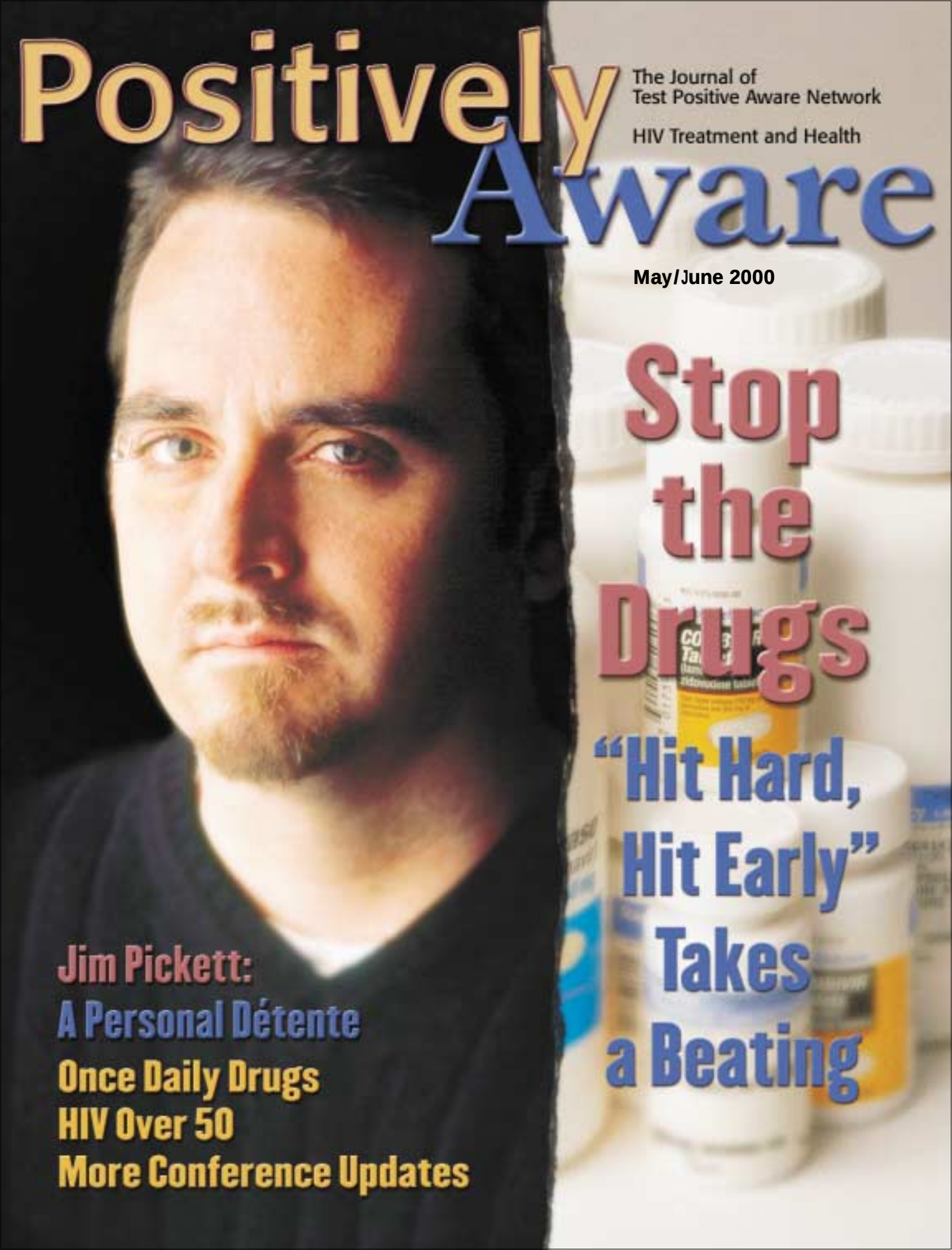
Positively Aware

The Journal of
Test Positive Aware Network

HIV Treatment and Health

May/June 2000



Stop the Drugs

"Hit Hard, Hit Early" Takes a Beating

Jim Pickett: A Personal Détente

Once Daily Drugs

HIV Over 50

More Conference Updates

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May/June 2000 • Volume 11 Number 3

Table of Contents

Departments

Features

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

You can view these (and other stories from previous issues) online at http://www.tpan.com

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Editor's Note

Stop the Confusion

When I came to *Positively Aware* four years ago, AIDS was the issue. I was writing about things like blindness and care of the dying. Soon AIDS was out and HIV was in. The number of HIV drugs quadrupled and the magazine filled with the latest potent combination news. Stories of blindness and dying were no longer greatly needed.

Now there seems to be the confusion that everyone with HIV needs to be on drugs.

Sure the medications are good, but they're hard to take. It ain't a "cocktail." It's chemo. Sick people may benefit, but almost *everyone* with HIV is pushed onto meds, often with bad results.

Then once you start, you have to keep your viral load undetectable, but you can't. At least a lot of people can't. And the ones who can often get sick and tired of it. "Success" doesn't always feel so good.

Maybe that's a new take home message people can start to understand.

Writing for *Positively Aware*, I learned something early on:

- never talk about the good aspects of drugs so that they sound like a cure; and
- never write about drug side effects in a way that makes people panic.

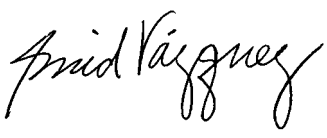
I always said if I tested positive today, I didn't know if I would start drugs tomorrow. I have to say, my answer is 80% "no." They make you sick, plain and simple. Then you turn around and there's a new theory in town, and your treatment is no longer considered to be as good. I wouldn't go on drugs tomorrow when I'm told you have to be undetectable–and nobody is. Not long term, and not without illnesses from drugs that have to be changed.

Absolutely, there are easy regimens to take. But I wouldn't want to get on the merry-go-round. Not when I have several years of good health in front of me, and knowledge of HIV will increase greatly in those years.

We write about drugs because they're important, not because we're pushing them. Back in the 80s, one of the slogans from ACT UP (AIDS Coalition to Unleash Power) was "Drugs into body," and they're no pharmaceutical company dupes. All around me here at Test Positive Aware Network people are talking about meds. They want to know the latest.

Mark Harrington's statement that no benefit has been seen from starting therapy in people with more than 350 T-cells hit me like a ton of bricks. Even though he's using a very strict standard, it's still a point that's not commonly recognized.

When you see the section "Stop the Drugs" in this issue–including a personal story and an impassioned defense of meds from a sensitive doctor–you'll see reasons why considering therapy early in HIV disease is complex and even contradictory. Maybe there's a new simple message people can take away: HIV medications aren't simple.



Enid Vázquez
Interim Editor

To Start or not to Start…

An old and controversial issue has re-emerged as a leading HIV treatment story–when to start therapy. There are not now, nor have there ever been, clear cut, black and white rules for the majority of people living with HIV. Sure, if your CD4 counts are very low (200 or less) and you have a high viral load (greater than 10,000) most "experts" agree you should start highly active anti-retroviral therapy (HAART). But what if your viral load is 10,000 and your CD4 count is 450? This is a less clear picture among the "experts".

As we (patients, doctors, and researchers) have gained experience with HAART the once clear picture of "hit hard, hit early" is much less clear. The rush to put every HIV positive person on HAART that many healthcare providers joined may not have been a good course. Clearly, for many people who had low CD4 counts and high viral loads, HAART has been a life saver. But for many people who had few signs of immune system damage and who felt good, HAART has proven to be a bad deal. Many of these people have suffered side effects that lower their quality of life while providing no proven benefit.

While there are many gray areas, there are a few points where most "experts" agree. If you have a high CD4 count (greater than 500) and a relatively low viral load (less than 10,000) you are not a high priority candidate for starting HAART. If you have a low CD4 (200) and a viral load over 10,000 you should very seriously consider HAART. If you do choose to go on therapy, it should be one of the multi-drug "cocktails" (HAART), not a one or two drug therapy. Once you decide to start therapy you must understand the importance of, and be committed to, taking the medicines on time, every day. Finally, whether you choose to be on HAART or not, you should continue to see a healthcare provider regularly (at least every four months) to monitor your CD4 count, viral load, and other important signs. Just because you choose not to be on HAART does not mean you should not monitor your health.

HIV therapy remains as much an art as it is a science. Every month brings new insight into how and when to treat. As I have said many times before, choosing a treatment is *your* option. Your healthcare provider can offer their "expert" opinion. We can provide you with "facts," guidelines and personal experiences. But ultimately the decision to go on therapy is *yours*.

Dennis Hartke

Dennis Hartke
Executive Director
Test Positive Aware Network

Keep those cards and letters coming…

Thank you to everyone who has already written letters to their Congressmen and Senators in support of the Ryan White CARE Act reauthorization (see the March/April issue of *Positively Aware* for more information). If you have not yet done so, please take a few moments to hand write a brief letter to your two Senators and your Representative urging their support for reauthorization. Briefly tell them how the CARE Act has positively impacted you or a loved one and urge them to reauthorize the act, particularly, allowing for state and local decisions as to how the monies are spent. Once you have written them, let us know you have done so by emailing us at tpanposaware@aol.com or dropping us a postcard.

Readers Forum

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

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For women only

I met a woman and when it was apparent we were "getting closer," she shared with me that she was HIV positive. (I can't express enough how much I respected her honesty and timing.) She also gave me a copy of *Positively Aware* to read. It was the November/December 1999 issue, Women and HIV.

I have to say I was disappointed in the article. You see, I, too, am a woman. I was hoping to find some statistic on my contracting the virus. We are "doing time" in a Georgia prison. There are a lot of positive women here and a lot of lesbians. Of course, this was my first issue and maybe you've addressed it before, but with a cover on Women & HIV, well…

The HIV+ and anyone who loves them will read your magazine to become *Positively Aware.*

Jennifer,
Davisboro, GA

There appears to be less than 10 cases of transmission from one woman to another, according to the latest number I have heard. However, the web site of the U.S. Centers for Disease Control and Prevention (CDC) notes that, "Women with AIDS whose only reported risk initially is sex with women are given high priority for follow-up investigation. As of December 1998, none of these investigations had confirmed female-to-female HIV transmission, either because other risks were subsequently identified or because, in a few cases, women declined to be interviewed."

The CDC also reports that, "Case reports of female-to-female transmission and the well documented risk of female-to-male transmission of HIV indicate that vaginal secretions and menstrual blood are potentially infectious and that mucous membrane (e.g., oral, vaginal) exposure to these secretions have the potential to lead to HIV infection." Dental dams, cut open condoms or plastic wrap can be used during oral sex to protect against bodily fluids.

I have put more information to you in the mail. For more information you can also write to the Lesbian AIDS Project, The Tisch Building, 119 West 24th St., 4th Floor, New York, NY 10011–1913; (212) 367-1355. LAP, a project of Gay Men's Health Crisis (GMHC), offers its newsletter free to women in prison. Good luck to you.
—Enid Vázquez

"Superinfection"

As a long-time treatment activist and reader of TPAN materials, I have come to expect a high level of reporting from you. However, in the March/April 2000 *Positively Aware*, there is an erroneous account that calls your other work into question.

Under the title "Superinfection," you write that HIV reinfection had "finally been documented" and that "so called 'superinfection'... was shown in this case," which is anything but an accurate representation of the facts of the report. It was met with enormous skepticism by the attending scientists, who believe it to be seriously flawed. At present, the HIV reinfection/superinfection theory remains *undemonstrated.*

Luke Adams,
Oakland, California

Writing that superinfection has been documented is an overstatement. However, written peer review information from the conference organizers stated, "The investigators have described a single HIV infected patient who appears to have become superinfected with a second strain of HIV after exposure to a new sexual partner. After acquisition of this new strain of virus, the rate of disease progression in the superinfected individual appears to have accelerated."

Unfortunately, it did not come to our attention that other researchers had serious problems with the case report. It did come to the attention of Paul Simmons, a registered nurse and Director of Treatment Information and Advocacy at the Center for AIDS in Houston, and a writer for their outstanding publication, RITA. *Says Paul, "There's enough intriguing evidence to say this deserves further investigation. But is it proven? No. However, it was presented as being documented. Any reasonable community person, or even many clinicians, would have thought it was documented. We're not virologists. Other HIV newsletters also reported it this way."*

We stand corrected. Thank you for bringing this important information to our immediate attention. For a longer report on this case study, see Paul's article at www.centerforaids.org, as part of the coverage of the 7th Conference on Retroviruses and Opportunistic Infections.
—Enid Vázquez

News Briefs

by Enid Vázquez

Genotyping added to latest guideline changes

Resistance testing is now recommended in U.S. HIV treatment guidelines. That's good news because it helps convince reluctant insurance companies to pay for the tests. These tests have been found useful in helping achieve the goal of reducing HIV in the blood to undetectable levels. According to the National Institutes of Health (NIH), the *Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents*, updated January 28, now "include a number of drugs the [expert] Panel feels can accomplish many therapeutic goals with minimal negative effects on an HIV-infected individual's quality of life." Also, a new section, titled "The Goals of Therapy," clarifies that eradication (getting rid of the virus in the body) is probably not possible with currently available treatments. The guidelines are available in PDF or HTML format at www.hivatis.org. Free single copies can be ordered from (800) 448-0440 or through e-mail at atis@hivatis.org; international callers dial (301) 519-0459. Write ATIS, P.O. Box 6303, Rockville, MD 20849-6303.

Pregnancy guidelines also updated

For the first time since 1998, the U.S. guidelines for HIV positive pregnant women have been updated. Included are discussions of mitochondrial (cell) toxicity, protease inhibitors and hyperglycemia, and pregnancy outcomes based on antiviral drug combinations. There's also a section outlining options for women in labor with no prior anti-HIV therapy. See the above item for how to obtain a copy. Ask for the perinatal guidelines.

Harm reduction conference

The 3rd National Harm Reduction Conference takes place October 21-25 in Miami. Titled "Communities Respond to Drug Related Harm: AIDS, Hepatitis, Prison, Overdose and Beyond," the conference includes a Spanish language track and a look at the effects of welfare reform on drug users. For a conference brochure, contact the Harm Reduction Coalition, 22 W. 27th St., 5th Floor, New York, NY 10001, Attn.: Conference Coordinator. Fax (212) 213-6582 or e-mail hrcconf@harmreduction.org. The cost of the conference is $360 before August 15 (or $90 a day) and $450 afterwards. The deadline for scholarships is July 3.

AIDS numbers: Men of color outpacing whites

The U.S. Centers for Disease Control and Prevention (CDC) has reported that for gay and bisexual men in 1998, there were more new cases of AIDS among men of color than among white men. For years AIDS cases among African Americans and Latinos (both men and women) have been out of proportion to their number in the general population. This is the first time, however, that their numbers outpaced that of whites in any category.

Stop-and-go therapy

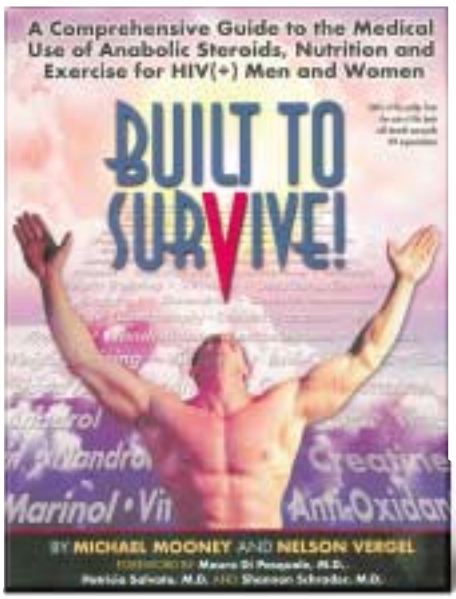
The National Institutes of Health still has openings in a study comparing a group of HIV positive people receiving continuous HAART (highly active antiretroviral therapy) with a group using HAART on and off ("intermittent therapy") with intervals of one month off therapy followed by two months on therapy for 22 months. Participants must have a T-cell count of at least 300 and a viral load less than 500 for three months prior to enrollment, and a viral load less than 50 on screening. NIH will provide travel to the Clinical Center in Bethesda, MD. For more information, contact Christian Yoder, RN, MPH, at (800) 772–5464, ext. 57745.

Crixivan and Viracept

Which is it–does Crixivan (indinavir) go up or down in the double protease inhibitor combination with Viracept (nelfinavir)? We had it both ways in our annual HIV Drug Guide in the January/February issue. It was correct on the Viracept page: Crixivan blood levels go up. However, the doses of both drugs remain standard. Thanks go to a careful reader in Kentucky for catching that.

Viracept now film coated

Oh, happy day. In March, Viracept (nelfinavir) protease inhibitor tablets became available with a film coating, so they no longer dissolve in your mouth, leaving that icky taste and feeling. They're also a little smaller. Dosage remains 750 mg three times a day (as with breakfast, lunch and dinner, three tablets each time). Or people can use the recent Food and Drug Administration (FDA) approved dosage of 1250 mg (five tablets) twice a day. For more information, call toll free (888) VIRACEPT (847-2237).



Muscle up for survival

HIV wrecks muscle tissue as well as immune cells. Weakness, fatigue, wasting and even death can result. Now the non-profit PoWeR (Program for Wellness Restoration) has come out with a new book on beating the virus at its own game. *Built to Survive: A Comprehensive Guide to the Medical Use of Anabolic Steroids, Nutrition and Exercise for HIV(+) Men and Women* is available for $24.95 retail or for $18 plus shipping and handling through the Houston Buyer Club, (800) 350-2392 or (713) 520-5288, or visit amazon.com. Founded in 1994, PoWeR helps people with HIV regain their health through a comprehensive program of nutrition, exercise and anabolic steroids. Perhaps by reading the book, you don't need to lose health in the first place. If you (or a stubborn doctor) are afraid of anabolic steroids, the book covers the myths behind such fears. Read the organization's newsletter, *Medibolics*, at www.medibolics.com. The group also runs a hotline (although not toll-free); call (310) 360–0650.

New HIV magazine

The Los Angeles-based AIDS Healthcare Foundation expects to have its first issue of *Thrive* magazine out this summer. The new national magazine targets minorities living with and impacted by HIV. According to a foundation press release, the publication "seeks to address the severity of the impact of AIDS among people of color by providing minority communities a unique, multicultural perspective on resources and information concerning HIV education and treatment." It goes on to quote editor Peter Hale as saying, "Our intent is to reach communities most challenged by the AIDS crisis, who, for a number of reasons, are not accessing medical care for the treatment of HIV. By providing a magazine that is informative, accessible and entertaining, we hope to empower readers with vital information to assist them in effectively managing their health." The magazine also hopes to make healthcare providers more sensitive to the needs of people of color living with HIV. AIDS Healthcare Foundation operates six full-service healthcare centers where patients are seen regardless of ability to pay. For more information, contact Monica Sudduth at (510) 450-0190. Visit www.aidshealth.org.

New Videx formulation

In late January the manufacturer of Videx (ddI) submitted an application to the FDA for approval of the long-awaited enteric coated formulation of the drug. "Enteric" means the drug won't dissolve until after it gets past the stomach. The big, chalky Videx tablets have an antacid buffer coating that's necessary for absorption by fighting off destructive stomach acid, but causes a bad taste, as well as diarrhea. An enteric coating eliminates all of that. The new formula is a capsule filled with enteric coated Videx beads. And it's a dose of only one capsule once a day, rather than the two tablets once a day. Last year Videx became the first nucleoside analog HIV drug (the kind that's in the same category as AZT and Epivir) to be given once a day. The FDA expects to make its decision by the end of July.

The Fair Price Working Group, made up of HIV treatment advocates, warns that, "Although Bristol Myers Squibb hopes to position the improved formulation as a virtually 'new drug' (and thus justify a major price increase) it is simply a new version of an old drug that solves a long-standing problem in its formulation. Discussions with the company suggest that they hope to be pricing the EC ddI as much as 35–40% above the price of the current version of the drug." The group said this proposal would add approximately $1,000 to the annual price of Videx.

Propulsid dead

Propulsid (cisapride) will be off the shelves come July. The drug, used for treating severe heartburn, has caused heart rhythm problems, and even death, in people with heart conditions or those taking certain drugs, including antidepressants and HIV medications.

Aidsmed.com website

There's a new website in town, and it's quite handy. Check it out: www.aidsmeds.com. It's written by people with HIV, including respected writers like Spencer Cox. Besides basic (but comprehensive) information, there are question-and-answer sections for various topics.

Stop the Drugs—"Hit Hard, Hit Early" Takes a Beating

by Enid Vázquez

True or false: Newly infected people with HIV are being put on powerful drug therapy long before they need it.

Answer: Depends on who you talk to.

In 1996, "hit hard, hit early" became popular in HIV therapy. Go in with as strong a drug combination as you can, as early in the disease as you can. Now, four years later, treatment advocate Carlton Hogan says, "It's so out of fashion these days." Another longtime treatment advocate, Theo Smart, calls this the era of "retrenchment."

No one disputes that strong drug combinations benefit people with advanced disease. Problem is, the assumption became that what's good for people with AIDS must be good for people with HIV. What looked like a simple solution–pop some pills–covered up the difficult realities of side effects and other problems with HIV treatment–such as, maybe it's not such a good idea to rush onto a drug regimen.

> *"Giving a complex three-drug regimen to someone who's not ready to take it is a recipe for resistance and failure. We're also plagued by a number of poorly understood long-term toxicities."*
>
> *–Dr. Joel E. Gallant,* Positively Aware *Annual HIV Drug Guide, January/February 2000*

Wait, wait, wait

Mark Harrington, a leading HIV treatment advocate, has been saying for years that waiting a long time to go on drugs can be a good thing. He calls the reasons to "hit hard and hit early" theoretical. In a talk last year at the 11th Annual AIDS Update Conference in San Francisco, Harrington pointed out that there are no data from randomized controlled trials (which generate the most scientifically reliable information) showing any clinical benefit from antiviral therapy in people with T-cell counts above 350. Of course, the way science operates, such evidence would take time and trouble to gather. It would be great to know what happens to one group of people on drugs and one group of people not on medication, but that study has not been done, and is not in the works. Such a trial would take a long time and require large numbers of participants to obtain scientifically valid answers. The question of viral load (amount of HIV in the blood) is less clear. Harrington says that at this time, a reasonable goal is to prevent AIDS from developing within three years, which might be indicated by having two consecutive viral loads over 100,000. But he notes that this concept is based on only one study. At a follow-up talk at this year's conference in March, Harrington gave his audience a new slogan to think about: Hit hard, but only when you need to.

Harrington had stunned doctors two years earlier at the World AIDS Conference in Geneva when in a speech there he announced that he was glad he waited until he had only 200 T-cells before going on therapy. With powerful drugs drastically cutting the death rate due to AIDS, shouldn't everyone with HIV be put on medicine?

The problem is that the survival and health benefits were seen in people with advanced disease. Harrington notes that one of the most frequently cited studies supporting strong combination therapy showed survival benefits, but in people who had less than 200 T-cells. More recently, five observational studies did not find a benefit for groups starting therapy above 200 T-cells compared to groups starting below that. AIDS deaths have gone down, but newly infected people aren't at risk of dying. Nor have they ever spent time in a hospital. It's the medicine that's making them sick. Yet, the public perception of the "cocktail" has developed to the point that even today many newly infected people are automatically put on medication.

Harrington, who tested positive in 1990, benefited from all the HIV knowledge gained by the time his T-cells went down to 200 in 1996. He benefited from all the mistakes of the past, and that is part of his message. As he told his audience in Geneva, he bypassed AZT monotherapy, which was later found to be inferior. Nor did he take AZT with Videx (ddI), the next therapy down the pike, also later found to be inferior. On he went,

until the best therapy to that date, triple combination with a protease inhibitor, came along just when he needed it most.

> *"There may be no advantage to starting therapy at a CD4 count above 200, according to a review of several large cohort studies presented at the British HIV Association Autumn meeting in London last week."*
>
> "Cohort Evidence Challenges Conventional Wisdom"
> *by Keith Alcorn, aidsmap.com, October 20, 1999*

In theory...

There are, of course, reasons behind "hit hard, hit early." People with HIV hope to protect their immune system and never progress to AIDS. There are difficulties with that premise, and the arguments for hitting early remain theoretical. Harrington lists some of the main arguments for early therapy and then refutes them.

"Hitting early preserves immune function." He says that in general, immune function is fine until T-cell counts go below 350. There might be some damage going on, but it's not threatening to your health, and it's not permanent. He also notes that according to various treatment guidelines, symptoms of disease are also an important indicator for starting therapy, not just a magic lab number.

"Hitting early delays resistance." Drug resistance usually doesn't develop until drug is in the body. Therapy that doesn't "work" well according to the goal of achieving undetectable viral load may actually speed up resistance.

"Hitting early may speed time to eradication." Very few people bought into the idea of eradication. Besides, it was first estimated that getting rid of HIV in the body would take three to five years and eradication is now estimated to take 60 to 70 or more years with current approaches.

"Hitting early preserves anti-HIV immune function, or anti-HIV CD4 cells." This may be true, if someone's been infected within the past six months. But even then, the evidence comes from only a small group of people. Moreover, more recent evidence indicates that HIV-specific T-cells are found throughout chronic infection, but decline when using HAART.

What if you wait? Harrington notes that "impressive" immune restoration has been seen in people who started therapy quite late in their disease. Waiting until you reach 350 T-cells, he suggests, does not cause irreversible immune system damage or disease. The recently updated (February 2000) treatment guidelines from the International AIDS Society (IAS-USA), along with the British, French and Brazilian guidelines, all suggest 350 T-cells for starting therapy.

There's nothing wrong with these theories, until people suffer for them. In HIV, the problems of side effects and adherence were underestimated. Sick people got better, but healthy people got sick. For them, the effects of the drugs on the body and mind were a big price to pay. Side effects (including disfigurements) deteriorate quality of life, a problem that many healthcare providers didn't care anything about. In addition, people sickened and sometimes died as a result of the side effects, not the disease itself. Doctors' answering services were often unhelpful, and many times doctors didn't respond to desperate calls from patients, or responded weakly. Then, too, taking pills every day for a serious disease creates a severe psychological burden, sometimes leading to the inability to take the drugs. Moreover, the many drug combinations themselves often had rigid requirements that were hard to adhere to.

For example, for a while the gold standard of care was a three-drug regimen that included a protease inhibitor, Crixivan (indinavir), which had to be taken every eight hours sharp. That was just too easy to forget. Plus it had to be taken without food and with lots and lots of water throughout the day. Few people could comply, and excruciatingly painful kidney stones were common.

Health benefits of HAART

True, the benefits of "hit hard, hit early" are theoretical. Nevertheless, there are obviously many benefits people get, at least from hitting hard, if not early. Women on HAART (highly active antiretroviral therapy) are much less likely to give birth to a positive child. Vanished or controlled are opportunistic infections (0Is), the illnesses that don't bother people with healthy immune systems but attack those with a weakened one. Even people with AIDS and OIs are able to stop taking medicines that prevent those serious complications from re-occurring. Regular infections become less severe and more easy to treat. healthcare providers who work with children seem unanimous on the tremendous improvements they see in kids on HIV meds. Without them, children are lethargic and their growth and development–even social–is stunted.

Still, side effects and being plain old sick-and-tired of taking pills cause many people to stop HAART. Yet, truth be told, others experience no side effects and take the same drugs for years with good lab numbers and better health. HIV is (as so many advocates and healthcare providers like to remind us) an individual disease.–Enid Vázquez

Yet adherence rates, for all the combinations, need to be higher than adherence for any other disease. Last year, researchers reported that if HIV drugs are not taken correctly 95% of the time, drug resistance (and treatment failure) usually results. In other diseases, 80% adherence is usually all right.

Research also continues to show that healthcare providers accidentally exposed to HIV are unable to take an HIV drug combination correctly for one month (the amount of time thought to prevent infection). The majority fail to do so. These findings give a clue to what people with HIV must put up with. Other researchers found that adherence in HIV goes down more and more with each passing year.

When drugs start to fail people (according to the treatment standard of having undetectable virus in the blood), a switch is needed to another drug regimen and options soon begin running out. Estimates of treatment "failure" range from 20 to 60% of all people on the therapies. (Viral load is one measure of treatment effect, and people with detectable viral load could still benefit from therapy when looking at other measures.)

"There is a trend to more doctors treating to preserve CD4 at this point, rather than to keep viral load undetectable at all costs, says Harrington. "The pendulum is swinging."

> *"If you go to a doctor, you're probably going to be put on drugs. And if you're not ready, maybe you shouldn't be on them. People come in here all the time and they'll say, 'Oh, I stopped taking all of that.' The doctors didn't explain the medicines and the side effects."*
>
> *—Joe McCue, support group facilitator, Test Positive Aware Network (publisher of* Positively Aware*), Chicago*

Disgruntled genius

Ironically, Harrington is part of the group of advocates who persuaded the Food and Drug Administration (FDA) to speed up the drug approval process so that people with HIV could get medicines faster. Part of the recognition he received for his role in that struggle came in a "genius" award from the MacArthur Foundation, with a $240,000 check attached.

"We wanted drugs available," he says of the struggle for accelerated approval. "It doesn't mean we wanted everyone to take them. It just means they should be taken by people who need them." Accelerated approval essentially puts drugs that are still experimental out on the market. They have been found to be safe and effective, but have not completed the full approval process of the FDA.

It's also ironic that he criticizes the HIV treatment guidelines of the U.S. Department of Health and Human Services (HHS), since he's a member of the panel of experts that puts those guidelines together (they're not unanimous opinions). But, he points out that even though the thick document states many times that the decision to start therapy is a highly individual choice, doctors instead simply focus on the chart listing the best drug combinations to take. The guidelines are just that, guidelines, created to help doctors and people with HIV understand the latest knowledge around treatment, since there is no standard of care for the disease.

> *"While the guidelines represent the current state of knowledge regarding the use of antiretroviral agents, this is a rapidly evolving field of science, and the availability of new agents or new clinical data regarding the use of existing [drugs] will result in changes in therapeutic options and preferences… Although there is theoretical benefit to treatment for patients with CD4+ T-cells greater than 500, no long term clinical benefit of treatment has yet been demonstrated."*
>
> HHS Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents, *January 28, 2000 (latest update)*

In a perfect world

If HIV medications were perfect, there would be no problem. Doctors, who used to watch hopelessly as their HIV patients got sick and died, were happy to see all that change with potent drugs. Today treatment advocates continue to press for early access to experimental drugs. Many of them are themselves waiting for a new drug, a new hope. But the severe problems with current treatments are clear. Many prominent HIV specialists have expressed frustration with the regimens. Even the ones who advocate hitting hard and early have trouble getting around the side effects issue, when the long-term results of treatment are still unknown.

Understanding of HIV and the immune system is continuously growing. What's important today may tomorrow be only a small part of the picture. As always, waiting to go on medications can preserve future options, with its promise of new and better therapies. That's not a new theory, but maybe it's one that didn't get enough weight. In HIV, people who are newly diagnosed often have no clue what's in store for them when they start therapy. There's only one thing that's for sure for all positive people whether they're on therapy or not: see a specialist and monitor closely .

> *"My take-home message is, There's nothing wrong with hitting HIV 'hard' when it's the right time. But, until we have evidence from randomized studies, there's no reason not to let the immune system control the virus until CD4 drops below 350."*
>
> *—Mark Harrington*

Stop the Drugs–A Personal Détente

by Jim Pickett

Can I ask you why it is that a 34-year old man with 1030 T-cells and a viral load measuring less than 50 ("undetectable"), who has never had a moment of HIV-related illness, is on HAART?

Doesn't that seem crazy?

That man is me, and I may be crazy, but the drugs themselves have given me the only HIV-related illnesses I have experienced. Why are we heavily treating people like me? *Why?* It's like using the atomic bomb on a village of 20 pygmies (my apologies to all pygmies). Over and over and over, day after day, decimating the same little village, the same little pygmies. We need to–I need to–save that firepower for something a little bigger, I think.

To be clear, when I started on HAART two and a half years ago, I had T-cells in the high 400's and a viral load that was rather detectable, in the 70,000 range. I started on a protease-based combination when I saw my numbers initially begin to change, from a stable T-cell count that had been numbering in the 700's and a stable viral load which had been happily hovering around the 10,000 mark. My numbers changed dramatically for the good, right away, as soon as I started the cocktail, and my counts continue to hold strong despite way less than perfect compliance. Way less than perfect.

Never, never, *never* once since I began drugs has anyone ever indicated that I may be able to take a breather. *Ever.* When I began my regimen I asked my doctor if this meant that I'd be popping pills forever, every single day, in some shape or form, for the many years I am planning on being here. Forever? He said yes.

But isn't that a ridiculous, completely impossible notion? And especially now, seeing the horrible things the drugs are in fact doing to people–the drugs, not the HIV, but the drugs used to "treat" HIV–AIDS wards treating "drug complications" and "adverse events," people with heart attacks, pickled livers, bad kidneys, anemia, "deadly rashes," lipodystrophy, permanently crippling neuropathy. Is the risk less than the benefit for someone with scads of T-cells and a few whimpy viruses?

I have felt like shit for the last two and a half years. Nauseous and bloated and gassy and urpy and poopy and tired and headachy and cranky... no, those ain't necessarily my normal states. Why am I making my life so exceedingly difficult, ball-and-chained to decidedly non-recreational drugs when I am basically healthy? Why am I not saving these drugs for when they will do me the most good, when the risk of nasty side effects is actually less than the benefits I will obtain? Why am I on state aid to receive these drugs? (I couldn't possibly pay for them after my clinical trial ended.) Because doctors and large, multinational pharmaceutical companies still actually push the agenda of "eradication" via the obsessive need to keep the viral load "undetectable." Why is that? We all know eradication is a fallacy, a very bad joke, so why, are we still telling it over and over and over in the hopes it will be funny? Well, there is a lot of money to be made. My simple little regimen of 18 pills per day runs about $12,000 a year–some pretty good coins.

Why are friends and family and lovers and social workers and fellow HIV-ers and everybody and their sister's cousin's childhood crush all on the bandwagon, too?

I certainly understand that the drugs have made for many miracles in many people's lives, have brought them back from the brink, have given them second and third lives. Their experience of side effects is fundamentally different from mine, they are nuisances and inconveniences to be sure, but a whole lotta nada compared to some of the terrifying, excruciating, degrading things that can and will happen to you with AIDS. There are *many people who need the kind of firepower HAART offers.* Won't argue with you there.

But I am not one of them, yet. Am I? So again, I ask, why am I using the big guns when I could still be playing with water pistols?

We are all obsessed with drugs. We, me included, have listened to people who whisper their stories of going off meds, or choosing not to do them period, with a particular look of pity/horror, and we, me included, try to talk them into thinking that decision through again. Drugs are the answer, after all. They whisper their stories because they are off the party line, out of the mainstream, challenging the status quo. They whisper them because they are heretical. Radical. Nuts. But that's all changing. Going off meds doesn't seem so crazy, so suicidal, anymore.

I am on a doctor-sanctioned drug holiday. Hooray! I have agreed to monitor the markers of health that are so important to everybody, i.e., T-cells and viral load. Hooray! I will dutifully give blood and have it tested, I will wisely discuss the results with my doctor. Hooray! But I am, and will be, much more hesitant, and cautious, about going back onto another cocktail, or anything at all for that matter. Hooray for care, caution, preparation! And I say this, not knowing, and without regard to, what the lab indicators will indicate. How I feel

should count somewhere. It's not just a viral load game. But there are no known lab tests to determine the amount of "feeling like shit" a person has.

We need to be wary, more wary. We don't need to panic, but we need to be wary. We need to carefully sift through the hype, through the many messages out there. Competing for our affection. Enticing us, wooing us. We need to be forever mindful that the drug companies are mighty. They do indeed have a lot of control and influence, too much, over research and our physicians–*we need to understand that*. It's not just their slick ads we need to question. We need to be clear of the role these pharmaceutical giants play when our doc advocates a toxic toxic toxic cocktail the very day we test positive. It's all part of the combination. We need to be clear that a "cure" will mess up this money making machine. We need to be clear that reducing consumption of their luxury-priced goods is not good for business.

I definitely think the meds have their place and time, and have the potential for great benefit. But there are forces who are very powerful and persuasive who want us to make the place for meds "here" and the time "now and forever." "Hit hard, hit early, never stop hitting." It is big business. And it is the message that continues to rule the day, glossily, breezily, rampantly, though I believe it is beginning to lose ground. And that makes me hopeful.

Armageddon

"If I was positive, I would go on antivirals within an hour," says Dr. Mary Romeyn, an HIV specialist in private practice in San Francisco. She calls HIV "Armageddon"–the final battle between good and evil.

Hit hard, hit early? Yes. "First, we know that our bodies reach a set point [the lowest viral load] early in HIV where the incredible virulence of the virus is matched by the incredible power of our immune system," she says. "Second, unlike the virus, our immune system is not replicating. Its ability to replicate is quite finite. HIV re-invents itself every day and a half. We reinvent ourselves every 80 years, if we're lucky. So the virus has an advantage.

"Also, early on the cells that are preferentially recognizing [thereby destroying] HIV are killed off. Past that set point, with a high viral load set point [allowed to occur], we're probably lost HIV specific immune power," Romeyn says.

Treatment–hard, and early–helps people fight off new strains of HIV from developing in their bodies and maintain the cell lines they have. Without therapy, she says, "the cell line is over–good-bye."

Still, she believes therapy continues to be useful beyond that point. There are also treatment advances that are coming, such as mediators that help put out naive cells to recognize [and fight] HIV."

"One guy won the Crixivan lottery. He's out five years on the same regimen suppressed [undetectable]. Some people in my clinic are four years on the same regimen suppressed. It's really hard to do," she admits. Her clinic might be more likely to attract people who also believe in hit hard, hit early. They're not necessarily put on HAART right away. Their emotional and social needs are considered before a treatment is agreed upon. "Immune systems are not the only thing we have to treat," she notes. Beyond that, we have to treat and support the will and character it requires to fully fight this fight.

"Critics like Mark Harrington have to be deeply respected because they live through it. But when others are researchers who don't work in the pit with patients and don't fall in love with them and have to keep them alive, I think they sometimes lose perspective. What's fashionable is not always what's right," Romeyn says. Still, she says, "if someone came in with a set point of 1000 T-cells and 93 viral load, I would feel I can't argue with that kind of success." Treatment then would be deferred with close monitoring. She said research presented early this year points to ways of monitoring how the set point is settling.

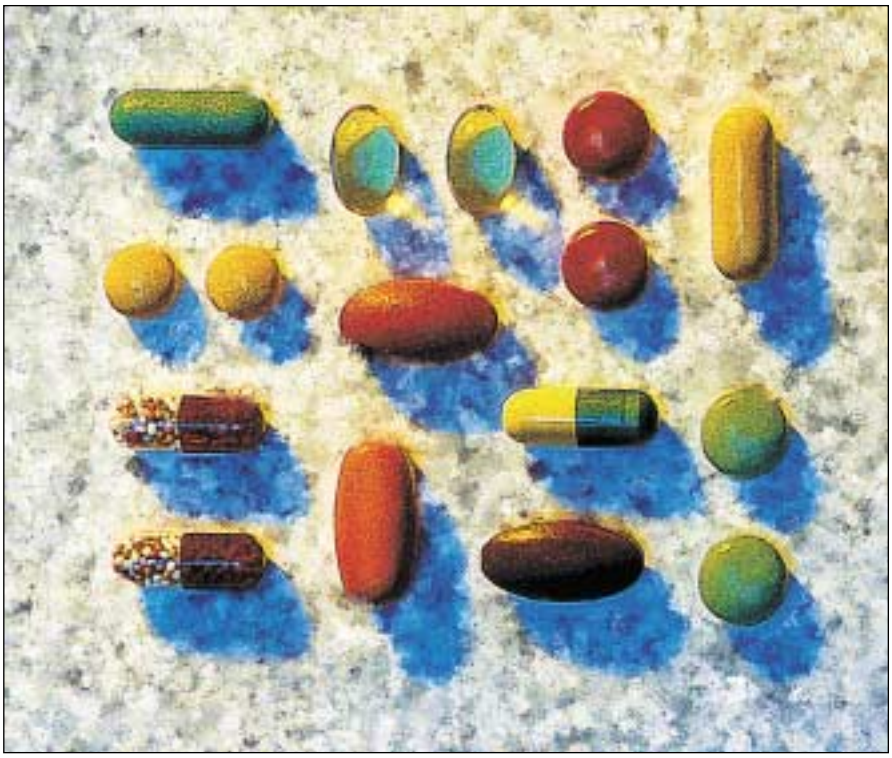
She takes issue with the idea that regimens are likely to fail people. "You should be able to suppress them," she insists. "Given a patient who is that aggressive about ordering their life and given the more tolerable regimens we have now, I want to hit hard. Just because there's a lot of mediocre medicine and a lot of mediocre adherence doesn't mean we say, 'forget it.' Strive for excellence." Dr. Romeyn would not list regimens she considers tolerable, because she says such decisions must be highly individualized.

Still, she admits that regimens are less likely to keep advanced patients suppressed, which she believes is only another argument for hitting early. "This is the battle for generations and generations to come. These are our kids and they're dying and we can't let them die."
–Enid Vázquez

Dr. Romeyn is the author of *HIV and Nutrition: A New Model for Treatment*.

New Drugs Coming Down the Pike

by Glen Pietrandoni, R.Ph.



"Once" upon a time…the alarm clock had to be set every few hours, 24/7, as a reminder to take a dose of AZT. You got through it. Then came combination therapies, 12 pills at a time, three times a day, with food, plus a few others on an empty stomach a couple of hours later. You got through it. Then came along Crixivan every 8 hours or chewable Videx twice a day. Once again you got through it. Norvir liquid, enough said. At last, there is some good news. Once daily dosing is here for some drug products and just around the corner are quite a few more drugs.

Ideally, drugs that can be dosed once a day must be very potent, have minimal side effects, and should be "forgiving" for late or missed doses. In order to allow prescription drugs to be brought to market quicker, pharmaceutical companies file for Food and Drug Administration (FDA) approval before dosing studies are finished. Once the drugs are on the market, they are still being studied in order to get approval for easier dosing. In some situations, clinicians can use pharmacokinetic (PK) data to make educated adjustments in dose and will prescribe drugs with "off label" directions. Basically, PK data tells us how much drug is in the blood and for how long. Blood levels need to be above a minimum level to be effective, but not too high as to cause toxic effects.

For example, because blood levels remain high for Viracept, it is now approved for twice daily dosing (5 tablets twice daily, instead of 3 tablets three times daily). Other times, the FDA rejects changes to originally approved dosing regimens, as in the case of Crixivan. Twice daily dosing of Crixivan did not show high enough levels of drug and the virus became resistant to the drug. Unless used in combination with other protease inhibitors, Crixivan is only approved for dosing every 8 hours, and never twice daily.

Before you get too excited about the possibility of leaving all your medicine at home and feeling free of the ball and chain, there are a few things you must know. If daily dosing were available, then each daily dose of the drug would become even more important. With adherence needing to be above the 95% level, even two missed doses per month could put you at risk for viral resistance and drug failure. It may also be important to be consistent with the time of the dose from day to day. The window for taking medication may not be much more flexible than 24 hours so drugs must be taken at the same time every day. The studies being conducted on once-a-day dosing regimens will address these issues, so don't try this at home. Only your doctor can change the way to take your prescription drugs.

As mentioned, there is a large effort by the pharmaceutical companies to make taking the drug cocktails easier for people to handle. It has been shown that a simple regimen is easier to take and is effective for a longer period of time than more complex drug therapies. (Duh). But until once a day dosing is available, you'll get through it.

Glen Pietrandoni is director of Clinical Pharmacy Services for the HIV-specialty Walgreens pharmacy located in the Howard Brown Health Center of Chicago.

See chart on following page.

Once-daily drugs available now

Sustiva	600 mg once daily approved; single 600 mg tablet soon
Videx (ddI)	400 mg once daily approved; 400 mg enteric coated tablet soon
Viramune	400 mg once daily being studied
Epivir (3TC)	300 mg once daily being studied
Crixivan/Norvir	1000 mg/100 mg or 1000 mg/200 mg once daily being studied
Fortovase/Norvir	1600 mg/100 mg once daily being studied

Once-daily drugs in research

Coviracil (FTC)	once daily nucleoside similar to 3TC
Lodanosine (F-dda)	once daily nucleoside similar to ddI
DOTC (BCH)	once daily nucleoside similar to 3TC
GW420867X	once daily nucleoside
Adefovir	once daily nucleotide, will not be available in the US
Tenofovir (bis-POC PMPA)	once daily nucleotide, limited expanded access in the US
DPC 961 and DPC 963	once daily non-nucleoside. Phase III studies for DPC 961
PNU142721	one or two times daily non-nucleoside, related to delavirdine
BMS 232632	one or two times daily protease inhibitor, phase I/II
L-756,424	one or two times daily protease inhibitor, will be dosed with indinavir 1600 mg/800 mg once daily, or 800 mg/400 mg twice daily
T-1249	once daily second generation fusion inhibitor (sub-Q injection)

Conference Update

by Enid Vázquez

More news from the 7th Conference on Retroviruses and Opportunistic Infections (see also page 37). This major HIV/AIDS conference took place in San Francisco, January 29–February 2. Visit www.retrovirus.com for complete information.

When T-cells and viral load don't match

Many people have a "discordant" response to HAART (highly active antiretroviral therapy). Either their T-cells go up but their viral load (amount of HIV in the blood) also goes up, or both numbers go down. A look at 956 German patients (half of them on therapy for the first time) found that a third of them had a discordant response. Researchers reported that an increase in T-cells was more important for clinical benefit than a decrease in viral load. People who had a decrease in viral load but no increase in T-cells had as much disease progression as those who didn't have a viral load drop and also didn't have a T-cell increase. People who responded well on both measures, not surprisingly, did the best clinically.

Is HAART enough?

That was the title of a report from Philadelphia researchers. They noted that more AIDS deaths in 1999 were being seen in an urban population despite earlier access to HIV care and HAART, plus higher T-cells and lower viral load, when compared to the deaths in their clinic in 1998. The patients also had better adherence and less illicit drug use. The three most common causes of death for both years were wasting, complications of hepatitis C infection and mycobacterial disease. The researchers reported that, "Further research is needed to develop additional interventions that will impact the mortality associated with this disease across a broad range of populations." They also reported that, "An increasing number of minority women initially presented undiagnosed or newly diagnosed with late complications of HIV infection. This may be due to a variety of factors, including lack of awareness of HIV, lack of perceived risk of HIV infection or fear of the stigma of HIV which persists in some communities."

Women's cancer

Certain strains of HPV (human papilloma virus) are associated with cervical cancer. Baltimore researchers reported that women benefit from HAART by being more likely to stop an HPV infection from getting worse, and even reversing HPV disease. The WIHS doctors (Women's Interagency HIV Study) called the finding "a major additional benefit" of HAART.

A multi-center WIHS analysis found that while most women with HIV will have an abnormal finding on a pap smear, the risk of serious abnormalities is much less.

Positive women with normal menstrual cycles have the same levels of the hormones progesterone and estradiol as do HIV negative women. In addition, the hormonal levels are the same among the positive women regardless of viral load, immune status or HIV drugs.

Women's deaths

The U.S. Centers for Disease Control (CDC) looked at the causes of death in 176 HIV positive women between 1993 and 1998. The majority (56%) died of AIDS or HIV-related causes. For the remaining women, a third died from drug-related causes, including overdoses (7%), endocarditis or sepsis (5%) and hepatitis (2%). The CDC urged drug treatment services and hepatitis vaccinations to help reduce deaths from these causes.

Infants and AZT

Infected infants who have drug resistance to AZT (Retrovir) (received during birth to prevent transmission from the mom) were twice as likely as other infected babies to have rapid disease progression, but the difference was not statistically significant. The information came from 57 infants in a multi-center Women and Infant Transmission Study (WITS) in 1994. The report went on to say that infant use of AZT during the first six months of life was not associated with disease progression.

Cesarean cost-effective

An elective cesarean section, which is major surgery used to prevent HIV transmission, was found to be cost-effective. This was true whether women received no prenatal anti-HIV treatment, took AZT or received AZT in combination with Epivir (3TC). The National Institutes of Health (NIH) doctors noted that, "Based on the findings of this study, elective cesarean section is likely to remain cost-effective over a wide range of clinical and economic scenarios." While there are health issues surrounding the use of elective C-sections, cost-effectiveness is helpful to address because it may help insurance companies to agree to pay for the surgery. In this report, as in others, elective C-sections were found to further decrease transmission above and beyond the use of medicine taken to reduce that risk.

Viramune in new moms

There was good news and bad news on the use of Viramune (nevirapine) to prevent transmission during childbirth. The good news is that Viramune was better than short-course AZT at preventing transmission. AZT is currently the standard of care for preventing infection from the mom to the infant. Viramune was used only twice (one 200 mg tablet given to the mom at the onset of labor and then 2 mg per kilogram of weight

given to the infant within 72 hours of birth). The bad news is that 3 out of 15 moms who received Viramune in a study went on to develop drug resistance. The risk of losing future treatment options must therefore be considered.

Once daily, truly

Preliminary results from an honest-to-God once-daily HAART combination were provided. French researchers looked at a combination of Sustiva (efavirenz), Videx (ddI) and the experimental drug emtricitabine (FTC), which is in the same drug class as Videx. At 24 weeks, 24 of 28 participants had less than 20 viral load. Of a total of 40 study participants, 60% experienced what the researchers called "transient" central nervous system side effects and 25% had "mild" diarrhea. There were six serious side effects (Grade 3 or 4) and one discontinuation. The study was conducted with people who had never before taken HIV therapy.

The newest protease

Coming soon (well, in several months) to a pharmacy near you is Aluviran (lopinavir, formerly ABT-378/r). In a trial with people whose previous protease inhibitor therapy failed to keep them undetectable, the powerful new protease inhibitor successfully dropped viral load to less than 400 copies in 84%. This was 49 of 58 people, at 48 weeks (a good long time, scientifically significant).

Looking at a tougher analysis, intent-to-treat, whereby all participants are included whether or not they're still on the drug or moved out of the country or whatever, 70% were below 400. The mean T-cell increase was 125 (half the participants had more than this, half had less). Side effects were nausea, diarrhea and asthenia (weakness or loss of strength). The drug is combined with a little bit of Norvir (ritonavir). Lopinavir is currently available through expanded access, a program making promising experimental drugs available to people who desperately need them.

Cholesterol-lowering drugs

(The following is taken directly from a newsletter of San Francisco's Project Inform). New information on the "statin" drugs used to lower cholesterol and their interaction with protease inhibitors show that they should be used with caution. Fifty-two volunteers took ritonavir (Norvir) and saquinavir (Fortovase) at the standard 400 mg dose each taken twice a day. They also took one of three statins: pravastatin (Pravachol), simvastatin (Zocor) or atorvastatin (Lipitor). The statin dose was 40 mg once a day. The study found that pravastatin levels decreased 47%, atorvastatin increased 343% and simvastatin increased 2,676%. These results suggest that pravastatin can be used safely with protease inhibitors without a dose adjustment. Other statins like fluvastatin (Lescol), cerivastatin (Baycol) and lovastatin (Mevacor) behave similarly to pravastatin, atorvastatin and simvastatin respectively.

The activity of the statins are not directly related to their drug levels found in blood, but statin side effects are directly related. Atorvastatin should be used with great caution. Simvastatin should not be used with ritonavir and saquinavir and likely applies to other protease inhibitors as well.

One serious side effect associated with increased statin levels is a muscle disorder called "rhabdomyolysis." People experiencing muscle aches should report this to their healthcare providers. People with mild kidney dysfunction (a creatinine clearance above 1.5 mg/dL) are more at risk for developing statin side effects. Gemfibrozil (Lopid), a drug sometimes combined with the statins to lower triglyceride levels, can also result in muscle disorders and kidney failure.

Doctors' Roundtable

edited by Enid Vázquez

The following transcript is edited down from a teleconference hosted by HIVandHepatitis.com, as part of their HIV Treatment Live! monthly teleconferences. The topic is "Report from the 7th Conference on Retroviruses & Opportunistic Infections," which was held during the first week of February. For a complete transcript, contact ronbaker@pacbell.net or write P.O. Box 14288, San Francisco, CA 94114. Request to be put on their mailing list for notices of future teleconferences. The clinicians and researchers speaking in this edited version are Michael S. Saag, University of Alabama at Birmingham; David Cooper, National Centre in HIV Epidemiology and Clinical Research, University of New South Wales in Australia; and Stephen Becker, private practice in San Francisco.

Saag (moderator): Let's jump right into antiretroviral therapy, especially on issues of when to start treatment. Steve, there was a poster by John Bartlett about a "meta-analysis." Can you tell us about that?

Becker: Sure, although I think it's important to say that the question of when to start therapy was not answered at this conference. It has been a pressing question and I think one that has in fact become more pressing as we've come to appreciate the complications of therapy. The poster was an analysis of approximately 10 randomized trials in treatment-naïve [no prior therapy] patients. These were trials performed in the United States and Europe and they included a number of drugs, including protease inhibitors (PIs), the non-nucleoside inhibitors [NNRTIs], and combinations that included three nucleoside [NRTI] drugs. Dr. Bartlett looked at the predictors of a successful virologic response–in other words, driving the HIV viral load to less than 50 copies and sustaining that for a 48-week period. Among the factors that he looked at was the baseline or entry CD4 T-cell count, the HIV viral load count, the type of drug that was used, and the number of pills taken in the regimen under study. The factor that emerged as the most predictive factor for treatment success was the number of pills. Study regimens that had the fewest number of pills were associated with the greatest success in terms of HIV viral load reduction [HIV in the blood].

Saag: David, could you summarize some of the data that was discussed about complications of treatment, especially metabolic complications?

> *One of the difficulties is that the fat wasting is probably not an aging phenomenon. But the fat accumulation is.*

Cooper: There was a lot of data presented at the meeting. In fact some people who were around the poster area on Sunday actually nicknamed the poster area "Side Effect Sunday"–that there were just so many posters there. I think the issues relate to how common are the metabolic disorders and lipodystrophy. I think that most cohorts are reporting on average about 50% of patients have some form of lipodystrophy. However, I think it's also pretty clear from these cohorts that only about 10% are severely affected with them–and that's probably a little bit encouraging. People of course are very disturbed about the body shape changes, the central fat accumulation and the fat loss in the arms and legs and face. But the big question is whether the other features that occur in these metabolic disturbances, such as the development of early diabetes which is related to insulin resistance and high cholesterol and high triglycerides are going to be problematic for you in the long term. There's no simple answer to that, but there are some initiatives now to look at that quite rapidly by taking very large numbers of people–about 30,000–all over the globe and looking at them for the development of any heart disease or stroke. So that's an important development.

Becker: David, could you comment on the difference between some of the body composition changes and normal aging changes? There was some discussion about the need to explore this as well.

Cooper: One of the difficulties is that the fat wasting is relatively easy to recognize and that's probably not an aging phenomenon. But the fat accumulation is. We tend to get fatter–particularly we become apple or pear-shaped–as we get older

depending on our fat distribution. It's a little bit hard to distinguish the fat accumulation from the drugs from just this natural tendency. There are studies going on to look at that in the U.S.

I think there was some encouraging data about lipodystrophy syndrome and its occurrence rates from the HOPS (HIV Outpatient Study) data. They showed that the more risk factors you had for lipodystrophy, besides being on the drugs, the more likely you were to have it. And that really is an important issue–that we ought to be watching these other risk factors for heart disease and fat changes and diabetes very carefully.

Saag: What can we do about it if a patient has, for example, hyperlipidemia [high blood fats]? Switch the components of the regimen or intervene with specific anti-lipid agents?

Cooper: There was quite a bit of data to give us some indication on that. There were at least a dozen what are called "switch studies" where people were switching off protease inhibitors to non-nucleosides. Basically, sadly, they were pretty disappointing. The body shape changes, particularly the fat wasting, didn't really improve. But the lipid levels–the cholesterol and triglycerides–did go down substantially. So that was a strategy. There was also one important abstract at the late breaker session which gives us some indication about the use of "statin" drugs. We've always been worried about these statin drugs because they can be quite toxic, particularly sometimes in the presence of other drugs–and this theoretically would include protease inhibitors. And there was some data from the ACTG, the AIDS Clinical Trials Group in the U.S., from their pharmacology groups to show that some of the statins at least were safe to use. Pravastatin (Pravachol) was probably the best, atorvastatin (Lipitor) was second, and it was rather hard to use simvastatin (Zocor)–you got very high levels with that.

…some of the statins at least were safe to use. Pravastatin (Pravachol) was probably the best, atorvastatin (Lipitor) was second, and it was rather hard to use simvastatin (Zocor)

Saag: One of the things we're also noticing is that people are failing therapy, or therapy is failing them, let's say, virologically [looking at viral load in the blood]. And some of the approaches to dealing with that included some new regimens, adding two PIs together.

There was a late breaker which showed that if you had a backbone of drugs that had either amprenavir (Agenerase) as a single PI or amprenavir with a number of other PIs including either nelfinavir (Viracept) or indinavir (Crixivan) together, that the dual PI combination actually had a better outcome. The concerning part about this is, while every regimen did include an NNRTI, as you might predict, the NNRTI naïve patients had a much better shot at getting the viral load under control. And probably the best that you could see in the NNRTI-experienced patients was about a 20% success rate at getting below 200 copies [vs. 45% for the naïve group].

There are other approaches though that may be coming into play, and one that's been talked about a lot is withdrawing therapy from patients who have had virologic failure for a period of time. Steven Deeks is here and he presented some data on that.

Deeks: This whole concept, this so-called "treatment interruption strategy" (STI) or "drug holiday," is based on the theory, the premise, the observation, that if you take away your medications and you no longer have drugs around that maintain the resistant mutations of the virus, that those resistant mutations will go away over time. We did a study that we reported today where we took 18 people who had been on therapy for a long time and had a detectable viral load for like 2 1/2 years now–so long-term virologic failure–people who were otherwise doing okay who stopped their drugs, and we observed that over a matter of anywhere from 6-12 weeks that their resistance disappeared completely. And we really had trouble detecting it during that period of time.

Now this was associated, as one might guess, with a significant drop in CD4 T-cell counts–T-cell counts dropped by about 100 cells. These people coming into the study had 200, 250 cells to begin with–so people in general lost about half of their T-cells as a consequence of stopping their medications. And this is because the medications they stopped were, to a certain degree, still working. So we looked at this issue, when you stop therapy, viral load went up by about 10-fold, T-cells dropped, and resistance sort of went away. Now, this raises questions as to whether this is a good thing–no resistance–or a bad thing–loss of T-cells–and there's just no way really to address that with our study. If this is a strategy that will be pursued outside of a clinical trial, people need to be aware that there is a lot of risk.

These people coming into the study had 200, 250 cells to begin with—so people in general lost about half of their T-cells as a consequence of stopping their medications.

Saag: I think some of the key points you made, Steve, just to kind of summarize, is one, that when the drugs were stopped it took a little while, 5 weeks or so, before the reversion to wild type [the original HIV] from resistance occurred, but when that did happen–which seemed to be pretty abrupt–that that's when the viral loads tended to shoot up and the CD4 counts drop. And your point, I think, was that that may have been an issue of fitness of that resistant virus, and when you switch back to wild type, that was a more aggressive form of the virus.

Deeks: Yes. In this whole issue of virologic failure, one of the dominant themes was this whole relationship between the fitness of a virus and resistance. And I think our combined data, including the "stop therapy" study, is that despite years of virologic failure, despite having high levels of resistance to the drug that people are on, the virus does not replicate that well. And we believe that this is because the virus is not that fit. And in our studies, this is associated with continued persistent CD4, and presumably clinical, benefit. And I think that that story was confirmed by multiple different observations at this particular conference.

Saag: I think another one that you presented a couple of days ago also plays to that in that there seems to be some residual clinical benefit even if the viral load is now detectable, but certainly significantly below baseline. Could you briefly describe what that study was about?

Deeks: Just looking at 450 patients who we've been following for years now at San Francisco General Hospital, we looked carefully and tried to determine why some people's T-cells remained elevated when the virus comes up. And we pretty much, I think, observed that again, in the state of long-term virologic failure, the virus can go to very high levels but rarely goes all the way back to baseline. And that for reasons that are unclear, just having a small reduction in the viral load is associated with a significant increase, and preservation of that increase, of the CD4 T-cells. And I think that has implications. We all know this, that there's a significant delay between virologic failure and what happens to the immune system.

Saag: Exactly. And I think it's consistent with some meta-analyses that have been done in the past, looking at clinical trials that had clinical endpoints from the old days. And that, if anything, if you could achieve a 0.5 log decrease from baseline and sustain that, that was associated with clinical benefit. And if you lost that, then you were more likely to see progression to a clinical endpoint [such as disease or death]. And while your study didn't exactly define a precise cut–it seemed like it was more of a continuum–I think it's safe to say if you're 0.5 log below baseline and don't have a whole lot of options to switch to, taking it all together, you might be better off to ride that horse a little while longer.

Deeks: I think, Michael, that's the key thing. If you run out of options, if you no longer have the ability to get that virus down to undetectable, or if you only have one class drug left and you don't want to use it up now (like the non-nukes), then I would take these observations and say, "Yes, let's keep the virus as far below baseline as we can and ride it for as long as we can." I think that's a reasonable strategy.

HIV Over 50

by Jane P. Fowler,
Co-chair, National Association on HIV Over Fifty

Editor's Note: The following story is taken from a talk given at the National AIDS Update Conference in San Francisco in March, held by the American Foundation for AIDS Research (amfAR).

Jane P. Fowler photographed by Marcio José Sanchez/The Kansas City Star

There was an earlier time when my name and the topic of HIV were proposed to a group of medical providers organizing a "senior" health symposium. I and my topic were promptly rejected by the program planners because, they asserted, "Old people don't need to hear about AIDS."

Wrong. They do need to hear that HIV can infect and affect older individuals. We all need to understand that between 10 and 15 percent of AIDS cases in the United States are in persons over 50 years of age.

HIV/AIDS is often not acknowledged in the aging community because of the common perception that older adults are no longer sexually active and, therefore, are not at risk for infection. This results in a lack of prevention programs targeted at older individuals and in the failure of health care and service providers to discuss matters of sexuality–or drug use, for that matter–with aging patients and clients.

For example, I recently asked a thirty-something gynecologist if she routinely took sexual histories of older women. "Oh, no, I wouldn't be comfortable in doing that," she answered. I suggested it is important that she overcome her reluctance.

HIV-infected elders are frequently invisible, isolated and ignored, due to the dual stigma of living with a sexually-transmitted disease and of being "old," a condition that in our U.S. culture is often not valued or respected. The dual stigma makes it especially difficult for seniors to disclose to family and friends, thereby forfeiting support that might be forthcoming.

I'm still seeking acknowledgment of HIV/AIDS in the aging community. I've been doing this work for five years. I don't do it because I adopted this cause out of the goodness of my heart. I do this work because I hope I can make a difference. It's because of a letter I opened on a Sunday in January in 1991. A health insurance company to which I had applied for new medical coverage announced that I had been rejected because of a "significant blood abnormality."

Distraught to discover that I apparently was suffering from a serious blood disorder, I slept little that night; the next morning, I telephoned the insurance underwriter. "What is this 'significant blood abnormality,'" I inquired. Her reply: "I'm sorry but that's confidential. Your doctor will have to tell you."

A few hours later, I was in the office of my family practitioner, who looked troubled as she referred to a fax and reported, "Jane, this insurance company claims your blood tested positive for HIV." Stunned, I had a second test two days later. After waiting two weeks–the longest two weeks of my life–I learned, sadly, that I do have the virus that causes AIDS.

My family and the few friends I told were as shocked as my doctor because I didn't fit an AIDS stereotype. At the time of my diagnosis nine years ago, I was a successful 55-year-old career woman. Before that I had lived a conventional, traditional lifestyle: I'd been a virgin on my wedding night in early 1959 and I remained monogamous during 23 years of marriage. But then, in the early 1980's, I was divorced, and for the first time in a quarter century I was dating again. I didn't consider myself promiscuous. I didn't frequent the singles bars. I went out with men my age who, like me, had been married and were divorced. And in those days I knew little about AIDS, only that a mysterious, fatal ailment was affecting the gay community.

It didn't occur to me that I would put myself at risk by engaging in unprotected sex with an attractive, intelligent, amusing man of many interests, a man who had been a close friend my entire adult life. But that's what happened to me at the end of 1985 at the age of 50. Infection with HIV.

Following my diagnosis, I withdrew. I did not have the courage to put myself in situations that might be painful–where I might experience discrimination, rejection, or prejudice. I lived in partial isolation, spending time mostly with family and the friends who knew my condition, who were supportive, compassionate and non-judgmental.

Four years passed. I took my prescribed antiviral drugs and I was blessed: I stayed well. But I remained shamed and humiliated, still hiding the fact of my HIV status. Encouraged by my son and my friends, I decided to put another face to the epidemic–an old, wrinkled face–to demonstrate that HIV does not discriminate, that "it's not who you are or how old you are, but what you do and don't do in regard to transmission of HIV." It was not easy. I had to become semi-comfortable with looking out into an audience and admitting: "I live with a stigmatizing sexually transmitted disease."

The aging community needs to be educated on transmission, prevention and available services. The education of the professionals, the health care and social service providers who minister to seniors, is also crucial.

In the years since my diagnosis, I've gone from professional journalist–an interviewer–into media interviewee, from private person to public activist. In the autumn of 1995 a group of us, gathered at the first National HIV/AIDS and Aging Conference in New York, founded the National Association on HIV Over Fifty (NAHOF). The aging community needs to be educated on transmission, prevention and available services. The education of the professionals, the health care and social service providers who minister to seniors, is also crucial. First, they must be taught to recognize that the disease can and does exist in the elder population; then the providers should begin to initiate discussions about sexuality and sexually transmitted diseases, explain prevention, even encourage HIV testing.

During my annual physical examination in 1989, I asked my family practitioner if I should take an HIV test. I had begun to hear that the disease was moving into the heterosexual population and, after all, I had enjoyed some intimacies after my divorce. This was the physician who would, two years later, pass on the insurance company test results, but at that earlier time she said simply, "Oh, no, Jane, not you. You don't need that test."

I would like to think that in the intervening 11 years things have changed. But physicians, for the most part, omit the topic of sexuality when dealing with seniors. When I have asked my peers if their clinicians take sexual histories during consultations, they say no.

If physicians would take a more proactive role in discussing sexuality and sexual histories with their patients, there might be fewer misdiagnoses of older people who are, in fact, HIV infected. Misdiagnoses occur because HIV symptoms can be similar to those associated with aging–weakened immune system, weight loss, fatigue, swollen lymph nodes, skin rashes, respiratory problems, depression, decreased cognitive or physical abilities. Too often older people are not diagnosed until an AIDS-defining opportunistic infection has already developed, and as a result the elderly often die sooner from AIDS complications than younger people do. There even have been cases in which HIV was not confirmed until after the patient had died.

I am reminded of a story passed on by a colleague about a 65-year-old man living in the Chicago area who encountered a "you've lived long enough" attitude from the physician who delivered the man's HIV+ diagnosis. Discouraged, the

man next went to an AIDS service organization for assistance. When he inquired about a doctor, he was told he'd have to select his own clinician from a list the ASO would give him. According to the man, the ASO counselor could see he was depressed, suggested he "cheer up," asked his age, and when told, said, "What do you want? You die of something after sixty." Later, this man found a physician he was seeing to be more caring and warmer to his younger patients. "I saw a difference in the treatment I was getting," he said.

How discouraging for him and all of us "over 50" who live with HIV disease, who are conscious of a cultural attitude that assumes, "Elderly people have lived their lives–so what if they die from AIDS?" Admittedly, I'm one of the fortunate ones, in that my current physician is attuned to aging with the virus. Sometimes a symptom that may be evidence of HIV progression is in fact just a sign of aging. Recently, a head cold evolved into a sinus infection, and when I requested an explanation as to why I am having more sinus infections, my doctor answered that the HIV-infected are more subject to such problems and, "so are old people." Zap! Unknowingly, she had reminded me of my years, and I cringed.

Try as one might to age with good humor and grace, it's not always easy to accept the limitations of decreased physical and mental capabilities–the loss of muscle strength, the lack of energy, the loss of physical attractiveness and, most discouraging, the forgetfulness. Couple these frustrations with the variety of feelings experienced by any HIV positive individual, and it is simple to conclude that seniors, especially those with self-image issues, may endure more emotional and physical stresses than do others living with the disease.

A beneficial solution could be support groups, often a mainstay of younger adults, but they are not a tradition with seniors, who, we are told, tend to be shy and uncomfortable in such settings. Concerns of older HIV-infected persons are not the same as those of younger people, and it becomes difficult to relate. Yet there are support groups for women and men that have achieved success.

I am nearly 65 years old, well past the childbearing years and I look as I did 36 years ago before the birth of my son. I appear robustly pregnant. This is one of the side effects of the antiviral drugs which can be more distressing to aging individuals. We oldsters who live with HIV have legitimate concerns about the fact that we have not been included in research and clinical drug trials. There are no published studies about the effects of antiviral drug therapy on older people, nor do we have information about possible interactions between antivirals and drugs that are routinely prescribed for a variety of older ailments. Personally, I wonder about my combination of two therapies: triple antiviral and hormone replacement.

Please join me in my passionate campaign to educate, and perhaps we can make a difference in all arenas of HIV/AIDS awareness.

For more information, NAHOF, c/o MATEC/UIC, 808 S. Wood, m/c 779, Chicago, IL 60612-7203; or call (312) 996-1426.

Confronting Teen HIV

By Vicki Burkitt

When Martha Diaz's uncle died of HIV in 1991, her parents knew that she would ask questions. Yet, to her, there were more questions than answers. One thing was clear–there was a growing need to help people, especially those her age (she was 17). What began as community outreach with HIV positive adults at the South Bronx Ecumenical AIDS Ministry at All Saint's Lutheran Parish, has taken Diaz down the path to teenagers with HIV. It's a decision she is glad to have taken. "Doing this helped me choose what I want to do for the rest of my life," she says. "HIV touches everyone's lives. Just being at risk makes you affected by it."

These days you will find Diaz at the Adolescent AIDS Program (AAP) at Montefiore Medical Center in Bronx, New York City, where she is peer educator, youth advocate and editor of *Peer Power*, a teen friendly newsletter about HIV, relationships and sexuality. Diaz takes her work seriously. "I have to do something." As the incidence of HIV escalates in urban youth, grass roots groups such as AAP are responding with novel HIV education, testing and treatment programs in their communities.

Convincing others that there's a problem isn't easy. "People don't 'get it' that teens are getting HIV," says Kathi Kuntz, outreach coordinator at Montefiore's AAP. Sexually active youth may assume that their partners are monogamous and HIV negative or free of other STDs (sexually-transmitted diseases). Often they are in relationships with a power imbalance. Adults may deny that teenagers have sex, or hope that fear of HIV will encourage abstinence. But perceptions differ markedly from reality. A 1997 study found that 55% of high school students (from eight U.S. cities) have had sexual intercourse by grade 12, while 21% had four or more sex partners. Despite the implementation of HIV education in American schools, one in three students weren't using condoms during their last sexual encounter.

In 1987, Dr. Karen Hein, founding director of the Montefiore AAP, observed increases in teen pregnancy and STDs. She predicted that teenagers would carry more of the HIV burden in the following ten years, since adolescents were already in the midst of an STD epidemic. Today, 25% of new HIV infections occur in American youth between 13 and 21 years of age, which corresponds to one new infection every hour. In 1997, AIDS was the seventh leading cause of death in adolescents aged 15 to 24 years. This trend will continue as the high rate of STDs among teenagers (25% of all reported cases) translates into an ever-growing HIV population. Girls, 15 to 19 years old, are particularly at risk since they represent almost half of all reported cases of chlamydia, a common STD.

Adolescents are as susceptible as anyone else to sexually transmitted diseases, but access to condoms is a problem. "Kids don't know where to get condoms at local health clinics," says Kathy Kuntz. "Some can get them at school clinics, but they have to ask. They can buy them at drug stores, but it's hard for teens to navigate these things." So the people at Montefiore hand out condoms and "kids dump baskets of them into their bags." Even if they come prepared, boys and girls are still vulnerable, since their partners may resist using rubbers. Kuntz also points out that these women pick partners from a pool of men with a higher HIV seroprevalence than other neighborhoods. "It's not a case of these girls prostituting, drug using or drinking," she says. "They do what every teen is doing." Boys face additional issues, Kuntz explains. "The boys are getting infected through male to male sex, but no-one is [acknowledging] that you don't necessarily need to identify as gay. Teen boys experiment."

A recent New York City study demonstrated that young men who have sex with men (MSM) are particularly susceptible to HIV infection. Researchers reported that 13% of the MSM that they surveyed were seropositive. HIV incidence was high-

est among African-American males, with a 22% infection rate, followed by mixed race (16%); Latinos (10%) and whites (4%). Seroprevalence increased with age, from 4% between 15 and 18 year olds to 19% between 19 and 22 year olds, but half of the 56 HIV positive men were HIV-negative two years earlier. Kathy Kuntz believes that prevention messages aren't effectively reaching youth. "There are an enormous number of kids in [New York] City," she says. "Even if every school had additional health education, peer mentors and after school programs, they are still missing all the kids not at school, the kids who aren't going to classes and not involving themselves in these activities."

Dr. Donna Futterman, director of the Adolescent AIDS Program since 1994, believes that educators need to tailor HIV education to the communities they serve, and speak in their language. It should be relevant and inclusive of all teenagers, including gay youth. Just as important, at-risk youth need access to HIV counseling and testing, social support and treatment.

In 1997, the Adolescent AIDS Program and an advertising agency conceptualized and created a social marketing campaign that targeted adolescents with references to sex they understood. Phrases such as "hittin' the skins" and "knockin' boots" became slogans on flyers and cards that encouraged teenagers to learn their HIV status: "Hittin' it? HIV. Live with it. Get tested. If you're 13–21 call citywide 718-881-TEST." When youth call the hotline, they are referred to one of eight New York City clinics that provide free, confidential HIV counseling and testing, and specialized care for HIV positive adolescents.

Montefiore's AAP hired a medical PR firm to generate community awareness and to promote the New York City "Get Tested Week" in April of 1998. The firm proposed launching the event with a public town hall meeting. In the lead up to the HIV testing week, the campaign ran broadcast and print news stories, public service announcements on television and cinema slides, advertisements on radio and bus shelters, and with other community partners distributed over 220,000 pieces of literature to peers, schools, stores, churches, restaurants, clubs and hair/nail salons throughout New York City.

Approximately 250 New York City adolescents attended that first "Let's talk about HIV" town hall meeting in the Bronx, a forum comprised of skits and discussions about HIV/AIDS and teen sexuality issues. During the "Get Tested Week," 500 calls were received on the listed hotline number. Of the 230 calls that were answered by volunteers, 55% were from 13 to 21 year-olds, and 93% accepted a referral. With increased funding from the federal government, the campaign was expanded to six U.S. cities in 1999: Baltimore, New York, Philadelphia, Washington DC, Los Angeles and Miami. Each city will provide similar literature as in New York, and all adolescents will be counseled and offered HIV testing with an oral HIV test.

For youth who take the next step and learn their HIV status, Alice Myerson, nurse practitioner at the Montefiore AAP says, "The majority of the kids [we] counsel and test are fortunately negative." Of the one hundred HIV positive adolescents who are currently receiving care at Montefiore Medical Center, half are girls and half are boys. The majority of young people are exposed sexually: females through heterosexual contact and males through sex with other males. Approximately ten to fifteen percent of teens were infected perinatally, but only identified during adolescence, and a handful were infected by injecting drugs. Myerson points out that there is also a very high incidence of sexual abuse among both the female and male teens that she sees. "Keep in mind," she says, "when we think of risk factors we think of promiscuity, [but] we have many young people–both male and female–who have become infected, who only had one or two partners. They're not promiscuous.

Making Plans for the Little Ones

by Justin Hayford,
AIDS Legal Council of Chicago

When you tested HIV positive, was there some idiot around to exclaim, "Oh my god! You've got to do a will! And a power of attorney! And what's going to happen to your children?!" If you were spared such histrionics, count yourself lucky. Few things are more unhelpful than dire pronouncements before you've even had a chance to understand what being HIV positive means to you.

So if I ask if you've made any plans for the future care of your children, please don't count me among the alarmists. After all, the question is pertinent to all parents, not just those who are HIV positive. Planes fall from the sky, houses catch fire, cars spin out of control; in an uncertain world, children can be left without parents in the blinking of an eye. Still, many parents don't take the time to make arrangements for their children. If HIV gives you an opportunity to think seriously about your children's future, consider it a minor blessing. Remember, states vary in the options available. Short-term and standby guardianships, for example, are not available in many states. This article specifically describes Illinois law. Check your state to see what is available and how options work there.

A lot of parents call me with a great fear hovering over them: if they pass away without making any legal arrangements, they think their kids will become wards of the state. For the great majority of parents, that fear will never become a reality. If there is another living parent, that person will take over automatically. But even if there is no other parent, so long as someone is around who is responsible enough to become a child's legal guardian, and so long as there are no allegations of abuse or neglect, the state child welfare agency won't even be notified that your children are temporarily without parents. Think of all the kids in child welfare custody–do you think they're eager to bring *more* into the system?

So what options do you have when it comes to making a plan for your children? Let's assume that right now you are perfectly able to care for your children; you don't need to make someone their legal guardian today. Here are some options to consider. It's important to know that these options are not mutually exclusive; you can do several at once.

Option 1:

- Do nothing. This is the option even well-paid professionals always forget to mention. No law says you have to do anything. If you do nothing and then pass away, just about anyone can petition the court to become guardian of your children. Of course, you would have no say in the matter, and you didn't even express your wishes ahead of time. But if you do nothing, you children can still end up under the care of a responsible adult. Then again, your nasty Aunt Midge might get them. Eek! Better make a plan.

Option 2:

- Write a will. In a will you can nominate someone to be the guardian of your children after you're deceased. A will cannot actually make someone guardian–only a judge can do that. But if, for example, you want your sister to care for your kids after you're gone, you could nominate her in your will, and she can use your will as evidence to convince the judge to appoint her guardian.

  Of course, someone else could also petition the court for guardianship of your children, and it would be up to the judge to decide which person is more fit to care for the kids. The judge would hold a "best interest hearing" to make this determination.

Option 3:

- Do a short-term guardianship. It's very simple to make someone the short-term guardian of your children. You don't even have to go to court. All you have to do is fill out a four-page form called (cleverly enough) "Appointment of Short-Term Guardian." This form allows you to give someone else full guardianship of your children for up to 60 days.

  Parents often use this form if they must be hospitalized for an extended period of time. The form also lets you determine a date in the future when the guardianship actually goes into effect. For example, you could appoint your mother as guardian, but her 60 days wouldn't start until the day you are confined to a nursing home. You can tailor the form to your specific needs.

  In most cases, the Appointment of Short-Term Guardian form is supposed to be signed by both of the children's parents. But if you truly do not know the whereabouts of your children's other parent, or if that other parent is not willing or able to carry out day-to-day child care, then the other parent does not have to sign the form.

  As the name implies, a short-term guardianship is not permanent; it's only good for 60 days. If you want something more permanent, you can consider the following options.

Option 4:

- Standby guardian. Making someone the standby guardian of your children requires going to court. Essentially, you would go to court and ask the judge to officially name someone to be the future guardian of your child. If the judge agrees, she will appoint that person guardian–but the guardian will standby until needed. In other words, you will continue to have "care, custody and control" of your kids until you are no longer able to care for them. Then the standby guardian will be able to take control. At that point, the standby guardian will have to go back to court to get a permanent guardianship order, but the process should be much easier than the first time around.

Option 5:

- Standby adoption. This is a brand new option here in Illinois. The procedure here is similar to standby guardian; someone can adopt your children, but that person won't actually become the adoptive parent until the day you can no longer care for your kids yourself. At that point, the person you appointed will become the full parent of your children in the eyes of the law. Note that standby adoption is a very new option which few states have.

I hope this article hasn't scared you off. It can be unpleasant to think about planning for the future care of your children. No one likes to consider the possibility of not being able to raise their children into adulthood. But parents owe it to their children to make arrangements in case something happens.