

INTRODUCTION

Updated: September 21, 2022

Reviewed: September 21, 2022

Antiretroviral therapy (ART) for the treatment of HIV infection has improved steadily since the advent of potent combination therapy in 1996. ART has dramatically reduced HIV-associated morbidity and mortality and has transformed HIV infection into a manageable chronic condition, with life expectancy approaching that for people without HIV.^{1,2} ART is also highly effective at preventing sexual transmission of HIV in patients who have adequately suppressed viral loads.³⁻⁵ Lack of viral load suppression is mostly due to undiagnosed HIV infection and failure to link or retain patients with HIV in care.

The U.S. Department of Health and Human Services (HHS) Panel on Antiretroviral Guidelines for Adults and Adolescents (the Panel) is a working group of the Office of AIDS Research Advisory Council (OARAC). The Panel's primary goal is to provide HIV care practitioners with recommendations that are based on current knowledge of the antiretroviral (ARV) drugs that are used to treat adults and adolescents with HIV in the United States. The Panel reviews new evidence and updates recommendations when needed. These guidelines include recommendations on baseline laboratory evaluations, treatment goals, benefits of ART and considerations when initiating therapy, choice of the initial regimen for ART-naïve people with HIV, ARV drugs or combinations to avoid, management of treatment failure, optimizing ARV regimens, management of adverse effects and drug interactions, and special ART-related considerations in specific populations. This Panel works closely with the HHS Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV to provide recommendations for adolescents at different stages of growth and development. Recommendations for ARV regimens in these guidelines are most appropriate for postpubertal adolescents (i.e., those with [sexual maturity ratings](#) [SMR] of 4 and 5). Clinicians should follow recommendations in the [Pediatric Antiretroviral Guidelines](#) when initiating ART in adolescents with an SMR of 3 or lower. For recommendations related to pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) for people who do not have HIV, clinicians should consult recommendations from the Centers for Disease Control and Prevention.⁶

These guidelines represent current knowledge regarding the use of ARV drugs. Because the science of HIV evolves rapidly, the availability of new agents and new clinical data may change therapeutic options and preferences. Information included in these guidelines may not always be consistent with approved labeling for the specific drugs or indications, and the use of the terms “safe” and “effective” may not be synonymous with the U.S. Food and Drug Administration–defined legal standards for drug approval. The Panel frequently updates the guidelines (current and archived versions of the guidelines are available on the [Clinical Info](#) website). However, updates to the guidelines may not keep pace with the release of new data, and the guidelines cannot offer guidance on care for all patients. Patient management decisions should be based on clinical judgement and attention to unique patient circumstances.

The Panel recognizes the importance of clinical research in generating evidence to address unanswered questions related to the optimal safety and efficacy of ART and encourages both the development of protocols and patient participation in well-designed Institutional Review Board–approved clinical trials.

HIV Expertise in Clinical Care

Several studies have demonstrated that overall outcomes in patients with HIV are better when care is delivered by clinicians with HIV expertise (e.g., those who have cared for a large group of patients

with HIV),⁷⁻¹¹ reflecting the complexity of HIV transmission and its treatment. Appropriate training, continuing education, and clinical experience are all components of optimal care. Providers who do not have this requisite training and experience should consult HIV experts when needed.

Guidelines Development Process

Table 1. Outline of the Guidelines Development Process

Topic	Comment
Goal of the guidelines	Provide guidance to HIV care practitioners on the optimal use of antiretroviral (ARV) agents for the treatment of HIV in adults and adolescents in the United States.
Panel members	The Panel is composed of approximately 50 voting members who have expertise in HIV care and research and includes at least one representative from each of the following U.S. Department of Health and Human Services (HHS) agencies: Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), Health Resource and Services Administration (HRSA), and National Institutes of Health (NIH). Approximately two-thirds of the Panel members are nongovernmental scientific members. The Panel also includes four to five community members with knowledge of HIV treatment and care. The U.S. government representatives are appointed by their respective agencies; other Panel members are selected after an open call for nominations. Each member serves on the Panel for a 4-year term, with an option for reappointment for an additional term. See the Panel Roster for a list of current Panel members.
Financial disclosure	All members of the Panel submit a written financial disclosure annually, reporting any association with manufacturers of ARV drugs or diagnostics used to manage HIV infection. The latest version of the Financial Disclosure list is available on the Clinical Info website.
Users of the guidelines	HIV treatment providers
Developer	Panel on Antiretroviral Guidelines for Adults and Adolescents—a working group of the Office of AIDS Research Advisory Council (OARAC)
Funding source	Office of AIDS Research, NIH
Evidence collection	The recommendations in the guidelines are based on studies published in peer-reviewed journals or data available in FDA drug labels. On some occasions, particularly when new information may affect patient safety, unpublished data presented at major conferences or prepared by the FDA and/or manufacturers as warnings to the public may be used as evidence to revise the guidelines.
Recommendation grading	As described in Table 2 below
Method of synthesizing data	Each section of the guidelines is assigned to a working group of Panel members with expertise in the section's area of interest. The working groups synthesize available data and propose recommendations to the Panel. The Panel discusses all proposals during monthly teleconferences. Recommendations endorsed by the Panel are included in the guidelines.

Table 1. Outline of the Guidelines Development Process

Topic	Comment
Other guidelines	<p>These guidelines focus on antiretroviral therapy (ART) for adults and adolescents with HIV. For a more detailed discussion on the use of ART in children and prepubertal adolescents (those with sexual maturity ratings of 1 to 3), clinicians should refer to the Pediatric Antiretroviral Guidelines.</p> <p>These guidelines also include a brief discussion on the management of women of childbearing potential and pregnant women. For more details on the use of ARV drugs during pregnancy, see the Perinatal Guidelines.</p>
Update plan	<p>The Panel meets monthly by teleconference to review data that may warrant modification of the guidelines. Updates may be prompted by new drug approvals (or new indications, dosing formulations, or frequency of dosing), new safety or efficacy data, or other information relating to ARV drugs that may have an impact on the clinical care of people with HIV. In the event of new data of clinical importance, the Panel may post an interim announcement with recommendations on the Clinical Info website until the guidelines can be updated with the appropriate changes. Updated guidelines are available on the Clinical Info website.</p>
Public comments	<p>A 2-week public comment period follows the release of the updated guidelines on the Clinical Info website. The Panel reviews comments to determine whether additional revisions to the guidelines are indicated. The public also may submit comments to the Panel at any time at HIVinfo@NIH.gov.</p>

Basis for Recommendations

Recommendations in these guidelines are based on scientific evidence and expert opinion. Each recommendation statement includes a letter (**A**, **B**, or **C**) that represents the strength of the recommendation and a Roman numeral (**I**, **II**, or **III**) that represents the quality of the evidence that supports the recommendation (see Table 2 below).

Table 2. Rating Scheme for Recommendations

Strength of Recommendation	Quality of Evidence for Recommendation
<p>A: Strong recommendation for the statement</p> <p>B: Moderate recommendation for the statement</p> <p>C: Weak recommendation for the statement</p>	<p>I: One or more randomized trials with clinical outcomes and/or validated laboratory endpoints</p> <p>II: One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes</p> <p>III: Expert opinion</p>

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