

EXECUTIVE SUMMARY

These guidelines provide guidance on the diagnosis of human immunodeficiency virus (HIV) infection, the use of antiretroviral (ARV) drugs for treating and preventing HIV infection and the care of people living with HIV. They are structured along the continuum of HIV testing, prevention, treatment and care.

Rationale

WHO first published guidelines on the use of antiretroviral therapy (ART) for HIV infection among adults and adolescents in 2002, and on the use of ARV drugs to prevent mother-to-child HIV transmission in 2004. The 2006 updates of the guidelines introduced the concept of a public health approach, with simplified and harmonized ART regimens. In 2013, for the first time, WHO revised and combined these and other ARV-related guidance documents into consolidated guidelines that address the use of ARV drugs for HIV treatment and prevention across all age groups and populations, based on the HIV service continuum. This edition updates the 2013 consolidated guidelines on the use of antiretroviral drugs following an extensive review of evidence and consultations in mid-2015, shared at the end of 2015, and now published in full in 2016.

Consolidated simplified guidance was developed in response to expressed needs of country programmes, to include all age groups and populations across both clinical and operational aspects of care. Continuing with this approach allows all guidelines impacting on the continuum of HIV care to be harmonized based on a public health approach.

Several significant developments have occurred in the HIV field since 2013. In treatment, strong evidence has emerged to show that using ART earlier results in better clinical outcomes for people living with HIV compared with delayed treatment. Further, safer and more efficacious ARV drugs are becoming available and a newer class of drugs – integrase inhibitors – is becoming more affordable for low- and middle-income countries. Most countries have moved or are moving to provide lifelong ART regardless of CD4 cell count to all pregnant and breastfeeding women, and many are moving to implement viral load testing as the preferred means of monitoring people who are taking ART. New point-of-care viral load testing technologies offer further potential to expand this approach.

In prevention, clinical trial results have strongly confirmed the efficacy of the ARV drug tenofovir disoproxil fumarate alone or in combination with emtricitabine for use as pre-exposure prophylaxis (PrEP) to prevent HIV acquisition in a wide variety of settings and populations. New innovative approaches to HIV testing are being implemented, including home testing, community-based testing and self-testing. The opportunity to use ARV drugs for treating and preventing HIV more effectively are growing rapidly.

Although countries are at different stages of ART coverage and implementation of the 2013 guidelines, there is a consistent trend towards initiating treatment earlier and

expanding the use of ARV drugs for HIV prevention to achieve greater impact. This is accompanied by strong recognition that expanding access to HIV testing, treatment and prevention in settings with the highest burden of HIV infection and for the most vulnerable populations, along with greater efforts to address stigma and discrimination, are essential to ensure continued focus and to accelerate the response to the epidemic.

These guidelines present several new recommendations, including the recommendation to provide lifelong ART to all children, adolescents and adults, including all pregnant and breastfeeding women living with HIV, regardless of CD4 cell count. WHO has also expanded earlier recommendations to offer PrEP to selected people at substantial risk of acquiring HIV. Alternative first-line treatment regimens are recommended, including an integrase inhibitor as an option in resource-limited settings and reduced dosage of a key recommended first-line drug, efavirenz, to improve tolerability and reduce costs. Because of their anticipated public health impact, the new recommendations on when to start ART and the use of PrEP contained in these guidelines were released in September 2015.

Implementing all the recommendations in these guidelines at the national and global levels will have important implications for programme priority-setting, funding and service delivery. As in 2013, operational guidance is included to help countries as they work to implement new approaches and strengthen the treatment cascade. These guidelines include 10 new recommendations to improve the quality and efficiency of services to people living with HIV. Implementation of the recommendation on universal eligibility for ART will mean that more people will start ART earlier. Importantly, in this guidance WHO emphasizes the need for differentiated approaches to care for people who are stable on ART, such as reducing the frequency of clinic visits and community ART distribution. Such efficiencies are essential if countries with a high burden of HIV infection are to manage their growing numbers of people receiving ART and reduce the burden on people receiving treatment and health facilities.

The second edition of the consolidated guidelines on the use of antiretroviral drugs is being published in a changing global context for HIV and for health more broadly. The goal of providing HIV treatment to 15 million people by the end of 2015 has been achieved. From 2016, countries need to further accelerate efforts to meet the ambitious Fast-Track target for 2020, including achieving major reductions in the number of people dying from HIV related causes and the 90–90–90 treatment target: ensuring that 90% of the people living with HIV know their HIV status; 90% of the people living with HIV who know their HIV status are accessing treatment; and 90% of people living with HIV who are receiving treatment have suppressed viral load. The clinical and operational recommendations in these guidelines together with two sets of consolidated guidelines on HIV testing services and strategic information published in 2015 should contribute strongly to achieving these goals in the coming years and to other health and development priorities in the Sustainable Development Goals. The forthcoming Global Health Sector Strategy on HIV 2016–2021 describes WHO's contribution to achieving the HIV- and health-related Sustainable Development Goals.

Process of guideline development

This edition of the guidelines was revised in accordance with procedures established by the WHO Guidelines Review Committee. New clinical and operational recommendations in the guidelines are based on the GRADE (Grading of Recommendations, Assessment,

Development and Evaluation) approach to reviewing evidence. Modelling, expert consultations and country case studies have all strongly informed the guidelines. The process has also identified key gaps in knowledge that will help to guide the future HIV research agenda.

Audience

The primary audience for these guidelines is national HIV programme managers in low- and middle-income countries. The guidelines will also be a useful resource for clinicians and should help to shape the priorities of policy-makers in development agencies, international organizations, nongovernmental organizations and other implementing partners during the next few years. The guidelines will also be of value to people living with HIV, communities and civil society organizations that will need to be engaged meaningfully to support their successful implementation.

The 2016 consolidated guidelines on the use of antiretroviral drugs represent an important step towards achieving the goal that the world set itself a decade ago, universal access to ARV drugs for treating and preventing HIV, and the ultimate goal of ending the HIV epidemic as a major public health threat by 2030.