



Effective Health Care Combination Therapies for HIV/AIDS Nomination Summary Document

Results of Topic Selection Process & Next Steps

- Combination therapies for HIV/AIDS was found to be addressed by the Department of Health and Human Services' *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*. Given that the existing guidelines cover this nomination, 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. October 14, 2011; 1–167. Available at <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>.
- Infrared sauna therapy for HIV/AIDS is not feasible for a full systematic review due to the limited data available for a review at this time.

Topic Description

Nominator: Individual

Nomination Summary: The nominator is interested in the comparative effectiveness of antiretroviral therapy in combination with other treatments, such as antibacterial, antifungal, and infrared sauna, to slow the progression of disease and improve symptoms in persons with HIV/AIDS or other immunosuppressive disorders.

Staff-Generated PICO

Population(s): Individuals at high risk for secondary HIV infection (e.g. sero-discordant couples, HIV-positive pregnant women)

Intervention(s): Treatment with HAART

Comparator(s): Various HAART regimens; other microbicides

Outcome(s): Health-related quality of life (HR-QOL), transmission rates, mortality and disability, intermediate outcomes (e.g., viremia, CD4 counts, and risky behavior), short- and long-term (e.g., cardiovascular disease) adverse drug effects

Staff-Generated PICO

Population(s): Patients diagnosed with HIV, both asymptomatic and symptomatic, including pregnant women

Intervention(s): Treatment with HAART (classes of agents: nucleoside or nucleotide reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), CCR5 antagonists, and integrase strand transfer inhibitors (INSTIs) and fusion inhibitors) alone or in combination

Comparator(s): Various HAART regimens; timing of treatment initiation (early versus delayed treatment)

Outcome(s): HR-QOL, transmission rates, effects of early treatment on death and disability, intermediate outcomes (e.g., viremia, CD4 counts, and risky behavior), short- and long-term (e.g., cardiovascular disease) adverse drug effects

Staff-Generated PICO

Population(s): HAART treatment-naïve or treatment-experienced patients diagnosed with HIV with acute OI

Intervention(s): Early versus delayed HAART

Comparator(s): Early versus delayed HAART

Outcome(s): Mortality (all causes), response to HAART intermediate outcomes (e.g., virologic response, CD4 counts), development of immune reconstitution inflammatory syndrome, development of ART resistance, proportion of patients discontinuing or switching ART due to virologic failure, as defined by the trial, proportion of patients remaining on ART and antibacterial/antifungal therapy as originally assigned at the end of the trial, HR-QOL, adverse drug effects.

Staff-Generated PICO

Population(s): HIV-infected individuals on chronic maintenance HAART with no evidence of concurrent OI

Intervention(s): Antibacterial/antifungal agents

Comparator(s): Other antibacterial or antifungal agents; behavioral strategies

Outcome(s): Incidence of opportunistic disease, mortality (all causes), response to HAART intermediate outcomes (e.g., virologic response, CD4 counts), development of ART resistance, proportion of patients discontinuing or switching ART due to virologic failure, proportion of patients remaining on ART and antibacterial/antifungal therapy as originally assigned at the end of the trial, HR-QOL, adverse drug effects.

Staff-Generated PICO

Population(s): Patients diagnosed with HIV at all stages, including pregnant women

Intervention(s): Infrared sauna therapy with HAART

Comparator(s): HAART alone; HAART with antibacterial or antifungal agents to prevent or treat opportunistic infection; HAART early or delayed

Outcome(s): Incidence of opportunistic disease, mortality (all causes), response to HAART intermediate outcomes (e.g., virologic response, CD4 counts), development of ART resistance, proportion of patients discontinuing or switching ART due to virologic failure, proportion of patients remaining on ART, infrared sauna therapy, or antibacterial/antifungal therapy as originally assigned at the end of the trial, HR-QOL, adverse drug effects.

Key Questions from Nominator:

1. For patients with HIV/AIDS, what is the comparative effectiveness of antiviral therapy and antibacterial therapy in combination with antifungal therapy and sauna therapy/infrared therapy?
2. How can they all be used together in order to decrease the growth process?

Considerations

- The topic meets EHC Program appropriateness and importance criteria. (For more information, see <http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/>.)
- Topic was found to be addressed by guidelines from the Department of Health and Human Services titled *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*. The primary goal of the Department of Health and Human Services Panel on Antiretroviral Guidelines for Adults and Adolescents is to provide recommendations for HIV care practitioners based on current knowledge of antiretroviral drugs used to treat adults and adolescents with HIV infection in the United States. The Panel reviews new evidence and updates recommendations when needed, with a focus on baseline assessment, treatment goals, indications for initiation of antiretroviral therapy (ART), choice of the initial regimen in ART-naïve patients, drugs or combinations to be avoided, management of adverse effects and drug interactions, management of treatment failure, and special ART-related considerations in specific patient populations.
- Very few studies have been conducted on the use of infrared sauna therapy in patients with HIV/AIDS. Therefore, this topic is not feasible for a full systematic review due to the limited data available for a review at this time.