



OCTOBER 2003

treatment

ALERTS!

inside:

2

WELCOME

A word or two from the editor

3

CONFERENCE HIGHLIGHTS

*Reports from last summer's
2nd International AIDS Society Conference in Paris*

6

TREATMENT NEWS

*The latest news on drug warnings, ways to stay
healthier, and more*

10

PATIENT DOCTOR Q&A

*Expert answers to real questions about HIV disease
and its treatment*

12

KEEPING IT REAL

Don't believe everything you read

CALENDAR

A look at upcoming events

13

CLINICAL TRIAL INFORMATION

*Locally enrolling studies on experimental treatments
or ways to better treat HIV*

14

BOTTOM LINES

Like news, but with some helpful advice

15

DEFINITIONS & USEFUL RESOURCES

The name says it all . . .

16

COMMUNITY SPOTLIGHT

Find out about Houston Area Community Services, Inc.

THE
CENTER
FOR
AIDS
HOPE and
REMEMBRANCE
PROJECT



This year has been busy in the fight against HIV. Several new HIV drugs were approved (Fuzeon, Reyataz, Lexiva, and Emtriva). While some of these offer people with HIV new ways to combat the virus, others offer modest advantages like improved convenience or fewer/different side effects. Surprisingly, the biggest overall challenge to people living with HIV this year has not necessarily been the virus, but the cuts in dollars for research and medication assistance programs. This year, federal funding for state AIDS Drug Assistance Programs (ADAPs) has severely fallen short. The battles to save ADAP have been many, with very few wins. People with HIV/AIDS in the US who are in dire need of life-saving medications are being put on waiting lists because there is not enough money. Somehow, our legislators can't see that investing around \$15,000 for a year's worth of HIV medications actually saves money by keeping a person out of the hospital because of preventable illnesses. If you haven't contacted your US senators and representatives to make sure they are supporting ADAP funding increases (part of the Ryan White Care Act), now might be a good time to do so. See the Useful Resources list on page 15 of this issue for information on how to contact your elected officials. Also, you can contact the Save ADAP Committee of the AIDS Treatment Activists Coalition (ATAC) if you'd like more information and to find out how to get more involved (www.atac-usa.org/adap.html).

No matter how many times we hear it, HIV is not a "chronic manageable disease"—it will always be controversial and always require a fight to keep people alive until there's a cure.

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.

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AIDS RESEARCH CONSORTIUM OF HOUSTON dba
The Center for AIDS: Remembrance & Hope Project
 P.O. Box 66306, Houston, Texas 77266-6306
 1407 Hawthorne, Houston, Texas 77006

Voice 713.527.8219
 888.341.1788

Fax 713.521.3679

Website <http://www.centerforaids.org>

E-mail rita@centerforaids.org

Senior Editor
 Thomas Gegeny, MS, ELS

Editor
 Jennifer Newcomb-Fernandez, PhD

Editorial Board
 Roberto Arduino, MD
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Graphics
 T. B. Southwell

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. . . ."



Conference

HIGHLIGHTS

... from the 2nd International AIDS Society Conference

EFFECTIVE ONCE-DAILY HIV REGIMEN

The once-daily regimen of Emtriva, Videx EC, and Sustiva was shown to be effective and safe in 40 HIV+ patients who had never before taken HIV medication. Patients were required to have T cell counts greater than 100 and a viral load greater than 5,000. At bedtime, patients took a total of 5 pills. Three years later, 75% of the patients had maintained a viral load of less than 400. **Drug-resistance mutations** developed in 5 patients. Treatment was well tolerated with only 3 patients stopping treatment because of side effects. Common side effects included high triglycerides (a type of fat that travels in the blood), changes in liver enzymes (which indicate stress on the liver), and body shape changes (**lipodystrophy**).

ROSIGLITAZONE UPS AND DOWNS

Rosiglitazone (brand name: Avandia), is a drug used to treat **diabetes**. This drug is being tested for the treatment of **lipodystrophy** and the related problems in body **metabolism**, such as with fats and sugars. One study compared rosiglitazone (4 mg) with a **placebo**. This study was a “double-blind” study, meaning that both patients and health care workers did not know which treatment each patient was receiving. After 3 months, patients and health-care workers knew which treatment each patient was receiving, and all patients were given the choice of taking rosiglitazone at a slightly higher dose (8 mg) for 3 additional months. During the first 3 months, rosiglitazone improved sensitivity to insulin (allowing better control of blood sugars). The drug also increased total body fat, **subcutaneous** fat, and adiponectin (a **hormone** secreted by fat

cells that affects the body’s response to insulin and may have other important effects), compared to patients in the placebo group. Unfortunately, levels of cholesterol increased in patients taking rosiglitazone. Over the next 3 months, rosiglitazone continued to improve insulin sensitivity and to increase subcutaneous fat. The researchers admit that larger studies are needed to figure out the best dose and length of time for treatment, as well as which patients will most likely benefit from this drug.

In related news, a recent double-blind study published in the journal *Antiviral Therapy* (8:3, p. 199, 2003) also reported that after 24 weeks of rosiglitazone, triglyceride and cholesterol levels were significantly increased compared to patients who took a placebo. In contrast to the first study (described above), this study found that rosiglitazone had no positive effects on total body fat, including fat in the gut and subcutaneous fat. On a positive note, rosiglitazone did improve **insulin resistance** and tests of liver function.

DEALING WITH DIARRHEA

While no one wants to talk about diarrhea, it is a common side effect of several HIV medications, especially the protease inhibitor Viracept. A small study of 18 patients focused on developing a step-wise plan to treat diarrhea. The strategy was adjusted every 2 weeks and additional treatments were added if the diarrhea persisted. Initial steps included 1) dietary counseling by a nutritionist to see if eating habits were contributing to the problem, 2) taking lactase if the patient had problems digesting dairy products, and

C O N T I N U E D

Conference HIGHLIGHTS

CONTINUED FROM PAGE 3



3) taking psyllium (pronounced “silly-um”), a source of dietary fiber. If the diarrhea persisted, calcium carbonate was added to their treatment. Two weeks later, if any patients were still experiencing diarrhea, they were also treated with loperamide (found in over-the-counter diarrhea medications such as Imodium). After completing the 9-week study, patients had fewer bowel movements per day and firmer stools. **Incontinence** and urgency (a strong desire to go to the bathroom usually caused by some abnormal stress) were also reduced. Patients reported that they felt better both physically and emotionally, and they worried less about the side effects of their HIV treatment.

ON THE LOOKOUT FOR KIDNEY PROBLEMS WITH VIREAD

The nucleotide reverse transcriptase inhibitor Viread has been linked to problems such as increased levels of a substance in the body called creatinine (pronounced “kree-at-n-need”). Elevations of creatinine in the blood can signal kidney damage. With the help of a large collection of patient records, researchers gathered information on 476 HIV+ patients who took Viread. Compared to patients using a Ziagen-containing regimen without Viread, patients taking Viread were more likely to have increased creatinine levels and signs of kidney damage. Patients with advanced HIV disease and low T cell counts were more likely to have kidney problems. In addition, more patients on Viread stopped it because of these problems. The researchers recommend keeping a close watch on patients who are taking Viread, especially if they have advanced HIV disease, even if they showed no signs of kidney problems before starting Viread.

RISKS OF VIRAMUNE

Viramune is commonly used to prevent HIV transmission from mother to child, but can cause a rash and inflammation of the liver, which are usually not life threatening. A study that exam-

ined 139 HIV+ pregnant women who took Viramune also observed these side effects. Unfortunately, 2 women in this study, both African-American, died from liver failure. In this study, women with serious liver inflammation tended to have higher T cell counts compared to women showing no signs of liver inflammation (524 versus 370). What is scary is that the doctors could not predict these deaths. Neither woman who died had hepatitis B or C, nor did they show any signs of liver problems during their frequent doctors’ visits. Currently, Viramune is often given to mothers to prevent mother-to-baby transmission. These findings suggest that this approach may need to be changed.

TAKE ALL OF YOUR MEDS

Not taking all of your HIV drugs leads to drug-resistant HIV mutations, according to a large study presented at the conference. Researchers examined the relationship between medication **adherence** (by checking prescription refill records and by looking for actual drug levels in blood samples) and the development of drug resistance in 1,219 HIV+ people who started triple combination therapy. The doctors found that development of resistance was more likely to happen in people with a high viral load before starting treatment. In addition, patients who took their medications 60% to 90% of the time (according to prescription refill records) were most likely to develop these mutations, compared to patients who took their medications less frequently or more frequently. Low levels of these HIV drugs in blood samples were related to a higher chance for **drug-resistance mutations**. Low drug levels could be caused by poor adherence, problems with drug **metabolism**, or drug interactions.

RISK FACTORS FOR BUFFALO HUMP

Buffalo hump, the accumulation of fat at the back of the neck, is a body change associated with **lipodystrophy**, but not all people with lipodystrophy get a buffalo hump. To see which patients get this condition, a study examined 417 HIV+ patients—all of whom

had lipodystrophy, while only some had a buffalo hump. Age, gender, response to HIV treatment, and immune system strength/control of virus were not linked to the development of a buffalo hump. Instead, patients with buffalo hump tended to have a higher body mass index (larger body size), more total body fat, and more fat in

their limbs and gut. Having **diabetes** or diabetic characteristics (such as a higher ratio of insulin to blood sugar) also increased the chance of developing buffalo hump. Patients who had taken protease inhibitors or Retrovir for longer periods of time were more likely to develop a buffalo hump as well.

New drugs and therapies

The following experimental drugs are in clinical study and are not yet approved by the US Food and Drug Administration (FDA). If they become approved, they may offer new treatment options for people with HIV.

TMC114 is an experimental protease inhibitor (PI) that may work in patients who have HIV with multiple protease inhibitor mutations. Researchers examined 50 patients who had taken several PIs in the past and who were failing their current treatment. Participants received 1 of 3 doses of TMC114 **boosted** with Norvir or continued to take the failing **regimen** as a **control group**. When given for 14 days, TMC114 reduced viral load and was generally well tolerated. Side effects included gastrointestinal symptoms (for example, nausea or diarrhea) and elevations in liver enzymes measured in the blood (which indicate stress on the liver).

SPD754 is an experimental nucleoside reverse transcriptase inhibitor (“nuke”) that may be active against HIV that is resistant to other nukes, such as Efavir or Retrovir. In a 10-day study of 63 patients who had never before received HIV treatment, patients were given 1 of 4 doses of SPD754 or a **placebo**. All doses of SPD754 reduced viral load and no new mutations were detected. Side effects were considered mild to moderate and were similar to side effects experienced by patients who took a placebo. These results are encouraging; however, more study is needed to examine SPD754 in treatment-experienced patients and for longer periods of time.



GW0385 is reported to be a very potent experimental PI that shows strong activity against natural forms of HIV (meaning without **drug-resistance mutations**; this is sometimes called “wild-type” HIV). However, this drug may also be active against HIV that is resistant to other PIs. Early study results show that the effects of GW0385 are enhanced when combined with other PIs or other drug classes like the nukes or non-nukes.

GW433908 (also known as 908 or fosamprenavir) is an experimental PI that will basically be a new formulation of the PI Agenerase, which is considered difficult to take because of the size of the pills and the number required for each dose. The new formulation decreases the pill count and size. At the conference, researchers from the company that is developing 908 presented results from 2 large studies. Both studies were 48 weeks long and compared 3 groups: 1) 908 plus nukes, 2) 908 boosted (with Norvir) plus nukes, and 3) Viracept plus nukes. The researchers studied the development of drug-resistant HIV and found that no patients taking boosted GW433908 developed any **drug-resistance mutations**, while about 1/3 of patients taking Viracept developed mutations. Some patients taking unboosted GW433908 developed mutations, but not as many as those taking Viracept. As of press time, the FDA approved this agent, which will have the brand name “Lexiva.”



Treatment News

transplantation

Justifiable

In the past, organ transplantation usually has not been recommended in HIV+ people because of the fear that the transplant surgery and necessary immune-suppressive drugs would cause HIV disease to get worse. Also, there were concerns that HIV+ patients would not live long enough to justify the transplant. The widespread use of combination HIV drugs has improved the health of HIV+ patients, but also increased the chance of developing liver and kidney disease as HIV-infected people are living longer. Recently, researchers have begun to reconsider liver, kidney, and heart transplants in HIV+ patients.

One study, published in the journal *Transplantation* (76:2, p. 370, 2003), reported on 10 patients who received kidney transplants and 4 patients who received liver transplants. All patients had stable HIV disease, good T cell counts, and no history of an opportunistic infection or cancer. All patients who received a kidney transplant survived, while one liver-transplant patient died after complications from hepatitis C co-infection. Organ rejection (when the body's immune system fights the new organ) occurred in half of the kidney-transplant patients,

but none of the liver-transplant patients. In general, there was no worsening of the HIV following the transplant in patients who took combination HIV therapy.

In addition, a study in *The New England Journal of Medicine* (348:23, p. 2323, 2003) reported a successful heart transplant in a patient with AIDS and serious heart problems, but who was responding well to HIV therapy. The patient previously had Kaposi's sarcoma (a type of skin cancer that is associated with AIDS) and the chemotherapy used to treat it may have caused the damage to his heart. Two years after the heart transplant, the patient is generally feeling well. However, he has suffered some complications, including anemia (that requires blood transfusions) and frequent episodes of rejection. While these results are promising, organ rejection and co-infection with hepatitis are still major problems in HIV+ transplantation recipients. In addition, there are complex and potentially dangerous interactions between HIV drugs and drugs used to prevent organ rejection. Regardless, these reports show that HIV+ status should not automatically disqualify someone from life-saving organ transplantation.

Predicting **DEMENTIA**



HIV-associated dementia (HAD) is a progressive brain problem that causes confusion, loss of memory, difficulties in thinking, and trouble keeping balanced. HIV-infected monocytes (a type of immune cell) carry HIV into the brains of infected people. These cells may release a substance that damages the brain and causes symptoms of dementia. Currently, doctors can only determine if a person is suffering from HAD by performing an **MRI** or lengthy medical evaluation. In a study described in the journal *Neurology* (60, p. 1931, 2003), researchers examined 21 HIV+ women and showed that HIV+ patients with HAD have a unique protein pattern compared to HIV+ patients without signs of HAD. One day, this new technique called "proteomic fingerprinting" (proteomics is the study of proteins) may allow doctors to find out if a person has initial signs of HAD by simply doing a blood test.

Positive effects of exercise and vitamin E

Lipodystrophy is common in many HIV+ people and can even affect HIV+ patients who have never taken HIV drugs. In addition, this condition is associated with other problems such as **dyslipidemia** and **insulin resistance**, which can lead to future heart problems. Researchers studied the effects of diet and exercise on lipodystrophy and **metabolic** changes in 120 people with HIV. They published their findings in the journal *Clinical Infectious Diseases* (36, p. 1593, 2003). Study participants completed questionnaires about their diet and exercise habits. These results show that diet and exercise can have a positive effect on some metabolic problems. While numerous dietary factors were studied, only vitamin E intake (from food and vitamin supplements) had any positive effect, including decreased amounts of body fat, possibly decreased insulin resistance, and improved blood pressure. Exercise led to

decreased levels of triglycerides (a type of fat that travels in the blood), but did not decrease cholesterol. Exercise also increased muscle mass and possibly decreased insulin resistance. Another study, published in the *Journal of Acquired Immune Deficiency Syndromes* (33, p. 605, 2003) reported that **antioxidant** supplements (vitamin E, vitamin C, and N-acetyl cysteine) did not have a major effect on body fat changes in HIV+ patients with lipodystrophy (loss of body fat in areas such as the arms, legs, face, and buttocks). In addition, vitamin supplementation with these antioxidants was linked to increased insulin resistance, in contrast to the first study discussed above. However, this study was very small (10 patients) and sensitive imaging techniques, such as **MRI** or **CT** scans, were not used to measure changes in body fat.

A better way to measure lipodystrophy

A recent report in the journal *AIDS* (17, p. 1857, 2003) described 4 HIV+ patients with **lipodystrophy** who also had excess fat accumulation at the front of the neck. Currently, diagnosing the severity of lipodystrophy is difficult because both doctor and patient reports can vary. Machines that scan the body, such as computed tomography (**CT**) or dual-energy x-ray absorptiometry (DEXA), are more objective and less variable, but these scans can be expensive and the measurements they provide depend on the sex of the patient. This can be problematic since body fat composition differs considerably between men and women. In addition, fat loss of the face cannot be measured by these scans. A study in the *Journal of Acquired Immune Deficiency Syndromes* (33, p. 571, 2003) describes a scoring method, called the Lipodystrophy Case Definition

(LDCD) score that may provide a better way to diagnose and to measure the severity of lipodystrophy in both men and women. The LDCD score uses several different categories that account for age, sex, stage of HIV by Centers for Disease Control and Prevention (CDC) classification, length of time of HIV infection, cholesterol level, waist-to-hip size ratio, trunk-to-limb fat ratio, percentage of leg fat, and other measurements. When researchers tested the scoring method in 417 patients with lipodystrophy and 371 patients in a **control group** with no signs of lipodystrophy, the LDCD score proved to be very accurate. The use of a scoring method like the LDCD score will be very helpful for large studies so that scores can be compared to one another more accurately.

CMV-related disease: The pros and cons of HAART



Cytomegalovirus (CMV) is a common co-infection in HIV+ people and can lead to serious and even fatal **opportunistic** disease of the eye, colon, esophagus, and brain. While the occurrence of CMV-related organ disease has dramatically decreased since the introduction of powerful combination HIV therapy (also known as highly active antiretroviral therapy or HAART), it still affects HIV+ patients. A recent study, published in the journal *Clinical Infectious Diseases* (37, p. 567, 2003) wanted to find out which HIV+ patients were still at risk for developing CMV-related organ disease in the HAART era (roughly since 1996). Researchers examined 403 HIV+ people and found that CMV-related organ disease and death tended to occur in patients with low T cell counts and high viral loads. In addition, higher levels of CMV **DNA** in the blood also made a

patient more likely to have organ disease or to die of organ disease. The researchers recommend screening for CMV DNA levels in HIV+ patients with low T cell counts and high viral loads because medications may stabilize the CMV infection and lessen the chances of getting CMV-related organ disease.

On the flip side, HAART can cause immune recovery, which is typically a “good thing;” however, this can lead to conditions such as “uveitis” or inflammation of the eye. A separate study, published in the *British Journal of Ophthalmology* (87, p. 853, 2003), examined 63 patients with CMV-related retinitis (inflammation of the retina of the eye) that had been previously treated and had healed. Unfortunately, in many of these patients, HAART also caused a variety of other inflammatory conditions, including **cataract** and **glaucoma**, which led to moderate to severe loss of vision.

The safety of STIs

Recent studies have examined structured treatment interruptions (STIs) to see if they are safe and if they benefit HIV+ patients. Giving patients a break from HIV drugs was thought to decrease drug side effects and give the immune system a chance to recover and to better fight HIV. Two recent studies show that STIs are not beneficial and could even be dangerous. One study, published in *The New England Journal of Medicine* (349:9, p. 837, 2003), examined the effect of STIs in 270 patients who had **multi-drug resistant HIV** and needed to switch HIV drugs (HAART) to try and control the virus. Patients were divided into 2 groups: those who immediately began a new drug combination and those who stopped taking HAART for 4 months before beginning a new drug combination (STI group). Researchers thought that a treatment interruption would cause the virus to switch from a drug-resistant form to a one that was more “natural” and sensitive to HAART. While this happened for many of the patients in the STI group, more patients experi-

enced a worsening of their HIV disease, including lower T cell counts and higher viral loads, compared to those patients who continued on treatment without an interruption.

Another study, published in the *Journal of Infectious Diseases* (188, p. 388, 2003), followed patients divided into 2 groups: those who received HAART continuously and those who participated in a treatment interruption (stopped taking drugs for 4 weeks and then received HAART for 8 weeks). This study was stopped early because 5 patients in the STI group developed drug-resistant HIV. No patients who received continuous HAART developed any drug resistance. Overall, the treatment interruptions had no benefit on the patient and there were no significant differences in blood fat levels, liver function, T cell count, or viral load, compared to the patients who received continuous HAART. The development of drug-resistant HIV in these patients shows that STIs could endanger future treatments in these patients.

FDA Bits

◆ **FDA approves 2 HIV drugs.** This summer, the Food and Drug Administration (FDA) approved 2 new drugs to help treat HIV. Each drug is taken once daily in combination with other HIV drugs. Emtriva is a nucleoside reverse transcriptase inhibitor (NRTI or nuke). The second drug, Reyataz, is a protease inhibitor. For more information, such as important drug interactions and possible side effects, see The CFA's fact sheets on Emtriva and Reyataz at www.centerforaids.org/rita/facts/emtriva.pdf and www.centerforaids.org/rita/facts/reyataz.pdf.

◆ **Boost Reyataz if taken with Viread.** Recent studies have shown that when the protease inhibitor Reyataz is taken with Viread (another HIV drug), Reyataz levels decrease, making it less effective at controlling HIV. If Reyataz and Viread are taken together in an HIV drug combination, the Reyataz dose should be **boosted** with another protease inhibitor called Norvir. For more information, see The CFA's fact sheets on Reyataz and Viread at www.centerforaids.org/rita/facts/reyataz.pdf and www.centerforaids.org/rita/facts/viread.pdf.

◆ **New information on Viread.** New precautions have been added to the labeling for the nucleotide reverse transcriptase inhibitor, Viread. In clinical studies, patients taking Viread experienced bone loss (lower bone density). Also, patients with kidney problems should take Viread less often than the usual one time per day (consult with your doctor). Viread can be taken with or without a meal.

Early response to HAART means longer survival

The majority of patients who have had long-term viral control during the first 18 months of combination HIV therapy (also known as highly active antiretroviral therapy or HAART) are still alive 5 years later, compared to patients who had viral rebound or who did not respond to treatment, according to a study published in the *Journal of Acquired Immune Deficiency Syndromes* (33, p. 321, 2003). The researchers also examined cases of **diabetes** and hyperlipidemia (excess fat or lipids in the blood), conditions that are risk factors for heart disease and linked to the use of HAART. They found that the longer a patient received HAART, the more likely they were to develop these conditions. As a result, patients who achieved and maintained viral control developed these conditions more frequently because they consistently received HAART for longer periods of time.

SWATCH

The idea of alternating HIV drug combinations is not new, but usually patients switch to a new combination after their virus becomes resistant to the first set of drugs. The SWATCH study (**SW**itching **A**ntiviral **T**herapy **C**ombination against **H**IV-1) examined what would happen if patients switched drug combinations before their current drugs actually stopped working. This study, published in the *Annals of Internal Medicine* (139, p. 81, 2003), examined 161 patients who had never before received highly active antiretroviral therapy (HAART). Patients either continuously received the same HAART **regimen** or switched between 2 different HAART regimens every

3 months. The researchers found that patients who switched regimens experienced viral rebound less than the patients who stayed on the same HAART. Factors such as T cell count, side effects, quality of life, and ability to take the drugs were the same for all of the patients, regardless of what treatment they received. However, these results must be interpreted with caution because the HIV drugs available today are better than those used when this study was done. In addition, the study did not examine the long-term effects of alternating treatment and how this switching approach might affect the course of HIV disease as well as death rates.



Fehmida Visnegarwala, MD, lends her expertise to questions from people living with HIV.

Q: I am a 44-year-old male and have had HIV for 8 years. I have always been on combination HIV drugs, but have switched around a lot because of side effects or better (simpler) drugs coming along. Right now, I am on Videx, Epivir, and Sustiva. I get bad leg cramps pretty frequently and sometimes feel weak in my arms. Is this anything I should worry about?

A: You should worry about both your symptoms. Your leg cramps are associated with high-frequency signals from nerves that usually last for seconds or minutes. Stretching the muscle may make it better. Muscle cramps can be caused by dehydration, low sodium in the body, kidney failure, or low thyroid activity. However, the most common cause of your cramps is **peripheral neuropathy** most probably caused by taking Videx. HIV disease itself and drugs such as Videx (ddI), Zerit (d4T), and Hivid (ddC)—the “d drugs”—are known to cause “distal symmetric peripheral neuropathy” (DSPN). This usually affects the feet first and then gradually climbs up the legs and then involves the hands and arms. DSPN caused by HIV usually gets better when HIV treatment is begun, but often there are other underlying causes such as heavy alcohol use, **diabetes**, or kidney failure that must be addressed. The DSPN caused by HIV medications is thought to be related to the **toxicity** of these drugs in nerves. The diagnosis of DSPN can be made using specific tests. However, your doctor will likely look for decreased or absent ankle reflex (done with a knee hammer) and/or vibration sense (done with a tuning fork).

The weakness in your arms is a little more worrisome and suggests you may have a local problem in your neck, which can be ruled out with an imaging study (**CT** or **MRI**) of the neck. If the above is normal, then an “electromyography” test may help diagnose the problem, whether it is chronic inflammatory demyelinating polyneuropathy (CIDP), Guillain-Barré-like syndrome (sometimes associated with the use of d drugs), and/or mononeuritis multiplex (see the following question). If Guillain-Barré-like syndrome is suspected, then the Videx needs to be discontinued. The management of DSPN will include drugs such as tricyclic antidepressants, or gabapentin (brand name: Neurontin) and pain management. L-carnitine (1500 mg 3 times a day) has been shown to help in some studies.

Finally, it may be useful to check the level of lactic acid in your blood. For this test, blood must be drawn correctly: do not do any vigorous exercise the day before, come in fasting, and rest in the waiting room for at least 20 minutes. Your doctor or nurse must make sure blood is drawn without the use of a tourniquet and

immediately placed on ice and transported to the lab within 20 minutes. **Lactic acidosis** may be associated with fatigue and weakness, as well as cramps, rapid breathing, nausea, belly pain, diarrhea, and tingling or pricking sensations on the skin.

Q: My T cells have recently slid to 314 and I am considering therapy for the first time. I heard that I should take HIV drugs that are from at least 2 or 3 different “families.” Is this true?

A: If you have had a stable CD4 for a long time and your viral load is less than 50,000, and you have no symptoms such as weight loss, fevers, chronic diarrhea, or enlarged glands, then the first thing to do is 1) confirm that your T cells are still less than 350 AND 2) make sure you feel truly ready to get on therapy. If so, then you should talk to your doctor about HIV drugs. The decision to start HIV therapy in someone like you (who is not acutely ill) should never be hasty. Starting HIV treatment will mean taking every dose of your drug everyday without missing a single dose for a very long time. If you do not adhere to your medications, it is likely that your virus may accumulate **drug-resistance mutations** and eventually not respond to the drugs you are on. This would require changing that **regimen**, which usually means more pills, more side effects, and even less chance of successfully controlling the virus.

So if you are ready to start and we have confirmed that your T cell count is indeed less than 350, we should talk about your drug options. The goal of HIV therapy is to get the HIV viral load under 50 within 12 to 24 weeks and keep it there as long as possible. The current US government treatment recommendations for a preferred first-line regimen are to combine drugs from 2 classes: either a boosted protease inhibitor (Kaletra) OR Sustiva plus any 2 nucleoside reverse transcriptase inhibitors (nukes). Certain nukes should not be combined, such as Retrovir/Zerit, Videx/Zerit, and Ziagen/Viread. The triple nuke regimen of Trizivir (Ziagen, Epivir, and Retrovir in 1 pill) is not recommended if your viral load before starting therapy is more than 100,000. Also, there is more doubt about the strength of this regimen because all the drugs are from 1 class; an advantage is the low pill burden (1 pill twice a day).

Currently, there is no favorable information for treating with 3 classes of drugs. In fact, it may be dangerous because it could increase **toxicity** and decrease **adherence**. Besides the preferred regimens described above, there are several alternative drugs that are effective. HIV therapy must be individualized based on many factors such as patient lifestyle, pill burden, future drug options, drug toxicities, patient cardiovascular risk, costs, etc.



Q: After a long period (8 months) of chronic pain almost everywhere, a doctor told me I may have mononeuritis multiplex. What exactly is this and is it related to my HIV or HIV drugs? I am an African American female, 28 years old, and am taking Viramune, Zerit, and Epivir.

A: Mononeuritis multiplex (MM) is uncommon and often difficult to diagnose. A diagnosis would need to be confirmed with an “electromyography and nerve conduction test,” where small needles are placed in your muscle and a small amount of electrical current is given to check your nerves. Mononeuritis multiplex involves the large nerves and develops over months to years. The most common causes of this disorder are low blood supply (involving small blood vessels that feed the nerves) or “demyelination” (loss of the insulation around the nerves). In HIV, the MM usually occurs early in disease state, though in patients with advanced disease this syndrome has been associated with CMV disease. In those with early disease, the cause is thought to be an autoimmune process (the immune system is reacting to some of the body’s own proteins). It is unlikely that your symptoms are caused by your HIV drugs. Zerit and most nukes can cause peripheral neuropathy, but this is not related to MM.

Since you are African American woman there is a small chance that you may have “sarcoidosis,” which may present with MM. If your doctor has not found any other symptoms then it is unlikely. If you have chronic hepatitis C, then a related condition called “cryoglobulinemia” may lead to MM. If not done already, it will be important to be checked for diabetes. The good news is that you may not need to change your therapy and even though you are dealing with a lot of pain, MM usually resolves on its own over time. Many patients with MM experience a lot of weakness associated with this disease. Pain management and not overexerting yourself are the mainstays of treatment. A vitamin B-12 shot and taking vitamins daily might be a good idea as well.

Q: Is there a relationship between high triglycerides and high blood sugar? I have both of these and have been on HIV medications for 6 years. Will this get worse? I am taking Glucophage for the high blood sugar, which my doctor says is early diabetes. I am a 38-year-old, white male, 5’10” and 180 pounds.

A: There is a definite relationship between high triglycerides and high blood sugar. Triglycerides are fat particles produced by absorption from the gut after eating; they can also be produced in the liver. These are broken down into smaller particles by a substance in the body called “lipoprotein lipase,” which needs insulin for its action. So, when there is lack of insulin (as in diabetes) these fat particles are not chewed up and therefore float around in the blood leading to high triglycerides. There are other related **metabolic** problems, but this is a rather simple explanation of a very complex interaction that occurs in the body.

You have been on HIV medications for 6 years. I wonder if this has included protease inhibitors (PIs). There is a known link between new or worsening diabetes in patients treated with PIs. This is related to the development of **insulin resistance** caused by these drugs. Insulin resistance means that if your body normally needed 20 units of insulin to digest all the sugar that you absorbed after eating a fast food hamburger, you may now require 80 units to digest the same amount of sugar. You need more insulin to do the same work. High triglycerides, insulin resistance, high blood pressure, low HDL (“good”) cholesterol, and central obesity (fat in the gut, resembling a pear shape) are all linked to the “metabolic syndrome” or “syndrome X.” Having syndrome X and insulin resistance is bad over the long term. It is a risk factor for future cardiovascular events such as heart attacks and strokes.

So first things first: if you are on a PI, then you should be switched, if possible, to regimen containing a non-nuke (like Sustiva or Viramune) or to a triple nuke regimen (like Trizivir). Medical studies have shown that diabetes gets better and may even reverse when you stop taking PIs. If you are unable to switch from PIs, then perhaps switching to Reyataz is an option because it affects fats and insulin less than other PIs.

Among the drugs used for diabetes, metformin (brand name: Glucophage) is known to reduce insulin resistance. However, it carries a small risk of lactic acidosis, which could be a problem if you are using either Zerit or Videx. The other class of drugs that might help manage your diabetes is the insulin-sensitizing drugs. These include rosiglitazone (brand name: Avandia) or Pioglitazone (brand name: Actos). These drugs not only have the advantage of treating insulin resistance but actually may improve HIV-associated **lipodystrophy**.

Besides drug treatment, the 2 cornerstones for management of diabetes and syndrome X are diet and exercise. Your ideal body weight is around 150 pounds. So a well-controlled diet with a nutritionist’s help will be extremely important. Detailed dietary recommendations can be found on the American Diabetes Association website (www.diabetes.org). Regular exercise not only will help your diabetes control, improve your weight control, and decrease your risk of heart attack, but will also decrease your risk of osteoporosis (brittle bones), which is an important complication of HIV disease and/or HIV therapy. If you have not been in an exercise program, starting a program such as brisk walking, jogging, cycling, or swimming for about 25 to 45 minutes several days a week will help. You may need medical clearance to join a more intensive exercise program such as the Houston Body Positive Wellness Program (www.montrose-clinic.org/BodyPos.htm).

Fehmida Visnegarwala, MD, is an assistant professor of medicine at Baylor College of Medicine, and the Director of Education and Research at Houston’s Thomas Street Clinic.

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



We all suffer from what has become known as TMI—too much information. Our televisions, magazines, newspapers, computers, cell phones, fax machines, etc. have provided us with TMI. This includes the area of HIV treatment. One reason there is so much information is because there is a lot happening. Much research is being done worldwide, including the development of promising new drugs in the “pipeline.” Some large-scale studies are underway, such as “SMART” (Strategies for Management of Anti-Retroviral Therapy) that will provide invaluable answers about crucial treatment issues. “SMART” and other studies will help answer the most important question we have: “How do we best use the HIV drugs available to increase the lifespan of people with HIV/AIDS?”

To look at this question, there are a couple of reference points that may come in handy. First, relative to other diseases the world has faced, the treatment of HIV infection is now just approaching its “adolescence.” What I mean is that when doctors treat other diseases (for example, cancer, **diabetes**, or heart disease), they have 30 or more years of studies to guide their treatment decisions. With HIV, we are just starting to get good information about patients treated for 8 years or more. Secondly, the challenges that face the physician specializing in HIV are formidable. For its community forums, The Center for AIDS recruits the “best and the brightest” HIV-treating physicians. I’m amazed at their honesty when they simply have to answer a question with, “I don’t know.” I have such respect for these physicians and their impossible task of overseeing HIV treatment.

Further complicating treatment decisions are the HIV treatment “philosophies” that seem to change almost as often as the weather. Some of these have been developed as the result of sound research, such as the switch from “hit hard, hit early” to “monitor and wait to treat.” Others, despite being widely known thanks to the Internet and other media, are not nearly as well founded.

In the last few weeks, you may have seen information regarding the triple nuke medication Trizivir, the single pill that combines Retrovir, Epivir, and Ziagen. Information distributed through a press release and advertisements from the Los Angeles-based AIDS Healthcare Foundation included a bold headline proclaiming, “Trizivir is Dangerous.”

We were stumped. The FDA doesn’t approve drugs that are “dangerous.” Do they often approve drugs that are difficult to take? Yes. What about drugs that have side effects? Yes. What about drugs that have varying levels of effectiveness in treating HIV? Yes. Anyone taking HIV meds know that there are benefits and pitfalls for each pill that is popped. The problem is this: in the midst of our “information overload,” we see such news reports and immediately think, “Oh my God, my doctor doesn’t know what he’s doing and is trying to kill me!” Newsflash: that’s not what’s happening.

Trizivir has been approved as a combination medication since November 2000. Its component drugs Retrovir, Epivir, and Ziagen have been in use since 1987, 1995, and 1998, respectively. Of course there are limitations to this medication. Everyone should be aware of the side effects from each of the drugs contained in Trizivir, some of which can be serious (including “hypersensitivity,” a dangerous kind of allergic reaction to Ziagen). Additionally, Trizivir isn’t the biggest bully against HIV on the medication playground—it is not the best (most powerful) treatment if you have a viral load of over 100,000. That said, there is a place for this medication in the spectrum of treatment options available for people with HIV. It definitely is an option for some people with HIV; that is something to work out with your doctor.

Do its limitations make Trizivir “dangerous?” Hardly. Should you use common sense when reading medication package inserts for HIV drugs, as well as press releases or advertisements issued by AIDS Healthcare Foundation? Always!

OCTOBER

- 23 Case manager training – treatment update**
9:00-11:30 am
1407 Hawthorne Street
713-527-8219 ext. 108 to register
- 28 Journal Club**
Noon at The Center for AIDS
1407 Hawthorne
Brown bag lunch

NOVEMBER

- 6 Conversations at The CFA**
Update on Women and HIV
1407 Hawthorne Street
713-527-8219 ext. 108 to register

DECEMBER

- 11 Journal Club**
Noon at The Center for AIDS
1407 Hawthorne
Brown bag lunch
- 18 “Get to Know The Center for AIDS” breakfast**
713-527-8219 ext. 103
for more information
- 20 Case manager training – HIV treatment update**
9:00-11:30 am
1407 Hawthorne Street
- 27-28** The Center for AIDS will be closed for Thanksgiving

- 1 World AIDS Day**
- 16 The Center for AIDS annual Holiday Schmooze benefit**
6-8 pm
For ticket information
contact 713-527-8219.

December 22, 2002 - January 4, 2003

The Center for AIDS will be closed for the holidays

CLINICAL TRIAL INFORMATION

Baylor College of Medicine

Researchers are looking into ways fat cells and fat **metabolism** are different in people with HIV. Studies can offer compensation (\$) and free parking to eligible participants. All lab work and tests are free. Contact Dr. Khaleel Rehman if you are interested or would like more information: 713-441-1654 (phone) or 281-952-3713 (pager). The following are 3 studies that are currently enrolling.

■ If you have been recently diagnosed with HIV and have never before taken HIV medications, you might be eligible for a 2-day study looking at fat breakdown in the body. The study involves 2 one-day admissions to the Clinical Research Center (CRC) at The Methodist Hospital in Houston's Texas Medical Center.

■ People with **lipodystrophy** have problems with fat metabolism. Leptin is a substance in the body that helps control fat breakdown. Levels of leptin may be low in some people with HIV. Patients with HIV and low leptin levels are eligible to participate in a study looking at the effects of leptin treatments (given by injection) on fat metabolism. A 2-hour screening is needed to measure leptin levels. If you qualify and decide to participate, 3 visits to the CRC will be required: before starting leptin, 2 months after starting leptin, and 4 months after starting leptin.

■ If you have been recently diagnosed with HIV and have never before taken HIV medications, you might consider participating in a study that will look at genetic changes in fat cells before and after starting HIV medications. Two visits to the Outpatient Department of Ben Taub Hospital are required to take fat cell samples under local anesthesia—before starting HIV therapy and then 6 months later (whether HIV medications were started or not).

Galveston

The AIDS Clinical Trials Unit (ACTU) at The University of Texas Medical Branch (UTMB) in Galveston is conducting several clinical trials. A few of these are listed below. For more information, contact the ACTU at 409-747-0214 or toll free at 877-324-2288.

■ ACTG A5163: Bone loss is a problem associated with HIV infection and possibly HIV treatment. This study will look at the effectiveness of alendronate (brand name: Fosamax) plus calcium and vitamin D for treating bone loss in people with HIV. To participate in this study, you must have a viral load less than 1000, a T cell count greater than 100, and be on HIV medications for at least 12 weeks with good virus control. Also, you should

not plan on changing your diet or exercise habits for the 48 weeks of the study.

■ ACTG 5093: Depo-medroxyprogesterone or DMPA (brand name: Depo-Provera) is a **hormone** treatment for women that helps regulate the menstrual cycle and is sometimes used for birth control, among other purposes. This study will look for possible drug interactions with HIV drugs. To participate in this 12-week study, females with HIV must have a viral load less than 10,000 and T cells greater than 200. Also, you cannot have taken DMPA within 180 days before the study, and you cannot have been through menopause. DMPA, but not HIV medications, will be provided for this study.

■ ACTG A5127: This study will look at the treatment of hepatitis B in HIV+ patients for whom Epivir will not work because of hepatitis B drug resistance. Participants will be given adefovir (brand name: Hepsera) or Viread to treat the hepatitis B. You must be co-infected with HIV and hepatitis B, with an HIV viral load less than 10,000 and a hepatitis B viral load more than 1 million. You cannot have hepatitis C or hepatitis D. You should be taking HIV therapy with good virus control; you should not be taking Ziagen (which is also in Trizivir).

Montrose Clinic

The following studies are enrolling at the Montrose Clinic in Houston.

■ GS-01-934: This 48-week study will look at an HIV treatment **regimen** of Viread, Emtriva, and Sustiva compared to Combivir and Sustiva. To participate, you must have never before taken HIV medications. You must also have a viral load greater than 10,000 and not have any kidney, liver, or bone problems. Also, you cannot have had an AIDS-defining condition within 30 days of starting on the study. For more information, contact Rick Witt at 713-830-3013 (ext. 521).

■ ZEST-QD: The ZEST study will see if HIV+ patients with undetectable viral loads (less than 50) can be switched from a twice-daily (or more) HIV medication regimen to once-daily treatment using Zerit XR, Epivir, and Sustiva. To participate in this study, you cannot be or plan to be pregnant or breastfeeding. You cannot have hepatitis or an active AIDS-defining condition. Also, you should have never before taken a non-nuke (Sustiva, Viramune, or Rescriptor). Other criteria apply. For more information, contact Mark Mall at 713-830-3018 (ext. 520).

BOTTOM LINES

TRIPLE NUKE NIGHTMARE

Last July, an Important Drug Warning was issued to healthcare providers concerning a high rate of virologic failure with a once-daily, 3-drug combination of Viread, Epivir, and Ziagen. Data from study ESS30009, which compared Sustiva versus Viread in combination with once-daily Ziagen/Epivir, revealed poor performance in patients taking Viread plus Ziagen/Epivir arm. Data from a pilot study presented at the 2nd IAS Conference in Paris also indicated a high rate of failure (inability to lower viral load and to keep it undetectable) with this combination. The warning recommended that this combination not be used in HIV+ patients and that patients experiencing good control of virus on this therapy should be closely monitored. Changing or strengthening treatment should be considered in these patients. The warning also recommended close monitoring of patients using this triple-drug combination with any other HIV drugs. Because the combination of Viread and Epivir has been widely used already, the problem is likely between Viread and Ziagen. Researchers from Gilead (maker of Viread) and GlaxoSmithKline (maker of Epivir and Ziagen) are working to try to determine the reason behind this “perfect storm” of a bad HIV regimen. In addition, at the time this issue of *HIV Treatment ALERTS!* went to press, a “Dear Healthcare Professional” letter was issued by Gilead warning about the once-daily combination of Viread, Videx, and Epivir.

BOTTOM LINE: Avoid therapy that is made up of all nucleoside reverse transcriptase inhibitors (“nukes”). The one possible exception right now is Retrovir, Epivir, and Ziagen (available in one pill as Trizivir), but even this combination is considered weaker than other options using non-nukes or protease inhibitors (see “Bottom Lines” in May 2003 issue of *HIV Treatment ALERTS!*) If you are taking a triple-nuke HIV regimen, talk to your doctor immediately about the possibility of switching to another combination—even if the current combination is working for you.

US GUIDELINES UPDATED

The *Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents* is published and updated by the US Department of Health and Human Services (DHHS). The Guidelines Panel is made up of researchers, physicians, community advocates, and other experts who meet regularly to review the guidelines, incorporate new knowledge, make changes, etc. The latest round of updates happened in July. The most striking change was the removal of a Chinese-menu-style list of HIV medications from which a doctor could choose a main “anchor” drug (a protease inhibitor or non-nuke) and two “background” drugs (usually nukes) for treating a patient. This was replaced with the actual recommendation of preferred regimens. The two preferred regimens were either:

1. Sustiva + Epivir + (Zerit or Viread or Retrovir), or
2. Kaletra + Epivir + (Zerit or Retrovir)

Alternative regimens were also listed under each preferred regimen. This marks a major change in philosophy for the DHHS guidelines, which have undergone other changes over the years such as recommending to wait until 350 T cells or lower to consider HIV treatment and that treatment definitely be started at 200 T cells or lower. (These thresholds were much higher just a few years ago). The 96-page guidelines document offers a great deal of information and is available online at www.aidsinfo.nih.gov/guidelines.

BOTTOM LINE: HIV treatment must be individualized to take into account disease stage, co-infection, gender, age, other health conditions, etc. There is no universally perfect HIV regimen, and each medication has its good and bad points. Just because you are not on a “preferred” regimen does not mean you aren’t being treated for HIV effectively. Talk to your healthcare provider about any questions you might have concerning HIV treatment.

definitions

Adherence: how well someone takes medication as directed, with respect to number and timing of doses.

Antioxidant: certain vitamins and other substances that provide protection from the damage caused by “free radicals,” which are created as a result of oxygen reactions in living tissues.

Boosted: elevated levels of drug in the body.

Cataract: a clouding of the lens of the eye resulting in poor vision.

Control group: 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 (or “placebo,” see below) might be compared to an experimental group that gets a real medication to see what the effects of the medication are.

CT: a scan showing a sectional view of the body and created by “computed tomography” (CT), also known as “computer-assisted tomography” (CAT).

Diabetes: a disorder involving insulin (a substance in the body that helps regulate blood sugar) that results in too much sugar in the blood and urine. Symptoms include hunger, thirst, weight loss, and frequent urination.

DNA (deoxyribonucleic acid): the genetic material that is found in all living things.

Drug-resistance mutation: a genetic change (mutation) that allows HIV to reproduce itself in the presence of an HIV medication.

Dyslipidemia: abnormal levels of lipid (fat) in the blood.

Glaucoma: an eye disease where increased pressure in the eye causes damage and loss of vision.

Hormone: a substance secreted by one part of the body that stimulates cells in another part of the body (for example, testosterone).

Incontinence: loss of bladder or bowel control.

Insulin resistance: decreased sensitivity to insulin that is associated with diabetes (see above).

Lactic acidosis: a build-up of lactic acid in the body. Lactic acid is a substance in blood and muscle produced by the body when it is processing sugar for energy (usually when exercising or if oxygen levels are low).

Lipodystrophy: changes in body fat such as loss of fat in the arms and legs and accumulation of fat in the gut or at the back of the neck.

Metabolism (metabolic): chemical reactions in the body that are part of life; for example, turning food into energy or breathing in oxygen and breathing out carbon dioxide.

MRI: magnetic resonance imaging, a non-invasive technique that creates a computer-generated image of the body.

Multi-drug resistant HIV: virus that has changed (mutated) genetically so that it is able to reproduce itself in the presence of several HIV medications.

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

Peripheral neuropathy: damage to peripheral nerves (such as those in the arms and legs) resulting in muscle weakness, pain, and numbness.

Placebo: sometimes just the act of taking a pill can make someone feel better; so, to watch for this, a placebo (a pill or substance with no effect, such as a sugar pill) is often used to compare with a real medication to see what the medication’s true effects might be. This would typically be used in a **control group** (see above).

Regimen: a combination or schedule of medications.

Subcutaneous: under or into the skin.

Toxicity: a poisonous or damaging effect on the body.



Useful Resources

The Well Project is a company conceived, developed, and administered by HIV+ women and those who work with them every day. The site features discussion groups, a women’s center, and much more. www.thewellproject.com

Project Vote Smart: with elections coming up and the many battles being fought over HIV/AIDS (ADAP, research funding, censorship of prevention messages, etc.), now would be a good time to look up how your elected officials have been voting and contact them to either thank them or complain accordingly. www.vote-smart.org

AIDS Treatment Data Network offers fact sheets, listings of expanded access and drug assistance programs, ADAP updates, and more. www.atdn.org

HIV/AIDS resources page from the National Library of Medicine. <http://sis.nlm.nih.gov/HIV/HIVMain.html>

Educational brochures, training materials, and more are available from the AIDS Education and Training Centers (AETC) National Resource Center. www.aids-etc.org

The Centers for Disease Control and Prevention (CDC) National AIDS Hotline. www.ashstd.org/nah, 800-342-2437 (English), 800-344-7432 (Spanish)

COMMUNITY SPOTLIGHT

Houston Area Community Services, Inc. (HACS) is a minority-focused, non-profit, community-based agency that provides health, social, and advocacy services to individuals and families within Houston and surrounding counties. HACS places a special emphasis on providing services to communities of color. HACS assists persons who are at risk for HIV infection or who are living with HIV/AIDS by offering services necessary to maintain or to improve overall quality of life.

SERVICES:

- ➔ Case management/care coordination
- ➔ HIV testing and counseling
- ➔ Prevention care for HIV and Hepatitis C
- ➔ Mental health counseling
- ➔ Education on medical management of HIV
- ➔ Housing coordination services
- ➔ Outpatient medical services (Joseph-Hines Clinic)
- ➔ Programs and services for youth

CONTACT INFORMATION

Location: 3730 Kirby (main office)
1710 West 25th (Joseph-Hines Clinic)
Houston, Texas

Phone: 713-526-0555 (main office)
713-426-0027 (Joseph-Hines Clinic)

Web: www.hacstxs.org

The above information was accessed from the HACS website in October 2003.

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