DECLARATION FOR A FRAMEWORK FOR ACTION: IMPROVING ACCESS TO HIV/AIDS CARE IN DEVELOPING COUNTRIES

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 fell better but they can't afford them because they cost almost $ 100 per month; almost all her mother's salary. Preeti is remorseful; only if 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 thirties and he lives in Rio de Janeiro, Brazil. He tested positive for the HIV virus in 1992 and developed AIDS 7 years later. It all started slowly with a recurring diarrhea and soon, he was too week to leave his bed. The suffering he got 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 doctor accepted. Paolo has been using ARV for 2 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 of persons 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?

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 have long been championed by international organizations, governments, non-governmental organizations 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 moving rapidly toward the minimum 7-10 billion dollar 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 secretariat and 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) programs. 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 9 out of 10 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 world-wide are symptomatic and/or in an advanced stage of immunodeficiency, 7.5 to 9 million living in developing countries are in urgent need of antiretroviral treatment (ARV). 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 (1,200 US$ per patient per year for both) the availability of 240 million US$ 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 to 9 million people estimated to be in immediate

need of treatment, additional funding is required for the Global Fund to Fight Against AIDS, TB and Malaria and from international co-operation, the private sector and insurance, as well as public budgets from national governments.

A number of national and smaller pilot programs 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 140 million US$ 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 subsidise their costs for their workforce. Antiretrovirals for the prevention of mother-to-child transmission 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 (50,000US$ 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 programs 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 programs 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 programs. 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 behavioral modification or entry into mother-to-child transmission prevention programs in the case of pregnant women. Increased testing capacity will also contribute to ensure a safe blood supply. A key element of strengthening VCT programs 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 programs. 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 percent 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 percent have already been demonstrated in the developing world through the use of nevirapine or short-course zidovudine (AZT). These programs 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 programs 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 programs. 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 programs 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. Programs which build on existing MTCT prevention (e.g., MTCT "plus") and tuberculosis control programs are key entry points for antiretroviral therapy programs. In addition, attempts should be made early on to put programs in place at regional centers, district centers 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 psycho-social support will more than ever be needed to facilitate access and adherence to treatment.

Framework for Implementation of Priority Programs

Approach for Efficient Implementation

While a demand-driven, participatory, and progressively decentralised 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 homecare programs, countries need to aggressively work toward transforming existing volunteer and community-based organisations 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 organisations). 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 nation-wide programs 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 organisations 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 mobilised 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 optimise use of resources and to the extent that they help promoting the goal of wider access to care.

The potential of care partnerships have been demonstrated in Zambia where a national facilitation team consisting of a resource group of more than twenty 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 programs 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 programs. 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 coinfected with tuberculosis and/or hepatitis viruses?
What patterns of drug resistance will emerge and what is the interplay of MTCT prevention programs with therapeutic antiretroviral programs?
What are the best strategies to scale up personnel and facilities infrastructure without delaying implementation of care programs?
What is the impact of improved access to care on behaviors 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 programs 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.
Failing 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.

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MEETING ON ACCESS TO CARE FOR PEOPLE LIVING WITH VIH/SIDA
29th-30th November & 1st December 2001

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This international experts meeting was held in Paris at the invitation of the French Ministry of Foreign Affairs, with the support of UNAIDS Secretariat and WHO.