TREATING 3 MILLION BY 2005

Making it happen

THE WHO STRATEGY

WORLD HEALTH ORGANIZATION

Joint United Nations Programme on HIV/AIDS
UNAIDS
UNICEF • WFP • UNDP • UNFPA • UNODC
ILO • UNESCO • WHO • WORLD BANK

THE WHO AND UNAIDS GLOBAL INITIATIVE TO PROVIDE ANTIRETROVIRAL THERAPY TO 3 MILLION PEOPLE WITH HIV/AIDS IN DEVELOPING COUNTRIES BY THE END OF 2005

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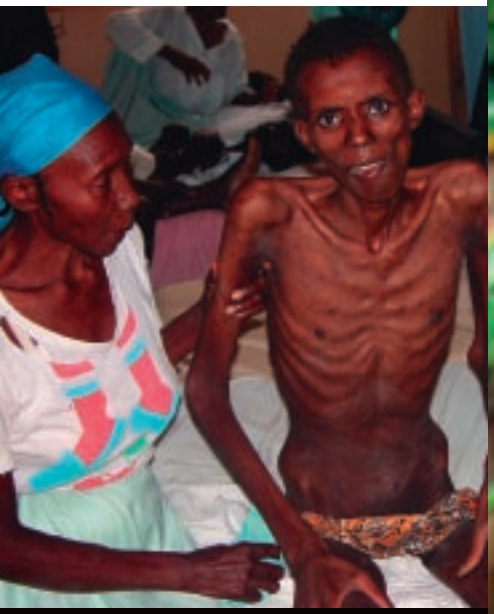


Joseph Jeune.
Patient, Lascahobas Clinic, Haiti.

Top: Before therapy for TB and AIDS, February/March 2003.

Right: After therapy for TB and AIDS, September 2003.

SUMMARY

"Lack of access to antiretroviral treatment is a global health emergency… To deliver antiretroviral treatment to the millions who need it, we must change the way we think and change the way we act."

– LEE Jong-wook, Director-General, World Health Organization

"We must meet the challenge of expanding access to HIV treatment. This requires overcoming the formidable barrier of creating sufficient operational capacity – a key area where UNAIDS Cosponsor WHO must play a critical role. We have adopted a target of 3 million people on antiretroviral treatment by 2005 – a massive challenge, but one we cannot afford to miss."

– Peter Piot, Executive Director, Joint United Nations Programme on HIV/AIDS (UNAIDS)

This WHO strategy aims to set out in clear detail how life-long antiretroviral treatment can be provided to 3 million people living with HIV/AIDS in poor countries by the end of 2005. Core principles include urgency, equity and sustainability. HIV/AIDS has devastated the populations and health services of many developing countries. We must act now. Further, since this magnitude of scaling up HIV/AIDS treatment has never been attempted before, we must learn by doing.

To ensure that no time is lost, WHO-led emergency missions have already been sent to several of the countries with the highest burden. Detailed and measurable national targets are being set to track progress. Long-term WHO teams will be sent to key countries and health and community workers trained to deliver antiretroviral therapy. Simple, standardized guidelines are needed for testing, treatment, monitoring and evaluation. These are already being developed. An AIDS Medicines and Diagnostics Service (AMDS) has been established to ensure that countries have access to good quality medicines and diagnostic tests at the best prices.

Each of these measures requires rapid action and great flexibility. To achieve this, funding needs have been calculated, requiring resource mobilization on an international level. The strategy will continue to be adapted as it is implemented and as new evidence emerges. A global partnership is being designed and built, action is underway. This may be the toughest health assignment the world has ever faced, but it is also the most urgent. The lives of millions of people are at stake. Everyone involved must find new ways of working together and new ways of learning from what they do. This strategy is a step towards achieving that aim.

BACKGROUND

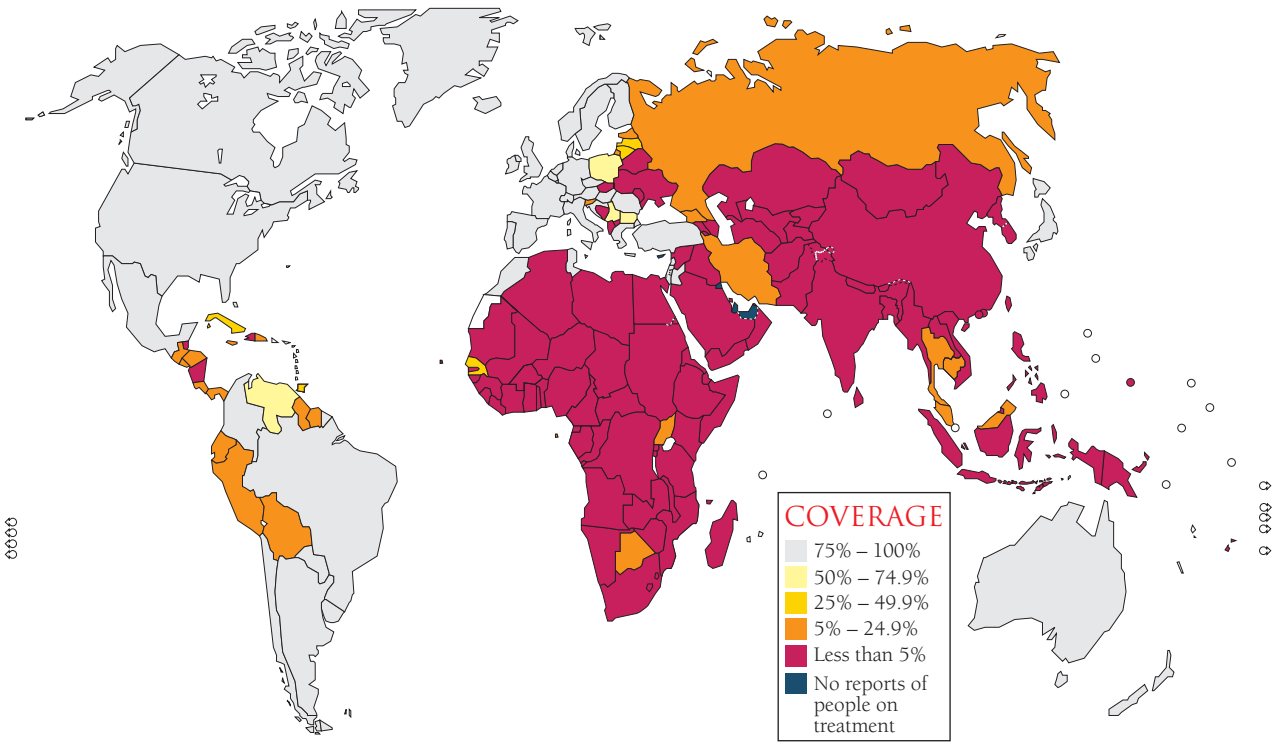
HIV/AIDS is the greatest health crisis the world faces today. In two decades, the pandemic has claimed nearly 30 million lives. An estimated 40 million people are now living with HIV/AIDS, 95% of them in developing countries, and 14 000 new infections occur daily. HIV/AIDS is destroying families and communities and sapping the economic vitality of countries. The loss of teachers to AIDS contributes to illiteracy and lack of skills. The decimation of civil servants weakens core government functions, threatening security. The burden of HIV/AIDS, including the death toll among health workers, is pushing health systems to the brink of collapse. In the most severely affected regions, the impact of disease and death is undermining the economic, social and political gains of the last past half-century and crushing hopes for a better future.

There is currently no cure for HIV infection, and viable vaccine candidates are years away, yet the development of life-saving antiretroviral drugs has brought new hope. In high-income countries, combination antiretroviral therapy has extended and improved life for large numbers of people living with HIV/AIDS and transformed perceptions of HIV/AIDS from a fatal disease to a manageable, chronic illness. In the poorer parts of the world – precisely the regions where HIV/AIDS has spread most rapidly – this transformation has not yet happened.

Of the 6 million people who currently urgently need antiretroviral therapy in developing countries, fewer than 8% are receiving it. Without rapid access to properly managed treatment, these millions of women, children and men will die.

This human toll and the accompanying social and economic devastation can be averted. The delivery of antiretroviral therapy in resource-poor settings, once thought impossible, has been shown to be feasible. The prices of antiretroviral

ESTIMATED PERCENTAGE OF ADULTS COVERED AMONG THOSE IN NEED OF ANTIRETROVIRAL TREATMENT, SITUATION AS OF NOVEMBER 2003



The designations employed and the presentation of material on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dashed lines represent approximate border lines for which there may not yet be full agreement.

COVERAGE OF ADULTS IN DEVELOPING COUNTRIES WITH ANTIRETROVIRAL THERAPY, BY WHO REGION, 2003

REGION	NUMBER OF PEOPLE ON TREATMENT	ESTIMATED NEED	COVERAGE
Africa	100 000	4 400 000	2%
Americas	210 000	250 000	84%
Europe (Eastern Europe, Central Asia)	15 000	80 000	19%
Eastern Mediterranean	5 000	100 000	5%
South-East Asia	60 000	900 000	7%
Western Pacific	10 000	170 000	6%
ALL WHO REGIONS	**400 000**	**5 900 000**	**7%**

drugs, which until recently put them far beyond the reach of low-income countries, have dropped sharply. A growing worldwide political mobilization, led by people living with HIV/AIDS, has educated communities and governments, affirming treatment as a human right. The World Bank has channelled increased funding into HIV/AIDS. New institutions such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and ambitious bilateral programmes, including the United States Presidential Emergency Plan for AIDS Relief, have been launched, reflecting an exceptional level of political will and unprecedented resources for the HIV/AIDS battle. This unique combination of opportunity and political will must now be translated into urgent action.

In 2001, partners within the Joint United Nations Programme on HIV/AIDS (UNAIDS) and other organizations along with scientists at WHO calculated that, under optimal conditions, 3 million people living in developing countries could be provided with antiretroviral therapy and access to medical services by the end of 2005. Nevertheless, treatment enrolment in afflicted countries continued to lag. On 22 September 2003, LEE Jong-wook, Director-General of WHO, joined with Peter Piot, Executive Director of UNAIDS, and Richard Feachem, Executive Director of the Global Fund to Fight AIDS, Tuberculosis and Malaria to declare

the lack of access to antiretroviral drugs to be a global health emergency. In response, WHO and its partners launched the "Treat 3 Million by 2005" (3 by 5) Initiative. Given the proven feasibility of treating people living with HIV/AIDS in industrialized and developing countries, a **global target of treating 3 million people with antiretroviral therapy by the end of 2005** is a necessary, achievable target on the way to the ultimate goal of universal access to antiretrovirals for everyone who requires such therapy.

A health emergency propels action and upends "business as usual" attitudes where they may exist. Reaching the 3 by 5 target demands new commitment and a new way of working across the global health community. Countries are on the front lines of the struggle, but they cannot succeed alone. Intensive, collaborative mobilization linking countries, multilateral organizations, bilateral agencies, communities and the non-state sector is required.

Prevention will remain central to all HIV interventions. Universal access to antiretroviral therapy for everyone who requires it according to medical criteria opens up ways to accelerate prevention in communities in which more people will know their HIV status – and, critically, will ***want*** to know their status. As HIV/AIDS becomes a disease that can be both prevented and treated, attitudes will change, and denial, stigma and discrimination will rapidly be reduced. Rolling out effective HIV/AIDS treatment is the single activity that can most effectively energize and accelerate the uptake and impact of prevention. Under 3 by 5, this will occur as part of a comprehensive strategy linking treatment, prevention, care and full social support for people affected by HIV/AIDS. Such support is critical – both to ensure adherence to antiretroviral therapy and to reinforce prevention.

The fight against HIV/AIDS has implications for the entire health sector. The impact of HIV/AIDS both directly and indirectly undermines the performance of national health systems. Effectively countering this impact requires both a core

response from within health systems and a broader societal response. As more health workers die from AIDS, health systems falter in delivering basic services. As workers across an economy die, revenues available for health systems fall, compounding damage to the health system. Increased access to integrated HIV treatment, prevention and care services is needed to reverse this pattern.

In addressing the needs of health systems in support of 3 by 5, the Initiative will consider both common and unique attributes of national and local health systems. The challenge of addressing these concerns across varied settings will entail the involvement of multiple stakeholders within health systems. Major new investment in countries' health systems will also be needed. New financial inputs must be carefully coordinated with existing resource and budgeting frameworks, including countries' Poverty Reduction Strategy Papers (PRSPs) and sector-wide approaches (SWAPs). Successful implementation of 3 by 5 will accelerate the attainment of Millennium Development Goals (MDG) for HIV/AIDS, as well as associated health and development MDGs. WHO is consulting intensively with national authorities and relevant international partners, including the World Bank, to ensure the coordination of efforts.

This document contains an initial strategic framework to guide WHO's contribution to the 3 by 5 Initiative. The framework will continue to evolve through dialogue with partners as treatment programmes roll out and knowledge grows. Thus, this strategy is a beginning, not an end-point. The urgency of the crisis means it is vital to get started, creating channels to share evidence and make necessary changes as the work proceeds. This document describes the goal and target and guiding principles of the 3 by 5 Initiative. It then examines the five pillars of the strategic framework guiding WHO's action. Finally, it shows how WHO is changing its structures and work patterns to push towards 3 by 5 and how WHO will work with partners to expand access to antiretroviral therapy through 2005 and beyond.

THE "TREAT 3 MILLION BY 2005" INITIATIVE

THE GOAL

The goal of the Initiative is for WHO and its partners to make the greatest possible contribution to prolonging the survival and restoring the quality of life of individuals with HIV/AIDS, advancing toward the ultimate goal of universal access to antiretroviral therapy for those in need of care, as a human right and within the context of a comprehensive response to HIV/AIDS.

THE TARGET

By the end of 2005, 3 million eligible people in developing countries who need antiretroviral therapy will be receiving effective antiretroviral therapy.

GUIDING PRINCIPLES

- **URGENCY**. Immediate action is required to avert millions of needless deaths. The HIV/AIDS treatment emergency demands new resources, swift redeployment of resources, streamlining of institutional procedures and a new spirit of goal-focused teamwork.
- **THE CENTRALITY OF PEOPLE LIVING WITH HIV/AIDS**. The Initiative clearly places the needs and involvement of people living with HIV/AIDS at the centre of all of its programming.

- **LIFE-LONG CARE**. Once started, antiretroviral therapy is for life. The world community has a responsibility to ensure uninterrupted medicine supply once antiretroviral therapy has been started.
- **COUNTRY OWNERSHIP**. Country ownership of the programme and its activities is essential. The Initiative will strive to avoid duplicating existing country-level coordination mechanisms and to build a sustained response.
- **TREATMENT AND HUMAN RIGHTS**. The Initiative will advance the United Nations goals of promoting human rights as codified in the Universal Declaration of Human Rights, as expressed in the WHO Constitution in seeking the attainment of the highest possible standards of health, and clarified in the Declaration of Commitment of the United Nations General Assembly Special Session on HIV/AIDS in 2001. Under 3 by 5, special attention will be given to protecting and serving vulnerable groups in prevention and treatment programmes.
- **PARTNERSHIP AND PLURALITY**. The Initiative and its activities are centred on developing and strengthening partnerships and networks that maximize the contribution of all stakeholders in a given country.
- **COMPLEMENTARITY**. The Initiative will strive to ensure complementarity by integrating planning and funding with existing programmes and activities.
- **LEARNING, INNOVATION AND SHARING**. Capturing and disseminating lessons across countries and regions in a rapid manner is essential to effectively and rapidly scaling up.
- **ETHICAL STANDARDS**. The Initiative will identify options for an ethical approach to meeting 3 by 5 targets.
- **EQUITY**. The Initiative will make special efforts to ensure access to antiretroviral therapy for people who risk exclusion because of economic, social, geographical or other barriers.
- **ACCOUNTABILITY**. The Initiative will support the development of national accountability among policy-makers, providers, people receiving therapy and all stakeholders.

THE STRATEGIC FRAMEWORK

Treating 3 million people by the end of 2005 will require concerted, sustained action by many partners. To chart the direction and to show what WHO itself will be doing to accelerate action, WHO has developed an initial strategic framework. WHO's 3 by 5 team assembled and refined the framework in intensive consultation with partners. This consultation will continue, and the framework itself will continue to evolve. Annex 1 presents the complete strategic framework in its current form, including action steps and time-bound indicators to measure progress. The framework is complex, because scaling up antiretroviral therapy delivery in developing countries is a multidimensional challenge. Although such challenges are daunting, they can be met, as WHO and its partners have shown. The expansion of tuberculosis control and the roll-out of programmes for the Integrated Management of Childhood Illness (IMCI) are just two recent examples.

WHO's strategic framework for emergency scaling up of antiretroviral therapy contains 14 key strategic elements. These elements fall into five categories – the pillars of the 3 by 5 campaign:

- global leadership, strong partnership and advocacy
- urgent, sustained country support
- simplified, standardized tools for delivering antiretroviral therapy
- effective, reliable supply of medicines and diagnostics
- rapidly identifying and reapplying new knowledge and successes.

PILLAR ONE

GLOBAL LEADERSHIP, ALLIANCES AND ADVOCACY

The most vital work toward the 3 by 5 target will happen in countries and communities, but global alliances and advocacy will be crucial enablers. UNAIDS has driven the global advocacy effort and catalysed growing international determination to respond to the HIV/AIDS crisis, including in the area of treatment access. Working within UNAIDS and alongside other partners, WHO will step forward and fully exercise its specific responsibility for the health sector – above all in advocating treatment.

WHO is committed to work in all global forums to spur urgent action towards universal access to antiretroviral therapy for everyone who needs according to medical criteria. This is reflected in WHO's budget, which will commit additional resources to 3 by 5, while maintaining full support for HIV prevention. The foundations for global advocacy are equity, human rights and the evidence base for treatment and prevention. WHO, UNAIDS and partners will develop principles and approaches for implementing antiretroviral therapy programmes that: promote gender equality; include children and marginalized groups; maintain explicit promotion of antiretroviral therapy among the poor; and ensure comprehensive, community-driven treatment, care, prevention and support for all affected people.

WHO and its international partners are moving swiftly to identify roles and responsibilities among all stakeholders in the antiretroviral therapy scale up process and to establish mechanisms for ongoing collaborative action with all partners. Meanwhile, WHO will work closely with other multilateral organizations and international partners to ensure that the 3 by 5 effort is integrated into

the broader global development agenda. International resources committed to 3 by 5 should be additional to the support for countries' efforts to achieve targets such as the internationally agreed Millennium Development Goals.
WHO will support all national antiretroviral therapy programmes while focusing particular efforts on the high-burden countries in greatest need.

KEY WHO ACTIONS AND DELIVERABLES UNDER PILLAR 1 INCLUDE

- establishing a WHO 3 by 5 budget committing hundreds of WHO personnel to be deployed at the country level;
- agreeing with all partners and stakeholders on their specific roles in 3 by 5;
- publishing with UNAIDS ethical guidelines promoting equity in antiretroviral therapy; and
- with UNAIDS, identifying the global funding gap and developing plans to close it.

PILLAR TWO

URGENT, SUSTAINED COUNTRY SUPPORT

The success of antiretroviral therapy programmes depends on coordinated, scaled-up country action. Countries must drive the process of expanding HIV/AIDS treatment, and countries' specific needs and capacities will shape the strategies and determine the scaling-up activities. WHO has significant opportunities to lend concrete support to these processes. WHO will provide implementers with essential technical and policy advice and tools and will cooperate with countries at every stage in designing and implementing national plans for scaling up antiretroviral therapy. Countries have demonstrated their demand for active collaboration from WHO by responding to the declaration of the global health emergency on 22 September 2003. Immediately following the declaration, more than 20 countries aligned their national goal to the global emergency and requested collaboration with WHO and partners, including visits by WHO 3 by 5 emergency missions.

WHO will use its leadership and advocacy position to encourage national political commitment to the 3 by 5 process within a comprehensive programme including HIV/AIDS prevention, treatment and long-term care. The Organization will support the preparation of coordinated national plans for scaling up with clearly defined roles and will also work to broker additional finances where these are required for scaling up in accordance with 3 by 5. WHO will support national operational capacity for scaling up antiretroviral therapy programmes, for example, by publishing simplified facility-level operational guidelines. The Organization will also use innovative strategies for quality assurance, such as certifying service

delivery points. WHO will work with countries to ensure that scaling up antiretroviral therapy catalyses the strengthening of health systems.

The crisis in the health workforce facing many countries has implications both for the 3 by 5 Initiative and for the viability of health systems. Expansion of human resources for health is a critical need. WHO and 3 by 5 partners will work with countries to find and implement solutions that can quickly fill gaps while laying the groundwork for long-term sustainability. Key actions would include: intensified recruitment for specific tasks; overcoming fiscal constraints related to public sector hiring; recruiting both young people and experienced people into health work; increasing community input; initiating large-scale in-service training focused on antiretroviral therapy; and expanding pre-service training. Issues of recruitment, funding, training, appropriate incentives and retention of health workers will require a broader cross-sector dialogue, involving health and non-health ministries, trade unions and the private sector. The health workforce administration should include the various service levels (local and regional) and sources of services (public and private). WHO will develop a range of policy options and tools to assist countries, including standardized training packages for all cadres involved in delivering antiretroviral therapy.

WHO is committed to supporting the expansion of community involvement in planning and delivering antiretroviral therapy programmes. It will advocate for the engagement of people living with HIV/AIDS in all stages of the planning and roll-out of national treatment programmes and will work to expand resources and capacity for involving community-based organizations in national advocacy, planning and delivery.

KEY WHO ACTIONS AND DELIVERABLES UNDER PILLAR 2 INCLUDE

- securing commitment to 3 by 5 targets and processes from all participating countries;
- agreeing on national 3 by 5 implementation plans with all stakeholders in each country;
- deploying WHO teams with appropriate skills to each country;
- training health and community workers in delivering antiretroviral therapy; and
- strengthening physical resources (laboratories and testing equipment) in each country by collaborating with funders.

THE 3 BY 5 INITIATIVE AND STRENGTHENING HEALTH SYSTEMS

In many countries, the impact of HIV/AIDS is severely distorting health systems. AIDS death tolls are rising among health workers. Hospital wards overflow with HIV-positive people for whom no effective therapy is available. The 3 by 5 Initiative has the potential to reduce these burdens and strengthen health systems through mechanisms including: attracting resources to the health system in addition to those required for antiretroviral therapy; improving physical infrastructure; reducing morbidity and mortality among health workers; improving procurement and distribution systems; and promoting community empowerment. 3 by 5 programmes should be designed to strengthen the capacity of health systems to reach broader health goals, for example, by promoting training and education that can expand a national health workforce for overall primary care.

LEADERSHIP. 3 by 5 creates a set of health system leadership challenges and opportunities that will require both strong central coordination and encouragement of local innovation and participation. To build and sustain momentum on 3 by 5, health and non-health ministries alike will need systems and skills to build coalitions and link their 3 by 5 activities.

FINANCING. Many high-burden countries are already engaged in policies to mobilize additional domestic resources for health, whether through fiscal policy or health systems financing, such as various forms of insurance. The aim will be to create sustainable financing mechanisms that ensure that poor people are exempt from co-payments. This issue is important for successful HIV/AIDS therapy because of evidence that co-payments reduce adherence to treatment regimens. Successful therapeutic outcomes depend directly on financing mechanisms that do not burden poor people. On the macroeconomic level, coordinating monetary and fiscal policies with foreign assistance could yield substantial benefits for 3 by 5 and health systems by overcoming bottlenecks or better aligning policies.

DELIVERY SYSTEMS. The mix of providers could change significantly as 3 by 5 scaling up proceeds. The public sector health programme could be expected to become more prominent among providers, but private sector efforts will remain substantial. As antiretroviral therapy expands, the demands on several essential delivery system capacities such as drug supply, laboratory facilities, patient monitoring and referral systems will increase dramatically. The operations of delivery system components must be coordinated to maximize impact.

MOBILIZING DEMAND. Uptake of antiretroviral therapy has been lower than anticipated in some high-prevalence settings, suggesting that, in addition to making antiretroviral therapy services available, physically accessible and affordable, demand must also be stimulated. Appropriate interventions include providing education on antiretroviral therapy and the availability of community-based services; reducing HIV/AIDS stigma and discrimination; strengthening entry points to HIV care; and improving referral from entry points to antiretroviral therapy. Community mobilization will be key to the process. The active involvement of community workers – especially to support uptake and adherence – will be a hallmark of the 3 by 5 strategy. Such community mobilization around the uptake of antiretroviral therapy will dramatically accelerate HIV prevention and catalyse wider public health benefits.

HEALTH INFORMATION SYSTEMS. Timely and accurate health information forms the essential foundation for making policy on, planning, implementing and evaluating all health programmes. The investments and innovation in monitoring and evaluating 3 by 5 will provide an opportunity to support the long-overdue strengthening and reform of country health information systems. WHO is working to strengthen health information systems and to advance a health metrics initiative that will contribute to monitoring and evaluating antiretroviral therapy.

PILLAR THREE

SIMPLIFIED, STANDARDIZED TOOLS FOR DELIVERING ANTIRETROVIRAL THERAPY

Rapidly scaling up antiretroviral therapy requires user-friendly guidelines to help health workers identify and enrol people living with HIV/AIDS, deliver therapy and monitor results. Providing these guidelines and updating them as new information comes in, is a central part of WHO's role.

Most people who have HIV/AIDS have no idea of their HIV status or the need to be evaluated for treatment. To help speed up the identification and enrolment of people needing antiretroviral therapy, WHO will simplify guidelines for HIV testing and counselling and for the referral of individuals at high risk of HIV disease. Guidelines will be developed for better use of multiple "entry points" to identify people who need antiretroviral therapy and to start or refer for therapy. Such entry points include: tuberculosis clinics; acute medical clinics; programmes for the prevention of mother-to-child transmission of HIV; sexually transmitted infection and other reproductive health services; and services for injecting drug users. WHO will provide operational models for effective ways in which entry points can link with antiretroviral therapy programmes without compromising their own core activities.

WHO will also simplify and standardize clinical protocols for delivering antiretroviral therapy. It will revise antiretroviral therapy guidelines to include recommendations for standard first- and second-line regimens. Guidelines for adherence support will be developed for use by facilities, those monitoring treatment and those receiving therapy. WHO will publish guidelines on the requirements for laboratory monitoring of antiretroviral therapy. WHO, UNAIDS and their partners will make guidelines available for the nutritional support of adults

and children on antiretroviral therapy. In addition, to enable programmes to be effectively monitored and ongoing performance improved, WHO will develop simple, standard, easy-to-use indicators for monitoring and evaluating antiretroviral therapy programmes. The Organization will publish guidelines and foster networks for the surveillance of antiretroviral drug resistance.

KEY WHO ACTIONS AND DELIVERABLES UNDER PILLAR 3 INCLUDE

- using multiple entry points to identify people needing antiretroviral therapy;
- publishing and implementing simple, standard testing procedures;
- publishing and implementing simple, standard technical guidelines; and
- publishing and implementing simple, standard monitoring and evaluation systems at the country level.

PILLAR FOUR

EFFECTIVE, RELIABLE SUPPLY OF MEDICINES AND DIAGNOSTICS

The viability of antiretroviral therapy programmes and the lives of people living with HIV/AIDS depend on a reliable, efficiently managed supply of quality medicines and diagnostics procured at a sustainable cost. WHO recognizes the importance of drug procurement and supply management for scaling up antiretroviral therapy and of the challenges many countries and providers face in this area. For this reason, a key component of the WHO 3 by 5 strategy is the establishment of an AIDS Medicines and Diagnostics Service (AMDS).

The AMDS will be a network hub, helping to coordinate the many ongoing efforts to improve access to medicines and diagnostics for treating HIV/AIDS. Accordingly, whenever possible the AMDS will seek to use and strengthen the capacity of partners already at work in this area.

The AMDS will not directly purchase medicine. However, such a service can do much to assist national authorities and programme implementers, drawing on the expertise of WHO and its partners in medicine policy and supply management. AMDS will provide an information clearinghouse for all market participants. It will give manufacturers, procurement agents and treatment programmes Web access to up-to-date demand forecasts, information on prices and sources and information on patent, customs and regulatory matters.

The AMDS will also build or disseminate technical tools to help programmes improve every step of the supply cycle. It will back these tools with a global network of experts who can be deployed in teams to help individual countries or

programmes to improve their procurement and drug management. As a key part of this work, the AMDS will seek to improve security in the supply chain. To ensure quality, the AMDS will link with the WHO Procurement, Quality and Sourcing Project (pre-qualification), which assesses products and manufacturers according to stringent standards. The AMDS will work to strengthen the Project and increase manufacturers' participation. Finally, the AMDS will establish global and/or regional networks of buyers to help them share information and coordinate their purchases. In a later phase, the AMDS may facilitate the procurement of essential medicines and diagnostics by aggregating demand on behalf of buyers and supporting joint competitive and open negotiations or tenders.

KEY WHO ACTIONS AND DELIVERABLES UNDER PILLAR 4 INCLUDE

- continuously updating demand forecasts and information on legal issues, prices and sources and making them available on the Web;
- disseminating technical tools for forecasting, procurement and management;
- supporting countries in all aspects of procurement, management and distribution through WHO teams;
- accelerating the pre-qualification of manufacturers, products, procurement agencies and laboratories;
- establishing global and/or regional networks of buyers; and
- deploying integrated monitoring and quality improvement teams.

PILLAR FIVE

RAPIDLY IDENTIFYING AND REAPPLYING NEW KNOWLEDGE AND SUCCESSES

The most successful organizations are those that have valued and applied experimentation, innovation and real-time learning with rapid diffusion. The many challenges surrounding the scaling up of antiretroviral therapy require a robust programme to consistently learn, document, share and act.

Recognizing and building on success is key. WHO will document experiences and lessons from successful antiretroviral therapy programmes, such as those in Botswana, Brazil, Senegal and Thailand and projects elsewhere supported by nongovernmental organizations. It will document experiences and draw lessons from successful programmes addressing other diseases, such as Stop TB, the Global Polio Eradication Initiative and the fight against SARS (severe acute respiratory syndrome). These will be used to develop learning and advocacy materials for scaling up antiretroviral therapy in accordance with 3 by 5. WHO will seek ways to support learning networks – especially among and between developing country partners – to rapidly disseminate successful strategies and innovative approaches among programmes on the ground.

The foundation of scaling up antiretroviral therapy is urgency. We must learn by doing. Although lessons can be drawn from previous health programmes, the effort to expand HIV/AIDS treatment is unprecedented in many ways. We do not have pre-set solutions to the problems that will arise. For this reason, mechanisms for ongoing evaluation and analysis of programme performance and a focused agenda for operations research are crucial. WHO will coordinate and help to develop an appropriate agenda for operations research relevant to the needs of antiretroviral therapy programmes and will seek to ensure that data and

new knowledge are rapidly incorporated back into the policy and practice of antiretroviral therapy programmes. Research priorities will include: identifying ways of measuring the externalities of scaling up antiretroviral therapy for the wider performance of health systems; monitoring resistance; and monitoring the impact of scaling up antiretroviral therapy on accelerating prevention programmes. WHO will carefully measure the impact of treatment programmes on prevention and then rapidly disseminate successful models to other countries.

KEY WHO ACTIONS AND DELIVERABLES UNDER PILLAR 5 INCLUDE

- establishing global collaboration and communication systems and processes to enable sharing and reapplication;
- tracking progress towards the milestones established for measuring project success at the country, regional and global levels;
- quickly documenting and disseminating successful models from early country experiences;
- identifying and funding specific operations research needs; and
- documenting and monitoring the impact of treatment programmes on prevention.

THE NEXT STEPS, TIMETABLES AND TRACKING

WHO's 3 by 5 strategy is a work in progress motivated by the antiretroviral treatment gap emergency. During December 2003 and early 2004, detailed plans for each element of the strategy will be developed in collaboration with all stakeholders, including countries, funding organizations, multilateral partners, implementers of treatment programmes and community-based organizations. Specific detailed timelines and action plans for each deliverable will be established, along with measurement and review processes to monitor progress. Risks will be identified and plans to mitigate them developed.

A set of major milestones has already been developed by which progress can be judged and assessed (Annex 2). Regular, transparent reviews of progress will help drive the Initiative forward. A situation room will be set up at WHO headquarters for tracking progress towards the targets.

The budget required for WHO to implement this strategy estimates a need of US$ 350 million for the 2004-2005 biennium. Of this amount, 84% is allocated to fund staffing and activities in countries and regions. The budget also calls for several hundred WHO staff to be sent to work in countries and regions. It is further anticipated that 3 by 5 countries' efforts will be supported not only by WHO resources but also by important contributions from various partner organizations active in each country.

GLOBAL FUNDING NEEDS FOR THE 3 BY 5 INITIATIVE

Achieving the 3 by 5. Based on current assumptions[1], the total cost of achieving the target of 3 million people on ARV treatment by end 2005 is estimated to be at least US $5.5 billion, some of which has already been pledged.

[1] *WHO 3 by 5 technical paper "Estimated cost to reach the target of 3 million with access the antiretroviral drugs.*

MAKING IT HAPPEN: CHANGES AT WHO

In response to appeals from countries, WHO and partners have begun deploying emergency response teams to countries to assess their specific situations in antiretroviral therapy and to identify how WHO and other partners can help accelerate the provision of treatment. By 12 December 2003, six country emergency missions will have been undertaken and a further 15 are planned. Each country is different, but common practical issues faced by all have enabled WHO to develop a broad-based country support strategy. The strategy is compatible with a wide variety of national programmes for accelerating the scaling up of antiretroviral therapy in accordance with the 3 by 5 target.

The 3 by 5 Initiative places the country at the centre of implementation. WHO is realigning its structures and redeploying resources to be optimally prepared to convert commitment into action. The changes will equip WHO country offices to better support national scaling-up efforts, to make use of the country-based resources of UNAIDS and the UNITED NATIONS at large, and to coordinate activities with other partners. Initial WHO country assessment missions will be followed by long-term teams to support antiretroviral therapy expansion in countries. The first long-term country-based 3 by 5 team will be on the ground in at least one country by the end of January 2004.

Each WHO regional office will have a team whose sole task is to support the implementation of the Initiative. Properly staffed and supported, the regional offices will play a critical facilitating and coordinating role, enabled by their close working relationship with countries.

At WHO headquarters, the 3 by 5 team is within the HIV/AIDS Department, in the new HIV/AIDS, Tuberculosis and Malaria cluster which will coordinate its planning and actions across WHO's clusters, regional and country offices. This will ensure linkage of all available expertise that contributes to antiretroviral therapy scale-up and health systems strengthening. This team is supported and complemented by a high-level WHO 3 by 5 Task Force that will coordinate the inputs of the Director-General and Assistant Directors-General.

The HIV/AIDS Department sponsors 10 working groups focused on specific issues that relate to:

- country support
- partnerships
- community involvement
- entry points to treatment
- treatment guidelines
- accelerating prevention
- monitoring, evaluation and surveillance
- capacity development
- operations research
- the AIDS Medicines and Diagnostics Service.

Each working group has developed a technical brief explaining its activities. These briefs are available. The working groups will be reviewed after 6 months; new groups may be established as the needs of antiretroviral therapy programmes evolve, and existing groups may be reformulated in the light of progress and experience. In addition, specific working groups in the HIV/AIDS, Tuberculosis and Malaria cluster will ensure effective sharing, lesson learning and problem solving across the cluster and Organization along certain themes. These include a working group on strengthening health systems and on access to medicines and diagnostics.

WORKING WITH PARTNERS

No single agency can achieve the target of 3 million people receiving antiretroviral therapy by the end of 2005. It could not be realized without the firm commitment to treatment already shown by many countries, the increased funding pledged or flowing from a variety of sources and the treatment centres already established in many settings with the help of numerous partners. There is significant activity on which to build in scaling up antiretroviral therapy.

This comprehensive Initiative requires the development and maintenance of a wide range of relationships. The alliances and partnerships necessary for 3 by 5 to succeed are extremely broad: national and local governments, civil society, bilateral donors, multilateral organizations, foundations, the private sector (as employers and as treatment implementers), trade unions, traditional authorities, faith-based organizations, nongovernmental organizations (international and national) and community-based organizations. People living with HIV/AIDS and the activist community are indispensable partners at all levels of WHO's activities.

Establishing and maintaining effective alliances and partnerships take time and resources. Coordination and collaboration are critical to fill gaps while avoiding duplication of effort – from the level of district-led initiatives right up to the international level and the United Nations system.

A 3 by 5 partners group has been formed, open to all who been active in and committed to scaling up antiretroviral therapy in resource-constrained settings. The strategic framework presented here was discussed in draft form with the group, and the rich feedback and comments have helped shape the final framework and text of this document.

At the country level, particular attention will be paid to strengthening the stewardship role of government while enabling constructive dialogue between the state and non-state sectors. Both the private health care sector and the wider business community will be crucial in expanding the availability of antiretroviral therapy.

At the international level, WHO is involved in close and ongoing consultation with major bilateral initiatives and donors. WHO will coordinate with all other United Nations agencies to harness each organization's comparative advantage. Among the specific resources that can be brought to bear for maximum impact are: UNICEF (United Nations International Children Emergency Fund) on issues involving AIDS and children, and in procurement; the International Labour Organization on work with the public-private interface, workplace and labour; the United Nations Development Programme on capacity-building; the United Nations World Food Programme on nutrition and food issues; the United Nations Population Fund on reproductive health; and the UNAIDS Secretariat on country coordination, advocacy and leadership for all activities related to HIV/AIDS. The active involvement of the World Bank and the Global Fund to Fight AIDS, Tuberculosis and Malaria is vital to ensure that financial resources flow quickly to countries and programmes that show commitment to scaling up.

BEYOND 2005

This Initiative does not end in 2005. Antiretroviral therapy does not cure HIV infection and must be taken for life. When properly managed, it can transform AIDS into a chronic disease similar in many ways to diabetes or hypertension. Nevertheless, withdrawing or ending treatment will lead to the recurrences of illness and with it the inevitability of premature death. Lifelong provision of therapy must be guaranteed to everyone who has started antiretroviral therapy. Thus, 3 by 5 is just the beginning of antiretroviral therapy scale-up and strengthening of health systems.

Further, although achieving the target of 3 million people on antiretroviral therapy will test the capability of the global health community, the target covers only half the global HIV/AIDS treatment gap. It will leave another 3 million people in urgent need of antiretroviral therapy. Progress achieved in scaling up access to antiretroviral medicines by 2005 must rapidly be extended to people who are still deprived.

Eventually, almost all of the more than 40 million people now infected with HIV worldwide will require access to therapy. Looking beyond 2005, WHO and its partners will be developing a new strategic approach to maintain the gains of 3 by 5 and to extend them, using sustainable financing and delivery mechanisms, so that antiretroviral therapy becomes part of the primary health care package provided at every health centre and clinic.

ANNEX ONE

HIV/AIDS 3 BY 5 STRATEGIC FRAMEWORK TO ADDRESS THE GLOBAL ANTIRETROVIRAL THERAPY GAP

The strategic framework has 14 elements in five categories: the pillars of the campaign

PILLAR ONE: Global leadership, strong partnership and advocacy
Strategic elements 1–4

PILLAR TWO: Urgent, sustained country support
Strategic elements 5–8

PILLAR THREE: Simplified, standardized tools for delivering antiretroviral therapy
Strategic elements 9–11

PILLAR FOUR: Effective, reliable supply of medicines and diagnostics
Strategic element 12

PILLAR FIVE: Rapidly identifying and reapplying new knowledge and successes
Strategic elements 13–14

HIV/AIDS 3 by 5 strategic framework to address the global antiretroviral therapy gap

GOAL. Prolong the survival and restore the quality of life of individuals with HIV/AIDS by providing universal access to antiretroviral therapy to those who need it, as a human right and within the context of a comprehensive response to HIV/AIDS.

TARGET. Providing effective antiretroviral therapy to 3 million people who need it by the end of 2005

PILLAR ONE GLOBAL LEADERSHIP, STRONG

STRATEGIES	ACTION STEPS
1. Visible WHO leadership and commitment to urgent action to reach the goal of universal access to antiretroviral therapy	1a WHO exercises its leadership role in care and treatment within UNAIDS and sets an ambitious, time-bound numerical target 1b WHO highlights the need for urgent action 1c WHO identifies the 3 by 5 target as an institutional priority and realigns expertise and activities across the Organization to achieve this target 1d WHO commits additional resources to 3 by 5, while maintaining full support for its overall programme in HIV/AIDS, including prevention 1e WHO establishes internal mechanisms for coordination and connectivity across the Organization to support the 3 by 5 Initiative 1f WHO enables all staff to access antiretroviral therapy
2. Locate the 3 by 5 Initiative within the broader development context	2a Develop guidelines for the ethical and equitable scaling up of antiretroviral therapy programmes in accordance with the 3 by 5 Initiative 2b Work with UNAIDS and partners to develop principles for implementing 3 by 5 programmes that promote gender equality, are inclusive of children and marginalized groups and maintain an overt pro-poor approach 2c Identify ways to link progress on 3 by 5 and beyond with relevant Millennium Development Goals and targets

PARTNERSHIP AND ADVOCACY

VERIFIABLE INDICATORS	ASSUMPTIONS
1a Announcement of 3 by 5 target 1b Declaration that the antiretroviral therapy gap is a global health emergency 1c Commitment to 3 by 5 in all relevant Forums, documents and policy statements New budget and appropriate resources devoted to 3 by 5, with more than 75% allocated to the regional and country levels 1d WHO HIV/AIDS budget for 2004–2005 Outputs and deliverables specific to HIV/AIDS 1e Establishment and activities of the internal steering group and cross-cluster task force Adequate information technology systems within WHO 1f Revision of staff treatment policy	■ WHO leadership endorsed and supported by UNAIDS and partners ■ 3 by 5 target adopted by UNAIDS and partners ■ Declaration of emergency accepted and acted on by WHO and UNAIDS ■ WHO commitment to 3 by 5 is maintained at the highest level and is manifested by concrete support from the entire Organization ■ Additional funding (US$ 350 million) is secured for the 3 by 5 Initiative to be fully implemented
2a Publication and use of ethics and equity guidelines 2b Publication and use of principles for 3 by 5 programmes Programme monitoring includes data on gender, age, socioeconomic status and marginalization 2c Progress on achieving relevant Millennium Development Goals is related and attributable to progress in 3 by 5 and beyond	■ Equitable and pro-poor approaches are formulated that high-burden countries can adopt and act upon ■ All donors recognize the importance of accelerated responses to scaling up antiretroviral therapy to mitigate the impact of HIV and to reverse declines in development indicators in high-burden countries ■ The specific contribution of 3 by 5 to achieving relevant Millennium Development Goals can be disaggregated and highlighted

STRATEGIES	ACTION STEPS
3. Support all countries in scaling up antiretroviral therapy, while focusing WHO efforts on the high-burden countries in greatest need	3a Identify countries with the greatest treatment burden and needs 3b Challenge countries as necessary to respond to the treatment gap as an emergency 3c Respond to appeals for assistance to close the treatment gap with appropriate urgency 3d Increase country office capacity to respond rapidly and effectively to 3 by 5 scale-up needs
4. Align and mobilize partner support and the private sector to achieve the 3 by 5 target at the global level	4a Agree specific roles and responsibilities with all stakeholders and the private sector in the process of scaling up and establish mechanisms for ongoing collaborative action with partners 4b Establish the level of the deficit in the global funding necessary to achieve 3 by 5 4c Work with partners to close the funding deficit and promote the principle of additionality for resources for scaling up antiretroviral therapy

VERIFIABLE INDICATORS	ASSUMPTIONS
3a List of countries that have a high burden and are most affected 3b Advocacy and lobbying materials Number of countries making appeal to WHO 3c Agreed action plan and timetable for scaling up with WHO involvement clearly identified 3d WHO staff and resources deployed according to country plan for scaling up	■ WHO has sufficient additional resources to implement the programme in high-burden countries ■ WHO is able to respond with sufficient speed to emergency appeals ■ WHO is able rapidly deploy sufficient resources to target countries to contribute to plans for scaling up
4a Partner roles are described and appear in the public domain in an appropriate location 4b Figures on the funding deficit are published with regular reviews and updates as resources are mobilized 4c Resources committed by respective partners Maintenance of funding streams for prevention	■ UNAIDS and all partners agree to coordinate strategies at the global level to scale up access to antiretroviral therapy in accordance with the 3 by 5 target ■ The private sector (employers and treatment implementers) fully integrate activities in line with 3 by 5 ■ Sufficient additional resources are mobilized and disbursed to countries to enable the 3 by 5 target to be achieved

PILLAR TWO URGENT, SUSTAINED COUNTRY

STRATEGIES	ACTION STEPS
5. Secure the key elements required at the national level to deliver the 3 by 5 target as part of a comprehensive response to HIV/AIDS and accelerate prevention	5a Secure national political commitment to the 3 by 5 process, standards and target within a comprehensive HIV/AIDS programme
	5b Support preparation of coordinated national plans for scaling up with all roles clearly defined
	5c Broker additional finances where required for scaling up in accordance with 3 by 5
	5d Build national awareness around the benefits of knowing HIV status and seeking treatment
	5e Utilize the capacity of antiretroviral therapy programmes to accelerate HIV prevention activities and to reduce stigma and discrimination
	5f Develop financing mechanisms for programmes that support equitable access to and use of antiretroviral therapy and that help to foster programme sustainability in the long term

SUPPORT

VERIFIABLE INDICATORS

5a Strong country leadership teams established
National targets set in accordance with 3 by 5
Adoption of WHO norms and standards for scaling up HIV prevention programmes maintained and enhanced

5b Number of national plans for scaling up that include strong mechanisms for coordinating multiple stakeholders

5c Bids for (further) funding submitted
Additional money received by countries for 3 by 5
Increased national financial commitment to antiretroviral therapy

5d Increased uptake of HIV testing
Technical and advocacy documents on "the right to know"

5e New and accelerated HIV prevention activities linked to antiretroviral therapy programmes
Technical brief on "prevention for positives"

5f Publication of guidelines on various mechanisms to finance antiretroviral therapy programmes
Transparent and accountable implementation of the financing mechanisms chosen

ASSUMPTIONS

- A sufficient number of high-burden countries commit to targets in accordance with 3 by 5
- UNAIDS and all relevant partners agree to coordinate activities at the national level
- Countries are successful in obtaining additional resources to scale up access to antiretroviral therapy in accordance with 3 by 5
- Mechanisms for long-term sustainable financing of antiretroviral therapy programmes can be developed and transparently implemented

STRATEGIES	ACTION STEPS
6. Strengthen and support the renewal of health systems and national operational capacity for scaling up antiretroviral therapy	6a Provide validated operational models for delivering antiretroviral therapy and integrated clinical guidelines for service delivery at the facility level
	6b Strengthen referral systems and develop sustainable models of chronic care delivery for the long-term support and management of individuals in antiretroviral therapy programmes
	6c Support national processes of physical resource planning consistent with the service delivery model(s) selected
	6d Upgrade laboratories, pharmacies, clinic buildings and information technology systems to support the scaling up of antiretroviral therapy
	6e Develop methods for accrediting service delivery points
7. Strengthen and build the human capacity for scaling up antiretroviral therapy	7a Develop standardized training packages for the key competencies necessary for 3 by 5
	7b Support national human resource planning processes consistent with appropriate service delivery model(s)
	7c Support countries in issuing certificates of HIV/AIDS competence
	7d Facilitate the training of key groups involved in scaling up simplified standardized antiretroviral therapy
	7e Develop standardized approaches to supervising staff and to monitoring service quality

VERIFIABLE INDICATORS	ASSUMPTIONS
6a Publication of technical and operational guidelines arising from consensus meetings Publication and use of IMAI (integrated management of adolescent and adult illness) training modules 6b Number of strengthened referral systems established Number of chronic care delivery services established Number of individuals accessing the services 6c National plans for physical resource development Number of units upgraded in accordance with plans 6d Extent of rehabilitation and upgrading conducted in key areas involved in delivering antiretroviral therapy 6e Publication and use of service delivery standards and accreditation criteria	■ Effective integrated models of antiretroviral therapy delivery can be developed at the district and health centre levels ■ Weak and stressed health systems in highly affected countries can absorb resources rapidly enough to permit the establishment of sufficient service delivery points to achieve the 3 by 5 targets ■ Potential distortions inherent in the rapid scaling up of large complex programmes are anticipated and overcome ■ The health sector is sufficiently strengthened globally by improvements fostered by 3 by 5 that other interventions relevant to the Millennium Development Goals are enhanced
7a Publication and use of standardized training packages 7b National plans for human resource development Measurable progress in their implementation 7c Number of training providers authorized to issue certificates of HIV/AIDS competence 7d Numbers of professional and lay staff trained in antiretroviral therapy 7e Publication and use of guidelines for supporting the quality of antiretroviral therapy services	■ Simple, standard training packages can be designed and rapidly deployed ■ Sufficient numbers of qualified staff are retained, recruited or return to the health sector to enable the 3 by 5 plans for scaling up to be implemented ■ Enough staff are trained in tight deadlines to enable the 3 by 5 target to be achieved ■ Ways to supervise staff and monitor performance quality can be designed and implemented

STRATEGIES	ACTION STEPS
8. Strengthen the capacity of affected communities, including vulnerable groups living with HIV/AIDS, to be fully involved in planning and delivering antiretroviral therapy programmes	8a Provide resources to stimulate and strengthen community-based and faith-based organizations in engaging in national advocacy for improving treatment access and in planning and implementing antiretroviral therapy programmes
	8b Broaden service delivery approaches to integrate formal health services with community-based approaches to treatment, care, prevention and support and to facilitate adherence to therapy
	8c Develop standardized training materials for community treatment supporters and educators
	8d Support greater involvement of people living with HIV/AIDS in operational research and quality assurance of services

VERIFIABLE INDICATORS	ASSUMPTIONS
8a WHO community advisory committees established Advocacy capacity-building grants made available	■ Sufficient financial resources are made available for community organizations ■ Community-based organizations can scale up activities rapidly and respond effectively in accordance with 3 by 5 national plans and targets ■ Stigma and discrimination are reduced sufficiently to allow the wide-scale engagement of people living with HIV/AIDS in 3 by 5
8b Publication of operational guidelines Number of community-based organizations and organizations of people living with HIV/AIDS involved in delivering antiretroviral therapy Adherence levels achieved	
8c Materials developed and published Numbers trained with standard package	
8d Materials developed for evaluation of antiretroviral therapy by people receiving therapy and by the community Number of community-based organizations and organizations of people living with HIV/AIDS involved in research and quality assurance	

PILLAR THREE SIMPLIFIED, STANDARDIZED TOOLS

STRATEGIES	ACTION STEPS
9. Simplify and standardize procedures to identify individuals who need therapy and to facilitate entry to antiretroviral therapy programmes	9a Simplify guidelines for HIV testing and counselling and referring individuals at high risk of HIV disease 9b Develop guidelines for better use of "entry points" (tuberculosis, acute medical clinics, preventing the mother-to-child transmission of HIV, sexually transmitted infections and services for injecting drug users) to identify people who need antiretroviral therapy and start or refer them for therapy 9c Provide validated operational models for effective linking entry points with antiretroviral therapy programmes without compromising core activities
10. Simplify and standardize antiretroviral therapy to facilitate adherence and to enable rapid scaling up to be implemented	10a Revise antiretroviral therapy guidelines to include recommendations for standard first- and second-line regimens 10b Develop guidelines for adherence support for use by facilities, treatment monitors and people receiving therapy 10c Develop guidelines on the requirements for laboratory monitoring of antiretroviral therapy and networks of HIV/AIDS diagnostic support 10d With UNAIDS partners, develop guidelines for the nutritional support of adults and children on antiretroviral therapy

FOR DELIVERING ANTIRETROVIRAL THERAPY

VERIFIABLE INDICATORS	ASSUMPTIONS
9a Publication and use of standard operational procedures for testing and counselling Production of rapid HIV testing guidelines 9b Publication and use of guidelines for entry points to identify and refer people who need antiretroviral therapy Number of service points implementing guidelines 9c Publication and use of technical and operational guidelines for entry points to expand into antiretroviral therapy while maintaining core functions	■ Simple ways to identify those in need of antiretroviral therapy can be devised and rapidly implemented ■ Entry points can be supported to engage with 3 by 5 programmes maintaining their focus on core business and activities
10a Publication of revised guidelines on antiretroviral therapy Use of recommended standard regimens 10b Publication and use of adherence guidelines Levels of adherence achieved and maintained 10c Publication and use of guidelines on requirements for laboratory monitoring of antiretroviral therapy 10d Publication and use of nutritional support guidelines	■ Simplified treatment regimens can be developed that allow universal access but do not compromise efficacy or the safety of the people receiving therapy ■ Appropriate laboratory services can rapidly be set up or renewed to monitor people receiving antiretroviral therapy ■ Equitable ways to nutritionally support individuals in antiretroviral therapy programmes can be identified, funded and implemented

STRATEGIES	ACTION STEPS
11. Simplify and standardize tools for tracking the performance of antiretroviral therapy programmes, including surveillance of drug resistance	11a Develop simple, standard, easy-to-use monitoring and evaluation indicators for antiretroviral therapy programmes 11b Promote the universal adoption and use of the core indicators for antiretroviral therapy programmes 11c Develop guidelines and networks for surveillance of antiretroviral drug resistance 11d Develop guidelines and networks for monitoring risk behaviour 11e Establish an "incident room" to track activities and progress towards 3 by 5

VERIFIABLE INDICATORS	ASSUMPTIONS
11a Publication of simple standard guidelines on monitoring and evaluation 11b Universal use of core indicators for antiretroviral therapy programmes 11c Facilities for antiretroviral resistance testing established Levels of antiretroviral drug resistance reported 11d Networks for monitoring risk behaviour set up and functioning 11e Regular updates on progress towards achieving the 3 by 5 target	■ Simplified standard monitoring and evaluation indicators for antiretroviral therapy programmes are universally used ■ Standard monitoring and evaluation indicators are simple enough for widespread and universal use but still accurate enough to track programme performance effectively ■ Antiretroviral drug resistance network can rapidly be set up and operationalized to generate useful data

PILLAR FOUR EFFECTIVE, RELIABLE SUPLY OF

STRATEGIES	ACTION STEPS
12. Support country access to and efficient distribution of high-quality, low-cost medicines and diagnostics	12a Develop and maintain tools and guidelines to assist implementers at the country level in overcoming barriers to procuring and distributing key commodities and devices
	12b Create and run a technical and operational support service for product selection, quality assurance, procurement and supply chain management
	12c Coordinate a buyers' network

MEDICINES AND DIAGNOSTICS

VERIFIABLE INDICATORS	ASSUMPTIONS
12a Creation of AMDS (AIDS Medicines and Diagnostics Service) Web site covering standards, specifications, sources, prices, pre-qualified products and suppliers, registration status, patent status etc. 12b Diagnostics and antiretroviral drugs sourced according to country and year Number of country procurement and supply chain management assessments Average prices for essential diagnostics and antiretroviral drugs Percentage of products procured that are pre-qualified Percentage of stock-outs Percentage of products tested that comply with quality norms 12c Resource-based forecasting system of demand established and maintained Commodities obtained with the technical support of AMDS	■ All partners agree to and support the creation and the activities of the AMDS ■ The AMDS successfully streamlines country access to medicines and diagnostics ■ Appropriate national quality assurance systems can be rapidly set up and maintained ■ The AMDS keeps down the prices of medicines and diagnostics

PILLAR FIVE RAPIDLY IDENTIFYING AND REAPPLYING

STRATEGIES	ACTION STEPS
13. Build on success	13a Document experiences and lessons from successful antiretroviral therapy programmes (such as Botswana, Brazil, Thailand and Médecins Sans Frontières) 13b Document experiences and lessons from other successful programmes (tuberculosis, poliomyelitis and SARS) 13c Demonstrate effective progress in countries with initial funds for antiretroviral therapy 13d Set up south–south networks to disseminate models of success rapidly to other programmes
14. Continuously learn by doing – with ongoing evaluation and analysis of programme performance and a focused operational research agenda	14a Coordinate and help to develop an appropriate operations research agenda relevant to the needs of antiretroviral therapy programmes 14b Seek data on the impact of scaling up antiretroviral therapy: on prevention and at-risk behaviour; on mitigation; and on stigma and discrimination 14c Identify ways to identify the externalities of scaling up antiretroviral therapy on the performance of health systems 14d Identify ways to cost antiretroviral therapy programmes and to link costs to impact and effectiveness 14e Improve programme design and find better tools to reduce "at-risk" behaviour and the evolution of drug resistance, based on analysis of data 14f Incorporate data and new knowledge rapidly back into the policy and practice of antiretroviral therapy programmes

NEW KNOWLEDGE AND SUCCESSES

VERIFIABLE INDICATORS	ASSUMPTIONS
13a Advocacy materials for scaling 3 by 5 up using success stories and results from countries and nongovernmental organizations 13b Lessons from other programmes understood and incorporated into the 3 by 5 strategy and activities 13c The incident room reports on global progress Countries report on national progress 13d Number of networks and south–south collaborations	■ New success stories and country champions rapidly emerge ■ Success models can be effectively communicated to donors and partners ■ Success stimulates interest and further commitment to scaling up antiretroviral therapy ■ Success in one programme can rapidly be translated to other settings
14a Publication and use of the coordinated operations research agenda by relevant research groups and partners 14b Results and data from operational research and monitoring and evaluation 14c Methods published and used Externalities identified and quantified 14d Methods published and used Cost–effectiveness and cost-saving data published 14e Analysis of monitoring and evaluation results and operational research data Better tools and programme improvements identified by data analysis 14f Examples of this feeding into policy and practice	■ Research community engages in 3 by 5 programme needs and allows a well coordinated approach to be adopted ■ Relevant data and new knowledge can be generated and then analysed quickly enough to feed back meaningfully into 3 by 5 scaling up and programme development ■ Effective means of rapidly connecting with everyone involved in scaling up antiretroviral therapy to share learning and best practices, and developments can be set up and maintained

ANNEX TWO

KEY MILESTONES FOR GLOBAL MONITORING INDICATORS OF THE 3 BY 5 INITIATIVE

	DECEMBER 2003	JUNE 2004	DECEMBER 2004	JUNE 2005	DECEMBER 2005
INPUT					
1. Amount of additional financial resources estimated to be obligated by WHO to 3 by 5 (in millions of US dollars)					
a) *within WHO overall*					
b) *within overall budget, at country offices*	8 3	86 54	174 107	262 161	350 214
2. Number of additional staff deployed and/or realigned to WHO country offices for 3 by 5	25	200	400	440	480
3. Number of standard training packages and other key guidance documents published (not including revisions of documents)	5	15	18	18	18
4. Number of partner organizations whose role in 3 by 5 is agreed and published	10	90	150	175	200

	DECEMBER 2003	JUNE 2004	DECEMBER 2004	JUNE 2005	DECEMBER 2005
PROCESS					
5. Countries appealing to WHO for support for 3 by 5	20	40	50	50	50
6. Countries establishing antiretroviral therapy targets in accordance with 3 by 5	4	35	50	60	60
7. Countries with a national implementation plan in accordance with the 3 by 5 target	3	25	35	60	60
8. Average price (in US dollars) per person per year for first-line antiretroviral therapy	150-400	100-350	100-300	50-250	50-200
9. Countries using the *AIDS Medicines and Diagnostics Service* (*AMDS*) to support procurement and distribution of commodities	0	20	30	40	50
10. Countries that have introduced training using WHO-supported certification of competence	0	30	40	50	50

	DECEMBER 2003	JUNE 2004	DECEMBER 2004	JUNE 2005	DECEMBER 2005
OUTPUT					
11. Number of health providers and community treatment supporters trained to deliver antiretroviral therapy in accordance with national standards		10 000	30 000	70 000	100 000
12. Number of service outlets providing antiretroviral therapy according to national standards		500	1 000	3 000	10 000
13. Number of partnerships between formal antiretroviral therapy outlets and community-based groups		1 500	3 000	9 000	30 000
14. Number of public and nongovernmental organization service outlets providing testing and counselling services		1 000	2 000	6 000	20 000
OUTCOME					
15. Number of men, women and children with advanced HIV infection receiving antiretroviral therapy	400 000	500 000	700 000	1 600 000	3 000 000