HIV AIDS Introduction for Clinicians

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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?

- Watch this tutorial on HIV/AIDS.
- 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):
 HIV Basics
- From the National Institute of Allergy and Infectious Diseases (NIAID): Understanding HIV/AIDS



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 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 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 (HIV viral load). 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.

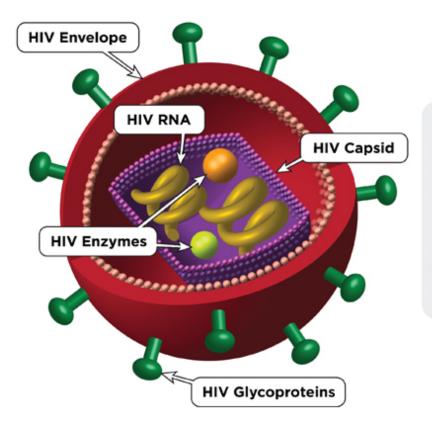
Because ART prevents HIV from multiplying at different stages of the HIV life cycle, the virus has fewer chances to mutate and produce new, drug-resistant HIV.

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.



Key to Terms

HIV capsid: HIV's bullet-shaped core that contains HIV RNA

HIV envelope: Outer surface of HIV

HIV enzymes: Proteins that carry out steps in the HIV life cycle

HIV glycoproteins: Protein "spikes" embedded in the HIV envelope

HIV RNA: HIV's genetic material

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. Binding (also called Attachment): HIV binds (attaches itself) to receptors on the surface of a CD4 cell. **Entry inhibitors** Fusion: The HIV envelope and the CD4 cell membrane fuse (join together), which allows HIV to enter the CD4 cell. Fusion inhibitors CD4 receptors Reverse transcriptase Reverse Transcription: Once inside a CD4 cell, HIV releases an HIV enzyme called reverse transcriptase. HIV uses reverse transcriptase to HIV DNA Membrane of CDA cell nucle convert its genetic material-HIV RNA-into HIV DNA. The conversion of HIV RNA to HIV DNA is necessary so that the HIV can enter the nucleus (center) of a CD4 cell and combine with the cell's genetic material-cell DNA. Non-nucleoside reverse transcriptase inhibitors (NNRTIs) Nucleoside reverse transcriptase inhibitors (NRTIs) Integrase Integration: HIV produces an enzyme called integrase, which allows HIV DNA to enter the CD4 cell Transcription and Translation: Once HIV is integrated into CD4 nucleus. Once inside the cell nucleus, cell DNA, the virus begins to use the machinery of the CD4 cell to create the HIV DNA is joined (integrated) long chains of HIV proteins. The protein chains are the building blocks for with the CD4 cell DNA. Integrase inhibitors

How can I learn more about the HIV life cycle?

HIV DNA

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

Protease inhibitors (PIs)

Assembly: An HIV enzyme called protease cuts up the long chains of HIV proteins. The smaller HIV proteins combine with HIV RNA to form a new virus.

Budding: The newly made HIV pushes out ("buds") from the CD4 cel

CD4 cell DNA

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

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



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) acquired immunodeficiency syndrome (AIDS).
- 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: Stages of HIV
- 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 window period. 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 HIV home test kits approved by FDA.

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: HIV Testing
- 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 <u>drug classes</u>.

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-Approved HIV Medicines

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 enzyme HIV needs to make copies of itself.	abacavir (abacavir sulfate, ABC)	Ziagen	GlaxoSmithKline 888-825-5249	December 17, 1998
	didanosine (ddl, ddl EC)	Videx	Bristol–Myers Squibb 800–332–2056	October 9
		Videx EC (enteric- coated)		October 31, 2000
	<u>emtricitabine</u>	Emtriva	Gilead Sciences	July 2,

3.33.1	nto.nin.gov/education-materials/t			
	(FTC)		800-445-3235	2003
	lamivudine (3TC)	Epivir	GlaxoSmithKline 888-825-5249	Novembe 17, 1995
	stavudine (d4T)	Zerit	Bristol–Myers Squibb 800–332–2056	June 24, 1994
	tenofovir disoproxil fumarate (tenofovir DF, TDF)	Viread	Gilead Sciences 800-445-3235	October 26, 2001
	zidovudine (azidothymidine, AZT, ZDV)	Retrovir	GlaxoSmithKline 888-825-5249	March 19 1987
Non-Nucleoside Reverse Transcrip	otase Inhibitors (NNR	TIs)		
NNRTIs bind to and later alter reverse transcriptase, an enzyme HIV needs to make copies of itself.	delavirdine (delavirdine mesylate, DLV)	Rescriptor	Pfizer 212-733-2323	April 4, 1997
	efavirenz (EFV)	Sustiva	Bristol-Myers Squibb 800-332-2056	Septemb 17, 1998
	etravirine (ETR)	Intelence	Janssen Pharmaceuticals, Inc. 800-526-7736	January 18, 2008
	nevirapine (NVP)	Viramune	Boehringer Ingelheim 800–243–0127	June 21, 1996
		Viramune XR (extended release)		March 25 2011
	rilpivirine (rilpivirine hydrochloride, RPV)	Edurant	Janssen Pharmaceuticals, Inc. 800-526-7736	May 20, 2011
Protease Inhibitors (PIs)	!	1		
Pls block HIV protease, an enzyme HIV needs to make copies of itself	atazanavir (atazanavir sulfate, ATV)	Reyataz	Bristol-Myers Squibb 800-332-2056	June 20, 2003
	darunavir (darunavir ethanolate, DRV)	Prezista	Janssen Pharmaceuticals, Inc. 800-526-7736	June 23, 2006
	fosamprenavir (fosamprenavir calcium, FPV)	Lexia	GlaxoSmithKline 888-825-5249	October 20, 2003
	indinavir (indinavir sulfate, IDV)	Crixivan	Merck 908-423-1000 800-727-5400	March 13
	nelfinavir (nelfinavir mesylate, NFV)	Viracept	Agouron Pharmaceuticals 619-622-3000	March 14

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	ritonavir (RTV)	Norvir	Abbott Laboratories 847-937-6100	March 1, 1996
	saquinavir (saquinavir mesylate, SQV)	Invirase	Hoffmann-La Roche 888-835-2555	December 6, 1995
	tipranavir (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</u> <u>system</u> .	enfuvirtide (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.	maraviroc (MVC)	Selzentry	Pfizer 212-733-2323	August 6, 2007
Integrase Inhibitors				
Integrase inhibitors block HIV integrase, an enzyme HIV needs to make copies of itself.	dolutegravir (DTG)	Tivicay	Viiv Healthcare 888-825-5249	August 13, 2013
	raltegravir (RAL)	Isentress	Merck 908-423-1000 800-727-5400	October 12, 2007
Combination HIV Medicines				
Combination HIV medicines contain two or more HIV medicines from one	abacavir and lamivudine	Epzicom	GlaxoSmithKline 888-825-5249	August 2, 2004
or more drug classes.	abacavir, lamivudine, and zidovudine	Trizivir	GlaxoSmithKline 888-825-5249	Nov. 14, 2000
	efavirenz, emtricitabine, and tenofovir DF	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
	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 <u>AIDSinfo</u> 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. Read this fact sheet on how to use condoms correctly.
- 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?

- Watch this video on HIV prevention.
- 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: How is HIV spread?
 - 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 mother—to-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 mother—to-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-to-child 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 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: Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States
- From the National Institute of Allergy and Infectious Diseasease: <u>HIV Infection in Women/Mother-to-Child Transmission (MTCT) of HIV</u>



HIV Treatment

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 drug interactions 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 drug resistance, 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 CD4 count 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>
 Antiretroviral Agents in HIV-1-Infected Adults and Adolescents
- From the Department of Veterans Affairs: <u>Treatment Decisions</u>
- From the National Institute of Allergy and Infectious Diseases: <u>Treatment of HIV</u> Infection



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 <u>AIDS</u>?
- · 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 infection-fighting 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> Care/Testing and Assessment
- From the Department of Health and Human Services: <u>Guidelines for the Use of</u>
 Antiretroviral Agents in HIV-1-Infected Adults and Adolescents/Baseline Evaluation



HIV Treatment

When to Start Antiretroviral Therapy

(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 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 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 CD4 count 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 infection-fighting 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 hepatitis B or hepatitis C 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 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/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 medicines 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)
- Nucleoside reverse transcriptase inhibitors (NRTIs)
- Protease inhibitors (PIs)
- Fusion inhibitors
- CCR5 antagonists (CCR5s) (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 class</u>.

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

Atripla

Atripla is a combination of three HIV medicines—efavirenz (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 Truvada
 - 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.
- darunavir (brand name: Prezista) boosted with ritonavir plus Truvada

INSTI-based regimens

- <u>dolutegravir</u> (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
- Stribild 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>
 Antiretroviral Agents in HIV-1-Infected Adults and Adolescents/What to Start: Initial
 <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>
 the HHS Panel on Antiretroviral Guidelines for Adults and Adolescents (October 30, 2013)
- 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 <u>drug</u> <u>classes</u>.

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-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 enzyme HIV needs to make copies of itself.	abacavir (abacavir sulfate, ABC)	Ziagen	GlaxoSmithKline 888-825-5249	December 17, 1998
	didanosine (ddl, ddl EC)	Videx	Bristol-Myers Squibb 800-332-2056	October 9,
		Videx EC (enteric- coated)		October 31, 2000
	emtricitabine (FTC)	Emtriva	Gilead Sciences 800-445-3235	July 2, 2003
	lamivudine (3TC)	Epivir	GlaxoSmithKline 888-825-5249	November 17, 1995
	stavudine (d4T)	Zerit	Bristol-Myers Squibb 800-332-2056	June 24, 1994

	tenofovir disoproxil fumarate (tenofovir DF, TDF)	Viread	Gilead Sciences 800-445-3235	October 26, 2001
	zidovudine (azidothymidine, AZT, ZDV)	Retrovir	GlaxoSmithKline 888-825-5249	March 19, 1987
Non-Nucleoside Reverse Tr	anscriptase Inhibitor	s (NNRTIs)		
NNRTIs bind to and later alter reverse transcriptase, an enzyme HIV needs to make copies of itself.	delavirdine (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
	etravirine (ETR)	Intelence	Janssen Pharmaceuticals, Inc. 800-526-7736	January 18, 2008
	nevirapine (NVP)	Viramune	Boehringer Ingelheim 800-243-0127	June 21, 1996
		Viramune XR (extended release)		March 25, 2011
	rilpivirine (rilpivirine hydrochloride, RPV)	Edurant	Janssen Pharmaceuticals, Inc. 800-526-7736	May 20, 2011
Protease Inhibitors (PIs)	<u>'</u>		'	
Pls block HIV protease, an enzyme HIV needs to make copies of itself	atazanavir (atazanavir sulfate, ATV)	Reyataz	Bristol-Myers Squibb 800-332-2056	June 20, 2003
	darunavir (darunavir ethanolate, DRV)	Prezista	Janssen Pharmaceuticals, Inc. 800-526-7736	June 23, 2006
	fosamprenavir (fosamprenavir calcium, FPV)	Lexia	GlaxoSmithKline 888-825-5249	October 20, 2003
	indinavir (indinavir sulfate, IDV)	Crixivan	Merck 908-423-1000 800-727-5400	March 13, 1996
	nelfinavir (nelfinavir mesylate, NFV)	Viracept	Agouron Pharmaceuticals 619-622-3000	March 14, 1997
	ritonavir (RTV)	Norvir	Abbott Laboratories 847-937-6100	March 1, 1996

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	saquinavir (saquinavir mesylate, SQV)	Invirase	Hoffmann-La Roche 888-835-2555	December 6, 1995
	tipranavir (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> .	enfuvirtide (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.	maraviroc (MVC)	Selzentry	Pfizer 212-733-2323	August 6, 2007
Integrase Inhibitors				
Integrase inhibitors block HIV integrase, an enzyme HIV needs to make copies of itself.	dolutegravir (DTG)	Tivicay	Viiv Healthcare 888-825-5249	August 13, 2013
	raltegravir (RAL)	Isentress	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.	abacavir and lamivudine	Epzicom	GlaxoSmithKline 888-825-5249	August 2, 2004
	abacavir, lamivudine, and zidovudine	Trizivir	GlaxoSmithKline 888-825-5249	Nov. 14, 2000
	efavirenz, emtricitabine, and tenofovir DF	Atripla	Bristol-Myers Squibb 800-332-2056 Gilead Sciences 800-445-3235	July 12, 2006
	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

lopinavir and	Kaletra	Abbott	September	
ritonavir (LPV/RTV)		Laboratories	15, 2000	
		847-937-6100		

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

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 drug-resistant 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.

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

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>
 Antiretroviral Agents in HIV-1-Infected Adults and Adolescents/Drug-Resistance
 Testing
- From the Health Resources and Services Administration: <u>Guide for HIV/AIDS Clinical</u> Care/Resistance Testing
- 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 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 Antiretroviral Agents in HIV-1-Infected Adults and Adolescents/Adherence to 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.
- Get tools and resources to help with 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 Antiretroviral Agents in HIV-1-Infected Adults and Adolescents: Adherence to 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: Managing your treatment of HIV/AIDS



HIV Treatment

HIV and Immunizations

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

Key Points

- 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</u>, <u>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 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): HIV Infection and Adult Vaccination.

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 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