

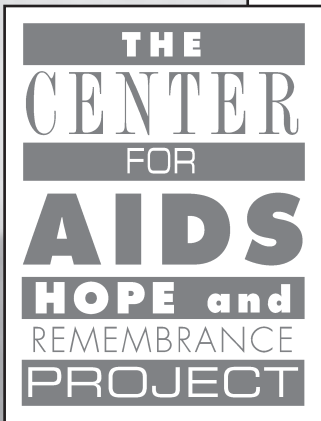


treatment

OCTOBER 2004

ALERTS!

inside:



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A word or two from the editor



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A quick introduction to a class of drugs that may be a true "next-generation" therapy



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DEFINITIONS & USEFUL RESOURCES

The name says it all . . .

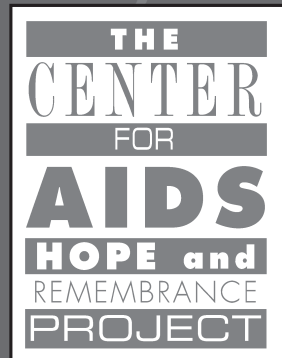


COMMUNITY SPOTLIGHT

Find out about the Houston Buyers Club for vitamins, nutritional supplements, and more

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. The Center acts as a catalyst for the creation and the establishment of innovative HIV/AIDS research in Houston and advocates for the entire affected population, ensuring that Houston's regional needs are factored into the national dialogue about HIV/AIDS."



About *HIV Treatment ALERTS!*

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

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

The CFA also publishes *Research Initiative/Treatment Action! (RITA!)*. *RITA!* is a literature-review journal that covers issues in HIV research and policy. This and other publications are available on The CFA website or can be requested by mail (see contact information below). CFA publications are supported in part with unrestricted funding from AIDS Walk Houston 2004, AIM Investments, CFP Foundation, Gilead Sciences, and GlaxoSmithKline. Publications funding from Abbott Laboratories was received in 2003, but was not sought in 2004 in protest of the company's Norvir pricing policy.

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It's election time. Four years can be a very long time, and much has happened in the world since the last presidential election. HIV/AIDS is no exception. In the last 4 years, millions more people have become infected worldwide, and thousands of people continue to die of this disease every day. In the US, a growing population of people living with HIV/AIDS, coupled with capped or even dwindling funding to ensure them lifesaving medication and care, have put many hundreds of people on waiting lists to receive medications. Rumors persist that eventually the Ryan White CARE Act will not be renewed, effectively dismantling an essential support network for the families and individuals who continue to be devastated by this disease every day.

The gains that were achieved after the deaths and struggles of so many stand to be eroded as many of our elected leaders fall victim to continuing indifference, insensitivity, and ignorance about AIDS. Find out where the presidential candidates stand on AIDS at www.aidsvote.com. Find out about where candidates stand on a variety of issues at www.ontheissues.org. Information on elected officials, voting records, etc. can be found at www.vote-smart.org. As election day (November 2) nears, please let your voice be heard both locally and nationally by voting for candidates who are aware of the gravity of AIDS and are committed to doing something about it.

We cannot falter in the battle against AIDS. The future of humanity depends upon it.

Entry Inhibitors: Hope on the Horizon?

Entry. It's what must happen for HIV to infect cells. Blocking HIV entry means the virus does not get inside the T cell. The only approved medication that does this is Fuzeon, which must be injected into the skin twice daily. Even so, other HIV medications must be taken at the same time or else HIV becomes **resistant** to Fuzeon very quickly. So, what if there were other entry inhibitors? What if they could be combined together to block HIV entry and not allow resistance to develop as quickly? This may be possible in a few years if several new drugs now being studied turn out to be safe and effective. The entry inhibitor "pipeline" for treating HIV has just become more promising.

Although the drug candidates listed still have at least 3 to 5 more years of study ahead, some may eventually become new options for people with HIV/AIDS. These agents work in different ways: some bind to parts of HIV, while others bind to parts of the

T cell that HIV needs for entering the cell. Plus, some people think these drugs may have fewer overall side effects because they work outside of the T cells, unlike current medications that work inside of the cells. But, it's way too early to say that for sure. Keep your fingers crossed and read upcoming issues of *HIV Treatment ALERTS!* for further updates!

HIV entry inhibitors in early development

DRUG NAME	CURRENTLY GIVEN	COMPANY
AMD-070	By mouth	Anormed
AMD-887	By mouth	Anormed
PRO-140	By injection or infusion*	Progenics
BMS-488043	By mouth	Bristol-Myers Squibb
UK 427,857	By mouth	Pfizer
SP-01A	By mouth	Samaritan Pharmaceuticals
SCH-D	By mouth	Schering Plough
TNX-355	By infusion	Tanox
GSK(GW)-873140	By mouth	GlaxoSmithKline
PRO-542	By injection or infusion*	Progenics

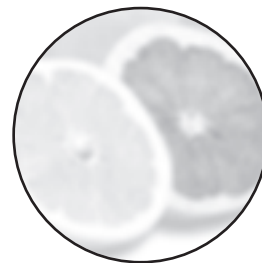
* infusion is when medication is given directly into a vein over a period of time.



Treatment News

STATINS to treat HIV?

Statins are a widely prescribed group of drugs used to treat high cholesterol. Sometimes, statins are also given to HIV+ individuals to treat **lipodystrophy**. A recent report in the *Journal of Experimental Medicine* (200, p. 541, 2004) describes how statins may actually fight HIV. Researchers initially did several studies in test tubes and mice showing that statins inhibited HIV infection. The researchers then examined the effect of one statin, Mevacor, in 6 patients with chronic and stable HIV infection who were not taking HIV medications. After taking Mevacor once a day for 1 month, all of the patients experienced a decrease in HIV viral load and an increase in T cells. These positive effects reversed once patients stopped taking Mevacor. The results suggest that different types of drugs, perhaps with fewer side effects than HIV medications, may be useful in the fight against HIV. However, this was a very small study and larger studies must be done to look at the effects of combining statins and HIV medications.



Grapefruit juice warnings continue

Many HIV+ individuals take statins to treat high cholesterol. This group of medications includes Zocor, Lipitor, Pravachol, Mevacor, Crestor, and Lescol. Unfortunately, some foods found in many refrigerators may interact with these drugs and could be dangerous. A report in the journal *Neurology* (62, p. 670, 2004) describes a 40-year-old HIV-negative woman who had been taking Zocor for high cholesterol for more than 2 years. After experiencing muscle weakness and pain for 10 days, she was diagnosed with a degeneration of skeletal muscle tissue called "rhabdomyolysis" (pronounced rab-doe-my-OL-i-sis). Evidently, the woman had eaten a grapefruit every morning for the last 14 days. Grapefruits and grapefruit juice contain a substance that increases the blood levels of some statins. In addition, this fruit can also interact with certain HIV medications. If you are taking a statin, check with your healthcare provider to find out more about potential drug interactions. Keep in mind that grapefruits and grapefruit juice could make any drug interactions between HIV medications and statins even worse.

Breast enlargement IN MEN

About 2% to 3% of HIV+ men have a condition called gynecomastia (pronounced guy-ni-ko-MAS-tee-uh), which means abnormal breast enlargement. This condition can also occur in HIV-negative men during puberty or when men are elderly or overweight. In addition, certain medications, including street drugs, can cause this condition. A study published in the journal *AIDS* (18:9, p. 1347, 2004) shows that the HIV medications Zerit and Videx may cause gynecomastia. When 47 HIV+ men with gynecomastia were examined, researchers found that a large percentage of these men were taking one of these drugs. However, another report published in *The Breast Journal* (10:3, p. 244, 2004) suggests a link between gynecomastia and the HIV medication Sustiva. The report describes 5 men with gynecomastia who were all taking Sustiva. Plus, the gynecomastia improved after the patients stopped taking Sustiva. While these 2 studies suggest that certain HIV medications could be responsible for gynecomastia, both studies were very small. HIV+ people who experience this type of side effect should discuss concerns with their healthcare providers.

New treatments for

PAIN

Neuropathy is a condition where people experience nerve damage, muscle weakness, pain, and numbness. Typically peripheral nerves, such as those in the arms and legs, are affected. Some types of HIV medications, particularly the nucleoside reverse transcriptase inhibitors (NRTIs or “nukes”) can make this condition worse. In HIV+ patients with this condition, blood levels of a natural substance called acetyl-L-carnitine (ALCAR) tend to be lower. In a study published in the journal *AIDS* (18, p. 1549, 2004), 21 HIV+ patients with HIV-related neuropathy took ALCAR by mouth twice a day for up to 33 months. Skin biopsies from the leg were taken every 6 to 12 months to assess nerve damage. For most of the patients, ALCOR lessened neuropathy pain and caused regrowth of nerves.

Acupuncture could be another potential treatment for neuropathy. This traditional Chinese therapy involves putting very thin needles into the skin at certain points on the body

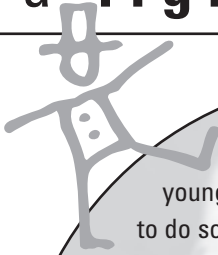
to produce energy flow. Though it is frequently used to treat chronic pain, its effect on HIV-related problems is unknown. In a study described in *The Journal of Alternative and Complementary Medicine* (10:3, p. 449, 2004), 21 patients with HIV-related neuropathy underwent 10 acupuncture sessions over a 5-week period. Patients reported a dramatic decrease in pain, aching, burning, tingling, and numbness.

In Houston, the American College of Acupuncture & Oriental Medicine (ACAOM) has partnered with Montrose Clinic to offer acupuncture to the clinic patients. ACAOM faculty members have begun treating patients with HIV/AIDS-related symptoms including neuropathy, depression, and other related disorders. Initial treatments have been very encouraging, with many experiencing relief of symptoms. For more information regarding ACAOM, visit www.acaom.edu. For more information about the Montrose Clinic, visit www.montroseclinic.org or call 713-830-3000.


TREATMENT for diarrhea

Excessive diarrhea and wasting are not that common in the US, but are major problems in developing countries. These problems can also cause decreased absorption of HIV medications into the body, resulting in virus that can become **resistant** to those HIV medications. A study conducted in Brazil and published in the journal *Clinical Infectious Diseases* (38, p. 1764, 2004) looked at 41 patients with AIDS who had diarrhea and/or wasting. Patients were randomly assigned (by chance, like flipping a coin) to receive a nutritional supplement or a **placebo** by mouth for 7 days. The supplement given was either glutamine or alanyl-glutamine, which is a more stable form of glutamine. This was a “double-blind” study, meaning that both patients and healthcare workers did not know which treatment each patient was receiving. Patients taking glutamine or alanyl-glutamine experienced less diarrhea and had higher blood levels of HIV medications compared with patients taking a placebo. These results show that taking glutamine (or alanyl-glutamine) in combination with HIV medications may help people with HIV/AIDS, especially in developing countries.

Giving kids a fighting chance



When to treat HIV+ infants and young children and how aggressively to do so are still unanswered questions. A recent study published in *The New England Journal of Medicine* (350:24, p. 2471, 2004) examined 3 different HIV **regimens** in 52 children. Children were grouped according to their age at the beginning of the study: 3 months or younger (considered “early therapy”) or older than 3 months (considered “delayed therapy”). While no serious side effects were seen with any of the combinations, the combination of Zerit, Epivir, Viamune, and Viracept suppressed HIV the best after 1 year and after almost 4 years of treatment. Researchers also found that treating children within 3 months of birth was better for suppressing HIV.

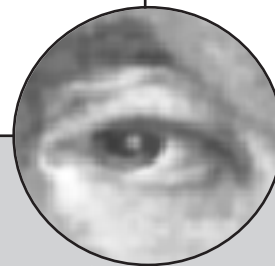




HIGH RISK of anal cancer

Anal cancer is a very real risk for HIV+ people, especially for men who have sex with men. In addition to HIV, human papillomavirus (HPV), a common sexually transmitted disease, also increases this risk. However, a recent study published in the journal *AIDS* (18, p. 1561, 2004) explains how other types of infections in the anus can also increase the risk of anal cancer. When researchers examined 199 men and women, both HIV+ and HIV-negative, they found that in addition to HIV and HPV, infections like herpes simplex virus, cytomegalovirus (CMV), Epstein-Barr virus, or gonorrhea increased this risk.

Typically, the "Pap" smear is used to identify abnormal cells that may indicate the development of certain types of cancer, including cervical and anal cancer. The cells are examined for abnormal changes referred to as "precancerous lesions," meaning that if they are not treated, these early lesions could develop into cancer. Another way to screen for anal cancer is to perform an anoscopy. This type of exam involves using a short lighted scope to look into the anal canal. A biopsy, or tissue sample, can then be removed and examined for abnormal changes. A study in the journal *Clinical Infectious Diseases* (38, p. 1490, 2004) examined 153 HIV+ and HIV-negative men who have sex with men and compared ways to detect these precancerous lesions. Researchers found that Pap smears, while cheaper to perform, were less accurate when compared with results from the biopsy. Any HIV+ person with an abnormal Pap smear should discuss having an anoscopy and tissue biopsy performed to rule out anal cancer or precancerous lesions.



CMV: a marker of disease progression?

Cytomegalovirus (or CMV, an **opportunistic infection**) is still a very real threat to HIV+ individuals, according to a study published in *The Lancet* (363, p. 2116, 2004). In this study, 374 HIV+ patients whose T cell count was less than 100 had their blood tested for CMV every 3 months. In fact, the researchers found that CMV in the blood was linked to a worsening of HIV disease or death, even in patients taking potent combination HIV therapy (also called HAART). CMV levels may predict whether HIV disease is getting worse and may be useful to identify patients at risk for disease progression. CMV is a fairly common type of herpes virus that usually only causes problems when the immune system is weak.

NIACIN

for dyslipidemia

Dyslipidemia (abnormal levels of fats in the blood) occurs in many HIV+ people and may be a side effect of HIV medications. The vitamin supplement niacin has been studied as a treatment for dyslipidemia, but it can cause side effects such as skin flushing and early signs of **diabetes**. However, a study published in the journal *Clinical Infectious Diseases* (39, p. 419, 2004) examined the effect of an extended-release form of niacin. This version of niacin may have fewer side effects because it is released into the body at a slower and more even rate. In this study, 14 HIV+ patients with dyslipidemia who were taking HIV medications took the extended-release niacin for 14 weeks. Patients also received nutritional counseling. Blood levels of cholesterol and triglycerides (a type of fat that travels in the blood) were dramatically lowered following the niacin treatment. In general, the extended-release version was safe and well tolerated. Some patients experienced skin flushing, but aspirin alleviated the flushing and symptoms typically stopped after 10 weeks of niacin treatment. However, some patients did have early signs of diabetes. The extended-release niacin may be option for HIV+ patients with dyslipidemia, but it may not be safe in patients with diabetes or early signs of diabetes.

Co-infection complications

Usual treatment for chronic hepatitis C is 6 months to 1 year of pegylated (longer-lasting) or standard interferon combined with ribavirin. Relapse (return) of hepatitis C virus (HCV) occurs in about 15% to 20% of patients who are HCV+ but HIV-negative. For patients co-infected with both HIV and HCV, the rate of relapse is unknown. In a study published in the journal *AIDS Research and Human Retroviruses* (20:4, p. 351, 2004), 58 co-infected patients who began the study with undetectable levels of HCV (after successful treatment) were followed to see if and when they relapsed. Within 6 months, 33% of the co-infected patients had relapsed, a number dramatically higher than for those patients who had just HCV. Because of these findings, the authors recommend that future studies examine treating co-infected patients for a longer period of time as a way to lessen the risk of relapse.

Recently, the New York-based HIV advocacy organization, Treatment Action Group, released a report titled, "Hepatitis C Virus (HCV) and HIV/HCV Coinfection: A Critical Review of Research and Treatment." This report reviews the **epidemiology**, transmission, diagnosis, and treatment guidelines for patients with hepatitis C and for patients co-infected with HIV and HCV. In addition, HCV drug development is discussed. This report is available online at www.aidsinfonyc.org/tag/coinf/hcv2004.

Triple PI therapy

for salvage

Researchers report in the *Journal of Acquired Immune Deficiency Syndromes* (36, p. 921, 2004) that an HIV treatment consisting of 3 protease inhibitors (PIs) may help salvage patients. These patients require new types of treatments because they have taken many HIV medications in the past and their HIV has developed **resistance** to these drugs. After 24 weeks, the combination of Invirase, Agenerase, and Norvir plus nucleoside reverse transcriptase inhibitors (NRTIs or "nukes") decreased viral load and increased T cell count. Diarrhea was a common side effect but was controlled with medications. Unfortunately, **adherence** was a major problem with this combination because patients had to take 13 pills twice a day, not including the nukes. In fact, 4 out of the 11 patients in this study dropped out because of poor adherence. However, with a new version of Invirase being developed and the recent re-creation of Agenerase as Lexiva, the pill burden may be significantly decreased, making this treatment combination easier to take in the future.

Get vaccinated

A study in the *Journal of Acquired Immune Deficiency Syndromes* (36, p. 869, 2004) reports the high rate of hepatitis B virus (HBV) in the HIV+ community in the US. When researchers examined blood samples from 240 HIV+ patients, they found that 65% of these patients had evidence of past or current HBV infection. In addition, 16% of the patients had evidence of "occult" HBV infection. This form of HBV is almost considered hidden because the infection is not detected with the standard tests and requires specific DNA tests to detect it. Occult HBV infection can cause serious liver damage. Importantly, many people with occult infection may not know they are infected and may spread the infection to others. These findings stress the importance of getting vaccinated for hepatitis A and B. (There is no vaccine

for hepatitis C). Vaccinations for both hepatitis A and B are available and recommended for people who are at high risk (men who have sex with men, injection drug users, and heterosexuals with a recent history of a sexually transmitted disease or multiple sexual partners). In addition, vaccination for hepatitis A is recommended for international travelers and persons with liver disease, including hepatitis C infection. However, according to a study in the journal *Clinical Infectious Diseases* (38, p. 1478, 2004) that examined the medical charts for 1071 HIV+ patients, only a third or fewer people received vaccinations for hepatitis A or B, and even fewer received the necessary number of vaccine doses. People at risk for getting these infections should discuss getting vaccinated with their healthcare providers.



BREATHING PROBLEMS

Pulmonary arterial hypertension (PAH) is a health condition where there is high blood pressure in the pulmonary artery, a major blood vessel in the lungs. Though somewhat rare, PAH affects HIV+ individuals more frequently than the general population and can be life-threatening. Symptoms of PAH includes shortness of breath (especially during exercise), chest pain, and fainting episodes. The exact cause of PAH is unknown, but it can sometimes be inherited from a family member. In addition, certain medications, particularly diet pills such as Fen-Phen (a combination of fenfluramine and phentermine that was taken off the market several years ago) may cause this condition. To make matters worse, treating PAH in HIV+ people is more complicated because many of the PAH medications interact with HIV medications. A drug called epoprostenol, combined with potent combination HIV therapy, may improve survival in those patients with PAH. HIV+ people who experience any of these symptoms should immediately contact their healthcare provider. As always, discussing any other drugs (over-the-counter, herbal, or prescription) with a healthcare provider is very important. Guidelines on PAH were published in the July 2004 supplement issue of the journal *Chest* (126:1).

Effects of smoking on CERVICAL CANCER RISK

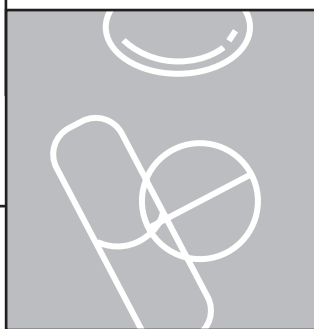
Smoking is known to be unhealthy, but a recent study shows that it may also increase a woman's risk of developing cervical cancer, especially if she is HIV+. This study, published in *The Journal of Infectious Diseases* (189, p. 1821, 2004), examined 1797 HIV+ women and 496 HIV-negative women for human papillomavirus (HPV), a common sexually transmitted disease that increases the risk of developing cervical cancer. Previous studies have reported that HIV+ women have HPV more frequently than HIV-negative women, but the current study showed that smoking also increases the chances of having HPV. As a result, the risk of HPV and cervical cancer is very high in HIV+ women who smoke. Other studies have shown that smoking has a negative effect on the immune system, and this study provides more evidence to support that.

The good news is that potent combination HIV therapy (HAART) is linked to regression, or improvement, of precancerous lesions in the cervix. HIV+ women are at a greater risk for developing these lesions and, if not treated, these lesions can develop into cervical cancer. A study published in the *Journal of the National Cancer Institute* (96:14, p. 1070, 2004) compared rates of cervical lesion regression before and after HAART became available several years ago. The researchers found that the chances of regression improved after HAART became available. In addition, higher T cell counts (probably as a result of HIV treatment) were linked to regression. However, the rate of improvement was still lower in HIV+ women compared with HIV-negative women. HIV+ women, even those taking HAART, should have regular gynecologic exams.

FUZEON

recommendations

Recommendations published in the journal *AIDS* (18, p. 1137, 2004) suggest taking the HIV medication Fuzeon only when T cell counts are over 100 and viral load is below 100,000 copies. The risks of pneumonia and skin reactions at the injection site must also be considered when taking Fuzeon. For more information, see The CFA's Fuzeon fact sheet online at www.centerforaids.org/rita/facts/fuzeon.pdf.



VIDEX+VIREAD interactions

The combination of the HIV medications, Videx and Viread, is linked to an increased risk of inflammation of the pancreas, according to a report in *The Lancet* (364, p. 65, 2004). For a variety of reasons, this combination may not be the best treatment for HIV in patients who have other options available. For more information, see The CFA's Videx and Viread fact sheets at www.centerforaids.org/rita/facts/videx.pdf and www.centerforaids.org/rita/facts/viread.pdf.

Pneumococcal disease:

Is it still a threat?

A study published in the journal *Clinical Infectious Diseases* (38, p. 1632, 2004) reported that even with the availability of potent combination HIV therapy (HAART), HIV+ individuals are still at risk for pneumococcal (pronounced new-moe-KAW-kul) disease. In fact, when researchers examined medical records from people treated at their hospital for pneumococcal disease between 1996 and 2002, they found that HIV+ people were 60 times more likely to get this potentially life-threatening disease compared with the general population. However, only one-third of the patients were being treated with HAART and most had a detectable viral load.

Getting vaccinated against pneumococcal disease is recommended for all young children and HIV+ individuals. However, some vaccines don't work in HIV+ people because of a suppressed immune system. A study published in the *Annals of Allergy, Asthma, and Immunology* (92, p. 558, 2004) examined 41 HIV+ children (taking HAART) and 95 HIV-negative children, all of whom received the pneumococcal vaccine. The HIV+ children did respond to the vaccine, as shown by increased levels of specific **antibodies**. The vaccine worked the best in HIV+ children with lower viral loads and higher T cell counts.

FDA Bits

Sculptra approved

In August, The Food and Drug Administration approved Sculptra, an injectable filler to correct facial **lipoatrophy** (loss of fat) in HIV+ people. Sculptra stimulates the production of the body's own skin proteins to help fill in where fat has been lost. Treatment with Sculptra may need to be repeated to maintain results. Common side effects include redness, swelling, and bruising at the injection site, as well as the possibility at the injection sites of developing small nodules that usually can be felt but not seen. Sculptra is very expensive and community members are working with Aventis/Dermik, the manufacturer, on a patient assistance program. Most health insurance companies do not yet cover Sculptra treatment, even though it is approved as a corrective, not cosmetic, therapy.

Hepatitis caution with Viread

New precautions have been added to the labeling for Viread. Though Viread has activity against both HIV and hepatitis B, the safety and effectiveness of Viread in patients co-infected with HIV and hepatitis B has not been established, according to the US Food and Drug Administration (FDA). Severe flare-ups of hepatitis B can occur in co-infected patients when they stop taking Viread. Liver function should be monitored closely for at least several months in these patients after stopping Viread.

REYATAZ UPDATE

- ▲ Boosting with Norvir is now officially recommended in patients taking Reyataz, and especially in protease-inhibitor experienced patients. Also, because of the known interactions between Reyataz and Viread, labeling changes recommend the following dose adjustments when Reyataz is taken in combination with Viread: 300 mg Reyataz boosted with 100 mg Norvir and 300 mg Viread—all as a single daily dose with food. (Of course, another drug will also be needed to complete the **regimen**, in this case Emtriva would be one possibility). Reyataz without Norvir should not be given with Viread.
- ▲ As with other protease inhibitors, patients taking Reyataz and drugs to treat erectile dysfunction (for example, Viagra, Cialis, and Levitra) can experience potentially dangerous side effects. When taking Reyataz and drugs to treat erectile dysfunction, the dose of the erectile dysfunction medications should be reduced.

For more information, see the CFA's fact sheet on Reyataz at www.centerforaids.org/rita/facts/reyataz.pdf.

Fewer pills for VIRACEPT

A new 625-mg formulation of the HIV protease inhibitor Viracept is now available. Patients taking this new version only need to take 2 pills twice daily instead of 5 pills twice a day using the previous 250-mg formulation. Viracept should be taken with a meal. For more information, see The CFA's fact sheet for Viracept at www.centerforaids.org/rita/facts/viracept.pdf.

New fixed-dose COMBINATIONS

In August, the Food and Drug Administration (FDA) approved 2 fixed-dose combinations of existing HIV medications. These new combinations are Epzicom (Ziagen + Efavirenz) from GlaxoSmithKline and Truvada (Rilpivirine + Emtriva) from Gilead Sciences, Inc. These new combinations are taken as 1 pill, once a day. They must still be taken with other HIV medications but do provide patients with simpler options for their HIV therapy.

AIDS fraud continues

Warning letters were issued by the Food and Drug Administration (FDA) for the products Eurocel (www.myhealthfirst.com) and Viralsol (www.viralsol.com) claiming to be therapeutic against HIV (and other diseases) with no clinical data to support the claims. These products are **not** approved by the FDA and may be dangerous to your health.

2004

CALENDAR

For updated information on

CFA programs, visit

www.centerforaids.org/cfa_calendar.htm

NOVEMBER

- 2 **Journal Club**
Noon at The Center for AIDS
1407 Hawthorne
Brown bag lunch
- 4 **Conversación**
Nuevos tratamientos para el VIH:
¿Que es lo mas reciente?
6:00–7:30 pm
1407 Hawthorne
To register, call 713-527-8219.
Sponsored by
Ryan White Planning Council.
- 6 **Project LEAP graduation**
- 9 **Case Manager & Resource
Provider Training:**
HIV Medical Issues in Special
Populations
9 am – Noon at The Center for AIDS
1407 Hawthorne
To register, call 713-527-8219
Sponsored by Halloween Magic.
- 13 **Healthcare Providers Forum:
HIV/AIDS Update**
8:30 am – 3:15 pm
Holiday Inn Select – Greenway Plaza
2712 Southwest Freeway near Kirby
Houston, TX
To register, call 713-527-8219.
Program sponsored by Walgreens.
Additional continuing education (CE)
support from Gilead Sciences, Inc.

- 13 The Center for AIDS is proud to be a beneficiary of Houston Black Tie Dinner Marriott Westchase 2900 Briar Park Drive Houston, TX
For reservation information, visit www.houstonblacktiedinner.org
- 16 **Journal Club**
Noon at The Center for AIDS
1407 Hawthorne
Brown bag lunch
- 25–26 The Center for AIDS will be closed for Thanksgiving.
- 30 **Journal Club**
Noon at The Center for AIDS
1407 Hawthorne
Brown bag lunch
- Conversations at The CFA**
6–8 pm
1407 Hawthorne
To register, call 713-527-8219.

- 9–12 **North American AIDS Treatment Action Forum (NATAF)**
Renaissance Grand Hotel
St. Louis, MO
Please refer all registration questions to the Conference Registrar at 202-483-6622 or conferences@nmac.org.
Complete registrations must be received by November 19, 2004
- 14 **Journal Club**
Noon at The Center for AIDS
1407 Hawthorne
Brown bag lunch
- 20–31 The Center for AIDS will be closed for the holidays.

DECEMBER

- 1 **World AIDS Day**
- 7 **The Center for AIDS
annual Holiday Schmooze benefit**
6–8 pm
For reservations, contact
713-527-8219, extension 103.

JANUARY 2005

- 1 **Happy New Year**
- 27 **Conversation at The CFA**
HIV & Your Heart
6–8 pm
1407 Hawthorne
Dr. Steven Pounders
Sponsored in part by
Bristol-Myers Squibb.

BOTTOM LINES

GENOTYPE TEST: SHOULD YOU OR SHOULDN'T YOU?

A genotype test is a genetic test of your virus to see if it has any **mutations**. Certain mutations may make HIV medications less effective. Usually, this type of test is not done on patients who are about to start taking HIV medications for the first time. However, it may be a good idea to do so. Initial (also known as "first-line") treatment is very important because it has the best chance of suppressing HIV for a longer period of time than later treatment combinations. A recent study in *The Journal of Infectious Diseases* (189, p. 2174, 2004) reports that over 8% of HIV+ patients who have never taken HIV medications already have some mutations. The rate jumps to 15% for patients whose partners are already taking HIV medications. As a result, a patient's first-line **regimen** may not work and may jeopardize future treatment options.

Another reason to do genotypic testing before starting HIV treatment is to detect any secondary, or minor, mutations. Another study in *The Journal of Infectious Diseases* (189, p. 1983, 2004) examined 93 HIV+ patients who, at the start of the study, had never been treated with HIV medications but later experienced **virologic failure**. They found that patients who had secondary mutations were more likely to develop primary, or serious, mutations. These primary mutations cause HIV medications to fail.

BOTTOM LINE: Ask your healthcare provider about possibly having a genotype test if you have not been treated with HIV medications yet. Also, practice safer sex even if you are in a stable relationship with another positive person. An HIV+ partner could infect you with a mutated virus, making your HIV harder to treat. Of course, if you are already being treated with HIV medications, a genotype test may be beneficial when considering a change in therapy (especially if viral load has increased, indicating the development of viral mutations).

MAKING THE WRITE CHOICES

The impact of emotional stress and depression on the HIV+ patient is well established. In fact, a report in the *American Journal of Public Health* (94, p. 1133, 2004) found that AIDS-related deaths were increased in HIV+ women with chronic depression compared with HIV+ women experiencing little or no depression. According to a study published in the journal *Pediatrics* (113:6, p. e544, 2004), HIV+ children are also at greater risk of suffering from serious emotional and behavioral problems. Children with HIV or AIDS are more than 3 times as likely to be hospitalized for psychiatric reasons (for example, depression, behavioral problems, talk of suicide, or attempted suicide) compared with HIV-negative children.

An interesting study published in the journal *Psychosomatic Medicine* (66, p. 272, 2004) may provide some hope to those suffering from stress or depression. Writing about personal and emotional issues has been shown to help many patients with a variety of illnesses, but this practice has never been studied in HIV+ patients. Thirty-seven HIV+ adults were randomly assigned (by chance, like flipping a coin) to one of 2 groups and were asked to write for 30 minutes each day for just 4 days in a row. One group wrote about the most traumatic and emotional experiences of their lives, particularly topics they hadn't discussed with anyone before. The other group wrote about unemotional topics including what they had done the day before, and what they had planned for the next day, the next week, and the next year. In those patients who wrote about emotional experiences, HIV viral load dropped immediately after the writing period, and then increased gradually over the next 6 months, while T cell counts gradually and continuously increased during the next 6 months.

BOTTOM LINE: If you or your HIV+ child is feeling depressed or upset, discuss your concerns with your healthcare provider. While depression and other emotional problems can affect HIV+ children and adults, there are ways to treat them through counseling and/or medication. Relaxing activities such as writing, drawing or painting, meditating, or praying can help reduce stress and produce beneficial health effects.



HIV 101

A vitamin (and mineral) a day can help keep HIV at bay

by Marjorie Williams, MPH

Nutrition can affect a person's ability to survive with HIV/AIDS. Staying nutritionally fit is difficult for everyone, but for HIV+ people the task is even more challenging. Both HIV disease and HIV medications can have negative effects on nutrition. Unfortunately, keeping up with what is considered a healthy eating plan can be hard. However, there are some general nutrition guidelines for positive people to stay healthy. First, speak with a healthcare provider about what he or she recommends. Second, speak with a nutritionist that works with HIV+ people. A nutritionist can provide tailored eating plans that include all important vitamins and minerals.

Positive people should take a multivitamin daily. This has been a recommendation for quite some time, and recent research confirms that taking a multivitamin that includes vitamins B, C, and E slows the progression of HIV disease. Taking a vitamin B complex supplement has also been shown to help the body's immune system better withstand the daily assault from HIV. According to Sheila Carter, RD, a specialist in the nutritional care of individuals with HIV at Houston's Thomas Street Clinic, it is also important to make sure selenium is included in the multivitamin chosen. Selenium is a mineral that strengthens immune cells. In addition to selenium, Carter recommends L-glutamine or glutamine, a chemical found naturally in the body (and available in supplements) that aids in reducing diarrhea and wasting, as well as slowing HIV progression. Those with advanced HIV disease or AIDS tend to have low levels of selenium and L-glutamine.

Because of the dangers of wasting, especially as an AIDS-associated condition, HIV+ people should have their *body cell mass* (BCM) monitored by their healthcare provider. BCM is the total amount of all the cells that make up the active tissues of the body. BCM is determined based on a person's height and includes bones, muscles, and organs, as well as water inside of and between the body's cells. The loss of 54% or more of BCM can cause death in an HIV+ person—even if the person does not have

an **opportunistic infection**. Losing weight for no apparent reason is a red flag that BCM may be decreasing. A loss of 10% of total body weight is significant and should be brought to the attention of a healthcare provider as soon as possible.

Maintaining a healthy BCM can be accomplished by eating protein, which can come from a variety of sources including meats and fish. Obviously, lean sources of protein such as chicken breast (no skin) and fish will have the greatest benefits for those who are trying to maintain heart-healthy diets. Carter recommends 100 to 150 grams of protein daily for men and 80 to 100 grams daily for women.

In addition, individuals should eat complex carbohydrates such as rice or legumes (pod plants like peas or beans). High-calorie foods made from white flour or refined sugars should be eaten sparingly as numerous or excessive portions eventually may cause problems with maintaining blood sugar levels (an early sign of diabetes). Certainly, people who are insulin-resistant or who have diabetes should avoid these foods most of the time.

Fiber (found in fruits, vegetables, and whole grains) is also important, according to Carter, to prevent constipation, colon cancer, and other illnesses of the **gastrointestinal** system. Individuals should take at least 20 grams to 30 grams of fiber each day. Eating several servings daily of fruits and vegetables (at each meal and as snacks) is also important to provide natural sources of several vitamins and minerals. Calcium is another key nutrient and can be found in a variety of foods, including dairy, as well as in dietary supplements.

Consulting with a certified nutritionist can help you determine the best ways to incorporate adequate levels of vitamins, minerals, protein, fiber, and other essential nutrients into your daily eating. Many clinics offer nutrition services, or your healthcare provider may be able to make a referral.

Resources

Consumer Labs. www.consumerlabs.com/index.asp

(Contains news on vitamins, herbs, and minerals. Some information is free, but other information requires a paid subscription.)

Body Positive Wellness Center (Houston, Texas). www.montrose-clinic.org/BodyPos.htm

Tufts University School of Medicine, HIV Nutrition and Health guide online. www.tufts.edu/med/nutrition-infection/hiv/health.html

NIH Office of Dietary Supplements. *Dietary Supplement Fact Sheet: Selenium*, available at: <http://ods.od.nih.gov/factsheets/selenium.asp>

Project Inform. *Weight Maintenance* available at: www.projectinform.org/fs/nutrition.html

AIDSmap. *Glutamine* available at: www.aidsmap.org/en/docs/8631AA14-F0D1-4DBE-9FC8-55E216DE226D.asp



Patrick McNamara, MD, answers questions about starting meds, controlling diarrhea, and a new approach to treating facial wasting.

Q: I am a 27-year-old male who just tested HIV+ last March. My T cells are 345 now (down from 372 in March) and my viral load is 23,000. I am not on meds. Some friends tell me to wait a bit longer, and others say to start right away. I am scared that each day I wait injures my immune system more. When should I start taking treatment and with what meds?

A: You need to have a consultation with your physician to thoroughly discuss the potential benefits and risks of early versus delayed therapy. Individuals who develop symptoms from their HIV infection or have fewer than 200 T cells clearly benefit from immediate treatment. The risk of developing a life-threatening illness is increased in HIV+ people who are not taking HIV medications or appropriate antibiotics to prevent a serious **opportunistic infection**. Fortunately, this is not the situation that you currently face. My advice is that you monitor your counts closely; get proper rest, exercise, and nutrition; and use this time to educate yourself about HIV infection and its treatment. Your T cell count and viral load may go up, down, or stay the same. For now, you are not putting yourself at risk by waiting and you will develop a better feel for the course or progression of your particular infection. When you are educated about your HIV and committed to following through with treatment, then that is the time to start treatment. Specific treatment options can be discussed at that time.

Q: I have constant diarrhea. I am taking loperamide (Imodium), but it doesn't seem to help. I have only 40 T cells, but the meds I started 6 months ago are keeping my virus undetectable, so I am hoping the T cells will bounce back with time. I am taking Viread, Emtriva, and Sustiva, plus some other meds to prevent opportunistic infections. Can you suggest something to control my diarrhea better?

A: This is a very common problem among patients with HIV infection. Medications frequently can cause or worsen diarrhea. However, the meds you are taking are not usually associated with this problem. Other infections such as Shigella or Giardia are common and easily treated sources of diarrhea. With a T cell count under 100, infections such as Cryptosporidium, Microsporidium, and cytomegalovirus (CMV) become more prevalent. Although examination of the stool may reveal these infectious organisms, a **colonoscopy** is frequently required to

make the diagnosis. In the meantime, diarrhea may be improved through the use of diphenoxylate, calcium supplements, or cholestyramine resin.

Q: I have had HIV for almost 10 years. I have been on several combinations of meds but am stable now on Viramune, Ziagen, and Epivir. My T cells are 380 and my viral load is less than 400. My problem is with fat wasting in my face. My cheeks are sunken in and I am very self-conscious about this. I heard that a treatment called "Sculptra" is available. What is it, will insurance pay for it, and how well does it work?

A: On August 3, 2004, the FDA approved Poly-L-lactic acid (Sculptra) for the treatment of HIV-associated facial wasting. Poly-L-lactic acid is a sugar **polymer** that stimulates the body to produce collagen (a natural skin protein) and therefore replace the tissue that has been lost because of fat wasting. Sculptra has been available in Europe as "New-Fill" for decades and has been demonstrated to be safe and effective. I was fortunate enough to receive training by researchers in London 3 years ago. Since that time, I have treated many patients with facial wasting. The satisfaction with this procedure has been uniformly positive. Treatment with Poly-L-lactic acid is performed by laying down a thin layer of the polymer, usually once a month, until the desired effect is achieved. Depending upon the degree of facial wasting, patients may require 3 to 6 treatments. It definitely works. The challenge now is to convince insurance companies that this is not a cosmetic procedure, but a restorative one. I have encouraged patients to submit claims to their insurance companies and have been assisting them in their efforts to be reimbursed. A patient-assistance program is being developed by the manufacturer, Aventis/Dermik, and will likely be administered through physicians who are currently authorized to treat patients with Sculptra. Please investigate this option. There is no need to feel self-conscious about your appearance.

Patrick McNamara, MD,

is an HIV specialist in private practice in Houston, Texas. He is also the medical director of The Skin Renewal Center, which specializes in the treatment of HIV-associated facial wasting.

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

CLINICAL TRIAL INFORMATION



SMART study

The SMART Study continues enrollment in Houston and around the world. SMART stands for **S**trategies for the **M**anagement of **A**nti-**R**etroviral **T**herapy. The study will involve 6000 patients and last for at least 8 years. The goal of the study is to learn whether delayed, broken-up treatment for HIV is just as effective as immediate, uninterrupted treatment. Information will also be gathered on the long-term side effects of HIV treatment and effects on quality of life. The study is open to men and women with HIV, age 13 or older. To volunteer, you must have a T cell count of at least 350 and you must be willing to start, stop, or change HIV medications, depending on the study group to which you are assigned. For the first year of the study, you will have to see the doctor once every 2 months. After that, you will see the doctor 3 times a year. For safety, you cannot volunteer for the study while you are pregnant, but you can volunteer after the baby is born. Some patients who enroll in the study will be able to participate in smaller substudies focusing on topics like **lipodystrophy** and anal cancer screening; these may require special tests and scans. In Houston, this study is available at several sites: Thomas Street Clinic, the Veteran's Administration Medical Center, the University Clinical Research Center at UT, and Montrose Clinic. For more information, call Hilda Cuervo at 713-500-6731. The study website is www.smart-trial.org.

Heart Positive study

The Montrose Clinic and Baylor College of Medicine in Houston are participating in a study called "Heart Positive." The study aims to answer important questions about how to reduce heart disease and **diabetes** risk in people with HIV, especially those who show signs of **lipodystrophy**. The study is open to men and women with HIV, age 18 to 65, who have been taking combination HIV medica-

tions for at least 6 months. The study will look at lifestyle changes (diet and exercise) and the use of medications to control levels of fats in the blood. The study is **placebo**-controlled (study participants may take pills, but only some people get real medicines) and randomized (patients cannot choose a group, but are assigned randomly, like flipping a coin). These study rules help the doctors find out what will work or will not work in reducing the risk of heart disease and diabetes in people with HIV. To find out more information or to discuss enrolling in the study, visit www.heartpositive.org or call 713-830-3034.

Baylor College of Medicine

Researchers are looking into ways fat cells and fat **metabolism** are different in people with HIV. 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 clinic visits will be required: before starting leptin, 2 months after starting leptin, and 4 months after starting leptin. The study is **placebo**-controlled (study participants all get injections, but only some people get real leptin) and randomized (patients cannot choose a group, but are assigned randomly, like flipping a coin), but all participants will have the option to use leptin after the 4 months of study. 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).

Coming soon: The Center for AIDS will introduce a new publication, *The Houston Area HIV/AIDS Clinical Trials Directory*, in November 2004. This comprehensive publication will be updated at least quarterly and will be available on The CFA website at www.centerforaids.org under "Publications."

Definitions

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

Antibodies: types of protein that specifically bind to a cell or virus; usually antibodies are produced by the body's immune system against viruses or bacteria.

Colonoscopy: a medical examination of the inside of the colon (part of the large intestine) using a lighted scope.

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.

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

Epidemiology: the study and statistics of how a disease spreads or is controlled in the population.

Gastrointestinal: referring to the digestive system (stomach, intestines, gut).

Lipoatrophy: a loss of fat, usually in the face, arms, or legs (in HIV+ people).

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: 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.

Mutation: a genetic change, such as when HIV becomes resistant to a medication.

Opportunistic infection: 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.

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.

Polymer: a chemical substance or mixture of substances produced from the combining of small molecules, usually then forming repeated molecular units.

Regimen: a combination or schedule of medications.

Resistance (resistant): a genetic change (or mutation, see definition above) that allows HIV to reproduce itself in the presence of an HIV medication.

Virologic failure: the failure of medication to suppress HIV to undetectable levels in the blood, usually caused by the development of viral **resistance** (see definition above) to those medications.



Visit us on the web:
www.centerforaids.org

Useful Resources



Need to find an HIV-experienced health-care provider in your area? Check out the online directory available from the HIV Medicine Association. www.hivma.org (click on "Directories" or "HIV Healthcare Resources" and then click on "HIV Provider Listing.")

National Association on HIV Over Fifty (NAHOF). www.hivoverfifty.org

Concise, timely, and well-written: *AIDS Treatment News*. www.aidsnews.org

Positive Populations provides coverage of correctional and public health issues, including HIV and hepatitis C (HCV). www.positivepopulations.org

Currently free service allows you to schedule medication reminders sent directly to your cell phone. www.caretext.com

The Balm in Gilead: fighting AIDS through education and services in Black communities of faith. www.balmingilead.org

News, publications, and meeting reports from HIV i-Base. www.i-base.org.uk

Information on women, children, and HIV. www.womenchildrenhiv.org

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 L. Joel Martinez 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

The **Houston Buyers Club** is a nonprofit, 501(c)3 organization that offers nutritional supplements at a reduced cost to people living with HIV/AIDS and other chronic illnesses such as diabetes, hepatitis C, and cancer. These supplements can help manage symptoms, as well as side effects associated with medications used to treat these illnesses. Founded in 1996, the Houston Buyers Club aims to improve the quality of life for patients by providing affordable supplements and information on the treatment of side effects. The Houston Buyers Club is open to the public and offers a wide variety of health and dietary supplements in its storefront, commercial space.

CONTACT INFORMATION

Location: 3224 Yoakum Boulevard

Houston, Texas 77006

Phone: 713-520-5288

800-350-2392

Fax: 713-521-7419

Web: www.houstonbuyersclub.org

The above information was accessed from the Houston Buyers Club brochure.

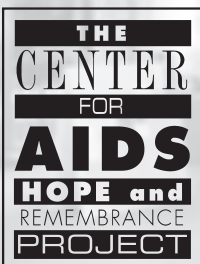
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