

EVALUATION OF WHO'S CONTRIBUTION TO "3 BY 5"

Main report

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Foreword from the "3 by 5" Evaluation Steering Committee

In December 2003, WHO and UNAIDS launched a plan to treat 3 million people living with HIV/AIDS in low- and middle-income countries by the end of 2005. The "3 by 5" strategy was intended to mobilize the international community to address the global inequity in access to antiretroviral therapy. It was endorsed by all 10 UNAIDS cosponsoring agencies and WHO Member States in 2004, and WHO undertook an ambitious, two-year programme of work to help countries scale up antiretroviral therapy as part of comprehensive national responses to the HIV/AIDS epidemic. The Steering Committee recognises the commitment and leadership of the late Dr Lee Jong Wook, then Director General of the WHO, in this global response.

Between July 2005 and March 2006 an independent evaluation, commissioned by the Canadian International Development Agency (CIDA) and WHO, was undertaken to review the accomplishments and lessons learnt by WHO during implementation of the "3 by 5" initiative.

An Evaluation Team was appointed by WHO in July 2005. At the same time, a Steering Committee was established to serve as an advisory body to the Evaluation Team and WHO at essential phases of the evaluation. The committee comprised 14 members representing key stakeholders and audiences for the evaluation (people living with HIV/AIDS and nongovernmental organizations, donors, Member States, the UNAIDS Secretariat, members of the WHO Strategic and Advisory Committee on HIV/AIDS and WHO staff). The Steering Committee's role was to ensure that the evaluation was performed according to the agreed terms of reference. The committee met with WHO and the Evaluation Team on three occasions at key moments in the evaluation process and provided guidance to WHO and the Evaluation Team through electronic communication between meetings.

In their report *Progress on global access to HIV antiretroviral therapy: a report on "3 by 5" and beyond* (March 2006), WHO and UNAIDS estimated that by December 2005 1.3 million people were receiving antiretroviral therapy in low- and middle-income countries, an increase of 233% on the baseline of 400 000 people on treatment two years before. In sub-Saharan Africa, an eight-fold increase in the number of people receiving treatment over the two-year period of the Initiative showed that with significant mobilization of resources and effort from communities, governments and international partners, antiretroviral therapy could be provided in even the most resource-constrained settings.

Would these gains have been achieved without "3 by 5"? WHO is not itself an implementing agency and many actors have played a central role in the progress made to date. The evaluation was challenging because it sought to assess WHO's specific contribution to the effort to achieve "3 by 5" barely 18 months after the "3 by 5" strategy was launched, and less than eight months after meaningful funding reached WHO itself. Accordingly, the evaluation focuses more on WHO's own processes than it does on the impact in countries. Nevertheless, it provides valuable lessons for both WHO and the countries and partners with whom WHO works as the international community now works towards achieving universal access to treatment by 2010.

Bearing in mind the constraints facing the Evaluation Team, the Steering Committee expected the evaluation to:

- focus on the WHO contribution to "3 by 5" and on the five strategic pillars of the "3 by 5" strategy;
- confine itself to the period of "3 by 5" implementation, while also recognizing the rapid evolution of events, notably the longer-term goal of universal access;
- evaluate HIV/AIDS-related activities across numerous WHO departments at its Geneva headquarters – rather than just the HIV/AIDS Department – and in regional and country offices;
- consult with key partners at global and country levels, undertake visits to eight countries (with a focus on Africa)^a and four regional WHO offices, commission focus studies in key technical areas and conduct surveys targeting key stakeholders in 49 focus countries;
- focus on processes and outcomes, rather than impact; and
- maintain independence and ensure transparency, while at the same time implementing a participatory approach, being open to other stakeholders and respecting national authorities.

Having closely followed the evaluation process and reviewed the final report, the Steering Committee is of the view that the Evaluation Team was constituted according to the terms of reference and received appropriate, complementary support through the commissioning of in-depth studies. Overall, the evaluation complied with the terms of reference and work plan. The Committee acknowledges the quality of the process and of the final report and the independence of the Evaluation Team. We recognize and commend the Evaluation Team for producing a significant body of work and breadth of evidence in a short time, working in many countries and under difficult constraints.

We note that there were challenges in bringing the project to a successful conclusion. The initial terms of reference and scope of work were ambitious. Time constraints compelled focus and lent urgency to consultation with and feedback from the Steering Committee. Security issues led to four, instead of five, countries being visited in sub Saharan Africa. Despite the efforts of the Evaluation Team to secure feedback, a low response rate to the questionnaire for national AIDS programme managers (31%) and an extremely low response rate for the survey of organizations of people living with HIV/AIDS (three responses), means that caution should be exercised in drawing generalizations from the results of these specific surveys. To some extent these shortcomings were compensated for by the numerous interviews performed in the country studies. The capacity to provide free and frank comment may have been affected by the presence of WHO staff in some of the stakeholder interviews conducted during country visits. The Evaluation Team reports, however, that sensitive interviews were conducted separately and that this effect was not significant.

^a Seven country visits were achieved during the evaluation process as one visit had to be cancelled for security reasons.

Reviewing the process and the findings, the Steering Committee is satisfied that the challenges encountered during the course of the evaluation have not affected its overall integrity, balance or independence. We feel that the information gathered allowed for a reasonable assessment of the "3 by 5" programme to be made. We consider the report to be clear, largely factual and accurate, and grounded in evidence. It provides a valuable reflection on WHO's role in and contribution to "3 by 5", in terms of both the accomplishments and shortcomings. There is much that is thought-provoking, including important insights into both WHO as an organization and the challenges of scaling up treatment for AIDS.

Time and other constraints have led to some limitations in the areas of commissioned focus studies, the adequacy of the evidence base for some judgements, the country level assessments, mapping of the diverse nature and types of collaboration between departments and clusters within WHO and in gathering case studies and lessons learnt that could be replicated in countries. The Steering Committee does not find adequate evidence in the report to support the conclusion on the failure of national governments and regional bodies to deliver on their commitments. The Steering Committee notes the real structural and resource problems that the report outlines in many countries, and the need for consistent support for such countries and mobilization of all social partners within such countries to implement adequate national responses.

The Steering Committee appreciates the efforts by the Evaluation Team to elaborate and integrate issues relating to health systems, equity and gender in the report and notes the continuing gaps in evidence and the need for more detailed work to support ongoing evaluation of these areas.

In line with its role, and based on its close involvement in the evaluation process, the Steering Committee accepts the WHO "3 by 5" Evaluation Final Report as an independent evaluation of the accomplishments and lessons learnt by WHO during implementation of "3 by 5". This acceptance does not imply Steering Committee endorsement of the conclusions and recommendations of the report, as these are based on the independent judgment of the Evaluation Team.

The Steering Committee recommends that WHO ensure wide public dissemination of this report and welcome debate on its conclusions and recommendations. We recommend that WHO actively use and build on the report in future planning.

We draw attention to the need for sustainable international financial support to help sustain the modest gains made on the ground so far, more so to realistically plan for universal access.

Finally, we suggest some areas that would merit further assessment or evaluation by WHO. These include:

- the evidence base for the public health approach to scaling up HIV treatment and prevention, and its implementation;

- the role of other global (regional and national) partners in "3 by 5";
- a gendered analysis of "3 by 5"; and
- a deeper assessment of the health system impacts of "3 by 5".

May 2006



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*Appendices are available in electronic format on the WHO website and in a CD-Rom.

Foreword and acknowledgements

An international Evaluation Team has had the pleasure of undertaking this important evaluation of WHO's role and contribution to the global "3 by 5" Initiative. The work started in July 2005 and the Draft Final Report was submitted to the World Health Organization (WHO) and the Steering Committee on 31 January 2006. For the evaluators, this has been an extremely interesting, challenging journey of learning and investigating. It has enriched considerably our professional experiences.

The Evaluation Team would like to thank WHO for having given us the opportunity to take part in this important evaluation.

The team would like to express its sincere appreciation for the support and guidance provided by the Steering Committee and especially its chair Dr Rene Loewenson. We would equally like to express our appreciation to all partners whom we visited and contacted for their openness and willingness to respond to our queries. These thanks include, of course, equally WHO colleagues, especially in those regional and country offices who were visited at times on very short notice.

Last but not least our sincere thanks to the Strategic Information and Research (SIR) unit of the Department of HIV/AIDS at WHO headquarters and its coordinator, Dr Yves Souteyrand, who provided continuous support to us from the day we began our work. In particular, we wish to thank Ms Veronique Collard and Ms Uzma Noon for all the practical and logistical arrangements and for their constant good spirits under pressure.

Having expressed our gratitude for all the valuable contributions, the Evaluation Team takes full responsibility for the content of this report.



Dr Ulrich Vogel,

Team Leader, on behalf of the entire team.

Montevideo/Frankfurt, January/March 2006

List of abbreviations and acronyms

AIDS	Acquired Immune Deficiency Syndrome
AMDS	AIDS Medicines and Diagnostics Service (WHO)
AOW(s)	Area(s) of work (WHO)
ART	Antiretroviral therapy
ARV	Antiretroviral (drugs)
ASD	AIDS and Sexually Transmitted Diseases (WHO)
CDC	Centers for Disease Control (United States of America)
CDN	Canadian dollar
CIDA	Canadian International Development Agency
CO	Country officer (WHO)
DfID	Department for International Development (United Kingdom)
DOTS (TB)	Directly observed treatment short course (Tuberculosis)
ESTHER	<i>Ensemble pour une Solidarité Thérapeutique Hospitalière En Réseau</i> (Working Together for Therapeutic Solidarity among Networked Hospitals)
FCH	Family and Community Health (WHO)
GAMET	Global AIDS Monitoring and Evaluation Team
GCWA	The Global Coalition on Women and AIDS
GFATM	Global Fund to Fight AIDS, TB and Malaria
GPA	Global Programme on AIDS (WHO)
GTT	Global Task Team
GTZ	<i>Gesellschaft für technische Zusammenarbeit</i> (German Agency for Technical Cooperation)
GWH	Gender, Women and Health (WHO)
HSI	HIV/AIDS/STI Initiative (WHO)
HIV	Human Immunodeficiency Virus
HIV-DR (S)	HIV drug resistance (surveillance)
HIVResNet	HIV Resistance Network
ICASA	International Conference on AIDS and STIs in Africa
ICW	International Community of Women Living with AIDS

IDU	Injecting drug users
ILO	International Labour Organization
IMAI	Integrated Management of Adolescent and Adult Illness (WHO)
IMCI	Integrated Management of Childhood Illness (WHO)
IMPAC	Integrated Management of Pregnancy and Childbirth (WHO)
ITPC	International Treatment Preparedness Coalition
LFA	Logical Framework Analysis
MAP	Multi-Country AIDS Programme (World Bank)
MOH	Ministry of health
MSM	Men having sex with men
MTCT	Mother-to-child transmission
NGO	Nongovernmental organization
NORAD	Norwegian Agency for Development Cooperation
OECD/ DAC	Organization for Economic Cooperation and Development/Development Assistance Committee
OGAC	Office of the Global AIDS Coordinator (USA)
OPEC	Organization of the Petroleum Exporting Countries
PAHO	Pan American Health Organization
PEC	Partnerships, External Relations, and Communication Unit (WHO)
PEPFAR	Presidential Emergency Plan for AIDS Relief (United States)
PHA	Public health approach
PLHA	People living with HIV/AIDS
PMTCT	Prevention of mother-to-child transmission of HIV
PRSPs	Poverty Reduction Strategy Papers
R&D	Research & Development
RBM	Results-based management
SAM	Service availability mapping
SIDA	Swedish International Development Agency
SIR	Strategic Information and Research Unit (WHO)
SRH	Sexual and reproductive health
STAC	WHO HIV/AIDS Strategic and Technical Advisory Committee

STARTOMS	Standardized ARV Treatment Outcome Monitoring System
STIs	Sexually transmitted infections
SWAp	Sector-wide approach
TAP	Treatment Acceleration Programme (World Bank)
TOR	Terms of reference
TPS	Treatment and Prevention Scale-up Unit (WHO)
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDAF	United Nations Development Assistance Framework
UNDP	United Nations Development Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNFPA	United Nations Population Fund
UNGASS	United Nations General Assembly Special Session on HIV/AIDS
UNICEF	United Nations Children's Fund
UNTG	United Nations Theme Group (on HIV/AIDS)
USAID	United States Agency for International Development
VCT	Voluntary counselling and testing
WB	World Bank
WCO	World Health Organization Country Office
WFP	World Food Programme
WHA	World Health Assembly
WHO	World Health Organization

Executive summary

Executive summary

The **"3 by 5" Evaluation** has taken place at a critical time in the global response to HIV and AIDS, which is already shifting focus towards the much more ambitious goal of *Universal Access* to HIV prevention, treatment and care.

Important progress was made during the two-year period of "3 by 5" leading up to December 2005, as the number of people on antiretroviral therapy (ART) in low- and middle-income countries nearly doubled in 2005 alone (to about 20% of those needing treatment)¹. However, this was less than half of what "3 by 5" set out to achieve and there are still huge disparities in who has access to treatment across regions and within countries.

It is also evident that HIV prevention efforts are not containing the pandemic, since some 4.9 million more people became infected with HIV during 2005².

This report provides an appraisal of the **role of WHO** in advocating and supporting the "3 by 5" target and reflects some of the insights gained through the "3 by 5" Initiative into the **continuing challenges** that face WHO, national governments and the development community in trying to contain further spread of HIV and reduce the impacts of AIDS.

The **lessons learnt from "3 by 5"** and recommendations for the way forward should be instructive to these constituencies. They should also be relevant to decisions about intensifying HIV prevention and continuing to scale up and sustain access to ART as an essential public health intervention.

Purpose of the evaluation and how it was conducted

This **independent formative evaluation** was conducted by a team of six international consultants between August 2005 and January 2006 to appraise WHO's contributions and roles in implementing the "3 by 5" Initiative. Funded by the Canadian Government, and as a requirement for its grant to WHO, the evaluation investigated all three levels at which WHO operates (headquarters, regional offices and country offices), placing particular emphasis on Africa. This included seven country assessments and an extensive consultation of international and country-level partners and stakeholders. A number of focused technical studies were also commissioned.

The evaluation reviewed how effectively WHO provided technical, managerial and administrative guidance and support pursuant to the "3 by 5" goals and target. An assessment was also made of the extent to which WHO has mobilized, sustained and contributed to this major global partnership through improving harmonization between United Nations agencies and working with other stakeholders and partners. Key lessons from "3 by 5" have been documented,

¹ WHO/UNAIDS. *Progress on global access to HIV antiretroviral therapy: A report on "3 by 5" and beyond*, March 2006.

² UNAIDS. *AIDS epidemic update*, December 2005.

including those on how the initiative contributed to health systems strengthening and HIV prevention, as well as the ways with which equity and gender concerns were dealt.

Potential opportunities for future collaboration between WHO, main donors and partners were identified and recommendations have been provided for future plans and the way forward for WHO and its partners.

The evaluation takes the view that the "missed" "3 by 5" target is not the primary indicator of WHO's performance. It has **not attempted to seek attribution** for these results. Remaining gaps in treatment access and weaknesses in the global response are seen as an important reminder of WHO's continued relevance and why the Organization must become even more effective in providing technical leadership as well as working to intensify country support for further scaling up.

The "3 by 5" Initiative

For the purpose of this evaluation, **"3 by 5" refers to the programme of work** over a two-year period from December 2003, undertaken by WHO in collaboration with UNAIDS and other partners "to support the expansion of access to ART to 3 million people with HIV/AIDS in developing countries by the end of 2005".

At the time this Initiative was launched, WHO estimated that 6 million people needed ART in developing countries, but less than 8% were receiving it (with the biggest gap in Africa). When United Nations partners declared this situation a global health emergency, it added to the growing worldwide political movement advocating the right to treatment.

The "3 by 5" target was based on the belief that it would be feasible to provide ART to 50% of those who needed it. This was considered a necessary, achievable milestone on the way to the ultimate goal of universal access. WHO also aimed to intensify HIV prevention efforts and expected the Initiative to contribute towards strengthening health systems.

The programme was pursued through **five strategic objectives** (the "3 by 5" pillars) that reflect core functions of the institution, described in the WHO strategy document *"Treating 3 million by 2005: Making it happen"* as:

- i. global leadership, strong partnership and advocacy;
- ii. urgent, sustained country support;
- iii. simplified, standardized tools for delivering ART ("the public health approach");
- iv. effective, reliable supply of medicines and diagnostics; and
- v. rapidly identifying and reapplying new knowledge and successes ("learning by doing").

The findings of this evaluation have been **analysed and reported within these "3 by 5" strategic objectives** and are accompanied by a brief organizational review and analysis of health systems strengthening; HIV prevention; equity; and gender concerns.

The main conclusions and lessons from this evaluation (with key recommendations for the way forward)

ART is not only a technical consideration; it must be seen in the context of global development processes, such as poverty reduction, the 2001 UNGASS Declaration and Millennium Development Goals.

This takes place in the highly politicized environment of development cooperation, where decisions about development priorities, resource allocation and the roles and functions of major global institutions are not always made impartially or purely based on what seems to be in the best interests of affected constituencies. The evaluation of a major global public health initiative, such as "3 by 5", cannot ignore the influences of these powerful externalities.

In looking forward, decisions will need to be made on the basis of these evaluation findings to strengthen WHO's position within the context of these developments, to ensure that the *Universal Access* goal does not follow "3 by 5" in missing the target.

I. Scaling up access to antiretroviral therapy (ART) and HIV prevention

- Many countries have made significant progress over a relatively short period to increase the total **numbers of people who are receiving ART** in low- and middle-income settings—from 400 000 in 2003 to about 1.3 million at the end of 2005³. There has been a corresponding exponential increase in the numbers of treatment sites in both the public and non-state sectors, supported by a diverse range of partners and funding sources.
- However, there are still **striking differences between regions and countries**, with many of the worst-affected African countries still far from containing their growing AIDS crisis. Sustaining this response, even at current levels, remains one of the biggest concerns of national governments.
- In these early phases of scaling up, treatment has been provided chiefly through hospital-based facilities or outreach clinics with existent infrastructural and staffing capacity. Since these facilities are now becoming "saturated" and since many people cannot reach them, coverage needs to be expanded by **decentralizing treatment access** to first-level primary care providers (in both the public and private sectors). Where this is starting to be done, new challenges are being introduced in both scale and complexity, since peripheral treatment sites are even more vulnerable to the underlying weaknesses of health systems.
- WHO has developed **integrated operational approaches** to support this process. There is renewed acknowledgement of the need to invest in strengthening health systems overall, although specific progress in this regard is still limited. The impacts of these developments on the underlying health systems need to be monitored and require further research.

³ Based on UNAIDS/WHO estimates.

- The "3 by 5" Initiative substantially contributed to promoting the right to health for people living with HIV/AIDS (PLHA). It has established **ART as an essential public health intervention**. Access to ART has become one of the most significant determinants of health in high-burden countries. However, there are many remaining barriers to individuals (and entire subpopulations) finding out their HIV status; starting ART when indicated; and continuing to benefit from chronic therapy.
- This has important implications for the health gains that can be achieved by pursuing the goal of *Universal Access*. It also requires serious consideration of the **health system constraints** that are limiting service coverage; inhibiting early care-seeking; and compromising the continuous supply and durability of treatment.
- New HIV infections are continuing to rise in many settings, adding to the global burden of AIDS. **HIV prevention** has been a technical area within the "3 by 5" Initiative that has received relatively little investment and effective prevention interventions, such as prevention of mother-to-child transmission of HIV (PMTCT), were not properly prioritized. It has not yet been demonstrated whether scaling up ART has any impact on HIV prevention.
- WHO has highlighted the special **needs of target communities and vulnerable populations** such as sex workers, intravenous drug users (IDUs) and men having sex with men (MSM). It has helped to facilitate their access to appropriate prevention and treatment interventions in a number of settings where these groups are usually marginalized.
- **Gender and equity** considerations are not yet routinely influencing how services are being delivered in most settings, with the risk of missed opportunities for prevention and treatment that will have continued consequences for HIV epidemics.
- The **treatment needs of children** have started being addressed only recently. In many settings, where fees are still charged at the point of care for ART, this has been shown to limit access and reduces adherence to therapy. However, WHO has elected not to take a firm position on abolishing user fees.
- **Target-setting for scaling up treatment access** is considered to have been an effective mechanism for driving both international and national responses through a necessary stage of development. The ambitious "3 by 5" global target has made the idea of a *Universal Access* goal possible – even though this target was not reached. Future targets, like the Millennium Development Goals and the UNGASS goals and targets, need to be realistic and country-owned if they are to serve as "beacons" for planning and measuring progress.
- **Disaggregated subtargets** are needed for subpopulations to guide equitable access, and specific prevention targets should be considered. There has been little emphasis on developing quality benchmarks as well as insufficient technical work done to forecast how to scale up services for maintaining current treatment populations, while further increasing access to care.

In order to further scale up access to ART and HIV prevention, WHO and its development partners need to

1. Advocate for increasing the **capital investment and operational support for health systems strengthening** (including through public–private partnerships and innovative financing mechanisms).
2. **Improve interagency cooperation within the United Nations** (especially between WHO and the World Bank, and with the Global Fund) to align the different sources of support for health systems strengthening and harmonize their technical and policy approaches.
3. Promote **cooperation between the various global health initiatives** to improve their combined efficiency and effectiveness in delivering health systems strengthening interventions.
4. Contribute technical **guidance to countries on how to mobilize and allocate new resources** for national AIDS responses, so that these can contribute to strengthening health systems overall more effectively.
5. Urgently **address the crisis in human resources for health**, through, *inter alia*, innovative approaches (such as regional training initiatives and public–private ventures).

WHO needs to

6. Promote investments in **targeted intervention approaches for addressing the public health needs of vulnerable communities and groups** affected by HIV and AIDS (including sex workers; IDUs; MSM; and children).
7. Adopt and promote a **stronger position on increasing equity** in access to services, including for "free access" to ART at the point of care.
8. **Systematically integrate the concept of "gender sensitivity"** into how WHO technical strategies, instruments and tools are developed and delivered.
9. Develop and disseminate **methodologies for countries to set appropriate targets** (including subtargets for focus populations) for HIV treatment *and prevention*, based on a sound assessment of their national capacity and resources.

II. WHO contributions to the health sector response to HIV and AIDS

- There is consensus among stakeholders, development partners, other United Nations institutions and national governments that WHO is the multilateral agency **mandated to lead the global health sector response to HIV**. But there are also perceptions that the Organization has yet to fulfil its role to meet this level of expectation.

WHO contributions through leadership, advocacy and partnerships

- When "3 by 5" was launched, WHO made a strong commitment to working with a broad range of partners, yet the mechanisms for achieving this have tended to be loosely defined. WHO is well positioned to lead global and country-level **partnerships and technical support networks**. However, the Organization could have engaged in partnership opportunities more effectively and it will be increasingly expected to work within a broader global partnership for *Universal Access*.
- There has been substantial progress in clarifying roles and assignments of key multilateral institutions and international donors through the establishment of the **Global Task Team** on Improving AIDS Coordination among Multilateral Institutions and International Donors in 2005. However, key bilateral institutions, particularly the Presidential Emergency Plan for AIDS Relief (PEPFAR) have not become active participants in this mechanism.
- There is still a need to resolve areas of "competition" between United Nations agencies and to establish a performance monitoring mechanism for this task team process. The working **relationships between WHO and other major funding and technical organizations**, such as the Global Fund to Fight AIDS, TB and Malaria (GFATM), the World Bank, PEPFAR and Ensemble pour une Solidarité Thérapeutique Hospitalière En Réseau (ESTHER), have only recently begun to be strengthened.
- Commitments that have been made through these partnership developments and the establishment of new mechanisms (such as the Global Joint Problem-solving and Implementation Support Team led by WHO) must still translate into systematic approaches to identifying country needs and establishing harmonized **technical assistance plans**, with arrangements for funding and implementing this assistance.
- WHO has the role of monitoring and coordinating partner contributions to national health sector responses. It is expected to take the lead in working with others to identify **country technical support needs** and ensure that relevant, good-quality technical assistance is delivered.

To strengthen WHO contributions to the health sector response to HIV and AIDS through leadership, advocacy and partnerships, the WHO HIV/AIDS Department needs to

10. Distinguish between strategic, scientific and operational partnerships and develop **more effective mechanisms for managing partnerships** (such as *Memoranda of Understanding*) that define clearly what the parameters and explicit expectations are for each type of collaboration.

11. Improve the structure and role of the Global Partners Group so that this could provide more value as a coordination mechanism, or consider whether WHO should strengthen the HIV and AIDS programme within a **more participatory partnership mechanism**, drawing on the models and lessons from existing global health partnerships.
12. Actively **promote the principle of South-to-South cooperation** by facilitating collaboration and drawing on the experience and expertise among developing countries, southern institutions and regional networks to deliver technical assistance.

WHO contributions in providing direct country support

- The budget and staffing made available to **WHO country offices** (WCOs) through "3 by 5" have dramatically strengthened its support role in countries, where the Organization works closely with national governments as the primary partner of ministries of health (MOHs). By introducing dedicated technical officers (WHO "3 by 5" officers) in 41 of the 49 focus countries, WHO has started to create a strategic network that has the potential to make an increasingly important contribution to learning what is happening "on the ground"; disseminate good practices; monitor national responses; and facilitate technical assistance. Many of these officers only took up their posts in the latter part of 2005, but have already proven indispensable to scaling up the WHO contribution in these focus countries.
- WHO is not an "implementing agency" and does not have the budget for funding much **external technical assistance**. It is weakly positioned relative to other highly resourced partners to operationalize technical support initiatives. Close coordination with the other multilateral and bilateral agencies (and especially UNAIDS) is therefore needed for WHO to plan and secure technical assistance that is aligned with national health sector priorities for further scaling up towards *Universal Access*.
- In some countries, WHO has been able to secure **additional funding for providing technical assistance** as a subrecipient of the Global Fund and this is an important mechanism for WHO to consider pursuing more actively.
- WHO has a unique responsibility within countries to assist governments with strategies and planning that position the HIV response within **broader health sector development** and to link this with development plans (including those for poverty reduction) that will improve population health overall. Despite intentions to work towards this, most WCOs have not yet achieved a great deal of synergy across areas of work (AOWs) that provide "vertical" support to counterpart programmes within MOHs.
- There is still very little **integration through joint planning or projects** between related technical or programmatic areas such as tuberculosis (TB), reproductive and sexual health, child and adolescent health, and health systems strengthening.

- In general, WHO has found it challenging to develop and influence new types of **partnerships within countries**, outside of its traditional relationship with the MOH. Many partners in countries request that WHO make better use of its advantageous position with the MOH and play a more active role in helping to establish and support better information and coordination mechanisms.
- WHO is expected to review and communicate the roles that it intends to have in countries (focusing more on what it is good at doing) and to better understand how to use its **comparative advantage and political mandate** for supporting the work of others.
- **Supporting national governments** to get public health approach (PHA) guidelines into practice will become increasingly important as countries scale up coverage by decentralizing their HIV treatment services (which requires direct support to primary care providers in first-level facilities). WHO has missed opportunities for expanding both the coverage and quality of HIV-related PHA interventions through the non-state (private) sector in a number of these settings and has not offered technical support to national governments to exercise more effective stewardship over private providers.

To strengthen its capacity to deliver direct country support for scaling up, WHO needs to

13. Construct a medium- (five-year) to long-term **health sector strategic "road map"** for integrating HIV response within broader health development and for health systems strengthening that can be adapted to the specific circumstances of regions, subregions and countries, within the context of the *Universal Access* commitment.
14. **Work more strategically within country partnerships** to support the mandate and comparative advantage of local partners, including PLHA, civil society and the non-state sector. This could include coordinating and facilitating advocacy, technical and operational networks and supporting private-sector providers to participate in delivering PHA interventions more effectively.
15. Transform the ways in which WCOs plan and implement their disease-specific programme activities, to **achieve greater coherence and integration across technical AOWs**, for the purpose of health systems strengthening.
16. More clearly define and communicate what the Organization's roles and responsibilities are within countries, with a **focus on what WHO does well** and taking into account the comparative value of the Organization in relation to other local partners.
17. Create **more effective mechanisms for delivering coordinated, high-quality technical expertise** in which WHO has a role to identify the technical support needs of countries; monitor the quality of technical assistance delivered; and to mobilize funds for technical assistance within countries (including from the Global Fund).

WHO contributions through developing and operationalizing standardized tools and guidelines

- WHO guidance for HIV/AIDS treatment, prevention and care based on a **public health approach** has made it possible to scale up these interventions. WHO has further demonstrated a promising strategy based on Integrated Management of Adolescent and Adult Illness (IMAI) for operationalizing the **PHA** through strengthening health systems to deliver decentralized, integrated primary health-care services that focus on priority PHA interventions.
- **Programmatic integration** with related primary care approaches for child health (IMCI) and maternal care (IMPAC) would make sense, but there is no institutional strategy for this and the effectiveness and feasibility of sustaining these integrated approaches still need to be demonstrated.
- WHO has produced an extensive range of high-quality **technical guidance** and tools for scaling up national health sector responses, mostly in collaboration with other technical partners. Resources that were allocated to WHO for this normative work, carried out at WHO headquarters and regional office levels, have been insufficient to produce these guidelines, as well as support scaling up their implementation within countries.
- Achieving a good **balance between the "normative guidance" and "direct support" functions** of WHO requires careful consideration of how resources are distributed, so as not to weaken this global technical expertise.
- WHO has an important responsibility to provide guidance and technical support for global **HIV drug-resistance surveillance**. Work that has already been done in this area provides an excellent example of the comparative advantage of the Organization. However, there has been insufficient funding for this technical area. This demonstrates the WHO programme's dependence (and vulnerability) since it relies on the contributions of very small technical teams working within unrealistic budgets.

To make more strategic contributions through developing and operationalizing standardized tools and guidelines for scaling up, the WHO HIV/AIDS Department needs to

18. **Define an essential package** of priority PHA interventions that will be made "universally accessible" through national HIV, AIDS and TB control programmes (with increased emphasis on HIV prevention and HIV testing).
19. **Reinforce the programmatic linkages between disease-specific AOWs** (in particular with Stop TB, Making Pregnancy Safer, Child and Adolescent Health) to achieve programmatic alignment across the related integrated approaches for child health (IMCI), adolescents and adults (IMAI), and maternal care (IMPAC).

20. Urgently **establish the effectiveness and feasibility of sustaining integrated service delivery approaches** as the "common platform" for strengthening primary health-care services (through which a broader public health approach package of essential disease control interventions can also be delivered).
21. Assist countries in **establishing benchmarks for service expectations and quality** (particularly to ensure the safety and durability of ART).
22. Maintain the **WHO leadership role in the HIV Drug Resistance Surveillance Network** and ensure that there are adequate resources to effectively operationalize drug resistance surveillance as a global public health priority.

WHO contributions to securing reliable supplies of effective medicines and diagnostics

- There are current concerns about whether secure **supplies of adequate quantities of quality antiretroviral drugs (ARVs) and diagnostics** can meet the growing global demand (based on existing supplies of the active pharmaceutical ingredients that are used to manufacture these drugs), both for current first-line treatments and for second-line drugs and paediatric formulations. Prices for second-line medicines are still over 10 times more costly than the first-line regimens that are now being produced by many competing generic manufacturers.
- **"Prequalification"** has been an important driver for making available affordable generic ARV medicines that are of acceptable quality. It has contributed to reducing the prices of these medicines. The WHO-managed Prequalification Project has been successful in establishing an innovative mechanism that encourages voluntary improvement in the manufacture and supply of quality drugs (especially generic ARVs). There is now a need to prioritize second-line drugs. The demand for this service is growing and requires increased financial support. It must retain the specialized regulatory expertise that has been developed. The Prequalification Project is also regarded as a successful example of how WHO can draw on the expertise of related technical areas within the Organization (beyond the HIV/AIDS Department) to support HIV responses.
- Further scaling up and increasing service coverage will place incremental demands on supply systems over the coming years. Coordinated efforts are therefore needed to make vertical supply arrangements available, while concurrently ensuring that national systems are strengthened. Mechanisms (such as the multi-agency Global Task Team process) for solving current **procurement and supply management** problems and the practical responses to these problems by WHO and its partners in the AIDS Medicines and Diagnostics Service (AMDS) network need to be continuously evaluated to ensure that they are succeeding.

To continue securing reliable supplies of effective HIV medicines and diagnostics, WHO needs to

23. **Provide the Prequalification Project with sufficient resources** to continue promoting the quality and availability of ARVs through the prequalification mechanism and ensure that immediate priority is given to medication used in second-line ART; paediatric treatment; and to HIV diagnostics.
24. Strengthen the capacity of the AMDS to **secure consistent supplies of ARVs and HIV diagnostics** (especially for second-line treatments and paediatric formulations) and to establish more effective mechanisms for working with partners to resolve procurement and supply management problems within countries.

WHO contributions through "learning by doing"

- WHO has undertaken **global reporting of treatment scale-up** (together with UNAIDS) and helped establish the metrics and standards for national programme-monitoring that are important for providing strategic information that can be used in decision-making. The Organization has a responsibility to support surveillance of the impacts of treatment scale-up on the epidemic, including for the emergence of drug resistance. This has only started to be implemented in a few settings and needs additional resources as a priority.
- WHO is ideally situated (and expected) to lead **knowledge management** through its country networks and international technical partnerships. It should serve as an effective "knowledge network" for the global response to HIV. The internal systems for routinely monitoring programme activities are not yet firmly established within WHO. Knowledge management functions are divided across departments and lack integration. This has impeded the Organization's ability to systematically "learn by doing" and to iteratively improve the programme.
- WHO has not done much to build the **evidence base for guiding decisions** about what service delivery approaches are most suitable and how to optimize the provision of chronic HIV care and support. Collaboration with the United States Government, to learn from the implementation experiences of the PEPFAR programme has not yet happened. There is an urgent need to systematize the 'real-time' operational research approaches that WHO has started to promote in a few settings.

To strengthen knowledge management and learning for more effective decision-making about scaling up, at all three levels of the Organization, WHO needs to

25. **Create and support purpose-oriented learning networks** that are based in communities of practice. These should espouse the principles of knowledge-sharing and providing practical humanitarian assistance, allowing broad and inclusive participation by leaders, technical experts, politicians, communities, businesses and nongovernmental organizations (NGOs) in jointly defining the problems; proposing innovative solutions and engaging in collaborative actions.
26. **Establish more robust programme monitoring and evaluation** mechanisms that encourage continuous improvement and learning within the Organization.
27. Mainstream **contemporary approaches to operational research into and programme improvement** of WHO programmes and provide technical support for WHO implementation partners to do the same.

III. Performance of the HIV programme area within WHO

- The lack of defined **programme structure** for "3 by 5" has been a weakness and to some extent reflects the uncertainty with which WHO was working with before funding commitments were secured. It also mirrors the reactive way in which this "emergency" initiative was managed. The "3 by 5" Initiative has been described as an ambitious, but weakly conceived programme with insufficient structure against which results could be measured or performance monitored for the enormous amount of effort that has gone into it.
- Much of this work has really only just started and although much has been achieved in this relatively short time, the **strength of the Organization** lies in its development perspective and ability to influence the medium- to longer-term health agenda.
- WHO is a large and bureaucratic **global organization** with a complex governance structure and many operational divisions that could not have realistically been expected to achieve the changes that were needed on this global scale through an "emergency" two-year programme. There was no commonly shared strategy across the three levels of the Organization for how to strengthen WHO to support scaling up in synergistic ways and to sustain this in the longer term.
- The **HIV/AIDS Department** at WHO headquarters was responsible for coordinating substantial involvement by other parts of the Organization for "3 by 5". There have been examples of excellent collaboration between internal WHO departments that resulted in strong technical outputs, but there is still room for improvement in the relationship with others, such as Stop TB and Making Pregnancy Safer.

- WHO regional offices play an important role in supporting country developments. The lack of a strong regional programme and leadership commitment in the **WHO Regional Office for Africa** (which faces the most dramatic challenges, but has not received sufficient support and attention by the Organization) is of significant concern since this has impeded progress in the Region.
- Significant delays occurred in implementing the planned programme of work due to the initial **lack of secured funding** and subsequent slow grant disbursement. The "3 by 5" Initiative (like most of WHO's work on HIV at global, regional and country level) was predominantly funded through extrabudgetary contributions. This makes WHO highly vulnerable to the perception of donors and their willingness to fund the Organization. Prospects for current funding are not good. The lack of a secured funding base in the medium term negatively affects the Organization's ability to fulfil its mandate.
- The HIV programme at WHO headquarters has experienced an extremely high turnover of directors during the past 10 years and has again taken on a new director in early 2006. This **unstable management of the HIV/AIDS programme** within WHO is likely to have affected the momentum and strength of this AOW over the period. It also reflects poorly on WHO's commitment at headquarters level to ensuring consistent leadership in HIV and AIDS.

To strengthen WHO as an institution that is better able to serve its purpose in the global response to HIV and AIDS, the senior leadership of WHO is advised to

28. Achieve **greater coherence at the three levels of the Organization** to support a shared strategy through joint planning and coordinated programme management for HIV. It should prioritize increasing resources (especially to the WHO regional and country offices in Africa) to carry out this strategy.
29. **Improve interdepartmental collaboration** and minimize the areas of conflict or duplication between technical departments (such as the HIV Department and the Making Pregnancy Safer Department as well as AMDS and the Health Technology and Pharmaceuticals cluster).
30. **Allocate internal resources more judiciously** for priority technical programme areas (such as Drug Prequalification and HIV Drug Resistance Surveillance (HIV-DRS)).
31. **Secure more stable tenure of the leadership position in the HIV programme area** and offer employment conditions that are conducive to attracting and retaining top technical personnel.
32. Implement an urgent plan of action to **substantially strengthen the technical and administrative capacity of the WHO Regional Office for Africa** and WCOs in Africa to improve their performance in responding to the crisis of the HIV epidemic in this Region.

IV. Influences of the broader development context and the particular challenges facing Africa

- The evaluation encountered substantial **variation among countries** in the ways that HIV and AIDS responses have been developed and implemented; how resources are allocated; how major organizations work together; and the extent to which people within their communities have the knowledge and resources to participate in improving their own health. Important lessons can be drawn from what is happening in practice, both about what works and what does not work.
- WHO has demonstrated the **flexibility to respond** to these different contexts, but the extent to which these WHO contributions have made a difference to national efforts among the many different players in each country has been highly variable. The Organization has not yet adequately addressed the lack of participation by civil society, and especially by affected constituencies, such as PLHA, in some countries.
- Despite important progress in responding to HIV and AIDS in recent years in many countries in Africa, the impacts of AIDS and the challenges faced in trying to curb the epidemic still seem to be overwhelming. It is also evident that the development community is not yet sufficiently prepared to make the additional investments that are needed so that countries can move into the **next phases of scaling up** their HIV and AIDS responses, towards the goal of *Universal Access*. UNAIDS has estimated that there is a funding gap of at least US\$ 18 billion over the next two years to provide the resources and technical support that are still needed to strengthen national health systems for this challenge.
- Many of the **worst-affected African countries** are still far from containing their growing AIDS crisis and the absolute number of people who need treatment and do not have access to this is still growing. National governments and regional bodies have not made sufficient efforts and often fail to live up to their own commitments and declarations.
- Even though WHO significantly increased its investments in Africa through "3 by 5", the Organization has not yet strengthened its **focus and capacity** adequately to provide the level of support necessary to meet the scale of these challenges in Africa.

To influence the broader development context and address the particular challenges facing Africa, multilateral institutions and international donors need to

33. Provide more secure, appropriate and **sustainable mechanisms for countries to fund their national HIV and AIDS responses.**
34. **Commit adequate, steady funding to WHO** and institute reforms to the mechanisms for funding WHO, so that the Organization can fulfil its mandate appropriately to provide technical leadership in scaling up HIV and health-sector responses as the multilateral technical agency for global public health.
35. Assign clear institutional roles and responsibilities globally (such as through the Global Task Team) and at country level to each partner to **ensure that there is mutual accountability between development partners and national governments** to achieve the goals of *Universal Access*. This process has to be inclusive of major bilateral programmes (such as PEPFAR).
36. **Enable broader and more effective involvement and participation** by PLHA, civil society organizations and the private sector in national HIV and health sector responses.
37. Mobilize political support for **appropriate action, including national efforts, in countries**, as a matter of public health safety and sustainable development.
38. **Intensify the focus on Africa** through a "quantum leap" in efforts and by substantially increasing funding to scale up HIV prevention, ART and poverty-reduction.

PART 1

Introduction, programme profile and evaluation profile



"We Declare a Total War on AIDS"
a commonly seen government slogan
in Kenya

1 Introduction

Purpose of the evaluation

The World Health Organization (WHO) and its partners decided that as part of the "3 by 5" Initiative an independent evaluation should be undertaken before the end of 2005, focusing on WHO's contributions and roles during the implementation of "3 by 5". The evaluation has reviewed the WHO contributions to scaling up access to antiretroviral therapy (ART) under the "3 by 5" Initiative to assess whether the Organization has achieved its objectives and to understand how it has added value in the global response to HIV and AIDS (particularly from the health-sector perspective). These findings have been analysed to evaluate how WHO could optimize its contributions over the next phases of the response, providing recommendations to guide future WHO strategy decisions.

Under a grant arrangement between WHO and the Canadian International Development Agency (CIDA) concluded in December 2004, CIDA agreed to contribute CDN\$ 100 million to support the "3 by 5" programme of work from 2004 to 2006. This specifies that monitoring and evaluation activities would be undertaken periodically and at the end of the grant period to measure progress in implementation of the programme of work and its impact on scaling up access to ART and accelerating HIV prevention at global and country levels.

The evaluation approach

As a formative evaluation, this activity was carried out to provide the main donors with an appraisal of what has been achieved and to assist WHO in improving the programme. This was done with the understanding that this contribution is not confined to the period under review since this is "Just the beginning of antiretroviral therapy scale-up and strengthening of health systems".⁴

Evaluation Steering Committee

The Steering Committee was established to serve as an advisory body to the Evaluation Team and WHO at essential phases of the evaluation. The role and composition of this committee is explained in further detail in the terms of reference (TOR) for the evaluation (See Annex 1 and Appendices).

Evaluation Team

A team of six independent international consultants⁵ was selected by WHO (in consultation with the head of the Evaluation Steering Committee), based on the need for a multidisciplinary team

⁴ WHO/UNAIDS, 2003, *Treating 3 million by 2005, Making it happen*, The WHO Strategy, December, p.31. See Appendices.

⁵ The team comprised two women and four men from six countries: Brazil, Canada, Germany, Norway, South Africa and Uganda.

of internationally recognized experts with an appropriate mix of technical skills and expertise in medicine, public health, epidemiology, sociology, programme evaluation, and community development.⁶ The team was assisted by a special adviser and contracted additional research assistance (as listed in Annex 4).⁷

Format of the final report

The final report is presented in two parts: Volume I contains the main report and Volume II* contains the annexes and other supporting documentation.

The Main Report (Volume I) has the following sections:

- **Chapter 2** contains the "3 by 5" *programme profile* as background to the evaluation. This briefly describes the circumstances under which "3 by 5" was launched and the strategic framework for the Initiative. An update on global progress towards the goals of "3 by 5" is also presented (based on the most recently reported data from WHO).
- **Chapter 3** describes the *evaluation profile* and provides a brief explanation of the TOR and evaluation methodology (detailed descriptions are provided in separate annexes). It also describes how the evaluation was carried out.
- **Chapter 4** presents the *main evaluation findings* and provides a retrospective analysis of the Initiative. This chapter is divided into seven subchapters according to the five strategic pillars of "3 by 5", followed by an organizational analysis. The last section discusses four issues WHO and the Evaluation Steering Committee identified as requiring particular consideration: HIV prevention, health systems strengthening, and gender and equity.
- **Chapter 5** contains the *main conclusions and key recommendations* to guide future decisions about WHO's role in the global response to HIV and how the Organization needs to be structured and supported to fulfil its mandate.

Volume II comprises the reports of focus studies that were commissioned as part of the evaluation, as well as the Annexes to the main report. These provide further details and some of the empirical findings of the Evaluation Team (summary notes from country and regional offices visits, data tables, figures, etc.), examples of the evaluation tools (such as questionnaires) and other relevant supporting documentation. Although key findings and insights from these focus studies have been integrated into the main report, these reports contain further valuable content and more detailed recommendations that should not be overlooked. As references for the interested reader, key WHO (and UNAIDS) published documents relevant to "3 by 5" were added as special appendices. For a full list of all documents consulted by the Evaluation Team, please refer to Annex 3.

*Annexes are available in electronic format on the WHO website and in a CD-Rom.

⁶ A profile of these individuals is provided in Annex 4 that describes the evaluation methodology.

⁷ The Evaluation Team relied on other people for support and contributions. Their names are listed in Annex 4 on evaluation methodology.

Audience

The audience for the evaluation includes WHO Member States, its main multilateral and bilateral partners and donors, nongovernmental organizations (NGOs) and civil society groups, as well as WHO offices at headquarters, regional and country levels.

2 Programme profile

2.1 Background

By 2003 approximately 7% of the 6 million people in need of ART in developing countries were receiving it, with the biggest gap in Africa (Table 1).

People living with HIV/AIDS (PLHA) and other sectors of civil society had led a growing worldwide political movement advocating treatment as a fundamental right. A number of low- and middle-income countries such as Argentina, Botswana, Brazil, Senegal, Thailand, Uganda and Uruguay were already implementing national treatment programmes.⁸ After years of contentious debate, a broad consensus was emerging that AIDS treatment and scale-up in resource-poor settings was feasible, effective and increasingly affordable. An unprecedented level of political will to deal with the HIV epidemic was becoming evident as new institutions, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and ambitious bilateral programmes, including the United States Presidential Emergency Plan for AIDS Relief (PEPFAR), were launched. However, the resolutions by multilateral organizations⁹ had not yet translated into a global effort to politically mobilize and technically support large-scale expansion of ART where it was needed most and access to ART was still expanding at a slow pace.

On 22 September 2003, the new Director-General of WHO Dr Jong-wook Lee joined with the Executive Director of UNAIDS Dr Peter Piot and the Executive Director of the GFATM Dr Richard Feachem to declare this lack of access to ARVs a global health emergency.

In response, WHO and UNAIDS announced their launch of a global target to "Treat 3 Million by 2005" that subsequently became established as the "3 by 5" Initiative. This was based on the proven feasibility of treating PLHA in industrialized countries and increasing evidence that this could be achieved in developing countries as well, where it was estimated that treatment could be provided to 50% of those who needed it as a necessary, achievable target on the way to the ultimate goal of universal access to treatment.¹⁰

It was evident to WHO and UNAIDS at the time that "this comprehensive Initiative requires the development and maintenance of a wide range of relationships with... national and local governments, civil society, bilateral donors, multilateral organizations, foundations, private sector (...), trade unions, traditional authorities, faith-based organizations, nongovernmental organizations (...) and community-based organizations" (WHO/UNAIDS, op. cit, p. 29). The important role as partners of PLHA and the activist community was equally highlighted.

⁸ These programmes had begun when major international organizations were still reluctant to engage themselves in the support of ART in the developing world.

⁹ The Human Rights Commission of the United Nations, in early 2001 and the 2001, 2002 and 2003 resolutions by the Executive Board and WHA.

¹⁰ Based on the analysis of Schwartzländer B et al. (Science, 2001, Jun 29, 292 (5526): 2434-6).

Table 1 **Antiretroviral therapy (ART) coverage for adults in developing countries, by WHO region, December 2003**

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

Source: WHO

The goal of "3 by 5" was expected to become a shared vision that would align partners within countries and regions with a common purpose and lead the international response to HIV with a focus on ART.

The funding needed to achieve this goal was estimated to be at least US\$ 5.5 billion, which was expected to come from multiple sources, including the budgets of low- and middle-income countries, multilateral and bilateral funders as well as private foundations and the private sector.

2.2 The "3 by 5" strategic framework

With the vision of a "3 by 5" target for scaling up access to HIV prevention, care and treatment, the **WHO mission** since December 2003 has been to contribute towards:

- increasing the numbers of people who are receiving ART;
- strengthening health systems; and
- intensifying prevention efforts (linked to care).

This has been pursued through **five strategic objectives** – the "pillars" of "3 by 5" – that reflect core functions of the wider Organization¹¹ described in the WHO strategy document *Treating 3 million by 2005: Making it happen* as:

- i. global leadership, strong partnership and advocacy;
- ii. urgent, sustained country support;

¹¹ WHO defines six core functions, as well as four strategic functions (for dealing with crisis situations), in its Global Programme of Work 2002–2005 adopted by the World Health Assembly, which are essentially summarized and applied to HIV in the five strategic objectives for the "3 by 5" Strategy. This description is available at http://www.who.int/gb/e/e_waha54.html.

- iii. simplified, standardized tools for delivering ART ("the public health approach");
- iv. effective, reliable supply of medicines and diagnostics; and
- v. rapidly identifying and reapplying new knowledge and successes ("learning by doing").

The **WHO programme of work** has been directed towards supporting countries through a range of activities and technical outputs linked to this "3 by 5" strategy, which have been incremental to usual levels of support for HIV and AIDS response that WHO provided before.

WHO adopted the following guiding principles for the Initiative:¹²

- urgency;
- the centrality of PLHA;
- life-long care;
- country ownership;
- treatment and human rights;
- partnership and plurality;
- complementarity;
- learning, innovation and sharing;
- ethical standards;
- equity; and
- accountability.

WHO expressed the hope that "access to ART for everyone who requires it according to medical criteria opens up ways to accelerate prevention in communities in which more people will know their HIV status – and, critically, will want to know their status." (WHO /UNAIDS, op cit, p.6). It was believed that "As HIV becomes treatable, this will hopefully reduce the stigma and discrimination attached to HIV/AIDS."

The strategy further stated that "The fight against HIV/AIDS has implications for the entire health sector. The impact of HIV/AIDS both directly and indirectly undermines the performance of national health systems. Effectively countering this impact requires both a core response from within health systems and a broader societal response. As more health workers die from AIDS, health systems falter in delivering basic services. As workers across an economy die, revenues available for health systems fall, compounding damage to the health system. Increased access to integrated HIV treatment, prevention and care services is needed to reverse this pattern."

WHO recognized that the Initiative would have to consider both common and unique attributes of national and local health systems. The challenge of addressing these concerns across varied settings would require the involvement of multiple stakeholders within health systems. Major new investment in national health systems would also be required. New financial inputs would need to be carefully coordinated with existing resource and budgeting frameworks, including

¹² WHO/UNAIDS, 2003, *Treating 3 million by 2005, Making it happen*, The WHO Strategy, December, p. 9-10. See Appendices.

countries' "Poverty Reduction Strategy Papers (PRSPs) and sector-wide approaches (SWAps)." (WHO/UNAIDS, op cit, p. 6-7)

2.3 Expected results of the Initiative

2.3.1 Goal (Impacts)

"The goal of the Initiative [was] for WHO and its partners to make the greatest possible contribution to prolonging the survival and restoring the quality of life of individuals with HIV/AIDS, advancing toward the ultimate goal of universal access to ART for those in need of care, as a human right and within the context of a comprehensive response to HIV/AIDS."¹³

2.3.2 Purpose (Effects)

- to support the expansion of access to ART to 3 million people with HIV/AIDS in developing countries by the end of 2005;
- to strengthen health systems;
- to simultaneously accelerate HIV-prevention efforts, pursuant to the WHO HIV/AIDS Plan, January 2004 to December 2005.¹⁴

2.3.3 Planned outputs

- equipped country teams;
- simplified AIDS treatment regimens, treatment guidelines, and diagnostic tools;
- establishment of an AIDS Medicines and Diagnostics Service (AMDS);
- uniform surveillance and monitoring tools;
- standardized training and capacity development programmes for health workers.

2.4 Programme inputs

In the "3 by 5" strategy published in December 2003, WHO defined four main categories of inputs¹⁵ required for the Initiative:

- financial resources;¹⁶
- staffing;
- training and guidance documents; and
- partnerships.

¹³ *Treating 3 million by 2005, Making it happen*, The WHO Strategy. Geneva, World Health Organization/UNAIDS, December 2003, p.9. See Appendices.

¹⁴ TOR, p.1.

¹⁵ From a Logical Framework Analysis perspective, inputs *Training and Guidance Documents* and *Partnerships* can also be considered as outputs.

¹⁶ Under a grant arrangement between WHO and CIDA concluded in December 2004, CIDA agreed to contribute CDN\$ 100 million to support the "3 by 5" programme of work from 2004 to 2006.

Budget¹⁷

Table 2 Summary of budget approvals for "3 by 5"

Input	A	B	C	D
Additional financial resources estimated to be obligated by WHO to "3 by 5"				
	Original figure (for Dec 2005)	Approved by the Executive Board	Resources allotted¹⁸ (as of end Nov 2005)	Obligations (as of end Nov 2005)
a) Within WHO overall	350	218	192	125
b) Within overall budget, at country offices (only)	214	142	90	51
Ratio country offices/ overall budget		65%	47%	41%

- Column A contains the figures that can be found in the "3 by 5" Strategy document "Making it happen". These figures have never been approved (not having been ratified by the WHA members).
- Column B contains the planned budget figures for the 2004-2005 period as approved by the WHA and Executive Board.
- Columns C and D contain the resources allotted and obligated as of end November 2005.

NOTE:

In late 2003, the funding target for WHO's HIV/AIDS activities in the 2004–2005 biennium was initially established at US\$ 400 million, with US\$ 350 million for scaling up ART and US\$ 50 million for prevention and other work. In January 2004, the WHO Executive Board revised the planned budget of US\$ 400 million to US\$ 218 million given that partner organizations were expected to increase their contribution to scaling up treatment in the form of both human and financial resources. Thus the revised milestone should be considered to be US\$ 218 million.

With regard to financial resources to WHO regional and country offices, when "3 by 5" was launched it was decided that approximately 60% of the total funding for WHO should be allocated to regional and country offices. Early in 2005 it was estimated that more funds should be allocated to the regional and country offices, thus, in 2005 about 65% of the total funding was shared with WHO regional and country offices.

¹⁷ Source: WHO comments on *The draft "3 by 5" evaluation report*, February 2006.

¹⁸ In the WHO environment, the two terms "contributions" and "resources allotted" refer to money from different perspectives, i.e. "contributions" being upstream and "resources allotted" further downstream of the income-generating and -spending process. The term "resources allotted" does not refer to funds mobilized but rather funds that are available in the HIV account to finance WHO's HIV work. In the WHO accounting procedures the most important variable is the allotted resources. Resources allotted is not limited to "contributions" but also includes funds carried over from previous biennia, interest earned as well as funds coming from the regular budget (RB), the latter being the total amount of the official assessments levied on all Member States. Once funds are mobilized, they do not immediately become allotted for expenditure, since there is a lag time.

- The term "contributions" refers to funds mobilized by the department to finance its work. By 10 November 2005 when the analysis of voluntary funds mobilized was undertaken, the total amounted to US\$ 194 796 786. This includes cash deposited in the HIV account as well as firm pledges (i.e. the money has not yet arrived in the WHO account but the donor has committed in writing to provide the funds).

Source: NOTES, 3 March 2006, HIV/AIDS Department, WHO headquarters.

Staff

The number of additional staff deployed and/or realigned to WHO country offices (WCOs) for "3 by 5" is 179.

These WHO staff members are all dedicated to specifically working on HIV at the country level. Moreover, other staff members are working on HIV along with other areas such as communicable diseases, TB or malaria.

Training and guidance documents

The number of standard training packages and other key guidance documents published (not including revisions of documents) is 60.

Partnerships

The number of partner organizations whose role in "3 by 5" is agreed and published is 210.

Figure 1 How the "3 by 5" Initiative was organized within WHO (2004-2005)

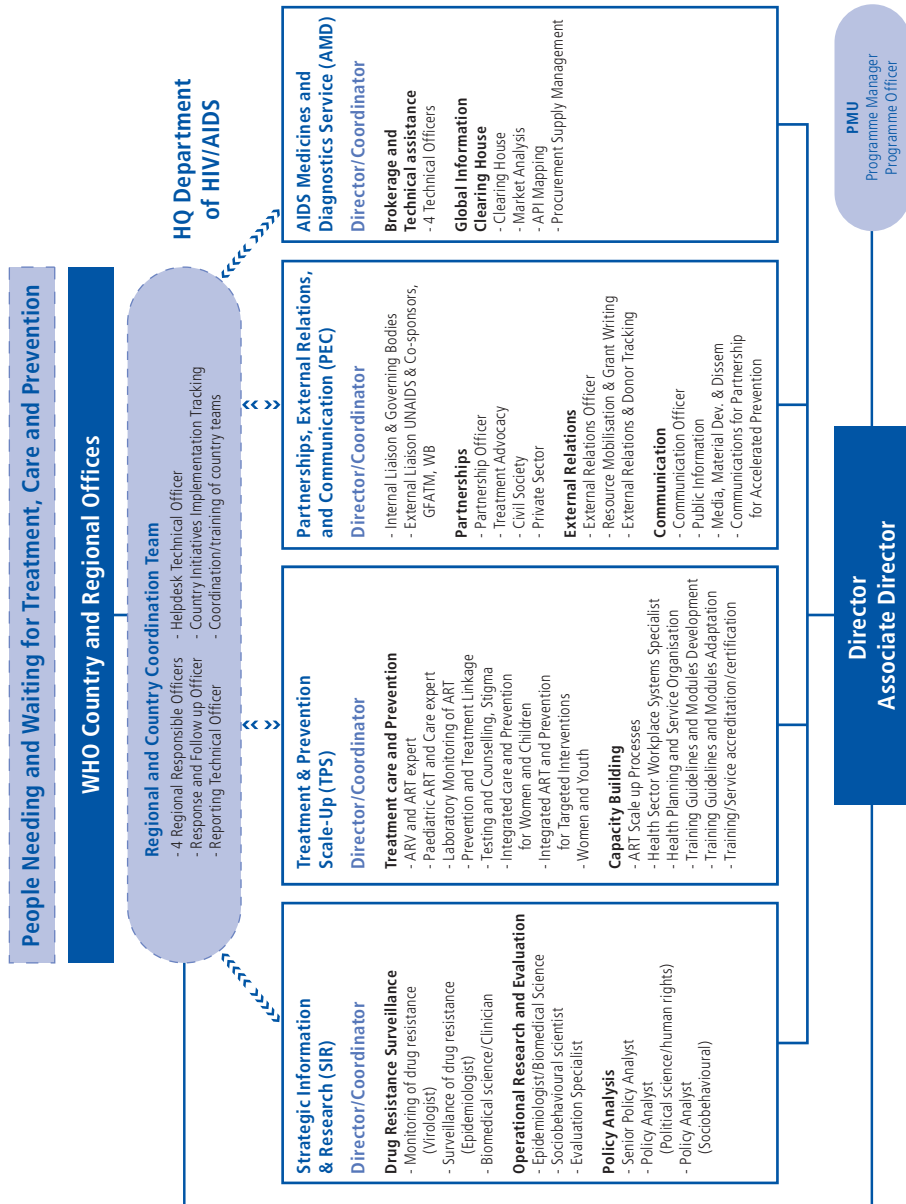
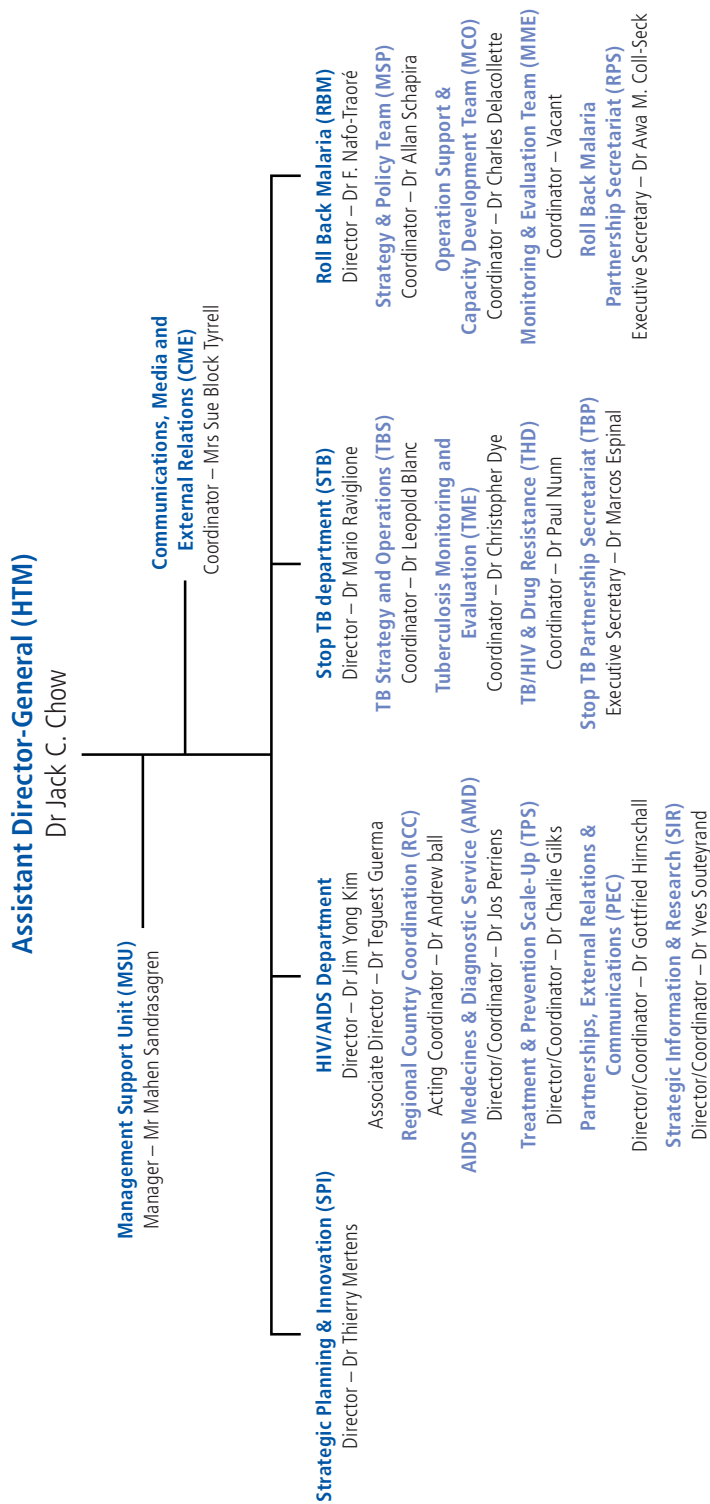


Figure 2 Organization of the HIV/AIDS, Tuberculosis, Malaria (HTM) Cluster as of 1 August 2005



2.5 Global progress by end of 2005

On World AIDS Day 2005 many commentators referred to the "missed target"¹⁹ and some considered WHO responsible for this failure. Overall, ART coverage in low- and middle-income countries increased from 7% at the end of 2003, to 12% by the close of 2004 and was estimated to be 20% in December 2005 (against the "3 by 5" target of 50%).²⁰

Table 3 Status of ART coverage by region, December 2003–December 2005

Geographical region	Estimated number of people receiving ART, Dec 2005 ^a	Estimated number of people 0–49 years old needing ART, 2005	ART coverage, Dec 2005 (%)	Estimated number of people receiving ART, Dec 2004 ^a	Estimated number of people receiving ART, Dec 2003 ^a
Sub-Saharan Africa	810 000 [730 000–890 000]	4 700 000	17%	500 000 [425 000–575 000]	100 000 [75 000–125 000]
Latin America and the Caribbean	315 000 [295 000–335 000]	465 000	68%	290 000 [270 000–310 000]	210 000 [160 000–260 000]
East, South and South-East Asia	180 000 [150 000–210 000]	1 100 000	16%	155 000 [125 000–185 000]	70 000 [52 000–88 000]
Europe and central Asia	21 000 [20 000–22 000]	160 000	13%	20 000 [18 000–22 000]	15 000 [11 000–19 000]
North Africa and the Middle East	4000 [3000–5000]	75 000	5%	4000 [2000–6000]	1000 [750–1250]
Total	1 330 000 [1 200 000–1 460 000]	6 500 000	20%	970 000 [840 000–1 100 000]	400 000 [300 000–500 000]

^a low estimate–high estimate

Notes:

- Some numbers in the table do not add up due to rounding off;
- Data on children are included;
- The coverage estimate is based on the estimated number of people receiving ART and need for ART.

¹⁹ The International Treatment Preparedness Coalition (ITPC), one of WHO's first partners in the scale-up process, published a report *Missing the Target* (28 November 2005) (<http://www.aidstreatmentaccess.org/itpcfinal.pdf>, accessed 14 April 2006).

²⁰ Preliminary monitoring data were made available to the Evaluation Team for this report. The complete WHO analysis of the status of treatment scale-up at the end of 2005 can be found in: *Progress on Global Access to HIV Antiretroviral Therapy – A Report on "3 by 5" and Beyond*. Geneva, World Health Organization/UNAIDS, March 2006.

- Table 3 from WHO/UNAIDS illustrates that although the overall target of 3 million was not reached, substantial increases in the numbers of people accessing treatment occurred over the past two years. The most significant of these increases were in sub-Saharan Africa, but there were major differences between countries in the degree of progress made.
- Countries such as Botswana and Uganda achieved coverage in excess of the 50% target, while others still have coverage levels below 10%. South Africa accounts for almost one quarter of those receiving treatment in the Region, despite not having reached its own targets (considering the large numbers of people infected with HIV in this populous country).
- Access to ART in East, South and South-East Asia has continued to increase, up to 175 000 (which is approximately 16% of those who need treatment) from 100 000 a year earlier, with Thailand making the biggest contribution to this increase. India accounts for more than 70% of the total need for treatment in this Region, but still only has a coverage level well below 10% (with most treatment provided through the private sector).
- In Latin America and the Caribbean, numbers have increased gradually to 315 000 (estimated coverage 68%) from 210 000 at the end of 2003. This varies considerably between countries in the Region, with Argentina, Brazil and Mexico having relatively high levels of coverage, and with the Dominican Republic, Haiti and Nicaragua providing treatment to fewer than 25% of people needing ART.
- In the low- and middle-income countries of eastern Europe and central Asia, North Africa and the Eastern Mediterranean, there have been less dramatic increases. Overall coverage in these regions is still below 20% (Just over 20 000 receive treatment in eastern Europe and central Asia and 4000 in North Africa and the Eastern Mediterranean).

Challenges identified by WHO

WHO acknowledged that the challenges of working towards the global target were enormous. One and a half years into the Initiative, the June 2005 "3 by 5" Progress Report reflected on the importance of national leadership and ownership, and highlighted the continuous need for further harmonization and alignment of the efforts of multilateral institutions and development partners and the importance of making the multilateral response more effective, with special reference to coordination, accountability and oversight within the United Nations system.

Further challenges were identified in the areas of:

- equitable access;
- integration of prevention with treatment;
- human resource capacity;
- procurement and supply management systems; and
- health infrastructure/health systems.

This evaluation is not an appraisal of the "3 by 5" target, or an assessment of whether WHO contributions had a direct impact on the number of patients in any specific country. The fact that the "3 by 5" target was not reached has therefore not been considered the main indicator of the Organization's performance, but it does serve as a reminder of the continuing relevance of WHO (why it is necessary for the Organization to continue advocating for and supporting sustained responses in scaling up access at both the international and country levels).



In a PLHA Association in Mozambique

3 Evaluation profile

3.1 Evaluation objectives

The objectives of the evaluation, as defined by the TOR, were to²¹:

- review how effectively WHO has contributed to the achievement of the "3 by 5" targets and milestones, including technical, managerial and administrative guidance and support provided by the programme across WHO at global, regional and country levels;
- document lessons learnt from "3 by 5", including its role in health systems strengthening, and develop recommendations for future plans and the way forward for WHO and its partners;
- assess WHO's ability to effectively mobilize, sustain and contribute to a major global partnership, including through improved harmonization between United Nations agencies and other stakeholders and partners; and
- identify potential opportunities for future collaboration between WHO, main donors and partners.

3.2 Focus of the evaluation

In addition to the "3 by 5" milestones and other areas already monitored in periodic WHO progress reports, the evaluation incorporated an assessment of lessons learnt in the following core evaluation areas:

- WHO global leadership, alliances and advocacy for "3 by 5";
- programme implementation, management and coordination at WHO headquarters, regional and country levels and across technical areas;
- utilization and effectiveness of WHO normative guidance and tools;
- strategic information;
- technical support and capacity-building;
- complementarity of WHO activities with partner efforts; and
- equity of access.

²¹ The complete TOR are found in Annex 1.

Additional focus themes²² were identified as being of special significance to the WHO contribution that could not be directly assessed by the Evaluation Team and were commissioned as focus studies:

- prequalification of antiretroviral drugs (ARVs);
- the WHO initiative to develop a global HIV resistance surveillance and monitoring network; and
- review of ARV pricing trends as a precursor of "3 by 5" and of the role of the AMDS in drugs and diagnostics procurement and supply management.

The main emphasis of the evaluation was on WHO's role in countries, especially in Africa. This prioritized the activities and time allocations of the Evaluation Team.

3.3 Methodology

3.3.1 General approach

- The Evaluation Team set out to undertake a learning-oriented investigation that would support the WHO development strategy of "learning by doing", based on an evaluation workplan that the Team proposed and the Evaluation Steering Committee reviewed in August/September 2005²³. This was oriented towards:
 - reviewing the performance of WHO's work (through retrospective analysis);
 - evaluating selected key technical contributions in greater depth; and
 - providing evidence to guide future decision-making (through a prospective analysis).
- The evaluation intended to appraise WHO contributions to the inputs, processes and outcomes that have influenced other actors and the individuals, groups and organizations implementing activities relevant to scaling up treatment access.
- The evaluation did not intend to demonstrate whether the WHO programme of work has already resulted in development impacts, or the extent to which the setting of the "3 by 5" target can, in itself, be directly attributed to increasing the numbers of people who are now receiving ART.
- The Evaluation Team felt that attempting to credit the complex developments in global and local responses to HIV and AIDS over the past two years to a single institution or goal would limit the potential to create knowledge through understanding how and why impact occurs (through a multitude of participants, contributions and influences) and would be an impediment to learning. Instead, the evaluation was designed to focus on finding evidence of changes that have come about through the sphere of influence of WHO programmes and its organizational structure, so that feedback could be provided about how this influence might be expanded in future.

²² These themes were chosen because they were considered to be of special importance to WHO's contribution and/or because sufficient expertise was not available inside the Evaluation Team to address them adequately.

²³ The latest version of the Workplan is dated 28 October 2005. No subsequent final revision was undertaken since the evaluation process was already well underway at that time.

3.3.2 Assumptions upon which the evaluation was based

- The "3 by 5" global target (intended impact) of the WHO programme of work was only considered as a directional beacon (and test of relevance), rather than as a yardstick against which the performance of the Organization could be measured.
- By focusing on what could be learnt from what has been done, the Evaluation Team hoped that WHO could be provided with useful information that would: reduce its risks in trying new approaches; help in developing further innovative programmes; and encourage new partnerships. The ethos of this evaluation is to help the Organization further scale up its positive influences (and minimize any harmful consequences) that have grown out of the passion, commitment and sense of mission represented by the "3 by 5" target.
- The threat of failing to find "hidden attribution" would be eliminated by providing feedback on performance towards improving, rather than proving; on understanding rather than reporting; and on creating knowledge rather than on attributing credit for outcomes.
- The evaluation recognized that many other partners at the global and national levels are often better positioned to implement change, whereas WHO could only influence this by providing access to new resources, ideas, exchanges and opportunities for a limited period of time.
- The most successful development programmes are those that devolve power and responsibility to "local ownership" actors. The success of these programmes should therefore be determined by the extent to which they have been able to influence this process.

3.3.3 Evaluation strategy

Based on the types of decisions that this evaluation was expected to inform and TOR, the Evaluation Team elected to use a predominantly qualitative approach, combining several evaluation tools to collect data through:

- extensive review of documentation;
- individual and/or group interviews with main (internal and external) partners and stakeholders;
- survey (complemented by interviews) of WHO headquarters technical team leaders;
- visits to 7 of the 49 focus countries (Burkina Faso, Guyana, India, Kenya, Malawi, Mozambique and Ukraine)²⁴ of which 4 are located in Africa;
- visits to four regional offices (the WHO Regional Office for Africa in Harare; the WHO Regional Office for the Americas/PAHO in Washington; the WHO Regional Office for the Eastern Mediterranean in Cairo and the WHO Regional Office for South-East Asia in New Delhi);

²⁴ Due to continuous unrest, the twice-scheduled mission to Ethiopia was cancelled at the last minute and could not be replaced by another country.

- electronic survey of WHO country officers (COs); national AIDS programme managers; and United Nations AIDS Country Theme Groups in the "3 by 5" focus countries; and
- commissioned focus studies.

Since much of the evidence for the findings was of a qualitative nature and based on individual beliefs or intuition, a strategy of **triangulation**²⁵ (different sources and a mixed-method to collect data) was used to assess the validity of this information. Procedures were undertaken to examine the internal coherence and external correspondence of findings against other existing data sources and the empirical evidence gathered (mainly through site visits). Most of the findings and recommendations in the report were reached by consensus. In a few cases, the decision was based on the majority of Evaluation Team members.

The countries to be visited were selected on the basis of criteria suggested in the TOR, which included being among the 49 "3 by 5" focus countries; having major global partners in country; and where a WHO "3 by 5" officer was present.

3.3.4 Evaluation activities

The evaluation covered global, regional and national levels. Over the four-month period from September to early December 2005, the Evaluation Team visited:

- WHO headquarters in Geneva (Director-General, HIV/AIDS Department, other departments involved in HIV/AIDS work);
- the seven selected countries and four regional offices; and
- representatives from an extensive range of global partners and stakeholders (listed in Annex 2).

In order to base the findings on not only the relatively small sample of 7 countries, it was decided to address all 49 focus countries through 3 surveys: to the national HIV/AIDS programme managers in the ministries of health (MOHs); the WHO "3 by 5" COs; and United Nations AIDS Country Theme Groups.

By agreement of the Steering Committee and following the general logic of the evaluation as a formative, learning exercise, WHO staff members from the head office and regional offices participated as observers in all the country assessments. While in country, local WHO staff (in most cases, the "3 by 5" CO) accompanied the Evaluation Team members to most nonconfidential meetings and interviews. In more sensitive meetings with senior representatives of stakeholders/partners (see contacts in Annex 2), this WHO participation was excluded. The Evaluation Team and Steering Committee reviewed the overall participation of WHO in the evaluation process and concluded that this had in no way impeded the independence of this evaluation.

²⁵ According to this strategy, evidence from diverse and mutually independent sources is compiled and compared to confirm or to negate assumptions. Decision theory uses "prior" information to infer which options are most likely to succeed when making decisions.

Visits to countries and regional offices were not expected to yield thorough individual assessments of WHO performance in each of these settings, but rather to provide illustrations of the challenges, opportunities and complexities of the environment in which WHO has been working. Country and regional office debriefings were undertaken, but detailed country reports were not provided back to these countries or regional offices²⁶.

3.3.5 Constraints

The Evaluation Team agreed that the following constraints could be seen as limitations on the scope and conduct of this evaluation.²⁷

1. The evaluation took place within a very tight time frame, during which a broad range of activities were planned in many different countries. This depended on the cooperation of a large number of people, including external stakeholders and WHO personnel. All of the planned activities were completed and the Team experienced excellent cooperation from almost all respondents.
2. The scope and focus of the evaluation were prescribed by the TOR and overseen by the Evaluation Team. As a result, some areas of the programme or specific concerns have not received the attention that some people feel they might have deserved.
3. There was no existing Logical Framework Analysis (LFA) for the programme against which to evaluate the results of this Initiative, which necessitated a non-traditional "programme evaluation" approach. A framework had to be constructed *post-ante* by the Team, derived from the documentation review, country visits, etc., and reflects a degree of interpretation by the evaluators of what the Organization actually set out to achieve within its programme of work.
4. The Evaluation Plan for this activity needed to be designed by the Evaluation Team within the first weeks of the assignment and was not based on an independently constructed existing design that the evaluators could implement (as is often done for large and complex evaluations of this nature). The time frame for developing the Evaluation Plan was unrealistic, although the proposed plan did undergo an intensive review by the Evaluation Steering Committee and an iterative process of modification.

²⁶ The notes on countries and regional offices visited provided in Annex 5 highlight the findings from the Evaluation Team perspective and should in no way be understood as a comprehensive "appraisal" of WHO's work or the country performance in these countries or regions.

²⁷ For further explanation of these constraints, see Annex 4 on evaluation methodology.

PART 2

Retrospective analysis

4 Evaluation findings

4.1 Strategic objective 1: Global leadership, advocacy and partnerships

4.1.1 Global leadership

1. The "3 by 5" Initiative played a major role in making access to ART a widely accepted essential public health intervention, by demonstrating that this is possible even under resource constraints. Broad consensus on the right to treatment among activists, development organizations and governments had evolved over the period from the XIIIth International AIDS Conference in Durban during 2000, to September 2003. However, launching "3 by 5" galvanized commitment to treatment access to the point of no return. It has been a crucial developmental step towards the *Universal Access* declaration.^{28,29} Through its institutional influence, WHO has convinced many national governments that ART could be provided through large-scale public health programmes in developing countries. This also encouraged funding organizations to invest in treatment.
2. In the process, WHO has regained a global leadership role in the health-sector response to HIV and AIDS. All national and international partners contacted through the process of this evaluation expect WHO to provide a continuous, strong technical and political leadership role in the health-sector HIV and AIDS response, and to position this within the broader health and development agenda. This should include increasing the focus on strengthening health systems and providing guidance and strategies for funding and supporting national governments to improve the health of their people towards achieving the Millennium Development Goals (e.g. through improving health sector policies and establishing financing instruments such as SWAps and common funds).
3. Global leadership is not only about advocacy, it has to be established and maintained through programmatic, normative and technical excellence, as well as by working through strong, effective partnerships. Some development partners consulted during the evaluation criticized WHO quite strongly for its lack of strategic and programmatic preparation for the "3 by 5" Initiative. It needs to be acknowledged that up to 2003 there was still no general consensus among leading institutions (or even within WHO) that large-scale ART access should be implemented as a priority public health intervention.³⁰

²⁸ The G8 has made a commitment to "... significantly reducing HIV infections and working with WHO, UNAIDS and other international bodies to develop and implement a package for prevention, treatment and care, with the aim of as close as possible to universal access to treatment for all those who need it by 2010" (Gleneagles, July 2005).

²⁹ "3 by 5" was presented in evidence to the United Kingdom Parliamentary International Development Committee to inform the position of the United Kingdom Government on "Universal Access" in preparation for the G8 Gleneagles Summit.

³⁰ As an example, the *Global Health-Sector Strategy for HIV/AIDS 2003–2007*, Geneva, World Health Organization, 2003, only refers to the "imbalance in treatment access" but does not call for a dramatic change in policy.

4. At the outset, WHO made it clear that this target could only be achieved if "human, technical and financial resources" were made available and if countries, the United Nations, national governments and civil society became engaged. A number of key consultations took place leading up to the launch of "3 by 5" to try to establish consensus for this target and to gain support for it to become a jointly owned priority. WHO obtained endorsements from other relevant partners to lead this as an "emergency initiative". However, the evaluation encountered senior representatives of the institutions who had formally committed to this Initiative that felt WHO had subsequently failed to lead "3 by 5" as an effective global partnership. As a result, in many international quarters the evaluation faced a perception that "3 by 5" was considered only as a "WHO initiative".

4.1.2 Advocacy

5. WHO (as a cosponsor of UNAIDS) was the only institution with the mandate and credibility to declare the lack of access to ART a global health emergency. The "3 by 5" target became a widely used slogan by most partners in the international development community (regardless of their individual convictions about whether this target was realistic), as "3 by 5" captured the growing global intention and commitment and gave this a name.
6. Advocacy for "3 by 5" had an important effect on WHO as an organization³¹. After years of ambivalence and lack of action on HIV and AIDS by the senior WHO leadership and for the first time since the end of the Global Programme on AIDS (GPA) in 1995³², "3 by 5" re-established this as a core priority throughout the Organization.
7. Despite being useful for advocacy, by the end of 2005 this global target of 3 million was considered by many partners consulted during the evaluation to have been unrealistic to implement as a public health programme goal because it was constructed without adequate participation by the countries it affected. Although WHO intended this to become a "universally" accepted target, it was perceived by many to be an aspirational "WHO" target. In a number of countries (particularly within Africa) that had already established national targets, "3 by 5" led them to revise these existing targets (often with expectations of substantially increased financial support that did not materialize). Some respondents from MOHs felt that WHO had encouraged national governments to make commitments that they could not be expected to achieve within their existing constraints. Beyond providing a handy "catch-phrase" with which to generate expectations, it was therefore unlikely that this target would be achieved because neither WHO nor the international community were really adequately prepared to make it happen.

³¹ See also Chapter 4.6 on organizational analysis.

³² An historical account of the HIV/AIDS programme area within WHO is provided in Annex 7.1.

8. Inadequate attention was given to what would happen to the Initiative beyond December 2005 (even WHO offices contacted during the evaluation were unclear about this next phase). The WHO communication strategy to explain the "missing the target" did not succeed in contextualizing the status of the global response, as a way of informing the process that is now underway within the United Nations (led by UNAIDS) to establish the framework for *Universal Access*³³. Some scepticism and reservations remain about how serious the WHO top leadership is about taking this bold initiative forward.

4.1.3 Partnerships³⁴

9. WHO realized the importance of working with many partners to achieve the "3 by 5" goal³⁵. A special unit was established within the HIV Department at WHO headquarters to promote and strengthen partnerships. At the regional and country levels this was equally perceived as a priority. Although many development partners had already started to give attention to ART, WHO support to the movement increased the acceptance in development organizations that ART should be considered a public health priority.
10. At the beginning of 2004, there were only 14 established partnerships with WHO, most of them technical and traditional in nature. WHO identified more than 180 potential partnerships after the first (and only) Global Partnership Meeting in May 2004.³⁶ Despite its intention, WHO never came anything close to establishing a global partnership network to "achieve the 3 by 5 target". All regional offices organized large meetings to identify all potential partners. However, with the exception of the Americas and the WHO Eastern Mediterranean Region, these did not result in any lasting concrete cooperation since they were too big and did not have the resources for planned follow-up. By the time the initial ideas of collaboration stemming from these meetings could have been put in practice, "3 by 5" was already history.
11. WHO did not start out with a strategy for identifying, selecting and managing partnerships for "3 by 5"³⁷. There has been an overall lack of strategic thinking on how partnerships should be developed and structured to serve different purposes, such as political, strategic, technical, operational and advocacy functions. As a result of these loosely managed arrangements, partners have often found it difficult to work with WHO

³³ For the widely negative reception of the failed target in the international media, see press clippings of the World AIDS Day 2005 media coverage in Annex 12. WHO maintains that it prepared the development community and the international media for not reaching the target. However, numerous statements and reports even from generally sympathetic partners were published at the end of 2005, which clearly were very critical of WHO.

³⁴ These paragraphs deal mainly with partnerships in general and selected groups of partners. Additional considerations relating to partnerships – especially with governments (the "primary" partners of WHO) will be found under Strategic objective 2 and the more technical partnerships are discussed under Strategic objectives 3 and 4; see also Organizational analysis.

³⁵ "No single agency can achieve the target of 3 million people", WHO/UNAIDS, 2003, p.29.

³⁶ A second meeting planned for October 2005 was postponed and then replaced by a *Universal Access* meeting.

³⁷ WHO points to the fact that UNAIDS is the main coordination structure for partnerships for HIV/AIDS. This raises an important point in the collaboration with UNAIDS: while both launched the "3 by 5" initiative, the subsequent commitment of the UNAIDS Secretariat (and other partners who initially signed in on the initiative) seemed to be less enthusiastic. Despite its intention and efforts, WHO never really succeeded in making "3 by 5" an initiative of the entire United Nations system and most partners contacted, perceived it up to the very end as a WHO initiative. The reasons why other organizations and partners did not buy into the initiative more strongly but rather supported acceleration of ART may be manifold and beyond the scope of this evaluation.

and opportunities for more effective collaboration have been missed in some cases. In a broadened partnership approach, strong emphasis is needed on good communication and transparency. While efforts to be more strategic evolved³⁸, and communication and information-sharing improved over time at the global level, the potential of partnerships remained largely underexploited.

12. Although WHO invested considerable efforts at global, regional and country levels to work with the nongovernmental (and non-United Nations) partners, including faith-based organizations; associations and PLHA networks; and the private business sector, many of them would like to see WHO being more visible, more facilitating in providing opportunities for them to lobby governments and in general, more open to sharing information and learning from others.
13. In contrast, WHO has been much more successful in establishing and maintaining technical partnerships, which is what the Organization has traditionally been good at doing. Nearly all the normative tools and guidelines developed in the context of "3 by 5" have been collaborative products contributed to by many organizations. These types of partnerships are profiled in subsequent sections of the report describing technical areas of work (AOWs) (especially 4.3 and 4.4).
14. WHO had not succeeded in mobilizing sufficient donor support for its own involvement in "3 by 5" before the initiative was launched. Intensive negotiations took place with potential donors, but these had limited success and a number of assurances of support were not forthcoming. WHO expected that funding from major institutions and programmes such as GFATM and PEPFAR would be available to finance its technical and leadership functions in "3 by 5". However, these expectations did not necessarily appreciate that the legal framework within which these programmes operate (especially for PEPFAR) restricts WHO from accessing funding in this way. In the case of GFATM, a decision was made by the governing body not to allow its funds to directly contribute to the work of the United Nations system at the global level. The main grant to WHO that the Canadian Government (CIDA) committed in early 2004 therefore rescued the "3 by 5" Initiative³⁹. As this initial two-year period of funding draws to a close, WHO has not succeeded in securing continued funding for this AOW. (A more detailed analysis of the precarious WHO funding situation and of the contributions by other donors appears in Section 4.6.4).⁴⁰
15. WHO (with UNAIDS) has provided considerable technical support in helping to establish the Global Fund and provided assistance to countries for submitting successful Global Fund applications. The work of WHO is critical to whether these funds are used successfully and the Global Fund has acknowledged that there needs to be more appropriate mechanisms to finance WHO (and others) to provide this technical assistance. Collaboration between

³⁸ Summary of the PEC Unit prepared for the attention of the Evaluation Team.

³⁹ For the financial aspects of WHO see Chapter 4.6: Organizational analysis and Annex 7.

⁴⁰ The fragility of WHO's funding for its HIV/AIDS work raises a fundamental issue for international development cooperation, which surfaced in numerous interviews, especially with donors and development partner organizations. Although the issue is much beyond the scope of this evaluation, the Evaluation Team regards it as one of the most fundamental challenges to be addressed in the context of harmonization and alignment. See Chapter 5: General conclusions.

WHO and the GFATM has taken some time to formalize and was recently improved through the establishment of a fast-track review and problem-solving (GIST) mechanism, in 2005.

16. The World Bank has been one of the strongest contributors to health systems strengthening and reform in countries over the past 20 years, but WHO and the World Bank did not take adequate advantage of "3 by 5" to join forces in providing more countries with coordinated support for strengthening their health sector responses.⁴¹ Although WHO did collaborate with the World Bank "Treatment Acceleration Programme" in Burkina Faso, Ghana and Mozambique, the Organization was apparently unable to offer the required technical assistance for this due to capacity constraints.⁴² This highlights how no single institution has the answers for resolving the health systems constraints that face many African countries and demonstrates that joint efforts and partnerships in this area are essential.
17. Two important meetings between the Office of the Global AIDS Coordinator (OGAC)/PEPFAR and WHO in July 2004 and February 2005 did not produce any strategic agreement to collaborate (and there is hardly any record of these interactions). This has been an extremely important missed opportunity for collaboration since PEPFAR provides enormous financial and technical resources in its 15 focus countries and the "3 by 5" Initiative may have benefited from a strategic arrangement between the two organizations.

Partnerships within the United Nations system

18. For a long time, WHO was perceived as a weak partner in the United Nations response to HIV. Since UNAIDS jointly launched the "3 by 5" Initiative with WHO it has been one of WHO's strongest allies at country level, using its influence to promote the initiative with hesitant governments and development partners⁴³. The WHO focus on ART is seen by many United Nations partners as providing the missing link in the strategy to control HIV and AIDS.
19. WHO has contributed to the process of establishing the Global Task Team (GTT)⁴⁴ in 2005, which has introduced the concept of "lead agency" into the United Nations system, thus helping to better define the division of labour in the global HIV response. WHO has been assigned the role of "lead technical agency" for the health sector response to HIV and AIDS within the United Nations. In nearly all the countries surveyed and visited⁴⁵, the Evaluation Team found that the focus on treatment (and prevention)

⁴¹ See also the chapter on health systems strengthening (4.7.2).

⁴² A high-level meeting was held between the WHO Director-General (Dr Lee) with the president of the World Bank (Mr Wolfowitz) and their respective technical teams early on in the initiative, in which WHO requested the financial assistance of the Bank and offered technical assistance for the World Bank's MAP/TAP programmes. No concrete arrangements beyond the TAP were reached.

⁴³ On the difficulties in the collaboration between the UNAIDS Secretariat and WHO headquarters after launching "3 by 5" see footnote 37.

⁴⁴ A Global Task Team (GTT) on improving coordination among multilateral institutions and international donors to further strengthen the AIDS response in countries. The GTT is working to improve the institutional architecture of the response to HIV and AIDS. The particular focus is on how the multilateral system can streamline, simplify and further harmonize procedures and practices to improve the effectiveness of country-led responses and reduce the burden placed on countries.

⁴⁵ 20 questionnaire responses plus five countries visited (two also provided questionnaires).

has now been well integrated into the United Nations country response⁴⁶. The extent to which WHO collaborates with individual United Nations partners in countries varies in each setting and how active these partners are in the scaling up response. From the perspective of WHO "3 by 5" COs, the most significant collaboration tends to take place with UNAIDS and UNICEF (Fig. 3).

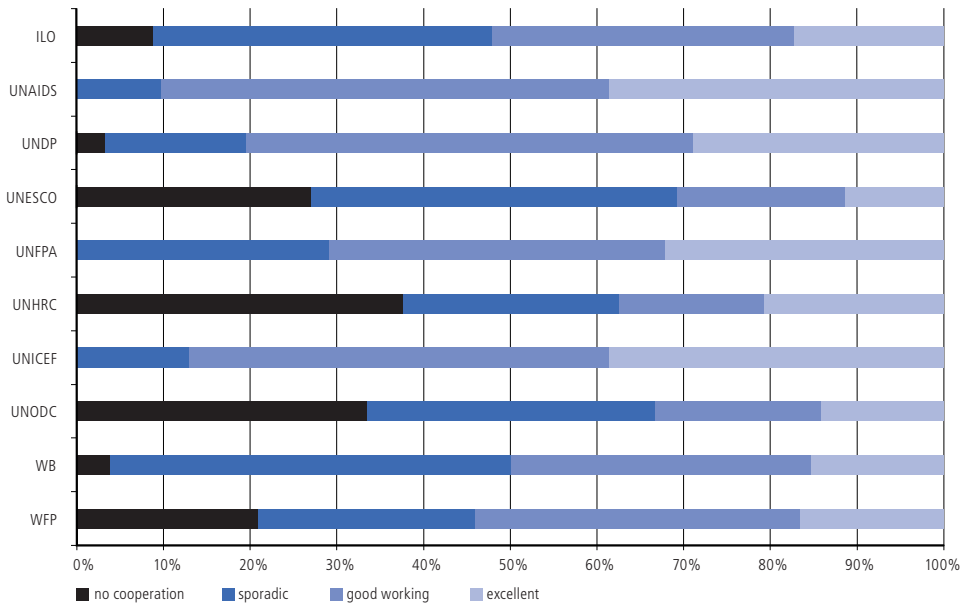
20. However, this allocation of tasks does not mean that there are no contested AOWs between WHO and its United Nations partners. An example is the ongoing lack of resolution between WHO and UNICEF about which organization is responsible for leading progress on PMTCT and paediatric ART. It seems that this is partly because of continuing ambivalence about what is considered "technical, normative work" (WHO's purview) as compared to "operational responses"⁴⁷. Numerous commentators believe that although there has been undeniable progress towards harmonizing the work of the United Nations, there are still counter-productive areas of competition between individual agencies that need to be addressed.⁴⁸
21. United Nations agencies within countries were seen to have placed much emphasis on working out their organizational delineation of tasks in accordance with these GTT recommendations through the national United Nations Theme Group on HIV/AIDS. Rather than taking a strategic perspective on what needs to be done to centre the HIV and AIDS response within a broader action plan for development, it seems that this process could be missing the point. For instance, in a country where little progress has been achieved in controlling the HIV epidemic in the last 20 years, it seems futile for this process to focus exclusively on distributing short-term roles and assignments for HIV and AIDS work to resident agencies rather than focus on addressing the underlying reasons for these failures.

⁴⁶ See Annex 6.3.

⁴⁷ In September, WHO and UNICEF (together with CDC and the Clinton Foundation) organized a joint review mission with national partners in Malawi to identify obstacles to PMTCT and the technical/normative issues relating to ART for children. This mission enabled participation by staff from head offices, regional and country offices and was an example of how differences between institutions can be overcome by directly working together on concrete issues.

⁴⁸ The accelerated pace of the political agenda (moving towards *Universal Access*) before lessons learnt from "3 by 5" were already established and integrated, has not allowed sufficient time for these organizations to reflect on what has happened through "3 by 5" in order to chart the way forward. This is potentially self-defeating to the United Nations harmonization process.

Figure 3 How WHO "3 by 5" officers rate their cooperation with other United Nations agencies within countries



Source: Result report on survey of WHO HIV/AIDS Treatment and Prevention COs, Annex 6.1

Partnerships with people living with HIV/AIDS (PLHA)

22. WHO has advocated and supported a paradigm shift in delivering ART based on the public health approach (PHA), which assigns crucial roles and functions to PLHA. Efforts to enable PLHA to participate in scaling up processes are widely acknowledged and appreciated by these constituencies (for instance, in India and Ukraine the Evaluation Team found that WHO had helped support PLHA organizations to participate in policy discussions and to become more involved in service delivery). In many countries, however, these types of partnerships and collaborations by WHO with PLHA have not yet been established.⁴⁹ This seems to be the case particularly where governments find it difficult to accept participation by PLHA in their national response. At times, a closer collaboration with UNAIDS could have contributed to WHO reaching out more effectively to PLHA.
23. In supporting this paradigm shift, WHO has promoted a successful principle of recruiting staff who have had links to the activist and NGO movements. However, there are also professionals in the Organization (especially at the country level) who lack experience in translating these principles into action. It is not always appreciated within the Organization that developing and maintaining partnerships is an activity that needs substantial investment – especially in human resources. Positive experiences across the

⁴⁹ It is not surprising that the ITPC in their own evaluation of "3 by 5" "Missing the Target" states that WHO lacks visibility at the country level and many of ITPC's members are unaware of what the Organization is doing in their country.

three levels of WHO seem to be more related to individuals rather than the result of systematic progress through an organizational policy.⁵⁰

24. Special attention needs to be given to girls and women living with HIV. While WHO headquarters has established contact and cooperation with the International Coalition of Women (ICW) at the head-office level, few of the specific concerns of girls and women seem to have been addressed within countries.
25. WHO provided US\$ 1 million towards establishing a collaborative fund for the International Treatment Preparedness Coalition (ITPC), which resulted in leveraging additional funding through the Tides Foundation to implement activities focused on preparing communities for treatment⁵¹. The ITPC now facilitates a rapidly growing and active network of PLHA, community-based organizations, and other like-minded individuals. This initiative is functioning quite independently of WHO and opportunities for more meaningful continued information-sharing and collaboration are not being actively pursued.

Other partnerships including with ESTHER

26. WHO has a Memorandum of Understanding with ESTHER to work collaboratively within French-speaking Africa, where WHO has been weaker historically. This has not yet achieved the full potential of this strategic collaboration or many concrete results, since ESTHER accepts that it was not always organized or ready to work with WHO and has only recently put in place its own staffing within countries that will help to make this possible.
27. WHO had interactions with a wide range of other international organizations (including faith-based, business coalitions and international NGOs). Very often these organizations lack their own clear understanding of how to participate in the global scale-up. There were partners who commented that WHO seemed more interested in using them for its own purposes, than achieving the full potential of collaboration and acknowledging that the Organization could learn something from them too. To a large extent, partnerships that happen at the international level are not always reflected in countries, where the same partners can be completely unaware of collaboration (or lack of collaboration) at their headquarters, and where often the resulting working relationships come from ad-hoc opportunities or personal networks.
28. The principle of South–South cooperation is spoken about in the Organization and there are some specific examples of how this is being achieved, such as the PAHO Regional Office support to the *Asociación de Facultades de Enfermería* in Colombia, which will work on the adaptation and training of Integrated Management of Adolescent and Adult Illness (IMAI) for nurses, first in Colombia and then in other parts of the Region through

⁵⁰ At the global, regional and country levels there are numerous examples (e.g. working with the International Treatment Preparedness Coalition, involvement of PLHA in delivering ART in Burkina Faso, India and Ukraine) showing that these partnerships have produced concrete and appreciated results.

⁵¹ A formative evaluation of the ITPC project is due to be completed at the end of 2005.

their regional network.⁵² Knowledge hubs have been established in each of three WHO regions for capacity-building in treatment and care.⁵³ Regional Offices (the WHO Regional Office for Africa and the WHO Regional Office for the Eastern Mediterranean) organized large partner meetings with participation by organizations from the South to encourage collaboration and there is increased focus on networking regarding technical support in the African Region.

South–South collaboration for implementing IMAI

In the process of disseminating IMAI across more African countries, WHO has increasingly relied on experienced regional consultants from the countries where IMAI has already been established, to assist their neighbours with adapting the materials and conducting initial training. In other instances, representatives from HIV programmes in one country have attended training in another where this is already taking place, to experience IMAI first hand. This practice has been successful in building regional competency to implement IMAI and for getting more countries interested in the approach. More recently, it has also extended from francophone Africa to Haiti through the exchange of translated materials and consultant expertise.

⁵² A further demonstration of the principle of South–South collaboration is the emergence of technical collaborations between low- and middle-income countries. A good example of this is the Technological Network on HIV/AIDS, a joint initiative between Brazil, China, Nigeria, the Russian Federation and Ukraine to cooperate on research, development and production of HIV medicines, diagnostics and other commodities. UNAIDS is also leading a drive to establish "Regional Technical Support Facilities" that will contribute to strengthening and better coordinating the provision of technical support by building on regional synergies.

⁵³ This is an initiative funded by *Gesellschaft für technische Zusammenarbeit* (GTZ) to build capacity through South-to-South collaboration for training and technical assistance between local organizations and HIV/AIDS services in each of the WHO European, WHO Eastern Mediterranean and WHO African Regions. By mid-2005 seven knowledge hubs had trained more than 1500 resource people reaching 41 countries. While these have made significant contributions with WHO to strengthen country capacity, their broader role and potential for expansion as a model must be clarified.

4.2 Strategic objective 2: Urgent, sustained country support⁵⁴

4.2.1 The role of WHO within countries

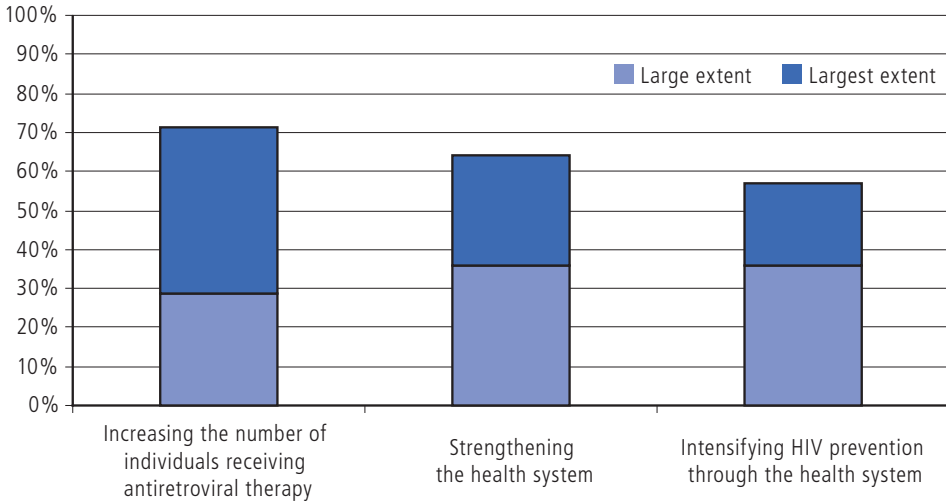
1. WHO set out to work with national governments in 49 focus countries to develop or revise their national treatment scale-up plans so that these would reflect the urgency and scale of the "3 by 5" goal. At the beginning of the Initiative only three had national plans in place, whereas most countries now have both a plan and a target guiding their programme. In many cases this led to new targets, or substantially revised commitments, aligned with the global goal (usually based on providing access to 50% of those who need treatment)⁵⁵. WHO was criticized by some MOHs for imposing these targets without providing adequate means through which they could be achieved.⁵⁶ However, in most cases, the national target functioned as an important motivator for national governments to speed up implementation of their operational plans and the majority of people interviewed believed that the positive consequences of the Initiative (even with its sometimes controversial target) outweighed the fact that this target would in many cases not be reached.
2. WHO's early technical support efforts in "3 by 5" focused on trying to achieve country preparedness for treatment scale-up and included technical assistance for resource mobilization; guideline development; capacity-building; procurement and supply management; and providing planning support. WHO delivered this assistance from a mix of sources, including the WCO; parachute missions from WHO headquarters and regional offices (especially in the earlier phases) and from WHO "3 by 5" officers. WHO was also assisted with providing contracted consultants and drew on the contributions of its technical partners (such as members of HIVResNet).
3. There is no doubt that the arrival of dedicated technical personnel (the "3 by 5" officers) has made an enormous difference in the consistency, quality and relevance of this technical support. The extent to which planned activities were implemented and the type of support that COs expect to deliver in the next programme cycle is extremely variable across settings and also depends on how long each officer has been in place. Surveyed "3 by 5" COs felt they could be more structured in planning and facilitating this country-level support if they had direct guidance and a clearly defined scope of what WHO could (or should) be offering.
4. In the 15 countries that have a strong PEPFAR presence and where there were already many other agencies working, WHO has tended to struggle with identifying its comparative advantage and with communicating its role to others. The evaluation found strong support from most partners within countries for WHO to assist the MOH's coordinating work within the health sector. This is an important mandate for WHO to operationalize; it demonstrates *in principle* commitment to "harmonization".

⁵⁴ The evidence in this pillar is based on the country visits by the Evaluation Team (see country notes in Annex 5) as well as the analysis of the questionnaires addressed to the national AIDS programme managers, WHO country staff and United Nations Theme Groups on HIV/AIDS (see Annex 6).

⁵⁵ WHO's position was based on the research and findings presented in the article by Schwartländer B et al. *Science*, 29 June 2001, 292 (5526): 2434-6.

⁵⁶ The South African Minister of Health was particularly public in her criticism of the WHO target-setting process.

Figure 4 Achievements of "3 by 5": contribution of WHO as rated by national AIDS programme managers

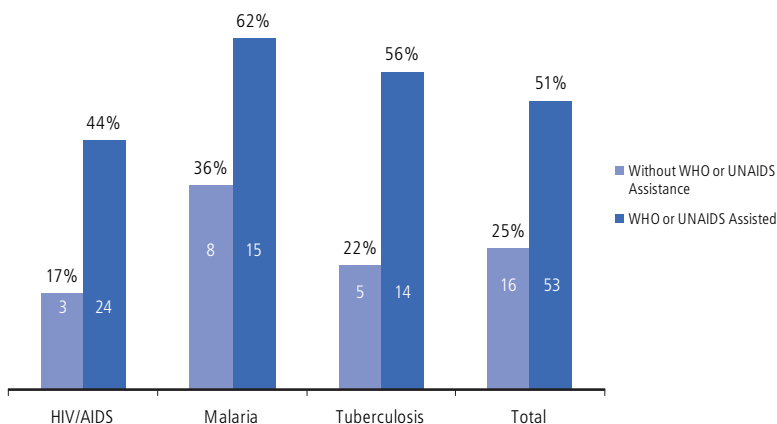


Source: Survey of national AIDS programme managers, Annex 6.2

- WHO has helped countries to mobilize new funds for treatment, mainly by providing technical support for proposals to the GFATM (together with UNAIDS). This has tended to be a time- and resource-intensive process in many countries that was inclined to divert attention from other programme priorities. However, the success rate for applications supported by WHO/UNAIDS was significantly higher than the average and this has made a difference to the national responses in a number of countries (Fig. 5).⁵⁷ The MOH in at least one country made an important observation that external consultants brought in for this purpose have, in the past, developed ambitious proposals that succeeded in being funded, but then were not available to provide assistance with implementing what had been proposed. This shows the importance of having continuity in providing direct technical support or securing technical assistance in partnership with other organizations. It also demonstrates the Global Fund's need to invest in technical assistance as part of its funding model as well as the vital role WHO has in its deliverance and in ensuring that consistent, relevant, high-quality technical assistance is requested and provided to national programmes.

⁵⁷ The fact that WHO (and UNAIDS) provided these consultancies out of their own resources while, in theory, GFATM funds are available for technical assistance to countries, points to the unresolved issue of harmonizing and rationalizing how technical assistance is made available and funded.

Figure 5 **Global Fund proposal success rates, with and without technical assistance from WHO or UNAIDS**



Source: The Global Fund to fight AIDS, TB and Malaria

WHO country offices (WCO)

6. In most WCOs, HIV and AIDS was previously the responsibility of a national professional officer, United Nations volunteer, or a staff member who also had other AOWs to cover, and thus did not receive adequate attention. Very limited financial resources (from the regular budget) were available to the WCOs for supporting national HIV responses, despite it having been identified as the first priority in many country cooperation strategy agreements between WHO and their national government counterparts (especially in Africa). With the arrival of "3 by 5" officers, most WCOs had at least one person dealing exclusively with HIV for the first time since the GPA (1995).
7. While the WHO presence in countries has generally grown stronger through its network of country offices over the past 10 to 15 years, technical cooperation with governments still tends to be delivered in a fragmentary, project-oriented manner. WHO has not yet achieved a great deal of synergy between AOWs within its country office programmes, despite intentions to work towards these changes. For instance, very little integration through joint planning or projects is seen between related technical or programmatic areas (such as TB, reproductive and sexual health, child and adolescent health, and health systems strengthening), as evidenced by workplans and how funding is allocated to projects. This limits progress towards achieving integrated health systems strengthening and for reinforcing the linkages between disease-specific initiatives.
8. WCOs tend to work mostly within a traditionally defined role of normative and technical functions. Governments and partners generally agree that this is WHO's core role, but the challenges of the health development agenda and need for mainstreamed HIV and AIDS responses requires WHO to play a much more "political" role (although WHO staff can

sometimes feel caught between the expectations of MOHs and civil society). Previously, in many countries, WHO did not participate in planning aid mechanisms (such as SWAPs or PRSPs) and was therefore not in a position to link HIV sufficiently to the wider health and development agenda. There are now exceptions where WHO has a more "strategic", "catalytic" and "relevant" role in supporting national health-sector development processes, although in many countries, WHO does not yet have much resident experience or technical expertise in this regard.

9. WHO prioritized supporting 49 "3 by 5" focus countries, which represent over 80% of the AIDS burden in developing countries. In Africa, WCOs have been provided with three levels of financial support to achieve this: the largest budgets (around US\$ 1 million) have been provided for populous, high-burden countries; the medium level of funding to medium and smaller high HIV-burden countries; and the lowest level to all others.^{58,59} Further prioritization of country support tends to have been made in a reactive way, responding to requests for assistance. As regional offices become more systematic in planning the HIV programme for their regions, prioritization should become more strategic (as already evident in the WHO Regional Office for the Eastern Mediterranean and PAHO plans).
10. In the area of HIV, WHO is relatively weakly positioned in relation to other better-resourced bilateral organizations and projects. This is particularly the case in the 15 PEPFAR countries. Major bilateral programmes outnumber WHO by far in technical staff (and financial resources) in many countries. WHO's leadership role at country level is therefore often challenged by these powerful bilateral players.
11. Many countries expressed their wish to see WHO play a more active role in promoting (sub) regional exchanges between countries (to disseminate good practices and facilitate learning through regional visits and meetings). There is a strong political endorsement for encouraging more active and strategic South–South collaborations.

4.2.2 Working with governments and partners at the national level

12. WHO country support is influenced largely by how governments (and especially MOHs) respond to the epidemic and relate to their own people. Based on its mandate, WHO's primary partners are these national governments. This close relationship is often a kind of symbiosis. Governments contacted during this evaluation expressed their high degree of satisfaction with WHO support in general and for the WHO role in scaling up treatment in particular. Criticism, if any, was expressed in very indirect ways (such as "having expected even more financial support"). The main contribution that WHO was perceived to have made was towards increasing the numbers of people who are receiving ART (Fig. 4). National AIDS programme managers perceived "3 by 5" as having made much less of a contribution towards HIV prevention and health systems strengthening.

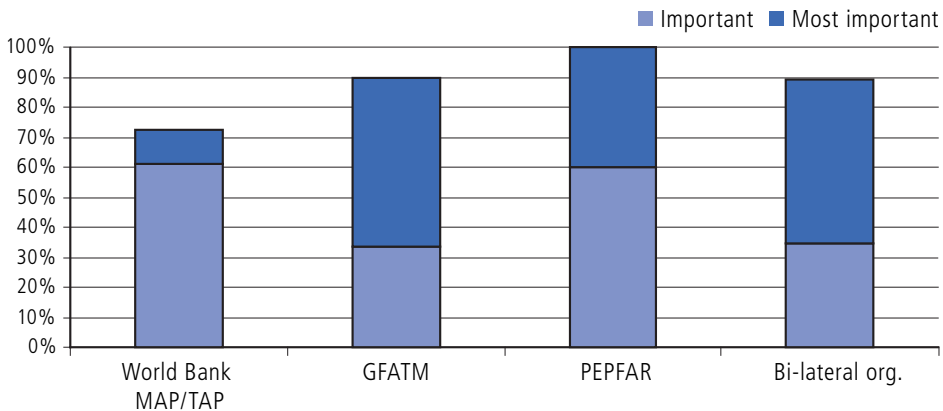
⁵⁸ WHO is required through its constitution and mandate to support all Member States. Whereas most other, especially bilateral organizations can choose their national partners and respond to requests selectively, WHO has to provide services to all countries.

⁵⁹ For a full picture of the financial support to countries see Annex 7.

13. Partners within countries (including development partners in the United Nations system, civil society, PLHA, and the private sector) often view the close relationship between WHO and government with ambivalence: they "envy" this relationship and are aware that if they want to exercise some influence or stimulate change, they might need WHO as a partner to add credibility and convince the government. In the best cases, they perceive as very positive that WHO encourages and promotes open participation by many groups of society and external support in shaping the national health agenda together with the government. However, WHO is often also criticized for being too close to the government, hiding behind government policy, not addressing controversial issues, neglecting other players, and so on.
14. In countries where the MOH has strong and consistent commitment to scaling up HIV treatment, WHO is able to work with the MOH as its main ally and source of support – where necessary even "substituting" some of the functions of the MOH. In contrast, there are countries where the WHO contribution is very limited or at times even paralyzed (South Africa is a case where the relationship between WHO and the MOH has broken down over the issue of ART access).
15. In general, WHO has found it challenging to develop and influence new types of partnerships within countries, outside of its traditional relationship with the MOH. This requires a different way of working. WHO needs to review the role it plays in countries to better understand how to more effectively use its comparative advantage and political mandate to support the work of others. There was a strong message from in-country partners that WHO should better define and communicate its role and focus on what it is good at doing.
16. Partnership development is most advanced within the context of the United Nations Country Team response, but even the United Nations system alignment does not yet include a more comprehensive approach linking HIV to the overall development and poverty issues. It is still predominantly restricted to specific areas such as PMTCT. Moreover, specific cooperation between UNAIDS and WHO in scaling up has not been very visible beyond the initial advocacy efforts.
17. In some countries visited (including Burkina Faso and Ukraine) WHO has succeeded in establishing closer links and cooperation with PLHA and contributed substantially to these groups becoming more active participants in treatment (and prevention) scale-up. In others (e.g. Malawi or Mozambique) this has not been the case. Overall, these achievements seemed to be more due to the efforts of dedicated and experienced individuals than the result of applying any organizational policy. This shows the value of recruiting staff at this level who have experience working with civil society.

18. Cooperation with other major organizations and support structures at the country level (such as PEPFAR, CDC and ESTHER) seems not to have progressed beyond good relations. Concrete agreements of work are missing and common reviews or planning have not been implemented. However, WHO is conscious that the other organizations play a major role in country support and that cooperation among the organizations is necessary (Fig. 6).

Figure 6 WHO "3 by 5" country officers' perceptions of other partners' contributions to scaling up access



Source: Survey of WHO HIV/AIDS Treatment and Prevention COs, Annex 6.1

19. Access to external technical expertise through WCOs is usually ad hoc and WHO has not had efficient systems for identifying, procuring and managing technical consultancies. This situation is improving with WHO setting up an international consultants database at WHO headquarters level that can be accessed by WCOs. This is currently being harmonized with the UNAIDS technical assistance database.⁶⁰ WHO can help countries identify their technical support needs more effectively and monitor the quality of technical assistance provided to the MOH by other agencies.

4.2.3 The role of "3 by 5" country officers (COs)

20. Despite the late arrival of many "3 by 5" COs in their duty stations,⁶¹ they have already begun to play an important role within countries, a contribution that has been appreciated by most partners. Their presence has reinforced WHO advocacy for scaling up and there are many examples of how critical inputs have already been made into planning national HIV programmes; adapting and disseminating WHO guidelines; and helping governments to access additional resources through supporting technical proposals to the GFATM. Having COs in place helps WHO to provide more effective support that is tailored to

⁶⁰ Future collaboration between WHO and UNAIDS in securing appropriate technical assistance will benefit from the establishment of a UNAIDS "Technical Support Facility".

⁶¹ For details of their reporting to duty see Annex 7.6.

the country's specific needs, such as adapting patient monitoring systems; supporting pilot projects for delivering treatment through decentralized service models; planning the implementation of IMAI and introducing substitution therapy for IDUs. The COs' role has generally been less prominent in supporting strategic information for planning and monitoring and evaluation; guiding health systems strengthening; integrating the AIDS response into broader health sector strategies; or in areas that are more closely related to prevention (such as PMTCT and sexual and reproductive health, including the treatment of sexually transmitted infections).

21. The impressive amount of support already rendered through the COs in some countries shows how crucial high-quality and experienced staff are to WHO. Even in the few countries where WHO had already played an important role in the national HIV response before (such as Guyana), the arrival of a CO has accelerated and extended the scope of these activities. The role and contribution of the COs has been very dependent on their personal experience and skills. Half of the COs had worked for WHO before being assigned as "3 by 5" officers. Most COs have been recruited on the basis of their experiences and skills as technical experts with a strong medical orientation. Given the challenges of the future (requiring a stronger focus on managing partnerships) and the need to support health systems strengthening and health development, it will be important for WHO to evaluate the staffing and skills mix that is required within country offices and to implement an organizational development strategy in accordance with this. Language was described as a barrier to COs' work in some countries where WHO had to recruit technical officers who do not speak the national language.

Country-level challenges to scaling up

The "3 by 5" officers see the main challenges for further scale-up at national level (listed in order of priority) as:⁶²

- lack of human resources (lack of capacity of the available personnel in MOHs and the wider health-care system; quantity of health personnel; staffing of HIV/AIDS departments of the MOHs; loss of skilled professionals);
- lack of coordination (multiple contributors; duplication; other vertical programmes of the health-care system; lack of coordination among departments in the MOHs);
- sustainability (e.g. drug supply and procurement of other supplies; financial resources after current GFATM grants expire);
- lack of political commitment and weak leadership (e.g. with regard to PHA); and
- lack of decentralization (of services and decision-making).

⁶² Source: Annex 6.1: Result Report on the Survey of WHO HIV/AIDS Treatment and Prevention COs in "3 by 5" focus countries.

4.2.4 Support from headquarters and regional offices

22. Most WHO COs were satisfied with the initial preparation and training they had received from WHO prior to their assignment. However, many expect more guidance on how to deal constructively with partners other than the government (and especially donors within countries).⁶³
23. Guidance for workplans provided by the WHO headquarters and the regional offices are too generic and have not been very useful for the COs to plan their contributions more strategically (for example, some mentioned that it would have helped to have a checklist of activities that WHO could be offering). Monthly reports of their activities that are required by regional offices have been used more as a compliance tool than to establish programme monitoring and review. This is not linked to any form of systematic follow-up.
24. While most COs seem happy with the support they receive from headquarters and regional offices, some of the missions undertaken to countries from these levels tend to lack sufficient preparation, strategic orientation or planned follow-up. COs also feel that they have multiple (sometimes conflicting) demands placed on them from higher up in the Organization, for example to facilitate concurrent technical missions from different areas of the programme.
25. Better support systems are needed for COs to access short-term technical assistance and external consultants. WHO has started building up a consultants database in collaboration with UNAIDS and there should be improved mechanisms to access technical consultancies through the UNAIDS Technical Support Facility, as this becomes more established. An important consideration is how this additional technical support will be funded and this requires further negotiation between WHO and the funding agencies.

4.2.5 Funding WHO contributions to "3 by 5" within countries

26. Most financial support for WHO activities within countries (in some cases over 95%) was channelled through extrabudgetary allocations (particularly from the Canadian grant).⁶⁴ These funds enabled WHO to employ "3 by 5" COs and supported crucial scale-up activities,⁶⁵ sometimes proving to be catalytic in moving the process forward (examples of this were seen in Guyana and Malawi). In many cases, however, this funding arrived too late to be systematically integrated into the country office planning cycle, or to contribute strategically to national programmes. These delays necessitated constant re-planning of scheduled activities, with resulting opportunity costs.

⁶³ These observations are from the questionnaires addressed to all 31 COs. See Annex 6.1.

⁶⁴ On the financial issue, see also 4.6 Organizational analysis.

⁶⁵ For the financial contributions to each of the countries, see Annex 7.

27. Although having funding available at country level to support activities is not meant to position WHO as a "minor donor" or implementing agency (and this is not expected by governments or other main partners),⁶⁶ having these funds available has been important for WHO's credibility since it enables the CO to solve problems or initiate processes that strategically reinforce WHO's technical role. There are countries where WHO has received funding from the Global Fund as a subrecipient.

Discretionary use of funding through WHO country offices can strategically achieve progress in scaling up

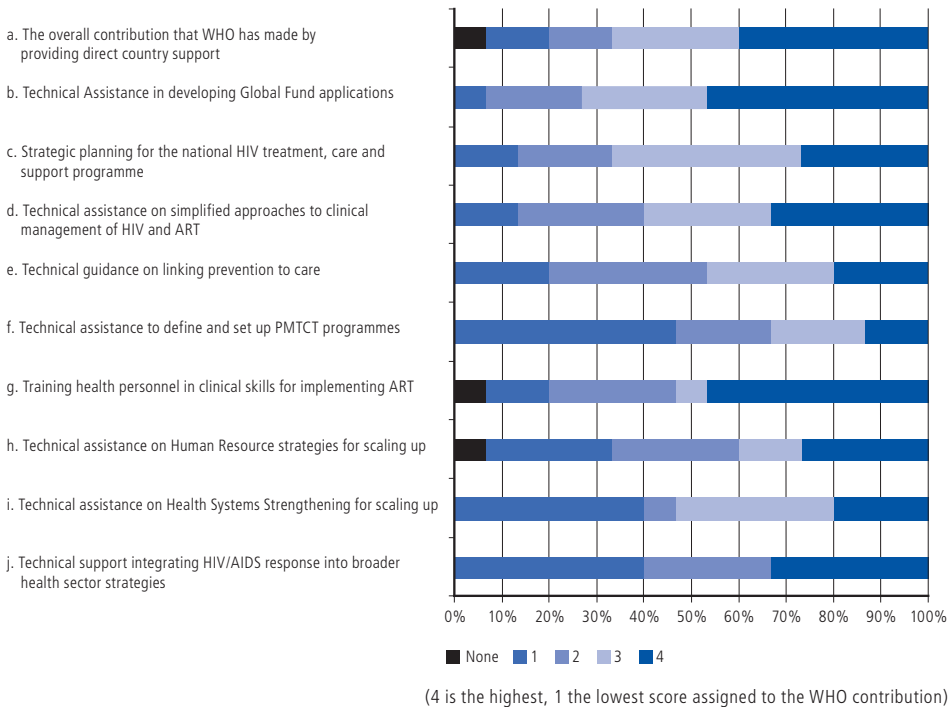
Extrabudgetary allocations (particularly from the Canadian grant) enabled WCOs and the "3 by 5" officer to support activities that sometimes proved catalytic in moving the scaling up process forward. In Guyana, the HIV epidemic is concentrated within high-risk groups and WHO made a strategic investment by funding a local NGO to implement a national project for HIV and STI awareness, prevention, behavioural change communication among the inmates and officers within prisons. A formative research project was also conducted among sex workers and men having sex with men (MSM) in order to determine their service needs and to map their distribution. Through these types of activities, WHO has contributed to linking marginalized groups to HIV prevention and care. Having some discretionary funding available gives COs more credibility and allows them to initiate key interventions that might not otherwise happen.

4.2.6 The results of WHO contributions within countries

28. The "3 by 5" Initiative was credited with having created an important incentive for hesitant governments or sceptical partners to make commitments to scaling up ART. WHO's leadership and credibility within countries are seen as key strengths in being able to mobilize such political support.
29. Progress that has already been made in scaling up in many of the poorest countries has generally exceeded the expectations of many people and organizations with direct experience of working within the severe constraints and challenges that are faced in these settings. This has been achieved through the efforts of national programmes and the contributions of many partners. In many cases, WHO made strategic contributions towards achieving these results. However, impressive scale-up developments were also reported from countries where WHO played only a minor role. Figure 7 provides a graphic summary of the scope of direct country support activities delivered and the extent to which these contributed to scaling up, as perceived by national AIDS programme managers.

⁶⁶ At times there seems to be a contradiction when (bilateral) funding is more easily available for WHO to implement activities than to recruit more technical personnel.

Figure 7 National AIDS programme managers' perceptions of WHO's contribution to scaling up through direct country support activities



Source: Survey of national AIDS programme managers, Annex 6.2

4.3 Strategic objective 3: Simplified, standardized tools for delivering antiretroviral therapy

4.3.1 The public health approach (PHA)

1. Progress in scaling up access to ART would not have been possible without the WHO simplified, standardized PHA, on which WHO normative guidance and tools for implementing ART and other HIV and AIDS-related interventions have been based⁶⁷. PHA guidelines for ART preceded "3 by 5" and arose from a conviction that treating HIV in high-prevalence populations could only be feasible using the public health principles of a strategy such as the directly observed treatment short course for tuberculosis (DOTS).⁶⁸ Since there was little evidence of using ARVs in this way at the time, WHO made an enormous contribution by advocating this progressive position. The approach is relevant

⁶⁷ As a population-based approach, the PHA to ART has been designed to achieve standardization, decentralized coverage and service integration that would benefit as many people as possible. The term "scaling up" has become widely used to describe how this approach is operationalized.

⁶⁸ ART guidelines based on this approach were first published in 2001. This preceded "3 by 5" and shifted a scientific paradigm that previously considered ART to be a specialized medical intervention requiring skilled clinical decision-making and "individualized" treatment approaches.

for most developing settings, although how it is implemented needs to be adapted to local circumstances.

2. This guidance remains one of the most visible and important contributions WHO has made to scaling up access to treatment for HIV-infected populations. The PHA has demonstrated value by:
 - providing a consistent message about the feasibility of ART that has built international consensus for implementing treatment scale-up;
 - serving as the basis for national HIV treatment scale-up policies and plans;
 - being translated into guidelines and tools that can be rapidly introduced, adapted and disseminated in countries;
 - harmonizing regional treatment protocols (with potential benefits for standardized training, common drug procurement, continuation of treatment for migrants, etc.);
 - providing confidence in drug manufacture and investments into treatment supply for the standardized regimens (with consequent implications for cost reduction);
 - standardizing operational and capacity-building approaches (such as IMAI);
 - decentralizing services through a replicable simplified model⁶⁹ (as has been achieved in Malawi);
 - making care more affordable, by enabling the use of restricted formularies and generic supplies;
 - involving PLHA in planning and supporting treatment services, by promoting the "chronic care model";
 - enabling protocol-led task shifting to use human resources for health more efficiently;
 - generating simplified patient monitoring data and enabling standardization of indicators; and
 - providing guidance and standards for public health priorities that would otherwise not receive adequate attention (such as HIV Drug Resistance Surveillance).

4.3.2 The normative role of WHO

3. WHO is the only organization with the credibility and mandate for establishing these global normative guidelines; it is the undisputed leader in this role. The PHA has opened the way to scaling up a more comprehensive package of essential public health-care interventions. It provides a sound basis for defining the interventions for which universal access should be achieved.

⁶⁹ The PHA decentralized service delivery model has been developed by WHO for rapid scaling up through increasing service coverage and includes: Delivering a "package" of priority public health interventions for prevention, treatment and care; simplified and standardized (protocol-led) approaches to patient management; and standardized, integrated training (based on IMAI).

4. WHO has produced an extensive range of guidance materials during the period of "3 by 5", by completing and reviewing various guidelines that were already in progress before the Initiative, as well as through publishing new guidance material that is well in excess of planned outputs and covers an impressive range of topics (see Annex 3 for a complete list).

Specific recent achievements have included:

- producing guidance on HIV diagnosis and treatment in children (which is a complex technical and ethical issue);
 - achieving international consensus on patient monitoring standards and a minimum indicator set;
 - providing innovative guidance on how to use "expert patient trainers" in training care teams;
 - introducing the chronic care model into service delivery models, through IMAI guidelines;
 - providing guidance on TB-HIV integration (developed in collaboration with *Stop TB*); and
 - developing a global HIV Drug Resistance Surveillance Strategy with guidelines for establishing national surveillance activities.
5. A few existing gaps in guidance were identified from country consultations,⁷⁰ such as:
- prevention policy guidance;⁷¹
 - laboratory standards for patient monitoring;
 - adherence interventions and monitoring; and
 - guidelines for linking treatment services to home-based care and community support.

There is also need for greater emphasis on quality improvement and standards-setting within existing guidelines.

6. Almost all "3 by 5" target countries surveyed by WHO in mid-2005 had already adopted the PHA standards into their national guidelines⁷² (see Annex 10). There is an acknowledgement within WHO that more emphasis now needs to be placed on continuing to provide direct support for improving how these guidelines are used in practice and to focus on the quality of guideline-led care for chronic ART (to optimize its safety and long-term effectiveness). This will become increasingly important as countries scale up coverage by decentralizing their HIV treatment services (which requires direct support to primary-care providers in first-level facilities). More attention should also be placed on working with the non-state (private) sector to implement these interventions, which has so far been a missed opportunity for expanding coverage.

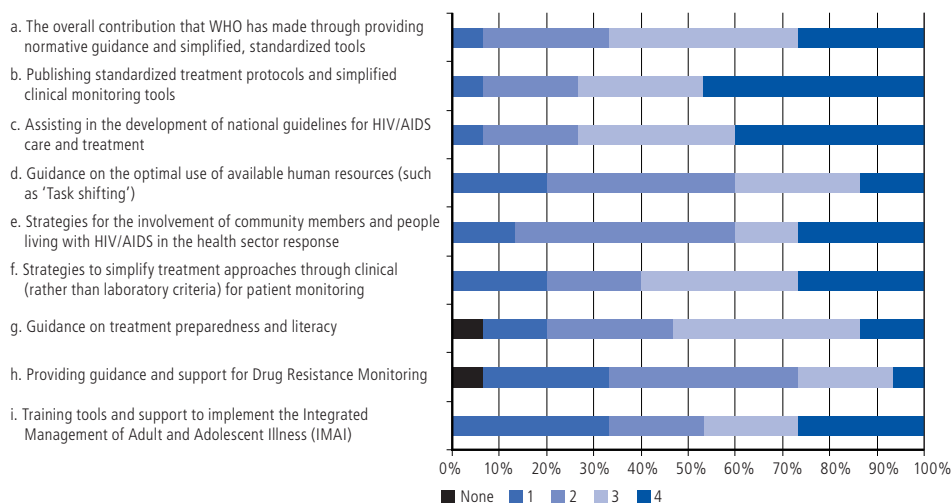
⁷⁰ Some of the gaps are already in the process of being addressed by WHO.

⁷¹ See Chapter 4.7.1.

⁷² Beck EJ et al. *ART guidelines in resource limited countries: do they exist and how do they match with 2003 WHO guidelines?* WHO-IAS Poster presentation, Geneva, World Health Organization, 2005.

7. Resources allocated to WHO for this normative work (carried out at WHO headquarters and regional office levels) have been inadequate to enable systematic development, dissemination, support and review of these guidelines, as well as to support scaling up the implementation process within countries. However, achieving a good balance between WHO's normative and direct support functions will need careful consideration of how resources are distributed to achieve a balance – so as not to diminish the strength of this global technical expertise, while using the important opportunity of having a global network of in-country presence to provide "intelligence" from the ground.⁷³ Figure 8 summarizes the extent to which a small sample of national AIDS programme managers believe that specific WHO normative tools, guidelines and activities have contributed to scaling up.

Figure 8 National AIDS programme managers' perceptions of contribution of WHO normative guidance & tools to scaling up



(4 is the highest score assigned to the WHO contribution)

Source: Survey of national AIDS programme managers, Annex 6.2

8. WHO has achieved a high level of consensus in this PHA guidance and needs to maintain confidence in this through continued technical leadership. This has resulted from good collaboration with many technical partners participating (and funding) consensus meetings; undertaking joint technical missions; and holding regional briefing and collaborator meetings, that can be further improved by:

- strengthening the working relationship between WHO and United Nations partners in joint technical areas (such as the Interagency Task Team on PMTCT that is co-hosted by WHO and UNICEF);

⁷³ WHO has implemented an organization-wide policy to shift the majority of the global budget progressively from headquarters to regional and country offices, with stringent performance targets to achieve this (as explained in more detail in Section 4.6.4).

- better internal collaboration between the HIV Department and other WHO units (such as the Making Pregnancy Safer and Stop TB departments);
- developing more systematic mechanisms for knowledge-sharing (especially in collaboration with the United States Government, to learn from the implementation experiences of the PEPFAR programme);
- building knowledge networks to improve the use of guidelines and systematize learning through communities of practice⁷⁴; and
- improving the mechanisms for partnership to achieve better-structured arrangements for delivering country-level technical support.

4.3.3 Guideline development

9. WHO learnt from the difficulties of implementing previous guidelines and has adopted a revised consultation approach in which regions and countries are provided much more opportunity to participate. The Internet is also being used increasingly as an efficient means of reviewing draft recommendations. Although national contributors appreciate this opportunity, some expressed frustration at the delays that can occur in receiving finalized outputs from consultations. Attention therefore needs to be given by WHO to streamlining guideline development processes and to better managing the expectations of participants. This includes making guideline review schedules more predictable and adhering to published timelines.
10. Guidelines cannot be promoted without technical support for implementation and mechanisms to provide early feedback about what is not working. WHO has an important responsibility to monitor the use of guidelines and the consequences of these recommendations in practice. This monitoring requires specific technical activities such as drug monitoring, drug resistance surveillance, and cohort analysis. WHO has not yet made much progress in providing the necessary technical guidance, analytical assistance and country-level support to operationalize these activities (either directly, or through strategic partnerships). COs have an extremely important role in providing feedback about what is happening "on the ground", although this has not yet been adequately developed into an effective knowledge network.
11. Finalization of the 2005–2006 revision of ART guidelines for adults and adolescents has been delayed and is expected to provide explicit recommendations for further simplified clinical monitoring and treatment regimens⁷⁵. This will be an important step in communicating an official standard for further decentralizing ART to the primary care level, with implications for making universal treatment access more feasible.

⁷⁴ *An approach to rapid scale-up: using HIV/AIDS treatment and care as an example*. Geneva, World Health Organization, 2004.

⁷⁵ The need for these guidelines was seen in Kenya, where the current national guidelines represent the existing WHO standards extremely well. However, patient monitoring standards are changing in the national programme (towards clinical, rather than laboratory criteria being recommended). Existing guidelines are therefore not ideal for guiding health workers at the subdistrict level (where laboratory services are mostly not accessible) and result in inconsistent practices, such as delaying treatment because laboratory examinations are not available.

4.3.4 Operationalizing the public health approach (PHA)

12. The PHA guidelines have been translated into operational tools for training and providing capacity to decentralized service delivery (through IMAI⁷⁶) that now needs a sustainable implementation strategy with strong institutional support. IMAI was reviewed in greater depth through a supplementary evaluation study (reported in Annex 8) that generated the findings below.
- IMAI has helped to translate policy-level guidance into protocols and operational procedures for “end-users” through a process of national adaptation, training and capacity building.
 - IMAI is valuable as a generic, simplified and institutionally endorsed set of tools and methodologies that all stakeholders can buy into, adapt and implement across a range of settings. However, WHO needs to promote IMAI more strategically to gain partnership support and avoid creating misperceptions that this is “WHO proprietary”, or restricted in its scope and applicability.⁷⁷.
 - IMAI assists the process of decentralization by offering an appropriate standardized service delivery model for primary care facilities that can be replicated and supported within districts.⁷⁸ However, for successful and sustainable implementation, this also requires investment in broader district systems strengthening and continued supervisory support. It is still too early to know whether this approach achieves durable practice changes or improves care outcomes, so it is important for WHO to build an evidence base for IMAI as soon as possible.
 - There is potential for IMAI to immediately integrate with Integrated Management of Childhood Illness (IMCI) and Integrated Management of Pregnancy and Childbirth (IMPAC) to provide a standard “platform” for integrating primary care level HIV interventions. This will increase opportunities for health systems strengthening and could improve the efficiency of capacity-building efforts. However, making this happen will require leadership support and improved interdepartmental collaboration within WHO, which has not yet happened.
 - The growing number of countries showing interest in IMAI demonstrates its relevance. However, it is still not evident whether this is a trend towards adopting IMAI in its comprehensive format or for limited (modular) use. WHO needs to provide a more explicit framework demonstrating how this approach fits into the health-sector strategy for scaling up and strengthening the health services within a country (especially for achieving *Universal Access*).

⁷⁶ The Integrated Management of Adult and Adolescent Illness.

⁷⁷ For example, countries with focused HIV epidemics and middle-income countries perceive IMAI as a “training package” that is only relevant for low-income African settings.

⁷⁸ Decentralizing delivery of this approach is necessary to increase coverage. In most settings, ART is currently still delivered through dedicated (usually hospital-based) clinics or “outreach” services, staffed by doctors or clinical officers. To increase access further, HIV care must be decentralized to the primary care level (as has been achieved in Malawi). This requires integrating HIV care into routine primary care and building a chronic care delivery approach within the context of these settings.

- WHO has not yet demonstrated whether it is feasible to rapidly scale-up IMAI beyond the first phases of implementation and a number of countries (particularly in regions with low-prevalence localized epidemics, such as eastern Europe) still have reservations about whether this is an appropriate strategy for their circumstances. Although in countries where IMAI adaptation has already taken place or training has been implemented, respondents tended to be more positive about the prospects for making IMAI a national standard.
 - The extent to which IMAI has adequately contributed to the goals of "3 by 5" during the period under review is difficult to judge because an intensive period of development was undertaken that required time. However, the full potential of these activities was probably not realized due to organizational barriers⁷⁹ that require immediate institutional action.
 - Despite these constraints, IMAI has achieved considerable progress during the relatively short period of "3 by 5"⁸⁰. Materials were produced quickly and an approach to adapting these at country level has been established (although the mechanisms and resources for rapidly scaling this up will need to become more robust).
 - Rather than focusing resources on further content development, WHO now needs to prioritize implementation and strengthen the mechanisms to deliver and support these integrated approaches. This should include working with countries (in partnership with training institutions) to have IMAI included in pre-service training, as a priority.
 - Undertaking this will require more stable funding and a more explicit strategy for delivering integrated service approaches (broader than IMAI). The strategy must be strongly supported by leadership within WHO and have the endorsement of partners (including major donors and MOHs).
13. To date, in most countries, treatment has been made available on a "first come, first served" basis and has resulted in implicit rationing that is increasing as treatment demand outgrows the existing supply. In the initial phase of scaling up, treatment sites have mostly been set up in large towns within established hospital-based clinics and access has only been provided to patients who could reach them. Where PLHA groups have been actively involved in the scaling up process, their members have tended to receive priority access. In order to now expand access in the next phases of scaling up, coverage must be improved by services becoming decentralized (closer to where people live). WHO has a particularly important role to play in this process, having developed service delivery models for first-level facilities and by working closely with MOHs. There are already good working examples of how ART can be delivered in this way (such as in Malawi). In India, WHO is assisting in setting up pilot ART programmes in rural areas and in primary and secondary health facilities, to increase coverage across larger geographical areas.

⁷⁹ These organizational barriers are described in more detail within the IMAI Study Report (Annex 8) and include the restrictions placed on recruiting new personnel; bureaucratic delays in authorizing travel, etc.

⁸⁰ A summary of the status of IMAI implementation at the end of 2005 appears in Annex 8.

4.3.5 HIV drug resistance surveillance

14. WHO has a vital global role in providing guidance and support for HIV drug resistance surveillance (HIV-DRS) that needs to become better resourced and operationalized as an immediate priority. Drug resistance to HIV will inevitably emerge in all countries where ART is being scaled up, with population-level health and economic consequences once this exceeds a threshold level.⁸¹ HIV-DRS requires prescriptive sampling methods to obtain valid information that can be used for public health action and this needs to be appropriately interpreted and monitored at the global level. HIV-DRS must therefore be included as an essential component of the PHA within national scale-up plans. Country-level expertise is needed to oversee this and to advise national MOHs. Local access to accredited HIV- resistance testing laboratories is a necessary infrastructural requirement of this strategy that is not yet in place.
15. By initiating a global HIV-DRS strategy during the period of "3 by 5", WHO has shown strategic leadership, although there are still very few countries that have fully implemented this intervention. Much work and technical support are now needed to ensure that drug resistance is addressed appropriately. WHO works with partners by coordinating an international HIV-resistance network (HIVResNet) to leverage their technical contributions. It has a strong collaboration with the United States Centers for Disease Control (CDC), which is active in the 15 PEPFAR countries.
16. The programme is currently under-resourced and dependent on one key technical officer who is externally funded. Failure to invest more in the WHO HIV-DRS programme infrastructure is likely to compromise the prospects for an effective global HIV-DRS strategy, with important implications for the sustainability and effectiveness of ART as a public health intervention in the future.

4.3.6 Evidence for the public health approach (PHA)

17. There is established evidence that treating AIDS with simplified ART regimens is both feasible and effective in low- and middle-income countries (including in very resource-constrained settings). As treatment scale-up has progressed, it is evident at least in the short-term that (first-line) ART delivered through this approach in large-scale public health programmes is improving the health and survival of many people who would otherwise have died of AIDS. However, whether scaling up ART through the PHA produces equivalent population-level outcomes across different settings is not yet clear, since there are many programmatic factors that could influence how well treatment is implemented and sustained. Recent reports are beginning to add to this evidence base, such as those listed below.

⁸¹ Havlir DV, Hammer SM. *New England Journal of Medicine*, 2005, 353:749-51.

- A WHO-sponsored case study in Botswana that shows preliminary evidence at the end of 2005 of the impact of ART, with a decline in adult mortality noticed across most health districts that were associated with the introduction of ART. (Mortality data are key in understanding these trends but not widely available, and there is a need for further validation)⁸².
- A recent report from Haiti documenting the feasibility and effectiveness of ART based on the WHO guidelines in a low-resource setting, where clinical outcomes were similar to those achieved in the United States.⁸³

Further scientific evidence from the large treatment cohorts currently being monitored by researchers in a number of low-resource settings will demonstrate whether the longer-term clinical outcomes of ART (both in terms of safety and efficacy) can be maintained. Establishing this evidence base needs to be seen as a priority.

18. WHO has not established adequate arrangements for tracking the evidence for scaling up PHA ART (including monitoring the outcomes of treatment at the population level, on survival and quality of life, or the public health consequences of treatment toxicity and treatment failure). There has not been a coordinated effort to evaluate the effects of treatment scale-up on health systems, HIV prevention or on other priority public health programmes. WHO could consider becoming a clearing-house for research in these areas. Countries expect the Organization to help articulate the research agenda and facilitate scientific endeavours for strengthening the evidence base to inform future decisions.
19. WHO anticipated that scaling up PHA to treatment would also have a direct impact on HIV prevention (mainly by stimulating demand for HIV testing and counselling and possibly by decreasing infectivity). Demonstrating this is scientifically challenging, but remains an important objective.⁸⁴

4.4 Strategic objective 4: Effective, reliable supply of medicines and diagnostics

4.4.1 Prequalification of antiretroviral drugs (ARVs)

1. The WHO-managed Prequalification Project⁸⁵ has been successful in establishing an innovative mechanism that encourages voluntary improvement in the manufacture and supply of quality drugs, especially generic ARVs.⁸⁶ Most partners mention prequalification as one of the most important contributions that WHO has made to "3 by 5". There is

⁸² In the case study of Botswana, *Triangulation analysis for enhanced monitoring and evaluation*, supported by WHO in 2005 and carried out by UCSF, retrospective routine national and district-based routine data from Botswana were reviewed with trends analysis from 1994 to the end of 2005.

⁸³ Severe P et al. Antiretroviral therapy in a thousand patients with AIDS in Haiti. *New England Journal of Medicine*, 1 Dec. 2005, 353 (22):2325-34.

⁸⁴ See also the chapter on prevention (4.7.1).

⁸⁵ The project is backed by WHO, UNICEF, UNFPA and UNAIDS, with additional support by the World Bank. WHO manages the project, providing all technical contributions and UNICEF is responsible for administrative support and infrastructure.

⁸⁶ A focus study on the WHO Prequalification Project was commissioned as part of this evaluation and provides the basis for many of these findings. This appears in Annex 9.1.

general consensus that "Prequalification" has been an important driver for making affordable generic ARV medicines that are of acceptable quality available. The project has:

- established quality benchmarks (that are considered to be even more stringent than the procedures required by regulatory authorities, such as the United States Food and Drug Administration (FDA));
 - increased confidence in the use of generic products (including fixed-dose combination ARVs);
 - driven down drug prices by enabling (generic) competition;
 - cooperated with procurement/funding organizations to define procurement standards (based on using prequalified drugs);
 - begun prequalification of quality control laboratories in countries (only three had been assessed, since this is a new area of work);
 - undertaken local capacity-building for national drug regulatory authorities; support for Good Manufacturing Practices; and training for assessors;
 - collaborated with the European Medicines Agency to create a supplementary mechanism for pre-qualifying drugs; and
 - influenced the United States FDA in establishing a "tentative approval" mechanism that now has many characteristics of the WHO Prequalification process. There is a mutual recognition of the assessments conducted by these two agencies, as well as other areas of constructive collaboration.
2. This work has been undertaken by an extremely dedicated and efficient, small team of only three professionals within WHO (with an unrealistic budget). Due to an increasing workload and limited resources, there is now a backlog of work, including site inspections, dossier assessments and finalized reports. In addition to taking on registration of new applicants and extending Prequalification to the active pharmaceutical ingredients (API) manufacturers, contract research organizations and quality control laboratories, the Prequalification team must periodically review those that have previously been prequalified. The delays that this is creating are problematic and could potentially compromise drug procurement since:
- procurement agencies will be under pressure to purchase more expensive branded products or generics that have not been prequalified (if existing prequalified suppliers cannot meet the increasing demand);
 - donor organizations could be forced into accepting to make exemptions to the procurement conditions they have established for assuring quality;
 - manufacturers might become discouraged by the process because of the delays in having their applications processed; and
 - programme managers could delay introducing second-line or paediatric therapy until these products are prequalified.

These outcomes could undermine confidence in the WHO Prequalification Project and lead to it becoming redundant, which would threaten the future quality of drug supplies.

3. At this time, paediatric first-line dosage forms and all second-line products should get priority in the prequalification process, since there are currently few prequalified options available.
4. The Prequalification Project is vulnerable to staff losses and has an unrealistic budget commitment from within WHO (with expectations that funding gaps should be addressed through external fundraising by the already over-extended team). This AOW needs guaranteed funding commitments and additional resources, in order to function effectively.

4.4.2 Antiretroviral drug prices

5. The price monitoring system and database that WHO has established provide useful tools and information for negotiating better ARV prices. Given the high costs of drugs that are used in second-line treatment and problems with drug formulations for paediatric treatment, WHO needs to help create a market for these drugs through advocacy and technical facilitation. There are concerns about whether secure supplies of adequate quantities of quality ARVs can meet the growing global demand.
6. A focus study commissioned as part of this evaluation reported that there is no evidence that "3 by 5" has reduced the prices of ARVs significantly in Africa (since most of the preparatory work had already been done by NGOs, the industry, the Clinton foundation and WHO before "3 by 5" was officially launched).⁸⁷ However, by advocating for standardized simplified ARV treatment regimens and launching "3 by 5", WHO contributed to creating a market for ARVs. The Prequalification Project has also effectively supported competition (and promoted an important generic manufacture industry). In the PAHO region, the Organization has been directly involved in successfully negotiating price reductions through two rounds of multi-stakeholder negotiations that resulted in first-line ARVs being secured at prices that are 55–95% cheaper for participating countries.
7. Work being undertaken by WHO to improve the availability and prices of HIV diagnostics has not achieved any significant breakthroughs, but WHO is continuing to prioritize this, since progress is urgently needed.

4.4.3 Drug procurement and supply management

8. Progress in strengthening drug supply systems for ARVs was seen in some countries, particularly where partnerships with supply agencies have been established and "push distribution" mechanisms are used.⁸⁸ However, constraints in drug procurement and supply management remain critical barriers to implementing treatment and have held back Global Fund disbursements. Consequences of these procurement and supply management

⁸⁷ A synopsis of this is provided in Annex 9.3.

⁸⁸ Such as by UNICEF, in Malawi.

constraints were seen in countries visited during this evaluation, where there were reports of:

- "stock-outs" due to poorly managed procurement and weak supply mechanisms. This requires providing capacity to pharmacy managers at each point of the supply chain to forecast more reliably the required drug quantities;
 - the cost of procurement being excessive in relation to current pricing norms. Although this is a complex issue, in some instances national governments could be encouraged to rely more on available international and regional bulk procurement mechanisms to improve the predictability of supplies and to benefit from better prices through pooled procurement;
 - diversion of drug supplies and irregularities in procurement practices that require urgent measures to be taken (the reality of counterfeit medicines was also mentioned by experienced pharmaceutical experts as a significant threat to drug security);
 - concerns by health workers about the quality of drugs that are delivered and in use, which requires that the capacity of national drug regulatory authorities and quality control laboratories be strengthened;
 - the capacity of current supply mechanisms potentially being exceeded, where governments have relied on external agencies (such as NGOs) to undertake this function;
 - mixed supplies of generic ARVs (from the national programme) with branded products (procured by United States Government agencies) in health facilities supported by PEPFAR, contributing to non-standard prescribing practices, adding administrative complexity, and undermining confidence in generics; and
 - lack of availability of other essential drugs and supplies (e.g. for opportunistic infections and STIs) where ARV supply has been supported in isolation, pointing to the need for strengthening pharmaceutical systems overall.
9. WHO has not become substantially involved in systematically resolving these procurement and supply chain problems at the country level and there is scope for much stronger collaboration with partners to achieve this.
 10. Concerns about drug procurement and supply management are receiving attention within a GTT working group in order to be addressed systematically by the participating multilateral institutions and international donors. Practical steps can immediately be taken by these agencies to harmonize their procurement regulations, guidelines and procedures to reduce the complexity and administrative demands these place on country procurement systems. The role of WHO (AMDS) in this forum must be clarified and working relationships among agencies should now improve.
 11. Within WHO, HIV also features prominently in the strategy of the Health Technology and Pharmaceuticals cluster. This part of the Organization has made significant progress in placing ARV drugs on the Essential Medicines List; leading the Prequalification Project; advancing the WHO position on intellectual property rights; strengthening supply systems

(through regional and country-level support); providing training on Good Manufacturing Practices, quality assurance and registration of generic drugs; building the capacity of national drug regulatory authorities and strengthening national drug policy. This has led to some overlap in the work of AMDS (located in the HIV Department), although there is now a clearer understanding of the division of responsibilities that should provide opportunity for more effective interdepartmental communication and collaboration.

4.4.4 The AIDS Medicines and Diagnostics Service (AMDS) network

12. WHO established an AMDS network that is beginning to coordinate efforts to overcome procurement and supply barriers. The HIV/AIDS Department rapidly brought this team together at the beginning of "3 by 5" with a mandate to explore the possibility of becoming a global procurement agency for ARVs.⁸⁹ The decision not to become directly involved in drug procurement was probably correct (first-line ARVs were becoming more accessible and WHO acknowledges that it does not have the systems for managing large-scale procurement). Instead, AMDS has functioned as a clearinghouse for information relating to drugs and diagnostics and has mostly provided emergency responses as problems have arisen. The AMDS secretariat also helped to arrange a series of procurement and supply management workshops and training events that were delivered by its network of collaborators in order to build capacity for Global Fund recipients to develop procurement and supply management plans (which are a prerequisite for having Global Fund grants disbursed).
13. AMDS has made progress within most of its planned activities (as outlined in Annex 11) although, at times, this overlapped with the work of other units and duplicated the efforts of external partners in ways that led to delays in achieving these outputs. AMDS seems to have finally negotiated its roles more clearly and should now focus on working through effective coordinated partnerships with departments in the Health Technology and Pharmaceuticals cluster and with external partners. AMDS now needs to focus on becoming more relevant and managing its partnerships to deliver effective country support.
14. Specific roles for AMDS were identified through the evaluation that include:
 - monitoring the impact of the "post-2005" TRIPS regulations on the prices of ARVs and other essential medicines;
 - researching the potential value of local production of ARVs in least-developed countries as a means of securing their price and availability;⁹⁰
 - continuing to serve as a source of knowledge and information on drugs and diagnostics (the AMDS web site is considered to be an excellent information resource by many partners, although some feel that the reliability of this information could be improved and others question whether this information is used optimally);

⁸⁹ Based on the model of the TB Global Drug Facility.

⁹⁰ Least-developed countries have dispensation from TRIPS until 2016. This allows them to make their own APIs and produce 2nd line ARVs or paediatric ARVs that are patented in other developing or developed countries.

- assisting countries with establishing drug monitoring activities to monitor the clinical effectiveness of drug formulations in use;
 - providing strategic information (such as epidemiological projections) for global forecasting that is necessary to plan the manufacture and distribution of drugs;
 - securing the markets for paediatric and second-line ARVs, through negotiations, by making information available and by soliciting expressions of interest from suppliers;
 - facilitating pricing negotiations for the end products, as well as for the APIs.⁹¹ This will involve a strong focus on China and India as potential sources of more affordable raw materials; and
 - applying the WHO initiative against counterfeit medicines to ARVs.⁹²
15. AMDS is the secretariat for a network of partners that could become an increasingly effective mechanism to deliver technical expertise and country-level support. These partners are currently loosely affiliated for the purpose of improving HIV drug procurement and supply and although they have already had opportunities to provide various inputs to the work of WHO, some partners interviewed expressed frustration that AMDS is not well structured or optimally managed. In contrast, departments within the HTP cluster work with many of the same partners and have an established partnership model that distinguishes between scientific, strategic and operational partners. Defined mechanisms have been developed that are appropriate for working with each type of partner to structure their contributions. This seems to be a sensible model that AMDS could adopt to become more effective in managing the partnerships within its own network (and this model could possibly be extended to the other technical areas in which WHO works through partnerships).

4.5 Strategic objective 5: Rapidly identifying and reapplying new knowledge and successes

4.5.1 "Learning by doing"

1. In implementing "3 by 5" as an "emergency" initiative, WHO could not wait for a more complete evidence base to guide its technical strategies. Because of this, the Organization made a commitment to "learning by doing" through continual evaluation, analysing the programme's performance and investing in a focused agenda for operational research. WHO expected to implement these activities through a "robust programme to consistently learn, document, share and act"⁹³, with the idea of creating learning networks that could rapidly disseminate successful strategies and innovative approaches among programmes on the ground. The importance of this function is reinforced by the perception of WHO "3 by 5" technical officers within countries that one of the most important contributions that the Organization can make to scaling up is "managing information" (including

⁹¹ Up to 75% of the cost of ARVs is determined by the cost of active pharmaceutical ingredients (API); ensuring API security, quality and economies of scale should receive top priority.

⁹² The WHO HTP cluster has identified counterfeit medicines as a major public health threat and is working to establish an International Medicinal Products Anti-Counterfeiting Taskforce.

⁹³ Described in the WHO strategy document *Treating 3 million by 2005: Making it happen*.

assessing trends and reporting on progress; setting the agenda for and helping to stimulate research and development).⁹⁴

2. The evaluation found that although various elements of learning systems have been put in place within different parts of the Organization, WHO has not yet succeeded in bringing these together optimally within a coherent "knowledge management" or "learning and improvement" strategy for its internal programme or to guide external partners.
3. Activities for generating and managing knowledge relating to "3 by 5" have been poorly organized at the WHO headquarters level (spread over five different departments/units) with inadequate coordination and cooperation between them to effectively harness the wealth of information that flows through the Organization. At times this has affected the ability of WHO to generate internal consensus on technical approaches (such as which monitoring systems to use) and has led to inconsistent collaboration with external partners (for example in countries where WHO has been promoting electronic patient registries while at the same time working with MOHs to implement paper-based systems through IMAI).
4. Significant resources have been invested in this programme area and WHO could benefit from becoming more systematic in the ways that information is collected, synthesized and disseminated to guide decision-making. Specific technical consideration is required on how to improve decision-making as a process, through decision-support tools and methodologies. For instance, countries will need models to project how patient populations on chronic care will grow over time (with changing intervention needs, such as second-line treatment) while scaling up coverage for *Universal Access*, so that future scenarios can be used for service planning and budgeting. WHO is ideally situated (and expected) to perform these functions through its country networks and international technical partnerships and should serve as an effective knowledge network for the global response to HIV and AIDS. WHO can also ensure that this takes place as part of other developments in global health (such as the threat of an avian flu pandemic).

4.5.2 Documenting and disseminating good practices and lessons learnt

5. The quality of WHO technical contributions is highly acknowledged by national AIDS programme managers in MOHs, who say that they most frequently consult WHO publications and the "3 by 5" CO as their key information resources.⁹⁵ However, it seems that there are often bottlenecks in managing information flows because the responsibility for generating new knowledge products lies within focused technical groups or is the responsibility of individuals in the Organization who already have an extensive workload and are not supported with adequate programme resources for this function. As a result, there has been a lack of documentation on lessons learnt in specific technical areas of work (such as IMAI and HIV-DRS).

⁹⁴ Based on the survey of WHO HIV/AIDS Treatment and Prevention COs reported in Annex 6.1.

⁹⁵ Based on responses to the survey of National AIDS Programme Managers reported in Annex 6.2.

6. The usual WHO activity of facilitating technical consultations for sharing lessons and generating consensus is still considered useful (especially by individuals who tend to be invited) and there has been a commendable trend towards holding a greater proportion of these meetings within countries at the regional level to enable local participation and provide more relevant contextualization. However, convening these meetings is extremely resource-intensive and it is not obvious that this is always the most effective means of undertaking consultation and consensus-building. Innovative alternatives, such as placing draft versions of documents on the WHO web site for comment, are becoming increasingly important.⁹⁶ This could also help to reduce turnaround time for applying the outcomes of consultations (which some country participants have criticized) and allow for a broader range of inputs and perspectives to be contributed.

4.5.3 Information and communication systems

7. At the beginning of "3 by 5" there were few shared information resources on treatment scale-up, but over the past two years WHO has invested in building impressive information and communication technology systems for collaboration and knowledge-sharing. The Organization now collects an increasingly impressive range of strategic, operational and general information from countries. Tools such as the WHO staff "e-Forum on HIV/AIDS" have recently been implemented to provide an electronic information-sharing platform and remote access by WHO staff to the Organization's internal databases. *WHO country fact sheets* are an example of the useful products that can be generated for external consumption from this information. It is important for WHO to continue investing in maintaining the quality of this "intelligence" and using it in ways that can more effectively guide decision-making (for example, by maintaining an inventory of lessons learnt, or synthesizing and reporting "real-time" global surveillance data on HIV resistance trends).
8. These information resources are still relatively under-utilized within the Organization – partly due to the lack of internal communication and understanding about what they provide, but also because poor Internet connectivity remains a barrier to users in some countries. With these systems in place, WHO is now focusing on improving how this information is managed and used by WHO staff and more investment in training and support for staff could be beneficial.
9. The WHO HIV/AIDS Department and "3 by 5" web sites provide an extremely useful source of public information that is mostly up-to-date and of high quality. However, these web sites could more effectively benefit learning by enabling bi-directional exchange of knowledge and information (for example, by hosting an electronic discussion forum that is directly linked to this site).

⁹⁶ The most recent review of paediatric ART guidelines on the WHO web site is a good example of this.

4.5.4 Operational research

10. Evidence for guiding decisions on what service delivery approaches are most suitable and how to optimize the ways of providing chronic HIV care and support, is still extremely limited. National AIDS programme managers have strongly expressed the need for WHO to be more proactive in defining an agenda for operational research; building research capacity; facilitating research partnerships; developing generic operational research tools and methodologies; and providing direct technical support for establishing operational research activities. WHO is already facilitating a small operational research programme that involves five countries, although this is limited by a lack of funding resources and the need to first build local capacity for research as part of the process. WHO is taking an approach to operational research that is country-owned, so that this is more likely to bring about policy change. The Organization has already started to develop generic research tools for operational research (such as standardized survey instruments on treatment adherence).
11. Traditional methods of operational research (based mostly on retrospective observational analysis) are not ideally suited to the rapidly advancing scale-up process that requires more "real-time" answers. Therefore, WHO has also started to promote more contemporary approaches to operational research (linking this to programme and service improvement methodologies, as well as the need to create networked "communities of practice"). This has been championed from the Evidence and Information for Policy cluster, but still needs to become more widely applied as an integral strategy for learning and improvement within the HIV and AIDS programme area. Since WHO is not a research institution, further partnerships are needed with the research community to move operational research forward as an important priority.

4.5.5 Monitoring and evaluation

12. WHO has led a technical collaboration through the Monitoring and Evaluation Reference Group (MERG) between UNAIDS, the GFATM and other partners (including United States Government agencies) to harmonize indicators for patient monitoring and to establish the definitions for a "minimum data set." This is seen as an important contribution towards aligning the many parallel systems for data collection and reporting that are still commonplace within countries.
13. Very few countries are at a stage yet where even basic information is available to measure the outcomes and impacts of chronic HIV treatment (including survival, quality of life and health status) or on the population health and health system consequences of scaling up. Negative outcomes such as drug resistance and toxicity are also not being routinely assessed to determine what guideline changes or service improvements could be necessary. More support to countries is needed for implementing the WHO *Guide to monitoring and evaluating national antiretroviral treatment (ART) programmes in the rapid scale-up to "3 by 5"* and to make progress in strengthening national monitoring and evaluation that is supported by more robust and harmonized health management information systems.

14. To learn from what is happening in countries, WHO has participated in joint evaluations or country reviews with key international partners (including in Burkina Faso, Mali, Rwanda and Thailand during 2005) that provide opportunities for sharing experiences and expertise. Reports from some of these missions and studies are made available through the WHO web site.
15. Internal programme monitoring (to learn from the results of WHO work and to track the progress of the "3 by 5" Initiative) has not been systematically addressed within WHO, since there is no clear responsibility for this and it is typically not included as a funded activity in workplans. Indicators established at the beginning of the Initiative as they appear in the *Treating 3 million by 2005: Making it happen* publication have not been systematically tracked to monitor results or whether the programme is achieving its objectives. Progress has only been reported periodically at a "global" level (mostly for external stakeholders), rather than being integral to performance improvement. The performance indicators used to measure this are often not appropriate (e.g. "3 by 5" officers using national indicators of the number of people on treatment to measure their own progress). More WHO staff training and guidance is needed on how to link monitoring with performance improvement.

4.5.6 Tracking progress through strategic information

16. Reporting on treatment numbers is necessary to track progress against the global target and this type of monitoring data is commonly referred to as "strategic information". Despite this being a complex task (where reported results can be controversial), WHO has refined its methodologies for improving the accuracy of these estimates so that they seem to be generally accepted. This has been useful for advocacy, but could be improved as a tool for monitoring equity by providing disaggregated reports that show who is receiving treatment and where this is accessible.
17. WHO has an important role in global surveillance, including for drug resistance (as described in 4.3.5), but it needs to link this more systematically into other areas of work. For example, there are currently no structured arrangements for information on ARV drug resistance to be reviewed and linked to information about medicine supply concerns (although "early warning" assessment indicators have been included in the indicator definitions for national programme monitoring).
18. National health management information systems (HMIS) are the source of this strategic data and WHO has provided some support to countries for strengthening these systems. It has also adapted specific tools to support this (such as service availability mapping, electronic medical records and patient monitoring forms). Efforts by national governments and their international partners to improve patient record systems (including through the use of electronic medical records and standards-compliant patient registry databases) need to be prioritized to secure more reliable and useful sources of data for monitoring progress in scaling up, since this information will be increasingly important in guiding decisions (about resource allocation, service planning, etc.) at all levels of the programme. WHO is hoping to improve the collection and use of this information based on guidelines

that were produced and has helped to define standards in electronic data transfer for patient databases.

19. Through the Health Metrics Network, WHO is supporting health systems strengthening for knowledge management (see Section 4.7.2). WHO has a specific role in monitoring the HIV and AIDS epidemic relative to other United Nations partners (such as UNAIDS and the GFATM) through its focus on strengthening health management information systems and in providing guidance and technical assistance for applying the data from programme and epidemiological surveillance to decision-making within the health sector.

4.5.7 Learning networks

20. WHO "3 by 5" officers place high priority on the need for continuous information-sharing and learning with their colleagues in other countries.⁹⁷ These programme officers should become a well-networked community of practice to generate information on the ground and improve the contribution they make in countries by continuously learning from others. This "network model" and the systems that WHO is establishing to support this effort (such as the internal e-Forum) can be extended to other areas of work where WHO acts with purpose-driven groups of partners (such as AMDS and HIVResNet).
21. WHO's traditional role of knowledge custodian and solutions provider for public health problems is changing as new ways of collaboration and knowledge-sharing are coming about through self-organizing communities of interest. A good example of this is the e-Forum hosted by the International Treatment Preparedness Coalition (ITPC), through which a diverse range of voluntary participants from around the world are helping each other to identify practical solutions for all types of problems relating to treatment scale-up and to provide "real-time" answers to requests for technical assistance. Although WHO initiated the ITPC, it does not formally participate in this forum (unless individuals from WHO do this in their personal capacity). There are people within WHO that believe the Organization should be encouraging these new ways of working and engaging opportunities to facilitate or participate in growing innovative collaboration through its institutional influence, technical linkages and relative advantage of having an extensive presence on the ground.
22. Policy analysis is an important knowledge management function and demonstrates both the political role of information, as well as how learning (evidence) should be used to shape "doing" (decision-making). The WHO role in policy analysis for "free access to ART at the point of care" is an example of how WHO responded to an expressed need for a policy position on this issue by hosting a consultation, drawing together existing evidence and facilitating technical review of the analysis.⁹⁸

⁹⁷ From the survey of WHO HIV/AIDS Treatment and Prevention COs reported in Annex 6.1.

⁹⁸ WHO has been criticized for producing a "discussion paper" (rather than a "policy paper") on this issue due to political pressure within the United Nations, despite the strong evidence base. This is further discussed in the Equity section of this report (4.7.3).

4.6 Organizational analysis

4.6.1 Design of the "3 by 5" Initiative

1. This evaluation encountered many varied interpretations of what "3 by 5" is: "a slogan"; "a marketing and fundraising strategy"; "an initiative"; "an indicator"; "a mindset"; "a wake-up call"; "an advocacy strategy"; "a programme of work"; "a very ambitious plan"; "a global political declaration"; as well as "the WHO strategy for treating 3 million people by the year 2005". Possibly all of these answers are correct in some way.
2. When WHO launched "3 by 5" in Nairobi on World AIDS Day in 2003, the Organization was barely able to finance its existing HIV work. With only two years to achieve the ambitious target and no definite funding commitment in place, "3 by 5" started off more as a political declaration and an "act of faith" than as a systematic programme of work. WHO still needed to prove its credibility and increase its international standing in HIV work in order to become the much-needed leader in the health sector response to HIV and AIDS.
3. After setting this highly publicized objective, WHO did not drive or manage the Initiative as a conventional programme of work, with milestones and a logical chain of results type of design. The most important planning reference document (*Treating 3 million by 2005: Making it happen*) refers to 76 indicators (61 verifiable indicators for 5 strategic "Pillars" and 15 monitoring indicators), with 48 assumptions.⁹⁹ This reflects an ambitious, but weakly conceived programme with insufficient structure against which results could be measured or performance monitored for the enormous amount of effort that has gone into it. Without a performance-monitoring strategy it became difficult to have a proper reporting strategy. This lack of programme design also made it difficult to properly plan what resources would be needed to achieve the objective. The fact that funding could not be secured until the middle of 2004 and was only received in later instalments delayed full-scale implementation of the programme.
4. WHO justified the lack of programme structure by taking the view that "3 by 5" needed to be conducted as an "emergency" response that would require unconventional organizational conduct to evolve as it gained momentum. Parallels were drawn to how WHO had managed the global response to SARS. However, this was not largely an appropriate operational model for urgently scaling up the systems, finances and activities that would be needed for implementing a global health initiative of this magnitude. HIV epidemics have been around for more than 20 years and everyone agrees that controlling the current pandemic will need medium- and long-term efforts spanning generations. The need to rapidly scale up ART cannot be characterized as an "emergency" in the traditional sense but rather as a medium- and long-term "urgent" effort by countries and partners alike. An essential criticism of WHO's launch of "3 by 5" as a global emergency response

⁹⁹ There are various planning documents, workplans, etc. for "3 by 5" that lack consistency in describing what the programme wanted to achieve in 2004 and 2005. In the inception document *Making it happen: the WHO strategy* no reference was made to the *Global Health Sector Strategy for HIV/AIDS 2004 – 2007*, which was the existing strategy approved by the World Health Assembly. In 2004, in the document *Investing in a Comprehensive Health Sector Response to HIV/AIDS*, (partly) re-situated the Initiative into the larger sectoral framework (and prioritized prevention and health systems strengthening).

is not that the target of 3 million was unrealistic, but rather that the two-year period to establish this as a programme disoriented planning and preparation for the longer term. As many partners put it, the problem was not with the "3" but with the "5" (referring to the very short time-span) of the initiative.

4.6.2 Organizational structure

WHO as a global institution

5. WHO is a complex global organization with significant regional variation and decentralized autonomy.¹⁰⁰ This is seen internally as a challenging structure to manage and through which to implement a global programme. However, its plurality is also part of the Organization's strength, as regional offices can be better connected to the geographical, political, social and cultural realities of their constituencies. Because of the relative autonomy of regional directors¹⁰¹ and the level of influence they have on the performance of WHO programmes within countries, their support for "3 by 5" and willingness to achieve programmatic coherence across the Organization has been an important determinant of the extent to which progress has been achieved in each region. The most concerning manifestation of this was the apparent lack of visible leadership from the WHO Regional Office for Africa in the "3 by 5" Initiative. The way in which "3 by 5" was launched and has been championed from a headquarters level possibly contributed to the lack of proactive participation in the Initiative by that Regional Office. This indicates a serious governance challenge to WHO that the Executive Board and senior leadership have not yet taken responsibility to adequately address.
6. Overall, WHO is still perceived as a large and bureaucratic organization that is more suited to undertaking longer-term development initiatives. The Organization's policies and operating procedures (such as how decisions are made through the World Health Assembly (WHA) or regional health committees, budgeting and fundraising processes, and recruitment regulations) make it difficult for WHO to respond quickly in implementing change. Thus, the planned two-year period to achieve this change was unrealistic.
7. WHO did apply some "extraordinary" measures that demonstrated the willingness of the Organization to move away from "business as usual" in its administrative and management procedures. Some 160 staff were recruited globally in the two-year period and the programme support cost (an "overhead" charge made on external grants to finance WHO administrative services) was reduced from 13% to 6% for the "3 by 5" budget. While these are substantial organizational improvements to be appreciated, many external partners still find it hard to accept that, in many cases, the key staffing for this initiative (the "3 by 5" officers in countries) was only put in place towards the end of the two-year period.

¹⁰⁰ WHO has three levels: headquarters in Geneva, six regional offices and over a hundred country offices (CO). Regional offices have their own elected directors and function semi-autonomously.

¹⁰¹ For instance, the WHO regional directors are appointed through the Regional Committee of national ministers of health and are not nominated by the Director-General of WHO.

At regional office level

8. For far too long, regional directors and regional offices approached HIV/AIDS and ART without the necessary priority and attention, as reflected by the insignificant budget and human resources previously allocated to this programme area. New resources made available through the "3 by 5" Initiative have contributed to strengthening the HIV and AIDS programme in all of the regional offices. This has produced positive changes in most cases (which the Evaluation Team was able to see in the WHO Regional Office for the Americas/PAHO, the WHO Regional Office for the Eastern Mediterranean, and the WHO Regional Office for South-East Asia).¹⁰² Increased staff and regional planning and programme development processes in these offices seem to address the challenges of HIV and AIDS appropriately for the first time in many years.

Good practice example of WHO regional offices facilitating support to the country level

The WHO Regional Office for the Americas /PAHO in Washington and the WCO in Haiti have established a weekly working group to "Intensify PAHO support to Haiti in the area of HIV/AIDS/STI prevention, treatment and control". During these meetings, staff from several divisions of PAHO (including procurement and finance sections) assembles around a table in Washington to link up via telephone with the country office in Port au Prince to review progress, identify problems and discuss ways of rapidly addressing these through their combined efforts. This is a very practical example of how an institutionalized working practice adapted to meet the support needs of the country can make a difference.

9. The WHO Regional Office for Africa faces the largest challenge in addressing the scale and complexities of the HIV and AIDS response in the Region, which has some of the poorest nations and worst epidemics. More than 60% of the global target is concentrated in Africa. Communication and transportation links to where the work needs to be done are often extremely challenging. The WHO Regional Office for Africa faces structural challenges because its offices are split between Brazzaville (Congo), which is where most administrative and technical functions are performed, and Harare (Zimbabwe), where only two out of six technical divisions are located, including those relevant to the HIV programme area. This makes it logistically difficult to establish synergies and to ensure efficient administration. Despite the undeniable efforts¹⁰³ by the WHO Regional Office for Africa to support Member States in their scaling up efforts (e.g. through recruitment of 21 "3 by 5" officers; numerous technical missions to focus countries; and facilitating regional consultations), the WHO Regional Office for Africa has been slow in scaling up its own regional resources with the additional funding from "3 by 5" and has the lowest

¹⁰² The WHO Regional Office for Europe and the WHO Regional Office for the Western Pacific were not visited during the evaluation, but reported equally increased commitments.

¹⁰³ See also the note on the WHO Regional Office for Africa visit in Annex 5.1.

performance in grant execution. Although there is a new plan within the Regional Office to establish three to four intercountry teams across the continent that will supplement it, implementation of this effort has only started.

10. WHO regional offices in general (and the WHO Regional Office for Africa in particular) are largely under-resourced to exercise the important support and coordination function of their country offices. There are indications that regional offices still operate in many respects without sufficiently taking into account the subsidiary principle (responsibility and authority of decision should be exercised at the level closest to the issue and objective) and continue to apply outdated management procedures that compromise their performance and generate a largely negative external perception.¹⁰⁴

At WHO headquarters level

11. The "3 by 5" Initiative was coordinated by the HIV/AIDS Department at WHO headquarters, which adopted its present structure in 2004 and currently employs around 105 staff.¹⁰⁵ At the end of 2004 most of the programme staff was on short-term (11-month) contracts. However, this was restructured during 2005, by which time 80% had received "fixed-term" (two-year) employment contracts. This was important for the programme's stability and for staff morale. Technical teams that mostly only consist of one or two key technical staff are located within five operational units. These are generally acknowledged as being highly skilled professionals who are extremely dedicated to their work. However, in most cases, these teams are extremely under-resourced and vulnerable to staff losses because each technical area depends on the leadership of one or two individuals (as highlighted in earlier sections of the report that deal with each technical area). This is the case despite the fact that WHO has invested in increasing staffing almost threefold to build "3 by 5" as an internal programme (the organizational chart is displayed in Section 2.4).
12. Reviewing the organizational model for "3 by 5" and decision by WHO to implement this as a headquarters-directed internal programme, in retrospect, needs to take into account the historical context of the HIV programme area within WHO¹⁰⁶ and lack of consensus on scaling up ART at the time. It was probably necessary to create the focus and momentum for the programme in this way, although this produced inefficiencies and areas of overlap with other WHO departments. It has created a need to re-balance how programme resources are allocated across the levels of the Organization. As the programme developed, almost all the technical areas within the HIV/AIDS Department began to establish partnership networks (such as AMDS; HIVResnet; ITPC; MERG; and the others described in earlier sections of this report). The global scaling up response has become increasingly institutionalized and is now shifting focus within the United Nations towards becoming a global health partnership for *Universal Access*. It could be relevant for WHO to reconsider at this time whether the current HIV programme structure is the

¹⁰⁴ An example of this was a highly critical editorial that appeared in *The Lancet* in August 2004: WHO's African regional office must evolve or die. *The Lancet* 364, 9433, 475-476.

¹⁰⁵ Based on a list provided by WHO to the Evaluation Team in August 2005.

¹⁰⁶ See Annex 7.1.

most appropriate for its purpose and look to possible alternative models that the Initiative might evolve into. The experience of existing Global Health partnerships within WHO (such as Stop TB) could be relevant to this effort.

13. The HIV AOW in WHO has a history of restructuring and changing leadership.¹⁰⁷ When Dr Jim Kim took up his position in February 2004, he was the 12th director since 1996 and this position once again changed at the beginning of 2006 after his resignation. It is very likely that the 10 years of constant organizational restructuring and changing leadership have contributed to WHO not having had an established programme or strong organizational capacity in HIV and AIDS before the period of "3 by 5".¹⁰⁸ Responsibility for this must lie with senior WHO management and this is also a reflection of the political processes that take place within the institution.
14. The HIV Department has worked with more than 20 other WHO departments and units to integrate HIV into related technical areas of work and provided them with substantial funding allocations (in excess of US\$ 18 million) through the "3 by 5" budget. Contributions by these units have been extremely variable and there are both instances where the funding has been supplemented with resources from other sources to produce excellent outputs, as well as a number of contrasting examples where funds remain under-spent and the collaboration has been suboptimal (as described in other sections of this chapter that deal with progress in specific technical areas). Some of these organizational dynamics have resulted from long-standing interdepartmental politics, overlaps in areas of work, or inter-personal conflict that need to be resolved through stronger managerial action.

At country office (WCO) level

15. WHO is engaged in an institutional change process that is aimed at decentralization through shifting funding allocations to the country level (through regional offices) within a prescribed time frame. This has major implications for the structure of the HIV Department. While most partners consulted agree that it is necessary to continue strengthening the WHO capacity at country (and regional) level, they also expressed caution that this development should not de-stabilize technical programme areas at the headquarters (and within regional offices) levels that serve the global community, by unrealistically reducing their budgets and staffing.
16. Most WCOs in the 49 focus countries have substantially increased their commitments and role in supporting national responses to HIV as the result of "3 by 5". However, this country presence is still under-resourced relative to the need in most places. Shifting resources to the country level should not transform WHO into an "implementing" agency, but needs to reinforce its strategic technical support roles. WCOs should be able to raise their own extrabudgetary funding for specific projects (as is already happening to some extent within certain countries, including as a subrecipient of Global Fund grants).
17. How "3 by 5" has been implemented through WCOs also depends on the organizational

¹⁰⁷ For some details of this history see Annex 7. Moreover, only 4 of the 15 professional staff of the WHO Regional Office for Africa Team on HIV/AIDS have a "fixed-term" contract.

¹⁰⁸ For a short overview of the organizational history between 1996 and 2003, see *Annex 7*.

culture within each office, leadership style of the resident WHO representative who heads the office, and overall "way of doing business". There are still countries where the WHO presence needs to become more relevant and effective. This includes placing greater emphasis on coordinating partner contributions, facilitating technical assistance and establishing stronger working relationships beyond the MOH. The current lack of WHO engagement with non-state providers in most countries is a specific example of gaps that need to be addressed.

18. WCOs can become more proactive and vigilant about how external funding is being utilized within some countries by demonstrating technical leadership that will influence how this money is spent ("Making the money work!"). The WCO's role in providing technical assistance to ensure that Global Fund grants are operationalized optimally is a key example of this, although WHO has not yet achieved this level of involvement in some countries. In Kenya, for instance, WHO is not officially represented on the National AIDS Control Council and has not been a very active member of the Interagency Coordinating Committee for AIDS (ICC-AIDS) that is responsible for providing the Council with technical inputs.¹⁰⁹
19. The WHO relationship "on the ground" with major bilateral programmes such as United States Government missions and agencies responsible for implementing the PEPFAR programme is variable, but overall not very influential. Evidently it is not easy for a WCO that has only a fraction of the (technical and financial) resources of these bilateral players at hand, to influence the better-resourced partners. Many observers at the country level were of the opinion that WHO had lost its key influential role in HIV to these partners before "3 by 5" and has only just begun to regain its position and influence since. If WHO does not continue bringing about organizational change to optimize how it does business within countries, the Organization runs the risk of becoming increasingly marginalized by other contributors.

4.6.3 Organizational performance

20. Contributions that WHO made during the period of "3 by 5" are mostly described in the preceding sections of this chapter. It has taken time for WHO to gear up the programme's internal structure and many of the activities undertaken were of a developmental nature. Due to the staggered inflow of resources and rapidly changing programme structure, it was not possible (or fair at this early stage) to evaluate how efficiently these resources were used.
21. Significant delays occurred in implementing planned activities (especially within countries) that WHO ascribes to the late arrival and delayed disbursement of funding, since almost all the money available to undertake this programme was extrabudgetary. For instance, the WHO Regional Office for the Eastern Mediterranean only received its first transfer of CIDA funds (of just under US\$ 1.4 million) in April 2005 and PAHO

¹⁰⁹ The role and functioning of National AIDS Councils and the Country Coordinating Mechanisms for Global Fund grants have been under review in a number of countries and they have been another crucial influence on how countries have responded to scaling up ART (however, further analysis of this is beyond the mandate of this evaluation).

received its allocation the following month (with only seven months to the end of the Initiative). Regional and country offices had to wait for long periods without knowing how much funding would be available to implement their plans (the WHO Regional Office for the Eastern Mediterranean originally budgeted for US\$ 11 million but finally only received US\$ 3.5 million and PAHO had to scale down from US\$ 12 million to US\$ 4.5 million, having to reorganize its workplan several times). Given these constraints, uncertainties and delays, it came as no surprise that four months before the end of the Initiative, the overall disbursement rate for the "3 by 5" budget was only 61% (and in the WHO Regional Office for Africa this was only 47%, despite Africa being the priority with 19 of the 34 focus countries having a high HIV burden).¹¹⁰

4.6.4 Financial considerations

22. WHO has had an increasing budget for HIV/AIDS over the past few years, as follows:
- 2002–2003: US\$ 136 325 000 (this was a 146% increase over the 2000–2001 biennium)
 - 2004–2005: US\$ 216 798 000 (59% increment)
 - 2006–2007: US\$ 260 650 000 (20% increment)
23. There has been an overall decrease in the "regular budget" portion of this funding. In the biennium 2000–2001, the regular budget contribution to the HIV AOW represented 13% of the total. This proportion is planned to decrease to 6% in the 2006–2007 biennium (at country level, only as little as 4% of planned expenditure is provided through the regular budget). Over the past 20 years, organization-wide, WHO has had to depend mostly on increasing extrabudgetary funding from external sources to carry out its work (accounting for up to 70% of the overall WHO budget in the last biennium).¹¹¹ This compromises the stability of this Organization and threatens to seriously affect the sustainability of the HIV programme area. Confronted with this (and the sobering financial prospects for 2006–2007) WHO senior management told the Evaluation Team that this situation has become part of the everyday reality of the broader Organization.¹¹²
24. The "3 by 5" Initiative was financially weak from the start, having only one main sponsor. The Canadian Government provided WHO with US\$ 81.7 million (CDN\$ 100 million), which contributed more than 50% of all government contributions and literally saved the Initiative from an early collapse. Other significant government contributions included: the United Kingdom (US\$ ~23.4 million), Sweden (US\$ ~14.8 million) and Norway (US\$ ~8.6 million). A total of 18 governments provided funding to WHO for HIV and AIDS work

¹¹⁰ The most recent available analysis of budget disbursement from September 2005 appears in Annex 7.3.

¹¹¹ There has been no increase in WHO's regular budget for a number of biennia until 2006–2007 when there was a 4% increase, which was assigned to six "under-invested" AOW. HIV was not included by the WHA as an "under-invested area".

¹¹² Interview with the Director-General of WHO. The way that WHO is funded is symptomatic of long-standing institutional arrangements and financial crisis within the United Nations system. This is a serious indictment on the global community, with Member States that are responsible for the biggest contributions (and nonpayments of their dues) reluctant to reform the system for political reasons. (An analysis of the United Nations financial crisis is provided by the Global Policy Forum at <http://www.globalpolicy.org/finance/index.htm>, accessed 10 March 2006).

(but many of these contributions were relatively small in relation to the overall "3 by 5" budget). Foundations and NGOs contributed a further US\$ ~5.7m; the private sector and general public US\$ ~0.1m; and the United Nations system and agencies a further US\$ ~28.5m (including an initial allocation from UNAIDS to WHO for starting up the Initiative).

25. Actual funding received by WHO for "3 by 5" was only just over half of the original budget estimate (Mapping 2004–2005 contributions¹¹³ to the HIV/AIDS Department, including firm pledges, indicates that only approximately US\$ 195 million¹¹⁴ was received against a budget estimation of US\$ 350 million).^{115,116} A proportion of the funds received are under-spent. This is partly due to the fact that the major funding decisions were not made at the beginning of "3 by 5" but only after it had already started. The disbursement of funds therefore occurred only while the Initiative was already well underway. If funding had been secured at the beginning, it is highly likely that implementation achieved over the period would have been higher.
26. Prospects for continued funding are not good. By November 2005, there had not been a single official commitment from previous donors. The sustainability of this essential AOW is *at stake* and WHO cannot continue to implement a systematic programme to support the process of scaling up (especially towards the even more ambitious *Universal Access* goal) without having adequate, predictable funding.

The WHO budget forecast for 2006–2007

WHO has detailed a budget for 2006–2007 and still needs to develop an indicative budget for 2008–2010. The approved WHO budget for the HIV AOW for 2006–2007 is US\$ 275 million, with 59.3% allocated to countries, 24.7% to regional offices and 16% to headquarters.

At the beginning of February 2006 there was an estimated funding shortfall of US\$ 164 million for the HIV AOW for 2006–2007. WHO will only be able to fulfil its mission and strategic directions for Universal Access once it receives the funding it requires to operationalize the 2006–2007 budget.

Source: WHO HIV/AIDS Department, *WHO's Contribution to Universal Access to HIV/AIDS Prevention, Care and Treatment*, February 2006, p.4.

¹¹³ For definition of "contribution" versus "resources allotted", see footnote in Section 2.4 Budget.

¹¹⁴ See Annex 7.2.

¹¹⁵ See Section 2.4 Budget, column A.

¹¹⁶ Actual receipts (US\$ 195 million) were 55.7% of the original US\$ 350 million budget estimation (see Section 2.4 Budget, column A) and 89.4% of the revised "planned budget" (US\$ 218 million) for the 2004–2005 biennium approved by the WHA and Executive Board (see Section 2.4 Budget, column B. The "planned budget" for "3 by 5" was approved, without reservation, by the Executive Board in January 2004 and was ratified by the WHA in June 2004).

4.7 HIV prevention; health systems strengthening; equity and gender

4.7.1 Prevention

1. WHO technical work on HIV prevention mostly focuses on interventions that are delivered through health services such as testing and counselling; diagnosing and treating STIs; health services for women, infants and young children; and targeted interventions for vulnerable groups such as sex workers and IDUs.¹¹⁷ This includes promoting access to condoms in these settings, where WHO leadership as a credible multilateral scientific agency is important to provide clarity overall on the rationale for investing in continuous condom promotion.¹¹⁸
2. WHO has developed a range of toolkits and guidance on HIV prevention, including for prevention among sex workers and for HIV testing. Prevention practice within the health facility is also well covered in the IMAI guidelines and tools. However, there is still a need for WHO to provide policy guidance on a number of more "controversial" prevention issues such as prevention for discordant couples; partner notification and disclosure; and routine HIV testing for children. Some respondents felt that WHO provides technical assistance and guidelines that are too "medically" focused and lack guidance on interpersonal communication and social marketing to improve the impact of prevention interventions. Translating these prevention theories and guidelines into practical service activities within the health system remains a challenge for most national HIV programmes.
3. HIV prevention policy and coordination is the responsibility of UNAIDS, but there was a lack of systematic cooperation between WHO and its UNAIDS partner in "3 by 5" on prevention issues. This was a missed opportunity for scaling up global prevention responses in synergy with efforts to expand access to HIV treatment. WHO was criticized by many commentators for not having prioritized HIV prevention strongly enough and there is a majority perception that "3 by 5" focused only on ART, even though WHO framed this from the start as needing to be implemented "within the context of a comprehensive response to HIV/AIDS". It was only some months after "3 by 5" was launched (around mid-2004) that WHO published its two-year plan for the HIV/AIDS programme,¹¹⁹ which made it explicit that prevention was also a key objective of "3 by 5" (some say that this was in response to the earlier criticisms that prevention had initially been "forgotten"). In the June 2005 progress report on "3 by 5", WHO wrote that "Expanded access to treatment initially gave rise to concerns that HIV treatment could divert both resources and attention away from prevention".

¹¹⁷ From the WHO HIV/AIDS plan 2004, p 36.

¹¹⁸ In regions where there are focused HIV epidemics and a low prevalence in the general population, WHO has a particularly strong emphasis on condom-promotion programmes led through its regional offices (the WHO Regional Office for the Western Pacific and the WHO Regional Office for South-East Asia).

¹¹⁹ *Investing in a Comprehensive Health Sector Response to HIV/AIDS, Scaling up treatment and accelerating prevention.* Geneva, World Health Organization, 2004.

4. Prevention-related work was relatively under-resourced as a technical area within WHO and was not well communicated or operationalized through the "3 by 5" initiative. However, this has begun to be addressed more explicitly through parts of the Organization taking a much stronger lead on prevention. This includes the WHO Regional Office for Africa declaring 2006 "a year for accelerating HIV prevention in the African Region". Other departments within WHO (beyond the HIV/AIDS Department), such as Reproductive Health and Research and Making Pregnancy Safer, have also contributed to HIV prevention work, although this was not as strategically linked to the "3 by 5" Initiative and budget as it might have been. WHO has invested relatively little into scaling up prevention activities, especially at the country level where the work of "3 by 5" officers is mostly focused on treatment-related issues. In some countries, the responsibility for prevention has been largely "delegated" by WHO to NGOs or other partners.
5. WHO has begun considering the need for measurable prevention targets (like the treatment targets) but is still working on the technical feasibility and appropriateness of this. The Regional HIV/STI Plan for the Health Sector 2006–2015 in the Americas (published by PAHO) already includes three primary targets related to prevention activities.¹²⁰
6. WHO has played an important role in harm-reduction strategies for IDUs and worked with partners at global, regional and country levels, to focus on affected populations. This has been particularly successful in the WHO Eastern Mediterranean Region, where WHO helped establish integrated centres for drug users (Triangle Clinics) in the Islamic Republic of Iran, as well as in the WHO Regional Office for Europe, focusing on the HIV epidemic among IDUs in the eastern European states. WHO was highly acknowledged by national partners for this work in Ukraine. In addition to providing technical support for this in these countries, WHO has taken the significant step of including opiate substitutes (for substitution therapy) on the Essential Drugs list and is in the process of establishing prequalification procedures for this category of drugs. Opiate substitution therapy is documented as an HIV-prevention strategy, but has also been used in Ukraine to improve ART adherence, providing an example of a treatment-related intervention that at the same time provides prevention benefits.

Integrating HIV prevention with antiretroviral therapy (ART)

7. WHO believed that ART delivered as a public health intervention could have a positive impact on HIV prevention at the population level (although conclusive evidence for this is still not yet available)¹²¹. There was an impression from countries visited during this evaluation that the availability of treatment has motivated many more people to know their HIV status (both those who are already seeking treatment, as well as the "worried-well"). HIV testing with counselling is considered by many experts to be the key link between treatment and prevention. This needs to be used more strategically as both

¹²⁰ The targets in the PAHO plan: to reduce new HIV infections (by 2010 and 2015 respectively); universal access to comprehensive care including prevention, care and ART; and to reduce the incidence of MCTC of HIV (and congenital syphilis).

¹²¹ There is documented evidence from developed countries where ART has been available for some time that HIV (as well as other STIs) infection rates have again been increasing in recent years. Activists in these countries are strongly lobbying against reducing the resources available for prevention.

- a diagnostic and prevention tool. There are specialists within WHO that believe the Organization should be taking a stronger lead on *targeted HIV testing interventions* that have already proven effective in some high-risk settings. As an example, there has been no strong WHO position encouraging HIV testing among health-care workers (who tend to have a low uptake of testing where this is not implemented through a targeted programme).
8. It has become more usual for prevention to be discussed within adherence counselling for ART in many settings where health workers (and HIV-infected peer counsellors) are already taking the lead on this. Condom use is also being discussed more openly with patients as part of "positive prevention". These are common sense practices in settings where the risks of HIV transmission are high and continued WHO guidance and support for these good practices is required so that governments will take a strong stand on proven prevention interventions (including condom promotion). A recently published study from Uganda shows that prevention counselling and follow-up for ART patients and their partners resulted in a significant reduction in their sexual risk behaviours (Bunnell et al., 2006).¹²²
 9. Many WHO personnel work in high HIV-prevalence settings and travel extensively – both of which are independent risk factors for HIV infection. The United Nations does make provision for medical benefits that includes ART for field staff, but WHO could have been more proactive in implementing visible workplace initiatives, such as actively promoting HIV prevention and voluntary testing and counselling (beyond just making testing available as an employee health benefit).
 10. Preventing mother-to-child transmission of HIV (PMTCT) is a critical prevention activity in the health sector that was not adequately prioritized within "3 by 5". This has been a missed opportunity for strengthening the linkages that PMTCT provides between prevention and treatment. PMTCT is also seen as an important entry point for family health interventions that is important for taking the health sector response to HIV beyond the health facility. Inter-departmental cooperation between the Making Pregnancy Safer Department and the HIV Department has been suboptimal, resulting in delayed outputs and lack of clear policy leadership in this area. In October 2005, UNICEF and UNAIDS launched a campaign (without WHO participation) to achieve 80% access to PMTCT by 2010. The Interagency Task Team on PMTCT that is intended to strengthen collaboration between WHO, UNICEF and other participants has apparently not made a great deal of progress in taking forward joint initiatives. This again emphasizes the need for better collaboration mechanisms and greater accountability among these agencies.

¹²² However, the study was not able to attribute the effect of reduction in risk behaviour to the specific combination of therapy and prevention counselling. Only a case-control study could demonstrate this but may not be feasible because of ethical issues.

4.7.2 Health systems strengthening

11. Health systems are the foundations on which the health sector response to HIV is being built. Successes in scaling up services through "3 by 5" has demonstrated that delivering ART through a PHA is feasible – even where health systems are weak overall. But this has mostly been achieved through established facilities (often within hospital outpatient clinics) where existing infrastructure and staffing could be re-deployed. Many of these sites also received targeted external funding and technical support from donors for infrastructural improvements and supplemental staffing (which has in many cases markedly improved the standards of these facilities over what is generally available in the health system), without addressing the underlying weaknesses in these systems.
12. There is growing demand from countries for increased support to strengthen their health systems, as evidenced by the 30 health systems strengthening proposals (25 from Africa) submitted to the GFATM in Round 5 during 2005. However, these had a low success rate and the Technical Review Panel of the Fund noted that many of the proposals were either too vague or over-ambitious.¹²³ This emphasizes the need for more pragmatic approaches that have a strong technical basis. National AIDS programme managers from MOHs surveyed through this evaluation did not rate the WHO contributions to health systems strengthening very highly overall (and specifically ranked WHO technical contributions to human resources strategies and financing as weak), but felt that this is a priority area in which WHO is expected to provide this assistance. Stronger country-level support is needed for implementing the various components of health systems strengthening in synergistic ways. Within WCOs, this integrated "Health Systems" perspective is often lacking, evidenced by the absence of joint planning for programmatic linkages between technical areas (e.g. malaria with HIV and AIDS) to optimize opportunities for health systems strengthening. Some WCOs have a Health Systems technical officer, but there tends to be no formal interaction with the HIV/AIDS officers. (In Kenya, for example, even though the WCO has been reorganized to have a Health Systems cluster, there was no evidence of formal collaboration or joint planning towards this objective, while much work is being done in isolation to support the MOH to develop broader health sector strategies). Regional interagency technical networks still need to become more effective in delivering predictable and sustainable direct technical support to countries.
13. In high HIV-burden settings, ART sites that have been established in the first phases of scaling up are fast becoming saturated and there is urgent need to take services to the decentralized level. Increasing coverage at the primary-care level will make ART more accessible to non-urban populations and marginalized communities. However, this introduces new challenges in both scale and complexity that are more vulnerable to the underlying weaknesses of these health systems. Investment in all the components of health systems strengthening¹²⁴ is therefore necessary to achieve targets that go beyond what is in relatively easy reach.

¹²³ Based on a note to the Executive Board of the GFATM prepared by the Technical Review Panel.

¹²⁴ WHO describes six generic components of health systems that need strengthening: 1) Policy, leadership and stewardship; 2) Health financing; 3) Health resources (including workforce mobilization, distribution, and motivation); 4) Supply systems; 5) Service management; 6) National information and monitoring systems.

14. There have been many different approaches to strengthening health systems for primary health care over the past 30 years, driven by the Alma-Ata commitment to achieving 'health for all' by the year 2000. These have tended to emphasize strengthening health systems from the bottom up.¹²⁵ Failure to achieve this goal of universal access to comprehensive primary health care has for some time been an argument for focusing on delivering selective primary health care that offers a limited number of cost-effective interventions to achieve disease control objectives¹²⁶. The WHO PHA offers a defined set of essential interventions that can be delivered at the primary care level, to produce high-value health impacts relevant to settings with uncontrolled HIV epidemics. This has the added advantage that HIV-related interventions are attracting unprecedented domestic and external funding and technical resources. However, these need to be better aligned with health systems strengthening. Since these interventions are closely linked with other acute and chronic primary care needs (including for TB; maternal and child health; sexual and reproductive health; and increasingly also for chronic disorders such as hypertension and diabetes), this approach provides an opportunity to strengthen primary care delivery more broadly.
15. WHO has developed integrated management approaches for strengthening service delivery that are based on a generic model. It provides simplified operational guidance; service planning and monitoring tools; and training and management support "within the framework of existing health systems". This has been applied to acute and chronic HIV care and ART through IMAI (and the IMCI and IMPAC approaches have also been updated to include HIV-related interventions). The IMAI team within the HIV Department led an extensive collaboration to adapt, implement and demonstrate the feasibility of IMAI during the period of "3 by 5". IMAI has introduced specific innovations for dealing with human resource constraints through "task shifting" and promotes a chronic care service delivery model that builds community linkages and involves PLHA in the care team. A focus study of IMAI and international consultations conducted through this evaluation (reported in Appendix 8) found that IMAI could potentially contribute towards strengthening health systems. This could possibly be implemented together with IMCI and IMPAC as a common "platform" for strengthening primary health care services more generally to deliver a broader PHA package. However, these integrated approaches are not yet operationally linked or supported by a common strategy within WHO; they are still located across different organizational clusters and are currently offered to countries as "stand-alone" packages. WHO needs to rapidly build evidence of the impacts that these approaches can have on health systems and must demonstrate that it is feasible to implement and sustain them on a much greater scale, before their full potential for health systems strengthening can be established.
16. Although innovative models for rapid scale-up and knowledge management are available within the Organization, these have not yet been translated into mainstream programmatic approaches. The WHO strategy of "learning by doing" has not produced

¹²⁵ Declaration of Alma-Ata. International conference on primary health care, Alma-Ata, USSR. 6-12 September 1978.

¹²⁶ Walsh JA, Warren KS. Selective primary health care: an interim strategy for disease control in developing countries. *New England Journal of Medicine*, 1979, 301:967-74.

significant advances in knowledge management and operational research for health systems strengthening that could be useful to programme managers. More emphasis is needed on problem-solving, modern service improvement and learning methodologies to address these weaknesses.

17. WHO has launched new health systems initiatives, including the "global course of action" for strengthening elements of the health system¹²⁷ through developing core technical frameworks (e.g. for human resources for health and knowledge management). This effort has already made progress in recent months, although more attention is needed in the important area of health financing to ensure sustainability of national AIDS responses. The interaction between public and non-state sectors has likewise received relatively little attention, although this is now starting to be addressed through a 'non-state sector' working group.
18. Even though most of these activities were not specific to HIV, there is general acknowledgement that scaling up (and by implication, "3 by 5") has provided impetus to this AOW within WHO. However, there is still little agreement about which actions are of highest priority in the near term and what the system-wide and longer-term implications of scaling up will be. Greater clarity and agreement is needed about what is meant by "health systems strengthening". Further work must also be done on developing the metrics for tracking progress, and improving the knowledge base on which technical strategies will produce more sustainable impacts on health systems strengthening (including health financing and health workforce development).
19. WHO needs to contribute guidance to countries on allocating the new resources that are becoming available for HIV response to most effectively achieve the objectives of health systems strengthening. Progress is beginning to be made in linking these broader initiatives with the disease-specific service strengthening interventions.
20. Health systems strengthening cannot be achieved in isolation and stronger, purpose-led partnerships are needed with other agencies. The United Nations system is seen as part of the problem as well as the solution to weak health systems. There is criticism that WHO has not worked more strategically with relevant United Nations and multilateral partners (such as the World Bank, UNDP and GFATM) to address these challenges. Greater consistency is also needed in the policy approaches across the United Nations (e.g. to resolve conflicting messages about user fees and the limitations on hiring human resources for health). As WHO has been provided with the leadership role on health systems responses for HIV, the Organization needs to demonstrate this in practice by facilitating a global strategy that brings all partners on board. Strong joint action to align sustainable financing, practical technical innovations and strong capacity-building is needed for real progress to be made – especially for *Universal Access* to become a reality.
21. The critical shortage of human resources and skills in all functions of managing, supporting and delivering health services in Africa is often quoted as the single biggest health system constraint to scaling up. WHO technical staff within these countries, MOHs and service providers, all reinforced this view. The technical strategies and global policies focusing on

¹²⁷ Through an international consultation meeting: *The Montreux Challenge: making health systems work*, April 2005.

- human resources for health have not yet begun to address many of the practical issues that can improve decision-making and bring about systematic solutions to these problems, such as identifying the gaps through establishing an inventory of available personnel; reviewing the relevance and efficiency of current training approaches; investigating more flexible employment practices (including contracting services to private providers) and improving work performance through contemporary management approaches. As an example, practical approaches to using health personnel more effectively through "task-shifting" have only just begun to be adopted within some countries, but the reluctance of policy-makers in some settings to make the regulatory and service changes to accommodate this demonstrates underlying policy, fiscal and other constraints that also should be addressed. WHO will be intensifying efforts to deal with these human resources for health challenges, since this is the focus of the 2006 World Health Report.
22. The international literature has expressed concern that pursuing ART targets (just one of a number of initiatives introducing multiple targets, additional resources and new interventions on already fragile health systems) could have negative, distorting effects, such as diverting health workers from other essential programmes, particularly in Africa. The Evaluation Team was shown facility-level improvements (e.g. in Kenya and Malawi, where there have been increased investment in human resources for health); examples of good integration between HIV and TB services; and improved coordination within health districts. It was encouraging to see that increasing investment is beginning to be made in health systems as the result of scaling up the HIV response. However, these improvements as regards HIV-related service delivery in a few settings cannot simply be interpreted as producing positive system-wide impacts (such as improving primary health care in general, or strengthening supplies of medicines other than ARVs). These good examples were also exceptional in health services that have, so far, adapted inconsistently to scaling up at the different levels and across geographical regions. Further studies will be needed to monitor the impacts of scaling up on health systems over time.
 23. Monitoring and evaluation systems are a prerequisite to the performance-based funding arrangements that major donors such as PEPFAR and the Global Fund require, but most countries have not put these systems in place and seem not to have prioritized investing programme resources towards strengthening these systems. More interagency technical support needs to be delivered within countries to harmonize the monitoring and evaluation systems for HIV response.
 24. Health systems strengthening has definitely become a more urgent priority because of the "3 by 5" Initiative and the profile of the health systems agenda seems to have been raised overall (including as part of the advocacy of AIDS activists). Investment already being made in service delivery interventions for scaling up ART is expected (by donors, governments and WHO) to have an effect on strengthening health systems overall and numerous political statements were made about this during the period of "3 by 5". WHO has a strong mandate¹²⁸ to strengthen health systems through the response to HIV.

¹²⁸ The World Health Assembly specifically requested WHO to: "provide support to countries to embed the scale-up of the response to HIV/AIDS into a broad effort to strengthen national health systems, with special reference to human resources development and health infrastructure, health systems financing and health information" (see Annex 7).

However, there was initially some delay in taking specific action on this until 2005 and it will need more resources and organization-wide support to deliver results in this area over the next five years. It is encouraging that health systems strengthening is now again being taken up as a renewed priority by other programmes within WHO (beyond HIV), with encouraging implications for broader health development. This is essential for optimizing the impacts that the HIV and AIDS response (and *Universal Access* commitment) could have on other health-related Millennium Development Goals. Sustained investments in health systems are also needed more broadly for the full potential of the health-sector response to HIV/AIDS to be achieved, so these requirements are mutually dependent.

4.7.3 Equity and gender

Evaluating how WHO has addressed gender and equity in the drive to scale-up treatment through "3 by 5" was challenging, since these are difficult performance expectations to measure. This section of the report therefore underscores these concerns and provides illustrations of WHO contributions. These are also relevant as cross-cutting issues in the technical work that the Organization undertakes described in the preceding sections of this chapter.

Equity in treatment scale-up

25. Underlying the notion of equity described here is the principle that "distribution of opportunities for well-being needs to be guided by people's needs".¹²⁹ There are many reasons why some people are not given equitable access to health services. Barriers might be linked to gender, ethnicity, age, geographical location, socioeconomic position or being in a particularly stigmatized or vulnerable group, such as commercial sex workers, MSM, or drug users. "Access" is a concept that relates to both supply (coverage) – the distribution, availability and capacity to provide ART, as well as to demand (utilization) – to what degree people make use of these services.
26. Inequities in access to information and prevention services are examples of the epidemic's key drivers. Finding ways of improving access to services for marginal groups is important to prevent the epidemic from spreading further into the general population. Harm reduction interventions are important both to facilitate access to treatment, and promote adherence to treatment, as well as to contribute towards prevention. In Ukraine it was evident that WHO has been working to systematically expand these types of interventions and the Evaluation Team was also told about major harm reduction interventions in the Islamic Republic of Iran and parts of India (although these could not be directly assessed).
27. In 2004 UNAIDS and WHO issued the ambitious guideline *Ethics and equitable access to HIV treatment and care*, stipulating that all countries should establish "a broadly representative ethics advisory board" to plan, promote and monitor equity in the scale-up and distribution of HIV treatment and care services. These mechanisms do not seem to have been operationalized in most countries and concerns about equity are not yet being actively addressed in most places.

¹²⁹ *Guidance on ethics and equitable access to HIV/AIDS treatment and care*. Geneva, World Health Organization/UNAIDS, 2004.

28. The PHA has major implications for equity. Since this is "population-based", it means that the effects of PHA interventions are expected to benefit "the many" over "the individual" so that more people ("the population") have access to the same basic level of intervention – and therefore the same chance of survival. However, it also means that a few ("the individual") could be disadvantaged because they need individualized treatment. For example, an individual who has previously received non-standard ART by his or her own means (before treatment becomes accessible through a national programme) might find that he or she is unable to benefit from the standard first-line treatments that are available through the public health programme and so could be refused further treatment. This has implications for how services are organized and delivered. Since the PHA may also mean barriers for marginalized and hard-to-reach groups who require special designs to be reached, the PHA need to be supplemented with special measures to facilitate access for such groups.
29. WHO has helped develop tools for mapping and monitoring coverage and utilization of services (e.g. Service Availability Mapping (SAM) which gathers location-specific information for monitoring and planning health services and links this to visual reports). Such tools are very useful in monitoring the geographical coverage of services for observations about equity.
30. It is important to emphasize that too much focus on equity in the beginning of a scale-up may drastically limit the expansion and number of people who can have access. Starting from well-equipped urban centres with trained personnel is important in order to gain experience and develop contextualized treatment systems, and should not be criticized for lack of equitable coverage and distribution. It is, however, important for services to be designed in such a way that they can be rapidly rolled out to low-resourced rural settings.
31. In selecting the 49 focus countries for "3 by 5", WHO demonstrated that equity was more important than only reaching high numbers of patients. More individuals could probably have gained access to ART if resources had been prioritized to "easier" countries. The decision to focus on those settings where there are still many obstacles signalled an intention to achieve equity across countries, even if this meant fewer people globally would thus access treatment in the short term. Ukraine provides several good examples of how WHO has helped to facilitate better access to ART for marginalized groups, such as IDUs (for whom WHO has also actively promoted the use and availability of substitution therapy to treat opiate addiction).
32. Equity is still a big challenge in relation to treatment for children. The "3 by 5" Initiative did not specifically set targets for children, although WHO has been working on the technical constraints to paediatric treatment (such as diagnostic guidelines and prequalification of paediatric ARV formulations). More emphasis still needs to be placed on linking access to treatment to sexual and reproductive health for youth, and to have a family focus on treatment access.
33. Payment for ART remains an important barrier to access; treatment is free in some countries and not in others. In Malawi, the default and death rates for patients paying for treatment were found to be twice as high as for patients receiving free ART (payments for ART in

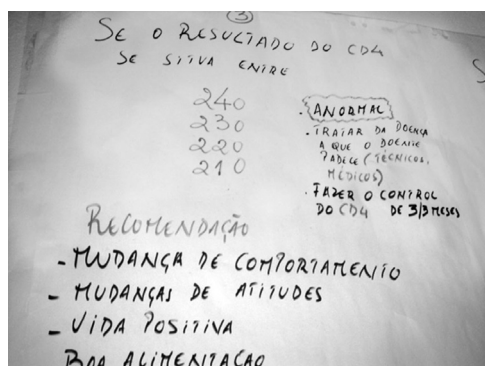
the public sector sites were stopped in 2003). Kenya had substantially reduced service fees and this directly resulted in an increase in patients coming from poor communities. In other countries (including Burkina Faso) there is still a belief that user fees are financially significant, despite evidence that these contribute very little to the overall sustainability of AIDS programmes. In December 2005, WHO issued a discussion paper on free access to ART that followed a process of consultation within the United Nations and was based on available evidence. Disappointment was expressed both within WHO and among external partners that the Organization had been swayed by political pressure not to publish this as normative guidance or a "position paper" in favour of "free access".

34. *Strategic information* can provide a way of monitoring equity. However, obtaining disaggregated data for this remains a challenge at most levels of data collation. Even the most basic data on the sex of people receiving ART are unreliable and not always reported. This highlights the need for strengthening health information systems.

Gender concerns relating to ART scale-up

35. WHO has made commitments to achieve gender equality. Nevertheless, this was not specifically addressed through "3 by 5". Gender mainstreaming is influenced by how an organization is gendered, since this can result in gender-biased decisions that might have an influence on access to treatment; the selection of treatment regimens (that might not work equally well for both sexes); how gender-specific health problems are addressed and monitored; and whether gender-specific barriers to access are addressed. It was beyond the scope of this evaluation to undertake a detailed gender analysis, but this could be an important consideration to address systematically through further studies.
36. There are not a lot of data relating to ART-seeking behaviour for men and women. Most reports from the public sector indicate that about half of those receiving ART are women. However, as an aggregate measure, this does not provide a picture of who is accessing this treatment where, or whether the barriers and opportunities for treatment are equal for men and women. For instance, men tend to seek treatment more frequently through private practitioners, which accounts for a significantly large proportion of the patients receiving ART in many countries. But the reports from the private sector are generally weak on indicating the patient's sex.
37. Stigma and discrimination work differently in different communities and for the two sexes. In most contexts women are more open to visiting health facilities, and may thus have easier access to the services, although payment could be an obstacle to them. Men seem to be more reluctant to come to health facilities and it is important to develop services that may be more adapted to their needs and where they feel they have access.
38. According to the International Community of Women Living with HIV/AIDS (ICW), there are women who obtain treatment to share this with their spouse. The scale of this problem is not known, but ICW and WHO are cooperating on a project to map women's access to treatment in Africa. ICW felt that gender issues relevant to HIV and AIDS were initially ignored in "3 by 5", but that the situation is now improving, with the importance of including gender issues becoming better understood.

39. HIV-positive women in Kenya were concerned about the proposed new AIDS bill, in which "spreading HIV" would be criminalized. Because of the way the bill was worded, they were afraid that HIV-positive women who got pregnant and gave birth to a child with HIV, could be accused of committing a criminal act.
40. The Global Coalition on Women and AIDS is a UNAIDS initiative in which WHO is one of 15 convening agencies working to promote equal access to care and treatment as one area of focus. In a study on women and violence, WHO has documented that violence against women is associated with higher levels of HIV infection.¹³⁰
41. Gender competence in relation to ART specifically and to HIV and AIDS in general is not part of the induction training for "3 by 5" officers. There has been no specific focal point person for gender in the HIV/AIDS Department,¹³¹ although the Gender, Women and Health (GWH) Department at WHO prepared a briefing package on *Gender and HIV/AIDS*, and works to mainstream gender into other training programmes. They have also outlined draft *WHO Guidelines on integrating gender into HIV/AIDS programmes* (WHO/GWH, 2005).



Counselling to patients in a day hospital – Mozambique

¹³⁰ *Violence against women and HIV/AIDS: Critical intersections. Sexual violence in conflict settings and the risk of HIV.* WHO. 2004

¹³¹ A new Women and Youth officer started working in the HIV/AIDS Department in January 2006.

PART 3

Looking forward

5 Overall conclusions and recommendations

5.1 The development context

AIDS response and ART are not only a technical consideration, they must be seen in the context of global development processes, such as poverty reduction, the UNGASS Declaration and Millennium Development Goals. Important commitments were made in the second half of 2005 to continue scaling up these responses, to come "as close as possible to the goal of universal access to ART by 2010 for all those who need it". This has significant implications for equity, human rights and international solidarity. It also requires an unprecedented global effort by all contributors working towards a common purpose and guided by strong technical agencies, with a particularly important role for WHO. The United Nations has already initiated an "inclusive, country-driven process involving the relevant stakeholders from NGOs, civil society and the private sector". This process is being facilitated by UNAIDS, to identify the key obstacles to HIV prevention, treatment and care, in order to find solutions and develop nationally agreed, targeted plans (or roadmaps) for building more comprehensive AIDS programmes.

This process takes place in the highly politicized environment of development cooperation, where decisions about development priorities, resource allocation and the roles and functions of major global institutions are not always made impartially or based purely on what seems in the best interests of affected constituencies. The evaluation of a major global public health initiative, such as "3 by 5", cannot ignore the influences of these powerful externalities. In reviewing the programmatic, technical and normative contributions that WHO has made to this global initiative, it is necessary to understand both the political and scientific dimensions of health and development, which go much beyond the narrowly defined programmatic aspects of "3 by 5".

Looking forward, decisions will have to be made on the basis of these evaluation findings to strengthen WHO's position within the context of these developments. This requires an appreciation of how such a complex organizational undertaking needs to relate to its rapidly changing and complex environment. It also points to the many macro issues beyond the scope of the Initiative that still need to be addressed and (hopefully) solved in order for *Universal Access* to treatment, prevention and care not to follow "3 by 5" in "missing the target"!

5.2 The main conclusions and lessons from this evaluation

I. Progress in scaling up access to antiretroviral therapy (ART) and HIV prevention

1. Many countries have made significant progress over a relatively short period to increase the total **numbers of people who are receiving ART** in low- and middle-income settings from 400 000 in 2003 to about 1.3 million at the end of 2005.¹³² There has been

¹³² Based on UNAIDS/WHO estimates.

a corresponding exponential increase in the numbers of treatment sites in both the public and non-state sectors, supported by a diverse range of partners and funding sources. However, there are still striking differences between regions and countries, with many of the worst-affected African countries still far from containing their growing AIDS crisis. Sustaining this response even at current levels remains one of the biggest concerns of national governments.

2. In these early phases of scaling up, treatment has been provided chiefly through hospital-based facilities or outreach clinics with existent infrastructural and staffing capacity. Since these facilities are now becoming "saturated" and since many people cannot reach them, coverage needs to be expanded by **decentralizing treatment access** to first-level primary care providers (in both the public and private sectors). Where this is starting to be done, new challenges are being introduced in both scale and complexity, since peripheral treatment sites are even more vulnerable to the underlying weaknesses of health systems. WHO has developed integrated operational approaches to support this process and there is renewed acknowledgement of the need to invest in strengthening health systems overall, although specific progress in this regard is still limited. The impacts of these developments on the underlying health systems need to be monitored and require further research.
3. The "3 by 5" Initiative substantially contributed to promoting the right to health for PLHA. It has established **ART as an essential public health intervention**. Access to ART has become one of the most significant determinants of health in high-burden countries. However, there are many remaining barriers to individuals (and entire subpopulations) finding out their HIV status; starting ART when indicated; and continuing to benefit from chronic therapy. This has important implications for the health gains that can be achieved by pursuing the goal of *Universal Access*. It also requires serious consideration of the **health system constraints** that are limiting service coverage; inhibiting early care-seeking; and compromising the continuous supply and durability of treatment.
4. New HIV infections are continuing to rise in many settings, adding to the global burden of AIDS. **HIV prevention** has been a technical area within the "3 by 5" Initiative that has received relatively little investment. Thus effective prevention interventions, such as PMTCT, were not properly prioritized. It has not yet been demonstrated whether scaling up ART has any impact on HIV prevention.
5. WHO has highlighted the special **needs of target communities and vulnerable populations** (such as sex workers, IDUs and MSM). It has helped to facilitate their access to appropriate prevention and treatment interventions in a number of settings where these groups are usually marginalized. **Gender and equity** considerations are not yet routinely influencing how services are being delivered in most settings, with the risk of missed opportunities for prevention and treatment that will continue to have consequences for HIV epidemics. Children's treatment needs started being addressed only recently. In many settings, where fees are still charged at the point of care for ART, this has been shown to limit access and to reduce adherence to therapy. However, WHO has elected not to take a firm position on abolishing user fees.

6. **Target-setting for scaling up treatment access** is considered to have been an effective mechanism for driving both international and national responses through a necessary stage of development. The aspirational "3 by 5" global target has made the idea of a *Universal Access* goal possible – even though this target was not reached. Future targets, like the Millennium Development Goals and the UNGASS goals and targets need to be realistic and country-owned if they are to serve as beacons for planning and measuring progress. Disaggregated subtargets are needed for subpopulations to guide equitable access, and specific prevention targets should be considered. There has been little emphasis on developing quality benchmarks and not enough technical work has been done to forecast how to scale up services for maintaining current treatment populations, while further increasing access to care.

II. WHO contributions to the health sector response to HIV and AIDS

7. There is consensus among stakeholders, development partners, other United Nations institutions and national governments that WHO is the multilateral agency **mandated to lead the global health sector response** to HIV. But there are also perceptions that the Organization has not yet fulfilled its role to this level of expectation.

II.1 Through leadership, advocacy and partnerships

8. When "3 by 5" was launched, WHO made a strong commitment to working with a broad range of partners, but the mechanisms for achieving this have tended to be loosely defined. WHO is well positioned to lead global and country-level **partnerships and technical support networks**. However, the Organization could have engaged in partnership opportunities more effectively. There will be an increasing expectation for WHO to work within a broader global partnership for *Universal Access*.
9. There has been substantial progress in clarifying roles and assignments of key multilateral institutions and international donors through the establishment of the **Global Task Team** on Improving AIDS Coordination among Multilateral Institutions and International Donors in 2005. However, key bilateral institutions (particularly PEPFAR) have not become active participants in this mechanism. There is still a need to resolve areas of "competition" between United Nations agencies and to establish a performance monitoring mechanism for this task team process. The working relationships between WHO and other major funding and technical organizations (such as the GFATM, the World Bank, PEPFAR and ESTHER) have only recently begun to be strengthened.
10. Commitments that have been made through these partnership developments and the establishment of new mechanisms (such as the WHO-led *Global Joint Problem-solving and Implementation Support Team*) must still translate into systematic approaches to identifying country needs and establishing harmonized **technical assistance plans**, with arrangements for funding and implementing this assistance. WHO has a role to monitor and coordinate partner contributions to national health-sector responses. It is expected to take the lead in working with others to identify country technical support needs and ensure that relevant, good-quality technical assistance is delivered.

II.2 Providing direct country support

11. The budget and staffing made available to WCOs through "3 by 5" have dramatically strengthened their support role in countries, where the Organization works closely with national governments (as the primary partner of MOHs). By introducing dedicated technical officers (WHO "3 by 5" officers) in 41 of the 49 focus countries, WHO has started to create a strategic network that has the potential to make an increasingly important contribution to learning what is happening "on the ground"; disseminate good practices; monitor national responses; and facilitate technical assistance. Many of these officers only took up their posts in the latter part of 2005, but they have already proven indispensable to scaling up the WHO contribution in these focus countries.
12. WHO is not an implementing agency and does not have the budget for funding much **external technical assistance**. It is weakly positioned relative to other highly resourced partners to operationalize technical support initiatives. Close coordination with the other multilateral and bilateral agencies (and especially UNAIDS) is therefore needed for WHO to plan and secure technical assistance that is aligned with national health sector priorities for further scaling up towards *Universal Access*. In some countries, WHO has been able to secure additional funding for providing technical assistance as a subrecipient of the Global Fund and this is an important mechanism for WHO to consider pursuing more actively.
13. WHO has a unique responsibility within countries to assist governments with strategies and planning to position the HIV response within **broader health sector development**. It also must link this with development plans, including those for poverty reduction, that will improve population health overall. Despite intentions to work towards this, most WCOs have not yet achieved a great deal of synergy across AOW that provide "vertical" support to counterpart programmes within MOHs. There is still very little integration through joint planning or projects between related technical or programmatic areas such as TB, reproductive and sexual health, child and adolescent health, and health systems strengthening.
14. In general, WHO has found it challenging to develop and influence new types of **partnerships within countries**, outside of its traditional relationship with the MOH. Many partners in countries request that WHO make better use of its privileged position with the MOH and play a more active role in helping to establish and support better information and coordination mechanisms. WHO is expected to review and communicate the roles that it intends to have in countries (focusing more on what it is good at doing) and to better understand how to use its comparative advantage and political mandate for supporting the work of others.

15. **Supporting national governments** in putting PHA guidelines into practice will become increasingly important as countries scale up coverage by decentralizing their HIV treatment services (which requires direct support to primary care providers in first-level facilities). WHO has missed opportunities for expanding both the coverage and quality of HIV-related PHA interventions through the non-state (private) sector in a number of these settings. Moreover, it has not offered technical support to national governments to exercise more effective stewardship over private providers.

11.3 Developing and operationalizing standardized tools and guidelines

16. WHO guidance for HIV/AIDS treatment, prevention and care based on a PHA has made it possible to scale up these interventions. WHO has further demonstrated a promising strategy (based on IMAI) for operationalizing the PHA through strengthening health systems to deliver decentralized, integrated primary health-care services that focus on priority PHA interventions. Programmatic integration with related approaches for child health (IMCI) and maternal care (IMPAC) would make sense, but there is no institutional strategy for this. The effectiveness and feasibility of sustaining these integrated approaches still needs to be demonstrated.
17. WHO has produced an extensive range of high-quality **technical guidance and tools** for scaling up national health sector responses, mostly in collaboration with other technical partners. Resources that were allocated to WHO for this normative work, carried out at headquarters and regional office levels, have been insufficient to produce these guidelines and support scaling up their implementation within countries. Achieving a good balance between the "normative guidance" and "direct support" functions of WHO requires careful consideration of how resources are distributed, so as not to weaken this global technical expertise.
18. WHO has an important responsibility to provide guidance and technical support for global **HIV drug resistance surveillance**. Work that has already been done in this area provides an excellent example of the comparative advantage of the Organization. However, there has been insufficient funding for this technical area. This demonstrates the dependence (and vulnerability) of the WHO programme, which relies on the contributions of very small technical teams working within unrealistic budgets.

11.4 Securing reliable supplies of effective medicines and diagnostics

19. There are current concerns about whether secure **supplies of adequate quantities of quality ARVs and diagnostics** can meet the growing global demand (based on existing supplies of the active pharmaceutical ingredients that are used to manufacture these drugs), both for current first-line treatments and for second-line drugs and paediatric formulations. Prices for second-line medicines are still over 10 times more costly than the first-line regimens that are now being produced by many competing generic manufacturers.
20. **"Prequalification"** has been a key driver for making available affordable generic ARV medicines that are of acceptable quality and has contributed to reducing their prices. The

WHO-managed Prequalification Project has been successful in establishing an innovative mechanism that encourages voluntary improvement in the manufacture and supply of quality drugs (especially generic ARVs). There is now a need to prioritize second-line drugs and the demand for this service is growing. It requires increased financial support and must retain the specialized regulatory expertise that has been developed. The Prequalification Project is also regarded as a successful example how WHO can draw on the expertise of related technical areas within the Organization (beyond the HIV/AIDS Department) to support HIV responses.

21. Further scaling up and increasing service coverage will place incremental demands on supply systems over the coming years. Coordinated efforts are therefore needed to make vertical supply arrangements available, while at the same time ensuring that national systems are strengthened. Mechanisms (such as the multi-agency Global Task Team process) for solving current **procurement and supply management** problems and the practical responses to these problems by WHO and its partners in the AMDS network need to be continuously evaluated to ensure that they are succeeding.

II.5 Through "learning by doing"

22. WHO contributions to **global reporting of treatment scale-up** (together with UNAIDS) and establishing the metrics and standards for national programme monitoring are important for providing strategic information that can be used in decision-making. The Organization has a responsibility to support surveillance of the impacts of treatment scale-up on the epidemic, including for the emergence of drug resistance. This has only started to be implemented in a few settings and needs additional resources as a priority.
23. WHO is ideally situated (and expected) to lead **knowledge management** through its country networks and international technical partnerships. It should serve as an effective "knowledge network" for the global response to HIV. The internal systems for routinely monitoring programme activities are not yet firmly established within WHO because knowledge management functions are divided across departments and lack integration. This has impeded the Organization's ability to systematically "learn by doing" and to iteratively improve the programme.
24. WHO has not done much to build the **evidence base for guiding decisions** about which service delivery approaches are most suitable and how to optimize the provision of chronic HIV care and support. Collaboration with the United States Government to learn from the implementation experiences of the PEPFAR programme has not yet happened. There is an urgent need to systematize the "real-time" operational research approaches that WHO has started to promote in a few settings.

III. Performance of the HIV programme area within WHO

25. The lack of defined **programme structure** for "3 by 5" has been a weakness and to some extent reflects the uncertainty with which WHO was working before funding commitments were secured. It also mirrors the reactive way in which this "emergency"

initiative was managed. The "3 by 5" Initiative has been described as an ambitious, but weakly conceived programme with insufficient structure against which results could be measured or performance monitored for the enormous amount of effort that has gone into it. Much of this work has really only just started and although much has been achieved in this relatively short time, the strength of the Organization lies in its development perspective and ability to influence the medium- to longer-term health agenda.

26. WHO is a large and bureaucratic **global organization** with a complex governance structure and many operational divisions that could not have realistically expected to achieve the changes that were needed on this global scale through an "emergency" two-year programme. There was no commonly shared strategy across the three levels of the Organization for how to strengthen WHO to support scaling up in synergistic ways and to sustain this in the longer term.
27. The **HIV/AIDS Department** at WHO headquarters was responsible for coordinating substantial involvement by other parts of the Organization for "3 by 5". There have been examples of excellent collaboration between internal WHO departments that resulted in strong technical outputs, but there is still scope for improvement in the relationship with others, such as Stop TB and Making Pregnancy Safer.
28. WHO regional offices play an important role in supporting country developments. However, the lack of a strong regional programme and leadership commitment in the **WHO Regional Office for Africa** (which faces the most dramatic challenges, but has not received sufficient support and attention by the Organization) is of significant concern since this has impeded progress in the Region.
29. Significant delays occurred in implementing the planned programme of work due to the initial **lack of secured funding** and subsequent slow grant disbursement. The "3 by 5" Initiative (like most of WHO's work on HIV at global, regional and country level) was predominantly funded through extrabudgetary contributions. This makes WHO highly vulnerable to the perception of donors and their willingness to fund the Organization. Prospects for continued funding are not good. The lack of a secured funding base in the medium term has a negative impact on the Organization's ability to fulfil its mandate.
30. The HIV programme at WHO headquarters, which has experienced an extremely high turnover of directors during the past 10 years, again took on a new director in early 2006. This **unstable management of the HIV/AIDS programme** within WHO is likely to have affected the momentum and strength of this AOW over this period. It also reflects poorly on WHO's commitment at the headquarters level to ensuring consistent leadership in HIV and AIDS.

IV. Influences of the broader development context and the particular challenges facing Africa

31. The evaluation encountered substantial **variation among countries** in the ways that HIV and AIDS responses have been developed and implemented; how resources are allocated; how major organizations work together; and the extent to which people within

their communities have the knowledge and resources to participate in improving their own health. Important lessons can be drawn from what is happening in practice – both about what works and what does not work. The Organization has demonstrated the flexibility to respond to these different contexts, but the extent to which these WHO contributions have made a difference to national efforts among the many different players in each country has been highly variable. WHO has not yet sufficiently addressed the lack of participation by civil society (and especially by affected constituencies, such as PLHA) in some countries.

32. Despite important progress in responding to HIV and AIDS in recent years in many countries in Africa, the impacts of AIDS and the challenges faced in trying to curb the epidemic still seem to be overwhelming. It is also evident that the development community is not yet adequately prepared for making the additional investments that are needed so that countries can move into the **next phases of scaling up** their HIV and AIDS responses, towards the goal of *Universal Access*. UNAIDS has estimated that there is a funding gap of at least US\$ 18 billion over the next two years to provide the resources and technical support that are still needed to strengthen national health systems for this challenge.
33. Many of the **worst-affected African countries** are still far from containing their growing AIDS crisis and the absolute number of people who need treatment and do not have access to it is still growing. National governments and regional bodies have not made sufficient efforts and often fail to live up to their own commitments and declarations. Even though WHO significantly increased its investments in Africa through "3 by 5", the Organization has not yet strengthened its focus and capacity adequately to provide the level of support necessary to meet the scale of these challenges in Africa.

5.3 Key recommendations for the way forward

Based on what has been learnt from the evaluation and taking into consideration the evolving development context in which WHO will be expected to fulfil its purpose over the next five years,¹³³ a number of key recommendations are presented here within strategically important areas of decision-making. As far as possible, these recommendations correspond with the preceding presentation of conclusions and lessons and they address WHO at different levels of the Organization and programme. Since WHO cannot operate in isolation, important actions that multilateral institutions and international donors need to take are also highlighted here.

I. Further scaling up access to antiretroviral therapy (ART) and HIV prevention

WHO and its development partners need to

1. Advocate for increasing the **capital investment and operational support for health systems strengthening** (including through public–private partnerships and innovative financing mechanisms).

¹³³ The period 2006 to 2010 is the time frame that the G8 set for achieving further progress towards *Universal Access*.

2. **Improve interagency cooperation within the United Nations** (especially between WHO and the World Bank, and with the Global Fund) to align the different sources of support for health systems strengthening and harmonize their technical and policy approaches.
3. Promote **cooperation between the various global health initiatives** to improve their combined efficiency and effectiveness in delivering health systems strengthening interventions.
4. Contribute technical **guidance to countries on how to mobilize and allocate new resources** for national AIDS responses, so that these can contribute more effectively to strengthening health systems overall.
5. Urgently **address the crisis in human resources for health**, including through innovative approaches (such as regional training initiatives and public–private ventures).

WHO needs to

6. Promote investments in **targeted intervention approaches for addressing the public health needs of vulnerable communities and groups** affected by HIV and AIDS (including sex workers; intravenous drug users; MSM; and children).
7. Adopt and promote a **stronger position on increasing equity** in access to services, including for "free access" to ART at the point of care.
8. **Systematically integrate gender-sensitivity** into how WHO technical strategies, instruments and tools are developed and delivered.
9. Develop and disseminate **methodologies for countries to set appropriate targets** (including subtargets for focus populations) for HIV treatment *and prevention*, based on a sound assessment of their national capacity and resources.

II. **Strengthening WHO to support national health sector responses to HIV and AIDS**

II.1 *Leadership, advocacy and partnerships*

The WHO HIV/AIDS Department needs to

10. Distinguish between strategic, scientific and operational partnerships and develop **more effective mechanisms for managing partnerships** (such as *Memoranda of Understanding*) that define clearly what the parameters and explicit expectations are for each type of collaboration.
11. Improve the structure and role of the Global Partners Group so that this can provide more value as a coordination mechanism, or consider whether WHO should strengthen the HIV and AIDS programme within a **more participatory partnership mechanism**, drawing on the models and lessons from existing global health partnerships.

12. Actively **promote the principle of South-to-South cooperation** by facilitating collaboration and drawing on the experience and expertise among developing countries, southern institutions and regional networks to deliver technical assistance.

II.2 Provision of direct country support

WHO country offices need to

13. Construct a medium- (five-year) to long-term **health sector strategic "road map"** for integrating HIV response within broader health development and for health systems strengthening that can be adapted to the specific circumstances of regions, subregions and countries, within the context of the *Universal Access* commitment.
14. **Work more strategically within country partnerships** to support the mandate and comparative advantage of local partners, including PLHA, civil society and the non-state sector. This could include coordinating and facilitating advocacy, technical and operational networks and supporting private-sector providers to participate more effectively in delivering PHA interventions.
15. Transform the ways in which WCOs plan and implement their disease-specific programme activities, to **achieve greater coherence and integration across technical AOW**, for the purpose of health systems strengthening.
16. More clearly define and communicate what the Organization's roles and responsibilities are within countries, with a **focus on what WHO does well**. Take into account the comparative value of the Organization in relation to other local partners.
17. Create **more effective mechanisms for delivering coordinated, high-quality technical expertise** in which WHO has a role to identify the technical support needs of countries; monitor the quality of technical assistance delivered; and mobilize funds for technical assistance within countries (including from the Global Fund).

II.3 Development of standardized tools and guidelines

WHO HIV Department needs to

18. **Define an essential package** of priority PHA interventions that will be made "universally accessible" through national HIV, AIDS and TB control programmes (with increased emphasis on HIV prevention and HIV testing).
19. **Reinforce the programmatic linkages between disease-specific AOWs** (in particular with Stop TB, Making Pregnancy Safer, Child and Adolescent Health) to achieve programmatic alignment across the related integrated approaches for child health (IMCI), adolescents and adults (IMAI), and maternal care (IMPAC).
20. Urgently **establish the effectiveness and feasibility of sustaining integrated service delivery approaches** as the "common platform" for strengthening primary

health care services (through which a broader PHA package of essential disease control interventions can also be delivered).

21. Assist countries in **establishing benchmarks for service expectations and quality** (particularly to ensure the safety and durability of ART).
22. Maintain the WHO **leadership role in the HIVResNet** and ensure that there are adequate resources to operationalize drug resistance surveillance effectively as a global public health priority.

11.4 Securing supplies of effective medicines and diagnostics

23. **Provide the Prequalification Project with sufficient resources** to continue promoting the quality and availability of ARVs through the prequalification mechanism and ensure that immediate priority is given to medication used in second-line ART; paediatric treatment; and to HIV diagnostics.
24. Strengthen the capacity of the AMDS to **secure consistent supplies of ARVs and HIV diagnostics** (especially for second-line treatments and paediatric formulations) and to establish more effective mechanisms for working with partners to resolve procurement and supply management problems within countries.

11.5 "Learning by doing"

WHO at all three levels of the Organization needs to

25. **Create and support purpose-oriented learning networks** that are based in communities of practice. These should espouse the principles of knowledge-sharing and providing practical humanitarian assistance, allowing broad and inclusive participation by leaders, technical experts, politicians, communities, businesses and NGOs in jointly: defining the problems; proposing innovative solutions; and engaging in collaborative actions.
26. **Establish more robust programme monitoring and evaluation** mechanisms that encourage continuous improvement and learning within the Organization.
27. Mainstream **contemporary approaches to operational research and programme improvement** into WHO programmes and provide technical support for WHO implementation partners to do the same.

III. Improving the performance of the HIV programme area within WHO

Senior leadership of WHO is advised to

28. Achieve **greater coherence at the three levels of the Organization** to support a shared strategy through joint planning and coordinated programme management for HIV and prioritize increasing resources (especially to the WHO Regional Office for Africa and WCOs in Africa) to carry out this strategy.

29. **Improve interdepartmental collaboration** and minimize the areas of conflict or duplication between technical departments (such as the HIV Department with Making Pregnancy Safer Department and AMDS with the Health Technology and Pharmaceuticals cluster).
30. **Allocate internal resources more judiciously** for priority technical programme areas (such as drug prequalification, HIV-DRS).
31. **Secure more stable tenure of the leadership position in the HIV programme area** and offer employment conditions that are conducive to attracting and retaining top technical personnel.
32. Implement an urgent plan of action to **substantially strengthen the technical and administrative capacity of the WHO Regional Office for Africa** and WCOs in Africa to improve their performance in responding to the HIV epidemic crisis in this Region.

IV. Influencing the broader development context and addressing the particular challenges facing Africa

Multilateral institutions and international donors need to

33. Provide more secure, appropriate and **sustainable mechanisms for countries to fund their national HIV and AIDS responses.**
34. **Commit adequate, steady funding to WHO** and institute reforms to the mechanisms for funding WHO, so that the Organization can fulfil appropriately its mandate to provide technical leadership in scaling up HIV and health-sector responses as the multilateral technical agency for global public health.
35. Assign clear institutional roles and responsibilities globally (such as through the Global Task Team) and at country level to each partner **to ensure that there is mutual accountability between development partners and national governments** to achieve the goals of *Universal Access*. This process has to be inclusive of major bilateral programmes (such as PEPFAR).
36. **Enable broader and more effective involvement and participation** by PLHA, civil society organizations and the private sector in national HIV and health-sector responses.
37. Mobilize political support for **appropriate action, including national efforts, in countries**, as a matter of public health safety and sustainable development.
38. **Intensify the focus on Africa** through a "quantum leap" in efforts and by substantially increasing funding to scale up HIV prevention, ART and poverty-reduction.

**WHO management response
to the “3 by5” evaluation report**

WHO management response to the "3 by 5" evaluation report

The evaluation of the "3 by 5" Initiative provided critical guidance to WHO at a crucial time in the global response to the HIV/AIDS epidemic. The Evaluation Team worked under major time and logistical constraints to review an enormous amount of material, interview key stakeholders within and outside WHO and undertake extensive field work. WHO sincerely thanks the members of the team for an evaluation report containing many useful recommendations for WHO, its partners and donors. Thanks are also due to the members of the Evaluation Steering Committee, chaired by Rene Loewenson, who advised the Evaluation Team and WHO at key stages of the evaluation process.

The "3 by 5" Initiative was, above all, a call for greater action and accountability, especially on the part of WHO itself. With less than 10% of those in need receiving antiretroviral therapy at the time the Initiative was launched, it was clear that WHO needed to play a far stronger role in mobilizing and supporting its Member States to scale up treatment, care and support for people living with HIV/AIDS as part of comprehensive national responses to the epidemic. The enthusiastic response to the "3 by 5" Initiative by a broad range of stakeholders has clearly demonstrated the importance of WHO continuing to exercise leadership in this key area of its mandate as a cosponsor of UNAIDS.

WHO welcomes the evaluation's finding that, despite not having met the target of 3 million people on treatment by the end of 2005, the "3 by 5" Initiative contributed substantially to promoting the right to health of people living with HIV/AIDS. It has helped to establish antiretroviral therapy as an essential public health intervention. Also very welcome are the Evaluation Team's conclusions concerning WHO's normative work – notably on treatment guidelines, the public health approach to scaling up, health-care provider training and prequalification of essential medicines – as well as work undertaken with partners through the AIDS Medicines and Diagnostics Service and the HIV Drug Resistance Surveillance Network. WHO is committed to continuing its leadership in these critical areas in the years ahead.

As the evaluation report notes, "3 by 5" was a preliminary step in the much longer-term effort necessary to strengthen health systems so that they are able to provide long-term care and support for people living with HIV/AIDS and other chronic diseases, and to use the opportunities afforded by the scale up of treatment to increase the coverage of HIV prevention interventions, particularly in health-care settings. The progress made to date in scaling up these interventions has focused attention, in many countries, on critical weaknesses in health systems that will need to be addressed as the international community works towards the goal of universal access to treatment by 2010. Among the many challenges ahead, the evaluation rightly emphasizes the need to further decentralize HIV services beyond urban centres and for greater integration of HIV interventions with other health services, including those for tuberculosis and reproductive health, particularly at the health-facility level. The global crisis in human resources for health and the need to strengthen systems for the procurement and supply of drugs and diagnostics

were also the subject of particular attention in the evaluation report, and addressing these major challenges is now a high priority for WHO and the broader international community.

The evaluation provides considerable insight into the internal operations of WHO. It makes valuable recommendations for improving coordination across technical areas and for more effective joint planning of activities across the three levels of the Organization. The report notes that WHO's capacity to provide technical assistance at country level has been significantly improved by the recruitment of HIV/AIDS technical experts in country offices. Continuing to strengthen the Organization's presence at both country and regional levels is central to WHO's effectiveness as a provider of technical support. WHO is particularly mindful of the need to reinforce the technical and administrative capacity of its Regional Office for Africa. Plans are currently being made to establish subregional HIV/AIDS teams and to grant greater financial and administrative autonomy to subregional team leaders and WHO representatives in the African Region.

Equally important are the recommendations aimed at strengthening WHO's relations with external partners. Since June 2005, WHO has participated in a range of activities with the aim of improving harmonization among United Nations agencies, as recommended by the Global Task Team on Improving AIDS Coordination among Multilateral Institutions and International Donors in June 2005. WHO has worked closely with the UNAIDS secretariat and other UNAIDS cosponsoring agencies, to establish a more functional division of labour and develop a consolidated technical support plan for the period 2006-2007. The plan includes costed technical support for activities to assist countries to make effective use of large grants from the Global Fund to Fight AIDS, Tuberculosis and Malaria and other sources. To further clarify roles and responsibilities in technical areas where WHO shares responsibility with other agencies, memoranda of understanding are being negotiated, for example, with the United Nations Office on Drugs and Crime (UNODC) on harm reduction and the United Nations Children's Fund (UNICEF) in the area of prevention of mother-to-child transmission of HIV. WHO is also considering ways in which it can improve its partnership work with civil society and the private sector.

Many of the recommendations contained in the evaluation report will be implemented in the context of a five-year strategic plan for WHO's work for scaling-up towards universal access in the period 2006-2010. The plan will focus on supporting countries to scale up an essential package of health-sector interventions against HIV/AIDS, including prevention, treatment, care and support. In addition, the plan will emphasize WHO's role in assisting countries to strengthen key components of health systems, such as procurement and supply management systems, laboratory infrastructure and human resources capacity. The plan will also highlight the important role to be played by WHO in promoting equitable access to services, building and disseminating the evidence base to support planning and decision-making, and assisting countries to set – and monitor progress against – targets and milestones. The plan for WHO's work towards universal access between now and 2010 will be released at the international AIDS conference in Toronto in August 2006.

As the evaluation report notes, significant additional financial resources need to be mobilized urgently by the international community if the momentum of the "3 by 5" Initiative is to

be maintained and universal access to treatment, as well as the longer-term Millennium Development Goals, are to be achieved. In this respect, WHO aims to do more – particularly at country level – to integrate HIV/AIDS into broader health and development efforts, such as sector-wide approaches. Efforts are being made to strengthen WHO's own resource base for HIV/AIDS work, which, as the evaluation report notes, has been heavily dependent on extra-budgetary support from a small number of donors.

The findings from the evaluation of the "3 by 5" Initiative are helping WHO to become a more effective organization. WHO is committed to widely disseminating the evaluation report so that its conclusions and recommendations may also inform the work of other partners and stakeholders involved in the global response to HIV/AIDS.

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