



TPAN Turns 15



The XIV International AIDS Conference

- What's New in Drug Regimens
- Expert Opinions From Barcelona
- Treatment Access is a Human Right



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Test Positive Aware Network
5537 North Broadway
Chicago, IL 60640

phone: (773) 989-9400
fax: (773) 989-9494
e-mail: tpan@tpan.com
<http://www.tpan.com>

Executive Director/
Editor **CHARLES E. CLIFTON, MA**

Associate Editor **ENID VÁZQUEZ**

Website,
Advertising and
Distribution
Manager **JEFF BERRY**

National Advertising
Representative **RIVENDALL MARKETING
(212) 242-6863**

Business Director **RICK BEJLOVEC**

Contributing
Reporters **MICHAEL BARNETT
DANIEL S. BERGER, M.D.
LAURA JONES
JIM PICKETT
GLEN PIETRANDONI, R. PH.**

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Editor's Note

On the Watch



Attending the XIV International AIDS Conference in Barcelona this July, my second trip to this conference, was a strange experience. On the one hand I was excited about visiting Barcelona and Spain, a city and country I have long romanticized about. I was also excited about the opportunity of being among so many different people, each in their own way making a difference in the struggle against AIDS. It brought an opportunity to revisit that “inner space” that inspired me so two years ago in Durban, South Africa.

However, on the other hand, this conference, more so than any other conference I've attended these past few years, reminds me of my own mortality. I know that no one lives forever, but when you come face-to-face with 15,000-odd people from nearly every corner of the world, each directly impacted or affected by HIV, it makes you stop and ponder. I'm not 25 anymore, hell I'm nearly twenty years removed from that age.

Two years ago in Durban, I watched in amazement as Winnie Madikizela-Mandela took to the streets with members of South Africa's Treatment Action Campaign (TAC) and ACT UP (AIDS Coalition To Unleash Power). I listened as the former first lady of South Africa declared in opposition to the country's president, Thabo Mbeki, “AIDS exists and HIV causes AIDS.” At the Durban closing ceremony, I sat mesmerized as Nelson Mandela, the founding father of the new South Africa, spoke. “In the face of the grave threat posed by HIV/AIDS we have to rise above our differences and combine our efforts to save our people,” he stated.

Two years have passed, and I, like many of us, continue to lose friends and associates to this supposedly “chronic, manageable disease.” Yes, it is true that the consequences of contracting HIV today-in countries where comprehensive HIV treatment and care are readily available-is not what they were as 10, 15, or 20 years ago. But, I still watch as HIV disease and the anti-retroviral therapy so many

depend on to extend their “lives,” slowly and sometimes not so silently reconstructs lives, through mind-altering changes, chemical imbalances, and internal and external body/organ transformations.

Enter Barcelona. A large majority of gay/bisexual young men in the U.S. are living with HIV, and don't even know it. Children are taking a four-drug regimen to achieve undetectable viral loads. Africa suffers from the “political and moral bankruptcy of wealthy nations.” South African AIDS activist Zackie Achmat declares that treatment access is a human right. No HIV positive muppets in the U.S. How's that for an immigration policy? And still we wait for a vaccine.

But despite this disturbing news, it was so invigorating to witness ACT UP/Paris shut down Roche, Gilead, Bristol-Myers Squibb and GlaxoSmithKline exhibition booths at the conference. It was great to see signs that read “Closed Due to Death” raised in these booths. Yes, I work very closely with representatives from each of these pharmaceutical companies, but it still remains inspiring to see anger and direct action having impact 20 years into this struggle. It was even more exciting to see ACT UP and U.S. activists join forces to denounce U.S. HIV/AIDS prevention and treatment policies, and shout down U.S. Health Secretary Tommy Thompson.

At the closing ceremony in Barcelona, I watched again, as Nelson Mandela took the stage to speak. And while it is always a privilege to hear this great man speak this time I noticed that he moved a little slower, spoke with less power in his voice, and appeared a bit more “grandfatherly” than I remembered in Durban. I listened as former President William Jefferson Clinton criticized the Bush administration for not doing enough to combat the AIDS epidemic. Clinton and Mandela are co-chairs of the International AIDS Trust, a non-governmental organization that was established to

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Readers' Forum

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

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

GRAPEFRUIT JUICE

Editor's Note: In the Medicine Chest for July/August, I mistakenly edited the article to say that grapefruit juice decreases the absorption of non-nukes and protease inhibitors. My apologies to the author, Glen Pietrandoni, a fine pharmacist and a fine writer. He says that, "In most cases, grapefruit is an inhibitor, like Norvir. It will usually raise the level of the drug."—Enid Vázquez

HEP C ATTITUDE

Editor's Note: Sylvia O'Shaughnessy wrote about her battle with hepatitis C in the July/August issue (Positive Empowerment). Good news: after three months of treatment, her hep C viral load was undetectable, and was still undetectable after six months, despite having type 1 hep C (which normally has a lower response rate). Her HIV viral load is down, too, so her doctor, Todd Hargan, thinks the hepatitis treatment is doing something for her HIV, as well. Because she's doing well, and side effects are infrequent and weak, he'll keep her on the year's course of treatment, which is standard for genotype 1—EV.

MOVING CHEEKS

Editor's Note: Writers to the (HIV) Lipidlist e-mail listserve gave us permission to reprint items regarding our article "New-Fill for an Old Face" (May/June 2002).

I was glad to see your cautious comments in a letter to the editor in [the July/August] *Positively Aware*, responding to Jeff Berry's article on his New-Fill experience. That article was far too positive in my opinion. I haven't seen Jeff since he finished his treatment, but I went to the same doctor with mild facial lipoatrophy with no results

that lasted longer than three weeks (post-op swelling made the face look full for a while). Another person who works with Jeff told me that after six treatments with that doctor, he had no results that lasted longer than six weeks and is looking into collagen injections. Collagen also yields short-term results, as we know. In your letter to the editor you mentioned going to Tijuana and being very happy with your polyacrylamide treatment. I've been to the facial wasting website several times and have not seen any before and long-term after photos for this treatment. I know there is now eight years of experience with the product.

Name withheld

I would not waste my money on collagen. The results dissipate too quickly. I am happy with the BioAlcamid (polyacrylamide gel) I got in Tijuana with Anna Love (she is a technician, not a doctor). The beauty of this product is that any excess can be extracted. It feels just like your flesh and is as permanent as silicone. I had a mild case of facial wasting, so my pics are not that impressive. It was nice to run into people in South Beach last week who said I looked "younger" and wanted to know what I had done. My friend and volunteer Ellen Hahn had a severe case. You can see her pics at www.houstonbuyersclub.com.

Nelson Vergel

The author responds: Not everyone sees the same results from New-Fill, a point which had been covered in previous articles. However, I did mention not to expect miracles, results are not guaranteed, and it's not for

everybody. I know of some people who have had great success with New-Fill, and others who have seen no improvement whatsoever. I have seen some improvement in myself, which to me has meant a great deal.—Jeff Berry

INSURANCE NIGHTMARE

For nearly nine years I have been a fanatic about taking my medications on time and without ever missing any. I am super organized with a detailed list of medications by name, manufacturer, strength, dosage, and the number assigned to me by my pharmacy. When I moved, the local druggists were purveyors of more gossip than good advice. Then I found Statscript. All went well for nearly two years.

Then they started running late. Oh, the stories I heard: Medicaid/Medicare changed the rules, Medicare wouldn't approve the liquid form (they did), the doctor was late with refill approval, I screwed up by getting diabetes medication not approved by Medicare (not really so). I missed a day, then two days, three. The manager of the local Statscript told me I was too difficult, too demanding, too un-understanding. I went to Chronimed. They wanted details; I refused at first. I finally revealed all (not my style). Suddenly everything they told me couldn't happen did. I got all my medications on one day—except for the one they forgot to include in the package and the one the doctor hadn't approved because he had "no record" of my existence! I told Chronimed I would give it another month. *Stupid.* Right back to arrogance and excuses and whines and groans.

My physician was livid and said I should not tolerate missing a dose for any reason. Chronimed wouldn't tell me their

opinion on missing doses. They did tell me the problem was Medicare/Medicaid's. So, next time you write about missing doses, know there are other reasons for this. I've taken action to help protect myself in the future. Chronimed talks a good story; so does my local Statscript manager. Neither will work with [me]. With no reasonable communication, there is little hope for success. The nurses and others at my doctor's very large practice have had similar experiences. I've been lucky and I've worked hard. I didn't expect this! Just thought you'd like to know.

Name withheld,
via the Internet

Editor's Note: Thank you for your story. There must be a thousand ways that all the insurers, private and public, in all the different towns, cities and states, can mess up your meds. People here had some advice: Don't wait until the last minute to get your prescriptions filled (you probably didn't).—EV

HELP FOR DIARRHEA

I have had severe diarrhea for more than two years and my doctor recently told me to try a new product. The maker of Imodium has created a product called Probiotica, sold over the counter as chewable tabs (60 for \$15.99 at my pharmacy). It replaces the lost healthy bacteria that is destroyed in our colon by taking medication. It only took a matter of a few days and my severe diarrhea stopped. I still have minor problems, but I am so much better and having the diarrhea stopped has helped me gain weight and feel and look better. I hope this information helps.

Name withheld,
via the Internet

IT'S STILL NOT SAFE

I just spent the past two weeks in Barcelona working at the International AIDS conference. There was a lot of sobering news about AIDS. The bottom line is that things are getting worse. Scientists are now saying that AIDS will kill 70 million people over the next 20 years, and that we've yet to reach the peak of the epidemic. In other sobering news, *The New York Times* reported on a study released at the conference showing that of 5,719 gay and bisexual men, a full 77% of those testing positive did not know that they

were infected [See "Perceived Safety Intenifies Danger for Gay and Bisexual Men" on page 40]. The figures were even worse for young black men. Folks, the younger generation is not getting the word about this plague (and some of the older folks are forgetting, thinking the worst is past). Everybody, get tested. And if you have any friends who think it's safe to play without a condom, yell at 'em, because it's not.

Name withheld,
via the Internet

A LAD AND HIS DOG

Editor's Note: The following letter was inadvertently dropped from a previous Readers Forum.

While Carlos Perez's article [*Positively Aware* May/June 2002] offers an interesting chronology of his personal battle with HIV, it hardly serves as a model for responsible pet ownership. Pets, of any kind, are not there merely to console us, provide companionship at our convenience, or "decrease [our] risk factors." Instead, they require ongoing attention and care, particularly a Pit-Bull like Dickie. To leave a dog locked in his crate for 24 hours without food, water, or bio-breaks—as Mr. Perez did while he drank himself into an alcoholic "stupor"—constitutes animal neglect and cruelty. As the owners of three German Shepherd Dogs, my partner of 10 years and I structure our lives in such a manner so as to ensure the needs of our beloved dogs are met. After all, when one accepts responsibility for any living being—human or otherwise—part of that responsibility often includes personal and financial sacrifice. While I highly recommend pet ownership—for the joy and unconditional love a pet offers is a rare gift, indeed—before you make the decision to bring an animal into your life, make certain you are physically, emotionally, and financially fit enough to provide for your pet. Please, don't waste an animal's precious love and devotion, as Mr. Perez seems to have done, simply as a means to console yourself. Instead, adopt a pet because you are mature and stable enough to provide a loving, nurturing environment for an animal in need...for those of you who are and do, the rewards you'll receive, in this life and the next, will be immeasurable.

Name withheld,
Chicago

The author responds: "A Lad and His Dog" is an article about somebody so depressed by HIV that they are suicidal; about how some HIV-positive people can't take care of themselves because of their depression. It's an article about how having a dog can lift a person's outlook and help them change their lifestyle and become well again. The reader was obviously completely unaware of what the article was all about. Incredible!—CP

ASK THE BUZZ

Upon my last visit to my primary care physician, I discovered that my triglyceride count was 510. He said that this was caused by Sustiva and my immune system improving (my CD4 count was 1,063). He prescribed 10 mg once a day of Lipitor and said that he'll double that dosage in September. He also suggested eating less red meat. Of course, I'm still supposed to keep my weight up. I don't get it. How should I prioritize this? Is it more important to keep my weight up (I'm 6'2 and weigh 165 pounds, the most I've ever weighed—negative or positive), watch what I eat, or can Lipitor take care of the problem? And let's not forget that I'm not on disability and am trying to work while juggling all these balls. I would appreciate some advice.

Name withheld,
via the Internet

Dr. Dan Berger replies: Your triglyceride level does not seem terrible. I would like to know if cholesterol is also elevated, though. It may be that the Lipitor may in fact take care of what appears to sound like a mild problem. Also, it is not clear that the 10 mg of Lipitor may absolutely need increasing; this depends on your lipid levels after treatment with 10 mg and whatever improvement can result from some dietary management. Watching diet by way of reducing some fat may not necessarily lead to your losing weight. All you may need to do is monitor your calorie intake and have a nutritionist calculate your requirements for maintaining your weight. Also, it is not the absolute weight that is the most important, but your lean body mass. I don't know if you've had a body composition test done, but an experienced dietician or nutritionist can also test for that, if your physician is not able to. Anyhow, it would be a good idea to have a nutritionist monitor you and help you through these hoops. Thanks for writing me. ☺

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News Briefs

by Enid Vázquez



WARNING: AGENERASE, METHADONE AND THE PILL

The U.S. Food and Drug Administration (FDA) announced a change in the product label for Agenerase (amprenavir) HIV protease inhibitor, both the capsules and the liquid formula. Agenerase might lower blood levels of methadone. It might also be less effective itself because of decreased blood levels when taken with methadone. The FDA reports, “Alternative antiretroviral [HIV] therapy should be considered. Dosage of methadone may need to be increased when coadministered with Agenerase.” As for the Pill, “Those taking Agenerase should be instructed not to use hormonal contraceptives because some birth control pills (those containing ethinyl estradiol/norethindrone) have been found to decrease the concentration of amprenavir. This may lead to loss of virologic response and possible resistance to Agenerase. Alternative methods of non-hormonal contraception are recommended.”

FDA APPROVES ONCE-DAILY EPIVIR

Great news: Epivir (lamivudine) can now be taken once a day. The U.S. Food and Drug Administration (FDA) in June approved a dose of 300 mg once a day. Once-a-day and twice-a-day dosing of Epivir was found to be equivalent. However, the maximum blood concentration was 66% higher and the minimum level (trough) was 53% lower with the once-daily dose, although the area under the curve was equivalent with both doses. (AUC is the total drug concentration between one dose and the next.) New 300 mg tablets should be available when you read this. Or, the 150 mg dose, which was taken as one tablet twice a day, can be taken as two tablets once a day. Many doctors have been prescribing that dose for years. Adherence becomes more important with a once-daily dose. People should make sure they take their dose, or take it as soon as they remember that they missed it. (But don't double a dose—which

means you take two doses within a small window of time from each other.)

FOR SHAME

Ronald Hill, a former San Francisco health commissioner, was ordered to pay his ex-lover \$5 million for lying about his positive HIV status and exposing the man to the virus. The former partner later tested positive for HIV. He told a San Francisco Superior Court commissioner that Hill repeatedly lied about his HIV status, even after the partner tested positive. According to court testimony, Hill, who was appointed to the health commission in 1997, had claimed his poor health symptoms were a result of cancer. Criminal charges may follow.

BAREBACKING

The U.S. Centers for Disease Control reported that more than a fifth of gay and bisexual men surveyed who had engaged in unprotected anal sex with casual partners were HIV-positive. The study, published in the March issue of *AIDS* medical journal, found that 38 out of 554 men said they had barebacked at least once in the previous two years. Better physical feeling was the most common reason given for barebacking, followed by “feeling emotionally connected.”

ACUPUNCTURE AND COCAINE

Acupuncture structured for treatment of cocaine addiction performed as well as relaxation techniques and acupuncture not used specifically for addiction. Researchers from the Yale University School of Medicine put study participants into one of the three treatments for eight weeks. Participants received 40 minutes of treatment each weekday. They were also given access to individual counseling and allowed to participate in a methadone program. Abstinence from drug use and satisfaction with treatment received were about the same in all three groups. All three also had a significant

decrease in the seriousness of their problems with mental health, the law, family relationships and alcohol. The study results match anecdotal reports to *Positively Aware* about the use of acupuncture for drug users—it does not cure serious habits. However, it can relieve symptoms of withdrawal. The study was published in the *Journal of the American Medical Association* (JAMA).

COST OF MEDICINES

“There is a Law: Drugs Don’t Have to Cost So Much” was the topic of a recent commentary in the *Houston Chronicle*. Authors Peter Arno and Michael Davis severely criticize the U.S. government for not using the law to lower the costs of medicines produced with taxpayer money. “Bayh-Dole is a provision of U.S. patent law that states that practically any new drug invented wholly or in part with federal funds will be made available to the public at a reasonable price. If it isn’t, the government can...license it to third parties that will make the drug available at a reasonable cost... The American public pumps more than \$20 billion a year in taxpayers funds into health-related research and development, making it the single largest investor in the pharmaceutical industry.” The writers state that, “as of 1997, 54 of 84 anticancer drugs approved by the Food and Drug Administration were the products of federal funding. The percentage is even higher with respect to AIDS drugs developed with federal funds.” Visit the U.S. Centers for Disease Control Web site to see more of the commentary: <ftp://ftp.cdcnpi.org/PrevNews/apr02/update041802.txt>.

WHO: HIV DRUGS “ESSENTIAL”

The World Health Organization has added almost all of the approved anti-HIV drugs on the market to its Essential Medicines List, along with treatment guidelines for poor countries. Previously, only Viamune and Retrovir were on the list, for the prevention of HIV transmission from a pregnant woman to her infant. A WHO official told the Associated Press that the “essential medicines” declaration could be used to negotiate price reductions with pharmaceutical companies. In addition, it is hoped that the WHO endorsement will eliminate questions about safety and effectiveness.

NEWS FROM THE XIV INTERNATIONAL AIDS CONFERENCE IN BARCELONA IN JULY. FOR MORE CONFERENCE NEWS, VISIT:

- <http://hivinsite.ucsf.edu/InSite.jsp?page=cfaids-02-00>
- www.aids2002.org
- www.medscape.com
- www.hivandhepatitis.com
- www.kff.org

RE-INFECTION: UPDATE

Can a positive person infect another positive person with a new strain of HIV? The idea of so-called “re-infection” was widely supported by HIV specialists all over the country, but so difficult to prove with solid scientific work that it was left in the area of the theoretical. An earlier report from Toronto of re-infection turned out to be flawed and therefore out-and-out wrong. But now one prominent research lab has evidence of a case of re-infection, and that’s enough to strongly indicate that the phenomenon really does exist.

Dr. Bruce Walker of Harvard Medical School had a patient with a blip in his cytotoxic (“killer”) T-lymphocytes. The patient admitted to having had an unprotected anonymous sexual encounter. Walker’s HIV lab documented the existence of another strain of the virus in the patient’s blood. Previously, his immune response worked wonders against his original strain of HIV. Now, it failed to keep the new one under control. This report demonstrates the importance of maintaining safe sexual practices, even though both partners are HIV-positive.

Walker’s report came from his vaccine work, and once again addressed the difficulty of creating a vaccine that can be effective against multiple strains of HIV.

Researchers from another lab, at the University of Geneva, also reported a case of re-infection. Their patient had a huge rise in viral load. Through sophisticated work in blood samples, the lab was able to show a new strain of HIV. They said this strain was one commonly seen in Brazil, and the patient had taken a trip to Brazil, where he had several unprotected sexual contacts, three weeks before the viral load rebound in question. The researchers wrote that this second strain had a much greater ability to replicate than his first. They also noted that, “Super-infection [one infection on top of another] has

implications for the ever increasing HIV-1 genetic diversity, public health, and vaccines development.” (HIV-1 is the type found in the North, such as the United States and Europe.)

In his report on this case for www.Medscape.com, HIV specialist Dr. W. David Hardy, of Los Angeles, wrote, “Thus, these investigators have used sophisticated molecular virology techniques coupled with epidemiologic data to demonstrate conclusively the occurrence of HIV-1 superinfection in this patient. Whereas previous reports strongly hinted at this phenomenon, proof from molecular virology was lacking. The fact that the two HIV-1 subtypes acquired by this patient were different subtypes (AE and then B) increases the certainty that superinfection occurred in this patient. Although this report holds significant virologic and epidemiologic interest, its most compelling message is that HIV-1 infected persons must avoid possibly multidrug-resistant virus. HIV-treating physicians and treatment advocates should take heed of this well-documented scientific report to inform their patients and clients of this phenomenon, and encourage them to observe safe sex guidelines.”

VIREAD

How does the relatively-new kid on the block stack up? Researchers randomized 550 study participants to take placebo (sugar pill) or Viread for six months, then everyone took Viread for the other six months. At six months of study, these heavily pre-treated people had a little over half-log viral load decrease. This was a significant reduction, and it remained throughout a year of study. Researchers for Study 907 concluded that Viread can significantly lower viral load even in people with extensive HIV drug resistance. However, because these individuals were heavily pre-treated, with underlying resistance to HIV meds, only 41% of the participants went to below 400 viral load, and only 18% to below 50. Side effects were the same as seen with placebo. Viread is a one-tablet, once-a-day drug. (See also “*What’s New with Drug Regimens?*” on page 27.)

VIREAD VS. ZERIT

At one year, Viread was as safe and effective as Zerit when taken in combination with Epivir and Sustiva. Results are from 600 participants in a large, randomized clinical trial.

All of these Study 903 participants were taking therapy for the first time. About 87% of all had less than 400 viral load (95% if you consider only those people who remained on therapy, rather than counting the people who dropped out of the trial). A T-cell increase of 150 was seen with both drugs.

Positively Aware columnist Dr. Dan Berger, of Chicago, who worked as an investigator in this trial, notes that the significant increases in cholesterol and triglycerides in the patients randomized to the Zerit arm was a very important and surprising finding. He said this study confirms the safety of Viread while Zerit continues to demonstrate concern, now in patients being started on treatment for the first time. Also, his clinic saw no toxicity with Videx after adding Viread in phase II and III trials or during early expanded access. There were about 50 patients total. However, other clinics have seen problems. For example, there have been cases of pancreatitis when using the two drugs together. (See “*For Experienced Folks*” on page 30.)

ONCE-A-DAY RETROVIR

Can you take Retrovir (zidovudine, AZT) once a day instead of twice a day? A two-week pharmacokinetic (PK) study looking at blood levels showed a significant viral load reduction either way (at least a half-log drop for all 32 participants). Further research looking at Retrovir in drug combinations is needed before recommendations can be made.

Also, the slope of viral load decline was smaller for the once daily dose over the 14 days, but this was not statistically significant. However, in different analyses comparing different days, the slope was statistically greater in favor of the twice-a-day dosing.

Moreover, the total viral load drop was greater in the twice-daily group. Reductions ranged from 1.067–0.630 log (mean 0.849) in the twice-daily group. In comparison, the once-a-day group reductions were 0.728–0.442 log (mean 0.585). This was almost a statistically significant difference ($p = 0.056$). The usual Retrovir dose of one 300 mg tablet, twice a day was compared to taking the two tablets once a day instead.

ONCE-A-DAY VIRAMUNE, VIDEX AND VIREAD

In 65 out of 159 clinical trial participants who reached 24 weeks of study, all but two had less than 80 viral load. They were

randomized to either continue their twice-a-day regimens or go on Viramune/Viread/Videx once a day (four pills at breakfast time). Researchers concluded that the once-daily dosing “seems to be equally suppressive” as standard of care regimens, with improvements in triglyceride levels and quality of life. However, 10 of the 65 (15%) stopped therapy: three because of hepatitis, two for rash, one for neuropathy (nerve damage), one for severe dry mouth and three did not continue visits. All participants were already on a HAART (highly active antiretroviral therapy) regimen for at least nine months when entering the study. They had less than 80 copies viral load at that time. The Spanish study is scheduled to continue for three years. No Viramune-associated liver toxicity or Videx toxicity was seen. Unfortunately, the report did not state the dosage or formula of Videx that was used. (See “*For Experienced Folks*” on p. 30.)

VIRAMUNE AND THE LIVER

The manufacturer of Viramune, Boehringer Ingelheim, presented results of its Viramune Hepatic Safety Project. To cut to the chase: “In cohort studies, nevirapine was not associated with a great risk of clinical hepatitis than other [antivirals].” Also, “The majority of NVP-associated hepatic events are asymptomatic and easily addressed by NVP interruption until the ALT/AST (liver function tests) return to baseline with subsequent reintroduction of NVP on a case-by-case basis.” Findings were based on data from thousands of people. Asymptomatic (no symptoms) increases in liver enzymes were seen in half-a-percent to nine percent of people taking Viramune in clinical trials, so the risk is greatly individualized. This study underlies the importance of liver function monitoring, even though one is asymptomatic.

VIRAMUNE AND KALETRA TO SPARE THE NUKES

Usually, a HAART regimen includes a backbone of two nucleoside analogs, also called “nukes.” These include Combivir, Zerit and Epivir. Here, researchers from Spain and Germany looked at a nucleoside-sparing regimen of only Viramune (a non-nucleoside analog) and Kaletra (a protease inhibitor with a small dose of another PI, Norvir, in each capsule).

The preliminary results of the small trial: Viramune/Kaletra compared favorably to Kaletra plus two nukes at six months. However, T-cell increases were higher in the nuke-sparing regimen—from 552 to 758, compared to from 640 to 668 in the nuke arm. The regimen consisted of one Viramune tablet and three Kaletra capsules twice a day. The 30 participants in this study were already on treatment for at least nine months before joining. They were already experiencing cholesterol increases, and this did not revert with either study arm.

SUSTIVA BEATS A DUAL PI COMBO

Sustiva has previously shown its superiority compared to protease inhibitor (PI) combinations. Now it beat out the once-daily dual PI combo of Agenerase with a Norvir mini-dose of 200 mg. Results from a randomized, open-label trial with almost 300 people who were on therapy for the first time were presented. Everyone received Ziagen/Epivir as a base for their combo, and the study’s finding that these were safe and well-tolerated when used together is an important advance for HIV therapy. Dr. Brian Boyle reported for www.hivandhepatitis.com that, “This [48 week—a statistically significant amount of time] analysis found that the Sustiva arm significantly outperformed the other two arms of the study in achieving a viral load of less than 50 copies/mL. Using an intent to treat, missing = failure analysis [a high standard], the Sustiva, Agenerase and Zerit arms of the trial had success rates of 76.3%, 59.4%, and 62.2%, respectively.

“[For people with] viral load greater than 100,000 copies, the Sustiva arm also proved superior to the other arms in achieving viral reduction to less than 400 and less than 50 copies. Finally, grade 2-4 adverse events occurring in at least 5% of patients were similar for all treatment arms: 38% for Sustiva patients and 35% each for Agenerase and Zerit patients... The CLASS study demonstrates the potency of Sustiva and adds Agenerase to the lengthy list of protease inhibitors it has outperformed. Further, the study shows the potential utility of a Ziagen and Epivir regimen, which appeared to be reasonably well tolerated in combination with other antiretrovirals.” ☒

So treatment guidelines keep changing—ain't that a good thing? New research, new recommendations.

The International AIDS Society-USA (IAS-USA) in July changed its recommendation that antiviral therapy could be started at less than 350 CD4 cells. They now say at 200, although, the society guidelines state, "It is known that therapy should not be delayed until the CD4+ count declines to 200 cells/microliter, because of the increased risk of death if therapy is started this late."

For all HIV doctors, as with this panel of experts, the real issue is the imperfection of the medications. If there were no toxicities and no drug resistance, putting people on meds would be a no-brainer.

But there's no HIV "cocktail." There's only HIV chemotherapy. In fact, a lower and lower T-cell count has been expected from different HIV guidelines in the U.S. and Europe, thanks in part to the onerous effects of many of the drug regimens while the benefits are debated by experts.

Although they're downshifting to 200 T-cells, a reading of the guidelines shows that the panel is never anti-therapy. Nor does the panel ever suggest that delaying HIV therapy is preferred. Rather, the guidelines go back and forth about the pros and cons of therapy, including when to start.

SO WHAT ARE SOME OF THESE CONSIDERATIONS?

- Since the last time the guidelines were updated in January 2000, two cohort studies have pointed to the greater importance of CD4 count for considering when to start therapy, showing "an increased mortality when antiretroviral therapy is initiated in patients with CD4 cells counts below 200 compared with initiation at higher levels."
- However, cohort studies—which are based on observational data with short-term follow-up rather than con-

trolled clinical trials—are not the best sources of medical information.

- Nevertheless, "these are the best available data." Also, "there is general con-



sistency across most studies, and it is questionable whether a randomized trial to study the issue of when to start therapy will ever be feasible."

- "The CD4 cell level above 200 at which to initiate therapy remains unclear. Some serious illnesses, especially active tuberculosis and bacteremic pneumonia, may occur when the CD4 cell count is above 200.
- In addition, the immune reconstitution syndrome and its associated [illnesses] may be observed in some patients starting antiretroviral therapy at low CD4 cell counts."

CRITICISM

The guidelines were published in the July 10th issue of *The Journal of the American Medical Association* (JAMA), during the XIV International AIDS Conference held in Barcelona. Some doctors shuddered at the idea of waiting until their patients "deteriorated" to the point of 200 T-cells. One HIV specialist and researcher also wondered if the door was open for insurance companies to deny therapy for people with more than 200 T-cells. But others sided with the commonsensical idea of choosing to wait if that's desirable.

Dr. Joseph Gathe, of the Montrose Clinic and the Houston Clinical Research Network, wasn't thrilled. "People hear what they want to hear," he said. "If you tell them they don't need medication, they hear that they're okay. Then they stay away from care. By the time they come back, they're down to 200 T-cells or have opportunistic infections."

These people may not get the message that they have to be monitored on a regular basis, or that T-cell count and viral load measurement aren't the only things that have to be considered for going on therapy. He said he's also had patients turned away from getting the HIV medications he prescribed after public health clinic personnel told them they didn't "need" to be on antivirals based on their T-cell counts, according to treatment guidelines.

Gathe also pointed out that there's no mention of hepatitis C, a common co-infection among people with HIV. HIV treatment is known to help keep hep C disease in check. "There's no mention of hep C in any of the guidelines," he said. (There are also guidelines from the U.S. Department of Health and Human Services and from the European Union.)

OTHER HIGHLIGHTS

- "Viral load remains an important marker of response to antiretroviral therapy."
- "Newer formulations of drugs and the availability/approval of new drugs have resulted in effective and more convenient regimens (e.g., once-daily dosing regimens, smaller pill size, protease inhibitor "boosting" strategies)."
- "Viruses resistant to an increasing number of drugs raise challenges... Several new recently released drugs are active against such viruses."

For people who've already been on therapy when they had more than 200 T-cells, who have had durable viral load suppression without adverse effects, "it is not clear whether it is safe to discontinue therapy." For women, there's no documented difference from men in terms of T-cell count and risk of infections, so there's no separate recommendation for them. Visit www.iasusa.org to see the entire document. ☒

Positive Empowerment

by Ida Byther-Smith

When I found out I had HIV in 1991, I was ready to cut my wrists. I was infected through my husband, who until the day he died never admitted that he had it. My husband wouldn't let the words "gay" or "bisexual" touch him with a 10-foot pole.

I was never sick a day after that, until a year and a half ago when I spent nearly three weeks in the hospital. I call it my 18 days of rebirth.

I was very sick on Christmas Day. I almost killed myself in the hospital by not telling the doctors and nurses about my HIV. I kept it a secret because I was afraid of being treated badly. My son said, "Ma, tell them." After I did, I heard a nurse say, "Oh, my God. Now we know what to do." They were so nice. I was the one with the prejudice I accused others of having, because I thought they were going to be evil to me.

My T-cells were zero. I had double pneumonia. They had to experiment with me because every drug they put in my mouth I threw up.

Now I see that I didn't start living until I almost died. Shame. Fear. Hatred. Depression. Stress. Ignorance. I put that behind when I left the hospital. I learned those things will kill you. I decided to fight.

I know other women just like me, who never used drugs or lived the street life. All they did was marry the wrong guy, or maybe not the wrong guy but a man who wasn't sure of his sexuality. There are lots of women living in shame and fear.

I am a member of the Church of God in Christ and I had a whole lot of denial. I kept praying for the HIV to go away. I thought

that I must not be a good enough Christian for this to have happened to me.

Instead, God must have been preparing me for the illness that was coming. Today I believe in LOVE. "L" for unconditionally loving your family. "O" for being open and honest with yourself. "V" for victory in Christ Jesus. "E" for education. If you know

what you're dealing with, you know how to fight it.



Before, I thought HIV drugs were a form of genocide. Then I got involved with the Coach House [here in Chicago] and one of the workers there, John Davis, told me, "Why don't you just give your body a chance? If you don't feel better, you can stop." On January 26, 2001, I started Sustiva and Combivir, and they worked. My T-cells are 384 and my viral load is undetectable, less than 50. I feel good.

So far no one has met me in the street and spit on me, but I still have a little fear on the back burner. I lived in so much fear, I was a ball of fear and hatred until 1996 when I forgave my husband. I had burning in my chest and when I forgave him that burning left. I moved him back into my house. When

I forgave him, I knew it... my body was set free.

Shame? I don't have any. I don't care what people think about me. I don't care what people say about me. I have no time for it.

My 39-year-old brother died of a massive heart attack last year. He was not ill or overweight. I thought, "Why not me, God?" I was already almost dead. One of my aunts heard me at the funeral. She said, "It wasn't your turn, baby, it wasn't your turn. God has something for you to do." That day I made up my mind to do my Father's work. I will tell the world how good God is.

With my brother's passing and with September 11, I learned you have to live every day as if it was your last. And you have to enjoy it. I used to be a procrastinator. Now I don't put off for tomorrow what I can do today. Sometimes I do too much. All those things I want to do—tomorrow is not promised. I have my good days and bad, but I try to make sure the good days are more than the bad ones.

My four children and my godchild never let me forget I have something beautiful to live for. I can't tell them to fight if I give up. My grandma used to tell me life is hard by the yard, but it's a cinch by the inch. I have a joke: When Death comes, I'm going to take off running so hard, he's going to have to stop to take a breath.

Maybe—just maybe—he'll decide to give me another day. ✚

Ida Byther-Smith is a peer advocate with the Chicago Women's AIDS Project-South. She is writing a book on her struggles with HIV, entitled I'll Go Down Fighting.

Why is the rate of HIV infection still out of control in a country that has nearly eradicated smallpox, polio and Legionnaire's Disease? Globally we have worked together to manage leprosy, malaria and sexually transmitted diseases like syphilis and gonorrhea, yet the numbers of HIV and STD infections keep rising. Our foremost problem is in the department of sexology. We suck at sex education and we suck at understanding sex and gender.

Why is it that intersexed infants must be assigned a gender as soon as they are born? Why can't we have male, female, transgender, hermaphrodite and intersexed appear on birth certificates and application forms? That would be too simple.

HIV is not under control because America is in denial that sex goes on, truly, madly, and deeply. The denial starts within the heterosexual communities and from there on the fish gets bigger and bigger. We have entire ethnic cultures within our population that flat out deny having any gays in their gene pool altogether. Most of these poor suckers have to grow up in the closet. Life is easier in the closet. The only good thing about the closet is we sometimes get pro-gay legislation or communal tolerance from our brothers and sisters who must stay in their closets for the time, because for them life is also easier in the closet.

We have a hard time dealing with sex and when in doubt turn to the holy books. It is literally hard to find proscribed homosexuals acts in these books but most of the time spent on prophesying is based on sex. Everybody has sex so it gets the highest point for a return engagement at next week's service. The African American community is uncomfortable with the Gay and Lesbian issue, let alone mention HIV because that brings up drug abuse as well. The Hispanic and Latino community is not too keen on accepting us either. I've been told by my own family members that there are no Cuban gays because we're all so fucking macho! Every other community feels the stigma as well. Many cowboys would rather die from any medical malady rather than admit to com-

plications from HIV. Even cancer and mental disease are now more easily accepted for cause of death than HIV. What if the definition for HIV meant Human Imperfection and Volatility? We have evolved into a biased, sexist, racist, imperfect and volatile race. Darwin, where are you?

The list of famous gay people who have molded creation with all its beauty and brilliance is so long. From Sappho and Marie Antoinette to Bella Abzug and Bessie Smith, what great combo meals they would have enjoyed together. If only Eleanor Roosevelt,

see the HIV, hepatitis and STD rates rise. The puritans who are in control of us as a nation are uncomfortable with sex. We have to stop agreeing with them and remember that sex is good and normal and hot.

I am hopeful that the respect for humanity and the courage to keep things beautiful and brilliant will shine on. I hope that Sylvester and Divine kicked some sense into Liberace and Rock Hudson when they met up in heaven. I hope they reincarnate into a future governing body that would demystify sex and therefore humanize sexually transmitted diseases.

Our society includes an ex-football player who got away with murder and is enjoying retirement quite nicely.

When Does the Healing Begin?

by Carlos A. Perez

Billie Jean King, Martina Navratilova, Rosie O'Donnell, Melissa Etheridge, k.d. lang and the Indigo Girls met all at once they could have come up with a band with Freddie Mercury singing lead with a song entitled We Are The Queen Champions.

And there's the list of famous gay men. I've even read that certain Popes were supposedly "family." Why do they keep that Sistine Chapel painting up there if the artist is truly their idea of an abominable deviant? If I felt this way about the art on the ceiling of my chapel I would have a morally respectable, upstanding artist paint over the ceiling for me. Priceless, huh?

What we do best is dramatize the murdered victims of our society's worst nightmare; the dark side of hate crimes. The crimes exist because the homophobic criminals believe they are doing society a favor and they believe they have proof—it is written—that is where they always point. The same book they need to be sworn in with. Matthew Sheppard becomes a made for television movie.

Now we are about to embark on a road of government cutbacks to HIV programs and we will be refocusing our funding for HIV education on abstinence based programs. That should work about as well as prohibition did. Everybody drank bathtub gin then and everybody will keep on having sex now, as always, and we will continue to

Millions of misappropriated tax dollars. A President who denied having a sexual tryst although his date saved her dress with his DNA print on it. We now blame the illicit drug trade for terrorism. These examples of bad examples does not give us the right to "act out" but it sure wears down on the populous' patience and you can feel the apathy everywhere. When will our healing begin?

We must have a renaissance of HIV prevention and rethink our plan to survive. In order to do that we have to overcome racism first, before we can get to the sexism, and you see how well we're doing with racism. Our current administration in the White House needs to sober up to reality. What was that again? Abstinence? Hasn't the Catholic Church been preaching abstinence throughout history? You see how well that plan worked for them.

Our leaders need to show encouragement and not give in to apathy and depression. They need to stay frisky, because after September 11th and now with a new administration in the house our social services are up for grabs! Our leaders need to inspire us instead of drowning us with senseless laws and making us feel like we don't matter. ☩

Carlos Perez is editor of the Chicago Area HIV Services Directory and Information Services Coordinator at Test Positive Aware Network.

Test Positive Aware Network Turns 15

This year marks the 15th anniversary of Chicago's Test Positive Aware Network. What began as an informal meeting, held in founder Chris Clason's living room nearly two decades ago, has survived the myriad growing pains becoming an established agency entails, and indeed, continues to thrive and move forward through often very difficult times. While the agency has expanded beyond serving its initial constituency of predominately gay white males to include a variety of impacted populations, its mission of serving people with HIV, providing all of us with information and empowering all of us to live fuller, healthier lives through peer-led programming, has never wavered.

"WE WERE THE PARIAS OF SOCIETY."

Bill Rydwels, a founding member of the organization, discovered he was HIV-positive in 1985. "There was nobody who wanted to talk to anyone who was HIV-positive," he recalls. "You didn't know if you could afford to tell your family. You knew that there might be a problem telling your friends, and certainly coworkers. You knew you could lose your job, and if you lost your job, where were your benefits? So a young man named Chris Clason, who was fabulous, put out an ad in Gay Chicago in 1987, and asked who would like to get together to offer support to one another. There were nineteen of us at that first meeting. We realized we needed a support group so we'd understand what to do,



by Jim Pickett

Positively Aware, the agency's bimonthly journal which started as a couple pages xeroxed, stapled and distributed hand to hand by volunteers, has grown into a national, and international voice for people living with and affected by HIV and AIDS. It's read by everyone from HIV-positive folks to the health care workers who care for them, coast to coast on multiple continents. Like the agency that spawned it, *Positively Aware* remains committed to disseminating information in a clear, understandable way, and most importantly, remains committed to living.

Over the course of a few weeks in July, a number of members, past and present staffers, and community leaders shared their stories about the epidemic and the important role TPAN has played, and continues to play, in the years since its inception.

how to do it, and to stroke one another's back. We were the pariahs of society. That actually hasn't changed over the years, we're still pariahs, but now very expensive ones."

Bill, a national advocate for people over 50, continues to attend support groups, specifically one that meets during the day called Daytimers. Paul, another member of Daytimers, has been coming to TPAN for many years himself. "Early on," he says, "I came to this group for the information. People were constantly dying. I also used the legal clinic twice to write and update my will, I've used the resource library a whole lot and I've gotten a lot of advice from people in the group about how to apply for and get disability."

"I used to come all the time," Paul continues, "and now I come maybe once every

two months, because now I have a different set of issues. Daytimers, though, was really critical for me, and not just for the information, but because I needed something to do during the day after I got my disability. Just contact.” He laughs. “You can only watch Oprah for so long, and I needed to have something else in my life. The chance to get out of the house and talk with other people, to kind of fill the hole that was there during the day. Nobody wants to hear about how devastated I was when I developed this buffalo hump, or wants to hear all the stories about my diarrhea. But these guys have been there and know what I am talking about. Other people don’t get it.”

“HE WAS SO AFRAID.”

“I remember this one guy, we used to call him Mercedes Benz,” reminisces Steve Wakefield, the first paid executive director of the organization. “He would park across the street, and then after he was sure there was no one walking down either side, he’d run into the building, grab a copy of the newsletter [the predecessor to the journal], sit in his car, read it, make notes, and then throw the newsletter in the trash can and drive away. He was so afraid that somebody might realize that he had come to a place like TPAN.”

Stigma affected those infected, and those who treated the infected as well. Wakefield recalls that, “hospitals who said they were affiliated with AIDS actually lost

were HIV-positive, they immediately became a part of the TPAN family. And all of the services and all of the care was available to them. It was people living with HIV caring for other people living with HIV. It was a great place to be, from that perspective, but it was also a very hard place to be, having to deal with a lot of loss. You met people, you became quickly attached, and then they were gone from your life.”

“WHAT WOULD MICHAEL DO?”

“Steve really put TPAN on the map,” Mark Ishaug, the executive director of the AIDS Foundation of Chicago, states emphatically. “His big brain and his razor sharp vision, created an organization like no other

“With the current political climate, we need more people to become more politically involved in HIV and AIDS policy. We have got to speak up for ourselves. We have to take ownership of this disease.”



Jerry has also been a longtime member of Daytimers. “For me it acted as an organizer for my life. When I was diagnosed I happened to be very sick,” he says. “After a year of recovery your life changes completely. I didn’t have the same friends, some of them didn’t want me as their friend anymore, both gay and straight people. And some didn’t know how to talk to me, because they didn’t want to say something wrong and felt better just leaving me alone. Monday and Thursday mornings I had something to do. Now, once you start that with a base for your week, you can work around it. You’re like everybody else, you have things to do. [Having AIDS] is like being retired without being able to tell anybody, the secretiveness of it.”

patients and sometimes staff members, who said they didn’t want to be in an AIDS hospital. Illinois Masonic and St. Joseph’s both made a major commitment to the community in Chicago by creating HIV/AIDS units. They actually lost some business, but both of them had boards whose mission was to take care of the local community.”

Wakefield, who currently is the director of community education and relations for the HIV Vaccine Trials Network and lives in Seattle, looks back at the intense bonding and emotional turmoil that were hallmarks of the earlier days of the epidemic. “Friendships were made quickly. Once you knew you were HIV-positive, often your life expectancy was very short. People didn’t have time to be picky about friendships,” he explains. “If someone came in and said they

in Chicago at the time.” He continues, “Then of course came Michael Thurnherr [the agency’s next executive director]. From the moment that I met him, I’m not sure that falling in love is the way to describe it, but I fell hard for Michael. I was amazingly drawn to him,” he says, “I had never met anybody like him—so smart, so brilliant, and so committed to the fight against AIDS. I’ve been doing this work as a volunteer and as a paid staffer for 15 years plus, and I really can honestly say that I’ve never worked with anybody like Michael. During challenging times and periods of great stress and disillusionment of which there can be many in this work, I really do say to myself, ‘What would Michael do?’ I think about his wit, his smarts, his charisma, his leadership, his laugh.”

Ishaug also learned a great deal of political savvy from him. “We had meetings together with ACT UP (AIDS Coalition to Unleash Power), we had meetings with the director of the state’s health department, we had meetings with the governor. We met with all these folks, and Michael had this uncanny ability to be as influential with the great folks from ACT UP, as he was with the governor, and with service providers, and with people living with AIDS. Everybody respected him.”

Thurnherr’s skills around activism and advocacy were somewhat held back, however, according to Ishaug. “I think that Michael’s biggest frustration was that he always wanted the organization to be a

“WILLING AND ABLE TO CHANGE.”

Perhaps TPAN was not then at the point to be able to realize Thurnherr’s full vision, but it never really lost sight of it’s mission to serve those who were being impacted by the epidemic. “I think one of the strengths of TPAN was that it was willing and able to change with the epidemic, and still is,” says Dennis Hartke, the executive director from 1999 to June 2002. “Clearly in the early 90’s, TPAN was mostly gay men in their 20’s and 30’s, gay white men. I think TPAN has been quite successful in recognizing the changing epidemic and working to address the new populations that were and are affected. Brothers United in Support (BUS) is an example of that. The way BUS came about

ed in a lot of organizations. My friend selected TPAN because he had seen information on the north side in the bars and everything, and decided to go north,” he explains. “There were not a lot of men of color present at the meetings, the support groups. Timothy Gates, a former program director, myself, and a couple more people had met at his home and just thought that TPAN needed a program for African American men specifically. Gay and bisexual, transgender did not happen ’til later. It was mainly a trial type of program, and we decided the brothers needed a safe space to meet and talk about their issues.”



TPAN staff members, Carlos Perez, Michael Barnett, Sylvia O’Shaughnessy, Rick Bejlovec, Charles Clifton, Jeff Allen, Enid Vázquez, Jeff Berry, Kathleen Barber and Anthony Clark.

stronger advocate for people with AIDS,” he believes. “Not just peer support, and groups, and mental health support groups—I mean, he wanted all that stuff. But I think he was a natural advocate, he was an activist advocate, and I think of his many special skills, that was his greatest. He could get things done, not just by screaming and shouting stronger than the next guy, which he could definitely do, but figuring out a program, figuring out a plan. I think he really wanted to make TPAN a real strong systems advocacy organization. And I don’t think he was able to make that happen, I just don’t think that was where the board was.”

was that it did not come from staff, it came from members. TPAN was willing to listen to community members who came to them who said they needed this type of support group, for African American gay and bisexual men, and will TPAN do it? In fact BUS had been peddled to two or three other agencies who had said no.”

One of the founding members of BUS is Lester Davis, who recently moved from Chicago to Washington, DC to further his education. “I remember coming to TPAN in 1995. I went to help a friend who was recently diagnosed, bisexual, and in my church. We were dating, and we went. I had already known about my own status since 1986,” he says. “Men of color were not well represent-

“THEY ARE FRIENDS.”

The program grew to be one of the agency’s strongest and best attended, and continues to be. Even when people move away or otherwise get on with their lives, BUS still provides a touchstone, a network, for many. “We can talk and give the support and love to each other but don’t necessarily have to be in the same city to stay in touch,” enthuses Davis. “In fact in D.C., there are two BUS members who live here already, and now I am the third. I still have a lot of connections with guys in Chicago, they’re in my little black book. You check on your brothers because you know them, and they check on you. If you’re doing something that they don’t like, they will check you,” he laughs.

“And I have those types of friends, these BUS members. Beyond membership of TPAN, they are friends.”

GROWING AND EVOLVING DOES ENTAIL SOME BUMPS IN THE ROAD, HOWEVER.

“One of the biggest challenges was the transition from what had been the traditional founding members to the new groups that were being impacted,” says Hartke. “I have talked to other peer led organizations around the country, and they have all had, and continue to have, that issue of making that transition from being a largely gay white male organization to one that is serving people of color, women, and injection drug users (IDUs). The problem that creates is that the original members, the old members, feel they are being ignored, feel that their issues are somehow not as important in the HIV field as African American men who have sex with men for instance, or IDUs,” he explains. “By and large, in the gay white community, there is much more community and social support systems in place for people now than there were ten years ago. Although, clearly, we haven’t made as much progress as we think by the very fact that when two men meet and are thinking of having sex, they are unlikely to discuss their HIV status. There is clearly stigma, but it isn’t the same that was there in 1990. In the African American community, from that standpoint, they are five to seven years behind the gay white community. It was interesting to watch that many of the things BUS has gone through were like *déjà vu* for the agency. It started off as, ‘Okay, we need to come together, but no, we can’t have a sign on the door, no, we can’t let anyone know why we’re here.’ And eventually became, ‘Yes, we have a sign on the door and I’ll tell you I’m a member of TPAN and a member of BUS.’”

“We have a really diverse clientele now,” says Rick Bejlovec, who has worked for TPAN for seven years, the last three as its business director. “Yes, we still see gay white men, but we have a much larger group of IDUs and people in recovery. Our recovery group is one of our biggest now. These groups of people are where, collectively, the people who started this organization were fifteen years ago. Scrambling for information, not knowing what’s out there, not knowing about services. The level of awareness of what HIV is and the services that are

available is lower in the communities that we see now. But they want to learn.”

“YOU NEED TO READ THE MISSION STATEMENT.”

He concurs with Hartke on the challenges that appear while moving to meet the needs of diverse populations. Bejlovec mentions that, “we have gotten a lot of criticism, even from some of the people who helped found this agency, saying we have betrayed the community we served. And I don’t think we have betrayed anybody.” He continues. “We have rolled with the changes, and have literally come to the people who now need the services, and not remained stagnant. I don’t know if it’s a racism issue or what, but there are people who think that we are not [serving] gay white men anymore. They will say that we have betrayed the community and betrayed our mission statement. I’m like, you need to read the mission statement. We’re here to provide information and support for people that are living with HIV, people that are impacted or affected by HIV. We’re here to empower people.”

AND PEOPLE ARE PEOPLE. PERIOD.

“I came to TPAN as a client. I tested positive, and a year and a half later, I came to a support group. This was ‘90 or ‘91. I was getting the magazine in the mail, and there was a notice about volunteering, so I started volunteering in July ‘92, and soon after I was hired,” says Jeff Berry who has been there ever since, making him the staff member who has been with the agency the longest. He has always worked on the journal, with responsibilities encompassing proofreading, maintaining the web site, distribution, and advertising.

“For me it’s always been about the magazine,” Berry states proudly. “We get letters from around the world, thanking us and telling us how it’s helped them, and the change it’s provided in their lives. We hear from a lot of prisoners, a lot of prisoners. I benefit a lot, it gives me a great deal of satisfaction to know that we’re helping so many people, we’re giving them hope. We’re not making it glossy or sexy, but we’re putting the information out in a way that’s easy to understand. Sometimes funny, and not morbid.”

He continues. “I think we’ll be around for a long time to come. I think the magazine will always somehow survive, because there

are so many people who depend on it and use it as a resource.”

If Charles Clifton has anything to say about it, both the agency and the journal will be around for a long time to come. Clifton took over as editor of *Positively Aware* two years ago, and in July succeeded Hartke to become the new executive director. He has a full plate, two full plates really, but seems undaunted by the amount of work he faces. In fact, he seems to relish the prospect of a 7-day work week, filled with issues around programming, funding, editorial deadlines, human resources, and politics.

“It’s my passion for the people we serve that has allowed me to work the way I have,” Clifton explains. “And I feel that the community here and nationally respects the work that we’ve done, and from that perspective, it’s given TPAN a renewed sense of respectability, credibility. It’s created this energy in the agency and within myself that allows me to keep going at the level I’m going. So even though I’m juggling basically two full-time jobs right now within the agency, I have a committed staff that’s willing to take on additional roles.”

“WE HAVE TO SPEAK UP FOR OURSELVES.”

Consciously or not, Clifton is following in the advocacy footsteps of Michael Thurnherr, as described earlier by Mark Ishaug. “I think my greatest input on the journal right now is my voice as an advocate and as a policy person. I think in the past the journal has focused more on treatment and the science, and without losing that, I think I’ve given our readers the feeling of being advocates.”

He plans to take that energy with him into the role of executive director. “I really want to position TPAN in Chicago and nationally as an agency that is interested in HIV policy, shaping it, changing it, and moving it forward. That’s my mission.”

And that mission has essentially remained the same for 15 years. People with HIV must be part of the process, as they always have been. Our voices, our input, our buy-in is critical, more so now than ever. “With the current political climate,” Clifton says, “we need more people to become more politically involved in HIV and AIDS policy. We have got to speak up for ourselves. We have to take ownership of this disease.” ☒



*Treatment overviews in brief from
The XIV International AIDS Conference
in Barcelona, Spain, July 2002.*



What's New with Drug Regimens?

by Charles E. Clifton

Since researchers unveiled protease inhibitor drugs at the 1996 world AIDS conference, researchers and treatment activists alike have come to each of the international gatherings hungry for the latest information on how to make these cumbersome but life saving medications more user friendly.

For patients who have never taken antiretroviral drugs, the selection of an initial regimen is crucial to long-term preservation of the body's immune system. Studies have shown that in order to successfully suppress HIV in the body, very high levels of adherence to an antiretroviral regimen is required. But lifetime adherence to HIV drug regimens is no easy task.

Pills must be taken as much as four times a day. Some require food with each dose; others need to be taken on an empty stomach. Many of the drugs cause painful side effects. Some of those side effects, like diarrhea, are immediate while others, such as liver damage and increased cholesterol levels, are long-term. Perhaps most visibly dramatic, some meds cause changes in the shape and size of the body by redistributing fat (a

condition known as lipodystrophy). Finally, many of the side effects worsen conditions that already plague African Americans, such as heart disease and high blood pressure.

Several presenters at the Barcelona conference have reported studies on new strategies to initiate treatment in HIV-positive



people who have never taken antiretroviral drugs. Following are some highlights of studies comparing the effectiveness of regimens that spare HIV-positive patients from using the punch-packing protease inhibitors in their initial treatment regimen. (Visit www.aids2002.org for more information.)

VIRAMUNE VS. VIRACEPT

J. Mallolas presented data comparing the effectiveness of two different regimens in “treatment naïve” HIV-positive clients—or people who have not previously received medication to combat their infections. One group of participants was given a regimen consisting of two nucleoside reverse transcriptase inhibitors (Videx [ddI] and Zerit [d4T]) plus one protease inhibitor (Viracept [nelfinavir]). A second group was given two NRTIs (Retrovir [AZT] and Epiriv [3TC]) and one NNRTI (Viramune [nevirapine]). The aim of this study was to determine whether individuals with fewer CD4 T-cells, in this case less than 500, could be treated successfully with a regimen that spared the use of protease inhibitors. The results of the 18-month study indicate that the

regimen consisting of Retrovir, Epiriv and Viramune was as effective and tolerable in this group of treatment naïve HIV-positive participants.

SUSTIVA BEATS DUAL PIS

J.R. Arribas discussed data comparing the effectiveness of a regimen using Sustiva



(efavirenz) from the NNRTI class against regimens using protease inhibitors. In this study of 214 participants with immune systems that were severely impacted by HIV, each participant had fewer than 100 CD4 T-cells. The partici-

pants were randomly divided into six different study groups. In the five groups using protease inhibitors, 47 participants were given regimens that included Crixivan (indinavir) in addition to drugs from the NRTI class, 47 were taking Viracept (nelfinavir), 25 with Norvir (ritonavir), three with Crixivan combined with Norvir, and three with Fortovase (saquinavir soft-gel) combined with Norvir. Ninety-two participants were taking Sustiva in addition to drugs from the NRTI class. Following 12 months of close study, the researchers determined that there was no difference between the Sustiva or the PI-based use of HAART in the initial treatment of HIV-positive individuals with severely suppressed immune systems, suggesting that Sustiva is an effective drug to use in initial regimen options.

A final study presented by O. Kirk examined data seeking to determine the effectiveness of a triple class HAART regimen, and the potential for greater levels of toxicity. Again treatment naïve HIV-positive participants were randomized into two study groups. One group of 118 participants was taking Viracept and Viramune plus two NRTIs, the second group of 115 individuals was taking Norvir and Fortovase plus two other NRTIs. After 48 weeks of study, researchers determined that a regimen of nelfinavir and nevirapine plus two NRTIs was well tolerated and was effective at suppressing HIV when compared to a regimen containing the Norvir and Fortovase (both protease inhibitors) plus two NRTIs.



A FEW HIGHLIGHTS IN ANTIRETROVIRAL THERAPY ISSUES IN THE TREATMENT EXPERIENCED INDIVIDUALS

SWITCHING PIs

Can you simplify your PI treatment by switching to Sustiva, Viramune or Ziagen? In a simplification study, researchers from Spain looked at the response of participants who switched from a HAART regimen containing a protease inhibitor to a regimen



containing either Viramune or Sustiva, both non-nucleoside analogue reverse transcriptase inhibitors (NNRTIs), or to a regimen containing the nucleoside analogue reverse transcriptase inhibitor (NRTI) Ziagen (abacavir). To date head-to-head studies comparing these three drugs have not been reported.

Researchers found that people were more likely to have detectable viral load with Ziagen. However, they were significantly more likely to discontinue Sustiva or Viramune because of side effects.

A total of 400 adult participants, on a regimen containing at least one protease inhibitor plus two NRTIs and with viral load less than 200 copies/mL were randomly switched from the PI to either of the three study drugs (Viramune 155, Sustiva 156, Ziagen 149). The goal was to maintain viral load below 200 copies/mL for 12 months following the switch. After 12 months, 94% (Viramune), 94% (Sustiva), and 87% (Ziagen) of participants remained below the 200 count. The mean changes in CD4 T-cells during the 12 months were +41 (Viramune), +51 (Sustiva), and +51 (Ziagen). A significantly higher number of participants discontinued therapy from

Viramune (16%) and Sustiva (17%), than on Ziagen (6%). People with treatment failure (detectable viral load) after one year were 23 (15%) of those on Ziagen compared with eight of those on Viramune and seven of those on Sustiva (about 5% each).

Results are from 18 months of follow-up. The Spanish researchers evaluated 460 patients who had less than 200 viral load. Everyone had a T-cell increase of around 45. Participants had a median of 30 months on their PI therapy (mostly Crixivan or Viracept) and had monotherapy before then. Half of them had an AIDS diagnosis. There

was no “evident” change in body fat abnormalities. (Abstract WeOrB1262)

FORTOVASE/NORVIR

Researchers lowered the dose of Norvir and increased the dose of Fortovase to see if side effects would be less and the twice-daily combination still effective. Yes and yes. Doctors said the 400/400 twice-a-day dose was poorly tolerated, and that Norvir significantly increased levels of cholesterol and triglycerides.

This small U.S. study examined the clinical benefits of switching 23 treatment experienced patients with viral loads less than 200 copies/mL to Fortovase 1000 mg/Norvir 100 mg dosed twice daily in a four-drug antiretroviral therapy. The goal was to examine the occurrence of hyperlipidemia and adverse side effects associated with the higher dosing of ritonavir. Previous data on drug level maintenance supports the use of a lower dose of ritonavir to boost saquinavir 1000 mg, twice daily. Other inclusion requirements were also that participants had to have been receiving saquinavir 400 mg/ritonavir 400 mg for at least six months prior to entering the study, and no prior use of more than one other protease inhibitor for more than three months.

Drug levels were measured at time of entry to the study, and at months one and six, fasting lipids (triglyceride and cholesterol) were measured every three months. Over the course of six months, the lower dose of ritonavir was tolerated better, fasting triglyceride levels fell from an average of 635 to 375 mg/dl, and cholesterol levels fell on an average of 326 to 236 mg/dl, supporting growing trends toward dose reduction of ritonavir. Some doctors wondered why the 1,000/100 twice-a-day dosing was being

studied, when 1,600/100 once a day is popular. They concluded that the drug companies had to show something to the Food and Drug Administration for lowering the Norvir dose. (Abstract WeOrB1263)

CRIXIVAN VS. FORTOVASE

International researchers reported on the first head-to-head comparison of riton-



avir boosted PIs Crixivan and Fortovase, in combination with more than two NRTIs or NNRTIs. The objectives of the study was to compare virological outcome between 306 participants randomly divided into two study groups, based on the percentage of participants whose viral load remained below 400 c/mL thru 48 weeks, the percentage of participants experiencing adverse side effects, and those who discontinued treatment prematurely. No clinical, laboratory nor demographic differences were observed at the beginning of the trial. As of December 2001, while viral load remained suppressed in the vast majority of study participants, an evaluated number of participants had difficulties tolerating both drugs. In the Crixivan group, 56 of 158 participants (35%) discontinued therapy due to drug toxicity. Fifty participants (32%) in this group reported grade 3 or 4 adverse events (serious). Seven were due to abnormal liver function test. In addition, serious adverse events that required hospitalization or were life-threatening occurred in 28 participants (18%).

In the Fortovase group, 42 of 148 participants (28%) discontinued therapy due to drug toxicity. Twenty-nine (20%) in this group reported grade 3 or 4 adverse events, four of which were due to abnormal liver function test. Serious adverse events occurred in 21 participants (14%) in this group. Interestingly, a third of each group had previously taken the protease inhibitor they were given—Crixivan or Fortovase—but it had not been boosted by Norvir before. The MaxCmin1 trial took place in the U.S., Latin America and Europe. This study is ongoing. (Abstract WeOrB1265)

VIREAD RESISTANCE

Forty-eight week data, from an international double-blind study, on the potent activity against wild-type virus and nucleoside resistant HIV of Viread (tenofovir) was reported. (Double-blind means that neither the patients nor the medical personnel knew what drug was being given, a process which helps to eliminate bias in a study.) A total of 550 treatment experienced participants with viral load between 400 and 10,000 c/mL were randomized to received either Viread 300 mg or placebo, with antiretroviral therapy, for 24 weeks. After week 24, all participants received Viread 300 mg through 48 weeks. The mean CD4 T-cell was 427, and prior antiretroviral use was 5.4 years, at the beginning of the trial. Through 48 weeks, viral load dropped below 400 c/mL in 41% of all participants, and 18% had a drop below 50 c/mL.

A sub-study of 253 randomly selected participants observed the long term pharmacokinetics (PK) of Viread. No changes in the PK of Viread was observed at week 12, 24, 36 or 48, when compared to day one, and no drug-related renal toxicity was reported. Through 48 weeks, only eight participants (3%) developed the K65R mutation (Viread associated drug resistance). (Abstract WeOrB1266) ☒

Expert Opinion From Barcelona

Edited by Enid Vázquez

FOR EXPERIENCED FOLKS

Dr. Julio Montaner of the B.C. Center for Excellence in HIV/AIDS at St. Paul's Hospital in Vancouver, gave a talk on "new challenges and perspectives" regarding treatment of people with HIV who've already been on therapy. He focused on three topics: treatment failure, therapeutic drug monitoring and inhibitory quotient (IQ), and new drugs on the horizon.

He said his clinic does not favor the idea of keeping people on partially suppressive regimens, where the viral load is at detectable levels. Some researchers have found that such therapy still provides health benefits to people with HIV. Rather, Montaner prefers to switch people to a new regimen to aim for undetectable viral load. He said people can always go back on their old therapy if the new one doesn't work out. One problem of staying on a partially suppressive regimen is that the drug resistance that builds up may cut off access to new drugs down the road.

However, in one analysis conducted by his clinic, even the experienced people on a partially suppressive regimen had survival similar to those people new to therapy (called treatment "naïve"). Naïve people generally respond better to therapy (e.g., they may achieve undetectable viral load).

Montaner said his clinic is building on the good response people are having with Kaletra. The drug does well for people with single or multiple protease inhibitor (PI) failure. The problem, he said, is complex interactions with other medications. Nevertheless, some research shows benefits with Kaletra despite its negative pharmacokinetic profile. He's waiting for more data.

In dual protease inhibitor combinations, when combined with a mini-dose of Norvir (100 or 200 mg), he said that with Agenerase, pharmacokinetic problems may not prevent a beneficial response. However, with Crixivan, look for renal (kidney) toxicity.

The movement towards therapeutic drug monitoring (TDM) and inhibitory quotient (IQ) tries to measure an individual's blood level of drug. This adds to the understanding of a person's response to therapy. It goes above and beyond the question of drug resistance, for example. "We no longer see resistance as a black-and-white issue," Montaner said.

On the Viread/Videx interaction, Montaner said the increased blood level of Videx was greater than had been thought. Higher blood levels may increase the risk of side effects, including serious ones. He says prescribers should reduce the level of Videx EC from 400 mg a day to 250 when taken with Viread and food. That's the preference of his clinic, although he said clinical trials are needed. "But, until we have clinical trials," he said, "this is what we're doing. We have to go forward."

T-20, an experimental drug taken as a twice-a-day injection, shows significant viral load drops in experienced patients after 24 weeks of adding it to stable HIV therapy. [However, T-20 has been showing this power for years. Other doctors at the conference said the question is durability.]

Preliminary results with tipranavir, an experimental once-daily protease inhibitor, show a very favorable drug resistance profile in multiple PI failures, Montaner said. He said tipranavir looks like a good secondary (second regimen) PI to use.

Overall, Montaner said doctors should think carefully about starting their patients on HIV therapy, should identify and correct reasons for treatment failure quickly and should switch failing regimens early. Adding an active new drug—one the patient is not resistant to—is not a clear measure for success as once hoped. Instead, the patient's entire HIV drug background is important, as is their clinical history (diseases) and resistance profile.

RESISTANCE: WHAT HAVE WE LEARNED?

That was the title of a talk by Dr. John Mellors, of the University of Pittsburgh. Resistance is the ability of HIV to mutate (change) in order to successfully fight drugs. Some of Dr. Mellors's remarks follow here.

"No antiviral is resistance proof, and it's very unlikely that one will be found. Incomplete suppression [a viral load that's still detectable] leads to resistance and resistance is common in the United States.

"Resistance limits treatment options and may lead to disease and death. Suppressing viral load to less than 50 copies can prevent resistance. Extensive evidence shows that resistance testing improves suppression when changing therapy.

"Resistance is not inevitable. Be careful when selecting drugs and follow suppression carefully. In patients who have never been on therapy, single and double mutations [changes in the virus that help it beat the meds] are likely to pre-exist. A 10-fold reduced susceptibility to therapy has been seen in acute [new] infection [because of infection with resistant virus]. Also, time to first treatment failure [usually defined as detectable viral load] is shortened in those with resistance.

"Incomplete suppression occurs because of limited drug potency or PK [pharmacokinetics, how a drug interacts with other substances], incomplete adherence—which most likely occurs because of intolerance (side effects)—or prior drug resistance. Even modest evolution [low but detectable viral load] evolves into resistance.

"In a HCSUS study (HIV Cost and Services Utilization Study), 63% of people after their first two years of HAART (highly active antiretroviral therapy) had greater than 500 copies viral load. Risk factors for resistance included having advanced AIDS or inexperienced doctors, and low CD4 count when starting treatment. Greater access to treatment was the greatest risk for resistance.

*Treatment overviews in brief from
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[HIV mutates most when antivirals are thrown at it.]

“Treatment failure that occurs within weeks or months limits future options. Progression should be anticipated if there is persistent viremia [detectable viral load]! Avoid blind switches. Test for resistance in people with more than 1,000 copies viral load. [You cannot run a resistance test with less than 1,000 copies.] Avoid impotent regimens or those that have a high pill burden and frequent dosing.”

VACCINES

Dr. Robert Gallo, one of the first people to isolate HIV, talked about the search for a vaccine. Finding the body’s reservoirs of HIV (its hiding spots) identify targets that are important to vaccine development, he said.

“Targeting extracellular [outside of the cell] factors which promote HIV replication or a diminished immune response is crucial,” Gallo said. He said dysregulative cytokines, a type of protein in the body, are an example of this. “We have to identify and find mechanisms of action for each HIV suppressive factor and exploit this information,” he said. In poor countries, a TAT vaccine such as the one his lab is looking at would be welcome because it can be taken as a shot two or three times a year.

Gallo criticized the idea that ethics demands triple therapy for the Third World. Instead, he believes that something is better than nothing. Therapeutic vaccines can help control disease progression in people living with HIV.

He said that when looking at reports on vaccines, look for the words “neutralizing antibodies,” not just “antibodies.” Antibodies are one of the targets of vaccines. [They help fight HIV and other invaders in the human body.]

Gallo said the discovery of the CCR5 co-receptor in 1995 was an important finding. CCR5 helps HIV enter the body. People without this gene, or with a defective one,

have higher immunity to HIV infection. They also have higher resistance to disease if they do get infected. “Targeting CCR5 is major today. CCR5 is dispensable, so it’s an important target [for vaccines and medications]. People can be born without it and do fine.” In other words, toxicity to the targeted CCR5 co-receptor is less of a concern.

Discovery of the gp120 receptor for HIV, which allows the virus to target the CD4 T-cells, was another important discovery. All together, there’s a “triple complex” of membrane fusion (entering the cell), virus-cell infection or cell-cell infection.

Another target is gp140, and peptides that can block this HIV co-receptor have been discovered. Overall, Gallo said a vaccine is critical, especially to counter the toxicity of current therapies and overcome the problems of drug resistance. (See “An AIDS Vaccine” on page 43.)

CURRENT CONTROVERSIES

That was the title of a talk by Dr. Michael S. Saag of the University of Alabama at Birmingham. Saag talked about when to start HIV therapy, what to start with, when and how to change therapy, Strategic Treatment Interruptions (STIs) and the benefits of therapy.

Appropriately enough, the *Journal of the American Medical Association* (JAMA) had that day published the new HIV treatment guidelines of the International AIDS Society-USA (IAS-USA), of which Saag was an author. [See “New treatment guidelines” on page 20.] Saag called CD4 cells “a moving target.”

The latently infected CD4+ lymphocytes—those that are not yet activated—lay around until one day they are activated, and then they too infect cells. It is these cells, which do not die off in two days as previously thought, but instead take six months to decay, that create the 60-plus years of treatment estimated for HIV eradication.

In Saag’s clinic, half of the patients looked at in one report did not stay on their first therapy for more than two years. For people with greater T-cell counts, toxicity was the biggest issue. For those with less T-cells, viral load rebound (increases) was the primary problem.

When and how to change, he said, depends on the definition of treatment failure. Generally, viral load rebound to detectable levels within 16 to 24 weeks of treatment is considered failure. Something should be done quickly to prevent the development of drug resistance. However, in subsequent regimens, the prevention of T-cell decline is more important than the concern for drug resistance. Nevertheless, he said, the definition of treatment failure needs to be individualized, as stated in the IAS-USA guidelines.

With STIs, research has shown a conversion to wildtype virus—which is good, but there’s also concern about a steep drop in CD4 cell count. The guidelines say more data is needed. Study 506 designed to look at STIs is “now up and running.”

As for benefits, Saag said the question is, How have benefits been derived? In New York City, there was a more rapid progression to death between 1990 and 1995 than there was in the HAART era post-1995. Moreover, New Yorkers were able to survive five years after PCP (*pneumocystis carinii* pneumonia, formerly the biggest killer of people with AIDS, and a quick killer at that).

A cost-benefit analysis from Saag’s clinic showed an average cost of \$18,000 a year to treat a patient with HIV. However, the figure was \$34,000 for people with advanced disease, and \$14,000 for the people with more than 350 T-cells. “There’s a direct cost benefit to keeping people healthy,” he said. ☒

Treatment Access as a Human Right

by Zackie Achmat

Editor's Note: At the XIV International AIDS Conference in Barcelona in July, science was practically dead. Politics was in. It seemed the doctors felt that research is useless if you can't use it to save lives. The movement that began in full force with the last international conference two years ago in Durban, South Africa, towards saving the countries that are dying, continued to get stronger. In his plenary address to the Barcelona conference, South African activist Zackie Achmat, of the Treatment Action Campaign, brought us up to date on how much progress has been made since Durban. Achmat delivered his talk by video because of a bacterial lung infection that kept him from traveling. He is a person living with AIDS who refuses to take antivirals until they are widely available in his country. An edited version of his speech follows.

But it is not only the activists and the advocates acting as a force for change. In his opening talk, Dr. Stefano Vella, the out-going president of the International AIDS Society, which organizes the international conference, talked about the growing advocacy role of medical providers. "I never saw in other fields of medicine this growing 'scientific activism' and the inclusion of the [concept of] universal access to health care in the scientific agenda of the most relevant AIDS research institutions of the world. Indeed, scientists progressively understood that they should take the lead with the idea that the advancements of medicine cannot be reserved to small numbers of people... If there is anything that should be globalized, it is the right to a healthy life."

And in his talk at the closing ceremony, incoming IAS president Dr. Joep Lange said, "A specific issue close to my heart is access to decent HIV care, including antiretroviral therapy, for the millions and millions of infected people in developing countries who need it. The world can simply not afford to let them die, from a humanitarian perspective, from a developmental perspective and from a security perspective. And it is possible to do something about it—it is actually quite simple. It is

going to require enormous effort, yet it is simple. Do not be fooled: People make simple things complex to condone their inertia, and the inertia of those who are living off this epidemic. Or maybe not inertia, but simple lack of imagination.

"We need to be creative. For instance, you do not need a lot of infrastructure [clinics, labs, etc.] to deliver HIV/AIDS care. You do not need complex regimens. You do not need doctors and nurses to deliver the care in every remote corner of Africa. If we can get cold Coca-Cola and beer [delivered by truck] to every remote corner of Africa, it should not be impossible to do the same with drugs.

"Bad government and lack of leadership has actually killed more people with HIV than anything else." As for the money, Lange said, "I am actually convinced that the 10 billion dollars that is often quoted is an underestimation of what is needed. But even if it were 25 billion dollars per year, it would still be peanuts. Do you know how much the England-Argentina World Cup football match cost the UK [United Kingdom] economy? Two billion dollars. It just takes five to 12 football matches and a concerted global effort to really do something about HIV/AIDS. What are we waiting for?"

The international conference has spoken. As one report noted, "Discussions here have

shifted from the feasibility of antiretroviral therapy for individuals in resource-poor countries to how quickly this can be accomplished." Leaders are demanding the world's political will to combat the epidemic.—Enid Vázquez

When we last met in Durban we had hope and we had arguments about HIV treatment. Today we have facts. In Khayelitsha, outside Cape Town, *Médicins Sans Frontières* (Doctors Without Borders) have illustrated that people with HIV/AIDS, a majority with a non-existent or severely damaged immune systems, could recover life, health and dignity with antiretroviral therapy.

TREATMENT WORKS

The majority of MSF's patients who started ARV [antivirals] at a primary health care level had fewer than 48 CD4 cells and viral loads greater than 170,000 copies. Over six months, the majority achieved undetectable viral loads, and more importantly were able to re-constitute their immune systems. This follows on the success of Paul Farmer, Partners in Health, and the people of Haiti. So today when we speak to you of ARV therapy access in poor countries, we speak not only with arguments, not only



*A few items from
The XIV International AIDS Conference
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with hopes, not only with desperation, but actually with faith and the lives of the people themselves.

THE DURBAN EFFECT

The global community decided to campaign for affordable medicines and ARV access for poor countries and communities in the wake of the Durban 2000 conference. That campaign has given many of us the hope and the will to survive. Our movement has achieved many successes and met

many challenges over the last few years. I want to highlight some of these successes and challenges.

In the constitutional court judgment on the issue of the mother to child HIV prevention, the court quotes the South African government's assessment of HIV and AIDS as an "incomprehensible calamity." Although the facts and arguments I will use are rooted in South African realities, in many instances the arguments elsewhere are similar, or they can be used to illustrate the differences.

THE IMPACT OF HIV/AIDS ON MORBIDITY AND MORTALITY

The Department of Health stated last September that 24% of all public hospital admissions were due to HIV/AIDS. This demand for hospitalization will increase steadily every year in the absence of significant alternative interventions. We would like to ask, what are these interventions?

To us this is not only a matter of the cost to the state, but the lives of mothers, the lives of women, the lives of children and the lives of men. Many of us in our productive years, many of us who have not yet reached the prime of our lives. Central to all our work on HIV prevention and treatment are the



issues of life, dignity and access to health care.

HIV prevention and treatment cannot be separated. Not to treat HIV effectively will destroy the already weakened health care systems in poor countries.

COMBINE PREVENTION AND TREATMENT

From a purely public health care perspective, it is shortsighted not to treat HIV, to say that we must focus on prevention and exclude treatment. On the other hand, it is unconscionable, because what we are speaking of are not cold statistics, but our lives. Our lives matter, the five million people in South Africa with HIV matter and the millions of people throughout the world already infected with HIV, their lives matter. And so, it is not simply the question of the cold statistics that we are putting to you, but a question of valuing every person's life equally. Just because we are poor, just because we are black, just because we live in environments and continents that are far from you, does not mean that our lives should be valued any less.

It is critical that every treatment activist also becomes a prevention activist. Active prevention of mother and child transmis-

sion, assisting rape survivors, all these issues and above all, the use of condoms for everyone who is positive. Making clear to people with HIV that they should use condoms—such a prevention message is critical to all our treatment efforts. Therefore the dichotomy between prevention and treatment is one that this conference should lay to rest immediately. We need to stop this counter productive debate.

Let us return to practical concerns. What are the practical obstacles to getting the vision of the World Health Organization that three million people should be on treatment by the year 2005?

VOLUNTARY LICENSES FOR GENERIC PRODUCTION

The partial price reductions and insufficient donations by drug companies will not assist in the long term to deal with the epidemic in a sustainable and an effective manner. What is required is generic competition and therefore we appeal to all the drug companies with brand name medicines to issue non-restrictive voluntary licenses at between 3-4% royalty, to ensure that poor countries and communities have access to ARV therapy. This will eliminate the unnecessary conflict between the activist community, government and drug companies.

HEALTH-CARE ESSENTIAL FOR DEVELOPMENT

To be able to deliver drugs to people, to be able to save the lives of the millions with HIV and AIDS, we need effective public health care systems. We can only start by endorsing both Amartya Sen and the World



Health Organization's Commissions on macro-economics report that regards health care as an essential public good. Not only for dignity and life, but as a component of a sustainable development strategy for most developing countries. We therefore endorse the request for additional funding for health care systems across the globe by the World Health Organization to ensure that public health care systems are effective and that they deal with HIV and AIDS, with TB, with malaria and with all the diseases of poor people.

SUPPORT THE GLOBAL FUND

A necessary element to enable public health care systems to deliver ARV therapy in poor countries is the funding of the Global Fund on AIDS, TB and Malaria. It is unfortunate that the fund has not received the necessary amount of between seven and 10 or 11 billion dollars called for by the UN Secretary General, Kofi Annan. We believe that the United States, Europe, Japan and countries like South Africa and Brazil all have an important contribution to make to that fund, to ensure that all poor people get access to treatment with ARV. We appeal to you to step up the activism in your countries to ensure that the Global Fund has the money that it needs.



POLITICAL WILL AND DENIALISM

There is an additional element essential for all of us to get access to life saving treatment and that is political will. Many of you know the South African government's position on HIV and AIDS was not only scandalous, did not only reduce many of us to despair, did not only take away the hope of many thousands of people in our country, but it also threw health care workers and our health system into disarray. That position has now fortunately changed. However, we still believe that we all have to be vigilant, that we should encourage the South African government and all its officials to maintain a position that HIV does in fact cause AIDS. And more importantly, that HIV can be treated as well as prevented.



Unfortunately, our government has not yet committed formally to a national treatment plan, in a country where nearly 300,000 people will die this year of AIDS-related illnesses. However, it is

not only our government that is lagging behind.

PRIVATE SECTOR RESPONSIBILITY

Regrettably, the richest corporation in our country, the Anglo-American Corporation, cancelled its pilot ARV programs to treat gold miners and miners who have suffered, who live in single sex hostels on their mines far from their families and who have HIV. We appeal to them to reinstate those programs and to treat those workers. Those workers have sacrificed their bodies and their families, allowing the company to make the enormous amounts of profit it does on the world market for gold and other minerals. We appeal to the entire private sector to make it possible for people to be treated, including companies such as Coca Cola, Ford Motors and Daimler Benz who have done a superb job. We appeal to all of them to work together to ensure that people across the globe have access to treatment, their workers in particular.

BRAZIL

We have seen many successes. A tremendous example to all of us has been the Brazilian program. We commend the Brazilian government for an effective program. As all of you will know, TAC supported MSF in importing generic ARV into South Africa for the program in Khayelitsha. We will continue to

support that action because we are opposed to patent abuse by the drug companies and we want to set an example that can work. However, we appeal to the Brazilian government to lead a political campaign to enable them to export its drugs to other countries in Latin America and Central America. There are many poor people in Ecuador, Nicaragua and other countries of that region who need these medicines urgently. This will sustain the Brazilian program in the long run because of economies of scale and cost effectiveness. But most importantly, it will give hope to the region itself.

BOTSWANA

On our doorstep in Botswana, the government has committed itself to a comprehensive treatment program for its people. However, its president, Festus Mogae, mentioned that he is not sure how sustainable that program will be. We appeal to the Gates Foundation, to the Merck Corporation and to the government of the United States to ensure that Botswana is able to use generic ARV to lower the prices and to be able to make its program sustainable, so that more than one third of its population who are already infected will be able to have treatment in a sustainable and an effective manner.

TREATMENT LITERACY

A critical element to be able to deliver treatment to people will be treatment literacy programs. Everyday in our communities we are able to educate people in workshops about nevirapine [Viramune], about AZT [Retrovir] and about side effects. We are able to sing songs about these drugs, we are able to educate people about fluconazole and cotrimoxazole. These are medical terms and



pharmacological names that none of us knew when we were first diagnosed, or even much later. But fighting for our lives has made it essential and necessary for us to learn these things. Everyone can learn them. In our communities we have done workshops with people who have never opened a pharmacological textbook, but most of our people can speak eloquently and articulately about the medicines that they need to take, their side effects and how to look after themselves.

We believe that by working together—nurses, doctors, scientists, patients and government—all of us—we can achieve the necessary required treatment literacy that will make our adherence possible.

Over the last few years, it has been the power of ordinary people that has held drug companies accountable, made governments accountable and made the global community accountable.

The TAC thanks the Health GAP Coalition [Global Access Project, Philadelphia], MSE, Gay Men's Health Crisis [New York City], all of our African comrades, our Brazilian comrades, Pela Vidda and people across Asia and Europe—you have made our work much easier. We hope our work at home will be of some assistance

to you. In the words of the labor movement, “an injury to one is an injury to all.” ☒

Born in 1962, Zackie Achmat joined the anti-apartheid movement in South Africa during the 1976 uprisings. He was detained and imprisoned on more than five occasions as a youth activist. He also organized for labor, health and community organizations. He was a founding member of the National Coalition for Gay and Lesbian Equality, which campaigned for the equality clause in the country's Constitution. He is still an active member of the African National Congress. Achmat was also director of the AIDS Law Project between 1994-97. He has researched, written, and directed numerous television documentaries.

In December 1998, he launched the Treatment Action Campaign (TAC). At the risk of arrest, Achmat volunteered for TAC's Defiance Campaign against Pfizer's patent to bring life-saving treatment for opportunistic infections into South Africa. TAC also opposed the HIV denialist positions in government and campaigned for access to antivirals for pregnant women with HIV. Achmat is also completing a master in philosophy of law at the University of Capetown.

The Politics of Africa's Pain

by John Price

More than 38 million of the world's 40 million people living with AIDS have no access to medical treatment—an immense catastrophe caused by the political and moral bankruptcy of wealthy nations, said AIDS treatment advocates gathered at the XIV International AIDS Conference in Barcelona.

Treatment activists and experts, convening a special session on the day before the opening of the conference, charged the U.S. and other Western countries with gross and willful neglect, if not criminal behavior, for their ineffective response to the global crisis of HIV/AIDS, the leading cause of death in Africa.

"If I as a doctor ignore a sick person in desperate need of care, I am committing medical malpractice, and can be charged with a crime," said Dr. Morten Rostrup, head of *Médicins Sans Frontières* (MSF), a humanitarian medical aid agency with operations in more than 80 countries

"Today and every day, more than 8,000 people with AIDS will die," warned Rostrup. "Yet the international community refuses to mount and fund an adequate global response—we are faced with nothing less than a crime against humanity."



Currently, of the 40 million people living with AIDS worldwide, about 730,000 people are receiving antiretroviral treatment—500,000 of whom live in high-income countries. In sub-Saharan Africa, where 2.2 million people died of AIDS last year, only 30,000 people received treatment.

Since their discovery in the mid 1990's, antiretroviral (ARV) drugs have proven

highly effective at combating the voracious growth of HIV within the human body. The virus attacks and destroys the body's natural immune system, making it susceptible to a legion of opportunistic infections. When unchecked by medication, the virus replicates with a fury, producing 10 billion copies each day.

Effective antiretroviral therapy not only directly benefits people living with AIDS, but also reduces the staggering social and economic impact of the epidemic in poorer countries. Yet, despite continued advances in AIDS medications, these drugs remain out of reach for the vast majority of HIV-infected people in the developing world.

Treatment advocates claim that the most obstinate barriers to accessing medication are caused by the dubious political will of affluent wealthy countries. For example, major pharmaceutical corporations, who largely control the world's treasure chest of ARV medications, seem wholly out of step with the global pandemic. Claiming the need to protect their investments, drug companies have held their medicinal formulas under lock and key, making it difficult if not impossible for poorer countries to manufacture or import generic versions of patented drugs.

*A few items from
The XIV International AIDS Conference
in Barcelona, Spain, July 2002.*



According to the Health Global Access Project (Health GAP), despite some recent slacking in the tight corporate grip on AIDS meds, patents block generic replication of at least four ARV drugs in 27 African countries and at least one ARV in another 31 countries.

It has also not gone unnoticed by treatment activists that the pharmaceutical industry spends \$13 billion per year

marketing their wares directly to doctors—more than the estimated cost of arresting the spread of AIDS globally. Advocates claim that the free market-driven system encourages investment in treatments of conditions like male baldness rather than HIV/AIDS.

Some Western experts, however, have claimed that even if a bottomless pot of funding were available for AIDS drugs in Africa and other developing countries, treatment would not be feasible in resource-poor settings. These experts argue that poorer countries lack the medical infrastructure to support ARV regimens.

Last year, Dr. Anthony Fauci, a National Institutes of Health infectious disease chief and one of Bush's key advisors on HIV/AIDS policy, stated that an adequate healthcare infrastructure that would support the use of ARV drugs in developing countries "just doesn't exist right now."



But treatment advocates at Barcelona flatly disagreed and brought their evidence in hand. "The feasibility of treatment has never been more certain," said Alan Berkman, founder of Health GAP, who joined colleagues from MSF to present a study on seven African nations that have successfully implemented ARV programs in resource-poor settings.

MSF researchers presented data at the conference from seven ARV pilot projects in developing countries including Cameroon, Kenya, Malawi, and South Africa. The data showed that providing effective treatment in resource-poor settings has concrete clinical benefits and dramatically improves the quality of life for individuals and families.

Patients in the seven observational projects entered treatment programs in advanced stages of AIDS and were treated with ARV therapy in local health clinics in poor town-

ships, rural areas, and outpatient units at district hospitals.

After six months, over 80 percent of patients showed undetectable levels of virus in their blood, and researchers reported that patient compliance was impressive, with 95 percent of patients taking their treatment properly at six months.

"There are some people who say that in Africa people will not be able to take these drugs because they cannot tell time," said Fred Minandi, an HIV-positive farmer from Malawi who has a wife and two children—invoking the now infamous statement of Bush U.S. Agency for International Development chief Andrew Natsios. "I may not have a watch, but I can assure you that since I started taking my triple therapy in August last year, I haven't missed one dose."

Minandi, who lives in the Chiradzulu district, is one of the first patients to get free



medications through the MSF project that began in Malawi in 2001. An estimated 800,000 people in Malawi are living with HIV/AIDS.

Treatment advocates argue that one of the most formidable barriers—and telling deficiencies—to scaling up the availability of AIDS drugs is the failure of wealthy nations to mobilize promised resources for the Global Fund to Fight AIDS, TB and Malaria and other financing mechanisms. Donor nations have aban-

doned their responsibility, say advocates, and repeatedly broken promises made over the last two years by pledging only 8 percent of the estimated funding necessary to fuel an effective global response to the AIDS pandemic.

Advocates say that the U.S. set the donor bar extremely low by initially offering only \$200 million, less than 10 percent of what many experts believed should have been offered by a country commanding the world's largest economy.

"The United States alone should provide \$1 billion at least for starters," declared U.S. Representative Barbara Lee to a crowd of around 1,500 activists gathered at a treatment access rally in Barcelona. "And then the entire world must step up to the plate."

The heavily burdened resources of the Global Fund were designed to be split between HIV/AIDS, malaria, and tuberculo-

sis. Moreover, funds allocated for AIDS must be spread across multiple programs for treatment, prevention, and care, leading many advocates to question whether the fund was designed as a formula for success or for failure.

"What we learned on September 11 is that in a few weeks it's possible to mobilize a massive political and financial response to a perceived common threat," said Rostrup, who recently returned from an ARV treatment project in Nairobi, Kenya. But when it comes to AIDS in Africa, said Rostrup, "There is clearly a problem of political will."

"The AIDS crisis is about political will and moral will," added Berkman, who believes that the pandemic has escalated "from a tragedy to a crime."

He also believes that the Western obligation for funding might best be understood in the historical light of reparations owed to

Africa for colonization and to African Americans for slavery. "The U.S. can say that we don't owe reparations but we do," said Berkman. "The disrespect for African lives that we are witnessing in the AIDS pandemic and in various other forms is deeply rooted in the racial patterns in colonialism, slavery, and American society."

John Price is a health reporter for the New York Amsterdam News. His work has also appeared in numerous publications including the New York Daily Journal, Quarterly Black Review, Tennessee Tribune, and the Milwaukee Courier. His work has also appeared online at BlackPressUSA.com and SeeingBlack.com. Price was recently awarded the Kaiser Media Fellowship in Health for 2002. Reprinted courtesy of www.BlackAIDS.org



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How the Global Fund Spent its Money

by *Erv Dyer*

The two-year-old Global Fund, an ambitious private-public partnership to battle HIV, tuberculosis and malaria in developing countries, in its first round of grant-making, was met with applause and criticism at the International AIDS Conference. With nearly two billion dollars in pledges from Industrial and Third World nations and assistance from foundation support, the Fund awarded a total of \$378 million over two years to 40 programs in 31 countries.

The Board also agreed to a fast-track process to approve an additional \$238 million for 18 proposals in 12 countries, plus three multi-country proposals, provided certain conditions are met. This would bring the total funding over two years to \$616 million.

The approved grants were selected from more than 300 proposals. In all, these proposals requested more than \$5 billion from the Global Fund over five years. More than 60 percent of those dollars went to proposals addressing HIV/AIDS. More than 55 percent of the funding was targeted toward sub-Saharan Africa, an area hit hardest by HIV infections. A second wave of funding is scheduled for early 2003 and proposals must be submitted by late September.

Almost before the checks were written, the announcement of the approved grants was quickly caught up in a swirl of criticisms and politics. Many wondered if developed nations were over-represented in funding and whether enough funding was committed to nations battling TB or malaria.

The most noise came from activists who felt that not enough dollars went toward HIV treatment. Too much was handed out to prevention rather than treatment, they charged, and what treatment dollars there were went

towards the promotion of patented medicines and generic brands.

Meanwhile, Richard Feachem, incoming executive director of the Global Fund, defended its grants. "We are committed to prevention and treatment funding," said Feachem, who was warmly received at an address in Barcelona. Grants will be balanced across the diseases and geographical regions, he pledged, saying, "HIV gets the lion's share and rightly so, but we will not turn our back on TB or malaria."

According to officials, Global Fund donations will make it possible over the next five years for 220,000 people living with HIV/AIDS to receive anti-retroviral treatments. It's a first step, but still more must be done, said Allison Dinsmore of Health GAP (Global Access Project), a U.S. group that monitors barriers to care for people living with HIV. After all, she said, that number represents only 10 percent of the people who have the virus in sub-Saharan Africa alone.

According to Milly Katana, a member of the Global Fund board representing non-governmental organizations, and who works with the group People Living with AIDS in Uganda, "it is just the beginning." More can be done, Katana argued, "to support people who have been fighting this plague with unlimited courage while lacking any other weapons. Billions more dollars are needed now for more prevention and treatment measures."

But activists remained skeptical. "We're not anti-Global Fund," explained Dinsmore, with Health GAP, "we're just concerned that the Fund, which is supposed to grow to \$10 billion, isn't being taken seriously by the U.S. government." The Bush administration has pledged \$500 million to the Fund. Dinsmore thinks it should commit more. "If we don't

give, other countries won't be giving much either," she said. "Then the fund will be always bankrupt and will not accomplish much."

Members of ACT UP/Paris (AIDS Coalition to Unleash Power), a vocal advocate for HIV/AIDS issues known for its sometimes disruptive tactics, were wearing stickers in Barcelona questioning the Global Fund's bottom line. A goal of \$10 billion was set when United Nations Secretary General Kofi Annan called for the creation of the fund. Annan suggested \$7 to \$10 billion was needed to address HIV, TB and malaria in the world's developing nations.

By mid-May, \$1.9 billion had been pledged to the Global Fund—less than 20 percent of the goal. The world's richest countries must contribute more to make a difference, said organizers with ACT UP/Paris. "To refuse to do so means the industrialized G-8 countries are responsible for the deaths of 10,000 persons every day," scolded Gaelle Krikorian, a member of ACT UP/Paris.

As officials with the Global Fund held meetings in Barcelona to explain its first round of funding, it asked participants to be patient with its growing pains. "We have to learn from our mistakes," said Christoph Brenn, an NGO representative with the Global Fund. "This is a new initiative, we have to make it work." ☩

Erv Dyer is a Pittsburgh reporter who covers issues of race relations, spirituality and black American health care. He can be reached at ellisdyer@aol.com. Reprinted courtesy of www.BlackAIDS.org

Perceived Safety Intensifies Danger for Gay and Bisexual Men

by Charles E. Clifton

At the XIV International AIDS Conference in Barcelona, Dr. Ron Valdiserri, deputy director of the U.S. Centers for Disease Control and Prevention (CDC) programs, released alarming data on the occurrence of unrecognized HIV infection and misperception of risk among young African American “men who have sex with men” (MSM)—the center’s technical designation for gay and bisexual men.

This latest CDC data revealed that nine out of ten HIV-positive African Americans who participated in a study of young gay men were unaware of their HIV status.

Dr. Valdiserri also released data that indicates that rates of HIV infection have stabilized in the U.S. in recent years. Meanwhile, the widespread use of antiretroviral therapy in the U.S. has dramatically reduced the number of AIDS cases and deaths in adults and children since 1996. Since 1998, reported AIDS cases have remained at approximately 40,000 per year in the U.S.

The decrease in AIDS deaths over the last half-decade has given many people the misperception that AIDS and HIV are no longer a major health issue. However, the hundreds of thousands of individuals living with HIV in the U.S. are living with the day-to-day challenges of HIV. They struggle to adhere to complex treatment regimens, the life-changing side effects those meds can create, and drug resistance—not to mention the socio-economic issues of work, housing and healthcare.

“Because of advances in treatment, HIV-positive individuals are living longer and healthier lives, and as new data clearly demonstrate—they are continuing to have sexually active lives,” Valdiserri stated. With the number of HIV-positive individuals continuing to increase, it is more urgent than ever that HIV prevention services for positives continue to expand and improve.

However, as Valdiserri emphasized, the “stability may not tell the whole story.” While

With the number of HIV-positive individuals continuing to increase, it is more urgent than ever that HIV prevention services for positives continue to expand and improve.



the overall rates of HIV infection may have stabilized, a closer look at the trends reveals that the majority of new infections are still occurring among gay and bisexual men, and specifically among African-Americans in that population. The CDC estimates that approximately twenty-five percent of HIV-infected individuals in the U.S. are unaware of their infection. We must as a nation “move from apathy to action; from barriers to solutions, and from skepticism to resolve,” Valdiserri declared in his opening statement.

Dr. Duncan MacKellar also presented new research data collected from the CDC’s Young Men’s Survey at the XIV International AIDS Conference. The CDC initiated a six-city study of men who have sex with men, or “MSM,” in order to acquire data on the prevalence of HIV infection and the number of HIV-infected men who were unaware of their infection.

MacKellar discussed data from a scheduled poster presentation of his research at the Conference. From 1994-2000, 5,719 sexually active young men were recruited at 264 “gay-identified” locales, such as dance clubs, street corners and bars, in Baltimore, Dallas, Los Angeles, Miami, New York City and Seattle. The study was conducted in two phases. From 1994 to 1998, researchers enrolled MSM aged 15-22 years old and from 1998 to 2000 they enrolled MSM aged 23-29 years old.

At the locales, study participants were interviewed, offered counseling, and given HIV tests. Nineteen percent (1,089) of the study participants were African-American, 26% (1,497) were Latino, and 42% were (2,421) Caucasian. The fact that the vast majority of the study participants (95%) self-identified as either gay or bisexual is attributed to the fact that recruitment occurred at primarily gay venues.

Nearly ten percent of the participants, or 573 individuals, tested positive for HIV—a rate nine times that of the general population. While African Americans only made up

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19% of the total study group, they represented 43 percent, or 243 individuals, of those who tested positive for HIV disease.

Seventy-seven percent (440 of 573 individuals) of all positive participants did not know that they were HIV-positive, and 59 percent of the individuals who tested positive perceived themselves and their sexual partners as being at low or very low risk for infection. A distressing 91% (221) of the HIV-positive African Americans in this study did not know their HIV status.

Dr. MacKellar noted that 55 percent of the HIV-positive group had never tested or had last tested for HIV more than one year prior to entering the study. And half had engaged in unprotected anal sex with partners who they did not feel were at risk for HIV infection.

The reasons given for not using condoms with sexual partners (male and female) were varied, including that the participant “knew” himself to be HIV negative, “knew” his partner was HIV negative, or thought his partner was at low risk for being HIV infected. The survey also measured demographic characteristics, prior HIV testing including results of the most recent test, participants’ perceived risk for HIV infection, and sexual

behavior with men and women in the prior six months, including reasons for not using condoms.

The startling data clearly speaks to the challenges currently facing gay and bisexual men in the U.S. It also points to the need for increased funding to expand and improve HIV prevention programs, including supporting the efforts of community based organizations to reduce the stigma associated with HIV and testing for HIV.

Why is there such a high prevalence of African American men who have sex with men living unknowingly with HIV disease? The reasons are both varied and plentiful. Many young men lack knowledge about how HIV is transmitted. Others live in areas with inadequate testing services or lack access to appropriate HIV prevention services.

That lack of appropriate and accessible prevention and testing interventions has several long-term implications. However, the immediate ramifications are two-fold. First, as the study points out, many MSM are unknowingly transmitting the virus to other men and women. Second, many HIV-positive individuals who do not know their HIV status are not accessing care and prevention services needed to live healthier lives.

Black gay activists responded to the study with a mixture of alarm and caution. While noting that the study further reveals the need for heightened efforts at stopping the spread of HIV among black gay youth, the advocates also urged observers not to further vilify an already stigmatized population.

As more researchers have focused on the startling HIV risk among black gay and bisexual men, some advocates have felt the media has responded to the new data by characterizing black gay men as sexually irresponsible. Those advocates now say McKellar’s findings disprove this notion, making it clear that the problem lies in getting these young men into testing.

“Now is the time to increase funding for HIV awareness and prevention programs for African-American gay men with messages that are culturally specific,” said Steven Walker, a spokesperson for the National Advocates for Black Gay Health. “We must make sure that the persons delivering the message are knowledgeable and have close connections with the target group. Black gay men can best do this for the black gay community.” ☞



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Children's Medications

by Enid Vázquez

FOUR-DRUG TREATMENT

Children *can* achieve undetectable viral loads with therapy. Dr. Garrett Tudor-Williams, of a London clinic, talked about a four-drug regimen for infants that did not include a protease inhibitor (PI). He said the four drugs were able to bring viral load down to undetectable, which does not always happen in children who use a three-drug regimen with a PI. (In fact, U.S. guidelines state that "although suppression of HIV RNA to undetectable levels... is desirable, few data among children indicate that such suppression is always achievable.")

The London infants had less than 50 viral load (undetectable) after 24 weeks. Also, their weight and CD4 counts were normal after a year of therapy.

The quadruple therapy consisted of four "palatable" suspensions taken twice a day without food restrictions. The medications were Retrovir, Epivir, Ziagen and Viamune. Protease inhibitors for children, he noted, are not easy to use long-term because of taste, formula and difficulty getting the dose right, as with Viracept.

His clinic provided the quadruple regimen to 18 infants who had no perinatal treatment. Half of them had PCP (*pneumocystis carinii* pneumonia) and six had disseminated cytomegalovirus infection (CMV). Three had encephalitis (swelling of the brain). Only one had no symptoms of disease.

Three of the children stopped therapy by 24 weeks (six months), two of them because of hepatitis due to the Viamune and one because of intolerance to Ziagen, although none of the infants had hypersensitivity to Ziagen. This child was switched to Kaletra (a protease inhibitor) and "is doing fine." If you take into consideration these three children, the undetectable rate was

60%, as opposed to 100% for the 15 children who stayed on therapy.

Dr. Tudor-Williams said the tiny number of children discussed here is problematic for evaluating the four-drug regimen, but that further evaluation is warranted, especially for children with a very high initial viral load, as with these children.

MEDICATION TRENDS

Michelle McConnell of the U.S. Centers for Disease Control and Prevention (CDC) reported on changes in children's HIV therapy between 1998 and 2000. Her report was based on the Pediatric Spectrum of Disease (PSD), a chart review of HIV-positive children from six sites. McConnell said that antiviral therapy is safe and effective in children, and that protease inhibitors have been associated with improved survival both in the U.S. and in Europe. Happily, the median age of the children in the PSD increased from four years in 1994 to nine in 2000, as HIV-positive children live longer.

Of the 1,541 children looked at in 2000, 98% were on antiviral therapy. Ninety-six percent of them were on nucleoside analogs (for example, Retrovir or Epivir), 70% were taking a protease inhibitor and 40% were taking a non-nucleoside analog (such as Sustiva or Viamune). The most commonly used medications were Zerit and Epivir (67% each) and the protease inhibitor Viracept (46%). Drugs with increasing use between 1998 and 2000 were the nucleoside Ziagen (up from 3% to 12%), Sustiva (up from 3% to 17%) and the protease inhibitor Agerase (up from 0.4% to 9.3%). The only other protease inhibitor with increasing use in pediatrics was Kaletra.

Drug failure (detectable viral load) accounted for a third of the changes made to children's therapy in 2000, while in adherence and side effects each accounted for 14%.

Fifteen to 20% of the children are on dual drugs only. More and more of the children are on their second or third drug regimen.

ADVERSE DRUG REACTIONS

Italian researchers looked at adverse drug reactions (ADRs) in children. This report also came from data collected between 1998 and 2000. Of 486 children, 191 (39%) reported at least one ADR. The total number of ADRs was 239. Thirteen percent were considered serious (grades 3 or 4). All of the ADRs resolved completely, except for two children who were left with permanent conditions (one with increased creatine levels and one with diarrhea). One child died.

What were the most common side effects? Lipodystrophy (abnormal increase or decrease of body fat) occurred in 20% of the children. Both lipodystrophy and high lipid levels (triglyceride or cholesterol) were also twice as likely to occur in kids over the age of 10. Bone marrow toxicity occurred in 11%.

However, 67% of cardiac disturbances and "alterations in pancreatic function" were considered severe, as were a quarter of the kidney stone cases and bone marrow toxicities. The researchers concluded that, "ADRs to HAART (highly active antiretroviral therapy) in HIV-positive children are similar to those described in adults. Even if they appear of mild severity (85% score grade 1-2), they can compromise compliance to therapy. Lipodystrophy and alterations of lipids were less frequent than expected, probably in relation to the lack of clear diagnostic criteria in childhood. Further analysis will help to clarify whether our results reflect a true lower incidence or is the effect of underreporting." The presenter also noted that CD4 count was only "marginally" related to side effects, but that taking more than three drugs increased the risk for ADRs. ☒

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An AIDS Vaccine: When?

by Carl Winfield

It's been suggested that HIV has a mind of its own. Unlike a simple bacterium, the virus changes, mutates, and "learns" in a matter of speaking how to get away with murder. This simple little viral pod sneaks in, injects its own genetic code into a cell and begins transcribing that information into cellular DNA, creating countless blueprints of itself. In the end, the cell doesn't belong to us anymore. It belongs to the virus.

Copies of the virus migrate out of the host, infect more cells and begin the process all over again.

The first attempts to create an HIV vaccine focused on identifying binding sites on the surfaces of both HIV and the host cell.

A multi-clustered molecule, glycoprotein 120 (gp120) on the surface of the virus was found to contain the CD4 or helper T-cell receptor. This receptor enables HIV to successfully attach itself to the body's first line of defense: a cell, which activates the immune response itself. Without it, the immune system's ability to communicate with the cytotoxic T-cells that destroy infection is irreparably damaged.

Scientists were confident that the presence of gp120 would elicit an immune response strong enough to attack gp120 on the surfaces of HIV.

Vaccines using gp120, like VaxGen's controversial AIDSVAX, are monomeric, meaning that there is only one molecule for every three present on the receptor. Moreover, research has shown that vaccines made up only of proteins tend to promote the creation of antibodies, but do little to activate cytotoxic T-cells.

Executives at VaxGen, have turned a deaf ear to their detractors, arguing that AIDSVAX successfully elicited antibody immune responses among nearly all who participated in phase I and II clinical trials and that even a partially effective vaccine would substantially affect HIV incidence rates around the world.

To this end, VaxGen has begun phase III trials of AIDSVAX B/B in the U.S., Canada,

Puerto Rico and The Netherlands, to determine how well the vaccine prevents the sexual transmission of HIV, and AIDSVAX B/E in Thailand to test its efficacy against blood borne infections.

No one knows how successful or unsuccessful the trials will be, but executives at VaxGen are prepared to market AIDSVAX as a preventative vaccine if phase III trials show as little as a 30% reduction in the likelihood of HIV infection among participants.

Researchers at VaxGen are confident that the results of the trials, which will be released in the first and fourth quarters of 2003, will silence detractors and open the door to a multivalent vaccine designed to affect all five major subtypes of HIV. The problem, according to VaxGen Chief Executive Officer, Lance K. Gordon, Ph.D is "how to move from those results to making products available."

Many researchers have theorized that vaccines using "logical molecules" like gp120 tend to be ineffective because gp120 blocks the binding site until the precise moment when CD4 is presented. At that moment, the docking site snaps open and closes around it almost immediately. This theory has made the idea of combining vaccines much more attractive to researchers.

Lawrence Corey, a principal investigator of the HIV Vaccine Trials Network says: "You'd like to have both [a cellular response and an antibody response], but the greatest progress has been in eliciting a cellular response."

Other researchers, like those at France's *Advantis/Pasteur* are currently working with a combination of AIDSVAX and a genetically engineered canarypox virus which will encode gp120 as well as a protein that makes up the HIV core and another which allows it to reproduce.

The benefit of the canarypox virus is that the presence of HIV in the cell will stimulate the creation of "killer" T-cells as well as an antibody response. Unfortunately, a duplicate trial of *Advantis/Pasteur's* vaccine

performed by the National Institute of Allergy and Infectious Diseases showed that less than 30 percent of the participants generated "killer" T-cells against HIV.

Merck Pharmaceuticals, one of the leaders in the production of HIV medications, is also trying its hand at two possible HIV vaccines. Both are based on the use of the HIV gag gene, which encodes the virus' core protein.

In the first, the HIV gag gene is administered as raw DNA. The cell will bond with the HIV gag gene and use its DNA to create a viral protein which, in turn will promote the development of both helper and cytotoxic T-cells.

Dr. Emilio Emini, Merck's Senior Vice President for Vaccine Research, reported that cytotoxic T-cells increased markedly in 42 percent of volunteers who received the highest dose of the raw DNA vaccine.

In the second trial, the gene enters the cell via the crippled adenovirus and proceeds to reproduce, allowing the body to create antibodies specific to the HIV gag gene.

Emini reported that between 44 and 67 percent of the participants who received the adenovirus-based vaccine experienced a cellular response proportionate with size of and time between receiving the shots.

While this represents a great leap forward in the search for a vaccine, experts are still stumbling around in the dark. Scientists are no closer now to determining what immune responses against HIV are required to ensure safety from infection than they were 17 years ago. The existing candidates for a vaccine are still in the trial phase and, what's more, even if a vaccine is developed it is unknown whether or not a vaccine would work on different strains of HIV.

Experts like Lawrence Corey and Dr. Emilio Emini are confident that a viable HIV vaccine conferring at least partial immunity is within reach. The only question is: Will it take another 17 years? ☒

once-a-day HIV treatment: Ready for prime time?

By Matt Sharp

and
Charles E. Clifton

*The HIV Treatment Series
is sponsored in part by an
unrestricted grant from
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Everywhere you look these days there are sound bites for the treatment of HIV: “...Simplify your HIV regimen” and “Now, one tablet, once daily for simpler HIV combination therapy.” Some pharmaceutical companies have been deploying ads, implementing educational programs and other concentrated marketing efforts to promote QD therapy (QD, meaning once daily). The once-a-day push is attracting the attention of people with HIV who are weary of popping fists full of pills two or three times a day, and some companies have also responded to these concerns with treatment options that reduce pill burden. Researchers, who are either employees or agents of pharmaceutical companies, are reformulating existing drugs and designing new drugs.

At the recent International AIDS conference in Barcelona, a lot of buzz was generated about the pros and cons of QD dosing. Doctors are already prescribing the QD drugs to their patients. Clearly, there is a need for simplified HIV regimens, be that fewer pills or once-a-day dosing. And for some people this is important, however it should not be the only factor when considering meds. Few QD drugs have been studied in randomized clinical trials in combinations—the way HIV drugs must be taken to be effective at slowing virus replication. Without these trials the following questions can’t really be addressed. What is the long-term effectiveness of QD drugs against HIV? Do they minimize resistance? Are they tolerable in HIV positive individuals?

Is once-a-day really ready for prime time? Are the QD regimens currently available proven to be better or equal to BID (twice a day) or TID (three times a day) in randomized clinical trials? Will once-a-day be an option for everyone with HIV? Is QD another pharmaceutical ploy to sell drugs? Will the QD drugs cost more? There are a lot of unanswered

questions. It is clear that people not sacrifice efficacy for dosing simplicity.

STANDARD OF CARE

The Health and Human Services (HHS) guidelines strongly recommend a combination of antiviral medications from two drug classes as the standard for HIV treatment. This may involve taking a combination of several drugs, two or three times a day. HIV treatment combinations require sometimes as much as 30 pills a day. Swallowing that many pills can create many problems for appropriate adherence. Progress has been made to reduce the numbers of pills, and there are now regimens that don't require as many pills. However, not all QD drugs are reformulated to reduce pill burden. The reality is that even though a drug may be approved for QD, it may mean swallowing the same number of pills at once rather than splitting up the amount in two or three doses. Therefore, pill burden remains an issue, even with QD dosing.

HAART (highly active antiretroviral therapy) has been shown to reduce sickness and death, making HIV a chronic condition for many people. As a result, the emphasis of treating HIV has been shifted to improving quality of life. Since HAART has to be taken indefinitely—not necessarily a rosy prospect for individuals living with HIV—this means better efficacy with less side effects, fewer pills and less dosing. This is not an easy task as the virus can mutate easily to resist the drugs. HIV meds have to be taken 95% of the time in order to be the most effective. And yet some drugs are adhered to 95% of the time and still resistance to them develops. On the one hand, you need a regimen that will continue to work long-term. On the other hand, you need a regimen that you can continue taking long-term.

The longer one has to “adhere” the more chances forgetfulness will occur. We are, after all, only human. So, the idea of simplified regimens, fewer pills, lower dosing and less

toxicity can ultimately help to achieve the goals of HIV therapy and the needs of HIV-positive individuals: keeping people healthy by keeping the amount of HIV in the body below detectable and CD4 T-cells as high as possible. Therefore in terms of having a regimen that works and is tolerable, is QD all that better than BID?

HOW DRUGS ARE BROKEN DOWN IN THE BODY

According to research on adherence, the biggest improvement in adherence is noted when there is no middle of the day dose. There is only a slight difference in adherence between once a day and twice a day. Food and Drug Administration (FDA) regulations require approved drugs to maintain blood levels in the body long enough to keep working. But that's assuming you don't miss a dose. What happens if you miss a QD dose? Will resistance set in faster if you miss a QD dose compared to a BID dose? Some drugs, like Sustiva, remain active in the body for much longer than 24 hours. If people remember to take their dose shortly after they miss it—at least not 24 hours later—the blood levels will remain at a safe level. As long as drug levels remain high enough to control virus replication, drug resistance is less likely to happen.

One important piece of information to remember is that what is “high enough” varies, from person to person and from drug to drug. HIV does not operate the same from one person to the next. For example, in some people, the virus is more difficult to treat in resistant form. In this form, drug levels may need to be consistently higher to keep the virus from developing additional mutations. With all of the buzz on increasing rates of resistant HIV, this is an important consideration for everyone, not just HIV-positive individuals who have been on therapy for awhile.

Another factor to consider is the drugs themselves. Some drugs are known for main-

taining higher levels in the body, whereas others have lower levels. How long after a missed dose before drug levels are dangerously low depends on, in part, two things. First, how high the drug levels were in the first place. And secondly, how long it takes the drug levels to drop.

In order to evaluate how once or twice dosing works one needs to understand how drugs are “metabolized” in the body. Drugs are swallowed, then broken down by saliva, stomach acid and liver or kidney enzymes so that the active chemical can get into the blood stream to do its work. Over time the amount of chemical is used up, then excreted. Then, more drug needs to be taken to keep up the level of the drug in the blood. In HIV it is critical to keep drug levels constant and well above the amount needed to control the virus. If the rate of HIV production can't be slowed down enough then the virus can change and go on multiplying, spreading a mutant virus. This is HIV's strategy for survival—clever yet dangerous, even more reason to adhere to drugs and more corroboration for QD therapies.

There is speculation by some physicians that the effectiveness of a once-a-day dose schedule may depend on how each person metabolizes the drug individually, and that different cellular levels absorbed in a QD regimen may be quite different than in a twice a day regimen, therefore raising concerns regarding toxicity. In a new move to monitor this phenomenon, therapeutic drug monitoring assays are being developed to look at how each individual processes different drugs, but the science is clearly lagging behind the realities of treatment.

The bottom line is that many QD meds are not as forgiving as certain BID meds, when a dose is missed. Therefore, taking a dose at or near the appropriate time is still the optimal choice and efforts should always be made to teach physicians and patients to adhere to a regular dosing schedule.

QD HIV DRUGS

There are currently five drugs available in once-a-day formulations today: Sustiva (efavirenz), Videx EC (didanosine enteric coated), Viread (tenofovir), boosted Agenerase (amprenavir), and Epivir (3TC). (See Newsbriefs on page 17.) New QD agents such as Zrivada (atazanavir), Coviracil (emtricitibine), and T-1249, a fusion inhibitor, may be available soon. New formulations of existing antivirals such as Viramune (nevirapine), Ziagen (abacavir) and Zerit XR (extended release stavudine) are in development. And Kaletra (lopinavir/ritonavir) is being studied as a QD option. One can see the interest and results of simplified drug development in our market-driven society.

PRICING

Will drug companies pursue a price increase for the new QD therapies? Their contention is that in order to develop the drugs they need to pay for the research. According to past history, new drugs, especially new classes, have always resulted in an increase in price. Any price increases in new therapies will place ADAPs (AIDS Drug Assistance Programs), already teetering on the verge of collapse, in jeopardy. Pricing is a complex issue. When a drug is reformulated to reduce pill burden or dosing in half, it does not mean that manufacturing costs associated with the drug are also cut in half. It will be up to the community to hold the companies accountable as far as pricing is concerned.

WHAT HAART REGIMENS ARE EFFECTIVE IN QD?

Up to this point only individual drugs have been discussed for once daily dosing, however, remember that HIV meds must be used in combination. Drug companies are promoting QD drugs individually, but they have not necessarily been studied together. Several different companies may produce the

drugs within any one given combination, but the question remains: Is QD a viable option available to those who need therapy?

The QD regimen with the most data demonstrating effectiveness is Videx, Epivir and Sustiva. An open label prospective study (people knew what they were taking and were followed from the time they were put on treatment) looked at the feasibility of using this QD regimen. Though the study was not compared with other drugs, everyone ended with a lower viral load and higher CD4 T-cells at the end of 48 weeks, showing the combination was effective. Another study looking at a new drug, Coviracil, in combination with Videx and Sustiva in treatment naïve patients (patients initiating therapy for the first time) has been reported. This combination has demonstrated an ability to suppress viral load for up to two years, showing another potential effective QD regimen. However, Coviracil has not yet been approved.

Doctors are prescribing combinations besides Videx EC, Epivir and Sustiva. Viramune is being looked at in combination with Videx and Epivir. Crixivan is being studied in combination with the same QD background. The studies are not complete. And therein lies the problem of combining drugs that have not been studied together in controlled clinical settings. Unknown cross reactions have been reported, as was found with Viread and Videx EC after the drugs were being combined in community practice. People using the new Videx EC capsule must not take it with any food, and Epivir and Sustiva should be taken with food, so the regimen is not a QD regimen as is thought.

FROM A CONSUMER'S PERSPECTIVE

How does switching to a QD regimen affect people in the real world? Paul Dalton, a PWA (person with AIDS) from San Francisco, switched to a once daily regimen of Epivir, Viread and Viramune. Previously, he was on the same drugs, but used

Viramune twice a day until studies showed that it was effective once daily. So, he made a relatively safe change based on what we know about these drugs. The outcome has been good in terms of viral control. However, he did have a 50% reduction in CD4 T-cells, but feels that the "disconnect" between his success in switching and his CD4 count was more related to stress in his life than to the therapy having failed (Does this constitute a failure?). Paul said he has been 100% adherent with the new QD regimen and believes it can be beneficial for others if they stick to the simpler strategy. "QD can make sense if people can construct a viable regimen based on their history." Still, the disconnect in Paul's case (viral load decline, T-cell decline) should be carefully monitored by a physician. Adherence is not the lone factor in determining whether or not a regimen is effective.

Jeff Gustavson, also from San Francisco, had trouble with his regimen, which was Viread (QD) in combination with twice daily drugs. He mistakenly took the Viread twice daily with his other drugs, doubling the dosage, which is one of Cafaro's concerns. This anecdote highlights the fact that QD dosing is individual and must be geared for each person. It remains a treatment model in transition until all the bugs can be worked out.

A MATTER OF CHOICE... HOW TO DECIDE?

Many factors, including lifestyle, emotional readiness and ability to adhere, come into play when you decide to initiate HIV therapy. However, other factors that are just as important are drug efficacy, tolerability and minimizing resistance. Someone who has never taken HIV treatment may have more treatment options than the more treatment experienced individuals. Individuals who have taken antivirals in the past may have fewer therapeutic options. However, as previously stated, HIV therapy must be individualized. A treatment naïve patient may



have acquired a resistant strain of HIV, and therefore have more drug resistance than a treatment experienced patient. So the question becomes, are pharmaceuticals doing what is really in the best interest of the patient? Should they develop more resistance minimizing meds, as well as those that are more tolerable and convenient? Or are they merely responding to market opportunities when promoting drugs as QD?

A hospital cohort study presented in Barcelona looked at 1,313 patients and their consecutive regimens. The rate of treatment change was high in the study due to adverse events. So, after five consecutive regimens, most patients had been exposed to almost every available antiretroviral drug. Therefore, in this heavily treated group, QD would likely be impossible.

For people who have previously used anti-HIV drugs, it is critical that resistance tests be performed and medical histories looked at before switching or constructing any regimen. The tests can help determine which drugs are still viable options for each individual. Individuality must be considered in deciding upon any regimen.

Howard Grossman, a physician from New York City, has been prescribing once daily regimens for years. According to Grossman's cohort data presented in Barcelona, his patients are benefiting from once daily dosing. Whereas many physicians would not offer QD to patients who can't adhere due to the risk of resistance,

Grossman offers patients with the worst adherence problems once-a-day regimens and looks at toxicity issues and effectiveness. His cohort was a retrospective analysis looking at 40 people from his clinic who either started on a QD regimen or switched from one QD regimen to another, or from BID to QD. At the completion of the study, viral load values were stable at less than 4,000 in all groups, not undetectable by any clinical standard. However, he states that those who began on a QD regimen did the best. But again research demonstrates that individuals have the best results on their initial regimen.

Virginia Cafaro, a long-term HIV doctor in San Francisco, presents an opposing point of view, "A lot of my patients are on BID and think it's fine, they have the rhythm and figure 'if it ain't broke, don't fix it.' They have been stable for years." Some motivated people are satisfied if they are doing well with their regimen. However, people who are having adherence problems, or who are dealing with pill fatigue, who can afford to switch may want to consider QD. But they should talk over their options with a doctor. According to Cafaro, a major concern is that people with HIV simply want to switch, whether QD is geared for them or not. Cafaro muses, "I think it's [QD] a lot of hype and marketing from drug companies all saying their drugs are, or will be able to go QD. Is QD really all meds at one time? We have to worry about drug interactions [such as] with tenofovir and ddI-EC. Patients hear 'once-a-

day' and may drop half of their present regimen or pile them all up into one dose."

Grossman believes that many progressive doctors are reluctant to switch their patients to QD. He states, "there are so many treatment options and they want to wait until more proof is in. No one wants to do harm [to the patient]." However, it begs the question, how are less experienced doctors who have fewer HIV-positive patients going to react to the new QD paradigm? In the land of HIV treatment and care, treatment trends always take time to take hold.

Experienced doctors such as Cafaro and Grossman, who understand the complexities, drug interactions and other restrictions of HIV treatments, are more in tune to their patient's needs, but care needs to be taken with those prescribing without a specialist's knowledge.

We are upon an era of a major treatment shift in HIV disease, where efficacy, tolerability, avoiding resistance and dosing convenience are all key factors. Adherence to mega-dosing of the older drugs has been a systematic and complex problem for people with HIV and their providers. However, progress has been made in this area. Treating a virus that is capable of a multitude of changes still has to be sorted out, so we must not put the cart before the horse in pushing ahead with simpler regimens that might fail for multiple reasons. ☒

FTC Superiority Over d4T in Phase III Trial

by Daniel S. Berger, MD

On July 30th, Triangle Pharmaceuticals announced the early plans to unblind a pivotal study investigating the effect of FTC (Coviracil) in the treatment of HIV disease. As an investigator for the study, the news came to us with much surprise, since the trial was expected to continue in its original blinded design for another six months.

TRIANGLE PHARMACEUTICALS BACKGROUND AND HISTORY

Triangle Pharmaceuticals is a small biotech company formed by David Barry in 1995. Dr. Barry was the former President of Wellcome Research Laboratories, who along with other of the company's senior management and scientists formed Triangle Pharmaceuticals. These former senior executives at Wellcome played pivotal roles in the development of drugs such as Zovirax (acyclovir) for the treatment of herpes infections, and in the discovery and development of Retrovir (zidovudine, AZT) for the treatment of HIV infection and AIDS. To put things in its historical perspective, the two drugs revolutionized antiviral therapy and established Wellcome's preeminent billion dollar anti-viral business, which eventually became Burroughs Wellcome, subsequent to acquisition by Glaxo, and today is GlaxoSmithKline. The clinical and regulatory pathways for Retrovir's approval have become models for the development of new products to treat life-threatening diseases.

Triangle Pharmaceuticals, based in Durham, North Carolina, began developing

a number of HIV antiviral compounds. In a very short time they were involved in a candidate non-nucleoside, several candidate nucleosides and even a prospective protease inhibitor. During the entire flurry, and in 1999, Triangle entered into a collaborative relationship with Abbott Laboratories to co-market several Triangle and Abbott drug candidates and to gain access to Abbott's manufacturing capacity and international sales and marketing capabilities. As part of this collaboration, Abbott also made a significant and needed investment in Triangle.

However, Triangle has gone through hard times. Their candidate non-nuke (MKC-442 or Coactinon) did not perform well in drug trials and was terminated. Also trials with FTC (Coviracil) had to undergo various hurdles. One snag was related to the original design of the study itself (FTC-301), which had to undergo changes months after the study had already begun. More than two years ago, it originally involved abacavir (Ziagen) as part of the study arms. Concern was voiced by the U.S. Food and Drug Administration (FDA) regarding the possible difficulties in differentiating a skin rash or drug reaction of abacavir to one due to efavirenz (Sustiva). Eventually the study was modified in its original approach, but also had to endure further difficulties in enrolling treatment naïve patients. (Fortunately however, the study did complete enrollment and has since been going smoothly.) Also, recently, Dr. Barry, the founder and CEO of Triangle, suddenly died.

Now, related to the recent positive news of this study, Triangle reacquired the rights to its drug candidate FTC (as well as their other drug candidates) from Abbott Laboratories.

THE NEWS

On July 26, in a conference call to us and the other investigator sites involved in the phase III study FTC-301, the surprising news was issued. The Data Safety Monitoring Board (an independent committee of experts that review and oversee studies for safety and efficacy throughout the length of a trial), after reviewing the interim data, found a significant difference in safety and effect favoring the FTC treated patients. Because of these differences the DSMB recommended that the study be unblinded and that all patients be offered FTC. The FTC arm showed statistically superior benefits in suppressing HIV over the d4T (Zerit) arm. Study drug-related adverse events also favored FTC as being safer.

Adverse event data showed that in most cases where patients dropped out of the study due to "study medication" side effects, it was a d4T-related problem or complication. Previously reported, side effects that have been observed by physicians associated with d4T treatment include lipodystrophy, facial atrophy and elevated lipids and peripheral neuropathy. One easily recalls the recently presented tenofovir trial, also of naïve patients, presented during the late-breaker

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Radical Red

Positively Sesame Street

By Laura Jones

When the news broke about the HIV-positive muppet being developed for South Africa Broadcasting Corporation's Takalani Sesame, I was excited. A ground-breaker from its inception back in the early 1970s, Sesame Street was the first children's show to feature developmentally disabled characters, physically disabled characters, and a happily interracial cast.

Over the past 30 years, Sesame Street has tackled sensitive subjects such as death, divorce, pregnancy and childbirth, lying, stealing, racism, and gender stereotyping. In some countries, difficult and painful political situations are depicted in an age-appropriate manner, including the bloody conflict between Israel and Palestine.

Surely, I thought, Sesame Street would do a great job with HIV.

Granted, it would've been great to see HIV-positive muppets or cast members on SS a long time ago, but better late than never. Even if it's not a regularly-featured character, the HIV-positive South African little-girl muppet could at least break the ice... hopefully one of the American muppets would then feel comfortable sharing their HIV status, after they saw how everyone accepted the South African muppet. Once everyone realized it was safe (and fun!) to play with fuzzy animated HIV-positive beings, surely other SS cast members would feel the great weight of stigma lifted and disclose as well. Maybe Maria or Gordon could explain how it's okay to eat or drink after someone with HIV, but that no one should touch anyone else's blood

or pick syringes out of the dumpster... but generally there'd just be lots of hugging and dancing with flailing arms, the way there always is on Sesame Street.

But almost immediately, some knobs from the GOP got all upset about whether U.S. tax dollars were funding the development of that Godless South African HIV-positive muppet, and demanded that there be no mention of HIV/AIDS in the American Sesame Street because—you know—they didn't feel "that subject" was "appropriate" for Sesame Street's target audience of children aged 2 to 5. And instead of breaking new ground once more time for our nation's children, Public Broadcasting Services President Pat Mitchell shot off a hasty letter to the concerned parties, assuring them that no U.S. public funding is being spent on the little girl-muppet in Takalani Sesame—and, even more importantly, that there are no plans underway for HIV-positive characters to appear on the American version of Sesame Street at all. While the HIV-positive South African muppet will be visiting other countries' Sesame Streets in the future, the USA has apparently refused her a visa or permission for a stopover.

So, help me with this: Do these GOPers actually believe there are no HIV-positive children watching Sesame Street these days? Does PBS and Sesame Workshop not feel that an HIV-positive muppet might be incredibly validating to children living with HIV/AIDS, or who have loved ones living with HIV/AIDS, in the U.S. or anywhere else? I mean, correct me if I'm wrong, but isn't

children's programming supposed to be relevant to children's lives?

Where exactly do HIV-positive or HIV/AIDS-impacted children see any images of themselves, outside of maybe some terrific camp programs and community support groups?

Apparently these GOPers and all the other folk who immediately went into high-battle gear when the HIV-positive muppet announcement was made were too stricken with the pornographic Sesame Street imagery that immediately leapt to mind: Bert topping Ernie over the bottlecap collection... Elmo and Prairie Dawn sharing syringes behind Oscar's trash can... Grover tooting a little Tina before heading over to the pansexual orgy at Maria and Luis's place... Kermit doing a condom demo on a banana after Cookie Monster confided that "Me no use condoms because them not feel natural to me—besides, all Cookie's monster-lovers clean! Me just know it!"

Did these images (colorful and exciting as they may be) so cloud the collective judgment that the potential good of an HIV-positive Sesame Street character was immediately discarded out of fear over the "transmission issue"?

It's as though introducing discussion of the global HIV/AIDS crisis would somehow lead to a Stonewall-esque Muppet Riot over the right of Bert and Ernie to finally come out of the closet and live openly as God made them. Or does their reaction simply stem

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Fighting AIDS with Peanuts

by Glen Pietrandoni, R.Ph.

It is estimated that the spending on prevention and treatment of HIV/AIDS worldwide needs to be at least 10 billion dollars annually and increased to 15 billion annually by 2010 to effectively respond to the global epidemic. This amount includes treatments and improvements in infrastructure of the health care systems. In the year 2002, the U.S. has pledged one billion dollars in the global fight. Contributions from other countries, private foundations, and the pharmaceutical industry have brought the total global spending for this year to approximately 1.5 billion to 2.8 billion dollars. We can see that there still exists a wide gap between current levels of spending and where we need to be in the next few years.

The location of the last International AIDS Conference in Durban, South Africa two years ago set the stage for this July's conference in Barcelona. Drugs used to treat HIV/AIDS, now almost taken for granted here in the United States, are still unavailable to the majority of the infected population throughout the developing world. Frequently, wealthy countries like the U.S. and large corporations are blamed for preventing life-saving medications from being more widely available. ACT UP/Paris [AIDS Coalition To Unleash Power] was out in full force during the Barcelona conference, making the issue of drugs and their accessibility a priority. They argue that copyright laws are preventing generic price competition between the large pharmaceutical companies and that prices for antiretroviral drugs are out of reach for most of the world.

In an attempt to come to an agreement with the drug makers, ACT UP/Paris has suggested that in exchange for peaceful co-existence, drug companies should accept a royalty on products made by generic companies and forgo any patent rights and pending legal action. Generic drugs could cost as little as 20% of the already discounted brand name drugs. The thought is that when companies producing generics compete with each other, the prices will go down even further. Even the poorest countries will be able to afford medication when the prices plummet. Laws governing international trade and patent protections mandate where these drugs can be sold and for how much. Former President Clinton said at the closing ceremony in Barcelona, "If a space ship landed on earth, how could we explain to our visitors that millions of people are infected with a disease that is preventable and treatable, but we are not doing enough to reduce its spread?"

Anyone with a heart could see that this makes sense. We all want this epidemic to be stopped. Why should only the rich countries have all of the medicine and the profits? Those drug companies are making millions of dollars because people are sick. Right?! Let's all take a deep breath and step back for a minute. There are other issues here that no one is talking about publicly, so I thought I would try to explain the reason that "cheaper drugs" alone are not the solution. Worldwide relief for underserved populations will need more than medicine. It's easy to blame the pharmaceutical industry. They

are sitting ducks for criticism. When they stop developing newer drugs that can overcome viral resistance, are we going to point the finger at them again and ask why they are not busy doing research? Many service agencies are already looking at new sources of funding as these same companies are cutting back spending on research and non-essential programs.

The price of drugs is only one issue when we think of generic drugs. Quality is also important. In the United States, the generic drug industry has brought larger brand name companies to their knees when patents expire on popular drug products. In recent years, the use of generic drugs have been mandated by insurance companies and Medicaid with cost saving results for patients and third party payers. In the United States, the Food and Drug Administration (FDA) makes sure that the quality of the generic products used are equivalent to the brand name originals. Generic drugs are manufactured with quality and are used safely in the United States. Some reports of the generic drug industry making antiretrovirals in India and Brazil cite large variation in blood levels that would be unacceptable by U.S. standards. Inter-patient and intra-patient drug variability alone can cause HIV resistance. Poor quality drug products would add another variable to drug absorption and require an even greater level of adherence.

Giving drugs to everyone who need them, even for free, in itself would not solve the worldwide epidemic of HIV. Without other medical facilities and trained practi-

tioners to administer and monitor the drug usage, drug resistance in the Third World could be rampant. We don't have to look too far to see how the improper use of anti-retrovirals can cause problems for future treatment options. I am not suggesting this is a reason to deny people drugs. My point is that an infrastructure for proper care of patients, which include drugs, must be in place before drugs are handed out. Critical components like food, water and nutrition, along with the drugs, will be needed in many parts of the developing world. The high cost of blood tests has also been cited by activists as being excessive. The proper monitoring of drug therapy will require viral load, genotype and phenotype testing to maximize the sequencing benefits of available drugs.

Even without drugs, HIV prevention programs can also stem the tide of new infections. New HIV infection rates have plummeted in countries whose limited resources were spent on educating their populations on HIV transmission. In our wealthy country, wouldn't we also benefit from spending on treatment and prevention?

We can all do more to make a difference in the fight against HIV/AIDS worldwide. Pressure on our elected officials to support increases in spending on programs benefiting developing countries of Africa and Asia is always needed. Pharmaceutical companies must always be aware of their corporate responsibility to the communities they serve. Uncontrolled HIV disease on the planet will certainly be at our doorstep tomorrow if we just throw peanuts at it today.

Editor's note: For a perspective on this debate from an individual living with HIV in the developing world, see "Treatment Access as a Human Right" on p. 32.—EV

Glen Pietrandoni is director of Clinical Pharmacy Services for the Walgreens Specialty Pharmacy, focusing on HIV, located in the Howard Brown Health Center of Chicago. Contact: Glen.Pietrandoni@walgreens.com.

Radical Red continued

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from the realization that people who interact with children (parents, teachers, etc.) might actually have to talk with them about HIV/AIDS if they hear about it on Sesame Street?

Like this would be a bad thing? Like we shouldn't be doing this already?

Obviously PBS and Sesame Workshop wouldn't even have to spend time on blowjobs or vaginal/anal sex or smack-shooting if they developed an HIV-positive character—to be honest, they wouldn't even really need to go into transmission at all, given their target age group. An HIV-positive muppet would simply afford children living with or impacted by HIV/AIDS a validation of their own experiences, and would show the rest of its viewers the same lessons Sesame Street has always taught: that it's okay to hang out with people who are a little different from you.

For those interested in writing letters concerning the introduction of HIV-positive muppets on American Sesame Street:

Sesame Workshop
One Lincoln Plaza
New York, NY 10023
www.pbs.org/kids/sesame/

PBS Headquarters
Public Broadcasting Service
1320 Braddock Place
Alexandria, VA 22314
(note: due to the anthrax scare post-9/11, PBS will only handle correspondence on postcards)
www.viewer@pbs.org

Editors Note: At press time, PBS officials switched gears and said they won't rule out the appearance of an HIV-positive muppet on Sesame Street.

Editor's Note continued

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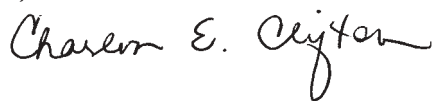
create strategic opportunities to mobilize against AIDS globally. Two weeks later, at the Rainbow/PUSH Coalition's annual conference in Chicago, I again heard Clinton declare, "our goal has to be to solve it, reverse it and end it... this is a disease that's 100 percent preventable." This is not the same Clinton that I remember from his eight years in the White House. But if Jessie Helms can change his view on AIDS, then I suppose even Clinton can.

We all can.

In these uncertain times with Big Brother looking over our shoulders, ADAP (AIDS Drug Assistance Program) shortfalls, and increasing rates of infection, we must be vigilant. On the watch.

I hold fast to the words of Nelson Mandela, "In the face of the grave threat posed by HIV/AIDS we have to rise above our differences and combine our efforts to save our people." We all can. We all must.

Dedicated to the memory of my Brothers United in Support - Bennett "pain in my ass" Williams, David "Yoda" Ferrell and Chester Lyles.



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



Pickett Fences

Seven's Up

by Jim Pickett

July 2002

Dear Mom, Dad, and Kevin,
I have HIV.

I have thought through a zillion ways of approaching this unwelcome announcement, indeed I have been thinking, and thinking and thinking for seven years... since the day I tested positive for HIV, the virus that causes AIDS, in August of 1995. All my options just got more and more convoluted, and I kept contemplating and procrastinating, and now I just want to spare you the dramatic buildup.

I have HIV.

Before I get into why it has taken me seven years to tell you, my family, what I tell people I do not even know in my writing and speaking activities, I want to say that I am okay. I am doing fine, my health is great. I have an excellent doctor who is a specialist in the field and with whom I have a strong relationship. I am currently taking a drug regimen that is keeping the virus at bay and is not giving me any side effects. So while I know that you will worry—and this was one of the reasons I have waited so long—I want to say that you don't have to, that I'm doing okay. Really.

Worry, because I know you will. But do not worry too much. Deal?

Let me explain that AIDS comes after a long time, after HIV has wreaked years of havoc on the immune system. A decimated immune system leaves one open to a host of illnesses and opportunistic infections that are collectively called AIDS. My immune system is nowhere near that. We discovered my

infection very early on, and therefore have been monitoring it closely and treating it before it had a chance to do a lot of damage. Since I found out, I also have been more careful about taking care of myself, not letting myself getting run down, keeping the partying to a minimum. Remember that I have come much closer to dying from asthma in my 36 years than anything else.

Besides being healthy and feeling good—rarely, if ever, do I get so much as a sniffle—the rest of my life is nothing to sneeze at (okay, I couldn't resist.) I enjoy what I do for a living immensely and I am in love with a very special man who has brought intense joy into my life. I'm not letting the fact that he lives in Spain and doesn't speak English dissuade me. It definitely ain't my first time at the rodeo, as you well know I have been following in Liz Taylor's bloated hoof prints, but I want you to understand that I am happy, taking it day by day, enjoying every moment, feeling like the luckiest man on earth... every moment. I am living a truly blessed life, filled with adventure and exciting challenges and populated by an amazing, brilliant, neurotic, funny and not a little insane group of friends and colleagues.

Today I rode my bike thirty miles.

I have HIV.

When I found out, seven years ago, I was devastated and thought my time was up. I was scared, and I cried. I was angry, and I yelled and I screamed. I was depressed, and I laid in a ball in a corner of my bed and prayed it would all go away. It didn't. And ya know, neither did my will to survive. Which,

surprise surprise, is pretty damn strong. I wonder who passed on the stubborn genes? We all have our struggles, human existence is not always a pretty picture, so this is something I have been given to deal with. I can be a miserable bitch about it. Or I can simply try to make the best of it. I guess I am doing a little bit of both, but leaning towards making the best of it. I hope.

I feel incredibly guilty that I have not told you 'til now. I have had a million excuses—always a birthday or holiday that I didn't want to spoil. I mean, I didn't want Arbor Day to be forever tinged with this disclosure! And there was always other family drama that I didn't want to add to with my own. Forgive me. I spent a lot of time worrying about this, spent a great many hours in therapy talking about this, and still, it took me seven years. I kept waiting for the right time, and realized there is no right time. And that the right time is now. And here we are...

I don't want to hurt you. I don't want to freak you out. I don't want you to worry too much about me, or worse, pity me. Or even worse still, fear me. You are not at risk being around me—I am sure you know that—but I just want to put it out there.

Please forgive me for waiting so long. The irony of tons of strangers knowing my status, while my own family doesn't, is not lost on me. Believe me, I see that it is rather schizophrenic. And yes, you are the last to know, of the ones I feel it is important to share this information, and I guess that's because I have wanted to protect you, to shield you, to spare you any suffering. But ya

The Buzz continued

continued from page 48

session at the International AIDS Conference in Barcelona in July comparing tenofovir and d4T. In this trial (Study 903) patients on the d4T arm also had significant increases in cholesterol and triglycerides. Also, lipodystrophy was more prominent in the patients taking d4T.

FURTHER STUDY DETAILS

FTC-301 was designed as a double-blinded randomized trial of FTC + ddI (Videx) + efavirenz vs. d4T + ddI + efavirenz in antiretroviral naïve patients (those taking their first antiviral regimen). Having passed the 96 week mark, we had just previously submitted protocol amendments to continue the study for 144 weeks when the company switched gears in announcing the aforementioned changes. The study will remain open for all patients to obtain open-label drug until FDA approval. Since the company plans to submit a new drug application (NDA) with the FDA during the third quarter of this year, we expect FTC's approval sometime in the early part of 2003.

FTC FACTS

FTC (Coviracil) is a very potent nucleoside reverse transcriptase inhibitor (NRTI). In addition to its activity against HIV, the drug showed activity against hepatitis B. Also, preliminary studies demonstrated FTC to be more potent than 3TC (Epivir) in that it was associated with a 2 log drop in HIV-RNA (viral load). It is also dosed once daily. However, in comparison to 3TC, patients who have developed resistance to 3TC are not likely to derive further benefit from FTC. Also, in preparation to FTC's expected launch and in response to market driven motivations to develop once-daily HIV regimens, 3TC also has been studied and found to be effective at once daily dosing. (See "FDA approves once-daily Epivir" in News Briefs on page 17). ☒

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

know, despite HIV—and also in many strange and beautiful ways because of HIV—I am leading a wonderful life. A life I never dreamed of, and a life I would never exchange.

You are my family and I love you.

I hope you will take some time to let this sink in. You have a right to be sad and angry, as I was. Freak out a little. Let yourself feel those things, but don't let them consume you. Please. And please, come to me with your questions and concerns. There is nothing you can ask me that will offend me or send me screaming into the streets, so let's talk.

We have a lot of catching up to do. ☒

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Test Positive Aware Network (TPAN) is a not-for-profit organization dedicated to providing support and information to all people impacted by HIV.

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

September 2002

Date	Time	Event
Tuesday, September 3	7:30 PM	Committed to Living Series: Navigating the System
Monday, September 9	6:00 PM	TPAN Client Advisory Board Meeting
Friday, September 13	7:30–11:30 PM	Annual Gala to benefit Test Positive Aware Network, at Germania Place
Tuesday, September 17	7:30 PM	Test Positive Aware Network Board Meeting
Sunday, September 29	10:00 AM	AIDS Run/Walk Chicago (Grant Park) Benefitting AIDS Foundation of Chicago

October 2002

Date	Time	Event
Tuesday, October 1	7:30 PM	Committed to Living Series: Alternative Therapies
Tuesday, October 15	7:30 PM	Test Positive Aware Network Board Meeting



Programs and Meetings

All meetings held at TPAN unless otherwise indicated:

5537 North Broadway, Chicago.

Office hours: Monday–Thursday, 9 am–8 pm. Friday, 9 am–6 pm

phone: (773) 989-9400 • fax: (773) 989-9494

e-mail: programs@tpan.com • www.tpan.com

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

MONDAY

TPAN DAYTIMERS

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

NEWLY DIAGNOSED

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

STRAIGHT TALK

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

TUESDAY

LIVING POSITIVE

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

POSITIVE PROGRESS

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

WEDNESDAY

MEDICAL CLINIC

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

NEEDLE EXCHANGE PROGRAM

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

YOGA

Wednesdays at 7:30 pm.

THURSDAY

TPAN DAYTIMERS

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

MEDICAL CLINIC

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

NEEDLE EXCHANGE PROGRAM

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

BROTHERS UNITED IN SUPPORT (BUS)

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

BERLIN HIV-POSITIVE SOCIAL HOUR

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

FRIDAY

MEDICAL CLINIC

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

POSITIVE PROGRESS II

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

NEEDLE EXCHANGE PROGRAM

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

SAFE PASSAGE

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

SCHEDULED BY APPOINTMENT

FAMILY AIDS SUPPORT NETWORK (FASN)

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

WOMEN'S GROUP

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

SPEAKERS BUREAU

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

PEER SUPPORT NETWORK

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

POSITIVE BUDDY

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

MISCELLANEOUS

CHICAGOPos18to24 AT AOL.COM

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

**AD
HERE**