HIV / AIDS Overview
**HIV in the United States: At A Glance**

**Fast Facts**

- More than 1.1 million people in the United States are living with HIV infection, and almost 1 in 6 (15.8%) are unaware of their infection.
- Gay, bisexual, and other men who have sex with men (MSM), particularly young black/African American MSM, are most seriously affected by HIV.
- By race, blacks/African Americans face the most severe burden of HIV.

CDC estimates that 1,144,500 persons aged 13 years and older are living with HIV infection, including 180,900 (15.8%) who are unaware of their infection [1]. Over the past decade, the number of people living with HIV has increased, while the annual number of new HIV infections has remained relatively stable. Still, the pace of new infections continues at far too high a level—particularly among certain groups.

**HIV Incidence** (new infections): The estimated incidence of HIV has remained stable overall in recent years, at about 50,000 new HIV infections per year [2]. Within the overall estimates, however, some groups are affected more than others. MSM continue to bear the greatest burden of HIV infection, and among races/ethnicities, African Americans continue to be disproportionately affected.

**HIV Diagnoses** (new diagnoses, regardless of when infection occurred): In 2011, an estimated 49,273 people were diagnosed with HIV infection in the United States. In that same year, an estimated 32,052 people were diagnosed with AIDS. Overall, an estimated 1,155,792 people in the United States have been diagnosed with AIDS [3].

**Deaths:** An estimated 15,529 people with an AIDS diagnosis died in 2010, and approximately 636,000 people in the United States with an AIDS diagnosis have overall. [3]. The deaths of persons with an AIDS diagnosis can be due to any cause—that is, the death may or may not be related to AIDS.

**By Risk Group**

**Gay, bisexual, and other men who have sex with men (MSM)** of all races and ethnicities remain the population most profoundly affected by HIV.

- In 2010, the estimated number of new HIV infections among MSM was 29,800, a significant 12% increase from the 26,700 new infections among MSM in 2008 [2].
- Although MSM represent about 4% of the male population in the United States [4], in 2010, MSM accounted for 78% of new HIV infections among males and 63% of all new infections [2]. MSM accounted for 52% of all people living with HIV infection in 2009, the most recent year these data are available [1].
- In 2010, white MSM continued to account for the largest number of new HIV infections (11,200), by transmission category, followed closely by black MSM (10,600) [2].
- The estimated number of new HIV infections was greatest among MSM in the youngest age group. In 2010, the greatest number of new HIV infections (4,800) among MSM occurred in young black/African American MSM aged 13–24. Young black MSM accounted for 45% of new HIV infections among black MSM and 55% of new HIV infections among young MSM overall [2].

![Estimates of New HIV Infections in the United States, 2010, for the Most Affected Subpopulations](chart.png)

Subpopulations representing 2% or less of the overall US epidemic are not reflected in this chart.

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1For assessing disease risk, the term MSM is often used instead of gay, homosexual, or bisexual because it refers to a risk behavior, rather than an identity that may or may not be tied to a behavior.
Since the epidemic began, an estimated 302,148 MSM with an AIDS diagnosis have died, including an estimated 5,909 in 2010 [3].

**Heterosexuals and injection drug users** also continue to be affected by HIV.

- Heterosexuals accounted for 25% of estimated new HIV infections in 2010 and 27% of people living with HIV infection in 2009 [1,2].
- Since the epidemic began, almost 85,000 persons with an AIDS diagnosis, infected through heterosexual sex, have died, included an estimated 4,003 in 2010 [3].
- New HIV infections among women are primarily attributed to heterosexual contact (84% in 2010) or injection drug use (16% in 2010). Women accounted for 20% of estimated new HIV infections in 2010 and 24% of those living with HIV infection in 2009 [1,2]. The 9,500 new infections among women in 2010 reflect a significant 21% decrease from the 12,000 new infections that occurred among this group in 2008 [2].
- Injection drug users represented 8% of new HIV infections in 2010 and 16% of those living with HIV in 2009 [1,2].
- Since the epidemic began, nearly 182,000 injection drug users with an AIDS diagnosis have died, including an estimated 4,218 in 2010 [3].

**By Race/Ethnicity**

Blacks/African Americans continue to experience the most severe burden of HIV, compared with other races and ethnicities.

- Blacks represent approximately 12% of the U.S. population, but accounted for an estimated 44% of new HIV infections in 2010. They also accounted for 44% of people living with HIV infection in 2009 [1,2].
- Since the epidemic began, more than 260,800 blacks with an AIDS diagnosis have died, including an estimated 7,678 in 2010 [3].
- Unless the course of the epidemic changes, at some point in their lifetime, an estimated 1 in 16 black men and 1 in 32 black women will be diagnosed with HIV infection [5].

Hispanics/Latinos are also disproportionately affected by HIV.

- Hispanics/Latinos represented 16% of the population but accounted for 21% of new HIV infections in 2010 [2]. Hispanics/Latinos accounted for 19% of people living with HIV infection in 2009 [1].
- Disparities persist in the estimated rate of new HIV infections in Hispanics/Latinos. In 2010, the rate of new HIV infections for Latino males was 2.9 times that for white males, and the rate of new infections for Latinas was 4.2 times that for white females [2].
- Since the epidemic began, more than 96,200 Hispanics/Latinos with an AIDS diagnosis have died, including 2,370 in 2010 [3].
HIV OVERVIEW: The Basics

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 HIV regimen) 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 CD4 cells of the immune system. 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 HIV regimen) 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 opportunistic infections 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.
Key Points

- HIV gradually destroys the immune system 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 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 drug resistance.

- 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 immune system. 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 AIDS. HIV medicines protect the immune system by blocking HIV at different stages of the HIV life cycle.

HIV medicines are grouped into different drug classes 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 drug resistance.

What is HIV drug resistance?

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

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

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

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

Can ART cure HIV?

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

What are the stages of the HIV life cycle?

To understand the HIV life cycle, it helps to first imagine what HIV looks like.
Now you are ready to follow HIV as it attacks a CD4 cell. The image below shows each stage of the HIV life cycle.
How can I learn more about the HIV life cycle?

Read information from the National Institute of Allergy and Infectious Diseases (NIAID) on how HIV causes AIDS. This fact sheet is based on this information.

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

The Stages of HIV Infection

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 immune system and eventually causes acquired immunodeficiency syndrome (AIDS).

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 CD4 cells 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 opportunistic infections and cancer. (Examples of opportunistic infections include pneumonia and tuberculosis.) AIDS is diagnosed when a person with HIV has a CD4 count of less than 200 cells/mm$^3$ and/or one or more opportunistic infections. Without treatment, people with AIDS typically survive about 3 years.

HIV Overview:

HIV Testing

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 sexual transmission of HIV. 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 HIV-positive 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.
HIV Overview:

FDA – Approved HIV Medicines

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

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

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

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Generic Name (Other names and acronyms)</th>
<th>Brand Name</th>
<th>Current Manufacturer</th>
<th>FDA Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nucleoside Reverse Transcriptase Inhibitors (NRTIs)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NRTIs block reverse transcriptase, an enzyme HIV needs to make copies of itself.</td>
<td>abacavir (abacavir sulfate, ABC)</td>
<td>Ziagen</td>
<td>GlaxoSmithKline</td>
<td>December 17, 1998</td>
</tr>
<tr>
<td></td>
<td>didanosine (ddl, ddl EC)</td>
<td>Videx</td>
<td>Bristol-Myers Squibb</td>
<td>October 9, 1991</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>800-332-2056</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Videx EC (enteric-coated)</td>
<td></td>
<td>October 31, 2000</td>
</tr>
</tbody>
</table>
### Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

| NNRTIs bind to and later alter reverse transcriptase, an enzyme HIV needs to make copies of itself. |
|---------------------------------|-----------------|-----------------|-----------------|
| **emtricitabine** (FTC) | Emtriva | Gilead Sciences | July 2, 2003 |
| **lamivudine** (3TC) | Epivir | GlaxoSmithKline | November 17, 1995 |
| **stavudine** (d4T) | Zerit | Bristol-Myers Squibb | June 24, 1994 |
| **tenofovir disoproxil fumarate** (tenofovir DF, TDF) | Viread | Gilead Sciences | October 26, 2001 |
| **zidovudine** (azidothymidine, AZT, ZDV) | Retrovir | GlaxoSmithKline | March 19, 1987 |

### Protease Inhibitors (PIs)

<p>| PIs block HIV protease, an enzyme HIV needs to make copies of itself. |
|---------------------------------|-----------------|-----------------|-----------------|
| <strong>atazanavir</strong> (atazanavir sulfate, ATV) | Reyataz | Bristol-Myers Squibb | June 20, 2003 |
| <strong>fosamprenavir</strong> (fosamprenavir calcium, FPV) | Lexia | GlaxoSmithKline | October 20, 2003 |
| <strong>indinavir</strong> (indinavir sulfate, | Crixivan | Merck | March 13, 1996 |
| | | | |</p>
<table>
<thead>
<tr>
<th>Drug</th>
<th>Company</th>
<th>Phone</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>nelfinavir (NFV)</td>
<td>Agouron Pharmaceuticals</td>
<td>819-622-3000</td>
<td>March 14, 1997</td>
</tr>
<tr>
<td>ritonavir (RTV)</td>
<td>Abbott Laboratories</td>
<td>847-937-6100</td>
<td>March 1, 1996</td>
</tr>
<tr>
<td>saquinavir (SQV)</td>
<td>Hoffmann-La Roche</td>
<td>888-835-2555</td>
<td>December 6, 1995</td>
</tr>
<tr>
<td>tipranavir (TPV)</td>
<td>Boehringer Ingelheim</td>
<td>800-243-0127</td>
<td>June 22, 2005</td>
</tr>
</tbody>
</table>

**Fusion Inhibitors**

*Fusion inhibitors block HIV from entering the CD4 cells of the immune system.*

<table>
<thead>
<tr>
<th>Drug</th>
<th>Company</th>
<th>Phone</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>enfuvirtide (T-20)</td>
<td>Hoffmann-La Roche</td>
<td>888-835-2555</td>
<td>March 13, 2003</td>
</tr>
</tbody>
</table>

**Entry Inhibitors**

*Entry inhibitors block proteins on the CD4 cells that HIV needs to enter the cells.*

<table>
<thead>
<tr>
<th>Drug</th>
<th>Company</th>
<th>Phone</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>maraviroc (MVC)</td>
<td>Pfizer</td>
<td>212-733-2323</td>
<td>August 6, 2007</td>
</tr>
</tbody>
</table>

**Integrase Inhibitors**

*Integrase inhibitors block HIV integrase, an enzyme HIV needs to make copies of itself.*

<table>
<thead>
<tr>
<th>Drug</th>
<th>Company</th>
<th>Phone</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>dolutegravir (DTG)</td>
<td>Viiv Healthcare</td>
<td>888-825-5249</td>
<td>August 13, 2013</td>
</tr>
<tr>
<td>raltegravir (RAL)</td>
<td>Merck</td>
<td>908-423-1000</td>
<td>October 12, 2007</td>
</tr>
</tbody>
</table>

**Combination HIV Medicines**

*Combination HIV medicines contain two or more HIV medicines from one or more drug classes.*

<table>
<thead>
<tr>
<th>Combination</th>
<th>Company</th>
<th>Phone</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>abacavir and lamivudine</td>
<td>GlaxoSmithKline</td>
<td>888-825-5249</td>
<td>August 2, 2004</td>
</tr>
<tr>
<td>efavirenz, emtricitabine, and tenofovir DF</td>
<td>Gilead Sciences</td>
<td>800-445-3235</td>
<td>July 12, 2006</td>
</tr>
<tr>
<td>elvitegravir*, cobicistat†, emtricitabine, and tenofovir DF</td>
<td>Gilead Sciences</td>
<td>800-445-3235</td>
<td>August 27, 2012</td>
</tr>
<tr>
<td>emtricitabine, rilpivirine, and tenofovir DF</td>
<td>Gilead Sciences</td>
<td>800-445-3235</td>
<td>August 10, 2011</td>
</tr>
</tbody>
</table>
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.

**HIV Overview:**

**HIV / AIDS Clinical Trials**

**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.
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 **informed consent**, 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.
Occupational HIV Transmission and Prevention Among Health Care Workers

Fast Facts

- Occupational transmission of HIV to health care workers is extremely rare.
- CDC recommends proper use of safety devices and barriers to prevent exposure to HIV in the health care setting.
- For workers who are exposed, CDC has developed recommendations to minimize the risk of developing HIV.

Fewer than 60 cases of occupational transmission of HIV to health care workers have occurred in the United States. The proper use of gloves and goggles, along with safety devices to prevent injuries from sharp medical devices, can help minimize the risk of exposure to HIV in the course of caring for patients with HIV. When workers are exposed, the Centers for Disease Control and Prevention (CDC) recommends immediate treatment with a short course of antiretroviral drugs to prevent infection.

The Numbers

- As of 2010, 57 documented transmissions and 143 possible transmissions had been reported in the United States.
- No confirmed cases of occupational HIV transmission to health care workers have been reported since 1999. Underreporting of cases to CDC is possible, however, because case reporting is voluntary.
- Health care workers who are exposed to HIV-infected blood at work have a 0.3% risk of becoming infected. In other words, 3 of every 1,000 such injuries, if untreated, will result in infection.

Prevention Strategies

To prevent transmission of HIV to health care workers in the workplace, CDC offers the following recommendations.

Health care workers should assume that the blood and other body fluids from all patients are potentially infectious. They should therefore follow infection control precautions at all times. These precautions include

- Routinely using barriers (such as gloves and/or goggles) when anticipating contact with blood or body fluids.
- Immediately washing hands and other skin surfaces after contact with blood or body fluids.
- Carefully handling and disposing of sharp instruments during and after use.

Safety devices have been developed to help prevent needlestick injuries. If used properly, these types of devices may reduce the risk of exposure to HIV. Many percutaneous injuries, such as needlesticks and cuts, are related to the disposal of sharp-ended medical devices. All used syringes or other sharp instruments should be routinely placed in “sharps” containers for proper disposal to prevent accidental injuries and risk of HIV transmission.

Although the most important strategy for reducing the risk of occupational HIV transmission is to prevent occupational exposures, plans for postexposure management of health care personnel should be in place. CDC issued guidelines in 2005 for the management of health care worker exposures to HIV and recommendations for postexposure prophylaxis (PEP): Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5409a1.htm).
These guidelines outline considerations in determining whether health care workers should receive PEP and in choosing the type of PEP regimen. For most HIV exposures that warrant PEP, a basic 4-week, two-drug (there are several options) regimen is recommended, starting as soon as possible after exposure. For HIV exposures that pose an increased risk of transmission (based on the infection status of the source and the type of exposure), a three-drug regimen may be recommended. Special circumstances, such as a delayed exposure report, unknown source person, pregnancy in the exposed person, resistance of the source virus to antiretroviral agents, and toxicity of PEP regimens, are also discussed in the guidelines. Occupational exposures should be considered urgent medical concerns, and PEP should be started within 72 hours—the sooner the better; every hour counts.

Building Better Prevention Programs for Health Care Workers

Continued diligence in the following areas is needed to help reduce the risk of occupational HIV transmission to health care workers.

Administrative efforts. All health care organizations should train health care workers in infection control procedures and the importance of reporting occupational exposures. Organizations should develop and distribute written policies for the management of occupational exposures.

Development and promotion of safety devices. Effective and competitively priced devices engineered to prevent sharps injuries should continue to be developed for health care workers who frequently come into contact with potentially HIV-infected blood. Proper and consistent use of such safety devices should be continuously evaluated.

Monitoring the effects of PEP. Data on the safety and acceptability of different regimens of PEP, particularly regimens that include new antiretroviral agents, should be monitored and evaluated continuously. Furthermore, health professionals who administer PEP should communicate possible side effects before treatment starts and should follow patients closely to make sure they take their medicine correctly.

All cases of suspected occupationally acquired HIV should be reported to state health department HIV surveillance staff and the CDC coordinator for “Cases of Public Health Importance” at 404-639-0934 or 404-639-2050.
The Centers for Disease Control and Prevention (CDC) works with other federal agencies, state and local health departments, national organizations, community-based organizations, the private sector, and advocates to reduce the spread of HIV in the U.S. This work encompasses many components, such as:

**Behavioral interventions**, which have proven effective in reducing the risk of acquiring or transmitting HIV. Ensuring people have the information, motivation, and skills necessary to reduce their risk continues to be important.

**HIV testing**, which is critical in preventing the spread of HIV. Most people change behaviors to protect their partners if they know they are infected with HIV.

**Linkage to treatment and care**, which enables individuals with HIV to live longer, healthier lives and reduce their risk of transmitting HIV. It is imperative that individuals with HIV know their HIV status and are linked to ongoing care and prevention services.

Data about transmission rates, incidence, testing behaviors, and linkages to care all contribute to provide the fullest possible picture about progress in the U.S. battle against HIV.

- More than 309 million people live in the U.S. and more than one million of those people are living with HIV (an estimated 1,106,400 adults and adolescents).
- The HIV transmission rate - the estimated annual number of new HIV infections per 100 persons living with HIV- has decreased over the past two decades.
  - Since the mid-1980s, the transmission rate declined approximately 89% (from 44 transmissions per 100 people with HIV in 1984 to 5 transmissions per 100 people in 2006).
- HIV incidence – the annual number of new HIV infections – has decreased from an estimated high of about 130,000 new infections a year in 1985 to about 56,300 in 2006, despite there being more people every year living with HIV.
- Perinatal HIV infections – those transmitted from mother to child – have decreased from 1,000-2,000 per year in the early 1990s to an estimated 138 per year in 2004.
- HIV infections among injection drug users declined by approximately 80% between 1988 and 2006.
- The proportion of persons who know they are infected with HIV increased from 75% in 2003 to 79% in 2006. In October 2007, CDC launched the Expanded Testing Initiative. In two years,
  - CDC grantees conducted nearly 1.4 million tests.
  - 17,000 persons tested positive for HIV.
    - Of these, 10,500 individuals had no previous diagnosis of HIV.
    - Nearly 6,500 of the 17,000 who tested positive had a previous diagnosis of HIV recorded in surveillance records. Yet many of these individuals were unaware of their diagnosis.
    - Of the more than 10,000 persons newly diagnosed with HIV, 86% received their positive HIV test result, 75% were successfully linked to medical care, and 78% were referred to partner services, so that their partners could be advised of their potential exposure to HIV and counseled to receive HIV testing.
HIV prevention saves lives and money. It is estimated that prevention efforts have averted more than 350,000 HIV infections in the United States (a conservative estimate for the period 1991-2006), as well as more than $125 billion in medical costs. For every HIV infection that is prevented, an estimated $355,000 is saved in the cost of providing lifetime HIV treatment – significant cost-savings for the U.S. federal government that spent an estimated $12.3 billion on HIV care and treatment in 2009, and for the U.S. health care system as a whole.

These successes reflect remarkable efforts by people with HIV, communities at risk, health departments, and other CDC partners. However, CDC recognizes there is much work to be done. There are still over 56,000 new HIV infections occurring annually in the U.S. Further, certain populations continue to be disproportionately affected by HIV – gay, bisexual, and other men who have sex with men (MSM), African Americans, Hispanics/Latinos, and injection drug users – and one HIV infection is estimated to occur every nine and a half minutes in the U.S. Only when all Americans are working together, making tough choices, and scaling efforts to match the scope of the epidemic, will the United States successfully turn the tide of HIV infections.
WHAT ARE VACCINES AND WHAT DO THEY DO?

A vaccine—also called a “shot” or “immunization”—is a substance that teaches your body's immune system to recognize and defend against harmful viruses or bacteria before you get infected. These are called “preventive vaccines” or “prophylactic vaccines,” and you get them while you are healthy. This allows your body to set up defenses against those dangers ahead of time. That way, you won't get sick if you're exposed to them later. Preventive vaccines are widely used to prevent diseases like polio, chicken pox, measles, mumps, rubella, influenza (flu), and hepatitis A and B.

In addition to preventive vaccines, there are also therapeutic vaccines. These are vaccines that are designed to treat people who already have a disease. Some scientists prefer to refer to therapeutic vaccines as “therapeutic immunogens.”

Currently, there is only one FDA-approved therapeutic vaccine for advanced prostate cancer (http://www.nlm.nih.gov/medlineplus/prostatecancer.html) in men.

IS THERE A VACCINE FOR HIV?

No. There is currently no vaccine that will prevent HIV infection or treat those who have it.

WHY DO WE NEED AN HIV VACCINE?

Today, more people living with HIV have access to life-saving antiretroviral therapy (ART) than ever before, which is good for their health and reduces the likelihood that they will transmit the virus to others if they adhere to their HIV medication. In addition, others who are at high risk for HIV infection have access to Pre-exposure Prophylaxis (PrEP), (http://aids.gov/hiv-aids-basics/prevention/reduce-your-risk/pre-exposure-prophylaxis/) or ART being used to prevent HIV. Yet, unfortunately, approximately 50,000 Americans and 2.3 million people worldwide still become newly HIV-infected each year. To control and ultimately end HIV globally, we need a powerful array of HIV prevention tools that are widely accessible to all who would benefit from them.

Vaccines historically have been the most effective means to prevent and even eradicate infectious diseases. They safely and cost-effectively prevent illness, disability and death. Like smallpox and polio vaccines, a preventive HIV vaccine could help save millions of lives.

Developing safe, effective and affordable vaccines that can prevent HIV infection in uninfected people is the best hope for controlling and/or ending the HIV epidemic.
The long-term goal is to develop a safe and effective vaccine that protects people worldwide from getting infected with HIV. However, even if a vaccine only protects some people, it could still have a major impact on the rates of transmission and help control the epidemic, particularly for populations where there is a high rate of HIV transmission. A partially effective vaccine could decrease the number of people who get infected with HIV, further reducing the number of people who can pass the virus on to others.

A therapeutic immunogen could also be beneficial for people living with HIV by helping slow the progression of the disease and prevent or delay the onset of AIDS.

For more information, see the video below with Dr. Anthony Fauci, Director of NIH’s National Institute of Allergy and Infectious Diseases (NIAID).

WHY DON'T WE HAVE AN HIV VACCINE YET?

HIV is a very complex, highly changeable virus, which makes speedy development of a successful preventive HIV vaccine very difficult, but not impossible. It also takes many years to conduct the research, including the careful clinical testing that will lead to a safe and effective vaccine.

Researchers from around the world have been working for more than two decades to create a vaccine that will protect people against HIV infection. NIAID supports the HIV Vaccine Trials Network (HVTN) (http://www.hvtn.org), an international collaboration of scientists and educators searching for an effective and safe HIV vaccine. The U.S. Military HIV Research Program (http://www.hivresearch.org/home.php) (MHRP) is also engaged in HIV vaccine research and led a large collaboration of clinical scientists also funded by NIAID in implementing a vaccine trial that showed for the first time that an HIV vaccine is possible. (For more on this trial, see “What's the Latest on HIV Vaccine Research,” below.)

HOW IS HIV DIFFERENT FROM OTHER VIRUSES?

In part, HIV is different from other viruses because your immune system never fully gets rid of it. Most people who are infected with a virus recover from the infection, and their immune systems “clear” the virus from their bodies. This is true even for viruses that can be deadly, like influenza (http://www.flu.gov/).

Once your body has cleared a particular virus, you often develop immunity to it—meaning it won’t make you sick the next time you are exposed to it. We’ve known since the late 1700s that you can create immunity by exposing people to dead or weakened viruses that will protect them from deadly diseases later.

But the human body can’t seem to fully clear HIV and develop immunity to it. The antibodies your immune system makes to fight HIV are not effective—and HIV actually targets, invades, and then destroys some of the most important cells in your immune system itself. This means that, over time, HIV does serious damage to your body's ability to fight disease.

So far, no person with an established HIV infection has managed to clear the virus naturally. This has made it more difficult to develop a preventive HIV vaccine.


WHAT’S THE LATEST ON HIV VACCINE RESEARCH?

Scientists are continuing to create and test HIV vaccines—in the lab, in animals, and even in human subjects. These vaccine trials help researchers to learn whether a vaccine will work and if it can be safely given to people.
In 2009, MHRP and collaborating researchers published findings from a large-scale HIV vaccine trial in Thailand called RV144. That trial involved more than 16,000 adults and showed that a combination vaccine was safe and could prevent about 32 percent of new infections. The scientific community, with leadership from NIAID, is working collaboratively to build on what was learned from RV144 in order to help speed the process of finding an HIV vaccine. Those efforts have provided information that certain antibodies (proteins produced by the body to fight infection) may serve either as a signal or provide a direct role to decreasing the risk of becoming HIV infected. This has led to a better understanding of the type of immune response that may be needed for a preventive HIV vaccine to be effective.

RELATED TOPICS ON AIDS.GOV

- Clinical Trials (/hiv-aids-basics/just-diagnosed-with-hiv-aids/treatment-options/clinical-trials/)
- HIV Vaccine Awareness Day (/news-and-events/awareness-days/hiv-vaccine-awareness-day/)
- Blog posts (http://blog.aids.gov/category/research/hiv-vaccine) about HIV vaccine research

FREQUENTLY ASKED QUESTIONS

How can I participate in an HIV vaccine trial?
For more information about HIV vaccines and how you can get involved in HIV vaccine trials, check out Be The Generation (http://www.bethegeneration.org/index.html). For information about specific HIV vaccine trials, go to the HVTN website at www.HVTN.org (http://www.HVTN.org) or http://www.AIDSinfo.nih.gov (http://www.AIDSinfo.nih.gov), which has information about all HIV trials.

Can I get HIV from participating in a vaccine clinical trial?
No. You can’t get HIV infection from participating in a vaccine trial because the vaccines being tested do not contain the virus itself.
"This course was developed from the public domain documents: HIV in the United States: At A Glance, and HIV Overview, Centers for Disease Control and Prevention (CDC)."