

including scaling up of testing and counselling, advocating for 'knowing your seropositive status' and for reduction of harm or risk through correct and proper condom use, the use of Nevirapine for prevention of mother to child transmission, needle exchange and the development of a vaccine, are vital in the fight against HIV/AIDS. WHO's view, supported by real-world experience, is that prevention and treatment are mutually reinforcing if done correctly and that treatment has accelerated prevention efforts in many settings.

To ensure a comprehensive response to HIV/AIDS, treatment and prevention programmes must enhance and accelerate each other. When people have hope that they can be treated and lead productive lives, the incentive to know their status and to protect themselves and their partners is much greater. Evidence and experience show that rapidly increasing the availability of ART leads to greater uptake of HIV testing. Availability of treatment, as well as enhanced community outreach can lead to more openness about AIDS which helps break down stigma and discrimination. People on effective treatment are also likely to be less infectious and less able to spread the virus.

Prevention and treatment must work together and anyone receiving HIV treatment must be counselled in effective prevention methods. Prevention messages must go together with treatment so that the risk of further infection is minimized.

See more about prevention in the 'Accelerated prevention' information sheet.

HOW IS IT DECIDED WHO GETS TREATMENT, AND WHO DOESN'T?

As part of its intention to locate "3 by 5" within a broader development context, WHO is preparing guidance on the ethical and equitable scaling up of ART programmes. In January 2004, a WHO-UNAIDS consultation on "Equitable Access to Care for HIV/AIDS" took place at WHO in Geneva, involving a wide range of stakeholders from human rights organizations, people living with HIV/AIDS, philosophical organizations, community based organizations and program managers. The report of that meeting, which is now being disseminated, provides an overview of the ethical issues, which were further elaborated in the three background papers.

The advice provided by the consultants not only informs the guidance document but is also being used to develop training materials and best practices case studies. These illustrate both the ethics and equity norms for ART programmes and fair processes for the development of policies within countries. Indicators to measure outcomes and fair decision-making processes are also being developed. WHO is working with its partners to ensure that the country-level monitoring of ART programmes provides disaggregated data on gender, age, socioeconomic status and marginalization.

Such data are important because, in principle, the demographics of those receiving treatment should closely reflect those of persons living with HIV/AIDS who need ART. For example, if 20% of those in need of treatment in a country are children under the age of 15, or are women, then roughly 20% of the participants in ART programmes in that country should likewise be children under 15 or women. To avoid under-representation of vulnerable populations, including orphans, injecting drug users, sex workers, and prison inmates, it is important that ART programmes are planned and implemented in ways that are sensitive to the needs of these groups

and that take account of the barriers they often face in obtaining health services.

WHO is working with UNAIDS and other partners to develop guidance for policymakers and administrators to aid in the development of ethically sound ART programmes, including the articulation of principles that will promote gender equality, that are inclusive of children and marginalized groups, and that maintain an overall pro-poor approach.

WHAT IS WHO DOING TO ENSURE THAT WOMEN BENEFIT PROPORTIONALLY FROM 3 BY 5?

Of the estimated five million cases of HIV that occurred last year among adults, about half were women, and this proportion is increasing. It is important to make the most of existing opportunities to reach women with key HIV prevention and care interventions through existing reproductive and sexual health services, such as family planning, reproductive tract infection/sexually transmitted infection care, and maternal health services. Renewed efforts are required to develop and expand effective interventions that alter the factors at individual, household and community level that determine women's vulnerability to HIV infection. These factors include livelihoods such as female sex workers and mobile workforces, poverty, gender-based violence, social constructions of masculinity, HIV risk behaviours in men and biological characteristics.

The most effective way to reduce the number of children born with the HIV virus is to prevent new infections in women and to avoid unwanted pregnancies in HIV infected women. WHO is working with key partners to increase the commitment of policymakers to formulate policies to strengthen the linkages between family planning and prevention of mother to child transmission. In doing so, the number of HIV-infected infants will be reduced and the health status of women improved.

HOW MUCH MONEY IS NEEDED FOR "3 BY 5" AND HOW MUCH DO YOU HAVE?

To achieve the "3 by 5" target to scale up treatment, WHO estimates that countries need US\$ 5.5 billion over the next two years.

WHO needs \$218 million over the next two years to provide the necessary technical assistance to help countries with scale up of prevention and treatment. As of May 2004, WHO had secured \$156 million of the required \$218 million, leaving a funding gap of \$62 million. Funds to date include the generous contribution of CAD 100 million (\$72 million) announced by the Canadian Government on May 10 2004, \$5 million from Swedish SIDA and \$5 million from UK DFID.

- 1 As of May 2004, Major pledges include: US\$ 15 billion by 2008 through the United States President's Emergency Plan for HIV/AIDS Relief; US\$ 5.5 billion has been pledged to the Global Fund to fight AIDS, Tuberculosis and Malaria; more than US\$ 1 billion had been made available through the World Bank Multi-Country HIV/AIDS Program (MAP)
- 2 Ministério da Saúde do Brasil, Coordenação Nacional de DST/AIDS: Política Brasileira de AIDS: Principais Resultados e Avanços - 1994 a 2002. Brasília, Ministério da Saúde, 2002, 16p. Available at www.aids.gov.br/final/biblioteca/politica_94_02.pdf
- 3 Galvão J.: Access to Antiretroviral Drugs in Brazil. *Lancet* 2002, 360 (9348), 1862-5. Available at <http://image.thelancet.com/extras/01art9038web.pdf>



Victor Savorov / WHO

3 BY 5 Q & A



Michael Jensen / WHO

TREATING THREE MILLION PEOPLE LIVING WITH HIV/AIDS IN DEVELOPING AND MIDDLE INCOME COUNTRIES BY 2005 - "3 BY 5"

WHY THREE MILLION PEOPLE ON ANTIRETROVIRAL THERAPY (ART) BY 2005? WHY THIS NUMBER, WHY THIS DATE?

Approximately six million people living with AIDS in the developing world are in need of antiretroviral therapy (ART) due to the seriousness of their illness. Every year, three million people die because they cannot get the treatment they need.

The "3 by 5" target is grounded in the analytical work of a number of scientists prior to the 2001 Special Session of the UN General Assembly which showed that with an all-out effort, it was feasible to reach 50% of those in need of ART treatment by this time (therefore three million).

Everyone who needs ART should have access to it. That is the longer term goal. "3 by 5" is a global target proposed by WHO and supported by UNAIDS and other partners.

PROVIDING THREE MILLION PEOPLE WITH ART BY 2005 IS A HIGHLY AMBITIOUS TARGET. CAN IT BE DONE?

WHO believes that a target of three million people on treatment by the end of 2005 is achievable, although this will require a major change in the way that WHO, countries and partners work. Important progress has already been made in a number of areas: there is unprecedented high-level political commitment to treatment access; far higher levels of national and international financing are available¹; there has been a significant reduction in the price of ART; the "3 by 5" strategy includes simplified treatment regimens, a new AIDS Medicines and Diagnostics Service and new delivery guidelines; and there are an increasing number of countries (such as Brazil, Thailand, Uganda and Senegal) where ART has been scaled up successfully.

Every day spent debating whether or not "3 by 5" is feasible, 8,000 people die from AIDS. The time to scale up treatment is now.

IS "3 BY 5" JUST A WHO INITIATIVE?

"3 by 5" is not a WHO project. It is a global target to get three million people living with AIDS on treatment by the end of 2005 that has

been adopted by 192 countries at the World Health Assembly held in May 2004. The goal is universal access to treatment for all those who need it. "3 by 5" is a target that many organizations are working together to achieve including national authorities, UN agencies, multilateral agencies, foundations, non-governmental, faith-based and community organizations, the private sector, labour unions and people living with HIV/AIDS. To succeed, full support and participation from all partners and governments is needed.

WHAT IS THE WHO "3 BY 5" STRATEGY?

On December 1, 2003, a strategy document - Making it Happen - was launched by WHO describing how - with appropriate resources - WHO could contribute to reaching the "3 by 5" target.

The strategy outlines key areas in which WHO will work to help countries reach this ambitious target. These include:

- Simplified, standardized treatment regimes for antiretroviral therapy
- Urgent, sustained support for countries to implement "3 by 5"
- New service to ensure an effective, reliable supply of medicines and diagnostics (The AIDS Medicines and Diagnostics service - AMDS)
- Assistance to countries and developing guidelines for training and capacity building
- Rapid identification and application of new knowledge and successes

WHAT IS WHO'S ROLE IN REACHING THE TARGET?

WHO provides normative guidance and technical assistance to countries to help them scale up their treatment activities. WHO develops and sets normative standards in (for example) prevention and treatment protocols; provides countries with technical assistance to strengthen health systems and to design and implement their programmes; and assists countries in choosing and procuring high-quality drugs and other commodities through its prequalification process (see Prequalification fact sheet).

The Global Fund to fight AIDS, TB and Malaria, the World Bank,



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MAKE IT HAPPEN



initiatives like the United States President's Emergency Plan for HIV/AIDS Relief, bilateral funding bodies and national government budgets provide substantial new resources for HIV/AIDS prevention, treatment and care in countries. National governments are responsible for the management and roll out of the programmes to increase treatment. Non-governmental, faith based and community organisations as well as the private sector also contribute to scaling up prevention and treatment programmes.

HOW DOES THE WHO STRATEGY SIMPLIFY THE PROVISION OF ART?

WHO has published simplified treatment guidelines to make it easier to increase the availability of treatment in poor countries. The guidelines recommend simplified and standardized approaches for treatment regimens and clinical monitoring so that resource-constrained countries can start ART scale up. Standardizing and simplifying processes in this way also makes it easier to train the thousands of health care workers needed to increase access to treatment

The number of treatment regimens recommended by WHO has been cut from 35 to four. This makes ART treatment easier to purchase, procure and prescribe meaning that more people can be treated in all countries. The treatment regimens recommended in the 2003 WHO treatment guidelines are comparable to those widely used in developing countries (such as Brazil, Haiti, Malawi and Thailand)

Another key element is the simplification of monitoring, so that easy-to-use tests such as body weight and colour-scale blood tests are used where more complicated and expensive tests for viral load and white cell (CD4) count are not yet available. The simpler tests, combined with clinical evaluations by adequately trained health workers, can be effective in monitoring the progress of AIDS, the effectiveness of treatment and its side effects.

DO SIMPLIFIED REGIMENS MEAN SECOND CLASS TREATMENT FOR POOR PEOPLE?

The regimens that are being recommended are widely used in developed countries. These are not second class treatments. The point is to provide the best and most appropriate treatment to countries with limited resources and infrastructure and to allow these countries to get scale up underway immediately. This is first class therapy in a simplified format.

ISN'T DRUG RESISTANCE A PROBLEM?

Because HIV has a very high mutation rate, and because ART should be continued for life once commenced, HIV drug resistance will inevitably emerge among people on treatment even if treatment protocols are followed and adherence is maximized. In many developed countries ART started with single and double combination treatment and resistance did emerge requiring more second line drugs. In contrast, with new WHO ART (2004) scale up guidelines which recommend initiating with triple therapy it is hoped that the emergence of resistance will be delayed and minimized. Despite a high level of drug resistance among people who began ART before triple-drug ART was available, transmitted drug resistance in these countries has not rendered any antiretroviral (ARV) drug ineffective on a population basis for initial HIV treatment. Contrary to popular perception, existing evidence, although limited, shows that resistance is actually higher in rich countries than in developing countries. In North America and Western Europe the resistance ranges from 11- 25% while in Brazil, the rate is around 6%.

The "3 by 5" strategy includes several steps to address the potential emergence of ART resistance. Firstly, it is implementing a global standardized surveillance programme for ART resistance in countries scaling up ART to measure the rate of resistance and to help ensure that the public health implications of drug resistant

virus are well understood. WHO and partners propose active monitoring of resistance emergence. WHO also recommends studies be done in treated populations who are taking therapy to see if resistance is emerging. Secondly, the strategy acknowledges the importance of putting in place effective pre-treatment education programs and sustained adherence support for patients on ART. Adherence support will form an important component of the curricula for health care providers and treatment supporters which WHO is developing. Finally, encouraging the use of fixed dose combinations will help to ensure that patients receive all the drugs at the right dosage, which is important to prevent drug resistance.

It should be noted that resistance-related risks have never been used as an argument against treatment of sick people in rich countries.

WHAT ABOUT CHILDREN? CAN THEY BE TREATED IN THE SAME WAY?

Children and infants can and should be treated. About half of the antiretroviral (ARV) drugs used in adults can be used for ART treatment in children. Aside from limited availability of ARV drugs in children, there are several constraints to expansion of ART in children, including:

- specialized HIV tests are needed to diagnose HIV in children less than 18 months as maternal antibodies to HIV are present in all HIV-exposed infants;
- many of the currently available syrup formulations are not palatable (taste terrible), require that large volumes of syrup be taken and / or may need refrigeration and once opened must be used within one month;
- drug doses must be adjusted as a child grows;
- lack of tools to help health professionals in countries to implement and deliver ART for children.

Despite these constraints, children who receive ART respond as well as adults. Thus far, advocacy has largely focused on increasing access to ART for adults and adolescents. Overcoming many of the hurdles that hinder children's access to ART requires similar advocacy.

WHO has developed guidelines on key aspects of ART in children. In addition, a recent consultative meeting with pediatric HIV experts was held in order to explore ways of addressing current gaps and obstacles to care and treatment of HIV-infected children. Guidelines on the diagnosis of HIV infection in HIV-exposed children will be published in the near future; this aims to assist with decisions on the timing and choice of HIV testing in children.

Future activities include the development of a comprehensive guide to ART in children and documentation of successful models of care for HIV-infected children. Furthermore, WHO is working closely with UNICEF and other key partners to ensure these forms of technical guidance are incorporated into child health and HIV programmes.

WHAT ARE FIXED DOSE COMBINATIONS (FDC)?

Fixed dose combinations (FDC) of ART are the combination of two or three drugs in one single-dose pill and are key to making the treatment process easier for countries to implement. FDCs are a major breakthrough for AIDS treatment in poor countries as they offer significant operational advantages including ease of distribution and storage, the likelihood of greater adherence, reduced incidence of treatment failure and drug resistance.

Their use will significantly further the realization of the "3 by 5" target as the products improve the reliability, sustainability and security of drug supplies, which have so far been major obstacles to expanding access to ART. As in TB or malaria combination therapy, they also ensure that the right dosage of each substance is given to the patient, which will minimize drug resistance.

WHO has 'prequalified' double and triple FDCs (read more about prequalification in the 'Prequalification' information sheet). These FDCs are saving lives now in many countries.

SHOULD TREATMENT BE PROVIDED FOR FREE OR WILL PATIENTS HAVE TO PAY SOMETHING?

WHO's position is that ideally, treatment should be free or as affordable as possible for all who need it. However, it is up to individual countries to decide their position on whether drugs will be provided free of charge, according to the means and policy of the country. Experience and evidence shows that when people have to pay for their treatment or any of the associated costs, they cannot always afford the medicines and therefore will not be able to adhere to the treatment. Thus, making the drugs as affordable or as cost-free as possible is essential to maintain equity, prevent resistance and reap the full benefits of treatment both for the individual and society.

WILL ART BE SUSTAINABLE?

"3 by 5" is a target. Universal access to ART is the goal. For this to happen it is essential to strengthen health systems as a whole which will mean making the most of the substantial existing resources in a co-ordinated way to ensure that patients get treatment for life. It is also essential that advocacy efforts to push forward the goal for access continue and that political commitment is maintained.

The "3 by 5" strategy recognizes that continuity and quality of the drug supply, building health care human resources through continuous training programmes, full engagement of local communities in advocacy, programme design, education and information and adherence support are all vital to the long-term effectiveness of antiretroviral therapy. Well-designed and implemented community-based treatment programmes are sustainable. But long-term national and international support will be essential to scale these programmes up to meet the ambitious "3 by 5" target and beyond.

HOW CAN YOU ENSURE THERE ARE ENOUGH HUMAN RESOURCES TO ACHIEVE "3 BY 5"?

The serious shortage of health workers in many of the countries worst hit by AIDS is clearly a major obstacle. Many health workers have died as a result of untreated AIDS; others have moved to seek better pay and job security in wealthier countries.

Globally up to 100,000 health workers and community treatment supporters need to be trained for their contribution to achieving the "3 by 5" target. This training must be a continuous process to ensure there are enough healthcare workers for continued treatment and care.

From a country perspective, major bottlenecks in successfully responding to human resource challenges in the health sector include the absence of a concerted human resource and training approach to recruiting, training and retaining the workforce necessary to deliver ART; multiple and sometime conflicting training materials in use; lack of training provider capacity; and insufficient quality control and certification systems in the training sector.

In January 2004, WHO published a "Human Capacity Building Plan" for scaling up HIV/AIDS treatment" outlining how WHO and its partners can help countries to overcome these barriers and ensure both the emergency training and recruitment of personnel into the HIV/AIDS workforce and long-term sustainability of human resources in the health sector. WHO is now working with countries to translate this plan into concrete action at national level.

In addition, WHO has launched an 'Integrated Management of Adolescent and Adult Illness' training package for health workers at first level facilities including a basic ART clinical training course,

a short course on opportunistic infections, and accompanying aids such as a patient education flipchart. Already some countries have successfully adopted this training approach, and WHO is working with others to support this process.

WILL THE USE OF COMMUNITY HEALTH WORKERS TO DELIVER MEDICINES UNDERMINE THE SAFETY OF PATIENTS?

One of the most innovative sections of the "3 by 5" strategy proposes urgent training of tens of thousands of non-medical community health workers to support the delivery and monitoring of treatment for people living with AIDS. Intensive training programmes will enable these non-medical health workers to evaluate and monitor patients, and make sure they receive and are taking their medicines.

Community health workers are critical to making scale up happen and will support the delivery and use of medicines and the monitoring of treatment for people living with AIDS. They will be part of a larger team that will always include a trained clinician. Community health workers will not prescribe medicines or take any of the clinical decisions currently taken by physicians.

HOW WILL "3 BY 5" CONTRIBUTE TO BROADER DEVELOPMENT GOALS?

The role of HIV/AIDS in halting or reversing economic and social development in many heavily-affected countries is now well-established. Providing access to ART is not only a necessary response to a public health crisis, it is vital in order to arrest this decline and to rescue ailing health systems. In the longer term, the approaches to human capacity building and service delivery recommended in the "3 by 5" strategy are exactly what is needed to help bring about sustained improvements in health systems overall and to expand the reach and effectiveness of primary health care and care for chronic conditions. There is every reason to believe that ART can help serve as a vehicle for long-term systemic recovery.

The "3 by 5" strategy contains approaches for sustaining and optimizing existing capacity in countries, for example, by minimizing the need for sophisticated health infrastructure. Few countries, even rich ones, make the best use of existing health infrastructure and capacity to deliver treatment, care and support to people living with HIV/AIDS. The fact that more capacity is needed cannot be used as an excuse for inaction. Existing health services can be effectively utilized as the basis for the rapid scaling up of ART, including TB, STI and antenatal care services in addition to traditional hospital services.

In Brazil, as a result of the national HIV/AIDS treatment programme it is estimated that between 1994 and 2002, almost 100,000 deaths have been averted (a 50% drop in mortality) through the introduction of ART.²

The programme in Brazil clearly demonstrates how scaling up can also help strengthen health systems and dramatically reduce public health costs. As a result of the programme, there has been a significant decline in the number of hospital admissions and cost savings in reduced hospital admissions and opportunistic infections are estimated at more than US \$ 1 billion.³ The question faced by many countries now is not simply whether it is economically feasible to provide ART, but whether they can afford not to.

IS WHO ONLY INTERESTED IN TREATMENT FOR AIDS? WHAT ABOUT PREVENTION AND OTHER APPROACHES?

WHO, UNAIDS and many other organisations have worked for many years on developing improved programmes for prevention of HIV transmission. We will continue and in fact accelerate our on prevention through the "3 by 5" initiative. Prevention activities,