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# HIV Alerts!

## *treatment*

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## MISSION

*"The Center for AIDS Information & Advocacy empowers people living with HIV to make informed decisions about their healthcare by providing the latest research and treatment information and by advocating for accessible, affordable, and effective treatment options until there's a cure."*

## About HIV Treatment ALERTS!

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AIDS RESEARCH CONSORTIUM OF HOUSTON dba

### **The Center for AIDS Information & Advocacy**

P.O. Box 66306, Houston, Texas 77266-6306

1407 Hawthorne, Houston, Texas 77006

**Voice** 713-527-8219

888-341-1788

**Fax** 713-521-3679

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

**E-mail** [rita@centerforaids.org](mailto:rita@centerforaids.org)

### **Senior Editor**

Thomas Gegeny, MS, ELS

### **Editor**

Jennifer Newcomb-Fernandez, PhD

### **Graphics & Layout**

Teresa Southwell

### **Editorial Board**

Roberto Arduino, MD

Thomas Giordano, MD

Brenda Haile, RN, DrPH

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# Entry Inhibitor Update: A Reality Check



We last reported on entry inhibitors in the October 2004 issue of *HIV Treatment ALERTS!* (see p. 3 of that issue at

[www.centerforaids.org/rita/alerts.htm](http://www.centerforaids.org/rita/alerts.htm)). Being the latest up-and-coming class of HIV meds, the article was appropriately titled "Entry Inhibitors: Hope on the Horizon?" But if you've been keeping up with what's been going on this past year, it feels as if our hopes have been diminished.

Remember that this new class of meds works by blocking HIV from entering the T cell, potentially preventing T cells from becoming infected with HIV. Right now, Fuzeon is the only approved entry inhibitor, but there are several others being studied. Fuzeon was approved by the FDA in 2003, but it is expensive (around \$25,000 per year) and must be mixed with water, injected twice daily, and stored in the refrigerator. If other entry inhibitors are approved, they might even have fewer of the well-known, sometimes toxic side effects associated with most current treatments. In addition, this class also offers hope to patients whose virus has developed **resistance** to existing HIV meds.

One type of entry inhibitor works by attaching to a protein on T cells called CCR5. (HIV uses CCR5, along with CD4, to get inside of T cells). Pharmaceutical companies literally have been racing one another to get this new kind of entry inhibitor through clinical trials. One advantage is that they can be given in pill form. The 3 frontrunners in this race have been GlaxoSmithKline (GSK) with aplavirac, Schering-Plough with vicriviroc, and Pfizer with maraviroc.

So where are we now? Here is this year's reality check:

■ April 12 – The European AIDS Treatment Group (EATG), an influential voice in European AIDS policy, demanded that Pfizer make changes to the clinical trial design for its entry inhibitor, maraviroc. The EATG believes the trial was unethical because patients who had never taken HIV meds would be enrolling in the clinical trials regardless of their health or viral loads and receive an unproven, investigational therapy instead of proven treatments. The studies were cancelled in some European countries.

■ September 16 – Because of liver toxicity seen in 2 patients, GSK stopped its clinical trials of aplavirac in patients who had never before taken HIV meds. GSK also announced it was implementing additional safety monitoring requirements and was making changes to patient eligibility requirements for its clinical trials in treatment-experienced patients.

■ October 25 – GSK ended all studies of aplavirac because patients continued having elevations in liver enzymes, indicating possible damage to the liver.

■ October 27 – Schering-Plough discontinued a study of its vicriviroc, which was tested as a once-daily dose in combination with twice-daily Combivir in HIV+ patients who had never taken HIV meds. Basically, the study was stopped because this regimen failed to lower HIV viral loads as well as Combivir plus Sustiva. The company is still studying the drug in treatment-experienced patients and may be looking at other combinations or doses that might work better.

But it's not all bad news. As Schering-Plough announced the discontinuation of a vicriviroc clinical trial, Houston-based biotech company Tanox released results from the clinical trial of its entry inhibitor TNX-355, a CD4-binding protein that is given about once a week by **infusion**. In a late October press release, Tanox reported that after 24 weeks, when compared to **placebo** results in HIV+ patients, TNX-355 produced "statistically significant reduction in viral load" when used in combination with optimized background therapy (OBT). OBT is considered the best possible combination of currently approved HIV meds that a person can take (according to his or her unique virus). Tanox will now move on to conduct a new trial in 2006 and apply for FDA approval in 2008. This potential therapy will be aimed toward patients with limited treatment options.

Bristol-Myers Squibb is also working on their experimental drugs called "attachment inhibitors." Preliminary studies have been conducted in HIV+ and HIV-negative people. BMS is working on improving the formulation and other issues as it continues clinical development of this type of entry inhibitor.

Other entry inhibitors (some in the same classes as those described above, and some totally different) are being developed as well. Only time will tell. . . so stay tuned!

# CONFERENCE **Highlights**

## **Reyataz during pregnancy**

Researchers reviewed medical charts from all pregnant women treated with Reyataz in one clinic (abstract TuPe5.2P01). In total, 8 women were treated with Reyataz (6 received **boosted** Reyataz) in combination with other HIV meds. Treatment was well tolerated by mothers and caused only minor side effects in the infants. All infants born at the time of the report were HIV negative. Although this was a small study, these results suggest that Reyataz may be an alternative treatment option for pregnant HIV+ women.

## **Aptivus + Fuzeon**

Aptivus is a new protease inhibitor that is active against strains of HIV that are **resistant** to other protease inhibitors currently available. Aptivus must be **boosted** with Norvir and is only approved for HIV+ people who are highly treatment-experienced with few or no treatment options (sometimes called “salvage patients”) or whose HIV is resistant to several protease inhibitors. A study presented at the conference (abstract WeOa0205) revealed that while Aptivus worked well at controlling HIV in highly treatment-experienced patients, adding the entry inhibitor Fuzeon to this **regimen** suppressed HIV even better. Recently, the US guidelines for treating HIV have recommended combining Fuzeon with an active, boosted protease inhibitor in this patient population.

## **Thyroid problems persist**

According to a study presented at the conference (abstract TuPe2.3C09), the number of HIV+ patients with thyroid disease has increased dramatically in the years following the availability of potent combination HIV therapy (also called HAART). The thyroid is a small gland (located in the front of the neck) that secretes **hormones** that help control **metabolism**. Incidence of hypothyroidism (which occurs when the thyroid does not make enough thyroid hormone) increased by more than 11 times in the period since potent, combination HIV meds have been available, while incidence of hyperthyroidism (occurs when the thyroid makes too much thyroid hormone) increased more than 8 times during that period. The authors believe that changes to the immune system caused by HIV meds may also be responsible for this increase in thyroid disease.

## **Kaletra monotherapy**

Two presentations reported results from a **pilot study** comparing Kaletra monotherapy (patients received Kaletra only) to Kaletra + 2 nucleoside reverse transcriptase inhibitors (NRTIs or “nukes”). All patients were initially

taking Kaletra + 2 nukes and needed to have an undetectable viral load for more than 6 months before taking part in the study. At the beginning of the study, patients were randomly assigned (by chance, like flipping a coin) to either continue receiving Kaletra + 2 nukes or just Kaletra alone (abstract WePe12.3C05). This strategy of Kaletra monotherapy is referred to as “maintenance therapy,” meaning that treatment is designed to “maintain” already suppressed viral loads. After almost 1 year, a majority (81%) of patients taking Kaletra monotherapy had an undetectable viral load, although not as many patients as in the Kaletra + 2 nukes group (95%).

These results suggest that Kaletra monotherapy may be an alternative treatment option for patients with controlled HIV; however, more research is required before this strategy becomes standard practice. For example, 4 patients receiving the Kaletra monotherapy experienced a treatment failure (defined as a detectable viral load) compared to only 1 patient receiving Kaletra + 2 nukes.

Another presentation (abstract WePe12.3C06) focused on why patients receiving Kaletra monotherapy had a treatment failure. The researchers found that patients who were less **adherent** to their HIV meds or who had an undetectable viral load for a shorter time before starting Kaletra monotherapy were more likely to experience a treatment failure.

## **Viread + Norvir: Proceed with caution**

Viread may increase the risk of kidney damage in some HIV+ patients. One study (TuPe3.5B01) used a large database to identify HIV+ patients with normal kidney function, but who later developed kidney problems while receiving Viread. They reported that patients taking Viread in combination with a protease inhibitor were more likely to have kidney problems. This risk was especially apparent in patients taking both Viread and Norvir as part of their HIV **regimen**. Nowadays, Norvir is used in small doses to **boost** levels of another protease inhibitor. (Norvir is part of the protease inhibitor Kaletra as well). Although med combinations containing Norvir and Viread are probably safe for most patients, those taking both these meds as part of their HIV treatment should have their kidneys monitored regularly. A related study performed in cells (WePe3.3C09) could help explain how Norvir and Viread interact. It appears that Norvir inhibits a special pump found in kidney cells that helps process or **metabolize** Viread. By inhibiting this pump, Viread is permitted to build up in kidney cells. This build-up could potentially damage the kidney cells and the kidneys. More research is still needed on this issue.

## MRSA and HIV

Methicillin-resistant *Staphylococcus aureus* (MRSA) is a type of bacteria that can cause infections in different parts of the body, including the skin, blood, lungs, or urinary tract (see Bottom Lines on page 13). HIV+ patients are at an increased risk for becoming infected with this type of “staph” infection. It is not known if T-cell counts or HIV viral load has an effect on whether a patient will become infected with MRSA. A study presented at the conference (TuPe7.5C04) identified 64 HIV+ men with MRSA and divided the men into groups based on their T-cell counts and HIV viral loads. They found that patients with different T-cell counts (for example, less than 200, between 200 and 500, and more than 500) had about the same risk of getting MRSA. The same was true for HIV viral load—there was no relationship between high viral load and risk of MRSA. The authors conclude that neither a patient’s immune system nor their HIV viral load is related to whether they will get MRSA. Instead, they note that most of the infections were caused by skin-to-skin contact and skin-to-wound contact.

## MACS update

**Metabolic** problems like **lipodystrophy**, **dyslipidemia**, and high blood sugar (hyperglycemia) affect HIV+ individuals, but the specific risk factors for developing these conditions are not well understood. The Multicenter AIDS Cohort Study (MACS) is a large and long-term study **cohort** that focuses on HIV infection and treatment in homosexual and bisexual men in 4 US cities: Baltimore, Chicago, Pittsburgh, and Los Angeles. As part of the MACS, researchers examined 679 HIV+ men and 391 HIV-negative men to look for differences between the groups (TuPe2.2B18). They found that HIV+ men were more than 1.5 times more likely to have metabolic problems compared with HIV-negative men. Risk factors for developing metabolic problems included lower T-cell count, tobacco use, older age, and use of HIV meds (especially protease inhibitors). In contrast, alcohol use was somewhat protective against developing metabolic problems. Of course any benefits to alcohol use usually happen with light to moderate drinking (1 or 2 drinks per day maximum) and not with heavy drinking, which has been shown to be harmful.

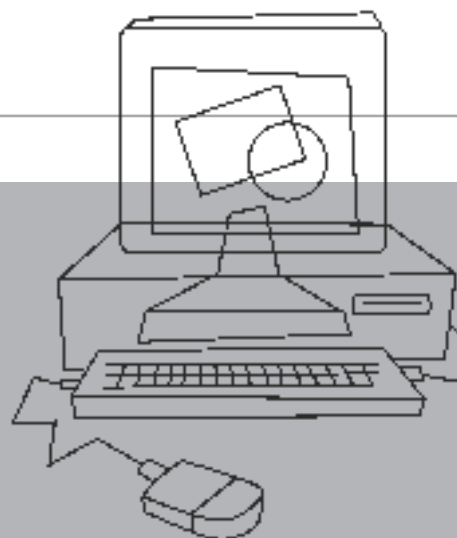
On a related note, a recent paper published in the *Archives of Internal Medicine* (165, p. 1179, 2005) also focuses on metabolic problems as part of the MACS study. Specifically, researchers examined the frequency

of **diabetes** in their HIV+ study population by comparing 568 HIV+ men (411 of whom were taking potent combination HIV therapy, also called HAART) and 710 HIV-negative men. Their findings show that in HIV+ men, diabetes occurs even more frequently than once believed. For example, HIV+ men not taking HAART were more than 2 times as likely to develop diabetes when compared with HIV-negative men. However, this number jumped to 4 times as likely when researchers examined HIV+ men who were taking HAART. Although taking HAART can lead to certain health problems, its benefits in terms of controlling HIV and slowing disease progression far outweigh these risks.

## Sustiva + fixed-dose combinations

According to results presented at the conference, the non-nucleoside reverse transcriptase inhibitor (NNRTI or “non-nuke”) Sustiva is effective when combined with different fixed-dose combination meds containing 2 nucleoside reverse transcriptase inhibitors (NRTIs or “nukes”). In one study (abstract WeOa0202), HIV+ patients who had never taken HIV meds were randomly assigned (by chance, like flipping a coin) to receive Sustiva + Truvada (Viread + Emtriva) or Sustiva + Combivir (Retrovir + Epivir). Patients taking Sustiva + Truvada were more likely to have an undetectable HIV viral load almost 1 year after starting treatment, have a higher T-cell count, and were less likely to experience a treatment failure. Patients taking Sustiva + Combivir had more side effects and were more likely to stop treatment because of side effects. This was most likely because of **anemia** caused by Retrovir (also known as AZT). The lower pill burden of Truvada (1 pill once a day versus 1 pill twice a day with Combivir) is another benefit for patients. While the combination of Sustiva + Combivir was not as optimal as Sustiva + Truvada as an initial HIV **regimen**, Combivir is certainly a worthwhile treatment option and could have a use for later treatment options. Another study presented (abstract WePe12.2C23) showed that the combination of Sustiva + Epzicom (Ziagen + Epivir) was effective and well tolerated as an initial HIV treatment regimen. Like Truvada, Epzicom is taken as 1 pill once a day. As expected, Ziagen-related **hypersensitivity reactions** occurred in about 7% of patients.

**DON'T HAVE INTERNET ACCESS?** If you are in the Houston area, remember that The Center for AIDS has a computer workstation 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.



## Who's to blame?

Problems with **dyslipidemia** and glucose (sugar) **metabolism** continue to plague HIV+ people. But is it the HIV meds causing the problems or the HIV itself? A study in *HIV Medicine* (6, p. 114, 2005) examined 419 HIV+ people who had never taken HIV meds before. Researchers found that patients with more advanced HIV disease (lower T-cell counts, higher viral loads, or a history of having an AIDS-defining illness) were more likely to show signs of dyslipidemia and **insulin resistance**, a condition associated with the development of **diabetes**. These findings indicate that the HIV disease itself can lead to many of the metabolic problems seen in HIV+ patients.



HIV meds, and perhaps HIV infection itself (see summary above), can lead to higher cholesterol levels in many HIV+ patients. As a way to treat this **dyslipidemia**, statins are frequently prescribed to lower cholesterol. Previous studies have already revealed drug interactions between protease inhibitors and statins, whereby protease inhibitors raise levels of a particular statin in the blood. However, not much is known about interactions between non-nucleoside reverse transcriptase inhibitors (NNRTIs or “non-nukes”) and statins. To study possible interactions between the non-nuke Sustiva and statins, 52 HIV-negative volunteers received Sustiva (on days 4 through 18) and one of the following statins (on days 0 through 3 and days 15 through 18): Zocor, Lipitor, or Pravachol. Researchers measured blood levels of Sustiva before volunteers received the statins. They also measured levels of the statins before volunteers received Sustiva. The results, which are published in the *Journal of Acquired Immune Deficiency Syndromes* (39, p. 307, 2005), show that the statins had no effect on Sustiva blood levels. In contrast, Sustiva sped up the **metabolism** of the statins, leading to dramatically lower blood levels of each of the statins. These findings indicate that patients taking a statin to lower their cholesterol levels may not be receiving the full benefit if they are also taking Sustiva. However, increasing the statin dose to counteract this effect is not safe. Patients should discuss such concerns with their healthcare provider.

When to start taking HIV meds is an important decision. Current guidelines focus on total CD4 T-cell count (the total number of T cells that have “CD4”) and HIV viral load. However, a recent study published in the *Journal of Infectious Diseases* (192, p. 950, 2005) suggests that these guidelines could also include the CD4 T-cell percentage (meaning, the *percentage* of all T cells with “CD4”). Routine blood tests (blood work or “labs”) show this number, in addition to total CD4 T-cell count. Previous studies have shown that even patients with a high CD4 T-cell count may have a low CD4 T-cell percentage (and therefore not as healthy an immune system as they thought). In this study, researchers looked at 788 HIV+ patients to see if and when they experienced an AIDS-defining illness or if they died. Patients with less than 17% CD4 T cells were more likely to have an AIDS-defining illness or die during the study, compared with patients who had a higher percentage of CD4 T cells. This was true even in patients who had a CD4 T-cell count above 350 when the study began. In fact, a CD4 T-cell percentage of less than 17% was the biggest risk factor for having an AIDS-defining illness or dying. Although often overlooked, CD4 T-cell percentage may be more accurate and a better predictor of HIV disease progression.

# Cancer updates

Good news—recent studies are showing that potent combination HIV therapy (also called HAART) improves a patient's ability to respond to cancer treatment. Before HAART was available, HIV+ patients with cancer did not have many options. Survival rates were disappointing and higher doses of chemotherapy, which are sometimes necessary to fight certain cancers, could not be used in these patients for fear of serious side effects. Fortunately, this situation is changing, possibly because of healthier immune systems in HIV+ people taking HAART. A study in the journal *Blood* (105, p. 1891, 2005) reports some success when HIV+ patients with a type of cancer called "non-Hodgkin's lymphoma" (NHL) are treated with aggressive chemotherapy. Patients received a combination of rituximab (a drug that kills the immune cells involved in NHL) and a 4-day infusion of the chemotherapy agents cyclophosphamide, doxorubicin, and etoposide. The majority of patients were also receiving HAART. Most patients responded quite well to this therapy, with 75% experiencing a complete or partial **remission**. Unfortunately, with this aggressive treatment came more serious side effects. In fact, 27 patients developed an infection and 6 patients died of an infection. While this treatment provides hope for HIV+ patients with cancer, the researchers caution that more studies are needed before this combination becomes a standard treatment.

According to a recent study in the *Journal of Acquired Immune Deficiency Syndromes* (39, p. 293, 2005), cancer survival does seem to be improving in people with AIDS. The study assessed cancer survival in people with AIDS and people without AIDS during the years 1980 through 2000 for a variety of cancers. Researchers reported dramatic

improvements in cancer survival for patients with AIDS in the years between 1996 and 2000, coinciding with the years that HAART became available. These findings indicate that the gap in cancer survival between patients with AIDS and those without AIDS is narrowing, most likely because of improved treatments for both cancer and HIV. However, this is not the case for all types of cancer. For example, survival is still worse in people with AIDS who have Hodgkin's disease, or cancer of the lung, larynx, or prostate.

Another study published in the *Journal of Clinical Oncology* (23, p. 4430, 2005) examined survival in HIV+ patients with 2 different types of lymphoma, AIDS-related Burkitt's Lymphoma (HIV-BL) and AIDS-related Diffuse Large-cell Lymphoma (HIV-DLCL). Evidently, HAART has dramatically improved survival for patients with HIV-DLCL, with rates similar to that of an HIV-negative patient with DLCL. In contrast, patients with HIV-BL have not done as well. One possible reason could be the choice of treatment. While HIV-negative and HIV+ patients with DLCL receive the same treatment, patients with HIV-BL are treated with standard doses of chemotherapy, which may not be aggressive enough.

With some cancers still prevalent in HIV+ people (despite being on successful HIV treatment), regular screening for cancer is important. One study published in the *American Journal of Gastroenterology* (100, p. 1805, 2005) indicates that HIV+ people are less likely to be screened for colorectal cancer—a cancer that greatly affects this population. This is a cancer where early detection could mean the difference between life and death.

## Check out those KIDNEYS

Guidelines for assessing and managing kidney disease in the HIV+ population were recently published in the journal *Clinical Infectious Diseases* (40, p. 1559, 2005). Because kidney disease can be fatal, the authors recommend that all patients be screened for existing kidney disease when they are first diagnosed with HIV. If there are no signs of kidney problems, those patients at risk for kidney problems (for example, people of African descent; those with T-cell counts less than 200 or viral loads above 4000; or those with diabetes, high blood pressure, or hepatitis C co-infection) should continue to be screened every year. Patients with signs of kidney damage should be referred to a nephrologist (a doctor specializing in kidney function and disease) for additional tests. The choice of HIV meds needs to be customized for each patient and certain HIV meds should be avoided depending on a person's risk factors for kidney disease. HIV meds should be started immediately in HIV+ persons with kidney disease who are not taking HIV meds. Those patients at risk for kidney disease who are taking HIV meds should undergo kidney screening 2 times a year.

## Liver problems in HIV/HCV

The job of HIV meds is to control a person's HIV infection, but these meds can also increase a patient's risk of liver disease, a potentially fatal condition. In people infected with both HIV and hepatitis C virus (HCV), liver disease is an even bigger threat. "Fatty liver" or steatosis (pronounced stay-ah-TOE-sis) refers to the build-up of fat in liver cells and can speed up the development of liver disease. People with steatosis also may not respond as well to interferon therapy, which is the standard treatment for HCV infection. Though steatosis can be a serious condition, little is known about how often it occurs in co-infected patients and how certain HIV meds can affect it. One study published in the journal *AIDS* (19, p. 585, 2005) examined liver tissue samples from 112 co-infected people who had used HIV meds for at least 2 years. The results showed that 40% of the group had steatosis and that these people had a greater chance of having more advanced liver disease. Steatosis was more common in those who were White, overweight, had high levels of blood sugar (hyperglycemia), and who had used the nucleoside reverse transcriptase inhibitor (NRTI or "nuke") Zerit. The findings suggest that losing weight, and perhaps changing your HIV meds, may improve the situation.



## Just say no!

By themselves, cocaine and HIV infection increase your risk of developing heart disease. According to a study in the *Archives of Internal Medicine* (165, p. 690, 2005), HIV+ people who use cocaine are more likely to have very early signs of heart disease before any symptoms are present. Specifically, researchers examined coronary artery calcification, a marker of early atherosclerosis (the thickening and hardening of artery walls caused by plaque formation or fat deposits). Researchers studied 224 black men and women between the ages of 25 and 45 who did not have existing heart disease. Individuals were divided into groups based on whether they used cocaine and were HIV+ or HIV-negative. People with just one of the risk factors (cocaine use or HIV infection) were slightly more likely to have coronary artery calcification, though not as much cocaine users who were HIV+. Those least likely to show early signs of artery disease were people who were HIV-negative and did not use cocaine. These findings indicate that HIV infection and cocaine use may contribute to the development of atherosclerosis and may increase the chances of developing heart disease.

In addition, a study in the journal *Neurology* (64, p. 1343, 2005) focused on the effects of methamphetamine ("crystal meth" or "meth") use, HIV infection, and hepatitis C virus (HCV) infection on **cognitive** function (the ability to think and understand information). Researchers studied 430 people who were either part of a **control group** or who were HIV+, HCV+, meth users, or a combination of these factors. Study participants underwent some mental tests to determine how well they processed and understood information. The results show that each of these factors can lead to cognitive problems. In addition, cognitive problems can be even more serious in people who have multiple risk factors (for example, a person co-infected with HIV and HCV, an HIV+ person who also uses meth, or a co-infected person who uses meth). However, there were some limitations to this study. For example, out of the 430 people, only 2 were HCV+, HIV-negative, and did not use meth, making it difficult to understand the effects of HCV infection alone. In addition, many of the people in the study drank large amounts of alcohol. Because alcohol abuse can also cause cognitive problems, it is hard to know to what extent alcohol use contributed to the results.

## thinking it over



Problems with **cognitive** function (the ability to think and understand information) can significantly affect those infected with HIV. A recent study in the *Proceedings of the National Academy of Sciences of the United States of America* (102, p. 15647, 2005) identified specific parts of the brain that are damaged by HIV. Researchers examined 29 patients with AIDS (13 of whom were receiving potent combination HIV therapy, also called HAART) and 14 healthy volunteers as part of the **control group**. Special scans (MRI or magnetic resonance imaging) were performed on everyone's brain. In addition, all subjects underwent mental tests to determine how well they processed and understood information. When MRI scans were compared, patients with AIDS had severe thinning of the cerebral cortex in several areas of the brain, including areas responsible for cognitive function. The cerebral cortex is the outer layer of the brain and is responsible for a variety of important functions, including the ability to think and understand information, remember things, solve problems, function in social situations, and control motor function (the ability to move different parts of the body). Those patients taking HAART also had this type of damage, indicating that the brain is still vulnerable to HIV infection even in people taking HIV meds. Because this was a small study, the researchers were unable to study whether the choice of HIV meds had an effect on this damage. Certain HIV meds may be more protective than other HIV meds if they cross into the brain from the bloodstream.

## CMV and AIDS

Cytomegalovirus (CMV) is an **opportunistic infection** that continues to be a threat even in patients receiving potent combination HIV therapy (also called HAART). According to a recent study in the *Journal of Acquired Immune Deficiency Syndromes* (38, p. 538, 2005), detection of CMV viral load in a person with AIDS can provide important information about their survival. A group of 187 individuals with AIDS who were positive for CMV (had **antibodies** for CMV in their blood), but who had no history or symptoms of actual CMV disease, were studied for an average of about 1 year (some people were followed for several years). The majority of patients were receiving HAART. During the study, 30 people died, though none died because of CMV disease. Of the people who died, almost half had detectable CMV viral loads at some point during the study. In fact, people with a detectable CMV viral load were about 2 to 4 times more likely to die from AIDS-related causes (but not from CMV) than those with undetectable CMV viral loads. These findings suggest that a detectable CMV viral load, in addition to T-cell count and HIV viral load, is an indicator of a person's health and their risk of dying.



## TMC 114 expanded access

TMC 114 is a new protease inhibitor that has not yet been approved by the Food and Drug Administration (FDA). Previous studies have shown that this protease inhibitor may be active against HIV that is **resistant** to other protease inhibitors. Tibotec, the makers of TMC 114, recently announced they will provide an early access program (EAP) for this HIV med. This means that HIV+ individuals with few or no other treatment options who need TMC 114 (as a way to create an effective multi-drug HIV **regimen**) can receive this med before it is FDA-approved. If you are in this situation, discuss TMC 114 with your doctor. He or she can get more information about this program by e-mailing **EAP@tibbo-jnj.com**. They can also search clinical trials information at the AIDS Community Research Initiative of America website at **www.acria.org** or the Clinical Trials.gov website at **www.clinicaltrials.gov**.



# GET YOUR SHOTS



HIV+ individuals should get vaccinated against hepatitis B (HBV) because HBV infection is a serious threat. While a **vaccine** is available, it doesn't always work in many HIV+ people. A recent study in the journal *Vaccine* (23, p. 2902, 2005) studied whether a double dose of the vaccine would work better. HIV+ patients were randomly assigned (by chance, like flipping a coin) to receive the standard dose of vaccine (94 patients) or a double dose of the vaccine (98 patients). In addition, this was a "double-blind" study, meaning that both patients and healthcare workers did not know which treatment each patient was receiving. Patients in both groups received the vaccine 3 times: immediately after beginning the study, and 1 month and 6 months later. Those patients who received the double dose were more likely to show **antibodies** against HBV compared with patients who received the standard dose. The study also showed that a patient's T-cell count and HIV viral load were important predictors of whether a patient would respond to the vaccine (this is true for other vaccines as well). While this was also the case when HIV+ patients receive the standard vaccine dose, it was even more dramatic when patients were given the double dose. For example, 64% of the double-dose patients with T-cell counts over 350 experienced **seroconversion** compared to 24% of the double-dose patients with T-cell counts under 350. In addition, 58% of the double-dose patients with an HIV viral load under 10,000 experienced seroconversion compared to 18% of the double-dose patients with an HIV viral load over 10,000. Side effects were the same in each group and included soreness at the injection site, headache, and fever. In general, the standard dose and the double dose worked about the same in patients with T-cell counts less than 350 or a viral load above 10,000. The best strategy may be to use a double dose of HBV vaccine in patients with controlled HIV and a healthy immune system.

On a related topic, the flu is serious business for everyone, but especially for people with weaker immune systems, like those infected with HIV. Not only can the flu raise HIV viral loads temporarily, it can be deadly in some people with HIV. The good news is that a recent study in the *Journal of Acquired Immune Deficiency Syndromes* (39, p. 167, 2005) confirmed that a flu shot can protect HIV+ individuals from getting the flu. Researchers studied 262 HIV+ people who received a flu shot and 66 HIV+ people who did not. The patients who did not get vaccinated were more than 3 times as likely to get the flu. Once again, T-cell counts were important. Patients with T-cell counts above 200 were more likely to experience seroconversion, leading to better protection against the flu virus, compared to those patients with lower T-cell counts. Those patients with antibodies against the flu *before* they received this flu shot (because they had received a flu shot the previous year) were more likely to make antibodies against the flu again, regardless of their T-cell counts. These results show the importance of getting a flu shot every year.

## A "boost" for Fuzeon

The US guidelines for treating HIV now recommend combining Fuzeon with an active, **boosted** protease inhibitor in HIV+ patients who are highly treatment-experienced ("salvage" patients). These patients require new types of treatments because they have taken many HIV meds in the past and their HIV is **resistant** to these drugs. Studies found that treatment-experienced patients were better able to control their HIV for longer periods of time when they added an active, boosted protease inhibitor to the Fuzeon in their treatment **regimen**.

## FDA Bits



### Once-daily Kaletra approved

In April, the Food and Drug Administration (FDA) approved the use of Kaletra as a once-daily HIV med (6 capsules taken once a day) for patients who have never before taken HIV meds (in particular protease inhibitors). Previously, Kaletra was only approved to be taken as 3 capsules twice a day. However, patients who have taken HIV meds before should not take Kaletra once a day. While this approval means a simpler dosing schedule for some patients, side effects tended to be more frequent and more serious in patients taking Kaletra once a day. Once-daily Kaletra should not be combined with the HIV meds Sustiva, Viramune, Lexiva, or Viracept. Once-daily Kaletra has not been studied in combination with Crixivan or Invirase. In addition, once-daily Kaletra should not be combined with carbamazepine, phenobarbital, or Dilantin (phenytoin). Kaletra capsules, whether taken once or twice a day, should be taken with food.

In October, the FDA approved a new tablet version of Kaletra. Previously, Kaletra was only available as a gelatin-like capsule. This new version can be taken with or without food and does not need to be refrigerated. While the total daily dose of Kaletra is unchanged, the number of Kaletra pills an adult must take has been reduced: 2 tablets twice a day or 4 tablets once a day, depending on whether patients are instructed to take the med once or twice daily.

### Hivid and Fortovase to be *discontinued*

Roche Pharmaceuticals, the makers of Fortovase (soft-gel saquinavir) and Hivid (zalcitabine, ddC), announced that it will stop making both drugs next year. Demand for these drugs has dropped dramatically as new HIV meds have been developed that have fewer side effects and more convenient dosing schedules. For example, **neuropathy** was a common side effect in patients taking Hivid, and it is no longer recommended as a preferred HIV drug. The hard-gel version of saquinavir, Invirase, will still be available and offers many advantages over Fortovase including fewer pills, smaller pill size, and no refrigeration. In addition, Invirase should be taken with Norvir to **boost** its levels.

## FDA Bits



### Update on fixed-dose combination of Truvada and Sustiva

Last December, Bristol-Myers Squibb and Gilead Sciences announced they would work together to develop a fixed-dose combination of Sustiva, a non-nucleoside reverse transcriptase inhibitor (NNRTI or “non-nuke”), and Truvada, a combination pill containing the nucleoside reverse transcriptase inhibitors (NRTIs or “nukes”) Emtriva and the related medication Viread. However, Gilead recently announced it was having some difficulty combining these meds in such a way that they still worked. The companies are still working on a solution, which may involve layering Truvada and Sustiva within one pill, rather than mixing the meds together. If successful, this would be the first complete HIV **regimen** contained in one pill that only needs to be taken once a day. Regardless, 2 companies working together to create better HIV meds is always a step in the right direction.

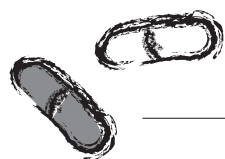
### FDA approves generic version of Retrovir

In September, the Food and Drug Administration (FDA) approved several generic versions of Retrovir (AZT, zidovudine) to use in combination with other HIV meds to treat HIV. Approved by the FDA in March 1987, Retrovir was the first HIV med to become available. Both zidovudine tablets (300 mg) and oral solution (50 mg/5mL) will be available as generic versions. This is the second generic version of an HIV med to be approved in the United States; a generic version of Videx was approved in December 2004.



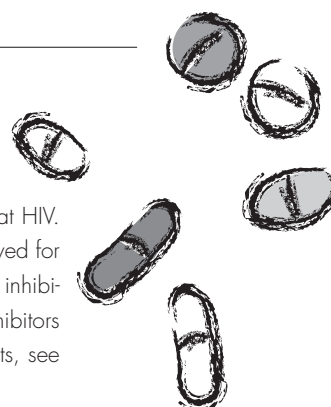
### Viread warnings

New precautions have been added to the labeling for Viread. A long-term study in patients taking Viread in combination with other HIV meds showed that patients were more likely to experience bone loss in the lower (lumbar) spine. Patients with a history of broken bones or fractures or who are at risk for bone loss or thinning bones should be monitored closely by their healthcare provider. Though not part of this study, taking calcium and vitamin D supplements may prevent some bone loss.



### FDA approves Aptivus

In June, the Food and Drug Administration (FDA) approved the protease inhibitor, Aptivus, to help treat HIV. Aptivus must be used in combination with Norvir and at least 2 other HIV meds. Aptivus is only approved for HIV+ people who are highly treatment-experienced or whose HIV is **resistant** to several protease inhibitors. This new protease inhibitor is active against strains of HIV that are resistant to the other protease inhibitors currently available. For more information, such as important drug interactions and possible side effects, see The CFA's fact sheet on Aptivus at [www.centerforaids.org/rita/facts/aptivus.pdf](http://www.centerforaids.org/rita/facts/aptivus.pdf).



# Advocacy Update: Medicare Rx (Medicare Part D)

By **Nita Costello**



On January 1, 2006, Medicare will offer a new prescription drug benefit called “Medicare Rx” (also known as “Medicare Part D”). All individuals with Medicare Part A or Medicare Part B are eligible to enroll regardless of age, income, or health conditions. Note that benefits for Medicaid-only recipients will not change.

By now, beneficiaries should have received the *Medicare & You* 2006 handbook, which explains in detail what prescription drug coverage includes and which plans are available in specific regions of the country. Prescription Drug Plans have started their advertising across the country. People just need to review the various Prescription Drug Plans to choose the one that best suits their needs. There will be national Prescription Drug Plans that will provide coverage to people in all states, and there will be regional ones that will be available in only certain areas.

**Enrollment.** The enrollment period begins November 15, 2005. People can sign up for Medicare Rx by calling 1-800-633-4227 (1-800-MEDICARE), by visiting **[www.medicare.gov](http://www.medicare.gov)**, or by calling the individual drug plan directly. Those who do not enroll by December 31, 2005 will have until May 15, 2006 to enroll in a plan. If a person does not enroll in a plan by May 15, 2006, the Centers for Medicare and Medicaid Services (CMS) will randomly assign a plan. In addition, a late fee will be charged for each month enrollment is delayed. After that, individuals will have to wait until the next open enrollment period to enroll, which will be November 15 through December 31, 2006.

If an application is approved between November 15 and December 31, 2005, the coverage becomes effective January 1, 2006. If an application is approved after January 1, 2006, the coverage becomes effective on the first day of the month following when the completed application was received.

Individuals with incomes greater than 150% of the “Federal Poverty Level” are eligible for the standard benefit. This plan will have a monthly premium (estimated at \$35) and provides prescription drug coverage. A \$250 yearly deductible (out-of-pocket) must be met before the initial coverage kicks in. After that, those enrolled will pay about 25% of their next \$2,000 in drug costs with Medicare Rx paying 75%. After that, those enrolled will pay 100% of the next \$2,850 in drug costs. Once a total of \$3,790 in out-of-pocket expenses is reached (which includes other expenses such as co-pays at the pharmacy), those enrolled will pay 5% of drug costs for the rest of the year with Medicare Rx paying 95%.

Individuals with incomes less than 150% of the Federal Poverty Level will have different deductibles, co-pays, and other out-of-pocket expenses.

There is “extra help” for people who qualify—such as those who are single with an annual income of up to \$14,000 or those who are married with an annual income of up to \$19,000. Other information is also considered, such as the value of what you own. People will also qualify if they get help from Medicaid to pay for Medicare premiums or if they receive supplemental Social Security Income (SSI). For information on “Extra Help,” or to apply, call the Social Security Administration at 1-800-772-1213 or visit **[www.ssa.gov](http://www.ssa.gov)**.

**If you are HIV+ AND have Medicare and Medicaid benefits (are fully “dual eligible”):** You will automatically be enrolled in Medicare Rx and randomly assigned to a plan, but can change plans before the December 31, 2005 deadline. The Medicare Rx plan will offer drug coverage for HIV meds; however, review your plan (comparing with others) to ensure it meets your specific needs. You will no longer receive Medicaid prescription coverage, but Medicaid will continue to pay for other medical costs. Note that all prescription drug plans are required to have all FDA-approved (as of January 1, 2006) HIV meds on their drug formularies.

**If you are HIV+ AND have Medicare AND get state assistance (partially “dual eligible”):** You will be able to receive full prescription coverage through Medicare Rx, but you will not automatically be enrolled in Medicare Rx on January 1, 2006, so review the plans and enroll in one by the December 31, 2005 deadline.

**If you are HIV+ AND have Medicare and Medicaid benefits AND live in Texas:** There are an estimated 21 Prescription Drug Plans in Texas. The Texas HIV Medication Program (THMP) will be sending out letters to all active clients identified as having Medicare. These letters will inform them about their particular situation and how THMP will work with them.

**If you are receiving prescriptions from the Department of Veterans Affairs (VA).** The VA prescription benefits do not change, so nothing has to be done.

Additional online information resources:

- The Centers for Medicare & Medicaid Services (CMS) at **[www.cms.hhs.gov](http://www.cms.hhs.gov)** and **[www.medicare.gov/medicarerereform/drugbenefit.asp](http://www.medicare.gov/medicarerereform/drugbenefit.asp)**
- WebMD Medicare Rx Benefits at **[www.webmd.com/medical\\_information/medicare\\_rx\\_benefits/default.htm](http://www.webmd.com/medical_information/medicare_rx_benefits/default.htm)**
- Social Security Online at **[www.socialsecurity.gov/prescriptionhelp](http://www.socialsecurity.gov/prescriptionhelp)**
- Medicare Rx Connect at **[www.maprx.info](http://www.maprx.info)**
- American Association of Retired Persons (AARP) at **[www.aarpmedicarerx.com/learn/learn\\_qa.aspx?tab=2](http://www.aarpmedicarerx.com/learn/learn_qa.aspx?tab=2)**
- Texas Department of Aging and Disability Services at **[www.txcares.org/medicare/index.html](http://www.txcares.org/medicare/index.html)**
- Kaiser Family Foundation Medicare Drug Benefit Calculator at **[www.kff.org/medicare/rxdrugscalculator.cfm](http://www.kff.org/medicare/rxdrugscalculator.cfm)**
- Medicare Today Drug Benefit Calculator at **<http://webstudies.lewin.com/pdb/medicare2.htm>**



## Stopping medications in an emergency: A guide for HIV+ people

# factSheet

### What should I do if I have been through an emergency situation, such as a hurricane, fire, or earthquake?

Anyone who has been through an emergency situation, been exposed to flood waters or contaminated air or water, been forced to evacuate, etc. should receive a medical evaluation right away. People with HIV/AIDS should see a healthcare provider, preferably someone with experience in HIV, right away. This is even more important if a person has other health conditions (**diabetes**, liver or kidney disease, heart disease, cancer, etc.) in addition to HIV/AIDS.

In any of these situations, if you have HIV disease or AIDS and you get a fever, rash, night sweats, muscle pain, headache, or infected cuts/scrapes, see a physician with experience in HIV as soon as possible. Even in an emergency situation, it's important to let medical personnel know about any conditions you have or any diagnoses you have. Finding any clinic staff or healthcare providers who specialize in HIV is an important thing to do once you are brought to safety.

### What should I do if I had to stop taking my HIV meds in an emergency situation?

In general, if your viral load is undetectable and you stop taking your HIV meds for a while, you can re-start them again and regain viral control. BUT, any individuals re-starting their HIV medications should see an HIV healthcare specialist first. *Some HIV medications require important consideration before re-starting them.*

- One example includes drugs that can stay in the body for a long time such as Sustiva, Viread, or Truvada. When a person stops taking a combination of HIV medications that includes a longer-lasting drug, the other drugs may be processed out of the body more quickly, leaving the longer-lasting drug "on its own." This is an opportunity for HIV to become "**resistant**" to that longer-lasting medication. "Resistant" means the drug will no longer work as part of a combination of HIV medications. In this case taking different medications may be best, so talk to an HIV specialist first.
- Another example is any combination of medications that includes the HIV drug Ziagen (also included in Epzicom and Trizivir). Re-starting this medication means looking out for a serious allergic ("**hypersensitivity**") reaction. Symptoms include skin rash and 2 or more of the following symptoms: fever, nausea, vomiting, diarrhea, abdominal pain, severe tiredness, achiness, sore throat, or shortness of breath. If you have ever had such a reaction in the past, do not re-start this medication because the repeat reaction can be fatal.

### What about other meds?

Even more importantly, if you were taking medications to treat or prevent **opportunistic infections** (PCP, CMV disease, MAC, cryptococcal meningitis, etc.), those medications should be re-started as soon as possible. These medications are usually needed for people with low T-cell counts. Staying on these medications (such as Bactrim for PCP) is even more important in the short-term than taking the HIV medications.

HIV or AIDS may not be a person's only health issue. People with HIV often have other diseases such as diabetes, heart disease, cancer, liver problems (such as hepatitis), etc. Many times these conditions require additional medications. *These non-HIV health issues may cause more problems if left untreated than HIV itself!*

### What if I have liver problems?

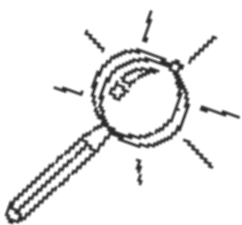
The liver is a very important organ that has many functions in the body, including regulating the amount of chemicals and drugs (including HIV medications) in the body. If a person's liver is not working properly, there may be higher levels of various HIV medications in the body, because the liver is not able to completely clear the drug out of the body. These higher levels of different HIV drugs may lead to a person developing serious side effects or toxicities. Liver problems can cause other issues with HIV medications as well.

If your healthcare provider has told you in the past that you have "elevated liver proteins" OR if you have hepatitis A, B, or C, OR some other problems with your liver, such as liver cancer or cirrhosis (scar tissue on the liver), please check with a healthcare provider that specializes in treating people living with HIV when considering re-starting your HIV medications.

### I have heard that stopping meds can hurt my T cells, is this true?

If you have ever had a very low T-cell count (such as 100 or lower), you should try to re-start your HIV medications as quickly as possible. Research has shown that people who have had a very low T-cell count in the past, but now have higher numbers of T cells, are more likely to have a quick drop in T cells if they stop taking their HIV medications. Usually, when an HIV+ person's T-cell count drops, the level of the virus in the body increases.

Also, any person with a low T-cell count can easily develop opportunistic infections, and it may be harder for this person to fight off illnesses (especially any that may have come from dirty flood waters, for example) or heal from cuts and bruises. Finding a doctor who specializes in HIV/AIDS is very important in this situation.



# Bottom Lines

## MRSA in the community: A serious problem

"Methicillin-resistant *Staphylococcus aureus*" (MRSA) is a type of bacteria that can cause infections in different parts of the body. This type of "staph" infection is tough to treat because it has become resistant to many antibiotics that used to work, including methicillin, amoxicillin, penicillin, and oxacillin. Some antibiotics still work against MRSA, but new antibiotics need to be developed because the bacteria keep changing.

MRSA infection often appears as a skin infection, like a **boil** or **abscess**. MRSA can also infect surgical wounds, the bloodstream, the lungs, or the urinary tract. Sometimes, MRSA infections can be very serious and even fatal. For example, deadly cases of pneumonia can occur in people who have MRSA and who are weakened by flu. While it was once believed that the skin infection called "necrotizing fasciitis" (also known as "flesh-eating" bacteria) was caused by other types of infection, researchers now know that MRSA can also cause this extremely serious infection. Until recently, MRSA was confined to hospitals and situations where people shared close quarters or had skin-to-skin contact (for examples, team athletes, military recruits, prisoners, and college students). This type of infection tended to affect individuals with weak immune systems who were living in hospitals, nursing homes, or other types of health care centers. Unfortunately, "community-associated" MRSA is becoming more widespread as cases are being seen in the general community, including healthy children and adults.

In fact, a recent study published in the *New England Journal of Medicine* (352, p. 1436, 2005) examined rates of MRSA in Baltimore, Atlanta, and several locations in Minnesota and found that between 8% and 20% of MRSA cases were community-associated. Another report in the same issue of the *New England Journal of Medicine* (352, p. 1445, 2005) discussed 14 cases of necrotizing fasciitis caused by community-associated MRSA. All cases occurred in Los Angeles in only 1 year. Though no one died from the necrotizing fasciitis, some required reconstructive surgery and a prolonged hospital stay. Most of the patients had 1 or more risk factors for becoming infected with MRSA, including injection drug use, **diabetes**, hepatitis C infection, HIV infection, or cancer. However, 4 patients had no known risk factors or underlying disease, indicating that even healthy people can develop this extremely serious condition.

**Bottom Line:** Conditions like necrotizing fasciitis are very rare. The most common types of infection caused by MRSA are mild skin infections that are easy to treat. An infected area will appear red, swollen, painful, or pus-filled. It may even resemble a spider bite. MRSA infection of the lungs can lead to pneumonia. In this case, you might have shortness of breath, fever, or chills. MRSA infection can cause a variety of symptoms because it can also infect the bloodstream and urinary tract.

HIV+ individuals have a higher risk of becoming infected with MRSA. Therefore, if you are HIV+ and have any of these symptoms, contact your healthcare provider immediately. Follow his or her advice for caring for

your wound or other type of infection. Remember to take all your medicine as prescribed, even if you feel better. If your skin infection is not getting better or keeps getting worse after a few days, or you have a fever or your fever gets worse, contact your healthcare provider. If you have MRSA, tell any healthcare provider who treats you that you have an antibiotic-resistant infection.

A staph infection, including MRSA, is spread by contact. You can get MRSA by touching a person who is carrying this type of bacteria or by touching something an infected person touched. The infection can also be spread by poor hygiene or by touching an infected person's skin wound (a cut or scrape). Multiple skin infections within the same family could mean that a member of your family has an MRSA skin infection. In turn, if you are infected with MRSA, you can spread it to family members or close contacts. The Centers for Disease Control and Prevention (CDC) recommend the following guidelines as ways to prevent the spread of MRSA:

- Wash your hands frequently and thoroughly during the day.
- Cover cuts and scrapes with a clean bandage. (Pus from skin infections and infected wounds can spread the infection to other people.)
- Do not touch other people's wounds or bandages.
- Do not share personal items like towels or razors.
- Dry bed linens, towels, and clothing in a hot dryer, not on the clothesline.
- If you use any shared gym equipment, wipe it down with disinfectant spray before and after you use it.
- Wear foot coverings in locker rooms and other commonly used areas.
- If you have an MRSA infection, tell your family and other close contacts to follow the above guidelines.

## A cure for HIV?

The journal *Lancet* recently generated a media buzz when the words "cure" and "HIV" were splashed across its cover to describe an interesting study published in that issue (366, p. 549, 2005). The focus of the study was to destroy hidden pockets of HIV-infected cells that are located in specific parts of the body. These are sometimes referred to as "latent reservoirs." These cells are infected with HIV, but they are not actively making virus and they can live a very long time. Available HIV meds can only work in cells that are actively making virus, so they have no effect on these reservoirs. HIV will only be "cured" if every single infected cell is killed and not allowed to reproduce. One idea is to use other drugs to make these cells active (so that they can be recognized and killed by HIV meds). In the current study, 4 HIV+ patients were given a drug called "valproic acid" to try and do just this. Patients were also taking combination HIV meds, which had been intensified with Fuzeon. The number of infected cells in the reservoirs dropped significantly in 3 out of the 4 patients.

*continued...*



**Bottom Line:** While this approach could potentially cure HIV, the authors of this study make no claims of finding a cure and correctly point out that this is an early study that only examined 4 patients. Much more research still has to be done. The idea of activating these “hidden” cells is not new, but the researchers deserve credit for studying creative ways to fight HIV. One thing is for sure, the currently available HIV meds will not cure HIV on their own. But perhaps they will allow those infected to live long enough for a cure to be discovered.

### Stopping meds in an emergency

A study in the journal *Antimicrobial Agents and Chemotherapy* (49, p. 1907, 2005) reports that after patients stop taking Viread, an HIV med, the drug may actually stay in your body for longer than once believed. In fact, Viread was still detected 3 weeks after patients stopped taking it. This can be a problem because when a person stops taking a combination of HIV meds that includes a longer-lasting drug, the other drugs may be

processed or **metabolized** out of the body more quickly, leaving the longer-lasting drug “on its own.” This is an opportunity for HIV to become **resistant** to that longer-lasting HIV med.

**Bottom Line:** Recent natural disasters have had a great impact both in the US and around the world. Thousands of people have been displaced from their homes, their cities, and even their countries. One consequence is that many HIV+ people have had to abruptly stop taking their HIV meds. Obviously, this is a dangerous situation for the reasons discussed above. Any time you stop your HIV meds (or any other meds you take to stay healthy), you should discuss this with your healthcare provider or any healthcare provider who is helping you at the time. For more information, please see The CFA’s fact sheet on stopping HIV meds in an emergency on page 12 or online at [www.centerforaids.org/rita/facts/emergency.pdf](http://www.centerforaids.org/rita/facts/emergency.pdf).

## Clinical Trial Information

### 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 meds for at least 6 months. The study will look at lifestyle changes (diet and exercise) and the use of other meds to control levels of fats in the blood. The study is **placebo**-controlled (study participants may take pills, but only some people get real meds) 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](http://www.heartpositive.org) or call 713-830-3034.

### 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 6,000 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 the 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 test 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](http://www.smart-trial.org).

### Possible Vaccine to Prevent HIV

Tell HIV-negative friends and family that they can participate in some important research on a possible HIV **vaccine**. This study is looking at the effectiveness of the “Merck Ad5 HIV-1 gag” (MRK) vaccine to see if it can help prevent HIV infection. Study participants will be randomly assigned (patients cannot choose a group, but are assigned randomly, like flipping a coin) to receive 3 injections of the MRK vaccine or a **placebo** (a harmless sugar solution). People considering taking part in this study must be 18 to 45 years old, **MUST BE HIV NEGATIVE**, and must not have been in an HIV vaccine study before. Interested individuals should speak with the study contact person for complete eligibility requirements. Contact Susan Warne at the Center for Clinical Studies in Houston (713-528-8818 or [swarne@ccstexas.com](mailto:swarne@ccstexas.com)).

Check it out: *The Houston Area HIV/AIDS Clinical Trials Directory* is produced by The CFA.

This comprehensive publication is updated quarterly and is available on The CFA website at [www.centerforaids.org](http://www.centerforaids.org) under “Publications.”





## Definitions

**Abscess:** a pocket of pus that forms at the site of infected tissue. An abscess can form on the skin or on tissues within the body and cause pain, swelling, and tenderness.

**Adherent (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.

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

**Boil:** like an abscess (see above).

**Boosted:** elevated levels of drug in the body.

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

**Cohort:** a group of individuals who share one or more characteristics in a research study and who are followed over time. For example, a vaccine (see below) trial might include 2 cohorts, a group at low risk for HIV and a group at higher risk for HIV.

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

**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.

**Genetic:** having to do with genes (which carry special biology blueprints made from DNA) and genetic information.

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

**Hypersensitivity (hypersensitivity reaction):** extreme sensitivity or allergic reaction to a specific food or drug.

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

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

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

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

**Opportunistic infection(s):** 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.

**Pilot study:** an initial study done in a few people to test possible treatments or ways to care for patients, to see if it is worth further study.

**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.

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

**Remission:** reversal or disappearance of disease symptoms.

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

**Seroconversion:** the presence of antibodies (see above) in the blood against something foreign and usually caused by an immune response to bacteria, viruses, vaccines (see below), etc.

**Vaccine:** something that stimulates an immune response that can prevent an infection or create resistance to an infection.

**Vascular:** relating to blood vessels.

## USEFUL Resources

Visit us online: [www.centerforaids.org](http://www.centerforaids.org)

AIDS 101: a review of the basics, from transmission to treatment to tests and more. [www.sfaf.org/aids101](http://www.sfaf.org/aids101)

Need help getting medications? Check out the information and resources at Needy Meds. [www.needymeds.com](http://www.needymeds.com)

Information on HIV/AIDS in the workplace. [www.brta-lrta.org](http://www.brta-lrta.org)

A new support group (online) for people with HIV who are either seeking transplantation, who are on a waiting list for a transplant, or who have received a transplant. [http://health.groups.yahoo.com/group/TX\\_Support\\_Group](http://health.groups.yahoo.com/group/TX_Support_Group)

The AIDS Coordination Project of the American Bar Association offers several resources, including a state-by-state Directory of Legal Resources for People with HIV/AIDS. [www.abanet.org/AIDS/home.html](http://www.abanet.org/AIDS/home.html)

Help build a powerful community-based movement bridging HIV/AIDS, human rights, and struggles for social and economic justice. [www.champnetwork.org](http://www.champnetwork.org)



# COMMUNITYspotlight

The **St. Hope Foundation** provides a variety of services and opportunities:

- Primary medical care in a private practice setting: clinic locations in Houston (Bellaire area), Conroe, and Stafford
- Medication assistance through the AIDS Drug Assistance Program (ADAP)
- Clinical research
- Well-woman and perinatal care
- Medical case management
- Mental health therapy
- Hepatitis C screening and treatment
- HIV/STD counseling, testing, and education
- Transportation services (including van-based transportation, METRO bus passes, and gas vouchers for rural clients)
- Community educational forums



ST. HOPE FOUNDATION

*"Offering HOPE to many lives"*

## Contact information

Main office: **6200 Savoy, Suite 540  
Houston, TX 77036**  
Phone: **713-778-1300**  
Fax: **713-778-0827**  
Toll-free: **1-877-559-HOPE**  
Web: **[www.offeringhope.org](http://www.offeringhope.org)**

The above information was accessed from the St. Hope Foundation website on October 30, 2005.

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