Revised U.S. Guidelines: HIV Treatment is Recommended for All People Living With HIV

March 28, 2012 By Tim Horn

Antiretroviral (ARV) therapy is now recommended for all U.S. residents living with HIV, according to revised HIV treatment guidelines released by the U.S. Department of Health and Human Services on March 27, 2012.

Though the guidelines now largely sidestep CD4 cell counts as a major factor to consider when starting therapy, the expert panelists continue to emphasize the importance of individual factors that should be considered by patients and their health care providers in deciding whether the benefits of immediate ARV therapy outweigh the potential risks.

The last iteration of the Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, published in October 2011, clearly recommended treatment for all people living with HIV with CD4 cells below 500. As for those with CD4 cell counts above 500, no definitive recommendation was provided by the panelists, largely due to the split in expert opinion at the time.

The majority of guidelines panelists now believe treatment should be started even when the CD4 cell count is above 500—essentially soon after HIV is diagnosed in all cases.

“The [March 2012] recommendation to initiate therapy at CD4 counts [greater than] 500 cells”—which received a “moderate” (as opposed to a “strong”) rating based on expert opinion, not on data from clinical trials or long-term cohort studies—“is based on growing awareness that untreated HIV infection or uncontrolled viremia may be associated with development of many non-AIDS-defining diseases, including cardiovascular disease (CVD), kidney disease, liver disease, neurologic complications, and malignancy; availability of [ARV] regimens that are more effective, more convenient, and better tolerated than earlier [ARV} combinations no longer widely used; and evidence from one observational cohort study that showed survival benefit in patients who started ART when their CD4 counts were [greater than 500],” the guidelines panelists write.

“Tempering the enthusiasm to treat all patients regardless of CD4 count is the absence of randomized data that definitively demonstrate a clear benefit of [ARV therapy] in patients with CD4 count [greater than] 500 and mixed results on the benefits of early [ARV therapy] from

observational cohort studies," the panelists caution. "In addition, potential risks of short- or long-term drug-related complications and nonadherence to long-term therapy in asymptomatic patients may offset possible benefits of earlier initiation of therapy.

"When resources are not available to initiate [ARV therapy] in all patients," they add, "treatment should be prioritized for patients with the lowest CD4 counts and those with the following clinical conditions: pregnancy, history of an AIDS-defining illness, HIV-associated nephropathy (HIVAN), or HIV/hepatitis B virus (HBV) coinfection." In fact, the panelists stress that ARV is strongly recommended—regardless of the CD4 cell count—for all HIV-positive individuals who meet any of these criteria.

The latest recommendations note that effective ARV therapy "also has been shown to prevent transmission of HIV from an infected individual to a sexual partner." Therefore, the guidelines conclude, ARV therapy "should be offered to patients who are at risk of transmitting HIV to sexual partners." This recommendation is strongest for heterosexuals, based on the results of HPTN 052. For other transmission groups, the recommendation is still strong, but based on expert opinion and not clinical trial data.

The panelists are careful to note that the decision to start therapy is best made by people living with HIV and their health care providers. "Patients starting [ARV therapy] should be willing and able to commit to treatment and should understand the benefits and risks of therapy and the importance of adherence," they write. "Patients may choose to postpone therapy, and providers, on a case-by-case basis, may elect to defer therapy on the basis of clinical and/or psychosocial factors."

Though the panelists assert that "newer ARV drugs are generally better tolerated, more convenient, and more effective than drugs used in older regimens," long-term data are not plentiful and "concerns for some adverse consequences of [ARV therapy} remain" in considering earlier initiation of therapy. Factors to consider include the possibility of ARV drug toxicities and quality of life, nonadherence to ARV therapy and the high cost of HIV treatment.

"The current recommendations are based on greater evidence supporting earlier initiation of [ARV therapy] than was advocated in previous guidelines," the panelists conclude. "The strength of the recommendations varies according to the quality and availability of existing evidence supporting each recommendation. In addition to the benefit of earlier initiation of therapy for the health of the HIV-infected individual, the reduction in sexual transmission to HIV-uninfected individuals provides further reason for earlier initiation of [HIV treatment]."

Other changes to the guidelines include new sections on HIV and the older patient and an ARV drug cost table. Key updates, in addition to the treatment-start recommendations, include an expanded discussion on the use of hormonal contraception in HIV-positive women, HIV/hepatitis C coinfection drug-drug interaction information, tuberculosis treatment guidelines and the prevention of secondary HIV transmission.

The preferred choices for first-line HIV treatment remain unchanged: Atripla, Norvir-boosted Prezista plus Truvada, Norvir-boosted Reyataz plus Truvada or Isentress plus Truvada. Kaletra plus Combivir remains the preferred regimen for pregnant women living with HIV.

To learn more about when to start treatment, based on the revised U.S. treatment guidelines, click here.

Editor's note: This article has been edited since it was first published on March 28. AIDSmeds was alerted to discrepancies between the .pdf version of the March 2012 guidelines and the HTML version of the March 2012 guidelines posted to aidsinfo.nih.gov. The erroneous information, suggesting a 50/50 split in expert opinion regarding ARV treatment commencement in people with CD4 counts above 500 in the March 2012 guidelines, has been corrected here and on aidsinfo.nih.gov.
