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WELCOME



This is the second year of *HIV Treatment ALERTS!* and we hope you find this newsletter helpful and informative. The science and medicine of HIV change constantly. The “best” way to treat HIV today could be very different tomorrow. That’s what *HIV Treatment ALERTS!* is for—to keep you informed of the latest changes in HIV medicine: new drugs, drug warnings and interactions, ways to treat side effects, clinical trial information, useful websites and phone numbers, special reports, and much more. However, some changes have been made to improve the newsletter. Each new issue will use a different color than the previous one, to make it easier to tell issues apart. Also, main articles will be shorter and more to-the-point. The amount of information on HIV disease is overwhelming and we want you, the reader, to get the most out of our publication without becoming overwhelmed yourself! Remember that words in **bold** are explained in the “Definitions” section. If you ever have any questions, feel free to contact us (see the shaded box below) or visit our walk-in information center.

Until there’s a cure, use HIV to find Hope, Inspiration, and Victory.

HIV Treatment ALERTS! is a publication of The Center for AIDS: Hope & Remembrance Project (The CFA). This newsletter is intended for those affected by HIV and their caregivers. The statements and opinions expressed in this newsletter do not imply recommendations or endorsement. Always consult your doctor before altering a prescribed drug regimen or taking any drug or supplement.

HIV Treatment ALERTS! is currently published twice a year. The print version of the newsletter is available for free at The CFA information center, various AIDS service organizations, some physician offices and health clinics, or by mail. Access to the newsletter is available online from The CFA website (www.centerforaids.org).

The CFA also publishes *Research Initiative/Treatment Action! (RITA!)* twice a year (spring and fall). *RITA!* is a literature-review journal that covers issues in HIV research and policy. This and other publications are available on The CFA website or can be requested by mail (see contact information below).

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MISSION & BELIEFS


“We believe the well being of HIV-infected individuals begins with their affirmative participation in the process of treatment, and that often they do not have access, resources, or abilities to participate on their own. As such, The Center for AIDS dedicates itself to providing the latest treatment and research information to persons with HIV/AIDS, their caregivers and healthcare providers. . . .”



TIPS for making the most of your medical care





Do doctor visits make you nervous? When you are sitting in the exam room with your health care provider, do you suddenly forget what you wanted to talk about? Try these 3 simple tips to prepare yourself and make the most out of each visit.



❶ **Write down a list of questions or concerns.** Sit down and think about what you have been experiencing. Anything unusual like rashes, headaches, bumps or sores that won't go away, painful areas? Use the list when visiting your health care provider.


❷ **Try bringing a friend, significant other, or caregiver with you.** Most clinics or doctor's offices will let you bring someone. Having this person there may help you stay relaxed. Also, he or she may remember to tell the doctor or nurse something that you might have forgotten.

❸ **Be 100% honest.** If questions come up about personal issues like sex, drug and alcohol use, or even how many doses of medication you miss, answer as truthfully as possible. Your health care provider is there to help you, not judge you, and needs to know the facts in order to make the right decisions for your care.



Always get health care from a provider who *specializes* in HIV/AIDS care. This means that he or she treats many patients with HIV. The longer the experience and the more patients treated, the better. Research shows that patients survive longer if their health care providers are experienced in HIV medicine. HIV specialists can be in private practice or in public clinics. In fact, some public clinics (like Houston's Thomas Street Clinic) specialize in treating people with HIV.

Some medical groups are working to have HIV become an official medical specialty. Both the American Academy of HIV Medicine (www.aahivm.org) and the Infectious Diseases Society of America (www.idsociety.org/HIV/toc.htm) have begun programs that give special certification to physicians and other medical professionals who treat HIV.




If you have been through most of the anti-HIV drugs out there and are running out of options because they no longer work against the virus, here are a few things to remember:

+ Staying on a "failing" anti-HIV drug combination (one where your viral load is detectable) may still have a benefit. For one, the drugs force the virus to change itself ("mutate") in order to keep reproducing. The mutated form is not the same as the normal, naturally occurring virus and may not reproduce as well. Also, staying on your meds may help preserve T cells longer.

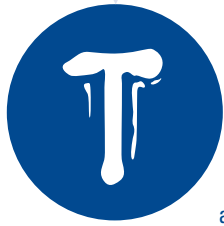
+ If you are getting a genetic resistance test (to see what mutations your virus has against HIV meds), make sure you are on your meds when the test is done. If you stop meds, the virus changes back to normal and the test will not show many of the mutations!

+ When you are going to start a new drug combination, try to hold out until at least 2 new drugs that you have *never been on before* are available. Drugs that are remade into simpler versions do not count. Be sure to check with your doctor about compassionate access programs for drugs that are being developed.



Conference

HIGHLIGHTS



The Annual **Retrovirus Conference** is the major HIV research meeting in the US. Each year, several thousand healthcare providers, researchers, and community activists meet for 5 days to review the latest developments in the field of HIV. Information at the conference covers new anti-HIV drugs, drug interactions, side effects, vaccine research, and more. You can learn about the conference, read many of the research posters, and even hear some of the science presentations by visiting the conference website: www.retroconference.org. The following are some reports from this year's 9th Annual Retrovirus Conference.

HEART ATTACK DEBATE CONTINUES

The debate rages on about whether or not elevated blood fats put HIV-infected individuals at increased risk of heart attack or stroke. One study (from multiple locations in the US) found that 13 out of 3013 patients taking protease inhibitors had heart attacks compared to only 2 out of 2663 patients not taking protease inhibitors. The number of heart attacks was small overall, and the heart attacks usually happened in people with other risk factors. However, protease inhibitor use was still "strongly associated" with the occurrence of heart attacks. A second study by researchers with the Kaiser Permanente Medical Care Program found no association between types of anti-HIV drugs and risk of heart attack after 5.5 years of follow-up. The study did find a greater rate of heart attacks in HIV-positive versus HIV-negative men and emphasized that longer follow-up is needed. Finally, a study of 36,766 patients treated in US Veterans Health Administration facilities over 8.5 years found no relationship between use of anti-HIV drugs and risk of

heart attack or stroke. In fact, when combination anti-HIV therapy was begun, the actual numbers of heart attacks and strokes dropped slightly. The study also found that patients on anti-HIV drugs for 12 months had a lower risk of heart attack or stroke than patients who had never been on anti-HIV drugs. Obviously the verdict is still out on this issue, but efforts to lower blood fat levels and reduce the risk of heart attack in HIV-infected people through diet and exercise couldn't hurt.

NOT-SO-ROSY GLITAZONE

A drug called "rosiglitazone" that is used for treating people with diabetes does not seem to have an effect on body fat changes commonly experienced by people taking anti-HIV drugs. The drug did seem to improve insulin resistance (a sign of diabetes), but also significantly increased blood fat levels. In addition, liver fat was decreased with rosiglitazone. However, the waist-to-hip ratio and amount of fat in the gut were not improved. The researchers conclude that rosiglitazone treatment cannot reverse body fat changes in HIV-infected patients.

TREATMENT INTERRUPTION DANGERS

A study from Europe presented at the conference suggests that treatment interruption increases the risk of AIDS-defining illnesses and death, especially in patients with T cell counts below 200. The risk of death was greatly increased when T cells were less than 50. The safest range for treatment interruption included T cell counts above 200. Always consult your health care provider before attempting to interrupt treatment. For more information on treatment interruption, see the CFA fact sheet at: www.centerforaids.org/rita/facts/STI.pdf.

RACIAL DIFFERENCES IN SUSTIVA EFFECTIVENESS?

A study of HIV-infected patients in a US Department of Defense health care program has found that African Americans may become resistant to efavirenz (Sustiva) therapy faster than Caucasian Americans. Half of the African American patients became resistant to Sustiva after little more than a year (422 days). However, half the Caucasians were still not resistant to Sustiva at almost 4 years (1400 days). Such differences were not seen in patients taking the protease inhibitors indinavir (Crixivan) or nelfinavir (Viracept) instead of Sustiva as part of their drug regimens. Age, T cell counts, anti-HIV treatment history, and health care access were similar between African Americans and Caucasians. The researchers have planned more studies to find out the cause for such differences.

POSSIBLE BENEFITS OF DRUG-RESISTANT VIRUS

Continuing their study of “viral fitness” (how well HIV reproduces and infects cells), researchers in California have found more evidence that drug-resistant virus may be weaker than wild-type (natural) virus. The researchers looked at 170 patients divided into 3 groups: those with undetectable viral loads (90), those with detectable viral loads and drug-resistant virus while on anti-HIV treatment (52), and untreated patients (28). The study found that the group with drug-resistant virus had greater HIV-specific immune responses (82%) than either the group with undetectable viral load (14%) or the untreated group (36%). The best responses were seen when viral load levels were 1000 to 10,000. This supports the idea that drug-resistant virus may not be as fit as wild-type virus, so people without many drug options left may still benefit from staying on a “failing” drug regimen.

LIFE-THREATENING EVENTS BECOMING MORE COMMON THAN AIDS

With the widespread use of combination anti-HIV therapy, life-threatening “grade 4” events may now be more common in HIV-infected patients than AIDS-defining illnesses. A report presented at the conference looked back at over 3000 patients enrolled in 5 large clinical trials during December 1996 to August 2001. Of these patients, 38% had a prior AIDS diagnosis and 45% had never taken anti-HIV therapy. A total of 642 patients had been studied for at least 2.5 years and in this group 27% had a grade 4 event, 13.4% had an AIDS-defining illness, and 10.6% died. The grade 4 events included liver problems (6.1%), low white blood cell counts (3.9%), heart-related or cardiovascular problems (3.2%), **pancreatitis** (2.2%), low red blood cell counts (2.1%), psychiatric problems (2.1%), kidney problems (1.5%), low blood platelets (1.2%), and internal bleeding or hemorrhage (0.9%). The risk of death associated with a grade 4 event and the risk of death associated with an AIDS-defining illness were both high. This study shows a changing profile of how people with HIV get sick. More studies are needed to look at the overall rates of such events and to better establish the risks and benefits of anti-HIV therapy.

SWITCHING STAVUDINE

The anti-HIV drug d4T or stavudine (Zerit) has been associated with body fat changes in HIV-infected patients. Although other drugs also have this risk, d4T seems to be most associated with loss of peripheral body fat (fat in the arms, legs, face, and buttocks). Several studies presented at the conference switched d4T for another drug to see if fat loss would improve in people with HIV. One study looked at switching d4T or AZT (Retrovir) for abacavir (Ziagen) in 111 patients. Of this group, 93 were taking d4T and only 18 were taking AZT. After

Conference

HIGHLIGHTS

6 months, special body scans showed significant increases in peripheral body fat in the group that switched to Ziagen compared to the group that stayed on d4T or AZT. However, the patients didn't report any noticeable changes. Two other studies sponsored by the pharmaceutical company that makes Ziagen and AZT looked at switching d4T and found improvements in peripheral fat 6 months and 1 year after the switch. The recovery of peripheral fat is likely to be slow and incomplete (meaning all the fat may not return).

VITAMIN B BELLY BUSTER?

A small study by researchers in San Francisco looked at whether or not daily doses of "immediate release" niacin could help boost HDL (good cholesterol) levels and decrease fat in the abdomens of HIV patients experiencing body fat changes. Niacin is an essential B vitamin. The middle dose of niacin taken by the patients was 3000 mg. Of 16 HIV-infected patients, 13 experienced a decrease in abdominal fat (average decrease of 27%) after taking niacin for 6 months or longer. HDL levels rose and total cholesterol dropped. The longer niacin was used, the greater the amount of fat reduction. It is important to note that this study looked at a small number of patients. However, other research has shown that high-potency B vitamin supplements help HIV-infected people stay healthier in general.

ANTI-HIV THERAPY NOT HELPING SOME IMMUNE CELLS

Combination anti-HIV therapy can help increase T cell counts and improve the health status of most HIV-infected patients. However, less is known about how anti-HIV treatment affects "B cells," the cousins of the T cells. B cells are an important part of the immune system and help organize antibody responses. (Antibodies are special proteins that are made when an infection happens so that the infection can be quickly stopped if it ever comes back again). Researchers in San Francisco found abnormal B cell function in patients taking anti-HIV therapy for more than 2 years. Even though T cells were restored, B cells were not. Such incomplete immune restoration may leave HIV-infected patients at increased risk of non-Hodgkin's lymphoma (a B cell cancer) and other immune diseases.

AMPRENAVIR AND DELAVIRDINE INTERACTION

Researchers in Denmark report that the protease inhibitor amprenavir (Agenerase) lowers the levels of delavirdine (Rescriptor). The

study was done to see if the combination of the two drugs would help reduce the number of Agenerase pills required per day (16 large pills). The researchers reduced the Agenerase in half. The dose of each drug was 600 mg twice a day. Even though Agenerase levels in the blood were increased, Rescriptor levels dropped dramatically. Until more information is available, caution should be used when prescribing these drugs in combination.

NEW DRUGS AND THERAPIES

Several potentially helpful drugs and therapies are making their way through clinical studies and may eventually become options for people with HIV. However, none of these is a cure.

- ▶ **Tipranavir** is a new protease inhibitor that seems to be effective against resistant virus from heavily treatment-experienced patients.
- ▶ **Atazanavir** is also a new, once-a-day protease inhibitor that does not affect blood fat and cholesterol levels as much as other protease inhibitors. Despite this "superior" fat profile, the drug can cause other side effects like increased bilirubin, a substance in the body that can cause yellow skin if levels are too high.
- ▶ **T-20** is continuing to show effectiveness in clinical trials, although one study paired T-20 with efavirenz (Sustiva) in patients who had never taken either class of drug. If the patients just switched to Sustiva, they would have likely experienced the same degree of success. Still, T-20 is a member of a new class of drug called "fusion inhibitors" that may be important for patients with few or no options left. One drawback is that the drug requires two injections per day.
- ▶ **Interleukin-2 (IL-2)** has been studied for several years. This therapy is not an anti-HIV drug but an immune therapy designed to boost T cell counts. IL-2 is injected in cycles that cover several weeks. There are many flu-like side effects associated with IL-2, but lower doses seem better tolerated. Studies presented at the conference indicate that IL-2 may increase the overall survival time of T cells in some patients and may also expand the numbers of naïve T cells (which are important because they can learn new "tricks" and aren't just copies of T cells already in the body).

Other new drugs and new classes of drugs are in development, but still need much more study before they can be evaluated. Look for updates in future issues of *HIV Treatment ALERTS!*

No, this isn't an article about problems with your voice box. It's a reflection of what has been happening around The Center for AIDS (The CFA) lately. Our client traffic and phone calls often keep us informed of what is "seen and heard" on the street, and lately we have noticed that things are kind of quiet out there.

Since "Treatment Information *and* Advocacy" is what we do, maybe it's time to stir the pot a bit. The question is, why is everyone so quiet? When we were kids, our parents told us, "Behave; don't speak unless you are spoken to." Now it seems like our doctors, in some cases, have replaced our parents.

The typical scenario is this: Patient A has a monthly appointment with Doctor X. Patient A goes to sleep the night before the appointment pondering several items to discuss with Doctor X. Instead of counting sheep, questions dance like sugarplums . . . "I wonder what those little bumps on my skin are? I have to ask the doc about this pain in my abdomen. I seem to feel more fatigued lately. I wonder if there's anything he can do to help me with that." The next morning the patient awakes, goes to the appointment, sees the nurse, and then visits Doctor X. The doc looks at the lab results and says "Everything looks fine, we'll do some more blood work on you for your next appointment. I'll see you in 2 months." The doc is on the way out the door and Patient A blurts out the concerns about fatigue. Without stopping, the doc says, "That's only a medication side effect, or it could just be HIV itself—I wouldn't worry about it too much." Doctor X exits and Patient A is left sitting on the exam table wondering, "Were my questions really answered?" On the drive home Patient A thinks about all of the things that should have been discussed during the appointment and regrets not having been more assertive.

This scenario doesn't occur all the time; many physicians take great care to translate to their patients the complicated factors in treating HIV. It is not unusual to hear from patients that their docs spend an hour or more with them during a routine office visit. However, several circumstances are occurring that infringe on a productive patient/physician relationship.

In this era of managed care, the medical profession is forced to squeeze every dollar out of every minute of every day. In addition, other factors are contributing to increased demands on your doc's time and energy:

- HIV infection rates in Houston continue to increase.
- People with HIV are living longer as the result of new drug therapies.
- Increased lifespan among the HIV-positive population has meant that medical issues are more complicated, encompassing not only HIV and side effects but also concerns related to aging and non-HIV causes of death (factors such as hepatitis and heart disease).

The CFA isn't worried about patients who have terrific relationships with their medical providers. What concern us are those who read the previous office visit scenario and said, "Yep, that could be me, I could be Patient A." We know that many patients walk out of their doc's offices more confused than when they arrived, and we constantly ask ourselves questions about this "silent" patient. The CFA receives calls from men

and women who often say, "I meant to ask my doctor several things, but just got nervous and forgot." Fortunately, The CFA is able to respond to those concerns and steer people to sources for the answers they need.

In Texas, there is a fixed pool of HIV-experienced medical providers and an increasing number of patients who require their attention. Given this set of circumstances, The CFA is compelled to tell HIV-positive individuals, "Speak up about the management of your disease!"

OK, that's the advice, but how can we help you to put it into action? What can The CFA do to stop the "disconnect" between patients and their medical providers? We have an answer called *Conversations at The CFA*, an ongoing monthly series of community forums designed with patients and health care providers in mind. With these forums we hope to accomplish several goals:

- To bring HIV-positive men and women together in a safe and comfortable setting;
- To provide information on a variety of HIV-related subjects from the best medical and service professionals available; and
- To foster honest and open dialogue between patients, physicians, researchers, and the pharmaceutical industry.

Early in the epidemic there was important input from people directly affected by this disease regarding treatment, drug approvals, and social services. As time has passed, many of those voices have disappeared. Perhaps it is because there were so few options available years ago. Now that HIV is widely perceived as a "chronic and manageable" disease, many folks think that they can just move from one treatment to the next. The

truth is that there are very **few** options out there because many treatments are too similar to one another.

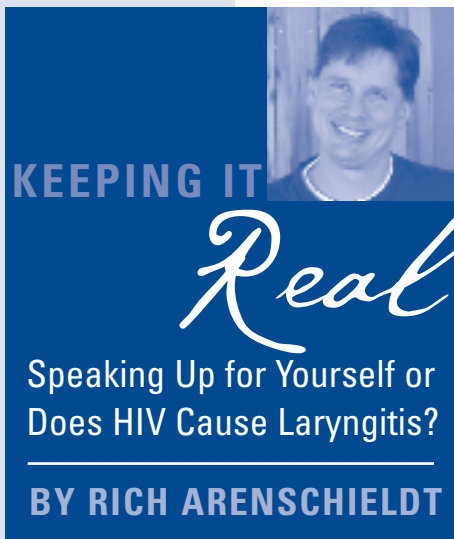
Conversations at The CFA can put patients back in charge of their care and increase their knowledge about HIV. These once-a-month dinner forums will cover upcoming topics such as:

- *Genotypic and Phenotypic Resistance Testing as a Tool for Managing HIV Infection*
- *Your Heart on HAART: Cardiac Health and HIV Disease*
- *Conversations with Researchers: What's Ahead in HIV Treatment?*
- *New Drugs in the Pipeline: Update from the Pharmaceutical Industry*

These forums provide an opportunity to meet and mingle with other HIV-positive men and women who are interested in learning about a variety of HIV-related topics and how to get more involved in their medical care. Our next "conversation" will be on Wednesday, April 24, at The CFA, 1407 Hawthorne, in Houston beginning at 6:30 pm. The topic will be *New Drugs for the Treatment of HIV Infection* and will focus on the new drug, tenofovir (Viread).

You don't have to be a scientist or doctor to attend, just a person interested in knowing more about what is available in the fast-changing world of HIV treatment. The CFA can help you find your voice!

If you'd like more information, contact Rich Arenschioldt, Director of Education and Outreach at The CFA (713.527.8219 or rich@centerforaids.org).



KEEPING IT *Real*
Speaking Up for Yourself or
Does HIV Cause Laryngitis?
BY RICH ARENSCHIELDT

Q & A

Patient/Doctor

Q: I have been taking nevirapine (Viramune) with d4T (Zerit) and 3TC (Epivir) for over 2 years. I am not taking any other medications. My T cells are at 420 and my viral load is undetectable. The drugs have been working fine, but lately my bloodwork shows somewhat elevated liver enzymes. How serious is this and should I switch drugs?

A: It's not possible from the information available right now to say how serious this is, but liver complications are never to be taken lightly. Although your medications might be **toxic** to the liver, you have been on them for a while and they have apparently not given you any problems before now. I would first, then, look to other possible explanations. You should have been tested for past and/or present infection by **hepatitis**-causing viruses as part of your initial medical assessment. If you had no prior infection by hepatitis A or B, you should have been vaccinated against these. Past infection by hepatitis C often means current infection also, so these results should all be checked. If you weren't vaccinated you may have been already immune, or it may have been overlooked. Chronic hepatitis B or C could cause your new elevated liver enzymes. Additionally, many over-the-counter medications may contain ingredients potentially toxic to the liver, especially acetaminophen (a common pain reliever like that found in Tylenol). Review the labels of any of these drugs you may be taking, including any herbal supplements. Also, honestly review how much alcohol you drink since alcohol puts stress on the liver. Finally, if none of these possibilities pan out, it may be your medications.

You may be developing a hepatitis and/or **lactic acidosis** from the medications. This is a relatively newly recognized side effect of these medications and needs to be specifically looked for, since it may not be apparent on routine testing. Depending on the results of this investigation and the degree of elevation of your enzymes, you may need to stop medication to see how your liver responds. If you stop, you may then need to decide with your doctor whether to re-try these same medications or move on to another combination.

Q: After several years of taking the protease inhibitor nelfinavir (Viracept) with the combination of AZT and 3TC (Combivir) as my first regimen, my viral load has started to climb above 2000. My

Chris Lahart, MD,
gives some expert advice on problems
faced by patients with HIV.

T cells are at 300. What drugs should I switch to? What about the new drug tenofovir (Viread)?

A: To be able to stay on the same medical **regimen** for several years is a real success and not a "failure." So far, so good. If this was your first regimen, you most likely have several options from this point forward. If available, resistance testing would be a good idea at this point. On this regimen we can often find a virus that has only learned to resist 3TC, or 3TC and nelfinavir. The presence or absence AZT resistance can be important. The results of resistance testing should then guide your next therapy. If there is no resistance testing available, a switch in therapy could be made trying to avoid any possible **cross-resistance**. With your situation, that could include d4T (Zerit) and ddl (Videx) plus a non-nucleoside like efavirenz (Sustiva) or nevirapine (Viramune), or a protease inhibitor that can be used after nelfinavir. "Boosted" protease inhibitors are commonly used in this situation. A protease inhibitor can be boosted by taking it with a small amount of another protease inhibitor called ritonavir (Norvir).

Tenofovir has actually been studied as a drug added on to an existing regimen that is in the early stages of viral rebound. Some consideration could be given to intensifying your current medications by adding this once-a-day pill. Some physicians will try this, while others feel it's best to make a true switch. That would be a good conversation to have with your doctor.

Q: I have a hard time keeping my pills down. I get very nauseous for up to a half hour after I take them. Sometimes I throw up and need to take them again. Is there anything that can help me with this problem?

A: This is a common problem. To understand why, all you have to do is look at what some people have to try and swallow. Not knowing what pills you're trying to put down limits the specifics of my suggestions, but here are some general ideas. First, review your pills and see what each one needs as far as being taken with or without food. You may be able to separate your pill-taking into separate times, allowing your stomach to deal with fewer pills at a time. This may also help you determine which medication may be the main cause of your problem. Second, review your whole regimen



with your doctor. You may be on some medications that are more optional than others. Maybe you have experienced enough recovery of your immune system to stop some of the **prophylactic** medications. Finally, after minimizing how many different medications you have to take and maximizing your tolerance for each one, you may need some medication to specifically ease your nausea. There are many options for this, including in some places, medical marijuana. It is always better, however, not to add even more medications when trying to treat drug side effects. That may be necessary if you have no other options.

Q: I am 44 years old and have been HIV-positive for 10 years. I have never been diagnosed with AIDS. My T cells are 220 and my viral load is 4500. I am taking lopinavir/ritonavir (Kaletra) and abacavir/AZT/3TC (Trizivir). Lately, I have been forgetful—sometimes I will forget what I am doing right in the middle of doing it! Is this related to my HIV? What should I do?

A: This is a common feeling and often can be bothersome once you start paying attention to it and it seems even more fre-

quent. In the setting of HIV infection, we all get concerned about dementia. **HIV-associated dementia** does not have to follow other signs of AIDS; it may occur first. You should mention your concerns to your doctor. You both should then review your medications to make sure there's nothing that could be interacting with the ritonavir, causing its levels to be too high and interfering with your concentration. If there does appear to be a problem that is not explained by prescription or other medications and/or drugs you should be examined for symptoms and signs of depression. If present, depression should be treated. If not present, full **neuropsychological** testing may be done to try and assess the presence of any real mental impairment. If testing does show an early dementia, further tests such as blood tests for vitamin deficiencies, kidney and liver function, thyroid function, and syphilis may be done. A scan (CT or MRI) of your brain may be done and this may or may not be followed by a lumbar puncture (spinal tap). Each step described would be dependent upon the outcome of previous steps and *may never be needed* should results provide an explanation for what you are noticing.

Send your questions for physicians to rita@centerforaids.org or by mail: Questions, P.O. Box 66306, Houston TX 77266-6306

Chris Lahart, MD, is the Medical Director at Thomas Street Clinic and an Assistant Professor of Medicine in the department of Infectious Diseases at Baylor College of Medicine in Houston.

APRIL

- 10 Journal Club**
Noon at The Center for AIDS
1407 Hawthorne
Brown bag lunch
- 11-14 Global Impact ToursSM**
Texas Trail of Independence Bike Tour to benefit The Center for AIDS
For more information, call 212.358.9852 or visit globalimpacttours.com.
- 24 Journal Club**
Noon at The Center for AIDS
1407 Hawthorne
Brown bag lunch
- Conversation at The CFA:**
New Drugs for the Treatment of HIV
6:30 pm at The Center for AIDS
1407 Hawthorne
Dinner provided. Call Rich at 713.527.8219 to Rsvp.

MAY

- 8 Journal Club**
Noon at The Center for AIDS
1407 Hawthorne
Brown bag lunch

- 16 Classical Action: Performing Arts Against AIDS**
presents a private concert to benefit The Center for AIDS.
For more information, call 212.997.7717.

- 22 Journal Club**
Noon at The Center for AIDS
1407 Hawthorne
Brown bag lunch

- 27** The Center for AIDS is closed for Memorial Day.

JUNE

- 5 Journal Club**
Noon at The Center for AIDS
1407 Hawthorne
Brown bag lunch

- 19 Journal Club**
Noon at The Center for AIDS
1407 Hawthorne
Brown bag lunch

- 27 National HIV Testing Day**

RECOMMENDED CALLS



CLINICAL TRIAL INFORMATION

STUDY TO FOCUS ON PATIENTS WITH DRUG-RESISTANT HIV

The Montrose Clinic is now enrolling patient volunteers for a study of multi-drug resistance. The study (called CPCRA 064) will use viral resistance testing to see what drugs might still work against a patient's HIV. From the resistance tests, new drug combinations will be figured out that hopefully should work against the virus. Two groups of patients will be studied: one that starts the new drug regimens right away, and one that starts the new drug regimens after a 4-month treatment interruption. Patients will participate in this study for at least 2 years. To be eligible, patients must be on anti-HIV therapy and have viral loads above 5000. Resistance testing should show virus resistant to multiple drugs. Patients are not eligible if they have been recently vaccinated, are ill (especially with an **opportunistic infection**), have recently used interleukin-2 (IL-2), or are pregnant. For more information, contact Jesse Rios, RN, at 713.830.3050.

ATAZANAVIR: AN EXPERIMENTAL PROTEASE INHIBITOR

A study sponsored by drug maker Bristol-Myers Squibb is looking at atazanavir in combination with other anti-HIV drugs. This study (called BMS 045) is being done to help determine the safety and effectiveness of atazanavir. This drug has not been approved yet by the Food and Drug Administration (FDA). The results from studies like this one usually help the FDA to decide whether or not to approve a drug. Patients with viral loads of 1000 or more and T cells greater than 50 are eligible. Patients are not eligible if they have a history of **pancreatitis**, heart disease, **hemophilia**, or recent **hepatitis** or **opportunistic infection**. Patients are also not eligible if they are pregnant or have received atazanavir or the other study drugs in the past. For complete details and more information, contact Mark Mall, RN, at the Montrose Clinic (713.830.3018).

MYCOPHENOLIC ACID STUDY

A study being done locally by Dr. Joseph Gathe will look at the effects of mycophenolic acid in combination with anti-HIV drugs as part of "salvage" therapy for highly drug-experienced patients. No specific T cell or viral load levels are required. For more information, contact Marketer Washington or Delishia Sapp at 713.526.9821.

SMART NOW ENROLLING

SMART stands for **S**trategies for the **M**anagement of **A**nti-**R**etroviral **T**herapy, and it will be the largest, most ambitious clinical trial in the history of the HIV/AIDS epidemic. The study will involve 6000 patients and last for as long as 8 years.

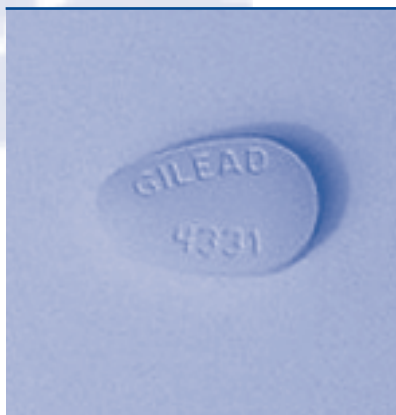
Driven by common knowledge that anti-HIV drugs are toxic, the study's planners are hoping to learn whether delayed, broken-up treatment for HIV is just as effective as immediate, uninterrupted treatment. The study will also gather information on the long-term side effects of HIV treatment and its effect on quality of life.

The study is open to anyone with HIV, male or female, who is at least 13 years old. To volunteer, you must have a T cell count of at least 350 and you must be willing to start, stop, or change anti-HIV drug therapy, depending on the study group to which you are assigned. For the first year of the study, you will have to see the doctor once every 2 months. After that, you will see the doctor 3 times a year. For safety, you cannot volunteer for the study while you are pregnant, but you can volunteer after you have had your baby.

In Houston, this study is available at 3 sites: Thomas Street Clinic, the Veteran's Administration Medical Center, and Montrose Clinic. The head doctor for the study is Roberto Arduino, MD, an associate professor of medicine at the University of Texas—Houston Medical School.

For more information on SMART,
call Hilda Cuervo at 713.500.6731.





Viread is supplied in 300 mg tablets that are almond shaped, light blue film coated, and embossed with "GILEAD" and "4331" on one side and with "300" on the other side.

Fact Sheet: Viread

Also known as: tenofovir, tenofovir DF, tenofovir disoproxil fumarate, PMPA, and bis(POC)PMPA.

Background. Viread is an anti-HIV drug manufactured by Gilead Sciences Inc. The FDA approved Viread for use in fighting HIV in October 2001.

Dose. The recommended dose of Viread is one 300-mg tablet once a day. It should be taken in combination with other anti-HIV drugs. If you are taking Videx (Videx EC, didanosine, ddl), you should take Viread 2 hours before or 1 hour after Videx.

Food restrictions. Viread should be taken with food, preferably a full meal containing some fat.

Storage. Viread should be stored at room temperature (77°F).

Who should *not* take Viread. Persons with kidney problems should not take Viread. Viread has not been tested in persons with liver problems. Pregnant women should not take Viread. It is not known whether Viread passes into breast milk and what effect it may have on a nursing baby. It is recommended that HIV-infected mothers not breastfeed to prevent transmission of HIV to the child.

Side effects and toxicity. The most common side effects of Viread are nausea, diarrhea, weakness, vomiting, and flatulence (intestin-

al gas). Bone thinning or softening was seen in some animals when they were given Viread at high doses. It is not clear whether bone damage will occur in human with long-term use of Viread. As with other anti-HIV drugs, changes in body shape may occur in persons taking Viread. Changes include increased fat in the upper back and neck, breasts, and the trunk of a person's body, as well as loss of fat from the legs, arms, and face.

Drug interactions. Viread increases the levels of Videx in your blood. This increase in Videx levels could cause an increase in Videx side effects. If you are taking Videx you should take Viread 2 hours before or 1 hour after Videx. (Some doctors recommend taking Videx with food to lower Videx levels in the blood; this way both Videx and Viread could be taken together *with food*.) There is some evidence that Viread may work better in persons whose virus is resistant to 3TC (Epivir); some doctors recommend taking the 2 drugs together. Viread is eliminated by the kidneys and may interact with other drugs that are eliminated by the kidneys. Examples of these drugs include Zovirax (acyclovir) or its generic version acyclovir, Valtrex (valacyclovir), Cytovene (ganciclovir), Valcyte (valganciclovir), and Vistide (cidofovir). Company officials have stated that Viread should *definitely not* be taken with Vistide (cidofovir).

Patient assistance. Gilead Sciences Inc. has a Reimbursement and Assistance Program for persons having problems getting Viread. The number is 800.226.5056.

Treatment News

FDA Bits

- ▲ The Food and Drug Administration (FDA) has approved an official recommended dose for combining the protease inhibitors amprenavir (Agenerase) and ritonavir (Norvir). When the two are used in combination, 1200 mg of Agenerase can be given with 200 mg of Norvir once a day, or 600 mg of Agenerase can be given with 100 mg of Norvir twice a day. The small amount of Norvir is used as a “boost” to increase the levels of Agenerase in the blood. In the case of Agenerase, which is one of the largest anti-HIV pills, this combination also helps reduce the number of pills needed.
- ▲ The FDA has approved a new version of the anti-HIV drug efavirenz (Sustiva). The new 600 mg tablet will replace the three 200-mg tablets that are usually required once a day. The new tablet reduces the number of pills needed, which is a small step toward making anti-HIV medication easier to take. However, the 200-mg tablets will still be available for people who prefer them.
- ▲ Add the dietary supplement *kava* to your list of herbs to watch out for: a recent FDA bulletin warns that the herb (sometimes called “kava kava” or “Piper methysticum”) may be **toxic** to the liver. Kava can be found as a supplement by itself, or as an ingredient in some herbal blends. Twenty-five cases of liver disease associated with the use of kava extracts have been reported in Germany and Switzerland. The FDA is investigating to see if there is a similar—but unrecognized—problem in the US. Kava is supposed to help relieve stress, insomnia, and even premenstrual syndrome (PMS).

Bad to worse?

Last issue's "Treatment News" (see *HIV Treatment ALERTS!* November 2001: www.centerforaids.org/rita/alerts/alerts1101.htm) described a possible side effect of NRTI drugs: muscle weakness as a sign of **lactic acidosis**. Bristol-Myers Squibb, the company that makes ddI (Videx) and d4T (Zerit) issued a special notice to doctors. Earlier this year, a drug warning was issued to doctors by the company's Vice-President for Medical Affairs, Virology. The warning basically says that if muscle weakness develops in someone taking d4T, the drug should be stopped immediately. Some cases have been fatal. Studies show that lactic acidosis may be more common when anti-HIV drug combinations contain d4T. However, it is important to remember that anyone experiencing lactic acidosis should stop taking all anti-HIV medications. Other symptoms of lactic acidosis include nausea, diarrhea, sudden weight loss, abdominal pain, rapid breathing, muscle pain or cramps, general fatigue, and feelings of tingling or pricking of the skin. Currently, regular measurements of lactic acid levels in the blood are not recommended.

LIFT!

Weight training (sometimes called “resistance training”) can be an important component to an exercise program, as shown by a recent study published in *Medicine & Science in Sports & Exercise* (33:11, p. 1811, 2001). In the study, researchers at Tufts University in Massachusetts worked with HIV-infected men and women for 16 weeks to see the effects of increasing strength and lean body mass (muscle) on health. Six of the men were experiencing AIDS wasting (meaning they lost 10% or more of their body weight in the previous year). Exercise included leg presses, leg extensions, chest presses, and rowing, and was meant to work large muscle groups. The study participants reported whether or not their physical performance had improved. The patients with wasting reported significant improvements, which were predicted by measured improvements in lean body mass and strength ability. The researchers plan other studies to find out the best strength-training methods for people with HIV.



Cancer concerns



- A review of medical records of patients with HIV shows that bacterial pneumonia and a cancer known as non-Hodgkin’s lymphoma (NHL) are now more common than back in 1993 to 1995. These years were during a time before combination anti-HIV therapy was being used. The main lung disease back then was PCP, a type of **opportunistic infection**, which is now much less common. Researchers suggest that the risk of NHL may be greater in patients who have experienced more advanced HIV disease, such as very low T cell counts, before receiving potent anti-HIV therapy. The research is published in the journal *Chest* (120:6, p. 1888, 2001). The main concern is that health care providers be aware of NHL symptoms (like unexplained fever or weight loss) and realize that people with HIV are at greater risk.
- According to a report in the *International Journal of Cancer* (94, p. 753, 2001) women with HIV are at greater risk of cancer than uninfected women. Over 1300 women were studied from 1993 through 2000. The HIV-infected group had 26 cancers (including 4 cases of lung cancer), while the uninfected group had 4 cancers (including 1 lung cancer). Even though both groups had similar histories of tobacco smoking, the women with HIV had twice the risk of getting lung cancer. Also, the HIV-infected women with lung cancer were young (average age of 40) and died within 6 months of diagnosis. This suggests that such cancers are more aggressive in HIV-infected women. Other cancers that were seen in the HIV-infected group were invasive cervical cancer and NHL.
- Finally, a recent study (*The Lancet*, 359, p. 108, 2002) found precancerous genital lesions and growths in 6% of 481 HIV-infected women, versus 1% of 437 HIV-negative women. The researchers recommend thorough gynecological examinations in women with HIV because of a potential increased risk of invasive cancer of the vulva.

Kidney **failure** in women with HIV

A study published in the journal *Kidney International* (61, p. 195, 2002) points to some factors that could predict kidney failure in women with HIV. The study looked at more than 2000 HIV-positive women and found that roughly one third of the women had elevated levels of protein in their urine. This condition is called “proteinuria” and indicates problems with kidney function. Kidneys help take waste products out of the body and bring them to the bladder for excretion as urine. Risk factors that predicted proteinuria in the women were: Black race, being positive for hepatitis C, and T cells at 200 or less. Also, the risk of proteinuria increased with HIV viral load (for instance a viral load of 400,000 showed a 5% greater risk than a viral load of 40,000). Other signs predicting kidney problems included rising systolic blood pressure, falling albumen levels, and increasing creatinine levels. (These are all usually measured in HIV-positive patients during a routine check-up). The researchers suggest that some of the damage may be caused by direct infection of the kidneys by HIV. Better control of HIV viral load and improved T cell counts may help reduce the risk and progression of kidney disease in HIV-infected people.



BOTTOM LINES

GETTING HIGH MAY DAMAGE THE IMMUNE SYSTEM

A study of specially bred mice transplanted with human immune cells has shown that cocaine increases the production and spread of HIV. Mice given cocaine by injection had much greater losses of T cells and increases in viral load than mice given ordinary salt water (used as a **control**). The research is published in the March 1 issue of *The Journal of Infectious Diseases* (185, p. 701, 2002). Also, a November 23, 2001, report by the *Canadian AIDS Treatment Information Exchange* (www.catie.ca) suggests that the recreational drug ecstasy may have a negative effect on the immune system as well. The report refers to several studies indicating that ecstasy lowers T cell counts and that the drug interferes with how the immune system fights infection. Also, anti-HIV drugs can cause the level of ecstasy to rise to dangerous levels in the body.

BOTTOM LINE: People with HIV need to take care of their immune systems. Frequent drug use puts your health at risk. Your immune system can't fight HIV if it is fighting the effects of drugs like cocaine or ecstasy. If you use and want to stop, take the first step by talking to a counselor or your health care provider.

BRAIN DRAIN

HIV-associated dementia is possible in people with AIDS. Fortunately, since new anti-HIV medications came out in the mid 90s, less dementia is being seen overall. However, medical professionals know that HIV still affects the brain. HIV can infect certain brain cells early on, and most anti-HIV medications cannot get into the central nervous

system (brain and spinal cord) very well. So what is HIV doing up there?

One recent study has found that individuals with HIV have problems with *verbal working memory*, in other words short-term storage and processing of words. The researchers, from Baylor College of Medicine in Houston, found that people with early HIV disease and those with later, **symptomatic** disease had problems with verbal memory span. (They had more trouble remembering information they heard). Also, those with later disease had less short-term storage ability. The research paper was published in *Psychological Medicine* (31, p. 1279, 2001). A second study, published in *AIDS* (16, p. 31, 2002), found that HIV-associated dementia has some similarities with Alzheimer's disease. Also, patients with dementia had higher levels of a T cell called "CD14/CD69" than patients without dementia. However, these levels overall seemed lower than in the time before anti-HIV medications were available. The researchers believe that anti-HIV medication helps save brain cells from dying, but that the virus still damages them.

BOTTOM LINE: Even when blood tests show HIV as "undetectable," there is still virus in almost every part of the body, including the brain. Remember that we all become more forgetful as we get older, so locking your keys in your car doesn't mean you are experiencing dementia! However, contact your health care provider if you are experiencing any of the following symptoms over a *period of time*: difficulty remembering things, getting lost in familiar places, difficulty making decisions or completing tasks, trouble doing simple math (working with money, for example). If you are having vision or balance problems, see a doctor right away.

definitions

Control: a special situation in research where no drug is given or no test is done. For example, a control group that gets a sugar pill might be compared to an *experimental* group that gets a real medication to see what are the effects of the medication.

Cross-resistance: the ability of a virus or bacteria to overcome the effects of more than one drug at a time. For example, if an infection was resistant to antibiotic A and cross-resistant to B and C, then a different antibiotic (D) would be needed.

Hemophilia: a disease that interferes with blood clotting and can result in uncontrolled bleeding.

Hepatitis: inflammation of the liver that can have a variety of causes including viruses, medications, etc.

HIV-associated dementia: a progressive brain problem that causes confusion, loss of memory, problems thinking, and trouble keeping balanced.

Lactic acidosis: accumulation of lactic acid in the body. Lactic acid is a substance in blood and muscle tissue pro-

duced by the body when it is processing sugar for energy (usually when exercising or in the absence of normal levels of oxygen).

Neuropsychological: looking at how the brain and nervous system relate to actual thoughts and behaviors.

Opportunistic infection: a disease caused by an organism that is usually harmless, but becomes activated when a person's immune system is impaired or damaged.

Pancreatitis: inflammation of the pancreas, an internal organ, usually involving pain in the upper abdomen (just under the ribs) and possible nausea and vomiting.

Prophylactic: preventing the spread or occurrence of disease.

Regimen: a combination or schedule of medications.

Symptomatic: showing visible or measurable signs or symptoms of a disease.

Toxic: being poisonous or damaging to the body.

Useful Resources



"A nationally syndicated, weekly, radio news-magazine delivering the latest information on personal health and well-being topics, including HIV disease, cancer, diabetes, stress, gay and lesbian health, women's health and more." www.awaretalkradio.org/home.htm (Note: this site uses lots of sound, so be careful with computer speaker volume or use earphones.)

Practical advice on disability benefits and related issues.
www.helpwithbenefits.com

HIV/AIDS News Digest twice a week on the Web or delivered by e-mail.
hiv.dailyliving.info

New "Ask the Doc" feature on AEGIS lets you post a question and get a response, or just browse the questions other HIV+ people are asking.
www.aegis.org/askdoc

HIV/AIDS information from the Centers for Disease Control and Prevention (CDC). www.cdcnpin.org/hiv/start.htm or 800.458.5231

The AIDS Treatment Data Network: counseling and advocacy services in English and Spanish, treatment information, and treatment access programs. www.aidsinfonyc.org/network or 800.734.7104

AIDS Community Research Initiative of America (ACRIA) has free brochures for people with HIV. www.acria.org/acria.html or 212.924.3934

A free online tool called "the wheel" that helps match up anti-HIV med combinations with personal lifestyle issues. The wheel gives you a schedule of when to take meds, a fact sheet about the specific drug combination, and more. www.aidsmap.com/wheel/starthere.htm

DON'T HAVE INTERNET ACCESS? If you are in the Houston area, remember that The Center for AIDS has 2 computer workstations available to search for information on HIV/AIDS. The workstations are provided by the Houston AIDS Information Link (HAIL). The walk-in information center (1407 Hawthorne) is open Monday through Friday, 9 a.m. to 5 p.m. Also, consider visiting a local branch of your public library.

COMMUNITY SPOTLIGHT

BREAD OF LIFE, INC.

Bread of Life began in 1992 as an outreach program of St. John's United Methodist Church. A cornerstone of this downtown Houston organization is its Daybreak Community Health Center, which offers health care services to uninsured or indigent individuals. Many Bread of Life services address the needs of children and adults with HIV/AIDS, as well as at-risk groups and the homeless.

PROGRAMS:

- ▲ Substance abuse counseling
- ▲ Mental health services
- ▲ Job training and placement
- ▲ Adult literacy training
- ▲ Meals
- ▲ Clothing and food pantry services
- ▲ Housing
- ▲ HIV/STD testing and education
- ▲ Primary medical care

CONTACT INFORMATION:

Location: 1703 Gray St.
Houston, Texas 77003
Phone: 713.650.0595
Fax: 713.650.0597

"Bread of Life is committed to restoring families by restoring individuals."

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