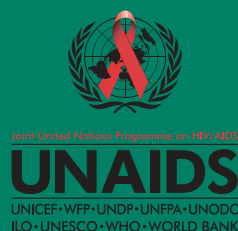


Emergency scale-up of antiretroviral therapy in resource-limited settings:
technical and operational recommendations to achieve 3 by 5



Report of the WHO/UNAIDS International Consensus Meeting on Technical and Operational Recommendations for Emergency Scaling-up of Antiretroviral Therapy in Resource-Limited Settings, 18–21 November 2003, Lusaka, Zambia



Emergency scale-up of antiretroviral therapy in resource-limited settings: technical and operational recommendations to achieve 3 by 5



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Introduction

This report is the report from the WHO/UNAIDS International Consensus Meeting on Technical and Operational Recommendations for Emergency Scaling-up of Antiretroviral Therapy in Resource-Limited Settings in Lusaka, Zambia between November 18 and 21, 2003. The Meeting brought together more than 100 experts, including people living with HIV/AIDS, treatment advocates, representatives of United Nations agencies, researchers, government officials, policy-makers, donors and nongovernmental organizations involved in HIV/AIDS treatment, care and support. The purpose of the Meeting and the preparatory work by five working groups in September and October 2003 was to develop emergency technical and operational recommendations to guide the scaling up of antiretroviral therapy for people living with HIV/AIDS in resource-limited settings. The recommendations contained in this report will be used in developing a technical and operational manual for scaling up antiretroviral therapy to be published by WHO and UNAIDS in early 2004.

Background

The global AIDS treatment gap – a public health emergency

More than 40 million people are living with HIV/AIDS, of whom 95% live in resource-limited settings. WHO and UNAIDS estimate that at least 6 million of these have advanced-stage HIV disease and urgently need antiretroviral therapy now. Of the approximately 6 million in need, 4.1 million live in sub-Saharan Africa, where health systems are weak and current access to HIV prevention, care and treatment is minimal.

On 22 September 2003, at the fifty-eighth session of the United Nations General Assembly, LEE Jong-Wook, Director-General of WHO and Peter Piot, Executive Director of UNAIDS declared the global AIDS treatment gap to be a public health emergency. WHO and UNAIDS are leading an international effort to address the emergency – the 3 by 5 Initiative – that aims to get 3 million people in resource-limited countries on antiretroviral therapy by the end of 2005.

The 3 by 5 Initiative – closing the treatment gap

The 3 by 5 target is a time-limited, measurable target towards the goal of universal access to antiretroviral therapy for those who require it according to medical criteria. WHO has developed a strategy outlining its contribution to achieving 3 by 5. The strategy is based on a public health approach to antiretroviral therapy, of which the following are key elements:

- ▶ standardized treatment protocols and simplified clinical monitoring;
- ▶ using existing physical infrastructure and human resources optimally;
- ▶ involving people living with HIV/AIDS as well as communities in designing and implementing programmes;
- ▶ simplified record-keeping; and
- ▶ minimizing costs, including reducing the costs of drugs and diagnostics.

Developing technical and operational strategies

As part of its initial contribution to achieving 3 by 5, WHO undertook a consultative process to determine the

immediate steps that need to be taken in resource-limited countries to rapidly expand the delivery of antiretroviral therapy.

Five working groups were established in September 2003, comprising individuals with direct experience in implementing antiretroviral therapy projects and programmes in resource-limited countries. The working groups communicated by teleconference and e-mail to develop draft recommendations on technical and operational aspects of scaling up antiretroviral therapy in the following areas:

- ▶ people living with HIV/AIDS and communities as leaders in antiretroviral therapy;
- ▶ the essential package of care and prevention services necessary to support antiretroviral therapy;
- ▶ human resources, service delivery and training;
- ▶ management of commodities and supplies; and
- ▶ strategic information.

The working groups convened in Lusaka, Zambia on 18–19 November to review and refine their preliminary recommendations. These were presented at a meeting on 19–21 November, also in Lusaka, that involved a wide range of stakeholders representing civil society and the public and private sectors. The recommendations were refined further at this stage, and consensus was achieved on most outstanding issues.

Following the meeting, WHO consolidated and harmonized the recommendations across each thematic area and prepared this report.

Purpose of this report

This report is intended to help those implementing antiretroviral therapy programmes in resource-limited settings to accelerate their work by identifying recommendations and priority actions that are required to deliver antiretroviral therapy now.

The report is primarily intended for use in low and middle-income countries with generalized and/or rapidly expanding epidemics and is applicable to those working in the public sector, the private sector, community-based and faith-based organizations associations of people living with HIV/AIDS and workplace programmes.

Background

Structure of the report

The report outlines the key principles, assumptions and definitions on which the recommendations are based. It is then divided into five sections, beginning with background information and proceeding to recommendations and priority actions, based on available evidence and experience, for each of four levels of the health system (Box 1).

Recommendations and priority actions are given for Phase 1 and Phase 2 of scaling up access to antiretroviral therapy. Phase 1 is the acute emergency phase in which efforts are directed at utilizing existing resources and available capac-

ity to deliver antiretroviral therapy to as many people as possible now. Phase 2 is an expansion and consolidation of Phase 1 activities to increasingly improve quality and expand services, to deepen and strengthen human resources and community involvement, and to integrate new activities more thoroughly across all sectors involved in primary health care.

The final section of the report summarizes the recommendations of WHO for immediate follow-up action as part of the 3 by 5 Initiative.

Box 1 – Levels of a health system

Community level

The community level includes people living with HIV/AIDS and their associations, community-based, faith-based and other nongovernmental organizations and community and home-based care services. Also included at this level are health posts or *cases de santé*, usually staffed by an auxiliary nurse or community health worker.

Health centre level

The health centre is the first level of the formal health care system. In this report, health centre refers to larger facilities that may have trained staff such as a nurse or clinical officer and more regular working hours. Maternity and minimal laboratory services are often available.

District level

The district level typically has a district hospital with general medical, paediatric and maternity care, limited surgical care, in- and outpatient care and sometimes intermittent specialty care. The health centres and private practitioners in the district refer to the district hospital.

The staff in a district hospital typically includes one or more generalist physicians, clinical officers, nurses, pharmacy technicians, dispensing clerks, medical assistants, nurse assistants and a laboratory technology assistants. Laboratory services normally available include full blood count, malaria smears, tuberculosis (TB) smears, HIV and syphilis serology and liver enzyme tests. Private and mission hospitals are often present at this level and may be associated with health centres and other levels of care.

District health teams under the district medical officer are responsible for integrating service delivery by various public and private health service organizations in the district and for coordinating, monitoring and supervising disease- and area-specific programmes (such as TB, Expanded Programme on Immunization and HIV/AIDS).

Central level

The central level has tertiary care hospitals with general and specialized care available for complex or acutely ill patients, surgery and multiple out- and inpatient services. All levels of health care providers, general medical and acute care and chronic care clinics (HIV/AIDS and other) are offered. More complete laboratory services and reference laboratories, where blood chemistry, CD4 counts, and viral load can be determined, are sometimes available at this level. Overall policy is also determined at the central level.

Assumptions

This report focuses on priority actions that need to take place in services at the community, health centre and district levels. Critical political, resource mobilization and legal and policy-related activities that must set the stage for scaling up antiretroviral therapy are beyond the scope of this report. The report therefore assumes that the following are either in place or in development in each country concurrently with the initiation of antiretroviral therapy:

- ▶ political commitment to antiretroviral therapy at the highest level;
- ▶ adequate financial resources for implementing antiretroviral therapy;
- ▶ an uninterrupted supply of commodities;
- ▶ an enabling regulatory framework for training and certifying new cadres of health and community workers; and
- ▶ national guidelines for antiretroviral therapy and related HIV care and guidelines for training.

Principles

The following principles have guided and informed this report:

- ▶ Antiretroviral therapy should be delivered equitably to everyone who needs it, including children, women, men and all vulnerable populations, including sex workers, injecting drug users, men who have sex with men, displaced persons, prisoners and migrant workers.
- ▶ Innovative and multisectoral partnerships between the public and private sectors and civil society are required for effectively scaling up antiretroviral therapy.
- ▶ Antiretroviral therapy programmes must strengthen overall health systems and primary health care.
- ▶ People living with HIV/AIDS and communities are leaders in the movement to provide universal access to antiretroviral therapy, in designing and implementing programmes, as volunteers and as a vital part of the paid work force of service providers. The most successful pilot programmes for antiretroviral therapy in resource-limited settings have made community involvement a central element of planning and implementation. Unless

the treatment and care provided are relevant to and respectful of community needs, people will not use the services.

- ▶ A rights-based approach to antiretroviral therapy programming should be used in designing and delivering antiretroviral therapy. A rights-based approach to health care is grounded in the empowerment of individuals and their communities by placing them at the centre of health services. Evidence indicates that violating the rights of those most vulnerable to HIV infection fuels the epidemic. Rights that must be realized for an effective response to the HIV epidemic include the right to health, the right to know one's HIV status, the right to information, the right to privacy and the right to non-discrimination.

Most participants considered that antiretroviral therapy should be provided free of charge to the person receiving the therapy, with a minority cautioning against stating this as a principle, as it would be difficult to implement in many health systems.

Definitions

The following terms, used throughout this report, are defined as follows:

Antiretroviral therapy – This includes antiretroviral drugs as well as the essential services needed to provide them (treatment support and laboratory testing).

Antiretroviral drugs – The essential medicines used to treat HIV infection.

Universal access – Availability of a service or good to everyone who needs it according to medical criteria, regardless of class, race, gender, religion, socioeconomic status, sexual orientation or other individual, cultural or other characteristics.

Adherence support – A component of treatment support that is geared to helping people take their medicines as prescribed.

Treatment support – Support for people receiving antiretroviral therapy comprising prevention, adherence, disclosure and psychosocial support.

Background

Treatment supporter – A trained person from the community, paid or volunteer, who provides treatment support.

Community health worker – A trained health worker who lives within the community and works with other health and development workers as a team. This person often provides the first contact between an individual and the health system. Types of community health workers vary between countries and communities, according to needs and available resources. In many societies, community health workers come from and are chosen by the communities where they work. Sometimes they work as volunteers; normally those who work part or full time are rewarded, in cash or in kind by the community and the formal health services.¹

Next steps – operational guidelines and beyond

WHO will use this report as one basis for developing an operational manual for scaling up antiretroviral therapy in resource-limited settings, which will be published and made available in early 2004.

This meeting is part of an iterative process that will continue to link the individuals, organizations and institutions implementing antiretroviral therapy programmes to exchange information, agree where possible and proceed towards achieving the 3 by 5 target. WHO has launched a moderated electronic forum to enable antiretroviral therapy implementers to share ideas and lessons learned.²

WHO will assess progress and strategies on a regular basis and periodically revise operational recommendations for antiretroviral therapy as further evidence becomes available.

¹ *Glossary of terms used in the "Health for All" series, no. 1–8.* Geneva, World Health Organization, 1984 (<http://whqlibdoc.who.int/publications/9241800097.pdf>, accessed 12 December 2003).

² To subscribe to this forum, send an e-mail to e-3x5-join@healthnet.org

People living with HIV/AIDS and communities as leaders in antiretroviral therapy

1. BACKGROUND

Definition of communities

Communities comprise many different types of people. An emergency response necessitates focusing specifically on the individuals and groups that have a key stake in antiretroviral therapy:

- ▶ people living with HIV/AIDS, and groups and associations of which they may be members;
- ▶ nongovernmental organizations, community-based organizations and faith-based organizations that are already providing prevention, care, treatment and/or support services, including those working specifically with marginalized communities, such as those including sex workers, men who have sex with men and injecting drug users;
- ▶ families and friends of people living with HIV/AIDS;
- ▶ community leaders (such as religious leaders and traditional healers); and
- ▶ community health workers.

These groups represent significant existing expertise and resources that can and should be built on for the rapid expansion of antiretroviral therapy.

The evidence shows that the involvement of communities in antiretroviral therapy programmes can be broadly delineated as follows.

Advocacy. This includes mobilizing political and financial support to ensure that antiretroviral therapy is sustainable, secure, equitable, accessible and acceptable and making efforts to counter stigma and discrimination.

Information, education and communication. This includes information, education and communication with local communities about HIV/AIDS, such as prevention and treatment (treatment literacy).

Direct service provision. This includes HIV testing and counselling, HIV prevention, treatment support (including prevention, adherence and psychosocial support), peer support, psychosocial and nutritional support, home support and palliative care, income generation, spiritual support for people with HIV and assistance with storing and distributing commodities.

Promoting and protecting rights. This includes realizing the right to treatment, participating in ethical and equitable selection of people to receive antiretroviral therapy and other decision-making, protecting human rights and community oversight of antiretroviral therapy programmes.

Assuring the quality of services and operations research. This includes evaluation of services by users and the community and partnerships between communities and academic research.

2. RECOMMENDATIONS AND ACTION

Recommendation 1. Build capacity for community-driven information, education, communication and advocacy related to antiretroviral therapy.

Priority actions

Community, health centre, district and central levels

Phase 1

- ▶ Identify and utilize existing community capacity for information, education, communication and advocacy in introducing antiretroviral therapy.
- ▶ At the same time that antiretroviral therapy is introduced, organize and resource support groups, post-test clubs and/or associations of people living with HIV/AIDS to conduct advocacy and education related to antiretroviral therapy. Target advocacy and education related to antiretroviral therapy at community leaders and key community organizations, with a focus on vulnerable populations.
- ▶ Build awareness in communities of the importance of recipients adhering to antiretroviral medication.

Additional actions at the health centre level

Phase 1

- ▶ Initiate training for those conducting community education and advocacy on antiretroviral therapy.
- ▶ Establish coordination of community education on antiretroviral therapy.

People living with HIV/AIDS and communities as leaders in antiretroviral therapy

Additional actions at the district level

Phase 1

Provide resources for antiretroviral therapy-related training and technical support to community health workers.

Additional actions at the central level

Phase 1

- ▶ Develop generic information, education and communication and treatment literacy materials that can be adapted at all levels.
- ▶ Provide resources to communities for ongoing education and advocacy on antiretroviral therapy.
- ▶ Conduct mass-media campaigns to catalyse communities into action.

Recommendation 2. Strengthen and expand prevention, care, treatment support and other services provided directly by communities.

Priority actions

Community, health centre, district and central levels

Phase 1

- ▶ Identify and utilize existing community capacity to provide the following prevention, care, treatment and support services:
 - ▮ outreach to vulnerable populations, including sex workers, men who have sex with men and injecting drug users;
 - ▮ HIV counselling;
 - ▮ prevention, including safer sex and injection counselling, distribution of condoms and needles and syringes and preventing sexually transmitted infections;
 - ▮ treatment and care for common conditions such as pain relief, diarrhoea and thrush;
 - ▮ psychosocial support;
 - ▮ nutritional support;
 - ▮ home visits;
 - ▮ links and referrals to community-based organizations and traditional practitioners; and

- ▮ referral to a health centre for more complex management.

- ▶ Initiate training and support for expanded community provision of the services listed above, plus:

- ▮ HIV testing and counselling (community health workers);
 - ▮ completing patient records (community health workers);
 - ▮ providing assistance with storage and distribution of drugs (community health workers and community based organizations involved in care); and
 - ▮ routine clinical monitoring (antiretroviral side effects, weight, minor infections and coughing).
- ▶ Initiate recruitment, training and the establishment of treatment support groups to provide adherence counselling, psychosocial support and treatment literacy.
 - ▶ Identify and train treatment educators and supporters (including friends and/or family members of people living with HIV/AIDS).

Phase 2

- ▶ Provide ongoing training of and support for treatment support groups.
- ▶ Provide ongoing training of and support for treatment educators and supporters.

Additional actions at the health centre level

Phase 1

- ▶ Initiate recruitment, training and support of sufficient numbers of community health workers who will supervise and coordinate community-level activities.
- ▶ Establish treatment support groups at health centres.
- ▶ Refer people living with HIV/AIDS to community health workers and community services.
- ▶ Recruit and train people living with HIV/AIDS to act as advocates for other people living with HIV/AIDS at the health centre.

Additional actions at the district level

Phase 1

- ▶ Initiate training and resources for communities to provide expanded prevention, care and support services, including outreach to vulnerable populations such as sex workers, men who have sex with men and injection drug users.
- ▶ Establish treatment support groups at the district facility.
- ▶ Refer people living with HIV/AIDS to health centre, community health workers and community services as appropriate.
- ▶ Recruit and train people living with HIV/AIDS as advocates for other people living with HIV/AIDS at the district facility.

Additional actions at the central level

Phase 1

- ▶ Immediately expand the provision of resources and provide policy guidance and support to enable a range of community services to be provided, including regulatory reform in the health profession.
- ▶ Establish treatment support groups at the central facility.
- ▶ Refer people living with HIV/AIDS to the district facility, a health centre and/or community health workers and community services.
- ▶ Recruit and train people living with HIV/AIDS as advocates for other people living with HIV/AIDS for the central facility.

Recommendation 3. Promote and protect the human rights of people living with HIV/AIDS and everyone affected by HIV, especially poor and vulnerable populations, including sex workers; injection drug users; men who have sex with men; displaced persons; and migrant workers. This must be done in an environment in which people living with HIV/AIDS are encouraged and supported to voluntarily disclose their HIV status.

Priority actions

Community, health centre, district and central levels

Phase 1

- ▶ Promote and provide education on internationally agreed standards for protecting and promoting the human rights of people living with HIV/AIDS and everyone affected by HIV. People living with HIV/AIDS have an important role to play in this.

Phase 2

- ▶ Create structures to enable people living with HIV/AIDS to effectively participate in planning, implementing and monitoring treatment services and policies at all levels.

Additional actions at the health centre level

Phase 1

- ▶ Establish community advisory committees to involve people living with HIV/AIDS and other community representatives. The community advisory committees will develop, implement and monitor policies and procedures for counselling, selection of people for antiretroviral therapy, informed consent, confidentiality, disclosure, protection from discrimination and mutual support. The community advisory committees will also perform a coordinating role.

Additional actions at the central level

Phase 1

- ▶ Develop policy rapidly to guide and support the expansion of community-based services as essential to realizing the right to treatment.

People living with HIV/AIDS and communities as leaders in antiretroviral therapy

Recommendation 4. Assure quality of care by involving communities in monitoring and evaluating antiretroviral therapy services.

Priority actions

Community and health centre levels

Phase 1

- ▶ Conduct user-centred evaluation of services including questionnaires and interviews focused on individual service users and groups of users, consultation of the community advisory committees, focus groups and other tools.

Phase 2

- ▶ Establish links with academic institutions to develop the community capacity for research.

District level

Phase 1

- ▶ Facilitate the development of community treatment plans based on the national treatment plan (include partners, targets and timelines).
- ▶ Integrate community plans into the district-level plan that identifies resources and involves all stakeholders.
- ▶ Establish mechanisms for coordinating user- and community-centred evaluation of services.

Central level

Phase 1

- ▶ Establish policy mechanisms for user-centred evaluation of services.

The essential package of care and prevention services necessary to support antiretroviral therapy

1. BACKGROUND

Antiretroviral therapy has been shown to dramatically improve the survival of people living with HIV/AIDS and is the optimal treatment for HIV disease. This section describes the essential package of care, prevention and support services that must be in place before antiretroviral therapy can be introduced into the health system and the services that can be introduced concurrently with antiretroviral therapy and then progressively expanded over time. Specific combinations of antiretroviral therapy are recommended as well as the laboratory tests needed to support their use.

Scaling up access to antiretroviral therapy will require that many services currently provided only at the central or district levels be progressively and quickly expanded to the health centre level and, in the case of many of the routine elements of patient management, into community settings in which expertise already exists and can be rapidly built upon with appropriate resources and training.

Recommendation 1.1. Antiretroviral therapy should be initiated in facilities at all levels of the formal health care system as soon as the following minimum conditions are available:

- ▶ HIV testing and counselling;
- ▶ personnel trained and certified to prescribe antiretroviral therapy and follow up recipients clinically;
- ▶ an uninterrupted supply of antiretroviral drugs; and
- ▶ a secure and confidential patient record system.

The following must be made available at all levels concurrent with (and following) the introduction of antiretroviral therapy:

- ▶ adherence support; and
- ▶ community mobilization and education on antiretroviral therapy.

2. ANTIRETROVIRAL THERAPY REGIMENS AND OTHER HIV-RELATED TREATMENT AND CARE

Recommendation 2.2. People with symptomatic WHO Stage III and IV conditions who have tested HIV positive and received post-test counselling should be offered antiretroviral therapy immediately.

These people can be started immediately on antiretroviral therapy based on clinical evaluation, even without CD4 count and other laboratory tests. Where CD4 is accessible at a higher level and performing a CD4 count does not constitute a financial barrier to antiretroviral therapy access, a baseline CD4 count is desirable to facilitate follow-up. Antiretroviral therapy should be initiated immediately, without waiting for the results of baseline CD4 testing.

Apart from antiretroviral therapy, HIV-related care includes treating acute and chronic illnesses, providing prophylaxis for some opportunistic infections, psychosocial support and education. Entry into care is essential to maintain optimum health for people living with HIV/AIDS, to identify people as they become eligible for antiretroviral therapy and to prepare them well for it. HIV-related care also represents an important opportunity to encourage and support prevention for people living with HIV/AIDS.

Recommendation 2.3. Stavudine + lamivudine + nevirapine should be the preferred first-line regimen for the immediate implementation of large-scale antiretroviral therapy programmes in resource-limited settings. Fixed-dose combinations should be used as soon as formulations of proven quality and bioequivalence are available and provide programmatic advantages.

Priority actions

Phase 1

All levels

- ▶ Immediately introduce stavudine + lamivudine + nevirapine as the first-line standard regimen in health facilities that have met the minimum conditions.

The essential package of care and prevention services necessary to support antiretroviral therapy

- ▶ Trained and certified nurses or other health workers with equivalent or higher clinical experience should initiate the first-line standard regimen in people living with HIV/AIDS who meet eligibility criteria and do not have complications.
- ▶ Refer to physicians and clinical officers for initiation of therapy in children, adults with severe illness or other complications, peripheral neuropathy, hepatitis, prior antiretroviral therapy (except nevirapine for preventing mother-to-child transmission of HIV) or TB coinfection.
- ▶ Refill prescriptions for antiretroviral therapy and other treatments.

District level

- ▶ Introduce alternative first-line drugs (zidovudine and efavirenz) in district-level facilities as soon as they are available to enable substitution with other first-line antiretroviral drugs in cases of toxicity and initiation of first-line antiretroviral therapy in children and in adults with severe peripheral neuropathy, hepatitis, previous antiretroviral therapy (except nevirapine for preventing mother-to-child transmission of HIV) or TB coinfection.
- ▶ Refer problems with second-line antiretroviral therapy to the central level.

Central level

- ▶ Introduce second-line therapy at the central level as soon as possible.
- ▶ Assess possible treatment failures and initiate second-line antiretroviral therapy if needed.

Phase 2

All levels

- ▶ Complete the introduction of antiretroviral therapy as in Phase 1.

Health centre level

- ▶ In centres with experience with first-line antiretroviral therapy using stavudine + lamivudine + nevirapine in adults, introduce alternative antiretroviral therapy drugs (zidovudine and efavirenz) to enable people with TB and pregnant women to be treated.
- ▶ Introduce paediatric formulations to enable children to be treated.

District level

- ▶ Introduce second-line antiretroviral therapy regimens in centres with experience in using first-line regimens.

Recommendation 2.4. Develop chronic care capacity in health facilities concurrent with – and not as a prerequisite for – the introduction of antiretroviral therapy.

Chronic care requires a clinical team and a clinic organized within the health facility for regular follow-up. Acute care can be provided by this team or by general medical services or can be the specific focus of a health care worker. Good communication and referral between the different levels of care and care providers are important.

Priority actions

Community level

Phase 1

Identify and utilize existing community capacity to provide the following care, treatment and support services, expanding the service package progressively so that it eventually includes:

- ▶ outreach to vulnerable populations, including sex workers, men who have sex with men and injection drug users;
- ▶ HIV counselling;
- ▶ prevention, including safer sex and injection counselling, distribution of condoms, needles and syringes and preventing sexually transmitted infections;
- ▶ treatment and care for common conditions such as pain relief, diarrhoea and thrush;
- ▶ psychosocial counselling and support;
- ▶ nutritional support;
- ▶ home visits;
- ▶ links and referrals to community-based organizations and traditional practitioners; and
- ▶ referral to a health centre for more complex management and/or unexpected or serious intercurrent illness.

Phase 2

Progressively expand community capacity to provide the following care, treatment and support services:

- ▶ adherence counselling and support for chronic treatments, such as antiretroviral therapy, cotrimoxazole, TB treatment and prophylaxis and antifungal prophylaxis;
- ▶ HIV testing (community health workers);
- ▶ completion of patient records (community health workers);
- ▶ routine refilling of prescriptions (antiretroviral drugs and others held in the community pharmacy) and assistance with storage and distribution of drugs (trained community health workers and personnel from community-based organizations involved in care); and
- ▶ routine clinical monitoring (of side effects, weight, gain and symptoms).

Health centre level

Phase 1

At the time that antiretroviral therapy is introduced, the package of services should be progressively expanded to include the following:

- ▶ initiating cotrimoxazole prophylaxis;
- ▶ initiating secondary cryptococcosis prophylaxis;
- ▶ initiating and refilling isoniazid prophylaxis when TB has been excluded (with the available means);
- ▶ linking with a TB diagnostic facility to detect and manage TB;
- ▶ referring to community health workers and community-based service providers for counselling, treatment adherence support and other routine clinical management;
- ▶ supervising community level service provision;
- ▶ referring to the district level for more complex management and/or unexpected or serious intercurrent illness.

Phase 2

- ▶ The package of services should be progressively expanded to include the diagnosis and treatment of TB.

District level

The district level should provide the same services as the health centre level, plus strengthening:

- ▶ the management of severe conditions of referred patients, including hospital admission where necessary;
- ▶ the diagnosis and treatment of TB-smear-negative and extrapulmonary TB;
- ▶ drug substitution therapy for injecting drug users;
- ▶ referral to the central level for specialized care if needed;
- ▶ referral to a health centre and the community level for chronic care; and
- ▶ the supervision of and support for clinical teams and service provision at the health centre level.

Central level

The central level should provide the same services as the health centre and district levels, plus strengthening:

- ▶ the management of complex conditions (such as malignancies);
- ▶ complex diagnostic investigations (laboratory and imaging studies);
- ▶ support and referral back to lower levels of care for the management of chronic conditions; and
- ▶ the supervision of and support for district-level service provision.

The essential package of care and prevention services necessary to support antiretroviral therapy

3. LABORATORY TESTING

Laboratory monitoring of people living with HIV/AIDS is important to improve the efficacy and quality of care. However, the unavailability or expense of these tests must not prevent the immediate provision of antiretroviral therapy to those who need it.

A key underlying principle is that laboratory evaluation for toxicity should be based on presence of symptoms and not be routinely performed at any level.

Recommendation 2.5. Laboratory tests should be used according to the 2003 treatment guidelines³ (as summarized in the action points below).

Priority actions

Phase 1

Health centre level

Make the following available:

- ▶ rapid HIV antibody test;
- ▶ haemoglobin (if zidovudine used); and
- ▶ a pregnancy test (if the use of efavirenz is considered for a women who might be pregnant).

District level

In addition to the tests available at the health centre level, the following should be available:

- ▶ confirmatory HIV antibody test;
- ▶ full blood count;
- ▶ alanine aminotransferase assay;
- ▶ TB smear; and
- ▶ CD4 count (optional).

Central level

In addition to the tests available at the district level, the following should be available:

- ▶ full serum chemistry; and
- ▶ CD4 count.

Phase 2

District level

- ▶ Make CD4 cell counts more widely available.
- ▶ As technology evolves and tests become easier to perform, the virological diagnosis of HIV infection with p24 antigen tests or polymerase chain reaction should be expanded.

Central level

- ▶ Viral load monitoring should be made available at the central level. In particular, determining the viral load supports the initiation of antiretroviral therapy in infants younger than 18 months.
- ▶ Surveillance of antiretroviral resistance needs to be introduced.

4. HIV TESTING AND COUNSELLING

HIV testing and counselling must precede any kind of HIV care. The low proportion of people who actually know their HIV status (5–7% of people living with HIV/AIDS), the limited number of sites at which HIV testing and counselling are available and lack of staff to support testing and counselling – even in existing clinical and antenatal care services – limit the rate of access to HIV care and prevention services.

All HIV testing should be voluntary, confidential and undertaken only with the informed consent of the person being tested. Post-test counselling and referral to community-based support services must be provided.

Use of rapid testing technology is a key element in expanding access to antiretroviral therapy. Results from rapid test training and use show that non-medical staff can administer and interpret rapid HIV tests just as effectively as medical and laboratory personnel. If human resources are to be used optimally, the number of non-medical personnel trained to perform HIV testing and counselling must therefore be increased. The immediacy of rapid testing also means that everyone receives their test results.

³ *Scaling up antiretroviral therapy in resource-limited settings: treatment guidelines for a public health approach – 2003 revision.* Geneva, World Health Organization, 2003 (http://www.who.int/3by5/publications/documents/arv_guidelines/en, accessed 12 December 2003).

Recommendation 2.6. HIV testing and counselling should be available in health facilities at all levels and should be included in the service package of programmes that target vulnerable and difficult-to-reach populations.

Priority actions
Community level

Phase 1

- ▶ Communities should promote HIV testing and counselling as part of treatment advocacy and literacy efforts, including information about the benefits associated with learning one's HIV status and how testing and counselling services may be accessed.

Phase 2

- ▶ Use outreach and mobile-testing facilities to conduct testing among vulnerable and difficult-to-reach populations.

Health centre level

- ▶ HIV testing and counselling should be offered to:
 - ▮ pregnant women and their partners;
 - ▮ everyone with TB in countries where the national HIV prevalence exceeds 5%;
 - ▮ everyone diagnosed with a sexually transmitted infection and their sexual partners;
 - ▮ everyone attending the general medical outpatient facility; and
 - ▮ the general population on request.
- ▶ All facilities offering HIV testing and counselling must have the ability to ensure access to post-test support and access to care, including antiretroviral therapy. In most settings, this will require establishing referral networks to provide a continuum of care.

District level

The same as the community and health centre levels, plus:

- ▶ Everyone admitted to medical wards in hospital should be offered HIV testing and counselling.

- ▶ On discharge, all people living with HIV/AIDS should be referred to primary health care services and community support services.

Central level

- ▶ All testing and counselling services should be subject to routine quality assurance to ensure that care, staff training and support are maintained according to WHO-certifiable standards.

Recommendation 2.7. Simple, rapid finger-prick tests should be the tests of choice in scaling up testing and counselling services.

Priority actions

All levels

Phase 1

- ▶ Start preparing at all levels of the health system for community health workers to perform HIV testing and counselling.

Phase 2

- ▶ Train, certify and supervise community health workers and lay counsellors to perform rapid tests, interpret and give results.

District level

- ▶ Ensure the availability of laboratory-based confirmatory HIV testing.
- ▶ Supervise testing and counselling in all community, health centre and district-level facilities.

Central level

- ▶ Monitor testing and diagnostic services, undertake quality assurance and implement routine WHO-standard monitoring procedures for HIV testing and counselling.

The essential package of care and prevention services necessary to support antiretroviral therapy

5. PREVENTING HIV TRANSMISSION

Preventing HIV transmission remains the mainstay of the response to the HIV epidemic and is integral to the effort to achieve 3 by 5. Where prevention efforts are already in place, existing outreach and service delivery points provide ready access to populations needing HIV testing and counselling as well as care, treatment and support. Nevertheless, scaling up access to antiretroviral therapy also provides opportunities to reinforce prevention efforts.

HIV prevention interventions have usually targeted HIV-negative people to help them remain uninfected. Interventions that can be delivered at the community and health centre facility levels include HIV testing and counselling, promoting safer sex, diagnosing and providing care for sexually transmitted infections, preventing mother-to-child transmission and promoting harm reduction services for injecting drug users. High-impact prevention approaches target these interventions where the risk of transmission is highest – such as sex work, injecting drug use and transport networks. Populations in these settings are also likely to have the greatest need for antiretroviral therapy. Many of these populations are marginalized and have poor access to services and low rates of HIV testing; they therefore have poor knowledge of their HIV status. They need to be reached through outreach programmes that can deliver a range of high-priority services.

An increased focus on prevention among people living with HIV/AIDS is necessary to reduce HIV transmission and strengthen overall prevention efforts. Expanding access to antiretroviral therapy is key to this neglected aspect of HIV prevention because it will provide new opportunities to promote prevention among those who are already infected. HIV prevention must be an integral part of treatment and care, including counselling and treatment support.

Rapid assessment and other methods developed for prevention involve the community in designing and implementing programmes. This involvement is well established in many of the more successful community-based prevention programmes, and these efforts can be built on to extend treatment services to the same populations

Recommendation 2.8. Strengthen existing HIV prevention services while antiretroviral therapy is being introduced.

Priority actions

Community level

Phase 1

- ▶ Engage existing community-based prevention programmes in efforts to scale up antiretroviral therapy.
- ▶ Start to develop direct outreach to marginalized and vulnerable populations with limited access to facility-based services, with a particular focus on poor people, sex workers, men who have sex with men and injecting drug users. Services should emphasize HIV testing and counselling, care of sexually transmitted infections, promotion of safer sex and condom distribution and harm reduction services for injecting drug users.

Phase 2

- ▶ Strengthen peer networks of sex workers, injecting drug users, men who have sex with men, youth and others to promote the use of both prevention and care services.
- ▶ Strengthen programmes and organizations that provide HIV services to vulnerable groups.

Health centre level

Phase 1

- ▶ Key HIV prevention interventions should be included in health centre services as antiretroviral therapy is made available. This includes HIV testing and counselling, promotion of safer sex and condom distribution, syndromic management of sexually transmitted infections, preventing mother-to-child transmission of HIV and providing drug dependence treatment.
- ▶ The safety of health care procedures should be ensured through the use of universal precautions, blood safety measures, safe injections and medical waste management.
- ▶ Treatment services for sexually transmitted infections, for drug dependence, and other programmes that reach people at high risk of HIV infection, family planning services should introduce

HIV testing and counselling in their service package to improve their ability to refer their clients for treatment-related services.

Phase 2

- ▶ Postexposure prophylaxis for accidental exposure to HIV should be available.

District level

The district level should be the same as the community and health centre levels, plus:

- ▶ Prevention and antiretroviral therapy services should be closely coordinated. For example, district prevention teams should work closely with counterparts developing antiretroviral therapy services to coordinate work with vulnerable communities and populations.

Central level

The central level should be the same as the community, health centre and district levels.

Recommendation 2.9. Ensure that people living with HIV/AIDS receive key HIV prevention services and commodities.

Priority actions

Phase 1

Community level

- ▶ Start preparing for the referral of people living with HIV/AIDS to peer support and other community-based or home-based care structures that can provide support for prevention in the context of care, including dealing with stigma, handling disclosure, partner counselling and referral for testing and supplies of condoms, needles and syringes.

Health centre level

- ▶ Introduce HIV prevention services linked to antiretroviral therapy programmes, including:
 - ▮ counselling, such as sexual and reproductive health and choice, prevention and risk reduction, and support for disclosure;
 - ▮ HIV testing and counselling, including testing and counselling for sexual partners;
 - ▮ condom distribution;
 - ▮ family planning;
 - ▮ syndromic management of sexually transmitted infections; and
 - ▮ preventing mother-to-child transmission of HIV.

These services can be provided by a member of the care team during clinic visits, with sufficient supplies (such as condoms, needles and syringes provided with antiretroviral drugs), or through appropriate referrals.

District and central levels

- ▶ Where injecting drug use is a significant mode of transmission, drug substitution therapy should be introduced or strengthened to facilitate good follow-up and adherence to antiretroviral therapy.

Service delivery, human resources and training

1. BACKGROUND

To date, much of the focus on providing antiretroviral therapy to the millions of people in need has been on the medicines themselves. Service delivery and human resource deficiencies require urgent attention to ensure that affordable medicines are not only available where they are needed but delivered with quality care. Small-scale antiretroviral therapy projects have been successfully initiated in some countries, most often in the private and not-for-profit sector, supported by external resources and management. Integral to their success has been a focus on providing adequate human resources, appropriate incentives, training and attention to service delivery. These successes must now be replicated on a national level.

In many resource-limited countries, especially in sub-Saharan Africa, health services face numerous challenges. These include fiscal constraints, which have led to public sector spending limits on staff hiring, migration of qualified staff from the public to private sector or to other sectors within countries or abroad, increased levels of absenteeism because HIV/AIDS affects staff and their families, burnout, maldistribution of staff throughout the country and the various levels of facilities and low attainment of national staffing norms in the public sector, with sometimes less than half the vacancies filled. Education and training systems are often not coordinated and geared to population health needs, and there is weak managerial and stewardship capacity to steer national health services and human resources planning and management in increasingly complex mixes of public, private and nongovernmental service provision.

2. RECOMMENDATIONS AND ACTIONS

Recommendation 1. Take emergency measures to expand the supply of health workers, including treatment supporters. Authorize trained and certified nurses or other health workers with equivalent clinical experience to initiate first-line standard regimen in people who do not have complications under the supervision of physicians and/or clinical officers.

Outside health facilities, this supply of health workers will manifest in community health workers, treatment buddies, family and friends and members of the community. In clinics, community health workers should carry out most support for treatment adherence. For scaling up antiretroviral therapy, certified and supervised clinical officers and nurses can manage and follow-up most aspects of care. Further, all health care providers at all levels should be familiar with and engaged in treatment literacy and preparedness, support and monitoring.

Priority actions

Phase 1

Community level

- ▶ Train people living with HIV/AIDS and other community members to address issues such as adherence and supportive counselling. Engage groups of people living with HIV/AIDS and community-based organizations to support treatment literacy and preparedness.

Health centre level

- ▶ Train treatment teams on providing and supervising antiretroviral therapy according to national guidelines.
- ▶ Authorize trained, certified nurses and other health workers with equivalent clinical experience to initiate and follow up first-line antiretroviral therapy in adults without significant complicating conditions under the supervision of a physician or clinical officer.
- ▶ Authorize trained and certified community health workers to provide HIV testing and counselling services.

District level

- ▶ Authorize trained and certified clinical officers to manage first-line and second-line antiretroviral therapy in all types of people living with HIV/AIDS.

Central level

- ▶ Prepare and pass legislation and regulation to support the above shifts in the authorization of health care workers to initiate and manage antiretroviral therapy.

Recommendation 2. Develop and implement national emergency plans to support the training of health care workers for antiretroviral therapy and related care.

Priority actions

All levels

Phase 1

- ▶ Identify and train key managers to improve their skills and competencies for rapidly scaling up antiretroviral therapy – give special consideration to monitoring and evaluation, supply chain management, and general management skills.
- ▶ Strengthen existing pre-service institutions in identify and appropriate training trainers to provide in-service and pre-service training in antiretroviral therapy and care.
- ▶ Immediately introduce education and training for antiretroviral therapy and care in both public and private institutions that train health workers.
- ▶ Define minimum standards of training for different types of service providers and for the certification of trainers.
- ▶ Ensure the rapid procurement and distribution of teaching and learning materials in appropriate languages.
- ▶ Establish mechanisms for mentorship at all levels.

Phase 2

- ▶ Actively coordinate training activities to avoid inefficiency in investment for training.
- ▶ Seek opportunities to expand access of training institutions to information technology.
- ▶ Introduce the accreditation of appropriate training courses and programmes.

Recommendation 3. Invest in concerted efforts to strengthen providers' motivation, reduce AIDS stigma in the health sector, improve working conditions and encourage positive attitudes toward providing antiretroviral therapy and care. Provide postexposure prophylaxis and antiretroviral therapy services to all health care providers, including community health workers.

Priority actions

Community level

- ▶ Engage community leaders and community-based organizations to support community health workers, health workers and service delivery centres.

Health centre and district levels

- ▶ Improve working conditions by providing information, training, incentives, equipment and support mechanisms for health care workers to play an active role.
- ▶ Identify clear tasks and roles and enable staff to perform them.
- ▶ Actively engage staff in decision-making on issues related to service delivery.
- ▶ Review and monitor staffing ratios to determine how they influence the quality of care and staff burnout.

District and central levels

Phase 1

- ▶ Minimize delays in paying salaries.
- ▶ Actively engage all politicians and the mass media in recognizing how health care providers contribute towards HIV/AIDS care.

Phase 2

- ▶ Develop and implement strategies to correct any identified deficits in staff ratios.
- ▶ Develop effective mechanisms for supervision and feedback.
- ▶ Provide incentives and remuneration, career path development, better working and living conditions.

Service delivery, human resources and training

Recommendation 4. Coordinate investment related to human resource development and training support.

Priority actions

Central level

Phase 1

- ▮ Re-examine workforce policies (such as those limiting spending and the hiring of health care staff), including addressing externally imposed fiscal constraints.
- ▮ Prepare short-term projection of personnel supply needs to guide rational investment for scaling-up antiretroviral therapy.
- ▮ Identify the bottlenecks in personnel supply to develop the creative redistribution of tasks.

Phase 2

- ▮ Strengthen the national coordinating ability to steer international support into financial and technical assistance.
- ▮ Strengthen or develop measures to facilitate the rapid absorption of funds and resources up to the community level, and enhance accountability by using mechanisms such as expenditure tracking.

Recommendation 5. Mobilize the human resources required for scaling up antiretroviral therapy and redistribute in the areas that have the greatest need.

Priority actions

Community, health centre and district levels

Phase 1

- ▮ Identify local potential providers and treatment supporters, including volunteers, and quickly upgrade their ability to provide support for antiretroviral therapy.

Phase 2

- ▮ Start a recruitment drive and/or deploy new providers of HIV care and prevention services (such as community health workers, volunteer or paid treatment supporters, nurses and clinical officers) to fill gaps.

Central level

- ▮ Define a framework and identify resources to ensure that volunteers can be given appropriate support and supervision to promote ongoing commitment.
- ▮ Consider post-retirement contracts and recruitment drives to bring inactive workers back into service.
- ▮ Mobilize students in health services training to provide services.
- ▮ Start mobilizing other people and resources such as teachers and religious leaders for education and support.
- ▮ Strengthen and develop national mechanisms for dialogue with trade unions and professional and civil service organizations to address recruitment.

Recommendation 6. Strengthen and build partnerships among all stakeholders for the provision of antiretroviral therapy and related services.

Priority actions

Phase 1

- ▮ At each of the community, health centre, district and central levels, map out and mobilize existing capacity for antiretroviral therapy and related essential services in collaboration with known service providers and community groups to create a permanent partnership mechanism. Models for partnership structures include:
 - ▮ **the community and health centre levels: community advisory committees;**
 - ▮ **the district level: district AIDS teams; and**
 - ▮ **the central level: the national treatment advisory boards of national AIDS control programmes or country coordinating mechanisms.**

Phase 2

- ▮ Consolidate partnership mechanisms for antiretroviral therapy and related essential services by such means as:
 - ▮ establishing accountability criteria;
 - ▮ concluding memoranda of agreement and service contracts between partners;

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- ▮ establishing joint fundraising, procurement and reporting services; and
 - ▮ developing national guidelines and tools, and standard operating procedures to foster the development of HIV care partnerships.
 - ▮ Strengthen existing mechanisms for public-private partnerships.
 - ▮ Establish guidelines for including sectors other than the public sector in scaling up antiretroviral therapy.

Recommendation 7. Decentralize service delivery as much as possible.

Phase 1

- ▮ Assess existing staffing and infrastructure in health care settings that have some ability to deliver antiretroviral therapy, and upgrade it immediately to meet essential antiretroviral therapy delivery standards. This could be done through in-service training of health care workers, including community health workers.
- ▮ Assess existing staffing and infrastructure in health care settings that have initiated antiretroviral therapy delivery but exhausted existing capacity. Train lower-level health care workers to carry out routine tasks (delegation of routine tasks normally performed by physicians to clinical officers and nurses and from nurses and pharmacists to community health workers) and by decentralizing service delivery from the central to district level, from the district level to health care centres and from health centres to community health services.

Phase 2

- ▮ Develop and expand flexible delivery systems (such as mobile clinics and outreach services) to reach underserved and difficult-to-reach populations.

Management of commodities and supplies

1. BACKGROUND

Commodities for antiretroviral therapy must be fully available and accessible for antiretroviral therapy. A wide range of commodities is required, including antiretroviral drugs, HIV tests, supplies for the care of opportunistic infections and other HIV-related illnesses, palliative care (including morphine), laboratory reagents and condoms.

Achieving full access to commodities requires:

- ▶ clearly defined and well performing logistics management information systems;
- ▶ secure transport to get the commodities close to where the people receiving antiretroviral therapy live; and
- ▶ integrating antiretroviral therapy supplies into the existing medical supply system if it is secure and reliable (if not, a separate system might be necessary in the early stages of scaling up).

2. ASSUMPTIONS

The following assumptions are made.

- ▶ National policies, quality of services and products, product registration and patent issues have been addressed to support access to treatment.
- ▶ Financing for supply management is secured, including human resources, commodities, training and information, transport, storage and dispensing facilities.
- ▶ Commodities for antiretroviral therapy will be selected and procured at the central level.
- ▶ Importation taxes and fees for antiretroviral therapy supplies have been eliminated.
- ▶ Patent laws have been updated in accordance with the Doha Declaration of November 2001.
- ▶ New products, such as fixed-dose combinations, will be used as soon as formulations of proven quality and bioequivalence are prequalified and provide programmatic advantages.
- ▶ Fast-track registration for new medicines or tests and for customs clearance are in place.

- ▶ Organizational accountability for supply chain management is in place. The supply chain will be monitored at the central level.
- ▶ Operations research will be built in to track how the supply system influences outcomes.

3. RECOMMENDATIONS AND ACTIONS

Recommendation 1. Simplify supply systems to support access to antiretroviral therapy.

Priority actions

Phase 1

- ▶ Limit the number of different formulations and items moving in the supply chain by standardizing the treatment regimens and diagnostics used.
- ▶ Supply drugs in either fixed-dose combinations or in blister packs whenever possible. In addition, consider using pill organizers (pill boxes) for dispensing to help the people receiving therapy in maintaining adherence.
- ▶ Keep inventory systems and documentation as simple as possible and integrate as far as possible with existing systems.
- ▶ Multidisciplinary management teams must work to exchange vital information between supply managers and clinicians through all levels of the system.

Recommendation 2. In Phase 1, use a “push” system to introduce antiretroviral therapy in health centres and district hospitals.

In a push system, the central supply unit provides supplies as standard kits, supplied at fixed intervals. This “push” system would use starter kits to jump-start activities in health centre and district-level facilities. These kits should be designed to treat a set number of people (such as 10–25) for a set period of time (such as 6 months). In addition to the antiretroviral drugs needed, a kit would contain all necessary manuals and flow-charts, education materials, HIV tests for 100–200 people, a fixed amount of antiretroviral drugs for preventing the mother-to-child transmission of HIV, a postexposure prophylaxis kit and a selected supply of drugs for opportunistic infections.

When the health care workers are being trained and/or an anti-retroviral therapy site accredited, the kit would be demonstrated and then left at the therapy site.

Health centre level

- ▶ Stocks would be subsequently replenished from the supply centre at set times according to how many people are enrolled.
- ▶ In this system, a monthly limit would be set on the number of new people that can be enrolled in the antiretroviral therapy programme to allow systems to develop and health workers to get used to treatment regimens.

District level

- ▶ Use expanded starter packs, which contain alternative first-line drugs to cover the treatment of people with TB, pregnant women and children.
- ▶ Help first-level facilities to ensure readiness for supply management.
- ▶ Act (where required) as the distribution centre for kit supplies for first-level care.
- ▶ Ensure accurate estimates of the numbers of people to be enrolled in therapy, based on eligibility criteria, the availability of HIV testing, the number of existing therapy recipients already in follow-up and HIV prevalence estimates, to determine the total demand for commodities.
- ▶ Forecast short-term demand and planned build-up of the numbers of people receiving therapy.

Central level

- ▶ Develop and provide starter packs for all levels and services according to treatment guidelines and protocols.
- ▶ For first-line regimens, select only products not needing refrigeration unless a cold chain can be guaranteed.
- ▶ Provide guidelines for managing supplies for districts and first-line facilities.
- ▶ Specify the maximum number of people to be recruited to therapy at each level per month.
- ▶ Ensure continuous training and supervision of staff.
- ▶ Ensure the availability of second-line antiretroviral drugs.

Recommendation 3. In Phase 2, move to a “pull” supply system.

In a “pull” system, health care or dispensing facilities must order supplies from one or more central-level supplier.

Health centre level

- ▶ Expand the supply to treat children and provide second-line treatment.
- ▶ Communicate the changing needs to the central supply level.

District level

- ▶ Provide training, supervision, distribution and treatment for more centres, including those that focus especially on children, people with TB and pregnant women.
- ▶ Communicate the changing needs to the central supply level.

Central level

- ▶ Ensure continuing, uninterrupted supplies of packs of medicines.

Recommendation 4. Enrolment of new therapy recipients during scale-up must not outpace resource mobilization for sustainable drugs and testing and other necessary commodity supplies. People already receiving therapy have priority for new supplies of drugs over people waiting to start.

Priority actions

Phase 1

For dispensing units at all levels

Reserved and marked stocks should be set aside for continued treatment of existing therapy recipients. Buffer stocks should be maintained at a minimum supply of 3–6 months.

Community level

- ▶ Support therapy recipients in accessing new supplies before the supply in their possession runs out.

Health centre level

Management of commodities and supplies

- ▶ Use standardized inventory control systems – patient register, ledgers, stock cards, prescriptions and dispensing register – and use them to trigger timely re-supply.

District level

- ▶ Provide drugs for therapy recipients in the district and ensure that supplies are transported to the health centre level.
- ▶ Assume responsibility for training health centre level providers on how to manage supplies.
- ▶ Forecast the commodities needed for treating children, pregnant women and people with TB for the whole district.

Central level

- ▶ The central level should take responsibility for the overall quantification, procurement, quality control of received drugs and coordination of financing, including:
 - | standardizing supply procedures for antiretroviral and laboratory supplies;
 - | carrying out operations research and, monitoring and supervising distribution and service delivery at all levels;
 - | monitoring the use of drugs and enrolment of therapy recipients and setting monthly limits on enrolment; and
 - | defining reorder levels, reserve stocks and lead times (this must be responsive and flexible in Phase 1 to deal with uncertainties or unexpected changes in treatment uptake).

Phase 2

Community level

- ▶ Assess whether members of the community are not getting access to antiretroviral drugs and the reasons why, and take corrective action.

Health centre level

- ▶ Expand the product range with paediatric formulations and alternative first-line drugs and introduce second-line drugs for maintaining second-line treatment initiated at the district level.

District level

- ▶ Conduct operations research.

- ▶ Districts collaborate and network to exchange experience.

Central level

- ▶ Use morbidity and consumption figures from districts to forecast and quantify future supply needs.

Recommendation 5. Ensure the security of commodities to minimize waste and costs.

Priority actions

Phase 1

Community level

- ▶ Identify problems with the use and abuse of supplies in the community.

Health centre level

- ▶ Use an inventory control system to identify losses of supplies.
- ▶ Identify sources of waste.
- ▶ Monitor expiry dates and request the redistribution of excess stock.

District level

- ▶ In addition to storage for district treatment, ensure secure storage for the redistribution of first-level supplies.
- ▶ Supervise commodity supply at the health centre level (extra staff and training may be needed).
- ▶ Ensure adequate storage conditions (secure storage space, inventory management, accountability, monitoring and a supervision system) before releasing starter packs into health centres.

Central level

- ▶ Monitor and analyse data from all levels to ensure that the numbers of people receiving therapy and the use of commodities correspond.
- ▶ Investigate discrepancies and take disciplinary action in cases of misuse or diversion.
- ▶ Ensure adequate storage conditions (secure storage space, inventory management, accountability, monitoring and a supervision system) before releasing starter packs at the district level.

Phase 2

At all levels

- ▶ Review security and storage within the whole distribution system; identify gaps and problems; and revise systems if necessary.
- ▶ Expand secure storage space to keep pace with programme expansion.
- ▶ Expand cold-chain capacity to keep pace with programme expansion.

Central level

- ▶ Develop systems of identifying people receiving therapy to prevent enrolment in two or more centres.
- ▶ Develop and implement guidelines to ensure the safety of community members or groups holding supplies of antiretroviral drugs and the supplies they hold.

Recommendation 6. Establish good dispensing practices to ensure the rational use of drugs.

Priority actions

Phase 1

Health centre level

- ▶ Train therapy recipients on antiretroviral use and ensure their commitment to adherence before antiretroviral therapy is initiated.
- ▶ Provide therapy recipients with an initial supply for a short period, such as 2 weeks, and then continue with monthly or longer supplies when they demonstrate the ability to adhere to the treatment regimen.
- ▶ As part of the dispensing process, oral and written drug information should be given to everyone receiving therapy (in language they understand).

District level

- ▶ Make a specific person responsible for dispensing antiretroviral drugs.
- ▶ Start planning the creation of a drug information centre to disseminate information to health care workers, to therapy recipients and to communities.

Central level

- ▶ Start developing pharmacovigilance systems for monitoring the effects of drugs on the recipients.
- ▶ Start designing and providing user information leaflets for all levels of health care, with appropriate language and content for the user of the information.
- ▶ Build continuous staff training into the supply management system, to keep staff up to date and accommodate for turnover of staff.
- ▶ Continue and complete Phase 1 priority activities.

Recommendation 7. Collaborate with the private sector to ensure the quality of commodities and care.

Priority actions

Phases 1 and 2

District and central levels

- ▶ Assess the ability and the willingness of private sector actors, including for-profit, not-for-profit and corporate organizations, to collaborate in managing HIV commodities and supplies.
- ▶ Outsource specific supply chain functions if this can improve performance. Monitor the success of public-private collaboration via performance indicators built into outsourcing contracts, and enforce sanctions for failure to reach targets.
- ▶ Share the lessons learned in different countries on public-private interactions for improving supply.

Strategic information

1. BACKGROUND

Strategic information for scaling up the provision of antiretroviral therapy includes surveillance, monitoring and evaluation and operations research. In addition, management information on the costs of service delivery can contribute to assessing the cost of achieving 3 by 5 at all levels of care delivery. Data from other sources, such as hospitalization rates, bed occupancy and mortality, can be used to track the impact of 3 by 5 roll-out on service needs and life expectancy. Units of analysis include the community, health centre, district and central levels.

The following cross-cutting principles should govern the generation and use of strategic information at all levels of care delivery and programming.

- ▶ Strategic information systems designed to meet the requirements for scaling up antiretroviral therapy should complement existing information systems.
- ▶ Information should be collected from all sites providing antiretroviral therapy, including public, private and nongovernmental organizations and workplace clinics.
- ▶ Facility-based data collection and monitoring should contribute directly to care outcomes by improving the clinical management of individual therapy recipients.
- ▶ Data gathering and analysis should be flexible, adaptable and acceptable to those implicated.
- ▶ Data collection should be simplified, standardized and given high priority to facilitate the efficient scale-up of care provision.
- ▶ Capacity should be built and incentives introduced to collect data in an appropriate form at the local levels and to interpret and disseminate aggregate findings at all levels.
- ▶ A culture of strategic information sharing (feedback and knowledge translation) should be strongly supported.
- ▶ The confidentiality of all health information should be protected.
- ▶ Individual patient records using unique personal identifiers are critical to both the quality of care and assessing progress towards achieving 3 by 5.
- ▶ People living with HIV/AIDS should be involved at all levels of strategic information generation and use.

2. COMMUNITY-LEVEL RECOMMENDATIONS

Recommendation 1. Collect information on supply systems to support access to antiretroviral therapy.

Knowing the extent to which communities are prepared and willing to support care services will allow districts to set priorities among health centres for scaling up antiretroviral therapy and to choose health centres to make plans for scaling up that are acceptable and that appropriately involve engaged communities.

Priority actions

Phase 1

- ▶ Collect data on the number of community-based organizations already active in HIV, of community health care workers and of associations of people living with HIV/AIDS.
- ▶ Collect data on the number of community structures, key organizations and opinion leaders critical to catalysing support for treatment that are willing to become engaged.
- ▶ Designate a person or organization from the health centre or the community to perform this assessment now and in the future.
- ▶ Standardize the structure (content and process) of this assessment across districts.

Indicator

1. Number of health centres that have completed these assessments

Recommendation 2. Access training and support needs of communities to provide support services for antiretroviral therapy.

Systematic training of community members will ensure that skill sets complement the care provided at the health centre.

Priority actions

Phase 1

- ▶ Use data from assessments to develop community training plans and inform the implementation of these plans.
- ▶ Designate a group that includes people from the district, health centre, community-based organizations and nongovernmental organizations to develop and implement training.

- ▶ Monitor progress in establishing of a community advisory committees for each health centre.

Indicator

1. Number of health centre catchment areas with community training plans
2. Number of support groups for people living with HIV/AIDS and post-test clubs established

Phase 2

- ▶ Collect data on the number of community people trained and providing services per health centre. Use the designated person or organization from the health centre or community for this activity.

Indicator

1. Number of community people trained to provide support for antiretroviral therapy
2. Number of trained community people who are actually providing support for antiretroviral therapy

3. RECOMMENDATIONS FOR HEALTH CENTRES AND ANTIRETROVIRAL THERAPY SITES

Recommendation 3. Maintain confidential and individual patient records at each antiretroviral therapy site, using a unique personal identifier to link information.

Recommendation 4. Use standardized patient records and data collection forms developed centrally for use across districts.

Confidential and individual patient records are essential for good quality continuous care. Unique personal identifiers help ensure the continuity of all services across place and time and facilitate monitoring of the quality of care. Standardized forms reduce the burden of providing information, improve care by assisting communication between providers and permit the aggregation of data, cross-site comparison and other analyses. Monitoring uptake of services allows progress toward achieving the 3 by 5 target to be quantified.

Priority actions

Phase 1

- ▶ Ensure that care providers have been trained in the use of forms as part of their antiretroviral therapy training prior to initiating care.
- ▶ Ensure that all other data collectors have been trained in using data collection forms (such as pharmacy forms, registration forms, laboratory forms, patient identification card, aggregate service information forms and individual patient records).

Indicators

1. Number of health centres or antiretroviral therapy sites that have care providers trained in the use of patient record forms
2. Number of health centres or antiretroviral therapy sites that have ancillary staff trained in the use of data collection forms

Recommendation 5. Monitor regularly the uptake of HIV testing, care provision, antiretroviral drug uptake and other key indicators.

Monitoring the uptake of services allows progress towards achieving the 3 by 5 target to be quantified.

Priority actions

Phase 1 – testing and care

- ▶ Record and report the number of HIV tests performed during a specified time period.
- ▶ Record and report the number of HIV tests performed during a specified time period for which the clients received results.
- ▶ Record and report the number of positive HIV test results during a specified time period.
- ▶ Record and report the number of people living with HIV/AIDS clinically assessed during a specified time period.
- ▶ Record and report the number of people living with HIV/AIDS who are clinically assessed and enter care.

Strategic information

Indicators

1. Number of HIV tests conducted
2. Number of positive HIV test results
3. Number of HIV test results received by clients
4. Number of people living with HIV/AIDS clinically assessed
5. Number of clinically assessed people living with HIV/AIDS who enter care

Phase 1 – antiretroviral therapy provision

- ▶ Record and report the number of people initiating antiretroviral therapy during a specified time period.
- ▶ Record and report the number of people who report having been on antiretroviral therapy prior to the specified time period (people currently receiving antiretroviral therapy).
- ▶ Record and report the number of people lost to follow-up or death during the specified time period.
- ▶ Record and report the number of people referred to district or higher level for assessment for second-line treatment.
- ▶ Record the reasons that people discontinue antiretroviral therapy (not routinely reported but could be examined by a special study or operations research).
- ▶ Record the self-reported adherence and pill counts at each visit for people continuing on antiretroviral therapy

Indicators

1. Number of people receiving antiretroviral therapy at the beginning of a specified time period
2. Number of people starting antiretroviral therapy during a specified time period
3. Number of people discontinuing antiretroviral therapy during a specified time period
4. Number of people referred to a higher level for second-line treatment

Phase 2

- ▶ Expand data collection from Phase 1 to more sites.
- ▶ Pilot electronic record-keeping systems developed at the national level.
- ▶ Enhance the ability to perform analysis at the level of health centres or antiretroviral therapy sites.

Indicators

In addition to those in Phase 1, others will be developed, including the following.

1. Number of health centres with the capability for simple analysis of health centres or antiretroviral therapy sites
2. Number of sites piloting electronic patient records and tracking mechanisms such as smart cards

4. DISTRICT-LEVEL RECOMMENDATIONS

Recommendation 6. Plan, monitor, evaluate and provide feedback on activities for scaling up antiretroviral therapy within each district's catchment area that include training, HIV testing, access and use of care, antiretroviral therapy and drug supply.

The district level is already responsible for health planning and would allow the quickest response to programmatic needs at the level of service. District-level planning permits integration with other services such as TB and sexually transmitted disease services and facilitates harmonization and integration with other health management information systems that may be in place.

Priority actions

Phase 1

- ▶ Obtain district-level estimates of HIV prevalence, two-year HIV mortality and 3 by 5 treatment targets by gender.
- ▶ Designate a person (information specialist) at the district level capable of analysing and interpreting data related to antiretroviral therapy.
- ▶ Collect data from all health centre and antiretroviral therapy site providers in the public, private, business and nongovernmental organization sectors.
- ▶ Disseminate strategic information (3 by 5 targets, training plans, number of people HIV tested and the number of people receiving care) to community, health centre and antiretroviral therapy site providers and district leaders and stakeholders (knowledge translation).
- ▶ Report all these activities to the central level.

Indicators

1. Number of districts with estimates of HIV prevalence, two-year HIV mortality and 3 by 5 treatment targets by gender
2. Number of districts with a designated person to analyse and interpret data
3. Proportion of health centre and antiretroviral therapy site providers reporting data to the district
4. Number of health centres and antiretroviral therapy sites completing Phase 1 planning and training activities
5. Number of reports given to communities, health centre and antiretroviral therapy site providers, district leaders and stakeholders from the district

Phase 2

- ▶ Analyse progress toward targets geographically (by community and health centre) and by gender, age, socioeconomic status and health centre and antiretroviral therapy provider.
- ▶ Analyse trends in all indicators, such as uptake, adherence, testing rates, gender and discontinuation of antiretroviral therapy.
- ▶ Analyse differences according to health centre and antiretroviral therapy provider and site in prescribing, adherence and clinical outcomes over time.
- ▶ Provide feedback based on these analyses to communities, providers and district-level planners to allow programme adjustments and further scale-up.
- ▶ Report these findings to the central level.

Indicators

1. Number of districts that have regularly performed these comprehensive analyses, provided feedback to stakeholders and reported nationally

5. CENTRAL-LEVEL RECOMMENDATIONS

Recommendation 7. Develop a harmonized, simple, standard national system for monitoring and evaluating antiretroviral therapy agreed upon by the national government in collaboration with donors and implementers to be used at all levels and linked to the overall national system of monitoring and evaluation.

Non-harmonized complex monitoring and evaluation systems create duplication of efforts, non-comparable data and an inability to track progress towards achieving the 3 by 5 target.

Priority actions

Phase 1

- ▶ Establish the priorities for a national strategic information system including surveillance, monitoring and evaluation, and operations research related to the national 3 by 5 initiative by convening all stakeholders and obtaining consensus.
- ▶ Develop a national strategic information system.
- ▶ Devise a national patient linkage system that protects confidentiality and provides for continuity of care.
- ▶ Develop simple, standardized self-explanatory forms for patient care records and data collection at each antiretroviral therapy site across the country. Where possible, records should be comprehensive and integrated with general patient records. Basic patient records from IMAI (integrated management of adolescent and adult illness) programmes are acceptable in Phase 1.
- ▶ Develop estimates of HIV prevalence, two-year HIV mortality and 3 by 5 treatment targets by gender using internationally recognized methods.
- ▶ Monitor drug procurement and supply management outcomes.

Indicators

1. Priorities for a national strategic information system agreed on
2. A national strategic information system developed
3. Standardized forms developed and disseminated to providers

Strategic information

4. Training for data collection and use of forms developed and implemented
5. Number of districts with HIV estimates and 3 by 5 targets
6. Percentage of people living with HIV/AIDS assessed and prescribed antiretroviral therapy drugs who receive medication within one month
7. Percentage of central, district and dispensing site drug storage locations whose stock cards for antiretroviral therapy drugs are up to date and accurate upon review every six months
8. Percentage of central, district and dispensing site drug storage locations that do not experience antiretroviral therapy drug stockouts each year

Phase 2

- ▶ Develop an electronic system for individual patient records and generating unique personal identifiers.
- ▶ Continue revising training modules.
- ▶ Analyse data for district comparisons and trends.
- ▶ Revise strategies based on the findings.
- ▶ Monitor antiretroviral drug resistance.
- ▶ Monitor the cost of providing care at different levels in the system.
- ▶ Conduct central or national analysis of how the national 3 by 5 initiative is influencing hospitalization rates, bed occupancy, mortality, TB rates and other factors.

Indicators

1. An electronic system for individual patient records and generating unique personal identifiers developed and piloted
2. Number of training modules reviewed and revised
3. District comparisons and trends analysed, findings disseminated to relevant stakeholders and strategies revised based on the findings
4. Number of treatment-naïve people living with HIV/AIDS assessed for genotypic drug resistance and the resistance rate reported
5. Number of people completing 2 years of treatment with genotypic resistance (sample size to be determined)
6. Cost of providing care determined at different levels in the system
7. Impact of the national 3 by 5 initiative on hospitalization rates, bed occupancy, mortality, TB rates and other factors

Annex 1

List of participants

Participants in the WHO/UNAIDS International Consensus Meeting on Technical and Operational Recommendations for Emergency Scaling-up of Antiretroviral Therapy in Resource-Limited Settings, 18–21 November 2003, Lusaka, Zambia

Orvill Adams

World Health Organization

EIP/OSD

SWITZERLAND

John Adungosi

Family Health International

KENYA

Michael Angaga

Network of African People Living with HIV/AIDS (NAP+)

KENYA

Chukwuemeka Anyamele

Centre for the Right to Healths

NIGERIA

Stella Anyangwe

Office of the WHO

Representative for Zambia

ZAMBIA

Magda Awases

WHO Regional

Office for Africa

CONGO

Mazuwa Banda

World Health Organization

HTM/HIV

SWITZERLAND

Wilbert Bannenberg

HERA

NETHERLANDS

Solomon Benatar

University of Cape Town

SOUTH AFRICA

George Brown

Rockefeller Foundation

USA

Alexandra Calmy

Médecins Sans Frontières

SWITZERLAND

Henry Chang

AHF Global Immunity

NETHERLANDS

Salome Charalambous

Aurum Health Research

SOUTH AFRICA

Augustine Chella

Zambian Network of People Living with HIV/AIDS

ZAMBIA

Lastone Chitembo

University Teaching Hospital

ZAMBIA

Marta Darder

Médecins Sans Frontières South Africa

SOUTH AFRICA

Ernest Darkoh

BroadReach Healthcare

BOTSWANA

John Darrah

Rockefeller Foundation

USA

Isabelle De Zoysa

World Health Organization

HTM/HIV/PRV

SWITZERLAND

Annex 1

List of participants

Mandeep Dhaliwal

International HIV/AIDS Alliance

UNITED KINGDOM

Teresa Diaz

Global AIDS Program

Centers for Disease Control and Prevention

USA

Julia Downing

Mildmay International Study Centre

UGANDA

Norbert Dreesch

World Health Organization

EIP/OSD

SWITZERLAND

Nomfundo Wythnia Dubula

Treatment Action Campaign

SOUTH AFRICA

Nicolas Durier

Médecins Sans Frontières

THAILAND

Tessa Tan Torres Edeger

World Health Organization

EIP/ADGO

SWITZERLAND

Wafaa El-Sadr

Columbia University (MTCT-Plus Initiative)

USA

Tito Fachi

Zambia Red Cross

ZAMBIA

Masami Fujita

WHO Regional Office for the Western Pacific,

PHILIPPINES

Eric Goemaere

Médecins Sans Frontières South Africa

SOUTH AFRICA

Valdilea Gonsalves Veloso dos Santos

Ministry of Health

BRAZIL

Sandy Gove

World Health Organization

CDS/CPE

SWITZERLAND

Peter Graaff,

World Health Organization

EDM/PAR

SWITZERLAND

Carolyn Green

Consultant

UNITED KINGDOM

Ian Grubb

World Health Organization

HTM/HIV

SWITZERLAND

Gianni Guidotti

Mozambique Dream Project

Sant'Egidio

ITALY

Catherine Hankins

UNAIDS

SWITZERLAND

Oliver Hazemba

MSH (Management Sciences for Health)

ZAMBIA

Mark Heywood

AIDS Law Project

University of the Witwatersrand

SOUTH AFRICA

Lisa Hirschhorn

JSI Research and Training Institute

USA

Alec Irwin

World Health Organization

EIP/ADGO

SWITZERLAND

Jantine Jacobi

UNAIDS

UKRAINE

Stephen Jarrett

UNICEF

USA

Violet Kabwe

Zambia Integrated Health Programme (ZIHP)

ZAMBIA

Rigobert Aka Kakou

University Teaching Hospital de Treichville

CÔTE D'IVOIRE

Francis Chisaka Kasolo

University Teaching Hospital

ZAMBIA

Toby Kasper

Global Fund to Fight AIDS

Tuberculosis and Malaria

SWITZERLAND

Elly Katabira

Makerere University

UGANDA

Cissy Kityo

Joint Clinical Research Centre (JCRC)

UGANDA

Herve Villard Lamah

RIP+ (Réseau ivoirien des personnes vivant avec le VIH)

CÔTE D'IVOIRE

Wesler Lambert

Partners in Health

HAITI

Joep Lange

University of Amsterdam Academic Medical Centre

NETHERLANDS

Elizabeth Madraa

National AIDS Control Programme

UGANDA

José Ricardo Marins

STD/AIDS Program

Ministry of Health

BRAZIL

Jane Masiga

MEDS (Mission of Essential Drugs and Supplies)

KENYA

Craig McClure,

World Health Organization

HTM/HIV

SWITZERLAND

Nicolas Meda

Centre Muraz

BURKINA FASO

Julienne Meno

Hôpital Laquintinie

CAMEROON

Zandile Mokgatle

Harmony Mines

SOUTH AFRICA

Helene Moller

UNICEF

DENMARK

Dominic Montagu

Institute of Global Health

USA

Solomon Mutetwa

AIDS Empowerment &
Treatment International (AIDSETI)

ZIMBABWE

Annex 1

List of participants

Christine Nabiryo

The AIDS Service Organization

UGANDA

Namposya Nampanya-Serpell

UNAIDS

SWITZERLAND

Buhle Ncube

WHO Regional Office for Africa

ZIMBABWE

Marilyn Noguera

JSI/Deliver

USA

Morolake Nwagwu

Pan-African Treatment Activists Movement

NIGERIA

Amolo Okero

World Health Organization

HTM/HIV

SWITZERLAND

Ariel Pablos-Mendez

Rockefeller Foundation

USA

Rik Peepkorn

UNAIDS

SWITZERLAND

Jorge Pérez

Instituto de Medicina Tropical Pedro Kouri

CUBA

Jos Perriëns

World Health Organization

HTM/HIV

SWITZERLAND

Sam Phiri

Lighthouse Project

MALAWI

Anil Purohit

François-Xavier Bagnoud (FXB)-US Foundation

USA

Miriam Rabkin

Columbia University (MTCT-Plus Initiative)

USA

Françoise Renaud-Théry

UNAIDS

SWITZERLAND

Jean-Loup Rey

ESTHER (Ensemble pour une solidarité thérapeutique hospitalière en réseau)

FRANCE

Fabio Scano

World Health Organization

HTM/STB

SWITZERLAND

Kathy Shapiro

World Health Organization

HTM/HIV

SWITZERLAND

Marks Shields

Global AIDS Program

Centers for Disease Control and Prevention

ZAMBIA

Alex Simwanza

National AIDS Council

ZAMBIA

Hayet Souissi

World Health Organization

HTM/HIV

SWITZERLAND

Catherine Sozi

UNAIDS

SOUTH AFRICA

Larissa Stabinski

United Nations Millenium Development Project
HIV/AIDS Task Force

USA

Kanyanta Sunkutu

Office of the WHO Representative for Zambia

ZAMBIA

Donald Sutherland

World Health Organization

HTM/HIV

SWITZERLAND

Helen Tata

World Health Organization

HTP/EDM

SWITZERLAND

Ogori Taylor

Office of the WHO Representative for Nigeria

NIGERIA

Marco Vitoria

World Health Organization

HTM/HIV

SWITZERLAND

Mean Chhi Vun

National Centre for HIV/AIDS

Dermatology and STDs

CAMBODIA

Edwina Yen

Pan American Health Organization and WHO

Regional Office for the Americas

USA

Melanie Zipperer

World Health Organization

HTM/HIV

SWITZERLAND

Winston Zulu

NZP+ (Network of Zambian People
Living with HIV/AIDS)

ZAMBIA

José Zuniga

International Association of Physicians in AIDS Care

USA

Annex 2

Preparatory working groups

These groups worked in September and October 2003.

Working Group 1: People living with HIV/AIDS and communities as leaders in antiretroviral therapy

Mandeep Dhaliwal

International HIV/AIDS Alliance

UNITED KINGDOM (Chair)

Morolake Nwagwu

Pan-African Treatment Activists Movement

NIGERIA (Chair)

Ian Grubb

World Health Organization

HTM/HIV

SWITZERLAND (Focal Point)

Solomon Benatar

University of Cape Town

SOUTH AFRICA

Shalini Bharah

PISF

INDIA

Augustine Chella

Zambian Network of People Living with HIV/AIDS

ZAMBIA

Alex Coutinho

The AIDS Service Organization

UGANDA

Tito Fachi

Zambia Red Cross

ZAMBIA

Julian Fleet

UNAIDS

SWITZERLAND

Mark Heywood

AIDS Law Project

University of the Witwatersrand

SOUTH AFRICA

Evelyn Isaacs

WHO Regional Office for Africa

ZIMBABWE

Jantine Jacobi

UNAIDS

UKRAINE

Quarraisha Abdool Karim

University of Natal

SOUTH AFRICA

Herve Villard Lamah

RIP+ (Réseau ivoirien des personnes vivant avec le VIH)

CÔTE D'IVOIRE

Rafael Mazin

Pan American Health Organization and WHO Regional Office for the Americas

USA

Craig McClure

World Health Organization

HTM/HIV

SWITZERLAND

Christine Nabiryo

The AIDS Support Organization

UGANDA

Jeanne Gapiya Nizonyima

ANSS (Association Nationale de soutien aux Séropositifs)

BURUNDI

Anil Purohit

François-Xavier Bagnoud (FXB)-US Foundation

USA

Annex 2

Preparatory working groups

Working Group 2: The Essential Package of Care and Prevention Services Necessary to Support antiretroviral therapy

Nicolas Durier
Médecins Sans Frontières
THAILAND (Chair)

José Ricardo Marins
STD/AIDS Program
Ministry of Health
BRAZIL (Chair)

Marco Vitoria
World Health Organization
HTM/HIV
SWITZERLAND (Focal Point)

Salome Charalambous
Aurum Health Research
SOUTH AFRICA

Anupong Chitwarakorn
Ministry of Health
HIV/AIDS/STI
THAILAND

Isabelle De Zoysa
World Health Organization
HTM/HIV/PRV
SWITZERLAND

Aylur Kailasam Ganesh
YR Gaitonde Centre for AIDS Research and Education
INDIA

Valdilea Gonsalves Veloso dos Santos
Ministry of Health
BRAZIL

Sandy Gove
World Health Organization
CDS/CPE
SWITZERLAND

Gianni Guidotti
Mozambique Dream Project
Sant'Egidio
ITALY

Rigobert Aka Kakou
University Teaching Hospital de Treichville
CÔTE D'IVOIRE

Wesler Lambert
Partners in Health
HAITI

Joia Mukerjee
Partners in Health
USA

Jorge Pérez
Instituto de Medicina Tropical Pedro Kouri
CUBA

Miriam Rabkin
Columbia University (MTCT-Plus Initiative)
USA

Fabio Scano
World Health Organization
HTM/STB
SWITZERLAND

Catherine Sozi
UNAIDS
SOUTH AFRICA

Kanyanta Sunkutu
Office of the WHO Representative for Zambia
ZAMBIA

Working Group 3: Service Delivery, Human Resources and Training

John Adungosi

Family Health International

KENYA (Chair)

Elly Katabira

Makerere University

UGANDA (Chair)

Orvill Adams

World Health Organization

EIP/OSD

SWITZERLAND (Focal Point)

Magda Awases

WHO Regional Office for Africa

CONGO

Mazuwa Banda

World Health Organization

HTM/HIV

SWITZERLAND

Alexandra Calmy

Médecins Sans Frontières

SWITZERLAND

Anyamele Chukwuemeka

NIGERIA

Julia Downing

Mildmay International Study Centre

UGANDA

Norbert Dreesch

World Health Organization

EIP/OSD

SWITZERLAND

Nomfundo Wythnia Dubula

Treatment Action Campaign

SOUTH AFRICA

Eric Goemaere

Médecins Sans Frontières South Africa

SOUTH AFRICA

Sandy Gove

World Health Organization

CDS/CPE

SWITZERLAND

Gulin Gedik

World Health Organization

EIP/OSD

SWITZERLAND

Lisa Hirschorn

JSI Research and Training

USA

Elizabeth Madraa

National AIDS Control Program

UGANDA

Fujita Masami

WHO Regional Office for the Western Pacific

PHILIPPINES

Zandile Mokgatle

Harmony Mines

SOUTH AFRICA

Sipokazi Mtathi

Treatment Action Campaign

SOUTH AFRICA

Virginia O'Dell

World Health Organization

EIP/OSD

SWITZERLAND

Rik Peeperkorn

UNAIDS

SWITZERLAND

Papa Salif Sow

University of Dakar

SENEGAL

Annex 2

Preparatory working groups

Mean Chhi Vun

National Centre for HIV/AIDS
Dermatology and STDs
CAMBODIA

Edwina Yen

Pan American Health Organization and
WHO Regional Office for the Americas
USA

Fox Mayada Youssef

World Health Organization
HTM/HIV
SWITZERLAND

Working Group 4: Management of Commodities and Supplies

Stephen Jarett

UNICEF
USA (Chair)

Jane Masiga

MEDS (Mission of Essential Drugs and Supplies)
KENYA (Chair)

Helen Tata

World Health Organization
HTP/EDM
SWITZERLAND (Focal Point)

Guido Bakker

Global Fund to Fight AIDS
Tuberculosis and Malaria
SWITZERLAND

Wilbert Bannenberg

HERA
NETHERLANDS

Yasmin Chandani

JSI Deliver
USA

Marta Dardar

Médecins Sans Frontières South Africa
SOUTH AFRICA

Carolyn Green

Consultant
UNITED KINGDOM

Cissy Kityo

Joint Clinical Research Centre (JCRC)
UGANDA

Marie Josée Mbuzenakamwe

ANSS (Association Nationale de soutien
aux Séropositifs)
BURUNDI

Julienne Meno

Hôpital Laquintinie
CAMEROON

Marilyn Noguera

JSI/Deliver
USA

Amolo Okero

World Health Organization
HTM/HIV
SWITZERLAND

Françoise Renaud-Théry

UNAIDS
SWITZERLAND

Ogori Taylor

Office of the WHO Representative for Nigeria
NIGERIA

Working Group 5: Strategic Information

Catherine Hankins

UNAIDS

SWITZERLAND (Chair)

Meda Nicolas

Ministry of Health

BURKINA FASO (Chair)

Donald Sutherland

World Health Organization

HTM/HIV

SWITZERLAND (Focal Point)

Silvia Bertagnolio

World Health Organization

HTM/HIV/SRM

SWITZERLAND

Theresa Diaz

Global AIDS Program

Centers for Disease Control and Prevention

USA

Wafaa El-Sadr

Columbia University (MTCT-Plus Initiative)

USA

Owen Kaluwa

WHO Regional Office for Africa

ZIMBABWE

Kevin O'Reilly

World Health Organization

HIV/SRM

SWITZERLAND

Sam Phiri

Lighthouse Project

MALAWI

Marks Shields

Global AIDS Program

Centers for Disease Control and Prevention

ZAMBIA

Larissa Stabinski

United Nations Millenium Development Project

HIV/AIDS Task Force

USA



For further information, contact:
WORLD HEALTH ORGANIZATION
Department of HIV/AIDS
20, avenue Appia – CH-1211 Geneva 27 – SWITZERLAND
E-mail: hiv-aids@who.int – <http://www.who.int/hiv/en>

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