HIV Treatment Guidelines [1]

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What Are Treatment Guidelines?

Treatment guidelines provide a lot of useful information to help health care 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 (HIV+) choose among the many available HIV drugs.

US Guidelines

A branch of the US government, called the Department of Health and Human Services, (DHHS), has put together a set of HIV treatment guidelines. The US DHHS provides several different treatment guidelines related to HIV care. These include the Perinatal Guidelines [2] which provide treatment recommendations for pregnant women with HIV, the Treatment of Opportunistic Infections Guidelines [3] which provide treatment recommendations for opportunistic infections [4], and the Pediatric Antiretroviral Treatment Guidelines [5]. This fact sheet discusses only the recommendations contained within the Guidelines for Antiretroviral Treatment in Adults and Adolescents.

The DHHS guidelines are written and reviewed regularly by a group of HIV experts, including researchers, health care 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 July 2016. The full version of the guidelines is available at http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf [6]. Some of the important updates in the most recent version of the DHHS 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 DHHS, 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 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.

*Click above to view or download this fact sheet as a **PDF slide presentation** [7]*

Treatment Goals

The guidelines describe the goals of HIV treatment. They 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 those who have been on treatment for a long time. These include:

- Preserve or improve the health of your immune system [8] by increasing your CD4 cells [9]
- Get your viral load [10] as low as possible for as long as possible
- Improve your quality of life and reduce illness and death
- Reduce your risk of spreading HIV [11] to others (also known as Treatment as Prevention [12]), including sexual partners and babies (through perinatal transmission, or mother-to-child transmission [13])

Key Changes in the Revised July 2016 US DHHS Guidelines

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

- New recommended treatment regimens in the "What to Start" section (see more below). These regimens contain tenofovir alafenamide fumarate (TAF). TAF is a close cousin of tenofovir disoproxil fumarate (TDF), which is the form of tenofovir known by the brand name Viread and found in other combination drugs such as Truvada. An advantage of TAF over TDF is it can be given at lower doses than TDF while achieving the same level of HIV suppression. It also appears to produce less bone loss and less reduction in kidney function than TDF.
- These treatment recommendations apply to all people living with HIV, including all women living with HIV. It is especially important that pregnant women receive HIV treatment as early as possible during pregnancy and continue to take it after pregnancy.
- Several new treatment recommendations for people co-infected with HIV and hepatitis C (HCV) [14], hepatitis B (HBV) [15], or tuberculosis (TB) [16]

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 [17] , especially for people living with HIV with high CD4 counts - those who have no signs of ill health and are relatively healthy. The guidelines have been changed a number of times. Some earlier versions recommended that people wait longer before starting HIV treatment. This was because of concerns about the HIV drugs, such as side effects [18] 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 this is not true.

The results of the START trial [19] have definitively 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. This includes people living with HIV who may have no outward signs of ill health. The study showed that taking HIV drugs earlier reduced the likelihood of developing both AIDS-related and non-AIDS-related illnesses.

The START trial clearly showed that the benefits of starting treatment early outweigh any potential risks. Consequently, scientific experts and policy makers came together in July 2015 and issued a consensus statement declaring all people living with HIV should have access to HIV treatment as soon as they are diagnosed. This statement was supported by agencies such as the International AIDS Society, the US President?s Emergency Plan for AIDS Relief (PEPFAR), and UNAIDS, among others.

Also, newer drug combinations now available are easier to take and have fewer side effects than older regimens. For all 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 [11] to others. Research has shown that taking HIV drugs as they are prescribed can reduce the amount of HIV in the blood and genital fluids. Therefore, people living with HIV and taking HIV treatment are less likely to spread the virus to others.
    - 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 [20])
- 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 [4], also called OIs)
    - are a pregnant [13] woman
    - have HIV-related kidney disease (HIVAN or HIV nephropathy)
    - are co-infected with hepatitis B [15] and/or hepatitis C [21]
    - have a lower CD4 count (<200 cells/mm)
    - have acute/early infection [22]
    - have HIV-related kidney disease (HIV-associated nephropathy, or HIVAN)
- HIV drugs should be offered to people who are at risk of spreading HIV to their sexual partners. This is referred to as Treatment as Prevention [12] (TasP) because research shows people with undetectable viral loads are very unlikely to transmit HIV to their sexual partners.

Because starting treatment [23] 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 health care 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 [23].

Benefits of Starting Early

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

- Having a higher CD4 cell count [9] and keeping it high
- Preventing further damage to the immune system [8]
- Decreasing risk for HIV-related and non-HIV-related health problems
- Reducing your risk of spreading HIV [11] to others (also known as Treatment as Prevention [12]), including sexual partners and babies (through perinatal transmission, or mother-to-child transmission [13])

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 [24] when you begin taking HIV drugs
- Spreading HIV to others, including sexual partners and babies, if you become pregnant

What to Start With?

Once you have decided to start treatment, you and your health care 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 [25]. 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 inhibitors (which includes fusion inhibitors and chemokine receptor 5 (CCR5) antagonists)
- Boosting agents

Your first treatment regimen will probably contain:

- An integrase inhibitor plus 2 NRTIs or
- A PI plus 2 NRTIs [the PI should be combined, or "boosted," with a small dose of a second PI called Norvir (ritonavir); this makes the first PI work better]

These combinations will attack HIV at different parts of its lifecycle to pack a strong punch against the virus.

In the US, the DHHS guidelines rank specific drug combinations as *recommended* or *alternative* (see below). While the *recommended* regimens are the best choices for HIV treatment, they may not be ideal for everyone. Because everyone's situation is different, there may be cases in which alternative treatments are actually better for you. You and your health care provider should choose drugs based on your specific needs. Think about what will fit into your lifestyle, including dose 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 [20]. 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 [26]. 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 [25]. For more information on individual drugs sorted by class see our HIV Drug Chart [27]. 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 DHHS Recommended Regimens

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. Recommended regimens include:

For people who have never taken HIV drugs before ("treatment naïve"), regardless of baseline viral load or CD4 count:

Integrase inhibitor-based regimens:

- Tivicay (dolutegravir) and Epzicom (abacavir + lamivudine)
- Tivicay and Truvada (tenofovir disoproxil fumarate + emtricitabine)
- Tivicay and Descovy (tenofovir alafenamide fumarate + emtricitabine)
- Stribild (elvitegravir + cobicistat + emtricitabine + tenofovir disoproxil fumarate)
- Isentress (raltegravir) and Truvada
- Isentress and Descovy
- Genvoya (elvitegravir + cobicistat + tenofovir alafenamide fumarate + emtricitabine)

Boosted PI-based regimen:

- Prezista (darunavir) and low-dose Norvir (ritonavir) and Truvada or Descovy

WHO Recommended Regimens

The WHO guidelines suggest that first-line HIV therapy be a combination of an NNRTI plus 2 NRTIs. Specifically, they recommend either: (1) Atripla (efavirenz + tenofovir disoproxil fumarate + emtricitabine) or (2) Sustiva (efavirenz) + Viread (tenofovir disoproxil fumarate) + Epivir (lamivudine). These two regimens are also those recommended for women who are pregnant or breastfeeding.

Alternative Regimens

There are many alternative HIV treatment regimens that have been proven effective and tolerable and are approved by the DHHS and WHO. Which one might be right for you is based on your specific characteristics and needs and is best discussed with your health care provider.

Regimens for Pregnant Women or Women Who Plan to Become Pregnant

Guidelines on taking efavirenz (brand name Sustiva; also found in Atripla) during early pregnancy remain conflicted. The US Department of Health and Human Services? July 2016 guidelines suggest that:

- women who wish to become pregnant should not take efavirenz because it may cause birth defects when taken during early pregnancy
- taking efavirenz appears safe after eight weeks of pregnancy
- women who are successfully virally suppressed on a treatment regimen containing efavirenz who become pregnant can continue on efavirenz throughout pregnancy

The World Health Organization (WHO)?s guidelines, however, suggest that efavirenz can be taken throughout pregnancy, including during the first trimester (12 weeks). The WHO?s recommendations are based on a report [28] in which researchers reviewed many different studies and found no connection between taking efavirenz during the first trimester of pregnancy and an increased risk of birth defects.

Changing or Stopping Treatment

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

Reasons for switching or changing your HIV drug regimen include:

- Side effects [18] ? In some cases, your health care provider can treat side effects without switching your HIV drugs. If the side effects cannot be controlled or are very serious, your health care 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 [10] not controlled ? If your viral load does not come down or starts increasing, it may be time for a change. In this case, your health care provider will check for drug resistance

[26] 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 [20] - 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 health care provider about adherence. If you have problems sticking to your medication schedule, your health care 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 health care provider.

Resistance Testing

Drug resistance tests can tell if your virus is resistant [26] to any HIV medications. This test tells you which HIV drugs will not work for you. It helps you and your health care provider choose the most effective drugs for you to take. The following are the US DHHS guidelines' recommendations on when to have a drug resistance test:

- Testing is recommended for people who:
  - have just become infected with HIV, regardless of whether or not they are going to take HIV drugs right away
  - have never been on HIV drugs and are planning to start
  - are on HIV drugs and see their viral load go up
  - have recently started HIV drugs and their viral load is not coming down enough
  - are pregnant and living with HIV
- Testing is not usually recommended for:
  - People who have stopped HIV drugs for four weeks or more
- The DHHS 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 [16], hepatitis B [15], or hepatitis C [14]. For women living with HIV, the guidelines contain important information on pregnancy [13] and women-specific treatment issues.

The guidelines are a set of recommendations to help you and your health care 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

to choose therapies for your specific situation. Use the guidelines as a resource to help you make well-informed treatment decisions that are right for you.

Tags:

- guidelines [29]
- HIV drugs [30]
- new hiv drugs [31]
- HIV prevention [32]
- hiv and aids symptoms [33]
- HIV Treatment Guidelines [34]
- DHHS guidelines [35]
- HIV guidelines [36]
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- What are HIV treatment guidelines? [39]
- What are DHHS Guidelines [40]
- Kaletra [41]
- Recommended HIV drugs [42]
- recommended HIV drug pregnancy [43]
- HIV pregnancy [44]
- when to start HIV treatment [45]

Additional Resources

Select the links below for additional material related to treatment guidelines.
US Antiretroviral Therapy Guidelines (AIDS InfoNet) [46]
HIV/AIDS Treatment Guidelines: Adults & Adolescents (The Body) [47]
HIV Treatment Recommendations (POZ) [48]
DHHS Treatment Guidelines (July 2016) [49]
Guideline on When to Start Antiretroviral Therapy and on Pre-Exposure Prophylaxis for HIV (WHO) [50]
With EACS Release, All International HIV Treatment Guidelines Agree on When to Start ? For the First Time Since 2006 (AIDSmap) [51]
British HIV Association Guidelines for the Treatment of HIV-1-Positive Adults with Antiretroviral Therapy (2016 interim update) [52]
Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care for Key Populations (WHO) [53]

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[19] https://www.niaid.nih.gov/news-events/starting-antiretroviral-treatment-early-improves-outcomes-hiv-infected-individuals
[20] http://www.thewellproject.org/hiv-information/adherence-0
[21] http://www.thewellproject.org/hiv-information/treatment-hepatitis-c-people-living-hiv
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