HIV Treatment Guidelines

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What Are Treatment Guidelines?

Treatment guidelines provide a lot of useful information to help healthcare providers and people living with HIV make decisions about when to start, when to stop, and when to change HIV medications. They also help providers and people living with HIV choose among the many available HIV drugs.

US Guidelines

A branch of the US government called the Department of Health and Human Services (HHS) has put together a set of HIV treatment guidelines. The US HHS provides several different treatment guidelines related to HIV care. These include the Perinatal Guidelines which provide treatment recommendations for pregnant people living with HIV, the Treatment of Opportunistic Infections Guidelines which provide treatment recommendations for opportunistic infections, and the Pediatric Antiretroviral Treatment Guidelines, which provide treatment recommendations for children living with HIV.

Most of the information in this fact sheet comes from the US Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV. For more information on the perinatal HIV clinical guidelines, see our fact sheet on HIV Treatment Guidelines for Pregnant People and Their Infants.

The HHS guidelines are written and reviewed regularly by a group of HIV experts, including researchers, healthcare providers, and community activists. They were first published in 1998 and have been updated many times since then. The most recent guidelines were released in February 2024. The full version of the guidelines is available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines. Some important updates in the most recent version of the HHS guidelines for the treatment of HIV in adults and adolescents are listed below.

Global Guidelines

In 2015, the World Health Organization (WHO) released new guidelines on when to start HIV treatment. By October 2015, all internationally-written guidelines were in agreement for the first time since 2006. The HHS, WHO, EACS (European AIDS Clinical Society), BHIVA (British HIV Association), and the IAS-USA (International Antiviral Society-USA) now all recommend that HIV treatment be offered to all people living with HIV, **regardless of their CD4 cell count**. Researchers have shown that people living with HIV who start treatment earlier, while their CD4 counts are still high, have a much lower risk of illness and death.

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Treatment Goals

The guidelines describe the goals of HIV treatment. These are basically to keep you as healthy and as well as possible using the best care and treatment available today. The goals are the same for people just starting treatment and for those who have been on treatment for a long time. They include:

- Preserve or improve the health of your immune system by increasing your CD4 cells
- Get your viral load as low as possible for as long as possible
- Improve your quality of life and reduce illness and death
- Reduce your chances of transmitting HIV to others, including sexual partners and babies (which can happen through perinatal transmission, also known as vertical transmission)

Key Changes in the Revised February 2024 US HHS Guidelines

Some important updates in the most recent version of the HHS guidelines for the treatment of HIV in adults and adolescents are:

Use of statins (cholesterol-lowering medications) to prevent cardiovascular (heart) disease: These drugs should be given sooner than they would be in the general population because people with HIV have a higher risk of heart disease. In people living with HIV, the drugs lowered the frequency of major cardiovascular events by 35% and should be considered even when the person's general heart disease risk score is low. The following drugs are recommended:

- Pitavastatin
- Atorvastatin
- Rosuvastatin

More information on what the guidelines recommend is included below.

When to Start Treatment?

Over the years, there has been a lot of discussion and debate about when to start treatment, especially for people living with HIV with high CD4 counts – those who have no signs of ill health and are relatively healthy. Earlier guidelines recommended that people wait longer before starting HIV treatment. This was because of concerns about the HIV drugs at the time, such as side effects and difficult dosing schedules. It was thought that HIV was not as harmful as possible drug side effects in people with higher CD4 counts. We now understand that this is not true.

The START trial definitively showed that people living with HIV who start treatment earlier, while their CD4 counts are still high, have a much lower risk of illness and death. Also, newer drug combinations are easier to take and have fewer side effects than older regimens. For these reasons, the newest guidelines recommend starting HIV treatment as soon as someone is diagnosed.

The current US guidelines state:

- HIV treatment is recommended for anyone who is living with HIV, regardless of their CD4 count. This recommendation also includes the following:
    - HIV treatment can prevent both AIDS-related and non-AIDS-related illness in people living with HIV
    - HIV treatment can prevent transmission of HIV to others. Research has shown that people who are taking HIV drugs and have an undetectable viral load (not enough HIV in the blood to measure with standard tests) cannot transmit the virus to their sexual partners. This fact is sometimes called U=U.
    - HIV treatment should only be started when people understand the risks and benefits of treatment and are willing and able to commit to taking HIV drugs as they are prescribed (this is known as adherence)
- While HIV treatment is recommended for all people living with HIV, it is especially urgent to start treatment if you:
    - have or had symptoms of AIDS (such as opportunistic infections, also called OIs)
    - are pregnant
    - have HIV-related kidney disease (HIVAN or HIV nephropathy)
    - are also living with hepatitis B and/or hepatitis C
    - have a CD4 count <200 cells/mm3
    - have acute/early infection
- As discussed above, HIV drugs should be offered to people who may transmit HIV to their sexual partners to reduce their viral load to undetectable levels.

Because starting treatment is such an important decision, the guidelines suggest that you and your provider discuss the benefits of treatment while also addressing any barriers. It is important to think about whether you are willing and able to take your HIV treatment as prescribed. In order to get the most benefit from HIV drugs, they must be used just the way they are prescribed. Taking your treatment

correctly is as important as which drugs you and your healthcare provider choose. So, before you get started, it is important to be prepared and commit to taking your HIV drugs the right way, every day for your own health. For more information, see our fact sheet on Considerations Before Starting HIV Treatment.

Benefits of Starting Early

There are benefits to starting HIV treatment early. These include:

- Having a higher CD4 cell count and keeping it high
- Preventing further damage to the immune system
- Decreasing the risk of HIV-related and non-HIV-related health problems
- Reducing – or even eliminating – the chances that you may transmit HIV to others, including sexual partners and babies

Risks of Starting Late

There are also risks to starting HIV treatment late, including:

- Having a severely weakened immune system. This can mean it takes longer to restore your immune system to full strength and you to full health. Recent studies have shown that delaying treatment can increase the chances that people living with HIV will develop AIDS and other serious illnesses.
- Having an increased chance of immune reconstitution syndrome when you begin taking HIV drugs. The syndrome happens when the immune system responds to the medications with too much inflammation at once, temporarily making symptoms worse.
- Transmitting HIV to others, including sexual partners – or babies, if you become pregnant

What to Start With?

Once you have decided to start treatment, you and your healthcare provider need to choose what combination of drugs you are going to take. No single HIV drug should ever be used by itself, though often several HIV drugs are combined into one tablet or combination pill. HIV drugs work in different ways to stop the virus at different points in its lifecycle. The drugs are divided into classes as follows:

- Nucleoside/nucleotide reverse transcriptase inhibitors ("nukes" or NRTIs)
- Non-nucleoside reverse transcriptase inhibitors ("non-nukes" or NNRTIs)
- Protease inhibitors (PIs)
- Integrase inhibitors
- Entry and fusion inhibitors
- Attachment inhibitor
- Post-attachment inhibitor
- Capsid inhibitor
- Boosting agents

Your first treatment regimen will most likely contain dolutegravir or bictegravir plus tenofovir (alafenamide or disoproxil fumarate) plus emtricitabine or lamivudine. These combinations will attack HIV at different parts of its lifecycle to pack a strong punch against the virus. The recommendations are different for people who have been on long-acting injectable cabotegravir to prevent HIV acquisition, for people with specific genetic mutations, and for people who also have hepatitis B.

If you want to start long-acting HIV treatment, the guidelines recommend that you first get your viral load to an undetectable level using oral HIV drugs (pills or tablets) before switching to injectable Cabenuva. Sometimes, a two-tablet regimen is taken for a short time before starting injections.

While the *recommended initial regimens for most people living with HIV* are the best choices for HIV treatment, they may not be ideal for everyone. Because everyone's situation is different, there may be certain situations in which different treatments are actually better for you. You and your healthcare provider should choose drugs based on your specific needs. Think about what will fit into your lifestyle, including dosing schedule, number of pills, and side effects. Also consider what other medications you are taking, any other medical conditions you have, and the results of resistance testing (see below).

Whatever regimen you choose to take, you need to take your drugs on schedule. This is called adherence. In order to get the most benefit from HIV treatment, good adherence is required. This is because HIV drugs need to be kept at a certain level in your body to fight the virus. If the drug level falls, HIV may have a chance to fight back and develop resistance. Skipping doses, not taking the drugs on time, or not following food requirements can cause your drugs to be less effective or stop working altogether.

For more information on the different classes of HIV drugs and how they work, see our fact sheet on HIV Drugs and the HIV Lifecycle. For more information on individual drugs sorted by class see our HIV Drug Chart. Please note: for the regimens listed below, the brand name of an HIV drug is listed first and capitalized, with the generic name lower-cased and in parentheses. For example: Truvada (emtricitabine + tenofovir disoproxil fumarate).

US HHS Recommended Initial Regimens for Most People with HIV

Study results of these combinations showed they were powerful and long-lasting, did not have a lot of side effects, and were easy to use.

For people who have never taken HIV drugs before ("treatment naïve") and have NOT used long-acting cabotegravir to prevent acquiring HIV (pre-exposure prophylaxis):

- Biktarvy (bictegravir/tenofovir alafenamide/emtricitabine)
- Triumeq (dolutegravir/abacavir/lamivudine), but only after testing for a genetic variation that could result in hypersensitivity to abacavir and only in people who do not also have chronic hepatitis B (HBV)
- Tivicay (dolutegravir) plus Truvada (tenofovir disoproxil fumarate/emtricitabine) or Descovy (tenofovir alafenamide/emtricitabine)
- Dovato (dolutegravir/lamivudine), except for people whose viral load before treatment is above 500,000 copies; people living with active hepatitis B (HBV); or those who have not been tested for resistance to these drugs, or tested for HBV

For people who have never taken HIV drugs before ("treatment naïve") and have used long-acting cabotegravir to prevent acquiring HIV:

- Symtuza (darunavir + cobicistat + emtricitabine + tenofovir alafenamide)

WHO Recommended Regimens

In July 2021, the World Health Organization (WHO) issued new consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring. The consolidated guidelines combine WHO's various earlier HIV-related guidelines into a single document and include recommendations on how to safely provide HIV care during the COVID-19 pandemic.

Recommended Regimens in Certain Situations

There are many HIV treatment regimens that have been proven effective and tolerable and are approved by the HHS and/or WHO. Which one might be right for you is based on your specific

characteristics and needs and is best discussed with your healthcare provider.

Changing or Stopping Treatment

After starting HIV treatment, you may need to make some changes to your drug regimen. The HHS panel of experts suggests that the primary focus when changing or switching drug regimens should be maintaining viral suppression without reducing future treatment options.

Reasons for switching or changing your HIV drug regimen include:

- Side effects – In some cases, your healthcare provider can treat side effects without switching your HIV drugs. If the side effects cannot be controlled or are very serious, your healthcare provider may be able to find the drug in your regimen that is causing the problem and switch that drug for another drug. In other cases, especially if it is not clear which drug is causing the problem, the entire regimen may need to be changed.
- Viral load not controlled – If your viral load does not come down or starts increasing, it may be time for a change. In this case, your healthcare provider will check for drug resistance and may change two or three medications at once.
- Simplifying the regimen – There may be new formulations or combination pills you can take so you have fewer pills or fewer doses.
- Trouble with adherence – If you miss doses of your medications, you can develop resistance to the drugs, and they will stop working. Before changing to new medications, talk with your healthcare provider about adherence. If you have problems sticking to your medication schedule, your healthcare provider can help you figure out ways to stay on track or find an easier regimen for you to take.
- Some people want to stop taking their HIV drugs altogether, but stopping or skipping treatment can be very bad for your health. It usually causes an increase in viral load and a drop in CD4 cells. Once HIV treatment is begun, it should not be stopped without speaking to your healthcare provider.

Resistance Testing

Drug resistance tests can tell which HIV drugs will not work for you. It helps you and your healthcare provider choose the most effective drugs for you to take. The following are the US HHS guidelines' recommendations on when to have a drug resistance test:

- Testing is recommended for people who:
    - have just acquired HIV, regardless of whether or not they are going to take HIV drugs right away
    - have never taken HIV drugs and are planning to start
    - are taking HIV drugs and see their viral load go up
    - have recently started HIV drugs and their viral load is not coming down to undetectable
    - are pregnant and living with HIV
- Testing is not usually recommended for:
    - People who have stopped HIV drugs for four weeks or more
      A resistance test may not be useful when someone has stopped taking HIV drugs, because some resistant virus in their blood may have been replaced by non-resistant virus (wild type). However, not all resistant virus will have been replaced, so the person still has mutated virus, just at a level that is not picked up by the resistance test. Having a detectable viral load of any type of HIV (resistant or wild type) can cause health problems. Stopping HIV drugs to get rid of drug-resistant virus is therefore not a good idea and does not work. It is much better to continue taking one's current HIV drugs, having a resistance test to find out which other drugs might work better and then switching to those drugs. Always talk to your healthcare provider first before switching

HIV drugs! For more information, see our fact sheet on Resistance.

- The HHS guidelines also recommend that people whose viral loads are not well-controlled using an integrase inhibitor-based drug combination should receive a genotype test for integrase resistance; they may also need a regular genotype test. This will help determine if any other drugs from the integrase class should be included in future drug combinations.

Taking Care of Yourself

There is much more information in the guidelines, including other possible drug regimens, what drugs not to take, and what types of resistance tests to use. There is also a lot of information on other aspects of HIV care and treatment, including adherence, drug side effects and interactions, special considerations for people with liver or kidney problems, treatment for people who have used and are resistant to many HIV drugs, and treatment when you have HIV and other infections, including tuberculosis, hepatitis B, or hepatitis C. For women living with HIV, the guidelines contain important information on pregnancy and women-specific treatment issues.

The guidelines are a set of recommendations to help you and your healthcare provider understand your treatment choices. They are based on the most up-to-date information from studies and clinical trials. But remember, they are only general suggestions. It is okay for you and your healthcare provider to choose therapies for your specific situation. Use the guidelines as a resource to help you and your provider make well-informed treatment decisions that are right for you.

Additional Resources

Select the links below for additional material related to treatment guidelines.

- Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Livin…
- HIV Treatment Guidelines (HIVinfo, for providers)
- British HIV Association Guidelines for the Treatment of HIV-1-Positive Adults w…
- Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care for Ke…
- With EACS Release, All International HIV Treatment Guidelines Agree on When to …
- Treatment Guidelines (i-base)
- Clinical Guidelines Program (New York State Department of Health AIDS Institute)
- Guidelines and Recommendations (US Centers for Disease Control and Prevention)
- EACS Guidelines (European AIDS Clinical Society)