

Committee on Oversight and Government Reform, Chairman Henry A. Waxman

HIV/AIDS Today

Vol. 1, Issue 6: February 22, 2008

Highly Active Anti-Retroviral Treatment

The development of highly active antiretroviral therapy (HAART) has helped transform HIV/ AIDS from a death sentence to a chronic yet manageable disease for most individuals. While highly effective at improving the chance of survival and the quality of life, HAART does not eliminate the virus from the body, and must be taken indefinitely. Today's HIV/AIDS factsheet addresses the science behind HAART and various aspects of the treatment.

THE BASIC SCIENCE

HIV is a retrovirus: it inserts itself into the cells that are part of the immune system and then uses the cells' machinery to replicate.ⁱ By killing or damaging cells of the body's immune system, HIV progressively destroys the body's ability to fight infections and certain cancers. The drugs that make up HAART disrupt HIV at different stages in this process in order to preserve or improve immune system function.ⁱⁱ

HAART typically involves a combination of three drugs from a number of different classes of antiviral medications. To date, 32 antiretroviral (ARV) drugs have been approved by the FDA for adults and adolescents.ⁱⁱⁱ

An effective combination of ARVs can cause the virus to drop to undetectable levels in the blood, greatly increasing lifespan and quality of life. However, the virus remains present, even if at undetectable levels, and transmission can still occur.^{iv}

CHOOSING A TREATMENT

A person who tests positive for HIV does not automatically begin to take antiretroviral drugs. The decision to initiate treatment is based on symptoms of advanced HIV disease and on the patient's level of CD4 T-cells, a key component of the immune system.^v

Antiretroviral therapy is recommended for patients with a history of an AIDS-defining illness or with a CD4 T-cell count less than 350 cells. In order to minimize the risk of mother-to-child HIV transmission, it is recommended that pregnant women initiate treatment regardless of CD4 count.^{vi}

TREATMENT ADHERENCE

For a patient on HAART, strict adherence to a prescribed regimen—taking the drugs consistently as prescribed—is crucial to realizing treatment benefits. Gaps in treatment can allow the virus to replicate rapidly compromising the patient's immunity

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Lack of adherence can also lead to the development of resistant strains of HIV because the virus has a rapid mutation rate. Resistant strains may require the patient to switch drug regimens, and can also be transmitted to others.

Despite its importance, adherence to HAART is not always easy. Many ARVs need to be taken several times a day at specific times and may require a change in meals and mealtimes. The drugs

can cause minor to severe negative side effects, such as skin rash, nausea, nerve problems, decreased bone density, abnormal fat distribution, high cholesterol, pancreatitis, liver problems, and diabetes.^{vii} Thus, it is essential that patients on antiviral therapy have regular evaluations by an experienced HIV provider to promptly report any new or unusual symptoms.

Adherence has been improved through the use of fixed dose combinations, which combine two or more medications in one pill.^{viii}

ENDNOTES

ⁱ See HIV/AIDS Today Number 2, *The Human Immunodeficiency Virus and AIDS* (Jan. 25, 2008) (online at http://oversight.house.gov/story.asp?ID=1702).

ⁱⁱ Panel on Antiretroviral Guidelines for Adult and Adolescents. *Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents*. Department of Health and Human Services (Jan. 29, 2008) (online at http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf).

ⁱⁱⁱ U.S. Food and Drug Administration, *Drugs Used in the Treatment of HIV Infection* (Oct. 2007) (online at http://www.fda.gov/oashi/aids/virals.html).

^{iv} The Human Immunodeficiency Virus and AIDS, supra note ii.

^v AIDS info, A Service of the U.S. Department of Health and Human Services. *Starting Anti-HIV Medications* (Aug. 2006) (online at http://aidsinfo.nih.gov/contentfiles/HIVandItsTreatment_cbrochure_en.pdf).

^{vi} Id.

^{vii} AIDS info, A Service of the U.S. Department of Health and Human Services. *What is Treatment Adherence?* (Aug. 2006) (online at http://aidsinfo.nih.gov/contentfiles/HIVandItsTreatment_cbrochure_en.pdf).

^{viii}U.S. Food and Drug Administration, *Guidance for Industry Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV* (May 2004) (online at http://www.fda.gov/oc/initiatives/hiv/hivguidance.html).