery of viral etiology of the disease, generating panic and fear, as the population perceived the disease as contagious, and, with no known cure, fatal. Some authors and discussions refer to stigma of AIDS as similar to leprosy in Europe several centuries ago²⁹.

The first organized response to AIDS in Brazil was set up by the São Paulo State Health Department, initially as a technical group in order to study and propose the necessary measures. These included the diagnosis, control, orientation and treatment of cases, the compulsory notification to health authorities and the epidemiological investigation of suspected and diagnosed cases. Information to the community and the involvement of activism groups was also a characteristic of the first initiatives in Brazil.

Several states in Brazil organized their own programmes before the federal government organized the national programme in 1985. These programmes were focused on epidemiological surveillance, medical care and prevention. Several other institutions (e.g. university

hospitals, religious organizations and other nongovernmental organizations) added their own efforts to the construction of a large network.

The initial epidemiological profile in Brazil, which included sexual, blood products and perinatal transmission, led to a nationwide movement regarding the importance of ensuring the quality of blood products. This is considered an important factor to be included in the formulation of national policies.

The further intensification of social movements, and the discovery of new and more effective medicines in the late 1980s, changed the perception of the disease from a mortal to a chronic disease: one which was manageable with the use of new drugs for treating the HIV infection, as well as those now available for related opportunistic infections. Associated with the pauperization of the disease, mainly in the developing world, activist organizations encouraged governments to promote access to treatment. This trend was supported by the recognition of AIDS as a world problem, as stated by the 1987 World Health Assembly, in need of global responses.

There is no doubt that the issue of access to medicines, and access to care in the case of HIV/AIDS, must be considered a priority in the agendas of all policy-makers worldwide. The WHO Medicines Strategy and the main objectives that are being prioritized as guidelines are well established, and their implementation should be emphasized as necessary within developing countries' public health programmes.

Regulatory capacity must be considered by all countries as a necessary framework for the setting up and implementing of general policies, and commitment must be requested from the national authorities, including the necessary intersectoral actions that each country may demand.

Access to medicines, as has been proposed and approved at the most recent forums, especially during the last United Nations Human Rights Commission, must be considered a fundamental human right. This therefore is reaffirmed by a commitment to the undertaking of effective policies capable of ensuring the progressive move toward attaining this right.

It is also clear, to our understanding, that the developing countries have characteristics and different levels of development of their national health systems and in-country capacity. This makes it impossible to render a strict universal model of responding to the challenge of delivering care for people living with HIV/AIDS. Nevertheless, it is possible to adapt imported models to the national reality, as well as the local civil and social organization.

The Brazilian experience has been solidly built over at least 16 years. It is a complex multi-approach model that must be taken into account, but not necessarily adopted whole *per se*. On the other hand, the Brazilian programme has had success because a series of historic factors rendered it possible. These factors include a solid academic base, domestic capacity for production of raw material, state production of medicines and a government policy for developing, manufacturing and delivering essential medicines within the public health system. In developing countries, the national health systems and financing, the industrial domestic capacity, the academic capacity and the social context must be the basis for building proposals with short- and medium-term objectives, regarding reducing the negative impacts of the epidemic and ensuring access to care and to medicines for all people living with HIV/AIDS. It is a difficult task, but surely it is not impossible, and political commitment and solid partnerships are the first steps to ensure progression to these objectives.

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Expert contribution

Some reflections of economists on prices of HIV/AIDS drugs in developing countries

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These reflections are mainly based on our contribution to the UNAIDS/Ivorian Ministry of Health Initiative on Access to HIV/AIDS drugs in Côte d'Ivoire¹ and on our contribution to the meeting held on 10 and 11 September 2001 in Geneva at the initiative of UNAIDS and the French Agence Nationale de Recherche sur le SIDA (ANRS). This latter meeting was held in the presence of 15 African countries and international experts (Médecins Sans Frontières (MSF), World Health Organization (WHO), UNICEF, Brazilian National AIDS/STD Control Programme, etc.), and recommended the establishment of a mechanism for monitoring prices of HIV/AIDS drugs in African countries.

While complete access to antiretroviral (ARV) therapies for all medically eligible HIV patients represents less than 0.1% of GDP in OECD countries at current international market prices, such a strategy would exhaust all public expenditures on health, as well as account for a significant share of GDP in sub-Saharan African countries where HIV prevalence among the adult population is over 10%². This would still be the case even if the clinical and biological criteria adopted for eligibility to ARV treatment were less rigorous than those used in North America and Europe, taking into account the fact that a significant part of the population, particularly those in the rural areas, would unfortunately remain outside the health system.

Estimates of the number of people infected who require urgent access to care for prophylaxis and treatment of opportunistic infections or/and for actual ARV treatment vary from more than 1 to 4 or 5 million people for sub-Saharan Africa alone. For these countries, the high price of HIV/AIDS drugs on the international market constitutes a major obstacle to access to treatment for the people concerned. Reducing the price of drugs is therefore a *sine qua non* condition of any extension of access to adequate care and treatment for infected people in these countries, although it is obvious that other factors should also be taken into account (e.g. improvement of the entire health infrastructure, stock management and supply of drugs, control of rationale of prescriptions, etc.).

Rational public interventions for reducing prices of HIV/AIDS drugs in order to promote their financial accessibility in countries of the South

Specificities of the structure of the international drug market: imperfections of competitiveness

The debate on the regulation of drug prices is not new^{3, 4}. The main argument in support of non-regulatory intervention on the drug market is the importance of investments required for research and development (R&D) of new drugs, both ARV and other types of drugs. The sale of a drug to “compensate” for amounts invested in R&D and the high prices charged by drug manufacturers may be economically justified for ensuring the sustainability of the activity. Pharmaceutical firms may command high prices, far above their marginal and even

average production costs, for drugs (or diagnosis kits) protected by patents that are “justified” by the need to defray the high costs of R&D, and compliance with procedures (particularly in the conduct of clinical tests) which are indispensable for obtaining authorizations to market (AM) their new products in North America and the European Union.

It is a fact that the development of a new drug entails high costs, which have regularly increased over the past 30 years. The pharmacy branch presents the highest R&D expenditures/turnover (To) ratio (between 12% and 20% for the 40 most important firms) of the whole of American industry (to be compared to an average of 7.2% for the computer branch and 3.4% for the entire industry outside pharmacy)⁵. The “investment return” of these R&D expenditures, which has been increasing steadily, is effectively confronted with two difficulties. The first is the extension of the duration of the R&D cycle itself. The average period for development of a drug up to AM in the United States increased from 8.1 years to 14.2 years between 1960/70 and 1990/96, while the average number of patients included in clinical tests for obtaining AM was multiplied by three (from 1300 to 4200 between 1980/85 and 1990/95^{6, 7}). This resulted in a high average cost of R&D per new drug arriving on the market (US\$ 500 million), and according to some estimates, the inability of seven out of ten drugs to obtain an AM to defray their R&D costs⁸. A second difficulty is the shortening of the life cycle of the commercial product. In the United States, 72% of new drugs put on the market have to compete with another product within 18 months and face increased competition from generic drugs, which represent an increasingly important share of the American pharmaceutical market (from 27.0% in 1987 to 44.3% in 1997). The share of pharmaceutical expenditures refunded by health insurance companies corresponding to products still protected by patent was estimated in 1996 at just 22% of the total for countries of the European Union.

On the other hand, the high prices of new drugs do not reflect their marginal production cost (the cost required to produce another drug unit), which is low. This explains why manufacturers of generic drugs charge very low prices. In fact, they either do not pay fees to the patent holder or they manufacture molecules that are already in the public domain. That is why an anti-bacteria drug, ciprofloxacin, can be sold in some countries for around 1.5% of the average prices charged in the United States, or why the Brazilian authorities, relying on their national capacity to produce generic drugs, very quickly proposed ARV therapies at prices ranging between US\$ 1000 and US\$ 1200 per patient/annum, representing price reductions by a factor of 10 to 15 compared to North American prices. Without conducting any specific studies on this subject, it is possible that economies of scale can guarantee the marginal costs of producing molecules required for an antiretroviral multitherapy of around US\$ 200 per person/annum. Economic theory predicts that in a pure and perfect competitive market, where consumers will be automatically encouraged to prefer product X to product Y, if product Y can be substituted for product X (i.e. if it meets a similar need) and at a lower price, the price tends to reflect the marginal cost. Similarly, regarding public goods and services, the optimal charge will be based on the marginal cost⁹.

However, from the moment a firm has a monopoly of the market, it can maximize its profit by matching its marginal income with its marginal cost, and impose a price that could even exceed the average cost. This of course results in both a reduction of the quantities produced and sold on the market and the monopolist making an excess profit corresponding to a monopolistic income. It may be demonstrated that the difference between the

monopolistic price and the price that would be charged on the competitive market would be all the more high since the flexibility of the demand in relation to the price (i.e. the % of variation of the quantities requested, depending on the variation in % of the price of the good) is low (i.e. a price rise has little impact on the quantities requested, for example, since the goods concerned are essential for public health).

Since the time of the great Austrian economist of the early 20th century, Josef Schumpeter, economic analysis has affirmed the idea that an economy can only benefit from a continuous flow of innovations if the innovators are effectively motivated. This is due, on the one hand, to the risk and uncertainty associated with investment in the R&D of new products and with competitive processes. On the other hand, the notion of public good conferred on an innovation from the moment it can be more or less easily imitated allows the possibility of temporarily exploiting a monopolistic rent as a “necessary evil” in the short term to stimulate R&D effort in the long term¹⁰. The entrepreneur who launches a new product is rewarded for his risk-taking by the fact that he is provisionally the sole controller of the market. However, depending on the more or less codifiable scientific and technological knowledge incorporated into this product, imitation through competition (spillover effect) will be more or less rapid.

The first justification for a patent system is to guarantee for the innovator the amortization of his R&D expenses by granting him a temporary exclusive use, since without such guarantee the private R&D effort may be sub-optimal and not promote the dynamic efficiency of the global economy. On the other hand, it is established that such systems may impede the dissemination of knowledge and, more generally, innovation, since the guarantee of monopolistic positions prevents the competitive mechanism from encouraging the widening of the range of products offered and selection of the most competitive enterprises.

Public policies on innovations, or definition of an optimal patent system, should always arbitrate between these two conflicting arguments – the argument supporting the protection of innovators even if it means restricting competition, and the one establishing the primacy of the competitive mechanism. Since the works of Nordhaus¹¹, it is established that using patents as an economic policy tool should simultaneously take into account both their field and their protection period, and that their optimal combination from the point of view of the collectively efficient incentive to innovation differs depending on the case in question. For innovations concerning oligopolistic final products, or oligopolistic markets, where innovation is in fact appropriable by a single enterprise, it has been shown that private incentive to disseminate R&D products may be inadequate and that using exploitation licences carries a social value that has the edge over private value, since the inclusion of licence obligations could condition efficiency of the award of a property right¹². This is actually what article 31 of the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights (WTO TRIPS Agreement) recognized when instituting a protection clause in the application of patents of national emergency. The highly oligopolistic nature of the ARVs market (limited number of products and manufacturing firms: 15 molecules produced by seven specialized firms and grouped into three therapeutic classes where the number of suppliers never exceeds four), corresponds to a situation where economic analysis poses a maximal risk of understanding between firms in order to preserve an “excessive” rent with regard to collective efficiency. It is also established that even in the case of such strong collective imperatives as those of public health, centralized negotiations

have little chance of achieving an efficient redistribution of the monopolistic rent among the holding firms and other agents (consumers, public authorities, etc.)¹³.

Another important point stressed by economic theory is that monopolists can use prices to practise discrimination, which consists of charging different prices depending on the clients or the markets. For example, even if the marginal cost is the same for supplying the same good in two different countries and the firm with the monopoly is confronted with different demand graphs, it may still charge different prices. These price differences between countries objectively create enterprises playing the role of intermediaries (buying from areas where the price is cheaper to resell it where it is higher) who may “share” the rent with the monopolist¹⁴. The existence of price difference between countries of the North and those of the South does not in itself constitute an economic anomaly. Moreover, the extension of markets of the South made possible by lower prices may be in the interest of the pharmaceutical branch as a whole.

Imperfections of competition and of information on prices of HIV/AIDS drugs

It is also established that the information asymmetries between suppliers and buyers are likely to be accentuated in imperfect competition markets¹⁵, as with those of new drugs, and that firms are not *a priori* motivated in such markets to reveal the full information on their production costs and the prices they are prepared to charge for their products.

Economic intuition suggests that consumers who are better informed of the prices proposed by the different firms contribute to a positive “externality” in favour of uninformed consumers by increasing the competition between the firms, which compels the latter to propose products with better quality/price ratio. This *a priori* ensures better information dissemination¹⁶. It has been shown by both theoretical¹⁶ and empirical studies that “uninformed” consumers will inevitably pay a higher price than those who are better “informed”. It has even been shown¹⁷ that an increase in the number of uninformed consumers will result in an increase in average prices and consequently impose a negative “externality” on informed consumers (who will obtain a price level higher than what they could have obtained in the absence of uninformed consumers). All these factors plead in favour of the benefit of buyers having a mechanism that can improve their information on all the prices and transactions in all relevant national markets. They also show that this information can never be generated spontaneously by the markets, but presupposes a joint effort aimed at producing it as a global collective good shared by the different countries.

If the publication of information for buyers constitutes an *a priori* price reduction policy tool, there is no guarantee that the information will always have an effect on prices. For example, it has been shown that in cases where buyers discriminate between products (for example, prefer an original product to a copy), the dissemination of the information may have a “paradoxical” result in a price increase; indeed, if informed consumers with prejudices reveal them while looking for information on products that correspond best to their preferences (and stop their research when they discover that the price of the product is not higher than they anticipated), this attitude will render the offer of the firms more inflexible *vis à vis* consumer demands. This phenomenon could translate into a rise in equilibrium prices¹⁸. This underscores, in the case of drugs, the need to combine information on prices with that on the quality of the product in order to avoid *a priori* preferences that would not reflect real differences in quality (in terms of therapeutic efficiency and/or comfort for the patient).

Empirical observations on recent trends in prices of HIV/AIDS drugs

Due to the temporary monopoly recognized by patents, it is inevitable that high prices of new drugs do not reflect their marginal production cost (the actual cost of producing an additional drug unit), which is low. This explains why manufacturers of generic drugs can afford to charge low prices. In fact, they either do not pay royalty to the patent holder or they produce molecules that have fallen into public domain. Relying on their national capacity to produce generics, the Brazilian authorities quickly managed to propose HIV/AIDS ARV therapies for prices ranging between US\$ 1000 and US\$ 1200 per patient/annum, lower by a factor of 10-15 compared to North American prices. Considering the data on production costs provided by manufacturers of generics, it seems possible that economies of scale may guarantee marginal production costs for molecules required for ARV multitherapy as low as US\$ 200 per person/annum.

Example of the UNAIDS/Côte d'Ivoire Ministry of Health initiative

Evaluation of the initiative included an econometric analysis of the comparative evolution of classes of drugs (ARVs, essential drugs for treating HIV/AIDS opportunistic infections, anti-hypertensives, the latter class being used to “control” general trends on the drug market for the period 1996-2000 in Côte d'Ivoire) and an assessment of the impact on the drug distribution network in Côte d'Ivoire. The detailed analysis focused on quantities bought and prices charged on the Ivorian market by the Pharmacie de Santé Publique (PSP), which plays the role of wholesaler-distributor for the entire public sector¹⁹.

Without going into the details, we would like to highlight the following conclusions:

- Concerning “tracing” drugs (anti-hypertensives), there was an increase of about 17% in the average price between 1996 and 1999. Although it represented only about 10 CFAF francs, the price variation of these drugs over the period studied was different from the two groups of HIV/AIDS drugs, whose prices started dropping from 1997.
- Over the period 1996-1999, for drugs associated with prophylaxis and treatment of opportunistic infections, there was a large reduction in prices (60%), which was accentuated in 1998. This significant reduction was partly due to increased competition between products in the quinolone class and partly due to the high volume of quantities sold, with monthly sales rising from over 500 000 units at the beginning of 1996 to more than 1 million units at the end of 1999, representing a 100% increase in sales within four years.
- Over the period 1997-2000, the average prices of nucleoside inhibitors marketed from 1996, antiproteases from 1997, and nucleoside inhibitors introduced in 1997, declined by 12%, 13% and 40% respectively. These figures show that the announcement of the UNAIDS initiative probably had a short-term effect on drug prices in 1998. The price reductions observed during the whole period were rather due to the evolution of the PSP policy in the context of the initiative, which used the competition between specialists and generics during its invitations to tender, whether they eventually resulted or not in the purchase of generics. It was also observed that the effective purchase of generics resulted in a significant decline in 2000. The stable economic situation further confirmed the impact that the existence of the generic product had on price reduction.

- The price reductions obtained, however, were not sufficient to facilitate greater access to ARV treatment, as shown by the limited price decline of a monthly treatment for an average adult of a ddI-d4T bitherapy and tritherapies such as ddI-d4T-indinavir, AZT-3TC-indinavir combinations, or Combivir®-indinavir, the most frequently prescribed in the country.

Recent trends in price declines

At the end of 2000, Uganda began the importation of generic ARV drugs for the first time, which immediately resulted in a reduction in the prices of the most commonly used tritherapies by 20% to 45% in the first quarter of 2001. Brazil's national potential for producing ARV generics enabled the country to cover, in 2000, 57% of its requirements for treating more than 90 000 patients nationwide. Data from the National AIDS/STD Control Programme show that competition with locally manufactured generic products resulted in price reductions of around 70% to 80%, whereas the reductions are marginal in the absence of a national drug supply capacity.

This phenomenon of price decline, through generic competition, is not surprising from the theoretical point of view and constitutes an empirical reality well established in the markets of the North²⁰. According to Wiggins and Manness, for the entire class of antibiotics sold in the United States between 1984 and 1990, the existence of at least one generic of the molecule on the market resulted in an average price reduction of 50% and the introduction of generics on the market resulted in an average price reduction of speciality drugs alone.

Mobilization of international opinion around the court case that threatened to reduce the facility of the Brazilian and South African Governments in terms of drug policies, and around debates on the potentially negative effects of the TRIPS Agreement²¹ on public health, coupled with the "virtual competition" from producers of generics, was clearly at the origin of the unilateral announcements of price reductions by some specialized firms in 2001. Following these reductions, in July 2001, the monthly cost of an ARV tritherapy was reduced by a factor of three to five and is now equivalent in Côte d'Ivoire to the minimum wage (which is around 500 FF). For patients who benefit from a subsidy of 75% to 95% of this cost, the financial share of the cost ranges between 20 and 600 FF depending on the regimen prescribed.

A study carried out in Uganda²², where for the moment there is no government subsidy on ARV treatments, showed that in the hypothesis, now a reality, of a cost reduction of less than US\$ 100 per month, it would be possible to immediately treat more than 50 000 people with limited investments in health infrastructures. Although these price reductions are still insufficient to ensure generalized access to ARV treatment, as in the treatment and complete prophylaxis of opportunistic infections, all the more so since they are not accompanied by equivalent price reductions for indispensable diagnosis tests (CD4 and viral tolerance), they have already contributed to a significant extension of the market.

However, access to these price reductions continues to be extremely variable depending on the countries and on the care sectors. The comparative data collected on prices of HIV/AIDS drugs by UNAIDS and MSF do not make it possible, in the case of ARVs and to a lesser extent the other therapeutic classes, to establish a clear link between a difference in source prices between countries and quantities bought or the seriousness of the epidemic.

Many factors other than solely the difference of price sources account for the difference

in retail prices currently paid by consumers and constitute key variables in terms of financial accessibility: transport (depending on the geographical location of the “purchasing country”), customs and import duties, distribution margins, retail margins and value added tax. The retail price also depends on the number of intermediaries between the manufacturers and the wholesale outlets and their profit margins. The functioning procedures of these supply structures and health policies, which vary from one country to the other, also have an impact on variations in the retail price of drugs²³. The management difficulties of the supply outlets, the non-conformity of the medical promotion and advertisement of drugs with scientifically validated data, the absence of national consensus on therapeutic protocols, economic incentives for the prescription, which are weighing on health professionals, as well as the tendency of medical consultants to dispense drugs, contribute further to the difference in prices paid by patients within the same country. The difficulties of controlling the entire dispensing modalities by the public authorities, and collaboration between public sector and private sector, further increase these differences. Finally, the source and type of funding of funds allocated for drugs may also contribute to the difference in source prices, depending on whether it comes from the state budget or a donation, the donations often being conditional on specific sources of purchase.

Conclusions

The experience of markets for HIV/AIDS drugs, between 1996 and 2000, shows that price negotiations should be conducted in a decentralized manner (even if the circulation of comparative information between countries and markets is vital for reducing information asymmetries to the benefit of suppliers) and should be supported by competitive mechanisms relying on the availability of generic drugs (or/and on the threat to resort to them). In this regard, it would be prejudicial to extrapolate, in the case of HIV/AIDS drugs, the strategy of bulk purchasing at the international level and free distribution to countries, which was adapted to the case of the expanded programmes of immunization, although the context is quite different. On the other hand, it remains to be determined whether inter-country regional negotiation strategies may prove more effective than negotiations on a country-by-country basis.

The modalities of intervention by international cooperation organizations should rather focus on the following areas:

- Supply of information (establishing an observatory for HIV/AIDS-related drugs, quality control, etc.) to help buyers of the different countries to negotiate for more advantageous source prices.
- Funding of seed money to facilitate the establishment of specific supply systems for HIV/AIDS drugs at national level.
- Support to possible public mechanisms for subsidizing treatment for the most disadvantaged groups.
- Support to investments in infrastructures and staff indispensable for a rational prescription of HIV/AIDS drugs.

Moreover, it is obvious that the trends of the TRIPS Agreement may have serious consequences on negotiation and price reduction processes. The integration of public health objectives into national and international plans in the definition of “optimal” patent fields and modalities is, from this point of view, decisive²⁴.

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indinavir (Crixivan) for an annual cost per patient of US\$ 600 (the latter affirms being the only firm to propose these prices to other developing countries outside the African continent).

Abbott Laboratories also announced its intention to sell in Africa its two antiproteases (ritonavir-norvir- and ABT378/r –Kaletra-), as well as its diagnosis kits at “production cost”.

As for Roche, it proposed under the cover of UNAIDS respective reductions of 50% and 15% in Africa for its two antiproteases (saquinavir in soft capsules –Fortovase- and nelfinavir –Viracept-) (Zimmerman R and Waldholdz M, *Wall Street Journal*, 27 March 2001).

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Chapter 4

Partnerships for care and support: role and responsibilities of the different partners

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More than any other health problem, HIV/AIDS reveals the weaknesses and strengths of the functioning of socioeconomic and health systems in developing countries. In order to counter the weaknesses and capitalize upon the strengths, a multisectoral approach is needed to the care and support of people infected and affected by the epidemic. Such an approach demands that the different actors involved work in partnership, and in a complementary manner, to tackle the multiple challenges involved in providing that care and support.

Individuals and families are often the first to react and respond in the face of a health problem. In the case of HIV/AIDS, they also bear the primary burden. Their reactions to the epidemic should be enhanced by therapeutic itineraries, which should involve different actors at different levels. Furthermore, networks of solidarity and genuine strategies for care and support should be created to maximize the contributions of all partners.

Among the many actors with significant roles to play are traditional healers, health professionals at peripheral and central levels, community and government leaders, the public and private sectors, and partners from civil society.

The purpose of this working group – Partnership roles and responsibilities – is to identify feasible action to be undertaken by relevant partners for care and support, and to allow, through the establishment of local partnerships, the appropriate psychological, community, social and medical support for people living with HIV/AIDS (PLWHA). This support includes the availability of, and access to, voluntary counselling and testing (VCT) services, and mechanisms for family, community and social support to PLWHA. Additionally, medical support should include access to medical care for the prevention and treatment of opportunistic infections, and antiretroviral (ARV) drugs.

Key partnership issues and principles for care and support

- Trust and respect, in order to mobilize and sustain partnerships.
- A supportive environment, free from stigma and discrimination, to allow people infected and affected by HIV/AIDS to adopt and sustain health-seeking behaviours (in turn, they may become real agents of change for prevention, which is directly linked to care and support).
- VCT should be a cornerstone of the partnerships, as up to 80% of people living with HIV in developing countries do not know their serostatus.

- Services should be available and accessible to people who need them, without bias in regard to geographic, social and economic situations. Indeed, the quality of services will determine the frequency of attendance, and the modalities of access should be commensurate to the socioeconomic status of people infected and affected.
- The availability and accessibility of drugs in health services constitute a real incentive for people to test for HIV and visit health and social services and will enhance the capability and credibility of health care professionals.

Forms of partnerships

While each group of actors has a valuable contribution to make, none of them can be responsible for the burden of care and support alone. Partnerships are therefore key in recognizing each other's efforts, and complementing each other in action.

In the last two decades of the response to HIV/AIDS, different forms of partnerships have been built on issues of common concern or around the needs of a particular constituency. These need to be further strengthened, and new forms must be promoted, in order to reduce the gaps in knowledge and increase access to services. This also creates a solid basis for local, national and global solidarity.

Many examples already exist. The development of public/private partnerships are inspiring, as illustrated by foundations working together with pharmaceutical companies to support government efforts. Also, civil society organizations are raising the voices of communities in searching for alternative strategies for wider access to care, including collaborations with generic producers of drugs. Faith-based institutions are reaching out to remote areas, complementing government actions and mobilizing communities to participate more actively in care and support efforts. The international community also seems to be more committed than ever before to show leadership, revise policies and mobilize resources to tackle HIV/AIDS as a key global issue.

The International Partnership Against AIDS in Africa (IPAA) brings together all major stakeholders (governments, nongovernmental organizations (NGOs), community-based organizations (CBOs), the private sector and the UN system) in a framework for joint action to support the national response to the epidemic. The current challenge is to communicate a greater sense of urgency while moving fast with a stronger collaboration that will commit partners in the longer term.

The partners and their actions

Developing countries

National governments should ultimately be responsible for putting in place the appropriate infrastructure and designing policy for the better health and well-being of their people. The coordination of the national response, mobilization of material and financial resources, management of human resources, facilitation of partnerships at all levels and support to NGOs/ CBOs are key areas of responsibility for the government. Governments should

continue to demonstrate leadership and make tough decisions, as the African leaders did in Abuja by committing 15% of their national budgets to health to respond to the challenges of HIV/AIDS, tuberculosis and malaria. Countries have also invested national financial resources into fighting HIV/AIDS through special taxation, reviewing public expenditure and national budgets, creating special funds or by mainstreaming HIV/AIDS into poverty reduction strategies.

Governments are increasingly recognizing the role of communities and are involving them through effective partnerships in the national response. Mali, for example, has approved an action plan to strengthen district capacities by building local partnerships with service providers, the result being the “One NGO-One District” Initiative on HIV/AIDS. In Burkina Faso, mechanisms to channel funds to local communities are being established in the framework of the District Response Initiative. In countries such as Côte d’Ivoire, Senegal, Kenya, Chad and Guinea, the community sector forms part of the expanded Theme Group on HIV/AIDS. Furthermore, mayors from many African countries have combined their efforts to address HIV/AIDS through the Alliance of Mayors Initiative for Community Action on AIDS at the Local Level (AMICAAL). A similar initiative is being formed in the Caribbean.

Industrial countries

Industrial countries have taken an active part in major initiatives such as the International Partnership Against AIDS in Africa, as well as in the Caribbean. They also strongly supported the commitments made at the United Nations General Assembly Special Session on HIV/AIDS (UNGASS), which resulted in the establishment of the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria. Activities to be financed through the Global Fund would supplement the current efforts in mobilizing the resources needed to effectively respond to the epidemic.

The commitments made by world leaders at UNGASS in June 2001 need close monitoring and follow-up actions in order to maintain the momentum of HIV/AIDS issues and actions as a key development priority. There are high expectations that the Global Fund to Fight AIDS, Tuberculosis and Malaria will vastly increase the level of resources available to support a broad care agenda, including the provision of ARV drugs.

Almost all industrial countries have made pledges to the fund. They have also been active in encouraging the establishment of partnership actions to be funded at national and local levels. These include a series of actions to support access to care and support in resource-poor settings. Their role includes financial and technical support, assistance in strengthening health systems, human resources development and support to HIV/AIDS research and development.

Major international government summits, including the G8 Summit in Genoa, Italy, have also focused attention on HIV/AIDS, and many governments have increased their contributions to direct support for the implementation of national strategic plans. One example is the programme *Partenariat hospitalier en réseau*, which was initiated by France and endorsed by a number of European countries. It promotes partnership and “twinning” between hospitals in the North and hospitals in the South, and thus reinforces local health systems and is able to facilitate, for example, the administration and monitoring of ARV treatments.

Individuals and families

The economic status, culture and belief systems of individuals and families will influence when and where care will be sought, and referral systems should be developed accordingly. In the absence of stronger health systems, individuals and families will opt, or be forced, to consult traditional healers or other health services. Alternatively, they may remain in denial and ignore their situation because of lack of incentives and fear of consequences resulting from stigma and discrimination.

Families are often the primary care providers and their efforts have been inspiring for home-based care programmes. These programmes have demonstrated their willingness to share the burden of care and support – in terms of financial contribution as well as investment of time and action – by creating a supportive environment for prevention, care and support.

However, the problem can be quite overwhelming and often economically and socially destructive. Individuals and families need to be supported to move from fear, stigma and discrimination to compassion, care and support. The interest and support from outside their homes is invaluable in helping them move from potential despair to hope. Again, the quality of services and the availability of drugs are very important incentives for people to develop health-seeking behaviour and continue to be active partners. As demonstrated in other established health programmes (e.g. against tuberculosis) individuals and families can also be the best guardians of compliance to treatment.

In order to maximize the contributions made by families and the immediate community, the GIPA (Greater Involvement of People Affected by AIDS) initiative must be reaffirmed so as to make people living with HIV/AIDS part of the solution and not just be simply stigmatized as “the problem”.

NGOs, CBOs and other civil society organizations

Communities and civil society have different forms of organizations that are either inherent to their culture and their social dynamics, or were created to respond to new challenges. These forms of organizations (e.g. traditional healers, faith-based groups, networks of solidarity, development and health NGOs) are often closer to the people and the communities, and can constitute excellent relays for care and support.

CBOs and NGOs can play a vital role in care and social services delivery. In the rural areas of many developing countries they are often the only actors that support and accompany people in their efforts to improve the quality of their lives. By their contributions, they have gained credibility within the communities in which they work, and this has led them to play an interface role in bringing community perspectives to the international arena. They are strong advocates for access to care by people in resource-poor settings, and make invaluable contributions to such areas as community preparedness for vaccines and other prevention technologies, as well as maintaining respect for ethical principles.

Amongst the most active of the CBOs are the people living with HIV/AIDS themselves and their associations, who tirelessly fight for better access to care and support, including access to ARV therapy. Simultaneously, they are a constant reminder of the reality of the epidemic and the urgency required in the response. The constituency that they represent, their advocacy and activism make them genuine and most valuable partners in the efforts for better access to care and support.

In regard to NGOs, the results achieved by Médecins Sans Frontières (MSF) and Oxfam

in negotiating lower drug prices with generic drugs manufacturers illustrate just one of the activities of the partnerships that need to be further promoted. As a result of their broad contributions and experience, NGOs can play a vital role in linking community actions with national and international programmes.

The supportive and advocacy role of civil society organizations should be strengthened, and they should be involved in the design, implementation and evaluation of care and support programmes.

Health system

Hospitals and other peripheral health infrastructures can often barely meet the primary health care needs of the population, without the added demands that are placed on them as a result of the HIV/AIDS epidemic. Therefore, the added burden often reveals the weaknesses of the health systems in most developing countries.

Patient-friendly services, quality of care and, most importantly, the availability of drugs must be dramatically improved in order to respond to HIV/AIDS care and support needs. This calls for infrastructure development and capacity-building of human resources.

The health system should collaborate with the communities they serve so as to better understand the perceptions of disease and care by the populations. Strategies should then be planned accordingly. Such forms of collaboration will nurture the continuum of care, involving all levels – the home, the district and the central hospital.

The administration and monitoring of ARV therapies will, however, need strong and long-term partnerships such as the one between public, private and religious hospitals. A further example is the national/international collaboration developed between hospitals in France and hospitals in developing countries. Despite the evident interest from so many countries, the main factors contributing to the low uptake of low-price ARVs cannot be blamed solely on limited infrastructure for managing patient care. While there is certainly a need to strengthen the infrastructure and train the personnel in developing countries, problems also exist in the uncertain and inadequate finance for the total cost of care in the most affected countries. These include the reluctance to fund ARV drugs on the part of many national governments and donors, and price levels that remain out of the reach of many developing country budgets constitute major constraints to access to care and treatment in resource-poor settings. Furthermore, even with limited funding to cover the cost of the drugs, there remains the associated need for providing laboratory support, laboratory reagents and other commodities.

Pharmaceutical companies

The high prices of HIV/AIDS-related drugs and the disparities in access have led to various discussions, negotiations and collaborations with pharmaceutical manufacturers by governments, civil actors and the UN system.

In May 2000, the UN (United Nations Population Fund (UNFPA), United Nations Children's Fund (UNICEF), World Health Organization (WHO), The World Bank and the UNAIDS Secretariat) and five pharmaceutical companies (Boehringer Ingelheim GmbH, Bristol-Myers Squibb, GlaxoSmithKline, Merck & Co., Inc., and F. Hoffmann-La Roche Ltd) initiated a partnership to increase access to HIV/AIDS care, treatment and support called the Accelerating Access Initiative.

The Accelerating Access Initiative has involved dialogue between the UN and the pharmaceutical industry in order to make quality drugs more affordable in developing countries, as well as technical collaboration with countries in the development of national programme capacity to deliver care, treatment and support. This consultation between governments, UN partners, the private sector and NGOs takes place through a body known as the Contact Group, which is a collaboration between interested parties that act as an advisory body to governments and proposed programmes.

While this is a collaborative process between many partners, there are limitations on agreements between pharmaceutical companies. Legal obligations require that the companies continue to act individually and independently, particularly involving matters relating to the discovery, development and commercialization of products. In regard to the issue at hand, this directly affects any cross-company arrangements in the pricing and availability of drugs for the treatment or prevention of HIV/AIDS and related opportunistic infections.

By mid-September 2001, 71 countries (comprising 40 countries in Africa, 24 in Latin America and the Caribbean, 4 in Europe and 3 in Asia) had indicated their interest in collaborating with UNAIDS in the Accelerating Access initiative.

Current functions at the global level which aim to strengthen access to HIV/AIDS care and treatment include:

- Sustaining dialogue between the UNAIDS Secretariat, WHO, other UNAIDS Cosponsors and the industry to explore specific opportunities and mechanisms to increase access to care.
- Global-level consultation and information-sharing with governments, the UN partners, private sector, CBOs and NGOs (the participation of representatives from industry and other sectors of civil society, along with governments and donors in a “contact group” will ensure the required level of transparency and openness in the dialogue).
- Development of procurement schemes so as to identify optimal mechanisms, including participation in the resource allocation process of the Global Fund (which should address care and support concerns, including ARV therapy).

Significant price reductions have been achieved on a range of HIV/AIDS-related drugs, yet prices still remain out of reach for the majority of people who need them.

The country-by-country process of consultation on national AIDS plans and agreement on implementing ARV therapy (including pricing discussions with individual companies) has been relatively slow and resource-intensive. Consideration has therefore been given to developing a regional approach whereby several neighbouring countries can, through cooperation, expand the potential for providing benefits more rapidly, for example through the possibility of bulk purchasing and shared technical assistance. Regional initiatives, involving the development of regional plans for care, treatment and support, are well under way in Western and Southern Africa, and the Caribbean. A first regional meeting on access is also being discussed for Southeast Asia.

Critical decisions will have to be made at country and inter-country levels to consider how national capacity can be strengthened to engage in evidence-based policy and programme development, choose the best sources of procurement and financing, and implement and monitor the expansion of care and treatment programmes. Mechanisms such as the UN Theme

group and other country-level coordinating mechanisms need to be engaged to support the process, and to ensure effective information exchange and decision-making between national and international partners.

The United Nations system

The United Nations system has recognized HIV/AIDS as the most formidable development challenge of our time. As a subject of debate on the agenda of the Security Council, it became the first time in history that the council had debated a health issue. More recently, the UN Secretary-General made HIV/AIDS his own personal priority and issued a Call to Action for countries to respond to the challenges of the epidemic. The General Assembly subsequently held a special session on AIDS, which resulted in a set of commitments made by heads of state and governments to address different aspects of the response to HIV/AIDS.

UNAIDS and the other agencies of the United Nations system undertook a series of initiatives (where care and support for PLWHA feature prominently) as illustrated by the following actions:

UNAIDS (Secretariat and Cosponsors including WHO) is actively involved in facilitating greater access to care and treatment, providing technical advice and assisting countries and governments to identify options to increase care and support. It also actively supports countries in the implementation of their chosen options.

UNAIDS, consistent with its mandate for advocacy and facilitation, has also been involved in mobilizing the vastly increased resources needed for care and treatment. In particular, they are supporting consultations on the establishment of the Global Fund and encouraging the flow of debt relief funds towards HIV/AIDS prevention and care programmes.

The World Bank's Multi Country HIV/AIDS Prevention and Control Program (MAP) has recently approved a package of International Bank for Reconstruction and Development (IBRD) loans and International Development Association (IDA) grants for several Caribbean countries and has agreed that, under certain conditions, parts of these loans may be assigned to the purchase of ARV drugs. Barbados was the first country to fulfil these conditions and has therefore been able to draw on World Bank loan funds to finance access to ARVs. While MAP Phase I objectives in Africa cover capacity building for HIV/AIDS activities, including the infrastructure to facilitate access to treatment, MAP Phase II will more directly address access in selected countries.

UNICEF is a key partner in UN efforts to implement programmes for the prevention of mother-to-child transmission (MTCT) of HIV/AIDS. Such programmes are becoming more financially possible in resource-poor settings due to price reductions and donations of ARV drugs.

WHO convened a consultative meeting on the use of ARV drugs in resource-limited settings and has established two technical working groups, which are working on the development of simplified ARV treatment guidelines and the creation of a surveillance network in regard to ARV drug resistance.

Current pricing information and data on suppliers is publicly available in *Sources and prices of selected drugs and diagnostics for people living with HIV/AIDS*, a document produced by WHO, UNICEF, the UNAIDS Secretariat and MSF, in June 2001.

The International Labour Organisation (ILO) is unique within the UN system in having a tripartite constituency so that its partners are not just governments but also employers, workers

and their organizations. This means that it has an existing network of “social partners” whom it can mobilize and support in the response to HIV/AIDS.

At the national level, the ILO is helping to create a policy environment that is conducive to the protection and support of those affected by HIV/AIDS by advising governments (a) on the revision of labour laws to make provisions for HIV/AIDS-related issues, and (b) on the extension of national AIDS plans to include a policy for the world of work. In the workplace itself, a critical partnership is that between employers and workers. It is a target of the ILO to promote the widespread adoption of workplace agreements, including a programme for AIDS prevention, care and mitigation.

Since the workplace has close connections with the local community (both through the families of workers and through sub-contracting and service provision) the ILO includes, in its guidance for the development of workplace programmes, ways to strengthen links with the community and NGOs/CBOs.

Conclusions

Partnership-building has been a key strategy in the response to HIV/AIDS, and indeed many actors have already entered into different forms of partnerships. The task ahead is to further build upon the major partnerships, to strengthen them and to scale them up, while continuing to explore other innovative forms that will accelerate access to care and support in resource-poor settings.

The IPAA provides a framework for such further developments. It has been endorsed by all major stakeholders, and is the inspiration for similar partnerships in the Caribbean.

The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria should consider the following elements, in order to build productive and creative partnerships of assistance to those most affected:

- Developing countries, PLWHA, communities and their organizations should play a major role in the definition of priorities and the *modus operandi* of the Global Fund.
- Attention should be given to the care and support needs in resource-poor settings, including HIV/AIDS-related treatment such as ARV therapy.
- Transparent mechanisms should be in place at country level to allow major national actors to work together with governments in the elaboration and funding of national plans, in addition to facilitating access to resources by communities through fast, friendly and flexible mechanisms.

Ongoing consultations should provide an opportunity for all stakeholders to renew their commitments to partnership-building and support for better access to care and support.

Generic production of HIV/AIDS-related drugs in Thailand

Krisana Kraissintu

Thailand is a middle-income country with an estimated HIV prevalence rate of 2.5% amongst a total population of 62 million. HIV/AIDS is a disease that affects many parts of Thai society. It decreases child survival and life expectancy. The health care system is overburdened and there is an increase in the number of orphans. Most people with HIV/AIDS are of working age, which means losses to business as well. The situation for people with HIV/AIDS has been made worse by an economic crisis that has affected Thailand since the middle of 1997.

In spite of Thailand's successful approach to prevention of HIV infection, which has caused the spread to stabilize, about 1.5 million people are infected with HIV and there are 30 000 to 50 000 new AIDS cases each year. Thailand is now moving into a more "mature" phase of the epidemic, with more and more people showing symptoms and requiring care. In 1995, a World Bank/World Health Organization (WHO) review advised Thailand to focus its limited HIV drug resources on the prevention of perinatal HIV infection and on the management of opportunistic infections. The AIDS division has issued guidelines for prevention and treatment of opportunistic infections, and the health care system in Thailand has sufficient resources to treat many of these. Short-course zidovudine treatment to limit perinatal transmission is also being implemented.

However, these interventions alone are not an answer to the huge amount of personal suffering and social disruption caused by the HIV epidemic. The reality is that few patients can afford antiretrovirals (ARVs): the monthly price of effective treatment regimens containing three drugs is about US\$ 675 per month, whereas a minimum salary is less than US\$ 120 per month. It is estimated that about 5% of HIV-infected people can get access to ARV double therapy and a very small number get treatment with three drugs.

One of the major factors that is critical for securing access to ARV drugs is affordability. Drugs should be available at affordable prices so that they may be within the financial reach of health services and of individuals in need.

Generic drugs in Thailand

Thai pharmaceutical companies produce high-quality, affordable generic drugs from imported raw materials.

In an effort to save costs and to promote rational use of drugs, the Thai Government, with the support of WHO, developed its National List of Essential Drugs (NLED). The NLED has been made a required list to guide public sector drug procurement since its inception in 1982. The first NLED consisted of approximately 400 drug items by generic name. The latest update, which has greatly expanded the number of drugs to 932 drug items, was completed and published in 1999.

The Government Pharmaceutical Organization (GPO) is a state enterprise under the

TABLE 1: HIV-related drugs available in Thailand

Drugs	Presentation	Price per unit in US\$
Didanosine (ddl)	Buffer oral powder 30, 60, 115, 170 mg	0.20, 0.33, 0.53, 0.75
Lamivudine	Tablets 150 mg	0.95
	Syrup 10 mg/ml	2.37 (60 ml)
Zidovudine (AZT)	Capsules 100 mg, 300 mg	0.22, 0.55
	Syrup 10 mg/ml	1.24 (60 ml)
Stavudine (d4T)	Capsules 20, 30, 40 mg	0.14, 0.22, 0.26
Nevirapine	Tablets 200 mg	0.74
Combination AZT 300 mg + 3TC 150 mg	Tablets	1.08
Ketoconazole	Tablets 200 mg	0.066
Ethambutol	Tablets 250, 400 mg	0.018, 0.033
Fluconazole	Capsules 50, 100 200 mg	0.075, 0.12, 0.23
Rifampicin	Capsules 300, 450 mg	0.12, 0.18
Cotrimoxazole	Tablets	0.016
Isoniazid (INH)	Tablets 100 mg	0.0027
Clarithromycin	Tablets 250, 500 mg	
	Dry suspension	

Ministry of Public Health. Its function is to supply pharmaceuticals and other medical products to support the health service activities of the Ministry of Public Health throughout the country. GPO manufactures more than 400 items of pharmaceuticals, with special emphasis on drugs on the National List of Essential Drugs as well as biological products. The total number of employees is 2200 and the annual sales volume is about US\$ 100 million. Approximately 1.6% of the sales volume is spent on research and development (R&D).

The Research and Development Institute performs basic, applied and pilot scale research, which is essential not only to develop new pharmaceutical products but also to complement and improve existing technologies. It has been working on the formulation, development and bioequivalence studies of HIV/AIDS-related drugs since 1992.

The manufacture of any generic product is possible only after bioequivalence study. All production phases take into consideration the ever more stringent good manufacturing practice (GMP) on manufacturing and quality assurance.

A price reduction to between a fifth and a tenth of the original cost, depending on the sources of raw materials, is now possible due to GPO's generic production of drugs. The average cost of triple combination therapy comprising stavudine, lamivudine and nevirapine is now US\$ 80.

Antiretroviral drugs currently available are zidovudine syrup and capsules, didanosine powder forms, stavudine syrup and capsules, lamivudine syrup and tablets, zidovudine and lamivudine tablets, and nevirapine tablets. Drugs for opportunistic infections are

TABLE 2: Antiretroviral drug prices in Thailand in comparison with other countries

Drugs	Defined daily dose	Prices in US\$				
		Brazil	Uganda	Côte d'Ivoire	USA	Thailand
AZT 100 mg	600	1.08	4.34	2.43	10.12	1.80
ddl 115 mg	400	2.04	5.26	3.48	7.25	2.60
d4T 40	80	0.56	6.19	4.10	9.07	0.75

clarithromycin tablets, itraconazole capsules, amphotericin B injection, fluconazole capsules, ketoconazole tablets, rifampicin capsules, ethambutol tablets, cotrimoxazole tablets and isoniazid tablets. Many more drugs in these categories are currently under investigation. The table above shows ARV drug prices in Thailand in comparison with other countries.

The cost of these HIV-related drugs poses the greatest single challenge to individuals and to the health care system. Although the price of expensive proprietary drugs will likely decrease in the years to come, through the effort of our generic competition and expiring patents, many products will probably remain financially out of reach for the majority of people living with HIV/AIDS.

It is hoped that Thailand will achieve the goal of improving affordability through an increase in local production when the costs are lower and quality can be maintained.

Appendix I

Declaration for a Framework for Action: Improving Access to HIV/AIDS Care in Developing Countries

Introduction and purpose of the document

With an estimated 40 million people infected with HIV worldwide and 26 million accumulated deaths, HIV now stands as the worst infectious disease pandemic in recorded history. The threat imposed by HIV is reflected not only in the tragedy of each individual case and his/her affected loved ones but on the global scale of human health and the potential for demographic, economic and political destabilization in many countries. Access to HIV prevention and care services has long been championed by international organizations, governments, nongovernmental organizations (NGOs) and community groups. However, we are far short of providing HIV-infected people worldwide with appropriate care. In the last two years, an extraordinary juxtaposition of events has given us an opportunity that must be seized. Since the International AIDS Conference in Durban in July 2000 and the United Nations General Assembly Special Session (UNGASS) in June 2001, the world is mobilized as never before to address the issue of HIV/AIDS in developing countries. The tools which can change the course of the epidemic are in our grasp. The benefits of treatment in terms of preventing illness and death from HIV infection have now been well demonstrated. Access to HIV medications must now be ensured for the millions of infected persons in the developing world within the broader context of appropriate care, prevention and support. Current resource allocations are woefully inadequate, substantially less than 25% of the annual estimated need, to meet this goal. Future generations will judge us harshly if we fail to move rapidly toward the minimum US\$ 7-10 billion per year allocation that was called for in June 2001.

The purpose of this document is two-fold. The first is to set forth a clear framework for improving and accelerating access to care for HIV-infected women and men in the developing world. In particular, the document proposes near-term goals that are achievable. Specific priorities are outlined with a timeline of 18-36 months. The second purpose is to serve as a start for mobilizing organizations and people to an ongoing, progressive, sustainable action plan that will help to make the UNGASS declaration become a reality.

This document is the product of a year-long consultative process involving 155 experts from 27 countries and 57 national and international organizations. It is the consensus of the participants who convened in Paris at the invitation of the French Ministry of Foreign Affairs with the support of UNAIDS and the World Health Organization (WHO) on 29 November – 1 December 2001.

Current status of HIV/AIDS care in developing countries (including achievements thus far)

Prevention, care and support (emphasizing synergy)

As already shown by successful local and community responses to HIV/AIDS, prevention and treatment are synergistic: access to HIV treatment enhances the effectiveness of prevention as well as voluntary counselling and testing (VCT) programmes. Prevention, or the reduction of new infections in the seronegative population, should not be pitted against care for those who are already HIV-infected. The idea that prevention could be more effective than treatment ignores their interdependence and indivisibility.

There is no disputing that targeted prevention strategies that take into consideration poverty, discrimination, inadequate education and gender inequality are effective in reducing HIV transmission. However, they will not be able to curb the pandemic in the absence of parallel efforts toward persons living with HIV. It is estimated that nine out of ten HIV-infected persons in sub-Saharan Africa do not know their serostatus. This is unlikely to change unless access to adequate care in case of a positive test result is offered. In addition, availability of effective care and treatment options reduces HIV/AIDS-related stigma and increases societal and local responses to the epidemic.

Economic opportunities and constraints

Assuming that 20-25% of the HIV-infected persons worldwide are symptomatic and/or in an advanced stage of immunodeficiency, 7.5-9 million living in developing countries are in urgent need of antiretroviral (ARV) treatment. In contrast, a total of only about 200 000 HIV-infected persons, of whom 100 000 live in Brazil, use these treatments. This is less than 3% of those in need. At current discounted prices of antiretroviral drugs plus other costs of treatment (US\$ 1200 per patient per year for both) the availability of US\$ 240 million in 2002 would result only in a doubling of the number of treated persons, a positive but only a small step forward.

Clearly there is an urgent need for supplemental resources if additional lives are to be saved. In order to reach at least a third to one half of the 7.5-9 million people estimated to be in immediate need of treatment, additional funding is required for the Global Fund to Fight AIDS, TB and Malaria and from international cooperation, the private sector and insurance, as well as public budgets from national governments.

A number of national and smaller pilot programmes in middle-income (Argentina, Brazil, Chile, Thailand, etc.) and low-income (Côte d'Ivoire, Senegal, Uganda, etc.) countries have demonstrated a comparable feasibility, efficacy and adherence with antiretroviral treatment to those obtained in high-income countries.

The Brazilian experience, which ensures universal access and enhances domestic drug production, shows that ARVs can be cost-saving for the health care system: extra costs of drugs are more than offset by further savings due to the reduced number of episodes of opportunistic infections and consequently reductions in hospitalization (according to the Brazilian Ministry of Health net savings through ARV use amounts to more than US\$ 140 million per year). Once indirect costs (i.e. productivity losses associated with morbidity in HIV-infected patients) are taken into account, antiretroviral treatment is clearly cost-saving for many economic sectors of developing countries, as suggested by the increasing number of private companies in Africa, Asia and South America which provide these treatments or

subsidize their costs for their workforce. Antiretrovirals for the prevention of mother-to-child transmission (MTCT) of HIV and prophylaxis for tuberculosis and other opportunistic infections are generally recognized to be cost-effective, and must be implemented on a large scale everywhere including in the countries with the lowest GDPs.

Even if they do not save money *per se*, new health interventions are considered as cost-effective in the North as soon as their marginal cost per additional life-year saved is below twice the GDP per capita (US\$ 50 000 in OECD countries). Applying the same criterion to developing countries with lower GDPs, means that antiretroviral treatment should also be considered cost-effective for eligible patients in low-resource settings. Moreover, human and social benefits from increased life expectancy and quality of life of HIV-infected patients go far beyond their direct economic impact for treated patients and include improved social and human development for their families, communities and country as a whole.

Key issues and opportunities

The care of HIV-infected persons is multidimensional and the components must be clearly delineated. In this context, it is important to re-emphasize that prevention of new infections and care of those already infected are tightly linked and synergize with one another. National AIDS programmes and international agencies have outlined many of these critical features and it is not the point of this declaration to reformulate these documents. Rather, it is to highlight the most critical areas which require resources, at the country level, in order to scale up the most effective programmes for access to care.

- **Uniform availability of voluntary counselling and testing (VCT).** Where this does not exist, appropriate measures should be taken immediately to scale up these programmes. Proper assessment of an individual's HIV status permits educational measures to help negative persons remain negative and positive persons to enter into care. The latter, in turn, facilitates prevention efforts through interventions to prevent secondary transmission whether this be behavioural modification or entry into mother-to-child transmission prevention programmes in the case of pregnant women. Increased testing capacity will also contribute to ensure a safe blood supply. A key element of strengthening VCT programmes is the parallel availability of antiretroviral drugs. The hope of accessing life-saving therapy will encourage more people to seek VCT services and thereby directly assist the prevention efforts.
- **Scaling up of MTCT prevention programmes.** One of the greatest achievements of the past decade is the demonstration that MTCT of HIV can be dramatically reduced by antiretroviral drugs. In the developed world the rate of infection of newborns is less than 2% and is near zero in women who receive proper antenatal care. Attaining this degree of success in the developing world will be difficult because of the absence of uniform access to antenatal care and the need for breastfeeding. In spite of these difficulties, reductions of MTCT by 50% have already been demonstrated in the developing world through the use

of nevirapine or short-course zidovudine (AZT). These programmes must be put in place in every health care setting. The availability of this service will increase the uptake of VCT in a synergistic fashion. MTCT prevention programmes are also a crucial entry point for the introduction of antiretroviral treatment of the mother and family when indicated.

- **Opportunistic infection (OI) prophylaxis and treatment.** The proper management and prevention of opportunistic infections has been proven to have a positive impact on morbidity. Uniform access to drugs, such as antituberculous drugs and cotrimoxazole, is a cost-effective intervention that is a mandatory component of care. Antiretroviral therapy is by itself the best prophylaxis for opportunistic infections. Scaling up antiretroviral treatment will progressively reduce the need for anti-OI drugs.
- **Improving access to antiretroviral therapy.** The revolution in care in the developed world is unquestionably linked to the availability of powerful combinations of antiretroviral drugs. Dramatic reductions in morbidity and mortality have been well documented and this benefit needs to be made broadly available to persons in the developing world. It should be re-emphasized that antiretroviral therapy is already being used in the developing world, although on a small scale in low-income countries, with the demonstration that it is feasible and effective. Further, drug adherence appears to be comparable to the developed world and the concern for the spread of drug resistance is not a valid reason to delay introduction of therapy anywhere. In addition, drug resistance can be minimized by improving drug adherence and utilizing potent drug combinations. Further, there are plans already in place to establish a Global HIV Drug Resistance Monitoring Project by the WHO and the International AIDS Society which will be put in place in parallel with the scale-up of antiretroviral treatment programmes. Conversely, failure to expand treatment in a systematic way will certainly increase the risk of non-rational prescription and use of antiretrovirals ensuring a greater incidence of drug resistance.

It should also be recognized that the benefits of antiretroviral therapy extend beyond the immediate medical result of an improved physical health. These benefits include an improved psychologic status, stabilization of the family unit, increased uptake of VCT, prevention of opportunistic infections and probable diminished transmission in the population.

Antiretroviral treatment programmes need to be scaled up as rapidly as possible simultaneously with provision of health care worker and facilities capacity to permit and facilitate care delivery. Programmes which build on existing MTCT prevention (e.g., MTCT “plus”) and tuberculosis control programmes are key entry points for antiretroviral therapy programmes. In addition, attempts should be made early on to put programmes in place at regional centres, district centres and rural settings as treatment needs to reach the affected population throughout the developing world. Within each country, financial sustainability and equity considerations imply that additional care and treatment resources, as well as public

subsidies for antiretroviral drugs (where they exist), need to be targeted to those who cannot afford them, or who can pay only a fraction of the costs.

- **Psychosocial support.** A key element of care for all HIV-infected persons is psychosocial support, including palliative care. The high incidence of depression and other emotional illnesses should be acknowledged in order for hope to be nurtured. Good quality care requires sufficient numbers of properly trained health care workers, traditional healers, religious and community leaders and volunteers to help patients and their families to develop the best ways of coping at all stages of HIV disease, and particularly with end-of-life issues. Appropriate psychosocial support will more than ever be needed to facilitate access and adherence to treatment.

Framework for implementation of priority programmes

Approach for efficient implementation

While a demand-driven, participatory, and progressively decentralized approach will enable broadening of health care services, a central capacity is also needed at national levels for protecting people's rights, promoting price reductions for HIV/AIDS drugs and services, quality control of drug and service delivery, monitoring and evaluation.

In order to create systems for delivering care to significantly more people, training of personnel will be critical. In addition to supporting clinics, hospitals and home care programmes, countries need to aggressively work toward transforming existing volunteer and community-based organizations into AIDS service organizations. Latent capacities to demand and provide for care and treatment are widespread in families, communities and organizations. To fully develop them requires a learning-by-doing approach in which the human, technical and organizational capacities are developed over time to handle progressively more complex care and treatment components.

Once reference centres in large cities are functioning, these centres should be used to train people working in smaller cities or rural communities as is being done in Brazil, Côte d'Ivoire, Senegal and Uganda. One innovative model for providing care is "association-based treatment" (e.g., Burundi, Zimbabwe, Venezuela). Within this model the financial and material treatment resources are controlled and managed by the associations of people living with HIV/AIDS, together with doctors and other providers. In this context HIV-infected women and men are directly involved in the decision-making process and organization of all aspects of HIV care.

Without medicines, reagents for diagnostic testing and monitoring, improved human resources will be compromised and ineffective. Therefore, how to offer international support to augment local and national procurement efforts will be critical. Since the availability and sources of commodities will vary dramatically, international funding sources should not attempt to dictate where and how drugs and other inputs will be purchased.

Decisions on how to procure should be left to the country which may decide to: conduct national tenders to foster competition between generic and proprietary companies, take advantage of regional procurement organizations or future international buying arrangements

managed by UNICEF (or other international, intergovernmental or private procurement organizations). Efforts to build local capacity for drug production, procurement and management of rational drug delivery should also be supported by international funds. Creating drug production capacity within developing countries can be an important factor in increasing access to medicines.

Patents must not constitute a barrier to access. The use of safeguards (such as compulsory licensing) to override patents is legal within the TRIPS international trade agreement and has been strongly reinforced in the 14 November 2001 WTO ministerial conference declaration on the TRIPS agreement and public health. It reads that “the TRIPS Agreement does not and should not prevent Members from taking measure to protect public health”. It also states that “each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted”.

To offer treatment to the highest number of people possible, it is essential that funds be used to buy quality commodities at the best possible price. Using the lowest cost suppliers, whether proprietary or generic companies, will increase the number of people who can be treated and will allow for greater investments in other important components of care and prevention. Increased competition is a powerful tool to reach this goal.

Next to mobilizing the financial resources, the testing of the tools and of the logistics to roll them out in district-wide and ultimately nationwide programmes is the greatest challenge to scaling up care, treatment, and support.

Partnerships

In the last two decades of the response to HIV/AIDS various forms of partnerships have been built. They need to be strengthened and new forms of partnerships, such as networking among hospitals in the North and in the South, health care delivery centres, community organizations and NGOs must be promoted to reduce the gaps in knowledge and access to services, and create a solid basis for local, national and global solidarity. Partnerships must be based on trust, respect and shared vision. They add value to the process of providing and utilizing care and support by taking advantage of their strengths to scale up local response. Technical expertise already existing at international level, notably in the UN system, and at country level, should be mobilized to facilitate these partnerships. Partnerships between the public and private sectors should be strongly encouraged for delivery of care, mobilization of funding, and/or procurement of commodities for HIV/AIDS care in order to optimize use of resources and to the extent that they help promote the goal of wider access to care.

The potential of care partnerships has been demonstrated in Zambia where a national facilitation team consisting of a resource group of more than 20 people from national networks and organizations has quickly increased local districts' capacity to deliver care to an increased patient population. Only these types of networks can ensure a continuum of care, from the home to the district clinic and hospital or between the public, private and faith-based health facilities.

Priorities for operational research

There are numerous questions that need to be answered in the context of care delivery in the developing world. The pressing need to deliver antiretroviral treatment as quickly as possible to as many persons means that care and treatment programmes should never be delayed pending the results of research projects. Rather, the opportunity should be taken to put practical,

simplified data-gathering mechanisms in place so that outcomes research can be successfully accomplished in parallel with the implementation of the programmes. One advantage to pursuing operational research in this manner is that the results will be directly applicable to the countries in which the data are gathered. Examples of the questions that need to be quickly answered are:

- What are the most relevant and cost-effective ways to deliver and monitor antiretroviral therapy including the identification of the cheapest effective regimens, the simplification of monitoring for toxicity and efficacy and the promotion of cheaper and simpler methods for CD4 cell count and viral load measurements?
- What are the best regimens for patients coinfecting with tuberculosis and/or hepatitis viruses?
- What patterns of drug resistance will emerge and what is the interplay of MTCT prevention programmes with therapeutic antiretroviral programmes?
- What are the best strategies to scale up personnel and facilities infrastructure without delaying implementation of care programmes?
- What is the impact of improved access to care on behaviours and on prevention of HIV transmission in the population, notably among youths?
- What is the impact of improved access to care on economic, social and human development as well as on strategies for poverty alleviation?

Conclusions

- A real opportunity to impact on the HIV/AIDS epidemic now exists.
- Care, treatment and prevention of HIV/AIDS are strongly linked.
- Care constitutes an entry point and a key element for effective prevention.
- In low- and middle-income countries a wide array of life-prolonging care and treatment interventions are feasible and cost-effective today.
- The sharp drop in the prices of antiretroviral drugs in these countries has dramatically improved their cost-effectiveness. Several nationwide and smaller ARV programmes have shown adherence levels and efficacy outcomes of therapy that are similar to those in the developed world.
- Governments, the private and not-for-profit sector, and the international community must now commit the required financial resources commensurate with the need as identified by the UNGASS declaration.
- Failure to seize this opportunity to expand care and treatment will perpetuate untold human suffering and increase poverty and inequity on a worldwide scale.
- We propose that this declaration be circulated to all international and national partners in the fight against HIV/AIDS with the view toward endorsement by appropriate forums, governments and concerned organizations. We hope that it will serve as a basis for immediate action.

Life stories

Seven-year-old Preeti goes to school in the neighbourhood of Mumbai, India. She's been regularly visiting the family doctor and several specialists since she was two years old. She's always wondered why she is unable to compete with her friends at play, feels exhausted after a short spell of sport, and frequently misses school due to fever and cough. Her mother tells her that she's not well but doesn't really know what's wrong with her. "When will I be normal like my friends?" asks Preeti. Her mother tells her that there are drugs now that can make her feel better but they can't afford them because they cost almost US\$ 100 per month; almost all her mother's salary. Preeti is remorseful; if only her father were alive, he would have arranged for her medications!

Theresa N. is a 35-year-old widow living with HIV in a low-income area of Bujumbura, Burundi. Her husband died of AIDS five years ago, leaving behind two sons aged 11 and 9. She is a member of a local support group for people living with HIV/AIDS. When she is at home, she likes to listen to the radio. In one meeting of the support group, she stood up and said: "I heard on the radio that there are new drugs that can help infected persons like me to live longer. I went to ask the local pharmacist and he told me that I should forget about them because I just can't afford them. I wonder now who they are made for. When will the likes of me get them? As a widow, I am the only support my children have. I want to live and see my sons grow. I need drugs."

Paolo R. is in his early 30s and he lives in Rio de Janeiro, Brazil. He tested positive for the HIV virus in 1992 and developed AIDS seven years later. It all started slowly with a recurring diarrhoea and soon he was too weak to leave his bed. The suffering he had from different sorts of infections and the way people looked at him made him feel that he would rather die. In fact, his doctor told Paolo's mother that his death was just a few months away. To the extent that, when the Brazilian Government started universal treatment with ARV for all Brazilians in need, Paolo's doctor hesitated. He thought Paolo was just too weak to undergo antiretroviral treatment. When he heard about it, Paolo insisted to be given a chance and his doctors accepted. Paolo has been using ARV for two years now. He is doing very well and it shows: he has gained weight, he looks happy and he's got a job. Says Paolo: "I was expecting death every day; but this treatment got me back to life. Today, I am proud to say that I am alive and making plans for life, not for death. I can walk down the street without fear. I feel a lot more confident."

Millions like Preeti and Theresa are in dire need of treatment. What are we going to do together to improve their lives and have millions of stories like Paolo's to tell the world?

List of participants at the meeting¹

29 November – 1 December 2001

Paris, France

Chair

- Prof. Scott HAMMER, Columbia University, New York, USA
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- Prof. Jean-Paul MOATTI, Université de la Méditerranée, Marseilles, France
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¹ International experts' meeting held in Paris at the invitation of the French Ministry of Foreign Affairs, with the support of the UNAIDS Secretariat and the World Health Organization.

Appendix II

Technical Network on Access to Care

Expert Group 1: Best practices

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Acronyms

ARV	Antiretroviral
ANRS	Agence Nationale de Recherche sur le SIDA
CBO	Community-based organizations
CHBC	Community home-based care
DOT	Directly observed therapy
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GIPA	Greater involvement of People Affected by AIDS
GMP	Good manufacturing practice
HAART	Highly active antiretroviral therapy
IAS	International AIDS Society
IDA	International Dispensary Association
ILO	International Labour Organisation
IPAA	International Partnership Against AIDS in Africa
MSF	Médecins Sans Frontières
MTCT	Mother-to-child transmission of HIV/AIDS
NGO	Nongovernmental organizations
NLED	National List of Essential Drugs
NNRTI	Non nucleoside reverse transcriptase inhibitor
NRTI	Nucleoside reverse transcriptase inhibitors
OI	Opportunistic infection
PI	Protease inhibitors
PLWHA	People living with HIV/AIDS
R&D	Research and development (of pharmaceuticals)
STD	Sexually transmitted disease
STI	Sexually transmitted infection
TB	Tuberculosis
TRIPS	WTO Agreement on Trade Related Aspects of Intellectual Property Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNGASS	United Nations General Assembly Special Session on HIV/AIDS
UNICEF	United Nations Children's Fund
VCT	Voluntary counselling and testing
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization



These background papers collate analyses on key issues and lessons learnt in the implementation of the care agenda. They are the product of 12 months of consultations initiated by the French Ministry of Foreign Affairs, with over 150 specialists representing a broad range of fields relevant to providing care for people living with HIV/AIDS. This publication features contributions from experts that reflect the breadth of a Technical Network on Access to Care. The papers were the background to the *Declaration for a Framework for Action: Improving Access to HIV/AIDS Care in Developing Countries* which was adopted on 1 December 2001 at a meeting held in Paris, convened at the invitation of the French Ministry of Foreign Affairs with the support of the UNAIDS Secretariat and the World Health Organization (WHO).

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