

# ADAPTING WHO NORMATIVE HIV GUIDELINES FOR NATIONAL PROGRAMMES

Essential principles and processes

July 2011

WHO Library Cataloguing-in-Publication Data

Adapting WHO normative HIV guidelines for national programmes: essential principles and processes.

1. HIV infections - prevention and control.
2. Acquired immunodeficiency syndrome - prevention and control.
3. National health programs.
4. Guidelines. I. World Health Organization.

ISBN 978 92 4 150182 8

(NLM classification: WC 503.6)

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# **Adapting WHO normative HIV guidelines for national programmes**

Essential principles and processes



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## ACRONYMS AND ABBREVIATIONS

<b>3TC</b>	lamivudine	<b>MDR-TB</b>	multi-drug resistant tuberculosis
<b>ABC</b>	abacavir	<b>mHealth</b>	mobile health, the provision of health services and information via mobile technologies, such as mobile phones and personal digital assistants (PDAs)
<b>ANC</b>	ante natal clinic	<b>MoH</b>	ministry of health
<b>ART</b>	antiretroviral therapy	<b>MSM</b>	men who have sex with men
<b>ARV</b>	antiretroviral drug	<b>MTCT</b>	mother-to-child transmission (of HIV)
<b>AZT</b>	zidovudine	<b>NGO</b>	nongovernmental organization
<b>CD4</b>	T-lymphocyte bearing CD4 receptor	<b>NIM-ART</b>	nurse initiated and managed antiretroviral therapy
<b>CHW</b>	community health worker	<b>NNRTI</b>	non-nucleoside reverse transcriptase inhibitor
<b>d4T</b>	stavudine	<b>NRTI</b>	nucleoside reverse transcriptase inhibitor
<b>DBS</b>	dried blood spot	<b>NVP</b>	nevirapine
<b>EFV</b>	efavirenz	<b>OI</b>	opportunistic infection (one that occurs only when the host's immune system is impaired)
<b>EP</b>	expert patient	<b>PCR</b>	polymerase chain reaction
<b>FDC</b>	fixed-dose combination	<b>PEPFAR</b>	U.S. President's Emergency Plan for AIDS Relief
<b>FTC</b>	emtricitabine	<b>PI</b>	protease inhibitor
<b>GFATM</b>	Global Fund to Fight AIDS, Tuberculosis and Malaria	<b>PITC</b>	provider-initiated testing and counselling
<b>GRADE</b>	grading of recommendations assessment, development and evaluation	<b>PLHIV</b>	people living with HIV
<b>GWG</b>	guideline working group	<b>PMTCT</b>	prevention of mother-to-child transmission (of HIV)
<b>HCW</b>	health-care worker	<b>PoC</b>	point of care
<b>HIV</b>	human immunodeficiency virus	<b>sd-NVP</b>	single dose nevirapine
<b>HSA</b>	health service assistant	<b>SMS</b>	short message service (mobile phone text message)
<b>HTC</b>	HIV testing and counselling	<b>SW</b>	sex worker
<b>ICF</b>	intensified tuberculosis case finding	<b>TB</b>	tuberculosis
<b>IDU</b>	injecting drug user	<b>TDF</b>	tenofovir disoproxil fumarate
<b>IMAI</b>	integrated management of adolescent and adult illness	<b>TST</b>	tuberculin skin test
<b>IMCI</b>	integrated management of childhood illness	<b>WHO</b>	World Health Organization
<b>IMPAC</b>	integrated management of pregnancy and childbirth	<b>XDR-TB</b>	extensively drug-resistant tuberculosis
<b>INH</b>	isoniazid		
<b>IPT</b>	isoniazid preventive therapy		
<b>LPV/r</b>	lopinavir/ritonavir		
<b>LTB</b>	latent tuberculosis		
<b>LTFU</b>	lost to follow-up		
<b>MARP</b>	most-at-risk population		
<b>MCH</b>	maternal and child health		
<b>MDG</b>	Millennium Development Goals		

## ACKNOWLEDGEMENTS

This guide was developed by the World Health Organization (WHO) Departments of HIV/AIDS (HIV), Maternal, Newborn, Child and Adolescent Health (MCH) and Stop TB (STB). WHO would like to thank the many individuals who contributed to the development of this document.

The compilation of this guide was directed and coordinated by Shaffiq Essajee. The efforts of the following for their contributions in preparation of the document are gratefully acknowledged, Sally Girvin, David Humphreys, Megan Wilson-Jones, John Kirkwood, the Adaptation Guide Working Group at WHO and others who provided background materials, reviewed drafts and offered insightful advice, including: Kim Dickson, Chris Duncombe, Sandy Gove, Reuben Granich, Ying-Ru Lo, Craig McClure, Eyerusalem Negussie, Nigel Rollins, Nathan Shaffer, Tin Tin Sint, Caoimhe Smyth, Padmini Srikantiah, Marco Vitoria and many colleagues from WHO regional offices who commented on earlier drafts.

An important contribution was also made by the members of the WHO Treatment Working Group who authored the Treatment White Paper in 2009 – a document that was the seed for the development of this guide.

In particular, WHO is very grateful to the individuals and organizations that have provided case studies and who we hope will provide more in the future.

## GLOSSARY

The following definitions are for terms used in the context of this document.

**Feasibility assessment** assists in determining the viability of a proposed intervention. In the context of adapting normative guidelines, a feasibility assessment is an analysis of the opportunities for and obstacles to implementing recommendations in a country. The process considers a number of pertinent factors that reflect what would be required of the health system to put the recommendations into practice.

**Guidance** is a generic term that refers to the provision of direction or advice to take a decision or course of action. WHO guidance comprises evidence-based normative recommendations and operational, programmatic or complementary non-normative advice necessary to implement a strategy or process.

**Guideline adaptation** transforms a global guideline document into a nationally focused guideline that is appropriate to a specific regional or country context and need. It may include the updating or revision of existing national guidelines.

**Guidelines** are normative documents that contain evidence-based recommendations about health interventions, whether they be clinical, public health or policy focussed.

**Implementation** is the process of applying a set of activities or interventions designed to put guidance into practice, whether they be clinical, public health or policy interventions.

**Recommendations** offer advice to programme managers, policy-makers, patients or health-care providers on interventions to improve public health. Recommendations are based on evidence as well as feasibility and public health values. In many instances, recommendations offer a choice (between different interventions) that must be considered within the local context.

**Situation analysis** is an assessment of the present state of a health programme, its structure, its capacity, its resources and the context in which it operates. A situation analysis should identify how effectively services are being provided, what barriers exist to scale-up and what needs remain unmet.

# INTRODUCTION

## Context

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The past six years have witnessed a tremendous global effort to improve access to interventions for HIV prevention and treatment. This effort has resulted in over five million people now receiving antiretroviral therapy (ART); approximately half of all HIV-infected pregnant women receiving prophylaxis to prevent vertical transmission; more than 350 000 children receiving treatment; and declining prevalence rates in many of the worst-affected countries in sub-Saharan Africa and Asia. As a direct result of improved access to HIV care and treatment, AIDS-related deaths are decreasing; as is the incidence of tuberculosis (TB) among people living with HIV. By the end of 2009, some higher prevalence countries, such as Rwanda and Botswana, had already achieved universal access to antiretroviral therapy (defined as more than 80% of need met), while a total of 29 low- and middle-income countries had coverage rates in excess of 50%.

At the same time, more than 60% of people living with HIV do not know their status and more than ten million people are still in urgent need of treatment (1).<sup>1</sup> During 2009, an estimated 1.2 million people with HIV had TB and 400 000 of those died from TB (2). Furthermore, progress is threatened by serious global funding constraints. Now, the response to the epidemic must evolve towards an integrated approach that strengthens health systems and improves all health outcomes while striving towards the goal of universal access to HIV prevention and treatment.

## The 2010 HIV guidelines

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In 2010, the World Health Organization (WHO) released a series of new and revised guidelines for antiretroviral treatment of HIV in adults and children, prevention of TB among people with HIV, and prevention of vertical transmission of HIV during pregnancy, delivery and breastfeeding. The new guidelines present a public health approach for resource-limited settings and make recommendations that:

- substantially increase the number of people eligible for treatment;
- improve the quality and tolerability of treatment regimens;
- decrease morbidity and mortality due to TB;

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<sup>1</sup> 2007–2009 median percentage of people living with HIV, based on population-based surveys.

- reduce the incidence of new HIV and TB infections through intensified TB case finding (ICF), isoniazid preventive therapy (IPT) and earlier initiation of antiretroviral therapy;
- markedly reduce the incidence of paediatric HIV and improve HIV-free survival among infants of HIV-infected mothers by strengthening the prevention of mother-to-child transmission of HIV (PMTCT).

Although these are cost-effective public health interventions, in the short term the implementation of the new recommendations will likely increase costs and stretch health systems. Therefore, programme managers will be required to make a number of important prioritization decisions.

These new guidelines complement each other and they are intended to be implemented in an integrated manner – programme managers are encouraged to coordinate the national adaptation process, adapting the guidelines at the same time where possible. Some basic themes, such as service decentralization, increasing testing to improve access to care, restructuring of human resources and programme integration, are common to all the guidelines. The recommendations themselves are also interdependent, for example, initiating antiretroviral therapy at a higher CD4 count reduces the mother-to-child HIV transmission rate as more women of childbearing age access treatment, and at the same time reduces the overall risk of people living with HIV developing TB.

This adaptation guide directly addresses five particular guidelines.

- [\*Antiretroviral therapy for HIV infection in adults and adolescents: recommendations for a public health approach: 2010 revision\*](#)
- [\*Antiretroviral therapy for HIV infection in infants and children: towards universal access: 2010 revision\*](#)
- [\*Antiretroviral drugs for treating pregnant women and preventing HIV infections in infants: recommendations for a public health approach: 2010 version\*](#)
- [\*Guidelines on HIV and infant feeding 2010: principles and recommendations for infant feeding in the context of HIV and a summary of evidence\*](#)
- [\*Guidelines for intensified tuberculosis case-finding and isoniazid preventive therapy for people living with HIV in resource constrained settings\*](#)

## About this guide

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The purpose of this guide is to facilitate the national-level adaptation of WHO's recently revised normative HIV guidelines. A structured, planned, and informed process is necessary to adapt and implement the recommendations in ways that are equitable and effective. It is this process that this adaptation guide serves to inform and support.

This document is primarily designed to be used by national technical advisory boards and working groups, policy-makers, programme managers, implementing partners and other health professionals who are embarking on a process to introduce or revise HIV guidelines within their national or local programmes.

This guide defines the principles of adaptation promoted by WHO and outlines a generic framework for the process of adapting HIV guidelines for national programmes. It does not provide full guidance on developing an operational plan, but does offer suggestions for strategic planning (or re-planning) for the national response to HIV. In addition, the document contains an annex of case studies. These are country examples that highlight specific elements of the adaptation and implementation of the five recently revised HIV guidelines. The examples are designed to inform decision-makers as countries undertake national guideline adaptation.

This guide is based on existing guideline adaptation materials developed by WHO and has been designed primarily as a web-based 'living document'. The document and the case studies will be updated as new clinical and programmatic experience becomes available.

While designed to inform the adaptation of HIV guidelines, many of the generic principles and processes outlined in this guide are also applicable when introducing other guidance into country health programmes. For instance, the involvement of stakeholders and representatives from the wider community is fundamental to ensure that any changes to national recommendations meet the needs of all members of the community and are realistic and sustainable.

Where 2010 HIV guidelines have already been adapted in-country, this document, especially the case studies, may be useful as a resource to programme managers who are guiding national efforts to support implementation.

## How to use this guide

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This document is organized into two sections.

**Part 1** addresses the essential principles, and takes the reader through the components that make up the processes for adapting any normative guideline for a national programme. These components are generic and may need adapting to the specific country context.

**Part 2** looks at the specific challenges in adopting the 2010 guidelines and includes a list of frequently asked questions and their answers.

A collection of case studies has also been developed to illustrate solutions to particular challenges that national programmes may face when adapting or implementing the recommendations contained within the five guidelines. These scenarios complement the generic process outlined in the document and will be added to over time, so please check the web site for updates (see below).

The document has been designed to be easily accessible:

- A dedicated web page is available on the WHO web site, with a section to download the case studies separately from the main document. This section will be added to as countries share their adaptation experience (see below).
- The dedicated web page is accessible from the web pages for each of the individual revised guidelines.
- Within the document itself, hyperlinks embedded within the text enable readers to access related content or case studies. Figure 1 is also hyperlinked so that it can be clicked on to access particular aspects of the guideline adaptation process.

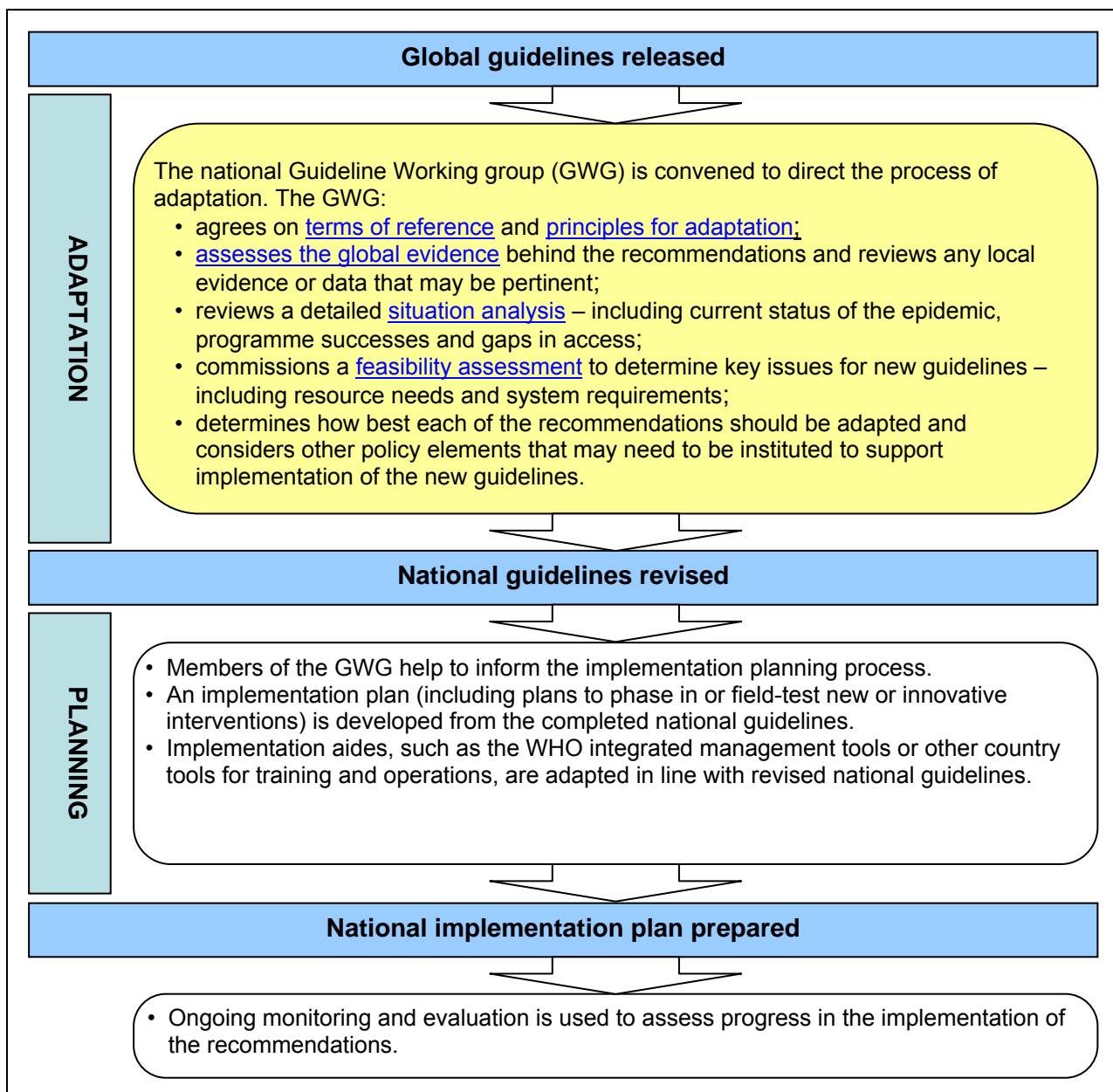
The WHO Department of HIV/AIDS encourages countries and programmes to communicate their experiences of the process of adapting national guidelines to incorporate revised recommendations, so that this information may be shared through the web site. Please send an outline or completed case study with full contact information by email to [hiv-aids@who.int](mailto:hiv-aids@who.int), with the subject line 'Guideline adaptation'.

# 1 ESSENTIAL PRINCIPLES AND PROCESSES OF ADAPTING HIV GUIDELINES FOR NATIONAL PROGRAMMES

## 1.1 An overview of guideline adaptation

The introduction of new or revised guidelines will achieve the greatest impact if a carefully considered process is undertaken to adapt global guidance to the national context (see Figure 1).

**Figure 1** Guideline adaptation process



Guideline introduction is presented here as a ‘top–down’ process where global recommendations shape public health policies and drive programme implementation at the national level. However, the global recommendations themselves have been developed through a ‘bottom–up’ process, where the guidance is synthesized from scientific evidence and the practical experience of national programmes.

Figure 1 identifies a series of components that are presented in sequence. In practice, however, the process may vary from guideline to guideline, and from country to country. Some of these components may be undertaken in parallel, while others may have already taken place. Importantly, this approach is not intended to be didactic but rather offer some principles and provide practical examples of guideline adaptation.

Certain components of guideline adaptation are always important to include in the process. For instance, it is essential that decision-makers understand the context of the epidemic in their country and the resources and tools available for implementation – information that is best obtained through a rigorous situation analysis.

In addition, decisions made regarding the adaptation and implementation of national guidelines should be consensus-based, and reflect the views of programme managers, clinicians, stakeholders and community members, including people living with HIV and representatives from key populations at higher risk. Broad community consultation is fundamental to ensuring that national adaptation of guidelines translates into HIV programmes that are equitable and acceptable to the community.

WHO recognizes that some countries may not have the means to implement all recommendations simultaneously. While recommendations may be cost-effective, they may not always be immediately feasible, especially when programme finances are constrained and infrastructural barriers impede implementation. National programmes should prioritize choices given the values and preferences of their stakeholders. Often, a phased approach to implementation can limit costs and enable programme managers to gain valuable initial experience upon which to base rapid programme expansion. Initial implementation on a small scale can also help provide important lessons to inform national roll-out.

## **1.2 Components in the generic process of national adaptation**

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WHO encourages adapting the complete collection of the 2010 HIV guidelines at the same time if possible. Although resources for implementation may be limited, a coordinated approach will make the adaptation process more efficient and also help to identify cost-

cutting synergies, such as combined forecasting and procurement of ARVs for treatment *and* prevention, or integrated in-service training.

While a country may choose to implement recommendations in a phased manner, over time all the adopted recommendations will eventually become integral components of the national HIV programme and broader health service. Considering this future scenario from the outset, and engaging an adaptation process that encourages collaboration among different health service sectors, including between HIV and TB departments and PMTCT and maternal and child health departments, will facilitate the integration of all related guideline recommendations into one health system.

The components outlined below may be helpful to national programmes in developing an adaptation process that will result in well-crafted national policies that will serve as the basis for a more effective, affordable and sustainable HIV response.

**Component 1 Forming the Guideline Working Group**

**Component 2 Agreeing on the principles of guideline adaptation**

**Component 3 Understanding the recommendations**

**Component 4 Situation analysis**

**Component 5 Feasibility assessment**

**Component 6 Determining the national guidelines and policies**

**Component 7 Strategic planning**

## **Component 1 Forming the Guideline Working Group**

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The process of guideline adaptation is best managed by a national Guideline Working Group (GWG) or by national technical advisory group, if it already exists. The GWG is a multi-disciplinary group that should be established by the national HIV programme. The primary purpose of the GWG is to make the choices and decisions necessary for developing updated national HIV recommendations, either in a single guideline or as a coordinated set of guidelines.

The GWG is a consultative body that represents HIV and other health sectors and includes technical experts, programme managers and local implementers. The composition of the GWG may vary over time and will depend to some extent on the content of the specific guideline(s) being adapted. However, in order to develop national guidelines and policies that will result in linked and integrated programmes, the GWG should bring together a broad spectrum of stakeholders, including from programmes such as HIV, sexual and reproductive

health, maternal and child health, nutrition and TB. Pharmacy, laboratory and nursing services should also be represented, and there should be a range of technical experts who can address specific clinical issues as needed. It is essential that the GWG contain representatives of civil society, including community-based organizations, and people living with HIV. A proposed list of key groups to consider including in the GWG is given in Box 1.

There may already be other in-country HIV working groups – for example a technical panel, a treatment working group or an implementers' forum – and these should be drawn on to help constitute the GWG, but existing groups often do not include community representatives or managers from other health service sectors.

<b>Box 1 Composition of the national Guideline Working Group</b>	
Programme experts and managers	Experts and representatives of sexual and reproductive health, maternal and child health, TB, HIV programmes (antiretroviral therapy, HIV testing and counselling, prevention of mother-to-child transmission)
Practicing clinicians	Doctors, nurses and counsellors from adult and child HIV clinics, maternal and child health, and TB clinics – in public and private sectors
Civil society representatives	People living with HIV groups, women and youth groups, religious leaders and advocates for most-at-risk populations
Technical specialists	Experts in specific technical areas, e.g. laboratory services, pharmacy, supply chain and community health
Government partners	International agencies, faith-based programmes, other local nongovernmental organizations and community-based organizations, and private-sector service providers
Financial analysts	Programme budget officers and health economists
Academic institutions	Guidance on operational research, training and supervision
Methodologists	People experienced in formulating national policy guidelines

Involving a range of stakeholders from an early stage will promote understanding of and familiarity with the issues and foster a collaborative approach to problem solving. A participatory and transparent adaptation process will make the revised national guidelines more acceptable to all stakeholders.

To be effective, the work of the GWG must be objective and independent, and needs to be widely perceived to be so. In particular, no commercial entities, especially pharmaceutical or infant food manufacturers, should exert influence on the development of clinical guidelines. It is important that all members of the GWG declare any potential conflict of interest, i.e. any interest that may affect or may be perceived to affect a member's objectivity and independence in providing advice.

This could include:

- Owning shares in a company that manufactures a product or technology that may be recommended for use in the new guideline;
- Holding a patent on a product or technology that may be recommended for use in the new guideline;
- Having a family member who works for a company that manufactures a product or technology that may be recommended for use in the new guideline;
- Involvement in a major academic programme of work that concerns a product or technology or intervention likely to be considered in a recommendation;
- Receiving funding from, consulting for, or acting as an adviser, paid speaker or opinion leader to a company, organization or donor with an interest in either a product or intervention related to the HIV programme;
- Involvement in ongoing research protocols that might be threatened by changes in the guidelines.

In order to document that members do not have a conflict of interest, each individual within the GWG should understand and sign a conflict of interest declaration form. As this is a new process in many programmes, an example of a declaration of interest form used by WHO is provided in Annex 1. A similar form should be developed at the start of the guideline adaptation process for use by the GWG. It is often a matter of judgment as to whether conflicts of interest are significant, but members should be encouraged to disclose any possible conflicts and all disclosures should be documented and discussed among the group. If a serious conflict of interest is identified, the GWG should determine whether the conflict could influence the guideline adaptation process, and may decide by consensus to excuse that member from the group.

All members of the GWG need to understand their individual roles and the overall aims of the GWG. WHO recommends that a formal set of Terms of Reference (ToR) be established for the GWG.

Box 2 provides a number of elements that may be useful to consider in development of the ToR. The GWG should appoint a chairperson, and determine a workplan, a timeline for deliverables and how to fund work that may need to be undertaken during the course of guideline adaptation. It may be helpful for the GWG to break into smaller subgroups or units to work on specific elements of the guideline adaptation process as such elements become clear.

## Box 2 Elements for the Terms of Reference for the Guideline Working Group

### Role

Guide the development or modification of national policies for HIV and TB treatment and prevention from accepted global guidelines.

### Specific functions

- Review or conduct, as needed, a situation analysis to understand the current context of the national HIV and TB epidemic and the health sector response to it.
- Assess the feasibility of proposed recommendations and advise on costs, resource requirements and other health system implications of implementing the new recommendations, including changes to systems, programmes, tools and infrastructure.
- Review evidence, global and local, related to the recommendations and advise on how best to interpret this within the local context.

### Deliverables

- Generate a report advising on the critical policy recommendations for the national guideline and justifying this decision-making to national authorities.
- Form a writing subgroup to produce a first draft of the guideline.
- Where stakeholders have not been directly involved with the Guideline Working Group, oversee a stakeholder consultation of the draft guidelines.
- Establish and coordinate an objective review of the revised guidelines by reviewers who are external to and independent of the Guideline Working Group.
- Finalize the new guideline, including translation as needed.
- Provide a representative of the Guideline Working Group to the implementation planning process.

## Component 2 Agreeing on the principles of guideline adaptation

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The work of the GWG should be guided by a set of agreed principles in order to ensure that revised national policies are equitable and make the most effective use of resources. The WHO considered the following six principles in the development of the global guidelines.

### 1. Ensure continuity for those already in care and maintain current progress:

Implementation of new recommendations should not become a barrier for access to treatment, disrupt the care of those already receiving treatment or compromise patients who are at the highest risk of poor outcomes. Examples include:

- If a new recommendation increases the CD4 count threshold for starting antiretroviral therapy to prevent morbidity, mortality and HIV and TB transmission, the guidelines should also underscore the importance of prioritizing those with more advanced disease.
- A move to more expensive antiretroviral drugs or regimens should not translate into fewer people receiving treatment.

- If an intervention is recommended that can only be provided in a small number of tertiary facilities, this should not become a barrier to accessing treatment for those living in rural communities. In other words, national guideline recommendations should be adaptable to suit both primary and tertiary settings.
  - Adopting CD4 testing as a standard of care for treatment initiation should not prevent clinicians from initiating treatment on the basis of clinical need.
2. **Use a public health approach:** Aim to provide the best proven standard of care on a large scale with the optimal use of limited resources, while ensuring equitable access to services in a public health framework that benefits individuals as well as communities and has maximal impact on the HIV and TB epidemics, and maternal and infant/child mortality.
  3. **Build consensus:** All members of the GWG, especially community representatives, must have the opportunity to participate in the adaptation processes and reach consensus on what needs to change, why it needs to change, and how best to make change happen. Broad involvement in and commitment to the development of national guidelines will improve the sense of ownership of policies, practices and implementation. With this in mind, no single group should be allowed to have disproportionate influence on guideline development, regardless of their technical expertise.
  4. **Build on what exists:** Almost all HIV-related programmes and services have existing guidelines, materials and tools to facilitate programme implementation. The new guidelines provide an opportunity to revise these core documents. These may include service delivery guidelines, protocols, clinical and laboratory standard operating procedures (SOPs), monitoring and evaluation tools, patient monitoring mechanisms or systems, reference manuals, health worker training materials, job aids, supervisory checklists, and materials for public information, education and communication. For example, countries already using the WHO integrated clinical and operational tools (IMAI, IMCI and IMPAC [3, 4, 5]) will need to update these. WHO has modified the tools to incorporate the most recent recommendations in preparation for further in-country adaptation. The modified set of tools is available at <http://www.who.int/hiv/pub/imai/en/>.
  5. **Plan for the long term:** Agreeing on a new set of guideline recommendations is the first step to implementation, and the GWG should plan from the outset how to turn recommendations into practice. For example, new programme structures (e.g. pharmacovigilance or resistance surveillance programmes) may be needed before a

particular recommendation can be implemented. In addition, it may be necessary to take a phased approach or to implement interventions on a small scale in order to learn how these may best be implemented on a national scale. Pilot interventions should not be developed as vertical or standalone projects but rather with the intention of contributing to and informing the national scale-up process.

- 6. Funding and sustainability:** It is essential for the GWG to consider how best to make the national HIV programme sustainable through resource mobilization and health system integration. In addition, the adaptation process should consider the mechanisms required for making systems accountable for the delivery of interventions to entire populations.
- 7. Promote best practice:** Promote the implementation of best practice modalities of HIV care service delivery (such as partnership development and involvement of communities and in particular of support groups, as part of a continuum of care) in order to increase acceptance, sustainability and improved outcomes of treatment that incorporate the new recommendations.

### **Component 3      Understanding the recommendations**

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WHO guidelines contain two distinct classes of recommendation – either ‘**strong**’ or ‘**conditional**’. The class of the recommendation is derived from two separate elements: the quality of evidence; and the balance of desirable and undesirable effects. It is important for the GWG to understand and appreciate this distinction. Strong recommendations infer that the desirable effects definitely outweigh the undesirable effects, whereas for conditional recommendations, the desirable effects *may* outweigh the undesirable effects in a particular context.

#### **Quality of evidence**

For the 2010 guidelines, the quality of evidence was determined using a detailed review process known as GRADE (6). The GRADE approach assesses three factors: the nature of the data (randomized clinical trial or observational); how directly the data addresses the specific recommendation; and the relevance of the data to the population or setting in question. The combination of factors allows the evidence to be divided into one of four levels of quality:

- High:**            There is a high level of confidence that the reported estimate of effect of the intervention is reliable and further research is very unlikely to change the level of confidence.

**Moderate:** There is a moderate level of confidence in the estimate of effect, and further research is likely to have an important impact on the level of confidence.

**Low:** There is a low level of confidence in the estimate of effect, and further research is very likely to have an important impact on confidence in the estimate. This does not necessarily mean that completed studies are of low quality.

**Very low:** Any estimate of effect is very uncertain.

### **Balance of desirable and undesirable effects**

The balance of desirable and undesirable effects has also been established through a rigorous process that considered the risks and benefits of the recommendation, the values and preferences that might influence what is thought of as a desirable outcome and whether the intervention represents a wise use of resources. These are summarized in Box 3.

<b>Box 3 Determining the balance of desirable and undesirable effects</b>	
Risk–benefit analysis	How do the positive effects (benefits) weigh up against the negative effects (risks), and how do these compare to previous or alternate recommendations?
Values and preferences (acceptability)	Is the recommendation likely to be widely accepted or highly valued?
Costs and resource use	Will implementation of the recommendation have reasonable costs or be cost-effective?

The WHO panel of experts that developed the global guidelines considered both the quality of evidence and the balance of desirable and undesirable effects in order to classify each recommendation as strong or conditional. A strong recommendation implies that the evidence supporting the recommendation is of higher quality and that the desirable effects clearly outweigh the undesirable effects. By contrast, conditional recommendations are typically supported by less high quality evidence or have a less favourable risk–benefit balance. Strong recommendations are generally applicable in all situations, whereas conditional recommendations may only apply to specific settings.

Although this process has been carefully undertaken and vetted by WHO for each of the recommendations in the new guidelines, the GWG may wish to reassess the evidence for specific recommendations. The GWG should prioritize which recommendations require what level of scrutiny. To assist countries in this process, WHO has made available a series of evidence maps for all the 2010 guidelines, which describe how the strength of each recommendation was established and provide the evidence on which it was based (see Box 4).

<b>Box 4 Evidence maps for the new guidelines</b>	
<b>Guideline</b>	<b>Evidence map URL</b>
Prevention of mother-to-child transmission	<a href="http://www.who.int/hiv/topics/mtct/evidence2010/en/index.html">http://www.who.int/hiv/topics/mtct/evidence2010/en/index.html</a>
Adult antiretroviral therapy	<a href="http://www.who.int/hiv/topics/treatment/evidence/en/index.html">http://www.who.int/hiv/topics/treatment/evidence/en/index.html</a>
Paediatric antiretroviral therapy	<a href="http://www.who.int/hiv/topics/paediatric/evidence/en/index.html">http://www.who.int/hiv/topics/paediatric/evidence/en/index.html</a>
Infant feeding	<a href="http://www.who.int/child_adolescent_health/documents/9789241599535/en/index.html">http://www.who.int/child_adolescent_health/documents/9789241599535/en/index.html</a>
Isoniazid preventive therapy/intensified case finding	<a href="http://www.who.int/tb/publications/2010/whohtmtb_2010_13_annex.pdf">http://www.who.int/tb/publications/2010/whohtmtb_2010_13_annex.pdf</a>

Apart from reviewing the global evidence base that underpins the new guidelines, it is important for the GWG to also consider relevant local evidence. This may include clinical studies, operational research findings, new data on disease prevalence or local health systems research. A transparent process that clearly shows the evidence behind new national policies can be very persuasive in convincing community representatives, policy-makers and clinicians that change is necessary. A risk–benefit table can be a useful tool for guiding the decision-making process and for communicating the results. See Annex 4 for a risk–benefit analysis template. It is important that the GWG document this process and the justification for the decisions it makes, and then makes this information publicly available.

## **Component 4 Situation analysis**

Analysing the current situation is an important step in the process of adapting guidelines and may be used to inform the feasibility assessment. In some countries, an assessment of the HIV and TB programme and the health system may have been conducted recently for programme management or strategic planning purposes, and it may be sufficient to update

this data or add to it where needed. In other settings, assessments may be out of date or not focused on the required elements and a formal situation analysis may be warranted. Carrying out a situation analysis can be a lengthy process – some countries may decide it is more useful to conduct a rapid (yet accurate) assessment of the current situation to serve as background information for making the decisions required by the adaptation process.

A situation analysis describes the extent of the epidemic, which populations are affected, what is driving it and what is being done to address it. The specific content of the situation analysis is driven by the context of the programme, however the six themes list below should be considered in a situation analysis for a national HIV programme. The specific questions listed are illustrative, providing ideas for what might be addressed.

The purpose of the situation analysis is to present an accurate, transparent and reliable picture of the HIV response in a country. The information contained within the analysis should be discussed by the GWG and clearly understood by all members of the group. For more information on interpreting the findings from specific components of a situation analysis, see the *WHO Planning guide for the health sector response to HIV*, 2011.<sup>1</sup>

## **1. Socioeconomic analysis**

- Where and how is HIV transmission occurring, and what are the social, behavioural or economic groups that have the greatest need for access to treatment and care? For example, does the epidemic affect the general population? Are there specific populations that are more at risk?
- What are the social issues and vulnerabilities, including gender, that drive the epidemic?
- What are the human rights issues related to the epidemic and to access treatment and care for people with HIV, especially in populations served by public health services?
- What are the potential socioeconomic costs and benefits of the existing national HIV programme?

## **2. Epidemiological analysis**

- What is the burden of HIV and TB across the population in terms of incidence and prevalence? Are the epidemics generalized or concentrated within particular communities? What is the prevalence among pregnant women and women of child-bearing age?

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<sup>1</sup> <http://www.who.int/hiv/topics/ppm/en/index.html>

- What proportion of pregnant women receive antenatal care and what proportion are offered HIV testing and counselling?
- What are the incidence and prevalence rates among the general population and in specific key populations at higher risk, e.g. men who have sex with men, injecting drug users, sex workers, and those in prison?
- What is the distribution of HIV disease stage among people living with HIV (by CD4 count and WHO clinical stage)?
- To what extent are care and treatment needs being met?
- What is the incidence and prevalence of HIV/TB co-infection, and what is the number of HIV/TB related deaths?
- What is the incidence and prevalence of hepatitis B and C, and what role do these play in the HIV epidemic?
- What are the primary causes of maternal, infant and child mortality? What proportion of maternal and child deaths are due to HIV?
- What is the prevalence and distribution of child and maternal under-nutrition?
- Is there access to safe water for all?

### **3. Programme response analysis**

- What is the budget for programme implementation and does the current budget address current needs?
- What has been done so far by the health sector in responding to the epidemic in terms of coverage for antiretroviral therapy in adults, children and pregnant women, prevention of mother-to-child transmission, infant feeding, co-trimoxazole prophylaxis?
- What are the strengths and weaknesses of the health sector response? How well integrated is the response?
- Is there a coordinating body for integrated HIV activities such as HIV/TB and HIV and maternal child health (MCH)?
- Is surveillance of HIV prevalence being conducted among TB patients?
- Are integrated TB/HIV activities being implemented?
- Are there good models for integrated HIV/MCH services?

- Is HIV testing being conducted among TB patients? How are people with HIV being screened for TB? Is isoniazid preventive therapy widely available and provided? Are TB infection control measures in place in health care and congregate settings?
- What do the current guidelines recommend for antiretroviral therapy and prevention of mother-to-child transmission of HIV in terms of drugs and specific formulations that are used in the country?
- How are women attending antenatal care clinics referred to HIV care and treatment? Is there coordination or integration among antiretroviral treatment services and antenatal care or PMTCT services?
- What are the key programme success indicators and are there data collection systems in place to capture these systematically?
- What instruments or data collection forms are currently used for patient management at different levels of the health system?
- How do HIV programmes integrate and collaborate with other areas of the health system, including programmes for HIV and TB prevention, hepatitis, maternal and child health, nutrition, reproductive health, and primary health care?
- What laws, policies and regulations related to the provision of services may affect uptake of new practices?

#### **4. Stakeholder analysis**

- Who are the key contributors in the health sector response to HIV?
- How do stakeholders contribute currently and what can be expected of them?
- What is the role of the private sector in the provision of services and commodities?
- What agencies or groups are responsible for decision-making?

#### **5. Health system analysis**

- What is the broad health system context in which HIV services are currently offered or could be offered in the future?
- How is the health system structured and how do health programmes function across different levels of the health system? What mechanisms and tools are

available for site supervision? How are human resources currently deployed across the health system to deliver HIV care?

- How many health service delivery sites exist in the country (e.g. primary, secondary and tertiary level facilities), and what types of services are available at these sites (e.g. inpatient care, maternal and child health, labour and delivery, antiretroviral therapy, HIV testing and counselling, prevention of mother-to-child transmission, TB diagnosis and treatment, pharmacy and laboratory facilities, including CD4 count and polymerase chain reaction for infant diagnosis)? How do different levels of the health system compare in terms of capacity and resources?
- What opportunities exist for further expansion of HIV services, such as decentralization and integration?
- What tools, curricula and materials are currently used for in-service HIV training, such as *Integrated management of adolescent and adult illness (IMAI)* and *Integrated management of childhood illness (IMCI)*?
- How many skilled health-care workers (physicians, nurses, pharmacists, others) are working in the various types of services?
- What procurement and inventory systems are in place for medical and laboratory commodities?
- How is the supply chain for health commodities managed across facilities? Are required medicines and other commodities available at all levels of the health system as necessary?
- What is the potential impact of new HIV guidelines on other national policies?

## **6. Programmatic gap analysis**

- What are the unmet needs for HIV prevention, treatment and care, in urban and rural communities, for pregnant women, children, adolescents, older people, and any populations at higher risk?
- What systems are in place to combat stigma and discrimination in the community and in the health-care system?
- What is the quality of health system data for review?
- What gaps or barriers exist in the current policy landscape that result in a weaker health sector response? For example, are there laws in place that criminalize groups at higher risk of acquiring HIV infection?

- Does lack of access to education (particularly for women) impact the uptake of health services?

In addition to these general questions, it may be important to include a range of more specific questions that focus on a topic area of particular interest. Annex 2 and Annex 3 show examples of situation analyses that are tailored towards specifically evaluating the status of programmes for adult antiretroviral therapy and the prevention of mother-to-child transmission, respectively. These examples are given as illustrations of the elements that could be considered. In order to avoid delays in the adaptation process, the GWG should use information that is readily available and identify focused areas where it may be important to gather additional data.

## **Component 5      Feasibility assessment**

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Before global guidelines are adapted, the GWG should determine the feasibility of implementing new WHO recommendations in the national programme. For example, if a recommendation is deemed feasible at one type of facility, is it feasible at all levels of the health system? Is it affordable and how can it be sustained? What are the preferences of people living with HIV in the community or of the doctors and nurses who are the front-line service providers? How can access for vulnerable or marginalized groups be protected?

If implementing an important recommendation at the current time appears unfeasible, what added resources may need to be mobilized for implementation to be achieved?

A feasibility assessment is often based on the findings of the situation analysis, and considers what factors may promote or constrain implementation of each of the recommendations.

Annex 2 and Annex 3 show examples of some of the specific questions that should be addressed in a feasibility assessment to make determinations about implementing the adult antiretroviral therapy and prevention of mother-to-child transmission recommendations, respectively. These are linked to related elements for the situation analysis.

A feasibility assessment should not be seen as a tool to determine whether a particular recommendation needs to be included or excluded from the national guideline, but rather as a tool to understand the impact of that recommendation and how best to adapt it and mobilize resources to implement it at a national level. An example of a generic feasibility assessment checklist is shown in Box 5.

## **Box 5 A generic feasibility assessment checklist**

### **Effective, equitable, accessible health service delivery**

- Given the landscape of the health system and the distribution of service sites, what is needed to ensure that the health system infrastructure can effectively deliver care to all those in need of services?
- What opportunities exist to link programmes or build integrated service delivery?

### **Responsive and competent health workforce**

- How many additional staff and what cadres will be needed to implement guideline changes?
- What training and capacity building would be needed?
- How can health workers be best supported to implement the new guidelines?
- What is the process for prioritizing the introduction of new guidelines work in terms of the need for human resources?
- What opportunities and barriers exist for task shifting and greater use of lay providers in the health system?

### **Efficient, equitable and sustainable health financing (also see Box 6)**

- What is the distribution of current funding (e.g. government budget, Global Fund, PEPFAR, private foundations, and others.)?
- What is the funding cycle and lengths of commitment for outside funding from donors listed above?
- Have cost modelling projections been done to estimate costs and how can the programme continue to evaluate costs?
- What services are paid for by patients, e.g. ART, OI medicines, HIV testing, laboratory services?
- What potential cost efficiencies can be achieved by economies of scale?
- What is the process for prioritizing the introduction of new guidelines work in terms of the needs for financial resources for other critical public health deliverables?

### **Access to essential medical products and technologies**

- What forecasting procurement and inventory systems are in place for medical and laboratory supplies?
- What new drugs and technologies will need to be introduced to implement guideline changes, and will additional infrastructure be required?
- What additional technology maintenance costs may be necessary?
- Is a system in place to register new drugs and new diagnostics for HIV prevention, treatment and care?
- Do national laws allow for the purchase and importation of generic equivalents?
- What resources would be necessary to create a transition plan to new medication regimes?
- What transportation barriers exist for patients?
- What transportation barriers exist for the commodity supply chain?

### **Well functioning health information systems**

- What resources, updates, and training would be required to expand existing health information systems in order to introduce changes to the guidelines?
- What changes would be needed to update delivery of information to patients?

### **Ensuring a human rights-based approach**

- What are the values and preferences of the community with respect to the new guidelines?
- Are human rights protection mechanisms in place at facilities for people who seek advice and support related to HIV treatment and prevention?

- How can the national programme ensure the protection of the rights of all, including people living with HIV, irrespective of gender, risk behaviour and sexual orientation?

National programmes should review and modify this list in consideration of both the national context and the specifics of the guideline(s) to be adapted. The Malawi and Tanzania national programmes have used a modification of this tool to assess the feasibility of introducing the 2010 adult antiretroviral therapy guidelines (see Case Study 1 for a summary of the Malawi feasibility study).

Costing of the recommendations is an important aspect of the feasibility analysis. A number of costing tools and resources are available to assist countries in estimating costs for planning and budgeting of HIV and related programmes and services. Some of these are highlighted in Box 6. WHO does not endorse the tools listed here, but each may be useful for specific contexts. Further information can be obtained through the links provided.

<b>Box 6 Costing tools</b>	
<b>Organization</b>	<b>Tool description</b>
The Clinton Health Access Initiative (CHAI)	<p><b>PMTCT and Pediatric HIV Impact and Cost Model, version 2.0</b></p> <p>A spreadsheet-based model developed in Microsoft Excel to help countries estimate the impact and cost of the 2010 PMTCT and paediatric guidelines. The model is designed to assist with guideline adaptation decision-making, as well as implementation planning. Using locally available data and assumptions from the scientific literature as inputs, the model outputs (for a given scenario) the number of infections averted, the rate of mother-to-child transmission (MTCT), and the costs in terms of drugs, human resources, and laboratory commodities required to implement the scenario. The model estimates MTCT rates according to ARV access, guideline regimen given, maternal baseline CD4 count and breastfeeding practices. The model also calculates the cost per infection averted of Option A and B of the 2010 guidelines. Paediatric costs are calculated under different scenarios of access and adoption of the “when to start” and “what to start” recommendations for children.</p> <p>More information: e-mail <a href="mailto:PMTCTpedsmodel@clintonhealthaccess.org">PMTCTpedsmodel@clintonhealthaccess.org</a>.</p>
	<p><b>Costing tool for ART for adults and adolescents</b></p> <p>A Microsoft Excel-based tool to assist countries to make informed decisions by determining the impact in costs from adopting the new HIV treatment guidelines. The tool forecasts the annual costs over a five-year time span and allows flexibility of regimen assignment and scale-up targets. Country epidemiologic data and population characteristics are used to determine the current state of treatment and potential for scale-up. Patients on d4T can be switched onto AZT or TDF at different migration rates. The model allows for different scale-up based on CD4 count at antiretroviral therapy initiation. The tool can run up to five adaptation scenarios side-by-side to compare and contrast different costs and opportunities for guideline adaptation.</p> <p>More information: e-mail <a href="mailto:adultmodel@clintonhealthaccess.org">adultmodel@clintonhealthaccess.org</a>.</p>

<p>Elizabeth Glaser Pediatric AIDS Foundation</p>	<p><b>Tool for costing implementation of the revised PMTCT guidelines</b> This is a tool for national or local programme planners and can be used to estimate a comprehensive range of costs associated with implementation of the revised PMTCT guidelines – from drugs to service delivery costs. Users are requested to fill in a worksheet with different inputs and submit this for analysis. The worksheet is available at <a href="http://www.pedaids.org/Publications/Toolkits/Phase-2-Toolkit-(2011)/Tool_Set_3_Jan_2011">http://www.pedaids.org/Publications/Toolkits/Phase-2-Toolkit-(2011)/Tool_Set_3_Jan_2011</a>. More information: e-mail <a href="mailto:eghanotakis@pedaids.org">eghanotakis@pedaids.org</a>.</p>
<p>Futures Institute</p>	<p><b>Future ART costs model</b> The scale-up of treatment implies a long-term commitment to continue support well into the future. This tool enables policy makers, funders and fund managers to answer forwarding looking questions including the average cost of maintaining one person on ART, the cost of supporting current patients on treatment, the funding needed to achieve universal access, the impact of prevention on ART requirements and numbers of people that can be supported on treatment with currently available funding? More information: <a href="http://www.futureartcosts.org/">http://www.futureartcosts.org/</a>.</p> <p><b>The resource needs model</b> An Excel worksheet for calculating the funding required for an expanded response to HIV/AIDS at the national level. The worksheet contains three submodels: the prevention models, which calculate the cost of 12 prevention interventions, including PMTCT; the care and treatment models, which estimate the cost of five types of care and treatment programmes; and the orphan support model, which calculates the cost of three interventions to support children orphaned by AIDS. The program and manual are available in English, Spanish and French. More information: <a href="http://www.futuresinstitute.org/Pages/ResourceNeeds.aspx">http://www.futuresinstitute.org/Pages/ResourceNeeds.aspx</a>.</p>
<p>USAID</p>	<p><b>ART costing crosswalk analysis</b> This is an analysis published in September 2010 by the AIDS Support and Technical Assistance Resources (AIDSTAR-One) Project. It lists a number of different resources tools and models for AIDS programme costing and planning and provides links to download tools or to obtain support with using the model. More information: <a href="http://www.aidstar-one.com/sites/default/files/ARTCostingCrosswalkAnalysis.pdf">http://www.aidstar-one.com/sites/default/files/ARTCostingCrosswalkAnalysis.pdf</a>.</p>

## Component 6      Determining the national guidelines and policies

The overall goal of adapting WHO’s HIV guidelines is to enable the national HIV programme to deliver high quality HIV care services for all those in need. This requires two distinct elements to be in place – the right clinical recommendations *and* a conducive legal and policy environment to make those recommendations feasible and effective. The GWG is a technical body with no legislative authority, and its main role is to determine clinical recommendations, not the laws of the land. At the same time, the members of the GWG will have a wealth of local knowledge and experience when it comes to health service delivery,

and a critical secondary role should be to identify areas where legal and policy changes are necessary in order to maximise the impact of new national guidelines.

The importance of this secondary role of the GWG cannot be understated, as many of the clinical recommendations will be un-implementable without changes in legislative policy. Indeed, in Section 2 of this adaptation guide, where some of the specific challenges of adapting the 2010 guidelines are discussed, both clinical and policy elements are considered together. Box 7 shows some examples of the ways in which clinical recommendations may be linked to policy requirements.

<b>Box 7 Examples of clinical and policy linkages in the context of the 2010 guidelines</b>	
Clinical recommendation	Possible policy requirements
Universal access to HIV testing for all infants at the first point of contact with the health system	<ul style="list-style-type: none"> <li>• Implement routine testing of mothers or infants with unknown HIV infection status in immunization clinics</li> <li>• Modify child health cards to include HIV status information</li> </ul>
Offer ART to all eligible HV positive mothers as part of routine ANC care	<ul style="list-style-type: none"> <li>• Permit MCH nurses to prescribe medications</li> </ul>
Increase access to ART for adolescents	<ul style="list-style-type: none"> <li>• Lower the age of consent for HIV testing to enable more adolescents to access testing</li> </ul>

The policy requirements that relate to a specific recommendation will vary from country to country depending on the specific barriers to implementation. As part of the work of guideline adaptation, the GWG should consider whether policy changes will be required and make recommendations to the appropriate legislative authorities.

## **Component 7 Strategic planning**

The work of the GWG does not end with the creation of a new or revised national guideline. Ultimately, guidelines have to be put into practice and, while developing a national implementation plan may not be within the mandate of the GWG, it is essential that the GWG considers *how* recommendations will be implemented and what elements an implementation plan might include.

Implementation plans can have many different formats but all define the actions to be taken in a specified period of time in order to achieve targeted outcomes. Typically, an implementation plan answers the questions:

- What needs to be done?

- Who is responsible (including partners, institutions and other stakeholders) and are stakeholders supportive of the proposed changes?
- What is the timeline (time and sequencing of activities)?
- What are the available resources (materials, technology, infrastructure)?
- What is the estimated cost and what budget resources are available?
- What are the desired outcomes?
- What are the plans for monitoring, evaluation and validation?

It may be valuable for the GWG to identify the individuals within the ministry of health who will be leading the development of the implementation plan and ensure that they also participate actively in the adaptation process. Alternatively, the national programme may appoint members of the GWG to the implementation planning team, in order to incorporate the thinking of the GWG in the development of the implementation plan.

#### **Specific elements of the implementation plan for consideration during guideline adaptation**

- **Targets:** The intended goals of the national programme in terms of coverage of services. Coverage targets are fundamentally linked to the choices that the GWG makes in adapting the global guidelines. Where targets have already been defined, these need to be considered by the GWG and may influence decision-making.
- **Activities:** The specific activities that need to be undertaken to achieve targets and goals within each area of the HIV programme.
- **Effects of new guidelines on related work and health system areas:** Implementing new or revised recommendations has implications that will require planned activities to address other related elements of the HIV programme and the national health system. For example, relevant policy, training and operational tools will need to be updated and advocacy and communications activities may be required to build community support.
- **Roles and responsibilities:** The management and clinical responsibilities across the levels of the health system required to undertake activities. Define the role that community and civil society can play in implementing activities and achieving targets.
- **Timeline:** The timing and the sequencing of activities. Rolling out new recommendations may need to be done gradually, implementing some activities in a phased manner. A specific timeline also enables monitoring of the process.

- **Monitoring and evaluation:** Process and outcome indicators for the different levels of care, and for specific populations that need to be reached. Tracking the roll-out of programme activities enables progress, quality and impact to be assessed over time and for corrections to be made to the implementation plan, if necessary.
- **Barriers and facilitating factors:** Implementation of new guidelines provides an opportunity to improve the national programme by addressing barriers and identifying opportunities to enhance the quality of services. Examples of potential barriers include:
  - Human resource constraints involving supervision, remuneration, and deployment of health personnel;
  - Laws and policies that may hamper access and uptake of services, such as laws that criminalize risk behaviours, or policies that prevent non-physicians from prescribing antiretroviral therapy;
  - Poor health systems management, including referral systems, equipment maintenance, procurement processes and supply chain management (especially if the new guidelines advocate for new drug or laboratory tests to be made available);
  - Sociocultural issues, including gender norms, access to services, and religious or cultural beliefs.
- **Training:** Clinician training materials will probably need to be adapted or updated. The WHO offers a range of operational tools and training/mentoring materials for integrated HIV training that have already incorporated the new 2010 guidance and that are suited to a training of trainers approach (see the WHO IMAI, IMCI and IMPAC guidelines and training materials)<sup>1</sup>. Updating the content of pre-service training materials will usually involve collaboration between departments of health and education as well as other professional medical and nursing bodies. It is imperative for new practices to become institutionalized over time, so that newly graduating health workers are able to provide services in accordance with national policies.
- **Supervision:** For new practices to be implemented successfully, health workers need both training and supervision. It may be necessary to update or create supervisory tools, checklists and performance evaluation tools.

<sup>1</sup> IMAI/IMCI publications are available at: <http://www.who.int/hiv/topics/capacity/en/>; IMPAC publications are available at: [http://www.who.int/making\\_pregnancy\\_safer/about/impac/en/](http://www.who.int/making_pregnancy_safer/about/impac/en/).

### **Taking the national plan to the provincial and district level**

The national implementation plan defines the national response framework and provides guidance to health facilities and institutions that are involved in implementing the programme. However, each facility – whether ministry of health, NGO or private sector – must modify the national plan and develop a site-level workplan that is tailored to the particular facility. It is likely that these facility-level plans will differ between provincial, district and primary care facilities, and will be more detailed than the national plan. For example, the workplan may contain additional elements such as standard operating procedures (SOPs), which are necessary for site-level implementation. At the same time, site-level workplans should follow the overall framework of the national plan and link to the activities described within the national plan.

### **Communicating the guidelines to health managers and health workers**

WHO advocates for a structured communication strategy that incorporates both the physical distribution of the guidelines (or electronic versions of the document) and orientation activities (such as workshops) to build a better understanding of the new guidelines and greater commitment to achieving programme targets.

In some cases, the new guidelines will mandate a fundamental change in practice, for example, allowing nurses to initiate treatment, or initiating universal testing in antenatal care settings. There may be resistance to such changes and a number of different strategies may be needed to convince health professionals of their importance.

Orientation workshops may need to be combined with more detailed training so that clinicians, pharmacy and laboratory personnel understand not only the content but also the reasoning behind the recommendations. Communication materials may need to be developed or updated to support this type of advocacy, such as research summaries, presentations, posters, leaflets, flipcharts and job aids. Box 8 shows some strategies that may be useful to encourage the adoption of new strategies.

## Box 8 Strategies to encourage health-care providers to adopt new practices

One of the primary objectives in the implementation of evidence-based guidelines and tools is to promote changes in the practices and behaviour of providers. Research and experience from countries has shown that, while many different approaches can be used to instil these changes in practice, some strategies are more effective than others.

This list provides an overview of different strategies that can be considered in the design of guideline dissemination plans and highlights how effective each may be. Wherever possible, programmes should take a multipronged approach, and all of these strategies are more effective if implemented as a package of interventions. The goal of these communication strategies is to establish a common vision and purpose among health-care providers.

### Strategies to change health-care provider practices

1. Distribution of educational materials. To be effective, producing educational materials must be coupled with the other strategies outlined below. The passive dissemination of guidelines, tools or other materials, on their own, is not effective at changing practices.
2. Classroom lectures. Lecture-based training alone is also known not to be effective at changing provider practices. Lectures may be made more effective if combined with other strategies, such as interactive workshops that allow discussion and include practice sessions.
3. Reminders about the new practices. When providers are reminded of the newly taught practices, for example through job aids, checklists, information leaflets or supervisory materials, this increases the chances that changes in behaviour will be sustained.
4. Educational outreach visits. Follow-up visits from trainers, supervisors, programme managers or mentors are very effective at encouraging the adoption of new practices.
5. Audit and feedback. The monitoring of performance through surveys or supervisory tools, coupled with constructive feedback to providers on their performance, is also very effective at ensuring the application of new practices.
6. Use of local experts. Influential providers or specialists can have an important role in encouraging the adoption of new guideline recommendations, especially if they are regarded as opinion leaders whose practice should be emulated.
7. Local consensus building. Involving providers in local planning when introducing new guidance can be an important supportive strategy to ensure providers accept the new practices.
8. Client/patient-mediated interventions. When information about new practices is given to clients/patients, or when clients/patients are informed of their rights to quality care, this can be an effective strategy to encourage their providers to adopt these same practices.

Adapted from:

World Health Organization. *Introducing WHO's reproductive health guidelines and tools into national programmes: principles and processes of adaptation and implementation*. Geneva, 2007 ([http://www.who.int/reproductivehealth/publications/general/RHR\\_07\\_09/en/](http://www.who.int/reproductivehealth/publications/general/RHR_07_09/en/), accessed 10 April 2011).

### Phasing in recommendations and scaling up

If a new recommendation is straightforward or if it represents only a small deviation from established practice, it may be possible to simply introduce it nationally on an agreed date. However, if the new recommendation proposes a novel approach to programme management, a significant policy shift or an innovative model for service delivery, the GWG should carefully consider the capacity of existing systems to cope with the new guidance and determine how best to phase it in.

Pilot testing involves the rapid implementation of a recommendation on a sub-national scale in order to gain a better understanding of what will be required to make the recommendation feasible at national level. Piloting an intervention provides a valuable opportunity for learning early lessons to apply to scaling up, such as how to define the needs for training, capacity building, and supervision, as well as how to assess the impact of the intervention. It is important to distinguish this type of early learning implementation from other types of pilot programmes, which are often vertically structured and separate from the national system. Rather, piloting a new recommendation should be seen as the first step towards rapid national scale-up.

On completion of a learning pilot, relevant stakeholders should be convened to discuss and review the results and modify the scale-up plan as necessary. A successful pilot builds confidence among providers and disseminating the results of a pilot project can be an important mechanism to mobilize resources and get commitment from stakeholders to promote the intervention on a national scale.

Although scale-up can be a complex process, experience has demonstrated several key lessons for scaling up new practices within national programmes:

- **Begin with the end in mind.** Scaling up should be planned early in the guidance introduction process. It should not be considered only after a pilot test has been conducted.
- **The resource environment must be taken into account.** The costs of taking a programme to scale, i.e. ensuring nationwide implementation, must be carefully considered from the beginning, and programmatic goals must be adjusted to the likely funding situation.
- **Use a phased but rapid approach to scaling up programmes.** The process of scaling up programmes is best achieved by incorporating lessons learned from one phase into the next phase of the scale-up process. At the same time, the high mortality of HIV disease and the global extent of the epidemic warrant rapid introduction of new guidance. Therefore, if pilot interventions show that new practices are effective, they should be introduced broadly as soon as is feasible, so as to avoid inequalities in service provision.

## 2 SPECIFIC CHALLENGES IN ADAPTING THE 2010 GUIDELINES

The generic processes described in the first part of this guide will help to ensure that the Guideline Working Group (GWG) is both well prepared and well informed as it develops the national guidelines. At the same time, countries that have already begun to adapt the new guidelines have identified a number of specific challenges that national programmes have faced.

In this section, illustrative examples and country case studies are used to offer guidance on how some of these challenges can be addressed. Although case studies may provide valuable insights into in-country adaptation, they are not presented as definitive solutions. Indeed, it is not expected that all national programmes will arrive at the same technical and policy decisions.

Guideline adaptation is dependent on the national context and the choices that the GWG makes will be determined by national priorities, resource realities and (to some extent) by the composition of the GWG itself. The collection of case studies will be updated as new programme experiences are shared: WHO encourages users of this document to submit additional case studies by emailing them to the following address: [hiv-aids@who.int](mailto:hiv-aids@who.int), with the subject line 'Guideline adaptation'.

## 2.1 Frequently asked questions about the recommendations

The following section presents a series of tables (Tables 1 to 4) containing frequently asked questions (FAQs) related to technical elements of the recommendations contained within each of the guidelines. These are not intended to be exhaustive and the WHO encourages users of this guide to submit additional technical FAQs by emailing them to the following address: [hiv-aids@who.int](mailto:hiv-aids@who.int) with the subject line 'Guideline adaptation'.

**Table 1 FAQs for antiretroviral therapy in adults and adolescents**

Question	Answer
Why is lamivudine (3TC) (or emtricitabine (FTC)) included as a first- and second-line drug?	Although both 3TC and FTC result in the rapid emergence of resistance, the mutation that they select for (M184V) has reduced viral fitness and actually confers increased susceptibility to both AZT and TDF. Hence 3TC and FTC remain useful for second-line therapy, especially in settings where second-line therapy options are limited by cost, access and availability (7).
If introduction of both earlier treatment and newer drugs is not possible, which one is the priority?	In settings where immediate implementation of all the new recommendations is not feasible, population-based survival benefits are expected to be greatest with earlier antiretroviral therapy initiation compared to the introduction of improved drugs and monitoring. Initiation of antiretroviral therapy at a CD4 count of $\leq 350$ cells/mm <sup>3</sup> will reduce HIV and TB-related mortality and morbidity (8).
What is the cost and cost-effectiveness of earlier initiation?	While the numbers of people receiving antiretroviral therapy are projected to increase, late presentation into care remains one of the most significant correlates of mortality and has a negative impact on the cost-effectiveness of antiretroviral therapy. Although earlier initiation of antiretroviral therapy increases costs, it is also cost-effective: in a model-based analysis, early initiation was reported to be resource efficient with a cost-effectiveness ratio of US\$ 610 for every year of life saved (8).
There are two preferred	AZT and TDF have comparable efficacy but different toxicity

Question	Answer
NRTIs in the first-line recommendations, TDF and AZT. Which is better?	profiles and dosing schedules. AZT is given twice daily and can cause anaemia, while TDF is given once daily and is associated with renal toxicity and bone mineral loss. Toxicity-driven regimen changes are more frequent with AZT, while TDF is better tolerated and does not require close monitoring. Currently, the cost of TDF is marginally higher than AZT and both drugs are available as fixed-dose combinations (FDCs).

**Table 2 FAQs for prevention of mother-to-child transmission and infant feeding in the context of HIV**

Question	Answer
Why do the new guidelines emphasize the importance of access to CD4 testing in antenatal settings, when this test is not necessary to start PMTCT prophylaxis?	<p>In HIV-infected pregnant women, more than 80% of all postpartum maternal deaths occur among women whose CD4 count is <math>\leq 350</math> cells/mm<sup>3</sup>. Additionally, the risk of mother-to-child HIV transmission is greatest among women with a CD4 count of <math>\leq 350</math> cells/mm<sup>3</sup>, and this population accounts for the majority of postpartum HIV transmission risk (9). Therefore, assessment of CD4 count and initiation of antiretroviral therapy among pregnant women with a CD4 count of <math>\leq 350</math> cells/mm<sup>3</sup> is important both for maternal health reasons as well as for the prevention of mother-to-child transmission.</p> <p>If on-site CD4 testing is not available, blood samples should be sent for CD4 cell count testing. While awaiting these results, prophylactic AZT or Option B should be initiated. Once the CD4 results are known, decisions regarding which antiretroviral regimen to follow can then be made.</p>
Is it necessary to provide antiretroviral prophylaxis to infants born to women who are receiving antiretroviral therapy?	<p>All infants born to HIV-infected women receiving antiretroviral therapy for their own health, regardless of infant feeding choice, should receive antiretroviral prophylaxis for 4–6 weeks (there is no need to continue beyond 4–6 weeks since the mother is on antiretroviral therapy).</p> <p>This is particularly important when women start antiretroviral</p>

Question	Answer
	therapy late in pregnancy, as infant prophylaxis provides added protection from early postpartum transmission where there may not be full viral suppression. The two choices of infant prophylaxis include twice daily AZT or once daily NVP.
When should a pregnant woman begin antiretroviral prophylaxis?	Both Option A or Option B can be initiated at any time from 14 weeks gestation onwards. To achieve the full benefit of the antiretroviral drugs, it is important to start the regimen as early as possible prior to delivery.
If a woman comes to the hospital during labour or after delivery, what prophylaxis should be provided?	<p>If a known HIV-positive pregnant woman presents to the health facility during labour or immediately after delivery, the intrapartum and postpartum components of the prophylactic regimen should be commenced and she should be assessed for antiretroviral therapy eligibility. The details of the antiretroviral drugs to be given to either the mother or the infant can be found in Section IV of the WHO guidelines for the prevention of mother-to-child transmission ( ).</p> <p>If a pregnant woman whose HIV status is unknown presents to the health facility, she should have a rapid test to establish her HIV status.</p>
If using Option B, when should maternal triple antiretroviral prophylaxis be stopped?	The 2010 guidelines recommend stopping triple antiretroviral prophylaxis at delivery if the mother chooses not to breastfeed, or one week after the end of breastfeeding if the child receives breast milk. When using two NRTIs and one NNRTI as the triple antiretroviral prophylaxis regimen, it is recommended to continue the two NRTIs for a period of 2 weeks after stopping the NNRTI to prevent the emergence of NNRTI resistance.
What about using single or dual maternal prophylactic regimens other than AZT?	Some countries have been using antiretroviral drugs other than AZT as antenatal prophylaxis, such as AZT/3TC. There is limited data to support the use of other prophylactic regimens and WHO does not recommend the use of AZT/3TC before 28 weeks of pregnancy. There are well-

Question	Answer
	documented side-effects of anaemia and neutropenia in exposed infants, and resistance to 3TC can develop with prolonged exposure.
Is it advisable to do a routine Caesarean section in all HIV-infected pregnant women?	HIV infection in a pregnant woman is in itself no longer considered an absolute indication for Caesarean section. Caesarean section may reduce the likelihood of mother-to-child transmission, but this must be balanced against the risks of infection and bleeding, as well as the cost. In women who are not on prophylaxis or ART, and in those whose HIV disease is not well controlled on ART, rates of mother-to-child transmission are high and the benefits of Caesarean section may outweigh the risks. Programmes that choose to recommend Caesarean section as a standard of care should ensure that cost does not become a barrier for women to access health care facilities for antenatal care and delivery.
If the mother has taken AZT for more than 4 weeks during pregnancy, and she does not need sd-NVP and the AZT/3TC tail, does she still need to take AZT during labour?	Yes, if the mother does not need sd-NVP and the AZT/3TC tail, she should still take AZT twice-daily during labour and until delivery (see the WHO guidelines for the prevention of mother-to-child transmission, Table 2 []).
How long should an exposed infant stay on daily NVP if their mother begins antiretroviral therapy while breastfeeding?	The ideal recommendation for this situation was not reviewed by the expert panel that helped to develop the revised 2010 prevention of mother-to-child transmission guidelines. However, it would be reasonable and safe to continue to provide infant NVP for 4 weeks after initiation of maternal antiretroviral therapy. A 4-week overlap between infant prophylaxis and maternal antiretroviral therapy would help to ensure that the infant remains protected from breast-milk transmission.
What are the best	Syrup formulations of AZT and NVP remain the best option

Question	Answer
<p>formulations to use for administering NVP or AZT prophylaxis to breastfed HIV-exposed infants?</p>	<p>for delivering antiretroviral prophylaxis to newborns up to the age of 6 weeks. Beyond that age, for countries that choose Option A, there is an urgent need for a dispersible NVP tablet that can be used for long-term prophylaxis to breast-feeding infants. At present however, no such formulation exists, and the only choice that is available and appropriate is NVP syrup. Dosing for infant prophylaxis is available in the WHO guidelines for the prevention of mother-to-child transmission ().</p>
<p>The recommendations say that mothers should breastfeed for 12 months. Can a national authority recommend longer than this?</p>	<p>Yes. There may be circumstances in specific regions or all of a country that may lead national authorities to extend the recommended period of breastfeeding beyond 12 months. Where women cannot safely provide foods to replace breast-milk after 12 months, then national authorities can specify a different duration, and provide antiretroviral drugs over this longer time. Other circumstances when it may be appropriate to recommend that HIV-infected mothers breastfeed for longer than 12 months may include an emergency, such as an earthquake, drought or conflict, or a region with very high infant mortality and/or limited health services.</p> <p>The guidelines indicate that 12 months is the time period when the benefits of breastfeeding with antiretroviral drugs are most evident for most infants in most countries where the burden of HIV is high. However, they do not prevent authorities recommending longer durations if this is judged to be the best for the populations served by the national HIV/AIDS programme.</p>

Question	Answer
<p>What is the best timing of visits for dispensing infant nevirapine or maternal prophylaxis and providing counselling and support for infant feeding?</p>	<p>Infants should be coming to clinics for immunizations at 6, 10 and 14 weeks. It makes sense to capitalize on these visits to provide prescriptions for antiretroviral drugs to infants or mothers and counsel mothers about feeding practices. These visits also coincide with some of the times when mothers have difficulty with infant feeding; at around 6 weeks and also at 14 weeks, infants often have growth spurts and are more hungry than usual.</p> <p>It is likely that even after infants have reached 3 months of age, continued visits every month would be the optimum frequency to dispense ARVs and provide infant feeding counselling and support. Longer intervals may result in loss to follow-up. For some mothers who are managing very well, longer intervals, such as every 2 months, might be considered. Specific counselling could be provided at particular times such as when the infant is 6 months of age and complementary feeds should be introduced, or at 12 months when considering whether breastfeeding and prophylaxis should stop.</p>
<p>Where should ARVs for prophylaxis be dispensed from and who should dispense them?</p>	<p>The organization of services will vary according to the local epidemiology of HIV, the prevalence of breastfeeding, local dispensing regulations and use of existing health interventions (such as immunization clinics) as opportunities for PMTCT care delivery. Several different models can be considered:</p> <ul style="list-style-type: none"> <li>• within routine maternal and child health services with antiretroviral drugs prescribed by nurses;</li> <li>• within integrated family treatment sites;</li> <li>• within antenatal care with specific PMTCT nurses prescribing the antiretroviral drugs and infant feeding support.</li> </ul> <p>In most high HIV prevalence settings, the provision of</p>

Question	Answer
	antiretroviral drugs and support of infant feeding should be 'normalized' and regarded as general services that all health-care workers should be able to support, rather than being the responsibility of one or two specific nurses or other health-care providers.

For additional FAQs on infant feeding, see [http://www.who.int/maternal\\_newborn\\_child\\_adolescent\\_health/en/index.html](http://www.who.int/maternal_newborn_child_adolescent_health/en/index.html).

**Table 3 FAQs for antiretroviral therapy in infants and children**

Question	Answer
Do the guidelines recommend treatment for all children under 24 months of age?	<p>Yes, the guidelines do recommend treatment for all children under 24 months of age, irrespective of immune status or clinical stage. However, the <i>strength</i> of the recommendation depends on the age of the child. Mortality is very high in infants and there is clear evidence to support immediate initiation in all infants less than 12 months of age with confirmed infection (10). For infants less than 12 months of age, the recommendation to initiate antiretroviral therapy is <b>strong</b>.</p> <p>However, for children aged 12–24 months, mortality remains high, but there is no direct evidence to support immediate treatment, hence this is a <b>conditional</b> recommendation. Some programmes may prefer to use clinical/CD4 staging to determine antiretroviral therapy eligibility in children 12–24 months of age.</p>
Why has the recommended dose for isoniazid prophylaxis in children changed?	As per the <i>Rapid advice on the treatment of tuberculosis in children</i> , the recommended dose of isoniazid is now 10mg/kg per day (11). The increase is based on pharmacokinetic data that suggests that 5mg/kg per day under-doses a significant proportion of children (12).
Why do the new guidelines prefer AZT to ABC for first-line use in children, when a	A number of clinical trials demonstrate that ABC and AZT both work equally well in antiretroviral therapy-naïve children (13). There is a theoretical benefit to using ABC as a first-line

Question	Answer
<p>sequence using ABC in first-line and AZT in second-line might be better from the point of view of viral resistance?</p>	<p>drug, since ABC resistance does not give rise to AZT resistance. However, at present the cost of ABC is significantly higher than AZT. In addition, the risks of ABC hypersensitivity in patients from developing countries are poorly understood. In consideration of all the possible desirable and undesirable effects, the guidelines expert panel chose to make AZT the preferred option and ABC an alternate option.</p>
<p>The paediatric antiretroviral drug dosing guidance provided by WHO conflicts with doses proposed by other agencies. What should we be using?</p>	<p>WHO recognizes the difficulty of accurately dosing children of all ages. Annex E of the revised WHO guidelines for paediatric antiretroviral therapy (14), provides revised and simplified dosing recommendations that contain <b>weight-band</b> based (rather than weight-based or body surface area-based) doses for all antiretroviral drugs and combination tablets.</p> <p>Weight-band dosing compromises a degree of accuracy for improved convenience and simplicity. However, all the recommended doses have been carefully evaluated to ensure that no child would be under- or over-dosed by using this approach. Drug dosing schedules recommended by all agencies are always based on the same target dosing, so while they may not be identical, they should be equivalent.</p>
<p>The new guidelines provide a strong recommendation to use LPV/r as first-line treatment in all infected infants exposed to NNRTIs for maternal treatment or prophylaxis. Is there another option?</p>	<p>If it is not possible to access LPV/r as a first-line option in NNRTI-exposed infants, an alternative is to start with NVP-containing antiretroviral therapy and, where possible, assess viral load at 6 months after initiation to determine if there is persistent viral replication.</p>
<p>From what age can paediatric FDCs be used in infants?</p>	<p>WHO provides dosing guidance for FDCs in infants and children from 6 weeks of age. The doses contained within the FDCs are appropriate for children of this age, and all the dual</p>

Question	Answer
	and triple FDCs are designed to be crushable or dispersible in a small amount of water for administration even to young infants. Providers who prescribe FDCs to infants should provide concrete and practical guidance to caregivers on how to administer FDCs.

**Table 4 FAQs for TB/HIV IPT/ICF guidelines**

Question	Answer
What are the links between HIV and TB?	<p>In 2009, TB contributed to 24% of the estimated HIV-related mortality.</p> <p>When a patient is infected with both <i>Mycobacterium tuberculosis</i> and HIV, the two pathogens interact synergistically, speeding the progression of illness and increasing the likelihood of death. The presence of HIV makes a person more vulnerable to developing TB disease, and having TB disease accelerates HIV disease progression.</p> <p>HIV is the strongest risk factor for developing TB disease in those with latent new <i>M. tuberculosis</i> infection. The risk of developing TB is estimated to be 20–37 times greater in people with HIV than among those who do not have HIV (15).</p>
What are the Three I's for HIV/TB?	<ol style="list-style-type: none"> <li>1. Intensified TB case finding (ICF);</li> <li>2. Isoniazid preventive therapy (IPT); and</li> <li>3. Infection control for TB in health-care and congregate settings (IC).</li> </ol> <p>These three interventions are called the “Three I’s for HIV/TB”. This acronym reflects the importance of them to be implemented together as part of a TB prevention package in addition to antiretroviral therapy. The Three I’s should be core components of HIV prevention and care.</p>
What is IPT?	Isoniazid preventive therapy (IPT) is the administration of isoniazid (INH), an antibiotic; to people with latent TB to

Question	Answer
	<p>prevent progression to active TB disease.</p> <p>IPT reduces the overall risk of developing TB by up to 64% and is one of the strategies recommended by WHO to decrease the burden of TB in people living with HIV. HIV/AIDS programmes should provide IPT as part of the package of care for people living with HIV when active TB is safely excluded.</p> <p>Tuberculin skin test (TST) and chest radiography are no longer mandatory investigations before initiating IPT.</p>
<p>What is the rationale behind IPT?</p>	<p>A person living with HIV who is infected with M. tuberculosis but does not develop active TB cannot die from TB, spread TB to others, or develop drug-resistant TB (16). Therefore, treatment of latent infection with M. tuberculosis in people living with HIV is a way of reducing the risk of resistant TB and thus contributing to the control of multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB). Among the available regimens for treatment of latent TB, isoniazid preventive therapy (IPT) is the one most commonly recommended and also the one shown to be most effective and safe among people living with HIV.</p>
<p>What are the key recommendations for screening before giving IPT?</p>	<p>Adults and adolescents living with HIV should be screened for TB using a clinical algorithm. Those who do not report any one of the symptoms of current cough, fever, weight loss or night sweats are unlikely to have active TB and should be offered IPT.</p> <p>Adults and adolescents living with HIV and screened with a clinical algorithm for TB who report any one of the symptoms of current cough, fever, weight loss or night sweats may have active TB and should be evaluated for TB and other diseases.</p>
<p>Who should receive IPT?</p>	<p>Adults and adolescents living with HIV who have an unknown or positive tuberculin skin test (TST) status and are unlikely to</p>

Question	Answer
	<p>have active TB should receive at least 6 months of IPT as part of a comprehensive package of HIV care. IPT should be given to such individuals irrespective of the degree of immunosuppression, and also to those on antiretroviral therapy, those who have previously been treated for TB, and to pregnant women and children.</p>

## 2.2 When to start and what to start with – prioritizing decisions for antiretroviral therapy

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The new guidelines call for increasing access to treatment by changing the CD4 count eligibility threshold to  $\leq 350$  cell/mm<sup>3</sup>, as well as changing the first-line antiretroviral therapy regimen to zidovudine (AZT) or tenofovir (TDF) – drugs that are more costly but better tolerated than the previous recommendation, stavudine (d4T). Both of these are strong recommendations based on high quality evidence, and both will result in significant improvements, including fewer hospitalizations, reduced morbidity and mortality and less HIV transmission. In the long term, this overall health improvement will translate to less work for providers and reduced programme costs, but in the short term, implementation of these recommendations will inevitably increase programme costs and strain health resources. How should countries think about this balance as they determine which recommendation to focus on?

The decision is ultimately based on local circumstances and national priorities. For example, in some countries, the level of antiretroviral therapy coverage may already be very high and the need to switch patients to better-tolerated regimens might be more important. In other settings where coverage is low, increasing access may be the more urgent priority. For a description of the rapid assessment that Malawi undertook to answer the question of when to start and what to start with, see Case Study 1. Antiretroviral therapy coverage is influenced to some extent by the initiation threshold set by the national programme. In this way, a lower CD4 count threshold has implications in universal access targets and achieving the Millennium Development Goals (MDGs) as the number of people in need of treatment expands. Acknowledging this change will be important in helping policy-makers at the ministry of health and government to continue to report progress.

Box 9 summarizes how some countries have chosen to adapt these particular recommendations.

<b>Box 9 When to start and what to start with: national choices</b>						
<b>Country*</b>	<b>Adults</b>		<b>Pregnant women</b>		<b>TB/HIV co-infection</b>	
	<b>CD4 threshold for initiation (cells/mm<sup>3</sup>)</b>	<b>Choice of first-line NRTI</b>	<b>CD4 threshold for initiation (cells/mm<sup>3</sup>)</b>	<b>Choice of first-line NRTI</b>	<b>ART initiation criteria (cells/mm<sup>3</sup>)</b>	<b>Choice of first-line NNRTI</b>
India	≤250	AZT	≤350	AZT	≤350 Start ART 8 weeks after anti-TB therapy initiated	EFV is preferred
Kenya	≤350	AZT and TDF	≤350	AZT and TDF	≤350 Start ART 8 weeks after anti-TB therapy, initiated	EFV is preferred
Malawi	≤250	TDF	All HIV+ pregnant women (irrespective of CD4)	TDF	Start ART in all 8 weeks after anti-TB therapy, initiated	NVP
Mozambique	≤250	AZT	≤350	AZT	≤350	EFV is preferred
Nigeria	≤350	TDF	≤350	TDF	Start ART in all	EFV preferred
South Africa	≤200	TDF	≤350	TDF	≤350 Start ART 2-8 weeks after anti-TB therapy	EFV preferred
Thailand	≤350	AZT	≤350	AZT	≤350 Start ART 8 weeks after anti-TB therapy initiated	EFV is preferred
Zimbabwe	<350	TDF	≤350	TDF	Start ART in all 2-8 weeks after anti-TB therapy initiated	EFV is preferred

\* Based data, current as of February 2011.

Many programmes prioritize access to antiretroviral therapy in pregnant women as recommended in the adult and prevention of mother-to-child transmission guidelines. Treatment in this population lowers the risk of mother-to-child transmission, decreases

maternal mortality and improves the health of the mother, thereby improving the health of her whole family. In addition, active TB disease in an HIV-infected patient is also regarded as a high priority for antiretroviral therapy.

A key principle that needs to be considered in determining the ‘when to start’ policy is to ensure that people living with HIV with a CD4 count of  $\leq 200$  cells/mm<sup>3</sup> are recognized as an urgent priority, even as the recommendations change to a threshold of  $\leq 350$  cells/mm<sup>3</sup>. For example, if there are waiting lists for treatment at the current threshold, these should be addressed before new patients with a higher CD4 count are enrolled on antiretroviral therapy.

In terms of choice of first-line regimen, countries are making decisions between AZT and TDF and between NVP and EFV. Some of the relative merits of TDF as compared to AZT are given in Table 5 and Table 6 provides a comparison between NVP and EFV. As much as possible, the GWG should make a selection that applies to the majority of people living with HIV in the country. For example, countries with a high burden of hepatitis B co-infection may choose to make TDF the preferred option.

**Table 5 Choosing between TDF and AZT for first-line antiretroviral therapy**

Issue	Comparison	
	TDF	AZT
Efficacy	Available evidence supports equivalence.	
Safety	Low level risk of renal and bone toxicity.	Higher risk of anaemia and bone marrow toxicity, but reversible.
Cost*	No significant difference in cost. However, when formulated in an FDC, TDF is combined with the more expensive EFV, which is preferred as the NNRTI component due to its longer half-life, and this brings a significant cost increase in order to achieve a once-daily FDC.	No significant differences, although lower cost when prescribed as an FDC with NVP.
Monitoring	Ideally needs access to renal monitoring, including creatinine, to assess possible complications.	Ideally needs access to haemoglobin monitoring to assess possible complications.

\* Consult the WHO Global Price Reporting Mechanism for current cost data at <http://www.who.int/hiv/amds/gprm/en/index.html>.

**Table 6 Choosing between EFV and NVP for first-line antiretroviral therapy**

Issue	Comparison	
	EFV	NVP
Efficacy	Comparable. Both drugs equally likely to induce NNRTI resistance in the case of poor adherence or stopping. EFV has a longer half-life than NVP.	
Safety	EFV has less severe or life-threatening toxicity compared to NVP.	NVP is suspected to be safer to use during the first trimester of pregnancy than EFV, but may have more adverse events at higher CD4 counts.
Cost*	The cost of EFV is significant (currently 30–40% more expensive than NVP) but the cost of other drugs when used in FDCs and the costs associated with the monitoring strategy selected (e.g. haemoglobin for AZT, renal function tests for TDF, liver function test for NVP) should also be considered.	
Specific populations	EFV is preferred for all TB patients.  Consider the safety of EFV in early pregnancy and in women of reproductive age.	If NVP is chosen, will those with TB switch to EFV and then back to NVP after TB treatment or stay on EFV for life?  Safety of NVP in women with high or unknown CD4 cell counts is not clear.

\* Consult the WHO Global Price Reporting Mechanism for current cost data at <http://www.who.int/hiv/amds/gprm/en/index.html>.

An important consideration relates to the availability of fixed-dose combinations. AZT is available as a twice-daily triple fixed-dose combination combined with NVP. TDF is once-daily, but currently only available in an EFV-based fixed-dose combination, which makes it significantly more costly. One of the important functions of the GWG is to make decisions on

the choice of first- and second-line antiretroviral therapy regimens for adults, children and pregnant women, but it is also essential for this decision-making process to extend to the choice of formulations. The formulation choice will impact the budget, the supply chain and the type of training that is provided to clinicians. WHO strongly advocates the use of fixed-dose combinations, as these improve adherence and simplify prescribing and administration, in both adults and children.

A recent analysis (Box 10) that used a well-established HIV outcomes model to evaluate the impact on life expectancy of changing treatment recommendations, showed that while both changing the threshold and switching to TDF in first-line regimens were cost-effective interventions, changing the threshold was by far the more cost-effective measure, resulting in the largest increase in life expectancy per dollar spent.

The consideration of when to start antiretroviral therapy in adults, children and pregnant women and the choice of what to use for first-line therapy are some of the most critical decisions for the GWG to address in its deliberations. Earlier initiation of antiretroviral therapy will impact morbidity, mortality and rates of transmission and reduce incidence of TB. It is estimated that the new guidance will result in most patients receiving an additional 1–2 years of antiretroviral therapy, and inevitably this will cost more money, although it is important to remember that there will be some cost reductions associated with reduced toxicity and opportunistic infections management. The impact of changing the first-line regimen away from d4T will reduce toxicity and improve quality of care but at increased cost. These choices fundamentally affect the approach to implementation and scale-up and have a direct impact on national target-setting for antiretroviral therapy and prevention of mother-to-child transmission coverage goals.

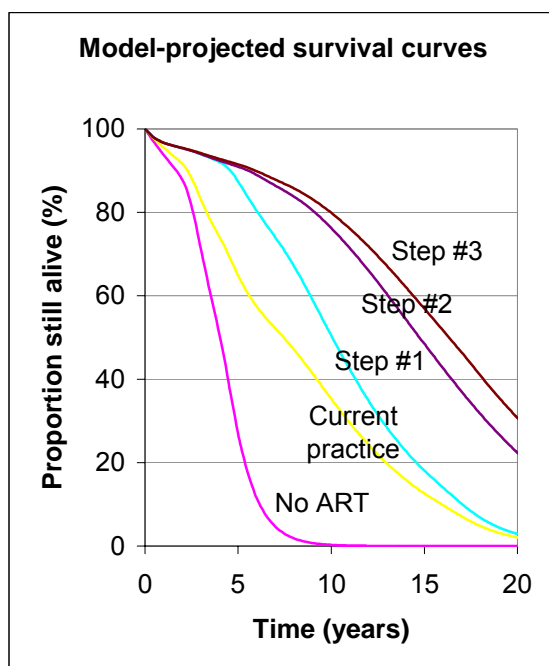
## Box 10 When to start, what to start: modelling cost-effectiveness

For adults, the WHO 2010 antiretroviral therapy guidelines make several recommendations, including to initiate antiretroviral therapy earlier (at CD4 count  $\leq 350$  cells/mm<sup>3</sup> instead of CD4 count  $\leq 200$  cells/mm<sup>3</sup>), replace d4T with TDF or AZT, and ensure second-line regimens are available and used when needed.

Implementation of all recommendations at the same time may not be immediately feasible, so it may be necessary to prioritize some recommendations over others.

A recent publication used the 'Cost effectiveness of preventing AIDS complications' (CEPAC) model to determine the short- and long-term survival benefits and cost-effectiveness of implementing various recommendations from the 2010 adult antiretroviral therapy guidelines. The results suggest that the intervention that is both most cost-effective and confers the greatest clinical benefit is to change the CD4 count threshold to  $\leq 350$  cells/mm<sup>3</sup> (and ensure that CD4 monitoring is available).

Earlier initiation of antiretroviral therapy and availability of second-line regimens have the greatest impact on life expectancy, but access to second-line regimens has a greater overall cost than switching from d4T to TDF. The study data are summarized below.



The graph highlights the three strategies that can maximize life expectancy in a stepwise progression from current practice. By initiating antiretroviral therapy earlier, median survival is increased by approximately 30 months (Step 1). Having a second-line regimen available further increases survival (Step 2) and introducing a switch from d4T to TDF has a comparatively modest survival advantage (Step 3).

For more information:

Walensky RP et al. Scaling up the 2010 World Health Organization HIV treatment guidelines in resource-limited settings: a model-based analysis. *PLoS Medicine*, 2010, 7(12):e1000382.

## 2.3 Phasing out stavudine (d4T) as a preferred first-line treatment

The tremendous scale-up of global HIV care and treatment programmes would not have been possible without access to convenient and affordable options for antiretroviral therapy. Stavudine (d4T) is among the cheapest of antiretroviral drugs and is both effective and, in the short term, relatively well tolerated. As a result, d4T has historically been the mainstay of antiretroviral therapy in adults and children. However, experience over the last five years has convincingly shown that, after long-term use, a high proportion of patients on d4T will develop drug-related toxicity, including lipoatrophy, peripheral neuropathy and mitochondrial dysfunction. These conditions are disfiguring, debilitating and may often be irreversible. Children seem less affected than adults, but patients over 35 years of age, women with high

body mass index (BMI), pregnant women and patients on other neurotoxic drugs are especially vulnerable.

The new guidelines for isoniazid preventive therapy (IPT) advocate for the use of isoniazid (INH) in all HIV-infected patients who do not have evidence of active TB disease. Implementation of these recommendations will be difficult in patients who are receiving d4T, due to overlapping neurological toxicities between INH and d4T. As a result of all of these factors, the 2010 recommendations for antiretroviral therapy in adults and children have shifted away from d4T as a recommended choice for first-line antiretroviral therapy. Suggestions for how this might be approached are given in Table 7.

**Table 7 Approach to phase out of stavudine (d4T)**

Issue	Suggestion
Funding	<p>What will the cost be to switch current and new patients (adults and children) away from d4T over time?</p> <p>What rate of phase-out can the current programme afford: immediate, staggered or deferred?</p> <p>What additional funds should be secured from government and donor agencies?</p>
Supply chain and commodity management	<p>What is the current inventory of required first-line drugs?</p> <p>What procurement orders need to be made to accommodate the pace of phase-out?</p>
Engaging people living with HIV	<p>What are the concerns and aspirations of people living with HIV?</p>
Training	<p>How will health workers be informed about and trained in these changes?</p>
Monitoring	<p>How will the national programme keep track of this process?</p>

Most programmes no longer routinely use d4T in patients who are starting antiretroviral therapy for the first time, but globally almost 60% of patients are still receiving d4T as part of their first-line treatment regimen. In the 2010 guidelines, WHO recommends a gradual phase-out of d4T use and a number of countries have begun to do this. Case Study 2

highlights the Uganda experience in d4T phase-out, successfully reducing the use of d4T by almost 50% in the space of one year. At the start of 2008, more than 70% of patients were receiving d4T and this had fallen to 40% by the end of the year. The Uganda experience underscores the importance of taking a planned approach to avoid both stock-outs and wastage.

Switching out d4T for one of the preferred NRTIs is only appropriate in patients who are well controlled on their d4T-containing first-line regimen. Clinicians should be given clear guidance on how to identify patients who are, in fact, failing on a d4T-based regimen and who need definitive second-line therapy rather than a switch to TDF or AZT. Where there is national capacity to perform viral load testing, this may be helpful in managing d4T phase-out.

## **2.4 Improving access to treatment for ART-eligible pregnant women**

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HIV-positive pregnant women whose CD4 count is  $\leq 350$  cells/mm<sup>3</sup> account for more than 80% of all postpartum maternal deaths and over 70% of all mother-to-child transmissions. As a result, one of the central principles of the 2010 prevention of mother-to-child transmission guidelines is the importance of providing antiretroviral therapy to pregnant women with a CD4 count of  $\leq 350$  cells/mm<sup>3</sup>. As recommended in both the antiretroviral therapy and prevention of mother-to-child transmission guidelines, the GWG should prioritize HIV-positive pregnant women to receive CD4 testing and early antiretroviral therapy, but beyond making the policy decision, it is also essential to consider how this might be implemented.

HIV-positive pregnant women typically do not attend antiretroviral therapy centres where CD4 is routinely available. By contrast, antenatal care sites may not have access to CD4 testing or the capacity to administer antiretroviral therapy. Given the importance of starting eligible pregnant women on antiretroviral therapy and of ensuring that they continue on treatment, there needs to be strong integration and coordination between antiretroviral programmes and PMTCT/MCH settings where women are tested for HIV. While CD4 testing may not be a prerequisite for antiretroviral therapy initiation, there will be less gains from changing the eligibility criteria for pregnant women (to a CD4 count of  $\leq 350$  cells/mm<sup>3</sup>) if CD4 testing is not available. Table 8 summarizes some of the approaches that may be considered to address this issue and the associated benefits and potential risks of each approach. The GWG should define how best this can be accomplished at the national level.

**Table 8 Improving CD4 testing access for HIV-positive pregnant women**

Issue	Benefits	Risks
<p>Prioritize access to CD4 testing and initiation of ART at antenatal sites.</p> <p>Where this is not possible, refer HIV-positive pregnant women for CD4 testing.</p>	<ul style="list-style-type: none"> <li>• ‘One-stop’ services avoid delays, are more acceptable to patients and are more cost- and time-efficient for women, children, providers and the health system.</li> <li>• Uses existing services, so faster to roll out.</li> <li>• Linking women to ART centres makes it easier for them to access ART if they are eligible and promotes long-term follow-up and adherence.</li> </ul>	<ul style="list-style-type: none"> <li>• Unless antenatal care and ART sites are co-located, many mothers will be lost to follow-up.</li> <li>• May need additional human resources to strengthen the linkage.</li> <li>• Pregnant women may be reluctant to visit an ART centre because of the stigma of being HIV-positive and pregnant, and because many ART centres are not set up to cater to the needs of pregnant women.</li> <li>• Investments are needed for CD4 testing technologies and to build laboratory capacity.</li> <li>• The best mechanisms for linking, PMTCT, postpartum and ART services with MCH systems are difficult to define within any particular health system. Countries may benefit from pilot testing efforts to link or integrate these services before scaling up.</li> </ul>
<p>Transport of blood samples to a central laboratory for testing</p>	<ul style="list-style-type: none"> <li>• Mechanisms often already exist for other types of sample, e.g. infant DBS for PCR, standard</li> </ul>	<ul style="list-style-type: none"> <li>• Samples must be transported fresh (within 48 hours).</li> <li>• Samples need to be</li> </ul>

	<p>MCH/pregnancy-related laboratory tests.</p> <ul style="list-style-type: none"> <li>• These systems could be modified to manage CD4 sample transport.</li> <li>• SMS technology can be used to return results.</li> </ul>	<p>anticoagulated whole blood, which is more hazardous to transport.</p> <ul style="list-style-type: none"> <li>• Centralized processing may be slower and this could delay initiation.</li> </ul>
Point of care CD4 testing	<ul style="list-style-type: none"> <li>• Point of care, therefore immediate results.</li> <li>• Offers a 'one-stop' service to mothers, rather than referral.</li> </ul>	<ul style="list-style-type: none"> <li>• New technology requires additional funds, validation and certification, training and maintenance.</li> </ul>

Point of care testing for CD4 (PoC-CD4) has recently been successfully implemented in a pilot project in Mozambique (Case Study 3). The National Institute of Health of Mozambique installed PoC-CD4 instruments in four primary care clinics that were already offering testing and treatment services. Their results showed that nurses and health technicians were able to perform CD4 testing, and that access to PoC-CD4 improved antiretroviral therapy initiation rates and reduced the percentage of patients lost to follow-up.

## 2.5 Optimizing prevention of mother-to-child transmission for women not eligible for antiretroviral therapy

For all HIV-infected pregnant women who are not in need of antiretroviral therapy for their own health, two equally efficacious antiretroviral prophylaxis options are recommended: Option A and Option B (see Table 9). There are strong benefits to providing effective and sustained antiretroviral prophylaxis to such women during pregnancy, labour and delivery, as well as to the mother or infant throughout the period when the infant receives any breastfeeding. Both recommended options provide significant reduction of the risk of mother-to-child transmission in the presence of breastfeeding. The advantages and disadvantages to each in terms of feasibility, cost, acceptability and safety for mothers and infants are summarized in Table 10.

**Table 9 What are Option A and Option B for prevention of mother-to-child transmission?**

<b>Recommended antiretroviral prophylaxis regimens for HIV-positive mothers</b>	
<p><b>Option A: maternal AZT</b></p> <ul style="list-style-type: none"> <li>AZT during pregnancy</li> </ul> <p><b>and</b></p> <ul style="list-style-type: none"> <li>sd-NVP+AZT+3TC during labour and delivery</li> </ul> <p><b>and</b></p> <ul style="list-style-type: none"> <li>AZT+3TC for 7 days postpartum</li> </ul>	<p><b>Option B: triple ARV prophylaxis</b></p> <p>Provided to pregnant women until one week after all exposure to breast milk has ended:</p> <ul style="list-style-type: none"> <li>AZT+3TC+LPV/r <b>or</b></li> <li>AZT+3TC+ABC <b>or</b></li> <li>AZT+3TC+EFV <b>or</b></li> <li>TDF+3TC (or FTC)+EFV</li> </ul>
<b>Recommended antiretroviral prophylaxis regimens for HIV-exposed infants</b>	
<p><b>Option A: maternal AZT</b></p> <p>Breastfeeding infants:</p> <ul style="list-style-type: none"> <li>sd-NVP at birth, then daily NVP until one week after all exposure to breastfeeding</li> </ul> <p>Infants receiving only replacement feeding:</p> <ul style="list-style-type: none"> <li>sd-NVP at birth, then daily NVP <b>or</b> twice-daily AZT for 4–6 weeks</li> </ul>	<p><b>Option B: triple ARV prophylaxis</b></p> <p>Irrespective of infant feeding mode:</p> <ul style="list-style-type: none"> <li>NVP <b>or</b> AZT for 4–6 weeks</li> </ul>

**Table 10 Risks and benefits of Option A compared to Option B for prevention of mother-to-child transmission for women not eligible for antiretroviral therapy**

<b>Option A: Maternal AZT plus infant ARV prophylaxis</b>	<b>Option B: Maternal triple ARV prophylaxis</b>
<b>Expected benefits</b>	
<ul style="list-style-type: none"> <li>Low rate of maternal NNRTI resistance with use of AZT+3TC.</li> <li>Low rate of adverse events in infants.</li> <li>The long half-life of NVP allows the infant to potentially miss some of the daily doses while still maintaining adequate</li> </ul>	<ul style="list-style-type: none"> <li>Significant reduction of the MTCT risk.</li> <li>Low rate of adverse events in infants.</li> <li>No change in regimen between antepartum and postpartum periods.</li> <li>This strategy may improve maternal health during the period she is receiving</li> </ul>

<b>Option A: Maternal AZT plus infant ARV prophylaxis</b>	<b>Option B: Maternal triple ARV prophylaxis</b>
<p>drug levels.</p> <ul style="list-style-type: none"> <li>Continuation and extension of current and simple practice.</li> <li>Drugs are available at primary care facilities.</li> <li>Cost is lower than Option B.</li> </ul>	<p>the regimen, as she is receiving treatment.</p> <ul style="list-style-type: none"> <li>May be more effective in settings where there is no access to CD4 testing or ART.</li> </ul>
<b>Potential risks</b>	
<ul style="list-style-type: none"> <li>The peripartum maternal regimen is more complex, requiring administration of AZT/3TC 'tail' if sd-NVP is given.</li> <li>Likelihood of NNRTI resistance in most infants who are infected despite prophylaxis. Initiation of a PI-based regimen is recommended for these infants.</li> <li>Safety, effectiveness and feasibility of daily infant NVP beyond six months of age is unknown.</li> <li>The maternal and infant acceptability of daily infant prophylaxis for a long period is unknown outside of a clinical trial setting.</li> <li>Potential to miss those who need treatment.</li> <li>Postpartum services do not exist to provide longer-term paediatric ARV prophylaxis.</li> </ul>	<ul style="list-style-type: none"> <li>The risk for maternal health of stopping prolonged (e.g. 12–18 months) maternal triple ARV prophylaxis after breastfeeding cessation is unknown.</li> <li>Potential risk of multi-ARV resistance in mother if she stops or does not adhere to the regimen.</li> <li>Likelihood of drug resistance (NRTI, NNRTI) in infants who are infected despite prophylaxis.</li> <li>Monitoring visits are required to assess both maternal and infant safety.</li> <li>The maternal acceptability of prolonged use (antepartum and up to 12 months postpartum) of triple ARV regimens followed by discontinuation among women with high CD4 counts is unknown, and acceptability in programme settings is also unknown.</li> <li>In terms of drug costs, Option B is more costly than Option A.</li> <li>Health system may not be ready to accommodate Option B.</li> </ul>

In selecting the best option at the country level, the GWG should assess the patient and provider acceptability of administering extended triple ARV prophylaxis to mothers, or extended NVP prophylaxis to babies and evaluate whether existing HIV and maternal and child health human resources and infrastructure can support the national choice. Commodity costs are lower for Option A than for Option B, and this may be an important consideration, especially for countries with high HIV prevalence among pregnant women.

In Tanzania, for example, the National AIDS Programme decided to choose Option A after assessing a range of issues including cost. The cost modelling exercise is shown in Case Study 4. By contrast, in Thailand, the national programme has elected to adopt Option B, and start all pregnant women on a three-drug regimen of AZT+3TC+LPV/r. The Ministry of Health field-tested the feasibility and outcome of highly active antiretroviral therapy for the prevention of mother-to-child transmission in a sub-national pilot prior to endorsing Option B as the national policy (see Case Study 5).

For most resource-limited settings, delivering Option A or Option B will likely add complexity to the current prevention of mother-to-child transmission programme. In particular, postpartum services are often rudimentary and insufficient for mothers and infants who are receiving ongoing antiretroviral prophylaxis for prevention of breast-milk transmission. Expanded programme on immunization programmes may be useful for scheduling certain follow-up visits, especially the six-week postpartum visit that coincides with the first set of routine newborn immunizations. However, concerns about how best to deliver HIV services in the context of the infant immunization programme must be addressed. There is an urgent need to better understand how to provide postpartum services for both Option A and Option B and programmes are encouraged to evaluate different models of service delivery and share their experiences broadly. It should also be noted that the relative advantages of adherence and tolerance for Option A as compared to Option B for long-term prophylaxis are still unknown.

The elimination of new paediatric HIV infections through improved prevention of mother-to-child transmission interventions is now feasible in a number of high-burden countries. As the GWG adapts global prevention of mother-to-child transmission recommendations, close consideration should be given to the broad range of interventions that must be linked and coordinated in order to maximize the success of the prevention of mother-to-child transmission programme. These include: preventing HIV infection in young women; providing comprehensive family planning to all; offering routine HIV testing to pregnant women; improving access to CD4 testing in antenatal care settings to establish antiretroviral

therapy eligibility among pregnant women; and strengthening infant diagnosis and follow-up for HIV-positive mothers and their infants.

## 2.6 Infant feeding in the context of HIV

Previously, the dilemma of infant feeding in the context of HIV was to balance the risk of infants being exposed to HIV through breastfeeding with the risk of death from causes other than HIV if infants were not breastfed. Today, antiretroviral drugs can significantly reduce the risk of transmitting HIV through breastfeeding when given according to the 2010 WHO recommendations, either as lifelong antiretroviral therapy to the mother or as a prophylactic antiretroviral intervention to the mother or infant.

### Box 11 Key interventions in the 2010 guidelines on infant feeding in the context of HIV

- National authorities formulate policy on infant feeding practices for HIV-infected mothers.
- HIV infant feeding policies should align with and reinforce existing policies and practices for infant feeding.
- If HIV-infected mothers are recommended to breastfeed, then:
  - they should exclusively breastfeed for the first six months, then introduce complementary foods and continue breastfeeding up to 12 months;
  - breastfeeding should then only stop once a nutritionally adequate and safe diet without breast milk can be provided.
- Throughout the period of breastfeeding, it is important to prevent mother-to-child transmission of HIV by using either maternal antiretroviral therapy in mothers who are eligible for antiretroviral therapy or antiretroviral prophylaxis given to mother and infant.
- National authorities should help to ensure that all facilities have the resources and support to implement the revised feeding policy. This may include: standard operating procedures and protocols on infant feeding and prevention of mother-to-child transmission; staff and systems for dosing and dispensing antiretroviral drugs; and mechanisms to assess and support adherence to feeding policies in known HIV-positive children.
- New approaches should be integrated with maternal and child health services as far as possible and should be accompanied by outreach campaigns and awareness raising among community health workers and women attending antenatal care in order to explain any changes.
- Monitoring and evaluation to measure indicators of infant feeding and antiretroviral drug usage.

For more information:

World Health Organization. *Guidelines on HIV and infant feeding 2010: principles and recommendations for infant feeding in the context of HIV and a summary of evidence*. Geneva, 2010 ([http://www.who.int/child\\_adolescent\\_health/documents/9789241599535/en/](http://www.who.int/child_adolescent_health/documents/9789241599535/en/), accessed 10 April 2011).

The revised recommendation is that national health authorities should promote a single infant feeding practice as the standard of care, whereas the previous guidelines suggested that health workers in clinics should counsel HIV-positive mothers on the most appropriate

choice for infant feeding. Information about other practices should be made available to mothers, but the health system should principally support one approach.

As part of the process of adaptation, the GWG should consider the best infant feeding approach for the national context and provide a policy recommendation to the ministry of health. Involvement of representatives from infant feeding and from maternal and child health is essential for this decision-making. The revised HIV infant feeding guidelines offer an opportunity to simplify messages around infant feeding for the whole population and increase the rate of HIV-free survival, as well improved health outcomes for all children. Factors that may be important for the GWG to consider include:

1. What is the contribution of serious infectious diseases, especially diarrhoea and pneumonia, and malnutrition to infant mortality in the infants in the general population and among HIV-exposed (not HIV-infected) infants?
2. What is the quality and coverage of prevention of mother-to-child transmission and antiretroviral interventions through maternal and child health services?
3. What is the potential to promote better infant feeding practices in the general population?
4. What are the resource implications of the different infant feeding strategies?

Once an approach has been determined and the national policy formulated, operational planning at district level will need to be developed to guide introduction, scaling-up and support of the infant feeding recommendation. A phased implementation approach that includes the opportunity for early learning may be especially helpful. This early learning phase could involve the community as well as a representative selection of health facilities to rapidly test the different elements of the operational plan – communication strategies, training for all cadres of health care workers (including lay counsellors, midwives, nurses and community health workers), general health messages to women attending antenatal clinics, and systems for recording monitoring and evaluation indicators. In the course of this learning phase, problems faced in each of these areas and the solutions devised to overcome them can be fed back and used to revise the national implementation plan.

A comprehensive set of '*Commonly Asked Questions and Answers*' regarding the 2010 HIV and Infant Feeding WHO guidelines as well as additional guidance on implementation is available at [http://www.who.int/child\\_adolescent\\_health/en/index.html](http://www.who.int/child_adolescent_health/en/index.html).

## 2.7 Functional integration of HIV into the health system

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In most countries, HIV prevention, care and treatment services have been implemented as vertical programmes that are often poorly connected to other health services. Increasingly, programme managers are being challenged to better integrate HIV into the health system by building linkages to related programmes. Acknowledging that various definitions of 'integration' exist at different levels of a health-care system, the practical realization of 'complete integration' is difficult to structure but 'functional integration' may be more easily achieved.

Functional integration is where people are getting all the care and services they need through a coordinated network of linkages and referrals to the required programmes and services. A truly 'functioning' system of coordinated linkages may be more realistic than full integration of services. Functional integration helps move away from vertical services that impose additional burdens on already weakened systems and that are difficult for clients to negotiate, and promotes a more sustainable, efficient and cost-effective approach to care. Functional integration is also a prerequisite for decentralization of HIV services to the primary level (see section 2.8).

Functional integration should involve all levels of the health system and all relevant stakeholders including government and nongovernmental organization partners to ensure coordinated efforts. A sound approach to integration is driven first and foremost by a clearly communicated plan with common aims and objectives, followed by a strong political commitment and leadership. Political and policy obstacles are often the most challenging to overcome, but the process of guideline adaptation offers an opportunity to address such concerns.

For example, by bringing together programme staff and experts from a range of health services, the GWG provides a forum to enable discussion of how best to promote integration. From the perspective of HIV service delivery, efforts should particularly focus on the integration of TB and HIV programmes, of prevention of mother-to-child transmission and maternal and child health programmes, and of HIV and primary health care services. Where sex workers and men who have sex with men are a focus, integration with sexual health services is necessary; where injecting drug users are a focus, integration of services should include harm reduction programmes and other services relevant for injecting drug users, such as drug dependence treatment programmes and hepatitis clinics. Apart from policy issues, a number of other health system components should also be addressed in order to

support an integrated model of care. These include, governance, financing, human resources, information systems and the commodity supply chain.

Functional integration of service delivery benefits programmes by strengthening the health system overall and by reducing costs. In particular, costs of pharmacy management, supply chain and health information collection may be reduced by combining programmes, rather than maintaining independent vertical systems. At the same time, integrated programmes also benefit clients by offering 'one-stop' clinical services. For example, when families are affected by HIV, integrated and family-centred care coordinates services and support for the entire family, prevents family members from having to go to multiple locations for care and reduces costs, time and stress (17). In addition, integration is the cornerstone of achieving global health goals such as the Millennium Development Goals and the elimination of new paediatric infections. In Mozambique, the integration of HIV treatment into primary health care settings led to a marked increase in antiretroviral therapy enrolment and adherence in two provinces (Case Study 3).

How the national programme chooses to integrate services will depend on the specifics of the local health system, the HIV epidemic profile, and the actors involved. It is worth noting that in some settings, HIV programmes may be reluctant to integrate into the broader health system because of the perceived risk of losing resources and compromising service delivery. However, evidence suggests that integration often improves service quality and is necessary to expand access and keep services sustainable. Careful consideration of which levels to integrate is needed in order to ensure that the process of combining and adding services does not diminish quality or affect planned outcomes through overloading existing staff or systems. Where this is perceived to be a risk, building *functional* linkages may be a useful interim approach.

**Box 12 Building the capacity of maternal and child health service providers to integrate HIV prevention, care and treatment into routine services**

Building the capacity of maternal and child health services and service providers is an essential prerequisite for integration of HIV into routine maternal and child health services. This entails training antenatal and child health providers on the urgency associated with early identification and management of HIV-positive mothers and their infants, on the prevention of mother-to-child transmission of HIV, and on the importance of providing ongoing HIV care and treatment throughout breastfeeding and thereafter. Laboratory and pharmacy personnel also require orientation on the need to prioritize pregnant and breastfeeding women to support timely access to prevention of mother-to-child transmission interventions.

The WHO IMAI/IMPAC clinical course for integrated prevention of mother-to-child transmission is tailored to build the clinical skill and knowledge of existing maternal and child health service providers to integrate services at primary health centre levels. Countries that are already using these tools need to update them in line with national guideline updates.

For more information:

Training tools for prevention of mother-to-child transmission of HIV  
(<http://www.who.int/hiv/topics/mtct/training/en/index.html>).

### **Box 13 Integrating prevention of mother-to-child transmission with paediatric HIV and maternal and child health services**

Strengthening the public health system is central to supporting the sustained delivery of an integrated package of prevention of mother-to-child transmission of HIV, paediatric HIV and maternal and child health services. Investments in multiple areas of the health system will impact positively on a country's ability to provide a fully integrated package of care. The following areas are examples where investments to strengthen the health system will facilitate integration.

#### **Policies and guidelines**

- Policies addressing human resources for health and supporting task shifting to allow increased access to integrated services.
- Clear policies describing roles and responsibilities between the involved services, including budget responsibilities.
- Complementary clinical service guidelines and tools.
- Strong information systems and referral processes.
- Monitoring and evaluation at all levels of care.

#### **Leadership and governance**

- New or strengthened organizational units or governing bodies to manage aspects of integrated care – drawing members from across multiple levels of the health system.

#### **Financial management**

- Coordinated national-level resource management and leveraging of external and internal partners.
- Locally managed financial management systems.

#### **Human resources**

- Strategies for hiring, training and retaining health-care workers who can deliver integrated care.
- Design and implement integrated pre-service and in-service training for students and staff.
- Support task shifting and mentorship to facilitate the implementation of integrated services, including delivery of ART and complex ARV regimens for PMTCT.
- Empower and involve non-facility-based organizations and individuals in the community.

#### **Information systems**

- Develop and strengthen existing national health management information systems to harmonize patient reporting of all aspects of integrated care.
- Support development of patient tracking and follow-up tools.
- Establish integrated national disease surveillance.

#### **Supply chain management**

- Improve supply chain procedures to promote integrated delivery of drugs and commodities that are essential for PMTCT and maternal treatment to the lowest levels of the health system. This may include provision of antiretroviral therapy and complex antiretroviral drug regimens in primary care maternal and child health settings.

#### **Laboratory networks and services**

- Improve the capacity of laboratories in testing for multiple programmes and diseases, develop point-of-care testing and improve logistics around specimen transportation and expediting test results.
- Promote appropriate levels of laboratory services as part of an integrated primary health care package.
- Supporting the integration of prevention of mother-to-child transmission of HIV, paediatric HIV and maternal and child health services is an important way to increase coverage of prevention of mother-to-child transmission and paediatric services, improve quality of service delivery and ensure programme sustainability. Evidence from maternal and child health service integration suggests that overall morbidity and mortality are reduced following integration through the timely diagnosis, intervention and follow-up of women and infants.

For more information:

PEPFAR Guidance on integrating prevention of mother to child transmission of HIV, maternal, neonatal, and child health and paediatric HIV services. 2011 ([http://www.aidstar-one.com/PEPFAR\\_PMTCT\\_HIV\\_Integration\\_Guidance\\_January\\_2011](http://www.aidstar-one.com/PEPFAR_PMTCT_HIV_Integration_Guidance_January_2011), accessed 10 April 2011)

## 2.8 Decentralizing services

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In the midst of a large-scale global HIV epidemic, achieving universal access to antiretroviral drugs for all those in need will require ambitious scale-up efforts. In high HIV prevalence settings, in order to achieve the greatest impact for the largest number of people, HIV programmes will probably need to both integrate and decentralize services down to the primary care level. As the demand for antiretroviral therapy continues to grow, it will become increasingly challenging to deliver services to the expanding numbers of patients, particularly in rural settings. Delivery of HIV services to rural communities poses unique challenges in which centralized service delivery models are insufficient. Integration with TB services that are often already functioning at a community level is one approach to dealing with the dual epidemic of HIV and TB. In low HIV-prevalence settings, other models of integrating and delivering HIV care and services may be required.

Decentralizing HIV services is feasible if there is commitment from local authorities as well from primary level facilities and staff. Despite concerns about the potential impact on quality of care, experience from South Africa has shown that the decentralization of services and a rapid expansion of access to antiretroviral therapy does not reduce clinical outcomes and can even result in better outcomes than with centralized services (18). Indeed, in this case, decentralization allowed more people in need to be reached and initiated on antiretroviral therapy, thus decreasing loss-to-follow-up and mortality (19). Malawi, through a well-designed programme focused on using available resources for community-level antiretroviral therapy delivery, was able to scale up antiretroviral therapy to over 240 000 people in only a few years.

As the GWG considers adaptation of the global guidelines to develop national level policies, it is important to consider how these policies might be implemented in a decentralized service delivery model. Six elements are critical for successful decentralization.

### **1. Decentralization of programme management and building local capacity to manage and coordinate implementation**

Decentralization of services should occur in conjunction with district/local/sub-national-level planning, supervision and capacity building. When services are decentralized to distal facilities, it is often difficult for national programme managers to continue supporting and supervising such primary facilities. Programme managers at the peripheral level will need support in managing and coordinating programme implementation. Efforts to use community volunteers will be crucial in moving towards a decentralized system.

## **2. Adequate numbers of trained people to manage workload**

Strategies to overcome staffing constraints should consider establishing new cadres of health-care workers, task shifting among existing health-care workers or the use of people living with HIV as lay counsellors or health assistants (see section 2.10 and Case Study 6). Mechanisms for health workers' continued learning, such as clinical mentoring, regular supportive supervision, providing job aids and reference materials at the facility level, and using technology-based self-learning tools may all be useful, depending on the local context.

## **3. Better health management information systems**

Improved mechanisms for record keeping and focusing on key indicators at the primary level will strengthen continuity of care, improve programme monitoring and evaluation, and simplify communication across different levels of the health system to facilitate patient referrals and consultation (see Box 14 and Case Study 7)

## **4. Improved access to laboratory tests at the primary level**

This has been a key bottleneck to effective decentralization. Point-of-care (PoC) testing for HIV, CD4 count and other diagnostic assays is one approach to address the problem. Recent experience from Mozambique has shown that point-of-care technology is both accurate (see Box 15) and improves access to antiretroviral therapy (Case study 3).

## **5. Expanded supply chain**

Supply chain management is often inherently weak within the national health system. As a result, many countries manage parallel mechanisms for the supply of HIV commodities. Rationalizing and strengthening the national supply chain system is vital for decentralization to ensure that tests and drugs are available where patients are accessing care. Using new technologies such as mobile scanning devices to support supply chain management can help to unify and integrate parallel systems and extend the supply chain to primary level facilities (see Case Study 8).

## **6. Training resources**

A large number of curricula and training materials are available to enable health-care workers in primary settings to deliver HIV care and treatment. WHO produces a set of complementary tools (IMAI, IMCI and IMPAC) that are specifically designed for primary care clinicians and offer integrated HIV clinical training and programmatic capacity building for decentralized service delivery. These tools have recently been

updated to reflect the revised HIV guidelines and they benefit from having been extensively adapted for specific national settings and widely tested in the field.

## 7. Operational planning

Decentralization requires detailed facility-level operational planning. WHO has recently published an operations manual to guide clinical teams at primary health centres, programme managers and site administrators for the planning of decentralization (see Box 16). The *Operations manual* includes guidance on building integrated systems that allow for clinical management and programme monitoring at primary and secondary levels (20).

### **Box 14 Interlinked patient monitoring systems for HIV care/antiretroviral therapy, maternal and child health/prevention of mother-to-child transmission and TB/HIV: standardized minimum data set and illustrative tools**

A good patient monitoring system supports continuity of care by enabling the transfer of patient-related information across multiple care and service delivery points. Standardized patient monitoring generates data for programme monitoring and for assessing and improving the quality of data.

The three revised WHO interlinked patient monitoring systems build and improve on the original WHO 2006 patient monitoring tools by supporting integrated service provision, follow-up of mother–infant pairs, and monitoring of key TB-related and paediatric variables. The maternal and child health minimum data set includes all routine core maternal and infant variables plus key HIV-related variables. The simplified generic antiretroviral therapy cohort and the cross-sectional quarterly report is integrated to collect not only HIV indicators, but also key prevention of mother-to-child transmission, maternal and child health, and TB/HIV indicators. The generic tools are illustrative, for country adaptation at the national level.

For more information:

World Health Organization. *Three interlinked patient monitoring systems for HIV care/ART, MCH/PMTCT and TB/HIV. Standardized and minimum data set and illustrative tools.* Geneva, 2010 ([http://www.who.int/hiv/pub/imai/three\\_patient\\_monitor/en/index.html](http://www.who.int/hiv/pub/imai/three_patient_monitor/en/index.html)).

### **Box 15 Decentralization of lab services**

The accuracy of point-of-care (PoC) tests for CD4 count, clinical chemistry and haemoglobin conducted in a primary health setting has recently been reported in a study from Mozambique. Three PoC assays were tested against laboratory-based assays conducted on HIV-positive adults enrolled consecutively at two clinics within primary health care centres that deliver HIV services including ART, but have no on-site laboratory facilities. Patients were tested with PoC CD4 count (Pima™), clinical chemistry (Reflotron™) and haemoglobin (HemoCue™) devices using finger-prick blood at the clinic. At the same time, samples of blood drawn by venepuncture were also sent to a central laboratory for comparison testing.

The study showed that for all three assays, haemoglobin, CD4 count and alanine aminotransferase (ALT), PoC and laboratory test results were in close agreement. Furthermore, nurses were able to operate the PoC devices reliably and reproducibly. PoC diagnostics are technically feasible and have value in decentralization of HIV treatment services.

For more information:

Jani I et al. Accurate CD4 T-cell enumeration and antiretroviral drug toxicity monitoring in primary health care clinics using point-of-care testing. *AIDS*, 2011, 25(6):807–812.

### **Box 16 Operations manual for delivery of HIV prevention, care and treatment at health centre level in high-prevalence and resource-constrained settings**

Decentralization and integration of services supports access, equity and adherence to care by bringing the service closer to patients' home. The WHO *Operations manual* provides guidance on planning and delivering HIV prevention, care, and treatment services at primary health centres in countries with high HIV prevalence. It provides an operational framework to ensure that HIV services can be provided in an integrated, efficient and quality-assured manner.

The manual is based on the public health approach to scaling up HIV services in resource-constrained settings, which includes simple, standardized regimens and formularies; standardized supervision and patient monitoring approaches; as well as integrated delivery of care at primary health centres within a district network. It supports efforts to deliver and scale up HIV prevention, care and treatment including provided-initiated testing and counselling (PITC), prevention of mother-to-child transmission, prevention of HIV and TB transmission in health care settings, and HIV treatment and care.

The *Operations manual* deals with logistic, managerial and infrastructure requirements for delivery of the essential HIV and primary care services as laid out in clinical practice guides, such as country-adapted WHO integrated management tools IMAI, IMCI and IMPAC, or other national clinical guidelines for provision of acute and chronic HIV care at primary health centre level. It incorporates essential pharmacy and laboratory services required at health centre level. Specific chapters may be particularly useful for those with tasks such as managing the supply chain, providing laboratory services, or managing patient records, registers and reports.

The manual is designed to serve as a learning aid and job aid for the health centre team, and in particular the health centre manager (often an in-charge nurse). It should be adapted for use within a specific national context and includes content that can be readily presented as wall charts or used to develop standard operating procedures for various services or specific types of patients.

District management teams, which supervise and support health centre services, should also find this manual helpful, as should national ministries of health and other partners responsible for planning and supporting the decentralization of HIV services.

For more information:

World Health Organization. *Operations manual for delivery of HIV prevention, care and treatment at primary health centres in high prevalence, resource-constrained settings*. Geneva, 2008 ([http://www.who.int/hiv/pub/imai/operations\\_manual/en/](http://www.who.int/hiv/pub/imai/operations_manual/en/)).

## **2.9 Integrating TB and HIV services**

HIV infection is the leading risk factor for and drives TB incidence – in some African countries over 76% of people with TB have HIV infection. In 2009, there were an estimated 33.3 million people living with HIV globally. Of these, 1.2 million were estimated to have TB and an estimated 400 000 died from TB.

The WHO *Interim policy on collaborative TB/HIV activities* was released in 2004 by the Stop TB Department and the Department of HIV/AIDS – it aims to decrease the joint burden of TB and HIV in populations affected by both diseases (see Box 17). Prevention of TB among people living with HIV requires prevention interventions for both HIV infection and TB, including earlier antiretroviral therapy and, as part of the collaborative activities, WHO recommends Three I's for HIV/TB: isoniazid preventive therapy (IPT), intensified case finding (ICF) and infection control for TB.

The implementation of the Three I's for HIV/TB has been slow. IPT reduces the overall risk of developing TB by up to 64%, yet during 2009 only 86 000 people living with HIV had received IPT and only 1.7 million people living with HIV were screened for TB. Barriers to the implementation of the Three I's for HIV/TB include: a lack of operational linkages between TB and HIV programmes; lack of national guidance, training, supervision and local coordination mechanism; misconceptions about IPT, including fear of contributing to drug resistance if active disease is not excluded, concerns about toxicity and adherence; drug logistics and procurement; a lack of health-care worker experience and knowledge of IPT; missing monitoring and evaluation systems for collaborative TB/HIV activities; and a lack of advocacy.

### **Box 17 WHO recommended twelve collaborative TB/HIV activities**

#### **Establish the mechanisms for collaboration**

1. Ensure a coordinating body exists for effective TB/HIV collaboration at all levels  
To ensure TB and HIV services get to those who need them most.
2. Conduct surveillance of HIV prevalence among TB patients and TB prevalence among HIV patients  
To understand the size of the problem.
3. Carry out joint HIV/TB planning  
To coordinate the efforts of both programmes and make best use of resources.
4. Conduct monitoring and evaluation  
To be sure we know that people are able to access the services they need.

#### **Decrease the burden of TB in people living with HIV, (Three I's for HIV/TB)**

5. Establish intensified TB case-finding  
TB screening to find undiagnosed TB cases in people living with HIV.
6. Introduce Isoniazid Prevention Therapy  
To prevent the progression of latent TB infection to active disease.
7. Ensure TB infection control in health care and congregate settings  
To prevent anyone from becoming infected with TB while in a health facility or other congregate settings such as prisons.

#### **Decrease the burden of HIV in TB patients**

8. Provide HIV testing and counselling  
To prevent anyone from catching TB while in a health facility or other congregate settings such as prisons.
9. Introduce HIV prevention methods  
To ensure TB patients know how to prevent HIV, which will in turn reduce transmission of both HIV and TB.

#### **Decrease the burden for people living with HIV and TB**

10. Introduce co-trimoxazole prevention therapy  
To reduce the risk of people living with HIV and TB from dying during treatment.
11. Ensure HIV and TB care and support  
To provide people living with HIV and TB with the care and support they need to manage their illness.
12. Provide antiretroviral therapy  
To ensure that all people living with HIV and TB receive ART where appropriate – this will reduce their risk of death and improve their quality of life.

Source: WHO. 2004. *Interim policy for collaborative TB/HIV activities*.

The recent WHO antiretroviral therapy and TB guidelines addressed in this adaptation guide offer four key recommendations to decrease the burden of TB in people with HIV.

1. Immediate antiretroviral therapy for all people with HIV who are diagnosed with TB, irrespective of CD4 count and other clinical conditions, not later than eight weeks after diagnosis of TB.
2. Initiate earlier antiretroviral therapy at a CD4 count of  $\leq 350$  cells/mm<sup>3</sup> and thus reduce TB incidence.
3. Adults and adolescents with HIV should be screened for TB with a clinical algorithm. Those who report no current cough, fever, weight loss or night sweats are unlikely to have active TB and should be offered IPT. IPT should be prescribed for at least six months, irrespective of the degree of immunosuppression, and should be given to all people living with HIV, including those on antiretroviral therapy, those who have been previously treated for TB, pregnant women, children over one year of age and patients with an unknown or positive tuberculin skin test (TST).
4. Adults and adolescents with HIV who have been screened with a clinical algorithm for TB and who report any current cough, fever, weight loss or night sweats, may have active TB and should be evaluated for TB and other diseases.

Decreasing the burden of TB in people living with HIV also relies on incorporating TB infection control measures aimed at minimizing the risk of TB transmission. This forms the foundation of early, rapid diagnosis and proper management of TB patients.

Adaptation of these recommendations by the GWG will require consideration of a number of elements in order to establish mechanisms for co-located TB and HIV service delivery. These include the local epidemiology of TB and HIV, the way in which TB and HIV care is currently provided and managed, knowledge of TB and HIV among health workers, the supply chain for TB and HIV commodities, and overall implementation costs. A simple model for estimating the costs associated with implementing these TB/HIV recommendations is being developed by WHO. The model suggests that early antiretroviral therapy and IPT are both highly cost-effective interventions.

The GWG should identify local examples of successful TB/HIV service integration and determine how best to scale these up. Box 18 shows how one programme in South Africa linked TB and HIV services to develop an integrated service delivery model, and Case

Study 9 showcases the results of a pilot programme to integrate monitoring and evaluation for TB and HIV in Malawi.

### Box 18 Integrated TB/HIV service delivery

The integration of TB and HIV services at Ubuntu clinic, in South Africa, began in 2003 and has improved the efficiency of service delivery for both conditions. Integration has resulted in increased rates of HIV testing among TB clients (from <50% to 97%), earlier diagnosis of TB in patients with HIV and improved adherence to both TB and HIV regimens (with an increase in TB cure rates from 26% to 67%). This was accomplished by implementing a series of changes to the existing service delivery model.

- Prioritizing HIV counselling and testing for all new TB cases not recently tested.
- Building staff capacity to manage both TB and HIV.
- Training district TB nurses in HIV staging and management.
- Integrating TB and HIV health information systems.
- Refocusing the adherence support model for TB treatment to a more patient-centred model in which TB patients are:
  - educated about their medications;
  - educated about the long-term commitment required for treatment;
  - provided with easy-to-read materials;
  - linked to support groups;
  - offered the option of weekly drug supplies for demonstrated adherence.

Over four years, the model has proved very successful and is highly rated by both staff and clients. Integrated and context-sensitive models of TB and HIV care can contain and reverse the evolution of the dual TB/HIV epidemic in the southern Africa region. Integration of TB and HIV services at the primary health care level has proven successful.

For more information:

*Report on the Integration of TB and HIV Services in Ubuntu clinic (Site B), Khayelitsha.*  
<http://www.msf.org.za/docs/Khayelitsha%20TB-HIV%20Report%20November%202007.pdf>.

## 2.10 Addressing human resources

In the countries hit hardest by HIV, human resources are severely limited in the public health system – especially within maternal and child health services and at the primary care level. Without addressing these constraints, it will be difficult to scale up services, integrate HIV into the health system and decentralize HIV treatment and care. Human resource issues must be tackled in innovative ways, in order to expand the number of providers without incurring a large increase in costs.

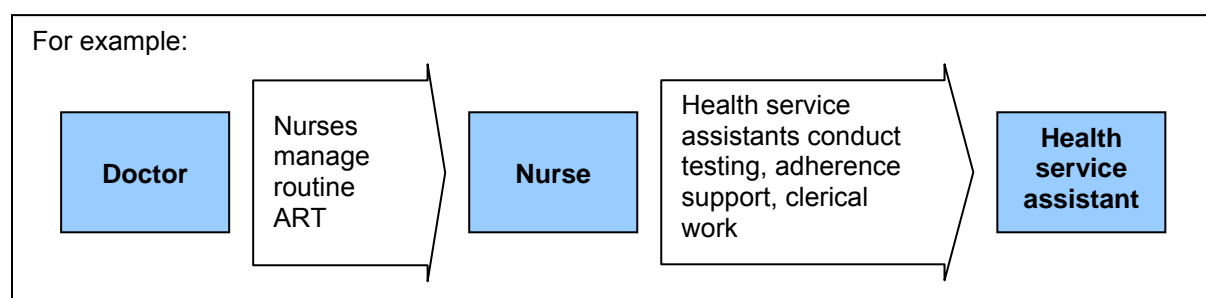
While many innovations exist, one approach is to redistribute clinical tasks among health workers in order to better use staff and reduce the workload for physicians who often become a bottleneck for patient flow or, in other scenarios, to fill the gap where there are no physicians to prescribe medications. Another model involves people living with HIV in the

provision of care as ‘expert clients (or patients)’. These two approaches, task shifting and expert patients, are summarized in Boxes 19 and 20.

### Box 19 Task shifting to improve services for HIV

The HIV epidemic has intensified the crisis in human resources for health, especially in sub-Saharan Africa. Task shifting or task sharing is one way of addressing this crisis, and involves the rational redistribution of clinical tasks and responsibilities in order to streamline services, while maintaining high standards of quality. Most commonly, task shifting involves transferring work from physicians to nurses and from nursing staff to lower-level health workers. More innovative approaches to task shifting are now extending beyond traditional health-care providers and increasingly involving people living with HIV as health service assistants, sometimes called expert clients.

Examples include:



Task shifting in the context of the new guidelines facilitates decentralization of HIV services, thereby increasing access to treatment and prevention. Task shifting builds confidence and capacity in health providers and allows communities to get involved in their own care.

#### Challenges include:

- adequate training;
- agreement to take on new roles;
- ongoing support and mentoring;
- compensation for new responsibilities;
- regulatory/legal issues;
- integration of new members and roles into existing health-care teams;
- maintaining quality of care.

For more information:

Callaghan M, Ford N, Schneider H. A systematic review of task-shifting for HIV treatment and care in Africa. *Human Resources for Health*, 2010, 8:8.

Selke HM et al. Task-shifting of antiretroviral delivery from health care workers to persons living with HIV/AIDS: clinical outcomes of a community-based program in Kenya. *Journal of Acquired Immune Deficiency Syndromes*, 2010, 55(4):483–90.

PlusNews. Mozambique: task-shifting brings rapid scale-up of ART rollout. 30 October 2009 (<http://www.plusnews.org/report.aspx?ReportId=86813>, accessed 10 April 2011).

WHO, PEPFAR, UNAIDS. *Task shifting: rational redistribution of tasks among health workforce teams: global recommendations and guidelines*. Geneva, World Health Organization, 2007 ([http://www.who.int/healthsystems/task\\_shifting/en/](http://www.who.int/healthsystems/task_shifting/en/), accessed 10 April 2011).

## Box 20 Expert patients in paediatric HIV clinics

Paediatric AIDS Treatment for Africa (PATA) is a non-profit organization that supports 'expert patients' (EPs) in 47 paediatric HIV clinics across 14 countries in sub-Saharan Africa. This programme was initiated to address the severe human resource crisis affecting HIV care and treatment clinics in sub-Saharan Africa. The objectives were to:

1. **reassign less technical tasks** to expert patients and reduce the burden on overworked health-care workers;
2. **involve community members** in the clinics, enabling community outreach;
3. **provide employment**, training and a small financial income for unemployed people living and working with HIV/AIDS.

PATA's programme currently employs 202 expert patients, who perform a range of functions.

Clinic tasks	Counselling	Education	Outreach
Triage and patient flow	Counsel patients on testing and adherence	Conduct patient training sessions on nutrition, adherence, infant feeding, etc.	Undertake home visits
Anthropometric assessments	Lead support groups		Outreach for cases lost to follow-up
Pharmacy assistants	Serve as treatment buddies		Gardening demonstrations
Translation			
Supervise children in play areas			

The key lessons learned from PATA's experience include:

- The energy and passion of people living with HIV can be a very valuable resource for service delivery.
- The success of an expert patient programme is often determined by the attitude of the clinic staff. When expert patient support is requested by clinic staff rather than imposed on them, expert patients are more likely to be accepted.
- Expert patients should be paid and recognized as valuable members of the clinical team.
- Expert patients empower patients and allow clinicians to access local knowledge systems by serving as 'cultural brokers'.
- Selection criteria for expert patients, e.g. education level or demonstrated adherence, should be clearly defined.
- Expert patients should receive a structured training, as well as ongoing mentoring by clinic staff.

For more information:

PATA Projects - Mexico World Aids Conference. ([http://www.teampata.org/project\\_mexicoworldaidsconf.asp](http://www.teampata.org/project_mexicoworldaidsconf.asp), accessed 10 April 2011).

One type of task shifting that has proven especially successful is nurse initiation and management of antiretroviral therapy (NIM-ART). A number of examples in several countries have demonstrated that NIM-ART delivers high quality care to significantly more patients (see Box 21).

Case Study 6 provides a case study from a large NIM-ART programme in Lesotho that shows that patient enrolment for adults and children doubled over the course of three years without any increase in the total amount of human resources. In Swaziland, nurses have been trained to initiate ART and manage patients in primary and secondary settings using adapted IMAI training tools. Their experience is highlighted in Case Study 10).

### **Box 21 Nurse initiation and management of ART**

In areas of high HIV prevalence where resources are constrained, the health-care workforce is often limited and not enough doctors are available to provide antiretroviral therapy to all those in need. Add to this the earlier initiation of antiretroviral therapy and the health systems are stretched beyond capacity to provide services. Innovative approaches to the provision of HIV-related treatment and care are needed in order to achieve treatment targets.

One such approach that several countries are turning to is 'nurse initiation and management of antiretroviral therapy' (NIM-ART), that is, nurses are trained to prescribe and manage patients on antiretroviral therapy.

The concept requires focused capacity building and coordination within the existing health system. Nurses must be willing to accept the additional workload and responsibility. A careful plan to roll out the approach and incrementally scale it up is essential, as a rapid and disjointed expansion may not be successful. Effective training and ongoing support are needed to boost confidence.

Where NIM-ART has been realistically initiated and scaled up, more HIV-infected people are enrolled on antiretroviral therapy earlier, HIV mortality rates decrease, retention on treatment increases, and nurses are satisfied.

For more information:

Sanne I et al. Nurse versus doctor management of HIV-infected patients receiving antiretroviral therapy (CIPRA-SA): a randomised non-inferiority trial. *The Lancet*, 2010, 376(9734):33–40.

Bemelmans M et al. Providing universal access to antiretroviral therapy in Thyolo, Malawi through task shifting and decentralization of HIV/AIDS care. *Tropical Medicine and International Health*, 2010, 15(12):141.

Shumbusho F et al. Task shifting for scale-up of HIV care: evaluation of nurse-centered antiretroviral treatment at rural health centers in Rwanda. *PLoS Medicine*, 2009, 6(10):e1000163.

## **2.11 Scaling up paediatric care and treatment**

The 2010 paediatric guidelines call for an aggressive approach to the care and treatment of HIV-exposed and HIV-infected children. New recommendations advocate that, in countries with a generalized epidemic, all infants with unknown HIV exposure should ideally have their exposure status established at birth, or at least by 4–6 weeks of age (or otherwise as early as possible). Furthermore, infants found to be HIV-exposed should receive a virologic test to determine if they are HIV-infected and all HIV-infected children under two years of age should be started on antiretroviral therapy irrespective of clinical or immune status. Implementing these recommendations would markedly reduce the very high mortality among young children with HIV and, in those countries where HIV is a major driver of overall under-five mortality, improved coverage of paediatric HIV services would also contribute to the achievement of MDG 4. If HIV investments were designed so that they improved general child health services, this would be important in achieving the MDGs.



centres. Recent experience with using dried blood spot collection and courier services to transport samples to a central laboratory has shown that it is feasible to deliver a national service with a relatively small number of laboratories.

For infants and children who need antiretroviral therapy, there have always been fewer therapeutic options than for adults and poorer access because of the complex nature of antiretroviral dosing using syrups. However, a range of child-friendly fixed-dose combinations (FDCs) have recently been developed that make it easier to prescribe and administer antiretroviral therapy and that are considerably cheaper to procure and transport than syrup formulations (see Box 23).

**Box 23 Switching to fixed-dose combinations (FDCs)**

Replacing syrups with fixed-dose combinations (FDCs) for paediatric HIV/AIDS patients is important in optimizing treatment regimens. FDCs have many advantages over syrups.

**1. Simplifying administration**

With two or three drugs in one pill, FDCs decrease the number of products required to treat paediatric patients, decrease the risk of dosing inaccuracies that result from measurement errors of individual syrups and increase compliance. FDC formulations are crushable or dispersible, and can be given to infants and children of all ages and weights through mixing with food or water.

**2. Reducing cost**

FDCs are cheaper than syrups. It is estimated that switching to FDCs can reduce ART budgets by 25–60%. In resource-poor settings, this cost saving can have a significant impact on the number of people accessing treatment.

**3. Easier to manage**

Storage and transportation of FDCs is easier than with syrups because one pack of FDC tablets is much smaller and lighter than the equivalent six or seven syrup bottles that would be required to make up the regimen.

**4. High quality and readily accessible**

All the FDC formulations available for paediatric ART are WHO prequalified and/or FDA approved and can be procured using both GFATM and PEPFAR funds.

Formulation	Dose	Supplier	Regulatory status
d4T+3TC+NVP	6/30/50 mg 12/60/100 mg	Cipla Cipla	WHO prequalified and USFDA approved
d4T+3TC	6/30 mg 12/60 mg	Cipla Cipla	USFDA approved
AZT+3TC	60/30 mg	Matrix Aurobindo	WHO prequalified USFDA approved
AZT+3TC+NVP	60/30/50 mg	Matrix	USFDA approved
ABC+3TC	60/30 mg	Aurobindo Matrix	USFDA approved WHO prequalified

With the exception of regimens containing didanosine (ddl), all of the recommended NRTI combinations for first- and second-line therapy in children are now available in fixed-dose combination preparations. Moreover, fixed-dose combination dosing is **weight-band** based



## ADDITIONAL RESOURCES

### Adaptation guides and resources

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World Health Organization. *Introducing WHO's reproductive health guidelines and tools into national programmes: principles and processes of adaptation and implementation*. Geneva, 2007.

World Health Organization. *IMAI national planning/adaptation guide*. For more information, contact [imaimail@who.int](mailto:imaimail@who.int)

Elizabeth Glaser Pediatric AIDS Foundation. *WHO phase 1 toolkit: understanding the revised WHO recommendations and supporting their adaptation into national guidelines*. ([http://www.pedaids.org/Publications/Toolkits#WHO\\_Phase\\_1\\_Toolkit](http://www.pedaids.org/Publications/Toolkits#WHO_Phase_1_Toolkit), accessed 10 April 2011).

Elizabeth Glaser Pediatric AIDS Foundation. *WHO phase 2 toolkit: program, district and facility-level planning for implementation of the 2010 revised WHO guidelines*. ([http://www.pedaids.org/Publications/Toolkits#WHO\\_Phase\\_2\\_Toolkit](http://www.pedaids.org/Publications/Toolkits#WHO_Phase_2_Toolkit), accessed 10 April 2011).

International Center for AIDS Care and Treatment Programs. *Final meeting report: third annual PMTCT.Pediatrics meeting*. Columbia University Mailman School of Public Health. (<http://www.columbia-icap.org/resources/pmtct/PMTCT.PEDS%20Meeting%202010.Final%20Report.pdf>, accessed 5 July 2011).

### Guidance on programme design and management

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Helfenbein S, Severo CA. *Scaling up HIV/AIDS programs: a manual for multisectoral planning*. Management Sciences for Health, 2004. (<http://www.msh.org/resource-center/scaling-up-hiv-aids-programs.cfm>, accessed 10 April 2011).

*HIV programme planning and management*. Geneva, World Health Organization, 2011 (<http://www.who.int/hiv/topics/ppm/en/index.html>, accessed 10 April 2011).

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- label, randomised phase 2/3 trial. *The Lancet Infectious Diseases*, 2011, 11(4):273–283.
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## ANNEXES

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## Annex 1 Sample declaration of interests form (WHO, 2010)

WHO's work on global health issues requires the assistance of external experts who **may have interests related to their expertise**. To ensure the highest integrity and public confidence in its activities, WHO requires that experts serving in an advisory role disclose any circumstances that could give rise to a potential conflict of interest related to the subject of the activity in which they will be involved.

All experts serving in an advisory role must disclose any circumstances that could represent a **potential conflict of interest** (i.e. any interest that may affect, or may reasonably be perceived to affect, the expert's objectivity and independence). You must disclose on this Declaration of Interest (DOI) form any financial, professional or other interest relevant to the subject of the work or meeting in which you have been asked to participate in or contribute towards and any interest that could be affected by the outcome of the meeting or work. You must also declare relevant interests of your immediate family members (see definition below) and, if you are aware of it, relevant interests of other parties with whom you have substantial common interests and which may be perceived as unduly influencing your judgement (e.g. employer, close professional associates, administrative unit or department).

Please complete this form and submit it to WHO Secretariat if possible at least four weeks but no later than two weeks before the meeting or work. You must also promptly inform the Secretariat if there is any change in this information prior to, or during the course of, the meeting or work. All experts must complete this form before participation in a WHO activity can be confirmed.

Answering "Yes" to a question on this form does not automatically disqualify you or limit your participation in a WHO activity. Your answers will be reviewed by the Secretariat to determine whether you have a conflict of interest relevant to the subject at hand. One of the outcomes listed in the next paragraph can occur depending on the circumstances (e.g. nature and magnitude of the interest, timeframe and duration of the interest).

The Secretariat may conclude that no potential conflict exists or that the interest is irrelevant or insignificant. If, however, a declared interest is determined to be potentially or clearly significant, one or more of the following three measures for managing the conflict of interest may be applied. The Secretariat: (i) allows full participation, with public disclosure of your interest; (ii) mandates partial exclusion (i.e. you will be excluded from that portion of the meeting or work related to the declared interest and from the corresponding decision-making process); or (iii) mandates total exclusion (i.e. you will not be able to participate in any part of the meeting or work).

All potentially significant interests will be **disclosed** to the other participants at the start of the activity and you will be asked if there have been any changes. A summary of all declarations and actions taken to manage any declared interests will be **published** in resulting reports and work products. Furthermore, if the objectivity of the work or meeting in which you are involved is subsequently questioned, the contents of your DOI form may be made available by the Secretariat to persons outside WHO if the Director-General considers such disclosure to be in the best interest of the Organization, after consulting with you. Completing this DOI form means that you agree to these conditions.

If you are unable or unwilling to disclose the details of an interest that may pose a real or perceived conflict, you must disclose that a conflict of interest may exist and the Secretariat may decide that you be totally recused from the meeting or work concerned, after consulting with you.

Name:  
Institution:  
Email:

**Date and title of meeting or work, including description of subject matter to be considered (if a number of substances or processes are to be evaluated, a list should be attached by the organizer of the activity):**

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*Please answer each of the questions below. If the answer to any of the questions is "yes", briefly describe the circumstances on the last page of the form.*

*The term "you" refers to yourself and your immediate family members (i.e., spouse (or partner with whom you have a similar close personal relationship) and your children). "Commercial entity" includes any commercial business, an industry association, research institution or other enterprise whose funding is significantly derived from commercial sources with an interest related to the subject of the meeting or work. "Organization" includes a governmental, international or non-profit organization. "Meeting" includes a series or cycle of meetings.*

### **EMPLOYMENT AND CONSULTING**

Within the past four years, have you received remuneration from a commercial entity or other organization with an interest related to the subject of the meeting or work?

- 1a Employment Yes  No
- 1b Consulting, including service as a technical or other adviser Yes  No

### **RESEARCH SUPPORT**

Within the past four years, have you or has your research unit received support from a commercial entity or other organization with an interest related to the subject of the meeting or work?

- 2a Research support, including grants, collaborations, sponsorships, and other funding Yes  No
- 2b Non-monetary support valued at more than US\$ 1000 overall (include equipment, facilities, research assistants, paid travel to meetings, etc.) Yes  No
- Support (including honoraria) for being on a speakers bureau, giving speeches or training for a commercial entity or other organization with an interest related to the subject of the meeting or work?

### **INVESTMENT INTERESTS**

Do you have current investments (valued at more than US\$ 10 000 overall) in a commercial entity with an interest related to the subject of the meeting or work? Please also include indirect investments such as a trust or holding company. You may exclude mutual funds, pension funds or similar investments that are broadly diversified and on which you exercise no control.

- 3a Stocks, bonds, stock options, other securities (e.g., short sales) Yes  No
- 3b Commercial business interests (e.g., proprietorships, partnerships, joint ventures, board memberships, controlling interest in a company) Yes  No

### INTELLECTUAL PROPERTY

Do you have any intellectual property rights that might be enhanced or diminished by the outcome of the meeting or work?

- 4a Patents, trademarks, or copyrights (including pending applications) Yes  No
- 4b Proprietary know-how in a substance, technology or process Yes  No

### PUBLIC STATEMENTS AND POSITIONS (during the past three years)

- 5a As part of a regulatory, legislative or judicial process, have you provided an expert opinion or testimony, related to the subject of the meeting or work, for a commercial entity or other organization? Yes  No
- 5b Have you held an office or other position, paid or unpaid, where you represented interests or defended a position related to the subject of the meeting or work? Yes  No

### ADDITIONAL INFORMATION

- 6a If not already disclosed above, have you worked for the competitor of a product that is the subject of the meeting or work, or will your participation in the meeting or work enable you to obtain access to a competitor's confidential proprietary information, or create for you a personal, professional, financial or business competitive advantage? Yes  No
- 6b To your knowledge, would the outcome of the meeting or work benefit or adversely affect interests of others with whom you have substantial common personal, professional, financial or business interests (such as your adult children or siblings, close professional colleagues, administrative unit or department)? Yes  No
- 6c Excluding WHO, has any person or entity paid or contributed towards your travel costs in connection with this WHO meeting or work? Yes  No
- 6d Have you received any payments (other than for travel costs) or honoraria for speaking publicly on the subject of this WHO meeting or work? Yes  No
- 6e Is there any other aspect of your background or present circumstances not addressed above that might be perceived as affecting your objectivity or independence? Yes  No

7. **TOBACCO OR TOBACCO PRODUCTS** (answer without regard to relevance to the subject of the meeting or work) Yes  No

Within the past four years, have you had employment or received research support or other funding from, or had any other professional relationship with, an entity directly involved in the production, manufacture, distribution or sale of tobacco or tobacco products or representing the interests of any such entity?

EXPLANATION OF "YES" RESPONSES: If the answer to any of the above questions is "yes", check above and briefly describe the circumstances on this page. If you do not describe the nature of an interest or if you do not provide the amount or value involved where relevant, the conflict will be assumed to be significant.

<b>Nos. 1–4:</b> <b>Type of interest, question number and category (e.g., Intellectual Property 4.a copyrights) and basic descriptive details.</b>	<b>Name of company, organization, or institution</b>	<b>Belongs to you, a family member, employer, research unit or other?</b>	<b>Amount of income or value of interest (if not disclosed, is assumed to be significant)</b>	<b>Current interest (or year ceased)</b>
<b>Nos. 5–6: Describe the subject, specific circumstances, parties involved, timeframe and other relevant details</b>				

CONSENT TO DISCLOSURE. By completing and signing this form, you consent to the disclosure of any relevant conflicts to other meeting participants and in the resulting report or work product.

**DECLARATION.** I hereby declare on my honour that the disclosed information is true and complete to the best of my knowledge.

Should there be any change to the above information, I will promptly notify the responsible staff of WHO and complete a new declaration of interest form that describes the changes. This includes any change that occurs before or during the meeting or work itself and through the period up to the publication of the final results or completion of the activity concerned.

Date: \_\_\_\_\_

Signature \_\_\_\_\_

Source: Reproduced from form WHO 850 E LEG (16/06/2010)

## Annex 2 Suggested approach for a situation analysis and feasibility assessment for antiretroviral therapy in adults and adolescents

An analysis of current antiretroviral therapy (ART) services across the country will assist the Guideline Working Group as they determine priorities and make choices about updating guidelines for antiretroviral therapy in adults and adolescents.

The feasibility assessment is linked to the situation analysis and determines the feasibility of implementing new antiretroviral therapy recommendations, in particular to assess the ability of health systems and laboratory services to adapt to changes.

The Table A-1 lists some of the key questions to consider when conducting a situation analysis and feasibility assessment for the provision of antiretroviral therapy to adults and adolescents. These illustrative questions focus specifically on antiretroviral therapy service delivery and complement the more general thematic areas for situation analysis and feasibility assessment, which are described in Steps 3 and 4 in section 1.2 *Components in the generic process of national adaptation*.

**Table A-1 Situation analysis and feasibility assessment tool for antiretroviral therapy (ART) in children, adults and adolescents**

Elements	Considerations: Situation analysis considerations	Considerations: Feasibility assessment
ART coverage	<ul style="list-style-type: none"> <li>• What are the current levels of ART coverage?</li> <li>• How successful have present efforts been at reaching those in need at current CD4 count thresholds?</li> </ul>	<ul style="list-style-type: none"> <li>• What are the projected levels of ART coverage?</li> <li>• How will the new recommendations impact the national treatment targets?</li> </ul>
Specific populations	<ul style="list-style-type: none"> <li>• Does the current treatment and care programme serve the needs of specific populations (pregnant women, infants, people co-infected with TB or hepatitis, injecting drug users, men who have sex with men or sex workers)?</li> </ul>	<ul style="list-style-type: none"> <li>• What will be the effect of a new recommendation on treatment and care of specific populations (pregnant women, people co-infected with TB or hepatitis, injecting drug users, men who have sex with men or sex workers)?</li> <li>• Will changes have unintended effects on specific populations?</li> <li>• Could prioritizing specific populations help phase-in changes?</li> <li>• How can equity be ensured?</li> </ul>

Elements	Considerations: Situation analysis considerations	Considerations: Feasibility assessment
New CD4 eligibility criteria	<ul style="list-style-type: none"> <li>• What is the availability of CD4 testing in the country?</li> </ul>	<ul style="list-style-type: none"> <li>• How many additional individuals will be eligible for ART under new CD4 eligibility criteria?</li> <li>• What is the scale of the likely increase in demand for ART?</li> </ul>
Laboratory capacity	<ul style="list-style-type: none"> <li>• Does the current laboratory capacity meet the current needs?</li> <li>• Are laboratory services decentralized?</li> <li>• Does the current laboratory supply chain system function effectively?</li> <li>• Does the current laboratory budget support the requirements of laboratory services?</li> <li>• Is there capacity for infant diagnosis in the national programme?</li> </ul>	<ul style="list-style-type: none"> <li>• What are the projected laboratory needs and will the current number of laboratories be sufficient?</li> <li>• What can be done to make laboratory services more efficient?</li> <li>• Should laboratory services be decentralized?</li> <li>• Will new infrastructure be required?</li> <li>• Is it possible to use existing laboratory systems linked to sample transport?</li> <li>• Will the laboratory supply chain system need to change?</li> <li>• Will new personnel be required?</li> <li>• Will changes in recommendations require new technologies?</li> <li>• How will changes impact laboratory budgets?</li> </ul>
ART delivery site capacity	<ul style="list-style-type: none"> <li>• Are there ART waiting lists?</li> <li>• Is the current infrastructure satisfactory?</li> <li>• Are there enough trained personnel?</li> <li>• Are there enough sites trained in paediatric care and treatment?</li> <li>• Do nurses initiate and maintain patients on ART, including adults and children?</li> <li>• Do lower level sites initiate and maintain patients on ART?</li> </ul>	<ul style="list-style-type: none"> <li>• What are the site level projections for the proposed recommendations?</li> <li>• Will new infrastructure be required?</li> <li>• Will new personnel be required?</li> <li>• What will be needed for lower level sites to initiate and maintain patients on ART beyond what is currently being done?</li> <li>• What resources might be needed to help health-care workers cope with an increased workload?</li> <li>• What level of integration of ART into primary care is achievable?</li> </ul>

Elements	Considerations: Situation analysis considerations	Considerations: Feasibility assessment
ARV procurement, storage and delivery	<ul style="list-style-type: none"> <li>• What is the mechanism for procurement and supply of ARVs?</li> <li>• Are fixed-dose combinations for adults and children procured and recommended?</li> <li>• Are measures in place to prevent occurrence of stock-outs?</li> </ul>	<ul style="list-style-type: none"> <li>• Are all the proposed new ARVs registered in the country?</li> <li>• Are there identified national or international producers of the new ARVs?</li> <li>• Are there opportunities to reduce costs using generic suppliers or fixed-dose combinations?</li> <li>• Are additional measures needed to prevent occurrence of stock-outs?</li> </ul>
Training	<ul style="list-style-type: none"> <li>• Are current health-care workers adequately trained for the work they doing?</li> <li>• What tools are currently used for training?</li> <li>• Are there opportunities to link with other HIV training programmes?</li> </ul>	<ul style="list-style-type: none"> <li>• What additional training is required and among what cadres of health-care workers?</li> <li>• Are there opportunities to train across multiple areas and maximize efficiency?</li> <li>• Are updated versions of the training tools available?</li> <li>• What are the best local models for training in HIV care and treatment?</li> </ul>
Costs	<ul style="list-style-type: none"> <li>• What are the costs of providing ART per patient per year in adults and children?</li> </ul>	<ul style="list-style-type: none"> <li>• What are the anticipated net costs resulting from proposed guideline changes (e.g. increased initial programme costs but decreased costs due to fewer hospitalizations)?</li> <li>• Which guideline components will cost the least and provide the greatest health benefit?</li> <li>• Could changes to procurement patterns lead to cost reductions (through economies of scale)?</li> </ul>
Financial resources	<ul style="list-style-type: none"> <li>• Does the current budget meet current costs?</li> <li>• Are current funding streams secure?</li> </ul>	<ul style="list-style-type: none"> <li>• Does the current budget meet the projected increases due to guideline changes? If not, how could guideline components be phased to control costs?</li> <li>• Are current funding streams sustainable?</li> <li>• Is there a national strategy to secure additional sources of funding for new programmes and services?</li> </ul>
Key stakeholders	<ul style="list-style-type: none"> <li>• Are people living with HIV, health-care workers, nongovernmental organizations, civil society, and government involved in decision-making for HIV and related programmes?</li> </ul>	<ul style="list-style-type: none"> <li>• Are the proposed changes acceptable to all stakeholders?</li> <li>• Is there support from key stakeholders for implementing changes?</li> </ul>

<b>Elements</b>	<b>Considerations: Situation analysis considerations</b>	<b>Considerations: Feasibility assessment</b>
Sustainability	<ul style="list-style-type: none"> <li>• What elements of the current ART programmes are sustainable?</li> </ul>	<ul style="list-style-type: none"> <li>• What is the likelihood that the proposed changes in recommendations can be implemented?</li> <li>• Will these changes be sustainable over time?</li> </ul>
Health systems	<ul style="list-style-type: none"> <li>• To what extent are ARV treatment and care interventions currently integrated with other services in the health-care system?</li> </ul>	<ul style="list-style-type: none"> <li>• What are the potential effects of guideline changes on national and local health systems?</li> <li>• Would changes help strengthen the existing health system or could they divert resources from or compromise the performance of existing programmes?</li> <li>• How will changes impact other health priorities (e.g. TB, viral hepatitis, maternal and child health)?</li> </ul>

### Annex 3 Suggested approach for a situation analysis and feasibility assessment for prevention of mother-to-child transmission programmes

An analysis of current maternal and child health and prevention of mother-to-child transmission of HIV (PMTCT) services will assist the Guideline Working Group as they determine priorities and make choices about updating antiretroviral-based prevention of mother-to-child transmission recommendations. Because pregnant women may access prevention of mother-to-child transmission-related services in a variety of health-care settings, not limited to antenatal clinics, this assessment should consider issues of access and delivery of antenatal and child health-care services, the status of current prevention of mother-to-child transmission policies and implementation, infant feeding policies and practices, costing and funding streams, and laboratory capacity to deliver prevention of mother-to-child transmission services.

The feasibility assessment is linked to the situation analysis and determines the feasibility of implementing new prevention of mother-to-child transmission recommendations, in particular to assess the ability of health and laboratory systems to adapt to changes.

Table A-2 suggests some of the key questions to consider when conducting a situation analysis and feasibility assessment for the provision of prevention of mother-to-child transmission of HIV services. These illustrative questions focus specifically on prevention of mother-to-child transmission and complement the more general theme areas for situation analysis and feasibility assessment, which are described in Steps 3 and 4 in section 1.2 *Components in the generic process of national adaptation*.

**Table A-2 Situation analysis and feasibility assessment tool for prevention of mother-to-child transmission (PMTCT)**

Elements	Considerations: Situation analysis considerations	Considerations: Feasibility assessment
PMTCT guidelines	<ul style="list-style-type: none"> <li>• Do national PMTCT guidelines exist? If so, when were they last revised?</li> <li>• What was the adaptation and implementation process used for developing the existing guidelines? What were the lessons learned from this process?</li> </ul>	<ul style="list-style-type: none"> <li>• What will be the process for updating existing PMTCT guidelines or writing new ones?</li> <li>• How will new guidelines be disseminated?</li> </ul>

Elements	Considerations: Situation analysis considerations	Considerations: Feasibility assessment
Current PMTCT recommendations and practice	<ul style="list-style-type: none"> <li>• What are current ART eligibility criteria for HIV-infected pregnant women? What are the current recommended ART regimens?</li> <li>• What is the current recommended ARV prophylaxis for women who do not require ART for their own health?</li> </ul>	<ul style="list-style-type: none"> <li>• What is different between the existing recommendations and the proposed new recommendations?</li> </ul>
HIV testing policy in pregnant women	<ul style="list-style-type: none"> <li>• What is the national policy for HIV testing of pregnant women?</li> <li>• Is routine HIV provider-initiated testing and counselling currently recommended for all pregnant women?</li> <li>• What is the uptake of HIV testing and counselling among pregnant women?</li> </ul>	<ul style="list-style-type: none"> <li>• How does the current policy need to change in order to implement new recommendations?</li> <li>• How will new policy recommendations on testing in ANC and labour wards be communicated to clinicians?</li> </ul>
Antenatal services	<ul style="list-style-type: none"> <li>• What is the national rate of ANC coverage?</li> <li>• Where and when during pregnancy do women access antenatal services?</li> <li>• What delivery practices are used?</li> </ul>	<ul style="list-style-type: none"> <li>• How will these issues affect implementation of new recommendations?</li> </ul>
PMTCT coverage	<ul style="list-style-type: none"> <li>• Facility-based coverage: What proportion of health-care facilities currently provide PMTCT services? What do these services include and what cadres of health care staff are able to provide them?</li> <li>• Population-based coverage: What proportion of pregnant women is assessed for HIV? What is the percentage of HIV-infected pregnant women who are assessed for treatment eligibility? Of those who are eligible, what proportion receives ART?</li> </ul>	<ul style="list-style-type: none"> <li>• How would implementation of updated recommendations affect coverage?</li> <li>• How can maternal and child health services manage the added complexity of the updated recommendations?</li> </ul>
Infant feeding practices	<ul style="list-style-type: none"> <li>• What are the current national policies and practices on infant feeding and support for mothers, in general and in the context of HIV?</li> </ul>	<ul style="list-style-type: none"> <li>• How will these policies and practices impact implementation of changes?</li> <li>• How would implementation of updated PMTCT recommendations affect infant feeding practices?</li> </ul>
Infant/child health services	<ul style="list-style-type: none"> <li>• What is the coverage of routine infant/child health services, particularly in the first 12 months?</li> </ul>	<ul style="list-style-type: none"> <li>• Can current child health service sites monitor and manage the provision of extended infant ARV prophylaxis?</li> </ul>

Elements	Considerations: Situation analysis considerations	Considerations: Feasibility assessment
CD4 eligibility criteria	<ul style="list-style-type: none"> <li>• What are the current CD4 count criteria for eligibility for ART?</li> </ul>	<ul style="list-style-type: none"> <li>• How many additional pregnant women will be eligible for ART under the new CD4 eligibility criteria? (Global data indicate that ~40% of pregnant women diagnosed with HIV have CD4 counts <math>\leq 350</math> cells/mm<sup>3</sup>)</li> </ul>
Laboratory capacity	<ul style="list-style-type: none"> <li>• What laboratory services are available and adequately functioning at ANC sites?</li> <li>• What is the availability of CD4 testing at PMTCT/ANC sites?</li> </ul>	<ul style="list-style-type: none"> <li>• What additional laboratory capacity will be required to implement changes?</li> <li>• Will new laboratories and new personnel be required?</li> <li>• How will changes impact laboratory budgets?</li> </ul>
ARV/ART delivery site capacity	<ul style="list-style-type: none"> <li>• What services do current PMTCT/ANC sites, including lower level sites, offer in terms of ART initiation and maintenance?</li> <li>• What services do current PMTCT/ANC sites, including lower level sites, offer in terms of ARV prophylaxis options for PMTCT?</li> </ul>	<ul style="list-style-type: none"> <li>• How could the system provide follow-up of women on extended PMTCT prophylaxis for prevention of breast-milk transmission?</li> <li>• Can current PMTCT sites, including lower level sites, initiate and maintain ART?</li> <li>• Will new infrastructure or personnel be required?</li> <li>• What level of integration with ART sites is achievable?</li> </ul>
ARV procurement, storage and delivery	<ul style="list-style-type: none"> <li>• How are antiretroviral drugs for PMTCT and ART in pregnant women currently procured and supplied?</li> <li>• What systems or measures are in place to prevent stock-outs?</li> </ul>	<ul style="list-style-type: none"> <li>• Are the proposed new drugs for PMTCT and ART in pregnant women on the national drug formulary?</li> <li>• Have national or international producers been identified for the proposed ARVs?</li> <li>• Is the programme accessing the lowest prices and the best fixed-dose combination options for ARVs?</li> <li>• What changes might be needed to strengthen the supply chain and prevent stock-outs, especially at lower-level ANC sites?</li> </ul>
Costs	<ul style="list-style-type: none"> <li>• What is the current cost of drugs and commodities for PMTCT service delivery?</li> <li>• What are the costs of providing treatment to an HIV-infected infant/child?</li> <li>• What are the cost differences of Option A versus Option B for PMTCT?</li> </ul>	<ul style="list-style-type: none"> <li>• What are the anticipated net costs resulting from proposed guideline changes?</li> <li>• Which guideline components will cost the least and provide the greatest health benefit?</li> <li>• How do these costs compare with the current cost of providing care and treatment to an HIV-infected pregnant woman and an HIV-infected infant/child?</li> </ul>

Elements	Considerations: Situation analysis considerations	Considerations: Feasibility assessment
Financial resources	<ul style="list-style-type: none"> <li>• Does the current budget meet current costs?</li> <li>• Are current funding streams sustainable?</li> </ul>	<ul style="list-style-type: none"> <li>• Does the current budget meet projected increases due to guideline changes? If not, which guideline components should be implemented first?</li> <li>• Are current funding streams sustainable?</li> <li>• Is there a national strategy to secure additional sources of funding for new programmes and services?</li> </ul>
Key stakeholders	<ul style="list-style-type: none"> <li>• Are people living with HIV, health-care workers, nongovernmental organizations, civil society, and government involved in decision-making for both HIV and maternal and child health (and other pertinent) health programmes?</li> </ul>	<ul style="list-style-type: none"> <li>• Would the proposed changes be acceptable to people living with HIV, health-care workers, civil society and the ministry of health, including both HIV and maternal and child health programmes?</li> <li>• Is there support from key stakeholders for implementing changes?</li> </ul>
Integration and health systems	<ul style="list-style-type: none"> <li>• To what extent is the delivery of PMTCT interventions currently integrated between HIV and maternal and child health (and other) services?</li> </ul>	<ul style="list-style-type: none"> <li>• What are the potential effects of guidelines changes on national and local health systems?</li> <li>• Which changes will help strengthen existing health systems and which could divert resources from or compromise performance of existing programmes?</li> </ul>

## Annex 4 Risk–benefit analysis checklist

<b>Topic for analysis</b> [e.g. “When to start antiretroviral therapy”]
<b>The recommendations</b> [List the associated recommendations from the revised guidelines]
<b>Domains and considerations</b>
<b>Quality of evidence</b> [Describe key points about the evidence, determine if there is any uncertainty about the quality of the evidence and assign a level of quality (high, moderate, low, very low).]  [Note if there is <b>certainty</b> or <b>uncertainty</b> about the quality of evidence.]
<b>Risks/benefits</b> <b>Benefits</b> [List benefits] <b>Risks</b> [List risks]  [Note whether <b>benefits outweigh risks</b> or <b>risks outweigh benefits</b> .]
<b>Values and acceptability</b> <b>In favour</b> [List issues in favour] <b>Against</b> [List issues against]  [Note if there is <b>certainty</b> or <b>uncertainty</b> about the values and acceptability.]
<b>Cost</b> [Describe issues, key points]  [Note if there is <b>certainty</b> or <b>uncertainty</b> about cost issues]
<b>Feasibility</b> [Describe issues, key points] [Note if there is <b>certainty</b> or <b>uncertainty</b> as to the feasibility of the recommendations]
<b>Gaps, research needs, comments</b> [List any gaps in information or implementation planning, research needs, comments]
<b>Final comment</b> In developing these recommendations, the panel placed high value upon ... [Examples: <ul style="list-style-type: none"> <li>• ...the reduction of early mortality from HIV/TB co-infection.</li> <li>• ...addressing adherence, but have concerns as to the quality of evidence to support these recommendations.</li> <li>• ...keeping laboratory monitoring as simple and as cheap as possible without compromising clinical outcomes.]</li> </ul>

For an example of a completed risk–benefit analysis, see:

<http://www.who.int/hiv/topics/treatment/risk-benefit-analysis-when-to-start.pdf>.

## CASE STUDIES

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## Case study 1: Implications of early initiation of antiretroviral therapy, Malawi



**The challenge:** In Malawi, the epidemic is generalized, with an overall HIV prevalence around 12%, but it is now showing signs of stabilization. In 2009, 840 000 adults and 112 000 children were living with HIV, with an ART treatment coverage around 56%, based on CD4 cut-off at 250 cells/mm<sup>3</sup>. WHO revised the global antiretroviral treatment (ART) guidelines and is now recommending an earlier initiation of treatment, moving the CD4 cut-off to start ART to  $\leq 350$  cells/mm<sup>3</sup> for HIV-infected adults, adolescents and pregnant women. The introduction of an earlier start to ART will have programmatic implications for national HIV care and treatment scale-up, which need to be assessed.

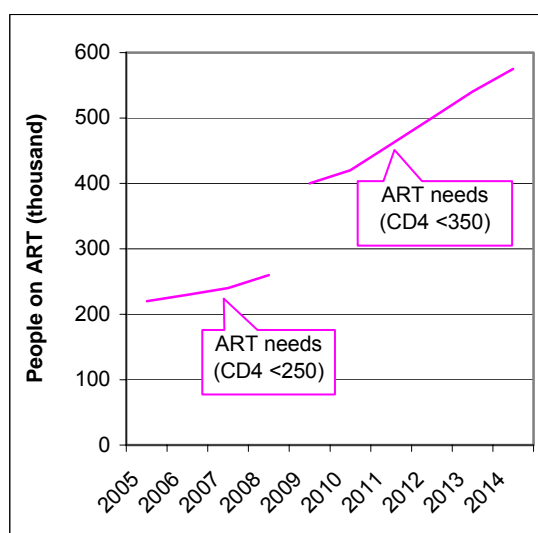
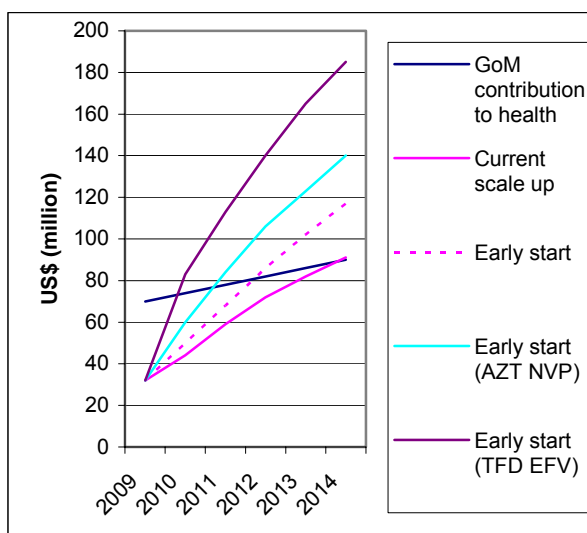
**The solution:** A feasibility appraisal of earlier initiation of ART was developed by the Ministry of Health with support from WHO. The appraisal included desk reviews of current policies and guidelines, ART scale up plans and financial and programmatic reports. Field visits were conducted in selected ART sites. Projections of patient numbers with earlier treatment initiation, based on different regimens were calculated. Estimates were made of the cost/resource implications up to 2014. A SWOT analysis was performed to determine the programmatic implications of earlier initiation.

**The results:** Using combined data from large ART clinics in Chiradzulu, Lilongwe and Thyolo, from patients with WHO clinical stage 2 and a CD4 cell count  $\leq 350$  cells/mm<sup>3</sup>, a 35–40% increase in patients eligible for ART will occur with earlier initiation on ART (see Figure A).

In terms of resource implications, an additional 200 health workforce personnel are estimated to be needed in 2010 and 780 (double the current workforce) by 2014. Cost modelling was conducted for the additional CD4 testing and ART required to implement the new initiation threshold. Assuming all known HIV-positive patients receive a CD4 test and based on a cost of US\$ 2 per test, 200 000 additional tests costing US\$ 400 000 would be required in one year.

This has cost/resource implications in terms of equipment, reagents and laboratory personnel (recruitment and training). Under current scale-up plans, ART costs will be US\$ 90 million by 2014. Earlier initiation is projected to increase drug costs by two to threefold, amounting to US\$ 200–300 million by 2014, depending on the regimen chosen (see Figure B).

In resource-constrained settings, countries should consider a rapid appraisal similar to this one in deciding which recommendations to adopt immediately, which to phase in and which to defer so that existing scale-up and access for those most in need are prioritized.



### Learn more:

Maida A with Schouten E, Njala J. *Feasibility of introducing revised global antiretroviral therapy guidelines for adults and adolescents in Malawi: review commissioned by the Ministry of Health with the support of WHO.*

[http://www.irinnews.org/pdf/who\\_feasibility\\_report\\_complete\\_amended\\_29thOct091.pdf](http://www.irinnews.org/pdf/who_feasibility_report_complete_amended_29thOct091.pdf); summary: [http://www.who.int/hiv/topics/treatment/Feasibility\\_in\\_Malawi.pdf](http://www.who.int/hiv/topics/treatment/Feasibility_in_Malawi.pdf).

## Case study 2: Phasing out the use of stavudine in first-line antiretroviral regimens, Uganda



**The challenge:** Following the recommendations of the 2006 WHO ART guidelines, the Ministry of Health, Uganda decided (in March 2008) to phase out the use of stavudine (d4T)-based regimens. By this time, a number of PEPFAR-supported antiretroviral therapy (ART) programmes, such as the Joint Clinical Research Centre, had already started to phase out d4T. However, the major challenge for the country was to organize a smooth transfer of large numbers of patients from d4T to zidovudine (AZT) and tenofovir (TDF)-based regimens, while avoiding wastage and depletion of other antiretroviral (ARV) regimens.

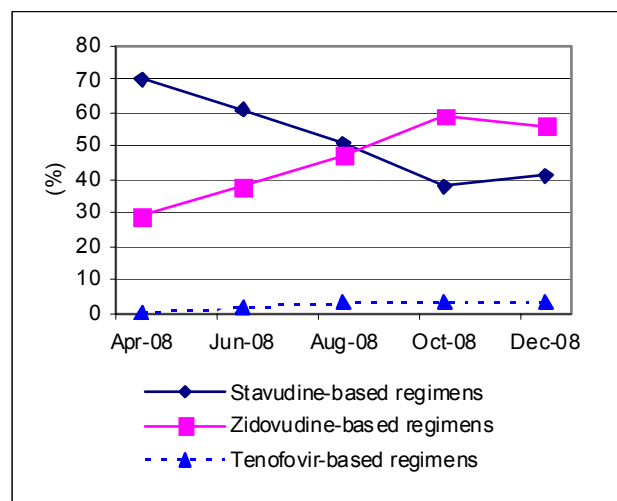
**The solution:** The phasing out of d4T involved a number of key steps:

1. Revision of the national ARV guidelines: The national ARV guidelines were revised to incorporate the 2006 WHO ARV recommendations. d4T regimens were changed from being the preferred first-line ARV regimen to become the second alternative for first-line therapy.
2. Revision of the national ARV quantification and procurement plan: The proportion of d4T regimens procured for adults and adolescents in the public sector ART programme was initially reduced from 85% to 50%, then to 15%.
3. Rapid dissemination of the revised guidelines: The Ministry of Health rapidly disseminated the revised guidelines and sent circulars to all implementing ART sites explaining the d4T phase-out. All patients initiating ART for the first time were to be started on AZT regimens while those already started on d4T regimens were to be changed to AZT regimens, unless they had anaemia. Those with anaemia were started on TDF regimens.
4. Support supervision for ART logistics management: Mentoring and supervision of ART sites with logistics problems was carried out to ensure smooth transfer of patients to new ART regimens.
5. Cessation of procurement of d4T-based regimens: The public sector ART programme stopped procuring d4T regimens as of 2010, other than for children less than five years of age.

**The results:** Since 2008, the number of patients treated with d4T regimens has dramatically reduced (see graph).

By August 2009, in the public sector, 31% of patients were on d4T regimens with 64% on AZT regimens and 5% on TDF regimens. Further by end of December 2009, only 18% were on d4T regimens while 66% were on AZT regimens and 17% on TDF regimens. In June 2010, only 5.3% of a total 237 070 patients on ART in the country were treated with d4T.

Some PEPFAR-funded partners are still procuring d4T regimens for a small number of adult patients who may not tolerate AZT regimens because they have anaemia and cannot start TDF regimens due to renal toxicity, and d4T regimens are still being procured for children less than five years of age (Triomune Junior and Baby – fixed-dose tablets). However, frequent stock-outs of the AZT regimens in some public health facilities forced some health workers to put patients back on Triomune, leading to the slowing down of the d4T phase-out. In some ART sites, patients who were responding well on Triomune initially resisted being changed to other regimens. The National Advisory Committee for Adult ART recently recommended that the country continue to procure a small amount of d4T regimens for the few patients who may not be able to tolerate AZT and TDF regimens, due to having both anaemia and renal insufficiency.



**Learn more:** Contact: Elizabeth Namagala and Norah Namuwenge, MoH Uganda.

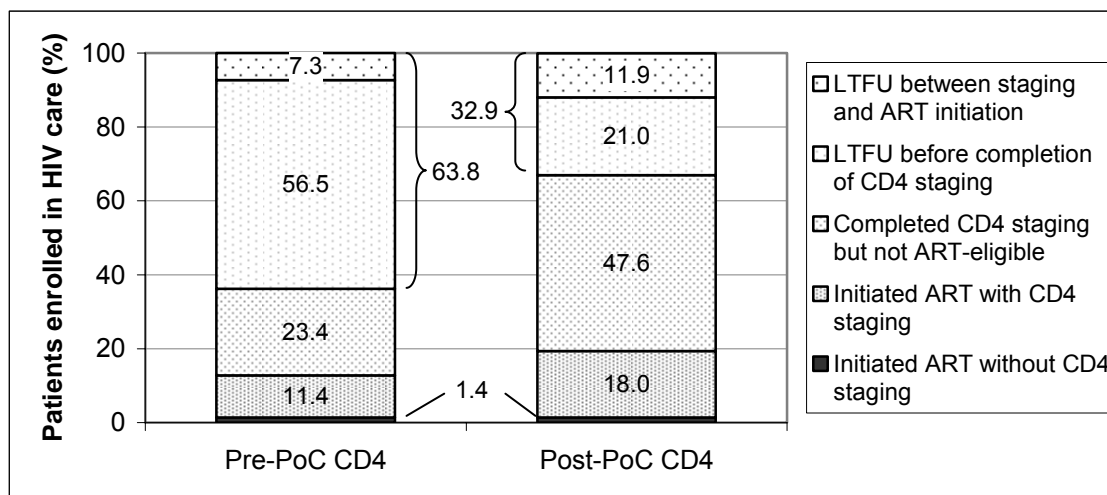
## Case study 3: Implementing point of care CD4 testing, Mozambique



**The challenge:** Delivery of CD4 testing services is hindered by the long distances between laboratories and many rural primary health clinics. Lack of access to CD4 testing affects the initial enrolment of HIV-positive patients, including pregnant women, onto ART. The construction of laboratories will take time and is expensive. New approaches to providing CD4 tests are therefore needed. Recent studies demonstrated that patient loss-to-follow-up (LTFU) before ART initiation is as high as 50%. The majority of this loss occurs between HIV diagnosis and CD4 staging and may be related to the time required to send samples for testing in laboratories. The ability to conduct CD4 testing on-site may help reduce this rate of loss, increase enrolment rates and improve the efficiency of service delivery.

**The solution:** Point-of-care CD4 (PoC CD4) technologies have recently become available. To evaluate their impact, the Alere PIMA point-of-care CD4 device was implemented at selected primary health clinics in the southern Maputo and central Sofala provinces of Mozambique. The test was used for immunological staging of all patients diagnosed as HIV-positive and enrolling into HIV care. Data were collected retrospectively from clinic records and used to calculate the time taken for patients to proceed through each pre-ART stage and the LTFU associated with each stage.

**The results:** After the introduction of PoC CD4, total LTFU of enrolled HIV patients reduced by half from 63.8% to 33.0% and the proportion of patients initiating ART with CD4 staging increased from 11.4% to 18.0% (see figure). This was mainly an increase in the proportion of patients successfully completing CD4 staging – this nearly doubled from 42.1% to 77.6%. Faster CD4 results also reduced the time between enrolment and ART initiation from an median of 48.0 days to 20.0 days. The time taken to complete CD4 staging reduced from an median of 27.5 days to 1.0 days. PoC CD4 did not reduce LTFU between CD4 staging and ART initiation; this remained close to 40% of successfully staged, ART-eligible patients, highlighting the need for additional initiatives to reduce LTFU.



PoC CD4 may have several advantages as it both improves the delivery of health services by reducing delays and empowers peripheral clinics in the management of their patients. Tracing LTFU patients can be costly and difficult, and mortality is high amongst LTFU pre-ART patients. Interventions like PoC CD4 can prevent LTFU in the first place. The implementation of PoC CD4 testing in PHC clinics requires careful planning and coordination to ensure it does not exacerbate existing human resource shortages, congest clinics and increase patient wait-times. In order to gain the most positive benefit from PoC CD4, systems to support expanded diagnostic menus at clinic level need to be established or strengthened. The cost of PoC CD4 testing was approximately on par with that of laboratory-based CD4 tests. The Ministry of Health of Mozambique recently endorsed the expanded use of PoC CD4 testing around the country in order to capitalize on the patient benefits observed in this study.

**Learn more:** Contact: Dr. Ilesh Jani, Director, Instituto Nacional de Saúde, Maputo, Mozambique, [ivjani@email.com](mailto:ivjani@email.com).

## Case study 4: Costing PMTCT Options A and B, Tanzania

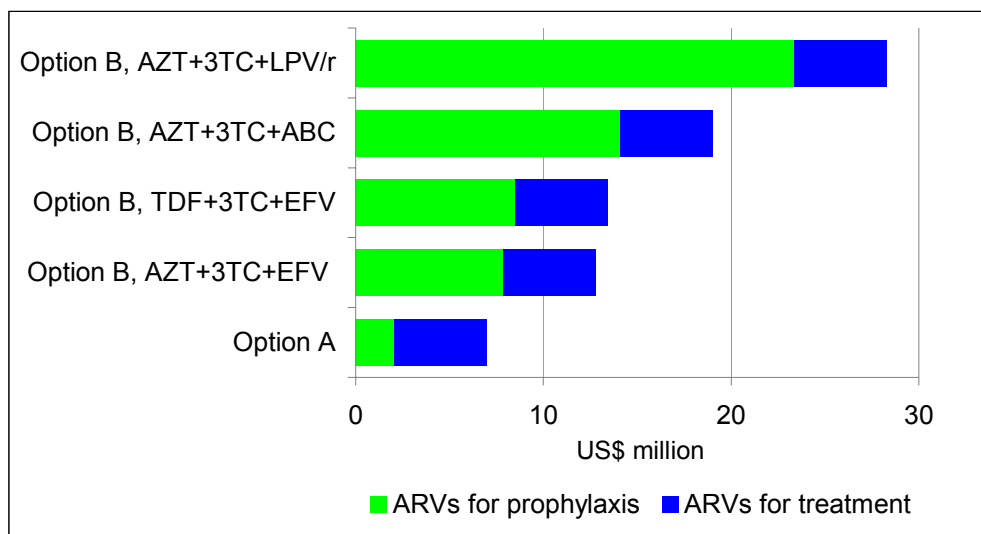


**The challenge:** In Tanzania the National AIDS Control Program (NACP) wanted to adopt the 2010 PMTCT and paediatrics guidelines while seeing maximum impact from their investment. They needed to decide between Option A and Option B for women not eligible for antiretroviral therapy (ART). Option A involves maternal AZT from 14 weeks of pregnancy through delivery and NVP for the HIV-exposed infant through cessation of breastfeeding, while Option B is triple-drug ARV prophylaxis for the mother from 14 weeks of pregnancy through cessation of breastfeeding, and 6 weeks of NVP for the infant.

**The solution:** The NACP worked to develop a model, in collaboration with the Clinton Health Access Initiative (CHAI), to compare different strategies such as: the new PMTCT guidelines to the old; Option A to Option B; the costs of treatment to the costs of prophylaxis; and the cost per infection averted. The model also estimated the impact of both options on the number of children eligible and the regimens they would require in order to be treated within the 2010 paediatric guidelines.

Together, they defined the key questions to be analyzed, gathered the necessary inputs, and modelled various scenarios to help anticipate the expected outcomes of different strategies. In order to reflect the most accurate cost estimates, the model used actual figures for the numbers of HIV-positive pregnant women in Tanzania and current costs for antiretroviral drugs accessible in Tanzania.

**The results:** The figure illustrates the cost differential of the various options. Based on this and other considerations, Tanzania has decided to adopt Option A of the PMTCT guidelines. According to the evidence available, both options are equally effective at preventing new infections, yet the cost of Option A is less than any of the four Option B recommended regimens. Therefore, the cost per infection averted is much less with Option A.



For paediatrics cases, all HIV-positive children aged less than 24 months will be initiated on treatment, phasing out d4T regimens in favour of AZT-based regimens, and introducing LPV/r for NVP-exposed infants.

**Learn more:** Contact: Angela Ramadhani, NACP, [arshayo@yahoo.com](mailto:arshayo@yahoo.com); Yahya Ipuge, CHAI, [yipuge@clintonhealthaccess.org](mailto:yipuge@clintonhealthaccess.org); or Elizabeth McCarthy, CHAI, [emccarthy@clintonhealthaccess.org](mailto:emccarthy@clintonhealthaccess.org).

## Case study 5: Implementing Option B of the WHO 2010 PMTCT guidelines, Thailand



**The challenge:** With an estimated 0.74% prevalence rate of HIV in pregnant women and a transmission rate of 3–6% in 2008, MTCT of HIV poses a major threat and is a significant obstacle to controlling and reducing the incidence of HIV. Although Thailand has adopted a strong PMTCT approach since 2001 (including replacement feeding for all HIV-positive women), a recent evaluation of the national PMTCT programme found that overall MTCT transmission rates during the period 2006 to 2007 were higher than expected at 5.4%. Given the regional target of less than 2%, the national programme wanted to adopt a more efficacious strategy for PMTCT.

**The solution:** During 2009, a feasibility pilot was implemented in 46 hospitals across four provinces to evaluate costs, values and challenges of adopting Option B – triple ARV prophylaxis – as the national PMTCT regimen. All HIV-positive antenatal clinic attendees who had CD4 counts >250 cells/mm<sup>3</sup> were given a three-drug regimen of AZT/3TC and LPV/r or AZT/3TC and NVP or EFV. HIV-positive pregnant women and health care workers (HCWs) participated in interviews, self-administered questionnaires and focus group discussions around the use and acceptability of triple ARV prophylaxis for PMTCT. A financial analysis of the original regimen (AZT+sd-NVP) and the proposed new triple ARV prophylaxis regimen was completed by the Health Intervention and Technology Assessment Program (HITAP). An estimate of costs in the context of the national ARV budget for PMTCT was also completed by the National Health Security Office (NHSO).

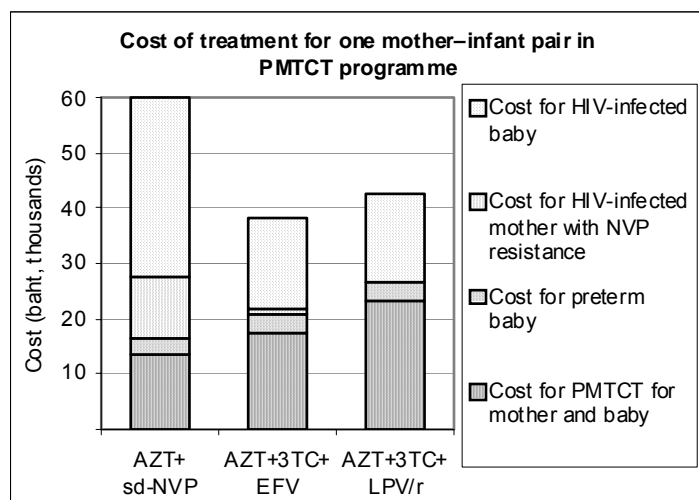
**The results:** Triple ARV prophylaxis was well tolerated by mothers, with good adherence reported (>95%) with very few changing regimens due to side effects. An analysis by the HITAP showed that compared with AZT+sd-NVP, triple ARV prophylaxis could save the hospital up to US\$ 667 per mother–infant pair, primarily due to the reduced costs of care and treatment for infected infants (see figure).

Of the 74 HCWs interviewed, there was high acceptability of triple ARV prophylaxis, provided that clear PMTCT policies and guidelines were in place, along with tools and materials.

A cost estimation from the NHSO had shown that Option B with AZT+3TC+LPV/r would be more expensive, but could result in 132 additional infections prevented, at a cost of US\$ 14 800 per life saved.

Following completion of the study and the commitment of financial support for triple ARV prophylaxis from the NHSO, the Ministry of Public Health (MOPH), the Ministry of Public Health (MOPH) technical working group met to discuss updating the national PMTCT guidelines to AZT+3TC+LPV/r for all pregnant women, regardless of CD4 count.

The new policy was implemented in October 2010, following a series of two-day PMTCT trainings to over 2000 HCWs across four geographical areas. Implementation of the new guidelines relies on leadership from government and partners, strong public health infrastructure, capacity building for HCWs and the provision of clear guidelines, tools and materials. Experience from Thailand shows that when these prerequisites are in place, Option B is feasible in both tertiary care and community hospitals. In Thailand, the choice of Option B offers an effective ARV regimen for all HIV-positive pregnant women, regardless of CD4 count.



**Learn more:** Contact: Nipunporn Voramongkol M.D. MPH, Chief, MCH group, Bureau of Health Promotion, Department of Health, Ministry of Public Health, [nvoramongkol@hotmail.com](mailto:nvoramongkol@hotmail.com); Rangsim Lolekha, M.D., Chief, PMTCT and Pediatric Section, Global AIDS Program, Asia Regional Office, CDC, [rangsimal@th.cdc.gov](mailto:rangsimal@th.cdc.gov).

## Case study 6: Nurse initiation and management of ART, Lesotho



**The challenge:** Lesotho is one of Africa's poorest countries and has the third highest prevalence of HIV worldwide (23.2%). With constrained resources, the health care work force is severely limited and health systems are stretched to provide ART to all those in need. Nevertheless in late 2007, Lesotho adopted initiation at a CD4 count of  $\leq 350$  cells/mm<sup>3</sup> and TDF-based first-line therapy ahead of the WHO recommendations.

**The solution:** Lesotho has been notable in introducing innovative strategies into the national HIV/AIDS programme to overcome the barriers of extreme poverty and health system constraints as found in the country. In 2006, Médecins Sans Frontières (MSF) and the Ministry of Health and Social Welfare (MOHSW) launched a joint pilot programme to provide decentralized HIV/AIDS care and treatment at the primary health care level.

The programme, which relies on a nurse-driven approach, was launched in a rural health zone with a population in a catchment area of 200 000 people and an estimated 30 000 people with HIV/AIDS. The nurses provide all primary health care, including a full range of HIV/AIDS services: HIV testing and counselling, prevention of mother-to-child transmission of HIV, TB and HIV care, and antiretroviral therapy, as part of the package of primary health care offered at the health centre level.

**The results:** By 2008, 13 243 people had been enrolled in HIV care (5% children), and 5 376 initiated on ART (6.5% children), 80% at primary care level. Between 2006 and 2008, annual enrolment more than doubled for adults and children, with no major external increase in human resources.

The proportion of adults arriving sick (CD4 count  $< 50$  cells/mm<sup>3</sup>) decreased from 22.2% in 2006 to 11.9% in 2008. Twelve months after initiating ART, 80% of adults and 89% of children were alive and in care, meaning they were still taking their treatment; at 24 months, 77% of adults remained in care. These figures are higher than other reports from Africa.

Despite an initial increase in workload with the introduction of the new initiation threshold, nurses did not feel overwhelmed as patients presented less sick and a dramatic reduction in mortality (68%) and hospitalizations (63%) were seen. Using TDF also proved simpler due to it having far fewer side-effects: half that of AZT and six times less than d4T. Renal function was monitored with six-monthly creatinine clearance but renal toxicity was very rare and mild.

These findings demonstrate that the introduction of the new WHO guidelines is feasible and safe in such a setting.

### Learn more:

Cohen R, Lynch S, Bygrave H, Eggers E, Vlahakis N, et al. (2009) Antiretroviral treatment outcomes from a nurse-driven, community-supported HIV/AIDS treatment programme in rural Lesotho: observational cohort assessment at two years. *Journal of AIDS* 12:23.

<http://www.jiasociety.org/content/12/1/23>

Ford N, Kranzer K, Hilderbrand K, Jouquet G, Goemaere E, Vlahakis N, Triviño L, Makakole L, Bygrave H. Early initiation of antiretroviral therapy and associated reduction in mortality and morbidity and defaulting in a nurse-managed, community cohort in Lesotho. *AIDS* 2010;24:2645–2650.

## Case study 7: National patient and programme monitoring systems, Ethiopia

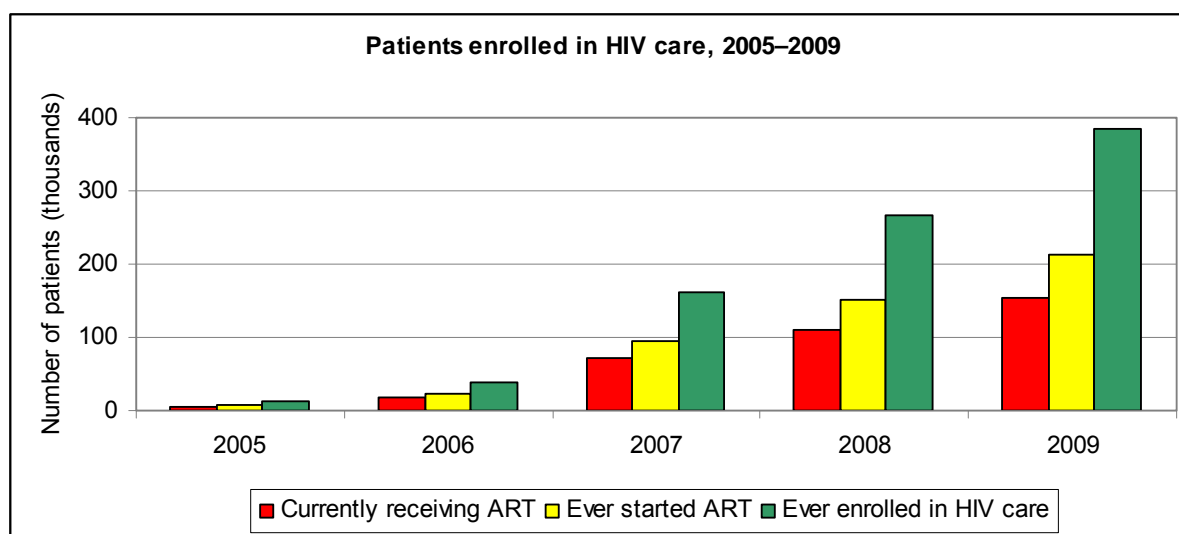


**The challenge:** Developing and implementing a uniform national patient monitoring system given the lifelong nature of antiretroviral therapy and the significant increase in the number of people receiving antiretroviral therapy.

**The solution:** Patient monitoring is the routine collection, compilation and analysis of patient data over time and across service delivery points. Ethiopia adapted the WHO generic patient monitoring systems for HIV care/ART. The tools are standardized, easy to understand and user-friendly especially to the front-line field worker. This makes it possible for the system to capture, store and process patient information both cross-sectionally and longitudinally.

In 2005, under the leadership of the Federal HIV/AIDS Prevention and Control Office, clear roles and responsibilities were developed for all stakeholders and partners to accelerate the process of implementing the national patient monitoring system in the areas of capacity building, training, supervision, mentoring, data collection and review with financial support primarily from the Global Fund and PEPFAR. Regional data managers and ART site data managers were trained to manage the system under the guidance of centrally located monitoring and evaluation experts.

**The results:** Within four years, partners and HIV care and treatment providers in all the 517 antiretroviral therapy service delivery points in Ethiopia were using the standardized national patient monitoring systems. As of the end of 2009, almost 400 000 HIV-positive patients ever enrolled into HIV care and over 150 000 patients receiving antiretroviral therapy were being monitored using the system.



The patient monitoring systems have provided an opportunity for improving data collection and management for HIV testing and counselling, prevention of mother-to-child transmission and ART data, and provide lessons for the new national Health Management Information System (HMIS). Currently, Ethiopia is integrating the HIV care/ART patient monitoring systems into the national HMIS. Having one M&E system that is set by the MoH and supported by partners addresses the challenges of M&E fragmentation and improves the standards of M&E across the country.

**Learn more:** Contact: Eleni Seyoum, WHO Ethiopia, [elenies@et.afro.who.int](mailto:elenies@et.afro.who.int); Dick Chamla, WHO AFRO, [chamlad@zw.afro.who.int](mailto:chamlad@zw.afro.who.int).

## Case study 8: Strengthening inventory management of ARVs using a mobile scanner, Namibia



**The challenge:** Data on ARV dispensing from outreach ART sites in Namibia is often incomplete or missing, leading to poor inventory management, a lack of information for quantifying medicine needs, poor scheduling of appointments and ineffective adherence monitoring. Staff at outreach ART sites fill in paper records which are then transferred manually into the Electronic Dispensing Tool (EDT) upon return to the main ART site.

**The solution:** Management Sciences for Health supported the MoHSS in developing a mobile scanner platform for the EDT, using a handheld scanner device. The device has the same functionality as the EDT at the main ART site and enables stock management, dispensing, patient scheduling and adherence monitoring through pill counts. Data from the EDT at the main site is downloaded onto the mobile device before an outreach visit is conducted. The scanner is then used to dispense medicines at the outreach site, and upon return to the main site, stock and patient information is uploaded back into the EDT at the main site.

### The results:

- 14% (12 320) of all MoHSS ART patients are serviced at outreach sites through the EDT mobile scanner.
- Increased speed and accuracy of dispensing at outreach sites as both dispensing and label printing is automated.
- Elimination of the need for double recording thus freeing staff to perform other critical tasks.
- Improved stock control at outreach sites due to accurate data on quantities of each ARV dispensed at the outreach site.
- Improved patient and data management at outreach sites allowing for patient monitoring, stock management, and quantification of ARVs.
- Eliminated the need to computerize smaller outreach sites as had been envisaged hence saving on costs.
- Allowed pill count recording which helps to objectively assess patient adherence as well as the facility average adherence.



The EDT mobile scanner is a fast, cost-effective and efficient way to manage ART records in remote settings. Because it uses batteries, the scanner can be employed in areas where there is no electricity. The record-holding capacity of the scanner enables use for multiple outreach sites and eliminates the need to update the EDT daily (updates can be done monthly or quarterly). The EDT mobile scanner is effective where record management is essential, but installation of a desktop computer is not feasible. This novel approach can facilitate the dispensing of ARVs and drugs for other chronic diseases in hard-to-reach populations in resource-limited settings.

EDT mobile will be rolled out to all facilities for use both in outreach and as additional dispensing points in high-volume facilities (in fact, this has been done for Oshakati and Onandjokwe and has been rolled out to Odibo, Ongwediva and WCH for use in outreach).

**Learn more:** Contact: Qamar Niaz, MoHSS, [qniaz@nmpc.com.na](mailto:qniaz@nmpc.com.na); Mwape Kunda, MoHSS, [mwapeks@yahoo.com](mailto:mwapeks@yahoo.com); and Dineo Pereko, MSH, [dpereko@msh.org.na](mailto:dpereko@msh.org.na).

# Case study 9: Integrated TB/HIV monitoring, Malawi



**The challenge:** In 2004, data collection and reporting by the national HIV and TB control programmes in Malawi were not integrated, which resulted in a duplication of effort, inconsistencies in data collection, and suboptimal HIV and TB programme outcomes.

**The solution:** The national HIV and TB programmes introduced a simple, standardized and integrated monitoring and evaluation system whereby HIV monitoring tools started providing routine and standardized data on HIV related TB and TB monitoring tools started providing routine and standardized data on HIV related TB which focussed on programme delivery.

**The results:** The collection of standardized data facilitated the reconciliation of data, which was disseminated and used to improve both HIV and TB programmes. By the end of 2008, the national HIV control programme had kept 147 479 people alive on ART, representing approximately 75% of those who had been registered cumulatively since the start of the programme in 2003, and the national TB control programme had a treatment success rate of 75%.

**Figure 1 Integrated TB/HIV treatment card, Malawi**

**NATIONAL TUBERCULOSIS PROGRAMME MALAWI**

**TUBERCULOSIS TREATMENT CARD**

District TB No:

Health Unit:

Registr. Date:

**Management of HIV+ Patients**

ARV      CTX

Start Date:

ARV No.:

ARV-Status: 

A	B	C
---	---	---

Update ARV-Status in Register from this card:  
A: started ARV before starting TB treatment  
B: started ARV while on TB treatment  
C: ARV not started by the time when discharged from TB treat.

Name:

Address: (in full)

Name and address of Guardian:

Sex:  M  F    Age:

Disease Class & Patient Category:  P  EP     New  Relapse  TI  Def  Fail  Oth    Specify other:

P= Pulmonary TB    EP= Extra-pulmonary TB    New= New case    TI= Transfer In  
Def= Retreatment after default    Fail= Treatment failure    Oth= Other

**1. INITIAL INTENSIVE PHASE**

Regimen and daily dosage of tablets / grams of S

Regimen 1:  RHZE    Regimen 2:  RHZE    TB Meningitis:  RHZ

S     S

R: rifampicin    H: isoniazid    Z: pyrazinamide    E: ethambutol  
S: streptomycin (S for 2 months only in Regimen 2)

Time	Sputum Results				Weight (kg)	Documented HIV Test History (see back)					
	Test	Date	Serial No	Result		Recent Negative	Past Positive	Never tested / old negative		Unknown	
Initiation	smear					RN	PP	NN	NP	NT	Unk
Month 2	smear					RN	PP	NN	NP	NT	Unk
Month 3	smear					RN	PP	NN	NP	NT	Unk
Month 5	smear					RN	PP	NN	NP	NT	Unk
Last month	smear					RN	PP	NN	NP	NT	Unk

\* 3 month repeat only if 2 month smear was still positive

DOT Option:  Guardian     Hospital     Health Centre

Month	Day *																																
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	

At 2 months: If HIV Positive, Start ART

Version 3    January 2008

**Learn more:**

World Health Organization. *WHO monograph on integrated monitoring of tuberculosis and human immunodeficiency virus: a case study from Malawi*. 2009.

[http://www.who.int/hiv/pub/tb/hiv\\_tb\\_malawi.pdf](http://www.who.int/hiv/pub/tb/hiv_tb_malawi.pdf)

## Case study 10: Using IMAI to support nurse-led ART initiation, Swaziland



**The challenge:** Swaziland has one of the highest HIV prevalence rates in the world. Universal access to HIV prevention, care and treatment is only possible if care is decentralized to the primary level and nurses are able to prescribe ART. For the Ministry of Health, the challenge was how to do this in the most effective way.

**The solution:** Swaziland adapted the WHO IMAI (Integrated Management of Adolescent and Adult Illness) approaches for HIV service decentralization and integration, clinical training, and operational tools through a national consultative process that incorporated local stakeholders under the leadership of the MoH. The adapted IMAI tools were used to train national trainers, who in turn trained health workers and expert clients at the regional level. Trainings were funded by the Global Fund to fight AIDS, Tuberculosis, and Malaria (Global Fund) and supported by government partners such as The International Center for AIDS Care and Treatment Programs (ICAP), The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), Médecins Sans Frontières (MSF) and the Nazarene Mission. The main objective of the training was to build the capacity of clinical teams in primary health facilities identified for the decentralization of HIV and TB services, to pilot nurse-led ART initiation, and to provide integrated TB and HIV services. In addition, the MoH established a clinical mentoring team, with the assistance of partners, which consists of one medical doctor (trained in basic and advanced IMAI), a nurse (trained to NARTIS), and a psychologist. Clinical mentors visit a number of primary clinics in a region at regular intervals.

The national accreditation of health facilities to provide decentralized and integrated TB and HIV services is based on two key elements: health workers trained in the nationally adapted IMAI basic HIV clinical course, and facilities establishing a multidisciplinary team and task-shifting approach to HIV service delivery. Nurses, assisted by lay providers and expert clients are responsible for the entire management of the patient – including HIV testing and counselling, CD4 assessment, evaluation for TB, co-trimoxazole prophylaxis and initiating ART. More complex cases are managed by referral to visiting physicians. Nurses are supported by trained expert clients who provide adherence counselling and other types of support at the facility level.

**The results:** Evaluations and follow-up indicate that IMAI training is helping Swaziland in the following ways:

- The provision of HIV prevention, care and treatment services at primary-level health facilities has been possible through nurse-initiated and -led HIV management.
- Involvement of people living with HIV as expert clients and expert client trainers has been broadened through IMAI implementation. The benefits of integrating expert clients into this model of care delivery are now well recognized.
- IMAI has helped to decentralize TB services to the primary health level because it has fostered a clearer understanding of the role of nurses in providing integrated TB and HIV services.

The challenges for the national programme are:

- The high turnover of health workers after training makes it difficult to follow through with implementation.
- HIV care and treatment is rapidly evolving and health workers need refresher training and opportunities for continued education. Sustaining a mechanism to ensure health workers education is a challenge.

Although there is an initiative to incorporate IMAI basic training in the nurses' pre-service course, there is still a need to strengthen and intensify the training of nurse tutors and instructors in nurse-training institutions.

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## Case study 11: Scaling-up use of child-friendly fixed-dose combinations, Uganda



**The challenge:** Paediatric fixed-dose combination (FDC) antiretroviral drugs offer many advantages over syrups, especially greater convenience and lower costs. The Ministry of Health (MoH) in Uganda wanted to ensure rapid uptake of paediatric FDCs and ensure a smooth transition away from syrups and single-drug formulations. However, due to the multi-stakeholder nature of Uganda's paediatric treatment programme and the fragmented supply chain mechanism, the MoH needed to devise a carefully coordinated approach to training and procurement in order to minimize drug wastage and stock-outs.

**The solution:** The MoH partnered with UNITAID and CHAI to achieve this by:

- Hands-on training-of-trainers with clinicians representing both government facilities and major paediatric implementing partners to educate them on the benefits of FDCs for dosing, adherence and ease of drug supply.
- Providing additional support to the forecasting unit to help with procurement of the new FDCs.
- Developing a logistics plan to track existing stocks of syrups and single-drug formulations and transfer them from one region to another and across separate supply chains to ensure that drugs were not wasted during the transition process.

**The results:** Within 18 months, from January 2009 to June 2010, 65% of eligible paediatric patients were switched to FDCs, raising the national number of children on FDCs from 17% to 82%. With the scale-up of FDCs, the use of d4T 15mg, d4T 20mg, ddl 100mg, ddl syrup, and EFV syrup were phased out while patients were switched to optimal formulations.

For the national programme, there were several advantages to using paediatric FDCs, including simpler forecasting, easier supply chain management, less need for storage space at central and facility levels and more efficient use of funds.

From 2007–2009, Uganda more than doubled the number of paediatric patients receiving treatment (120% increase from 7 166 to 15 622) but the total commodity cost of paediatric ARVs during the same time period increased by only 55%. Overall, the medicine costs for a child weighing 10–13.9kg on an AZT+3TC+NVP regimen was reduced by 56% between 2008 and 2010. Over half of this saving is attributable to the switch from syrups to FDCs.

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ISBN 978 92 4 150182 8



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