Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents

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What's New in the Guidelines? (Last updated July 14, 2016; last reviewed July 14, 2016)

Revisions to the January 28, 2016, version of the *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents* include key updates to several sections. Significant updates are highlighted throughout the document.

Key Updates

What to Start: Initial Combination Regimens for the Antiretroviral-Naive Patient

The approval of 3 fixed-dose combination products containing tenofovir alafenamide (an oral prodrug of tenofovir) and emtricitabine (TAF/FTC) prompted several changes in the What to Start section. The key changes are highlighted below:

- TAF/FTC was added as a 2-NRTI option in several Recommended and Alternative regimens, as noted in Table 6 of the guidelines. The addition of TAF/FTC to these recommendations is based on data from comparative trials demonstrating that TAF-containing regimens are as effective in achieving or maintaining virologic suppression as tenofovir disoproxil fumarate (TDF)-containing regimens and with more favorable effects on markers of bone and renal health.
- In the What to Start section, the evidence quality rating "II" was expanded to include "relative bioavailability/bioequivalence studies or regimen comparisons from randomized switch studies." This evidence rating was broadened because not all recommended regimens were evaluated in randomized, controlled trials in antiretroviral therapy (ART)-naive patients. The Panel on Antiretroviral Guidelines for Adults and Adolescents (the Panel) based their recommendations for some regimens on either data from bioequivalence or relative bioavailability studies, or by extrapolating results from randomized "switch" studies that evaluated a drug's or regimen's ability to maintain virologic suppression in patients whose HIV was suppressed on a previous regimen. Guidance for clinicians on choosing between abacavir (ABC)-, TAF-, and TDF-containing regimens was added to What to Start.
- The lopinavir/ritonavir (LPV/r) plus 2-NRTI regimen was removed from the list of Other regimens because regimens containing this protease inhibitor (PI) combination have a larger pill burden and greater toxicity than other currently available options.

Regimen Switching

- Based on the most current data, this section was simplified to focus on switch strategies for virologically suppressed patients. The strategies are categorized as Strategies with Good Supporting Evidence, Strategies Under Evaluation, and Strategies Not Recommended.

HIV-Infected Women

- The Panel emphasizes that ART is recommended for all HIV-infected patients, including all HIV-infected women.
- The Panel also stresses the importance of early treatment for HIV-infected women during pregnancy and continuation of ART after pregnancy.
- This section was updated to include new data on interactions between antiretroviral (ARV) drugs and hormonal contraceptives.

Hepatitis B Virus (HBV)/HIV Coinfection

- This section was updated to include TAF/FTC as a treatment option for patients with HBV/HIV

coinfection. Data on the virologic efficacy of TAF for the treatment of HBV in persons without HIV infection and TAF/FTC in persons with HBV/HIV coinfection are discussed.

- The Panel no longer recommends adefovir or telbivudine as options for HBV/HIV coinfected patients, as there is limited safety and efficacy data on their use in this population. In addition, these agents have a higher incidence of toxicities than other recommended treatments.

Hepatitis C Virus (HCV)/HIV Coinfection

- The text and Table 12 in this section were updated with information regarding the potential pharmacokinetic (PK) interactions between different ARV drugs and the recently approved hepatitis C drugs daclatasvir and the fixed-dose combination product of elbasvir and grazoprevir.
- Peginterferon alfa and ribavirin were removed from Table 12, as these agents do not have significant PK interactions with ARV drugs.

Tuberculosis (TB)/HIV Coinfection

- This section was updated to include a discussion on the treatment of latent tuberculosis infection (LTBI) in HIV-infected persons. The added discussion notes that a 12-week course of once-weekly rifapentine and isoniazid is an option for patients receiving either an efavirenz (EFV)- or a raltegravir (RAL)-based regimen.
- This section addresses the data from the TEMPRANO and START studies demonstrating a potential role of ART in reducing TB disease.
- The recommendations and discussion regarding when to initiate ART in patients with active TB were simplified.
- As rifamycins are potent inducers of P-glycoprotein (P-gp), and TAF is a P-gp substrate, coadministration of TAF and rifamycins is not recommended.

Additional Updates

Minor revisions were made to the following sections:

- Laboratory Testing for Initial Assessment and Monitoring of HIV-Infected Patients on Antiretroviral Therapy
- Drug Resistance Testing
- Adverse Effects of Antiretroviral Agents and Tables 14 and 15
- Monthly Average Wholesale Price of Commonly Used Antiretroviral Drugs (Table 16)
- Drug Interaction Tables 18, 19a-e, and 20b
- Drug Characteristics Tables (Appendix B, Tables 1–7)