



## Effective Health Care Beginning a HIV Antiviral Regimen

### Results of Topic Selection Process & Next Steps

*Beginning a HIV Antiviral Regimen* relates to the benefits and costs of beginning treatment for HIV in patients who have CD4 counts over 500. This topic was found to be addressed by the Department of Health and Human Services (DHHS) guidelines. The guidelines were updated in January 2016 to reflect findings from two randomized controlled trials (RCT) published in 2015, which provide strong evidence for early antiretroviral initiation. The updated recommendations are classified as AI (strong recommendation based on RCTs), and apply to all patients, regardless of CD4 count. No further activity will be undertaken on this topic.

- Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Accessed May 12, 2016

### Topic Description

**Nominator(s):** Individual

**Nomination Summary:** The nominator is interested in the benefits and costs of starting HIV antiviral drugs with a CD4 count of over 500. Specifically, the nominator is interested in an evidence review of the efficacy of different drugs, and whether the benefits outweigh the side effects with a CD4 still above 500.

**Key Questions from Nominator:** What are the benefits and costs of starting a HIV antiviral regimen among patients who had CD4 counts over 500?

### Considerations

- The topic meets EHC Program selection criteria. (For more information, see <http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/>.)
- As outlined in the DHHS guidelines, the START Trial found that starting HIV-infected patients with CD4 counts over 500 on ART immediately resulted in a decrease in the combined endpoint of AIDS-defining illnesses, serious non-AIDS events, or death. Though the START Trial did not include adolescents, the recommendation to start patients on ART was extended to include this younger population.<sup>1</sup>
- The TEMPRANO Trial shows decreased risk of death or severe HIV-related illness in HIV-infected patients who started ART with a CD4 count over 500. Like the START trial, the TEMPRANO trial did not assess adolescents, but outcomes of early ART initiation have been extrapolated to adolescents.<sup>2</sup>

- The Panel on Antiretroviral Guidelines for Adults and Adolescents with the Department of Health and Human Services recommend early detection of HIV, prompt ART initiation, and, in adolescents, a multidisciplinary health care team in order to best treat and control this globally-recognized epidemic.<sup>3</sup>

## References

1. INSIGHT START Study Group. Initiation of antiretroviral therapy in early asymptomatic HIV infection. N Engl J Med. Jul 20 2015. Available at <http://www.ncbi.nlm.nih.gov/pubmed/26192873>
2. TEMPRANO ANRS Study Group, Danel C, Moh R, et al. A trial of early antiretrovirals and Isoniazid preventive therapy in Africa. N Engl J Med. Aug 27 2015;373(9):808-822. Available at <http://www.ncbi.nlm.nih.gov/pubmed/26193126>.
3. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Accessed May 12, 2016

## Original Nomination

### Topic Suggestion Description

Date submitted: October 16, 2012

Briefly describe a specific question, or set of related questions, about a health care test or treatment that this program should consider.

Should I start HIV antiviral drugs? Indications for beginning treatment. Benefits and cost of new medication regimens among patients who have CD4 counts over 500.

### Importance

Describe why this topic is important.

Only 25% of patients with HIV infection have viral control. Despite programs that make the medications available, we are not doing a good job of convincing patients that being on medications is imperative in maintaining their quality of life.

### Potential Impact

How will an answer to your research question be used or help inform decisions for you or your group?

It will distill information from international and national studies, to the level of providers who are interacting with patients groups, or to the one-to-one interaction between a provider and his or her patient.

### Technical Experts and Stakeholders

Are there health care-focused, disease-focused, or patient-focused organizations or technical experts that you see as being relevant to this issue? Who do you think we should contact as we consider your nomination? This information will not influence the progress of your suggestion through the selection process, but it may be helpful to those considering your suggestion for further development?

Academy of HIV Medicine, International AIDS Society, Office of National AIDS Policy

### Nominator Information

Other Information About You: (optional)

Please choose a description that best describes your role or perspective: (you may select more than one category if appropriate)

Physician

May we contact you if we have questions about your nomination?

Yes