AIDSinfo

A Service of the U.S. Department of Health and Human Services

HIV and Its Treatment

What You Should Know

2nd edition

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HIV and Its Treatment: What You Should Know

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The information in this document is based on *Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents*, developed by the Panel on Clinical Practices for the Treatment of HIV Infection, which is convened by the U.S. Department of Health and Human Services (DHHS) in conjunction with the Henry J. Kaiser Family Foundation.

The *Guidelines*, which is a "living document," provides updates in new advances in the treatment of HIV. The current version of the document is available on our web site: **http://aidsinfo.nih.gov**

HIV and Its Treatment: What You Should Know is a publication of *AIDSinfo*. *AIDSinfo* (formerly the HIV/AIDS Treatment Information Service) offers access to Federal HIV/AIDS information on clinical research, HIV treatment and prevention, and medical practice guidelines for consumers and health care providers.

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HIV and Its Treatment: What You Should Know

I am HIV positive. What does that mean? Does it mean I have AIDS?

Receiving a positive HIV test result means that you have been infected with HIV (Human Immunodeficiency Virus), the virus that causes AIDS (Acquired Immune Deficiency Syndrome). HIV disease progresses to AIDS when your $CD4^+$ T cell count drops below 200 cells/mm^3, and/or you develop an AIDS-defining condition (an illness that is very unusual in someone who is not HIV positive).

What is a $CD4^+$ T cell count?

This is a test to count the number of $CD4^+$ T cells in a sample of blood. $CD4^+$ T cells are a type of white blood cell that fights infections. When HIV enters a person's $CD4^+$ T cell, it uses the cell to make copies of itself. This process destroys the $CD4^+$ T cells, weakening the immune system and making it harder for your body to fight infections.

What is viral load?

This is a test to measure the amount of HIV in a sample of blood. People with a high viral load usually develop AIDS faster than people with a low viral load.

What is HIV treatment? (also called drug therapy)

HIV treatment is the use of drugs to keep an HIV positive person healthy. For most people who start HIV drug (antiretroviral) therapy, their viral load drops to an undetectable level (below 50 copies/mL) within 16-20 weeks. However, HIV drug treatment is complicated and different people have different results. HIV treatment can help people at all stages of HIV disease stay healthy.

When to Start Treatment

What kind of a doctor do I need?

Your doctor should be an expert in treating HIV and AIDS. Your doctor also should be someone you feel comfortable with, since you will need to work closely with him or her to make informed decisions about your treatment.

What questions should I ask my doctor?

Ask your doctor about the risks and benefits of HIV treatment. Write down your questions and take them with you to your appointment. This will help you remember everything you want to ask.

What can I expect?
What tests will be needed?

Before starting HIV treatment, your doctor will ask you questions about your health, do a physical examination, and do blood tests. Blood tests will include a complete blood count, blood chemistry profile, a test for hepatitis B and C, a viral load test, and a $CD4^+$ T cell count (see next page). Your doctor should also perform other tests for infections (such as syphilis screening, tuberculin skin test, and toxoplasma antibody test). Women should have a gynecologic examination with Pap smear and a pregnancy test (see page 13 for more on pregnancy and HIV). Your doctor also may do other tests.

Both the viral load test and the $CD4^+$ T cell count will be done before you start HIV treatment.

- **Viral Load Test**

The viral load test measures the amount of HIV in a sample of blood. Getting a viral load test before starting HIV treatment is important for two reasons.

- It shows how well the body's immune system is controlling the virus.
- It provides a baseline measurement for viral load.

After you start treatment, your viral load will be compared to the baseline. This will help your doctor see how well the drugs are working.

At first, viral load testing should be done at two different times, by the same laboratory, using the same type of test, to ensure accurate results. Currently, the RT-PCR assay (Roche) and the NucliSens HIV-1 QT (bioMerieux) are the only viral load tests approved by the Food and Drug Administration (FDA). The bDNA (Chiron) viral load test is also commonly used, but is not FDA-approved.

- **$CD4^+$ T Cell Count**

The $CD4^+$ T cell count is the number of $CD4^+$ T cells in a sample of blood. There are two important reasons to have a $CD4^+$ T cell count before starting treatment.

- It shows how well your immune system is working.
- It provides a baseline measurement of your $CD4^+$ T cell count.

After you start treatment, your $CD4^+$ T cell counts will be compared to the baseline. This will help your doctor see how well the drugs are working.

How will my doctor and I decide whether to start HIV drug treatment?

General guidance for starting HIV drug treatment is on page 7. You should talk to your doctor about whether starting treatment is right for you and about other options you may have.

Some important factors in deciding whether to start treatment include the following:

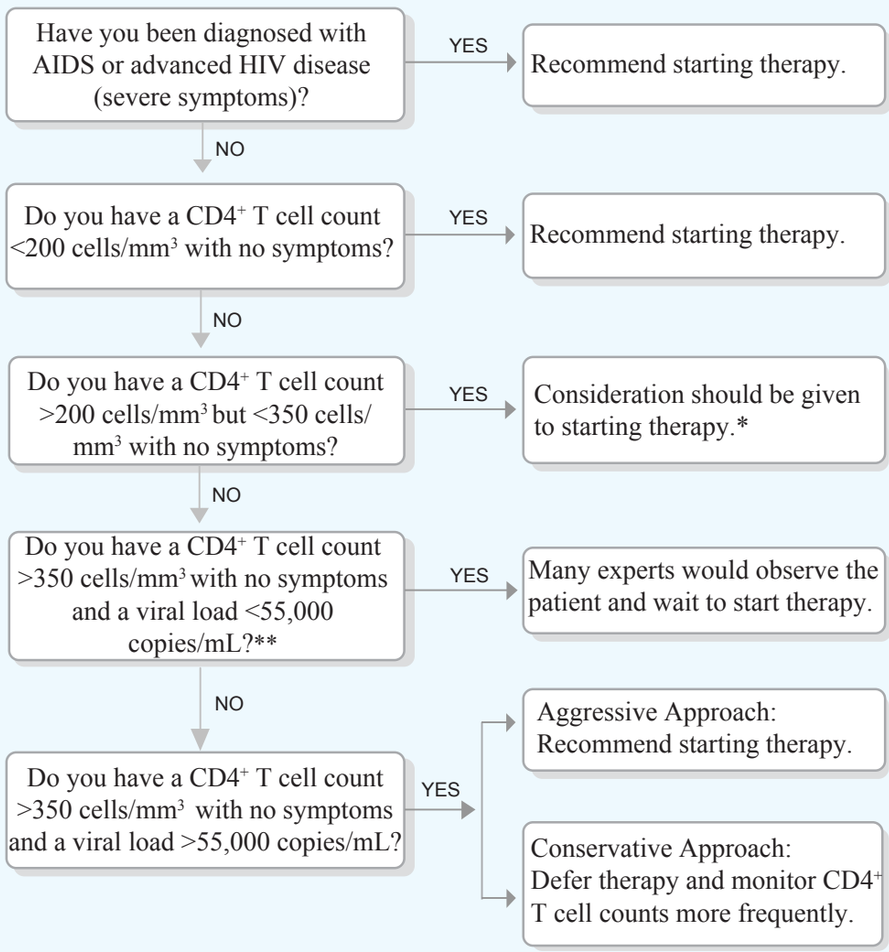
- Do you have advanced HIV disease or HIV symptoms?
- What are the results of your viral load test and $CD4^+$ T cell count?
- Are you willing to begin drug therapy?
- Are you willing and able to take all your medications as prescribed by your doctor?

Because drug resistance often occurs when doses are skipped, adherence is very important in HIV drug treatment. (For more information on adherence, turn to page 16.)

I am HIV-infected but do not have any symptoms. Should I start treatment?

You and your doctor should consider several factors in deciding when to start drug therapy. As discussed above, your viral load and $CD4^+$ T cell count will help determine whether you should consider treatment. You should keep in mind that once you begin drug treatment, you may need to continue for the rest of your life. You will also need to consider how well you will be able to follow your treatment plan, and weigh the known benefits and potential risks of drug therapy.

Making Decisions about HIV Drug Treatment: When to Start Therapy



* The decision to begin therapy in patients with no symptoms and >200 $CD4^+$ T cells/mm^3 is complex and must be made carefully with your doctor.

** See page 5 for more information on viral load tests.

What are the benefits and risks of starting early drug therapy?	**Benefits of starting early therapy:** • Easier to achieve and maintain control of viral load. • Less risk of drug resistance if viral load is undetectable. • Delay or prevent a weakened immune system. **Risks of starting early therapy:** • Potential for serious side effects (For more information on negative side effects, see page 10.) • Earlier development of drug resistance if viral load is not undetectable. • Possible limitation of future therapy options. • Negative effects on quality of life resulting from drug regimens.
What are the benefits and risks of delayed drug therapy?	**Benefits of delaying therapy:** • Avoid negative effects on quality of life resulting from drug regimens. • Avoid side effects (drug toxicities). • Less risk of drug resistance. • Preserve future drug options. **Risks of delaying therapy:** • Possible permanent immune system damage from HIV virus. • Possible difficulty with controlling viral load.
If my doctor and I decide to delay treating my HIV infection, will I need to have my viral load and $CD4^+$ T cell count tested again?	Yes. HIV-infected persons who have not started drug therapy should have a viral load test every 3–4 months and a $CD4^+$ T cell count every 3–6 months. Talk to your doctor about how often you should be tested.

Starting Drug Therapy

When I start therapy, what kinds of medications will I have to take?

HIV drugs are used to slow the reproduction of the virus, thus slowing the progression of HIV disease to AIDS.

There are three classes of FDA-approved antiretroviral drugs: NRTIs, PIs, and NNRTIs. (For the full names of these drugs, see the chart below.)

The recommended treatment for HIV is a combination drug treatment called **H**ighly **A**ctive **A**nti-**R**etroviral **T**herapy, or HAART. HAART combines three or more HIV drugs.

NRTIs (Nucleoside/Nucleotide Reverse Transcriptase Inhibitors)

Zidovudine (AZT, ZDV) (Retrovir®)
Lamivudine (3TC) (Epivir®)
Tenofovir (Viread™)
Abacavir (Ziagen™)
Zidovudine + Lamivudine + Abacavir (Trizivir®)
Didanosine (ddI) (Videx®)
Stavudine (d4T) (Zerit®)
Zalcitabine (ddC) (HIVID®)
Zidovudine + Lamivudine (Combivir™)

PIs (Protease Inhibitors)

Saquinavir (Invirase™ & Fortovase™)
Indinavir (Crixivan®)
Amprenavir (Agenerase®)
Ritonavir (Norvir™)
Nelfinavir (Viracept®)
Ritonavir/Lopinavir (Kaletra™)

NNRTIs (Non-Nucleoside Reverse Transcriptase Inhibitors)

Nevirapine (Viramune®)
Efavirenz (Sustiva™)
Delavirdine (Rescriptor®)

The recommended HAART regimens are efavirenz plus two NRTIs, indinavir plus two NRTIs, nelfinavir plus two NRTIs, ritonavir and indinavir plus two NRTIs, ritonavir and lopinavir plus two NRTIs, or ritonavir and saquinavir plus two NRTIs.

In general, taking only two drugs is not recommended, because the resulting decrease in viral load is temporary for most people. For most people, taking only one antiretroviral drug is also not recommended (the exception is pregnant women, who may be offered zidovudine alone or with other drugs to reduce the risk of passing HIV to their infants).

If you are pregnant or considering becoming pregnant, there are additional drug considerations. (See page 13 for more information.)

What are some of the negative side effects of HAART?

You may experience negative side effects (drug toxicities) when you take HIV drugs. Some of these side effects are serious, even life threatening, so you may have to change drugs.

Possible side effects of HAART:

- liver problems,
- diabetes,
- fat maldistribution (lipodystrophy syndrome),
- high cholesterol,
- increased bleeding in patients with hemophilia,
- decreased bone density, and
- skin rash.

Side effects that may seem minor, such as fever, nausea, and fatigue, can mean there are serious problems. You should always discuss any side effects you are having with your doctor.

How will I know if my treatment is working?

In general, your viral load is the most important indicator that your treatment is working. Other important factors are:

- your $CD4^+$ T cell count,
- your recent health history, and
- results of physical examinations.

Your viral load should be tested 2–8 weeks after you start treatment. If your drugs are working, your viral load should decrease. It should continue to decrease as you continue to take your medication.

Throughout HIV treatment, your viral load should be tested every 3–4 months to make sure your drugs are still working. If your viral load is still detectable within 4–6 months after starting treatment, you should talk to your doctor about possibly changing your HIV drugs.

How fast, or how much, your viral load decreases may depend on other factors as well. These factors can include your baseline viral load and $CD4^+$ T cell count (before starting therapy), whether you have used HIV drugs before, whether you have any AIDS-related illnesses, and how closely you have followed (adhered to) your therapy. Talk to your doctor if you are concerned about the results of your viral load tests.

$CD4^+$ T cell counts may also help show how well your medications are working. After starting HIV treatment, your $CD4^+$ T cell count should be tested every 3–6 months. Talk to your doctor if you are concerned about your $CD4^+$ T cell counts.

My doctor wants to change my drug therapy. Why would this be recommended?

There are several reasons for this. Two of the more important reasons are drug intolerance and drug failure.

Drug intolerance means that there are side effects that make it difficult to take the drugs as directed.

Drug failure means that the drugs are not working well enough to decrease your viral load.

You should ask your doctor to explain why any changes are needed in your treatment.

If the reason is drug intolerance, your doctor may change the drug(s). He or she may replace one or more of your current drugs with different ones of the same strength and class.

If the reason is drug failure, your doctor should change all your drugs to new ones you have never taken. If you have been taking three drugs, and all three drugs cannot be changed, then at least two drugs should be changed. Using new drugs will reduce the risk of developing drug resistance.

Before changing HIV drugs, you should talk to your doctor about

- all HIV drugs you have taken before,
- the strength of the new drugs your doctor recommends,
- possible side effects of the new drugs,
- how well you will be able to follow (adhere to) the new treatment, and
- the number of HIV drugs remaining that you have not yet used.

You may be eligible to participate in a clinical trial using new drugs or treatment strategies. For more information about participating in a clinical trial, ask your doctor, or visit the National Library of Medicine's *ClinicalTrials.gov* Web site at: **http://www.*ClinicalTrials.gov***.

HIV and Pregnancy

I am HIV positive and pregnant. What should I do about drug treatment?

If you are pregnant or want to become pregnant, you must consider the general risks and benefits of drug treatment to both you and your child. Some of the drugs (such as efavirenz and hydroxyurea) should be avoided, because they may cause birth defects if taken early in pregnancy. The effects of other drugs are not yet known. It is important for you to talk with your doctor before and during your pregnancy so that you can decide together on the best treatment for you and your baby.

If you are already taking HIV drugs, talk to your doctor about the potential risks and known benefits to your baby if you continue drug treatment during your pregnancy.

Will my baby be born HIV-infected?

No one can tell you for sure if your baby will be born HIV-infected. But there are steps you can take to reduce the risk of transmitting HIV to your baby. Talk to your doctor. He or she should offer you zidovudine (AZT) therapy by itself or with other HIV drugs. AZT has been shown to reduce the risk of passing HIV to your baby by almost 70%. The additional HIV drugs will treat your infection and may provide extra protection for your baby.

However, the possible side effects for you and your baby of using multiple drugs during pregnancy are not well understood.

Other actions to help protect your baby include getting regular prenatal care and adhering to your HIV drug treatment plan.

Understanding Prevention

Why does my doctor want to discuss HIV prevention with me?

It is important that you understand how HIV is transmitted so that you can prevent transmitting HIV to others. Every time you visit your doctor, discuss any high-risk behaviors such as unprotected sex and needle sharing. Then you and your doctor can find ways to prevent transmission.

Successful HIV treatment can lower the viral load which may reduce the chance of HIV transmission. But there are other factors that influence sexual transmission of HIV, such as the following:

- presence of other sexually transmitted infections,
- genital irritation,
- menstruation,
- lack of circumcision in men,
- taking birth control pills,
- hormone imbalances, and
- vitamin and mineral deficiencies.

Successful treatment does not prevent transmission. You should always use prevention strategies, such as condoms, safer sex practices and clean needles.

I am HIV-infected, but my viral load is undetectable. What does that mean? Am I cured of HIV?

No, this does not mean that you are cured of HIV or AIDS. It means that the amount of HIV virus in your blood is so low that the viral load tests cannot detect it. You are still infected with HIV and should continue to practice risk-free behaviors, such as not sharing drug needles with anyone and using safer sexual practices. You will also need to see your doctor on a regular basis.

Adherence

What is "adherence"?

Adherence refers to how closely you follow—or adhere to—a prescribed drug treatment plan. It includes your willingness to begin treatment and your ability to take medications (antiretroviral drugs) as directed. Studies have shown that adherence may be difficult for many patients, including people who are HIV-infected as well as those who take daily medications for other diseases.

Is adherence important for HIV treatment?

Yes. Adherence is a major issue in HIV treatment for two reasons.

- First, adherence affects how well the HIV drugs decrease viral load. When you skip medication doses even once, the virus has the opportunity to make copies of itself more rapidly. This makes it difficult for the drugs to be effective. Other factors that may affect treatment effectiveness include your baseline viral load and $CD4^+$ T cell count, whether you have any AIDS-related illnesses, and whether you have used HIV drugs before.
- Second, adherence to HIV treatment is very important to prevent drug resistance. Studies have shown that when you skip doses, you may develop strains of HIV that are drug-resistant. This may leave you with fewer treatment options if your viral load does not decrease. Because drug-resistant strains can be transmitted to others, it has serious consequences for anyone with whom you engage in risky behavior.

What makes adherence difficult for many HIV-infected patients?

There are several reasons why many patients have difficulty adhering to an HIV treatment plan.

- One reason is that HIV treatment plans are very complicated. Studies have shown that many people may have difficulty adhering to even simple treatment plans. Yet HIV treatment may involve taking 25 or more pills each day. In addition, some HIV drugs must be taken on an empty stomach, while others must be taken with meals. This can be difficult for many people, especially those who are sick or experiencing HIV symptoms. Also, HIV-infected patients may need to continue their treatment regimens for a long time, perhaps for their entire lives.

- HIV-infected patients have reported other reasons for poor adherence, including unpleasant side effects (like nausea), sleeping through doses, travelling away from home, being too busy, feeling sick or depressed, or simply forgetting to take their medications.

I'm considering starting HIV treatment. How can I be sure I'll be able to adhere to a treatment plan?

If you are considering HIV treatment, there are several steps you can take before starting treatment to help adherence:

1. Play an active role in your treatment plan. Ask your doctor to describe all your treatment options, including known benefits and potential risks of starting treatment. Also ask your doctor to explain any side effects or other problems that may result from the drugs. It is important for you to understand the goals of treatment and to be fully committed to the treatment plan.

2. Talk to your doctor about personal issues that may affect your adherence. Studies have shown that adherence may be harder for people dealing with substance abuse or alcoholism, unstable housing, mental illness, or major life crises. Adherence also may be harder for other patients who:
   - do not have advanced HIV disease,
   - must follow very complex treatment regimens, and
   - have had problems taking medications in the past.

   Talk to your doctor about these or any other issues that you feel may affect your adherence to a treatment plan.
3. Consider a "dry run"—practice your treatment plan using vitamins, jelly beans, or mints. This will help you determine ahead of time which doses might be difficult.
4. After you and your doctor decide on a treatment plan, ask for a written copy. This should list each medication, when and how much to take, and if it must be taken with food or on an empty stomach. It also should include your doctor's name and phone number and the date of your next visit.
5. Most important, talk to your doctor about how to tailor your treatment plan to your lifestyle. For example, many patients find it helpful to identify things they normally do at the times they will be taking their medication. Studies have shown that patients who arrange their medication schedule around their daily routines adhere to their treatment plans better than those who do not. Activities that may be helpful in remembering your medication schedule include getting out of bed in the morning, taking a child to school, leaving work, or watching a TV show. If you decide take medicine as part of your regular activities, make sure you take it before the activity, not after.

Your commitment to a treatment plan is critical. Talk to your doctor about any concerns you may have about starting—and adhering to—your treatment plan. For many people, it takes two or three office visits to feel comfortable about starting HIV treatment.

I've started HIV treatment. What can I do to help my treatment work?

As described previously, the effectiveness of your treatment will depend on several factors. One of the most important things you can do is find a strategy that works for you. This will help you adhere to your treatment plan as closely as possible. Here are some other ways to improve your adherence:

1. Use daily or weekly pill boxes or egg cartons to organize your medications. Some people find it helpful to count and set out a week's worth of medications at a time, with one space of the pill box or egg carton for each part of the day. Try to do this at the same time each week, for example, every Sunday night at bedtime.
2. Use timers, alarm clocks, or pagers to remind you when to take your medication. For each dose, try to take your medication at the same time each day.
3. Try keeping your medications where you will take them. Some patients find it helpful to keep their first morning dose next to the alarm clock or coffee pot. Others like to keep backup supplies of their medications at their workplace or in their briefcase.
4. Keep a medication diary. Try writing the names of your drugs on a 3 x 5 card or in your daily planner, and then check off each dose as you take it. You might want to try write yourself a reminder in your calendar or planner to take any doses that are difficult to remember.
5. Plan ahead for weekends, holidays, and changes in routine. Many studies have shown that weekends are a serious problem for adherence. Decide ahead of time how you will remember to take all of your doses. Also, if you are going on vacation, traveling on business, or changing jobs, write out a plan for remembering your medications.

6. Develop a support network. This may include family members, friends, or coworkers who can remind you to take your medication. Some patients also find it helpful to join a support group for people living with HIV infection.
7. Don't run out of your medication. Contact your doctor or clinic if your supply will not last until your next visit.

I'm having problems taking my medication. What should I do?

Tell your doctor if you are having any problems related to your medication, including those below:

- Side effects. If you are experiencing any side effects, tell your doctor what they are, and when you notice them.
- Skipped doses. Do not be afraid to admit to skipped doses. Your doctor knows that some people do have difficulty taking each dose as prescribed. If you have skipped doses, tell your doctor which medication(s) you skipped, and when.
- Difficulty taking your medication as directed. If you are supposed to take medications on an empty stomach, or with food, and this is difficult for you, tell your doctor. If there is a time of day that is difficult for you to take your dose, tell your doctor this.
- Your treatment plan interferes with your lifestyle. If you feel your treatment plan is too complicated or unrealistic for you to follow, talk to your doctor about other options you may have. It is important that you tell your doctor right away about any problems you are having with your treatment plan. Your doctor needs this information to help you get the most out of your treatment plan and provide workable options, if necessary.

Summary

Managing HIV infection is complicated, but new treatments can both improve the quality of your life and extend your life. To help you successfully manage your health, remember these tips:

See your doctor regularly (every 3-6 months or as advised) to check your $CD4^+$ T cell count, viral load, and general health, and to discuss treatment and prevention strategies.

Be an active part of your health care team. Tell your doctor about any problems, and be sure your doctor explains concepts to you in such a way that you clearly understand your options.

Educate yourself. The more you know about HIV infection and HIV treatment, the better you will be able to judge the risks and benefits of your options.

For more information on HIV infection and treatment,
including pregnancy and HIV,
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