AIDS InfoNet **www.aidsinfonet.org** **Fact Sheet Number 404**

2006 ANTIRETROVIRAL THERAPY GUIDELINES

WHY DO THE GUIDELINES KEEP CHANGING?

We keep learning more about the best way to fight HIV. In 1998, the US Department of Health and Human Services created a panel of physicians, researchers, and consumers to develop treatment guidelines. They constantly review AIDS research results. The guidelines are updated about once each year. The panel released the latest guidelines in October 2006.

NOTE: These are guidelines, not rules. Patients should receive individualized care from a health care provider with experience treating HIV infection. ***The full text of these guidelines is available on the Internet at http://www.aidsinfo.nih.gov/guidelines***

VIRAL LOAD AND CD4 CELL TESTING

Viral load and CD4 cell tests provide critical information for decisions on antiretroviral therapy (ART). Before changing treatment, the tests should be repeated to confirm the results. Fact Sheet 124 has more information on CD4 cell tests and Fact Sheet 125 covers viral load testing.

Viral load should be tested:

- Before starting or changing medications. This provides a reference value;
- About 2 to 8 weeks after starting or changing medications. This shows whether the new drugs are working;
- Every 3 or 4 months. This helps make sure the medications are still working. For patients who haven't started taking medications, it helps decide when to start.

CD4 cell counts should be done:

- When someone first tests HIV-positive
- Every 3 to 6 months to monitor the strength of the immune system

RESISTANCE TESTING

Viral resistance testing helps health care providers choose the most effective drugs. See Fact Sheet 126 for more information. Resistance testing is recommended when viral load is not controlled by new medications, or when it "breaks through" a regimen that used to work. The guidelines recommend resistance testing before starting antiretroviral treatment (ART.) It can also make sense for people who don't need to start ART yet. This can show if the person got infected with drug-resistant virus.

WHEN TO START TREATMENT

Patients with symptoms of HIV disease or with less than 200 CD4 cells should be treated.

Patients with no symptoms who have less than 350 CD4 cells OR viral load over 100,000 should be offered treatment. Consider the risk of disease progression and the patient's willingness to start therapy. Some experts would delay treatment for patients with 200 to 350 CD4 cells and viral loads under 100,000.

Patients with no symptoms, more than 350 CD4 cells AND a viral load below 100,000 do not need to start treatment. They should get regular viral load and CD4 tests. However, some experts would treat these patients.

GOALS OF THERAPY

The guidelines list the following goals for HIV therapy:

- Reduce viral load as much as possible for as long as possible
- Restore or preserve the immune system
- Improve the patient's quality of life
- Reduce sickness and death due to HIV

The following tools are suggested to help achieve these goals:

- Maximize adherence. Help the patient take medications correctly.
- Think about future regimens when choosing drugs. Keep future options open
- Use resistance testing when it will help.

WHAT DRUGS SHOULD BE USED FIRST?

The guidelines list several preferred regimens for people starting anti-HIV treatment. They include efavirenz (Sustiva), or atazanavir (Reyataz), fosamprenavir (Lexiva), or lopinavir (Kaletra), each boosted with ritonavir, plus Truvada or Combivir (each of which contains two nucleoside analog drugs in a single pill). Many other combinations are listed as "alternative regimens." They include nevirapine (Viramune), Kaletra, fosamprenavir boosted or unboosted, or atazanavir unboosted, together with Truvada, Combivir, or Epzicom (abacavir plus lamivudine in a single pill. Other combinations are listed for use only when a preferred or alternative NNRTI- or PI-containing regiment cannot or should not be used.

Several drugs or combinations are listed as "Not Recommended." Some are not recommended for initial therapy due to low anti-HIV activity or inconvenience. Others are not recommended at any time. These include any nuke or non-nuke by itself (monotherapy) or just two nukes because these treatments generally have only limited benefits for a short period of time. Also, the guidelines recommend ***not using*** the triple-nuke regimens except for Trizivir (abacavir + zidovudine + lamivudine) or possibly tenofovir + Combivir (zidovudine + lamivudine).

There are special considerations for the treatment of pregnant women, adolescents, drug users, people also infected with hepatitis B or C or with tuberculosis.

INTERRUPTING TREATMENT

A patient may need to interrupt treatment for several reasons: side effects are intolerable, there's a drug interaction, if they run out of any of their medications, or if they have surgery scheduled, Women might choose to stop treatment during the first 3 months of pregnancy. Treatment interruptions are **not** recommended in response to treatment failure.

ART should only be stopped if your health care provider recommends it. Two large studies showed that people who interrupted treatment had a higher rate of HIV-related health problems or death. For more information see fact sheet 406, Treatment Interruptions.

WHEN TO CHANGE

Treatment should be changed due to treatment failure, or intolerance of current drugs.

Treatment failure: Within 6 months after starting a treatment, the viral load should drop below 400 copies. Within 1 year, it should be less than 50 copies. If the viral load does not drop this much, change the treatment.
Other signs of treatment failure include:

- An increase in viral load from undetectable to detectable levels
- Failure to increase CD4 cells by 25 to 50 during the first year; or
- A new AIDS-related illness.

Intolerance: If a patient cannot take the prescribed drugs because of their side effects or interactions with other needed medications, the drugs should be changed.

WHAT TO CHANGE TO?

Decisions to change ART should include a review of prior treatments, physical exam, resistance testing, adherence and side effects. Ideally, three drugs that the virus will respond to can be identified and used in a new regimen.

If there are few options for change, and viral load was reduced, it may make sense not to change medications. Another option is to use combinations that are more experimental. Treatment interruptions are not recommended.

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