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1. INTRODUCTION

1.1 Background and context

WHO first published guidelines on the use of ART for HIV infection among adults and adolescents in 2002 (1) and on the use of ARV drugs for PMTCT in 2004 (2). The 2006 updates of the guidelines (3–5) introduced the concept of a public health approach, with simplified and harmonized ART regimens (6). These publications and their updates, most recently in 2010 (7–9), have provided important guidance to countries that have scaled up national ARV programmes during the past decade. In 2013, for the first time, WHO has revised and combined these and other ARV-related guidance documents into one set of consolidated guidelines that addresses the use of ARV drugs for HIV treatment and prevention across all age groups and populations, based on the broad continuum of HIV care.

These guidelines were updated in late 2012 and early 2013. The ARV regimens now available, even in the poorest countries, are safer, simpler, more efficacious and more affordable than ever before. New testing strategies and approaches are enabling earlier diagnosis of HIV in a wider range of settings, and new, more affordable technologies for monitoring people receiving ART are becoming available. Countries are moving towards triple-drug regimens and simplified programming for PMTCT that emphasizes the long-term health of pregnant women and mothers living with HIV as well as their children. Important new evidence has shown that ARV drugs offer significant benefits in preventing HIV transmission (10). Although countries are at different stages of ART coverage and implementation of the 2010 guidelines (7–9) and there are still important gaps in research, there is a consistent global trend towards expanding access and the earlier initiation of treatment.

Expanding the eligibility criteria for ART and the options for using ARV drugs creates opportunities to save lives and reduce HIV transmission but can pose significant technical, operational, programmatic and ethical challenges to policy-makers and implementers in many low- and middle-income countries. These include implementing a strategic mix of approaches to ensure more timely diagnosis of HIV infection in both health facility and community settings. Effective linkage and referrals between care settings, innovative, decentralized approaches to delivering ART services and effective adherence support and interventions are also needed to ensure that people are retained in long-term care. Reliable, quality-assured and affordable laboratory monitoring tools, adequate health workforce capacity and uninterrupted drug supplies are also essential.

At the programmatic level, countries often encounter difficulties in reaching the people who need ARV drugs the most. They may face difficult choices in allocating limited resources and determining programme priorities to make the best use of ARV drugs for treatment and prevention in combination with other HIV prevention methods. National HIV programmes may need to justify increased investment in ARV programmes by assessing the costs and benefits and demonstrating how they impact on HIV morbidity, mortality and incidence.

1.2 Rationale for consolidated guidelines

The consolidated guidelines offer the following anticipated benefits.

Guidance on using ARV drugs is presented within the context of the continuum of HIV-related prevention, treatment and care. In addition to providing recommendations on the clinical use of ARV drugs for treatment, the guidelines address other major aspects of HIV-related care.
The guidelines address the use of ARV drugs for all age groups and populations. Previously separate WHO guidelines on using ART among adults and adolescents have been combined with those for children and for PMTCT, harmonizing ARV regimens and treatment approaches to the extent possible across age groups and populations.

New and existing guidance is harmonized. Consolidation has allowed for new recommendations to be harmonized with relevant, existing WHO guidance.

Consolidation promotes the consistency of approaches and linkage between settings. Consolidated recommendations help to facilitate linkage and promote consistency of approaches across the various settings in which ARV drugs and related services may be provided, including specialized HIV care, primary care, community-based care, maternal and child health services, TB services and services for people who use drugs.

Updates will be more timely and comprehensive. Consolidated guidelines enable key clinical, operational and programmatic implications of new science and emerging practice in the use of ARV drugs to be comprehensively reviewed every two years across populations, age groups and settings.

1.3 Objectives

The objectives of the consolidated guidelines are:

- to provide updated, evidence-based clinical recommendations outlining a public health approach to providing ARV drugs for HIV treatment and prevention in the context of the continuum of HIV care, with a focus on settings with limited capacity and resources in the health system;
- to provide guidance on key operational and service delivery issues that need to be addressed to increase access to HIV services, strengthen the continuum of HIV care and further integrate the provision of ARV drugs into health systems; and
- to provide programmatic guidance for decision-makers and planners at the national level on adapting, setting priorities for and implementing the clinical and operational recommendations and monitoring their implementation and impact.

1.4 Target audience

The guidelines are intended primarily for use by national HIV programme managers. They will also be of interest to the following audiences:

- national HIV treatment and prevention advisory boards;
- national TB programme managers;
- managers of maternal, newborn and child health and reproductive health programmes;
- clinicians and other health service providers;
- managers of national laboratory services;
- people living with HIV and community-based organizations; and
- international and bilateral agencies and organizations that provide financial and technical support to HIV programmes in resource-limited settings.
1.5 **Scope and components**

The guidelines address clinical, operational and programmatic aspects of using ARV drugs for HIV treatment and prevention (Fig. 1.1).

### 1.5.1 Introductory chapters

The guidelines include several introductory chapters.

- **Chapter 1**: Describes the background, context, rationale and objectives of the guidelines and the target audience.
- **Chapter 2**: Outlines the guiding principles that underpin the guidelines.
- **Chapter 3**: Describes the methods and process for developing the guidelines.
- **Chapter 4**: Presents the format used to present new recommendations.

### 1.5.2 Clinical guidance

The recommendations in Chapters 5, 6 and 7 address key aspects of using ARV drugs for HIV treatment and prevention for all age groups and populations along the continuum of care from HIV-related diagnosis to care and treatment.

- **Chapter 5**: Summarizes HIV testing and counselling approaches, with links to existing WHO guidance. In addition, it summarizes approaches to using ARV drugs for preventing HIV transmission (pre-exposure prophylaxis and post-exposure prophylaxis of HIV and ARV drugs for prevention in serodiscordant couples) within the context of comprehensive combination HIV prevention, with links to existing WHO guidance. Note that the guidelines do not address behavioural, structural and biomedical prevention interventions that do not involve the use of ARV drugs.

- **Chapter 6**: Summarizes general HIV care for individuals from the time that they are diagnosed with HIV infection to the time that they are initiated on ART, including practices for linking people diagnosed with HIV infection to HIV care and treatment, the components of a general care package and preparing individuals for starting ART.

- **Chapter 7**: Includes recommendations on ART for adults (including pregnant and breastfeeding women), adolescents and children, including updated recommendations applicable to the majority of populations regarding the optimal timing for initiating ART (when to start); updated recommendations on the most effective and feasible first- and second-line treatment regimens (what to start and what to switch to); updated recommendations for monitoring the response to and toxicity of ART; and a discussion of third-line ART.

- **Chapter 8**: Includes a summary of approaches to preventing and managing common HIV-related opportunistic infections, other coinfections and other comorbidities, with links to existing WHO guidance.

### 1.5.3 Operational and service delivery guidance

- **Chapter 9**: Includes recommendations in six major operational and service delivery areas in which action is essential to further scaling up ARV programmes and ensuring their effectiveness and sustainability across the health system. These areas are: retention in care; adherence to ART; human resources; models of service delivery, focusing on decentralizing ART to primary health care services and integrating ART with TB treatment, antenatal care and maternal and child health programmes and drug dependence services; laboratory services; and drug supply management.
1.5.4 Guidance for programme managers

Chapter 10: Aims to assist countries in decision-making and programme planning. Implementation will involve various policy mixes based on local context, including the prevalence and dynamics of HIV infection; modes of transmission; the organization and capacity of health systems; relative income; and the current coverage of interventions. The chapter proposes steps to ensure fair, inclusive and transparent decision-making processes at the country level; discusses parameters to consider in assessing and adapting the global recommendations in countries; and suggests tools for costing and planning. Considerations for implementation across the health system and for specific, key recommendations in the guidelines are also discussed.

1.5.5 Monitoring and evaluation

Chapter 11: Provides guidance on the implications for monitoring of key new recommendations in these guidelines. It proposes a range of indicators that may be used to track the implementation of new recommendations and indicators to monitor the performance of programmes across the continuum of care. Chapter 11 also highlights opportunities provided by new recommendations to review and strengthen monitoring and evaluation systems.

Fig. 1.1 Components of the consolidated guidelines