July / August 2002

Positively Aware

The Journal of Test Positive Aware Network

Living Healthier with HIV

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A model, photograph, or author's HIV status should not be assumed based on their appearance in *Positively Aware*.

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TPAN recommends that all medical treatments or products be discussed thoroughly and frankly with a licensed and fully HIV-informed medical practitioner, preferably a personal physician.

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Editor's Note

Perceptions: It's All in the Name

I happened to meet a friend, Stan, who tells me that he is going to the store to purchase some plants for his balcony. As we part, I begin to think about Stan's "balcony." I've been over to Stan's apartment enough times to know that he doesn't have one.

It hit me later that day—Stan was now referring to the fire escape outside of his window as a balcony. Referring to one's balcony certainly sounds more fashionable, more glamorous than using the term fire escape for your trendy Lake View pad. But isn't it against the city fire code to place obstructions in the path of an emergency escape route?

People and their perceptions have always been very interesting to me. Obviously my definition of a balcony varies greatly from my friend Stan's. And when it comes to matters of housing and real estate, economics further complicates perceptions.

People, typically government politicos, use the term "affordable" when describing new housing options for people of moderate to low income. Most of these policy makers are at the end of the socioeconomic spectrum from the people whom they are developing these housing programs for.

Here in Chicago, numerous housing initiatives and programs have been created to address the limited housing options for people of modest means with and without disabilities. Many of these city-financed housing developments are marketed as being affordable. But, what does affordable mean?

For one of these programs, affordable means, based on family size and income, qualifying for subsidies that lower the price for a single family home, in neighborhoods targeted for redevelopment, to around $110,000 and a 2-flat around $181,000.

For a person who is a Supplemental Security Income (SSI) beneficiary receiving approximately $545 a month, $110,000 might as well be $1,100,000. As Social Security Disability Insurance (SSDI) beneficiary payments also reflect prior employment history, monthly allotments are often more than $545, but below the necessary income to purchase such an affordable home. But even as a renter, $545 a month doesn't go far in the urban jungle.

The federal Housing Opportunities for Persons with AIDS (HOPWA) program is supposed to help expand housing options. And HOPWA does work. By 2004, Chicago will be home to an $11 million HIV/AIDS care campus located on the city's West Side. Through funding from various private, state and federal sources, this facility will provide support and independent housing, social services, health treatments and independent living skills for low-income and homeless people with HIV/AIDS.

However, San Francisco appears to be on the opposite end of the spectrum. The San Francisco Board of Supervisors is considering reductions in housing subsidies to the San Francisco AIDS Foundation. According to Patrick Monette-Shaw (an independent community observer), over three years the San Francisco Department of Health has invested nearly $2.5 million in a database – "REGGIE" – developed by independent consultants to perform "needs assessment of SF people living with HIV/AIDS." Thus far REGGIE (which has produced no data) has cost PWAs 55 housing slots, plus another 20 this year, approaching 10% of the total slots available from the roughly 1,000 in the inventory to help people with HIV/AIDS. It doesn't make sense for government to continue investing in administrative waste, when many domestic social programs like HOPWA are being cut back, turning the lives of persons living with AIDS and others, from barely affordable to unaffordable. We all deserve options that meet our needs. When our options are threatened, there is only one alternative—to demand action from our representatives. There is no room for complacency.

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Drug Ads vs. Personal Responsibility

I don't get it. I do not understand the argument that advertisements for medicines to treat HIV are somehow contributing to the rise in HIV infections by "encouraging" unsafe behavior.

I do not accept the argument in part, because I do not believe individuals who are HIV negative read the ads. If you are not HIV positive why read the ads? I don't read ads for drugs or products for which I have no need, for example allergy medications or diabetic supplies. Nor do I read ads for tampons.

As for the message and imagery of the ads, do they really promote the idea that becoming infected is a good thing? Much has changed since the FDA insisted on a different emphasis. No longer does one see "buff," "sexy" women and men climbing mountains, sailing, running track, or generally "looking hot and attractive." So the argument that Americans are so body-conscious that they run out and become infected so they could be that mountain climber no longer applies. Current drug ads show modestly dressed people or no people at all. The ads may imply a better, healthier life, but only compared to living with HIV without their product.

Where I do have criticism with the ads is with the information provided to potential users – to those of us who are HIV positive. Like all advertising, they tend to downplay the bad aspects of the product, known as side effects. While mention is made of the common side effects they are not the headlines, but rather in the general text of the ad. And the ads could be more assertive that the medications do not cure HIV or prevent transmission. (Such a statement is present in all ads making specific claims, but it could be made more prominent.)

I think the attacks on drug ads as promoting unsafe behavior is born out of frustration. Those of us in the HIV industry and in public health are frustrated with the continued level of new infections in this country. Prevention efforts seem to be failing or missing the target. And there is a long standing reluctance to point a finger of blame at either the HIV positive person who took part in the risky behavior that infected someone or at the person who was negative and who put themselves at risk.

Most HIV infections in this country occur between two consenting, willing adults. Both of whom decided to engage in the risky behavior. Both of whom decided to not accept their responsibility for stopping this disease. The HIV positive persons did not accept their responsibility of minimizing the exposure of others to the virus. The previously HIV negative persons ignored their responsibility of minimizing their chance to be exposed to the virus.

The reasons for each person's actions are many and often complex. And once done, many seek to rationalize why they did it. But, like most of our actions, in the end we are responsible for what we do. To blame the unwillingness on "misleading" drug ads is to say "I am not responsible for my actions, for actions I now regret." It is yet another way to avoid accepting personal responsibility.

If someone you find attractive were to ask you to play Russian roulette with them, would you hand them the pistol with one bullet in the six or seven chambers? Would you spin the chambers and then pull the trigger? Would you allow them to do this to you? Unprotected sex and sharing syringes are similar to Russian roulette. How do you know when your luck is going to run out and that penis or vagina or needle will be "loaded" with HIV? How do you know you did not infect your partner?

Moving on...

As of the end of June I have left TPAN. My nine years with the agency have been an incredible experience for me. I feel very fortunate to have worked with a tremendous staff and to have met so many wonderful people. And I am very proud of

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Readers' Forum

Positively Aware will treat all communications (letters, faxes, e-mail, etc.) as letters to the editor unless otherwise instructed. We reserve the right to edit for length, style or clarity.

Write to: Positively Aware,
5537 North Broadway
Chicago, IL 60640
Fax: (773) 989-9494
E-mail: readersforum@tpan.com

Of service

Please find my enclosed donation in response to your recent letter. I wish it could be more, but it's all I can afford at this time. I am a 14-year survivor of HIV infection, Burkitt's B-Cell Lymphoma (four years ago) and a myocardial infarction (last year). I recently celebrated my 40th birthday. Your publication is an outstanding service to the community, especially to those of us long-term survivors who look to it for the latest developments in HIV treatment. Thank you for your noble service to the community and I hope *Positively Aware* is published until a cure is found.

Name withheld,
Pembroke Pines, FL

Animal Rights

In "A Lad and His Dog" [May/June 2002], we hear of a dog locked up for 24 hours. Dogs are not there to "take care" of you. We must provide for them. My partner and I have three German Shepherds, and we would never think of going all day without attending to their needs.

Name withheld,
Chicago, IL

Editor's Note: You are absolutely right. However, the point of the article was that Dickie helped a depressed man with AIDS to live a full life once again. Thank you for reminding us all that we need to take adequate care of our animal companions.

Positive Empowerment

You warmed my heart when you asked to publish my article [May/June 2002]. Thank you. I will try my best to stay in contact with you and I hope more positive sisters in prison will contribute empowerment messages.

Beverly Henry 72830
510 23 02L POB 1508
Chowchilla, CA 93610-1508

10 Ways to Mess Up Your Meds

Item No. 8 [Medicine Chest, May/June 2002] hit home with me because a couple of my meds are twice a day and one is three times a day. I just started the later med earlier this month. After reading your article and talking to my sister, a nurse, I will begin taking my meds at the appropriate interval. Thank you very much for the insight.

Name withheld,
via the Internet

Positive Riders

Thanks to Jeff Allen for a great write-up about the AIDS ride. Out here in the [Chicago] 'burbs, I've been posing the challenge that the experience of the ride is invaluable (the health benefit, as well as experiencing the power of positive support and positive community). It does about as much as any medical and psychological treatment for effective healing.

Brad Ogilvie,
via the Internet

We have an annual Life Ride in Michigan, and we ride from Jackson to Saugatuck. This year's ride is on July 19 - 20. The cost is just $50 and there's no minimum pledge requirement. We always have some positive riders, and would love information on how we can get the orange flags.

Mary Boudreau,
Lansing Area AIDS Network,
boudrea1@pilot.msu.edu

Knowledge

I am sick with both HIV and HCV [hepatitis C virus]. I can only blame myself for being sick. And I can only blame myself for not knowing everything about my illnesses. But this I can change by getting a hold of everything I can to read and study. *Positively Aware* could help me to gain more years to my life. Not only for myself, but for other sick prisoners here.

Name withheld,
Beaumont, TX 77705-7635

Survival

I live out in the country surrounded by people who are afraid of me because of HIV. I'm also Native American, and the people here are prejudiced against me on both issues. Your publication is a bright star in my universe. I will not surrender in my struggle to survive.

Name withheld,
Spavinaw, OK

Who moved my cheeks?

Jeff, I recently found your article on the Internet ("Who Moved My Cheeks?," Nov/Dec 2000). It has a very positive feel to it and I needed that. I am just starting to think about doing some type of cosmetic changes, although I must tell you that I think there has been an improvement to the fat

wasting in my face over the past three years since I stopped using d4T [Zerit]. I have changed a number of the drugs, so it could have been any of them. It is just that most of what I read seems to point toward d4T. The clinic I go to in London is beginning to do work with New-Fill [facial filling]. Thanks again and enjoy life.

Name withheld,
via the Internet

Jeff, I liked your article about your New-Fill experience [May/June 2002]. You may want to check my Web site, www.facialwasting.org for all options. As you will realize, New-Fill does not last very long. Polyacrylamide gel or Artecol are permanent and so far safe solutions (8 years). You can access them in Tijuana or Canada. I got polyacylamide in TJ and loved it.

Nelson Vergel,
Program for Wellness Restoration
(PoWeR), www.medibolics.com

Yes, New-Fill is a great product, but Dr. Stein's technique is unusual. It doesn't seem to be the method used by Drs. Amard or LeGlenne in Paris. Why didn't he massage the patient afterwards? Why did he use so many injections? It is wonderful that Mr. Berry's treatment is a success and the HIV community should be campaigning hard for government and private insurance coverage for lipoatrophy treatments. This is not cosmetic, but akin to breast reconstruction or skin grafts. Keep up the information.

Name withheld, via the Internet

Editor's Note: Dr. Daniel Berger (also trained by Dr. Jorge Tagle) responds. "Dr. Stein's technique is one pioneered by Dr. Tagle, a plastic surgeon who has been one of the other individuals who have revolutionized treatment of facial atrophy in HIV-positive patients. Dr. Tagle is internationally recognized for his work. Various surgeons have different techniques, based on their experience and training. Not to criticize one technique over another, Dr. Stein and Dr. Tagle use different methods from Dr. Amard in Paris, not just the injections in themselves, but they instill a separate (third) layer close to the bone (periosteum), which Dr. Tagle has found improves the outcome, potentiates New-Fill's effect and increases its durability. Also, there is no clear proof that massaging the face has any further benefit, unless the product is not placed in the right area; then massaging helps move the product around in a general location."

Sudden death at Corcoran

Dear friends, please take a minute to send a letter of protest to California Department of Corrections Director Ed Alameida demanding an immediate investigation into Jennnifer Sutton's death—a sample letter is attached. For those of you who can, please also fax copies to Senator Polanco. Thank you. Judy Greenspan, HIV/Hepatitis C in Prison Committee, California Prison Focus, 2940 16th Street, Room 307, San Francisco, CA 94103; voice mail/fax (510) 665-1935; www.prisons.org/hivin.htm.

Another death at Corcoran state prison

"I have full blown AIDS and can catch anything at any time. We are treated like animals here and something should be done about it. I am dying and I'm suffering and there is nothing I can do about it." This statement was part of a larger article written by Jennifer (aka Jeffrey) Sutton, a transgender woman prisoner living with HIV and hepatitis C at Corcoran state prison. Jennifer died early Friday morning, May 3, 2002. She had tried to access sick call and was feeling ill for a couple of weeks. Corcoran staff did not even try to diagnose her failing kidneys or her rapid deterioration. Jennifer finally received attention when she collapsed on Thursday night and was rushed out to the hospital, but it was too late to save her.

After our last visit with Jennifer in October 2001, we wrote to the warden and chief medical officer about her deteriorating condition. The return letter we received was typical of the lies consistently made by the Corcoran prison administration. We were assured that Jennifer was receiving excellent care. I wonder if Warden George Galaza and Chief Physician Nandan Bhatt still think that Jennifer received good care?

Jennifer was not the only prisoner receiving criminally negligent care at Corcoran. We have always maintained that Corcoran is a punishment prison, not a medical care facility (despite its sparkling new Acute Care Hospital). Over the past six months, we have learned of two other prisoners at Corcoran living with HIV whose kidneys have failed. These two prisoners survived and are currently on kidney dialysis three times a week. We have heard many alarming reports about the state of medical neglect at the prison. Last month, the only infectious disease doctor was fired. Now the prisoners in the Chronic Infectious Disease unit cannot even see a specialist for their condition.

Please send the letter below or feel free to write your own.

Date: _____
Edward Alameida, Director
California Department of Corrections
P.O. Box 942883
Sacramento, CA 94283
Fax No. (916) 322-2877

Dear Director Alameida:

I have recently learned of the death of Jeffrey (Jennifer) Sutton, C-01736, a transgender prisoner with HIV and hepatitis C who died suddenly of kidney failure at California State Prison - Corcoran on May 3, 2002. Two other prisoners co-infected with HIV and hepatitis C have also suffered kidney failure at this prison since December 2001. I demand that you immediately investigate this prisoner's medical treatment and death. Corcoran prison is well-known around the country for its brutality against prisoners. Just a few years ago, prison guards were indicted for staging gladiator fights during which prisoners were shot and killed in the exercise yard. I am concerned that prisoners with HIV and hepatitis C will not be able to access adequate medical treatment. If Corcoran cannot and will not give these prisoners the care that they need to survive, I urge you to immediately transfer these prisoners to a medical facility that will.

cc: Senator Richard Polanco, Chair, Joint Committee on Prison Construction and Operations; fax (916) 327-8817

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News Briefs

by Enid Vázquez

Drug warning

A recently reported HIV drug side effect, severe muscular weakness, has been associated with several deaths. This neuromuscular toxicity (NT) is related to other conditions already recognized as a risk of therapy: lactic acidosis (LA), pancreatitis, liver damage and mitochondrial toxicity (cell damage). The condition mimics another disease, Guillain-Barré syndrome (GBS). The U.S. Food and Drug Administration (FDA) found seven deaths among 25 cases of serious LA and NT reported last year (28%). Of the 25, 18 people continued their drugs despite symptoms, including six of the seven who died.

Although increased lactic acid level with HIV treatment is relatively common, there are usually no symptoms or serious problems. Serious side effects are obviously rare, but people living with HIV and health care providers should be aware of them. The number of severe cases and the deaths were greater among women. Last year, five cases of profound motor weakness were reported to the FDA. Also, in 2000, two pregnant women and one fetus died as a result of lactic acidosis and liver damage (hepatotoxicity) during a clinical trial.

In a search of its Adverse Event Reporting System (AERS), the FDA found that 24 of the 25 patients were hospitalized, and 12 of the 25 cases were women. Of the seven people who died, six were women. The vast majority, 22, were taking a medical regimen that included Zerit (stavudine, d4T). "Although a voluntary AERS clearly has limitations, profound motor weakness that resembles GBS can be a manifestation of LA," the FDA reported.

There were eight pregnant women who developed pancreatitis and/or LA by the eight month of pregnancy, and seven of them (88%) were taking medications that included Zerit and Videx (didanosine, ddI). Taking the two together is known to increase the risk of pancreatitis, liver failure and peripheral neuropathy. Three of those women died. The eighth woman was taking Zerit and Epivir (3TC). There were three fetal deaths, including one in the woman on Zerit/Epivir. The FDA concluded that, "The risk appears to be greatest in the third trimester and with longer duration of ddI/d4T therapy [on average, more than two years for these eight women]. The combination of ddI/d4T should be given only to those pregnant women in whom the potential benefits clearly outweigh the risks."

Zerit's manufacturer, Bristol-Myers Squibb (BMS), sent a letter to health care providers warning them about the potentially fatal neuromuscular reaction. BMS stated that Zerit should be stopped in people who develop muscle weakness or suspected cases of lactic acidosis with or without muscle weakness. The drug should never be taken again in people who have *confirmed* lactic acidosis. In its letter, BMS noted that, "The early signs and symptoms of clinical events associated with hyperlactatemia should receive careful attention because of the life-threatening potential of the most extreme manifestation, lactic acidosis syndrome (LAS)."

BMS also laid out a number of symptoms to consider. "Confirmed elevations of serum lactate may be associated with a broad spectrum of clinical manifestations, ranging from asymptomatic hyperlactatemia [in other words, there are no symptoms, and these cases in fact are not a problem], through symptomatic non-acidotic hyperlactatemia (SHL), to acute severe LAS [lactic acidosis syndrome]. Early signs and symptoms associated with a high lactate may be subtle and include generalized fatigue, digestive symptoms (nausea, vomiting, abdominal pain, and sudden unexplained weight loss), respiratory symptoms (tachypnea [rapid breathing] and dyspnea [breathlessness or difficulty breathing]), or neurologic symptoms (including motor weakness)… It is important to note that symptoms associated with hyperlactatemia may continue or worsen following discontinuation of antiretroviral [HIV] treatment.

At this time, prospective monitoring of lactate levels does not appear to be helpful in predicting the subsequent occurrence of SHL or LAS."

In the medical journal *Clinical Infectious Diseases* earlier this year, Spanish doctors discussed 12 cases of unexplained lactic acidosis out of 5,400 HIV positive people on therapy, as well as a review of other reports (60 cases). Again, women made up about half of all cases. Of the 12, four died (33%). In the 60 cases, 57% died. Age and CD4 count did not correlate with death, but having a serum (blood) lactate level above 10mM was strongly associated with death. Among seven of the 12 who were given riboflavin, with or without thiamine, only one patient died. In the literature review, three out of 11 people treated with these nutritional supplements died, a smaller percent than seen with the larger group of 60. The researchers recommended the use of thiamine and riboflavin for treatment of severe cases, because there was almost no potential for toxicity seen with them. L-carinitine, vitamin C and other antioxidants can also be used. As for Zerit, the number of cases only increased as use of the drug increased. The most commonly used nucleoside analog before 1996 was Retrovir (zidovudine, AZT), and it accounted for most of the LA cases before 1996. However, the number of cases reported from 1991–1996 was 23, all but one of them were users of Retrovir. In 2000–2001 alone there were 34 cases, 33 of them were Zerit users. Possibly some of these cases include people who were previously on Retrovir.

If experiencing symptoms of lactic acidosis, make sure your blood is drawn without use of a tourniquet or making a fist. Be well rested too—don't take the stairs. There are no tests for mitochondrial toxicity available in clinics.

Clarification: hep B virus

News Briefs in the last issue discussed preliminary findings of the effectiveness of both Viread and adefovir against resistant virus in people co-infected with HIV and hepatitis B. To clarify, the resistance discussed was in the hepatitis B virus of the study participants, not their HIV.

Combivir mix-up

Check your med! Combivir maker GlaxoSmithKline received four reports of Combivir bottles that contained instead Ziagen, another of their HIV medications. Anyone who's previously ever had an allergic (hypersensitivity) reaction to Ziagen or Trizivir (you know, it's Combivir plus Ziagen in one tablet) cannot take either of the two meds ever again. GlaxoSmithKline alerted pharmacists, physicians and patients to immediately examine the contents of every Combivir bottle. Combivir is a white capsule-shaped tablet engraved with "GX FC3" on one side; the other side of the tablet is plain. Ziagen is a yellow capsule-shaped tablet engraved with "GX 623" on one face; the other side is plain. The company found that in two of the cases, Combivir labels were put on Ziagen bottles.

Videx-EC/Viread combo

A new warning to doctors dated May 7 notes that the potential side effects of Videx-EC (ddI) may be increased by use of Viread. Serious side effects of Videx and Videx-EC (the time-release formula) include pancreatitis and peripheral neuropathy. When both medications were taken on an empty stomach two hours apart, Videx-EC levels went up by 46%. But if the Videx-EC and the Viread were taken together with a light meal (not explained), the Videx-EC levels went up by 60%. It is not clear yet as to whether dosing changes of Videx-EC should be made because of the increased blood levels and it is not yet clear whether these findings will result in increased potential for side effects. As always for any HIV meds, monitoring for side effects is urged for people with both Videx or Videx-EC and Viread in their HIV combination.

Gay men: get tested

The U.S. Centers for Disease Control and Prevention (CDC) recently updated its Sexually Transmitted Diseases Treatment Guidelines. For the first time, the CDC recommends that sexually active men who have sex with men (MSM) get tested for HIV once a year. Moreover, they should also be annually screened for syphilis, gonorrhea and chlamydia. Those who have had receptive oral sex should have a throat culture taken for gonorrhea. Those who have had receptive anal intercourse should be tested for rectal gonorrhea and chlamydia. Plus, all MSM should be vaccinated against hepatitis A and B (there is no vaccine for hep C). The guidelines were published in the May 10 issue of the CDC's *Morbidity and Mortality Weekly Report*.

Surgical risk for women

A comparison between HIV positive women and HIV negative women found the risk of post-surgical complications to be significantly higher among the positive women. Researchers looked at the records of 470 women who underwent obstetric and gynecological procedures. The greatest difference was in fever lasting more than 48 hours that required treatment with antibiotics. Lower T-cell counts increased risk of complications. A fever is one indication of infection. The study was published by Grubert *et al.* in *Clinical Infectious Diseases*.

Fauci wins prestigious award

HIV researcher Dr. Anthony S. Fauci in March was awarded the largest prize for medicine in the United States, the Albany Medical Center Prize in Medicine and Biomedical Research, a $500,000 research award. Fauci is director of the National Institute of Allergy and Infectious Diseases (NIAID), one of the National Institutes of Health (NIH), and the one that oversees HIV/AIDS research. He also became prominent in the fight against threats of bioterrorism after 9/11. Fauci said part of the award will be used on a trip to Africa to investigate ways to combat the global epidemic.

Children's confidants

According to a report from the British Broadcasting Corporation, a three-year study of Scottish children with HIV positive parents found they had no one to talk to about their fears and concerns. Children told researchers representing the agency Children in Scotland that they could not talk with parents for fear of upsetting them, nor to adults at school out of discretion. They also reported that they were not given the chance to talk with health care providers.

Genetic defects in baby monkeys

A report in the April 1st issue of the *Journal of Acquired Immune Deficiency Syndrome* (JAIDS) noted a greater risk of genetic defects in fetal monkeys exposed to both Retrovir (zidovudine or AZT) and Epivir than to those exposed only to Retrovir. (The two medications are also available in one drug, called Combivir.) However, defects have not been noted in children exposed to

the medications. Nevertheless, the researchers noted the need for long-term follow-up of these children (a desire expressed by doctors for all children exposed to HIV antivirals before birth). Also, the combination of the two drugs was more effective at reducing transmission of the virus to the baby monkeys.

Hep C, cotton and cookers

Hepatitis C virus is easier to transmit than HIV, and it can be deadly. Like HIV, it's transmitted through blood contact. An estimated 80% of people with a history of injection drug use have HCV. As with HIV, people need to be careful about sharing drug supplies other than the syringe. In a recent study, University of Illinois researchers confirmed the risk of acquiring HCV through injection equipment. After subtracting the risk of infection through syringe sharing, the researchers said that sharing "cookers," something used to melt down drugs to allow it to be sucked up by a syringe, increased the risk of getting HCV by four times. Just sharing the cotton used to filter out impurities in drugs doubled the risk of HCV. The study was published in the April issue of the *American Journal of Epidemiology*. The report was based on 702 drug users, between the years 1997 and 1999.

HIV blame

Of people surveyed in the late 1990s, about 25% said they would feel uncomfortable being in contact with someone with HIV, 20% had a fear of people with AIDS, and almost a third said they would avoid their local grocery store if the owner had AIDS. Researchers reported that education campaigns have been effective at explaining how HIV is transmitted and promoting individual responsibility, but not so effective at stressing the lack of transmission through casual contact. They also believed the campaigns hurt people with HIV without meaning to by leading the public to blame them for their infections, due to the stress on individual decision-making in sexual contact. Gregory M. Herek and colleagues reported their findings in the *American Journal of Public Health*.

Pap/HPV guidelines

A panel of gynecological experts recently created new guidelines for following up inconclusive Pap smears. Previously, women could have the Pap smear re-done, have a colposcopy (a look through a microscope) and painless biopsy taken of their cervix, or be tested for human papillomavirus (HPV), some strains of which have been associated with cervical cancer. The recommendation now is to simply test for the presence of the most dangerous form of HPV, which can be done at the time of the Pap smear. The change saves time, trouble, and money, and can relieve anxiety. The guidelines appeared in the April 24 issue of the *Journal of the American Medical Association* (JAMA).

Risky Behavour in San Francisco

This year, HIV infections hit a high the city hasn't seen in 20 years. And once again, Dr. Mitchell H. Katz and colleagues reported on the continued practice of unprotected sex in the gay community. Thanks to HAART (highly active antiretroviral therapy), men say they are less worried about getting infected, and positive men are less concerned about infecting others. One result was a decrease in condom usage. The research results come from a review of surveys conducted in various public places, such as bars or on the street. The report was published in the March issue of the *American Journal of Public Health*.

Breasts in men

The development of breasts in men (gynecomastia) has been seen with the use of HIV medications. Nelson Vergel of PoWeR (Program for Wellness Restoration) has found a pharmacy that sells compounded DHT, a treatment that has been successfully used for gynecomastia. A doctor's prescription should be written as "testosterone topical gel 10%, dispense 60 grams." Cost is $36 plus $15 for shipping and handling. Mail to Gulfsouth Pharmacy, 3207 International Drive, Suite C, Mobile, AL 36606. The phone number is 1-877-729-1015. Vergel also found this description of DHT used in gynecomastia from MedScape.com, written by Dr. William G. Powderly, the principal investigator at the Washington University AIDS Clinical Trials Unit, in St. Louis. "It is important to exclude other causes of gynecomastia (e.g., renal disease, liver disease, tumors with increased estrogen, inhibitors of testosterone, and other drugs) before attributing the condition to antiretroviral therapy…An intriguing recent report studied the use of dihydrotestosterone gel applied to the skin…A total of four patients were treated with dihydrotestosterone gel, which has an anti-estrogen effect, and all had rapid and dramatic reductions in breast tissue within 10 to 21 days…the interesting response to dihydrotestosterone does suggest that other androgens or anti-estrogens might be beneficial, and other trials are certainly warranted." Dr. Dan Berger often prescribes tamoxiphen at 10 mg per day, an anti-estrogen in pill form, for the treatment of gynecomastia when due to hormonal imbalance in HIV positive individuals. In some weight training circles, individuals who take high dose steroids for anabolism and weight training have even used this agent to *prevent* the onset of gynecomastia. [*See "The Buzz" by Dr. Berger in the Nov./Dec. 2001 issue of* Positively Aware.]

Annual ADAP report

The National Alliance of State and Territorial AIDS Directors, the Kaiser Family Foundation and the AIDS Treatment Data Network recently released a number of new reports and fact sheets on states' AIDS Drug Assistance Programs, which use federal funds to provide prescription drugs for uninsured and low-income individuals with HIV/AIDS. Among the findings: 10 states or territories reported having one or more ADAP restrictions, including capped enrollment, limited antiretroviral access or expenditure caps. Among the reports: ways for states to control the costs of ADAP. Visit www.nastad.org.

Creator of Red Ribbon dies

Frank C. Moore II, a prominent Manhattan painter who created the AIDS red ribbon, died in April of complications due to AIDS, at the age of 48. Moore was a board member of Visual AIDS, a Manhattan-based group that raises money to fund artists with HIV/AIDS and helps maintain the art of people living with the virus. His work is found in the collections at the Museum of Modern Art and the Whitney. "Between Life & Death," a book about his work, was published this year.

Nkosi Johnson Honored with Children's Nobel Prize

He was one of the world's littlest AIDS activists. At the International AIDS Conference in Durban, South Africa two

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Positive Empowerment

by Sylvia O'Shaughnessy

Okay, here I go! I have often had people ask me, "Why don't you write about that, Sylvia?" I smile with the same reply: "I will," knowing damn well that writing is not my strong point. Hey, that's Enid's job, not mine. But just for today, the need to express myself is great.

For many years, I have advocated for things that are needed to help make life easier for those living with HIV. Today, my story has to do with HIV/HCV co-infection. I remember how I felt 17 years ago, when I was told, "You have AIDS; you're going to die. Do you have any questions? Have a good day." No information about AIDS, no support. Now I am facing another serious viral infection. This time I am not waiting five years to talk about it.

It's funny to me that my anger towards HIV turned into a positive emotion that got me to where I am today. I believe that fighting is also going to get me through HCV. I was told years ago at the doctor's office, "You have hepatitis C." Just that. Once again, no information. I did not think anything about it since it seemed like no big deal to the doctor. So why should I worry, right? Wrong! Today it's known that for every case of HIV infection, there are four cases of HCV. It's also estimated that 30 to 40% of all people with HIV are co-infected with HCV.

Now, I have been off HIV medication for three years. Yes, three years, something that most doctors would tell you not to do. But my counts remain stable. I know that some day I might have to get back on medication. But the reason why I write all this is to say: I am in charge of my body and health.

I want to live, so let the fight begin. I have started my treatment of Peg-intron (one shot a week), along with Rebetol 200 mg capsules. I take three Rebetol pills twice a day, in the morning and in the evening. My doctor and I have been working together for this treatment in advance because the side effects are so severe. I was put on an anti-depressant, Effexor 150 mg a day. What was I told to expect? Fever, aches and pain, loss of appetite, depression, damage to the red blood cells and bone marrow, and thyroid problems. In other words, expect the worst and hope for the best.

I want to stress what I feel is the important part of this treatment. My frame of mind and attitude is the key. I had made up my mind to do away with this hep C and not allow myself to become suicidal. Here I was on my third cycle of Peg-Intron, and with little to no side effects at this point, I thought I was being given a placebo. Later I had aches and pain, flu-like symptoms. But 15 years ago I kicked a $400 a day habit in a cold jail cell, with pneumonia and my period. This is nothing compared to that. And flu medicine helps a lot.

I work full-time, I am involved in this committee and that one. I have a full house with grandbabies to keep me smiling. So how do I fit this treatment into my daily activities? I started by involving my children and loved ones. We held a family meeting. We went through all the side effects and how we can work together to make this process

go as smooth as possible. Then I told my boss along with my co-workers, and I am getting a lot of support from them as well. I have a great caring and loving doctor, and that is very important.

I do not allow my mind to think of the treatment I am on. I take my medication and if I am not at work, I am playing games with the kids. I have even joined a health club. The only thing that I am aware of is that I lost six pounds in one week. With that, I hope to lose 50 more pounds and bust out with a new look and the great feeling that I beat this virus.

My hope is that for anyone who is considering going on treatment for hep C, to work out a plan that will help things run smoother. Don't think that because other people were not able to tolerate this treatment, that you will not be able to either. Just like treatment for HIV has different side effects for different people, so does the treatment for hepatitis C. I still have an open mind and know that I can get sick, but until that happens, I do not sit around waiting. I continue on with life and plan to come out of this on top.

Sylvia O'Shaughnessy is Associate Program Director at Test Positive Aware Network. Her sister Enid Vázquez is associate editor of Positively Aware. *Although Sylvia has genotype 1 HCV, which does not respond very well to treatment, her liver enzyme elevations have been dramatically reduced. E-mail Sylvia@tpan.com.*

Update on the 9th Conference on Retroviruses and Opportunistic Infections

by Charles E. Clifton

Lipodystrophy: Easy to read, but not so easy to treat

Lipodystrophy (LD) was first documented in HIV positive individuals nearly 6 years ago. Over the years some antiretroviral drugs (ARV) have received more blame than others in the resulting body changes and metabolic complications associated with LD. There were several switch and treatment studies presented at the 9th Conference on Retroviruses and Opportunistic Infections (visit www.retroconference.org). The researchers are seeking to determine if switching one drug for another, in HAART, would improve LD.

Protease inhibitors (PIs) have been implicated in the accumulation of fat. They are believed to cause a major role in body shape and metabolic complications (increased triglyceride and cholesterol levels) associated with ARV therapy. Six-month data presented from one study (poster 699-T) examined the changes observed in participants switching from a PI containing regimen to Ziagen (abacavir), Sustiva (efavirenz) or Viramune (nevirapine). The results showed metabolic improvement, as observed in a lowering of bad cholesterol (LDL) and higher good cholesterol levels (HDL), in participants who switched to a PI-sparing regimen.

The NRTIs have also been implicated in the cause of LD, but primarily with fat loss (lipoatrophy). One study (poster 701-T) examined Zerit (d4T), which several randomized trials and cohort studies have shown to have a greater association with lipoatrophy. Results at week 24 from the 48-week study observed the regression of lipoatrophy and hyperlactatemia when Ziagen or Retrovir (AZT) were substituted for Zerit. There were self-reports of body fat changes, but overall, the changes were clinically insignificant (meaning the results could not be seen with the naked eye) in the limb and abdominal areas (the abdomen remained enlarged).

Another report (poster 703-T) investigated the relationship between increases in intra-abdominal fat and lower levels of HDL. Researchers studied the effects of niacin on fat redistribution in 16 participants. The participants were given a median dose of 3000 mg/day of niacin. Intra-abdominal fat was measured at baseline and participants continued to take niacin, in addition to ARV regimens that included PIs, for up to a year. Of the participants who tolerated niacin treatment for greater than 6 months, the intra-abdominal fat diminished by a mean of 27% in 13 of 16 clients (81%) and HDL increased.

Heart disease or HAART disease?

Several poster presentations at the conference examined the overall risk of heart attacks and strokes in people with HIV and on ARV therapy. The risk of developing cardiovascular disease is being more aggressively evaluated in people living with HIV infection. Concern exists that ARV therapy, particularly protease inhibitors, may increase the risk for heart disease among HIV positive individuals. However, studies continue to produce inconclusive results.

One study (poster 695-T) looked at the risk of cardiovascular disease in HIV positive persons taking different ARV regimens. The researchers tested for cholesterol, LDL, triglycerides, and HDL in 111 participants. Other factors contributing to heart disease, including cigarette smoking, hypertension, diabetes and family history, were also considered. They concluded that there is a significant prevalence

of risk for the progression of heart disease in persons with HIV infection, and the risk is higher for those being treated with protease inhibitors.

An international study (poster 697-T) also evaluated the risk of heart disease in 235 HIV positive men from France being treated with regimens containing protease inhibitors. Their results were inconclusive, but called for long-term follow up to determine if the observed progression of heart disease is directly related to HAART.

However, the facts are as we grow older the risks associated with developing heart disease continue to increase. And some individuals have a built in genetic predisposition for developing heart disease. Diets that you could get away with in your 20s and 30s are unhealthy for the 40s and 50s crowd. People living with HIV and on HAART should at least attempt to reduce their risks for heart disease. How? Stop smoking. Exercise (take a 30 minute walk a few times a week). Eat healthier.

While the data is not yet conclusive of a relationship between ARV therapy, lipodystrophy and heart disease, taken as a whole these switch studies at least suggest that ARV is a contributing factor in the body changes and metabolic complications observed in HIV positive individuals on ARV therapy. In women, there is a higher rate of fat accumulation in the breasts. In men, there is a higher rate of peripheral fat wasting. However, none of the switch studies to date have been able to confirm a dramatic change in fat levels, when substituting one drug or class for another. Additional studies are required to determine if long-term toxicities are irreversible or if there are yet other non-identified factors at play in lipodystrophy.

New drugs on the horizon

Integrase inhibitors

One of the newest classes of drugs in development, which looks encouraging, is the integrase inhibitor. Integrase is an enzyme that is used by HIV to insert its DNA into CD4 T cells. The integrase inhibitors have been under study for years, but to date there have been too many side effects to move further into clinical trials involving human subjects.

Shiongi, a Japanese company, reported on its new integrase inhibitor called S-1360 (Abstract 8). S-1360 is in early development, however thus far, it demonstrates good activity against virus resistant to all current therapeutic classes in test tubes and few side effects in animal testing. Since the conference, Shiongi has joined forces with GSK to form Shionogi-GlaxoSmithKline Pharmaceuticals to initiate phase I clinical trials of S-1360. At a recent GSK meeting, plans for phase I/II U.S. trials were discussed. The trials, involving ARV treatment experienced individuals, are expected to commence during this summer and into next year. Sites selected in the U.S. include New York City, Houston, Tampa, Los Angeles and Birmingham.

Entry inhibitors

The other new class is the entry inhibitors. Simply put, entry inhibitors block HIV from entering and infecting CD4 T cells. The fusion inhibitor T-20 (Roche-Trimeris) is the furthest along in development at this point.

A poster detailing a 48 week (phase II) study on the safety and tolerability of T-20 in 71 treatment-experienced participants (all but 3 were male), with previous exposure to PIs and nucleoside reverse transcriptase inhibitors (NRTIs), was presented. The study participants were randomized to a fixed ARV regimen or to the fixed regimen plus one of three doses of T-20. The fixed regimen included: Ziagen 300 mg twice daily (BID), Agenerase (amprenavir) 1200 mg BID, low-dose Norvir (ritonavir) 200 mg BID, and Sustiva 600 mg once daily (QD). The T-20 formulation (50 mg/mL) required 2 daily injections at the 50 mg BID dose and 4 daily injections at the 75 mg and 100 mg BID doses. The baseline mean viral loads were 3.99 to 4.47 log copies/mL (approximately 8,000 to 26,000) and CD4 T cell counts of 176-314.

At week 48, 54.9% of those receiving T-20 had viral loads less than or equal to 400 copies/mL and 47.1% had viral loads less than or equal to 50 copies/mL, compared to 36.8% (both 400 and 50 copies/mL) in the control group. Sixty-eight percent (37 of 54) of the participants receiving T-20 experienced at least one injection site reaction. The vast majority of the reactions were mild-to-moderate. Three participants discontinued treatment due to injection site reactions.

Another drug in development in this class is a compound called SCH-C (Schering Plough). Researchers are testing SCH-C as a compound that will block the ability of HIV to bind to the CCR5 co-receptor of the CD4 T cell. SCH-C has shown the ability to inhibit HIV replication in test tubes. Preliminary safety and efficacy data was presented from a phase I study. Twelve HIV positive participants were treated with 25 mg SCH-C as monotherapy (with no other drugs) twice daily for 10 days. By day three of the study there was a significant reduction in viral load in participants, one-third (4 out of 12) had a greater than 1-log decline. In this low dose study SCH-C was well tolerated. Another upside of SCH-C is that it can be taken orally.

Simplified treatments on the horizon?

Recently there's been a lot noise in the AIDS industry, media and community about "once daily" dosing and the benefits of reducing pill burden. There's a lot of buzz about reducing the number of pills and the number of times per day HIV positive individuals have to take their medicine. However, be mindful, before you rush to your physician's office demanding the newest once-a-day medicine for your regimen. The current FDA approved ARV regimens are not once daily dosing. A complete ARV regimen may still require one class of pill(s) in the morning and another in the evening. Food restrictions (no food, with food, avoid high fat food) and immediate side effects (nausea, diarrhea, dizziness) are other factors that figure into when and how ARV are taken. Also think about the potential long-term sequencing ramifications. If you switch to brand X from the PI class because of its lower pill count and fewer daily doses, how might that limit your options somewhere down the road if it increases your risk of becoming drug resistant? It could possibly mean that you are resistant to the entire PI class. HIV therapy is for the long-term. Don't play the "switch" simply because it appears to be easy. It's important to save yourself some options. With that said, let's take a look at some of the new, simplified treatments on the horizon.

Atazanavir

HIV positive, ARV treatment naïve individuals given a regimen of atazanavir (a new protease inhibitor in development), plus two NRTIs had good viral and immune responses when compared to a regimen of Viracept (nelfinavir) plus two NRTIs. Atazanavir also demonstrated a superior lipid profile in 48 week results presented on two Bristol-Myers Squibb (BMS) studies (007 and 008). There were no significant elevations in lipid levels in the atazanavir group, as compared to the Viracept group. The fasting low-density lipoprotein (LDL) increased by 5% in the atazanavir arm of the study, as compared to 23% of the Viracept group in trial AI424-008 through 48 weeks. Atazanavir is dosed at 400 mg per day in phase III clinical trials (Poster 706-T).

Zerit extended release (Zerit XR)

Results were also presented on BMS's one capsule, once daily extended release formulation of Zerit (stavudine/d4T). At 24 weeks Zerit XR had comparable virologic response as the currently marketed immediate release formulation of Zerit. Each drug was combined with standard doses of Sustiva (efavirenz) and Epivir (3TC) in ARV naïve HIV positive individuals. The Zerit XR was dosed at 100 mg once daily for 392 clients, and 391 clients received 40 mg of Zerit immediate release (IR) twice daily. Doses were adjusted for participants weighing less than 132 lbs/60 kg. At week 24, 80% of participants in both arms had achieved viral load below 400 copies/mL, and about 55% had viral loads less than 50 copies/mL. CD4 T cells increased by 142 and 136 cells in the XR and IR arms of the study, respectively. The median viral load at the beginning of the study was about 48,000 copies, and CD4 T cells were about 285 in both arms of the study. With all of the recent focus on the lack of "minorities" in clinical trials, it should be noted that 58% of this study's 783 participants were non-white and 31% were female. The study is ongoing.

Zerit XR is released over 16-18 hours. As Zerit XR is absorbed in the gastrointestinal tract, BMS is also conducting studies that are examining how this drug will work in people dealing with chronic diarrhea. There are no food restrictions in the XR formulation; high fat diets (60% fat) thus far indicate no adverse effects. No new toxicities have been associated with Zerit XR (Poster 411-W).

Viread (tenofovir)

In treatment experienced individuals, the recently approved Viread (tenofovir disoproxil fumarate) was shown to provide reductions in viral loads through 48 week results (Study 907), despite NRTI-associated mutations. Among the entire 168 study group, Viread showed a 0.5 mean log copies/mL drop from baseline through week 48, including in participants with the M184V mutation (similar results have also been demonstrated in Study 902 through 96 weeks on treatment). Viread is a 300 mg tablet taken once daily, manufactured by Gilead Sciences.

Kaletra

Data was presented from Abbott Laboratories' M99-056 study, examining the safety, efficacy and pharmacokinetics of once daily (QD) vs. twice daily (BID) Kaletra (as currently marketed) in ARV treatment naïve HIV positive individuals. Kaletra QD (800 mg lopinavir/200 mg ritonavir) or Kaletra BID (400 mg lopinavir/200 mg ritonavir) were used in combination with standard doses of Zerit and Epivir—both dosed twice daily.

Thirty-eight participants were divided equally into two study arms. At week 48, the mean increase in triglycerides from baseline was 100 mg/dL in each group. The total increase in cholesterol was 42 mg/dL for the QD group and 53 mg/dL for the BID group, neither clinically significant. The mean CD4 T cell count increases were 235 and 248 in the QD and BID groups, respectively. Viral loads at baseline were 4.6-4.7 log copies/mL (around 40,00 to 50,000). Intent to treat analysis (including 4 individuals who discontinued treatment before week 48) showed that 74% QD and 79% BID participants had viral load below 50 copies/mL at week 48 (Poster 409-W).

Agenerase (amprenavir)

Data evaluating the safety and efficacy of the compound 908, a tablet form, prodrug of Agenerase (turns into that drug in the body), and Norvir was presented (poster 431-W). Compound 908 was administered at 700 mg (equivalent to Agenerase 600 mg) plus Norvir 100 mg, twice daily, in combination with Sustiva. Since the conference, GSK has released preliminary information on phase III trials involving Compound 908. Study APV30001 is a head-to-head trial vs. Viracept in ARV treatment naïve subjects, with 908 unboosted (without Norvir and dosed twice daily). A second study, APV30002, also involving ARV treatment naïve subjects, measures the safety and efficacy of 908 boosted with Norvir and dosed once daily vs. Viracept. Both studies, ongoing for 48 weeks, are using Ziagen and Epivir to make up the regimen, and enrolled a demographically diverse population with low CD4 T cells and high viral loads.

Other news

T-20

The second of two phase III studies, this one conducted on 504 HIV infected participants, show T-20 having significant benefits for individuals with advanced HIV and with limited treatment options due to resistance to HIV drugs. T-20 appears to represent an important new treatment for patients with resistance to current drugs and advanced HIV. T-20 is the furthest in clinical development in an investigational class of antiretrovirals called fusion inhibitors. Roche and Trimeris, manufacturers of T-20, plan to file for drug approval with the FDA in the second half of 2002. An access program for T-20 to individuals with immediate need is expected to open when an increased drug supply is available.

Saquinavir once daily?

A team of Australian, Dutch and Thai researchers are testing a combination of the soft-gel formulation of saquinavir (Fortovase) 1600 mg in combination with Norvir (ritonavir) 100 mg, both protease inhibitors taken once daily. Taken in this way, Norvir greatly increases saquinavir levels in the blood and prolongs the time that Fortovase remains in circulation. After six months of treatment, of the 69 HIV positive participants who were taking this combination with two nucleoside reverse transcriptase inhibitors (NRTIs), 93% had viral loads less than 50 copies/mL. The boosted regimen of saquinavir was associated with a significant increase in CD4+ T-cells.

update on micronutrient needs in HIV

Micronutrient deficiencies appear to be common in person(s) living with HIV/AIDS (PLWHA) as a result of HIV infection itself, malabsorption, and/or eating less due to being HIV positive. Even PLWHA who are asymptomatic or appear to eat a well-balanced diet may be deficient or in the low normal range for certain nutrients.

Whole foods, fruits and vegetables, and lean protein are a paramount part of a PWLHA's diet. There are many vitamins, minerals, and antioxidants, like vitamin A and C, available in fruits and vegetables for optimal health. There are many other antioxidants, such as polyphenols, flavonoids, allium compounds, and glucosinolates in fruits/vegetables as well. Research on these nutrients is continuing and new findings are emerging. By consuming whole foods, such as whole-grains, fruits and vegetables, a PLWHA is including these and other antioxidants as well that may turn out to be very beneficial.

In a perfect world, eating a variety of healthy foods is all a PLWHA would need to do in order to meet all their nutritional needs. But we do not live in a perfect world and a prudent amount of "insurance" in the form of a supplement makes sense, especially if a PLWHA has a poor appetite or is experiencing nausea. There are certain micronutrients like vitamin E that cannot be eaten in high enough quantities in foods for an antioxidant level dosage. Remember, however, that taking supplements is no excuse for poor dietary habits. PLWHA should discuss their eating habits with a Registered Dietitian (RD) and have the RD compare their eating habits and intake to their estimated needs.

Much of the published research conducted on micronutrient intake in PLWHA to predict morbidity and mortality studied individuals before the advent of highly active anti-retroviral therapy (HAART). It is still too soon to tell what effects HAART may have on micronutrient needs. One recent study by Rosseau *et al.* evaluated 44 patients while on HAART in 1998 and found HAART contributed to selenium and zinc deficiencies. This is consistent with published data that shows people with AIDS tend to have more severe selenium deficiencies than those who have a healthier immune system.

It is outside the scope of this article to review every micronutrient in depth, but rather to highlight certain micronutrients (selenium, vitamin B12, vitamin A, C, and E) that have considerable amounts of research in relation to HIV in the medical literature.

Selenium

Selenium is part of the body's antioxidant defense system. It is a component of the enzyme gluthathione peroxidase. Selenium is the most studied micronutrient to date, with profound nutritional implications for PLWHA. Low selenium levels are associated with low gluthathione activity. A landmark study by Baum *et al.* in 1997 looked at 125 HIV positive intravenous drug users in Miami. This cohort was followed in 6-month intervals for 3.5 years. Only a selenium deficiency and CD4 count were shown to be significantly associated with mortality. The relative risk of mortality with selenium deficiency was almost 11 times greater, and was statistically significant. These results indicate that selenium deficiency is an independent predictor of survival.

A recommended daily selenium intake can range from the Daily Value (DV) of 70 mcg to 200 mcg. Keep in mind however that the DV is established by the FDA (Food and Drug Administration) to represent the minimum amount required to prevent a clear deficiency in a healthy sedentary adult population without chronic diseases. I hazard to state that the DV's do not apply to the majority of PLWHA. The Upper Tolerable Limit (UTL) set by the National Academy of Sciences for selenium is 400 mcg. The best sources of selenium from food are Brazil nuts, seafood, liver, meat and grains.

Vitamin B12

B12 is a water-soluble vitamin and important in the formation of proteins, messengers in the nervous system, red blood cells, proper functioning of a large number of enzymes and in maintaining a good immune system. B12 absorption requires intrinsic factor, a glycoprotein made in the gastrointestinal tract that allows it to be absorbed in the small intestine. B12 deficiencies may occur in malabsorption and in PLWHA. The symptoms of a B12 deficiency include anemia and changes in mental function that can lead to dementia. Tang *et al.* studied 310 HIV positive participants for nine years from 1984–1993 and found that people with low serum B12 levels (<120pmol/L) had significantly shorter AIDS-free time than those with normal B12 levels (>120pmol/L). The average AIDS-free time was 4 years vs. 8 years respectively. The risk of progression to AIDS for those with low B12 levels was significant with a relative hazard of 2.21 (the risk was more than dou-

bled), which shows that low B12 levels precede disease progression.

A recommended daily B12 intake can range from the DV of 6 mcg to 1000 mcg. The Physician's Desk Reference (PDR) for Nutritional Supplements states that oral vitamin B12 is well tolerated even at high doses. There is no established UTL for B12 and there is no documentation in the literature of overdosages. The best sources of B12 from food are meat, fish, poultry, milk and eggs. A PLWHA who is also a vegan (eats no animal products) vegetarian clearly needs a B12 supplement.

Vitamin A and Beta-Carotene

Vitamin A is a fat-soluble vitamin and beta-carotene (water-soluble) is the preferred source that can be converted into vitamin A in the body. Some studies show that a vitamin A deficiency appears to be an independent predictor of survival and levels may be low in PLWHA. In one study by Tang *et al.* in 1993 there seems to be a U-shape relationship between progression of HIV and vitamin A intake. This means that the highest and lowest quartiles of intake did the poorest, while the middle two quartiles were associated with slower progression to AIDS. Several clinical trials since have shown no benefit beyond correcting a vitamin A deficiency for sustained or significant improvements in the immune system. An excess of vitamin A is toxic, may promote free radicals, and therefore should be avoided.

A recommended daily vitamin A and beta-carotene intake can range from the DV of 5000 IU to 10,000 IU, which is the UTL. The best sources of vitamin A and beta-carotene from food are green leafy vegetables, carrots, cantaloupe, peppers, oranges, meat, milk, and other red, green, orange or yellow colored fruits/vegetables.

Vitamin C

Vitamin C is a water-soluble vitamin that is an important antioxidant. It also has the ability to regenerate the antioxidant form of vitamin E. Vitamin C has been shown in studies to reduce the symptoms and severities in acute viral infections, such as the cold and flu. The need for vitamin C increases with infection or injury. It is essential for the maintenance of bones, teeth, blood vessels and connective tissue.

A recommended daily vitamin C can range from the DV of 60 mg to 1,000 mg. 2000 mg of vitamin C is the UTL. The best sources of vitamin C from food are oranges and other red, green, orange or yellow colored fruits and vegetables.

Vitamin E

Vitamin E is a fat-soluble antioxidant that plays an important role in protecting the cell membrane, bone marrow toxicity (possible side-effect of AZT), fats, the immune system and vitamin A from oxidative stress. Low levels of vitamin E in the body have been associated with an increase in oxidative stress in PLWHA. *In vitro* (in the test tube), vitamin E appears to have an anti-viral effect. One study by Abrams *et al.*, with 296 HIV positive men followed over six years, showed a decreased risk of progression to AIDS with a doubling of vitamin E intake.

A recommended daily vitamin E intake can range from the DV of 30 IU to 800 IU. The UTL for vitamin E is 1000 IU. Be sure to avoid extra vitamin E if a PLWHA is on the protease inhibitor Agenerase (amprenavir), as it already has 1744 IU in the standard dose. The best sources of vitamin E from food are vegetable oils, eggs, and whole-grain cereals.

The body of research shows micronutrient needs are typically higher for PLWHA than for the general population. As a result, in some instances a supplement may be warranted, in addition to a healthy well-balanced eating plan to ensure optimal health and longevity. A basic multivitamin with minerals once or twice a day with meals is a good foundation. Beyond that make sure you discuss any plans on taking supplemental forms of micronutrients with your doctor and nutritionist.

by **Alan Lee, RD, CDN, CFT**

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Treating Unintentional Weight Loss Nutrition Options: An Important Piece of the HIV Puzzle

by Denise DeTommaso MA, RD, CNSD, LD

Unintentional weight loss has long been recognized as a reason for concern in people living with HIV/AIDS (PLWHA). Both studies and experience have helped us to understand that unintentional weight loss can be a signal of a potential secondary problem and ultimately an indication of increased risk for disease progression and poor outcome.

Different factors contribute to unintentional weight loss and malnutrition. Unintentional weight loss can result from starvation, a condition called cachexia, or a combination of the two.

Starvation is a form of weight loss that occurs because of decreased intake of calories and protein. It can also occur in an individual who is eating enough, but who is losing many calories because of altered bowel function and diarrhea, more commonly referred to as malabsorption. Starvation can result from a combination of both decreased intake of food and increased calorie losses. If the bowel can absorb normally, starvation can be corrected by increased intake of calories and protein. If the bowel cannot absorb normally, then the reason for the bowel problem needs to be identified and the problem corrected, so the individual can eat and absorb nutrients. Initially, starvation mainly causes a decrease in body fat, rather than skeletal muscle. If starvation progresses over a long period of time, more muscle tissue will be lost and the individual will begin to experience loss of body muscle or "wasting."

Cachexia differs from starvation. The loss of weight is mostly from loss of muscle tissue, known as a loss of "Lean Body Mass" (LBM) or "Body Cell Mass" (BCM). Both the muscle and protein tissues in our body are the tissues in which most of our metabolic function occurs, including immune tissue, organ tissue, tissue that produces energy and support movement, and tissue that supports body functions. No protein tissue can be considered storage tissue. All protein tissues have a role and are part of body function homeostasis or balance. Loss of LBM alters the balance and can affect the body functions that support maintenance of optimal health. Cachexia is caused by metabolic alterations. These metabolic alterations affect how the body uses the nutrients that come from food. The end result of cachexia is that the body uses protein tissues for energy. When an individual suffers from cachexia simply eating adequate protein, calories and micronutrients may not reverse this form of unintentional weight loss. This is defined as "wasting syndrome."

Designing a treatment plan

Weight loss can be caused by a number of factors including:

- decreased intake of food, medication side effects
- decreased absorption of nutrients
- untreated secondary infection
- alterations in metabolism

Identifying the cause of the weight loss is the first step in developing an appropriate treatment plan. Whether the cause is related to decreased intake, increased nutrient losses or changes in metabolic function, nutrition plays an important role in stopping the weight loss, and in regaining lost weight and lost LBM.

Both food and food supplements can play a valuable role in developing a successful treatment plan. The use of oral supplements can be particularly useful when an individual is unable to take in food as a source of calories and protein because of difficulty with chewing, swallowing and fatigue. Additionally, in the real world, not all people will take the time (or have the time) to prepare meals properly (even when they can), and in these instances supplements can also be helpful to those individuals. Second line nutrition supplements, which include micronutrient supplements or amino acid supplements, can also be useful in specific situations to support the treatment of weight loss. We know that specific foods and nutrition supplements are helpful to specific symptom management such as diarrhea, decreased intake, or when a patient is wasting secondary to metabolic changes. Research continues to help us understand options for nutrition and its role in conjunction with medical care, in treating unintentional weight loss.

Adequate calories, protein and micronutrients

The first line in nutrition treatment for unintentional weight loss is assuring the intake of adequate calories, protein and micronutrients, preferably from food. However, both medical symptoms and social conditions can affect an individual's ability to eat enough food to meet optimal energy and nutrient needs. Side effects of HIV/AIDS and/or medications can cause symptoms such as nausea, vomiting, and diarrhea, thereby also making the consumption of adequate nutrients difficult. In addition, alterations in metabolism can cause increased energy needs. Other issues such as economic and social conditions, including a physical inability to prepare meals can also affect the ability to eat properly. All of these

symptoms and conditions can affect intake, in addition to making one feel overwhelmed by attempting to eat what appears to be so much.

Depending on the specific symptom(s), dietary intakes can be adjusted to help manage the symptoms. Examples of dietary strategies for diarrhea symptom management include:

- identification of lactose intolerance
- reduced intake of fatty foods
- addition of foods high in soluble fiber, e.g. applesauce, canned pears or peaches, fruit nectars and bananas
- low-fat yogurt with lactobacillus
- oatbran
- white rice
- glutamine

If an individual needs to add calories and protein, other strategies can come into play. Altering your meal plan to include 6 small meals per day can be helpful, as well as the inclusion of high calorie, high protein nutrient dense snacks. Suggestions for such foods include:

- 1/2 tuna sandwich made with canola oil mayonnaise
- instant breakfast, soy milk, or lactase treated milk
- peanut butter on crackers
- yogurt
- a bowl of cereal
- low fat cheese and crackers
- leftovers from last night's dinner

You can also whip up healthy shakes with milk or soymilk, yogurt, sherbet, wheat germ, fruit nectar or ice cream. If you are lactose tolerant, adding dried milk powder to shakes, soups, and milk is also a great way to add extra calories and protein. Work with your dietitian to find creative, simple ways to add extra calories and protein to your meals and to identify strategies for meal planning that meet your individual needs.

Commercial Nutrition Supplements

A number of commercial nutritional supplements are also available and can help a person living with HIV/AIDS (PLWHA) gain back lost weight. Studies have been conducted that support use of nutrition supplements to induce weight gain. However, it is important to differentiate weight gain from gain of BCM or lost lean tissue. In the case of significant losses of lean tissue (LBM), the goal is to regain the lost lean tissue. Clinical studies performed to evaluate the effect of using oral liquid supplements on weight gain and body cell mass have produced conflicting results. Some studies have shown weight gain only in fat tissue. Others conclude with no weight gain. Still others claim an increase in both weight and BCM. In choosing a supplement consideration should be given to a number of things, including presence of diarrhea, lactose intolerance, individual nutrient requirements, and taste, as well as weight gain and body cell mass goals.

For those who are lactose tolerant, instant breakfast mixes or sports shakes are an inexpensive alternative. They can also be mixed with soy milk or lactase treated milk.

Basic supplement	Designed to improve absorption	Other
Boost	Subdue	Resource juices
Ensure	Peptamin	Resource bars
Sustacal	Advera	Nubasics soups
Scandishake	Lipisorb	Boost pudding
instant breakfast		Syst-amune
		Juven

In the presence of diarrhea, a low fat supplement, one with MCT oil, and a semi-elemental formula might be the best choice. The amino acid glutamine is also commonly used to manage diarrhea, which can be helpful in managing weight loss when the loss is associated with altered GI function and malabsorption. There are also juice-based supplements on the market. (See list)

Other supplements, known as modulars, are commonly used for weight gain. A clinical study completed in 1999 used a product called Immune System Booster (now called Syst-amune, Baxter Healthcare). This product contains a combination of glutamine, N-acetyl-cysteine, and micronutrients. Another glutamine based product, Juven (MTI BioTech), has also been used in trials to enhance lean body mass in PLWHA. Other modular products being marketed for weight gain include whey protein based products, as well as sports powders that include combinations of creatine, glutamine and taurine.

Research in nutrition including HIV positive participants has informed our understanding of the different nutritional needs of HIV positive and negative individuals. It has also demonstrated the correlation between nutrition, quality of life and managing disease progression. Malnutrition, weight loss, and lost lean body mass have been associated with poor patient prognosis and should be aggressively managed. Once lost, it can take 10 times longer to gain back lost weight and lost body cell mass. Because the causes of unintentional weight loss are so variable, treatment plans should be individualized and based on the cause of the lost weight, as well as goals for regaining both lost weight and lost lean body mass.

Nutrition is one key piece of the medical management puzzle of HIV and the treatment for lost weight in conjunction with medications, exercise, and other medical management. Addressing unintentional weight loss proactively and vigorously can improve the overall health and outcomes for PLWHA. A Registered Dietitian can help you develop a sound nutrition plan, as well as assist you in selecting supplements that might be helpful in support of your nutrition, weight gain, and BCM goals.

Denise DeTommaso is a Registered Dietitian with a wide range of experience in clinical dietetics, teaching and industry. She recently left her private HIV/AIDS practice to relocate. She currently lives in Lawrence, Kansas and is employed at Lawrence Memorial Hospital and as a Nutrition consultant to Baxter Healthcare. She can be reached at wellcafe@prodigy.net. References are available from author upon request.

Diarrhea...Again? Treatment Options for Medication-Induced Diarrhea

by Susan Basinger, RD

Let's face it. Diarrhea is not a glamorous subject to talk about. But it does occur, especially in HIV infection. It affects as many as 30-50% of HIV positive individuals at some point in time. Diarrhea is defined by the Centers for Disease Control and Prevention (CDC) as an average of greater than or equal to two loose or watery stools per day for one month or longer.

Why is this happening?

Diarrhea has many causes, including opportunistic infections (OI), diet, traditional herbs, stress, and infectious pathogens (bacteria, virus, parasite). Additionally, several medications may cause diarrhea. These include antibiotics, immunosuppressives (corticosteroids), antacids and H2 blockers (cimetidine, ranitidine, famotidine), excessive antidiarrheals, and highly active antiretroviral therapy (HAART), particularly protease inhibitors (PIs).

It is useful to find out the cause of diarrhea in order to provide effective treatment. One of the most important tests is the CD4 count, as this value shows the strength of the immune system. Generally, the lower the CD4 count (below 200 cells/mm3) the higher the chance of developing an OI. Microbiological evaluation of a stool specimen is necessary to rule out infectious pathogens (e.g. salmonella, shigella, campylobacter, C. Difficile toxin, ova and parasite, cryptosporidia, Isospora, cyclospora, microsporidia, Giardia, etc.) and fat malabsorption. This is done by providing the medical provider with a stool sample, which is then sent to a laboratory for analysis. Routine blood tests are also helpful to objectively check the severity of the diarrhea, such as electrolyte abnormalities and state of hydration. Finally, a thorough medical check-up is necessary to document diet history, medications and herbal products used currently or in the recent past.

What if I don't treat the diarrhea?

It is well known that diarrhea left untreated can result in a significant increase in morbidity and mortality, reduced quality of life (QOL), and higher health care costs. Many HIV-infected individuals may have to remain indoors or near a bathroom because of the unpredictability of the diarrhea. A fear of eating may result as the diarrhea progresses, causing malnutrition, weight loss, further weakening of the immune system, infections, and depression. Diarrhea may also have a big impact on adherence to HAART, especially if the PIs are thought to cause the diarrhea.

Treatment options

The treatment options range from over the counter (OTC) and prescription medications to dietary changes. It is important to note that some of the remedies may work better than others and often more than one agent is necessary for maximum relief. The following information comes mainly from studies performed on small numbers of subjects and from retrospective data.

What are these agents and where can they be found?

Glutamine

Glutamine is a non-essential amino acid that is used as an energy source for certain cells. It is reduced with conditions of metabolic stress, long-lasting illness, gastrointestinal tract diseases and surgery. Reliable sources of glutamine include Baxter Healthcare and Novartis Nutrition Corporation.

Calcium

Calcium is known to act as a constipating agent, and therefore may reduce diarrhea. Calcium can be purchased OTC in various formulations, including calcium carbonate and calcium citrate.

Psyllium

Psyllium is a concentrated vegetable powder that acts as a stool bulking agent on one hand, and a laxative on the other. Side-effects include bloating and flatulence (gas). The taste of psyllium is often a complaint, so it is also available in the form of fiber bars. Psyllium is available at many grocery stores and pharmacies, in products such as Metamucil.

Oat Bran

A good source of soluble fiber, oat bran adds bulk to stool and moves the digested food quickly through the intestines. Like psyllium, it can cause bloating and flatulence. Oat bran can be purchased OTC in tablet form.

SP-303

SP-303 is found in the South American Croton lechleri plant. It has been shown to decrease stool weight and stool frequency. For many years it has been used by the people of South America for the relief of diarrhea and has been more recently studied in the treatment of HIV-associated diarrhea. An herbal product, SB Normal Stool Formula contains SP-303 and can be purchased from the website of Shaman Botanicals, San Francisco, CA (www.shamanbotanicals.com).

Pancrealipase

The combination of lipase, amylase, and protrease are the pancreatic enzymes known as pancrealipase. They reduce the fat content of stool; increasing stool consistency and decreasing stool frequency. Patients may also report a reduction in bloating, flatulence, and stomach cramps. Pancrealipase is sold both OTC and by prescription. It is important to note that the products have different amounts of enzymes and various formulations (enteric coating preferred). The products available by prescription include Ultrase MT-20, Viokase and Pancrecarb (studies of the first two are included in this review). Side-effects of pancreatic enzymes include nausea and stomach cramps.

Medical Nutrition Therapy

Changing the diet is another way to reduce diarrhea. Certain foods and drinks

continued on page 41

Review of studies regarding the management of PI-induced diarrhea

Medication	Over-The-Counter (OTC) or Prescription	Study Design	Dose	Number of subjects (PI used)	Study Results
Glutamine	OTC	Randomized, double-blind, placebo-controlled crossover study	10 gm three times daily	25 (nelfinavir)	Significant decrease in diarrheal severity and improved QOL (quality of life) in both treatment groups
Calcium	OTC	Open-label, prospective trial	500 mg twice daily	15 (nelfinavir)	13 (87%) reported normal stools; 15 (100%) reported decrease in symptoms
Psyllium	OTC	Survey	1-2 Tbsp, 1-3 times daily	77 (nelfinavir)	20 patients tried psyllium; 55% reported less frequent stools, 40% reported improved stool quality
Psyllium	OTC	Open-label, prospective trial	2 fiber bars before bedtime	16 (PI not specified)	14 patients completed the study; 53% had decreased diarrhea and all had improved taste tolerability
Oat Bran	OTC	Open-label, prospective trial	1500 mg with each dose of PI medication	51 (43% nelfinavir, 27% ritonavir/ saquinavir, 30% other)	Frequency of diarrhea decreased from a mean grading score of two (4-7 loose stools/day) to 1.04 (<3 loose stools/day); 84% had improved symptoms
SP-303	OTC	Randomized, double-blind, placebo-controlled trial	500 mg every six hours for four days	51 (PI not specified)	Reduction in stool weight and frequency compared with placebo group
Ultrase MT 20	Prescription	Retrospective trial	1-2 tablets with meals and snacks	26 (nelfinavir)	25 patients (96%) had a decrease in # of stools per day
Viokase	Prescription	Open-label, prospective trial	325 mg	55 (19 saquinavir, 36 nelfinavir)	87% reported bowel control with no further diarrhea, most had relief within 12 hours

Nutrition and Lipodystrophy

by shelley scott, RD, LD

What should you eat if you're dealing with HIV and lipodystrophy?

That's a simple-sounding question without one simple answer. Lipodystrophy is a complicated syndrome, including high blood fats, insulin resistance, and fat redistribution. Because the causes of lipodystrophy are not fully understood, optimal treatment strategies—including dietary strategies—are not yet established. Can food choices prevent or reverse lipodystrophy? Nutrition may not be the one "magic bullet" for treating lipodystrophy, but combined with medical treatment, nutrition is a vital component of your treatment arsenal.

Early in the epidemic, HIV nutrition education materials focused on preventing and reversing weight loss and wasting. Butter, cream, rich cheese dishes and the like were often suggested to get in more calories. While wasting and weight loss are still problems in HIV today, we emphasize foods that are high in calories and protein, but that are also heart-healthy. Unlike the early years of HIV disease, now as people are living longer with HIV, we are contending with all those long-term health problems like heart disease, stroke, and diabetes.

What we know so far...

Blood fats

Cholesterol and triglycerides (TG) are types of lipids (fats) that travel in the bloodstream. High levels of cholesterol and TG don't cause physical symptoms. (The one exception is really high TG, which can cause pancreatitis.) But while you won't "feel" high blood fats, the increased risk for cardiovascular problems is very real. Elevated low-density lipoprotein (LDL) cholesterol (the "bad" cholesterol), elevated TG, and decreased high-density lipoprotein (HDL) cholesterol (the "good" one) all put you at risk for cardiovascular disease.

If your cholesterol and TG are normal and then jump after starting highly active antiretroviral therapy (HAART), changes in eating habits likely won't bring your levels all the way back to normal. But, diet changes likely will yield some improvement. Switching HIV medications helps bring down blood fats in some cases, but changing meds often isn't clinically appropriate. Lipid-lowering medications are an option, but that doesn't mean that nutrition changes are fruitless. Because of drug-drug interactions, the number of lipid-lowering medications is limited for people on HAART. So, it's critical to do as much as possible to bring down blood fats through eating habits and exercise.

Simply stated, diet and exercise can improve blood fats in people with HIV. And for those who need a lipid-lowering medication, lifestyle changes will improve lipids more than the medication alone.

Insulin resistance

The role of food in insulin resistance is still under investigation. Insulin resistance is a condition that often develops into diabetes. Blood sugar levels are often normal in insulin resistance, so the condition is not as easy to spot. The goal of treating insulin resistance is to improve insulin sensitivity and prevent diabetes.

Most of what is known about food and insulin resistance comes from studies of people without HIV. Among HIV negative people with insulin resistance, insulin sensitivity improves by achieving and maintaining a healthy weight, exercising, and eating a fiber-rich diet that is low in fat, processed foods and sugars, and alcohol. Whether these findings apply to people with HIV is not known, but it's a hot area of research. One study that evaluated past dietary habits of people with HIV (both with and without fat redistribution) found no connection between dietary fats and blood levels of fats, sugar, or insulin (Batterham *et al.*). Another recent study analyzed eating patterns of people with HIV and fat redistribution and found that those with lower fiber intakes and higher intakes of polyunsaturated fats and alcohol were more likely to have high lipids and insulin resistance (Hadigan *et al.*). However, this study didn't try to show if increasing fiber, reducing alcohol, and moderating polyunsaturated fats would actually prevent or reverse lipodystrophy. More studies are needed.

Fat redistribution

Insulin resistance often occurs along with fat redistribution, particularly abdominal fat accumulation. This increased visceral fat is not only uncomfortable and distressing, but it also increases cardiovascular disease risk. Which specific dietary factors might affect this fat accumulation are not fully understood, but a few reports have found improvement through strict adherence to a low-fat, high-fiber diet combined with exercise (Roubenoff *et al.* 1999, Roubenoff *et al.* 2002, Yarasheski *et al.* 2001). A case report published earlier this year found that a combination of diet and exercise reduced abdominal fat in a man with HIV (Roubenoff *et al.* 2002). The diet was high in fiber (more than 25 g per day) and low glycemic index foods (see "Limit Highly Processed Foods and Sugars" on page 34),

and low in saturated fat. To date there are no nutrition guidelines specifically targeting lipoatrophy.

Nutrition Recommendations

So, you may be asking, what am I supposed to eat?

Just as high blood fats, insulin resistance, and fat redistribution in HIV seem to be interrelated, the nutrition advice for all is similar. In general: Maintain a healthy weight, exercise regularly, cut back on dietary fats (and choose healthy fats), eat more fiber, and cut back on processed foods, sugar, and alcohol. What exactly does this mean as you walk down the aisle of the grocery store or scrutinize a restaurant menu?

Choose your fats wisely (and cut back on fats overall)

There are several types of fats in food, some healthy and some not-so-healthy. Limiting your intake of the not-so-healthy ones (saturated and trans fats) or replacing them with more healthy fats (unsaturated fats) helps bring down LDL (bad cholesterol) and TG, and may help improve insulin sensitivity.

Saturated fats are mostly found in animal fats, such as fatty cuts of meat, skin on poultry, whole-milk, cheese, cream, butter and lard. Cut back on these.

Unsaturated fats, which are found mostly in plant-based foods, don't raise blood fats, and if used in place of saturated fats may help bring LDL and TG down without decreasing the HDL (good) cholesterol. Unsaturated fats are further classified as monounsaturated or polyunsaturated. The **monounsaturated fats** seem to be the most healthy. These include: olive oil, canola oil, most nuts and nut butters, seeds, seed pastes, avacado and olives. Although **polyunsaturated fats** (found in corn oil, soybean oil, walnuts, oily fish) probably don't increase your blood fats like saturated fats, there is controversy over whether excessive amounts of polyunsaturated fats should be avoided. Avoiding polyunsaturated fats altogether is not necessarily a good idea. Foods rich in a particular type of polyunsaturated fat—**omega-3 fatty acids**—seem to help bring down TG and may have other unique cardiovascular protective effects. Omega-3s are found in fatty fish (salmon, mackeral, sardines, herring, trout, tuna), flax seed, and breads and cereals fortified with flax.

Another type of fat in food is **trans fats**. Like saturated fats, trans fats seem to raise blood fats. Trans fats are created through a process called "hydrogenation." Hydrogenation is how vegetable fats are transformed to be solid at room temperature (such as margarine or shortening.) Foods made with hydrogenated fats have a longer shelf-life, so you'll find them in many packaged and processed foods. There is no requirement for listing trans fats on food labels, so the best way to know if a food has trans fats is to look for the words "partially hydrogenated oil" in the ingredient list.

A common question: which is better, butter or margarine? My answer: use less of either. Butter has more saturated fat, but margarine has a lot of trans fat, so neither is particularly healthy. Your best bet is to look for an alternative spread: for people who use butter or margarine every day, switching to a spread with plant stanols (Benecol, Take Control, etc.) may actually help bring down your LDL. Or, look for reduced-fat spreads or spreads made with part low-fat yogurt.

For a person who needs about 2,000 calories a day, the recommended breakdown of fat in the diet looks something like this: 35 g of monounsaturated fat, 16 g of polyunsaturated fat, and less than 16 g of saturated and trans fat combined.

Remember that even healthy fats should be used in moderation—reducing the amount of fat you eat overall seems to help reduce abdominal fat. And remember that all fats are high in calories, and excess calories leads to excess weight. Being overweight in and of itself increases the risk of elevated blood fats and insulin resistance.

...reducing the amount of fat you eat overall seems to help reduce abdominal fat.

Eat less dietary cholesterol

The cholesterol in food does not increase blood cholesterol as much as saturated and trans fats, but it's a good idea to avoid excessive amounts. Egg yolks are high in cholesterol, so you should limit yourself to the equivalent of one yolk per day. Other foods that are high in cholesterol (such as shrimp, shellfish, and organ meats) should probably only be eaten once or twice a week.

Eat more fiber

To help bring down blood fats and improve insulin sensitivity, eat 25 to 35 g of fiber per day or more. On average, the typical American eats only about 12 g, or half the recommended level. Fiber is found primarily in vegetables, fruits, beans/legumes, and whole grains. If your current fiber intake is low, increase your intake gradually and drink more fluids—a quick jump in fiber intake without added fluids may cause digestive distress.

Limit highly processed foods and sugars

Excessive amounts of sugar and refined carbohydrate foods may raise TG and decrease insulin sensitivity. Limiting these foods and eating smaller portion sizes may help. Carbohydrate foods are not "fattening" per se, since they often have minimal fat in them. But in our "supersize" society, portion sizes are often large and those excess calories have to go somewhere!

Some researchers advocate choosing carbohydrate foods according to their "glycemic index." The glycemic index (GI) is a measure of how quickly the sugar from a carbohydrate gets into the bloodstream. The higher the GI the faster the sugar from the carbohydrate is absorbed.

Beans/legumes, most dairy foods, vegetables, and whole grains have a low GI, whereas refined grain products, instant rice, and potatoes have a higher GI. Fruits vary in their GI. Choosing low GI carbohydrates over high GI carbohydrates seems to help diabetics control their blood sugars. Whether following the GI index will help improve insulin sensitivity in HIV, however, is not known. It certainly makes sense, however, to eat a diet rich in beans/legumes, vegetables, and whole grains (all lower GI foods), which are all rich in nutrients and high in fiber.

Eat more soyfoods

Soy seems to help bring down LDL cholesterol, and since soyfoods are also high in fiber they may also help with TG and insulin resistance. If you're wrinkling your nose at the thought of tasteless tofu, you'll be happy to know that more types of soy foods are emerging. Soy milk, roasted soy nuts, soy beans, edamame (soy beans in the pod), soy-fortified cereals, soy cheese, and soyburgers are just some of the products available at many mainstream grocery stores.

Limit alcohol

Alcohol raises TG and may reduce insulin sensitivity. Alcohol also has "empty" calories and may impede weight loss efforts. So, when it comes to alcohol, less is probably better.

Other lifestyle factors

Exercise is an essential component in treating lipodystrophy. A combination of aerobic exercise, weight training, and flexibility/stretching is ideal, but any exercise program should be specifically designed for the individual and his/her medical condition. You also need to nourish your body adequately to support physical activity. (See "Eating for Exercise.")

While studies of the relationship between smoking and lipodystrophy are lacking, it certainly is advisable to cut back and ultimately quit to cross off a huge risk factor for cardiovascular disease.

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Nutritional strategies to improve lipid profile and increase insulin sensitivity

Tip	Foods to choose	Menu ideas	How it helps
Aim for at least 25-35 g of fiber per day (or more). Focus particularly on soluble fiber.	• Dried beans/legumes • Fruits and vegetables at LEAST five servings per day • Oats/oatmeal, whole grain breads, cereals, pasta, rice	• Eat more vegetable-based meals (such as beans and rice) • Choose bean spreads (such as hummus, black bean dips) instead of sour-cream or cheese-based dips and spreads • Choose cereals and bread made with oatmeal • Add fruit to salads, cereal, desserts • Choose fruits for snacks • Add extra vegetables to sandwiches, soups, casseroles	• Reduce LDL (bad) cholesterol • Reduce triglycerides (TG) • Minimize insulin resistance
Use less fat, especially saturated fats		• Use nonstick pans or cooking sprays in place of butter, oil, etc. • Replace half or more of the fat in baked goods with applesauce or low-fat yogurt • Try broiling, baking or grilling instead of frying food • Try low-fat versions of dairy foods, salad dressings, etc. • Trim visible fat from meat • Remove skin from chicken or turkey	• Reduces calorie intake and promotes weight loss • Reduce LDL and TG

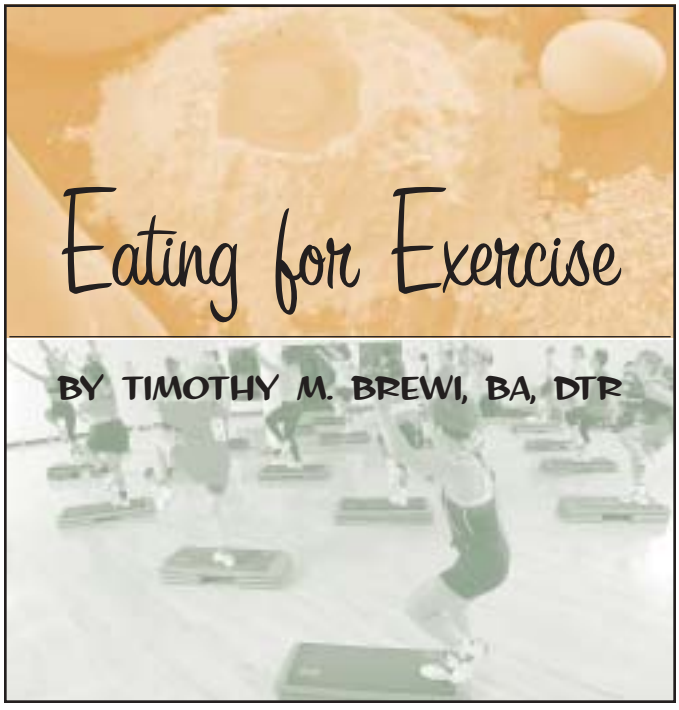
Nutritional strategies to improve lipid profile and increase insulin sensitivity continued

Tip	Foods to Choose	Menu ideas	How it helps
Use monounsaturated fats in place of saturated fats or hydrogenated (trans) fats	• Olive oil • Canola oil	• Use oils in place of butter • Use oil/vinegar salad dressings • Use oils in place of butter in baked goods	• Reduce LDL • Reduce TG • May minimize insulin resistance
Choose "healthy" fats	• Peanuts, nuts • Nut butters • Seeds • Olives • Avocado	• Snack on nuts, sunflower seeds • Use olives and avacado in salads and sandwiches • Try different nut butters (cashew butter, almond butter, etc.) for a new sandwich flavor • Add sunflower seeds or sesame seeds to salads	• Decrease LDL • Decrease TG • May increase HDL (particularly if healthy fats are replacing unhealthy fats)
Increase omega-3 fatty acids.	• Fatty fish (salmon, mackeral, sardines, herring, lake trout, tuna) • Flax seed	• Aim to eat fish at least twice a week • Spread canned tuna on crackers for a quick and healthy snack • Try flax-fortified cereals and breads • Add ground flax seed to baked goods, cereals, soups, salads	•Reduce TG • May increase HDL
Eat more soy foods	• Soybeans, Edamame • Tofu • Soymilk • Soy cheese • Soy franks/soyburgers • Tempeh • Soynuts • Soy flour	• Blend silken tofu into dips • Add tofu or soybeans to casseroles and stirfries • Snack on Edamame or soynuts • Try soymilk on cereal or in place of milk • Grill soy franks/burgers and top with tomatoes, peppers, relish etc. • In baked goods, replace one-fourth of the regular flour with soy flour	• Reduce LDL
If you use butter or margarine regularly, try plant stanol ester spreads (a "functional food" developed to help improve lipids)	•Brand names: Benecol, Take Control, Smart Balance	• Use these in place of butter or margarine as a spread on sandwiches, toast etc. • Some of these may be used in baking and frying in place of butter, margarine, or shortening (be sure to check the label)	• If you typically have used several servings of butter or margarine per day, replacing this with plant stanol spreads may help reduce LDL
Decrease alcohol intake		• For men, drink no more than 2 servings of alcohol per day, and preferably less • For women, drink no more than 1 serving per day (*1 serving = 12 oz beer, 5 oz wine, 1 oz liquor*)	• Reduce TG • Improve insulin sensitivity
Limit intake of sugar and refined flour		• Avoid excessive intake of sweets/cakes/cookies/ etc. • Choose fruit instead for snacks or dessert • Limit intake of soda and sugar-sweetened beverages • Choose whole-grain, high-fiber cereals or oatmeal in place of sugary cereals • Choose whole-grain breads over white breads or rolls • In baking, if a recipe calls for regular flour, replace half with whole-grain flour	• Reduces TG • Minimizes insulin resistance

Cut back on....	...and replace with
75% lean ground beef (this means it's 25% fat)	85% or 90% lean ground beef Ground (skinless) turkey breast
Marbled meats (that marbling is fat!)	Leaner cuts: round, loin, sirloin or chuck arm
Regular breakfast sausage	Low-fat sausage or turkey sausage
Pork bacon	Low-fat bacon, turkey bacon, ham or Canadian bacon
Fried chicken	Skinless chicken (Try coating skinless chicken with seasoned breadcrumbs and baking it in the oven for a healthy crispy coating.)
Beef or pork frankfurters, Polish sausage, Bratwurst	Low-fat hotdogs, turkey franks, tofu or soy-based franks
High-fat pizza toppings, such as pepperoni, sausage, extra cheese	Lower-fat toppings, such as Canadian bacon, low-fat ground beef, vegetables
High fat lunch meats, such as bologna, salami, pastrami, corned beef	Lower fat sandwich meats, such as turkey, chicken, boiled ham, lean roast beef
Egg yolks	Egg-replacement products; use two egg whites in place of one whole egg.
Whole milk, 2% milk, Whole chocolate milk	Fat-free milk (also called "skim") or 1% milk, Reduced-fat chocolate milk
Whole milk yogurt	Low-fat yogurt
Regular cheese	Low-fat cheese
Regular cream cheese	Low-fat cream cheese alternative spreads (such as jam or nut butters)
Regular sour cream	Low-fat sour cream, low-fat yogurt
Butter, margarine, lard, shortening	Plant stanol spreads, canola oil-based spreads (labeled "trans fat free"), yogurt-based spreads (In cooking, use olive oil or canola oil in place of butter, margarine, or lard)
Fatback (in cooking)	Skinless chicken or turkey thigh, smoked turkey
Cream in cooking,	use low-fat milk or yogurt instead
Mayonnaise	Low-fat mayo, alternative sandwich spreads such as mustard
Cream-based salad dressings	Low-fat salad dressings, vinegar/oil dressings
Tartar sauce for fish	Lemon juice
Packaged cookies, cakes, crackers (high in trans fatty acids from hydrogenated oils)	Low-fat snacks, homemade baked goods (using healthy fats)

Eating for Exercise

BY TIMOTHY M. BREWI, BA, DTR



1. Food Before Exercise

- Most importantly, be sure you're well hydrated before exercise. Exercise performance suffers with as little as 2% loss of body weight due to dehydration. Drink at least 2 cups of water about 2 hours before exercise. Drink another 2 cups of water within 20 minutes of exercise.
- Don't exercise when the body is depleted of nutrients (like before breakfast). Note that performing aerobic exercise on an empty stomach or when you're hungry does not increase the amount of fat you burn; rather, it may cause protein to be sacrificed as fuel.
- For optimum exercise performance, be sure to consume a healthy, well-balanced diet all through the day! (For more information on healthy food choices, go to http://www.tbrewi.com/hivfitness/food.htm)
- Don't exercise immediately after eating, because the body shifts fluid away from muscles and into the gastrointestinal tract during digestion. The ideal time for fitness activities is about…
  - 1/2 hour after a light snack.
  - 1 hour after a light meal, heavy snack, or meal replacement drink.
  - 2 hours after a regular meal.
  - 3 hours after a Thanksgiving-type feast.
- Consuming sweets (such as honey, candy, or soda) immediately before exercise does not provide a quick burst of energy, but may cause a rise in insulin followed by a drop in blood sugar resulting in fatigue.

2. Food During Exercise

- Most importantly, be sure to drink plenty of water during exercise. Drinking water during exercise does not cause upset stomach or cramps; whereas restricting water during exercise may cause severe dehydration and limit performance. Be aware that exercise blunts the sense of thirst. "If you wait until you notice your thirst, you're already becoming dehydrated." So whether you feel thirsty or not, drink 1/2 cup of water every 10-15 minutes. Ideally, exercisers should consume adequate fluids during activity so that body weight remains relatively unchanged before and after exercise.
- Note that muscle cramps are not caused by inadequate salt intake, but by excess water loss through perspiration. Salt tablets will aggravate dehydration by drawing fluids into the stomach. Prevent muscle cramps during exercise by keeping well hydrated.
- For people who exercise up to an hour in moderate environmental conditions, the most appropriate fluid to drink is cool water. The typical American diet provides ample electrolytes (sodium, potassium, chloride, and magnesium) to replace what is lost by sweat. However, persons who exercise strenuously for more than an hour or exercise in extreme environmental conditions (neither of which is recommended!) may require a sports beverage containing carbohydrates and electrolytes.
- Don't consume food during exercise, because the body shifts fluid away from muscles and into the gastrointestinal tract for digestion.

3. Food After Exercise

- Most importantly, drink more water! If you don't believe you lose much water during exercise, weigh yourself immediately before and after exercise. The difference is water loss. Ideally, exercisers should consume adequate fluids during activity so that body weight remains relatively unchanged before and after exercise.
- Sorry… If you lost weight during exercise, the loss is not due to burning fat but to losing water. Consume 2 cups of water for every pound of body weight lost during exercise.
- Note that muscle cramps are not caused by inadequate salt intake but by excess water loss through perspiration. Salt tablets will aggravate dehydration by drawing fluids into the stomach. Prevent muscle cramps after exercise (especially the night after exercise) by keeping well hydrated.
- Don't consume a heavy meal in the first hour after exercise.
- Do enjoy a snack or light meal about 30 minutes after exercise. The ideal post-exercise snack is light and nutritious, containing mainly carbohydrates and protein in a ratio of about 2:1. Examples:
  - 1 cup of fruit juice with protein powder.
  - 1 cup of 1% milk, fat-free ice cream, or nonfat yogurt.
  - 1 apple with 1 inch cube of low-fat cheese.
  - 2 slices of whole wheat bread with 2 thin slices of turkey, optional mustard.
  - To achieve the best results from exercise, be sure to consume a healthy, well-balanced diet all through the day!

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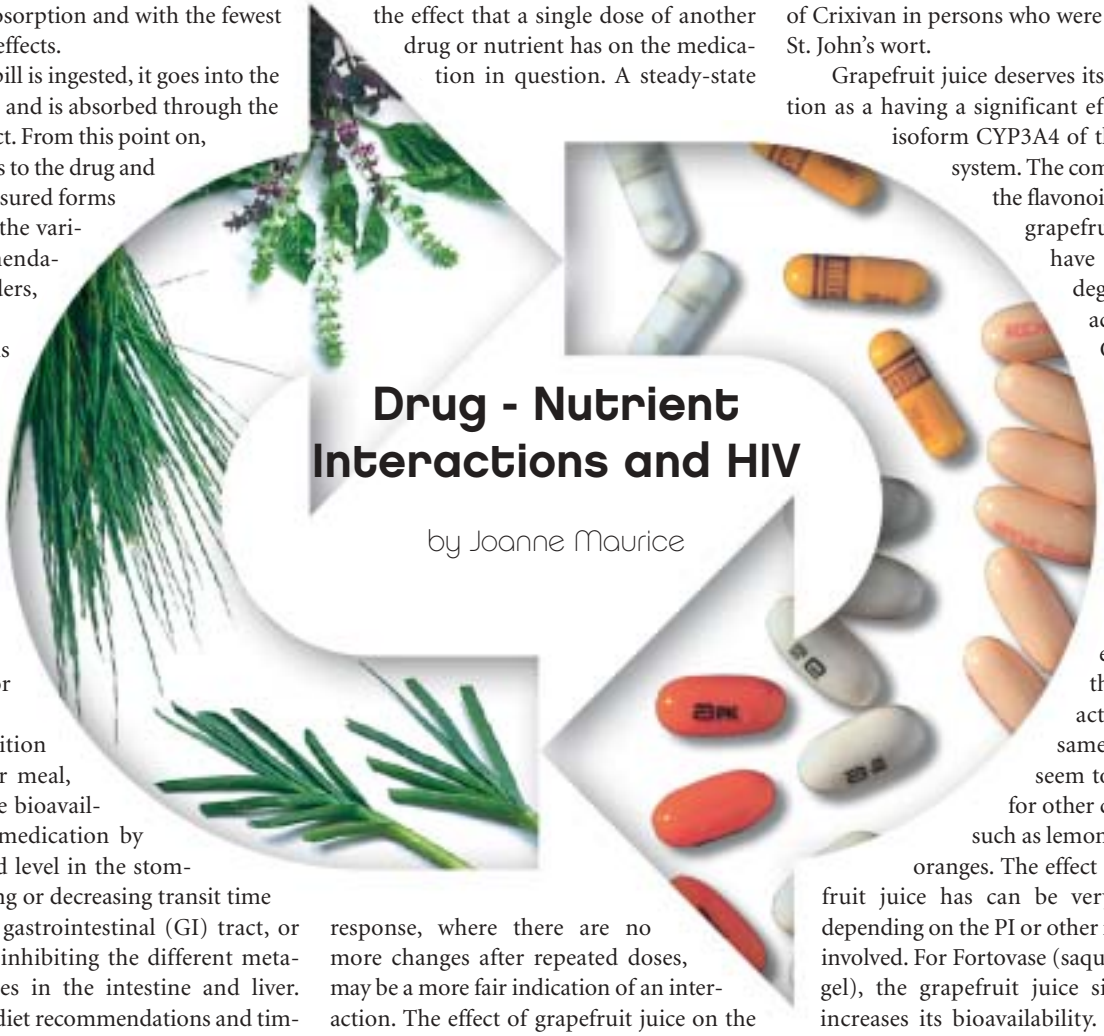
Drug - Nutrient Interactions and HIV

by Joanne Maurice



The science of drug-drug interactions and drug-nutrient interactions has advanced and improved in the past few years. There are several interactions and mechanisms that take place that can affect how well a drug is or is not absorbed, and many of these factors we have no control over. Drugs can be absorbed differently depending on race, age, gender, weight, and metabolic rates. Pharmaceutical companies have spent billions of dollars running drug trials to discover the most effective methods of taking a medication that will result in the best absorption and with the fewest adverse side effects.

Once a pill is ingested, it goes into the gut, dissolves and is absorbed through the intestinal tract. From this point on, what happens to the drug and how it is measured forms the basis for the various recommendations providers, pharmacists and dietitians give to their clients.

Foods can have an effect on a drug by increasing, decreasing or accelerating its absorption or metabolism. The composition of a food, or meal, can affect the bioavailability of a medication by affecting acid level in the stomach, increasing or decreasing transit time through the gastrointestinal (GI) tract, or inducing or inhibiting the different metabolic enzymes in the intestine and liver. Adhering to diet recommendations and timing of meals can make the difference between a drug having the most effect, or helping to decrease the side effects that can come with the medications.

To understand what is happening after a drug is ingested, a little background and some definitions are needed. Pharmacists and drug companies often cite the Cmax of a drug. This is the maximun concentration reached by a drug, where the rate for a drug being absorbed into the plasma is the same rate that it is being eliminated from the plasma. Cmin, or minimum concentration, is when a drug is at its lowest concentration, often just before the next recommended dose. Area under the curve or AUC, is a way of measuring the exposure to a drug during a full dosing interval. AUC is often viewed as the best way to see if a drug is working. Cmin is often used to predict the efficacy of the drug, where Cmax is associated with the severity and frequency of side effects.

Many studies and drug trials will list the effect that a single dose of another drug or nutrient has on the medication in question. A steady-state response, where there are no more changes after repeated doses, may be a more fair indication of an interaction. The effect of grapefruit juice on the absorption of Crixivan (indinavir) is one example where the effect seen during a single dose was different during steady-state conditions.

Once a drug is absorbed, it must be metabolized (broken down by the body's system). There are several systems in the body, one of the best known is the cytochrome P450 (CYP450) system. Within this system there are several isoforms that can be induced or inhibited by a multitude of drugs and some nutrients. The level that a drug reaches in the plasma can be determined by the extent to which these isoforms are induced or inhibited. St. John's wort is an example of such a drug-nutrient interaction. It can compete with Crixivan for the isoform CYP3A4 system, reducing significantly the amount of Crixivan available to fight the virus. The AUC for Crixivan is reduced by about 60% with St. John's wort, prompting the warning of increased risk of drug failure and viral resistance due to suboptimal levels of Crixivan in persons who were also taking St. John's wort.

Grapefruit juice deserves its own mention as a having a significant effect on the isoform CYP3A4 of the CYP450 system. The components of the flavonoids found in grapefruit juice have various degrees of activity on CYP3A4. There are other components besides the flavonoids in grapefruit juice that can have an effect on the CYP3A4 activity. The same does not seem to hold true for other citrus fruits such as lemon, limes and oranges. The effect that grapefruit juice has can be very different depending on the PI or other medication involved. For Fortovase (saquinavir softgel), the grapefruit juice significantly increases its bioavailability. Grapefruit juice, in the first studies of Crixivan, indicated a significant decrease in the bioavailability of Crixivan with a single dose of grapefruit juice. However, when studied during steady-state conditions, the adverse effect on Crixivan was not seen.

Using the AUC, it was found that a high fat meal increased the bioavailability of saquinavir by 670%, Viracept (nelfinavir) by 200 to 300%, and Norvir (ritonavir) by 15%.

There are thoughts that not taking these medications with a meal providing adequate fat could be the reason for some treatment failures. Every study seemed to define high fat differently, but for the most part a high fat meal was along the order of 50 grams of fat per meal. For those of you without your fat gram counting books, that works out to be a burger and fries kind of meal, a large muffin, or a significant amount of chips. On the other side of the coin, Crixivan, without the Norvir booster, needs to be taken with a meal containing essentially no fat. Agenerase (amprenavir) can be taken with food, but should not be taken with the same kind of high fat meal that boosts the efficacy of saquinavir. Sustiva (efavirenz), like Agenerase, should not be taken with a high fat meal, because the fat increases the absorption and increases the magnitude of the side effects.Due to the presence of Norvir, Kaletra (lopinavir/ritonavir) should also be taken with food to increase its bioavailability and decrease intra- and intervariability.

Garlic is also being studied for the effects it may have on HIV medications. Touted for its immune enhancing properties, and its safety as a supplement, garlic is beginning to be studied for potential adverse effects on medication metabolism. It appears to decrease the AUC significantly for saquinavir. There was a small decrease when looking at Norvir, but it was not significant.

The lesson here is that don't assume that it is okay to take medications without regard to the instructions given by qualified HIV health care providers. There are reasons when doctors and service providers inform you that a medication needs to be taken with more than just a cup of coffee or a banana. It's also not safe to assume that just because a product is "natural" or an herb, that there are no potential side effects or interactions with other medications. The process of metabolism is extremely complicated and the same substrate can be both an inhibitor or inducer of the process. So stay tuned, the science is young, and more answers are yet to come.

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Drug	Nutrient	Effect on medication
Crixivan (indinavir) (If taken without Norvir)	Grapefruit juice Protein > 6 grams/meal; Fat > 2 grams/meal	Decreases absorption
Norvir (ritonavir)	Fat > 15 grams/dose or meal	Increases absorption, decreases GI side effects
Fortavase, Invirase (saquinavir)	Fat > 20 grams/dose Grapefruit juice	Increases absorption
Viracept (nelfinavir)	Fat > 15 grams/meal	Increases absorption
Agenerase (amprenavir)	Fat > 50 grams Vitamin E any dose	Decreases absorption Increases risk for vitamin E toxicity
Kaletra (lopinavir, ritonavir)	Fat > 15 grams/dose	Increases absorption
Sustiva (efavirenz)	Fat > 40-60 grams/dose	Increases side effects
Videx (didanosine/ddI)	Food	Decreases absorption
Ganciclovir	Fat > 30 grams fat/meal	Increases absorption
Atovaquone	Fat > 40 grams/dose	Increases absorption

Drug	Herbs	Effect on medication
Crixivan	St. John's wort	Decreases absorption
PIs and NNRTIs	Cat's Claw	May increase serum levels
PIs	Echinacea	Could increase serum levels
Saquinavir (SQV)	Garlic	Significantly decreases SQV levels

Medicine Chest

Drugs and Food

Glen Pietrandoni, R.Ph.

Anti-retroviral drug therapy is just one way to help keep the immune system in check for people living with HIV. Other factors like stress reduction and good nutrition can help strengthen your body's own defenses against disease and some of those side effects of medication. Eating healthy, managing stress, exercise and integrating natural or alternative therapies are all important additions to the prescription drugs that your doctor may prescribe for you. Because HIV speeds up your body's metabolism, you need more vitamins and minerals than food can provide even when you are eating well. We have to be very careful that these vitamin supplements or meal replacements do not interfere with the way the pharmaceutical drugs work. The goal is to get the most of the food you eat while achieving proper levels of the medication that are prescribed. If you are a regular reader of this column, you already know about the importance of adherence to the drug cocktails and treatment success.

Alternative therapies, like herbal products and vitamins, can be an effective way to give your body a little extra boost. Unfortunately, natural vitamins and supplements do not have to be tested or studied as pharmaceutical agents do. We don't know how these agents interact with prescription drugs. There can be a large variation in the potency of natural products from batch to batch and between manufacturers. Because of these reasons, extra caution must be used when adding any supplements to your daily food and drug regimen. Something else to remember is the cost of supplements. The price has to be weighed against the benefit of the product. It is not uncommon to hear a patient spent hundreds of dollars on pretty brown bottles of vitamins and natural "immune system boosters." Spending that money on a good, balanced diet may be cheaper and better for you in the long run.

Certain foods themselves can interact with the drugs that are prescribed by physicians. To avoid upsetting your stomach, some prescription drugs can be taken with food. It is not that simple with the drugs used to treat HIV infection. The presence of food, in the case of Videx, can cause the drug to be destroyed by the acidity in the stomach. Other drugs like Fortovase require food to be present in order to achieve proper absorption. The effect that food or alternative therapies can make on the blood levels of the HIV drugs can mean the difference between success and failure of the drug combo.

Here are a few tips to remember when planning your medication regimen. However, please be advised that this is just a sample list, it is not an all-inclusive list.

Food - Drug interactions

- Grapefruit juice - decreases absorption of non-nukes and PIs
- Caffeine - Crixivan (may increase dehydration and kidney stones)
- Alcohol - Crixivan (may increase dehydration and kidney stones)

Supplement-drug interactions

- Garlic - decreases Fortovase levels
- St. Johns wort - decreases absorption of Crixivan and other protease inhibitors
- Vitamin E - high levels already included in Agenerase (amprenavir)

Drugs that need to be taken with food:

- Norvir (ritonavir)
- Kaletra (lopinavir/ritonavir)
- Viracept (nelfinavir)
- Crixivan/Norvir (when dosed together)
- Fortovase (saquinavir) and Fortovase/Norvir (when dosed together)
- Viread (tenofovir)

Drugs that need to be taken on an empty stomach

- Videx (didanosine, ddI) all formulations should be taken 30 minutes before or 2 hours after meals
- Crixivan (indinavir) can be taken with a light, low-fat snack
- Sustiva (efavirenz) 200 mg capsules or 600 mg tablets (new formulation). Food can increase blood levels, side effects

Drugs that can be taken with or without food

- Epivir (lamivudine, 3TC)
- Retrovir (zidovudine, AZT)
- Combivir (lamivudine/zidovudine)
- Ziagen (abacavir sulfate)

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- Trizivir (abacavir/lamivudine/zidovudine)
- Zerit (stavudine, d4T)
- Viramune (nevirapine)
- Rescriptor (delavirine)

Prescription drugs can cause side effects that change your appetite and digestion. Speak to your health care provider or pharmacist about tips that may help avoid these unwanted side effects. HIV disease or opportunistic infections can also interfere with eating or absorbing the nutrients you do get. Sometimes, thrush can cause a problem eating and enjoying food. Try rinsing your mouth or brushing your teeth before eating. Smoking and alcohol use can irritate the inside of your mouth. Hard candy and being well hydrated can help when you have a dry mouth.

Some of the most common questions I get as a pharmacist involve the use of herbal supplements and natural products. In general, it is always best to speak with your health care provider or pharmacist about using these products along with your prescription drugs. Make a list of all the items you take including over-the-counter drugs, vitamins, sports drinks, as well as all of the prescription drugs. Your health care provider can make a complete evaluation of any potential problems that may exist. When you are ready to buy, always make sure you purchase high quality products from reputable stores or buying clubs, but don't waste your money on "miracle cures" or high-pressure sales people. If it sounds too good to be true, it probably is.

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may cause diarrhea and may need to be avoided. The following tips may be helpful:

- Try peeled fresh fruit, steamed skinless vegetables, enriched white rice and bread (less insoluble fiber).
- Try lactose-reduced milk, soy milk or rice milk. The lactose in milk and milk containing products may not be well tolerated.
- Drink decaffeinated beverages (decaffeinated coffee and soda, herbal or decaffeinated teas).
- Avoid fried and high fat foods (such as butter, margarine, cream sauces and cream soups).
- Avoid alcoholic beverages.
- Take less than 2000 mg vitamin C per day.
- Drink more fluids (water, sport drinks).
- Tell your medical provider about any supplements, vitamins and minerals, or herbal products that you may be taking.
- Meet with a Registered Dietitian.

Severe diarrhea may be linked with malnutrition. It is important that foods and beverages that are tolerable be consumed on a daily basis. For people who do not absorb food well, nutritional supplements may also be helpful to reach better nutritional status. Included in this category are "elemental" products such as Peptamen and Subdue. These products may be ordered via a prescription from your medical provider, although keep in mind that such products may or may not be covered by the health insurance carrier. For severe cases of diarrhea and associated malnutrition, alternate nutrition support may be indicated. Delivery of nutrients via tube feeding or total parenteral nutrition are such options.

Other

Preventive measures such as good hygiene (hand washing) and good food safety are important. The phrase "keep hot foods hot and cold foods cold" is a good tip to keep in mind. It is also important to check expiration dates on food labels to make sure the food is fresh (especially meat, poultry, fish and dairy products). It is best to drink bottled, boiled or filtered water and to make sure fluids are replaced in cases of severe diarrhea. Psychosocial support may also be helpful for both the affected individual and/or the caregiver. Anxiety as a result of the diarrhea may be reduced with appropriate counseling.

Final words...

Diarrhea is a common problem that occurs in many individuals with HIV. Many reasons exist for the cause of diarrhea, including OIs, diet, herbs, stress, infectious pathogens and medications. Whatever the cause, it is important to talk to your medical provider to make sure the correct steps are taken to treat the diarrhea. This article has suggested many agents that have been studied, each leading to less diarrhea. Glutamine, calcium, psyllium, oat bran, SP-303, and pancreatic enzymes may be useful to try in cases of medication-induced diarrhea. A review of diet and lifestyle behaviors by an HIV savvy registered dietitian is also crucial in the management of diarrhea. It is important to note that each tip may work differently for each person and often more than one option may need to be used for the diarrhea to go away. The main goals remain—to maximize nutritional status, reduce weight loss, and improve quality of life while maintaining strict adherence to antiretroviral medication to effectively manage HIV.

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Drug Giant Bristol-Myers Squibb:
Atazanavir Moves Into the Spotlight While 083 Bites the Dust

by Daniel S. Berger, MD

Bristol-Myers Squibb and DuPont Pharmaceuticals

Bristol-Myers Squibb (BMS), a large entity within the pharmaceutical industry, has from the beginning of the AIDS epidemic been involved in HIV drug development, research, education and community support. One of the first antiretroviral drugs to reach the market was ddI (Videx) in 1989. Several years later they brought us d4T (Zerit). However, as HIV drug development progressed so did many dynamics within the industry. During the past year, another drug company, DuPont, manufacturer of the non-nuke drug efavirenz (Sustiva), was acquired by BMS.

DuPont Pharmaceuticals successfully brought Sustiva to market in record time, and with a rich drug pipeline of HIV drugs sought to develop the next generation of non-nukes. DuPont originally began clinical trials with one of their experimental non-nucleoside reverse transcriptase inhibitors, DPC-083, as an option for those patients failing other currently available non-nukes. Moreover, since 083 has activity against virus that is resistant to nevirapine (Viramune) and Sustiva, it would be vitally important to patients in the future.

Phase 2 Study Hurdles

However, right from the outset there were snags; changes and decisions occurred at various levels of DuPont and within the scientific staff. The variety of difficulties included attempting to begin trials with their second-generation non-nuke at a differently proposed dosage; this then was followed with various hurdles with the actual conducting and dynamics of the trial, and then finally to the BMS acquisition.

DuPont scientists were the originators of the protocol design implemented at five sites within the U.S. As principle investigator at one of these sites, NorthStar Healthcare, I and our dedicated staff provided a great deal of effort towards conducting this study. Initially, the FDA had problems with the intended dosing—they required the original proposed dosing to be decreased due to safety issues. The protocol consequently had to be re-written. Naturally, one wonders whether the decreased dose may have been less efficacious (although this was studied in Europe), and could a third dose have the potential for demonstrating better results? Also, a tight set of inclusion criteria and rigid protocol design made it quite difficult to enroll patients.

During the course of the trial, DuPont executives decided to put their pharmaceutical division up for sale. When word leaked, most of their senior clinical trial people left the company for other opportunities within the industry. A second or "transition staff," upon taking over the reins, did not seem to us as committed to the study. Eventually the well endowed and experienced BMS, with a new set of goals and priorities, looked at the project from their own perspective.

Termination of DPC-083 Study

Bristol-Myers Squibb recently decided to halt trials with 083. On May 14th, I received a memo from Dr. Nancy Ruiz, BMS Director of Infectious Diseases Clinical Development and Evaluation, stating that the phase 2 study, DPC083-203 had indeed been terminated. Reasons that were cited included recruitment, logistical issues and cumbersome implementation. Also the heterogeneity of patient population and their management made results of the study "difficult to interpret." The discontinuation of the study was not related to any adverse events encountered during the study, but because the study objectives could not be met. These explanations were discussed in a follow-up telephone conversation with Dr. Ruiz. New study designs may be discussed, but probably the other experimental non-nukes of DuPont will be considered for future clinical trials.

Harriett Wittert, RN senior coordinator at NorthStar Healthcare and the research coordinator of the 083 protocol stated, "…to these pharmaceutical companies, 083 may be a small fish in a large fish tank, but to our patients and the community a second generation non-nuke could have vital implications." Clearly, as regimens continue to fail AIDS patients and drug resistance increases, there is a greater need for more treatment options, which should include the development of second generation of non-nukes.

Atazanavir

Bristol-Myers Squibb has developed a new protease inhibitor that is about to be added to the U.S. market, making it number seven of the protease inhibitors being cur-

rently prescribed. Atazanavir (marketed under the name Zrivada) will be the first new protease inhibitor (PI) to hit the market since Kaletra became available almost two years ago.

Of the several protease inhibitors that are presently available for patients by prescription, most have similar complications associated with their use. Well known to most individuals taking these drugs are the body habitus changes that can potentially occur, increased levels of cholesterol and/or triglycerides are often seen and there are many pills to swallow per dose. Other problems associated with PIs include abdominal bloating, nausea and diarrhea. Unfortunately there are not many drugs in development near approval now and more often than not the "new" drugs are not milestone improvements over present available therapies. Often pharmaceutical companies try to tout their agent as being superior and various marketing ploys are always being attempted. Sometimes it is not until the wide and general use of a drug that the final assessments of its "treatment niche" are understood.

However, uniquely and very importantly, atazanavir's profile demonstrates it is less likely to cause lipid abnormalities. There has been concern that eventually those patients who have untreated elevations in lipids, due to protease inhibitors, will develop premature onset of cardiovascular disease. These lipid elevations are often associated with body habitus changes or lipodystrophy. Thus the big question is, will atazanavir have less associated fat redistribution complications?

Another unique property of this PI drug, that many patients can look forward to, is a low pill burden and its once daily dosing. There has been a movement to attempt construction of once daily regimens. This movement has recently gained momentum with the advent of Viread (tenofovir), Gilead Sciences' recently approved nucleotide reverse transcriptase inhibitor that is taken once a day. There are also other once-a-day drugs currently available.

In terms of resistance, various laboratory studies have demonstrated atazanavir to have similar resistance mutations as other available protease inhibitors. A study with patients who were previously treated with protease inhibitors was done; those individuals were placed on their second-line treatment. They were administered either 400 or 600 mg of atazanavir in combination with 1200 mg saquinavir (Fortovase) once daily and were compared with a third patient group on a ritonavir (Norvir)/saquinavir regimen. Of the two atazanavir patient arms, 53% and 40%, respectively, reached undetectability (less than 400 copies) vs. 38% on the ritonavir/saquinavir arm. Also, patients on the atazanavir arms did not have elevations in cholesterol or triglycerides vs. the patients on ritonavir/saquinavir, who had significant elevations.

BMS has also recently opened an early access program for this new drug to treat HIV disease for patients with greater need. In summary, the eligibility criteria for gaining access to this program includes CD4 count less than 300 cells/mm3. Also, patients must have a lack of response to HAART with HIV RNA (viral load) being greater than 5,000 copies, due to failure with other available antivirals, and are required to be unable to construct an effective alternative treatment regimen. Various toxicities or intolerance to other agents and/or significant hyperlipidemia (high cholesterol or triglycerides) are also listed as separate inclusion criteria for an inability to construct an effective regimen in this program. The toll-free phone number for the atazanavir study hotline is (877) 726-7327 (8 AM–5 PM CST).

Daniel S. Berger, MD is Medical Director for NorthStar Healthcare; Clinical Assistant Professor of Medicine at the University of Illinois at Chicago and editor of AIDS Infosource (www.aidsinfosource.com). He also serves as medical consultant and columnist for Positively Aware. *Dr. Berger can be reached at DSBergerMD@aol.com or (773) 296–2400.*

Editor's Note continued

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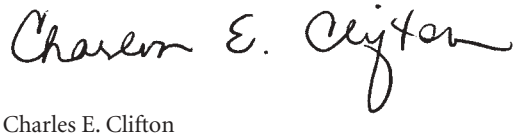
Special thanks

On behalf of the TPAN staff, I extend warm thanks and best wishes to our executive director, Dennis Hartke, as he moves on to new endeavors. Dennis gave us nine years of outstanding service and commitment. In those years he frequently worked 10 to 12-hour days with no apparent fatigue. His knowledge of the latest medical news in HIV never ceased to amaze us. Moreover, we relied on him for his kindness and generosity, his wit and his friendship. He will be greatly missed.



Charles E. Clifton
Editor
Send comments and reactions to publications@tpan.com

From TPAN continued

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TPAN. I am proud that TPAN continues to believe in peer-led services and information sharing. I am proud that TPAN has maintained a focus on HIV services. I am proud that through this publication, and its sister publication, *Positively Aware en Español*, TPAN is a national resource for persons living with HIV. And I am proud that through a wide variety of services, TPAN is a vital resource to people living in Chicago.

Dennis Hartke
Executive Director
Thoughts, comments, reactions? Write me at ed@tpan.com

Pickett Fences

Fatty Acid

by Jim Pickett

There was that unmistakable sound of horror swaddled in pity, a blend served with equal parts condescension and hope for a better tomorrow. A sort of gasp, and then a silence as full as a fat baby's diapers.

I have heard this sound before.

I was talking with an old friend, someone who has been my friend since the late 80's. We haven't lived in the same city much—he's done San Francisco, natch, and is doing New York now, natch natch—while I have kept my booty deeply rooted here in the City of Broad Bottoms.

A Cowtown I adore thoroughly, except the fact that there are disproportionately FAR too many aforementioned bottoms here.

I stand before you today and call for the immediate export of superfluous bottoms, you know who you are, along with the simultaneous import of authentic, bona fide, test-driven tops.

Can we get this on the radar screen please?

So back to the terror. He recently came to visit, my "New York" friend, and prior to his triumphant arrival in this quaint little hamlet, here on our beautiful midwestern shoreline, we were on the phone plotting and making arrangements. This is when the awful truth became known, and the world was now some kind of insane Sustiva nightmare. Though I had uttered this awful truth before, yes many times, it is my college-dropout guess that I had been previously unable to pierce the dense layers of his denial, self-absorption and time-share on Fire Island with the "right people" mentality.

Ya know, you'd have thunk I'd admitted to selling orphaned seven-year-olds from Sierra Leone to Saddam Hussein who in turn harvested their organs for cash to buy strippers for Osama.

You'da thunk.

You'd have thunk I said, "I have no desire, WHATSOEVER, to ever, EVER live in New York." Which I have said, more than twice, but even that is not as scary as what did issue like antiretroviral vomit from betwixt my foul, pursed lips.

Who knew I could be so shocking, so gelatinous, so outré.

"Well doll," I said, calmly responding to his rather ludicrous proposition that we meet at the gym, "my" gym. "As you may or may not recall," I continued clearly, firmly, "I have no gym to call my own—as I have not worked out nary a single day, Mary, since a cold gray May in 1994 when I said… no more."

Stunned. A shriek, followed by a pause pregnant with Siamese octuplets, and then, "You don't work out?" The desolation, the despair in his voice—was he crying? Mind you, this is the man who used to laugh hysterically about nipple ponies and steroid sissies, who was convinced pecs and biceps were for other people. This is the man who is now so deeply traumatized by my, "I don't belong to a gym," announcement. But underneath the shriek and the fertile pause, there was a dash of hope, that perhaps I was just joking, that, surely I was only acting like a silly nelly… "Oh golly, there goes that wacky and unpredictable sense of humor, oh you slay me! I thought maybe dementia was setting in… like you don't have a gym."

"No hon… I… DON'T…"

Nope. I don't work out, aight? My six-pack's on the inside, umkay? I'm eating for two, maybe three now. And no matter how many times I "accidentally" fall down the stairs or loll in chemical spills, I continue to eat for two, maybe three. Babies are tougher than we give them credit for.

I don't have time neither, anymore, like I used to, back in the old days, back when things were different. I have a fascinating career now, that takes me to fabulous places like Omaha and Springfield. The Simpsons are on three times a day during the week now. I have more lying on the couch to do, more naps to take, more stalking on the internet, more downloading of porn, more international long distance phone calls to dial than ever. And I require a lot of time for reflection. It's about balance. There's simply no room in my life for "working out." Yes, if I made it a priority, I'd make time. I could make cuts. I could combine my couch time with my reflection time. I could find twenty or thirty hours a week to go pump on the iron, to go work, work, work, my body, to lie in wait in the steam room, patiently, for hours… and hours… and hours.

But ya know what? I don't fucking care. My couch is lovely. It's a Jennifer convertible, and I love her.

I buy my underwear on sale at Marshall's, my flat-ware is from the dollar

store, and I don't know WHERE the hell the gym is anymore. And despite all that, somehow I continue to survive—a big fat cockroach clutching a can of Pringles and a nicely chilled liter of Coke.

Hate me because I'm bigger. Hate me because I'm better. Hate me because I will always beat you.

But don't hate me for being bountiful.

News Briefs continued

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years ago, 11-year-old Nkosi Johnson spoke at the opening ceremonies, pleading with his government to provide access to HIV medications to pregnant women in order to prevent transmission to their child, as had happened with him. He died a year later. In April, the Swedish organization The Children's World recognized Nkosi's contributions with a Children's Nobel Prize. Together with his foster mother, Nkosi had established a home for impoverished HIV positive women and their children. The Children's World called Nkosi a "role model for children with AIDS and for the healthy children whom he taught not to be afraid of children with HIV/AIDS and to respect them." To make donations to Nkosi's Haven, visit http://nkosi.iafrica.com.

South African doctors: treat pregnancy now

Once again, South African physicians urge their government leaders to make HIV treatment of positive pregnant women a reality. In a letter to the British medical journal *The Lancet*, the Southern African HIV Clinicians Society lists strong scientific data supporting the need for, and use of, HIV medications for preventing transmission to unborn children. The doctors cited Retrovir (zidovudine or AZT) and Viramune (nevirapine) as particularly beneficial and cost-effective. They said Viramune would be beneficial even if it was 42 times more toxic than what was seen in clinical trials. Around the time the letter appeared, AIDS activists in the country organized a march leading nearly 5,000 people to protest the government's appeal of a court decision forcing it to provide Viramune to prevent mother-to-infant transmission of HIV.

TPAN Calendar of Events

All events held at TPAN unless otherwise indicated.
For additional information on these events please contact Michael Barnett at (773) 989-9400.

JULY 2002

Date	Time	Event
Tuesday, July 2nd	7:30 PM	Committed to Living Series: Ask the Doc
Tuesday, July 9th	6:00 PM	Client Advisory Board Meeting
Tuesday, July 16th	7:30 PM	TPAN Board Meeting
Sunday, July 14th	1:30–4 PM	TPAN 15th Anniversary Brunch, The Room, 5900 North Broadway, $45. Contact Jeff Allen
Saturday, 27th		HIV Positive Women's Summit Contact Sylvia O'Shaughnessy

AUGUST 2002

Date	Time	Event
Tuesday, 6th	7:30 PM	Committed to Living Series: Disclosure
Tuesday, 20th	7:30 PM	TPAN Board Meeting
Wednesday, 21st	6:30 PM	International AIDS Conference Update

BROTHERS UNITED IN SUPPORT

Brothers United in Support

8th Annual Retreat for HIV Positive Gay, Bisexual and Transgender Men of African Descent

Thursday-Sunday, July 25th-28th

Camp Renora, Michigan

Registration fee: $92.00

Contact: Anthony Clark at 773-989-9400 for more information

2nd Annual HIV Positive Women's Summit

SATURDAY, JULY 27TH

10:00 AM – 5:00 PM

MARSHALL FIELD'S EVENT CENTER, 7TH FLOOR

NO REGISTRATION FEE,
SPACE IS LIMITED AND RSVP IS REQUIRED

CONTACT:
SYLVIA O'SHAUGNESSY AT
773-989-9400

Programs and Meetings

All meetings held at TPAN unless otherwise indicated:
5537 North Broadway, Chicago.
Office hours: Monday–Thursday, 9 am–8 pm. Friday, 9 am–6 pm
phone: (773) 989-9400 • fax: (773) 989-9494
e-mail: programs@tpan.com • www.tpan.com

Support groups sponsored by the Chicago Department of Public Health
Peer Support and Buddy programs sponsored by the AIDS Foundation of Chicago

Monday

TPAN Daytimers

A group for people with HIV who prefer to meet during the day. Mondays and Thursdays at 10:30 am.

Newly Diagnosed

A group for newly diagnosed individuals. Mondays at 7:30 pm. 2nd and 4th Mondays include HIV 101 education.

Straight Talk

A group for HIV positive heterosexuals. Mondays at 7:30 pm.

Tuesday

Living Positive

HIV positive gay men discuss how being positive affects relationships and deal with the impact of HIV as single men. Tuesdays at 7:30 pm.

Positive Progress

A group for HIV positive people in recovery. Tuesdays from 7:00–9:00 pm.

Wednesday

Medical Clinic

Free medical care provided by a nurse practitioner. This program is in conjunction with the Needle Exchange Program and is offered by Access Community Health Network. Call for an appointment. Wednesdays 3:30 pm–7:30 pm.

Needle Exchange Program

Free, anonymous, legal syringe exchange and HIV/AIDS prevention. Every Wednesday 5:00 pm–7:00 pm at TPAN office. In association with Chicago Recovery Alliance.

Yoga

Wednesdays at 7:30 pm.

Thursday

TPAN Daytimers

A group for people with HIV who prefer to meet during the day. Mondays and Thursdays at 10:30 am.

Medical Clinic

See description in Friday's listing. Thursdays 2:00 pm–5:00 pm.

Needle Exchange Program

See description in Wednesday's listing. Thursdays 2:00 pm–5:00 pm.

Brothers United in Support (BUS)

A group for HIV positive gay and bisexual men of African descent. Thursdays at 7:00 pm.

Berlin HIV positive Social Hour

Berlin, 954 W. Belmont, Chicago. Thursdays from 6:00–10:00 pm.

Friday

Medical Clinic

Free medical care provided by a nurse practitioner. This program is in conjunction with the Needle Exchange Program and is offered by Access Community Health Network. Call for an appointment. Fridays 2:00 pm–5:00 pm.

Positive Progress II

A group for HIV positive people in recovery. Fridays 2:00–4:00 pm.

Needle Exchange Program

See description in Wednesday's listing. Fridays 2:00 pm–5:00 pm.

Safe Passage

A group for young adults (ages 18-24) who are HIV positive. 2nd and 4th Fridays at 7:00 pm.

Scheduled By Appointment

Family AIDS Support Network (FASN)

A group for family, friends, and caregivers. Call Betty Stern at (773) 989-9490.

Women's Group

A group for HIV positive women. Call Sylvia at (773) 989-9400 for more information.

Speakers Bureau

Individuals are available to community groups and organizations to educate on HIV, safer sex, harm reduction and experiences of living with HIV. Call Sylvia at (773) 989-9400.

Peer Support Network

Provides one-on-one support for recently diagnosed individuals. Volunteers provide support, information and referrals. Call Derek at (773) 989-9400 to get a buddy!

Positive Buddy

Volunteers provide individuals living with HIV/AIDS one-on-one emotional / physical support. Call Derek at (773) 989-9400 to get a buddy!

Miscellaneous

ChicagoPos18to24 at aol.com

AOL chat room for young adults (ages 18-24) who are HIV positive. Hosted by TPAN's Young Adult Program. Go to AOL town square. Monday through Friday 3:00 pm–5:00 pm.

Inaugural

Pride Ride 2002

A two-day bicycle event conceived of and driven by volunteers to raise needed funds for AIDS Service and Community Based Organizations.

August 24 & 25
Completely a volunteer effort to raise needed funds for ASO's

50 riders, each raising $1000.
TPAN is sole beneficiary of 2002 event.

Two days-Leaving Chicago (Saturday, August 24)-riders will travel through the North Shore, riding along Lake Michigan to Lake Geneva, WI. Overnight in Lake Geneva and return to Chicago (Sunday, August 25). 85 miles each way.

Gear will be transported to Lake Geneva, otherwise this ride is unsupported, keeping costs to an absolute minimum.

"We're pedaling over 190 miles in two days, and we need your help! Support Team Positively Aware in raising needed funds to provide information and services to those living with and impacted by HIV."

Contact Jeffrey Allen at 773.989.9400, or jeffrey@tpan.com

Team Positively Aware

test positive aware NETWORK