

HIV Overview HIV/AIDS: The Basics

(Last updated 9/27/2013; last reviewed 9/27/2013)

Key Points

- HIV is the virus that causes HIV infection. AIDS is the most advanced stage of HIV infection.
- HIV is spread through contact with the blood, semen, vaginal fluids, or breast milk of a person infected with HIV. The most common ways HIV is transmitted are through anal or vaginal sex and sharing of drug injection equipment with a person infected with HIV.
- The treatment for HIV infection is called antiretroviral therapy (ART). ART involves taking a combination of HIV medicines (called an <u>HIV regimen</u>) every day.
- ART can't cure HIV infection, but it can help people infected with HIV live longer, healthier lives.

What is HIV?

HIV stands for human immunodeficiency virus. HIV is the virus that causes HIV infection. HIV attacks and destroys the infection-fighting <u>CD4 cells</u> of the <u>immune system</u>. Loss of CD4 cells makes it difficult for the body to fight infections and certain cancers.

What is AIDS?

AIDS stands for acquired immunodeficiency syndrome. AIDS is the most advanced stage of HIV infection.

How is HIV spread?

HIV is spread through the blood, semen, vaginal fluids, or breast milk of a person infected with HIV. The spread of HIV from person to person is called HIV transmission.

The most common ways HIV is transmitted are through anal or vaginal sex and sharing of drug injection equipment with a person infected with HIV.

HIV can pass from an HIV-infected woman to her child during pregnancy or childbirth, or by breastfeeding. This spread of HIV is called mother-to-child transmission of HIV.

You can't get HIV by shaking hands or hugging a person infected with HIV. And you can't get HIV from contact with objects such as dishes, toilet seats, or doorknobs used by a person with HIV.

What is the treatment for HIV?

The treatment for HIV infection is called antiretroviral therapy (ART). ART involves taking a

combination of HIV medicines (called an <u>HIV regimen</u>) every day. (HIV medicines are often called antiretrovirals or ARVs.) ART prevents HIV from multiplying and destroying infection-fighting CD4 cells, which helps the body fight off infections and certain cancers. ART can prevent HIV infection from advancing to AIDS.

ART can't cure HIV, but it can help people infected with HIV live longer, healthier lives. By reducing the amount of HIV in the body, ART also reduces the risk of HIV transmission.

What are the symptoms of HIV/AIDS?

The first signs of HIV infection may be flu-like symptoms, such as fever, headache, and rash. The symptoms may come and go for a month or two after infection. After this earliest stage of HIV infection, more severe symptoms of HIV infection generally don't appear for many years.

HIV transmission is possible at any stage of HIV infection—even if a person infected with the virus has no symptoms of HIV.

How long does it take for HIV infection to advance to AIDS?

Without treatment, HIV can advance to AIDS. The time it takes for HIV to advance to AIDS varies, but it can take 10 years or more.

The following criteria are used to determine if a person with HIV has AIDS:

- A CD4 count of less than 200 cells/mm³. A CD4 count measures the number of CD4 cells in a sample of blood. The CD4 count of a healthy person ranges from 500 to 1,200 cells/mm³.
 - OR
- An AIDS-defining condition. AIDS-defining conditions include <u>opportunistic infections</u> and cancers that are life-threatening in a person with HIV.

How can I learn more about HIV/AIDS?

- <u>Watch this tutorial on HIV/AIDS</u>.
- Read about risk factors for HIV infection.

This fact sheet is based on information from the following sources:

- From the Centers for Disease Control and Prevention (CDC): <u>HIV Basics</u>
- From the National Institute of Allergy and Infectious Diseases (NIAID): <u>Understanding HIV/AIDS</u>



HIV Overview The HIV Life Cycle

(Last updated 10/16/2013; last reviewed 10/16/2013)

Key Points

• HIV gradually destroys the <u>immune system</u> by attacking and killing CD4 cells. CD4 cells are a type of white blood cell that plays a major role in protecting the body from infection.

- HIV uses the machinery of the CD4 cells to multiply (make copies of itself) and spread throughout the body. This process is called the HIV life cycle. HIV medicines protect the immune system by blocking HIV at different stages of the HIV life cycle.
- Antiretroviral therapy (ART) involves taking a combination of HIV medicines from at least two different HIV <u>drug classes</u> every day. Because HIV medicines in different drug classes block HIV at different stages of the HIV life cycle, ART is highly effective in reducing the amount of HIV in a person's body (<u>HIV</u> <u>viral load</u>). ART also reduces the risk of HIV <u>drug resistance</u>.
- ART can't cure HIV, but it does protect the immune system, which helps people with HIV live longer, healthier lives.

Once a person is infected with HIV, the virus begins to attack and destroy the CD4 cells of the <u>immune</u> <u>system</u>. CD4 cells are a type of white blood cell that plays a major role in protecting the body from infection. HIV uses the machinery of the CD4 cells to multiply (make copies of itself) and spread throughout the body. This process is called the HIV life cycle.

What is the connection between HIV medicines and the HIV life cycle?

Without treatment, HIV infection gradually destroys the immune system and advances to <u>AIDS</u>. HIV medicines protect the immune system by blocking HIV at different stages of the HIV life cycle.

HIV medicines are grouped into different <u>drug classes</u> according to how they fight HIV. Each class of drugs attacks HIV at a different stage of the HIV life cycle. Standard HIV treatment (also called antiretroviral therapy or ART) involves taking a combination of HIV medicines from at least two different HIV drug classes every day. Because HIV medicines in different drug classes block HIV at different stages of the HIV life cycle, ART is highly effective in reducing the amount of HIV in a person's body (<u>HIV viral load</u>). ART also reduces the risk of HIV <u>drug resistance</u>.

What is HIV drug resistance?

Drug resistance is when HIV is no longer suppressed by HIV medicines that previously prevented the virus from multiplying.

Drug resistance can develop as HIV multiplies in the body. When HIV multiplies, the virus sometimes mutates (changes form) and makes variations of itself. Variations of HIV that develop while a person is taking HIV medicines can lead to new, drug-resistant strains of HIV. The drug-resistant HIV no longer responds to the HIV medicines that used to effectively suppress a person's strain of HIV. In other words, the person's HIV continues to multiply.

Once drug-resistant HIV develops, it remains in the body. Drug resistance limits the number of HIV medicines available to include in an HIV regimen.

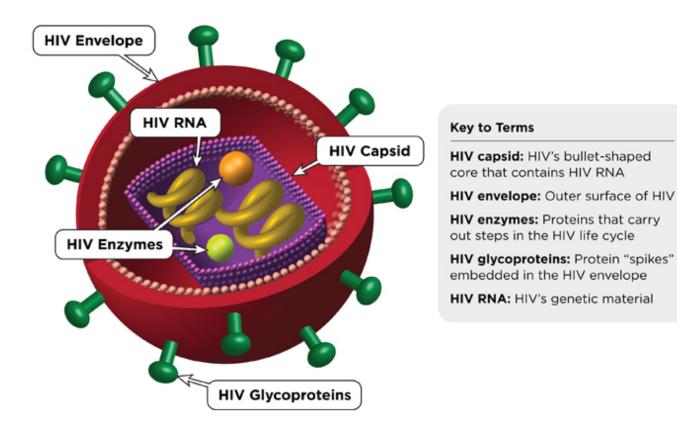
Because ART prevents HIV from multiplying at different stages of the HIV life cycle, the virus has fewer chances to mutate and produce new, drug-resistant HIV.

Can ART cure HIV?

ART can't cure HIV, but by blocking HIV at different stages of the HIV life cycle, ART protects the immune system. A healthier immune system helps people with HIV live longer, healthier lives.

What are the stages of the HIV life cycle?

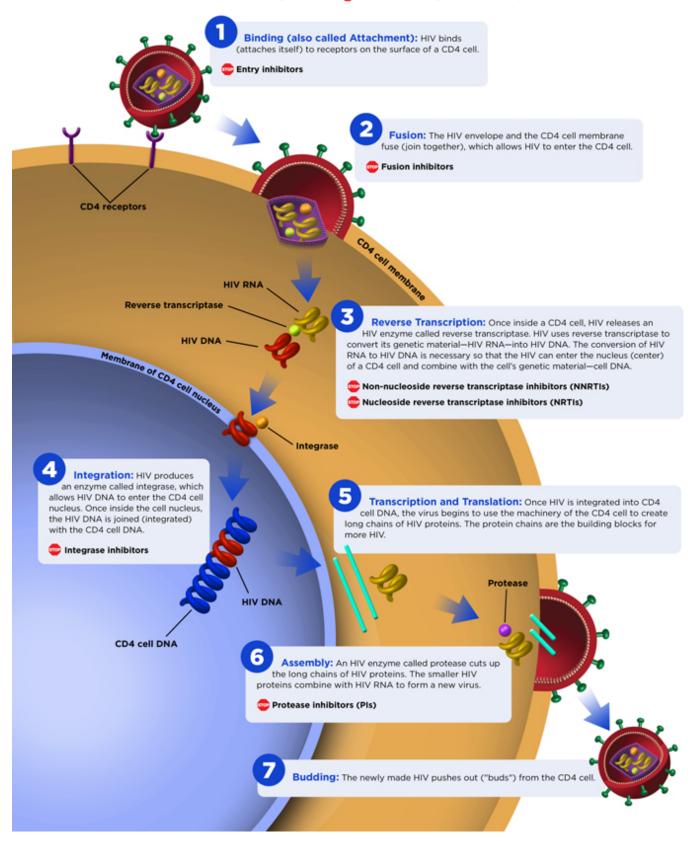
To understand the HIV life cycle, it helps to first imagine what HIV looks like.



Now you are ready to follow HIV as it attacks a CD4 cell. The image below shows each stage of the HIV life cycle.

The HIV Life Cycle

HIV medicines in six drug classes stop 🎰 HIV at different stages in the HIV life cycle.



How can I learn more about the HIV life cycle?

Read information from the National Institute of Allergy and Infectious Diseases (NIAID) on how HIV

causes AIDS. This fact sheet is based on this information.

- How HIV Causes AIDS
- More on How HIV Causes AIDS
- <u>Types of HIV/AIDS Antiretroviral Drugs</u>



HIV Overview The Stages of HIV Infection

(Last updated 9/27/2013; last reviewed 9/27/2013)

Key Points

- Without treatment, HIV infection advances in stages, getting worse over time.
- The three stages of HIV infection are (1) acute HIV infection, (2) chronic HIV infection, and (3) <u>acquired immunodeficiency syndrome (AIDS)</u>.
- HIV can be transmitted (spread) during any stage of infection, but the risk is greatest during acute HIV infection.
- There is no cure for HIV infection, but HIV medicines can prevent the advance of HIV to AIDS. HIV medicines help people with HIV live longer, healthier lives. HIV medicines also reduce the risk of HIV transmission (the spread of HIV to others).

Without treatment, HIV infection advances in stages, getting worse over time. HIV gradually destroys the <u>immune system</u> and eventually causes <u>acquired immunodeficiency syndrome (AIDS)</u>.

There is no cure for HIV infection, but HIV medicines can prevent the advance of HIV to AIDS. HIV medicines help people with HIV live longer, healthier lives. HIV medicines also reduce the risk of HIV transmission (the spread of HIV to others).

There are three stages of HIV infection:

1.) Acute HIV Infection

Acute HIV infection is the earliest stage of HIV. Acute HIV infection can occur within 2 to 4 weeks after a person is infected with HIV. In some people, this stage of HIV infection can take up to 3 months to develop. During acute HIV infection, many people have flu-like symptoms, such as fever, headache, and rash. In the acute stage of infection, HIV multiplies rapidly and spreads throughout the body. The virus attacks and destroys the infection-fighting <u>CD4 cells</u> of the immune system. HIV can be transmitted during any stage of infection, but the risk is greatest during acute HIV infection.

2.) Chronic HIV Infection

The second stage of HIV infection is chronic HIV infection (also called asymptomatic HIV infection or clinical latency.) During this stage of the disease, HIV continues to multiply in the body but at very low levels. People with chronic HIV infection may not have any HIV-related symptoms, but they can still

spread HIV to others. Chronic HIV infection can last up to 10 years or longer.

3.) AIDS

AIDS is the final stage of HIV infection. Because HIV has destroyed the immune system, the body can't fight off <u>opportunistic infections</u> and cancer. (Examples of opportunistic infections include pneumonia and tuberculosis.) AIDS is diagnosed when a person with HIV has a <u>CD4 count</u> of less than 200 cells/mm³ and/or one or more opportunistic infections. Without treatment, people with AIDS typically

survive about 3 years.

This fact sheet is based on information from the following sources:

- From AIDS.gov: <u>Stages of HIV</u>
- From the Centers for Disease Control and Prevention (CDC): <u>HIV and AIDS 101 The</u> <u>Basics</u>
- From the National Institute of Allergy and Infectious Diseases (NIAID): <u>Clinical</u> <u>Progression of HIV</u>



HIV Overview

HIV Testing

(Last updated 9/27/2013; last reviewed 9/27/2013)

Key Points

- HIV testing shows if a person is infected with HIV. HIV is the virus that causes AIDS. AIDS is the most advanced stage of HIV infection.
- The Centers for Disease Control and Prevention (CDC) recommends HIV testing for everyone 13 to 64 years old as part of routine medical care. CDC also recommends that people at high risk of HIV infection get tested at least once a year. Risk factors for HIV infection include unprotected sex (sex without a condom), having sex with many partners, and sharing needles or other drug equipment with others.
- In addition, CDC recommends that all pregnant women get tested for HIV.
- HIV medicines are available for people who test HIV positive. HIV medicines help people with HIV live longer, healthier lives and reduce the risk of HIV transmission.

What is HIV testing?

HIV testing shows if a person is infected with HIV. HIV is the virus that causes AIDS. AIDS is the most advanced stage of HIV infection.

HIV testing can detect HIV infection but it can't tell how long a person has been HIV infected or if the person has AIDS.

Why is HIV testing important?

HIV testing helps protect your health. Whether testing shows you are HIV-negative or HIV-positive, you can take steps to protect your health.

If you are HIV-negative:

Testing shows that you don't have HIV. Continue taking steps to avoid getting HIV, such as using a condom during sex. For more information read the AIDSinfo fact sheet on HIV prevention.

If you are HIV-positive:

Testing shows that you are infected with HIV, but you can still take steps to protect your health. Begin by talking to your health care provider about antiretroviral therapy (ART). ART is the use of HIV medicines to treat HIV infection. ART involves taking a combination of HIV medicines every day. ART helps people with HIV live longer, healthier lives. ART also reduces the risk of <u>sexual transmission of HIV</u>. Your health care provider will help you decide when to start treatment and what HIV medicines to take.

Who should get tested for HIV?

The Centers for Disease Control and Prevention (CDC) recommends HIV testing for everyone 13 to 64 years old as part of routine medical care.

CDC recommends HIV testing at least once a year for people at high risk of HIV infection. Factors that increase the risk of HIV infection include:

- Having unprotected sex (sex without using a condom) with someone who is HIVpositive or whose HIV status is unknown
- Having sex with many partners
- Exchanging sex for money or drugs
- Having a sexually transmitted disease (STD), such as syphilis
- Using drugs with needles and sharing needles, syringes, or other drug equipment ("works") with others

Talk to your health care provider about your risk of HIV infection and a testing schedule that suits you.

Should pregnant women get tested for HIV?

CDC also recommends that all pregnant women get tested for HIV. Women who test HIV positive take HIV medicines during pregnancy and childbirth to reduce the risk of mother-to-child transmission of HIV. Babies born to HIV-infected women receive HIV medicines for 6 weeks after birth to reduce the risk of mother-to-child transmission of HIV.

Because HIV can be transmitted in breast milk, HIV-infected women in the United States should not breastfeed their babies. In the United States, baby formula is a safe and healthy alternative to breast milk.

What are the types of HIV tests?

The three main HIV tests are the HIV antibody test, the HIV RNA test, and the Western blot test.

HIV antibody test

The HIV antibody test is the most common HIV test. The test checks for HIV antibodies in blood, urine, or fluids from the mouth. HIV antibodies are a type of protein the body produces in response to HIV infection.

Once a person is infected with HIV, it generally takes about 3 months for the body to produce enough antibodies to be detected by an HIV antibody test. (For some people, it can take up to 6 months.) This time period between infection with HIV and the appearance of detectable HIV antibodies is called the <u>window period</u>. During the window period, the level of antibodies in the body is too low to be detected by an HIV antibody test. For this reason, the HIV antibody test isn't used during the window period.

It usually takes a few days to a few weeks to get results of an HIV antibody test. Some rapid HIV antibody tests can produce results within 30 minutes.

HIV RNA test

An HIV RNA test can detect HIV in a person's blood within 9 to 11 days after the person is infected with HIV—before the body has produced enough antibodies to be detected by an HIV antibody test.

The HIV RNA test is used during the window period when recent infection is suspected—for example, soon after a person has had unprotected sex with a partner infected with HIV. Immediately after infection, the amount of HIV in the body is very high, which increases the risk of HIV transmission. Detecting HIV at the earliest stage of infection lets a person take steps right away to prevent spreading HIV to others. This includes the option to start taking HIV medicines.

Results from an HIV RNA test are usually available within a few days to a few weeks.

Western blot test

HIV is diagnosed on the basis of positive results from two HIV tests. The first test can be either an HIV antibody test (using blood, urine, or fluids from the mouth) or an HIV RNA test (using blood). A positive result on a first HIV test must be confirmed by a second HIV test (always using blood). The confirmatory test typically used is a different type of antibody test called a Western blot test.

Results from a Western blot test are usually available within a few days to a few weeks. A positive Western blot test result confirms that a person is infected with HIV.

Is there an HIV test for home use?

There are two HIV tests approved by the U.S. Food and Drug Administration (FDA) for home use. One test involves collecting a blood sample at home and then sending the sample to a lab for testing. The person using the test must wait about 1 week before calling the lab to get the test results.

The other approved home use test doesn't depend on a lab for test results. Using the test involves swabbing the gums with a test device to get a sample of oral fluids and then inserting the test device into a test solution. Test results are ready in 20 to 40 minutes.

A positive result on a home HIV test must always be confirmed by a Western blot test done in a health care setting.

Learn more about <u>HIV home test kits approved by FDA</u>.

Is HIV testing confidential?

If you get tested at a doctor's office or clinic, you can ask for a confidential HIV test. This means that only people allowed to see your medical records will see your test results. If your HIV test results show that you are infected with HIV, this information may be reported to your state health department to be counted in statistical reports. Your name will not be attached to the information.

Some states have "anonymous" testing, which means you don't have to give your name when you take an HIV test. When you take the test, you receive a number. To get your test results, you give the number instead of your name.

How can I learn more about HIV testing?

- Read information about HIV testing from CDC.
- Find an HIV testing location near you.

This fact sheet is based on information from the following sources:

- From CDC: <u>HIV Testing</u>
- From the Department of Veteran's Affairs: Getting Tested for HIV/AIDS
- From the Food and Drug Administration: Testing for HIV
- From the U.S. Preventive Services Task Force: Screening for HIV



HIV Overview

FDA-Approved HIV Medicines

(Last updated 9/30/2013; last reviewed 9/30/2013)

Antiretroviral therapy (ART) is the use of HIV medicines to treat HIV infection. ART involves taking a combination of HIV medicines (called an HIV regimen) every day. A person's initial HIV regimen generally includes three or more HIV medicines from at least two different drug classes.

ART is recommended for all people infected with HIV. ART can't cure HIV, but it can help people with HIV live longer, healthier lives. HIV medicines can also reduce the risk of HIV transmission.

The following table lists HIV medicines approved by the U.S. Food and Drug Administration (FDA) for the treatment of HIV infection in the United States. The HIV medicines are listed according to drug class and identified by generic and brand names.

FDA-A	pproved HIV Medici	nes		
Drug Class	Generic Name (Other names and acronyms)	Brand Name	Current Manufacturer	FDA Approval Date
Nucleoside Reverse Transcriptase	Inhibitors (NRTIs)			
NRTIs block reverse transcriptase, an <u>enzyme</u> HIV needs to make copies of itself.	<u>abacavir</u> (abacavir sulfate, ABC)	Ziagen	GlaxoSmithKline 888-825-5249	December 17, 1998
	didanosine (ddl, ddl EC)	Videx	Bristol–Myers Squibb	October 9, 1991
		Videx EC (enteric- coated)	800-332-2056	October 31, 2000
	<u>emtricitabine</u>	Emtriva	Gilead Sciences	July 2,

aidsinfo.nih.gov/education-materials/fact-sheets/print/19/45/0/1

U	•		
(FTC)		800-445-3235	2003
<u>lamivudine</u> (3TC)	Epivir	GlaxoSmithKline 888-825-5249	November 17, 1995
<u>stavudine</u> (d4T)	Zerit	Bristol–Myers Squibb 800–332–2056	June 24, 1994
<u>tenofovir disoproxil</u> <u>fumarate</u> (tenofovir DF, TDF)	Viread	Gilead Sciences 800-445-3235	October 26, 2001
<u>zidovudine</u> (azidothymidine, AZT, ZDV)	Retrovir	GlaxoSmithKline 888-825-5249	March 19, 1987

Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIS)

	NNRTIs bind to and later alter reverse transcriptase, an enzyme HIV needs to make copies of itself.	<u>delavirdine</u> (delavirdine mesylate, DLV)	Rescriptor	Pfizer 212-733-2323	April 4, 1997
	<u>efavirenz</u> (EFV)	Sustiva	Bristol–Myers Squibb 800–332–2056	September 17, 1998	
		<u>etravirine</u> (ETR)	Intelence	Janssen Pharmaceuticals, Inc. 800-526-7736	January 18, 2008
		<u>nevirapine</u> (NVP)	Viramune	Boehringer Ingelheim	June 21, 1996
			Viramune XR (extended release)	800-243-0127	March 25, 2011
		<u>rilpivirine</u> (rilpivirine hydrochloride, RPV)	Edurant	Janssen Pharmaceuticals, Inc. 800-526-7736	May 20, 2011

Protease Inhibitors (PIs)

PIs block HIV protease, an enzyme HIV needs to make copies of itself	<u>atazanavir</u> (atazanavir sulfate, ATV)	Reyataz	Bristol–Myers Squibb 800–332–2056	June 20, 2003
	<u>darunavir</u> (darunavir ethanolate, DRV)	Prezista	Janssen Pharmaceuticals, Inc. 800-526-7736	June 23, 2006
	<u>fosamprenavir</u> (fosamprenavir calcium, FPV)	Lexia	GlaxoSmithKline 888-825-5249	October 20, 2003
	<u>indinavir</u> (indinavir sulfate, IDV)	Crixivan	Merck 908-423-1000 800-727-5400	March 13 1996
	<u>nelfinavir</u> (nelfinavir mesylate, NFV)	Viracept	Agouron Pharmaceuticals 619-622-3000	March 14 1997

aidsinfo.nih.gov/education-materials/fact-sheets/print/19/45/0/1

diusi	nfo.nih.gov/education-materials/	lact-sneets/print/19	/45/0/1	
	<u>ritonavir</u> (RTV)	Norvir	Abbott Laboratories 847-937-6100	March 1, 1996
	<u>saquinavir</u> (saquinavir mesylate, SQV)	Invirase	Hoffmann-La Roche 888-835-2555	December 6, 1995
	<u>tipranavir</u> (TPV)	Aptivus	Boehringer Ingelheim 800–243–0127	June 22, 2005
Fusion Inhibitors				1
Fusion inhibitors block HIV from entering the <u>CD4 cells</u> of the <u>immune</u> <u>system</u> .	<u>enfuvirtide</u> (T-20)	Fuzeon	Hoffmann-La Roche 888-835-2555	March 13, 2003
Entry Inhibitors			-	
Entry inhibitors block proteins on the CD4 cells that HIV needs to enter the cells.	<u>maraviroc</u> (MVC)	Selzentry	Pfizer 212-733-2323	August 6, 2007
Integrase Inhibitors				
Integrase inhibitors block HIV integrase, an enzyme HIV needs to	<u>dolutegravir</u> (DTG)	Tivicay	Viiv Healthcare 888-825-5249	August 13, 2013
make copies of itself.	<u>raltegravir</u> (RAL)	lsentress	Merck 908-423-1000 800-727-5400	October 12, 2007
Combination HIV Medicines				1
Combination HIV medicines contain two or more HIV medicines from one	<u>abacavir and</u> <u>lamivudine</u>	Epzicom	GlaxoSmithKline 888-825-5249	August 2, 2004
or more drug classes.	<u>abacavir, lamivudine,</u> <u>and zidovudine</u>	Trizivir	GlaxoSmithKline 888-825-5249	Nov. 14, 2000
	<u>efavirenz,</u> <u>emtricitabine, and</u> <u>tenofovir DF</u>	Atripla	Bristol-Myers Squibb 800-332-2056 Gilead Sciences 800-445-3235	July 12, 2006
	<u>elvitegravir*,</u> <u>cobicistat†,</u> <u>emtricitabine, and</u> <u>tenofovir DF</u>	Stribild	Gilead Sciences 800-445-3235	August 27, 2012
	<u>emtricitabine,</u> <u>rilpivirine, and</u> <u>tenofovir DF</u>	Complera	Gilead Sciences 800-445-3235	August 10, 2011
	<u>emtricitabine and</u> <u>tenofovir DF</u>	Truvada	Gilead Sciences 800-445-3235	August 2, 2004
	<u>lamivudine and</u> zidovudine	Combivir	GlaxoSmithKline 888-825-5249	September 27, 1997
	lopinavir and ritonavir (LPV/RTV)	Kaletra	Abbott Laboratories 847-937-6100	September 15, 2000

* Elvitegravir is an integrase inhibitor that is approved only for use as a component of Stribild.

+ Cobicistat is a type of medicine called a pharmacokinetic enhancer. It is used to increase the effectiveness of

elvitegravir.

This fact sheet is based on information from the following sources:

- From FDA: Antiretroviral Drugs Used in the Treatment of HIV Infection
- From the National Institute of Allergy and Infectious Diseases: Drugs That Fight HIV



HIV Overview HIV/AIDS Clinical Trials

(Last updated 9/27/2013; last reviewed 9/27/2013)

Key Points

- HIV/AIDS clinical trials are research studies done to look at new ways to prevent, detect, or treat HIV/AIDS. Clinical trials are the fastest way to determine if new medical approaches to HIV/AIDS are safe and effective in people.
- Examples of HIV/AIDS clinical trials under way include studies of new HIV medicines, studies of vaccines to prevent and treat HIV, and studies of medicines to treat infections related to HIV.
- The benefits and possible risks of participating in an HIV/AIDS clinical trial are explained to study volunteers before they decide whether to participate in a study.
- Use the AIDSinfo clinical trial search to find HIV/AIDS studies looking for volunteer participants. Some HIV/AIDS clinical trials enroll only people infected with HIV. Other studies enroll people who aren't infected with HIV.

What is a clinical trial?

A clinical trial is a research study done to evaluate new medical approaches in people. New approaches can include:

- new medicines or new combinations of medicines
- new surgical procedures or devices
- new ways to use an existing medicine or device

Clinical trials are the fastest way to determine if new medical approaches are safe and effective in people.

What is an HIV/AIDS clinical trial?

HIV/AIDS clinical trials help researchers find better ways to prevent, detect, or treat HIV/AIDS. All the medicines used to treat HIV/AIDS in the United States were first studied in clinical trials.

Examples of HIV/AIDS clinical trials under way include:

- · studies of new medicines to treat HIV
- studies of vaccines to prevent and treat HIV
- studies of medicines to treat infections related to HIV

Can anyone participate in an HIV/AIDS clinical trial?

It depends on the needs of the study. Some HIV/AIDS clinical trials enroll only people infected with HIV. Other studies include people who aren't infected with HIV.

Other factors such as age, gender, HIV treatment history, or other medical conditions may also restrict who can participate in an HIV/AIDS clinical trial.

What are the benefits of participating in an HIV/AIDS clinical trial?

Participating in an HIV/AIDS clinical trial can provide benefits. For example, many people participate in HIV/AIDS clinical trials because they want to contribute to HIV/AIDS research. They may have HIV or know somebody who is infected with HIV.

People with HIV who participate in an HIV/AIDS clinical trial may benefit from new HIV medicines before they are widely available. They can also receive regular and careful medical care from a research team that includes doctors and other health professionals. Often the medicines and medical care are free of charge.

Sometimes people get paid for participating in a clinical trial. For example, they may receive money or a gift card. They may be reimbursed for the cost of meals or transportation.

Are HIV/AIDS clinical trials safe?

Researchers try to make HIV/AIDS clinical trials as safe as possible. However, volunteering to participate in a study that is testing an experimental treatment for HIV can involve risks of varying degrees. Risks can include unpleasant, serious, or even life-threatening side effects from the treatment being studied.

In a process called <u>informed consent</u>, study volunteers are informed of the possible risks and benefits of a clinical trial. Understanding the risks and benefits helps volunteers decide whether to participate in the study.

If I decide to participate in a clinical trial, will my personal information be shared?

The privacy of study volunteers is important to everyone involved in an HIV/AIDS clinical trial. The informed consent process includes an explanation of how a study volunteer's personal information is protected.

How can I find an HIV/AIDS trial in which to participate?

To find an HIV/AIDS clinical trial looking for volunteers, use the <u>AIDSinfo clinical trial search</u>. For help with your search, call an AIDSinfo health information specialist at 1-800-448-0440 or e-mail contactus@aidsinfo.nih.gov.

This fact sheet is based on information from the following sources:

- From the National Institutes of Health (NIH):
 - Learn About Clinical Studies
 - NIH Clinical Research Trials and You: The Basics
 - A Patient's Guide to Clinical Trials

- From the Food and Drug Administration (FDA):
 - Basic Questions and Answers about Clinical Trials



HIV Prevention The Basics of HIV Prevention

(Last updated 9/27/2013; last reviewed 9/27/2013)

Key Points

- HIV is spread through contact with the blood, semen, vaginal fluid, or breast milk of a person infected with HIV.
- The most common way to get HIV is by having unprotected sex with a person who has HIV. (Unprotected sex means not using a condom.) Another common way to get HIV is by sharing drug injection equipment (such as needles and syringes) with a person infected with HIV.
- To reduce your risk of HIV infection, use condoms correctly every time you have vaginal, oral, or anal sex. Don't inject drugs. If you do, use only clean needles and equipment and don't share your equipment with others.
- Treatment with HIV medicines (called antiretroviral therapy or ART for short) helps people with HIV live longer, healthier lives. Although ART can reduce the risk of HIV transmission, it's still important to use condoms during sex.

How is HIV spread?

HIV is spread through contact with the blood, semen, vaginal fluid, or breast milk of a person infected with HIV. The spread of HIV from person to person is called HIV transmission.

The most common way to get HIV is by having unprotected sex with a person who has HIV. (Unprotected sex means not using a condom.) During unprotected vaginal, oral, or anal sex, HIV can enter the opening to the penis or the lining of the vagina, mouth, anus, or rectum. It can also enter through cuts and sores in the mouth or on the skin.

Another common way to get HIV is by sharing drug injection equipment (such as needles and syringes) with a person who has HIV.

HIV can also pass from an HIV-infected woman to her child during pregnancy, childbirth (also called labor and delivery), or breastfeeding. This spread of HIV is called mother-to-child transmission of HIV.

In the past, some people were infected with HIV after receiving a blood transfusion or organ transplant from an HIV-infected donor. Today, this risk is very low because the supply of donated blood and organs is carefully tested in the United States.

You can't get HIV by shaking hands with, hugging, or closed-mouth kissing a person infected with HIV. And you can't get HIV from contact with objects such as toilet seats, doorknobs, or dishes used by a person infected with HIV.

How can I reduce my risk of getting HIV?

Anybody can get HIV, but you can take steps to protect yourself from HIV infection.

- Don't have sex. Abstinence (not having sex of any kind) is a sure way to avoid HIV infection through sexual contact.
- Get tested and know your partner's HIV status. Talk to your partner about HIV testing and get tested before you have sex.
- Be faithful to your partner. If you and your partner are both HIV negative and have sex only with each other, you are not at risk of HIV infection through sexual contact.
- Use condoms. Use a condom every time you have vaginal, anal, or oral sex. <u>Read this</u> <u>fact sheet on how to use condoms correctly.</u>
- Limit your number of sexual partners. If you have more than one sexual partner, get tested for HIV regularly. Get tested and treated for sexually transmitted infections (STIs), and insist that your partners do, too. Having an STI can increase your risk of becoming infected with HIV.
- Don't inject drugs. But if you do, use only clean needles and equipment and don't share your equipment with others.

I am HIV positive but my partner is HIV negative. How can I protect my partner from HIV?

To protect your partner, use condoms correctly every time you have sex. Don't share sex toys, razor blades, toothbrushes, or other items that may have your blood or sexual fluids on them. If you inject drugs, don't share your needles, syringes, or other drug equipment with your partner.

Treatment with HIV medicines (called antiretroviral therapy or ART for short) helps people with HIV live longer, healthier lives. ART can't cure HIV infection but it can reduce the amount of HIV in an HIV-infected person's body. Having less HIV in the body reduces the risk of HIV transmission.

If you aren't already taking HIV medicines, talk to your health care provider about the benefits of ART for your health and to protect your partner from HIV. If you are taking HIV medicines, remember it's still important to use condoms.

To learn more, read this fact sheet: When One Partner is HIV+.

Are HIV medicines used to prevent HIV infection?

Yes, in some situations HIV medicines are used to reduce the risk of HIV infection.

• Pre-exposure prophylaxis (PrEP)

PrEP is an HIV prevention method that involves taking an HIV medicine every day. PrEP is intended for people who don't have HIV but who are at high risk of sexually

transmitted HIV infection. PrEP should always be combined with other prevention methods, including condom use.

- Post-exposure prophylaxis (PEP) PEP involves taking HIV medicines as soon as possible after exposure to HIV to reduce the risk of HIV infection. For example, a health care worker exposed to HIV in the workplace may require PEP.
- Prevention of mother-to-child transmission of HIV HIV-infected women take HIV medicines during pregnancy and childbirth to reduce the risk of mother-to-child transmission of HIV. To further reduce the risk, their newborn babies also receive HIV medicine for six weeks after birth. In the United States, women with HIV are counseled not to breastfeed their babies to prevent mother-to-child transmission of HIV in breast milk.

How can I learn more about preventing HIV?

- <u>Watch this video on HIV prevention</u>.
- Browse through the following information. This fact sheet is based on this information.
 - From the Centers for Disease Control and Prevention: HIV Transmission
 - From the Department of Veterans Affairs: <u>How is HIV spread?</u>
 - From the Office on Women's Health: Preventing HIV infection



HIV Prevention Prevention of Mother-to-Child Transmission of HIV

(Last updated 9/29/2013; last reviewed 9/29/2013)

Key Points

- The spread of HIV from an HIV-infected woman to her child is called motherto-child transmission of HIV. A woman with HIV can spread HIV to her baby during pregnancy, childbirth (also called labor and delivery), or through breastfeeding.
- Pregnant women with HIV receive HIV medicines to reduce the risk of motherto-child transmission of HIV. In some situations, a woman with HIV may have a scheduled cesarean delivery (also called a <u>C-section</u>) to prevent mother-tochild transmission of HIV.
- Babies born to women with HIV receive HIV medicine for 6 weeks after birth. The HIV medicine reduces the babies' risk of infection from any HIV that passes from mother to child during childbirth.
- Because HIV can be transmitted in breast milk, women with HIV living in the United States should not breastfeed their babies. In the United States, baby formula is a safe and healthy alternative to breast milk.

What is mother-to-child transmission of HIV?

The spread of HIV from an HIV-infected woman to her child is called mother-to-child transmission of HIV. (It's also called perinatal transmission of HIV.) A woman with HIV can pass HIV to her child:

- during pregnancy
- during childbirth (also called labor and delivery)
- through breastfeeding (HIV can be transmitted in breast milk.)

Mother-to-child transmission is the most common way that children become infected with HIV.

Can mother-to-child transmission of HIV be prevented?

Yes. The risk of mother-to-child transmission of HIV is low when:

- Women with HIV receive HIV medicine during pregnancy and childbirth and, in certain situations, have a scheduled cesarean delivery (also called a <u>C-section</u>)
- Babies born to women with HIV receive HIV medicines for 6 weeks after birth and are not breastfed

Is HIV testing recommended for pregnant women?

The Centers for Disease Control and Prevention (CDC) recommends that all pregnant women get tested for HIV as early as possible in their pregnancy. A woman who knows early in her pregnancy that she is HIV infected can take steps to reduce the risk of passing HIV to her baby. Starting HIV medicines early in pregnancy is the best way to prevent mother-to-child transmission of HIV.

How do HIV medicines prevent mother-to-child transmission of HIV?

Women with HIV take medicines during pregnancy and childbirth to reduce the amount of HIV in the body. Having less HIV in the body reduces the risk of mother-to-child transmission of HIV. The HIV medicines also protect the mothers' health.

Some of the HIV medicine passes from the pregnant woman to her unborn baby across the <u>placenta</u> (also called the afterbirth). This transfer of HIV medicine protects the baby from HIV infection, especially during a vaginal delivery when the baby may be exposed to HIV in the mother's blood or other fluids. In some situations, a woman with HIV may have a cesarean delivery (C-section) to reduce the risk of mother-to-child transmission of HIV.

Babies born to women with HIV receive HIV medicine for 6 weeks after birth. The HIV medicine reduces the risk of infection from HIV that may have entered a baby's body during childbirth.

Are HIV medicines safe to use during pregnancy?

Pregnant women with HIV can safely use many HIV medicines during pregnancy to prevent mother-to-child transmission of HIV and to protect their own health. However, the following factors affect the use of HIV medicines during pregnancy:

- Changes during pregnancy that can affect how the body processes HIV medicines. Because of these changes, the dose of an HIV medicine may change during pregnancy.
- The increased risk of certain side effects from some HIV medicines.
- The potential risk of birth defects with use of some HIV medicines, although no HIV medicines have been clearly linked to birth defects. Women with HIV who take HIV medicines during pregnancy are encouraged to enroll in the <u>Antiretroviral Pregnancy Registry</u>. The registry is a project established to monitor prenatal exposures to HIV medicines and to detect any potential increase in the risk of related birth defects. Pregnant women exposed to HIV medicines voluntarily enroll in the Registry through their health care providers.

Pregnant women and their health care providers carefully consider the benefits and the risks of specific HIV medicines when choosing HIV medicines to use during pregnancy.

Are there other ways to prevent mother-to-child transmission of HIV?

Because HIV can be transmitted in breast milk, HIV-infected woman in the United States should not breastfeed their babies. In the United States, baby formula is a safe and healthy alternative to breast milk.

There is evidence that HIV can spread in food that was previously chewed by a person infected with HIV. To be safe, babies should not be fed pre-chewed food.

How can I learn more about preventing mother-to-child transmission of HIV?

- Watch this video on preventing mother-to-child transmission of HIV.
- Read about approaches to HIV testing in pregnant women.
- Read the following AIDSinfo fact sheets: <u>Use of HIV Medicines During</u> <u>Pregnancy</u>, <u>Preventing Mother-to-Child Transmission During Childbirth</u>, and <u>Preventing</u> <u>Mother-to-Child Transmission After Birth</u>.

This fact sheet is based on information from the following sources:

- From CDC: HIV Among Pregnant Women, Infants, and Children
- From the Department of Health and Human Services: <u>Recommendations for Use of</u> <u>Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and</u> <u>Interventions to Reduce Perinatal HIV Transmission in the United States</u>
- From the National Institute of Allergy and Infectious Diseasease: <u>HIV Infection in</u> <u>Women/Mother-to-Child Transmission (MTCT) of HIV</u>



HIV Treatment: The Basics

(Last updated 9/29/2013; last reviewed 9/29/2013)

Key Points

- Antiretroviral therapy (ART) is the use of HIV medicines to treat HIV infection. ART involves taking a combination of HIV medicines (called an <u>HIV regimen</u>) every day.
- ART is recommended for all people infected with HIV. ART can't cure HIV, but it can help people infected with HIV live longer, healthier lives. ART also reduces the risk of <u>sexual transmission</u> of HIV.
- Potential risks of ART include side effects from HIV medicines and <u>drug</u> <u>interactions</u> between HIV medicines or between HIV medicines and other medicines a person is taking. Poor adherence—not taking HIV medicines every day and exactly as prescribed—can lead to <u>drug resistance</u>, which is another risk of ART.
- When to start ART and what HIV medicines to take depend on a person's individual needs. People with HIV work closely with their health care providers to make decisions regarding the use of HIV medicines.

What is antiretroviral therapy?

Antiretroviral therapy (ART) is the use of HIV medicines to treat HIV infection. ART involves taking a combination of HIV medicines (called an <u>HIV regimen</u>) every day. ART is recommended for everyone with HIV. ART can't cure HIV, but it helps people with HIV live longer, healthier lives.

How do HIV medicines work?

HIV attacks and destroys the infection-fighting <u>CD4 cells</u> of the <u>immune system</u>. Loss of CD4 cells makes it hard for the body to fight off infections.

HIV medicines prevent HIV from multiplying (making copies of itself), which reduces the amount of HIV in the body. Having less HIV in the body gives the immune system a chance to recover. Even though there is still some HIV in the body, the immune system is strong enough to fight off infections and cancers.

By reducing the amount of HIV in the body, HIV medicines also reduce the risk of HIV transmission to sexual partners.

What are risks of taking HIV medicines?

Potential risks of ART include side effects from HIV medicines and <u>drug interactions</u> between HIV medicines or between HIV medicines and other medicines a person is taking. Poor adherence—not taking HIV medicines every day and exactly as prescribed—can lead to <u>drug resistance</u>, which is another risk of ART.

Side effects

Side effects from HIV medicines can vary depending on the medicine and the person taking the medicine. People taking the same HIV medicine can have very different side effects. Some side effects, for example, headache or occasional dizziness, may not be serious. Other side effects, such as swelling of the mouth and tongue or liver damage, can be life-threatening.

Drug interactions

HIV medicines can interact with other HIV medicines in an HIV regimen. They can also interact with other medicines that a person with HIV is taking. A drug interaction can cause a medicine to be less effective or stronger than desired. Drug interactions can also cause side effects.

Drug resistance

When HIV multiplies, the virus sometimes mutates (changes form) and makes variations of itself. Variations of HIV that develop while a person is taking HIV medicines can lead to drug-resistant strains of HIV. HIV medicines that previously worked against a person's HIV can't suppress the new, drug-resistant HIV. In other words, the person's HIV continues to multiply. Drug resistance can cause HIV treatment to fail. Poor adherence to an HIV regimen increases the risk of drug resistance.

When is it time to start treatment with HIV medicines?

When to start ART depends on a person's individual needs. Factors that influence the decision to start ART include:

- The overall health of the person with HIV, including any other medical conditions or HIV-related illnesses the person may have
- The person's test results, especially <u>CD4 count</u> results
- The person's readiness for lifelong treatment with HIV medicines

What HIV medicines should be included in an HIV regimen?

There are more than 20 HIV medicines available to make up an HIV regimen. The HIV medicines are grouped into six <u>drug classes</u> according to how they fight HIV. A person's initial HIV regimen usually includes three or more HIV medicines from at least two different HIV drug classes.

Selection of an HIV regimen depends on several factors, including possible side effects of HIV medicines and potential drug interactions between medicines. Because the needs of people with HIV vary, there are several HIV regimens to choose from.

How can I learn more about ART?

To learn more about ART, read the fact sheets in the AIDSinfo HIV Treatment series. Topics covered in the series include starting ART, recommended HIV regimens, side effects of HIV medicines, HIV drug resistance, and medication adherence.

This fact sheet is based on information from the following sources:

- From the Department of Health and Human Services: <u>Guidelines for the Use of</u> <u>Antiretroviral Agents in HIV-1-Infected Adults and Adolescents</u>
- From the Department of Veterans Affairs: Treatment Decisions
- From the National Institute of Allergy and Infectious Diseases: <u>Treatment of HIV</u>
 <u>Infection</u>



HIV Treatment Just Diagnosed: Next Steps After Testing Positive for HIV

(Last updated 9/30/2013; last reviewed 9/30/2013)

Key Points

- For people with HIV, the first step after testing HIV positive is to see a health care provider.
- People with HIV work closely with their health care providers to make important decisions, such as when to start treatment and what HIV medicines to take. Making these decisions begins with a baseline evaluation.
- A baseline evaluation includes a review of the person's health and medical history, a physical exam, and lab tests.
- Results from a baseline evaluation are used to determine the stage of the person's HIV infection, assess the person's readiness to start HIV medicines, and guide selection of the person's first <u>HIV regimen</u>

What is the next step after testing positive for HIV?

Testing positive for HIV often leaves a person overwhelmed with questions and concerns. So the first step after testing positive is to see a health care provider.

People with HIV work closely with their health care providers to make important decisions, such as when to start treatment and what HIV medicines to take. Making these decisions begins with a baseline evaluation.

What is an HIV baseline evaluation?

A baseline evaluation includes all the information collected during a person's initial visits with a health care provider. An HIV baseline evaluation involves a review of the person's health and medical history, a physical exam, and lab tests.

The purpose of a baseline evaluation is to:

- Determine the stage of the person's HIV infection
- Evaluate the person's readiness to start treatment
- Collect information to guide selection of the person's first HIV regimen

As part of the baseline evaluation process, the health care provider also explains the benefits and risks of HIV treatment and discusses ways to reduce the risk of passing HIV to others. The health care provider also takes time to answer any questions.

What are some questions people with HIV typically ask during their first visits with an HIV health care provider?

People often ask their health care providers the following questions:

- Because I have HIV, will I eventually get AIDS?
- What can I do to stay healthy and avoid getting other infections?
- How will HIV treatment affect my lifestyle?
- How should I tell my partner that I have HIV?
- Is there any reason to tell my employer and those I work with that I have HIV?
- Are there support groups for people with HIV?

Many people find it helpful to write down questions before a medical appointment. Some people bring a family member or friend to their HIV appointments to remind them of questions to ask and to jot down the answers.

What lab tests are included in a baseline evaluation?

The following tests are conducted as part of a baseline evaluation.

CD4 count

A CD4 count measures the number of CD4 cells in a sample of blood. CD4 cells are infectionfighting cells of the <u>immune system</u>. HIV destroys CD4 cells, which damages the immune system. A damaged immune system makes it hard for the body to fight off infections. Treatment with HIV medicines (<u>antiretroviral therapy [ART]</u>) prevents HIV from destroying CD4 cells.

Because a falling CD4 count indicates that HIV is advancing and damaging the immune system, the test is an important factor in the decision to start ART. The test is also used to monitor the effectiveness of HIV medicines once treatment is started.

Viral load

A viral load test measures how much virus is in the blood (viral load). A goal of HIV treatment is to keep a person's viral load so low that the virus can't be detected by a viral load test. A high viral load increases the urgency to start ART.

Drug-resistance testing

Drug-resistance testing identifies which, if any, HIV medicines will not be effective against a person's strain of HIV. Drug resistance test results are used to guide selection of an HIV regimen.

Testing for sexually transmitted infections (STIs)

<u>Coinfection</u> with another STI can cause HIV infection to advance faster and increase the risk of HIV transmission to a sexual partner. STI testing makes it possible to detect and treat any STIs promptly.

A baseline evaluation also includes other tests, such as a blood cell count, kidney and liver function tests, and tests for hepatitis.

How does a baseline evaluation help determine if a person is ready to start HIV treatment?

Before starting treatment, people with HIV must be prepared to take HIV medicines every day for the rest of their lives. A baseline evaluation can help to identify any issues that can make medication adherence difficult, such as lack of health insurance or alcohol or drug abuse. (Medication adherence means taking HIV medicines every day and exactly as prescribed.) Health care providers can recommend additional support to help people deal with these issues before treatment starts.

How can I find more resources for a person who has just tested HIV positive?

- Share this fact sheet on finding HIV/AIDS care.
- Print out this list of questions to ask a health care provider.
- Share this fact sheet about AIDS myths and misunderstandings.

This fact sheet is based on information from these sources:

- From the Department of Veterans Affairs: Just Diagnosed
- From the Health Resources and Services Administration: <u>Guide for HIV/AIDS Clinical</u> <u>Care/Testing and Assessment</u>
- From the Department of Health and Human Services: <u>Guidelines for the Use of</u> <u>Antiretroviral Agents in HIV-1-Infected Adults and Adolescents/Baseline Evaluation</u>



HIV Treatment When to Start Antiretroviral Therapy

(Last updated 9/29/2013; last reviewed 9/29/2013)

Key Points

- <u>Antiretroviral therapy (ART)</u> is the use of HIV medicines to treat HIV infection. ART is recommended for everyone infected with HIV. When to start ART, however, depends on a person's unique needs and circumstances.
- A person's <u>CD4 count</u> is an important factor in the decision to start ART. A falling CD4 count indicates that HIV is advancing and damaging the <u>immune</u> <u>system</u>. A rapidly decreasing CD4 count increases the urgency to start ART.
- The U.S. Department of Health and Human Services (HHS) provides guidelines on the use of HIV medicines to treat HIV infection. The <u>HHS guidelines</u> recommend ART for everyone infected with HIV, but the recommendation is strongest for those with CD4 counts less than 350 cells/mm³.
- Regardless of CD4 count, there is greater urgency to start ART when a person has a high <u>viral load</u> or any of the following conditions: pregnancy, <u>AIDS</u>, and certain HIV-related illnesses and <u>coinfections</u>.
- ART is a life-long treatment that helps people with HIV live longer, healthier lives. But effective ART depends on adherence— taking HIV medicines every day and exactly as prescribed. Before starting ART, it's important to address issues that can make adherence difficult.

When is it time to start treatment with HIV medicines?

Treatment with HIV medicines (called antiretroviral therapy or ART for short) is recommended for everyone infected with HIV. When to start ART, however, depends on a person's unique needs and circumstances.

What factors influence the decision to start ART?

The following factors influence the decision to start ART:

- A person's <u>CD4 count</u> and other test results
- Pregnancy
- HIV-related illness or AIDS (AIDS is the most advanced stage of HIV infection.)

• A person's ability and willingness to commit to lifelong treatment with HIV medicines Why is a person's CD4 count an important factor in deciding when to start ART?

A CD4 count measures the number of CD4 cells in a sample of blood. CD4 cells are infectionfighting cells of the <u>immune system</u>. HIV attacks and destroys CD4 cells, making it hard for the body to fight off infection. A falling CD4 count indicates that HIV is advancing and damaging the immune system. If a person's CD4 count is rapidly decreasing, there is greater urgency to start ART.

The U.S. Department of Health and Human Services (HHS) provides guidelines on the use of HIV medicines to treat HIV infection. The <u>HHS guidelines</u> recommend ART for everyone with HIV, but the recommendation is strongest for those with CD4 counts less than 350

cells/mm³. (The CD4 count of a healthy person ranges from 500 to 1,200 cells/mm³.)

Once a person starts taking HIV medicines, an increasing CD4 count is a sign that the immune system is recovering.

What other factors increase the urgency to start ART?

Other factors that increase the urgency to start ART include high viral loads and conditions such as pregnancy, AIDS, and certain HIV-related illnesses and co-infections.

• High viral loads

An HIV viral load test measures the amount of HIV in a person's blood. The urgency for ART increases when a person's viral load is greater than 100, 000 copies/mL.

• Pregnancy

Pregnant women with HIV should take HIV medicines to prevent mother-to-child transmission of HIV and to protect their own health. Women who have a high viral load or symptoms of HIV infection should start taking HIV medicines as soon as possible in pregnancy. Women without symptoms of HIV infection and a high viral load may consider waiting until after the first trimester of pregnancy (12 weeks of pregnancy) to begin taking HIV medicines.

• AIDS

People whose HIV has advanced to AIDS need to take HIV medicines. A diagnosis of AIDS is based on the following:

• A CD4 count less than 200 cells/mm³

OR

- The presence of an AIDS-defining condition. AIDS-defining conditions are infections and cancers that are life-threatening when they develop in people with HIV. Certain forms of cervical cancer and tuberculosis are examples of AIDSdefining conditions.
- HIV-related illnesses and co-infections Some illnesses that develop in people infected with HIV increase the urgency for ART. These illnesses include HIV-related kidney disease and certain opportunistic infections (OIs). OIs are infections that develop more often or are more severe in people with weakened immune systems, such as people with HIV.

Coinfection is when a person has two or more infections at the same time. The urgency for ART is increased in individuals who are infected with HIV and <u>hepatitis B</u> or <u>hepatitis C</u> virus.

How does a person's readiness to take HIV medicines every day affect the decision to start treatment?

ART is a life-long treatment that helps people with HIV live longer, healthier lives. But effective treatment depends on adherence—taking HIV medicines every day and exactly as prescribed. Before starting ART, it's important to address issues that can make adherence difficult.

How can I learn more about factors that affect the decision to start ART?

- Read this fact sheet on CD4 count.
- Read the AIDSinfo fact sheet on <u>HIV Medication Adherence</u>.

This fact sheet is based on information from the following sources:

- From the Department of Health and Human Services: <u>Guidelines for the Use of</u> <u>Antiretroviral Agents in HIV-1-Infected Adults and Adolescents/Initiating Antiretroviral</u> <u>Therapy in Treatment-Naive Patients</u>
- From the Department of Veterans Affairs: Treatment Decisions for HIV
- From the Health Resources and Services Administration: <u>Guide for HIV/AIDS Clinical</u> <u>Care/Antiretroviral Therapy</u>



HIV Treatment What to Start: Selecting a First

HIV Regimen

(Last updated 11/7/2013; last reviewed 11/7/2013)

Key Points

- The use of HIV medicines to treat HIV infection is called antiretroviral therapy (ART). ART involves taking a combination of HIV medicines (called an HIV regimen) every day.
- HIV medicines are grouped into six drug classes according to how they fight HIV. The six drug classes include over 20 HIV medicines.
- The U.S. Department of Health and Human Services (HHS) provides guidelines on the use of HIV medicines to treat HIV infection. The <u>HHS guidelines</u> recommend starting treatment with a regimen of three or more HIV medicines from at least two different drug classes.
- The choice of HIV medicines to include in an HIV regimen varies depending on a person's individual needs. Factors to consider when choosing an HIV regimen include possible side effects of HIV medicines, the potential for <u>drug</u> <u>interactions</u>, and the health of the person with HIV.

What is the next step after deciding to start HIV treatment?

The next step is choosing the HIV medicines to take. The use of HIV medicines to treat HIV infection is called antiretroviral therapy (ART). ART involves taking a combination of HIV medicines (called an HIV regimen) every day.

There are over 20 HIV medicines approved for use in an HIV regimen. Some HIV medicines are available in combination (in other words, two or more different HIV medicines combined in one pill).

The U.S. Department of Health and Human Services (HHS) guidelines on the use of HIV

<u>medicines</u> recommend starting treatment with a regimen of three or more HIV medicines from at least two different drug classes.

What are the HIV drug classes?

HIV medicines are grouped into six drug classes according to how they fight HIV. The six drug classes are:

- Non-nucleoside reverse transcriptase inhibitors (NNRTIs)
- <u>Nucleoside reverse transcriptase inhibitors (NRTIs)</u>
- Protease inhibitors (PIs)
- Fusion inhibitors
- <u>CCR5 antagonists (CCR5s)</u> (also called entry inhibitors)
- Integrase inhibitors (INSTIs)

In general, a person's first HIV regimen includes two NRTIs in combination with an NNRTI, a PI, an INSTI, or a CCR5.

Click here to see the <u>AIDSinfo fact sheet that lists the FDA-approved HIV medicines by drug</u> class.

What factors are considered when choosing an HIV regimen?

The choice of HIV medicines to include in an HIV regimen depends on a person's individual needs. When deciding on an HIV regimen, people with HIV and their health care providers consider the following factors:

- Other diseases or conditions that the person with HIV may have
- Possible side effects of HIV medicines
- Potential interactions between HIV medicines or between HIV medicines and other medicines the person with HIV is taking
- Results of <u>drug-resistance testing</u> and other tests
- Convenience of the regimen. For example, a regimen that includes two or more HIV medicines combined in a single pill is convenient to follow.
- Any personal issues that can make it difficult to follow an HIV regimen, for example, a busy schedule that changes from day to day

Careful consideration of these factors helps guide selection of an HIV regimen from the list of recommended regimens.

What are the preferred regimens for people taking HIV medicines for the first time?

The HHS guidelines recommend the following preferred regimens for people taking HIV medicines for the first time:

NNRTI-based regimen

• <u>Atripla</u>

Atripla is a combination of three HIV medicines—<u>efavirenz</u> (brand name: Sustiva),

<u>emtricitabine</u> (brand name: Emtriva), and <u>tenofovir disoproxil fumarate</u> (brand name: Viread)—in one pill.

PI-based regimens

• <u>atazanavir</u> (brand name: Reyataz) boosted with <u>ritonavir</u> (brand name: Norvir) plus <u>Truvada</u>

Ritonavir is an HIV medicine given with other HIV medicines to increase (boost) their effectiveness. Truvada is a combination of two HIV medicines—emtricitabine and tenofovir disoproxil fumarate—in one pill.

• <u>darunavir</u> (brand name: Prezista) boosted with ritonavir plus Truvada INSTI-based regimens

- dolutegravir (brand name: Tivicay) plus Truvada
- dolutegravir plus <u>Epzicom</u> for those who are <u>HLA B*5701</u> negative.
 Epzicom is a combination of two HIV medicines—<u>abacavir</u> (brand name: Ziagen) and <u>lamivudine</u> (brand name: Epivir)—in one pill. Stribild includes the following four
- raltegravir (brand name: Isentress) plus Truvada
- <u>Stribild</u> for those with estimated <u>creatinine clearance (CrCl)</u> ≥70 mL/min medicines combined in one pill: <u>elvitegravir</u>, an HIV medicine only approved for use in Stribild; cobicistat, a medicine used to increase the effectiveness of elvitegravir; emtricitabine; and tenofovir disoproxil fumarate.

Because the needs of people with HIV vary, the preferred regimens may not be right for everyone. The HHS guidelines list alternative HIV regimens to use if none of the preferred regimens meet a person's individual needs.

How long does it take for treatment to work?

Viral load is the measure of HIV in a person's blood. A main goal of HIV treatment is to reduce a person's viral load to an undetectable level. An undetectable viral load means that the level of HIV in the blood is too low to be detected by a viral load test. An undetectable viral load is the best sign that HIV treatment is effective.

Once a person starts treatment, it's possible to have an undetectable viral load within 3 to 6 months. Having an undetectable viral load doesn't mean a person's HIV is cured. There is still some HIV in the person's body, but the undetectable viral load signals that HIV treatment is working effectively. Effective ART helps people with HIV live longer, healthier lives and reduces the risk of HIV transmission.

This fact sheet is based on information from the following sources:

- From the Department of Health and Human Services: <u>Guidelines for the Use of</u> <u>Antiretroviral Agents in HIV-1-Infected Adults and Adolescents/What to Start: Initial</u> <u>Combination Regimens for the Antiretroviral-Naive Patient</u> and <u>Recommendation on</u> <u>Integrase Inhibitor Use in Antiretroviral Treatment-Naive HIV-Infected Individuals from</u> <u>the HHS Panel on Antiretroviral Guidelines for Adults and Adolescents (October 30,</u> <u>2013)</u>
- From the Department of Veterans Affairs: Treatment Decisions
- From the Health Resources and Services Administration: Guide for HIV/AIDS Clinical

Care/Antiretroviral Therapy



HIV Treatment FDA-Approved HIV Medicines

(Last updated 9/30/2013; last reviewed 9/30/2013)

Antiretroviral therapy (ART) is the use of HIV medicines to treat HIV infection. ART involves taking a combination of HIV medicines (called an HIV regimen) every day. A person's initial HIV regimen generally includes three or more HIV medicines from at least two different drug classes.

ART is recommended for all people infected with HIV. ART can't cure HIV, but it can help people with HIV live longer, healthier lives. HIV medicines can also reduce the risk of HIV transmission.

The following table lists HIV medicines approved by the U.S. Food and Drug Administration (FDA) for the treatment of HIV infection in the United States. The HIV medicines are listed according to drug class and identified by generic and brand names.

F	DA-Approved HIV	Medicines		
Drug Class	Generic Name (Other names and acronyms)	Brand Name	Current Manufacturer	FDA Approval Date
Nucleoside Reverse Transcr	iptase Inhibitors (NF	RTIS)		
NRTIs block reverse transcriptase, an <u>enzyme</u> HIV needs to make copies of itself.	<u>abacavir</u> (abacavir sulfate, ABC)	Ziagen	GlaxoSmithKline 888-825-5249	December 17, 1998
	<u>didanosine</u> (ddl, ddl EC)	Videx	Bristol–Myers Squibb 800–332–2056	October 9 1991
		Videx EC (enteric- coated)		October 31, 2000
	<u>emtricitabine</u> (FTC)	Emtriva	Gilead Sciences 800-445-3235	July 2, 2003
	lamivudine (3TC)	Epivir	GlaxoSmithKline 888-825-5249	November 17, 1995
	<u>stavudine</u> (d4T)	Zerit	Bristol-Myers Squibb 800-332-2056	June 24, 1994

ai	dsinfo.nih.gov/education-materi	als/fact-sheets/prin	t/21/51/0/1	
	tenofovir disoproxil fumarate (tenofovir DF, TDF)	Viread	Gilead Sciences 800-445-3235	October 26, 2001
	<u>zidovudine</u> (azidothymidine, AZT, ZDV)	Retrovir	GlaxoSmithKline 888-825-5249	March 19, 1987
Non-Nucleoside Reverse Tra	nscriptase Inhibitor	s (NNRTIS)		
NNRTIs bind to and later alter reverse transcriptase, an enzyme HIV needs to make	<u>delavirdine</u> (delavirdine mesylate, DLV)	Rescriptor	Pfizer 212-733-2323	April 4, 1997
copies of itself.	<u>efavirenz</u> (EFV)	Sustiva	Bristol–Myers Squibb 800–332–2056	September 17, 1998
	<u>etravirine</u> (ETR)	Intelence	Janssen Pharmaceuticals, Inc. 800-526-7736	January 18, 2008
	<u>nevirapine</u> (NVP)	Viramune	Boehringer Ingelheim	June 21, 1996
		Viramune XR (extended release)	800-243-0127	March 25, 2011
	<u>rilpivirine</u> (rilpivirine hydrochloride, RPV)	Edurant	Janssen Pharmaceuticals, Inc. 800-526-7736	May 20, 2011
Protease Inhibitors (PIs)				
PIs block HIV protease, an enzyme HIV needs to make copies of itself	<u>atazanavir</u> (atazanavir sulfate, ATV)	Reyataz	Bristol–Myers Squibb 800–332–2056	June 20, 2003
	<u>darunavir</u> (darunavir ethanolate, DRV)	Prezista	Janssen Pharmaceuticals, Inc. 800-526-7736	June 23, 2006
	<u>fosamprenavir</u> (fosamprenavir calcium, FPV)	Lexia	GlaxoSmithKline 888-825-5249	October 20, 2003
	<u>indinavir</u> (indinavir sulfate, IDV)	Crixivan	Merck 908–423–1000 800–727–5400	March 13, 1996
	<u>nelfinavir</u> (nelfinavir mesylate, NFV)	Viracept	Agouron Pharmaceuticals 619-622-3000	March 14, 1997

<u>ritonavir</u>

(RTV)

Norvir

Abbott

Laboratories 847-937-6100 March 1,

1996

aidsinfo.nih.gov/education-materials/fact-sheets/print/21/51/0/1

	<u>saquinavir</u> (saquinavir mesylate, SQV)	Invirase	Hoffmann-La Roche 888-835-2555	December 6, 1995
	<u>tipranavir</u> (TPV)	Aptivus	Boehringer Ingelheim 800–243–0127	June 22, 2005
Fusion Inhibitors				
Fusion inhibitors block HIV from entering the <u>CD4 cells</u> of the <u>immune system</u> .	<u>enfuvirtide</u> (T–20)	Fuzeon	Hoffmann-La Roche 888-835-2555	March 13, 2003
Entry Inhibitors				
Entry inhibitors block proteins on the CD4 cells that HIV needs to enter the cells.	<u>maraviroc</u> (MVC)	Selzentry	Pfizer 212-733-2323	August 6, 2007
Integrase Inhibitors				
Integrase inhibitors block HIV integrase, an enzyme HIV needs	<u>dolutegravir</u> (DTG)	Tivicay	Viiv Healthcare 888-825-5249	August 13, 2013
to make copies of itself.	<u>raltegravir</u> (RAL)	lsentress	Merck 908–423–1000 800–727–5400	October 12, 2007
Combination HIV Medicines				
Combination HIV medicines contain two or more HIV medicines from one or more drug classes.	<u>abacavir and</u> <u>lamivudine</u>	Epzicom	GlaxoSmithKline 888-825-5249	August 2, 2004
	<u>abacavir,</u> <u>lamivudine, and</u> zidovudine	Trizivir	GlaxoSmithKline 888-825-5249	Nov. 14, 2000
	<u>efavirenz.</u> <u>emtricitabine. and</u> <u>tenofovir DF</u>	Atripla	Bristol–Myers Squibb 800–332–2056	July 12, 2006
			Gilead Sciences 800-445-3235	
	elvitegravir*. cobicistat†. emtricitabine, and tenofovir DF	Stribild	Gilead Sciences 800-445-3235	August 27, 2012
	emtricitabine, rilpivirine, and tenofovir DF	Complera	Gilead Sciences 800-445-3235	August 10, 2011
	emtricitabine and tenofovir DF	Truvada	Gilead Sciences 800-445-3235	August 2, 2004
	lamivudine and zidovudine	Combivir	GlaxoSmithKline 888-825-5249	September 27, 1997

* Elvitegravir is an integrase inhibitor that is approved only for use as a component of Stribild.

+ Cobicistat is a type of medicine called a pharmacokinetic enhancer. It is used to increase the effectiveness of elvitegravir.

This fact sheet is based on information from the following sources:

- From FDA: Antiretroviral Drugs Used in the Treatment of HIV Infection
- From the National Institute of Allergy and Infectious Diseases: Drugs That Fight HIV



HIV Treatment

Drug Resistance

(Last updated 9/29/2013; last reviewed 9/29/2013)

Key Points

- Drug resistance is when HIV creates variations of itself that can't be controlled by HIV medicines that were previously effective. In other words, the HIV medicines no longer prevent a person's HIV from multiplying. Drug resistance can cause HIV treatment to fail.
- A person can initially be infected with drug-resistant HIV or develop drugresistant HIV after starting HIV medicines.
- <u>Drug-resistance testing</u> identifies which, if any, HIV medicines won't be effective against a person's HIV. Drug-resistance testing results help determine which HIV medicines to include in an <u>HIV treatment regimen</u>.
- Adherence to an effective HIV treatment regimen reduces the risk of drug resistance. Adherence means taking HIV medicines every day and exactly as prescribed.

What is drug resistance?

Once a person becomes infected with HIV, the virus begins to multiply (make copies of itself) in the body. As HIV multiplies, it sometimes mutates (changes form) and produces variations of itself. Variations of HIV that develop while a person is taking HIV medicines can lead to drug-resistant strains of HIV. HIV medicines that previously controlled the person's HIV are no longer effective against the new, drug-resistant HIV. In other words, the person's HIV continues to multiply. Drug resistance can cause HIV treatment to fail.

Because drug-resistant HIV can spread from person to person, some people are initially infected with a drug-resistant strain of HIV.

How does poor medication adherence increase the risk of drug resistance?

Medication adherence means taking HIV medicines every day and exactly as prescribed. Skipping HIV medicines allows HIV to multiply, which increases the risk that the virus will mutate and produce drug-resistant HIV.

As a result of drug resistance, one or more HIV medicines in a person's <u>HIV regimen</u> may no longer be effective.

What is cross resistance?

Cross resistance is when resistance to one HIV medicine causes resistance to other medicines in the same HIV drug class. (HIV medicines are grouped into drug classes according to how they fight HIV.) As a result of cross resistance, a person's HIV may be resistant even to HIV medicines that the person has never taken. Cross resistance limits the number of HIV medicines available to include in an HIV regimen.

What is drug-resistance testing?

Drug-resistance testing is done to identify which, if any, HIV medicines won't be effective against a person's strain of HIV. Drug-resistance testing is done using a sample of blood.

Drug-resistance testing is done when a person first begins receiving care for HIV infection. Resistance testing should be done whether the person decides to start taking HIV medicines immediately or to delay treatment. If treatment is delayed, resistance testing should be repeated when treatment begins.

Drug-resistance testing done before a person starts taking HIV medicines for the first time can show whether the person was initially infected with a drug-resistant strain of HIV. The results can also guide the choice of HIV medicines to include in a person's first HIV regimen.

After treatment is started, drug-resistance testing is also done if <u>viral load testing</u> indicates that a person's HIV regimen isn't controlling the virus. If drug-resistance testing shows that the HIV regimen isn't effective because of drug resistance, the test results can be used to select a new HIV regimen.

How can a person taking HIV medicines reduce the risk of drug resistance?

Adherence to an effective HIV treatment regimen reduces the risk of drug resistance.

Here are some tips on adherence for people living with HIV:

- Once you decide to start treatment, work closely with your health care provider to choose an HIV regimen that suits your needs. A regimen that meets your needs will make adherence easier. Tell your health care provider about any personal issues that can make adherence difficult, for example, a busy schedule or an illness such as depression.
- When you start treatment, closely follow your HIV regimen. Take your HIV medicines

every day and exactly as prescribed.

• Keep your medical appointments so that your health care provider can monitor your treatment. Appointments are a good time to ask questions and ask for help to manage problems that make it hard to follow an HIV regimen.

How can I learn more about drug resistance?

- Read about HIV resistance testing.
- Get more tips on HIV medication adherence.

This fact sheet is based on information from the following sources:

- From the Department of Health and Human Services: <u>Guidelines for the Use of</u> <u>Antiretroviral Agents in HIV-1-Infected Adults and Adolescents/Drug-Resistance</u> <u>Testing</u>
- From the Health Resources and Services Administration: <u>Guide for HIV/AIDS Clinical</u> <u>Care/Resistance Testing</u>
- From the National Institute of Allergy and Infectious Diseases: <u>Adherence and Drug</u> <u>Resistance</u>



HIV Treatment HIV Medication Adherence

(Last updated 9/29/2013; last reviewed 9/29/2013)

Key Points

- Medication adherence means sticking firmly to an HIV regimen—taking HIV medicines every day and exactly as prescribed.
- Adherence to an HIV regimen gives HIV medicines the chance to do their job. HIV medicines prevent HIV from multiplying, which protects the <u>immune</u> <u>system</u> and reduces the risk of <u>drug resistance</u>.
- Adherence can be difficult for many reasons. For example, side effects from HIV medicines can make it hard to stick to an HIV regimen.
- To get tips on medication adherence, read this AIDSinfo fact sheet: Following an HIV Regimen: Steps to Take Before and After Starting HIV Medicines.

What is medication adherence?

Adherence means "to stick firmly." So for people with HIV, medication adherence means sticking firmly to an <u>HIV regimen</u>—taking HIV medicines every day and exactly as prescribed.

Why is adherence to an HIV regimen important?

Adherence to an HIV regimen gives HIV medicines the chance to do their job: to prevent HIV from multiplying and destroying the <u>immune system</u>.

Poor adherence to an HIV regimen allows HIV to destroy the immune system. A damaged immune system makes it hard for the body to fight off infections and certain cancers. Poor adherence also increases the risk of drug resistance.

What is drug resistance?

Drug resistance is when HIV is no longer suppressed by HIV medicines that previously prevented the virus from multiplying.

Drug resistance can develop as HIV multiplies in the body. When HIV multiplies, the virus sometimes mutates (changes form) and makes variations of itself. Variations of HIV that develop while a person is taking HIV medicines can lead to new, drug-resistant strains of HIV. The drug-resistant HIV no longer responds to the HIV medicines that used to suppress the person's HIV. In other words, the person's HIV continues to multiply.

Once drug-resistant HIV develops, it remains in the body. Drug resistance limits the number of HIV medicines available to include in a current or future HIV regimen.

What is the connection between medication adherence and drug resistance?

Taking HIV medicines every day prevents HIV from multiplying, which reduces the risk that HIV will mutate and produce drug-resistant HIV. Skipping HIV medicines allows HIV to multiply, which increases the risk of drug-resistant HIV developing.

Research shows that a person's first HIV regimen offers the best chance for long-term treatment success. So adherence is important from the start—when a person first begins taking HIV medicines.

Why is medication adherence sometimes difficult?

Adherence to an HIV regimen can be difficult for several reasons. For example, side effects from HIV medicines, such as nausea or diarrhea, can make it hard to follow an HIV regimen. A complicated regimen that involves taking several pills at different times every day can also be hard to follow.

The following is a list of other factors that can make medication adherence difficult:

- Interactions between HIV medicines and other medicines a person may take
- Trouble swallowing pills or other difficulty taking medicines
- A busy schedule, shift work, or travel away from home that makes it hard to take pills on time
- Illness or depression
- Alcohol or drug use that interferes with the activities of daily life
- Fear of disclosing one's HIV-positive status to others
- Lack of health insurance to pay for HIV medicines

Planning ahead can help. For example, it helps to have a plan in place to manage any issues that can make adherence difficult.

To get tips on adherence, read the <u>AIDSinfo fact sheet: Following an HIV Regimen: Steps to</u> <u>Take Before and After Starting Treatment</u>.

This fact sheet is based on information from the following sources.

- From the Department of Health and Human Services: <u>Guidelines for the Use of</u> <u>Antiretroviral Agents in HIV-1-Infected Adults and Adolescents/Adherence to</u> <u>Antiretroviral Therapy</u>
- From the Health Resources and Services Administration: <u>Guide for HIV/AIDS Clinical</u> <u>Care/HIV Treatment/Adherence</u>



HIV Treatment Following an HIV Regimen: Steps to Take Before and After Starting HIV Medicines

(Last updated 9/29/2013; last reviewed 9/29/2013)

Key Points

- For people with HIV, medication adherence means sticking firmly to an <u>HIV</u> regimen—taking HIV medicines every day and exactly as prescribed.
- Adherence to an HIV regimen gives HIV medicines a chance to do their job. HIV medicines prevent HIV from multiplying, which protects the <u>immune</u> <u>system</u> and reduces the risk of <u>drug resistance</u>.
- This fact sheet offers people living with HIV tips on adherence to try before and after starting an HIV regimen.

Before starting an HIV regimen, talk to your health care provider about medication adherence.

Talking with your health care provider will help you understand why you're starting HIV treatment and why medication adherence is important. Information that you share with your health care provider will make it easier to select an <u>HIV regimen</u> that suits your needs. The information will also help you and your health care provider plan ahead for any issues that may make adherence difficult.

Tell your health care provider about other medicines you take, including vitamins, herbal supplements, and other medicines you buy without a prescription. Other medicines you take may interact with the HIV medicines in your HIV regimen. A <u>drug interaction</u> can cause a medicine to be less effective or stronger than desired. Drug interactions can also cause side

effects.

Tell your health care provider about any personal issues that can make adherence difficult, such as depression or alcohol or drug use that interferes with the activities of daily life. If needed, your health care provider can recommend resources to help you address these issues before you start treatment.

Describe your schedule at home and at work to your health care provider. Working together, you can arrange your HIV medication schedule to match your day-to-day routine.

Ask your health care provider for written instructions on how to follow your HIV regimen. The instructions should include the following details:

- Each HIV medicine included in your regimen
- · How many pills of each medicine to take
- When to take each medicine
- How to take each medicine (for example, with or without food)
- Possible side effects from each medicine, including serious side effects
- How to store each medicine

Try practicing the instructions by using small candies instead of actual HIV medicines. The practice will help you identify and address problems with adherence before you start your HIV regimen.

After you start an HIV regimen, use a variety of strategies to maintain adherence.

To maintain adherence over the long term, try some of the following strategies:

- Use a 7-day pill box. Once a week, fill the pill box with your HIV medicines for the entire week.
- Take your HIV medicines at the same time every day.
- Set the alarm on your cell phone to remind you to take your medicines. (An alarm clock or timer works too.)
- Ask your family members, friends, or coworkers to remind you to take your medicines.
- Keep your medicines nearby. Keep a back-up supply of medicines at work or in your purse or briefcase.
- Plan ahead for changes in your daily routine, including weekends and holidays. If you're going away, pack enough medicine to last the entire trip.
- Use a medicine diary to stay on track. There are many apps available for smartphones that you can use to record when you take your medicines. (Or if you prefer, use a paper bound diary.) Enter the name of each medicine; include the dose, number of pills to take, and when to take them. Record each medicine as you take it. Reviewing your diary will help you identify the times that you're most likely to forget to take your medicines.
- Keep all your medical appointments. Use a calendar to keep track of your appointments. If you run low on medicines before your next appointment, call your health care provider to renew your prescriptions.
- Get additional tips on adherence by joining a support group for people living with HIV.

Don't panic if you forget to take your HIV medicines.

Unless your health care provider tells you otherwise, take a medicine you missed as soon as you realize you skipped it. But if it's almost time for the next dose of the medicine, don't take the missed dose and just continue on your regular medication schedule. Don't take a double dose of a medicine to make up for a missed dose.

Discuss medication adherence at each appointment with your health care provider.

Tell your health care provider if you're having difficulty following your regimen. Don't forget to mention any side effects you're having. Side effects from HIV medicines are a major reason medication adherence can be difficult.

Let your health care provider know if your regimen is too complicated to follow. Your health care provider may recommend another regimen that involves taking fewer pills.

Discuss any personal issues that are causing you to skip medicines. Your health care provider can recommend resources to help you deal with the issues.

Learn more about adherence.

- Read this fact sheet on adherence.
- <u>Get tools and resources to help with medication adherence</u>.

This fact sheet is based on information from the following sources:

- From the Department of Health and Human Services: <u>Guidelines for the Use of</u> <u>Antiretroviral Agents in HIV-1-Infected Adults and Adolescents: Adherence to</u> <u>Antiretroviral Therapy</u>
- From the Health Resources and Services Administration: <u>Guide for HIV/AIDS Clinical</u> <u>Care: Section 4: HIV Treatment/Adherence</u>
- From the Office on Women's Health: <u>Managing your treatment of HIV/AIDS</u>



HIV Treatment HIV and Immunizations

(Last updated 9/29/2013; last reviewed 9/29/2013)

- Vaccines are products designed to protect people from disease, for example, chicken pox, flu, and polio. Vaccines are given by needle injections, by mouth, or by aerosol sprays. The process of getting a vaccine is called vaccination or immunization.
- There is no vaccine to prevent or cure HIV, but people with HIV can benefit from vaccines against other diseases. The following vaccines are

recommended for all people with HIV: hepatitis B; influenza (flu); human papillomavirus (HPV) (for those up to age 26); pneumococcal (pneumonia); and tetanus, diphtheria, and pertussis (a single vaccine that protects against the three diseases). Every 10 years, a repeat vaccine against tetanus and diphtheria is also recommended. Other vaccines may be recommended for some people with HIV.

- In general, people with HIV should not get <u>live, attenuated vaccines</u> unless the benefit outweighs the risk.
- Because HIV medicines strengthen the immune system and reduce HIV viral load, whenever possible people with HIV may want to start <u>antiretroviral</u> <u>therapy (ART)</u> before getting immunizations.

What are vaccines?

Vaccines are products designed to protect people from disease. There are vaccines against many diseases, for example, chicken pox, flu, and polio. The process of getting a vaccine is called vaccination or immunization.

Most vaccines are designed to prevent a person from ever having a particular disease or to only have a mild case of the disease. When a person gets a vaccine (by needle injection, by mouth, or by aerosol spray), the body responds by mounting an immune response against the particular disease. An immune response includes all the actions of the <u>immune system</u> to defend the body against the disease-causing bacteria, virus, or other foreign organism.

Vaccines not only protect individuals from disease, they protect communities as well. When most people in a community get immunized against a disease, there is little chance of a disease outbreak.

Is there a vaccine against HIV?

Testing is underway on experimental vaccines to prevent and treat HIV/AIDS, but no HIV vaccine is approved for use outside of <u>clinical trials</u>. Even though there isn't a vaccine to prevent or cure HIV, people with HIV can benefit from vaccines against other diseases.

Can HIV infection affect the safety and effectiveness of vaccines?

Yes. Damage to the immune system due to HIV can reduce the body's immune response to a vaccine. A weakened immune response makes a vaccine less effective. In general, vaccines work best when an HIV-infected person's <u>CD4 count</u> is above 200 copies/mm³.

By stimulating the immune system, vaccines may also cause a person's level of HIV (<u>viral</u> <u>load</u>) to increase temporarily.

Because HIV medicines strengthen the immune system and reduce HIV viral load, people with HIV may want to start <u>antiretroviral therapy (ART)</u> before getting vaccinated whenever possible. In some situations, however, immunizations should not be delayed to start ART. For example, it's important for people with HIV to get vaccinated against the flu at the time of year when the risk of flu is greatest.

Are all types of vaccines safe for people with HIV?

The design of a vaccine depends on several factors, such as how a <u>microbe</u> infects the body and how the immune system responds. For this reason, there are several types of vaccines, including live, attenuated vaccines and inactivated vaccines.

A live, attenuated vaccine contains a weakened but live form of a disease-causing microbe. Although the attenuated (weakened) microbe cannot cause the disease (or can cause only mild disease), the vaccine can still trigger an immune response.

Inactivated vaccines are made from microbes that have been killed with chemicals, heat, or radiation. There is no chance that an inactivated vaccine can cause the disease it was designed to prevent.

In general, to be safe, people with HIV should get inactivated vaccines to avoid even the remote chance of getting a disease from a live, attenuated vaccine. However, for some diseases, only live, attenuated vaccines are available. In this case, the protection offered by the live vaccine may outweigh the risks. Vaccines against chicken pox and shingles are examples of live, attenuated vaccines that, in certain situations, may be recommended for people with HIV.

Do vaccines cause side effects?

In general, side effects from vaccines are minor (for example, a sore arm or low-grade fever) and go away within a few days. Severe reactions to vaccines are rare. Before getting a vaccine, talk to your health care provider about the benefits and risks of the vaccine and possible side effects.

Which vaccines are recommended for people with HIV?

The following vaccines are recommended for people with HIV:

- Hepatitis B
- Influenza (flu)
- Pneumococcal (pneumonia)
- Tetanus, diphtheria, and pertussis. A single vaccine called Tdap protects against the three diseases. Every 10 years, a repeat vaccine against tetanus and diphtheria (called Td) is recommended.
- Human papillomavirus (HPV) (for those up to age 26)

Additional vaccines may be recommended on the basis of an HIV-infected person's age, previous vaccinations, risk factors for a particular disease, or certain HIV-related factors, For more information, read this information from the Centers for Disease Control and Prevention (CDC): <u>HIV Infection and Adult Vaccination</u>.

What about travel and immunizations?

Regardless of destination, all travelers should be up to date on routine vaccinations. Those traveling to destinations outside the United States may need immunizations against diseases

present in other parts of the world, for example, cholera or yellow fever.

If you have HIV, talk to your health care provider about any vaccines you may need before you travel. If a required immunization is only available as a live, attenuated vaccine, your health care provider can give you a letter that excuses you from getting the vaccine. If your CD4 count is less than 200 copies/mm³, your health care provider may recommend that you delay your trip to give HIV medicines time to strengthen your immune system. To prepare for your trip, read information from CDC on <u>Travelers with Weakened Immune Systems</u>.

This fact sheet is based on information from the following sources:

- From the Department of Veterans Affairs: <u>Primary Care of Veterans with</u> <u>HIV/Immunizations</u>
- From the Health Resources and Services Administration: <u>Guide for HIV/AIDS Clinical</u> <u>Care/Immunizations for HIV-Infected Adults and Adolescents</u>
- From the National Institute of Allergy and Infectious Diseases: Vaccines



Side Effects of HIV Medicines HIV Medicines and Side Effects

(Last updated 9/30/2013; last reviewed 9/30/2013)

Key Points

- HIV medicines help people with HIV live longer, healthier lives. Sometimes HIV medicines can also cause side effects. Most side effects from HIV medicines are manageable, but a few can be very serious.
- Different HIV medicines can cause different side effects. In addition, people taking the same HIV medicine can have very different side effects.
- If you are taking HIV medicines, tell your health care provider about any side effects that you are having. Some side effects, for example headache or occasional dizziness, may not be serious. Other side effects, such as swelling of the mouth and tongue or damage to the liver, can be life-threatening. However, do NOT cut down on, skip, or stop taking your HIV medicines unless your health care provider tells you to.
- When side effects from HIV medicines become unbearable or life-threatening, it's time to change medicines. Fortunately, there are more than 20 HIV medicines available to include in an <u>HIV regimen</u>. The choice of HIV medicines to replace those causing side effects will depend on a person's individual needs.

Can HIV medicines cause side effects?

HIV medicines help people with HIV live longer, healthier lives. Sometimes HIV medicines can also cause side effects. Most side effects from HIV medicines are manageable, but a few can be very serious. If you are taking HIV medicines, tell your health care provider about any side effects that you are having.

Different HIV medicines can cause different side effects. In addition, people taking the same HIV medicine can have very different side effects.

Some side effects, for example headache or occasional dizziness, may not be serious. Other side effects, such as swelling of the mouth and tongue or damage to the liver, can be life threatening.

Side effects from HIV medicines can last only a few days or weeks or continue for a much

longer time. Some side effects may not appear until many months or even years after starting an HIV medicine.

What are common short-term side effects from HIV medicines?

When starting an HIV medicine for the first time, it's common to have side effects that last a couple of weeks. These short-term side effects can include:

- Feeling tired
- Nausea (upset stomach)
- Vomiting
- Diarrhea
- Headache
- Fever
- Muscle pain
- Occasional dizziness

Sometimes, side effects that may not seem serious, such as fever, rash, nausea, or fatigue can be a sign of a life-threatening condition. Any swelling of the face, eyes, lips, or tongue is considered a life-threatening side effect that requires immediate medical attention. If you are taking HIV medicines, tell your health care provider about any side effects that you are having. Do NOT cut down on, skip, or stop taking your HIV medicines unless your health care provider tells you to. Stopping HIV medicines allows HIV to multiply and damage the <u>immune system</u>. This increases the risk of infections and cancer. Stopping HIV medicines also increases the risk of <u>drug resistance</u>.

What are some long-term side effects from HIV medicines?

Some side effects from HIV medicines appear months or even years after starting a medicine and continue for a long time. Examples of long-term side effects include:

- Changes in how the body uses and stores fat (lipodystrophy)
- An increase in fat levels in the blood (<u>hyperlipidemia</u>)
- Thinning of the bones (osteoporosis)

What are ways to manage side effects from HIV medicines?

When taking HIV medicines, it helps to plan ahead. If you are starting HIV medicines, talk to your health care provider about possible side effects. Tell your health care provider about your lifestyle and point out any possible side effects that would be especially hard for you to manage. The information will help your health care provider recommend medicines best suited to your needs.

Depending on the HIV medicines you take, your health care provider will:

- Tell you which specific side effects to look out for.
- Offer you suggestions on how to deal with those side effects. For example, to manage nausea and vomiting, eat smaller meals more often and avoid spicy foods.
- Tell you about the signs of life-threatening side effects (for example, swelling of the mouth and tongue) that require immediate medical attention.

When side effects from HIV medicines become unbearable or life-threatening, it's time to

change medicines. Fortunately, there are more than 20 HIV medicines available to include in an <u>HIV regimen</u>. The choice of HIV medicines to replace those causing side effects will depend on a person's individual needs.

How can I learn more about HIV medicines and side effects?

- Read the AIDSinfo fact sheets on specific side effects from HIV medicines.
- Use the <u>AIDSinfo drug database</u> to find easy-to-understand information about HIVrelated medicines. For help using the drug database, call an AIDSinfo health information specialist at 1-800-448-0440.

This fact sheet is based on information from the following sources:

- From the Department of Health and Human Services: <u>Guidelines for the Use of</u> <u>Antiretroviral Agents in HIV-1-Infected Adults and Adolescents/Adverse Effects of</u> <u>Antiretroviral Agents</u>
- From the Food and Drug Administration: <u>HIV and AIDS--Medicines to Help You</u>
- From the Office on Women's Health: <u>HIV/AIDS drugs and side effects</u>



Side Effects of HIV Medicines

HIV and Diabetes

(Last updated 9/30/2013; last reviewed 9/30/2013)

- Diabetes is a disorder that makes it hard for the body to process <u>glucose</u> (sugar) for growth and energy. Glucose comes from the breakdown of the foods we eat. People who have diabetes may have too much glucose in their blood.
- Use of some HIV medicines may increase blood glucose (also called blood sugar) and lead to diabetes. Other risk factors for diabetes include a family history of diabetes, being overweight, and lack of physical activity.
- People with HIV should have their blood glucose levels checked before they start taking HIV medicines. People with higher-than-normal glucose levels may need to avoid taking some HIV medicines and use other HIV medicines instead.
- Blood glucose testing is also important after starting HIV medicines. If testing shows high glucose levels, a change in HIV medicines may be necessary.
- Diabetes can be controlled with a healthy diet, regular exercise, and medicines. A healthy diet includes vegetables, fruits, and lean meats and is low in processed foods high in sugar and salt. Regular exercise means being active for a half an hour on most days of the week. Sometimes, in addition to a healthy diet and regular physical activity, medicines are needed to control

diabetes.

What is diabetes?

Diabetes is a disorder that makes it hard for the body to process <u>glucose</u> (sugar) for growth and energy. Glucose comes from the breakdown of the foods we eat. People who have diabetes may have too much glucose in their blood.

If not controlled, diabetes can lead to serious complications, including heart and blood vessel disease, nerve damage, blindness, and kidney disease. Fortunately, diabetes can be controlled with diet, exercise, and medicines.

How does diabetes develop?

Glucose is carried in the blood to cells throughout the body. A hormone called insulin helps move the glucose into the cells. Once in the cells, glucose is used to make energy. When the body has trouble moving glucose into the cells, glucose builds up in the blood and can lead to diabetes.

There are two types of diabetes: type 1 diabetes and type 2 diabetes. Type 1 diabetes develops when the body does not make any (or enough) insulin. In type 2 diabetes, the body makes enough insulin but can't use it effectively to move glucose into the cells. Type 2 diabetes is more common than type 1 diabetes.

What are the risk factors for diabetes?

Risk factors for diabetes include a family history of diabetes, being overweight, and lack of physical activity. In people with HIV, use of some HIV medicines may increase blood glucose and lead to type 2 diabetes.

What HIV medicines increase the risk of type 2 diabetes?

Some HIV medicines in the <u>nucleoside reverse transcriptase inhibitor (NRTI)</u> and <u>protease</u> <u>inhibitor (PI)</u> drug classes may increase the risk of diabetes.

NRTIs:

- didanosine (brand name: Videx)
- stavudine (brand name: Zerit)
- <u>zidovudine</u> (brand name: Retrovir). Zidovudine is one of the HIV medicines in the following combination drugs: <u>Combivir</u> and <u>Trizivir</u>. (Combination drugs include two or more different HIV medicines in one pill.)

Pls:

- indinavir (brand name: Crixivan)
- lopinavir/ritonavir (brand name: Kaletra)

These HIV medicines seem to lessen the body's ability to respond to and use insulin (<u>insulin</u> <u>resistance</u>). Insulin resistance leads to high blood glucose levels, which can result in type 2 diabetes.

What are the symptoms of insulin resistance and diabetes?

Usually the symptoms of insulin resistance are mild and may not be noticeable. Symptoms of insulin resistance may include:

- Drowsiness, especially after meals
- Intense mood swings or extreme hunger after eating sugary snacks or high carbohydrate meals
- High cholesterol and triglyceride levels (high levels of fat in the blood)

Most people who are insulin resistant are overweight or obese and carry their fat around the abdomen (stomach area). Dark patches of skin on the neck and armpit area are another symptom of insulin resistance.

The symptoms of diabetes can include:

- Unusual thirst
- Frequent urination
- Extreme hunger
- Unusual weight loss or weight gain
- Extreme fatigue and irritability
- Frequent infections
- Blurred vision
- Tingling or numbness in the hands and feet
- Slow healing of cuts or bruises

How is diabetes diagnosed?

A common test used to diagnose diabetes is called a fasting glucose test. The test measures the amount of glucose in the blood after a person has not eaten for 8 hours.

People with HIV should have their blood glucose levels checked before starting treatment with HIV medicines. People with higher-than-normal glucose levels may need to avoid taking some HIV medicines.

Blood glucose testing is also important after starting HIV medicines. If testing shows high glucose levels, a change in HIV medicines may be necessary.

Can diabetes be treated?

Diabetes can be controlled with diet, exercise, and medicines.

A healthy diet includes lots of vegetables, some fruit, and lean meats and is low in processed foods high in sugar and salt.

Regular exercise means being active for a half an hour on most days of the week. Diet and exercise can help a person reach and maintain a healthy weight.

Sometimes, in addition to a healthy diet and regular physical activity, medicines are needed to control diabetes. Controlling diabetes in people with HIV may include avoiding some HIV medicines and using other HIV medicines instead.

If you have HIV, talk to your health care provider about your risk for diabetes. Ask your health care provider about the link between HIV infection and HIV medicines and diabetes and about testing for diabetes.

How can I learn more about diabetes?

- Read this fact sheet about HIV and diabetes.
- Browse this webpage to find diabetes-related information.
- Watch this video on diabetes and meal planning.

This fact sheet is based on information from the following sources:

- From the Department of Health and Human Services: <u>Guidelines for the Use of</u> <u>Antiretroviral Agents in HIV-1-Infected Adults and Adolescents/Adverse Effects of</u> <u>Antiretroviral Agents</u>
- From the Department of Veterans Affairs: Primary Care of Veterans with HIV/Diabetes
- From the National Institute of Allergy and Infectious Diseases: <u>A Helpful Guide to HIV</u> <u>and Metabolic Complications</u>



Side Effects of HIV Medicines

HIV and Hepatotoxicity

(Last updated 9/30/2013; last reviewed 9/30/2013)

- Hepatotoxicity means damage to the liver caused by a medicine, chemical, or herbal or dietary supplement. Hepatotoxicity can be a side effect of many different kinds of HIV medicines.
- People who are taking HIV medicines should be aware of this potential side effect of some HIV medicines. In some cases, liver damage can be life threatening.
- Signs of damage to the liver may include stomach pain, unusual tiredness, nausea (upset stomach), dark-colored urine, light or clay-colored stools, and jaundice (yellow skin and eyes). If you are taking HIV medicines and have any of the symptoms listed, contact your health care provider immediately.
- Management of hepatotoxicity due to HIV medicines varies depending on the extent of damage to the liver. Sometimes it's necessary to stop the HIV medicine that is causing the hepatotoxicity. In other cases, the liver problems will go away without stopping the HIV medicine.

Hepatotoxicity means damage to the liver caused by a medicine, chemical, or herbal or dietary supplement. Hepatotoxicity can be a side effect of many different kinds of HIV medicines.

People taking HIV medicines should be aware of this potential side effect of some HIV medicines. In some cases, damage to the liver can be life threatening.

What HIV medicines can cause hepatotoxicity?

HIV medicines in the following <u>drug classes</u> can cause hepatotoxicity:

- <u>nucleoside reverse transcriptase inhibitors (NRTIs)</u> Hepatotoxicity is a risk with most NRTIs.
- <u>non-nucleoside reverse transcriptase inhibitors (NNRTIs)</u> Among NNRTIs, the risk of hepatotoxicity is greatest with <u>nevirapine</u> (brand name: Viramune). The risk is greatest for women who have <u>CD4 counts</u> above 250 cells/mm³ before starting nevirapine.

Treatment with nevirapine involves starting the HIV medicine on a gradual schedule. The schedule gives the person taking the medicine 2 weeks to reach the full recommended dose of nevirapine. During the 2-week period, the person is carefully monitored for signs of hepatotoxicity due to nevirapine.

If you are starting nevirapine, it's important to work closely with your health care provider during this 2-week period. Do not miss any medical appointments. Tell your health care provider about any symptoms that you are having (for example, stomach pain, upset stomach, or unusual tiredness). Your symptoms could be a sign of liver damage.

• protease inhibitors (PIs)

Among PIs, the risk of hepatotoxicity is greatest with <u>tipranavir</u> (brand name: Aptivus) boosted with <u>ritonavir</u> (brand name: Norvir). When the HIV medicines are given together, ritonavir increases or "boosts" the effectiveness of tipranavir.

• CCR5 antagonists

<u>Maraviroc</u> (brand name: Selzentry) has been reported to cause hepatotoxicity. Use the <u>AIDSinfo drug database</u> to find information on all the drugs in the NRTI, NNRTI, and PI drug classes.

Are there other factors that can increase the risk of hepatotoxicity?

The following factors may increase the risk of hepatotoxicity due to HIV medicines:

- Being a woman
- Pregnancy
- Being over 50 years of age
- Also having hepatitis B and/or hepatitis C infection
- Taking other medicines that can cause liver damage
- Alcohol or drug abuse
- Obesity
- Past history of liver damage

What are the symptoms of hepatotoxicity?

Symptoms of hepatotoxicity include the following:

- Stomach pain
- Nausea (upset stomach)
- Unusual tiredness
- Dark-colored urine
- Light or clay-colored stools
- Jaundice (yellow skin and eyes)

In addition to these symptoms, the liver may be enlarged (bigger than usual).

If you are taking HIV medicines and have any of these symptoms, contact your health care provider immediately. However, do NOT cut down on, skip, or stop taking your HIV medicines unless your health care provider tells you to.

How is hepatotoxicity detected?

Liver function tests (LFTs) are a group of blood tests used to check for damage to the liver. Before treatment with HIV medicines is started, LFTs are done to check for already-existing liver damage. The risk of hepatotoxicity is greater in people who have liver damage before they start taking HIV medicines. If LFT results show pre-existing liver damage, HIV medicines that may cause hepatotoxicity should be avoided. There are many other HIV medicines available to use instead.

Once treatment with HIV medicines begins, LFTs are done to monitor for signs of hepatotoxicity.

How is hepatotoxicity managed?

Management of hepatotoxicity due to HIV medicines varies depending on the extent of damage to the liver. Sometimes it's necessary to stop the HIV medicine that is causing the hepatotoxicity. However, the decision to stop taking an HIV medicine should only be done in consultation with a health care provider. If you are taking HIV medicines, do NOT cut down on, skip, or stop taking your HIV medicines unless your health care provider tells you to.

If you are taking or plan to take HIV medicines, talk to your health care provider about the risk of hepatotoxicity.

This fact sheet is based on information from the following sources:

- From the Department of Health and Human Services: <u>Guidelines for the Use of</u> <u>Antiretroviral Agents in HIV-1-Infected Adults and Adolescents/Adverse Effects of</u> <u>Antiretroviral Agents</u>
- From the Department of Veterans Affairs: <u>Primary Care of Veterans with HIV/Liver</u> <u>Disease and Cirrhosis</u>
- From the National Institutes of Health: MedlinePlus/Liver Disease



Side Effects of HIV Medicines HIV and Hyperlipidemia

(Last updated 9/30/2013; last reviewed 9/30/2013)

Key Points

- Hyperlipidemia refers to high levels of fat in the blood, including cholesterol and triglycerides. Hyperlipidemia increases the risk of heart disease, gall bladder disease, and pancreatitis (inflammation of the pancreas).
- HIV infection and treatment with some HIV medicines can increase the risk of hyperlipidemia. Other risk factors for hyperlipidemia include a family history of hyperlipidemia, a high-fat diet, and smoking.
- Eating foods that are low in saturated fat, trans fat, and cholesterol and being active on most days of the week can help control blood fat levels. Medicines are also used to reduce high blood fat levels.
- In people with HIV, treatment for hyperlipidemia may include changing an <u>HIV</u> regimen to avoid taking HIV medicines that can increase blood fat levels.

What is hyperlipidemia?

Hyperlipidemia is the medical term for high levels of fat in the blood. Fats in the blood (also called <u>lipids</u>) include cholesterol and triglycerides. The body needs cholesterol and triglycerides to function properly but having too much can cause problems. High levels of cholesterol and triglycerides increase the risk of heart disease, gall bladder disease, and pancreatitis (inflammation of the pancreas).

What are the symptoms of hyperlipidemia?

Usually hyperlipidemia has no symptoms. A blood test is used to measure levels of fat in the blood and to detect hyperlipidemia.

Testing for hyperlipidemia is recommended both before and after a person starts taking HIV medicines. If blood fat levels are normal, testing is recommended once a year. If blood fat levels are too high, more frequent testing is recommended.

What are risk factors for hyperlipidemia in people with HIV?

HIV infection and treatment with some HIV medicines can increase the risk of hyperlipidemia.

The following HIV medicines can raise blood fat levels:

• All HIV medicines in the protease inhibitor (PI) drug class. (HIV medicines are grouped

into drug classes according to how they fight HIV.) The <u>AIDSinfo drug database</u> includes information for all HIV medicines, including those in the PI drug class.

- <u>Efavirenz</u> (brand name: Sustiva), which belongs to the <u>non-nucleoside reverse</u> <u>transcriptase inhibitor (NNRTI) drug class</u>. Efavirenz is one of the components of the combination medicine <u>Atripla</u>. Combination medicines include two or more different HIV medicines in one pill.
- <u>Stavudine</u> (brand name: Zerit) and <u>zidovudine</u> (brand name: Retrovir), which belong to the <u>nucleoside reverse transcriptase inhibitor (NRTI) drug class</u>. The combination medicines <u>Combivir</u> and <u>Trizivir</u> include zidovudine.

Are there other risk factors for hyperlipidemia?

The following risk factors for hyperlipidemia vary from person to person:

- Family history of hyperlipidemia
- Other medical conditions, including high blood pressure, <u>diabetes</u>, and an underactive thyroid gland
- A high-fat, high-carbohydrate diet
- Obesity
- Smoking
- Heavy alcohol use
- Lack of physical activity

Fortunately, many of these risk factors can be controlled by lifestyle choices. For example, maintaining a healthy weight is one way to reduce the risk of hyperlipidemia.

What are other steps a person can take to prevent hyperlipidemia?

Here are additional steps to take to reduce the risk of hyperlipidemia:

- Eat foods low in saturated fat, trans fat, and cholesterol. To do this, eat less full-fat dairy products, fatty meats, and desserts high in fat and sugar. Limit foods that are high in cholesterol, such as egg yolks, fatty meats, and organ meat (like liver and kidney). Instead, choose low-fat or fat-free milk, cheese, and yogurt; eat more foods that are high in fiber, like oatmeal, oat bran, beans, and lentils; and eat more vegetables and fruits.
- Get active. The <u>Physical Activity Guidelines for Americans</u> recommend 30 minutes of physical aerobic activity daily for adults 18 to 64 years of age. Aerobic activities include walking quickly, biking slowly, and gardening.
- If you smoke, quit. Strategies to make quitting easier include use of nicotine gum, patches, and lozenges. Support from websites and hotlines can also help. To learn more about strategies to quit smoking, <u>read this fact sheet</u>.

People who already have hyperlipidemia can also follow these steps to lower their blood fat levels.

What is the treatment for hyperlipidemia?

In people with HIV, treatment for hyperlipidemia may include changing an <u>HIV regimen</u> to avoid taking HIV medicines that can increase blood fat levels.

There are also medicines that can help control blood fat levels. The most common medicines

used to reduce cholesterol levels are called statins. Fibrates are a type of medicine used to lower triglycerides.

HIV medicines can interact with medicines that lower blood fat levels. If you have HIV and need medicine to control hyperlipidemia, your health care provider can recommend medicines that are safe to take with your HIV regimen.

How can I learn more about hyperlipidemia?

- Download this booklet that includes information about HIV and hyperlipidemia.
- Read more about cholesterol.
- Use this collection of recipes to cook a heart-healthy meal.

This fact sheet is based on information from the following sources:

- From the Department of Health and Human Services: <u>Guidelines for the Use of</u> <u>Antiretroviral Agents in HIV-1-Infected Adults and Adolescents/Adverse Effects of</u> <u>Antiretroviral Agents</u>
- From the Health Resources and Services Administration: <u>Guide for HIV/AIDS Clinical</u> <u>Care/Dyslipidemia</u>
- From the National Institute of Allergy and Infectious Diseases: <u>A Helpful Guide to HIV</u> and <u>Metabolic Complications/Lipid Abnormalities</u>



Side Effects of HIV Medicines HIV and Lactic Acidosis

(Last updated 9/30/2013; last reviewed 9/30/2013)

- Lactic acidosis is a condition caused by the buildup of <u>lactic acid</u> in the blood. Lactic acid is produced when the body converts food into energy.
- All HIV medicines in the <u>nucleoside reverse transcriptase inhibitor (NRTI) drug</u> <u>class</u> may cause lactic acidosis, but the risk is greatest with <u>didanosine</u> (brand name: Videx), <u>stavudine</u> (brand name: Zerit), and <u>zidovudine</u> (brand name: Retrovir). Zidovudine is one of the HIV medicines in the following combination drugs: <u>Combivir</u> and <u>Trizivir</u>. (Combination drugs include two or more different HIV medicines in one pill.)
- Early signs of lactic acidosis can include loss of appetite, nausea and vomiting, and stomach pain. Although these symptoms may not seem serious, they can be the first signs of potentially life-threatening lactic acidosis. If you are taking HIV medicines, always tell your health care provider about any symptoms that you are having—even symptoms that may not seem serious.
- Signs of life-threatening lactic acidosis can include above normal heart rate,

rapid breathing, jaundice (yellowing of the skin and the whites of the eyes), and muscle weakness. If you are taking HIV medicines and have these signs of lactic acidosis, get medical help <u>immediately</u>.

• Treatment for lactic acidosis involves stopping the HIV medicine that is causing the condition. In the rare cases when lactic acidosis becomes life-threatening, immediate, in-hospital treatment is necessary.

What is lactic acidosis?

Lactic acidosis is a condition caused by the buildup of <u>lactic acid</u> in the blood. Lactic acid (also called lactate) is produced when the body converts food into energy. Lactic acidosis is a rare but serious side effect of some HIV medicines.

Which HIV medicines can cause lactic acidosis?

HIV medicines in the <u>nucleoside reverse transcriptase inhibitor (NRTI) drug class</u> can cause the body to produce too much lactic acid. NRTIs can also damage the <u>liver</u> so that it can't break down lactate in the blood.

If you are taking NRTIs, it's important to be aware of this rare side effect of NRTIs. The condition can be life threatening.

Are there specific NRTIs that can cause lactic acidosis?

All medicines in the NRTI drug class have been linked to lactic acidosis, but the link is strongest for the following NRTIs:

- didanosine (brand name: Videx)
- stavudine (brand name: Zerit)
- <u>zidovudine</u> (brand name: Retrovir). Zidovudine is one of the HIV medicines in the following combination drugs: <u>Combivir</u> and <u>Trizivir</u>. (Combination drugs include two or more different HIV medicines in one pill.)

Are there other risk factors for lactic acidosis?

Additional risk factors for lactic acidosis include:

- Being female
- Pregnancy
- Obesity
- Older age
- Lower <u>CD4 count</u>

What are the symptoms of lactic acidosis?

Lactic acidosis often develops gradually. Early signs of the condition can include loss of appetite, nausea and vomiting, and stomach pain. Although these symptoms may not seem serious, they can be the first signs of potentially life-threatening lactic acidosis. If you are taking HIV medicines, always tell your health care provider about any symptoms that you are having—even symptoms that may not seem serious.

Lactic acidosis can advance rapidly. Signs of dangerously high levels of lactate in blood

include:

- Above normal heart rate
- Rapid breathing
- Jaundice (yellowing of the skin and the whites of the eyes)
- Muscle weakness

If you are taking HIV medicines and have any of these symptoms, get medical help immediately.

What tests are used to detect lactic acidosis?

Tests used to diagnose lactic acidosis include:

- A test to measure the level of lactate in the blood
- Other blood tests, including tests to check the functioning of the liver
- A physical exam to check for an enlarged liver

What is the treatment for lactic acidosis?

Treatment for lactic acidosis involves stopping the HIV medicine that is causing the condition. However, stopping a medicine because of lactic acidosis doesn't mean stopping HIV treatment. There are more than 20 HIV medicines to include in an <u>HIV regimen</u>. But if you are taking HIV medicines, do NOT cut down on, skip, or stop taking your medicines unless your health care provider tells you to.

In the rare cases when lactic acidosis becomes life-threatening, immediate, in-hospital treatment is necessary.

How can I learn more about lactic acidosis?

- Read this fact sheet to learn more about how lactic acidosis develops.
- Use the AIDSinfo drug database to find easy-to-understand information on NRTIs.

This fact sheet is based on information from the following sources:

- From the Department of Health and Human Services: <u>Guidelines for the Use of</u> <u>Antiretroviral Agents in HIV-1-Infected Adults and Adolescents/Adverse Effects of</u> <u>Antiretroviral Agents</u>
- From the University of California San Francisco Center for HIV Information: <u>HIV InSite</u> <u>Knowledge Base Chapter/Metabolic Complications of HIV Therapy</u>



Side Effects of HIV Medicines HIV and Lipodystrophy

(Last updated 9/30/2013; last reviewed 9/30/2013)

Key Points

• Lipodystrophy refers to the changes in body fat and metabolism seen in some

people with HIV. The changes can include buildup of body fat, loss of body fat, or high levels of fats and sugar in the blood.

- A person with HIV can have fat loss or fat buildup or both. Whether the changes are obvious to see or not noticeable depends on the degree of fat loss or fat buildup.
- The exact cause of lipodystrophy is unknown. It may be due to HIV infection itself or medicines used to treat HIV. Fortunately, current HIV medicines are less likely to cause the condition than medicines developed in the past. Many people with HIV never develop lipodystrophy.
- There isn't a cure for lipodystrophy, but switching HIV medicines may help. Other ways to manage lipodystrophy include liposuction (surgical removal of fat) and injections of fat or a fat-like substance as a filler to make up for fat loss in the face.

What is lipodystrophy?

Lipodystrophy refers to the changes in body fat and <u>metabolism</u> seen in some people with HIV. Lipodystrophy can include:

- Buildup of body fat
- Loss of body fat
- High levels of fats and sugar in the blood. To learn more, read the AIDSinfo fact sheets on <u>Hyperlipidemia</u> and <u>Diabetes</u>.

What causes lipodystrophy?

The exact cause of lipodystrophy is unknown. It may be due to HIV infection itself or medicines used to treat HIV. Fortunately, current HIV medicines are less likely to cause lipodystrophy than medicines developed in the past. Many people with HIV never develop lipodystrophy.

Other risk factors for developing lipodystrophy include:

- Age: Older people are at higher risk.
- Race: Whites have the highest risk.
- Gender: Men are more likely to have fat loss in the arms and legs. Women are more likely to have buildup of breast and abdominal fat.
- Length and severity of HIV infection: The risk is higher with longer and more severe HIV infection.

Lipodystrophy can't be cured, but switching HIV medicines may help.

What parts of the body are affected by lipodystrophy?

Fat buildup (also called <u>lipohypertrophy</u>) can occur:

- Deep in the abdominal cavity. This is the part of the body that contains the stomach, the intestines (also called the gut), and other organs.
- On the back of the neck between the shoulders (called buffalo hump)

- In the breasts
- Just under the skin. (The fatty bumps are called lipomas.)

Fat loss (also called <u>lipoatrophy</u>) tends to occur:

- In the arms and legs
- In the buttocks
- In the face

A person with HIV can have fat loss or fat buildup or both. Whether the changes are obvious to see or not noticeable depends on the degree of fat loss or fat buildup. <u>See images of fat</u> <u>buildup around the neck and fat loss on the face and leg</u>.

High levels of fats and sugar in the blood can increase the risk for heart disease and <u>diabetes</u>. To learn more about these conditions, read the AIDSinfo fact sheets on <u>Hyperlipidemia</u> and <u>Diabetes</u>.

Which HIV medicines are linked to lipodystrophy?

More research is needed to prove that there is a link between HIV medicines and lipodystrophy, but some HIV medicines have been associated with the condition.

Fat loss has been linked to the use of <u>stavudine</u> (brand name: Zerit) and <u>zidovudine</u> (brand name: Retrovir). Both HIV medicines belong to the <u>nucleoside reverse transcriptase inhibitor</u> (<u>NRTI</u>) <u>drug class</u>. (HIV medicines are grouped into drug classes according to how they fight HIV.) Zidovudine is also a component of the following combination medicines: <u>Combivir</u> and <u>Trizivir</u>. Combination medicines include more than one HIV medicine in a single pill.

Fat gain has been linked to <u>HIV regimens</u> that include the following HIV medicines:

- HIV medicines in the <u>protease inhibitor (PI) drug class</u>. The <u>AIDSinfo drug database</u> offers easy-to-understand information on HIV medicines, including medicines in the PI drug class.
- <u>Efavirenz</u> (brand name: Sustiva), which is an HIV medicine in the <u>non-nucleoside</u> <u>reverse transcriptase inhibitor (NNRTI) drug class</u>. Efavirenz is one of the HIV medicines included in <u>Atripla</u>, a combination HIV medicine.
- <u>Raltegravir</u> (brand name: Isentress), which is an HIV medicine in the <u>integrase inhibitor</u> (<u>INSTI</u>) drug class

Is lipodystrophy a serious health problem?

It can be. Too much fat gain in the abdominal cavity can increase the risk for heart attack and diabetes.

Fat gain in the breasts can be painful. Buffalo humps may cause headaches and problems with breathing.

The changes in appearance caused by lipodystrophy can be upsetting and affect a person's self-esteem. Because of lipodystrophy, a person may decide to stop taking HIV medicines. However, the decision to stop taking HIV medicines (or cut down on the dose of a medicine) should be made only in consultation with a health care provider. Stopping HIV medicines

allows HIV to multiply and damage the <u>immune system</u>, which increases the risk of HIVrelated infections and cancer. Stopping HIV medicines also increases the risk of <u>drug</u> <u>resistance</u>.

Can lipodystrophy be cured?

Unfortunately, there isn't a cure for lipodystrophy. More research is needed to understand the cause of lipodystrophy in people with HIV and to find a cure for the condition. However, there are ways to manage lipodystrophy.

In some people, changing HIV medicines may lessen the effects of lipodystrophy. But, if you are taking HIV medicines, do NOT cut down on, skip, or stop taking your medicines unless your health care provider tells you to.

Liposuction (surgical removal of fat) is sometimes used to reduce a buffalo hump. This procedure is not recommended for removal of abdominal fat because of possible damage to surrounding organs. Fat or a fat-like substance can be used as a filler to make up for fat loss in the face. The filler is injected in the cheeks or around the eyes and mouth.

Medicines may help lessen the effects of lipodystrophy. For example, Egrifta is a medicine used to reduce the buildup of abdominal fat due to lipodystrophy.

Diet and exercise may also help to manage lipodystrophy. More fiber in the diet, for example, may reduce the risk for developing diabetes. Daily exercise can help strengthen muscles and reduce the buildup of fat.

This fact sheet is based on information from the following sources:

- From the Department of Health and Human Services: <u>Guidelines for the Use of</u> <u>Antiretroviral Agents in HIV-1-Infected Adults and Adolescents/Adverse Effects of</u> <u>Antiretroviral Agents</u>
- From the Department of Veterans Affairs: Body Shape Changes with HIV
- From the Health Resources and Services Administration: <u>Guide for HIV/AIDS Clinical</u> <u>Care/Abnormalities of Body-Fat Distribution</u>
- From the National Institute of Allergy and Infectious Diseases: <u>A Helpful Guide to HIV</u> <u>and Metabolic Complications/Body Fat Complications</u>



Side Effects of HIV Medicines HIV and Osteoporosis

(Last updated 9/30/2013; last reviewed 9/30/2013)

- Osteoporosis is a disease that causes bones to become weak and easy to break. Osteoporosis increases the risk of fractures of the hip, spine, and wrist.
- The main risk factor for osteoporosis is advancing age beyond 30. Anyone can get osteoporosis, but it's most common in older women.
- Factors that may increase the risk of osteoporosis in people living with HIV include HIV infection itself and some HIV medicines (for example tenofovir, [brand name: Viread]). Also, people with HIV are living longer because of HIV medicines, and advancing age increases the risk of osteoporosis.
- Other risk factors for osteoporosis include a poor diet, physical inactivity, and smoking. These risk factors can be managed by lifestyle changes. For example, eating a healthy diet that includes foods rich in calcium and vitamin D and doing weight-bearing exercises can make bones stronger and help slow the rate of bone loss.

What is osteoporosis?

The human body is made up of more than 200 bones, ranging from the skull to the bones of the toes. We depend on bones to hold us up, help us move, and protect our internal organs, such as the heart, kidneys, and liver. Osteoporosis is a disease that causes bones to become weak and easy to break. Osteoporosis increases the risk of fractures of the hip, spine, and wrist.

The main risk factor for osteoporosis is advancing age beyond 30. Anyone can get osteoporosis, but it's most common in older women.

Are people with HIV at risk for osteoporosis?

Yes. Experts are not sure why, but bone loss occurs at a higher rate in people living with HIV. Factors that increase the rate of bone loss in people with HIV may include:

- HIV infection itself
- Some HIV medicines. For example, in several studies, bone loss has been linked to the use of <u>tenofovir</u> (brand name: Viread). (<u>Atripla, Complera, Stribild</u>, and <u>Truvada</u> are combination medicines that include tenofovir. Combination medicines contain two or more different HIV medicines in one pill.) Taking other medicines for a long time (for example, steroids or antacids) can also increase the risk for osteoporosis.
- Older age. Because of HIV medicines, people with HIV are living longer, and advancing age increases the risk of osteoporosis.

Staying healthy with HIV includes taking steps to prevent osteoporosis.

What are other risk factors for osteoporosis?

There are many risk factors for osteoporosis. Some risk factors, such as HIV infection, can't be changed. Other risks factors, for example a poor diet or lack of exercise, can be managed with lifestyle choices.

Risk factors for osteoporosis that can't be changed include:

- Age: The risk of osteoporosis increases as people get older and the bones become thinner and weaker.
- Gender: Compared to men, women have smaller bones, and after menopause, women lose bone more rapidly than men do.
- Race/ethnicity: The risk of osteoporosis is greatest for white and Asian women. However, even though African-American women tend to have higher bone density than white women, they are still at risk for osteoporosis. Factors that increase the risk of osteoporosis in African-American women include a low-calcium diet, intolerance to lactose (the main sugar in milk), and presence of diseases such as sickle cell anemia and lupus that are more common in African Americans. African-American women are also more likely to die from osteoporosis-related fractures than white women.
- Family history: Osteoporosis tends to run in families.
- History of a previous fracture: People who have had a fracture after the age of 50 are at high risk of having another.

The following risk factors for osteoporosis can be controlled by lifestyle choices:

- Poor diet: A diet low in calcium and vitamin D increases the risk of osteoporosis.
- Physical inactivity: Bones become stronger with exercise, so physical inactivity increases the risk of osteoporosis.
- Smoking: Smoking is bad for the bones.

How does osteoporosis develop?

To maintain healthy bones, our body constantly replaces old bone tissue with new bone tissue. Up to about age 30, bone tissue is replaced at a faster rate than it is lost. But beyond age 30, the reverse is true: more bone is broken down than is replaced.

Osteoporosis develops when bone loss is so great that bones can break easily. There is no cure for osteoporosis. However, once the disease develops, there are medicines that can slow down bone loss or increase bone formation.

What are the symptoms of osteoporosis?

Osteoporosis is often called a silent disease because bone loss occurs without symptoms. The first sign of osteoporosis is often a broken bone.

A bone density test is used to measure bone strength and diagnose osteoporosis. The test takes about 15 minutes and is safe, painless, and requires no preparation. The U.S. Preventive Services Task Force recommends all women above the age of 65 have a bone density test to screen for osteoporosis. There are currently no recommendations for routine screening for osteoporosis in people living with HIV, but individuals infected with HIV may wish to discuss bone density testing with their health care providers.

What are steps to take to prevent osteoporosis?

Preventing osteoporosis means making lifestyle choices to reduce the risk of the disease.

- Eat a healthy diet rich in calcium and vitamin D. Foods high in calcium include dairy products, such as milk, yogurt, and cheese. Milk is also fortified with vitamin D. Other foods high in calcium include broccoli, sardines, tofu, and oranges. If needed, heath care providers can offer guidance on taking calcium and vitamin D supplements.
- Stay active. Weight-bearing exercises, such as walking, jogging, and dancing, can make bones stronger and help slow the rate of bone loss.
- Don't smoke.
- Cut down on alcohol. Drinking a lot can lead to bone loss and increase the risk of fractures due to both bone loss and falling. People who drink should consume alcohol in moderation. Moderate drinking means limiting alcohol intake to 1 drink per day for women and up to 2 drinks per day for men.
- Avoid falls. Keeping rooms well lit and free of clutter is one way to prevent falls at home.

How can I learn more about osteoporosis?

- Read this fact sheet about osteoporosis and HIV.
- <u>Watch this video about osteoporosis</u>.
- Learn more about <u>tenofovir</u> (brand name: Viread), an HIV medicine that may increase the risk of osteoporosis.

This fact sheet is based on information from the following sources:

- From the Department of Agriculture: Dietary Guidelines for Americans 2010
- From the Department of Health and Human Services: <u>Guidelines for the Use of</u> <u>Antiretroviral Agents in HIV-1-Infected Adults and Adolescents: Adverse Effects of</u> <u>Antiretroviral Agents</u>
- From the National Institutes of Health Osteoporosis and Related Bone Diseases National Resource Center: <u>Osteoporosis Overview</u> and <u>Osteoporosis and African</u> <u>American Women</u>



Side Effects of HIV Medicines

HIV and Rash

(Last updated 9/30/2013; last reviewed 9/30/2013)

- A rash is an irritated area of the skin that is sometimes itchy, red, and painful.
- Possible causes for rash in people with HIV include HIV infection itself, other infections, and HIV medicines.
- Rash is among the most common side effects of HIV medicines. Rash due to HIV medicines is often not serious and goes away in several days to weeks without treatment. Sometimes it may be necessary to switch to another HIV medicine. In rare cases, a rash caused by an HIV medicine can be a sign of a

serious, life-threatening condition.

• If you have HIV, tell your health care provider if you have a rash. A rash that may not seem serious can be a sign of a life-threatening condition that requires immediate medical attention.

Why do people with HIV develop rash?

A rash is an irritated area of the skin that is sometimes itchy, red, and painful. Possible causes of rash in people with HIV include:

- HIV infection itself
- Other infections
- HIV medicines

HIV infection

A rash may be the first sign that a person is infected with HIV. This earliest stage of HIV infection is called <u>acute HIV infection</u>. A rash may also be a symptom of HIV infection at any stage of the disease.

Other infections

Rash may be a symptom of other infections. HIV destroys the infection-fighting cells of the <u>immune system</u>. Damage to the immune system puts people with HIV at risk for infections, and rash is a symptom of many infections.

HIV medicines

Rash is among the most common side effects of HIV medicines. HIV medicines in all HIV drug classes can cause a rash. (HIV medicines are grouped into drug classes according to how they fight HIV.)

Rash due to HIV medicines is often not serious and goes away in several days to weeks without treatment. Sometimes it may be necessary to switch to another HIV medicine. If you are taking HIV medicines, tell your health care provider if you have a rash. In rare cases, a rash caused by an HIV medicine can be a sign of a serious, life-threatening condition.

What are serious rash-related conditions?

Rash can be a sign of a serious hypersensitivity reaction. A hypersensitivity reaction is an unusual allergic reaction to a medicine. In addition to rash, signs of a hypersensitivity reaction can include fever, fatigue, difficulty breathing, and kidney damage.

<u>Stevens–Johnson syndrome (SJS)</u> is a rare but life-threatening hypersensitivity reaction reported with use of some HIV medicines. (When SJS affects at least 30% of the total surface area of the skin, the condition is called toxic epidermal necrolysis [TEN].) People taking HIV medicines should be aware of the condition. It rarely occurs, but when it does, it can cause death.

Symptoms of SJS include fever; pain or itching of the skin; swelling of the tongue and face; blisters that develop on the skin and mucous membranes, especially around the mouth, nose,

and eyes; and a rash that starts quickly and may spread.

A severe hypersensitivity reaction can be life threatening and requires immediate medical attention. SJS must be treated immediately. Go to the emergency room or call 911 if you have symptoms of SJS. However, do NOT cut down on, skip, or stop taking your HIV medicines unless your health care provider tells you to.

What HIV medicines can cause a hypersensitivity reaction?

<u>Nevirapine</u> (brand name: Viramune) and <u>abacavir</u> (brand name: Ziagen) are two HIV medicines that can cause a hypersensitivity reaction.

Nevirapine

To reduce the risk of a hypersensitivity reaction due to nevirapine, the medicine is started on a gradual schedule. The schedule allows the person taking the medicine 2 weeks to reach the full recommended dose of nevirapine. During the 2-week period, the person is carefully monitored for signs of a hypersensitivity reaction to nevirapine.

Abacavir

Hypersensitivity reaction to abacavir has been linked to the HLA-B*5701 molecule. <u>Testing</u> for HLA-B*5701 is done before starting treatment with abacavir. People who test positive for HLA-B*5701 should not use abacavir. People who are taking abacavir and develop signs of hypersensitivity reaction to abacavir must stop the medicine immediately. They can never take abacavir again. In addition, they can never take the combination medicine <u>Trizivir</u>, which contains abacavir. (Combination medicines include two or more different HIV medicines in one pill.)

This fact sheet is based on information from the following sources:

- From the Department of Health and Human Services: <u>Guidelines for the Use of</u> <u>Antiretroviral Agents in HIV-1-Infected Adults and Adolescents/Adverse Effects of</u> <u>Antiretroviral Agents</u>
- From the Health Resources and Services Administration: <u>Guide for HIV/AIDS Clinical</u> <u>Care/Adverse Reactions to HIV Medications</u>
- From the National Institutes of Health: MedlinePlus/Erythema multiforme