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# HIV treatment ALERTS!

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THE CENTER FOR AIDS HOPE and REMEMBRANCE PROJECT

inside:



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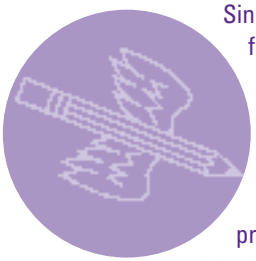
# WELCOME



Since the last issue of this newsletter (October 2003), much has happened at The CFA. Our founder, L. Joel Martinez (who stepped down as Director in early 2003), lost his battle with cancer. Over the December holidays, a dedicated member of our editorial board, Norma Brown, RN, also passed away quite unexpectedly. In the midst of these losses, we watched in disbelief as Abbott Laboratories decided to cash in on its protease inhibitor Norvir (commonly used in small doses to "boost" the levels of other, less toxic protease inhibitors) by raising the price by more than 400% and ensuring that its own boosted product, Kaletra, became the cheapest boosted protease inhibitor on the market. Then came the announcement recently that more than 1200 people in the US are on waiting lists for life-saving HIV medications. Some people on waiting lists have even died because they could not access HIV medications. Funding for HIV services and medications is being slashed (see page 10). Even research dollars are in jeopardy. Drug companies are raising their prices while reporting solid, if not record, earnings. What in the world can we do? The answer is simple: fight back. Energize, organize, and mobilize. AIDS activism has certainly changed over the years, but it is not dead. With greater pressures on the HIV/AIDS community, sleeping giants will awaken. To tap into what is happening in activism today (lawsuits, boycotts, and demonstrations against Abbott and other groups; government actions; campaigns and conferences), contact and join the AIDS Treatment Activists Coalition (***www.atac-usa.org***).

AIDS is the single most devastating epidemic to ever affect humankind. Some politicians, industry executives, and others are making decisions that adversely affect people living with the disease both in the US and abroad; they should reconsider their positions and tactics immediately.

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

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

# 11th Retrovirus Conference HIGHLIGHTS

## Alternative therapies for neuropathy

**Neuropathy** is a painful nerve condition that affects about 1 in every 3 HIV+ patients. HIV medications sometimes known as "d-drugs" like ddI (Videx), ddC (Hivid), and d4T (Zerit) can make this condition worse. At this year's conference, several studies were presented that looked at alternative therapies to reduce the pain associated with neuropathy. Capsaicin (pronounced "cap-say-sen") is the substance in chili peppers that makes them spicy and was one such therapy studied (abstract 490). In this small study, 12 patients were first treated with a topical (on the skin) **anesthetic** for 1 hour followed by a 1-hour application of a capsaicin skin patch to the painful area. Patients were only treated one time and then studied for 12 weeks. Over half of the patients felt less pain at that site during the 12-week study period. Patients did experience mild discomfort during and shortly after treatment, but generally tolerated the patch well. In another small study, marijuana was also shown to lessen the pain associated with this condition (abstract 496). Ten out of 16 patients had a significant reduction in pain after smoking cigarettes containing THC (the active ingredient in marijuana) 3 times a day for 7 days.

Another study looked at the effect of a specially formulated multivitamin supplement (consisting of several pills) on reducing neuropathy pain (abstract 494). This study was a "double-blind" study, meaning that both patients and healthcare workers did not know which treatment each patient was receiving. Forty patients with neuropathy who were taking Zerit or Videx were randomly assigned (by chance, like flipping a coin) to receive the specially formulated multivitamin supplement or a **placebo** twice daily for 12 weeks. Though patients taking the multivitamin experienced some pain relief, the effect was small. However, the researchers discovered that the multivitamin did increase T cell counts, suggesting this type of supplement may benefit people with HIV.

## Surgery anyone?

There is a perception that HIV+ patients will have more complications after surgery because of a suppressed immune system. However, a study presented at the conference may put these fears to rest (abstract 82). To see if HIV+ patients actually had more surgical complications than the general population, researchers compared HIV+ patients to HIV-negative patients who had the same type of surgery in the same year and who were the same age and sex. In all, 295 pairs of patients were examined (a pair was made up of an HIV+ patient and an HIV-negative patient), including HIV+ patients who had an AIDS diagnosis or a history of an opportunistic infection. The researchers discovered that the number of surgical complications and deaths was similar for HIV+ and HIV-negative patients. However, those patients with viral loads greater than 10,000 were more at risk for complications. The researchers caution that many high-risk HIV+ patients may not have had surgery, and therefore this study may not tell the complete story.

## Slimming down with Serostim

A previous study showed that 4 mg a day of Serostim (human growth **hormone)** given for 12 weeks decreased the amount of fat in the abdominal area (a condition associated with **lipodystrophy**). Serostim also reduced cholesterol levels. Unfortunately, some patients had side effects at that dose and any positive changes reversed once patients stopped taking Serostim. A follow-up study presented at the conference showed that in patients previously treated with the higher dose of Serostim, a smaller dose (1 or 2 mg per day) could maintain these positive changes with fewer side effects (abstract 80).

## Does Sculptra work?

**Lipoatrophy** is the loss of fat in the face, arms, or legs and is a side effect of HIV treatment. Injections of polylactic acid (also known as NewFill and to be sold upon US approval as Sculptra) have been used for the treatment of facial lipoatrophy for several years, but the long-term effects are not known. A study presented at the conference (abstract 726) described 94 patients who received at least 1 injection of polylactic acid (mixed with an **anesthetic**). Patients received an average of 5 injections of polylactic acid in both cheeks every 15 days. At the end of treatment, 87% of patients reported that they were more satisfied with their face in terms of the lipoatrophy. However, statistical tests showed that almost half of the patients would require additional injections within 15 months. The most common side effects of this treatment included mild to moderate pain and swelling at the injection site.

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## The new face of cancer

As more patients are taking combination antiretroviral therapy (known as HAART), the types and frequency of cancers affecting HIV+ patients are changing dramatically. Prior to the introduction of HAART in 1996, 3 types of cancer were common in HIV+ individuals: Kaposi's sarcoma (KS), cervical cancer, and non-Hodgkin's lymphoma (NHL). With the help of a large collection of patient records, one study showed that the rates of KS and cervical cancer have decreased (abstract 81). However, rates of other types of cancer have increased, including Hodgkin's disease, melanoma, and cancers of the lung, anus and rectum, and head and neck. While this particular analysis showed that incidence of NHL has not changed much, another study reported that the number of cases of NHL in patients with AIDS has dropped significantly (abstract 786), demonstrating the complexity of this issue. Other studies presented also found that cancer of the anus and rectum is more common in HIV+ people compared to the general population (abstract 777) and that these rates have increased since the introduction of HAART (abstract 778). Some possible explanations are that people with HIV are living long enough to get such diseases, which may occur because of immune problems not fixed by HIV medications. In addition, another research group reported that cancer was responsible for over a quarter of AIDS deaths when they studied a group of 964 HIV+ people (abstract 875).

## Obesity epidemic

Chronic weight loss and wasting are well-known features of AIDS. However, in the current era of HIV treatment, obesity is affecting HIV+ people almost as much as it is affecting the general population. A study presented at the conference examined 1654 HIV+ individuals and found that obesity was 5 times more common than wasting (abstract 879). Women, African-Americans, and those with T cell counts over 200 were more likely to be obese. As treatment options for HIV improve and patients continue to live longer, obesity may lead to problems that also affect lifespan, such as heart disease and stroke.

## Bone problems

Several studies looked at bone mineral density, which is a measurement of bone strength, in HIV+ people. One study examined 272 women (both HIV+ and HIV-negative) and found that HIV+ women were 3 times more likely to have decreased bone strength (abstract 744). This loss in bone strength can lead to serious bone fractures, such as hip fractures, that can result in an extended hospital stay and the need for physical therapy. In addition, this condition may even lead to **fragility** fractures. These types of fractures can occur with little or no trauma. According to another study presented at the conference, patients who have fragility fractures commonly have more serious bone fractures later (abstract 743). The effects of Fosamax (alendronate) in treating this loss of bone strength was tested in an "open-label" study, meaning that patients knew which treatment they were receiving (abstract 742). Forty-one HIV+ men and women were randomly assigned (by chance, like flipping a coin) to receive Fosamax combined with calcium and vitamin D supplements or just calcium and vitamin D supplements. Fosamax had no effect on increasing bone mineral density, but had other beneficial effects.

## Diabetes risks

According to a study presented at the conference, HIV+ men are 3 times more likely to develop **diabetes** compared to HIV-negative men (abstract 73). Researchers studied 1107 HIV+ and HIV-negative men and found that taking the HIV medications Zerit or Sustiva further increased this risk. Another study presented at the conference specifically looked at HIV+ women (abstract 701). Contrary to what was shown in HIV+ men, there was no difference in incidence of diabetes when 134 HIV+ women were compared to 88 at-risk but HIV-negative women. In both groups, women at the greatest risk for having diabetes or pre-diabetes symptoms (**insulin resistance**) were 50 years old or older, overweight, or had a history of smoking cigarettes. Unlike findings from other studies, protease inhibitors did not increase the risk of diabetes in this group of HIV+ women. In fact, insulin resistance was greater among HIV+ women on HIV medications who had never received a protease inhibitor. Because protease inhibitor use has been associated with the development of diabetes, these studies clearly show that more research is needed in this area.

## Rosiglitazone update

Rosiglitazone (brand name: Avandia) is a drug used to treat **diabetes**. This drug is being tested for the treatment of fat wasting (**lipoatrophy**) and related problems in body **metabolism**, such as with fats and sugars, found in people with HIV. Unfortunately, the most recent results of rosiglitazone's effect on lipoatrophy are disappointing. In a "double-blind" study, meaning that both patients and healthcare workers did not know which treatment each patient was receiving, HIV+ patients with lipoatrophy were randomly assigned (by chance, like flipping a coin) to receive a **placebo** (55 patients) or 4 mg of rosiglitazone twice a day

(53 patients) for 48 weeks (abstract 79). Rosiglitazone had no beneficial effect on body changes associated with lipoatrophy. However, patients taking this drug did experience increased levels of adiponectin (a **hormone** secreted by fat cells that affects the body's response to insulin and may have other important effects) and improved insulin sensitivity (allowing better control of blood sugars), both of which are beneficial. These findings were recently published in *The Lancet* (363:9407, p. 429, 2004).

## Mental challenges

Several studies presented at the conference looked at **cognitive** function (the ability to think and understand information) in patients with HIV or AIDS. Most of these studies used a group of mental tests to determine how well patients processed and understood information. In one study of 240 patients, this type of testing showed that about 40% of patients with advanced AIDS had difficulty with these tests (abstract 498). This study also showed that patients with an undetectable viral load (less than 500) did better on these tests compared to patients with detectable viral load. Another study showed that being co-infected with hepatitis C (HCV) also appears to have a negative effect on cognitive function. Researchers tested 235 HIV+ patients (25 of these patients were co-infected with HIV and HCV) and found that co-infected patients were more likely to show symptoms of cognitive difficulties (abstract 26). In addition, co-infected patients tended to be more depressed. In a separate study, HIV+ patients who had impaired cognitive function were more likely to die during the 7-year study period, compared to patients without these symptoms (abstract 507). This study also reported that higher viral loads and co-infection with HCV were linked to difficulties in understanding and processing information. Actual damage to the brain caused by HIV could be responsible for these problems. One study reported that minor brain damage, specifically loss of nerve insulation, occurs in some HIV+ patients despite being on HIV medications (abstract 33LB). This damage was more apparent in those patients with detectable viral loads. A common theme in these studies is the importance of suppressing HIV and avoiding HCV infection, which can make health issues worse.

## Managing lipids

High levels of triglycerides (a type of fat that travels in the blood) and cholesterol can be common in HIV+ patients and are risk factors for heart disease. This condition can be made worse by certain HIV medications. One small study looked at the effect of Pravachol (pravastatin), a drug used to lower cholesterol (abstract 77). In this "double-blind" study, meaning that patients and healthcare workers did not know which treatment each patient was receiving, patients were randomly chosen (by chance, like flipping a coin) to receive Pravachol or a **placebo**. Pravachol significantly reduced cholesterol levels and had other beneficial effects. The combination of Pravachol and Tricor (fenofibrate), a drug used to treat high triglyceride levels, was also investigated in another study (abstract 723). Here, patients initially took Pravachol (86 patients) or Tricor (88 patients), but later received both drugs if their cholesterol and triglyceride levels had not dropped after 12 weeks. The combination of these 2 drugs appeared safe, but few patients had significant decreases in triglycerides or cholesterol. In a separate study (abstract 724), patients were randomly assigned to take fish oil (about 3 grams a day) combined with diet and exercise counseling (25 patients) or to just receive diet and exercise counseling alone (19 patients). In general, fish oil reduces the risk of heart disease. While triglyceride levels dropped in patients who received fish oil, the drop was not dramatic. However, these results are encouraging since patients tolerated the fish oil and reported few side effects. The studies are difficult to compare directly because their definitions of success are different. One study (abstract 723) wanted to see if patients could achieve cholesterol and triglyceride levels cited by the National Cholesterol Education Program, while another study (abstract 77) just looked at whether these levels had decreased significantly.

## HIV and the BBB

HIV can cause damage to the brain, including problems in thinking and understanding information. This damage is thought to occur because certain HIV drugs cannot get into the brain to suppress the HIV infection. The blood-brain barrier (BBB) is a tightly connected network of cells that surrounds the brain and protects it from outside substances. However, the BBB also prevents many beneficial drugs from entering the brain. At the conference, 2 studies questioned whether using HIV medications that are able to get through the BBB actually protect against damage caused by HIV. In the first study (abstract 501), the **cognitive** ability of 32 HIV+ patients taking one of the medications believed to penetrate the BBB was compared to that of 14 HIV+ patients not taking one of these drugs. A second study (abstract 508) examined 165 HIV+ patients and compared cognitive ability in those patients taking an HIV medication thought to penetrate the BBB to those patients who were not. Both studies found that a higher viral load was associated with cognitive problems, rather than the specific HIV medications. In the second study, higher levels of education were shown to protect patients against these types of problems. In terms of protecting the brain and the body from HIV, the most important factor is keeping viral load low. Patients should be sure to have their viral load measured every 3 to 4 months and take HIV medications regularly and on-time.

# TreatmentNews

## IT'S ALL ABOUT ATTITUDE

A report in the journal *Biological Psychiatry* (54, p. 1444, 2003) describes how researchers assessed 54 homosexual HIV+ men to study the connection between shyness (feeling inhibited in social situations) and physical health. Men who were shy had a significantly higher viral load set-point (a starting point for viral load after early or "acute" HIV infection) and had a poor response to HIV drugs compared to the HIV+ men who were not shy. In a related study published in the *British Medical Journal* (328, p. 15, 2004), researchers followed over 3700 HIV+ patients and found that people who were in a stable relationship did not progress to AIDS or die as quickly as those who were not in a stable relationship. The reasons for these benefits are not known, but the researchers believe that being part of a stable relationship may prevent depression and improve drug **adherence**, therefore improving the health of these patients.

## MEDS on your mind

Can HIV medications protect the brain from damage caused by HIV infection? In a study published in the journal *NeuroReport* (14:16, p. 2111, 2003), researchers measured electrical activity in the brain and performed **MRI** scans to look at brain function and structure in 39 HIV+ people. Patients were also tested with various mental exercises to see how well they processed and understood information and to test their reaction time. Compared to the **control group** (39 HIV-negative people), brain structure and electrical activity in HIV+ people were affected by HIV infection. In addition, tests showed that HIV+ patients had more difficulty processing and understanding information. Patients with detectable viral loads (over 50 copies) tended to perform worse on these tests compared to HIV+ patients with an undetectable viral load. The findings show that while HIV medications are beneficial, they do not completely protect the brain against HIV.

## Danger: methamphetamine

The risk of contracting HIV infection through sex is dramatically increased in those who use methamphetamine (meth or crystal meth). Individually, both meth and HIV cause damage to the brain and brain cells. A study published in the *Journal of Acquired Immune Deficiency Syndromes* (34:5, p. 467, 2003) examined brains (during an autopsy) from 34 HIV+ men who used meth regularly and 43 HIV+ men who did not use meth. While brain damage and cell death were apparent in all patients regardless of whether they used meth, different types of damage were detected in the brains of meth users. The researchers believe that HIV and meth work together to cause this damage. It is important that research continues in this area to find ways to protect the brain from HIV.

## SIDE EFFECTS greater threat than AIDS

Though HIV medications have dramatically improved the lives of persons with HIV, their side effects can be serious. According to a study in the *Journal of Acquired Immune Deficiency Syndromes* (34:4, p. 379, 2003), an HIV+ person is more likely to have a serious or life-threatening side effect than an AIDS-related event. In this study, the number of serious or life-threatening side effects, AIDS-related events, and deaths were recorded for 2947 HIV+ patients taking HIV medications. The researchers found that these types of side effects occurred about twice as often as AIDS-related events. Common issues included liver problems, decreases in white blood cells, **anemia**, and heart problems, and these were sometimes life-threatening. The researchers suggest that tailoring a drug **regimen** according to each patient's risk factors may reduce these kinds of side effects.

## Reasons for 86ing HAART

First-line HIV treatment, that is, the first treatment you are prescribed after being diagnosed with HIV, is very important because it has the best chance of suppressing HIV. A study published in the *Journal of Acquired Immune Deficiency Syndromes* (34:4, p. 407, 2003) looked at medical records from 345 HIV+ patients who had recently started taking HIV medications and found that 61% of the patients stopped or changed their drugs after about 8 months. Side effects such as nausea, vomiting, and diarrhea were frequently responsible. These findings stress the importance of understanding why patients sometimes stop taking their medications. Good communication between the healthcare provider and patient is very important because healthcare providers can counsel patients on what to expect and perhaps provide medications to treat or to prevent these side effects.

## Stroke in AIDS

According to a study published in the journal *Stroke* (35, p. 51, 2004), young adults (aged 15 to 44 years) with AIDS are 10 times more likely to have a stroke or intracerebral hemorrhage (bleeding inside the brain caused by a ruptured blood vessel) than people in the same age group without AIDS. When researchers examined hospital charts from 556 patients who had a stroke or intracerebral hemorrhage, the risk of these conditions was much higher in patients with AIDS compared to patients without AIDS. While the incidence of stroke was higher in patients with AIDS, risk factors associated with stroke (for example, high blood pressure, elevated cholesterol levels, or smoking) were similar in both groups. These findings suggest that damage to the brain caused by HIV may be responsible for this increased risk. However, a few things should be pointed out about this study. First, patients who were HIV+ but who had not progressed to AIDS were grouped in the "no AIDS" category. In addition, the researchers studied medical records from patients in 1988 and in 1991, before combination HIV therapy was available. It will be important to see how the widespread use of combination therapy affects this risk.

## Fighting FAT changes

Can a healthy diet prevent **lipodystrophy** in HIV+ patients? A study published in the *American Journal of Clinical Nutrition* (78, p. 790, 2003) followed HIV+ men who had no signs of lipodystrophy at the beginning of the study. The researchers met with patients every 6 months to discuss their food habits and to see if signs of lipodystrophy were apparent. The food habits of the 47 patients who eventually showed signs of lipodystrophy were compared with 47 patients in the **control group** who did not have lipodystrophy. HIV+ men without lipodystrophy tended to consume more dietary fiber, pectin (a nutrient found in fruits), and protein. These men were also more likely to include resistance training (weight lifting) in their exercise routine and to not smoke cigarettes.

In another study, published in the journal *Antiviral Therapy* (8, p. 403, 2003), researchers studied the effect of various medications on treating lipodystrophy. Patients were randomly assigned (by chance, like flipping a coin) to receive gemfibrozil (Lopid), a drug used to treat **dyslipidemia** (37 patients); metformin (Glucophage), a drug used to treat **insulin resistance** (35 patients); or a **placebo** (36 patients). This was a "double-blind" study, meaning that both patients and healthcare workers did not know which treatment each patient was receiving. During the 1-year study period, all patients experienced a total loss of fat, regardless of which treatment they received (including the placebo). However, none of these medications had a major effect on abdominal obesity, a common problem in patients with lipodystrophy.

Though the jury is still out on whether certain drugs can actually treat lipodystrophy, a preventative approach is important, and good nutrition and a healthy lifestyle should never be overlooked.

# RISK FACTORS for lipodystrophy

Understanding the risk factors for **lipodystrophy** may allow researchers to find successful treatments. According to a study in the journal *Clinical and Experimental Immunology* (135, p. 273, 2004), there may be a link among blood levels of adiponectin (a **hormone** secreted by fat cells that affects the body's response to insulin and may have other important effects); previous or current treatment with the HIV drug, Zerit; and the development of lipodystrophy. Researchers studied 42 HIV+ men, 27 of whom had lipodystrophy. Healthy HIV-negative men were also included as a **control group**. HIV+ patients with lipodystrophy had lower blood levels of adiponectin, especially those patients who had used Zerit, compared to HIV+ patients without lipodystrophy. In fact, all HIV+ patients who had taken Zerit (regardless of whether they had lipodystrophy), had lower levels of adiponectin.

## HEART ATTACK RISKS

The issue of whether combination HIV therapy (HAART) leads to an increased risk of having a heart attack is controversial. However, a recent study published in *The New England Journal of Medicine* (349:21, p. 1993, 2003) may provide some answers. This large study looked at over 23,000 HIV+ patients from 21 different countries including the US, Australia, and countries in Europe to determine the number of heart attacks in this population. During the study period, 126 patients had a heart attack. The number of heart attacks increased as exposure to HAART increased, showing a possible connection between heart attack risk and the use of HAART. Patients who had never taken HIV medications had the lowest incidence of heart attacks. Other risk factors included those that also affect the general population, such as older age, cigarette smoking, history of heart disease, **diabetes**, being male, and having high levels of triglycerides (a type of fat that travels in the blood) and cholesterol. The researchers point out that the risk of a heart attack was still relatively rare in HIV+ patients taking HAART and that the obvious benefits of HAART still outweigh the risks.

# BEST FIRST TREATMENT

According to 2 studies done by the same research group (the AIDS Clinical Trials Group 384 Team), the combination of Retrovir, Epivir, and Sustiva is the best initial treatment for HIV infection. Initial (also known as "first-line") treatment is very important because it has the best chance of suppressing HIV. The first study, published in *The New England Journal of Medicine* (349:24, p. 2293, 2003), looked at 620 HIV+ patients, the vast majority of whom had never taken HIV medications before. Researchers tested the effect of various HIV medications when taken in different combinations, including Videx, Zerit, Retrovir, Epivir, Viracept, and Sustiva. Patients were randomly chosen (by chance, like flipping a coin) to receive 3 of these drugs (2 nukes and either Viracept or Sustiva). If patients had serious side effects or if their treatment stopped working, patients were switched to another 3-drug combination. Patients taking the combination of Retrovir, Epivir, and Sustiva had fewer side effects and this combination suppressed HIV the fastest and longest after starting treatment. In fact, patients who initially took this combination also responded better to the second drug combination. Note: Retrovir and Epivir are available in one pill called "combivir."

The second study, also published in *The New England Journal of Medicine* (349:24, p. 2304, 2003), investigated whether 4 HIV medications were better than 3 for controlling HIV infection (currently, most HIV+ patients take 3 medications). This study examined the same medications as the above study and used various combinations of 3 or 4 medications. A total of 980 HIV+ patients who had never taken HIV drugs before were randomly chosen to receive one of these combinations. Researchers found that there was no significant benefit when patients took the 4-drug combination. In agreement with the above study, this study also showed that the combination of Retrovir, Epivir, and Sustiva suppressed HIV the best. The researchers caution that the combination of Zerit and Videx should not be used for initial therapy because it can cause serious side effects.

# DIABETES alert

**Diabetes** affects many HIV+ individuals and may be associated with specific types of HIV medications. A recent study published in the *Journal of Acquired Immune Deficiency Syndromes* (33, p. 577, 2003) explored some of the risk factors associated with the development of diabetes in HIV+ patients. Researchers studied 1230 HIV+ patients who had recently started taking HIV medications and found that hyperglycemia (high blood sugar, a condition associated with diabetes) was significantly more common in patients who were co-infected with hepatitis C (HCV). In addition, patients taking a protease inhibitor were more likely to have hyperglycemia compared to patients taking a non-nucleoside reverse transcriptase inhibitor (NNRTI or "non-nuke"). Incidence was even higher in co-infected patients taking a protease inhibitor. More studies on HIV and diabetes were presented at the 2004 Retrovirus Conference last February (see Conference Highlights beginning on page 3).

# FDA Bits

## VIRAMUNE WARNING

New precautions have been added to the labeling for Viramune, a non-nucleoside reverse transcriptase inhibitor (NNRTI or "non-nuke"). Women with T cell counts greater than 250, including pregnant women, who are treated with Viramune are at a greater risk for developing liver damage. Viramune should not be used in women with T cell counts greater than 250 because this type of liver damage can be life-threatening. Anyone (both men and women) taking Viramune should be carefully monitored by a healthcare provider because serious liver damage can occur in anyone. Patients developing a skin rash should tell their healthcare provider immediately as this may be a sign that the medication is causing problems.

FDA Bits

## New dosing for Invirase and Fortovase

In December, the FDA approved new dosing guidelines for Invirase and Fortovase, 2 brand-name versions of the HIV medication, saquinavir. The new dose for both Invirase and Fortovase is 1000 mg two times a day when taken with Norvir (another protease inhibitor used to boost levels of other medications). Invirase should always be used with Norvir. Fortovase can be taken with or without Norvir, though patients may need to take Fortovase more frequently if Norvir is not taken.

## FDA approves HIV drug

Last fall, the Food and Drug Administration (FDA) approved the protease inhibitor, Lexiva, to help treat HIV. Lexiva is a new version of the drug Agenerase and is taken in combination with other HIV drugs. For patients who have never taken protease inhibitors, Lexiva can be taken once or twice a day, depending on the Lexiva dose and whether Norvir (another protease inhibitor) is taken to boost Lexiva. For patients who have previously taken many protease inhibitors, Lexiva should only be taken twice a day with Norvir. For more information, such as important drug interactions and possible side effects, see The CFA's fact sheet on Lexiva at ***www.centerforaids.org/rita/facts/lexiva.pdf***.

# ADVOCACY Update

## AIDS funding dwindles

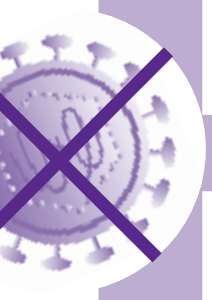
The Ryan White CARE Act is the federally mandated legislation created in 1990 that provides medical care and services to people living with HIV/AIDS across the country. This act is re-authorized every 5 years and appropriated (by Congress) annually. CARE Act funding comes to Houston and the surrounding areas essentially as a $19,128,572 "pie." This pie is then sliced up to support various services needed here in the local community. This process is accomplished by a group of dedicated volunteers known as the Ryan White Planning Council. They examine the needs within our community, prioritize services, and allocate funding to meet those needs—within the confines of the "pie" that the federal government allots. The problem is the pie is getting smaller and the number of people needing a piece of it is increasing.


As the actual funded amounts for fiscal year 2004 were finally distributed, Houston and 41 other regions throughout the nation will have to try to provide services in the face of a 6.8% decrease from the previous year's funding levels.

A 6.8% decrease may not sound like much. But the problem is that we have a national campaign that encourages people to know their HIV status, to get themselves into care if they have HIV, and to improve their health outcomes and lifespan. However, in this political and economic climate, it appears that many, if not all, of the benefits for people living with HIV/AIDS may soon be derailed. To preserve the 3 most important services (Primary Medical Care, Access to Medications, and Dental Care) for Houston area clients in 2004, every other Ryan White-funded service category was cut a minimum of 14%. Programs such as food pantry and medication assistance already had shortfalls at the end 2003.

The future for HIV funding looks bleak. The proposed budget resolution that sets spending levels for all federally funded programs for the next 5 years is in front of Congress now. As part of this resolution, spending on health-related issues would be reduced 11% by 2009. Under this current resolution, services and treatment offered through The Ryan White CARE Act will decrease by 19%. Additional and substantive cuts in research and Medicaid will further compound the crisis. Also, the President's Emergency Plan for AIDS Relief transfers money to the new Global AIDS Initiative (GAI), resulting in decreased funding to other federal agencies confronting the epidemic. The GAI is poised to receive an almost 200% increase in funding, while the CARE Act will receive only a 1.7% increase. The bottom line is that unless there is radical intervention on the part of the HIV/AIDS community, only medically necessary services will be funded by The Ryan White CARE Act beyond 2005.

How can you make a difference in this situation? The Center for AIDS offers *Project LEAP*, the nation's finest advocacy training program for HIV+ individuals. If you want to become involved in deciding how federal resources are prioritized and allocated here in Houston, check it out at ***www.centerforaids.org/cfa_programs.htm#LEAP***. Classes are scheduled to begin on July 14. For more information, call 713.527.8219.



HIV 101

by Marjorie Williams, MPH

# HIV Drug Therapy—The HAART of the Matter

While it is true that less expensive and less toxic HIV medications are needed, it can hardly be denied that what is available today is far better than what was available just a few years ago—and slowly, more treatment options are coming.

Currently, there are 4 groups of **antiretroviral** medications used to treat HIV/AIDS: 1) nucleoside/nucleotide reverse transcriptase inhibitors or "nukes," 2) non-nucleoside reverse transcriptase inhibitors or "non-nukes," 3) protease inhibitors, and 4) entry inhibitors (see table below). These different groups of drugs interact with HIV in different ways to interrupt the HIV lifecycle (see diagram on page 12).

When an individual starts to take a combination of HIV medications, this type of therapy is known as HAART. HAART stands for Highly Active Antiretroviral Therapy. HAART usually combines 2 nukes with either a non-nuke or a protease inhibitor. In some situations (especially if HIV **drug resistance** is a problem), these types of medications may be combined together in different ways, sometimes also including an entry inhibitor. Scientists have found that combining the groups of HIV medications helps to decrease the chances that the virus will become resistant to any one group. Patients recently diagnosed with HIV may assume that they will immediately begin HAART. However, current guidelines established by the US Department of Health and Human Services actually recommend that treatment should be considered by any individual who has a T cell count of less than or equal to 350 or who has a viral load of more than 55,000. HAART is definitely recommended for anyone with a T cell count of 250 or less or for anyone who has an opportunistic infection (For a complete copy of the latest guidelines, visit ***www.AIDSinfo.nih.gov***).

There are 3 main reasons for these treatment guidelines. First, HIV medications are toxic and they can cause dangerous side effects, including allergic reactions and **gastrointestinal** difficulties. Second, HIV is able to change itself so that treatments become less effective. This makes it difficult for people to stay on any one drug combination for a long time. Finally, HIV drugs can be very expensive. As new medications are approved and new research tells us more about the best ways to treat HIV, the guidelines change accordingly. The treatment of HIV and what we knew back in the 1990s is very different from today.

Overall, HAART can be an effective way to manage HIV/AIDS. Individuals on therapy have lived longer and experienced a higher quality of life. However, it is important to remember that although most people with HIV will have to be treated with HAART eventually, being diagnosed with HIV does not mean one should start HAART immediately. Individuals with HIV should work closely with their healthcare providers to determine if they have a need for therapy and to discuss the benefits and liabilities of being on HAART.

**TABLE:** Currently approved medications for treating HIV/AIDS

| Nukes | Non-nukes | Protease Inhibitors | Entry Inhibitors |
|---|---|---|---|
| Combivir (Epivir + Retrovir) | Rescriptor | Agenerase | Fuzeon |
| Emtriva | Sustiva | Crixivan | |
| Epivir | Viramune | Fortovase | |
| Hivid | | Invirase | |
| Retrovir | | Kaletra | |
| Trizivir (Epivir + Retrovir + Ziagen) | | Lexiva | |
| Videx (regular or EC) | | Norvir | |
| Viread | | Reyataz | |
| Zerit | | Viracept | |
| Ziagen | | | |

...continued

# HIV101

continued from page 11

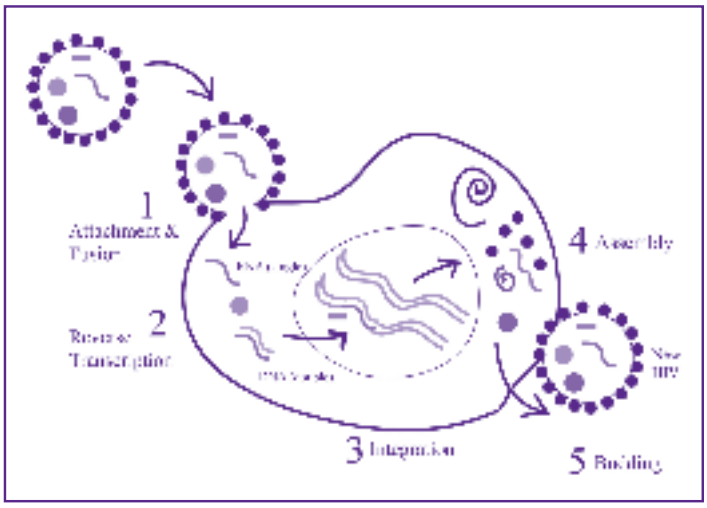
### DIAGRAM: THE HIV LIFECYCLE

Entry Inhibitors: This type of medication blocks HIV from fusing with the T cell **membrane** and subsequently reproducing in the cell (see #1 in diagram).

Nucleoside/Nucleotide reverse transcriptase inhibitors (nukes): These medications interfere with viral reverse transcriptase by acting as "fake building blocks" that disrupt the creation of proviral DNA needed to take over the infected cell to build new viruses (see #2 in diagram).

Non-nucleoside reverse transcriptase inhibitors (non-nukes): These medications also block the viral reverse transcriptase but do so by directly binding to that **enzyme** (see #2 in diagram).

Protease inhibitors: These medications block protease enzymes, which cut viral proteins into the appropriate sizes for placement into new HIV particles. Thus, the virus is unable to produce new infectious particles (see #4 in diagram).




## MAY

23 The Center for AIDS is proud to be a beneficiary of **Bunnies on the Bayou, Inc.**

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

31 The Center for AIDS is closed on Memorial Day.

For updated information on CFA programs, visit ***www.centerforaids.org/cfa_calendar.htm.***

## 2004 CALENDAR

## JUNE

3 **"Get to Know The Center for AIDS"**
breakfast and update on the AIDS epidemic
8–9 am
1407 Hawthorne
Rsvp 713-527-8219, extension 103

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

17 ***Conversation* with Shannon Schrader, MD**
"The ABCs of Hepatitis"
6–8 pm at The Center for AIDS
1407 Hawthorne
Rsvp to 713-527-8219 extension 108 for dinner and seating

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

## JULY

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

14 **Project LEAP** classes begin

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

## AUGUST

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

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

## SEPTEMBER

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

9-12 Give your Grandparents the gift of theater to benefit The Center for AIDS. **Bayou City Concert Musicals**, a performing arts program of The Center for AIDS, presents "70, Girls, 70" at Zilkha Hall.

Call Hobby Center for the Performing Arts box office 713-315-2525 for ticket information and 713-527-8219, extension 103 for underwriting opportunities.

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

# Q&A Patient/Doctor

**Wayne Bockmon, MD**, fields questions on a variety of HIV-related topics.

**Q: I am female, 44 years old, and have had HIV for 8 years (taking HIV medications all that time). My T cells have ranged from 320 to 550 (where they are now) and my viral load is less than 50. Are there any vitamins, supplements, or medications I can take to help keep me healthy? One friend mentioned that I should take fish oil, baby aspirin, vitamin B, and a multivitamin. Do you agree? Is there anything else?**

A: I think your friend's advice is sound. The issue of what vitamins and supplements are advisable for anyone living with HIV is a topic about which even experts disagree. We know that people with HIV have a higher daily requirement of nutrients, including vitamins and essential minerals. We also know from some clinical trial data that people with HIV who do take vitamins and other supplements seem to maintain a healthier immune response. The question becomes how much of what. For a person like you, I think a really good multivitamin including B complex, antioxidants, and trace minerals like zinc and selenium makes sense. The fish oil supplement is a good idea in HIV, especially if you are on medications, because of the beneficial effects on lipids (fats in the blood). People with HIV often have excessive coagulation or blood clotting that can lead to heart and other circulatory problems. The baby aspirin can thin the blood just enough to prevent that. Other nutrients may be recommended depending on your specific needs. A good nutritionist could help you decide if any of the many other supplements would be right for you.

**Q: I am a 34-year-old male and have had HIV for 6 years. I have been on and off medications (stopped for 2 years with my doctor's supervision), but was always undetectable while taking them. I get a pain that comes and goes on the right side of my hip. It's particularly uncomfortable when I am sitting on the floor or if I have been standing a lot. An X-ray last year showed no problems, but should I be worried about HIV-related bone problems? Should I get an MRI?**

A: Many things can produce joint pain. Osteoarthritis, a condition of aging that we all experience to some degree, could cause your symptoms even at age 34. A physical activity or sport that strains the joint could cause the recurring pain. In people with HIV, however, we sometimes see a serious condition that presents as hip pain and goes by the name of avascular necrosis (AVN). This condition is a loss of adequate blood flow to the bone resulting in actual death of part of the bone. AVN generally will not be picked up on a routine x-ray. An **MRI** will detect AVN and should be done if it strongly suspected. Factors associated with AVN are steroid use (including megace), smoking, heavy consumption of alcohol, and elevated lipids. If your symptoms are persistent, unrelieved by over-the-counter pain medicines, and if other causes have been ruled out, then an MRI is probably a good idea. AVN is serious and best managed if caught early.

**Q: After surviving with AIDS for more than 15 years, I really feel like I am running out of options. The only drug I have not taken yet is the injectable Fuzeon, but my doctor wants to wait for a new drug to come along because I have virus that is resistant to everything currently available. My T cells are 95 and my viral load is 44,000. I am taking Combivir and Viracept just to slow down my AIDS progression if possible. Any suggestions?**

A: Good question. I've had many debates with HIV experts about this one and I can tell you that there is no consensus of opinion. Fuzeon is a potent drug, but will only work in the long term if combined with other drugs to which your virus is sensitive. If used as the only effective antiviral, it is doomed to eventual failure. I would start with a **genotype** test and **phenotype** test to see if any of the currently available drugs might be used in some kind of combination strategy with Fuzeon. If not, your next best bet is to locate a clinical trial of a new agent with a unique **drug resistance** profile to pair with the Fuzeon.

**Q: Is cryptosporidium still a problem? If so, how do I protect myself from it? I have 380 T cells and a viral load of 12,000 on a combination of Viread, Emtriva, and Sustiva.**

A: Cryptosporidium still exists, but fortunately today we seldom see the horror stories of the past when people had no effective treatment for HIV and could not rid themselves of this infection. Cryptosporidiosis in immune-healthy people is a **gastrointestinal** disease with a predictable course and is characterized by lots of diarrhea. In HIV, especially in those with T cell counts below 200, the infection may not clear and can become chronic and debilitating. With your numbers, you are not at much risk. It's hard to "protect" oneself from exposure to cryptosporidium because it is found in soil and water, including tap water. Some water filtration systems can filter out cryptosporidium. Keeping your T cell count up is the best option. By the way, I notice that your viral load is quite high (12,000) on treatment. This tells me that either you are not taking enough of your drugs to control your virus or that resistance has developed. Two of your drugs can fail with a single **mutation** in your virus. You need to discuss this with your doctor immediately. Continuing a failing regimen is a formula for disaster, especially when you may still have other options to suppress HIV and keep viral load undetectable.

***Wayne Bockmon, MD,***
*is an HIV-treating physician at the Montrose Clinic in Houston.*

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 country. 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 3 sites: Thomas Street Clinic, the Veteran's Administration Medical Center, 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 medications 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 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.

## Study for HIV-related neuropathy

People with HIV can experience pain called **neuropathy** in their feet and sometimes their hands. This pain can be caused by HIV itself, the medications for treating HIV, or both. A research study is now enrolling to study the effectiveness of an injectable medication called Prosaptide in treating neuropathy. The 13-week trial is **placebo**-controlled (some people will not be injecting actual medicine). The self-injections must be given once a day. The study requires 2 visits for screening/interviews and 6 study visits for 2 to 3 hours each. Money is given to participants who finish the study. To be eligible, participants must be diagnosed with neuropathy by a study doctor. For more information, call Ghous Khan at 713-773-1331.

## New protease inhibitor being studied

For patients with drug-resistant HIV, a new protease inhibitor "TMC 114" may offer some hope. The drug has not been approved yet, but is being studied in people with HIV to determine its effectiveness. The study is open to men and women with HIV, age 18 or older. To be eligible, participants must have experience with the 3 main classes of HIV medications, be currently taking HIV medications that include a protease inhibitor, and have virus with up to 2 major protease inhibitor **mutations**. Certain issues may prevent participation in the study including current AIDS-defining conditions (**opportunistic infections**), current treatment interruption, and pregnancy. People who enroll in this study may not be able to take certain other medications. For more information, contact study coordinator Raúl Nuñez at 713-500-5483 (phone) or 713-608-0689 (pager).

# definitions

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

**Anemia:** low levels of red blood cells or hemoglobin in the blood, resulting in poor oxygen transport and usually feelings of tiredness or fatigue.

**Anesthetic:** a substance that dulls the senses or causes unconsciousness, usually to reduce pain during surgery or other procedures.

**Antiretroviral:** having effects against HIV, which is a type of "retrovirus."

**Cognitive:** referring to mental activities such as thinking, remembering, imagining, and learning.

**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 are the effects of the medication.

**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.

**Drug-resistance mutation (drug resistance):** 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.

**Enzyme:** a complex protein that carries out a specific job in the body.

**Fragility:** a state of being easily broken.

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

**Genotype:** a test that measures specific genetic changes (mutations) in HIV associated with drug resistance (see above).

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

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

**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.

**Membrane:** the outer coating or shell of a cell, like a water balloon or a soap bubble where the inside has all the main parts of the cell.

**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.

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

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

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

**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. This would typically be used in a control group (see above).

**Phenotype:** a test that measures drug resistance (see above) of HIV by seeing what medications still work against a person's virus in a test tube.

**Regimen:** a combination or schedule of medications.

Visit us on the web:
***www.centerforaids.org***

# Useful Resources

AEGiS online support forums for people dealing with HIV/AIDS.
***http://webboard.aegis.com:81/~1/login***

HIV news, publications, and more from AIDSmap.
***www.aidsmap.com***

Information on legal issues and HIV from Gay Men's Health Crisis (GMHC). ***www.gmhc.org/policy/legal.html***

AIDS Survival Project has a newsletter, *Survival News*, and more. ***www.aidssurvivalproject.org***

HIV Insite comes from the University of California San Francisco School of Medicine and offers a wide variety of news and information on HIV/AIDS. ***http://hivinsite.ucsf.edu***

Test Positive Aware Network publishes the newsletter, *Positively Aware*, which features an updated guide to HIV meds each year. ***www.tpan.com/tpan_home.html***

AIDSinfo now offers Live Help via the Internet, Monday through Friday, 12:00 to 4:00 pm Eastern Time. ***www.AIDSinfo.nih.gov*** (choose "Live Help") or ***http://webcontact.aspensys.com/AidsInfo/intro.jsp***

Search for clinical trials around the US on HIV or anything else. ***www.clinicaltrials.gov***

**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 walk-in information center (1407 Hawthorne) is open Monday through Friday, 9 am to 5 pm. Also, consider visiting a local branch of your public library.

# COMMUNITY SPOTLIGHT

**The Bering Support Network** is a counseling program of the Bering Memorial United Methodist Church. The program offers nurturing and healing to men and women affected by HIV/AIDS. Counseling for men, women, couples, and families is offered by licensed mental health professionals (by appointment) with fees based on a sliding scale according to ability to pay. In addition, several support groups are available:

- ***Positive Attitudes*** (a support group for HIV+ women only)
- ***Bering Spiritual Support Group*** (open to men and women)
- ***Lunch Bunch Gang*** (a weekly, walk-in support group for retired HIV+ men and women)
- Topic-specific groups open to both men and women include *"HIV and the Spiritual Journey"* (begins June 9), *"Magnetic Couples"* for couples where one partner is HIV+ and one is not (begins August 8), and *"HIV and Intimacy"* (begins September 29)
- ***Grief Therapy Group*** (6-week sessions for people who have lost a loved one through death)
- ***Loss of Relationship Group*** (6-week sessions for people recovering from the end of a committed relationship)
- Other support groups are also offered

**CONTACT INFORMATION**

**Location:** **1440 Harold Street**
**Houston, Texas**
**Phone:** **713-526-1017 (main office)**
**Web:** ***www.beringumc.org***

***"We unite in the Spirit of celebrating life and wholeness through sharing, mutual support, strength, acceptance, and love."***

The above information was accessed from the Bering Support Network brochure for 2004.