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Table of Contents

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March / April 2004
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Departments

Articles

11th Annual Retrovirus Conference

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Norvir Hangover

On December 4, 2003 Abbott Laboratories announced that it was increasing the price of Norvir by some 400% or from $1.72 per pill to $8.57 per pill. Never in the short history of antiretroviral therapy has a company announced such a price increase on an existing drug. Norvir was the second protease inhibitor to reach the market in 1996, and has enjoyed a long life when compared to other anti-HIV medicines. However, because of the adverse side effects and other limitations of the drug, basically no one currently uses full-dose Norvir. However, if someone were using full-dose Norvir, the new annual price for the drug would be nearly $50,000 per year. If not for its capacity to "boost" the levels of other protease inhibitors (PIs), Norvir would have minimal value. It is reported that 80% of the HIV-positive patients who take Norvir are using it as a boosting agent at the 100 mg or 200 mg dose in combination with another PI, including Abbott's best selling PI, Kaletra (lopinavir/Norvir).

Four Seasons of Betrayal

In the spring of 2003, AIDS activists were infuriated by the $25,000 per year price tag of Roche's fusion inhibitor Fuzeon (T-20). Over the summer and into the fall we were stunned again by the sizzling prices of new two new PIs, first Bristol-Myers Squibb's Reyataz at $20,000/year and then GlaxoSmithKline's Lexiva at $18,000/year. Finally to add insult to injury, Abbott froze us out this winter with the unprecedented price hike of Norvir. Abbott's timing and misreading of the reaction from AIDS activists and the HIV physicians could not have been more ill-conceived.

What is so offensive about the price hike? Most stunning about this price hike was the timing and what did not happen in regards to the price increase on Norvir. First, Abbott did not bring a new drug to the market. They didn't even bring a "new and improved" version of Norvir to market. Secondly, and even more calculating to many, the price of Kaletra, while boosted with Norvir, remained fixed. Norvir is also used to boost Kaletra's two main competitors from the PI class, Reyataz and Lexiva, in treatment-experienced and salvage patients. With the price hike of Norvir (and not Kaletra) the price of all boosted PIs have become far more expensive than Kaletra. Abbott representatives strongly deny that the price increase was done to get patients and providers to switch to or remain with Kaletra.

Abbott's Kaletra is currently the #1 prescribed PI on the market. While the drug has demonstrated good durability, critics argue that Abbott's intention with the price increase is to force prescribers and patients away from using Norvir in combination with other protease inhibitors and switch and/or remain with Kaletra (already boosted with Norvir).

Representatives from Abbott Laboratories have spent the better part of the last three months "justifying" the price hike. They've been living a public relations nightmare and trying to do damage control with HIV physicians, AIDS activists, and community-based organizations (CBOs). According to Abbott reps the price increase was done for two primary concerns: 1) a result of "the changing role of Norvir" in the field of HIV treatment and 2) to support future HIV drug research and development.

In a public letter to HIV treating clinicians, John Leonard, M.D. Vice President of Global Pharmaceutical Development for Abbott writes, "This new price is necessary to support our ability to continue research to bring a next generation HIV medication to market, to develop improved formulations of our existing products, and to continue our commitment to the developing world."

Many AIDS activists wonder if this is yet another threat from Abbott to exit AIDS research and development, to discontinue long-promised plans to reformulate Norvir and Kaletra, and to not support HIV initiatives in developing nations without this price increase. Abbott has been hinting at a reformulation of Kaletra and Norvir for a couple of years, however, the company has not committed the expected new profits towards offsetting the future prices of reformulated Kaletra and Norvir.

I've listened to several different explanations and justifications of the price increase and something about them just doesn't add up.

If a price increase is necessary to support the areas of concern that the company has gone to such lengths to outline, why wasn't the price of Kaletra increased? If Abbott really wants to make additional revenue to support research and development why not "boost" the price of the best selling PI on the market. Or better yet, why not wait for the reformulated versions of Norvir and Kaletra and then hit us with a price hike. Maybe then we could stomach an increase.

American Academy of HIV Medicine (AAHIVM) member Dr. Benjamin Young, PhD. and Dr. Edwin DeJesus, medical director of Infectious Disease Consultants (IDC) Research Initiative, have both publicly condemned Abbott's recent move. DeJesus writes that "we do not see other companies, with even less HIV market share, hiking the prices of already FDA approved drugs to fund their

Photo © Russell McGonagle

research and development programs." And what happens if Norvir and Kaletra can't be reformulated? Do we get a refund?

Abbott Laboratories has been slammed from the front, back and center by AIDS activists, consumer groups and HIV physicians; and rightly so. From the State of Washington, down the coast of California, cross country to New York City and down to South Florida this price increase has fueled a level of protest from AIDS activists, patients and doctors not witnessed in years. Even after the company gave reassurances on ADAP (AIDS Drug Assistance Program) price freezes and expanded patient assistance programs, many remain unconvinced and won't settle for anything less than a price rollback on Norvir.

Abbott responds

In response to sharp criticism, Abbott expanded its Patient Assistance Program (PAP) so that all uninsured patients, regardless of income, can receive Norvir at no cost [(800) 222–6885 or www.abbottvirology.com]. The company maintains that all patients who have requested Norvir through the PAP program since the price hike have been approved within 24 hours and received drug within 2-3 days. This also includes those patients who will exceed their annual prescription insurance maximum and patients currently on an ADAP waiting list. When questioned about the number of individuals currently enrolled in the PAP, Abbott states that due to reasons of confidentiality they cannot disclose that number. However, Abbott states that expanded benefits will be in place permanently.

Whereas Abbott had already committed to freeze the price of Norvir for ADAPs through June 2005, they are now extending that commitment and have permanently frozen the ADAP price for the current formulation of Norvir. Abbott pledges to keep the current formulation of Norvir on market—even after the new formulated tablet (requiring no refrigeration) becomes available. This measure will ensure that public programs like Medicaid and ADAP continue to have this alternative at this low cost.

In addition, to calm fears of AIDS activists and HIV physicians that the price hike will have detrimental impact on salvage patients and drug development, Abbott maintains it will make the current formulation of Norvir available to researchers seeking a New Drug Application (NDA) for new HIV compounds at a price of $1.71 or less for 100 mg of Norvir. However, the new price of Norvir will severely impact the cost of ongoing Phase IV clinical trials on approved drugs.

Finally, Abbott maintains that beyond reformulating Kaletra as a one pill, once-a-day treatment option, their goal is "to develop new compounds that will continue the evolution in HIV therapy." However, they claim it's going to take time and money. We are still awaiting word on exactly what is in Abbott's HIV pipeline.

The Legacy

Personally I was stunned, embarrassed and disappointed by the price increase of Norvir. Maybe I'm naïve, but I've come to expect better—better communication, better cooperation, and better partnership from Abbott Laboratories. What is most disturbing about this move on Abbott's part is that I have worked for years with them to gain the trust of my clients and community. And in my opinion that that trust has been shattered. And now I'm being asked to continue to work with them and trust them—again. For the sake of my clients and community, I'm willing to try to work through this calamity, however, as in all relationships, it will take time to rebuild that trust.

However, Abbott is not the only bad guy on the HIV block. More times than not, AIDS activists have petitioned government officials to provide more dollars to ADAP. Repeatedly we have seen those dollars "eaten alive" by expensive new drugs, including Fuzeon, Reyataz, Lexiva, and on exorbitant price hikes, rather than assisting the increasing number of patients needing access to ADAP programs. Yes, pharmaceuticals have a right to charge whatever price they want for their drugs, however I find this particular price hike morally wrong because of the role of Norvir in HIV treatment.

This price increase has created an enormous ill will on levels that extend far beyond Abbott Park, IL. Although many HIV publications, activist groups and AIDS service organizations (ASOs) are heavily dependent upon pharmaceutical companies for advertising revenue and unrestricted educational grants, there is a heightened level of distrust among AIDS activists and ASOs with the pharmaceutical industry that I haven't seen in years.

I feel I must state for the record, this next statement is not directed towards my friends who work for the "industry" (you know who you are). On more than one occasion over the last three years I've had representatives from industry pull their advertising dollars from this journal or not support programmatic activities at TPAN, because they did not agree with our editorial comment on a particular drug at a particular moment in time.

So which situation is worse—forcing us to settle for their drugs because we can't afford anything else or threatening to financially

cripple us if we don't write and say exactly what they want to read and hear? These other companies with their shiny new drugs, sitting on the sidelines watching Abbott twist in the wind, are just as guilty as Abbott of playing marketing games with their competitors at the expense of our lives.

This is a watershed moment in HIV care and treatment. Because of the current trend in pricing of antiretroviral medicines, bankrupt ADAPs and restricted Medicaid, patients may eventually have their treatment regimens interrupted or their treatment options severely limited. Existing partnerships with pharma are threatened, because treatment activists and AIDS service organizations have been totally blindsided and humiliated by this price hike and other failed attempts to partner with the pharmaceutical industry. We are under pressure from our clients, financial supporters and board members to justify these relationships—TPAN and *Positively Aware* are no exception.

And even if Abbott finally does agree to rescind the price increase of Norvir—as I still demand—the damage has already been done. We are left with the legacy of December 4, 2003. From this point forward, all bets are off and relationships with pharmaceutical companies are forever compromised. Do struggling CBOs and ASOs continue to partner with pharma and hold our collective breath? What choice do we really have at this point? Sure, we can just restrain from publicly contricizing pharma or say no to pharma money, but at what cost? Over the long-term have any other pharmaceuticals proven to be better community partners? Where do we draw the line? And can we redraw that line tomorrow if we need to?

Difficult choices.

Charles E. Clifton

Charles E. Clifton
Executive Director / Editor
Send comments and reactions to ed@tpan.com

Readers Forum

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HIV drug guide

Thanks to TPAN for all of your wonderful publications, but especially the drug guides. They are so useful for us here in the HIV Health Library. I wanted to express my gratitude for this most excellent resource.

James Apt, HIV Health Specialist, AIDS Action Committee, Boston

Publications manager Jeff Berry responds: James, thanks for your e-mail. The Drug Guide is a labor of love and a lot of hard work goes into it. It's nice to hear your kind words and to know that all our efforts are appreciated.

Just permit me to say that I really appreciate the 2004 Eighth Annual HIV Drug Guide. I cannot imagine the work that went into this. This guide once again speaks to why Chicago has some of the best AIDS service organizations in the world and why TPAN leads the pack. Thank you so much for your hard work and dedication.

Janice (Jano) Layne, Program Coordinator/Kevin's Room Project, Chicago Department of Public Health

Hepatitis C

I just wanted to applaud the article on co-infection treatment by Gerald Moreno (November/December 2003). I appreciate his candor on how difficult the treatment is. I would like to see more people discuss their experiences on HCV meds. I am HCV positive (no HIV). Tomorrow I take my last dose of ribavirin. I will be completing nine months of hell. For starters, I am a genotype 3. It took me 20 weeks of treatment to reach undetectable. My viral load was low pre-treatment. I was non-responsive at 12 weeks. I was ready to stop with the first set of labs.

Nothing has been as all the literature reports. I did not get symptoms after my first injection. I started with body aches and chronic fatigue two weeks in. It was all downhill from there. By 10 weeks I had nausea, vomiting, blurred vision, vertigo, rigor and a mental breakdown. (I had started antidepressants pre-treatment). The anemia started at about six weeks but did not get severe until 10. My hemoglobin has not to date returned to normal, even with Procrit.

The powerlessness of not knowing what day of the week I would be sick made functioning difficult. I tried charting common denominators and they did not coincide. It was day, then night, then Monday, then Friday… there were no "normal" symptoms.

At twelve weeks I started with petty maul seizures. I had to limit my driving and stop riding my motorcycle. My bike is one of my greatest stress relievers. I began missing work and became totally out of control with my emotions.

I am also clean and sober 12 years. I came closer to relapsing on treatment than at any other time in my sobriety. When my body hurts my brain says I know how to feel good. I also have a needle fetish with the idea of "fixing." Thank God I also had a wonderful recovery support system.

After this experience I really feel we are treating people too soon. The drug companies are saying you need three to six months clean before treatment. You're not clean in that time frame, at least not clean enough to endure the psychological roller coaster of these medications. I know there is a movement to treat active users. I wonder if we aren't creating a bigger problem. Are we putting dirty needles on the street? What happens if someone is treated, clears the virus and gets re-infected?

The best treatment for HCV is no drugs, no alcohol. We have the time to really evaluate each individual. HCV does not require immediate medication. If you are in that severe of a state, you may not be a good candidate for treatment anyway.

I am not saying don't treat. I am saying wait and do better evaluation. Most people can get through treatment with the right support system. The problem is those supports are not in place for most patients. I have seen medication and syringes prescribed with no education on injections. I have also seen medication prescribed to individuals who were in the 15% who cleared virus.

We are still too early in research. I want to see everyone with HCV healthy, not set up for bad results. More will be revealed on the horizon. I would like to see us return to the early intervention strategies we used in the early days of HIV—learn how to slow the disease progression.

Keep up the good work.

Christina L. Hurst, MSW, Arizona

Androgel

While "I Love My Androgel" was informative and well-written (November/December 2003), it did overlook one additional complication with Androgel therapy: possible testicle shrinkage. While only cosmetic, at least as far as I understand, it can be more than disconcerting and is often glossed over.

While the potential gains of testosterone replacement therapy with Androgel far outweigh this one issue, it's worth noting so the individual accepting the therapy can be prepared for all the results, including the negative.

Terry Hemphill, San Francisco

Carlos Perez replies: Thank you for writing to us—this is an important issue to discuss. Testicles will not shrink from using testosterone or Testim since the dosage is so low. The only way the testicles will shrink is by injecting testosterone and by using very large doses. Believe me, I know of a few who have and they shrunk, but they were "popping" large doses and going at it alone through the black market or by overdosing a prescription. At 5 or 10 grams per serving, as

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the transdermal application serves, testicle shrinkage can't really happen unless they got a hold of more than the prescribed amount and just lathered and bathed in it.

There is a very easy, simple, cheap and effective way to increase one's testosterone level. It's a generic pill called clomiphene citrate, 50 mg every other morning. The drug is actually a fertility drug for men and women, which is not something you'd normally be interested in, except that it has an almost universal side effect in men and women—it raises one's testosterone level. I use it. It works. And it has very few other side effects or drug interactions (i.e., it's not metabolized through P450). I hope you will try it.

Ross Thomas, AIDS Survival Project volunteer, Atlanta

Carlos Perez replies: Mr. Thomas, Now here is something new and truly different! I never heard of clomiphene, its use in fertility or its advantage as a testosterone booster. I'll pass this news around here at the office and I will ask my doctor next time we meet. Thank you for your input.

Crystal meth

Considering that I have been addicted to meth as well as serving an 87-month sentence for distribution, I can certainly relate to every word in your article (My Kind of Life, "Crystal Death-amphetamine," July/August 2003). Although I have been incarcerated since 2000, I was taken back to the smells, the tweaks, the loss of jobs, the coming up financially, the coming down emotionally, the incredible and erotic sexual experiences that lasted for days and finally the harsh realization in December of 2000 that I was HIV-positive. As of today, my viral load is zero and my CD4 is around 875, due to Viracept and Combivir and of course, my higher power, which I choose to call God. When one comes to prison, it seems as though everyone forgets about you, especially living with a disease that only you and your doctor know about. It can be quite lonely. I want to thank Carlos Perez for the obvious hard work he puts into his articles and to let you know how much I respect and appreciate all the staff at TPAN for publishing such a fine magazine.

Name and institution withheld by request, Florida

Exercise

Editor's note: Greg Braxton, author of Positive Empowerment ("I Get Blessings, I Get Lessons," July/August 2003), responds to a reader who wanted to know if he believes it was his exercise routine that reversed his lipodystrophy.

The answer is a very big yes! For a while I was walking around looking like Kermit the Frog. I had very small arms and legs while entertaining a huge mid-section. I was also very weak. Today I am as solid as a rock and full of energy. I also sleep very soundly. I get so many benefits from exercise, which include stress reduction, self-esteem and confidence. I feel great in spite of the fact that my last T-cell count was 20 and viral load around a million copies.

I understand that you are going through some difficult times as I was. If you decide to start a routine, I suggest that you start out very slow and gradually increase your time as well as intensity. Always listen to your body. It will communicate if you are pushing it too much by producing pain. If you experience pain, slow down or stop. I would also suggest a balanced workout that includes cardio, strength and flexibility training. It is also wise to enlist the help of an experienced trainer or some other knowledgeable person to ensure that you are performing the exercises properly so that not only will you get the best bang for the buck, but will less likely get injured in the process.

The best advice is to consult your physician before you start. Also, make sure you drink plenty of water before, during, and after your routine. If you add exercise with a sensible diet you will be amazed at the results. Consistency is key.

I am so glad that you found my article helpful. Your reply gives me the incentive to continue the fight. Thanks and good luck.

Vietnam

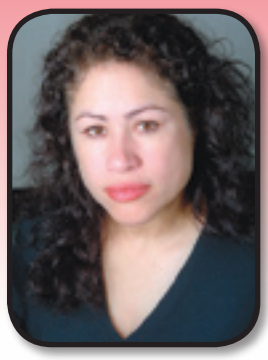
After reading "Finding a Voice in Vietnam" (November/December 2003), it reminds me of something that my mother has told me time and time again since I was a child. Good things always come from what we think or perceive as being bad things. The story touched me deeply. I have been HIV-positive since 1985 with no major complications and currently with treatment have an undetectable viral load and a T-cell count that hovers around 375.

I worked in the tour industry in the past and have been able to visit many of the poorest areas in Central America and Thailand as well as some of the more affluent areas worldwide. As 9/11 took its toll, I lost my job. I didn't know what I was going to do and fell into a deep depression until one day a friend talked me into going back to school at the age of 40. I'm currently a Certified Nursing Assistant and working to become a Registered Nurse. I plan to work for a temporary agency six to nine months of each year and donate the rest of my time to an organization that gives free health care to people living in developing countries.

I thank Michael McColly and James Tuong Nguyen for taking the time to document their life experiences. It is because of people like them that I can be inspired and find the inner strength to reach my goal.

Rick Fores, Milwaukee

News Briefs



by Enid Vázquez

Drug Guide clarification

Viracept is approved for three times a day dosing. However, the newer twice-a-day dosing is preferred by most patients and should have been depicted in the drug photo at the top of our page. Our apologies.

New dose for Invirase and Fortovase

It's official: you shouldn't take Invirase without Norvir. The U.S. Food and Drug Administration (FDA) in December approved a change to Invirase's label—its dose is now 1,000 mg with 100 mg of Norvir both twice a day (five 200 mg capsules plus one 100 mg capsule). The two drugs are each protease inhibitors. Invirase is poorly absorbed without a mini-dose of Norvir.

Fortovase is a better absorbed (about four times as much) version of Invirase. Fortovase can still be given as the only protease inhibitor in a combination—but not really recommended by most HIV doctors without another protease inhibitor (PI). The change to Invarase's label makes official the often-used dosing of 1,000 mg plus 100 mg of Norvir twice a day. Combining a protease inhibitor with a mini-dose of Norvir (between 100 and 400 mg) usually helps cut down the number of pills people need to take, lower the risk of side effects and make the drug more effective. The FDA notes that Fortovase by itself remains an option "for patients who are unable to tolerate ritonavir [Norvir]." Norvir can make you sick to your stomach, as they say. Lots of gastrointestinal side effects.

Crixivan label changes

The FDA in January approved changes to the package insert for Crixivan (indinavir), one of the HIV protease inhibitor drugs. The changes add new forms of possible kidney damage to watch out for (tubulointerstitial nephritis with medullary calcification and cortical atrophy in people with asymptomatic severe leukocyturia, or excess white blood cells in their urine). The FDA says discontinuation of Crixivan should be considered in people with this type of leukocyturia.

The FDA also added the following wording, "Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy (CART), including Crixivan. During the initial phase of treatment, patients responding to antiretroviral therapy whose immune system responds to CART may develop an inflammatory response to indolent or residual opportunistic infections (such as MAI, CMV, PCP, or TB), which may necessitate further evaluation and treatment." This may be seen with other anti-HIV medicines, but Crixivan's label has been changed to reflect its documented cases.

The FDA notes that both Crixivan and one of newest protease inhibitors on the market, Reyataz (atazanavir), are associated with indirect (unconjugated) hyperbilirubinemia. While they have not been studied in combination, taking Crixivan with Reyataz is not recommended. Unconjugated hyperbilirubinemia is not associated with disease the way conjugated hyperbilirubinemia is, but it can cause yellowing of the skin and eyes. That's the reason why the manufacturer of Reyataz has already recommended that the two drugs not be taken together.

Lastly, the FDA added "increased cholesterol" to the list of possible side effects in the section on Marketing Experience (what's been reported since the drug was approved and put in the pharmacy).

New Viramune warning

The FDA in February updated the black box warning for Viramune (nevirapine). It now cautions that women with CD4 cell counts above 250, including pregnant women, have a 12-fold greater risk of serious liver side effects, and that these have sometimes been fatal. Liver events present the greatest risk of fatality if they occur in the first six weeks of treatment, and are often associated with rash. However, manufacturer Boehringer Ingelheim advises doctors to closely monitor patients for the first 18 weeks of therapy. Even when treatment is discontinued, in some instances hepatic injury has continued to progress. Individuals experiencing an allergy to Viramune should "discontinue…treatment and seek medical evaluation immediately" and Viramune "should not be restarted in these patients," the company adds. Some experts recommend that liver function be monitored at least once a month.

Another One Bites the Dust: T-1249

Anticipating the need for patients who may develop resistance to T-20 (Fuzeon), Trimeris and its Swiss partner, Roche, worked on another fusion inhibitor, T-1249. Because T-1249's activity site was more broad than Fuzeon's, it held the potential of helping those individuals who may develop resistance to Fuzeon. Additionally, T-1249 was expected to be administered once daily, less than the twice-a-day injections needed for Fuzeon.

However, Trimeris recently announced that development of T-1249 has been discontinued. Once-daily injections of T-1249 may not have been optimum. Also, Trimeris and Roche felt that as other competitive compounds are already undergoing clinical trials by other pharmaceutical

companies, by the time T-1249 would get into the marketplace, better options may beat 1249's development. Trimeris and Roche also announced that they've signed "a further research agreement to discover, develop and commercialize the next generation of HIV fusion inhibitors."

For patients who need further options to combat resistance to current treatments, the news may not all be bad. Schering Plough presented a preliminary study of their entry inhibitor SCH-D at the Conference on Retroviruses and Opportunistic Infections in February. Patients who took three different oral doses of SCH D, twice daily, demonstrated good suppression of HIV. A larger clinical trial is expected to begin this spring. Bristol-Myers Squibb also has a drug candidate in this class that can also reach market in the next three to four years.—Daniel S. Berger, MD

Vaccine fails again

The AIDSVax trial in Thailand reported in November 2003 that the HIV vaccine was safe, but it was not effective in stopping new transmissions. Results from the first AIDSVax trial reported early last year were the same (see May/June 2003). AIDSVax was the first preventive HIV vaccine tested in large studies.

Of 2,546 participants, half were given the vaccine and half were given placebo (fake drug). There were the same number of infections in both groups, 106 in the vaccinated people and 105 in the placebo group. (There were 5,400 people in the first trial.) There are also therapeutic trials with other vaccines which are given to people already living with HIV, in the hopes of preventing disease. It was hoped that if vaccinated people did become infected, AIDSVax would slow the progression of HIV disease, but this did not happen.

In a press release, International AIDS Vaccine Initiative (IAVI) president and CEO Dr. Seth Berkley noted that, "Although AIDSVax was found not to work, the trials themselves were a success. VaxGen demonstrated that it is possible to conduct large-scale trials of AIDS vaccines in both industrialized and developing countries." VAXGEN reported that more than 90% of the volunteers, all injection drug users, completed the three-year study.

For Shame, Part 2

The former San Francisco city health commissioner who had been fined $5 million for lying to an ex-lover about having HIV had his case thrown out in a higher court in December. A Superior Court judge in that city determined that Ronald Hill was not guilty of intentionally infecting others with HIV, as required for prosecution in the state of California. Two men had told a grand jury that they were infected by Hill, and that Hill told them he didn't have HIV. Hill had supposedly claimed he had poor health due to cancer. One of the men, Thomas Listor, was quoted by the *San Francisco Chronicle* as saying, "It's a law that is not working—and we need to change that." Here in Illinois we have a law called "disclosure." You tell someone you have HIV and they decide whether or not to take their chances. It's not perfect, but California may want to consider something better than what it has now. Intentionally infect? Get real.

New rapid HIV test

The U.S. Food and Drug Administration (FDA) in December approved the Uni-Gold Recombigen HIV rapid test. Results from either plasma, serum or whole blood are available in 10 minutes, but the test is only available in places with clinical laboratory professionals and a quality assurance program (like a hospital or some walk-in clinics). (OraQuick, a rapid HIV test already on the market, can only be used on whole blood.) Results showed that Uni-Gold Recombigen HIV was able to correctly detect 100% of HIV-positive results (sensitivity) and more than 99.7% of the negative results (specificity). As usual with an HIV test, positive results require a confirmatory test. Cost is approximately $10 per test.

The winner: Sustiva/Combivir

If you're starting HIV therapy for the first time, Sustiva and Combivir may be the way to go. So reports the National Institutes of Health (NIH). In a press release the NIH reported that, "Until now, it has been unclear which sequences of antiretroviral regimens provide the greatest benefit to patients previously untreated," according to Gregory K. Robbins, M.D., of Massachusetts General Hospital and Harvard Medical School, and lead author of one of the two papers on this study.

In a complicated trial with six combinations of HIV drugs in 620 study participants, NIH found that starting out with Sustiva/Combivir was the most effective over the longest period of time. Moreover, it was successful longer even when given as a second regimen, compared to other combinations people were switched to (see "Starting Therapy" table).

After one year (48 weeks), Sustiva/Combivir therapy failed for 10% of the people taking it. This compared to 30–40% failure with the other regimens: Sustiva/Zerit/Videx; Viracept/Zerit/Videx; and Viracept/Combivir. (Combivir is a combination of two HIV drugs in one—AZT, brand name Retrovir, and Epivir).

What the researchers were most interested in was the sequence of drug combinations. It's well-known that HIV therapies stop working after a while and the people taking them have to go on a new drug combination (if that's what they decide they

Starting Therapy—ACTG 384

First regimen	Second regimen
Three-drug combinations	
Sustiva + Combivir	Viracept + Videx + Zerit
Sustiva + Videx + Zerit	Viracept + Combivir
Viracept + Videx + Zerit	Sustiva + Combivir
Viracept + Combivir	Sustiva + Videx + Zerit
Four-drug combinations	
Sustiva + Viracept + Combivir	None
Sustiva + Viracept + Videx + Zerit	None

want to, or should, do). Here researchers found that treatment success on a second regimen was greater for people starting with Sustiva/Combivir than with any of the other combinations studied.

The study also looked to see if a couple of four-drug combinations were more potent than the three-drug combos (Sustiva/Viracept/Combivir and Sustiva/Viracept/Videx/Zerit). They weren't, but they did delay time to a second regimen and the development of drug resistance compared to all the triple therapies except one—Sustiva/Combivir. Interestingly, the four-drug combos did not cause more side effects than did the three-drug regimens.

However, any group starting with Videx/Zerit did experience more toxicity. These toxicities included two serious ones associated with the drugs: peripheral neuropathy, a neurological disorder resulting from damage to the peripheral nerves, and inflammation to the pancreas, among other problems. NIH notes that, "Based in part on the results of this study, leading researchers now recommend that anti-HIV treatment should not begin with regimens that contain both ddI and d4T [Videx and Zerit]."

There are many other strong combinations that can be taken, but nearly all are taken with either Retrovir, Combivir, or Zerit. Remember, Sustiva must be avoided by women who hope to become pregnant. It also has a wide range of neural-psychiatric side effects. However, many people find it extremely tolerable. Epivir has probably the least amount of side effects of any HIV drug, but Retrovir is known for fatigue, headaches and anemia. Sustiva/Combivir has long been one of the most popular triple combinations used for first time therapy. This study confirms the value of that choice.

The findings were reported in the December 11 issue of *The New England Journal of Medicine*. See www.niaid.nih.gov.

News Briefs from the 11th Annual Retrovirus Conference

The following items were among several hundred presented at the 11th Annual Retrovirus Conference, held in February in San Francisco. For more information on these and other news, visit the conference website at www.retroconference.org.

Genetics affect Sustiva side effects

Researchers from the AIDS Clinical Trials Group (ACTG) found a correlation between genetics and nervous system syndroms side effects in people taking Sustiva. The association was seen in the very first four weeks of therapy, but disappeared out to six months time despite the continued high blood levels of Sustiva. The ACTG analysis found that a particular genetic marker caused people to clear the drug out of their body more slowly. This led to higher blood levels of the drug—three times greater than the average area under the curve (AUC)—with a higher rate of central nervous syndroms.

Nevertheless, the researchers said that long-term toxicity remains to be determined. The people taking Sustiva noted their side effects through a questionnaire taken regularly throughout a sub-study of ACTG 5095.

The genetic marker, found on the CYP2B6 liver enzyme, was more common in African Americans than in Caucasians. (CYP enzymes process drugs in the liver.) The form of the gene associated with the highest Sustiva levels was present in 20% of African Americans but only 3% of Caucasians. Either group, however (as well as Latinos) can have the CYP2B6 G516T polymorphism marker, and with it, greater side effects. There was a lot of overlap. Some of the African American participants had lower Sustiva concentrations, and some of the Caucasians had higher concentrations. Of the few Latinos in the sub-study, the one who was homozygous for TT at position 516 had the highest Sustiva blood levels. There were 157 persons on Sustiva included in the genetic analysis, 57% of them Caucasian, 32% African American and 10% Latino. No gender difference was found.

After adjusting for weight there was still an association with decreased Sustiva clearance. Analysis of DNA from a separate group of individuals, including about 100 Caucasians and 100 African Americans, confirmed that the G516T polymorphism is much more common in African Americans than in Caucasians. Previous research, including an ACTG study presented at CROI, found higher blood levels of Sustiva on average in African Americans than in Caucasians.

The researchers said their findings raise several questions, including whether the same genetic markers also affect Viramune, an HIV antiviral in the same drug class as Sustiva; the effect on viral load, T-cell count and HIV drug resistance; and the effect on different ethnic and racial groups around the world. They noted that their findings need to be confirmed.

Of special interest is the fact that due to results from previously published data, no one expected these findings. Presenter Dr. David Haas of Vanderbilt University gave credit to Dr. Edward Acosta of the University of Alabama for the idea leading to this analysis (as well as to the people who carried it out). Said Dr. Haas, "I think we're just hitting the tip of the iceberg on all this. It's very complicated."

Disparities workshop at Vanderbilt

Dr. Haas invited the audience to attend the 2004 Workshop on Disparities and the HIV Epidemic November 18–19. The national meeting will present up-to-date information about racial, ethnic and gender disparities that affect clinical practice, including disparities in the epidemiology, pathogenesis, and treatment/vaccine responses of HIV and other pathogens (such as hepatitis C virus and M. tuberculosis) and current research on

biological and genetic mechanisms that may underlie these disparities (such as pharmacogenomics and host factors involved in HIV replication). For more information, contact R. Renae Speck, Ph.D. at renae.speck@vanderbilt.edu or 615-322-6126.

Viramune resistance after labor

Viramune very effectively cuts the rate of HIV transmission from mothers to infants, but even a single dose given to a woman at the time of labor has been shown to cause drug resistance. Researchers looked for drug resistance in women who recently gave birth and whether it had any effect on their HIV therapy later on.

They looked at women in a study conducted in Thailand. That study found that HIV transmission to infants was further cut—by 80%—when one dose of Viramune was added to ongoing Retrovir (AZT).

Researchers looked for HIV drug resistance in blood samples 10 days after the women gave birth. In a random sample of 90 women, 18% had at least one HIV genetic mutation associated with resistance to Viramune (expected to decrease the drug's effectiveness). Three months after giving birth, 80% of the 66 women with at least one mutation and 87% of the 112 women who received a single dose of Viramune had less than 400 viral load, compared to 88% of the 41 women who did not receive Viramune. Six months after giving birth, those figures were 68% of 50 women, 80% of 90 women and 85% of 27 women, respectively (presumably the missing numbers are for women who had dropped out of the study or did not reach the study time point when the analysis was conducted). This was not statistically different, although there was a trend to a statistical significant difference.

However, there was a large statistical difference when looking at women who started HIV therapy immediately after labor or those who waited six months. Women who waited did much better on therapy. For the women who received a single dose of Viramune and started therapy six months after birth, 77% of the women with mutations and 91% of the women without mutations had less than 400 viral load. This compared to 58% and 69%, respectively, of the women who started therapy earlier.

The researchers said that while single-dose Viramune may reduce the effectiveness of a woman's HIV therapy later on, there was still a large number of women in this group who achieved an effective response against the virus with therapy. The difference in when to start therapy gives hope to finding effective strategies for reducing transmission to infants while not compromising future therapy for either mother or infant. They noted that HIV resistance to Viramune may last a long time and may re-emerge when the patient is once again exposed to Viramune or another non-nucleoside analog.

Prevention for sex partners

University of California, San Francisco researchers updated their previous report on the use of HIV drugs to prevent infection in sexual partners. In that report they found that drug therapy did not cause people to become lax about safe sex. Although the study was not designed to study efficacy, they did report that there were no new infections within 6 months of starting PEP. This time, however, they were presented some information that causes a more cautious interpretation.

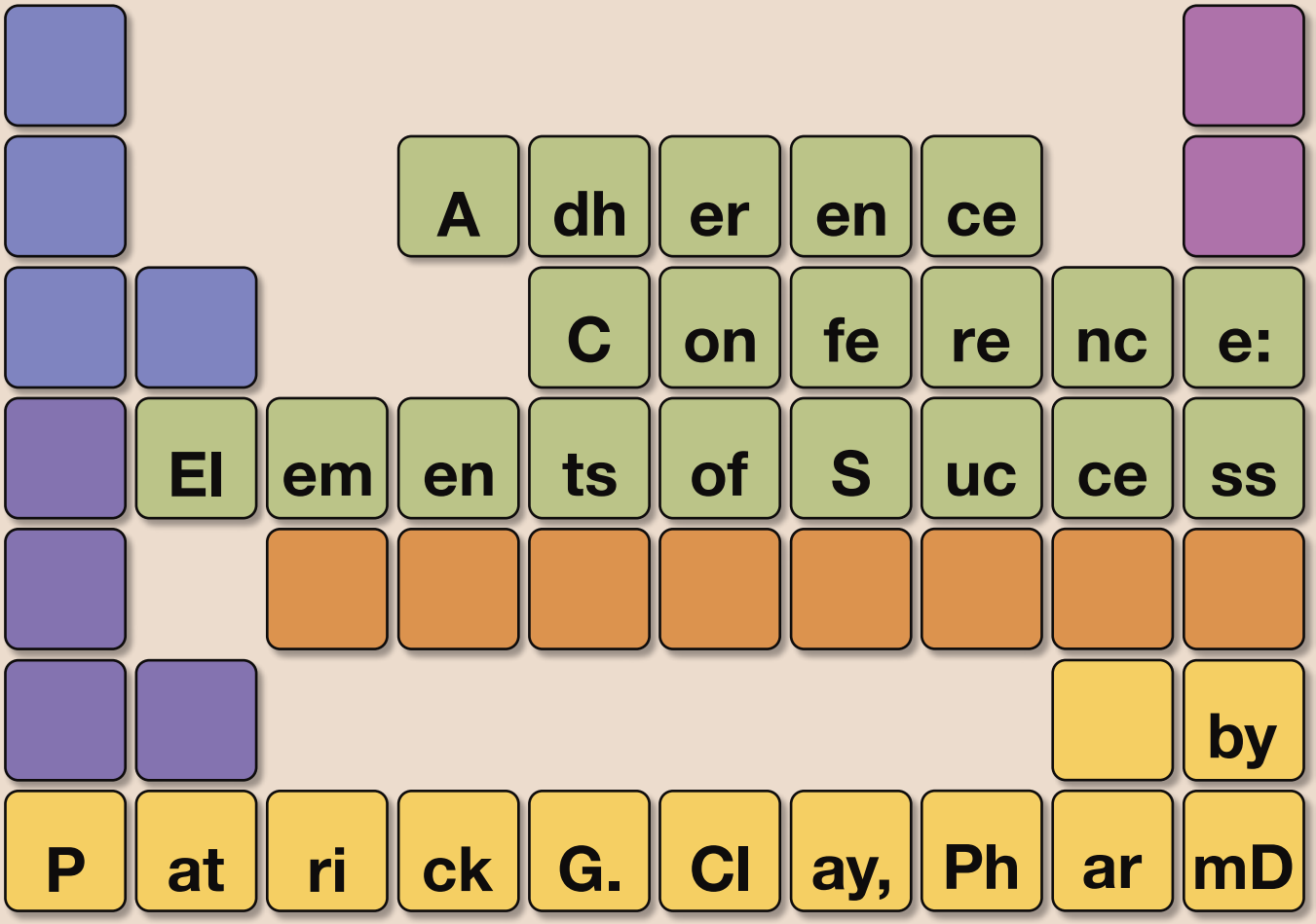
At 12 weeks after starting PEP, there were seven infections out of 700 people. Those seven persons had high-risk sexual activity before and after receiving therapy and there was never virus available from the potential source of infection, making it impossible to know if these infections resulted from another exposure or from the failure of PEP to prevent infection . These type of cases will make the effectiveness of prevention therapy difficult to determine. (You could remove this sentence Infection may occur as much as six months after exposure, so it can be hard to determine which exposure led to infection.)

Post-exposure prophylaxis (PEP for short—prophylaxis means "prevention") was given within 72 hours of a sexual or needle-sharing exposure. PEP consisted of either Combivir, Zerit plus Epivir or Zerit plus Videx (a combination that is no longer recommended in U.S. treatment guidelines). Treatment was given for 28 days. People exposed to a partner who had a detectable viral load while on antiretroviral therapy were also offered a protease inhibitor drug in addition to two of the drugs listed above. Risks reduction and adherence counseling were also provided. The researchers noted that for needlestick injuries in healthcare, the use of AZT (Retrovir) for a month was known to cut the transmission of HIV by 81%.

All seven of the men who seroconverted had had unprotected anal receptive intercourse (four of them with partners who they knew had had HIV; the others were at risk for HIV) within 72 hours before PEP, compared to half of the people who did not seroconvert. All also had additional high risk behaviors in the 6 months prior to starting PEP. Three of the seven also had unprotected anal receptive sex within months after PEP and at least one may have already been HIV-infected at the time of PEP although his antibody test was negative.

The seroconverters started PEP at a mean of 45.5 hours compared to 32.5 hours among those who did not seroconvert, but this was only a trend towards statistical significance. One of them reported fair adherence to the medications while two reported poor adherence—the drugs can be very hard to take. The poster presentation noted that, "Most importantly, primary prevention efforts must be reinforced to reduce both occupational and non-occupational HIV exposures."

Lead researcher Dr. Michelle Rolland said, "I have always been very cautious in letting people know that this is an unproven strategy. The immune system of the mucosa [in sexual contact] is different from what the virus will confront in a needlestick injury. Given all the related data in the occupational, mother-to-child transmission and animal studies I suspect there must be at least partial effectiveness of PEP after non-occupational exposures, but we don't know that for sure."



The 2nd International Conference on Adherence to Antiretroviral Therapy, dedicated to sharing and demonstrating experiences and mechanisms of improving adherence, was held in Richardson (just outside Dallas), Texas, December 4-7, 2003. Once again, this conference brought in attendees from around the world who have decided to take action against complacency in adherence initiatives by developing novel assessment techniques, make improvements to patterns of adherence to antiretrovirals in historically difficult populations, creatively institute programs in environments with limited resources and be confident enough to share that data over three days with others in related practice and outreach settings. Clinicians and others presented findings of their initiatives to enhance adherence, medication tolerability and outcomes in their respective institutions that dealt directly with patients. A small sample of those presentations is summarized here.

Pharmacist counseling

Dr. Lamberjack of the Children's Hospital of Columbus, Ohio provided attendees with approaches to enhancement of adherence in a family practice setting serving 42 counties in central and southern Ohio. Dr. Lamberjack's study's objective was to increase adherence in recognized non-compliance by providing pharmacist-based medication and adherence counseling. After interviewing patients and families regarding antiretrovirals, medication-taking patterns and reasons for missing doses, a compliance score was determined (scale 1-3: 3 = > 90% compliant, 2 = 50% - 90% compliant, 1 = <50% compliant).

If patients fell into the categories of 1 or 2, they were scheduled for intervention by the pharmacist. Interventions were: 1) provision of medication-specific counseling and adherence importance, 2) written information on drug, dosing and adverse effect, 3) distribution of pill boxes and assorted reminders, and 4) follow-up phone calls and visits. Results were presented after 12 months of the program.

Twenty-six patients were targeted for interventions. The population was 85% female, 62% African-American, 8% Hispanic and ages ranged from 7-41 years. Where were they when they started? Eight percent were 3's, 27% were 2's and 65% were 1's (remember—it's not good to be #1 here!). After the interventions? Sixty-one percent were 3's, 31% were 2's and only 8% were 1's. Accompanying the score changes were 62% of patients with reduced viral loads and improvements in CD4 counts.

Conclusions? Improvement in clinical markers and compliance can be realized by pharmacist counseling and interventions after those patients are identified. For more information on the scoring process and results, contact Dr. Lamberjack at lamberjk@chi.osu.edu.

Multiple avenues

Non-adherence was the reason Dr. Lee and a team of providers of the McAuley Health Center at St. Mary's Mercy Medical Center in Grand Rapids, Michigan became involved in a multi-disciplinary approach to improving outcomes in the patients. This presentation described the initiatives just underway at this clinic.

A readiness assessment is performed by the team prior to any antiretroviral regimens being prescribed at this center. Potential barriers are addressed and the patient is encouraged to recruit friends and family members to assist in the treatment program. After this is completed, a one-on-one session with the clinical pharmacist is scheduled. This one-time educational session provides in-depth information, appropriate for the patient's understanding and education level, on the medications, side-effects, dosing and diet requirements.

Once completed, the patient receives: a one week follow-up phone call, a week two laboratory assessment and a visit with nurse-case management, a week 4 phone call from the clinical pharmacist, nurse-case management visits at weeks 6 and 12 and finally back to see the physician at week 14.

Multiple measures of adherence are done by self-report, pharmacy logs, pill counts and biological markers. Patients also receive a 24-hour prior to appointment reminder phone call and have access to clinical staff during non-clinic hours. Some limited results were presented that included prevention of ER visits due to on-call consultations with the pharmacists regarding adverse effects of medications and that adherence is improved. As mentioned in the most recent DHHS guidelines (U.S. Department of Health and Human Services), using multiple approaches, disciplines and levels of intervention are being shown to positively influence adherence.

Readiness

Using readiness as a predictor of adherence is a sound approach to deciding if it is time to start antiretrovirals, according to a formal presentation by Dr. Enriquez of the University of North Carolina, Chapel Hill. This real-time observational study examined the level of readiness for health behavioral change and adherence in 36 HIV-positive persons who had previously failed therapy. An index of readiness was completed by patients prior to beginning new antiretroviral regimens. After six months of therapy, patients were divided into those who reached and sustained viral suppression and those who had not. A higher index of readiness was a significant predictor for virologic success ($p<0.05$). The researchers propose this follow-up study to a previously completed one reinforces the clinical utility of an index of readiness as a valid predictor for adherence. They also suggest that interventions enhancing readiness prior to prescribing antiretrovirals can improve adherence. These types of interventions were not provided however.

The buddy system

"Project HAART" was a small study conducted by Plummer and Simoni at an outpatient HIV clinic in the Bronx that targeted improving adherence by enhancing social services for patients. This project established "buddies" for four domains of support: affirmational, emotional, spiritual and informational. Participants (study subjects) were patients recruited from the clinic and randomly assigned to the buddy program or to a control group.

The buddy group has six meetings (one every two weeks) with other buddies and others. Phone calls from a designated buddy were done two to three times per week. Participants completed questionnaires at the start, half-way through the program and at the end of the six-month study period. One-hundred thirty-six patients were enrolled. Forty-six percent were African-American, 44% Hispanic, 45% female, average age was 43, 85% were unemployed and 75% acknowledged heavy drug use. Results are based on the 86 participants completing the program. They reported an improved adherence at 6-month follow up based on patient self-reporting, although exact numbers were not provided nor were viral load and CD4 changes. This component of the conference was to provide proof-of-concept studies and not necessarily medical outcomes. This is, however, another reinforcement of how providing more than just direct medical-associated interventions can improve adherence.

Peer support in the clinic

Along similar lines, but seemingly a more formal program was presented by Micki McCaffery of the Kansas City Free Health Clinic based in Kansas City, Missouri. This clinic provides HIV and primary medical care to approximately 400 medically indigent HIV-positive adults. A peer-adherence program was put in place in late 2001. Eight clinic-based, peer, paraprofessional counselors (one Caucasian, five male) provide engagement support for medical care and adherence to patients on either an individual or group basis. These individuals, by maintaining contact with patients on a routine basis, provide the medical team critical information with respect to the patient's understanding and state of medical, social and economic status. Peer counselors, being on-site, are incorporated into each primary care visit and bring to the visit unique support, insight and skills to patients. Further information on this invaluable component and how to integrate it into a medical service model can be gained by contacting Ms. McCaffrey at mickim@kcfree.org.

More peer support

Another peer-counselor program is going on at the University of Maryland's Evelyn Jordan Center. At this other Ryan White-funded clinic, a social worker and three to four peer counselors provide interventions to patients identified by providers to be non-adherent (missing more than three medical appointments per year or difficulty with a prescribed regimen). Here an adherence intervention care plan is set-up after an interview with the patient. These interventions include the list of usual suspects: pill boxes, phone calls, case management, group education, and others. The findings of this project were based upon four years of follow-up and beyond the scope of this summary. Conclusions made by the researchers reinforce the need for continual assessments and ongoing interventions.

Sharing experience

These and many other incredible success stories were presented over the three-day conference. The primary source of funding for the conference was pharmaceutical companies, but the vast majority of presenters were not easily recognized names on a national level. Instead, they are irreplaceable in their respective practice settings as was evident by the passion and level of excitement in learning mechanisms to improve adherence in resource-poor settings. The conference will be held once again this December, likely again in Dallas. More information on this conference can be found at: http://elements.netsos.com.

Patrick G. Clay, PharmD, is an Assistant Professor at the University of Missouri, Kansas City and HIV Clinical Pharmacist at the Kansas City Free Clinic.

Using Nutrition to Ward Off Side Effects

by Carla Heiser, RD and Tom Barrett, MD

Understanding the relationship between food and medicine has been of interest for centuries. The earliest medicines were derived from plants and animals. Digitalis, used in the treatment of heart conditions, is a medicine derived originally from a plant source—foxglove. Pharmaceutical grade (pure) medications were developed to standardize both the quality and concentration of a drug in a medicine. Today Western medicine has grown reliant on pharmaceutical technology to produce drugs that will treat many conditions.

In disease treatment we try to impact biochemical pathways (how medications and foods are processed). We "push" a pathway to produce specific chemical endpoint and to affect metabolism. We can also use what is known about the way medicine and nutrients work together to improve effectiveness and allow the use of lower doses—translating to lower healthcare costs and lower side effects.

However, not all medicines work that way. HIV medications can not be dose adjusted based on diet. Also, in HIV disease nutrient requirements are affected by the disease itself and the interactions of multiple medications. Still, we can minimize side effects and changes in metabolism with diet and nutrient supplements. Medication effectiveness and potency is increased through improved drug absorption and tolerability and less side effects.

Many of these medicines require nutrients to improve results. For example, in the treatment of diabetes there are many medicines that may control blood sugars and prevent further complications. Proper nutritional intake to correct problems in metabolism and body composition is also necessary. Achieving nutritional health may even erase diabetes completely. However, if a patient does not follow healthful practices, the medicines do not work effectively and the disease progresses.

Some of the diseases that are impacted by the power of food include allergy and food sensitivities, cancer, endocrine disorders, gastrointestinal disease, other infectious diseases besides HIV, hormonal imbalance and neurological disorders. Specific conditions where diet composition are crucial include co-therapies for treating high cholesterol, diabetes, high blood pressure, birth defects, learning disabilities, heart disease, and even Alzheimer's disease. There also is a growing body of evidence that nutritional strategies play a direct role in disease prevention.

Consider that the human body is like a Corvette. Putting diesel fuel into the gas tank should be unthinkable. Similar to a high performance vehicle, our bodies convert food into energy. Foods that contain highly processed sugars and bad fats are "improper" fuel. Our body is unable to convert these foods into energy efficiently. Pathways are diverted to fat storage. Not only does this scenario promote obesity and obesity-related disease, but it also leaves our "gas tank" low on fuel, and we become deficient in energy and nutrients.

Studies show that the standard American diet is sub-standard in basic nutrients—including vitamins, minerals, anti-oxidants and fiber. Diets are commonly deficient in essential and healing fats and oils, like flax, borage, evening primrose and fish oil. On the other hand, the intake of other nutrients such as simple sugars (table sugar, juices, sodas and white refined starches) and processed hydrogenated or highly saturated fats (fats that are hard at room temperature, such as chicken skin and white fat marbled in meats) is excessive.

In our medical practice we seek to improve the nutritional value of a patient's diet as an adjunct therapy to primary care. Our clinical nutritionists teach strategies to improve disease-reducing complications and medication side effects. Most notable is the impact of nutritional approaches to control diabetes, high blood pressure, high cholesterol, and gastrointestinal or stomach problems. Fatigue, hormonal imbalance and pain management also respond well to a holistic care approach.

Messages to consumers and patients are misleading. Yet the bottom line is simple—eat wholesome food, including the proper fats and oils. Limit junk food and bad fats.

Perhaps the most important thing for our patients to do is to keep an open mind about the process. Often patients have the idea that they will never have another French fry again. They are frequently surprised by the variety of foods that we recommend including in their diets.

Carla Heiser, MS RD, LD and Tom Barrett, MD specialize in caring for people with HIV at the Howard Brown Health Center in Chicago, established to serve the city's gay, lesbian, bisexual and transgender community. Visit www.howardbrown.org. Contributing authors Jennifer Zawaski, RD, LD and Emily Lindner, MD also work for Howard Brown. Contributing author Judith A Ernst, DMSc, RD is an Associate Professor of Nutrition and Dietetics for the School of Health and Rehabilitation Sciences at Indiana University School of Medicine. Heiser is also the president of the Center for Functional Nutrition at Advocate, Illinois Masonic Hospital in Chicago. The authors are on staff at the Center. Visit www.ics.meta-ehealth.com. Online assessment and nutritional intervention is available, as well as recommended supplements.

The following are examples of our medically supervised recommendations.

Overall nutritional Guidelines (for non-vegetarians)

- Include a quality assured (see below), potent multivitamin and mineral supplement daily
- Eat natural, whole foods, the less processed, the better
- Limit simple sugar and refined white carbohydrates
- Use 100% whole grains in moderate amounts divided over meals and snacks
- Use lean, hormone-free meats, poultry and eggs
- Eat cold water fish 3-5 times a week (wild salmon, canned salmon or yellow fin tuna)*
- Eat plenty of fresh or frozen vegetables
- Include low-sugar, high-fiber fruits (apples, pears, berries, cherries, citrus)
- Use teas or coffees that are organic (processed by water, not chemicals)

Nutritional protocol for treating diarrhea and other gastrointestinal side effects

- Take out offending foods
- Eliminate wheat and gluten-containing foods
- Consider options for replacing cow milk dairy
  - Switch to hormone-free or organic dairy products
  - Consider fortified soy, rice or almond nut milk
- Add soluble fiber
  - Food sources: ground flax meal, 100% whole grains, legumes, peas and lentils, low-sugar fruits (see above) and vegetables
  - Supplements: Metamucil, Citrucel, Benefiber
- Drink plenty of hydrating fluids including water and decaffeinated tea
- Limit, or avoid, caffeine, sodas and alcohol
- Add probiotics (a blend of acidophilus and bifidobacteria)
- For severe diarrhea associated with weight loss, use L-glutamine up to 30 g (2 Tbsp. worth) a day in divided doses.**

Nutritional protocol for treating high cholesterol and triglyceride levels

- Limit sugar and refined, white carbohydrates
- Include the right dietary fats (avoid processing or high heat): flax/borage oil blend—add to foods or liquids without heating it; cold water fish; olives; avocado; cold-pressed oils (olive, sesame, canola, walnut, sunflower and safflower); raw nuts and seeds; flax meal/oil; raw nut butter (peanut, almond or cashew)
- Eliminate bad dietary fats: saturated animal fats and hydrogenated (trans) fat (typically found in processed, long shelf-life convenience foods like popcorn, crackers, snack cakes, many salad dressings and margarines, etc.)
- Improve dietary fiber intake
- Add quality assured supplements including fish oil, policosanol or non-flush niacin***
- Improve physical activity

Nutritional protocol for enhancing immune function

- Nutrient-rich, whole foods
- Include the right dietary fats (see above)
- Eliminate bad dietary fats (see above)
- Vitamin/mineral/antioxidant supplementation

Nutritional protocol for improving glucose tolerance and managing diabetes

- Limit sugar and refined, white carbohydrates
- Include the right dietary fats (see above)
- Ensure adequate protein and "good fats"
- Divide meal intake into small portions, eating every 3-4 hours
- Limit starches at meal based on blood sugar levels before and 2 hours after a meal
- Include chromium and vanadium supplement with each meal

Quality assured—look for the Good Manufacturing Practices (GMP) rating on the label, given by the National Nutritional Foods Association (NNFA). NNFA is the oldest and largest non-profit organization dedicated to the natural products industry in the U.S. The "A" rating is given for compliance to rigorous standards. The NNFA's GMP certification program ensures that all elements of the company's manufacturing processes meet specified performance standards of each measure, including quality and disease control, cleanliness and training, receiving and testing of raw materials, and procedures for storage and distribution. "GMP Certified" is different from "GMP compliant." Few companies allocate the financial resources to independently verify that their GMP programs achieve GMP certification.

* Beware of higher mercury levels in other cold-water fish (such as trout, cod and sardines). The wild salmon should be farm-raised from Chile or North America. Don't eat swordfish, King Mackerel or tilefish.

** L-glutamine is expensive and is provided through some public aid formularies. The Houston Buyers Club offers it at a lower price. Once you heal the gut and maintain that with good nutrition, you can lower the dose or cycle on-and-off the glutamine.

*** Non-flush formulation (inositol hexanicotinate) in 500 to 1,000 mg one or two times a day may help avoid flushing. Check with your doctor or pharmacist to see if it's okay to add a baby aspirin before taking niacin to reduce potential side effects. Look for "GMP certified."

Drug Update: The Old, The New, The Still to Come

by Patrick G. Clay, PharmD

This summary provides a limited and brief overview of abstracts presented at the 11th Conference on Retroviruses and Opportunistic Infections in San Francisco in February. The focus of this review involves drug interactions between antiretrovirals, agents that might be given at the same time as HIV medicines and pharmacokinetic data that may affect how HIV medicines are given or for those newer agents that are likely to be recruiting for patients in clinical trials in the coming months.

Lexiva + Kaletra—still a bad idea

Dr. Angela Corbett of the University of North Carolina—Chapel Hill presented data that provides more information on the dual detrimental drug interaction that occurs between Lexiva and Kaletra, initially presented by Dr. Angela Kashuba on behalf of the AIDS Clinical Trials Group (ACTG) at the ICAAC conference in September 2003. Dr. Kashuba had shown that when Kaletra and Lexiva were given together, the drug levels for both drugs were significantly reduced—meaning these two drugs could not be taken together. Dr. Kashuba's group also showed that giving more Lexiva and/or Kaletra did not overcome this interaction.

However, Dr. Corbett's group tried to determine if the interaction occurred because of the two protease inhibitors (PIs) being taken at the same time, so they separated the doses by 4 and 12 hours in a group of non-HIV infected volunteers. Eleven seronegative persons took Lexiva and Kaletra at full doses (700 mg + 400/100 mg, respectively) together for 10 days at the same time. They then were randomized to either take their PIs at regular doses twice a day at the same time (0H), twice a day four hours apart (4H) or taking 1400 mg of Lexiva (4 tablets) and 800/200 mg of Kaletra (6 capsules) 12 hours apart (12H). The amount of drug in their blood was then checked after seven days of this new dosing scheme. Dr. Corbett's group found that separating the doses did not improve the Lexiva levels, but did improve the Kaletra levels when the drugs were given twice daily. Even when double doses were administered once daily, the levels were still reduced from historical controls. The authors caution that more research to find out how to dose these two PIs together has to be done and until then, these two medicines should not be used together.

Dosing Agenerase + Kaletra—trying to juggle, walk and chew gum all at the same time

Dr. Heather Wynn Vezina presented clinical results of dosing alterations done on patients receiving Agenerase and Kaletra (lopinavir/ritonavir). Given the recent data showing lowering of both lopinavir and Agenerase when these agents are given together, but still having patients in clinic on this regimen, Dr. Wynn Vezina measured levels of these two agents and made dose adjustments based on those. Levels at the end of the dosing interval for lopinavir were 2-3 times lower than the manufacturer recommends. Agenerase levels were similar to previous reports when given with 100 mg of Norvir. Still, the doses of lopinavir and/or Agenerase were increased in an attempt to improve the levels. Six patients had an extra one or two lopinavir capsules added to their regimen every 12 hours and 3 patients increased their Agenerase intake by one or two capsules every 12 hours as well. Two patients had both done. Diarrhea forced one patient to reduce lopinavir dosing. Lopinavir dose increases in the 6 patients resulted in improvement of plasma levels and improvement in viral loads and CD4 counts at the 12-week time point. This data, again short-term, demonstrates some utility of TDM (therapeutic drug monitoring) in HIV and how select instances may benefit from use of measuring plasma levels of antiretrovirals.

Caveat emptor—Buyer Beware!

Dr. Scott Penzak of the National Institutes of Health's Warren G. Magnuson Clinical Center presented some important findings revealed when his group decided to test generic anti-HIV medications abroad for how much drug was actually in there. This is vital as many in the world cannot afford the high price for antiretrovirals and seek alternative sources for the drugs—including black market and counterfeit suppliers.

Dr. Penzak's group tested five PIs and Sustiva (efavirenz) obtained from sources outside the United States. Specifically, they tested products from Zambia, South Africa, Lithuania and Jamaica. The tests they used to determine if the medications contained the amount of drug they were supposed to were the same used by the U.S. Food and Drug Administration (FDA) and applied to manufacturers selling products here in the United States.

They found that most of the drugs were as labeled, despite some being beyond their labeled date of expiration! Most important of the findings was that across the board, ritonavir-containing products (Norvir) failed to meet the standards. Dr. Penzak's group noted these products arrived without having been stored properly—meaning no refrigeration. Shipping of medicines without proper storage sends an important signal to anyone even thinking about getting their anti-HIV medicines outside of regulated sources—buyer beware!

Dr. Ramachandran also evaluated the quantity of available generic antiretrovirals, but limited his analysis to those agents available from India-based manufacturers (three of them). This group assessed levels of Sustiva, Viramune (nevirapine), Retrovir (AZT), and Epivir (3TC)—but not protease inhibitors as was done by the NIH group. They also looked at a combination pill containing Viramune, Epivir, and Zerit (stavudine)—this is not available in the U.S. and therefore there are no standards to which to compare the concentrations found. These investigators found that the quantity of the single medication in the majority of instances was within the expected range allowed by the FDA (range 0.01–8.3%).

It keeps going, and going, and going…

How long does Sustiva hang around after it is stopped? The common thinking was that after about one week plasma levels of Sustiva were not detectable. Data presented by Dr. Stephen Taylor of the University of Birmingham showed that may not be the case. Dr. Taylor measured Sustiva levels in seven HIV-positive patients who had to stop taking the medication for various reasons. These patients had levels measured one, two and three weeks after stopping their Sustiva. This study showed 4, 3 and 2 out of 7 patients still had Sustiva present in therapeutic levels one, two and three weeks after discontinuing therapy. Importantly, this did not result in resistance development in these patients.

Along the same lines was a study conducted in non-HIV infected women in the Netherlands and presented by Dr. Muro of Tumaini, Kilimanjaro Christian Medical College. Single-dose Viramune was administered to 44 women. Blood levels were sampled twice weekly for 21 days. Drug was still detectable in 40 patients at day 11, 28 patients at day 15, 16 patients at day 18, 9 patients at day 21 and still detectable in 7 patients at day 22. There were no predictors for the long duration of drug exposure in this population. This half-life was calculated to be 56.7 hours, or a little more than 2 ¼ days. No resistance data is available as these patients were all HIV-negative.

These two studies provided important data as patients who discontinue Viramune or Sustiva due to side effects may have to wait a little longer before the drug goes away completely. It also questions the amount of time between regimens that may need to take place to avoid drug interactions.

Sustiva neurologic side effects not related to levels

As more information is learned about how the body breaks down anti-HIV agents, correlations to adverse effects are ruled in and out. Sustiva's predominant side effect is neurological toxicity (dizziness, drowsiness, altered dreams, etc.) and a group of researchers from Harvard tried to see if this is related to drug levels. Dr. Heather Ribaudo presented on behalf of this group the pharmacokinetics of Sustiva in various patient populations and how levels related to adverse events, outcomes and drug discontinuation. They found no correlation between levels, outcomes and discontinuation rates, however, they did find that non-Hispanic Caucasians got rid of the drug faster and this may result in higher levels in this population. They found no higher rates of drug discontinuation in other ethnic groups, so it is thought that though this difference may exist, it doesn't warrant concern for patients.

Drug levels of the newer agents for HIV: so far, so good

The experimental drugs Reverset and SPD754 showed encouraging results to date.

Reverset

Dr. Robert Murphy of Northwestern University School of Medicine presented pharmacokinetic information on Reverset (RVT, D-D4FC), a new once-daily nucleoside drug being studied by Pharmasset, Inc. Thirty HIV-positive patients were given this drug as monotherapy in a dose escalating trial. Patients were assigned to receive 50, 100 or 200 mg for 10 days. After 10 days of therapy, viral loads were decreased in all three groups with the 50 and 100 mg groups reporting drops of (on average) 1.67 and 1.8 log10 copies/mL, respectively. Dr. Murphy reported no significant adverse events, but cautioned this is a short-term study and longer studies in combination and in treatment-experienced patients need to be conducted prior to being made more widely available.

SPD754

Another group of researchers working on the twice-daily nucleoside SPD754 in combination with Epivir had their data presented by Dr. John Bethell. These investigators looked at how SPD754 and Epivir impacted each other in the plasma and inside the cell (remember, it is inside the cells—CD4 and others—where these drugs have to work). Twenty-one non-HIV infected individuals took 600 mg SPD754 twice daily with or without 300 mg Epivir once daily for four days. This duration is considered acceptable as neither of these two drugs is expected to accumulate to any great extent in the body of cells over time.

What Dr. Bethell showed was a lack of interaction when the plasma levels of these drugs are examined. However, when the intracellular levels of these agents were looked at, a significant reduction of SPD754 was seen when it was given with Epivir compared to intracellular levels when these agents are given alone. This has significant ramifications in that these two agents will likely not be able to be co-administered (much like Zerit and AZT cannot be given together). It also reinforces that intracellular pharmacokinetic drug interaction studies should be conducted with all new (and existing!) agents to maximize understanding of these agents before they are given to patients.

Of course, this is meaningless if the drug doesn't affect those with HIV. Dr. Collins of Shire Biochem presented clinical findings of SPD754. Sixty-three patients were given SPD754 as monotherapy in dosing regimens once or twice daily and ranging from 200 to 1600 mg total daily dosing. These HIV-positive volunteers took these doses for 10 days. Viral loads and resistance tests were done after 10 days. In three patients who had baseline mutations that would have limited efficacy of other nucleosides, a strong decrease in viral loads of around one log were seen after this time period. While this data is limited to very small numbers and only for a short period of time, given the need for new agents, it is important for studies to be continued in the population of resistance patients sorely lacking for new agents.

Dr. Adams of Inveresk presented data on the pharmacokinetics—blood and intracellular of SPD754—in the group of 63 HIV-positive patients reported above. What he reported was the preferable accumulation intracellularly when the medication was given twice daily compared to once-daily across all of the dosing arms. Also shown was the possible correlation between blood levels and intracellular levels. This is the first agent to be able to demonstrate this. Other nucleosides and protease inhibitors have had to rely on something in the cells to get across the cell's membrane where these drugs need to be in order to work. This may the first agent that would tell us what is inside the cells by measuring blood levels—a very beneficial aspect if it holds true in repeated studies.

Receptor blockers: GW873140, SCH C, SCH D

HIV has to connect or bind to the CD4 cell before it can enter and infect the cell. Blocking binding of HIV to the CD4 cell has long been a site for drug discovery.

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Approaches to this include going after the CD4 cell's surface membrane receptors, CXCR4, CCR5 and gp120. Though these sites for action have long been known, it has only been recently that orally available drugs have been given to humans. These drugs are being referred to as small molecules, attachment inhibitors or receptor antagonists.

GW873140

A drug discovered by GlaxoSmithKline, GW873140 is designed to impede viral entry by affecting the receptor CCR5. Dr. Piscetelli of GlaxoSmithKline presented the first human pharmacokinetic data of this compound. Seventy non-HIV infected persons (57 males, 13 females) were administered single doses escalating from 50 mg to 1200 mg. This was followed by administering the drug twice daily in doses ranging from 200 mg to 800 mg for seven days. Though plasma levels were obtained after the multiple dosing studies, with these drugs what is important is what percent of the CCR5 receptors are occupied—which were also done. Overall, the drug was well tolerated by the volunteers with some mild gastrointestinal side effects. From the plasma levels, dietary factors are going to be important with this drug as levels went up around two times when given with food. For the percent of receptors bound while taking the medicines, 97% of the CCR5 receptors were occupied 2 and 12 hours after the drug was taken in the multiple dosing studies. This very preliminary information is good news, as these novel approaches to therapy may prove the most effective yet—but only time and properly conducted studies will tell.

SCH D

Schering-Plough also has developed two blockers of CCR5 called SCH C and SCH D and their data was presented by a group of researchers led by Dr. Shurmann. SCH D is being pursued for further development due to its higher activity compared to SCH C. This agent was administered to 48 HIV-positive persons, who had to have been off their antiretrovirals for at least eight weeks and have a CD4 count at or above 200 cells/μL, in doses ranging from 0 to 50 mg twice daily for 14 days. After 14 days of dosing, decreases in viral loads ranged from 1.08 to 1.62 log with a trend reflecting increasing doses of SCH D. Viral loads rapidly returned to baseline after discontinuing the medication.

BMS 488043

Dr. Hanna presented Bristol Myers Squibb's small molecule, BMS 488043, that it has developed to target the gp120 receptor on the CD4 cell's surface. Though this drug has been studied in dose ranging studies before, more focused dosing strategies were shown. Thirty patients were assigned to get, as monotherapy, either 800 mg (12 persons, 3 placebo) or 1800 mg. Only the 800 mg data was presented. These 12 HIV-infected patients had a mean decrease in viral loads after 14 days of dosing of 1 log10 copies/mL. A significant increase in CD4 counts was seen (106 cells/μL) in the BMS488043 group compared to placebo. Importantly, no serious adverse effects were seen and no patient had to be discontinued due to side effects.

The pharmacokinetic studies done in non-HIV infected persons over 14 days of this molecule were also presented by Dr. Hanna during a different session. Comparisons of blood levels of this agent when given with or without food showed that improvement was seen when it was given with food—3–5 times as much of the drug was in the body. There was no difference seen when the drug was given with a low-fat versus a high-fat meal, thus it seems instructions for this agent would be to take with food. Total drug exposure of the body to this drug was increased by Norvir by 43%—what that means now is unknown. Also presented by this data was the likelihood of this agent being dosed at 800 mg twice daily, as it would provide sufficient blood levels to suppress viral replication.

These three studies show that progress is being made in exploring new targets for HIV therapies. It is important to realize all of the data presented is short-term, limited numbers and in non-infected populations at times. Despite this, these results are encouraging for continued pursuit of these agents in combination trials for longer durations of time.

Momma always said to take your vitamins!

Researchers from the University of California presented data on the ability of a micronutrient supplement to improve peripheral neuropathy symptoms related to Videx (didanosine) or Zerit. Forty patients took either a vitamin supplement containing L-carnitine, n-acetyl cysteine and alpha lipoic acid or a placebo twice daily for 12 weeks. Every month the patients returned for assessment of improvement in peripheral neuropathic symptoms and other measures of mitochondrial toxicity. After three months, there was no difference seen between the two arms. What was surprising was the increase in CD4 counts in the micronutrient group versus the placebo. Those taking the vitamin twice daily saw a 26% increase in the absolute CD4 count versus a 2% increase in the placebo group. Dr. Kaiser's group reported failing to meet the primary objective of the study in that no improvement in peripheral neuropathy was seen, but no adverse effects resulted from the additional nutritional supplement and an unexpected increase in CD count was noted.

Neupogen stimulates more than just white blood cells

Filgrastim (Neupogen, rG-CSF), the white blood cell stimulator used after transplants and in persons with neutropenia (low white blood cells—a not infrequent complication of HIV and its therapy), was shown to increase viral replication in a study presented by Dr. Rapaport of the University of Colorado Health Sciences Center. In a laboratory setting, cells were exposed to levels of filgrastim that would routinely be used in clinical situations. As the amount of filgrastim was increased, HIV replication increased—similar to the increase seen when IL-2 is given in other viral replication experiments. This research provides an explanation why viral replication may be more likely when patients are given filgrastim to treat incidences of extremely low white blood cells.

COX-2 inhibitors and CD4—drug-disease interaction?

The commonly used medications for arthritis and chronic inflammatory conditions, Celebrex and Vioxx, were evaluated for their influence on T-cells by Dr. Kvale and a group from the University of Oslo in Norway. Having only 24 persons who had been on these medications (12 in each group) for six months, they compared the changes in T-cells between these persons and those on similar regimens and responses. Though it was difficult to control for a number of factors, only those persons on the COX-2 inhibitors had increases in two components of the T-cells. Again, the data is no "smoking gun," but they did find that there were small, albeit significant, changes in the CD38 and CD28 sub-fractions of T-cells. Why is this significant? Mainly because it is the CD38 sub-fraction that correlates with HIV progression in patients with detectable viral loads. These investigators plan on evaluating further more patients and for longer durations of time. In the meantime, this would not be cause to consider stopping the COX-2's or not considering initiating them, only a curious fact that warrants further investigation.

Sustiva, Lipitor and Zocor

Already known is that with protease inhibitors, the only two cholesterol-lowering medicines available for use are pravastatin and atorvastatin. But what about the non-nukes? The AIDS Clinical Trials Group (ACTG) looked at this question in ACTG 5180. Dr. John G. Gerber from the University of colorado Health Science Center in Denver presented important information on the interaction between either Zocor (simvastatin) or Lipitor (atorvastatin) with Sustiva when given to 27 HIV-negative volunteers. The blood levels of Zocor and Lipitor were measured in patients when given by themselves for three days, then they took Sustiva for two weeks and had Sustiva levels measured. They then restarted Zocor and Lipitor while on Sustiva for another three days and then had the levels measured again.

What they found was a significant reduction in levels of both Zocor (60%) and Lipitor (~45%) when given with Sustiva. Those two drugs did not affect Sustiva levels, thankfully. If these agents are being considered in patients with elevated cholesterol and they are also on Sustiva, then higher doses may be needed in order to get an effect. A word of caution—this data showed only short-term exposure and close monitoring of side effects should be done when using these agents in combination. There are a number of labs that can run levels on cholesterol-lowering medicines and this may prove beneficial instead of increasing a dose of either of these agents because a drug interaction is expected.

To measure or not to measure drug levels—that is the question

A poster presented by Dr. Ana Rendon of Hospital Carlos III in Madrid demonstrates the complexity and diversity of using therapeutic drug monitoring (TDM) in patients on antiretrovirals. They looked back at all requests for levels in patients to see why levels were being drawn, and importantly, what is being done with the information given to the provider. Most of the requests resulted from toxicity with a particular agent that the provider wanted to either rule out or rule in the role of elevated levels of the drug in that toxicity. Drug toxicity represented 59% of requests, with unexpected virologic failure being the reason for 39% and only 2% for drug interactions.

Higher than expected drug levels were found in 37% of patients with suspected drug toxicity, and lower than expected drug levels were found in 42% of patients unexpectedly failing therapy. The researchers found that 32% of patients had levels changed based on TDM (10 dose reductions, 8 dose increases and 2 regimen changes). Of these 20 who changed therapy based on TDM, 16 or 80% achieved their goal (toxicity resolved or improved viral suppression). In 11 patients in whom follow-up levels have been done, all have achieved expected concentrations. This and Dr. Wynn-Vezina's study are the first data that have shown changes to therapy based on TDM in clinical practice and the results are encouraging. Though retrospective, the positive outcomes support TDM use in select situations and open communication between laboratories running the levels and providers ordering the tests.

Summary

Overall, a busy conference with many ideas tossed around for how to better manage this disease. A number of the newer drugs in development are raising curiosity and how they are studied may alter how we approach treatment in persons acutely and chronically infected. Drug interactions and dosing alterations continue to be discovered and with more information comes a better ability of clinicians to manage patients with less side effects. More data is forthwith at Bangkok this summer during the World AIDS Conference—so look forward to more summaries from that meeting in the coming months.

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Hepatitis C Co-Infection Review

by Daniel Raymond

Chronic infection with the hepatitis C virus (HCV) has become a major concern for people living with HIV (PLWH). In the United States, over 200,000 people—an estimated 25% of all PLWH—also have hepatitis C. The majority of HIV/HCV co-infected persons acquired both viruses from injection drug use with contaminated equipment. While the course of hepatitis C infection varies widely, research indicates that HIV can accelerate the course of hepatitis C, leading to more rapid progression of liver disease and increasing HCV viral loads. Hepatitis C treatment does not work as well in HIV-positive people, and people with hepatitis C can have more trouble tolerating antiretrovirals for HIV, which can be hard on the liver (hepatotoxic). In recent years, end-stage liver disease from hepatitis C has become a leading cause of death for people living with HIV. This article will review recent research on hepatitis C and HIV co-infection, with a focus on new data on hepatitis C treatment for PLWH.

How hepatitis C works

The hepatitis C virus infects the liver, the organ responsible for storing, filtering, and metabolizing chemicals that pass through the body, including nutrients from food, drugs, and medications. Most people who acquire HCV develop chronic infection, though about 30% can clear the virus spontaneously within a few months after being infected. Hepatitis C is thought to damage the liver by triggering immune responses that attempt to kill infected liver cells. As cells die, the liver responds by producing fibers to seal up the damaged areas, a process called fibrosis. This allows the liver to regenerate while preventing further damage.

With chronic hepatitis C infection, the liver often fails to maintain the balance between damage and regeneration. The immune system tries to keep hepatitis C in check, but this requires the on-going destruction of potentially infected liver cells. Over time, fibrous tissue can build up, leading to cirrhosis, or scarring of the liver. Many people have well-compensated cirrhosis, where the liver can still function in spite of significant scarring. Some people progress to decompensated cirrhosis, a life-threatening conditioning that occurs when the accumulation of scar tissue interferes with the proper functioning of the liver, ultimately leading to liver failure. People with cirrhosis are also at risk of developing liver cancer, also called hepatocellular carcinoma, which is potentially fatal.

The good news is that for people with hepatitis C, liver damage is typically a very slow process, occurring over decades. Some people never develop any significant liver damage, and the majority does not progress to cirrhosis. However, several studies have documented more rapid fibrosis progression in people co-infected with hepatitis C and HIV. It is unclear why co-infected people experience more rapid and severe liver disease, though people with low CD4 T-cell counts are at highest risk of cirrhosis and end-stage liver disease. HIV may impair the immune system's ability to respond

effectively to hepatitis C, particularly in people with low CD4 T-cell counts. The result is the worst of both worlds—higher hepatitis C viral loads and more liver damage. Some people hope that successful highly active antiretroviral therapy (HAART) might offset HIV's effect on fibrosis progression, while others worry that HIV medications may worsen liver disease due to hepatotoxicity. Available research has been inconclusive or shown little effect of HAART on fibrosis, positive or negative. Some HIV medications—particularly Viramune (nevirapine) and full-dose Norvir (ritonavir) are more likely to be hepatotoxic, particularly in people co-infected with hepatitis C, and require careful monitoring.

Update on fibrosis

Despite this grim outlook, two recent reports from Johns Hopkins University, presented at the 11th Conference on Retroviruses and Opportunistic Infections (CROI) in February, offer some good news for people co-infected with hepatitis C and HIV. Both studies used liver biopsies, the most accurate test for liver damage. The liver biopsy is a procedure that uses a long needle to take a small sample of liver tissue that can be examined for signs of fibrosis and inflammation. One study looked at a random selection of 115 co-infected patients in a clinical cohort. Only 17% had cirrhosis, and 43% showed no fibrosis. A second study looked at fibrosis progression in 116 injection drug users with chronic hepatitis C who had received two liver biopsies, averaging four years apart. Over half of the people in the study showed little or no fibrosis, and only 6% had cirrhosis. Fibrosis progression was fairly slow overall. Though 28% of the study group was co-infected with HIV, HIV status did not influence the rate of fibrosis progression. Together, these studies suggest that earlier assessments of fibrosis in co-infected people may have been overly pessimistic.

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In the Johns Hopkins studies, elevated liver enzyme levels (ALTs, for alanine aminotransferase, or ASTs, for aspartate aminotransferase) were associated with greater risk of fibrosis progression and/or serious fibrosis. Another report from Italian researchers supports these results, finding that 75% of co-infected persons with persistently normal ALT levels had little or no fibrosis, while those with elevated ALTs tended to have more serious fibrosis. However, some people with normal liver enzyme levels do have cirrhosis, which can only be determined through liver biopsy. Because biopsies are invasive procedures that can be painful and carry a small risk of complications, several researchers are looking for ways to gauge fibrosis and cirrhosis through blood tests. So far, results from various types of blood tests have not been as accurate at fibrosis, though another Johns Hopkins poster at CROI described a combination of tests that could identify a substantial proportion of co-infected people with minimal liver damage, reducing the need for biopsy.

Hepatitis C treatment

Liver biopsies provide crucial information for people considering hepatitis C treatment. People with minimal fibrosis may choose to defer treatment and get a follow-up biopsy in another 2–3 years. However, HCV treatment is recommended for people with moderate to severe fibrosis or compensated cirrhosis. Treatment is not indicated for people with decompensated cirrhosis, where damage to the liver has compromised its ability to function. Decompensated cirrhosis generally requires a liver transplant.

Treatment for hepatitis C consists of a combination of two drugs, pegylated interferon and ribavirin. Pegylated interferon is a synthetic form of interferon alpha, an antiviral molecule naturally produced by the body. Pegylated interferon is taken once a week by injection. The FDA has approved two forms of pegylated interferon: Pegasys, made by Roche, and Peg-Intron, marketed by Schering-Plough. Ribavirin is a nucleoside analogue (like AZT and Epivir) that comes in pill form, taken orally twice a day. Both drugs can have serious side effects, including flu-like symptoms, fatigue and anemia, and depression and insomnia. A substantial number of people have to reduce their doses of pegylated interferon and/or ribavirin at least temporarily due to side effects, and some people cannot tolerate a full course of therapy and discontinue treatment early. A small but worrisome number of suicides have been reported among people undergoing hepatitis C treatment. People with histories of drug use may have particular difficulty dealing with the side effects of treatment, putting them at risk of relapse to addiction.

The goal of hepatitis C treatment is total clearance of HCV, with an undetectable hepatitis C viral load. People maintaining an undetectable viral load six months after the end of treatment are called sustained virologic responders. Studies in people with hepatitis C alone show that the vast majority of people who experience a

sustained virologic response (SVR) remain undetectable after several years of follow-up. Many people that clear hepatitis C during treatment relapse on or after therapy, with their viral load rebounding to detectable levels, and do not achieve an SVR. Even people who do not achieve an SVR may benefit from hepatitis C treatment; some people who do not clear HCV experience improvements in the condition of their liver, which may reduce long-term risk of end-stage liver disease.

Three large clinical trials reported their final results at the 11th CROI, and this data will shape treatment decisions for the foreseeable future.

The main determinant of treatment success is hepatitis C genotype, or strain of HCV. At least six HCV genotypes exist; genotype 1 is most common in the United States, followed by genotypes 2 and 3. Genotype 1 is the hardest to clear. In hepatitis C monoinfection (HIV-negitive), those with genotype 1 are treated for a full year, and treatment results in an SVR in about half of people receiving therapy. In contrast, people with genotype 2 or 3 require a shorter duration of treatment, typically 6 months. In people with hepatitis C alone, those with genotype 2 or 3 respond very well to HCV treatment, and the majority—over 80%—achieve a sustained virologic response. Studies in people infected with hepatitis C alone (HCV monoinfection) show that for all genotypes, if their HCV viral load does not drop 100-fold or become undetectable by the end of 12 weeks of hepatitis C treatment, they will not achieve an SVR.

The latest studies

Until recently, most information about HCV treatment has come from studies of people with hepatitis C monoinfection. The FDA approved combination therapy with Pegasys or Peg-Intron and ribavirin without any substantive data on the safety and efficacy of these treatments in co-infected people. The tolerability of these drugs in people with HIV was a central concern. For instance, interferon reduces the CD4 T-cell count during treatment, though levels return to baseline after therapy. Ribavirin can induce anemia, a condition already common in people living with HIV, especially among those taking AZT-containing regimens (including Combivir and Trizivir). Moreover, rates of depression run high among PLWH, and the majority of co-infected persons have histories of drug use, indicating that management of mental health and substance abuse would be vital. Finally, preliminary studies suggested that co-infected people may be less likely to achieve an SVR on hepatitis C treatment, especially since their hepatitis C viral loads tend to be higher than people with HCV alone; studies in HCV monoinfection show that people with lower hepatitis C viral loads respond better to treatment. All of these issues raise thorny questions about the relative risks and benefits of HCV treatment for co-infected people, who have a higher risk of progressing to liver disease.

Three large clinical trials examining the efficacy and safety of hepatitis C treatment in co-infected people reported their final results at the 11th CROI, and this data will shape treatment decisions for the foreseeable future. All three studies compared pegylated interferon/ribavirin to the previous standard of care, combination therapy with standard interferon (requiring three injections per week, compared to once a week for the longer-acting pegylated versions) and ribavirin. One study also compared pegylated interferon/ribavirin to pegylated interferon alone. All showed that pegylated interferon/ribavirin was superior, though SVR rates were lower than those seen in HCV monoinfection studies.

APRICOT (AIDS Pegasys-Ribavirin International Co-infection Trial): An international trial of 860 co-infected persons (289 receiving 180 µg of Pegasys once a week and 800 mg of ribavirin daily). About 60% had HCV genotype 1. Median CD4 T-cell count was about 530, and 85% were receiving antiretroviral therapy, with 60% having undetectable HIV viral loads. About 60% had a history of injection drug use.

ACTG 5071: A U.S. study conducted by the Adult AIDS Clinical Trials Group of 133 co-infected persons (66 receiving 180 µg of Pegasys once a week with daily ribavirin). Ribavirin was initially dosed at 600 mg/day, with the ribavirin dose increasing every four weeks by 200 mg to a maximum 1000 mg/day as tolerated. About 77% had HCV genotype 1. Median CD4 T-cell counts ranged from 444–492, and about 86% were receiving antiretroviral therapy, with 60% having undetectable HIV viral loads.

RIBAVIC (ANRS HC02): A French study conducted by the Agence nationale de recherches sur le sida of 412 co-infected persons (205 receiving 1.5 µg/kg of Peg-Intron once a week and 800 mg of ribavirin daily). About 60% had HCV genotype 1. Median CD4 T-cell count ranged from 501–527, and about 83% were receiving antiretroviral therapy, with 66% having HIV viral loads below 400. About 79% had a history of injection drug use.

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Results of these studies for participants in the pegylated interferon/ribavirin arms appear below, with discontinuation rates for adverse events (side effects and lab abnormalities, see table below).

The highest SVR in co-infected people with genotype 1 was seen in APRICOT—about twice as high as rates in the other studies. Both APRICOT and ACTG 5071 had fairly high SVR rates for people with genotype 2 or 3. RIBAVIC had the highest rate of premature treatment discontinuations for adverse events. While it can be difficult and misleading to compare results across studies, due to differences between protocols and patient populations, several reasons for the disparate results have been proposed:

- The APRICOT participants may have been healthier (less advanced liver disease) than those in the other studies, and had a lower proportion of people with a history of injection drug use—thus representing a best-case scenario. ACTG 5071 had a higher proportion of African Americans (about 33%), who are less likely to achieve an SVR.

- ACTG 5071 may have started people on too low a dose of ribavirin. Evidence from HCV monoinfection studies indicate that higher doses of ribavirin increase the chances of achieving an SVR; in HCV monoinfection, people receive 1,000-1,200 mg of ribavirin daily with Pegasys. Increasingly, EPO (epoetin alfa, a red cell growth factor) is used to reverse or prevent ribavirin-induced anemia, allowing people to maintain optimal doses of ribavirin during HCV treatment.

- While Pegasys and Peg-Intron work similarly, they have different pharmacokinetic properties—Pegasys appears to have a longer half-life. These differences may influence their efficacy and safety profiles.

Further analyses of these studies are on-going, in an attempt to clarify factors that influence treatment response. The next major question for co-infection research is whether extending the duration of treatment can improve sustained virologic response (SVR) rates. APRICOT treated people with genotypes 2 and 3 for 48 weeks, rather than the standard 24 weeks used in HCV monoinfection, and found that virtually no people relapsed. Some doctors have already begun extending treatment for people with genotype 1. Further research is also underway investigating whether long-term maintenance therapy with a half-dose of pegylated interferon can improve or stabilize the condition of the liver in people who do not achieve an SVR.

The next major question for co-infection research is whether extending the duration of treatment can improve sustained virologic response (SVR) rates.

In the meantime, co-infected people now have more information for making hepatitis C treatment decisions. Beyond treatment, PLWH should make sure that they have been successfully vaccinated for the hepatitis A and hepatitis B viruses. Other strategies for liver health include reducing or eliminating alcohol, careful monitoring of liver enzyme levels when starting new medications, good nutrition, and reducing stress. These factors can help to protect your liver until better hepatitis C medications become available, hopefully in the next four or five years.

Daniel Raymond is Hepatitis C Policy Analyst for the Harm Reduction Coalition, in New York City. *Special thanks to Tracy Swan for her comments and suggestions.*

Study (regimen):	Genotype 1 SVR:	Genotype 2/3 SVR:	Discontinuations (adverse events):
APRICOT (Pegasys/RBV)	29%	62%	15%
ACTG 5071 (Pegasys/RBV)	14%	73%	12%
RIBAVIC (Peg-Intron/RBV)	15%	44%	31%

RBV = ribavirin

Did You Ever Know That You're My Hero?

by Laura Jones

Our staff, volunteers, and clients are my heroes, and how many people are lucky enough to spend 40+ hours of their week surrounded by their heroes?

The latest holiday season passed full of parties and socializing even for relative introverts like me. I rang in the New Year over at a friend's house—one of those hyper-organized social engineers who sets up little "Activities" for guests to do at parties, little rituals arranged decoratively on tables in special corners of the room. There was a chalkboard upon which we were all to write our Biggest Goal for the New Year ("Learn Polish" was one of mine, in case anyone knows where I might take lessons), a bowl of apple slices in another corner to eat in celebration of the freshness of the new year, and a table in the bathtub that held a ceramic plate, a bowl of matches, and slips of paper for writing down Things to be Released (which you then set on fire, in the safety of the bathtub). And in the living room, there were more pieces of paper, markers, and tape—so you could write down your favorite memory of 2003 and tape it to the archway above the entry to the "entertainment area" (i.e. the stereo/TV/sofa corner of the room).

People had some pretty exciting stuff taped up on that archway: "My trip to Iran", "The birth of my first child", "My wedding", "Skydiving in Colorado"—that kind of thing. I was trying to remember if I'd even taken a real vacation in 2003 when my own response struck me… but it sounded ridiculously homestyle (especially compared to the births of first children, weddings, and trips to Iran). Still, the more I mulled it over the more I realized it was the truth—it really was my favorite memory of 2003, the image that will forever leap to mind when I'm old and crippled with osteoporosis and thinking back on the salad days of my early 30s. So I wrote it down and taped it up, and left it fluttering there on the archway with First Children and Iran and someone's Wedding.

What'd I write? I wrote this: "Going to Work", because it's the truth. Our staff, volunteers, and clients are my heroes, and how many people are lucky enough to spend 40+ hours of their week surrounded by their heroes? Not many, probably. But I get to, so why not brag on that at a New Year's party?

The friends and others I've known for a few years thought that was a pretty cool response, since they know where I work and what I do and how much I enjoy my place of employment and everyone I rub elbows with there. But there were many new faces at this party, and lots of people took the opportunity to ask what kind of work I do once they read my response. Surely it must be something uber-exotic and exciting, if it's my Best Experience of 2003.

People who are not "in the field", as we say, often don't know quite what to say when they learn that you love your HIV/AIDS-related job. This is especially true when you reveal yourself to be neither Case Manager, Social Worker, Lobbyist, nor any of those other Noble Helpers or Glamorous Activists, but rather just a plain old grantwriter-cum-program developer-cum-fill-in-the-blank-when-no-one-else-is-available-to-do-it person for a small "peer-led" agency. "What's in it for you?" their faces say, while "Isn't that depressing?" comes out of their mouths with some frequency.

They're always surprised when I tell them "No. Why should it be?" I work with people who, by the simple fact of getting up every day and going about their business, tell both a virus and a stigmatizing society to bite them. I work with people who aren't afraid to talk openly about sex, drugs, sickness, and death in plain, down-to-earth terms. Best of all, I work with people who don't take their lives or their health for granted, and are able to make black-humored jokes about chronic conditions and ailments that would send most others back to bed in two minutes—all while going about their business, same as anyone else. Pretty damn inspiring, when you think about it.

As for the "What's in it for me?" part… well, anyone who can laugh instead of cry while describing the best way to navigate an ice slick while trying not to unleash a diarrhea spill in their pants is my hero. Anyone who considers it a blessing to lose only four close friends a year instead of 14 is my hero. Anyone who is able to stick with a commitment to recovery while dealing with the stresses of HIV-positive life is my extra-special hero—as is anyone who is brave enough to go back to school or consider parenthood while living with HIV, especially when so many people at parties seem to believe that being HIV-positive renders a person pretty much unable to tie their own shoes, let alone hold down a job or a have a healthy sex life.

I'm surrounded by Everyday Heroes, every time I go to work. Who can ask for more than that?

The Dating Game

by Tom Setto

Ken was recovering from choking on his omelet and our waitress at the Montrose Diner, Jenny, was helping Gary wipe his spilled coffee from the table. Miguel and Jerome were staring in disbelief with their mouths open. Finally Joey was able to speak, "What did you say?"

I repeated, "I've been thinking about starting to date again."

You see, I have been thinking a lot about trying the dating world again and quite frankly I'm frightened. My exile from the world of one-on-one relations has been self-imposed. The relationships I have with my friends and family have been enough to satisfy my social needs. I haven't been on a real date in nearly nine years.

Dating for a 45-year-old gay man is tough enough but for a 45-year-old gay man living with AIDS it's downright complicated. That's why I've been avoiding it. Jerome and Miguel have each been in a committed relationship for a few years now but the other men at the table date regularly. I was just hoping to get some help and advice dealing with the new rules of the game.

"Man, I thought you were campaigning to be the poster boy for the George Bush Abstinence Program," Jerome joked.

"I didn't think that sex and dating were necessarily one and the same," I said. "I'm not just looking for a quickie. Been there, done that and that's still somewhat easy to find if I want it. Sex is not the only thing on my mind anymore. What I want is friendship, commitment, and intimacy, the things I had in my last long-term relationship after the immediate excitement of the sex ended. I just don't know where to find it anymore. Is it selfish to want to meet someone who has just a little less baggage to deal with than I do? I figured you guys could give me a few tips for dating in the new millennium.

"And I think the rules have changed. At first I thought it wouldn't matter if the other person was positive or negative but now I'm not so sure," I added.

"You're so right," Gary said. "I've been dating this guy who is HIV negative and it just doesn't feel right. Everything is good but there is that one big issue that he just doesn't get. We both understand that protection is mandatory. And yes, we are having sex."

"I know a lot of couples that are serodiscordant, that's what it's called," Ken jumped in. "They are very happy, they just know their limits when it comes to sex. You shouldn't look at only positive guys to date, there are negative men who don't use status as a barrier for dating."

"I just think that since I am so out of practice, at dating and I guess sex too, I really should stick with positive men though. That would probably keep things less complicated. But where do I find them?"

"There's always the Internet," Joey answered. "I've had some great time with guys I met online or through personals."

"That's exactly what I'm trying to say," I answered. "Everywhere I look it seems to be all about the sex. Where are all the guys who want to get to know someone before hopping in the sack? Remember, that's how most of us got to this point in the first place.

"Don't bother suggesting the bars either. You guys know I'm not real big on bars anymore. I still go now and then but I don't feel as comfortable in clubs as when I was more of a party boy. Plus now that I feel like I have the 'look of HIV' there are times that I don't feel very attractive and that others can tell right away what my status is."

"Does that really matter to you?" Jerome asked. "You said that you preferred a positive guy so that will make things easier."

"That brings up another problem," I interrupted. "When do you tell someone? How do you all deal with it?"

Ken answered right away, "I think you should say something as quickly as possible. Don't force it like, 'Nice weather we're having. By the way I have AIDS' but do it as quickly as you can, especially since it is important to you."

"You know sometimes I wait. I almost always tell before we have sex, but there have been times when I haven't. I'm not perfect, but I try," Gary said.

"The whole sex thing has me worried. It's been awhile. I have no problem talking about it. It's been so long I don't know what I like anymore. I guess it should be fun finding out. I can't believe it's been so long. When I got really sick I didn't feel like it, when I got KS I didn't think anyone would want me, when I started the meds I lost the desire. All of a sudden it was like seven years and was just easier to go without."

"And now you're ready to jump back in, literally," Miguel laughed. "You know once you start you aren't going to quit. And if you need help you can always use the little blue pill. It's supposed to be helpful for guys your age," he said jokingly.

"That's another thing, I'm not over the hill but I am on the other side of middle age. It was much easier way back when. All you had to do is hook up and find a dark corner. Miguel, you and Jerome never really got to experience the free love of the seventies.

continued on page 37

Phat

by Jim Pickett

Gym bunnies, nipple ponies, steroid sissies, muscle Marys.

Pumping it up, posing and strutting, perking them out, lifting and separating, working it, feeling the burn, getting ripped, making it hurt for Daddy...

The poor dears. I used to find enormous pleasure making fun of these body-obsessed queers. Having not stepped hoof into a health club or gymateria for something like a decade, and with the growing America's Dairyland waistline to prove my disdain—the proof was in the pudding for real—I felt sorry, pity really, for the hordes addicted to the Pec Decks and Stairmistresses and all the other devices of narcissistic torture that swelled ones titty titty bang bangs and emptied their heads of reason

Of course, prior to my fitness ban, I was one of them, or rather, trying my gosh durndest to be one of them. I worked out every day. I pushed and I pulled, I grunted, heaved and strained, gettin' physical, physical, wantin' to feel my body, wantin' to get a body to feel. I even got a trainer who worked me out so hard, I couldn't get up, or down, the stairs on the Broadway bus. Grannies in Blue-Blockers were poking me in the back with their seeing-eye canes, growling, "move your ass, skinny."

And that's just it. All that hard work, all that limping and crying, and I was still, still a skinny dork. Sure, it was a firm skinny, but I continued to disappear if I turned sideways. I was still, still but a sparrow, flap, flap, flapping my bony wings against the wintry winds that gust through the greater Cowtopolis, getting blown over by octogenarians in a hurry.

So, when I got a day job that not only messed with my work out schedule but required continuous pot smoking and enforced breaks (state mandate) to eat boxes of chocolate Entemanns and hit the Indian buffet across the street, I left my dreams of muscular pulchritude behind without a second thought. Ballys no longer received its buck two fifty a month, and maybe some of the boys in the steamroom missed me, but to be honest, I didn't miss them. I was liberated, I was free. The madness was gratefully over.

Then I tested positive, then I turned 30 a couple of years after that. And lo and behold, I started to get fat. Baby started to get some back and ya know what? I loved it. I loved being called "big guy" and it not being a snide swipe at my wispiness. I really was a "big and tall man" with a big, fat, juicy ass shake shake shaking and it all just kept getting bigger. By 37, that eensy weensy 31 waist had become a 36. There were a pair of short pants that were, clutch the rolls, a size 38. That's plumped my darlings, not pumped.

Part of me, okay, a big part, felt like this large living was insurance. When the HIV started to work its evil magic, I had plenty of raw material, which I embraced. I was not going to waste away into a skeleton anytime soon. And the plump cheeks on my moonface just kept expanding. Fat and happy. Mootastic, mootacular, moorific, moopendous…

Then 2003 came along. Sometime in mid-January, before my 37th birthday, I ran out of mowiewowie, and was too fat and lazy to go get some more. No more pot meant no more cans of Pringles and no more double orders of fetuccini alfredo with cheesy garlic bread wolfed down with a couple of cokes at midnight. And lo and behold, I started to lose weight.

By April, I was buying a whole new wardrobe with waistlines at the 34 marker, and some sluttier 33's even for the occasional hot date.

A few months after that, I met someone, a triathlete someone, who would inspire me, unbeknownst to him, to start becoming physically active again. His lifestyle integrates physical fitness and working out in a way that is not manic or looks-obsessed. He's in great shape so his body can do the many things he enjoys, not to stand and model in too-tight clothing.

Being pretty quick on the uptake, I sensed this. And one day, out of the moo, I was walking into the neighborhood gym and asking for a tour. Ching-ching and I was a member. Soon I was swimming, lifting weights, and yes, even running (something I had always detested) on a regular basis. The whole new wardrobe was soon obsolete, and for the first time in my life, I could actually touch my toes. I can't tell you how much joy touching my toes brings me. What can I say, I'm a simple gal….

I've found that I love the gym and exercising, like I never did in my twenties. My perspective has changed, and the reasons I am doing this are different from the herd mentality I was subscribing to. While there have been some improvements in my body appearance—though the slimming did come with clucks from worried hens in my coop who thought I was getting sick cuz I no longer sported that hearty Scandinavian farmer look—that is not why I relish my daily physical exertions. Okay, I do like being phat, not fat, but it's all about the endorphins, babe, the natural high, the stress reduction, the way my rollercoaster emotional and mental states are managed, and it's the oodles and tons and bundles of newfound energy. My job has become increasingly demanding and I could never keep up if I didn't have this new source of vim and vigor that gets me up at the crack, leaping out of bed excited to face

Photo © Russell McGonagle

the day, and keeps me going, going, going til I crawl back under the covers, and fall asleep in seconds. Interestingly, I crave only healthy food now, fruits (go figure) and vegetables. Before it was an apple a year… Now I munch them like I used to munch Milky Ways, without trying, without feeling like I am giving anything up. Dig them apples.

Several months into this new regimen I went in for my quarterly T-cell and viral load tests. I was sure that my T's would have skyrocketed with all this healthy granola cardiovascular protein-conscious living. I was wrong. They came back the same, though the percentage figure had gone up one point. Big whoop. I wanted something to show for all this hard work and all I get is one lousy percentage point?

Alas, lassies, some things tests can't measure. My overall state of emotional bliss, the increased ability to manage stress, and the thrill of touching my toes and being able to swim a mile again, will never show up in hard numbers on a blood chemistry panel. Though I'd argue they play a crucial role in those measurements, visible or not.

My next T-cell count is coming soon. I'm hoping for a dramatic increase, cuz that's just how I am.

Livin' with it continued

continued from page 35

AIDS has been around almost all of your adult lives. It sure has complicated things, to put it lightly."

"And not just for gay men either," Miguel added. "In one of my support groups we were talking about this very thing. A woman in the group was complaining that it is so hard to find men. Being HIV-positive for a woman, she said, really limits her choices. For her to find a heterosexual man living with HIV who is not just looking for easy sex is next to impossible."

"I hope in my case that's not the issue. We'll see. There's so much for me to absorb, so much to learn. I'll keep you posted."

TPAN Events Calendar

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

March 2004

Date	Time	Event
Wednesday 3rd	7:30-9:00pm	Committed to Living, Nutrition & Management of HIV Disease featuring HIV nutritionist Carla Heiser
Tuesday 9th	7:30-9:00pm	Committed to Living - Update from the 2004 Conference of Retroviruses and Opportunistic Infections featuring Dr. Kimberly Smith, Rush-Presbyterian-St. Luke's Medical Center
Saturday 13th	10:00am-1:00pm	Ride for AIDS Chicago Training begins. Visit www.RIDEforAIDS.org for more information
Wednesday 17th	7:30-9:00pm	Committed to Living - Regimen Simplification featuring Dr. Amadu Dean
Wednesday 24th	7:30-9:00pm	S.H.E. Social, Women impacted by HIV celebrating life
Thursday 25th	6:00-10:00pm	PULSE, End of the month party, drink specials and prizes

April 2004

Date	Time	Event
Thursday 1st	6:00-9:00pm	Celebrations of Spring, Wine, Food and more, Belloc-Lowndes Gallery
Wednesday 7th	7:30-9:00pm	Committed to Living, Body Changes and Lypodystrophy
Wednesday 28th	7:30-9:00pm	S.H.E. Social, Women impacted by HIV celebrating life
Thursday 25th	6:00-10:00pm	PULSE, End of the month party, drink specials and prizes

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

Medical Clinic

HIV/STD screenings and full medical care for HIV-positive clients is available. Program is offered by Access Community Health Network. Call for an appointment. 10 am–6 pm.

TPAN Daytimers

A support group for people with HIV who prefer to meet during the day. Meets from 10:30 am–12:30 pm.

HEALTH (HIV Empowerment And Living Together with Hepatitis)

New support group for people living with HIV and hepatitis. HEALTH focuses on therapy and treatment concerns of people who have experienced HBV/HCV/HIV co-infection. Meets from 7:30–9 pm.

Spirit Alive!

Through a collaborative effort of AIDS Pastoral Care Network (APCN) and TPAN, Spirit Alive! fosters discussions on topics such as hope vs. despair or strength in times of adversity. Meets from 7:30–9 pm.

Tuesday

Medical Clinic

See description on Monday. Call for an appointment. From 9 am–5 pm.

Yoga

All levels of yoga are welcome. Meets from 10–11 am.

Positive Progress

A peer-led group for HIV-positive individuals in recovery. Special emphasis is placed on sobriety as a priority to effectively living and dealing with HIV. Meets from 7–9 pm.

Living Positive

HIV-positive individuals discuss how being positive affects life and relationships. Socials and speakers on occasion. Meets from 7:30–9 pm.

Wednesday

Needle Exchange Program

Through a collaborative effort of Chicago Recovery Alliance and TPAN, a free, anonymous, legal syringe exchange and HIV/AIDS prevention is offered Wednesdays from 5–7 pm, or by appointment.

SHE (Strong, Healthy and Empowered)

HIV-positive women discuss needs, concerns and issues facing women with HIV. Meets from 7:30–9 pm.

Poz Leathermen

New support and social group for HIV-positive leathermen and friends. Meets from 7:30–9 pm.

Yoga

All levels of yoga are welcome. Meets from 7:30–8:30 pm.

Thursday

Medical Clinic

See description on Monday. HIV/STD screenings and testing is available. Call for an appointment. From 12 pm–8 pm.

TPAN Daytimers

See description on Monday. Meets from 10:30 am–12:30 pm.

Needle Exchange Program

See description on Wednesday. Thursdays from 2–5 pm, or by appointment.

BUS (Brothers United in Support)

Support group for HIV-positive gay and bisexual men of African descent. Monthly socials and speakers on occasion. Meets from 7–9 pm.

Positive Now

Support group for newly diagnosed HIV-positive individuals who seek support, education and the opportunity to share their experiences in a relaxing, empowering environment. Meets from 7–9 pm.

Pulse at Berlin

A weekly social for HIV-positive individuals and friends. 6–10 pm at Berlin Nightclub, 954 W. Belmont, Chicago.

Friday

Needle Exchange Program

See description on Wednesday. Fridays from 2–5 pm, or by appointment.

Scheduled By Appointment

FASN (Family AIDS Support Network)

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

Individual Counseling

AIDS Pastoral Care Network (APCN) professionals provide individuals with one-on-one counseling on Mondays. Ask for Sherry or Betsy at (708) 681-6327.

Peer Support Network/Buddy Program

Trained volunteers provide one-on-one peer, emotional support to individuals living with HIV. Call Jim at (773) 989-9400.

Speakers Bureau

Individuals are available to community groups to educate peers on HIV, safer sex, and harm reduction. Call Matt at (773) 989-9400.

TEAM (Treatment, Education, Advocacy and Management)

This peer-led program integrates secondary prevention and treatment education to provide individuals the training and knowledge to more successfully support other individuals impacted by HIV. Call Montré at (773) 989-9400.

Reiki

Energetic healing practice that utilizes hands-on touch and focused visualization. Meets Tuesdays and Thursdays by appointment only from 2–5 pm.

Miscellaneous

livingpos18to24@aol.com

An AOL chat room for young adults (ages 18–24) who are HIV-positive. Monday through Friday from 3–5 pm.

whatever happened to that thing called "AIDS"? MAKE YOUR VOICE HEARD... VOTE 2004!

Photo provided by NAMES Project Foundation