HIV treatment ALERTS!

SEPTEMBER 2002

inside:

THE CENTER FOR AIDS HOPE and [illegible] PROJECT

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WELCOME

For many people in our community, living with HIV is not easy. Nobody wants to think about having an incurable disease, getting sick, or dying. This is especially difficult with HIV because the disease is largely transmitted in younger and sexually active people. For some, issues such as education, career, and family or relationships may take a back seat to worries about health care, disability, and just staying alive. But life cannot go on hold because of HIV. Life MUST go on. That's the true challenge of living with HIV or any long-term disease: learning how to get the most out of life and still take care of yourself. One part of taking care of yourself involves proper nutrition and exercise. Another part involves faith, meditation, or counseling for mental health. A third part involves regular doctor visits and taking anti-HIV therapy or other medications as necessary. *HIV Treatment ALERTS!* can be a tool to help with the third part by keeping people with HIV informed about new treatments, clinical trials, drug warnings, etc. In fact, that's the entire purpose of The Center for AIDS: bringing people the knowledge they need to make informed decisions about their health.

If "knowledge is power," then our goal is to give people the power to survive HIV.

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. Words in **bold** are explained in the "Definitions" section.

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!* (RI*TA!*) twice a year. RI*TA!* 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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RI*TA!*

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 health-care providers. . ."

THE CENTER FOR AIDS HOPE and REMEMBRANCE PROJECT

ATAC needs you!

The AIDS Treatment Activists Coalition (ATAC) was formed roughly 1 year ago at a meeting in Houston of national HIV/AIDS activists. The group spent several days discussing the treatment challenges of people with HIV/AIDS and the need for effective advocacy in areas such as novel therapies, vaccines, and microbicides (used during sexual intercourse to prevent transmission of HIV). One theme was especially clear: the need for new people to become involved in the fight to cure HIV/AIDS. ATAC was formed to create a national organization of treatment activists that could deal with issues as a united front, to train and mentor new treatment activists, and to provide a forum for discussion and debate of emerging issues.

ATAC is open to anyone interested in HIV/AIDS treatment activism (except for people employed by pharmaceutical companies). Training and educational sessions are now scheduled several times a year in locations across the country. The next sessions will be in December at the North American AIDS Treatment Action Forum (NATAF) in New Orleans.

To find out more about ATAC, go to ***www.atac-usa.org.*** You can join the ATAC e-mail list, by sending a message to ***info@atac-usa.org*** that lists your real name, your e-mail address, and the reason why you are interested in HIV/AIDS treatment education or advocacy.

ATAC's mission and goals:

MISSION STATEMENT

We are a national coalition of people living with HIV/AIDS and advocates working together to end the AIDS epidemic by improving HIV research and treatment access. We seek to encourage greater and more effective involvement of all people with HIV in the decisions that affect their lives by identifying, mentoring, and empowering new treatment activists in all communities affected by the epidemic.

GOALS

1. To enable people with HIV/AIDS and their advocates to speak with a united, powerful voice to provide meaningful input into the following issues concerning HIV disease and related complications and coinfections:
   a. Drug, diagnostic, vaccine and microbicide research, development, approval, pricing, and access; and
   b. Prevention, education, and health care delivery.
2. To develop within all communities affected by HIV and related coinfections the leadership to provide the knowledge and skills needed to advocate for improved research, treatment, and access.
3. To facilitate communication and set agenda items:
   a. Between HIV treatment activists and government, industry, and academia in matters affecting research, treatment, and access;
   b. Among HIV treatment activists and the larger HIV community in keeping up-to-date with the latest developments in research, treatment, and access; and
   c. Among HIV treatment activists in the USA and between activists in the USA and activists in other countries, including developing countries.

Conference HIGHLIGHTS

The International AIDS Conference occurs every 2 years and most recently was held in Barcelona, Spain, in July 2002. The meeting draws many thousands of researchers, doctors, social and health care workers, people with HIV/AIDS, political figures, and religious leaders. The conference website is ***www.aids2002.com***. Below are some research and treatment highlights from this year's 14th International AIDS Conference.

Does Gender Predict T Cell Response to HAART?

Studies have shown that Blacks and Hispanics with AIDS have a greater likelihood of dying than Whites with AIDS and that women with AIDS have a 20% greater likelihood of dying than men with AIDS. A study conducted at Houston's Thomas Street Clinic by Baylor of College of Medicine researchers looked at whether the T cell response of persons who had "sustained viral suppression" differed by ethnicity or gender, and whether this difference in T cell response might account for the difference in survival. "Sustained viral suppression" was defined as 2 consecutive viral load counts less than 400, the last of which was at least 120 to 240 days from the beginning of highly active antiretroviral therapy (HAART). A total of 79 men and 24 women were included in this analysis. Even after adjusting for variables like AIDS, baseline viral load and T cell count, and use of a protease inhibitor, women were found to have a better T cell response (+66 cells) to sustained viral suppression than men. No difference was found by ethnicity. The researchers conclude that "gender-specific optimal therapy needs to be defined."

Getting HIV Twice

Doctors and physicians have debated the question of whether a person can be infected with HIV and then re-infected with another strain. In other words, once you have an established infection with one strain of the virus, can you get another strain? A case was presented at the Barcelona conference suggesting that indeed a person can be infected *a second time with a different strain* of virus. In that case, a patient was taking anti-HIV medications and undergoing a series of treatment interruptions. After controlling the virus well for some time, the patient's viral load suddenly shot up unexpectedly. At first, the researchers thought that the patient's virus might have mutated into a different, more aggressive strain. After analyzing the patient's virus, they found a different strain of HIV than the one that had originally been detected. After questioning, the patient admitted to having unprotected sex during the time of the appearance of the new strain of HIV. Despite the fact that many doctors and researchers have warned about the possibility of this type of second infection, generally referred to as "superinfection," very few actual cases have been reported.

Early Treatment to Preserve Immunity

Studies presented at the International AIDS Conference in Barcelona continue to suggest that early treatment to preserve defenses against HIV may work best in persons treated during the earliest time of infection and may not work as well in persons treated even a few weeks later. In one study, patients treated after infection but *before testing positive for antibodies* were able to maintain a viral load less than 5000 while off anti-HIV drugs for up to 3 years after a series of treatment interruptions. In contrast, patients treated after about 2 months of the initial symptoms of HIV infection (also known as **acute retroviral syndrome**) were not able to control their viral load when drugs were stopped, even when some of them received a vaccine to help their immune system. The bottom line seems to be that early treatment preserves the immune system's defenses against HIV only if it is started during the earliest moments of that infection, preferably during acute retroviral syndrome.

The Times, They Are A'Changing

It used to be that doctors were advised to begin anti-HIV therapy as soon as the patient's T cell count dropped below 500. After a few years it became apparent that HIV would not be eliminated with early treatment and that while anti-HIV drugs are good at suppressing the virus, they also have long-term toxicities. Soon the recommendations changed and the current guidelines for treatment recommend that patients without symptoms wait until their T cell count has dropped below 350 before starting treatment. What if you were one of the patients who started treatment under the previous guidelines? For instance, what if you started therapy when you had 450 T cells? Is it safe to stop your drugs until your T cell count drops to below 350?

A study reported at the Barcelona conference indicates that patients who started anti-HIV drugs at higher T cell counts may safely stop their drugs. In that study, patients who started anti-HIV drugs with more than 350 T cells and a viral load of less than 60,000 were divided into 2 groups. In one group, the patients continued their medications; in the other group, they stopped their drugs. The patients who stopped therapy had a rebound in their viral load, but it was still lower than the viral load they had at the beginning of treatment. Those who stopped had a small drop in their T cell count (only 14 cells at about 6 months). Given the long-term **toxicities** of anti-HIV drugs, it may be worthwhile stopping them until a time when they become necessary.

First in CLASS

A study known as CLASS sponsored by GlaxoSmithKline was reported at the Barcelona conference. It combined Ziagen + Epivir with one of the following:

Sustiva
Zerit
Agenerase/Norvir

A total of 297 patients who had never taken anti-HIV drugs were enrolled in the study. Half had a viral load less than 79,500, the other half had a viral load higher than 79,500 (44% of the patients had a viral load of over 100,000 copies). Half the patients had a T cell count greater than 300 and the other half had a T cell count less than 300 (35% had less 200). The combination of Sustiva/Ziagen/Epivir resulted in better viral suppression than the other combinations, even among persons with viral loads greater than 100,000. The T cell count increases were comparable among all 3 regimens.

ACTG 384

The AIDS Clinical Trials Group (ACTG) presented the results of Study 384 at the Barcelona Conference. The study was designed to answer the following questions:

1. Which is better as a backbone drug combination: Retrovir + Epivir or Videx + Zerit?
2. Is Sustiva better than Viracept as an anchor drug?
3. Is a 4-drug regimen better than a 3-drug regimen?

Results in persons who had never taken anti-HIV drugs before this study showed the combination of Retrovir + Epivir to be superior to Videx + Zerit, but only when combined with Sustiva. Sustiva was superior to Viracept, but only when combined with Retrovir + Epivir. Overall, the 4-drug regimen outperformed the 3-drug regimen, but not when compared with the best 3-drug regimen, which was Sustiva + Retrovir + Epivir. Part of the problem with this study is that the twice-a-day tablets of Videx were used in the comparison. The results might have been different if the once-a-day Videx EC had been used. In the end, the results suggest that the combination of Sustiva + Retrovir + Epivir is a good first combination for persons who have never taken anti-HIV drugs.

Is Viread as Effective as Zerit?

Gilead Sciences reported the results of Study 903 at the Barcelona Conference. The study combined Sustiva + Epivir with one of the following:

Viread
Zerit

The study involved about 600 patients who had never taken anti-HIV drugs. Half the patients had T cell counts greater than 279 and the other half had less than 279. After 48 weeks on the anti-HIV drugs, the 2 combinations produced almost identical viral suppression and T cell increases. The study seems to prove that Zerit and Viread are equivalent when taken as part of a first regimen.

Sustiva for Advanced HIV

A study called EFAVIP-2 (**EFA**virenz in **V**ery **I**mmunosuppressed **P**atients) compared the use of Sustiva and protease inhibitors *not boosted by Norvir*. The patients in the study all had T cell counts less than 100, high viral loads

(half of them with greater than 250,000), and started with an initial regimen that had Sustiva or a protease inhibitor as an anchor drug. More patients quit the study because of side effects and adverse effects in the protease inhibitor group. More patients had continued viral suppression and better T cell increases in the Sustiva group. Some commentators point out that this may not be a fair comparison because almost all protease inhibitors are currently boosted by a small dose of Norvir. But the bottom line is that Sustiva produced good results in patients with very advanced HIV disease.

Look Ma! No Nukes!

In a study reported in the Barcelona conference, 33 patients with multiple drug failures were given a combination of only Kaletra and Fortovase (2 protease inhibitors boosted with Norvir) after resistance testing showed the patients were resistant to most nucleoside drugs. After 24 weeks, 82% of patients had a viral load less than 400 and 58% had a viral load less than 50. Half the group experienced a T cell count increase of greater than 158.

Mild Liver Enzyme Elevations: Should You Worry?!

Physicians often comment to their patients that "mild liver enzymes elevations are common among HIV-positive patients" and not a cause for concern. A study reported at the Barcelona conference seems to indicate that this attitude may be wrong. Researchers from Pittsburgh analyzed data from more than 5700 patients and found that persons with mild to moderate elevations of liver enzymes (0.5 times up to 2 times the normal levels) had an increased risk of death—almost double the risk of those with normal enzyme levels. Patients with 2 or more times the normal range had a greater than 5 times increased risk of death. Elevated enzymes are generally associated with damage to the liver that can result from the use of anti-HIV drugs, viral hepatitis, or alcohol abuse. Chronic hepatitis in particular has been known to increase substantially the risk of liver cancer and the researchers conclude that additional research is needed to ensure that anti-HIV drugs are not increasing this risk.

Fuzeon

No, it's not the latest water-resistant, fuchsia-colored lipstick from Maybelline. It's a new type of experimental anti-HIV drug that keeps HIV from entering T cells and other susceptible cells. In studies reported at the Barcelona conference, this drug (also known as enfuvirtide and commonly known as T-20) was added to the "optimized" regimen of highly drug-experienced patients. How do you optimize a drug regimen? By taking into account the drug history and using resistance (genotypic and phenotypic) testing, the researchers were able to choose the drugs most likely to work in these drug-experienced patients. The patients were then divided into 2 groups. In one group, the participants were given the optimized regimen; in the other group, the participants were given the optimized regimen plus Fuzeon. Two studies using this design were reported. The first study called TORO-1 (**T**-20 versus **O**ptimized **R**egimen **O**nly) had the following results:

	T-20 + Optimized Regimen	Optimized Regimen Only
Viral Load less than 400	37%	16%
Viral Load less than 50	19%	7%
T cell increase	+76 cells	+32 cells

The second study called TORO-2 had the following results:

	T-20 + Optimized Regimen	Optimized Regimen Only
Viral Load less than 400	28%	13%
Viral Load less than 50	12%	5%
T cell increase	+76 cells	+32 cells

Fuzeon is given by an injection and almost all patients receiving it reported some injection site inflammation, although less than 3% discontinued for this reason. Fuzeon is expected to go before the FDA sometime late this year or early next year.

KEEPING IT Real

NOTHING LASTS FOREVER

BY RICH ARENSCHIELDT

Much of the information that you read in *HIV Treatment ALERTS!* is geared towards how to use drugs to manage HIV infection. The next few paragraphs will discuss something even more important: how to keep receiving those very drugs. There's a crisis looming with regards to drug access; your attention and action are needed.

Many who access the public health care system for their medical care receive HIV meds through the *AIDS Drug Assistance Program* or ADAP. This program is funded by the federal government as part of the Ryan White CARE Act. Its purpose is to make sure that folks without insurance or resources can still obtain meds they need to manage HIV disease.

This sounds simple, but, in fact, several things are happening that our friends in Washington, DC, didn't forecast:

- Infection rates are still increasing
- People with HIV are living longer
- HIV meds are becoming more expensive

This simultaneous trio of events translates into one issue: more and more people need HIV meds at a time when there are declining federal and state dollars being appropriated to pay for them.

Each of these ADAP programs is administered by state health departments. Sixteen states are currently implementing *new restrictions* to their ADAP clients. These include:

- Stopping enrollment and "capping" their programs
- Establishing patient waiting lists
- Limiting the number and type of drugs available
- Making eligibility requirements more stringent

For those of us in the great state of Texas, state health officials are looking at all of these options and appear to be leaning toward the most exclusionary ones. The state legislature is also involved; they are not willing to provide any assistance to cover ADAP budgetary shortfalls. Furthermore, they have the legislative authority to abolish the program if it does not maintain a balanced budget. With a projected $7 million dollar shortfall this fiscal year, things don't look too promising.

While this all seems to be happening in some faraway bureaucratic place, it is just weeks away from landing right in your lap. Sometime in the near future you or someone you know could walk into your clinic pharmacy and receive the following notice:

"The eligibility requirements for the Texas State ADAP program have changed. As the result of these changes, your current reported level of income exceeds the percentage of the federal poverty level currently required to maintain participation in this program. As a result, you will be ineligible for ADAP-funded medications effective sixty (60) days from the date of this letter."

There it is folks—no breakfast, no goodbye kiss, not even a phone number. You've been sailing along with an undetectable viral load and stable T cell count, and then, *Shazaaam!* the medical throw-rug gets yanked out from under you.

What to do?

While you may know The CFA because of its HIV treatment information, we also have a long history of advocating for HIV-positive folks. The inside cover of this issue has the first part of our mission statement. The statement ends:

"(The CFA) . . . advocates for the entire affected population, ensuring that Houston's regional needs are factored into the national dialogue about HIV/AIDS."

As proof of this, last summer The CFA hosted a meeting of HIV advocates from around the country. In our humble opinion, we thought that the views of HIV-positive folks would be better expressed by a *single* national group, speaking with a unified, scientifically informed voice. As a result of our efforts, the *AIDS Treatment Activists Coalition* (ATAC) was born (see page 3). This is a group of motivated, focused, and informed individuals. Though many ATAC members have been involved in AIDS activism for years, one of their central concerns is training and mentoring new individuals to reinvigorate the field of HIV-related advocacy.

The ADAP crisis is one of ATAC's main policy concerns right now. Through discussion groups and educational "teach-ins" ATAC is able to transform interested individuals into powerful advocates representing HIV-positive people. Membership in ATAC is free and you can join the group by sending an e-mail message to: ***info@atac-usa.org***.

While you read this article, government officials in the house and senate are debating whether or not to increase ADAP funding. As you can imagine, with the current attitude towards terrorism and shrinking budgets, HIV meds are not a high priority in the minds of our congressional representatives. Remember the cardinal rule: politicians change their views as the result of reading letters *written by voters in their districts.* To find your representative visit ***www.house.gov/house/MemberWWW.html*** on the Internet and enter your complete zip code and state. To contact your Texas senators:

Phil Gramm (R-TX)
370 Russell Senate Office Building
Washington DC 20510
Phil_Gramm@gramm.senate.gov
202.224.2934

Kay Bailey Hutchison (R-TX)
284 Russell Senate Office Building
Washington DC 20510
senator@hutchison.senate.gov
202.224.5922

There is also a toll-free phone number for The Capitol switchboard 800.648.3516. They will be able to connect you to a representative. If you prefer, you also may contact The White House at 202.456.1111. Ask for President Bush; if he's not too busy . . . he may take your call.

For the last few years federal and state health officials have been saying, "Take your pills! Take your pills!" Are you now ready to let them say, "They're too expensive, you can't have them"?

Patient/Doctor Q&A

Pennye Rohde, PA-C, lends a physician assistant's perspective to some issues sent in by fellow *ALERTS!* readers.

Q: I have floaters in my vision (both eyes). Although I have had them since I was a kid, they are much worse now that I am in my early 30s. A visit to an eye doctor last year showed nothing is wrong—I just have a lot of floaters. My T cells are just under 500 and my viral load is at 9500. I am not on any HIV meds. Should I be worried about the floaters? I am scared it means I will eventually get CMV disease.

A: **Vitreous floaters** in both eyes are a common but harmless condition. In an HIV-infected individual, however, floaters in only one eye and/or blurred vision could be signs of CMV retinal disease. **CMV retinitis** may occur in the late stages of HIV disease, usually with a T cell count of less than 50.

With a T cell count of 500 and a viral load of 9500, CMV retinitis is unlikely to be responsible for your current symptoms. If you remain off HIV medications, it is possible that your T cell count eventually may drop low enough for CMV retinitis to develop. Yearly ophthalmologic (eye) exams are recommended for HIV-infected people with T cell counts above 50. If the T cell count drops below 50, eye exams should happen every 3 to 6 months. Vitreous floaters *do not* indicate that you will develop CMV retinal disease later on.

Q: I am 33 years old and HIV positive. Although my virus is undetectable on anti-HIV drugs, I worry about any health complications that I might be particularly at-risk for as an HIV-infected woman. I am not a worry-wort, but are there any risk factors that I should be aware of?

A: As an HIV-infected woman, you are at an increased risk for developing cervical cancer. Infection with HPV (human papillomavirus) is believed to be a possible cause for the development of cervical cancer. The rate of HPV infection is much higher in HIV-positive women. So, HIV-infected women should receive Pap smears every 6 months, especially at T cell counts below 200. Abnormal **Pap smears** must be followed up with a **colposcopic exam**.

Q: What is MRSA and how can I get rid of it?

A: MRSA, or methicillin-resistant *Staphylococcus aureus*, is a type of bacterial infection that is common in HIV-infected people. This bacteria often causes skin infections including **boils, abscesses, impetigo,** and **folliculitis.** Many individuals can be carriers of MRSA in their nostrils. As much as 20% to 40% of the general population may unknowingly harbor these bacteria. These carriers can transfer MRSA to their skin. Trauma to the skin (cuts, scratches, insect bites, etc.) can provide an entryway for the bacteria, which may result in localized or possibly generalized infections.

MRSA is usually resistant to many antibiotics. This makes the bacteria very difficult to treat. **Intravenous** antibiotics are sometimes necessary. To reduce the possibility of infections returning, people with MRSA should also be treated **intranasally** with a topical antibiotic preparation. Also, the use of antibacterial soaps is recommended to reduce the amount of MRSA on the skin.

Q: I took a break from HIV treatment last year and my platelets dropped to dangerously low levels (about 10,000). After a transfusion and returning to anti-HIV medications, they increased but are still low (80,000 to 108,000). Why did this happen? Is there any way to further increase my platelets to normal levels?

A: A low platelet count (officially known as idiopathic **thrombocytopenia** purpura or ITP) is the most common platelet abnormality found in people with HIV. The causes of HIV-related thrombocytopenia may include **autoimmune** destruction of platelets, increased clearance of platelets in the blood by the **spleen**, or direct HIV infection of platelet-producing cells in the bone marrow. Your platelets may have dropped to dangerously low levels during your HIV treatment interruption for any of these reasons. An autoimmune reaction is the most likely cause for the drop.

Patient/Doctor Q&A

Thrombocytopenia can be treated in several ways. For autoimmune-related ITP, steroids and special antibodies may be used when immediate normalization of platelets is necessary. Sometimes removal of the spleen is necessary when steroid therapy does not work. Potent anti-HIV therapy is often successful for treating this disorder—especially regimens that include Retrovir (also in Combivir and Trizivir). By remaining on your HIV medications, your platelet count should remain stable.

Send your questions for physicians to

rita@centerforaids.org or by mail:

Questions, P.O. Box 66306, Houston TX 77266-6306

***Pennye Rohde, PA-C**, is the Physician Assistant to Dr. Shannon Schrader at Houston's Southampton Medical Group.*

CALENDAR

OCTOBER

3 **Conversation with Dr. Judy Aberg–The Heart on HAART**
5:30-8:00 pm at The Center for AIDS
Call Rich at 713.527.8219 to Rsvp.

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

19-20 The Center for AIDS is proud to be a beneficiary of **Halloween Magic**, producing 2 evenings of the hilarious musical spoof *The Women: A Ya-Ya Montrose Sisterhood*
Edwin Hornberger Conference Center,
2151 Holcombe, Houston
For ticket information, call the Halloween Magic hotline at 713.226.2342

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

24-27 The Center for AIDS is proud to be the beneficiary of **Global Impact Tours**sm
Texas Trail of Independence Bike Tour.
For more information, call 212.358.9852
or visit ***www.globalimpacttours.com***

NOVEMBER

5 **Conversation with Byron Russell – T-20**
5:30-8:00 pm
Call Rich at 713.527.8219 to Rsvp.

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

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

28-29 The Center for AIDS will be closed for Thanksgiving.

DECEMBER

1 **World AIDS Day**

5 **Basic Science Workshop**
Sponsored by The Center for AIDS &
Center for AIDS Research at Baylor College of Medicine
For information, call L. Joel Martinez at 713.527.8219

8-11 **National AIDS Treatment Action Forum**
Astor Crowne Plaza Hotel, New Orleans, LA
Contact Paul Woods, Conference Registrar:
202.483.6622 or ***pwoods@nmac.org***

8 The Center for AIDS is proud to be a beneficiary of the **15th Anniversary Christmas Songfest**
5-9 pm
Hornberger Conference Center,
2151 Holcombe, Houston
For ticket information, contact
Christmassongfest@yahoo.com

12 The Center for AIDS
annual *Holiday Schmooze* benefit
6-8 pm
For ticket information, call 713.527.8219

December 23, 2002–January 3, 2003
The Center for AIDS will be closed for the holidays.

Visit us on the web:
www.centerforaids.org

CLINICAL TRIAL INFORMATION

FAT WASTING STUDY LOOKS AT SWITCHING DRUGS

Some people with HIV experience what is commonly known as lipodystrophy, which includes such symptoms as fat loss in the face, arms, and legs and/or fat gain in the gut, breasts, or back of the neck. A study called "ACTG A5110" is looking at whether fat loss in the arms and legs is caused by specific types of anti-HIV drugs. The study also wants to see if such fat loss can be reversed if a certain type of anti-HIV drug is stopped and replaced with other types. The answers to such questions *are not known.* The purpose of the study is to try to answer the questions. The study is available locally through the AIDS Clinical Trials Unit (ACTU) at The University of Texas Medical Branch (UTMB) in Galveston. HIV-positive adults (18 years or older) are eligible to participate. Study drugs and study-related clinic visits will be provided at no cost. Some travel or childcare assistance may be available on a limited basis. People are eligible if they are on HIV meds that include either Retrovir or Zerit, if they have undetectable viral loads and T cell counts of at least 100, and if they have experienced fat loss or wasting in their arms and legs. For more information, contact the ACTU at 409.772.3991 or toll free at 877.324.2288.

IMMUNE RESTORATION STUDY

One of the challenges in HIV medicine is to try to restore the immune system to a healthier state after it has been attacked by HIV. Combination HIV therapy helps, but the restoration is still incomplete. Doctors from the AIDS Clinical Trials Unit (ACTU) at The University of Texas Medical Branch (UTMB) in Galveston are trying to find ways to improve immune restoration. In their study, they will use an experimental AIDS vaccine, interleukin-2 (an immune booster), and HIV treatment interruptions to see if immune restoration can be improved. To be eligible, patients must have been receiving combination anti-HIV therapy (3 or more drugs) for longer than 6 months; Ziagen (which is present in Trizivir) *cannot* be one of the drugs used. Also required are a T cell count greater than 350 and viral load less than 50, no previous or current AIDS-defining illness (except Kaposi's Sarcoma if less than 5 skin **lesions**), and no use of an HIV vaccine within the past year. For more information, contact the ACTU at 409.772.3991 or toll free at 877.324.2288. More information about the ACTU research group can be found on the Web at ***http://actu.utmb.edu/actu***.

STUDY TO TEST SAFETY AND ANTI-HIV EFFECTIVENESS OF POTENTIAL DRUG

An experimental nucleoside reverse transcriptase inhibitor (NRTI) called "ACH-126,443" is being tested for safety and anti-HIV effectiveness. This drug is in the same family as drugs like Epivir, Zerit, Videx, and Retrovir. The study (called "Achillion 006") will look at 3 groups of patients, where one group stays on Epivir, but the other groups switch Epivir for ACH-126,443 at either of 2 doses. The patients will be followed in the study for 4 weeks. Although this study does not have much advantage for treatment-experienced patients who need new treatment options, it is a preliminary and necessary step to move the drug forward into longer, more in-depth study. Entry criteria for this study include being on an Epivir-containing drug **regimen**, experiencing viral rebound after previous HIV suppression (current viral load between 1000 and 30,000), having T cells greater than 200, and test results showing viral resistance to Epivir. Also, patients must be older than 18 years, cannot be pregnant or breast-feeding, and cannot have any **opportunistic infections** or hepatitis B or C infection. The study is enrolling locally at Houston's Montrose Clinic. For more information, contact Rick Witt, PA-C, at 713.830.3013.

Mental Health Issues: with HIV/AIDS

When individuals are faced with HIV/AIDS, their physical health is not the only issue at hand. Along with the physical illness associated with the virus are mental health conditions. Common psychological disorders associated with HIV/AIDS are depression, anxiety, and sometimes dementia (AIDS Dementia Complex or ADC). There are many reasons for such conditions including societal stigma, grief (such as the loss of loved ones), ongoing struggles with illnesses, diminished quality of life, and medications (either direct side effects or the constant act of having to take medication).

Depression is the most common mental disorder found among HIV-infected individuals. Symptoms of depression generally include low self-esteem, anxiety, forgetfulness, sleep disturbances, changes in appetite, weight loss or gain, decreased libido, and a sense of hopelessness. An evaluation by a therapist should be sought if these symptoms persist every day for 2 weeks or interfere with personal care, work, or social life. The symptoms of anxiety include a sense of numbness, emotional detachment, or a dazed state. Different types of anxiety disorders include panic disorder, obsessive-compulsive disorder, post-traumatic stress disorder, generalized anxiety disorder, and phobias (fears of specific places, things, or situations). AIDS Dementia Complex (ADC) or **HIV-associated dementia** is common among people with advanced HIV disease (usually very low T cell counts). People with ADC have problems thinking clearly. Symptoms of dementia may include lack of concentration, loss of memory, social withdrawal, sluggish thinking, short attention span, **lethargy**, poor coordination, impaired judgment, vision problems, and altered personality. Treatments for depression, anxiety, and dementia include medications and professional counseling. One may be used without the other, but these methods are more effective when used together. Unless severe, symptoms like grief and low self-esteem may be treated with only professional counseling.

Professional counseling may involve individual support, interpersonal interaction, group support, and cognitive-behavioral treatment. Commonly used medications are antidepressants, stimulants, and anxiolytics. Patients should always consult with their physicians before taking any additional medications—even if prescribed by a psychiatrist. Psychiatrists, psychologists, and social workers all provide different forms of treatment for mental disorders. Treatment for these disorders may be costly, but some financial support is available through funding from sources like the Ryan White CARE Act. Those affected by HIV/AIDS may be eligible for free or reduced-fee services by agencies that receive such funding for mental health services. There are many different places to seek assistance. Below are a few centers that provide free or sliding-scale services.

This article was written by Nora Frankian, a summer intern with The Center for AIDS and a student at the University of Houston.

Some Houston-area counseling resources for people with HIV:

All Walks of Life
9106 Benthos
Houston, TX 77083
281.495.9226
Free; men and women
Location: Southwest Houston

Amigos Volunteers in Education and Services (AVES)
4126 Southwest Freeway, Suite 1310
Houston, TX 77027
713.626.2837
Free; men, women, youth (13-19), children
Location: Houston Inner Loop

Bering Omega Community Services
1427 Hawthorne
Houston, TX 77006
713.529.6071
Free; men and women
Location: Houston Inner Loop

Eleos Center, Inc.
9898 Bissonnet, Suite 430E
Houston, TX 77036
713.781.7003
Free; men, women, and youth (13-19)
Location: Southwest Houston

Family Service Center
4625 Lillian Street
Houston, TX 77007
713.861.4849
Free or sliding scale used to determine fees; men, women, and children
Location: Houston and surrounding areas

Mental Health Association of Greater Houston
2211 Norfolk, Suite 810
Houston, TX 77098
713.523.8963
Free; men and women
Location: Houston Inner Loop

Montrose Counseling Center
701 Richmond
Houston, TX 77006
713.529.0037
Free or sliding scale used to determine fees; men, women, and youth (13-19)*
Location: Houston Inner Loop
*Services provided primarily for gay, lesbian, bisexual, and transgender individuals and their significant others

New Hope Counseling Center
6420 Hillcroft, Suite 408
Houston, TX 77081
713.776.8006
Free; men, women, and youth (13-19)
Location: Southwest Houston

WAM Foundation, Inc.
12401½ South Post Oak Road, #121
Houston, TX 77045
713.721.2310
Free; men and women
Location: Southwest Houston

TreatmentNews

Another cardiovascular risk with protease inhibitors?

We have all heard the lipid (blood fat) story with many of the currently available protease inhibitors—cholesterol can go through the roof and the triglycerides are just not pretty. The worry, of course, is what a cholesterol count of 300 or 400 might do in the long term. Any cardiologist will tell you that the risk of a heart attack or cardiovascular disease will likely increase substantially. But now there's even more to worry about. A study published in the *Journal of Acquired Immune Deficiency Syndromes* (29, p. 441, 2002) has found that patients taking protease inhibitors experience a decreased ability to naturally break down blood clots in their body, thus increasing the risk of clot formation. (Blood clots can cause heart attacks or strokes by becoming stuck in blood vessels). Specifically the levels of a substance in the body called "PAI-1" were higher in patients taking protease inhibitors. The increased PAI-1 levels were also directly related to triglyceride levels, insulin levels, and body mass index. PAI-1 inhibits blood clot breakdown in the body, therefore abnormally elevated levels of PAI-1 may result in greater numbers of clots in the circulation.

Lowering DRUG doses for dialysis

Researchers from Duke University Medical Center in North Carolina have reported that HIV-infected patients with end-stage kidney disease requiring chronic dialysis can be given much lower doses of the anti-HIV drug Epivir. A once-daily dose of 25 mg in dialysis patients provided the same amount of drug in the body as 2 daily doses of 150 mg in patients with normal kidney function. These results could have an impact on the dosing of other anti-HIV drugs in dialysis patients. The study was published in the journal ***Antimicrobial Agents and Chemotherapy*** (46, p. 2387, 2002)

Causes of death in people with HIV

A recent report in the *Journal of Acquired Immune Deficiency Syndromes* (29:4, p. 378, 2002) looked at multiple-cause death certificates in the US from 1987 through 1999 that mentioned HIV infection. The analysis was conducted by researchers at the Centers for Disease Control and Prevention (CDC) in Atlanta. They found changes in causes of death for HIV-infected patients from 1995 through 1999 (when potent combination anti-HIV therapy was being widely used in the US). These trends included decreases in deaths from **CMV disease** (6.8% to 2.8%), wasting (9.8% to 6.8%), and **HIV-associated dementia** (6.3% to 3.9%), and increases in deaths from **sepsis** (9.2% to 13.4%), liver disease (4.9% to 11.6%), kidney disease (6.3% to 9.1%), and heart disease (4.2% to 6.9%). Although the number of deaths in people with HIV/AIDS decreased from 47,977 in 1995 to 16,061 in 1999, demographic changes in the infected population and the introduction of anti-HIV drugs appear to be having substantial effects on how people with HIV are dying.

Treatment News

FDA Bits

▲ The Food and Drug Administration (FDA) has approved a once-daily dosing for the anti-HIV drug Epivir, to be given in combination with other anti-HIV drugs. Now, instead of the 150-mg dose given twice a day, one 300-mg dose can be given just once a day. A new 300-mg tablet formulation was approved reducing the pill burden from 2 to 1.

▲ New precautions have been added to the labeling for the protease inhibitor Agenerase. First, taking Agenerase and Methadone is not recommended because Agenerase lowers the levels of Methadone in the blood, and Agenerase may not be absorbed as well when taken with Methadone. Second, oral contraceptives (birth control pills) containing Ethinyl estradiol/norethindrone should not be taken with Agenerase because they decrease Agenerase concentrations. Decreased levels of any anti-HIV drug put patients at risk for viral rebound and drug resistance.

▲ The FDA HIV/AIDS List has announced that nandrolone decanoate, a steroid product that can be used to build muscle tissue in people suffering from AIDS-related wasting, is once again available in the US, after having been discontinued by the manufacturer. The product is now available from Watson Pharmaceuticals, Inc. in limited supplies but should be more widely available at the end of October 2002. Watson customer service can be reached at 800.272.5525.

Lactic acidosis: watching and waiting

More and more HIV-infected patients are being given a drug called metformin (Glucophage) to control diabetes or early signs of diabetes such as insulin resistance or high blood sugar. A research letter in the May 15 issue of the *Journal of the American Medical Association* (287:19, p. 2505, 2002) reports that although metformin use is associated with an increased risk of **lactic acidosis** (as indicated on the drug's labeling), the drug is prescribed in patients who should not get it (such as people with kidney problems or congestive heart failure). What does this mean for people with HIV? If metformin increases the risk of lactic acidosis, and the use of certain anti-HIV drugs (like Zerit and Videx) also increase the risk of lactic acidosis, then how many risk factors can a person's body take? Pregnant women have already been warned not to take Zerit and Videx together because of the danger of lactic acidosis. Now some doctors are taking other patients off this combination as well. These drugs may be fine on their own, but in combination, their **toxicities** may be added together. Add a drug like metformin to the mix, and the situation only gets worse. Symptoms of lactic acidosis include nausea, diarrhea, abdominal pain, rapid breathing, muscle pain or cramps, general fatigue, and feelings of tingling or pricking of the skin. People with HIV should see a doctor *immediately* if they experience these symptoms.

BOTTOM LINES

West Nile Worries

Media coverage of the growing number of cases of West Nile Virus infection has been almost constant over the past few months. There is no doubt that the virus is spreading throughout North America and eventually may become an epidemic, but what does this mean for people with HIV/AIDS? First, people who get very sick or die from West Nile Virus include the elderly or those with weakened immune systems (such as transplant recipients, people on chemotherapy, or people with advanced HIV disease). Many healthy people who get the virus do not get sick or even know they have an infection. Obviously, the lower your T cell count, the weaker your immune system is likely to be.

Norma Brown, RN, a Director of Patient Care at Houston's Tenet Park Plaza hospital, points out that most people who die from West Nile Virus infection usually have something else wrong with them that puts additional strain on their health. According to Dr. Joseph Gathe, the best way to treat someone hospitalized with West Nile Virus infection is to treat any other infections and give the patient lots of fluids and nutrition.

The virus is transmitted by mosquitoes that carry it. Incubation time for the virus to infect a person after transmission is anywhere from 5 to 19 days. Some people can actually develop antibodies to West Nile Virus, and definitive test results can usually be received within 48 hours. Symptoms of West Nile Virus infection include disorientation or confusion, altered mental state, and headache. Sometimes nausea or vomiting is also present. A fever is not always present. General precautions include using insect repellant containing the ingredient DEET (for example, OFF! brand repellent), staying indoors between dusk and dawn, wearing long sleeves and long pants when outdoors, and killing any mosquitoes found indoors (swatting or using a spray that kills flying insects).

BOTTOM LINE: West Nile Virus infection kills very few people. Take general precautions (as listed above), especially if you have low T cell counts (say, less than 200). Having HIV does not mean you will get sick or die from West Nile Virus infection.

AIDS Treatment Fraud Still Going Strong

On June 27, 2002, the US Food and Drug Administration (FDA) sent a warning letter (***www.fda.gov/foi/warning_letters/g3398d.htm***) to Dr. Saiyid Rasheeq Wahid of Baton Rouge, Louisiana, regarding his alternative medicine "Dr. Wahid's Herbal Remedy." The product has been marketed to people with cancer and AIDS as a possible treatment or cure, with claims that the treatment has been "working well" in patients suffering from such diseases. Unfortunately, this is not the only case of AIDS treatment fraud. Both in this country and as far away as Thailand and Africa, products are sold as "cures" for many diseases. Without research and medical evaluation, treatments cannot be trusted to do what someone claims them to do, especially if money is changing hands. "Quacks" (people who promote and sell fake tonics, pills, potions, and other treatments) have been around since the beginning of medicine, if not earlier!

False treatments or hoaxes should not be confused with alternative or complementary medicines, which are not intended to cure or treat specific illnesses but are useful for relieving pain, reducing stress, decreasing depression, etc. More information is available at the National Center for Complementary and Alternative Medicine website (***www.nccam.nih.gov***).

BOTTOM LINE: For more information on AIDS treatment fraud, contact the Texas AIDS Health Fraud Network (800.758.5152 or ***www.tahfin.org***). To report possible fraud, contact the FDA (888.463.6332 or ***www.fda.gov***) or the Federal Trade Commission (877.382.4357 or ***www.ftc.gov***).

definitions

Abscesses: areas of infection, usually containing pus surrounded by inflamed tissue.

Acute Retroviral Syndrome: sickness caused by high levels of virus (HIV is a retrovirus) resulting in fevers and other flu-like symptoms.

Autoimmune: a reaction of the immune system (using T cells and antibodies) against its own body.

Boils: a hard, swollen, inflamed area of skin caused by bacterial infection in a skin gland.

CMV disease: an infection caused by a virus in the herpes family that can infect nervous tissue, in particular the retina of the eye (which can result in blindness).

Colposcopic exam: an examination of the vagina using a specialized device called a colposcope.

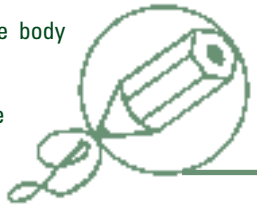
Folliculitis: inflammation of hair follicles.

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

Impetigo: a bacterial skin disease causing pus and yellow crust-like buildup.

Intranasally: taken into the body through the nose.

Intravenous: taken into the body through a vein.



Lactic acidosis: excess accumulation of lactic acid in the body. Lactic acid is a substance in blood and muscle tissue produced by the body when it is processing sugar for energy (usually when exercising or in the absence of normal levels of oxygen).

Lesion: an abnormal change to an area of the body, usually a well-defined mark.

Lethargy: abnormal drowsiness or sluggishness.

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.

Pap smear: a test for the early detection of cancer in females.

Regimen: a combination or schedule of medications.

Sepsis: a toxic condition caused by the spread of bacteria from one place in the body to all over the body (such as through the blood).

Spleen: a small organ in the body that helps destroy old red blood cells and filters the blood.

Thrombocytopenia: an abnormal loss of platelets in the blood that can lead to hemorrhage if severe.

Toxicities: poisonous or damaging effects on the body.

Vitreous floaters: debris (like dead cells) in the liquid of the eye that may be seen as a spot in the visual field.

Useful Resources

Links to many different HIV/AIDS sites on the Internet. ***www.hivaidssearch.com***

Find HIV-treating doctors and HIV/AIDS service organizations almost anywhere in the country. ***www.hivfinder.com***

AIDS start page: over 700 links including organizations listed by state and region. ***www.cbel.com/AIDS***

Basic HIV disease and treatment information, as well as stories of people living with HIV. ***www.managinghiv.com***

Free educational information on topics like lipodystrophy and blood fat abnormalities. ***www.freehivinfo.com*** (click on link for "Free Educational Programs")

Kaiser Daily HIV/AIDS Report (e-mail sign-up also available at website). ***www.kaisernetwork.org/daily_reports/rep_hiv.cfm***

Online library of webcasts on a variety of HIV-related topics (text transcripts also available). ***www.healthology.com/focus_index.asp?b=healthology&f=hiv***

Gay Men's Health Crisis, "first in the fight against AIDS," offers treatment information, publications, and advocacy. ***www.gmhc.org*** or 800.243.7692

Wise Words, a publication for women with HIV. ***www.projinf.org/pub/ww_index.html*** or e-mail ***WISE@projectinform.org*** to subscribe.

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 am to 5 pm. Also, consider visiting a local branch of your public library.

COMMUNITY SPOTLIGHT

STEVEN'S HOUSE is a small, intermediate-care facility for people living with AIDS. By establishing a home-like living environment, this organization offers care to residents and people in their support network 24 hours a day, 7 days a week. Steven's House is open to both men and women. The goal of Steven's House is to help people with AIDS to return to independent living.

Services available to residents at Steven's House:

- Room and board
- Dietary planning
- Monitoring of self-administered medications
- Weekly in-house support group (mandatory attendance)
- HIV/AIDS education to residents, family, and friends
- Counseling referrals for residents and family
- Assistance with transportation needs
- Social service referrals
- Psychological and social support

Eligibility requirements include:

- Medical certification of AIDS status (according to the definition of the Centers for Disease Control and Prevention)
- Documentation of tuberculosis (TB) skin test or chest x-ray within 3 months of application
- 18 years of age or older
- Proof of income and cooperation in enrollment for any public assistance, personal care planning, or support services
- Signing a Release of Information form (for health care providers, case managers, etc.) and a Residency Agreement
- Not using illegal drugs or abusing alcohol
- Participation in treatment, if necessary, for any mental illness

In addition, an application process (including an interview with house staff) is required.

CONTACT INFORMATION

Mailing address: P.O. Box 131303
Houston, Texas 77219-1303
Phone: 713.522.5757
Fax: 713.522.1910

"The mission of Steven's House is to strengthen the community by providing transitional housing and support services for people living with HIV/AIDS. . . ."

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