



World Health
Organization

GUIDELINES



GUIDELINE ON WHEN TO START ANTIRETROVIRAL THERAPY AND ON PRE-EXPOSURE PROPHYLAXIS FOR HIV

SEPTEMBER 2015

This early-release guideline will form part of the updated WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection due to be published in 2016.

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CONTENTS

Abbreviations and acronyms	6
Definition of key terms	7
Acknowledgements	9
Executive summary	12
Summary of recommendations	13
1. Introduction	16
1.1 Health sector response to HIV	16
1.2 Objectives	16
1.3 Target audience	17
1.4 Guiding principles	17
1.5 Methods for developing the guidelines	17
1.5.1 Competing interests	17
1.5.2 Guideline contributors	18
1.5.3 Methods for evidence synthesis	19
1.5.4 Peer review	21
2. Recommendations	24
2.1 When to start antiretroviral therapy	24
2.1.1 When to start ART among adults (>19 years old)	24
2.1.2 When to start ART among pregnant and breastfeeding women	30
2.1.3 When to start ART among adolescents (10–19 years of age)	35
2.1.4 When to start ART among children (younger than 10 years of age)	38
2.2 Oral pre-exposure prophylaxis for preventing the acquisition of HIV infection	42
2.3 Programmatic note on the recommendations	50
3. Publication, dissemination and evaluation	54
References	55
Annex 1. Declaration of interests, Clinical Guideline Development Group, June 2015	68
Annex 2. Evidence to decision-making tables and supporting evidence (available in web annex)	

ABBREVIATIONS AND ACRONYMS

AIDS	acquired immunodeficiency syndrome
ALT	alanine aminotransferase
ART	antiretroviral therapy
ARV	antiretroviral
FTC	emtricitabine
GRADE	grading of recommendations, assessment, development and evaluation
HBsAg	hepatitis B surface antigen
HIV	human immunodeficiency virus
PICO	population, intervention, comparison and outcome
PMTCT	prevention of mother-to-child HIV transmission
PrEP	pre-exposure prophylaxis
TB	tuberculosis
TDF	tenofovir disoproxil fumarate
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

DEFINITION OF KEY TERMS

General

HIV refers to the human immunodeficiency virus. There are two types of HIV: **HIV-1** and **HIV-2**. **HIV-1** is responsible for the vast majority of HIV infections globally.

Age groups and populations

The following definitions for adults, adolescents, children and infants are used to ensure consistency within these guidelines. Other agencies may use different definitions.

- An **adult** is a person older than 19 years.
- An **adolescent** is a person 10–19 years old inclusive.
- A **child** is a person younger than 10 years old.
- An **infant** is a child younger than one year of age.

Serodiscordant couples are couples in which one partner is living with HIV and the other is HIV-negative. A couple refers to two people in an ongoing sexual relationship; each of these people is referred to as a partner in the relationship. How individuals define their relationships will vary according to their cultural and social context.

Key populations are groups that have a disproportionate burden of HIV in many settings. They frequently face legal and social challenges that increase their vulnerability to HIV, including barriers to accessing HIV prevention and treatment. Key populations include (1) men who have sex with men, (2) people who inject drugs, (3) people in prisons and closed settings, (4) sex workers and (5) transgender people.

Vulnerable populations are populations that are vulnerable to HIV in certain situations or contexts, such as adolescents (particularly adolescent girls in sub-Saharan Africa), orphans, people with disabilities and migrant and mobile workers. They may also face social and legal barriers to accessing HIV prevention and treatment. These populations are not affected by HIV uniformly in all countries and epidemics. Each country should define the specific populations that are vulnerable and key to their epidemic and response, based on the epidemiological and social context.

Antiretroviral therapy

ARV (antiretroviral) drugs refer to the medicines used to treat HIV.

ART (antiretroviral therapy) refers to the use of a combination of three or more ARV drugs for treating HIV infection. ART involves lifelong treatment.

Use of ARV drugs for HIV prevention refers to the HIV prevention benefits of ARV drugs and includes ARV drugs given to the mother or infant for preventing the mother-to-child transmission of HIV (PMTCT), ARV drugs to reduce the transmission of HIV among serodiscordant couples and ARV drugs to prevent people from acquiring HIV when they are exposed (post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP).

Viral suppression refers to a viral load below the detection threshold using viral assays.

Viral failure refers to the inability to achieve or maintain viral suppression below a certain threshold.

Treatment failure: the current WHO virological criterion for treatment failure is 1000 copies per ml or more.

Universal access to ART is defined broadly as a high level of access (80% or more of the eligible population) that is accessible and affordable. It does not necessarily mean 100% coverage.

Preventing the mother-to-child transmission of HIV: Previous WHO guidelines have used the terms “options A, B and B+” to refer to different approaches to preventing the mother-to-child transmission of HIV. The 2013 WHO guidelines recommended a choice between two approaches: (1) providing ART during pregnancy and breastfeeding to women who are otherwise not eligible for ART (option B) and (2) providing lifelong ART to all pregnant and breastfeeding women living with HIV regardless of CD4 count or clinical stage (option B+).

Service delivery

Continuum of HIV services refers to a comprehensive package of HIV prevention, diagnostic, treatment, care and support services provided for people at risk of or living with HIV and their families. Examples of these services include combination HIV prevention including pre-exposure prophylaxis; HIV testing and linkage to care; management of opportunistic infections and other comorbid conditions; initiating, maintaining and monitoring ART; switching to second-line and third-line ART; and palliative care.

Continuum of HIV care refers to a comprehensive package of HIV services for people living with HIV.

A **public health approach** addresses the health needs of a population or the collective health status of the people rather than focusing primarily on individual case management. This approach aims to ensure the widest possible access to high quality services at the population level, based on simplified and standardized approaches, and to strike a balance between implementing the best-proven standard of care and what is feasible on a large scale in resource-limited settings. For HIV, key elements of a public health approach include simplified drug formularies; large-scale use of fixed-dose combinations for first-line treatment for adults, adolescents and children; care and drugs provided free at the point of service delivery; decentralization and integration of services, including task shifting; and simplified approaches to clinical monitoring.

HIV prevention

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