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inside:



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# REPRODUCTIVE OPTIONS of HIV-infected Patients

By **Nancy Eriksen, MD**

Advances in anti-HIV therapy and improved treatment of **opportunistic infections** have produced a significant increase in the life expectancy and quality of life of HIV-infected adults. Since the majority of HIV-infected men and women are of reproductive age, many are likely to consider becoming parents. To date, most of the attention in reproductive HIV medicine has focused on preventing mother-to-child (vertical) transmission of HIV. However, when only one partner is infected (**serodiscordant** couples), there is the added concern that the negative partner might become infected through unprotected intercourse (such as when attempting pregnancy). This article summarizes the reproductive options of HIV-infected individuals as well as the current treatment guidelines for pregnant women with HIV infection.

**Prior to planning any pregnancy, couples should assess their readiness to have a child.**

## PREGNANCY IN HIV-INFECTED COUPLES

Prior to planning any pregnancy, couples should assess their readiness to have a child. This includes looking at their emotional, physical, and financial well-being. In the case of HIV-infected couples, health status is of utmost concern. Assessing their anticipated life expectancy is important particularly if one or both partners is not on treatment, not adhering to treatment, or failing treatment. In this

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# WELCOME

Few issues in HIV are more controversial than HIV-infected individuals having children. Even when adopting a child, people with HIV may be criticized because their disease may cause illness that could interfere with parental responsibilities. Obviously, the possibility of the child becoming an orphan is also an issue. However, people with HIV who are taking anti-HIV medications (when needed) are living longer, healthier lives. Sure there are side effects and some potentially dangerous **toxicities,** but most HIV-infected people are experiencing an improved overall quality of life. For some individuals, wanting to have children may be a natural instinct. The reality is that although some people may plan to have children, there are still unplanned pregnancies. But medicine has made great progress in developing treatment that improves the newborn's chance of being born without HIV infection. Several articles in this issue of *HIV Treatment ALERTS!* look at some of the medical, as well as emotional, aspects of human reproduction where at least one partner is infected with HIV. These articles include quotes from HIV-positive women in Houston. Also included in this issue are some important questions in the patient/doctor Q&A section, treatment news, clinical trial information, and helpful phone numbers and websites. Remember that words in **bold** are explained in the "Definitions" section.

We may not have a cure for HIV yet, but every day brings us a little closer.

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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!*) twice a year (spring and fall). RI*TA!* is a literature-review journal that covers issues in HIV research and policy. This and other publications are available on The CFA website or can be requested by mail (see contact information below).

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## 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. . . ."*

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case they should seek expert medical advice about potential medical complications due to HIV.

For couples in which both individuals are infected with HIV, conception can occur naturally, but with the additional risk of transmitting drug-resistant HIV to the other partner. This can be minimized if both partners have an undetectable viral load and carefully time the unprotected intercourse (not using a condom) at the midcycle, when the woman is most fertile.

Treatment with highly active antiretroviral therapy (HAART) should be initiated or optimized prior to conception in an HIV-infected woman with the goal of achieving an undetectable viral load. This will nearly eliminate any risk of vertical transmission, assuming an undetectable viral load is maintained during the pregnancy. Triple combination therapy—including AZT (Retrovir) whenever possible—is the standard of care for the treatment of pregnant women. In some cases treatment may need to be changed. The current perinatal guidelines recommend against the use of ddI (Videx) and d4T (Zerit) during pregnancy because of 3 reported maternal deaths due to **lactic acidosis.**

Another drug that may need to be avoided is efavirenz (Sustiva), which has been shown to cause a type of neural tube defect in animal studies. Since these types of defects occur in the first 4 weeks of pregnancy, a woman conceiving on this drug has the greatest risk of this birth defect occurring. Women who desire to conceive a child should reconsider whether they should be started on this drug. Those who are currently on efavirenz and want to plan a family could switch to another non-nucleoside drug such as nevirapine (Viramune). Some women choose to remain on efavirenz because their prior drug history makes it difficult to switch to other drugs. Currently there are no data in humans to assess the risk of having a birth defect from efavirenz. However, we know that the general risk of having a birth defect in humans is 1 in 40 based on data about other animal **teratogens**. If a woman chooses to remain on efavirenz, there may be some theoretical benefit to taking folate supplements preconceptually through the first few weeks of pregnancy. Folic acid has been shown to substantially reduce the occurrence of neural tube defects in women who are at high risk for such defects.

Women with HIV should also consider being screened for Hepatitis B and C, which can be transmitted to the fetus. There is no treatment available to decrease the risk of vertical transmission of Hepatitis C virus (HCV). For HIV-infected pregnant women who test positive for HCV, 23 out of every 100 infants will be infected with HCV. Newborn infants should be tested for HCV by a pediatrician between 6 and 12 months. If the infant has HCV, then mother and child should be referred to a specialist who can manage this disease.

## PREGNANCY IN SERODISCORDANT COUPLES

If the ***woman is HIV positive*** and the male is negative, there is the risk of sexually transmitting the virus to the male during unprotected intercourse. Having an undetectable viral load in the blood does not eliminate the possibility of transmitting the virus because levels of HIV in the blood and semen or vaginal secretions are poorly correlated. The risk per act of unprotected intercourse is estimated to be between 1 in 500 and 1 in 1000. Nevertheless, a single act of unprotected intercourse is sufficient to infect a partner. Careful preconceptual counseling of the risks involved and advice on how to time intercourse accurately are necessary for couples prepared to risk unprotected intercourse to have a child. Couples may try to minimize the transmission by accurately timing intercourse using ovulation detection methods. The Centers for Disease Control and Prevention (CDC) does not recommend **postexposure prophylaxis** (taking anti-HIV medications after a possible exposure to try to prevent infection) in cases of repeated sexual intercourse between **serodiscordant** couples.

Another option to consider is washed intra-uterine insemination (IUI), commonly referred to as artificial insemination. IUI eliminates the need for intercourse and subsequent risk of HIV transmission. In this case special techniques are used to separate the sperm from the seminal fluid. The sperm are then placed directly into the uterus after accurately assessing the time of ovulation. The pregnancy rate per cycle of IUI is 10% to 12% and it costs approximately $350.

There are several options available to couples in whom the ***male is HIV positive*** and the woman is negative. *Conception through natural means* (intercourse) creates a risk of HIV transmission to the female and is not generally recommended for the reasons discussed earlier. *Insemination using donor sperm* eliminates the risk of transmitting the virus to the woman and subsequently to her infant. However, removing the possibility of genetic parenthood from one partner, particularly the one whose life is threatened with disease, has tremendous moral and ethical implications and requires thorough counseling beforehand. Although a perfectly safe method, this is not the option of choice for most **serodiscordant** couples.

Researchers in Italy (Semprini and colleagues) pioneered *inseminating HIV-negative women with sperm washed free of HIV.* By eliminating the cell-associated and free virus from the semen, this

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process significantly reduces the risk of transmitting the virus. Using a special technique they developed in the lab, the Italian doctors have successfully performed nearly 2000 IUIs without any reported seroconversions. Although this technique is widely used in Europe, especially Italy and Spain, the CDC does not recommend IUI of women with washed sperm from men infected with HIV. This position followed a single case report of HIV transmission to a woman who underwent IUI from her HIV-positive husband in 1990. This led the American Society of Reproductive Medicine to advise against the provision of assisted reproductive technology services to HIV-infected individuals. To date, this is the only documented case of HIV seroconversion following insemination and is presumed to be a result of inadequate washing. In Europe, washed IUI is usually tested for HIV using PCR technology, but this is not routinely done in the United States. This further step essentially eliminates the possibility of HIV transmission to the woman.

Another option that is more commonly performed in the US is *in vitro fertilization.* This should be considered when IUI is not feasible or is unsuccessful. The specific technique used is called intracytoplasmic sperm injection (ICSI). The woman's oocytes (eggs) are harvested after undergoing ovulation induction and the male's sperm is isolated. The ICSI technique involves fertilizing each egg with one sperm instead of exposing the egg to millions of sperm as is done in IUI. Once several eggs have developed into embryos, they are then transferred back to the uterus and the woman is monitored using a blood pregnancy test to determine if implantation was successful. The success rate of ICSI in a woman under the age of 35 is 45% to 50% per cycle. Although this technique yields a higher rate of pregnancy, it is also considerably more expensive and costs approximately $12,000 per cycle.

*Adoption* is a final option for those couples that do not want to risk HIV transmission from unprotected intercourse or who fail or choose not to undergo assisted reproductive techniques. In practice, the presence of HIV infection in one or both partners may make adoption a challenge.

## MANAGEMENT OF HIV IN LABOR AND MODE OF DELIVERY

Approximately 50% of pregnant women with HIV are diagnosed for the first time during pregnancy. Also, of those women who know they are HIV positive, only half are on HAART prior to their pregnancy. This is unfortunate since almost all **perinatal** HIV transmission could be eliminated if women were diagnosed with HIV *and* treated so as to achieve an undetectable viral load before pregnancy.

The current standard of care is to treat pregnant women with HAART to try to obtain an undetectable viral load. Women who are newly diagnosed or who are currently not on treatment are offered triple combination drug therapy. Therapy is delayed until the woman is more than 10 weeks pregnant to avoid the risk of birth defects altogether. A viral load test is performed 4 to 6 weeks after starting therapy and every 3 months thereafter. The test should be performed at 35 to 37 weeks gestation in order to plan the mode of delivery. If the viral load is less than 1000, the woman can go into labor because the risk of vertical transmission is less than 1%. AZT is given intravenously to the mother during labor and in a syrup formulation to the infant for 6 weeks to further reduce the chance of HIV transmission. Based on expert opinion of the American College of Obstetricians and Gynecologists (ACOG), women whose viral loads exceed 1000, whether or not on HAART, are offered a Cesarean section. This opinion was formed solely on data that transmission of HIV is less than 1% for a viral load less than 1000. There are no data yet that examine the risk of HIV in women with a viral load greater than 1000 who are on HAART and undergo a Cesarean. If a Cesarean is done, it should be elective, before the onset of labor or rupture of the membranes. Studies show absolutely no benefit to a Cesarean if it is not done electively. ACOG also recommends that AZT be given for 3 hours prior to an elective Cesarean. Infants who are delivered by Cesarean are also given AZT syrup for 6 weeks.

## CONCLUSION

The options available to couples with HIV infection are far greater today than even 5 years ago. Advances in treatment have significantly reduced the **perinatal** transmission rate and offer new hope to women with HIV infection who desire to have a pregnancy. Ideally, HIV-infected women should achieve an undetectable viral load prior to conception to eliminate almost entirely the risk of HIV transmission. However, even those who start HAART during pregnancy have less than 1% risk of transmission if they obtain and maintain an undetectable viral load.

## surveyquestions

**Q:** "What was your biggest worry about having a child while being HIV positive?"

**A:** "I was afraid that my baby would be positive."

— Hispanic Female, age 27

**Q:** "Are you considering having a child (getting pregnant)?"

**A:** "Yes, I've been thinking about it for 4 years. My husband really wants a baby. (He's negative.)

— HIV-positive Black Female, age 30

# Pediatric HIV/AIDS CARE



By **Marilyn Doyle, MD, FAAP**

In 1987, while practicing in a walk-in pediatric clinic, I encountered an infant who was born to a newly diagnosed HIV-infected mother. At that time medical understanding of HIV infection was rudimentary at best, and our knowledge of pediatric HIV was even more primitive. I credit myself with recognizing that this infant required immunization with the inactivated (killed) polio vaccine as opposed to the live vaccine, which at that time was the standard vaccine administered to all children. Armed with this knowledge, I decided that these infants merited special attention and thus began my career as a pediatric HIV specialist. In the past 14 years, progress in the prevention and treatment of pediatric HIV infection has been extraordinary. I have had the privilege of seeing infants and children originally given grim prognoses, grow to be healthy, active teens and young adults.

## PREVENTION OF PERINATAL HIV TRANSMISSION

One of the most practical advances in the field of pediatric HIV disease was the development of the Polymerase Chain Reaction (PCR) or viral load test, which allows us to make the diagnosis of HIV infection in an infant within the first few months of life. Prior to this technology, we had to wait 18 months to determine definitively whether an infant was infected or not. HIV infection in adults and children older than 18 months of age is diagnosed if the individual has a blood test that is positive for HIV. The problem with these tests is that they test for antibody to the HIV virus, not for the virus itself. Antibodies are the proteins that the body makes when it is exposed to an infectious organism. The antibodies help in fighting off the infection. When a woman is pregnant, she passes her antibodies (for example, antibodies to chicken pox, measles, or HIV) to her infant. It takes 18 months for the antibodies from the mother to disappear from the infant's blood. Thus, despite the fact that most infants born to HIV-infected mothers are not infected, they all have positive HIV antibody tests. The PCR detects HIV viral genetic material, not antibodies. It is a direct test for virus. An infant with a positive HIV PCR is infected. More importantly, an infant who has 2 negative HIV PCR tests obtained at greater than one month and greater than 4 months of age is not infected with HIV.

The most critical accomplishment in the field of pediatric HIV was the discovery that transmission of the HIV virus from mother to child can be prevented. The landmark ACTG 076 clinical trial demonstrated that when mothers took AZT (Retrovir) during pregnancy, the transmission rate was reduced from 25% to 8%. It is rapidly becoming apparent that with the use of highly active antiretroviral therapy (HAART) and perhaps elective Cesarean section, the transmission rate can be reduced even further to 2% or less. (See Dr. Eriksen's article, p. 1). Institution of these measures in pregnancy has had a dramatic impact on the incidence of perinatally acquired HIV in the developed world. In my own practice, I see 60 to 80 infants born to HIV-infected women each year. Without maternal treatment, I would predict 15 to 20 of these infants would become infected each year. However, because of successful treatment, I saw only one infected infant in 1999, no infected infants in 2000, and 2 infected infants in 2001.

Obviously, mothers must be identified during pregnancy for this strategy to be effective. Most women identified in pregnancy accept treatment. There is only a 5% refusal rate. More problematic is the fact that 15% of mothers are identified at the time of delivery of the infant. Most of these women have had no, or very late, prenatal care. Under these circumstances, transmission of the virus can be prevented by rapid treatment of the infant. Treatment of the infant with AZT within 24 to 72 hours can reduce transmission from 25% to 12%. It is fairly common practice for pediatric HIV specialists faced with this situation to give the infant one dose of nevirapine (Viramune) in addition to the standard regimen of 6 weeks of AZT. This strategy is based on findings of HIV NET 012, a clinical trial conducted in Uganda (published in the journal *Lancet*, 354, p. 1795, 1999). Pregnant women were given one dose of nevirapine during labor and the infant was given one dose of the drug at 48 to 72 hours after birth. This treatment resulted in a 50% reduction in transmission. At present there is no information on the outcomes of infants treated in this manner.

**Anemia** and **neutropenia** are the most common side effects observed in treated infants. The majority of infants do not require any treatment for these blood abnormalities other than withdrawal of medication. Rarely, an infant may need a blood transfusion. While the prevention of **perinatal** transmission appears to be an unqualified success, we must remain vigilant in our care and follow-up of these infants to detect any undesirable side effects, some of which may not be apparent for years.

## TREATMENT OF PEDIATRIC HIV/AIDS

Guidelines for treatment of pediatric AIDS developed by the Working Group on Antiretroviral Therapy and Medical Management of HIV-infected Children is available at the website **www.hivatis.org.** These recommendations were developed by pediatric HIV specialists. The clinical and immunologic classification of children differs from that of adults. Children normally have higher T cell counts than adults and manifest somewhat different clinical symptoms. For instance, a normal T cell count in a newborn infant is on the order of 3000 to 4000, much higher than in adults. Children are classified immunologically by T cell count and per-

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centage. Children in class 1 are regarded has having normal immunologic response, whereas children in class 3 are severely immunosuppressed. Children who have mild clinical symptoms are in class A and those with severe clinical symptoms, usually opportunistic infections, are in class C. Almost all children are on antiretroviral therapy as recommended by the Working Group. Although American children rarely get Kaposi's sarcoma, cerebral toxoplasmosis, or cryptococcal meningitis, they do have significant problems with bacterial infections such as pneumonia.

Treatment with highly active antiretroviral therapy (HAART) has dramatically improved the health and well-being of HIV-infected children, but many challenges remain. The practical reality of pediatric HIV treatment is that we have problems with **adherence** to drug regimens, as well as resistance of the virus to drugs. Many drugs don't come in liquid formulations or taste so bad that children refuse to take them. Given the fact that most of these children will live into adulthood, we are concerned with the long-term side effects of treatment such as **lipodystrophy**, **hypercholesterolemia**, and **osteopenia**.

**Adherence** is a major issue. Only 33% of my pediatric patients have undetectable viral loads. Most adult HIV practices report 40% to 60% of patients with undetectable viral loads. Seventy percent of my patients have had serious problems with adherence at some point in their treatment. Treatment of newly infected infants illustrates some of the difficulty. Since it is not possible to distinguish between infants who will have a rapid and downhill course from those who will progress much more slowly, initiation of HAART is recommended for all infants less than 12 months of age. Unfortunately these infants are often born to mothers with substance abuse problems or mental health diagnoses. Many mothers are teenagers. Some are undocumented resident aliens with poor access to health care and are non-English monolingual. Many women have no social support such as family or friends to whom they can disclose their HIV status. They are almost all poor. Despite intense interaction with physicians, nurses, social workers, and case managers, it may take 1 to 2 years to establish an effective treatment plan. Even once an effective plan is in place, it is always in jeopardy. Many of the families exist in such marginal social situations that they often experience destabilizing circumstances such as eviction, break-ups of couples, or incarceration. Also, parents can become sick and die. When these situations occur, it is not uncommon for the children's viral loads to rise, necessitating medication changes because of resistance development. We really do not have enough drug options to cover these scenarios and many of my patients are on fourth and fifth regimens.

Adherence is a special issue in pediatrics not only because of social situations, but because many of the drugs are not child friendly. While AZT, 3TC (Epivir), d4T (Zerit), and abacavir (Ziagen) come in tolerable liquid formulations, ddI (Videx) has to be given on an empty stomach, twice a day, and is mixed in an unpalatable Maalox suspension. If didanosine is part of a child's regimen, then the child gets medicine at least 4 times a day. Adherence is clearly a problem in this situation. The introduction of Videx EC (ddI in a capsule given once daily) should make this drug more accessible to the pediatric population.

The protease inhibitors nelfinavir (Viracept), ritonavir (Norvir), lopinavir/ritonavir (Kaletra), and amprenavir (Agenerase) come in pediatric formulations. None are particularly palatable. Amprenavir cannot be given to children less than 4 years of age because of the high concentrations of vitamin E and propylene glycol. The taste of ritonavir liquid is particularly problematic. Consistent use of protease inhibitors requires patience, persistence, and creativity on the part of the mother or caregiver. The medical team must be supportive and available because these are difficult drugs to give. Nevirapine (Viramune) and efavirenz (Sustiva) are easy to give and are well tolerated, but lapses in **adherence** can allow the virus to develop resistance almost immediately.

Drug resistance is a problem in pediatrics because so many of the children have been sequentially treated with antiretroviral drugs. The average age of HIV-infected children in my practice is 11 years. None of the children born before 1996 were treated with HAART initially because it was simply not available when they were first diagnosed. Thus, they received less potent regimens and developed drug resistance, particularly to the nucleoside drugs like AZT, ddI, 3TC, and d4T.

Despite the problems associated with the management of HIV-infected children, the advances in treatment have prolonged their lives and made them healthier. Most attend school and fully participate in the activities of childhood. I have not had a child die in 4 years and it is rare for a child to be hospitalized for any long period of time. I expect these children to live well into adulthood and hope that they will continue to benefit from advances in treatment and ultimately be cured.

## surveyquestions

**Q:** "Have you had any children while being HIV positive?"
**A:** "Yes. Two—both negative."

—White Female, age 26

**Q:** "When your child is old enough, will you tell him you have HIV?"
**A:** "I will tell him when he's more mature, like 15 or 16, and talk to him about safer sex."

—Hispanic Female, age 27

# Emotional Issues **OF WOMEN** with HIV/AIDS

By **Tobi E. Newman, LMSW-ACP**

People with HIV face a number of medical, social, legal, and emotional issues associated with their diagnosis. Twenty years ago, in the beginning of the epidemic, HIV/AIDS was considered a fatal diagnosis, and the emotional issues were often those of loss: of health, of body image, of income, of family and friends, and of time. Entire social service agencies were established for gay men with HIV/AIDS to address many of these issues. Support groups and networks flourished to meet those social and emotional needs. But the so-called face of HIV/AIDS has changed and now increasingly reflects a female face, frequently poor and often a woman of color.

Women now account for more than 25% of AIDS cases in the US. These women are primarily of childbearing age and, many times, are caught completely off-guard at their initial diagnosis. Many of these women report having gone from doctor to doctor trying to find out what was wrong with them. Often times, if they did not report a history of drug use or multiple sexual partners, their physicians did not even suggest an HIV test as part of their medical work-up. Once diagnosed, these same women often report a negative change in the attitude of their medical care professional. The message given is that "good" girls don't get HIV.

The initial HIV epidemic was defined as a gay-related infectious disease, which was followed by the recognition of injection drug users and prostitutes as "high-risk groups" likely to become infected. In 1990, sexual partners of injection drug users and bisexual men were recognized, and the idea of "high-risk groups" evolved into "high-risk behaviors." But no one looked at, wrote about, or talked about, ordinary women with no high-risk behaviors of their own who were vulnerable because of the unknown risky behaviors of their sexual partners. These women are often overwhelmed and confused by their diagnosis. They often feel blamed for their disease, which may lead to feelings of shame and guilt.

Finding coordinated and comprehensive care for women and children remains a challenge. Poor women with HIV face a wide range of barriers to care. Welfare reform and anti-immigration legislation have served to deny health care access and services. Those who still retain medical benefits are being forced into HMOs with constantly changing provider lists and few HIV-knowledgeable physicians. Tracking down HMO benefit information and receiving approvals for care may take many hours. Also, transportation difficulties like long rides, coupled with long waits in clinics, often interfere with children's school schedules.

Women with HIV/AIDS are often diagnosed late in the course of their illness. They usually delay seeking treatment or simply give up because of the time constraints thrust upon them by their traditional roles as caregivers to others. Women are often financially dependent and isolated, and the chores of caring for spouses and children interfere with their ability to seek assistance for themselves. These women may feel shame and guilt at their diagnosis but also at their inability to continue to provide for other family members' needs. Women worry about how they will be provided for financially and how they will take care of their children. Even women in higher socioeconomic situations feel ashamed and anxious about their ability to provide for themselves and their families.

Over the last 15 years, I have worked with thousands of men and women dealing with HIV issues. While many of the emotional issues are the same, far more women are also reliving past issues of abuse and trauma. Stressors and knowledge of past coping skills need to be explored in order for the social worker to assist clients in developing good coping skills for the present and future. Many of the women I have seen feel blamed by society and tell me they feel as if they are "damaged goods." They yearn for human touch, but feel frightened of having intimate relationships and *of being rejected.* Trust issues are important and must be repeatedly reinforced. Alcohol, drug use, and other possibly harmful behaviors should be addressed. Common emotions like anxiety, depression, and despair—coupled with fear of abandonment—can be overpowering and require the skills of a trained mental health professional. Individual therapy, appropriate medication, and support groups are all recommended interventions.

Regarding pregnancy, some women decide that their seropositivity precludes their becoming a mother. But other women are diagnosed while pregnant or at delivery and have added emotional issues to deal with besides the tremendous needs of a newborn. These situations can be complicated and call for competent, nonjudgmental clinicians to assist in dealing with these issues.

If you are a woman dealing with HIV, here are some ways to take control of your health and find inner strength:

- Talk to your case manager.
- Read through services listed in an HIV/AIDS services directory like *The Blue Book* (available at The Center for AIDS and many Houston HIV/AIDS service providers).
- Talk to a friend, family member, or another woman with HIV.
- Get a referral to a mental health professional at a treatment facility such as Thomas Street Clinic (713.873.4030), Montrose Clinic (713.830.3000), or Baylor Adult Psychiatry Clinic (713.798.4856).
- Find a counselor at a United Way Agency that operates on a sliding scale fee, such as Montrose Counseling Center (713.529.0037), Jewish Family Service (713.667.9336), or Family Service Center (713.861.4849).
- Get educated; subscribe to HIV publications like *Project Inform Perspectives* and *WISE Words* (800.822.7422; **www.projinf.org**), *WORLD* (510.986.0341), or *Women Alive* (800.554.4876).

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## survey questions

**Q:** "What makes you a strong person—what keeps you going?"

**A:** "My involvement as a volunteer at Thomas Street Clinic and women's support groups. And God!"

—HIV-positive Black Female, age 39

# TreatmentNews

## Ingrown toenails still a possible side effect

A case series report published in *The Annals of Pharmacotherapy* (35, p. 881, 2001) has confirmed the well-established link between the protease inhibitor indinavir (Crixivan) and complications like ingrown toenails. However, the study looked specifically at patients receiving indinavir with ritonavir (Norvir), a combination that eases the difficult 8-hour dosing of indinavir alone. Ritonavir slows the metabolism of indinavir, which then builds up better concentrations in the blood. Typically, the 2 drugs are dosed as 400 mg indinavir + 400 mg ritonavir twice a day or 800 mg indinavir + 200 mg ritonavir twice a day—although neither dose has been shown to affect the frequency or recurrence of side effects more than the other. Out of 74 patients taking indinavir and ritonavir, the researchers found 5 patients (or 6.76%) who were suffering from ingrown toenails (involving the big toe). Ingrown toenails are often accompanied by **paronychia** (inflammation of skin near the nails). The drug 3TC (Epivir) has been linked to paronychia, but only one of the 5 cases reported was also taking 3TC. Ingrown toenails can be treated with minor surgery, best performed by a podiatrist. The researchers stress that as indinavir/ritonavir combinations become more widely used, dose-related adverse events like ingrown toenails, kidney stones, and elevated liver enzyme levels in the blood may increase in frequency. They recommend that health care providers examine the hands and feet of patients taking 3TC and indinavir, especially in combination with ritonavir. Also, the decision of whether or not to continue the same therapy should be made with the patient.

## **Good** News..... and **Bad** News

Seven HIV-infected individuals with symptoms of amyotrophic lateral sclerosis (ALS), commonly called Lou Gehrig's disease, are described in the September 25 issue of *Neurology* (57:6, pp. 1094 & 995, 2001). ALS is a disease of motor neurons (nerve cells that control muscle actions) resulting in progressive muscle weakness and **neuromuscular** degeneration. Unlike patients with classic ALS, the *HIV-infected individuals experienced stabilization or partial recovery* of their disease after starting anti-HIV therapy. Many of these patients were identified with symptoms before anti-HIV combination therapy was available. The incidence of ALS is relatively rare, but people with HIV are 27 times more likely to suffer ALS symptoms than the general population. An editorial in the same issue of *Neurology* (p. 945) points out that ALS syndromes can have many causes ranging from heavy metal toxicity to thyroid disease. The authors recommend that when a patient has classic symptoms of ALS, a viral cause should be considered since HIV-associated ALS is treatable with anti-HIV therapy.

Fourteen cases of "ascending **neuromuscular** weakness" in HIV-infected individuals (5 of whom died) prompted Bristol-Myers Squibb, the company that makes ddI (Videx) and d4T (Zerit), to issue a special notice to doctors. The neuromuscular weakness resembles a disease called Guillain-Barré syndrome. The 14 patients were taking nucleoside reverse transcriptase inhibitors (NRTIs), a family of anti-HIV drugs that includes ddI, d4T, ddC (Hivid), 3TC (Epivir), AZT (Retrovir), and abacavir (Ziagen). 3TC and AZT are available in one pill called Combivir. Abacavir, AZT, and 3TC are available in one pill called Trizivir. The letter states that in most of the 14 cases, early symptoms of **lactic acidosis** preceded the neuromuscular problems. These symptoms include nausea, diarrhea, abdominal pain, rapid breathing, muscle pain or cramps, and feelings of tingling or pricking of the skin. According to the letter, muscle weakness should now be added to this list of symptoms. Severe lactic acidosis can lead to kidney or liver failure, **pancreatitis**, or paralysis, and is usually fatal. If drug-induced lactic acidosis is caught early, stopping the drug(s) can reverse it.

## DRUG INTERACTION: ritonavir and fluticasone

Two cases of drug-induced **Cushing's syndrome** were reported at the *13th Annual Conference of the Australasian Society of HIV Medicine* in Melbourne, Australia. The patients were HIV-infected and taking ritonavir (Norvir) as well as fluticasone (Flovent). Ritonavir is a protease inhibitor used for treating HIV and fluticasone is an inhaled corticosteroid used for treating asthma. Symptoms of Cushing's syndrome developed in one patient after taking both drugs for 5 months. The other patient developed symptoms after taking both drugs for 20 months. Symptoms resolved after one of the two drugs was stopped. Healthcare professionals who treat HIV should be aware of this potential drug interaction. Since Cushing's syndrome is caused by an overproduction of corticosteroids in the body, ritonavir may be slowing down the liver's **metabolism** of fluticasone, causing it to build up. Ritonavir acts in a similar (and beneficial) way with other protease inhibitors like indinavir (Crixivan) and saquinavir (Fortovase), causing the levels of these drugs to increase in the blood. This is the idea behind the anti-HIV drug Kaletra, which is made up of a ritonavir and another protease inhibitor called lopinavir.

# FDA Bits

➡ The US Food and Drug Administration (FDA) has approved tenofovir (Viread) for the treatment of HIV infection in combination with other anti-HIV medications. Tenofovir is a nucleotide reverse transcriptase inhibitor, which acts against an important viral protein used by HIV to reproduce itself. Other drugs that act against this protein include the families of nucleoside reverse transcriptase inhibitors (NRTIs) and non-nucleoside reverse transcriptase inhibitors (NNRTIs). For more information about tenofovir, ask your doctor or visit **www.viread.com**.

➡ After a year of review, the FDA has approved the first genetic test designed to look at virus mutations in an HIV-infected person. Virus mutations (changes in the genetic code) are known to contribute to drug resistance, which means that a certain drug may no longer be effective against the virus. The genetic test, called *Trugene*, will cost $300 to $500. The test may be a useful tool for doctors who need to change a patient's anti-HIV drugs because of resistance. For more information about this test, visit **www.trugene.com**.

# Nevirapine notes

In a paper published in the journal *AIDS* (15, p. 1843, 2001), European researchers recommend immediately stopping the drug nevirapine (Viramune) if signs of a rash appear in a patient during the first month of treatment. Current practice is to dose the drug at 200 mg once a day as a "lead-in" period for 2 weeks before switching to the full dose of 200 mg twice a day. If a severe rash or a rash accompanied by symptoms like fever, blistering, oral sores, or muscle aches occurs, nevirapine must be stopped immediately and never taken again. These symptoms may indicate a potentially deadly condition called Stevens-Johnson syndrome. If a mild rash erupts, doctors will sometimes "treat through" the rash by continuing the medication, with close monitoring and sometimes the addition of an anti-allergic drug. The researchers argue that because nevaripine takes longer to process and may build up in the body, treating through a mild rash may endanger the patient. On a related note, another report in *AIDS* (15, p. 1579, 2001) confirms that women are more likely than men to experience nevirapine rash. Nevirapine rash is also more likely to occur if glucocorticoids or antihistamines (anti-allergic drugs) are used or if a patient has higher T cell count. The researchers conclude that the risks and benefits must be weighed before choosing any particular anti-HIV therapy.

# Q&A Patient/Doctor

**Gary Brewton, MD,**
tackles some tough patient questions.

**Q:** I began taking d4T and 3TC in 1996 with a viral load of almost 30,000 and a T cell count of about 380. The drugs kept my viral load undetectable and my T cell count as high as 950. However, I got off drugs one year ago when signs of **peripheral neuropathy** (pain and loss of sensation in my feet) and **lipodystrophy** (veins popping out all over my arms and legs and a fat pad on the back of my neck) started to really affect me. I now have a viral load of 11,000 and a T cell count of 700. When should I restart therapy, and if I do, can I still try a 2-drug regimen in order to save my options for the future?

**A:** Most physicians would not recommend resuming treatment at present with the test results you describe, unless there was some other indication for treatment such as unexplained fever, weight loss, thrush, or HIV encephalopathy (brain disease). Whether you will be able to remain off treatment indefinitely is uncertain, so for my patients in a similar situation, I recommend re-evaluation every 3 months with blood tests and a visit to the doctor. If the viral load goes above 50,000, if the T cell count goes below 500, or if symptoms of HIV disease emerge, I'd repeat the tests sooner, say after one additional month. If these results remain unfavorable, I'd consider restarting treatment. If your virus escapes from control by your own immune system, the T cell count can drop abruptly, so it is important to closely monitor you while not on treatment. For an excellent discussion of the subject of immune control of the virus, see the chapter by Bruce D. Walker, MD, in the *HIV/AIDS Annual Update* at the Medscape* website:**www.medscape.com/Medscape/HIV/AnnualUpdate/2001/public/TOC-update.html.**

What treatment to use in that case depends on several factors: 1) the likelihood that the virus would be sensitive to the d4T (Zerit) and 3TC (Epivir) you previously took, which I would estimate to be good since your viral load was undetectable when you stopped treatment; 2) the likelihood that if you took these 2 drugs again you would experience the same symptoms that caused you to stop the treatment one year ago, which (at least in the case of neuropathy) I would judge to be high; and (3) the feasibility of constructing an alternate combination of 2 or perhaps 3 drugs that would likely have durable and potent benefits. Considering all these factors, if you were willing, I might suggest a 3-drug, nucleoside-based regimen such as AZT (Retrovir), 3TC, and abacavir (Ziagen) combined in 1 pill taken twice a day (Trizivir). I would not introduce drugs you have never taken before, except as part of a 3-drug regimen. If you preferred a 2-drug regimen, you could give d4T and 3TC another try, but the risk of recurrent symptoms might make this less appealing to you.

You did not mention whether your symptoms got better being off treatment the last year. I'd expect the neuropathy did improve, but the **lipodystrophy** did not.

**Q:** The drugs I am taking for my HIV give me diarrhea. Are there any ways to minimize this side effect? I have tried products like Imodium, but with very limited success. What would you suggest?

**A:** First, I'd test to make sure that there is no treatable cause of diarrhea such as infection with *Clostridium difficile, Giardia lamblia, Entamoeba histolytica,* or other intestinal pathogens. Three separate stool samples are required to be certain there are no parasites, since even the best laboratories can only screen with about 70% accuracy. Each sample for ova and parasite examination ("O&P") must be placed into appropriate transport media containing preservatives within 30 minutes after the stool is passed. You might also want to try eliminating lactose (all dairy products) from your diet to see if this helps, since lactose intolerance is common—especially in non-Caucasians.

Assuming no other cause of diarrhea is identified, a number of adjunct therapies make a major difference in the control of diarrhea due to HIV medications. First, using a *regular daily dose* of loperamide (Imodium), perhaps as little as one pill every day, seems to help people better than using loperamide on an "as needed" basis. Second, fiber supplements such as psyllium (Metamucil) and methylcellulose (Citrucel) are useful to absorb the excess water content of the stool, making the bowel movement firmer. Fiber may also reduce elevated cholesterol levels, which are another complication of HIV therapy. Third, calcium supplements help reduce diarrhea and may reduce the risk of osteoporosis (bone loss) and avascular necrosis of the femoral head (hip degeneration), also seen in people with HIV. Finally, the amino acid glutamine may also be helpful.

**Q:** I am reasonably healthy (T cell count is 450, viral load is 600) and have not experienced any symptoms of AIDS in the 7 years I have been HIV positive. I heard that getting tuberculosis can make my HIV disease worse. What should I do to protect myself from getting TB? Are there other things that I should worry about?

**A:** Pulmonary tuberculosis (TB) is a concern for people with HIV infection. The primary way to avoid getting TB is to avoid contact with individuals who have it and are contagious. Prolonged contact

is frequently required to transmit TB. Settings such as prisons, hospital wards, group residences, and homeless shelters contribute to outbreaks of TB. Transmission can occur by travel to countries where TB is endemic. Earlier this year there was a report of a cluster of 18 TB cases in Kansas that occurred from 1994 to 2000 among women with a history of working as dancers in adult entertainment clubs (exotic dancers) and persons who were close contacts of exotic dancers (*Morbidity and Mortality Weekly Report* 50:15, p. 291, 2001).

After first getting infected with the TB germ, most people develop a latent infection as the body's immune system, at least temporarily, controls the TB infection. In this latent stage the TB is not transmitted to other people. As time goes on, the latent infection can become active, and then it can be spread to other people by droplets containing the TB germs that are produced when the person with active TB coughs, talks, laughs, or sneezes. In someone with HIV, the risk of developing active TB disease is 10% to 15% per year, much higher than for someone without HIV. Treatment for latent TB (to prevent development of active TB disease) is given if a person has a positive skin test and has not previously received TB treatment or if the person has close contact with a patient with active tuberculosis. It is very important for individuals to complete the prescribed course of treatment, which can last up to 9 months. If the treatment is not exactly followed, there is a risk the infection will not be eliminated, and the TB germs in that person can become resistant to the best drugs used for treatment.

## Patient/Doctor Q&A

Persons with HIV need to be screened regularly for latent and active TB by medical evaluation and skin testing. Some individuals may need additional tests including chest x-ray and sputum examination and culture for TB germs. Health care workers with HIV infection need to discuss with their physicians whether or not they can safely take care of patients who might have TB.

**Q:** My T cell count is 425, and my viral load is 7500. I have never taken anti-HIV drugs. Do you think I should start taking them now?

**A:** You need to talk to your doctor. The decision to start treatment is based on clinical assessment, of which test results are only a part. I assume that you have no symptoms related to HIV such as fever, weight loss, unexplained diarrhea, thrush, or memory loss, and that there are no other specific conditions that could indicate a need for treatment such as thrombocytopenia (low platelet count), **psoriasis**, or HIV-related brain disease. If that is the case, then the other question to answer is what the T cell count and viral load have been in the past. If these results are stable, then I would not typically recommend treatment at this time, but rather only close follow-up with blood tests and a doctor visit every 3 months. If the T cell count is declining, then treatment should be seriously discussed even if you have a stable, relatively low viral load.

**Q:** My partner and I (both males) are positive and on anti-HIV drugs that keep our virus levels "undetectable." We are thinking about not using condoms anymore during sex. We are monogamous. What are the risks, if any, if we stop using condoms with each other?

**A:** To answer this question let's first consider the risk of HIV transmission between an HIV-positive partner and an HIV-negative partner, which is not your situation. The risk of transmission of HIV can be estimated only within a broad range. The risk of infection per act for anal intercourse is estimated to be higher for the receptive ("bottom") partner (closer to 1 out of every 10 acts) than for the insertive ("top") partner (about 1 out of every 100 to 1000 acts). Oral sex also carries a risk of HIV transmission from pre-ejaculatory fluid ("pre-cum"), which may contain virus even when the blood viral load is undetectable. The direction of transmission in oral sex is most likely one-way, from the penis of the infected partner to the mouth of the uninfected partner. Transmission is more likely to occur if either person has a sexually transmitted disease or other genital inflammation, or if the insertive partner is uncircumcised.

Since you both already have HIV infection, the consequences of transmission are less likely to be life-changing. The primary risk is that of infection with a different strain of HIV, particularly if the new virus is resistant to the medications the other partner has been taking. Such "superinfection" or infection with a different strain has been suggested to occur, although how frequently that happens is unknown. In one case (presented at the *2000 Retrovirus Conference* in San Francisco), a Canadian man appeared to contract a more virulent and drug-resistant strain of HIV from his partner. Another risk is that of transmitting other sexually transmitted diseases, which does not apply if both partners are monogamous. Finally, there may be an increased risk of prostate and urinary tract infections in men who practice insertive anal intercourse ("top") without condoms, regardless of their HIV status. You have to decide for yourself whether to use condoms in the situation you describe. One strategy might be to use condoms for anal sex but not for oral sex.

*Medscape requires a free, first-time only registration.

**Gary Brewton, MD,** is a physician specializing in HIV medicine in Houston.

# BOTTOM LINES

## TAKE CARE OF YOURSELF

Research continues to point to the benefits of improved diet, stress reduction, and exercise in HIV-infected people. One recent study, published in *Clinical Infectious Diseases* (33, p. 710, 2001), looked at the dietary habits of 85 HIV-infected men and women with symptoms of **lipodystrophy**. Each person was evaluated for dietary intake of alcohol, fiber, and fats; waist-to-hip ratio; body mass index; pattern of body fat changes; use of protease inhibitors (and for how long); and basic characteristics like age and sex. The researchers examined these traits to see if there was a relationship to problems like insulin resistance, which can lead to **diabetes**. Although the use of protease inhibitors increased the risk of insulin resistance (as other studies have shown), factors like a diet high in polyunsaturated fats or low in fiber were independently associated with insulin resistance. Also, alcohol consumption was tied to increased levels of LDL ("bad") cholesterol. The researchers suggest that dietary factors may contribute to the metabolic disturbances experienced by many people with HIV. They believe that clinical trials are needed to see if altering dietary habits can help improve symptoms of lipodystrophy in HIV-infected people.

A second study, in the journal *Proceedings of the National Academy of Sciences* (98:22, p. 12695, 2001), points out that stress may lessen the effectiveness of anti-HIV medications. The scientists measured characteristics like blood pressure, heart rate, and skin moisture (sweating) in 13 HIV-infected men who had never taken protease inhibitors. The men were divided into 2 categories: low stress and high stress, based on their characteristics. After starting these patients on highly active antiretroviral therapy (HAART) containing a protease inhibitor, the researchers found that individuals with higher stress levels tended to have detectable viral loads and smaller increases of T cells. Those with low stress levels mostly had undetectable viral loads and greater increases of T cells. Also, in cell cultures, the researchers found that the human **hormone** norepinephrine, which is produced in the body during times of stress, increased rates of T cell infection and HIV reproduction.

**BOTTOM LINE:** HIV can dominate your health concerns, causing you to lose sight of important factors like diet, exercise, and rest. Nutritionists, personal trainers, and mental health counselors can help you make key changes to improve your overall health—and this might help your body fight HIV even better. Remember that there's more to good health than viral load and T cell count.

## VIRUSES, TIGERS, AND BEARS. OH MY!

Two reports in *The New England Journal of Medicine* (345:10, pp. 707 & 715) indicate that infection with a virus called "GB virus C" (or hepatitis G) may slow down HIV disease progression, thus improving survival in HIV-infected people. GB virus C (GBC) is not associated with any known disease. In one report, 144 out of 362 HIV-infected patients were co-infected with GBC. During the follow-up period, only 28.5% of patients with both viruses died, while 56.4% of patients with just HIV died. In cell cultures, the researchers found that cells infected with both HIV and GBC produced 30% to 40% less HIV than cells infected with HIV alone. The other report found that in a group of 197 HIV-infected patients, individuals with GBC had significantly longer survival time and a slower progression to AIDS. The researchers believe that further study of GBC may lead to new developments for the treatment of HIV disease.

On a related note, scientists studying human cell cultures have discovered that Human herpesvirus 6 (HHV-6) may influence the course of HIV infection by inhibiting "CCR5-tropic HIV," a type of HIV that is active during early infection. The study, published in *Nature Medicine* (7:11, p. 1232, 2001), offers hope that drugs or vaccines can be developed to fight HIV in new ways.

**BOTTOM LINE:** Viruses and bacteria exist in all our bodies—usually in balance with a healthy immune system. Early research showing that certain viruses may improve survival for people with HIV is good news that must be studied in clinical trials. These reports do not *immediately* apply to people with HIV but do provide some hope.

# 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.
**Cushing's syndrome:** an abnormal condition of obesity and muscle weakness caused by an overproduction of corticosteroids in the body.
**Diabetes mellitus:** 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.
**Hormone:** a substance secreted by one part of the body that stimulates cells in another part of the body (for example, testosterone).
**Hypercholesterolemia:** elevated levels of cholesterol in the blood.
**Lactic acidosis:** accumulation of lactic acid in the body.
**Lipodystrophy:** in general, changes in body fat such as loss of fat in the arms and legs and accumulation of fat in the gut or at the back of the neck.
**Metabolism:** chemical reactions in the body that are part of life; for example, turning food into energy or breathing in oxygen and breathing out carbon dioxide.
**Neuromuscular:** affecting both nerves and muscles.
**Neutropenia:** loss of a kind of white blood cell called neutrophils.
**Opportunistic infection:** a disease caused by an organism that is usually harmless, but becomes activated when a person's immune system is impaired or damaged.
**Osteopenia:** loss of bone material in a person.
**Pancreatitis:** inflammation of the pancreas, an internal organ, usually involving pain in the upper abdomen (just under the ribs) and possible nausea and vomiting.
**Paronychia:** inflammation (and usually infection) of skin near the nail of a finger or toe.
**Perinatal:** happening around the time of birth.
**Peripheral neuropathy:** degeneration of peripheral nerves (such as those in the arms and legs) resulting in muscle weakness, pain, and numbness.
**Postexposure prophylaxis:** medication taken to prevent the spread or occurrence of disease.
**Psoriasis:** a chronic skin disease causing well-defined red areas of skin covered with white scales.
**Serodiscordant:** in HIV, a situation where one sexual partner is infected and the other is not.
**Teratogen:** an agent (like a drug or a virus) that can cause birth defects.
**Toxicities:** poisonous or damaging effects on the body.

## Useful Resources

HIV Nutrition Resources. **www.hivresources.com**

The *Moore News Quarterly*, a patient-friendly online newsletter from Johns Hopkins AIDS Service.
**www.hopkins-aids.edu/publications/mnq/mnq.html**

More information on HIV/AIDS than you can even imagine, plus an extensive "Ask the Experts" area where you can post questions for HIV docs to answer. **www.thebody.com**

An e-mail discussion list for topics relating to **lipodystrophy** and other metabolic problems in people with HIV. To join, send an e-mail message to **listproc@critpath.org** with the following 3 words in the body: subscribe lipidlist (your e-mail address).

*HIV/AIDS Treatment Directory from the American Foundation for AIDS Research* (amfAR). **www.amfar.org/td** or 800.39.amfAR (800.392.6327)

*Women Organized to Respond to Life-threatening Disease* (*WORLD*): a newsletter "by, for and about HIV+ women and their loved ones." **www.womenhiv.org** or 510.986.0341

General HIV/AIDS information with sections devoted to nutrition, caregivers, money matters, and more. **www.hivpositive.com**

The National Association of People With AIDS (NAPWA). **www.napwa.org** or 202.898.0414

DON'T HAVE INTERNET ACCESS? If you are in the Houston area, remember that The Center for AIDS has 2 computer workstations available to search for information on HIV/AIDS. The workstations are provided by the Houston AIDS Information Link (HAIL). The walk-in information center (1407 Hawthorne) is open Monday through Friday, 9 a.m. to 5 p.m. Also, consider visiting a local branch of your public library.

# CLINICAL TRIAL INFORMATION

## LIPODYSTROPHY STUDY: ROSIGLITAZONE

Highly active antiretroviral therapy (HAART) has revolutionized the treatment of HIV infection and offers many patients real hope of long-term survival without the acute complications of AIDS. However, a syndrome of body shape changes (commonly called **lipodystrophy**) has recently emerged that includes visceral (gut) fat accumulation, peripheral (arms and legs) loss of fat, high levels of fat in the blood, and even diabetes. These changes closely resemble a number of inherited non-HIV-related forms of lipodystrophy syndromes. Researchers are still not sure how much of this syndrome may be caused by anti-HIV drugs or by the virus itself.

There are very few studies addressing therapeutic strategies for HIV **lipodystrophy** syndrome. Studies that switch protease inhibitors for other drugs have had some success in lowering levels of cholesterol and triglycerides, and even have improved symptoms of diabetes, but the changes in body shape have not improved. Recombinant growth hormone is effective in reducing the appearance of buffalo hump and central obesity, but due to its cost, accompanying side effects, and the complete reversal of any improvements after stopping the drug, it may not be the best therapy. Except cosmetic surgery, there is no known long-term medical therapy for the body shape changes. These changes are obviously devastating to self-image and thus the psychological well-being of many affected patients.

Baylor College of Medicine researcher Dr. Fehmida Visnegarwala and colleagues plan to study rosiglitazone (Avandia), which belongs to a new class of drugs called thiazolidinediones, in the context of **lipodystrophy**. These drugs have been FDA approved for use as "insulin sensitizers" in the treatment of diabetes. This class of drugs also has effects on fat metabolism. There has been tremendous research interest in this class of drugs after a recent study demonstrated an increase in peripheral fat and decrease in central fat (reversal of abnormal body shape) in a group of subjects with non-HIV-associated lipodystrophy who were given troglitazone (Rezulin). Even though troglitazone has been withdrawn from the market due to severe liver toxicity, the newer drugs in this class (rosiglitazone and piaglitazone) have been used in more 10,000 patients worldwide without any apparent higher risk of liver toxicity.

The study will enroll a small number of HIV-infected patients with lipodystrophy who are on stable anti-HIV therapy containing PIs. This clinical trial is sponsored by GlaxoSmithKline. For more information, contact Dr. Visnegarwala at 713.873.4069 or Dr. Susana D'Amico at 713.873.8801.

### MOUTH SORES? HIV?

If you have mouth sores and are HIV positive, you may be eligible to test a new treatment for mouth sores.

- Receive excellent care from experts at the National Institutes of Health Clinical Center in Bethesda, Maryland
- Stay on your regular course of HIV/AIDS medical treatment while on the study
- There is no charge for study medication
- Assistance with transportation may be provided
- NIH staff will try to accommodate flexible scheduling needs
- All participants may have the opportunity to take part in additional NIH studies upon completion of this study

**For more information about this study, call 888.606.0220. Interested deaf or hard-of-hearing callers should use their state relay service to contact the number above.**

## HUMAN GROWTH HORMONE STUDY

Some research suggests that HIV-infected people who experience **lipodystrophy** (body fat changes) may have human growth hormone (GH) deficiency. GH is important for the normal growth and development of children and teenagers. In adults, GH may reduce abdominal fat accumulation, which is a risk factor for cardiovascular disease. Recent data suggest that patients with HIV-associated lipodystrophy may be mildly to moderately GH deficient. This suggests that treatment with GH may be a viable option for patients with lipodystrophy. The few studies that have looked at using GH in these patients did not measure GH levels at baseline (before starting therapy) and used very high doses of GH (up to 10 times the doses used in non-HIV-infected adults with GH deficiencies). The use of GH at high doses has many side effects, and the beneficial effects of GH are lost when it is stopped. Baylor College of Medicine and the Thomas Street Clinic are performing a GH-replacement study in HIV-infected patients with lipodystrophy. Patients who are GH deficient will be invited to participate in the study, in which they will receive GH at doses similar to those that non-HIV-infected GH-deficient individuals receive. Participants will be taught how to inject daily doses of GH, which will be provided to them at no cost. A team of specialists will follow the patients. The study will last 6 months. For more information, contact Dr. Susana D'Amico at 713.873.8801.

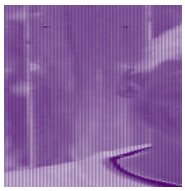
## CLINICAL TRIALS ENROLLING IN GALVESTON

Researchers at the University of Texas Medical Branch in Galveston, Texas, need volunteers for the study of anti-HIV drugs and their side effects. Qualified participants must be HIV positive and at least 18 years old. If you have been experiencing drug side effects or an increase in viral load and are considering changing therapy, you may be eligible to enroll in a study. For more information, contact Mike Reardon, RN, at 409.747.0203 or Dennis Cook, RN, at 409.747.2574.

## KEEPING IT *Real*

# Be Afraid of Osama, Not Your HIV

By **Rich Arenschieldt**



In my first few months as director of education and outreach here at The Center for AIDS (CFA), the world has turned topsy-turvy. The events of mid-September have affected us all. Upon receiving a recent phone call from a frantic person whose viral load had "spiked" from undetectable to 200, and several others like it, my coworkers and I pondered why this infinitesimal rise in HIV would cause someone such concern. The answer is simple and profound: uncertainty about life after September 11 has created increased anxiety about life in general, and to some degree, living with HIV.

But in the words of my coworker Paul Simmons, "I know what HIV is and I'm not afraid if it." If the recent "wait to treat" federal guidelines are to be believed, HIV'ers shouldn't be afraid either. Since their inception in 1986, the guidelines have been established in the hope that nonspecialists would have a slight inkling of how to treat a patient with HIV.

The newest guidelines tell us what we've known for a while—the side effects associated with long-lasting HIV drug therapy outweigh the benefits. In light of this, the feds have recommended that otherwise healthy patients not begin HIV therapy until their T cell count reaches 350. What? Are they crazy? The answer is no. Gone are the days of seeing your doc, getting a battery of tests done, and walking out with your own personal pharmacy, regardless of your T cell level.

The implication for the newly infected patient without symptoms of AIDS is clear: it's better to wait before beginning HIV "chemotherapy." However, what about someone who's been on drug for years and is now faced with a decision to divorce themselves from a lengthy marriage to their pharmaceuticals? This split-up also means leaving a "family" that includes two precious offspring—*undetectable viral load* and *high T cell count.*

Let's look at the facts in this family feud:

- In a recent Johns Hopkins medical study, over 1000 individuals with various T cell counts began therapy. There was a strong relationship between disease progression (getting sick) and beginning therapy at T cell counts below 200.
- In a Centers for Disease Control and Prevention study of 5100 people, the risk of death was significantly greater for those who started therapy at T cell counts less than 200 than for those who started therapy at counts greater than 200. Additionally, no clear benefit was observed in those who started therapy above 350.
- Data available as early as 1995 show that half of all first-time AIDS diagnoses occur at T cell counts less than 60, much lower than patients would normally expect.
- Loss of T cells as the result of HIV infection averages 50 per year from baseline (starting) levels. Using the revised treatment guidelines (suggesting therapy be offered at 350 T cells), a newly diagnosed individual with 900 T cells, could be spared 11 *years* of HIV drug therapy and its related toxic side effects.

So, it's probably time for chronically infected but otherwise healthy folks (and their docs) to re-examine the role that long-term drug therapy plays in their management of HIV disease. The CFA can provide information to help you make these tough decisions about when to start (or stop) therapy. Whether you've been recently diagnosed or are treatment experienced, there are options; most will require some suspension of fear from the past and a leap of faith into the future.

## CALENDAR

### DECEMBER

**1** **World AIDS Day**

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

**13** **7th Annual Holiday Schmooze**
6:00 – 8:00 p.m.
Call 713.527.8219 for reservation information

**17** The Center for AIDS is closed for the holiday season.

### JANUARY 2002

**2** The Center for AIDS is open for the new year.

**8** **Treatment Mixer**
7:00 p.m. at The Center for AIDS
1407 Hawthorne

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

**21** **The Center for AIDS and The Alley Theatre**
Present an encore performance of
*Falsettos* in concert
For tickets call The Alley Theatre
Box office 713.228.8421

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

### FEBRUARY 2002

**12** **Treatment Mixer**
7:00 p.m. at The Center for AIDS
1407 Hawthorne

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

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

# COMMUNITY SPOTLIGHT

## THE MONTROSE COUNSELING CENTER

The Montrose Counseling Center is a nonprofit, community-based organization providing culturally affirming, quality, and affordable outpatient mental health, substance abuse treatment, and case management services, as well as education and research in Metropolitan Houston and surrounding areas. Services are provided primarily for and about gay, lesbian, bisexual, and transgender individuals and their significant others.

PROGRAMS:

- Counseling for HIV/AIDS, substance abuse, and other issues
- Case management services for people with HIV/AIDS
- Educational presentations on topics including hate crimes, homophobia, sexual assault, and cultural sensitivity
- Group therapy sessions
- Services for crime survivors and victims of partner violence
- Women's and Men's Networks (informal education and support groups)

Intake required for all services. Sliding fee scale and limited grant funding available. Insurance accepted.

CONTACT INFORMATION:

Location: 701 Richmond Ave.
Houston, Texas 77006
Phone: 713.529.0037
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**The above information was accessed from the Montrose Counseling Center website in October 2001.**