

HIV/AIDS TREATMENT
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**HIV and Its Treatment:
*What You
Should Know***

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April 1999

The information in this document is based on *Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents*, developed 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://www.hivatis.org>

HIV and Its Treatment: What You Should Know is a publication of the HIV/AIDS Treatment Information Service (ATIS). ATIS provides timely, accurate information on the latest federally approved treatment guidelines for HIV and AIDS through a toll-free telephone service and a web site.

HIV/AIDS Treatment Information Service

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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 an HIV positive test result means that you have been infected with HIV (Human Immunodeficiency Virus), the virus that causes AIDS. HIV progresses to AIDS (Acquired Immune Deficiency Syndrome) when your CD4⁺ T cell count drops below 200 cells/mm³, and/or you develop an AIDS-defining condition.

What is a CD4⁺ T cell count?

A CD4⁺ T cell count is a measurement of a person's CD4⁺ T cells. HIV infects a person's CD4⁺ T cells and uses these cells to replicate (make copies of itself). As these cells are destroyed, the person's immune system is weakened, and the person is more likely to develop an opportunistic infection.

What is viral load?

Viral load is the amount of HIV in a person's blood. People with high viral loads are more likely to rapidly progress to AIDS than people with low levels of the virus.

What is HIV treatment?

HIV treatment is the use of antiretroviral drugs to decrease a patient's viral load. In most people who start HIV treatment (antiretroviral therapy), the viral load drops to undetectable levels (below 500 copies/ml) within 12-16 weeks. However, antiretroviral therapy is complex, and different people may have

different results. Antiretroviral therapy has been shown to benefit HIV-infected persons with advanced HIV disease and weakened immune systems. Many experts believe that treatment will also benefit people with earlier stages of HIV disease as well.

Deciding Whether To Start Treatment

What kind of a doctor do I need?

Since treating HIV is a complex process, your doctor should be an expert in treating HIV and AIDS. It is also important that your doctor be someone you feel comfortable with, since you will need to work closely with him/her in making decisions about your treatment. Write down your questions and take them with you to your appointment. This will help you remember everything you want to ask. Ask your doctor about the risks and benefits of HIV treatment.

What tests will be needed?

Before starting HIV treatment, your doctor should take your complete health history, perform a physical examination, and perform several blood tests. These include a complete blood count, a viral load test, and a CD4⁺ T cell count (see below). Your doctor should also perform other tests for infections (syphilis screening, tuberculin skin test, toxoplasma antibody test, and, for women, a gynecologic exam with Pap smear). Your doctor also may perform other tests, depending on your symptoms.

Both the viral load test and the CD4⁺ T cell count will be done on blood drawn at your doctor's office. Both tests should be done before starting HIV treatment.

- Viral Load Test

The viral load test measures the amount of HIV in a person's blood. Getting a viral load test before starting HIV treatment is important for two reasons. First, it shows how far a patient's HIV disease has progressed. Second, it provides a baseline value for viral load before treatment. After starting treatment, this baseline value will be used to help determine how well the drugs are working.

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

If you have advanced HIV disease, your doctor may recommend starting treatment after your first viral load test, rather than waiting for the results of your second test.

- CD4⁺ T Cell Count

The CD4⁺ T cell count provides 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. First, it helps show how well your immune system is working. Second, it provides a baseline value for the CD4⁺ T cell count before treatment. After starting therapy, this can be used to help determine how well the drugs are working.

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

The current recommendations for starting antiretroviral therapy are listed in the flowchart on page 7. You should talk to your

doctor about whether starting treatment is right for you, and about other options you may have.

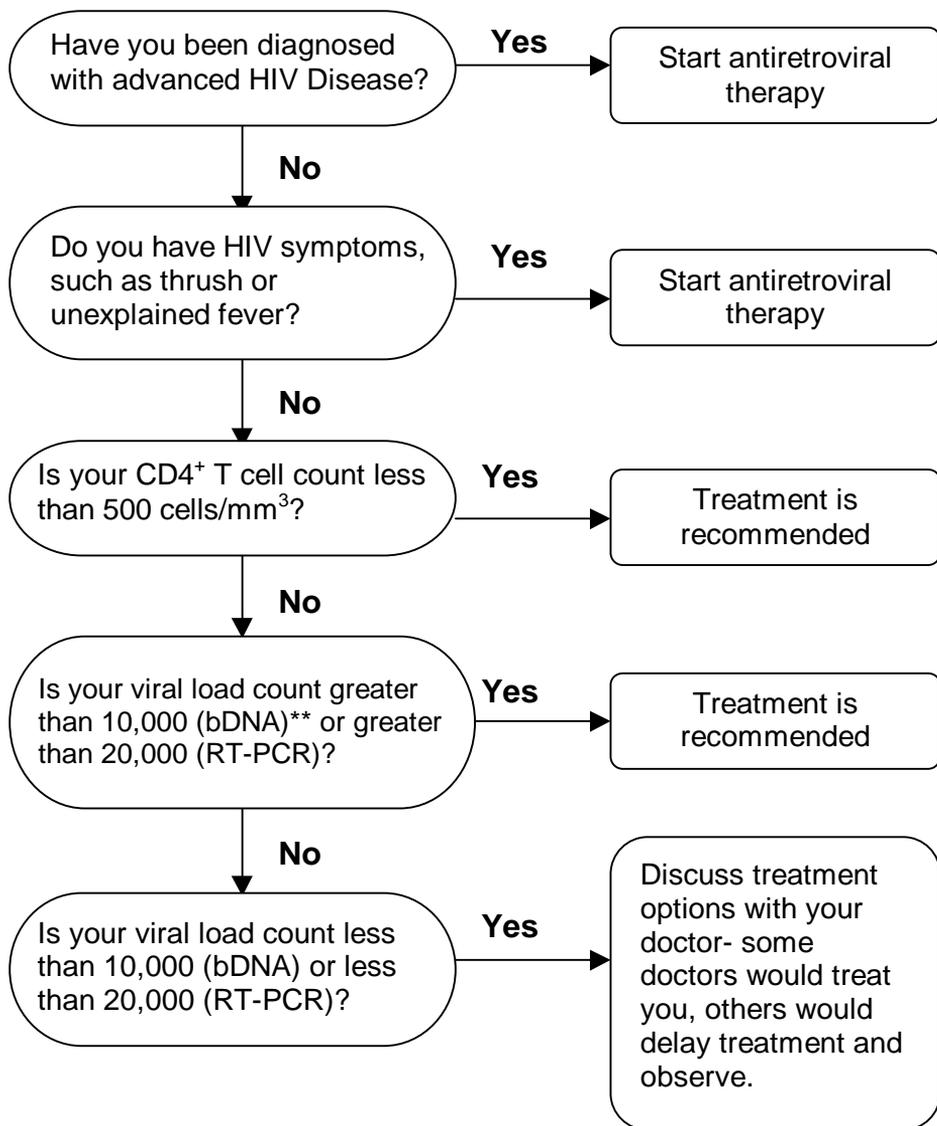
Some important factors in deciding whether to start treatment include whether you have advanced HIV disease or HIV symptoms, and the results of your viral load test and CD4⁺ T cell count. Other very important factors are your own willingness to begin drug therapy, and the likelihood that you will be willing and able to follow (adhere to) your treatment. Adherence is very important in HIV treatment, because drug resistance often occurs when a patient skips doses or takes a “drug holiday” (For more information on adherence, turn to page 13).

You also must weigh the potential benefits of drug therapy with the potential risks. For example, if you begin therapy, you might need to continue it for a long time, possibly for the rest of your life. Even with therapy there is a chance of developing drug resistance. Other potential risks include drug side effects, drug interactions and toxicity, and negative effects on lifestyle (including the inconvenience of having to take many medications each day). Talk to your doctor about the potential benefits and risks of therapy.

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 start treatment. You also should consider how well you will be able to follow your treatment, and weigh the potential benefits and risks.

Making Decisions about HIV Treatment



* The strength of this recommendation is based on prognosis for disease-free survival as shown by data from the Multi-Center AIDS Cohort Study (MACS) and the patient's willingness to accept therapy.

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

Starting Drug Therapy

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

Antiretroviral drugs are used to slow virus replication (that is, the virus making copies of itself). This will slow the progression of HIV disease.

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

- **NRTIs (Nucleoside Reverse Transcriptase Inhibitors):** zidovudine (AZT), didanosine (ddl), zalcitabine (ddC), stavudine (d4T), lamivudine (3TC), Combivir™ (AZT + 3TC), and abacavir (Ziagen™).
- **PIs (Protease Inhibitors):** saquinavir (Invirase™ & Fortovase™), ritonavir (Norvir™), indinavir (Crixivan®), and nelfinavir (Viracept®).
- **NNRTIs (Non-nucleoside Reverse Transcriptase Inhibitors):** nevirapine (Viramune®), delavirdine (Rescriptor®), and efavirenz (Sustiva™).

The preferred treatment for HIV is a triple drug combination (Highly Active Antiretroviral Therapy, or **HAART**). The preferred HAART regimens are two NRTIs and one PI, or two NRTIs plus efavirenz or two NRTIs plus ritonavir and saquinavir.

An alternative recommended HAART regimen is two NRTIs plus nevirapine or delavirdine. However, this regimen is less likely to keep the viral load suppressed.

In general, it is not recommended to take only two NRTIs (because the initial decrease in viral load is not sustained in most people). Also, it is not recommended to take only one antiretroviral drug (except for pregnant women, who should take zidovudine).

How will I know if my treatment is working?

In general, your viral load is the most important factor in determining whether your medications are working. Other important factors are your CD4⁺ T cell count, your recent clinical history, and findings from a physical examination by your doctor.

Your viral load should be tested again 2–4 weeks after you start treatment. If your drugs are working, your viral load should be decreasing, and 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 not undetectable within 4–6 months after starting treatment, you should talk to your doctor about possibly changing your medications.

How fast, or how much, your viral load decreases may depend not only on the drugs you are taking, but 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 antiretroviral 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 your viral load not decreasing. CD4⁺ T cell counts also may help show how well your medications are working. After starting drug therapy,

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 count.

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

There are two possible reasons for this. One possible reason is drug intolerance (side effects which make it difficult to take the drugs as prescribed). Another possible reason is drug failure (your viral load is not decreasing). You should ask your doctor to explain why the change is needed in your treatment.

If the reason is drug intolerance, your doctor may change the drug(s) causing the problem. In this case, your doctor may substitute drugs with different ones of the same potency and class.

If the reason for changing your medications is drug failure, your doctor should change all your drugs to new ones you have never taken, if possible. If you have been taking three drugs, and all three drugs cannot be changed, then at least two drugs should be changed. This is very important to reduce the risk of developing drug resistance. Before changing your medications, you should talk to your doctor about:

- all the antiretroviral medications you have taken before,
- the potency 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 antiretroviral drugs remaining that you have not yet used.

If you have no treatment options for approved drugs, you may be able to participate in a clinical trial using drugs that are being studied. For more information about *participating in a clinical trial*, ask your doctor, or call the AIDS Clinical Trials Information Service (ACTIS) at **1-800-874-2572** or connect to the ACTIS web site at **<http://www.actis.org>**.

Notes

Adherence

What is “adherence”?

Adherence refers to how closely you follow—or adhere to—a prescribed treatment plan. It includes your willingness to begin treatment, and your ability to take medications as prescribed. Studies have shown that adherence may be difficult for many patients, including people who are HIV infected as well as people 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 is important for treatment effectiveness (how well the medications work to decrease viral load). When you skip medication doses, the virus has the opportunity to replicate (make copies of itself) more rapidly thereby making 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 (before starting therapy), whether you have any AIDS-related illnesses, and whether you have used antiretroviral drugs before.

Second, adherence to HIV treatment is critical to prevent drug resistance. Clinical studies have shown that when you skip medication doses, or take a “drug holiday,” you may develop strains of HIV that are drug resistant. This may leave you with fewer treatment options if your viral load does not decline. Because drug-resistant strains can be transmitted to others, drug resistance has serious consequences not only for you, but for the larger population as well.

What makes adherence difficult for some HIV-infected patients?

There are several reasons why some patients may have difficulty adhering to an HIV treatment plan. One reason is that HIV treatment plans are very complicated. Studies have shown that people have difficulty adhering to even the simplest treatment plans. Yet HIV treatment may involve taking 25 or more pills each day. In addition, some HIV medications must be taken on an empty stomach while others must be taken with meals. This can be difficult for some people, especially for those who are sick or experiencing HIV symptoms. In addition, HIV-infected patients may need to continue their treatment regimen for a long time, perhaps indefinitely.

Other reasons that HIV-infected patients have given for non-adherence include unpleasant side effects such as nausea, sleeping through a dose, being away from home, being too busy, feeling sick or depressed, or simply forgetting to take their medication.

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 maximize adherence:

1. Play an active role in your treatment plan. Ask your doctor to describe all your treatment options, including potential benefits and risks of starting treatment now. Also ask your doctor to explain any side effects or other problems you may have related to your medication. It is important that you understand the goals of treatment, and

that you are fully committed to the treatment plan that you and your doctor decide on.

2. Talk to your doctor about personal issues that may affect your adherence. Studies have shown that adherence may be more difficult although not impossible for people dealing with substance abuse or alcoholism, unstable housing, mental illness, or major life crises. Adherence also may be more difficult for patients who do not have advanced HIV disease, who must follow a very complex treatment regimen, or who 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”—practicing your treatment regimen using 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 each time, 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 importantly, 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 don’t. Activities that you might use to help you remember when to take your medications include waking up in the morning, taking

a child to school, leaving work, or watching a TV show. If you decide to do this, make sure you remember to take your medication *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 a treatment plan.

I've started HIV treatment. What can I do to maximize my treatment success?

As described above, 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. Some other things you can do to improve adherence include:

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 box or egg space 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'll 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 3x5 card or in your daily planner, and then check off each dose as you take it. You might want to try writing 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 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:

- Side effects. If you are experiencing 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 prescribed. If you are supposed to take medication 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 too difficult for you to take your dose, tell your doctor this, too.
- Your treatment regimen interferes with your lifestyle. If you feel your treatment regimen 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 medication. Your doctor needs this information to help you maximize the benefit from your treatment plan and provide workable options, if necessary.

Other Questions You May Have

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 test cannot detect it. You are still infected with HIV and should continue to practice risk-free behaviors. You will also need to see your doctor on a regular basis.

My doctor and I have decided not to treat my HIV infection. Do 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, in general. Talk to your doctor about when you should be tested again.

I went to the doctor because I had flu-like symptoms. The doctor recommended an HIV test. Why?

The doctor wants to rule out HIV infection as a possible cause of your symptoms. Between 50% and 90% of people infected with HIV will have flu-like symptoms 2–4 weeks after infection. Some of these symptoms include fever, swollen lymph nodes, sore throat, rash, body aches, diarrhea, headache, nausea, and vomiting. This stage of infection is referred to as acute primary infection.

If your HIV test comes back positive, you should talk to your doctor about the potential benefits and risks of starting drug therapy. Most experts support starting therapy during acute primary infection. This is based on the theory that starting therapy early in the infection will keep an HIV-infected person healthier longer.

I am HIV positive and pregnant. What should I do about drug therapy, and will my baby be born HIV positive?

If you are HIV positive and pregnant, or if you suspect you are pregnant, you should talk with your doctor as soon as possible about your treatment options. No one can tell you for sure if your baby will be born HIV positive. However, there are steps you can take to reduce the risk of transmitting HIV to your baby.

Currently, the only drug proven to reduce the risk of transmitting the HIV virus to the baby is zidovudine (AZT). Treatment should begin after the 14th week of pregnancy and continue until delivery. During labor, zidovudine will be given to the mother intravenously. After birth, the baby will receive zidovudine for the first 6 weeks of life.

You should ask your doctor about the potential benefits and risks of antiretroviral therapy for you and your baby. Other factors to consider include your viral load and CD4⁺ T cell counts, whether you have already started antiretroviral drug therapy, and the stage of your pregnancy.

For more information on HIV infection and treatment, including pregnancy and HIV, call the HIV/AIDS Treatment Information Service at **1-800-448-0440** or connect to our web site at

<http://www.hivatis.org>. This service can also provide you with a copy of the DHHS recommendations for reducing perinatal HIV transmission.

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