

January / February 2001



Positively Aware

The Journal of Test Positive Aware Network

2001



A Drug Odyssey

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New with this issue of *Positively Aware*

Test Positive Aware Network members and *Positively Aware* readers have been integral to our growth and development. Over the past year, we have made note of your comments on the content and design of *Positively Aware*. In response to your suggestions we have made several changes to the journal, including the inclusion of a calendar of events and programs available through TPAN. As a result of these changes *TPAN Now*, our local HIV newsletter, will no longer be published. We hope that you find these changes positive. Please continue to send your comments and suggestions to the Readers' Forum.

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

Editor's Note

Odyssey 2001



Odyssey: a long wandering marked usually by many changes of fortune.

On the eve of World AIDS Day 2000, I had the privilege of attending a reception and dinner honoring the work of Dr. Beny J. Primm, held in Washington, DC. Dr. Primm has worked tirelessly in the treatment of drug addiction and was instrumental in raising awareness of the impact of HIV/AIDS in communities of color in the early 1980s. As a founding member of the National Minority AIDS Council (NMAC), major advisor to three U.S. presidents, and board member of the Black Leadership Commission on AIDS, Dr. Primm has been a mentor and inspiration to me and so many people who work in the AIDS community. Dr. Primm was integral in the development and passage of the African American AIDS Initiative in 1999, which has provided communities across the country with desperately needed dollars to combat the epidemic.

Paying tribute to Dr. Primm this evening with their presence and personal stories were Surgeon General David Satcher, Congresswoman Maxine Waters, Dr. Helene Gayle (Centers for Disease Control—HIV/AIDS/STDs), activists Debra Fraiser-Howe, Paul Kawata and Miguelina Leon (NMAC), Pernessa Seele (The Balm In Gilead), and Jane Silver (AmFAR) to name just a few. While I listened to the tributes, I couldn't help but to reflect upon my personal odyssey, the advances in the treatment of HIV and reality of AIDS in the year 2000.

It is estimated that 3 million people died from AIDS in the year 2000, and approximately 36.1 million people are now HIV-positive worldwide. In an era when products are available that slow down HIV replication and reduce the transmission from mother-to-child, the vast majority of HIV-positive people worldwide do not receive care and treatment. Most Americans are unaware that the services taken for granted here in the United States are unavailable in most parts of the world.

There were many highs and lows in the treatment of HIV in the year 2000. Didanosine, enteric

coated (EC) Videx. Adherence. Kaletra. Cross Resistance. Trizivir. Treatment failure. Lipodystrophy. Structured Treatment Interruption (STI). This drug odyssey makes it urgent for people living with HIV to understand how current treatment choices will affect future treatment options. To treat or not to treat? Adhere or STI? It is so vital that individuals living with HIV inform themselves and remain proactive in their treatment decisions.

In this our fifth annual HIV treatment guide, Associate Editor Enid Vázquez has compiled the latest on drugs currently used for HIV treatment, with the assistance of Glen Pietrandoni, R.Ph. We have included the opinions of community activist Mark Milano, and HIV specialist Dr. Kimberly Smith and Dr. Allan Tenario of Rush Presbyterian St. Luke's Medical Center, Chicago. Jeff Berry has compiled an index to *Positively Aware* articles published in 2000. Community activist and actor Sanford Gaylord discusses his personal war against HIV. Dr. Daniel Berger brings us the latest "buzz." Laura "Radical Red" Jones gives a well deserved shout out to women activists. And Jim Pickett fences.

This guide is not comprehensive, nor is it designed to tell you what drugs you should or should not take. Hopefully it will be a useful tool in your own odyssey with HIV. As always we encourage you to talk with your health care providers, your friends, family and partner and to seek out the advice of others living with HIV. Listen. Read. Question. Be active. You do have a choice.

Dr. Beny J. Primm has demonstrated that the actions of one individual can have a profound and lasting impact on the lives of an entire generation of activists. It is because of Dr. Primm that so many of us are better prepared for the odyssey that lays before us.

A handwritten signature in black ink that reads "Charles E. Clifton". The signature is fluid and cursive.

Charles E. Clifton
Editor

Not Perfect, But



There is no doubt that the HIV drugs and treatments we have today are less than ideal. After all, anything that isn't a cure is less than ideal. Today's treatments do not even qualify as realistic for long-term maintenance of HIV. No one, not even the drug companies, claim these are the treatments for "a lifetime." We all should recognize the need for better treatments. Treatments that are less harmful, are more forgiving of human nature to miss a dose once, twice, or more each week, that work better at stopping HIV, and that have fewer side effects.

There is no question that today's drugs are far from perfect. They do have nasty side effects, some occasionally fatal, some inconvenient, some simply intolerable to you. The drugs themselves are not good for us—elevated cholesterol, kidney problems, liver toxicity, and who knows what else that we have yet to identify. And of course HIV itself is not overly impressed by most of these drugs. Skip just 1 dose in 6 or maybe 1 in 7 on a regular basis and HIV will simply change so that the drug does not work. And not just that one drug, but often the whole group, or class of drugs.

But there should also be no question that what we have today is a blessing compared to just 6 or 7 years ago. Those of us living with HIV should remember what it was once like. Limited choices—AZT monotherapy, or AZT with ddI or ddC. Therapy that we hoped would buy us one, maybe two years of health. Bactrim, Biaxin, Diflucan and other drugs to hold off the seemingly endless opportunistic infections (OIs). And the ever present funeral or memorial service for yet another friend, loved one, or community member who had died of AIDS.

This is not to suggest that we as HIV-positive people should be complacent with, and meekly

accept the current treatments. It does not suggest that the drug companies and researchers have fulfilled their obligations to eradicate HIV, or at a minimum make it truly manageable. I merely suggest we look at where we are and the options we have, in historical perspective.

I have been fortunate to not personally experience the ravages that AIDS can inflict. But I have seen it numerous times in friends and loved ones. I have visited multiple hospitals and multiple rooms at a hospital to look in on friends who were suffering. I remember when HIV care was focused almost exclusively on the OIs, not on HIV itself. Today really is better than the past.

Today there is a much deeper understanding of HIV and how it works. But there is still much that is not understood about HIV, about our immune systems, about the intricacies of the human body, even about the effects of drugs on the entire body. Medicine has always been part art and part science. This is no less true today with HIV.

What is also true today is the importance of your participation in your own healthcare. *You* must decide what treatments to try. *You* must decide to commit to taking medicine every day as prescribed. *You* must be an active partner with your doctor or healthcare provider. Use this issue of *Positively Aware* as a tool to learn about the numerous drugs available so that *you* and your healthcare provider can choose the best treatment for *you*. Continue to be "Committed to Living".

A handwritten signature in black ink that reads "Dennis Hartke". The signature is written in a cursive, slightly slanted style.

Dennis Hartke
Executive Director

Readers' Forum

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

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Lipid survival

Regarding your Sept/Oct 2000 issue, "HIV Lipid Guidelines for Your Heart" by Enid Vázquez: After almost a year of bad breathing, chest pains, etc., I finally gave in to my own HIV doctor's urging for a stress test. I had stopped PI [protease inhibitor] therapy 11 months ago. My triglycerides had shot sky high along with my cholesterol (which *never* had been a problem for me). Your Gene Coughlin could have been my twin. I turned 46 in September. I had been having trouble walking, even to the bus stop or up our small hill. My stress test was halted when I reached only 136 bpm and had horrible chest pain. A cardiac cath was scheduled, during which I was told I had a 99% block, two 80% blocks & one 97% block. Upon thallium scan it was noted I had viable heart tissue and muscle beyond these blockages and a bypass would benefit me. An angioplasty wasn't the treatment needed. I was sent home on heart and blood pressure meds, my testosterone injections stopped (insert heavy sigh and sad face here) and I was scheduled for at least a triple bypass. I ended up having a quadruple bypass and was discharged to home the following Saturday. I also admit to being an adamant smoker of nearly 30 years. (Note: I am over two weeks smoke free now! See what a week's detox in an ICU can do?). Day 14 since the bypass. I am walking a mile and a half each day. I feel nearly 100% better with increased blood flow I haven't had in years. Who needs the testosterone now? My only concern has been *very* poor pain assessment and management. HIV/AIDS patients have an entirely different focus and priority, requiring something more like can-

cer pain management than surgical. I feel there needs to be better communication between the medical (Infectious Disease) and the surgical side of the hospital. (Sometimes thoracic surgeons tend to be much more *prima donna* than *any* us who usually tend to specialize in DRAMA. Big smile.) However, my point was made when I myself did the work and research to present to the surgeon's post-op, i.e., all the regular mega pills we take for various and sundry diagnosis' that preclude simple percocets for pain. Especially since JCAHO guidelines (Joint Commission on the Accreditation of Healthcare Organizations) are now forcing pain assessment as part of vital sign assessments, making all units, hospitals and clinics liable for pain assessment as a baseline documentation for vital signs, as important as temperature, blood pressure and heart/respiratory rate. I expect to be totally pain free (or close to it) very soon. I am told that reaching week 5 or 6 post operative is when one is *really* glad to have had the whole thing take place and well on the road to recovery. My lover and family are spoiling me rotten and I have wonderful support and rehab. So far my current antiretrovirals are holding (Sustiva, Ziagen, Combivir) and all is well for this tin man. Thank you ever so much for putting Enid Vázquez's article in print and may many more of us patients, nurses and physicians read it and take note and act appropriately. I am now off to enjoy my retirement and who knows? I may someday hit the ranks of the working wounded again!

J. Warner, Silver Spring, MD

Sex ethics

I was infected with HIV in 1987, at age 21, just as I was coming out. My first lover, who I believe infected me, died in 1992 when we were both 26. Since roughly 1992, I have worked in the field of HIV/AIDS either on a volunteer or professional basis. I continue to do so today as a case manager at a local AIDS service organization. While I applaud Jim Pickett's courage to even raise the issue of the morality of safer sex in an age of AIDS, and at this particular moment in our common gay history, I have concluded that his essay in ethics, that is, his attempt to spell out ethic imperatives that all gay men, regardless of HIV status, can live with and agree on, falls short. He says: "...it takes one to pass along the lovely and enchanting virus that causes AIDS." And again: "But it only takes one to infect." This is simply not true and, therefore, amounts to a false premise. The fact remains, it takes two persons to transmit HIV, at least one of whom is HIV positive. These statements, it seems to me, underscore the sad fact that here, 20 years into the AIDS pandemic, the gay community has still not confronted some of the most basic issues and questions surrounding sex and HIV with the brutal honesty that we need to in order to eradicate further transmission. Given human nature, our need for acceptance, love, kindness, dignity, and respect—I would say that we must start finding ways of killing the virus rather than killing the vessel that is carrying the virus. Persons have the right to have unsafe sex if they so choose regardless of their willingness to afterwards accept responsibility for the consequences of their own behavior.

Keith Carson, Absecon, NJ ☚

by Enid Vázquez

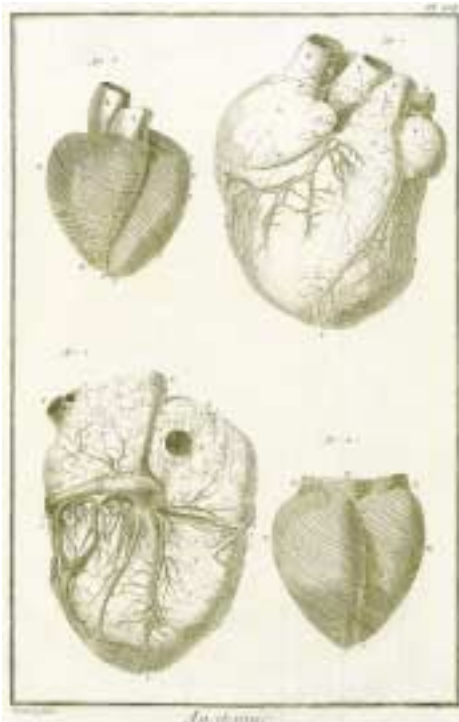


Trizivir: one pill, triple combination

The newest HIV drug on the market combines three Glaxo Wellcome HIV nucleoside analogs in one tablet (how financially convenient). Trizivir consists of Retrovir (AZT), Efavir and Ziagen. There's still a debate over whether the three-in-one powerful drug works well in people with more than 100,000 viral load. What is known is that the drug has held its own against a triple combination with a protease inhibitor (Combivir—which is made up of Retrovir and Efavir—along with Crixivan) for people taking HIV drugs for the first time. Not bad. It also saves protease inhibitors and non-nucleoside analogs (like Sustiva and Viramune) for later if needed. The price is approximately \$10,800 a year, or the cost of the three drugs combined. See the drug guide in this issue for more information on the meds in Trizivir.

Viramune liver warning

The hepatotoxicity (liver damaging) warning on Viramune has been strengthened to suggest close monitoring of liver function tests during the first 12 weeks of use, when two-thirds of severe liver problems seen occur. How often tests should be done is not known, but getting your levels before you go on Viramune is a good idea, in order to determine if your numbers go up significantly. People who start out with high AST or ALT (liver function levels) or who have hepatitis B or C are at greater risk of further liver problems. The label also reminds everyone that dose escalation is important. Why anyone has to be reminded of how important this is, especially doctors, is a testament to the widespread ignorance that continues to kill people. Read this issue's drug guide—please.



Artery damage from PIs

People with HIV who take protease inhibitors have a greater risk of lesions in their carotid vessels than those who are not on PIs. These two main arteries run through the neck. Heart troubles, including heart attacks and strokes, have been seen in people on HIV therapy, perhaps out of proportion to the risk seen by people not on therapy. Italian researchers looked at 102 people with HIV, 55 of who took protease inhibitors. Men, older people and people with high cholesterol levels had a greater risk of the lesions, as well. But smoking, high triglyceride levels and advanced disease increased risk even more, although not as much as use of PIs. The findings were reported in the November 10 issue of *AIDS*.

Pregnant women should get tested

The U.S. Public Health Service and the Centers for Disease Control and Prevention issued revised guidelines urging all pregnant women to test for HIV. However, testing should be voluntary. Healthcare providers are urged to explore reasons for refusing an HIV test and to offer testing again during delivery for women who have not been tested. So many women who believe they're "not at risk" learn that they are HIV positive only after giving birth. Now it's fairly easy to prevent the transmission of HIV to a newborn, including at the time of delivery. It would be a shame for infants to continue to be needlessly infected because of a perceived lack of risk that was never put to the test. For a copy of the guidelines, call the CDC National AIDS Hotline at 1 (800) 342-2437 (now 24 hours) or visit www.cdc.gov/hiv/frn/perinatal.pdf.



Hemophilia Relief Fund

The U.S. Department of Health and Human Services has begun contacting eligible families that will receive payments from the Ricky Ray Hemophilia Relief Fund.

As of August 28, more than 4,300 petitions were received since July 31, the first postmark day that petitions were accepted. Approximately 670 recipients will receive compensation with fiscal year 2000 funds, but an estimated 7,500 individuals are eligible to receive funds. The Ricky Ray Hemophilia Relief Fund was authorized in 1998 to provide compensation payments of \$100,000 to individuals with blood-clotting disorders, such as hemophilia, who contracted HIV from contaminated anti-hemophilic blood products between July 1, 1982 and Dec. 31, 1987. Spouses and children who contracted HIV from these individuals and certain survivors may also be eligible. For more information, call toll-free at 1 (888) 496-0338 or visit www.hrsa.gov/bhpr/rickyray.

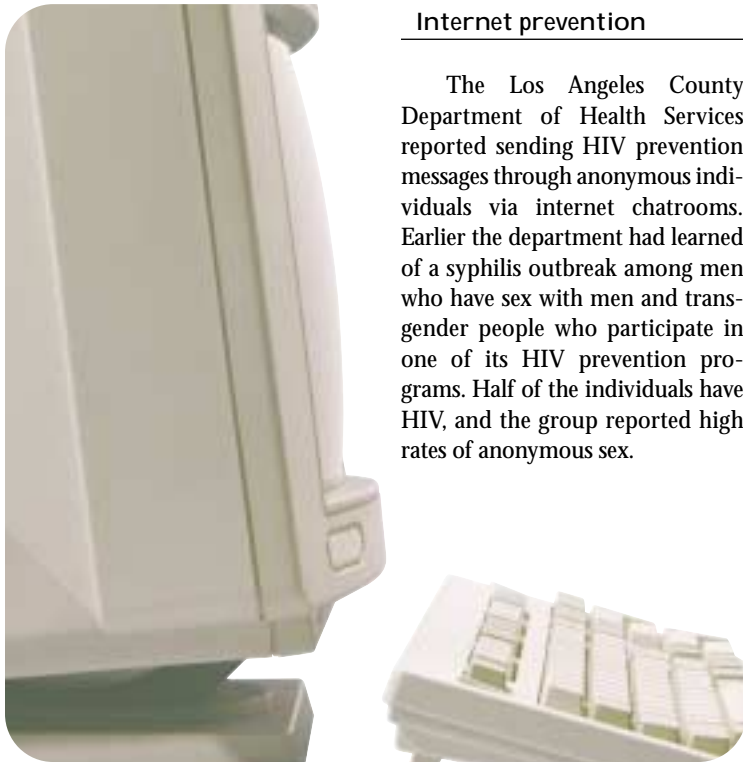


Phenotypic resistance test news

The PhenoSense HIV resistance test can now more closely tell you whether you have resistance to Kaletra or Ziagen. If your blood gets thrown into a test tube and Kaletra is dropped in, but it takes 10 times the normal dose of Kaletra to fight your virus, that's when you know the drug isn't working for you. For Ziagen, however, it only takes 4.5 times the amount of the normal dose to figure out that your virus is resistant (it resists the drug—successfully fights it off). The manufacturer plans to continue this process with the other HIV meds. Resistance tests are becoming increasingly important in HIV therapy, but are still widely confusing and not FDA-approved.

How you can help ACT UP continue to act up

In the last several years, ACT UP Philadelphia has been the most powerful of the few surviving chapters around the country. With the New York City chapter, Philly gained price reductions on a new HIV drug and organized the march for drug treatment access in South Africa during the international AIDS conference last July. They followed the presidential candidate Al Gore around the country, demanding that the U.S. allow third world countries to manufacture generic versions of HIV drugs. All of this depletes the money they manage to scavenge together, not to mention their round-the-clock time. Now, they're being dealt heavy blows by the powers that be. Instead of casual arrests during last summer's Republican Party Convention protests in Philadelphia, ACT UP Philly members along with other activists were kicked, beaten, hog-tied and had their heads slammed into a wall by police officers. They were levied extremely high bonds, including one for one million dollars. Please help the legal defense by sending contributions. The City of Philadelphia is refusing all plea bargaining. Show the authorities that freedom fighters will never be forsaken. Send donations and make checks out to: ACT UP Philadelphia, P.O. Box 22439, Land Title Station, Philadelphia, PA 19110-2439.



Internet prevention

The Los Angeles County Department of Health Services reported sending HIV prevention messages through anonymous individuals via internet chatrooms. Earlier the department had learned of a syphilis outbreak among men who have sex with men and transgender people who participate in one of its HIV prevention programs. Half of the individuals have HIV, and the group reported high rates of anonymous sex.

Black AIDS gets less money

The Baltimore Sun reported that a breast cancer fundraiser drew 25,000 participants and raised \$1.2 million, while the city's annual AIDS Walk attracted only 2,000 walkers and raised a little over \$176,000. Organizers of the AIDS Walk suggested that breast cancer affected more people, of all races and classes, while AIDS has become a disease of primarily poor and black people. In 1999, 82% of HIV positive people in Maryland were African American. AIDS Walk funding is down in Chicago and Los Angeles, but remain strong in New York City and San Francisco.

Marijuana study

The San Mateo County Health Center in northern California will provide marijuana to 60 people with HIV who have neurological problems under a study approved (miraculously) by the Drug Enforcement Administration. To date, government efforts to study the drug's medicinal use have been cruelly, and unnecessarily, slow.

Ryan White CARE Act Passes



A five-year extension of the Ryan White CARE Act unanimously passed both houses of Congress and has been signed into law by President Clinton. While the reauthorization keeps most provisions of the CARE act intact, some changes have occurred. The most significant of these include: expanding funding to medium-sized cities and rural areas, as well as a small number of ADAPs (AIDS Drug Assistance Programs); puts in place assurances that medical care provided under the act conforms to quality of care standards; and tries to assure that people receiving services under the act have access to appropriate medical care by encouraging agencies receiving funding to either offer the care themselves or establish linkages and referrals to medical care. Also included in the bill are some financial incentives to states to adopt some form of testing of all newborn infants, though it is not mandated. Overall, the bill that passed was one supported by HIV activists and service providers. This is an enormous victory for people living with HIV in that when this process started two years ago there was a sense among many in Congress (and the general public) that AIDS was over. Some credit for passage of this vital legislation goes to TPAN members and readers of *Positively Aware* for their efforts to help members of Congress understand the importance of this bill. Thank you to all of you who wrote or called your Senators and Representatives. —Dennis Hartke 🇺🇸



A Year of Endings and Beginnings

by Mark Milano

2000 finally saw the end of “Hit Hard, Hit Early.” People had been questioning the early use of anti-retrovirals for some time, but when Dr. Anthony Fauci, head of NIAID, gave a plenary speech at the Durban AIDS conference and said, “...prolonged courses of continuous HAART are not an option...” he sounded the death knell, in my book. While he was talking about STI’s (structured treatment interruptions), the inference seemed clear: if you can’t stay on antiretroviral treatment forever, make sure that you don’t start it until you need it. The NIH has been trying to design a “when to start” trial for some time now, but there are obviously many difficulties and opposing views to overcome. So, until we have data from that trial or one like it, the message seems to be that people with HIV should begin taking treatment when they need it, and not before.

Of course, there are different ideas as to when that is—some people think anyone below 500 CD4s needs to start therapy, others would wait until you’re closer to 200. For me, the most important factor has always been the “trend over time.” Have you been stable at 350 CD4 cells for some time? Then maybe it’s smart to wait. Are your CD4s lower each time you check? Maybe it’s time to start. I’m not proposing any answers to this truly unanswered question, but the

new information about long-term side effects has shown us that starting everyone on treatment as soon as possible is not the answer. When we have drugs that are effective and truly safe in the long-run, everyone will take them. But for now, the word is: wait ‘til it’s time, and wait until you’re ready to make a long-term commitment to adherence.

Structured Treatment Interruptions

STIs began to be taken seriously in Durban. Fauci presented some interesting data and theories about why stopping treatment for controlled periods of time may be beneficial. Here’s the theory he presented: one thing that has been found in Long Term Non-progressors (LTNPs), is their abundance of HIV-specific CD4 cells, cells that specifically target HIV for destruction. In almost all people with HIV, these cells are destroyed early in infection and never return. One reason they don’t return even in people who respond well to treatment is that they don’t have enough HIV in their body for the immune system to respond to, so no HIV-specific cells are produced.

People who stopped treatment in Fauci’s report saw their HIV viral load increase significantly, and then return to undetectable once treatment was restarted. But when treatment was stopped a

second time, the virus rebounded to a lower level than before—a new “viral set-point” had been established. Another interruption, after a few more weeks on therapy, and another, lower, viral set-point. The hope was that the return of the virus was stimulating the body to produce those invaluable HIV-specific CD4 cells. Fauci concluded by raising the hope that all people with HIV could be turned into LTNPs if we could just find the right STI system.

Well, like all fairy tales, this one doesn’t quite work in the real world. First, not all patients respond well to STIs—some don’t see lower viral set-points. And while Fauci showed that three of his patients had more cytotoxic (“killer”) T cells, another study showed that STIs did not increase HIV-specific CD4 cells, as hoped. Moreover, all STI work has been done in very small numbers of people, usually less than 20 per study, so it’s impossible to extrapolate these findings to the larger population.

Here’s what we know: some people can go off therapy for a short period of time and then restart, without developing resistance or doing permanent damage to CD4 counts. But this message comes with important caveats: drugs must be stopped together (and with drugs like Sustiva staying in the body for days after the last dose, this can be tricky), viral loads will rise and CD4 counts will drop when the drugs are

stopped (so if your CD4 count is already low, you may risk developing an opportunistic infection), some people with viral loads above 100,000 have had a hard time returning to undetectable, and finally, no confirmed benefit has been shown so far, other than giving the body a respite from the long-term side effects of these drugs.

But that's not such a bad thing, so researchers are looking carefully at how STIs can be used to give people a break from their drugs and perhaps even boost the body's own immune response to HIV. The safest thing right now is to wait until more data is in, but if you are thinking about an STI, be sure you do it with your doctor, and with a doctor who is on the cutting edge of research. Like they say on TV: "Don't try this at home."

New Treatments

2000 was largely a year of "more of the same" when it came to treatments. No ground-breaking new drugs, just small steps, like a new protease inhibitor (Kaletra) that seems to work in people who are resistant to other PIs, and a new form of an old drug (ddI), that is swallowed rather than chewed. Gilead finally pulled the plug on their ineffective, kidney-toxic drug (Preveon—this drug looked bad back in 1998), and pushed forward on a better, less toxic version (tenofovir). Boehringer-Ingelheim bought another PI (tipranavir) from Pharmacia-Upjohn, and was sent back to square one—finding the right dose! Roche teamed up with Trimeris to finally move their fusion inhibitor (T-20) into larger trials, but the company is claiming that low drug supplies will hinder attempts at a large scale Expanded Access program. (Hmm—where have I heard that before? Can you say "ritonavir?")

Money for Patients

2000 saw the beginning of a disturbing trend: the increasingly common practice of paying doctors large fees for each patient they enroll in a clinical trial. One of the hallmarks of clinical research

has always been that patients in trials received their primary care outside of the trial setting, so they always had a care provider who put their interests ahead of the research. But when your doctor has a financial stake in getting and keeping you in a trial, can you be sure s/he has no conflict of interest? I hate to say it, but I've heard horror stories: patients who didn't know they were enrolled in a trial, patients pressured to join a trial they weren't really interested in, etc.

Let's be clear: clinical trials are important for both individual patients and the general population. A trial can provide early access to new treatments and to cutting-edge researchers and lab tests. But no one should ever be pressured to join a trial they aren't interested in, and everyone in a trial needs an outside advocate to watch their butt. If you join a trial, do it with your eyes wide open and ask lots of questions. Many of my friends are alive today because they enrolled in clinical trials, but make sure it's right for you before you do. And maybe you could ask your doctor to split that finder's fee with you!

Drugs for Africa

Durban also saw the beginning of a new hope: the realization that treatment was a possibility for poor nations, if the drug companies and the U.S. government would stop fighting their legal efforts to produce generic versions of lifesaving meds. I joined a group of activists that hounded candidate Al Gore until he pressured the U.S. Trade Representative to change trade policies regarding nations that produce generic drugs without the permission of the patent holder. We won that battle in time to see South Africa's president Mbeki drop plans to begin making these drugs and start questioning whether HIV causes AIDS!

That was disheartening, but our work did lead generic manufacturers to finally reveal what we had suspected for years: that a three-drug combo could be

produced in large quantities for less than \$300 a year! That's right—the same drugs we pay over \$12,000 for could be made available to poor nations for a fraction of what we're charged for them. Now, no one denies that drug companies have to charge more than their manufacturing costs in order to make a profit (just how much they really have to mark-up the price is something I won't go into here), but when 33 million people are facing death in poor countries, it's clear that they shouldn't be paying for that research, especially when even the WTO recognizes the rights of sovereign nations to override patents in times of national emergencies.

This message came through loud and clear from numerous speakers and protests at Durban: treatment is a real possibility for people around the world, if we can get the generics made. And for those who claimed that the health infrastructure isn't there, a number of health workers made this point: Treatment drives infrastructure. When treatments are available, the clinics and doctors to administer them follow. We've had enough clinics in poor countries with no drugs in their pharmacies. Why not try the reverse for a while and see what happens? The workers in the field, including organizations like Doctors Without Borders, say that making treatments available is an important first step.

It's time for people with HIV in the U.S. to realize that as bad as it is for us (and let's not pretend it isn't bad—I lost a number of friends this year), it's incredibly worse for people overseas. And it's not a case of "it's just too big to get a grip on." There are specific things that we can work on here to improve access over there. Urging the drug companies that may be saving your life to stop opposing efforts to save lives in Africa would be a good place to start. ☪

Mark Milano, formerly with the New York State health department, is a long-time member of ACT UP/New York.

Antiretroviral Therapy 2001

by Kimberly Y. Smith, MD, MPH

The year 2000 began with the great excitement of entering a new millennium and ended with encouraging news of new agents and new options for treatment of HIV disease. The approval of a new formulation of didanosine, enteric coated (EC) Videx, (ddI), and a new combination pill, Trizivir, provide new options for improving tolerability while maintaining potency of antiretroviral therapy. Trizivir, which includes zidovudine, lamivudine, and abacavir in one pill, offers patients the convenience and simplicity of one pill twice per day while maintaining the potency of a 3 drug regimen. Enteric coated (EC) Videx (didanosine, ddI) provides a less cumbersome, once daily formulation of this agent that will hopefully improve its tolerability.

The most exciting new agent comes from the protease inhibitor (PI) class. Kaletra (lopinavir/ritonavir) is the first combination protease inhibitor and will clearly usher what will soon be known as the era of the "boosted PI." Kaletra is a combination tablet of lopinavir and low dose ritonavir that has demonstrated superior effectiveness in a twice daily regimen compared to a three times daily nelfinavir (Viracept) regimen. More importantly, this drug has demonstrated substantial efficacy in combination with efavirenz for patients with extensive protease inhibitor experience. Clinicians have been anxious to have access to new options for highly experienced patients and Kaletra appears to be one of the best new options to come along in some time. The enhanced potency of Kaletra seems to come from the "boost" lopinavir receives from the presence of low dose ritonavir.

Ritonavir inhibits the metabolism of lopinavir allowing this drug to attain blood levels well above the level needed to inhibit viral replication and in some cases levels high enough to overcome viral resistance. Thus this drug has great potential as a first PI for previously PI naive patients and as a PI for use in salvage therapy. Further information on the resistance that may develop following Kaletra therapy will help clinicians define the best uses for this exciting new agent.

Along with the news of newly approved antiretroviral agents comes news of several intriguing agents in the drug pipeline. A new nucleoside analog reverse transcriptase inhibitor (NRTI), DAPD, and a new nucleotide reverse transcriptase inhibitor, tenofovir, show potential for potent activity against a range of viruses which are resistant to current nucleoside analog RTIs. FTC, entricitabine, a nucleoside analog similar to 3TC (lamivudine, epivir) may add to the list of once daily agents.

In the non-nucleoside RTI class (NNRTI), the most interesting agent is capavirine (AG-1594). This agent will be dosed twice daily and has been shown to have activity against both wild-type and K103N mutant (NNRTI resistant) viruses. This agent is currently available in several phase III studies.

Although there is good news regarding new agents, there is no good news regarding drug toxicities. Lipodystrophy remains a large problem without a clear etiology or a clear definition. Meanwhile, we continue to add to the list of drug related problems. Osteoporosis, osteonecrosis (avascular necrosis), and lactic acidosis are gaining more attention as they seem to occur with

increasing frequency as complications of HIV therapy.

Each year brings more information but not necessarily a better understanding of drug resistance. In the year 2000, we learned more about resistance testing but we continue to debate about the situations in which it is best utilized. We have learned a bit more about cross-resistance, but we continue to debate the intricacies of drug sequencing.

What remains certain is that as years pass and our antiretroviral agent armamentarium becomes more expansive, HIV management becomes more complex. It is, therefore, increasingly important that the care of HIV infected persons be provided by clinicians experienced in HIV care. Too often medications are used inappropriately, toxicities are misdiagnosed or missed altogether by clinicians who are inexperienced in HIV management. This is particularly true in poor communities and communities inhabited primarily by people of color. Unfortunately, expert HIV clinicians are relatively rare particularly in the communities disproportionately affected by this disease. In Chicago, we have begun a project to provide HIV treatment updates and education to health care providers in predominantly African-American communities. Hopefully this and similar initiatives will improve the availability of quality HIV care in these communities. ☩

Kimberly Y. Smith, MD is Assistant Professor, Department of Medicine, Rush Medical College, Rush Presbyterian St. Luke's Medical Center, Chicago and is also with the CORE Center. Of recent, she is a medical consultant for Positively Aware.

Class: thymidine nucleoside analog (also called nucleoside reverse transcriptase inhibitor, NRTI or nuke)

Standard dose: One 300 mg tablet twice a day (two 100 mg capsules three times a day also available). Clear, strawberry-flavored liquid for pediatric use. Take missed dose as soon as possible, but do not double dose.

Wholesale cost: \$3,822/yr., \$318.52/month

Patient assistance number: 1 (800) 722-9294,

www.glaxowellcome.com

AIDS Treatment Information Service: 1 (800) HIV-0440

Potential side effects:

Headaches, fever, chills, muscle soreness, fatigue, anemia, nausea, and fingernail discoloration. Potential for severe anemia requiring blood transfusion or hospitalization when used with hydroxyurea. AZT has been associated with hematologic (blood) toxicity including neutropenia and severe anemia, particularly in people with advanced HIV. Bone marrow suppression: anemia and/or neutropenia. Prolonged use of AZT has been associated with symptomatic myopathy (muscle damage). Rarely seen with nukes but potentially fatal: pancreatitis (signs include nausea, vomiting, and abdominal pain that often spreads to the chest and back); lactic acidosis (seen mostly in women, especially obese women; greater risk for people with underlying liver disease; signs include deep muscle fatigue, especially in legs, and difficulty breathing); and enlarged, fatty liver (check for tenderness below ribs on right side).

Potential drug interactions:

Biaxin (clarithromycin), Mycobutin (rifabutin), and rifampin (under various brand names, used for treating tuberculosis) may decrease AZT blood levels. Benemid (probenecid) may increase AZT blood levels and decrease AZT clearance. Methadone and ganciclovir (Cytovene and Vitrasert) increase AZT blood levels. Prescriber may need to adjust doses accordingly. AZT and Zerit shouldn't be used together due to evidence

that one limits the other's bioavailability level in the test tube. Also, risk of bone marrow toxicity may increase with use of ganciclovir, amphotericin B, pentamidine (NebuPent, Pentam or Pentacarmat), dapsone, flucytosine, interferon-alpha ribavirin (Rebetol), and with other antineoplastics (anti-tumor treatment) such as hydroxyurea. Ribavirin and AZT may cancel each other out.

Tips:

Do not use with Hydrea (hydroxyurea). Retrovir has somewhat of a bad rep left over from its early years when the doses given were too high. Studies show that Retrovir crosses the blood-brain barrier to a useful degree, which may treat or prevent neurologic damage (such as dementia). Proven to significantly reduce mother-to-infant transmission. Also available combined with Efavir (**Combivir**, one tablet twice a day) and in a triple combination with both Efavir and Ziagen (**Trizivir**, one tablet twice a day; see News Briefs).



Brand Name:
Retrovir

Common Name:
zidovudine, AZT

Manufacturer

FDA-approved in March 1987, Retrovir (AZT) was the first authorized antiretroviral AIDS drug. Together with 3TC, Retrovir is one of the most widely used anti-HIV drugs and has become a staple in many three-drug studies for the treatment of HIV/AIDS. The combination of 3TC and Retrovir was generally well tolerated in clinical trials. The most commonly reported adverse events consisted of headache, nausea, malaise and fatigue, runny nose and nasal congestion, diarrhea, low white blood cells and anemia. Its labeled dosing is one 300 mg tablet twice daily. Studies have shown Retrovir to be effective in significantly reducing the risk of transmission of HIV from an infected mother to her baby.
—Glaxo Wellcome

Doctor

AZT, the first drug approved for HIV disease, is given as a single 300 mg pill twice a day, without any food restrictions. It can also be given as a combination with 3TC 150 mg taken as a single pill twice a day. A new pill combining AZT with 3TC and abacavir is available. The most common side effects associated with AZT use are headaches, fatigue, muscle pains, insomnia, nausea, vomiting and loss of appetite. Most of these side effects occur in the first few weeks of taking the drug and are mild and easily controlled with over the counter preparations. Occasionally patients, especially those with advanced HIV disease, can develop low red blood cell (anemia) and white blood cell (neutropenia) counts with AZT. Hence, blood counts should be monitored routinely when patients take AZT. Rarely, some patients develop liver and muscle toxicities, which require discontinuation of the drug. AZT can not be given with d4T, because they cancel each other's effects out.
—Dr. Allan Tenario

Activist

AZT has taught us many lessons: that more isn't always better, that earlier isn't always better (the Concorde study showed it did not extend life for those who took it before developing AIDS), and that companies can respond to pressure about overpriced drugs. AZT remains a staple largely due to its combo with 3TC to form Combivir. Though d4T plus 3TC has been shown to be as effective with fewer side effects, the convenience and marketing of Combivir keep it a popular choice. People taking AZT tend to fall into three categories: those who have such a bad reaction that they can't stand it for more than a few weeks; those who have initial side effects which then subside (the majority of users), and those who have no problem with the drug. I have friends who swear AZT is Drano, and others who have been on it for over a decade with no problems. The bottom line: as with any drug, you'll never know how you'll react until you take it.
—Mark Milano

Brand Name:
Videx



Common Name:
didanosine, ddi

lx

Class: nucleoside analog (also called nucleoside reverse transcriptase inhibitor, NRTI or nuke)

Standard dose: Recently approved enteric-coated formula (Videx EC) consists of one 400 mg capsule once a day, with adjustments for weight. Buffered tablets must be taken at least two at a time for adequate absorption. Also, powder for oral solution. Strictly on an empty stomach (an hour before or two hours after food or drink, except water). Adults with kidney dysfunction require dose adjustment. Take missed dose as soon as possible, but do not double dose.

Wholesale cost: \$2,972/yr., \$248/month

Patient assistance number: 1 (800) 426-7644, www.bms.com

AIDS Treatment Information Service: 1 (800) HIV-0440

Potential side effects:

Retinal changes, optic neuritis and peripheral neuropathy (tingling, burning, numbness or pain in the hands or feet, indicating nerve damage that can be reversible but could become permanent if not treated in time and that may be debilitating and painful). People with a history of peripheral neuropathy, pancreatitis and heavy alcohol use should avoid Videx. Have periodic retinal exam. Headache, increased uric acid levels (indicating a number of disorders, including kidney damage and metabolic diseases), and insomnia are other potential side effects. Pancreatitis can be life-threatening and is indicated by increased amylase and lipase levels in lab reports and pain in the stomach and back, along with nausea, vomiting and blood in the urine—risk increases with higher doses, advanced HIV, and alcohol use. Also rarely seen with nukes but potentially fatal are lactic acidosis (seen mostly in women, especially obese women; greater risk for people with underlying liver disease; signs include deep muscle fatigue, especially in legs, and difficulty breathing) and enlarged, fatty liver (check for tenderness below ribs on right side).

Potential drug interactions:

Consider increasing Videx dose when taken with methadone (which lowers Videx blood levels by 41%). Videx/Hivid combination is not recommended because of its higher incidence of peripheral neuropathy. Antineoplastics (anti-tumor treatment) such as AZT and hydroxyurea may increase risk of peripheral neuropathy. Alcohol, Cytovene, NebuPent, Zerit and hydroxyurea may increase risk of pancreatitis. Also, Cytovene raises Videx levels by up to 65 percent. Should not be taken with any prescription antibiotic containing any form of tetracycline. Videx tablets should be taken on an empty stomach two hours apart from protease inhibitors, Tagamet, Nizoral, Sporanox and dapsone, and one hour apart from Rescriptor, while Videx EC can be taken with them (still on an empty stomach).

Tips:

Swallow the new capsules whole (don't break open to get the beads). Capsules eliminate awful texture of the tablets and its enteric coating eliminates diarrhea. Technically, twice-daily with the tablets is "preferred dose" according to the FDA. But that's based on a small registrational trial—other studies not counted indicate that once-daily tablets are just as potent. Because of complex dosing requirements (fasting) once-daily dosing was common long before FDA approval. If you have kidney dysfunction, you need regular tests to check how they're working with Videx. Empty stomach requirement complicates treatment. Food can decrease absorption by as much as 50 percent. Notify your doctor immediately if peripheral neuropathy is suspected, but do not stop taking medication unless directed to do so by your healthcare provider.

Manufacturer

In 1999 Videx was approved as the first once-daily nucleoside analogue. In October 2000, the FDA granted approval of Videx EC delayed release capsules, containing enteric-coated beadlets designed to protect the active ingredient in Videx from stomach acids, eliminating the need for buffer. Videx EC capsules are easy to swallow, with no chewing or dispersing of tablets. Fatal and nonfatal pancreatitis has occurred during therapy with Videx. Videx should be suspended in patients with suspected pancreatitis and discontinued in patients with confirmed pancreatitis. Lactic acidosis, hepatitis and liver failure have been reported with the use of nucleoside analogues, including Videx. Other important toxicities include retinal changes, optic neuritis, and peripheral neuropathy. Patients treated with Videx in combination with Zerit, with or without hydroxyurea, may be at increased risk for adverse events such as pancreatitis, peripheral neuropathy, and liver failure.

—Bristol-Myers Squibb

Doctor

ddI is given as two 100 mg chewable tablets taken twice a day or two 200 mg tablets taken once a day, usually in the morning. The preferred dosing frequency is twice a day since there is more evidence supporting the efficacy of this dosing. Many patients find it difficult to take ddI due to its unpalatable nature and the food restrictions. Stomach acidity decreases the drug's absorption. Hence the drug needs to be taken 30 minutes before or 2 hours after eating. The tablets are also given with a buffer to protect it from being degraded by the stomach's acid, and can not be taken with indinavir, which is degraded by the buffer. Other drugs may also interact with the buffer used in the tablets. A new enteric coated formulation of the drug allows patients to take a single pill once a day, but with the same food restrictions. Side effects reported with ddI include diarrhea because of the tablet buffer, peripheral neuropathy (numbness, tingling, achiness or pain over the feet) and pancreatitis.

—Dr. Allan Tenorio

Activist

Old drug, new pill, higher price! Data showing it is synergistic with d4T and hydroxyurea, and approval for once-daily dosing have raised the drug's profile. From the package insert of the new version: "There are limited data to support the long-term durability of response with once-daily dosing. Therefore, the preferred dosing regimen is twice-daily (with the old ddI). Videx EC should be considered only for patients who require a once-daily regimen or an alternative formulation." That's not a big vote of confidence, in my book. In spite of all this, and ignoring activist pressure, BMS has hiked the price 20%—this after annual price hikes that had already raised the price nearly 70%! Wotta nerve. Tell your doctor if you experience peripheral neuropathy (tingling or numbness in the toes and fingers)—most likely, you should stop the drug immediately, since nerve damage can be permanent.

—Mark Milano

Class: nucleoside analog (also called nucleoside reverse transcriptase inhibitor, NRTI, or nuke)

Standard dose: One 0.75 mg tablet three times a day, with or without food. Liquid available through compassionate use program. Take missed dose as soon as possible, but do not double dose.

Wholesale cost: \$2,700/yr., \$225/month

Patient assistance number: 1 (800) 285-4484, www.rocheusa.com

AIDS Treatment Information Service: 1 (800) HIV-0440

Potential side effects:

Headache, fever, skin eruptions, canker sores, general inflammation of the mouth, nausea, pancreatitis, malaise (general ill-feeling, as with the blahs, fatigue or a flu) and peripheral neuropathy (tingling or numbness in the hands and feet, indicating nerve damage that can be reversible but could become permanent if not treated in time and that frequently becomes debilitating and painful). Rarely seen with nukes but potentially fatal: pancreatitis (signs include nausea, vomiting, and abdominal pain that often spreads to the chest and back); lactic acidosis (seen mostly in women, especially obese women; greater risk for people with underlying liver disease; signs include deep muscle fatigue, especially in legs, and difficulty breathing); and enlarged, fatty liver (check for tenderness below ribs on right side).

Potential drug interactions:

According to the U.S. Department of Health and Human Services (HHS) HIV guidelines, Hivid should not be taken with Epivir, Videx, or Zerit. Fungizone (amphotericin B), antineoplastics (anti-tumor treatment) such as Retrovir (AZT) and hydroxyurea, Chloromycetin (chloramphenicol), dapson, Antabuse (disulfiram), Foscovir (foscarnet), isoniazid (for treating tuberculosis), pentamidine (NebuPent, Pentam or Pentacarinat, used for treating *Pneumocystis carinii* pneumonia, that is, PCP), Dilantin (phenytoin) and Benemid

(probenecid) may increase risk of peripheral neuropathy. Antacids decrease Hivid levels by 25 percent. Tagamet (cimetidine), Maalox, Foscavir and Benemid may decrease Hivid levels. Pentamidine may increase risk of pancreatitis, inflammation of the pancreas that can be life-threatening. It is indicated by increased amylase and lipase levels in lab reports and pain in the stomach and back, along with nausea, vomiting and blood in the urine. However, increased amylase levels may not occur until after pancreatitis does. The risk of pancreatitis increases with higher doses, more advanced HIV, and alcohol use. If you experience these symptoms, stop taking Hivid and seek medical attention immediately. If symptoms go away after stopping Hivid, you can consider starting Hivid again at a smaller dose.

Tips:

Hivid/Videx not recommended by the manufacturer because of its association with a high incidence of peripheral neuropathy. Notify your doctor immediately if peripheral neuropathy is suspected, but do not stop medication unless directed to do so by your healthcare provider. Increased risk of drug-associated toxicity when taken with Foscavir (foscarnet).



Brand Name:
Hivid

Common Name:
zalcitabine, ddc

Manufacturer

Hivid (zalcitabine) is a nucleoside reverse transcriptase inhibitor (NRTI) used in combination with other antiretroviral agents for the treatment of HIV infection. Side effects associated with Hivid, when taken alone or in combination with AZT, are peripheral neuropathy and pancreatitis. Some patients also experience less serious side effects, including oral ulcers and rash.

—Roche



Doctor

Zalcitabine is a nucleoside reverse transcriptase inhibitor. It is probably the least commonly used RTI due to its relative lack of potency and its associated toxicities. The major toxicity is peripheral neuropathy which occurs in as many as a third of patients who take this drug. Other toxicities include stomatitis, aphthous ulceration, pancreatitis, and rash. The other major issue with this agent is that it requires three times daily dosing. Together these issues make this one of the least favorite of all the available antiretroviral agents.

—Dr. Kimberly Y. Smith



Activist

Activists fought to have ddC released early when it was first being studied, but it has since been eclipsed by other drugs in its class. It failed when compared to AZT, which is still the only nucleoside it can be combined with safely. It's used today largely as a back-up drug for people who have become resistant to other drugs, and need a new drug to construct a new regimen. Side effects such as mouth sores, peripheral neuropathy and pancreatitis should be watched for carefully.

—Mark Milano



Brand Name:
Zerit



Common Name:
stavudine, d4T

2x

Class: thymidine nucleoside analog (also called nucleoside reverse transcriptase inhibitor, NRTI, or nuke)

Standard dose: One 40 mg capsule (with or without food) twice a day for people weighing 132 pounds or more, one 30 mg capsule twice a day for people weighing less. Available in 15 mg, 20 mg, 30 mg and 40 mg capsules. Also powder for oral solution. Take missed dose as soon as possible, but do not double dose.

Wholesale cost: \$3,738/yr., \$312/month

Patient assistance number: 1 (800) 272-4878, www.bms.com

AIDS Treatment Information Service: 1 (800) HIV-0440

Potential side effects:

Headache, chills/fever, malaise (overall ill feeling, as with the blahs, fatigue or a flu), insomnia, anxiety, depression, rash, nausea, vomiting, diarrhea, abdominal pain and peripheral neuropathy (tingling, burning, numbness or pain in the hands or feet, indicating nerve damage that can be reversible but could become permanent if not treated in time and that may be debilitating and painful). Peripheral neuropathy is dose-related and occurs more often in people with advanced HIV or a history of the condition. Symptoms may worsen temporarily after stopping the drug. If symptoms go away after stopping Zerit, you can consider starting Zerit again at a smaller dose. Caregivers of young children should be instructed regarding noticing and reporting peripheral neuropathy. Adverse reactions and serious laboratory abnormalities in pediatric patients were similar in type and frequency to those seen in adults. Rarely seen with nukes but potentially fatal: pancreatitis (signs include nausea, vomiting, and abdominal pain that often spreads to the chest and back); lactic acidosis (seen mostly in women, especially obese women; greater risk for people with underlying liver disease; signs include deep muscle fatigue, especially in legs, and difficulty breathing); and enlarged, fatty liver (check for tenderness below ribs on right side).

Potential drug interactions:

Drugs such as Fungizone (amphotericin B), Foscavir (foscarnet), and dapsone may increase the risk of developing peripheral neuropathy. Cytovene and Vitraset (ganciclovir) and intravenous Pentam (pentamidine) may increase the risk of pancreatitis. To be used with caution by people with pre-existing bone marrow suppression, renal insufficiency or peripheral neuropathy. Videx and hydroxyurea may increase risk of pancreatitis.

Tips:

More retrospective studies have linked Zerit to facial atrophy (sunken cheeks), but it's not clear if previous Retrovir use is a contributor. Still, Zerit is sometimes found to have a greater association with atrophy where Retrovir use does not. One advocate noted this was seen from its FDA approval, long after Retrovir was on the market. Contact your doctor immediately if peripheral neuropathy is suspected, but do not stop taking medication unless directed to do so by your healthcare provider. Stop taking Zerit immediately if experiencing symptoms of pancreatitis: pain in the stomach that sometimes extends to the chest and the back, along with nausea, vomiting or blood in the urine. Get immediate medical attention. Increased amylase levels indicate pancreatitis, but sometimes levels do not increase until after pancreatitis occurs. Studies show that Zerit crosses the blood-brain barrier to a useful degree, which may treat or prevent neurological damage (such as dementia).

Manufacturer

Zerit, approved in 1994, provides effective, long-term therapy, is generally well tolerated and may encourage adherence with an easy to swallow small capsule taken twice daily regardless of meals. An increase of lactic acid in the blood, an enlarged liver and liver failure, which can cause death have been reported in patients receiving Zerit-containing regimens. Fatal and non-fatal pancreatitis (inflammation of the pancreas) has occurred with Zerit taken in combination with didanosine and other HIV drugs. Zerit may cause numbness, tingling or pain in the hands or feet (neuropathy). This risk is increased in patients with advanced HIV disease or a history of neuropathy. If you are taking Zerit in combination with other medicines that may cause similar side effects, you may have a higher chance of developing these effects. Frequent side effects in triple combination regimens are nausea, headache, diarrhea, rash, vomiting and neuropathy.

—Bristol-Myers Squibb

Doctor

Stavudine is a well-tolerated drug that is taken as a single capsule (40 mg) twice a day with no food restrictions. It should never be taken with zidovudine (AZT, Retrovir) since one drug will cancel out the other's effects. Side effects attributed to stavudine include headaches, fatigue, peripheral neuropathy and increased liver enzymes. A rare but potentially fatal side effect of the drug is liver toxicity with or without lactic acidosis (build-up of acid in the body). Patients with this side effect usually have two or more of the following: nausea, vomiting, diarrhea, loss of appetite or abdominal pain. Women seem to be more prone to this complication than men.

—Dr. Allan Tenorio

Activist

The Lady-In-Waiting, d4T languished in small Phase I trials for years while BMS pursued approval for ddI. When it was finally taken off the back burner, it was shown to be as effective as AZT, without causing the nausea, headaches and anemia AZT is known for. It is a part of many first-line regimens, even though switching from AZT to d4T is more effective than the reverse. It can cause peripheral neuropathy, so report any tingling or numbness in your toes or fingers to your doctor immediately. Monitor your liver enzymes closely, and be aware that d4T has been linked to the fat redistribution problems many people on triple combinations experience (though it's difficult to sort out exactly which drugs cause this more than others). A popular choice among doctors and patients for many three-drug combinations.

—Mark Milano

Class: nucleoside analog (also called nucleoside reverse transcriptase inhibitor, NRTI, or nuke)

Standard dose: One 150 mg tablet twice a day, with or without food. Strawberry/banana flavored liquid. Take missed dose as soon as possible, but do not double dose.

Wholesale cost: \$3,271/yr., \$273/month

Patient assistance number: 1 (800) 722-9294, www.glaxowellcome.com

AIDS Treatment Information Service: 1 (800) HIV-0440
Potential side effects:

Headache, nausea, diarrhea, fatigue, hair loss, insomnia, malaise (overall ill feeling, as with the blahs, fatigue or a flu), nasal symptoms, cough and peripheral neuropathy. In children, may cause pancreatitis, a potentially fatal condition. Children should be monitored carefully for this condition. Symptoms include nausea, vomiting, clammy skin, and stomach pain that often extends to the back, along with increased amylase in the blood. Rarely seen with nukes but potentially fatal: pancreatitis (signs include nausea, vomiting, and abdominal pain that often spreads to the chest and back); lactic acidosis (seen mostly in women, especially obese women; greater risk for people with underlying liver disease; signs include deep muscle fatigue, especially in legs, and difficulty breathing); and enlarged, fatty liver (check for tenderness below ribs on right side).

Potential drug interactions:

No significant interactions.

Tips:

Is also the first oral therapy for treatment of hepatitis B virus (HBV), under the brand name Epivir HBV and used at a different dose. The once-daily dose for HBV may cause drug resistance (it may no longer work) for people with HIV. Epivir dose needs to be lowered for people who weigh less than 110 pounds, to 2 mg/kg (a kilogram equals 2.2 pounds) twice daily when taken in combination with Retrovir (AZT). Also available com-

bined with Retrovir (**Combivir**, one tablet twice a day) and in a triple combination with both Retrovir and Ziagen (**Trizivir**, one tablet twice a day; see News Briefs).



Brand Name:
Epivir

Common Name:
Lamivudine, 3TC

Manufacturer

FDA-approved in November 1995, Epivir (3TC) has become a widely used antiviral in combination with Retrovir (AZT). The two popular drugs, which are a foundation for many three-drug regimens, have been approved as Combivir, a single dose tablet. Data from a small number of patients suggest that Epivir may delay the development of viral resistance to Retrovir in patients with no previous treatment history. Epivir may reverse resistance to Retrovir in a small number of patients who have received extensive prior therapy with Retrovir. These resistance data continue to be studied. The most commonly reported adverse events consist of headache, nausea, malaise and fatigue, runny nose and nasal congestion, diarrhea, low white blood cells, and anemia.

—Glaxo Wellcome

Doctor

Lamivudine is taken as a single 150 mg pill twice a day or as a combination pill with zidovudine. A new pill combining zidovudine with lamivudine and abacavir will be available soon. It is a well-tolerated drug with very little side effects and no food restrictions. Unfortunately, the virus easily becomes resistant to lamivudine. Fortunately, when given together with other nucleoside reverse transcriptase inhibitors and protease inhibitors, the emergence of resistance mutations is delayed. Missing doses of medications however can lead to incomplete viral suppression and emergence of these resistance mutations.

—Dr. Allan Tenorio

Activist

3TC seems to have become a mainstay of first-line regimens. Since it is synergistic with AZT (virus that is resistant to AZT is sensitive to 3TC, and vice versa), Glaxo combined it with that drug to form Combivir and now Trizivir (AZT/3TC/abacavir). 3TC taken by itself leads to quick resistance, but taken with either AZT or d4T (both combinations are equally effective), this problem is avoided. It also causes fewer side effects than most antiretrovirals, which is a blessing for people already dealing with their other meds. 3TC is effective against Hep C, but has not been approved for that use yet.

—Mark Milano

Brand Name:
Ziagen



Common Name:
abacavir sulfate

2x

Class: nucleoside analog (also called nucleoside reverse transcriptase inhibitor, NRTI, or nuke)

Standard dose: One 300 mg tablet twice a day, with or without food. Strawberry/banana flavored liquid. Take missed dose as soon as possible, but do not double dose.

Wholesale cost: \$4,396/yr., \$366/month

Patient assistance number: 1 (800) 513-3028, www.ziagen.com

AIDS Treatment Information Service: 1 (800) HIV-0440

Potential side effects:

A hypersensitivity reaction (allergy to the drug) can be fatal if Ziagen is stopped and then taken again (see below). Other potential side effects include nausea, vomiting, abdominal pain, diarrhea, fatigue, headache, fever, rash, anorexia (loss of appetite), high blood sugar and high triglyceride levels (fat in the blood). Rarely seen with nukes but potentially fatal: pancreatitis (signs include nausea, vomiting, and abdominal pain that often spreads to the chest and back); lactic acidosis (seen mostly in women, especially obese women; greater risk for people with underlying liver disease; signs include deep muscle fatigue, especially in legs, and difficulty breathing); and enlarged, fatty liver (check for tenderness below ribs on right side).

Potential drug interactions:

Alcohol increases Ziagen levels and its side effects. Avoid drugs that are processed through the liver the same way that alcohol is: Antabuse, Parafon Forte (chlorzoxazone, a muscle relaxant), Thorazine (chlorpromazine), chloral hydrate and INH (to treat tuberculosis).

Tips:

Black box warning strengthened last year when hypersensitivity (an allergic reaction) wasn't recognized and people went back on Ziagen, becoming seriously ill. It usually occurs within six weeks of starting therapy, gets progressively worse and resolves quickly after permanent discontinuation. People experiencing hypersensitivity

must stop taking Ziagen and cannot take it again later on (called "rechallenging") because of life-threatening, and in at least three cases fatal, reaction. Approximately 5% of people taking Ziagen experienced hypersensitivity. The primary symptom is low-grade fever with multi-organ symptoms: muscle ache, nausea, vomiting or other gastrointestinal upset, malaise (run-down feeling, as with the blahs, fatigue or a flu), respiratory symptoms (cough, difficulty breathing and sore throat) and possibly mild rash. Hypersensitivity might be confused with flu during flu season. The manufacturer recommends that people with symptoms of acute respiratory disease consider hypersensitivity even if other diagnosis such as pneumonia, bronchitis or flu is possible. They should stop Ziagen and contact their doctor immediately. There should be no problem with this if you miss your doses for a few days and did not have hypersensitivity before. Ziagen has the potential to cross the blood-brain barrier, which may prevent or treat neurological damage (such as dementia). For many individuals using HIV drugs for the first time and with a low-to-moderate viral load, Ziagen/Combivir can be a good triple nuke regimen (now in one tablet), based on strong results at 48 weeks against Crixivan/Combivir (both with a ton of nausea). The triple-nuke combo saves two classes of drugs for later if necessary. One small, early study suggests that it performs well in people with more than 100,000 viral load. Also performed well head-to-head against Viracept in preliminary results (24 weeks). Also available in a triple combination with Retrovir and Epivir (**Trizivir**, one tablet twice a day; see *News Briefs*).

Manufacturer

Ziagen (abacavir sulfate) is a one-tablet, twice daily nucleoside analogue reverse transcriptase inhibitor that, in combination with other anti-retrovirals, appears to have its greatest activity in treatment naïve patients. Results of study suggest similar antiviral effects—at 48 weeks—of Ziagen+Combivir and Crixivan+Combivir on the proportion of patients with viral loads below 400 copies/ml. Ziagen appears to be generally well tolerated with the most commonly reported adverse events consisting of headache, nausea, vomiting, malaise and diarrhea. The most serious adverse event is a hypersensitivity reaction in approximately 3–5 percent of patients, generally characterized by fever with nausea and/or malaise, and possibly an accompanying rash. Patients experiencing these symptoms must contact a physician immediately and suspend taking Ziagen. Patients must not take Ziagen again as restarting the drug after a hypersensitivity reaction has resulted in cases of life-threatening and fatal reactions.

—Glaxo Wellcome

Doctor

Abacavir is a potent NNRTI that has been in widespread use for two years. Its most positive aspects are potency, tolerability, and convenience. Abacavir-based regimens have been compared with several PI-based regimens and have demonstrated similar potency and efficacy, with equal or better tolerability and convenience. The recent approval of Trizivir, a combination pill that includes AZT, 3TC and abacavir may further improve the convenience of abacavir-based triple therapy. One major negative is the potential for hypersensitivity reaction (HSR), which includes fever, rash, GI upset, cough, shortness of breath, and flu-like arthralgias and myalgias. Clinicians and patients need to be well educated about abacavir-associated HSR in order to take advantage of the tremendous clinical benefit of this agent while minimizing the potential risks.

—Dr. Kimberly Y. Smith

Activist

Abacavir is a potent nucleoside, useful as a first-line regimen, but probably not effective for those who have become resistant to other nukes. Glaxo has worked hard to promote abacavir as the third arm of a combo with AZT/3TC, and has now released the three drugs in one pill, Trizivir (with convenient dosing). Approval used one trial considered unethical by many activists, which compared abacavir/AZT/3TC to AZT/3TC alone, at a time when two-drug combos were considered sub-optimal therapy. Later trials have shown that Trizivir compares favorably with PIs, including Crixivan/Combivir (this may be partly due to improved adherence, since abacavir is just one pill twice a day). But before starting a three nuke regimen, consider that the risk of mitochondrial toxicity and lactic acidosis may be increased. One study showed that Trizivir was not particularly effective for people with viral loads above 100,000. Only 33% of them achieved viral loads below 400.

—Mark Milano

Class: non-nucleoside analog (also called non-nucleoside reverse transcriptase inhibitor, NNRTI or non-nuke)

Standard dose: Two 200 mg tablets (smaller than the 100 mg) three times a day. Take missed dose as soon as possible, but do not double dose.

Wholesale cost: \$3,396/yr., \$283/month

Manufacturer Contact: www.agouron.com

AIDS Treatment Information Service: 1 (800) HIV-0440

Potential side effects:

Rash, headache, nausea, vomiting, diarrhea, fatigue and pruritus (itchy skin), . Severe rash can be life-threatening. Signs may include fever, blistering, oral lesions, conjunctivitis (pink eye, which if untreated may result in permanent loss of vision), swelling, muscle or joint aches, or general malaise (feeling unwell, as with a flu). Stop taking Rescriptor if these symptoms appear and seek immediate medical attention.

Potential drug interactions:

Do not use Zocor (simvastatin) or Mevacor (lovastatin) lipid lowering agents; suggested alternatives are Lipitor (atorvastatin), Lescol (fluvastatin), Baycol (cerivastatin), and Pravachol (pravastatin, the one that looks best on paper for people on protease inhibitors). Alternatives should still be used with caution because of potential for liver toxicity. Seldane (terfenadine), Hismanal (astemizole), Versed (midazolam) and Xanax (alprazolam) should not be used concurrently with Rescriptor. Potential toxicity when given with Biaxin (clarithromycin), dapson, Mycobutin (rifabutin), ergot derivatives (such as Wigraine and Cafergot, in any form—serious interactions seen with dilation during gynecological exams), Procardia (nifedipine), Coumadin (warfarin) and quinidine. Tegretol (carbamazepine, an anti-seizure medication used to treat peripheral neuropathy), phenobarbital, Dilantin (phenytoin), Mycobutin (rifabutin) and rifampin

(under various brand names, used to treat tuberculosis) are drugs that decrease Rescriptor levels. Certain amphetamines and antiarrhythmics drugs should not be used with Rescriptor. Use of Tagamet (cimetidine) and other drugs in that class is not recommended because they may reduce the absorption of Rescriptor. Rescriptor increases Crixivan, Fortovase, and Invirase levels. Absorption of Rescriptor is decreased with antacids, including Videx (because of its antacid buffer), so take one hour apart from these drugs. Prescriber may need to adjust doses of all these drugs accordingly.

Tips:

New owner trying to resurrect sales by pushing Rescriptor's ability to boost protease inhibitor blood levels, but research is behind the eight ball. Using Rescriptor instead of Norvir to raise a protease inhibitor's blood levels would use three HIV drug classes and create the potential for cross-resistance to other non-nukes. Also, antacids and gastric achlorhydria (low stomach acid) decreases absorption. Take one hour before or after antacids and with acidic beverages such as orange or cranberry juice for achlorhydria. The drug level is increased 20% when the 100 mg tablets are given as a slurry (disintegrating drug in water; drink the rinse as well).



Brand Name:
Rescriptor

Common Name:
delavirdine

Manufacturer

Rescriptor is a potent NNRTI. Rescriptor has been studied in both "protease-sparing" and "protease-containing" regimens. Rescriptor is an inhibitor of the cytochrome P450 enzyme system and therefore has the ability to raise blood levels of saquinavir, indinavir, nelfinavir, ritonavir and amprenavir, which may allow for potential reduction of dosages (e.g., reduce indinavir dose to 600 mg TID as per package insert). Rescriptor's ability to increase blood levels of these protease inhibitors makes it unique among the NNRTIs. Rescriptor is now available in 200 mg tablets, as well as 100 mg tablets that can be easily dissolved in liquid (avoid grapefruit juice); taking the drug as a liquid suspension actually increases its bioavailability by 20%. Rescriptor may be taken with or without food. The most common side effect seen in patients using Rescriptor has been skin rash that usually lasts less than two weeks.
—Agouron Pharmaceuticals

Doctor

Delavirdine (Rescriptor) is a non-nucleoside reverse transcriptase inhibitor (NNRTI). It is typically well tolerated and has rash as the major side effect similarly to other NNRTIs. The major difference between delavirdine and the other two available NNRTIs is its effect on other agents. Unlike nevirapine and efavirenz which may decrease blood levels of protease inhibitors when they are taken in combination, delavirdine can lead to higher blood levels of PIs thus increasing their potency. This PI boosting effect is similar to the boosting effect of ritonavir (although somewhat less potent) and has led some clinicians to use delavirdine in combination with PIs to increase their effect. Delavirdine requires three times per day dosing which lessens its convenience compared to other NNRTIs which are used once or twice per day.
—Dr. Kimberly Y. Smith

Activist

Delavirdine is the least popular of the NNRTIs not the least reason being that it must be dissolved in water before being taken three times a day. Also, since resistance to one NNRTI almost always means resistance to all the drugs in this class, most people tend to choose Sustiva first, since it is more potent. Delavirdine is not used to prevent mother-to-infant transmission, since serious birth defects have been seen in both rats and humans. It can boost levels of certain protease inhibitors, so use it carefully in combination with them.
—Mark Milano

Brand Name:
Viramune



Common Name:
nevirapine

2x

Class: non-nucleoside analog (also called non-nucleoside reverse transcriptase inhibitor, NNRTI, or non-nuke)

Standard dose: One 200 mg tablet daily for two weeks, then full dose of one 200 mg twice daily from then on, with or without food. (If rash occurs in first two weeks, continue on one tablet a day until rash goes away before going on full dose.) Liquid formulation has pleasant taste. Take missed dose as soon as possible, but do not double dose.

Wholesale cost: \$3,508/yr., \$293/month

Patient assistance number: 1 (800) 274-8651, www.viramune.com

AIDS Treatment Information Service: 1 (800) HIV-0440

Potential side effects:

Rash, headache, nausea, vomiting, diarrhea, and fatigue. Abnormal liver function tests, including the development of hepatitis. May need to stop taking nevirapine until liver function returns to normal. Permanently discontinue if abnormalities return. Severe and life-threatening skin reactions and hepatotoxicity (liver damage), including fatal cases of each, have occurred. Symptoms of severe rash may include fever, blistering, oral lesions, conjunctivitis (pink eye, which if untreated may result in permanent loss of vision), swelling, muscle or joint aches, or general malaise (feeling unwell, as with a flu). Stop taking nevirapine and seek immediate medical attention. Do not increase dose if rash develops during dose escalation or if you develop any rash accompanied by the above listed conditions. Small studies found that 40–50 mg prednisone during induction period can lessen the risk. (People with hypertension or diabetes were not allowed to take prednisone.) Granulocytopenia (the loss of a specific type of white blood cell) is more common in children than in adults.

Potential drug interactions:

May cause methadone withdrawal. Viramune reduces levels of protease inhibitors and they should not be taken at the same time or the doses must be increased. Crixivan should be increased to 1,000 mg every eight hours. Viramune interacts with rifampin requiring dose adjustment, but none with Mycobutin (rifabutin). The effectiveness of birth control pills may be decreased; use alternative contraception.

Tips:

Preliminary 32 weeks results in a small group (50 people) suggest equivalency to Crixivan, even in people with a high viral load (more than 100,000), plus greater T-cell increase (223 vs. 166). Other preliminary results (24 weeks in 142 people) suggest equivalency to Viracept, even in people with more than 100,000 viral load. Because of the high incidence of rash associated with Viramune, examine yourself thoroughly for the slightest sign of rash. Notify your doctor of any rash, even mild. Rash may be avoided by using dose escalation schedule. One analysis found more rash, and more severe rash, in women. Use of pretreatment, such as prednisone or Benadryl (diphenhydramine), a non-prescription oral antihistamine, may be used to minimize the risk of rash and to control itching. A topical (placed on the skin) hydrocortisone or an oatmeal-containing cream, such as Aveeno, may improve comfort. Topical antihistamine-containing products should be avoided since there have been reports of irritation and rashes spreading. Viramune given around the time of labor has shown effectiveness in preventing HIV transmission from a mother to her newborn, at an extremely low cost that many third-world families can afford without insurance. Studies suggest that Viramune crosses the blood-brain barrier to a useful degree. May cause abnormal liver function tests and clinical hepatitis. Monitor liver function tests during first six months.

Manufacturer

Available since 1996, Viramune is an NNRTI indicated for use in combination with other antiretrovirals (ARVs) for the treatment of HIV in adults and children. Viramune is available in 200 mg tablets and an oral suspension. Viramune in combination with other ARVs has been shown to reduce the amount of virus circulating in the body and increase CD4 counts. One study showed that a Viramune combination suppressed HIV for up to one year in patients with advanced HIV disease and high baseline viral loads (BI 1090). Viramune has also been studied for the prevention of mother-to-child transmission of HIV; however, it is not indicated for this use in the US. Side effects of Viramune include hepatic events, rash, nausea and headache. Inform your doctor if you are experiencing a rash or other side effects. Please see www.viramune.com for full prescribing information.

—Boehringer Ingelheim

Doctor

Nevirapine is a non-nucleoside reverse transcriptase inhibitor. It is taken as a 200 mg pill once a day for the first two weeks and twice a day after that. The reason for this dosing schedule is to minimize the occurrence of a rash, the most common side effect. This rash is usually mild, self-limited and occurs in the first 6 weeks of taking the drug. Other side effects include fever, fatigue, headache and elevated liver enzymes. Overall, nevirapine is a safe and well-tolerated drug. It has the added benefit of being easy to take: just 1 pill twice a day and with no food restrictions. Newer studies also suggest that it is just as potent as the protease inhibitors when used in combination with the nucleoside reverse transcriptase inhibitors.

—Dr. Allan Tenorio

Activist

Nevirapine gave us all a shock in the early 90s when a noted researcher announced that one of his students had virtually eliminated HIV in the test tube with a combination of NVP, AZT and ddI. The research was shown to be flawed, and the triple combination turned out to be just good, not outstanding. What is outstanding about NVP is its ability to significantly lower transmission from mother to infant with just a single dose. BI has announced a program to donate the drug free to poor countries, but of course this would only benefit the infant, and not the mother. The triple combo of NVP, AZT and ddI is an effective protease-sparing regimen, though not as long-lasting as one containing Sustiva. Still, if Sustiva's mental side effects are too much for you, NVP should be considered. BI recently changed the label of NVP, urging doctors to monitor closely for hepatitis, particularly in the first 12 weeks of use, and re-emphasizing the two-week ramp-up dosing period, to avoid rash.

—Mark Milano

Class: non-nucleoside analog (also called non-nucleoside reverse transcriptase inhibitor, NNRTI or non-nuke)

Standard dose: Three 200 mg (600 mg) capsules once a day, preferably at bedtime, with no food restrictions (avoid high fat meals). Also available in smaller 50 mg capsules. Dose can be split up. Approved for children three years and older. Strawberry/mint flavored solution available to children under expanded access program. Take missed dose as soon as possible, but do not double dose.

Wholesale cost: \$4,730/yr., \$394/month

Patient assistance number: 1 (800) 334-4486, www.sustiva.com

AIDS Treatment Information Service: 1 (800) HIV-0440
Potential side effects:

Central nervous system (CNS) symptoms (dizziness, headache, somnolence or hypnotic trance), psychiatric symptoms (confusion, insomnia, hallucinations, vivid dreams or nightmares, depression, euphoria or mania, agitation), rash, nausea, vomiting, diarrhea and increased liver enzymes. Women should not become pregnant because of the risk of birth defects. Rash is more common, and more severe, in children. Diarrhea, fever and low levels of neutrophils are also more common. Some people in recovery experience flashbacks.

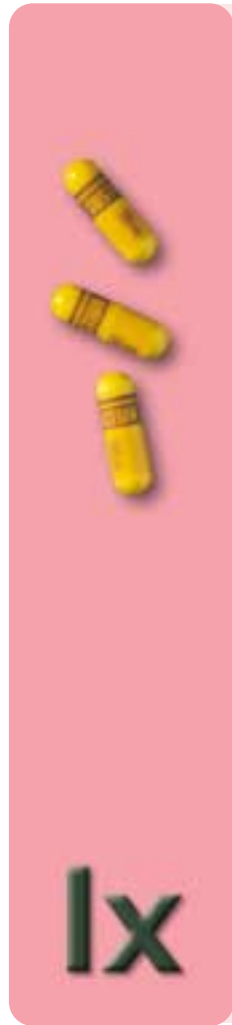
Potential drug interactions:

May cause methadone withdrawal. When taken with Sustiva, Crixivan should be increased to 1,000 mg every eight hours. Because Fortovase decreases 60%, it should be avoided. No interaction data available with Fortovase/Norvir—knowledgeable doctors double Fortovase to 800 mg twice a day. Sustiva and Norvir increase when used together and increase risk of liver damage and other potential side effects. Do not take with Hismanal (astemizole), Versed (midazolam), Halcion (triazolam), or ergot medications (such as

Wigraine and Cafergot, in any form—serious interactions seen with dilation during gynecological exams). Reduces Biaxin (clarithromycin) dose by 37%. May affect Coumadin (warfarin) therapy. Back-up birth control method to the Pill is recommended because of potential for fetal deformities.

Tips:

Received full FDA approval last year. Start taking Sustiva at bedtime to help reduce CNS symptoms (seen in half of all adults taking it), but can be taken at any time. Avoid driving or operating heavy machinery for a few hours after dose. Some people can handle Sustiva better when taking Atavan or Ambien to sleep for the first few weeks. High-fat food as well as alcohol may increase risk of side effects. Strong preliminary results with Combivir (slightly better than Crixivan/Combivir) led to making Sustiva the first drug that's not a protease inhibitor to be added to US guidelines for first-line HIV therapy. The combination was equally strong after 72 weeks of therapy. Recently shown to penetrate lymphoid tissue, an HIV hiding place. May raise levels of triglycerides and cholesterol. Monitor liver enzymes. Side effects may not go away soon. Some people have horror stories about Sustiva and others say it's "like taking candy." Second-generation Sustiva drug in development expected to be active against non-nuke resistance. Antihistamines or corticosteroids can hasten the resolution of rash. Severe rash can be life-threatening (see Viramune). Despite CNS side effects, Sustiva penetrates poorly. Children have the same side effects as adults (primarily in the CNS), but experience more rash (40%), and also diarrhea/loose stools (39%), fever (26%), cough (25%) and nausea/vomiting (16%).



Brand Name:
Sustiva

Common Name:
efavirenz

Manufacturer

U.S. guidelines named Sustiva as the only NNRTI to be "strongly recommended" for use in first-line HIV treatment. Data indicate that patients taking Sustiva+AZT+3TC experienced greater duration of response through 110 weeks of treatment compared to those patients taking indinavir+AZT+3TC. Additionally, data from ACTG 364 demonstrated that patients taking Sustiva plus two NRTIs achieved better virologic suppression than patients taking nelfinavir plus two NRTIs after 48 weeks of treatment. The most common adverse events are nervous system symptoms (e.g., dizziness, trouble sleeping, impaired concentration, drowsiness, and/or abnormal dreams) and mild to moderate rash. These symptoms occur early and generally resolve within two to four weeks. Serious psychiatric symptoms have been infrequently reported in patients receiving Sustiva. Sustiva was approved as the first once-daily anti-HIV drug for use in combination regimens.
—DuPont Pharmaceuticals

Doctor

Efavirenz is a non-nucleoside reverse transcriptase inhibitor that is taken as three 200 mg pills once a day. It is just as potent as the protease inhibitors when taken with 2 nucleoside reverse transcriptase inhibitors. The most commonly reported side effects are rash and central nervous system symptoms, including insomnia, sleepiness, abnormal dreams, dizziness, lightheadedness, impaired concentration and depression. These symptoms are usually mild to moderate in severity and resolve after a few weeks of continued therapy. A lot of patients prefer taking the drug at nighttime to minimize some of these side effects.
—Dr. Allan Tenorio

Activist

After the less-than-stellar success of other NNRTI's, no one expected Sustiva to stack up against the protease inhibitors, but it has. DuPont had the nerve and good ethics to compare Sustiva to the gold standard (Combivir/Crixivan), and succeeded. After two years, people on Combivir/Sustiva have a better chance of having a viral load below 50 than those on Combivir/Crixivan. DuPont destroyed all their good will in the community by pricing Sustiva far higher than other drugs in its class—the protests were long and loud, but DuPont would not budge. Sustiva's convenient once-a-day dosing is somewhat counteracted by its significant neurologic side effects. Though they last only a few weeks for most, others have strong psychological reactions, including nightmares and sleeplessness. Be sure and take your first dose of Sustiva at night, when you have some free time, such as a weekend, and be prepared to feel out of it for a few days.
—Mark Milano

Brand Name:

Not Yet Established

Common Name:

tenofovir disoproxil fumarate

Class: experimental nucleotide analog
Standard dose: Best dose found to date in studies is 300 mg (one tablet) once a day. Dose not yet established because of experimental drug status.

Wholesale cost: Not yet established because of experimental drug status

Patient assistance number: 1 (800) GILEAD-5 (445-3235), www.gilead.com

AIDS Clinical Trials Information Service: 1 (800) TRIALS-A (874-2572)

Potential Side Effects:

Grade 3 or 4 (serious) increased creatine (a sign of kidney or muscle damage) and AST/ALT (liver function tests, a sign of liver damage) shown in lab reports. In one study, serious side effects ranged from 6 to 16%. Elevation of creatine phosphokinase (CPK). Also nausea, headache, diarrhea, vomiting, neutropenia, triglyceride elevation, and amylase elevation.

Potential Drug Interactions:

Not yet reported. No concomitant nephrotoxic drugs allowed for small compassionate access program (now closed). Such drugs include Crixivan, Viracept, Ziagen, Hydroxyurea, Zovirax, Cytovene, Mepron, and streptomycin (rarely used for tuberculosis).

Tips:

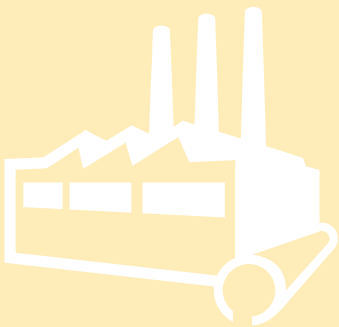
Pretty good results in people who've taken lots of HIV drugs before. Adding once-a-day 150 mg or 300 mg tenofovir DF to a stable drug combination (called "intensification") quickly showed a significant viral load decrease in 92 heavily pre-treated people, which was maintained after a year (drops of 0.6 and 0.7 log respectively). (A third of them also changed at least one drug halfway through the year.) T-cells did not go up significantly in trials, however. One doctor noted that you can see a greater drop (one log) when using a protease inhibitor for intensification, along with a good T-cell increase. But another noted tenofovir's potential in the

growing number of people whose triple-class therapy is failing. To its credit, tenofovir was successful in showing viral load decrease in people with nuke resistance. Epivir resistance seems to reverse tenofovir resistance. Also, because it's in a new drug class, tenofovir is not expected to have cross-resistance with other HIV medicines, and no new mutations were seen with its use in clinical trials. Unlike the nukes, nucleotides can enter uninfected cells, and once there, protect against infection. The body clears the drug through the kidneys, so watch creatine levels. So far, serious kidney problems have been rare. A lead-in dose is being tested to reduce side effects. At 32 weeks (54 people), 9% (5) patients experienced a serious adverse event, compared to 4% (1) in the placebo arm. Active against hepatitis B. Seems unlikely that tenofovir will be approved this year because of FDA concern about bone density. Manufacturer reported that preclinical studies show tenofovir is eliminated by the kidney, is not metabolized by the liver and is not associated with cytochrome p450 interactions.

Photo not available because of experimental drug status.

Manufacturer

Gilead Sciences did not respond to a request for a statement.



Doctor

Tenofovir is a new nucleotide reverse transcriptase inhibitor currently in phase II/III studies. This agent is similar to the first nucleotide reverse transcriptase inhibitor, adefovir, but has significantly less nephrotoxicity (kidney toxicity). It has shown significant activity against wild type and nucleoside resistant HIV. A recent study of tenofovir (300 mg once daily) given to highly nucleoside experienced individuals demonstrated a 0.7 log decline in HIV viral load at 48 weeks. No significant toxicities associated with the drug were reported. Additional studies are ongoing.

—Dr. Kimberly Y. Smith

Activist

Not a home-run drug for Gilead (their salvage trial saw only a 0.7 log drop in the viral load of people who were multi-drug resistant), but a necessary drug, since people who are putting together a new regimen need two or even three new drugs. Gilead has reluctantly responded to activist pressure to open an expanded access program for tenofovir, since the company feels burned by the fact that 10,000 people got free adefovir before they cut their losses and dropped that ineffective and toxic drug. Tenofovir looks better than adefovir, though—somewhat more potent and without any nasty side effects so far, and once-daily dosing. Loss of bone density has been seen in animals on this drug, but this has not appeared in people who have taken the drugs in clinical trials. Access to the drug for those in serious need is expected to start in January 2001. A large multi-site trial began enrolling in October of 2000.

—Mark Milano

Class: HIV protease inhibitor

Standard dose: Strict schedule of two 400 mg capsules (800 mg) every 8 hours (q8h) on empty stomach (an hour before or two hours after eating) or with low-fat snack (call for food list). If you miss a dose, take the next dose as soon as possible. Do not double the next dose. 200 mg and 333 mg capsules available.

Wholesale cost: \$5,762/yr., \$480/month

Patient assistance number: 1 (888) CRIVIVAN, www.crixivan.com

AIDS Treatment Information Service: 1 (800) HIV-0440

Potential side effects:

Headache, nausea and kidney stones, which may lead to more serious problems such as kidney failure. Signs include back pain, fever, abdominal tenderness, and painful urination. Call your doctor immediately if pain develops in the middle to lower stomach or the back, or if there is blood in the urine. Other potential side effects include hair loss, changed skin color, severe skin reactions (such as horribly dry skin), fatigue or weakness, malaise (feeling unwell, as with the blahs, fatigue or a flu), nausea, diarrhea, loss of appetite, ingrown toe nails (often requiring minor surgery), dry mouth, headache, taste changes, and liver toxicity. Increased uric acid indicates kidney damage. Symptoms include joint pain and arthritis. Hemolytic anemia, the premature destruction of red blood cells, is rare but dangerous: watch for unusual fatigue, jaundice (yellowing of eyes and skin), or reddish-brown urine, and monitor red blood cell counts. Watch out for other drugs also associated with this condition (such as Septra and dapsone). Protease inhibitors may cause high blood levels of cholesterol and triglycerides (fats) and perhaps associated heart disease, lipodystrophy (body fat changes, including thinning of the face, arms and legs, with or without fat accumulation in the stomach, breasts and sometimes the upper back), worsening or new cases of diabetes (symptoms include

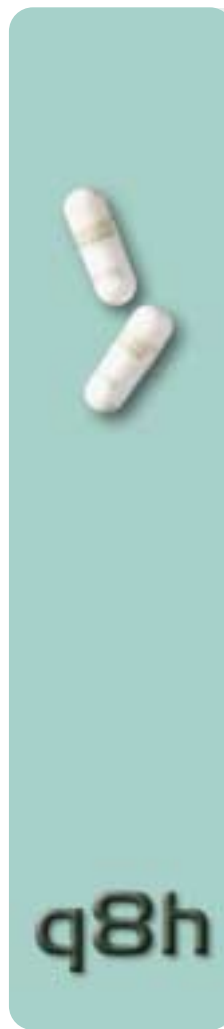
increased thirst and hunger, frequent urination, unexplained weight loss, fatigue, and dry itchy skin; see your doctor promptly) and increased bleeding in hemophiliacs.

Potential drug interactions:

Do not use Zocor or Mevacor; suggested alternatives are Lipitor, Lescol, Baycol, and Pravachol (looks best on paper for protease inhibitors). Viracept increases levels of Crixivan, but doses of both drugs remain standard. Increase Crixivan to 1,000 mg three times a day when taken with Viramune or Sustiva. Alcohol consumption may increase risk of stones. Reduce dosage if using Nizoral (600 mg every 8 hours). Do not take with Seldane, Hismanal, Halcion, Versed, ergot medications (such as Wigraine and Cafergot, in any form—serious interactions seen with dilation during gynecological exams) and rifampin. Protease inhibitors increase blood levels of Viagra (sildenafil citrate), and Viagra dose should be started at 12.5 mg and increased as needed and tolerated. It's recommended that people do not exceed 25 mg in a 48 hour period because of potential for fatal reaction.

Tips:

Full-dose Crixivan popularity has gone down the tubes, but combining with small doses of Norvir (100 or 200 mg) is popular. It avoids food restrictions and can be taken twice a day, but you need to drink even more water. Drink at least 48 oz fluids daily (about six 8-ounce glasses), preferably water or clear liquids (soda pop doesn't count!). Large amounts of coffee or alcohol can increase risk of stones. The pain of passing a kidney stone has been compared to that of giving birth to a baby. Stones may continue after stopping Crixivan. Grapefruit juice decreases Crixivan blood levels. Should be stored in original container. Hair loss grows back after switching to another potent drug. May be taken with fatty food twice a day with Norvir mini-dose.



Brand Name:
Crixivan

Common Name:
indinavir

Manufacturer

Merck and Co. did not respond to request for statement.

Doctor

Indinavir is one of the most potent protease inhibitors. It is given as two 400 mg pills every eight hours, preferably with water 1 hour before or 2 hours after a meal, or with coffee, tea, skim milk or a low-calorie low-fat small meal. Also, patients taking indinavir should make sure that they are adequately hydrated by drinking at least 1.5 liters of fluids per day. This is done to prevent the formation of kidney stones, a side effect of the drug. Other side effects include increased bilirubin levels, diarrhea, abdominal discomfort, nausea and vomiting. As with other protease inhibitors, increased blood cholesterol, diabetes and lipodystrophy have been seen in some patients taking this drug. Indinavir has also been used in combination with ritonavir as part of salvage regimens.

—Dr. Allan Tenario

Activist

The first "gold standard." Merck had long told activists that they weren't interested in developing an AIDS drug unless it was a "home run." Crixivan initially looked like a flop—people became resistant to it almost immediately, and the drug concentrations spiked and fell so rapidly in the body that dosing had to be extremely precise. But one patient in the early trials continued to benefit after months on the drug, and this convinced researchers to continue the trials. The right approach for this drug was finally found: as part of the classic three-drug combo: AZT/3TC/Crixivan, one of the first to lower viral loads to below detection in a large percentage of patients. Merck knew they had a hot drug, and could have charged more than Abbott's record-breaking price for Norvir (approved a month earlier), but those with ethics in the company had an effect, and Merck priced it as the lowest of the protease inhibitors (still far too high for most activists, but at least they tried). Combining Crixivan with Norvir makes twice a day dosing possible, but this has not been officially sanctioned by Merck. Crixivan remains the most difficult PI in terms of scheduling: the timing of doses must be as close to every 8 hours as possible, and only a light snack can be eaten for an hour before or two hours after dosing. So if you plan to take Crixivan, be sure to practice first with candy pills if you have any question as to whether you can stick to that schedule. I for one could never do it, but I have friends who have taken Crixivan properly for years—I have great respect for them! Kidney stones are not uncommon, so be sure to drink those 6 glasses of water.

—Mark Milano

Brand Name:
Norvir



Common Name:
ritonavir

2x

Class: HIV protease inhibitor

Standard dose: Six 100 mg (600 mg) soft gelatin capsules twice a day, preferably with food. Dose escalation is important to avoid side effects: 3 capsules twice a day for two or three days, then 4 capsules twice a day for two or three days, followed by 5 capsules twice a day for two or three days before beginning full dose. If you miss a dose, take the next dose as soon as possible. Do not double the next dose. Approved for children ages 3 and older. Liquid formula available, but tastes horrible.

Wholesale cost: \$8,618/yr., \$718/month
Patient assistance number: 1 (800) 637-2400,
www.norvir.com

AIDS Treatment Information Service: 1 (800) HIV-0440

Potential side effects:

Asthenia (weakness), nausea, diarrhea, vomiting, tingling/numbness around the mouth, hands or feet, loss of appetite, taste disturbance, headache, dizziness, pancreatitis (see nukés), and alcohol intolerance. Seen with all protease inhibitors are: high blood levels of cholesterol and triglycerides (fats) (especially with Norvir) and perhaps associated heart disease, lipodystrophy (body fat changes, including thinning of the face, arms and legs, with or without fat accumulation in the stomach, breasts and sometimes the upper back), worsening or new cases of diabetes (symptoms include increased thirst and hunger, frequent urination, unexplained weight loss, fatigue, and dry itchy skin; see your doctor promptly) and increased bleeding in hemophiliacs. Norvir has been shown to increase liver enzymes (AST, ALT and GGT), muscle enzyme (CPK), and uric acid.

Potential drug interactions:

May cause methadone withdrawal. Do not use Zocor or Mevacor; suggested alternatives are Lipitor, Lescol, Baycol, and Pravachol (looks best on paper for protease inhibitors). Alternatives should still be used with caution because of potential for liver toxicity. Cannot be taken

with Cordarone, ergot derivatives such as Cafergot (in any form—serious interactions seen with dilation during gynecological exams), Migranal, D.H.E. 45, Halcion, Hismanal, Orap, quindine, Rythmol, Seldane, Tambacor, Vasacor, and Versed. Protease inhibitors increase blood levels of Viagra (sildenafil citrate), and Viagra dose should be started at 25 mg and increased as needed and tolerated. One report suggested Viagra should start at half that when taken by someone on Norvir. It's recommended that people do not exceed 25 mg in a 48 hour period because of potential for fatal reaction. The street drug Ecstasy is greatly increased by Norvir, and at least one death has been attributed to the combination. GHB is also dangerous with Norvir. Tobacco and alcohol may lower blood levels of Norvir. Increases clarithromycin (Biaxin) levels by 80 percent. Rifampin decreases Norvir levels by 35 percent. Contains alcohol (but should not be enough to trigger relapse) and greatly hastens intoxication. Norvir should not be taken with Antabuse or Flaygl.

Tips:

Convenient twice-daily dosing with food is offset by high rate of side effects and early drop-out. Its real strength is in combination with other protease inhibitors, allowing for a lower dose of both. Take with fatty food with Fortovase or Viracept. Has also become popular to boost Crixivan levels. Capsules do not need refrigeration if used within 30 days. The capsules contain castor oil and have bitter taste. The liquid tastes foul and activates children's gag reflex (especially bad since it should be taken on a full stomach). Taking with food—especially high fat such as peanut butter or avocado—may help prevent stomach upset. Watch for increased cholesterol and triglyceride levels, especially if heart disease runs in your family. Remember to get fasting levels. Keep in original container.

Manufacturer

Norvir, a protease inhibitor, was approved by the FDA in 1996 for early and advanced patients with HIV and is widely used in dual protease inhibitor therapy as well as to boost drug levels of other PIs. Norvir boosting increases the levels of other PIs, and gives patients the opportunity to reach undetectable viral levels without discontinuing their current PI or sacrificing adherence. By boosting drug levels, Norvir minimizes drug resistance and decreases the risk of viral rebound. Most commonly used to boost levels of other protease inhibitors like amprenavir, saquinavir and indinavir, this drug may be critical for patients on salvage regimens who cannot switch to a new protease inhibitor because of resistance.

Most widely used doses:

RTV/IDV 400/400 BID, 800/100 BID or 800/200 BID

RTV/SQV 400/400 BID

RTV/APV 600/100 BID

—Abbott Laboratories

Doctor

Ritonavir was one of the first protease inhibitors approved by the FDA and was a significant part of the early triple drug "cocktails" that had a tremendous impact in reducing HIV/AIDS related deaths. Many patients continue to enjoy substantial benefit from this agent, however, unfortunately ritonavir has substantial problems with both short and long term tolerability. At present, ritonavir is used most commonly as a PI "boosting" agent. Ritonavir inhibits the metabolism of several other protease inhibitors such as indinavir (Crixivan), saquinavir (Fortovase), amprenavir (Agenerase), and as such is used to boost the blood levels of those agents allowing them more convenient dosing and increased efficacy. In Oct 2000, Kaletra (lopinavir/ritonavir) was the first agent to combine ritonavir with another PI specifically to take advantage of ritonavir's PI boosting effect.

—Dr. Kimberly Y. Smith

Activist

What an exciting moment—the fastest FDA approval in history for a drug. But after large numbers of people began taking it, the "7%" figure reported in clinical trials of people who experience nausea proved to be far underestimated. In real life, the majority of patients can not tolerate ritonavir at full dose. One doctor told me she has never had a patient able to tolerate full dosing for more than a few months. At full dose, Norvir is also strongly associated with fat/lipodystrophy problems. The good news is that ritonavir is quite effective and well-tolerated at lower doses with some other drugs. In fact, it seems to be used more and more often as a "booster" drug to keep other drugs—like Crixivan, Kaletra and tipranavir—in the body longer. Ritonavir comes with a long list of drugs which must be avoided or reduced when taking it. Abbott set a new benchmark for overpricing with ritonavir, a crown which has since passed to nelfinavir.

—Mark Milano

Class: HIV protease inhibitor

Standard dose: Five 250 mg tablets (1250 mg) twice a day with food. Take a missed dose as soon as possible, but do not double the next dose. Also granular formula to mix in juice or water. 625 mg tablets (two twice a day) expected soon.

Wholesale cost: 8,121/yr., \$677/month

Patient assistance number: 1 (888) VIRACEPT,

www.viracept.com

AIDS Treatment Information Service: 1 (800) HIV-0440

Potential side effects:

Diarrhea, stomach pain, asthenia (weakness), nausea, flatulence (gas), and rash. Seen with all protease inhibitors are: high blood levels of cholesterol and triglycerides (fats) and perhaps associated heart disease, lipodystrophy (body fat changes, including thinning of the face, arms and legs, with or without fat accumulation in the stomach, breasts and sometimes the upper back), worsening or new cases of diabetes (symptoms include increased thirst and hunger, frequent urination, unexplained weight loss, fatigue, and dry itchy skin; see your doctor promptly) and increased bleeding in hemophiliacs.

Potential drug interactions:

Do not use Zocor or Mevacor; suggested alternatives are Lipitor, Lescol, Baycol, and Pravachol (looks best on paper for protease inhibitors). Alternatives should still be used with caution because of potential for liver toxicity. Do not take with Seldane, Hismanal, Cordarone, quindine, ergot medications (such as Wigraine and Cafergot, in any form—serious interactions seen with dilation during gynecological exams), Halcion, or Versed. Blood levels of Viracept are reduced by rifampin and may be reduced by phenobarbital, phenytoin, and carbamazepine (Tegretol and others). Fortovase levels increase three- to five-fold, Crixivan increases 50% and Norvir levels are unchanged. Prescriber may need to adjust doses of any these drugs accordingly. Protease

inhibitors increase blood levels of Viagra (sildenafil citrate), and Viagra dose should be started at 25 mg and increased as needed and tolerated. It's recommended that people do not exceed 25 mg in a 48 hour period because of potential for fatal reaction. Mycobutin (rifabutin) dose must be decreased when used with Viracept. Rifampin and Viracept should not be used together. Reduces effectiveness of birth control pills; use alternative contraceptive.

Tips:

Study results since 1999 indicate that Viracept potency may be inferior to other protease inhibitors and to Sustiva and Viamune, which are supposedly in a weaker drug class. In preliminary findings (six months), Viamune did better even in people who began with a high viral load (more than 100,000). However, other drug companies compared their drug to Viracept three times a day dosing, which puts Viracept at a disadvantage due to adherence difficulties (what one HIV specialist called "cynical use of FDA regulations"). New tablets are film-coated, which avoids the old tablets' habit of beginning to dissolve in your mouth—yucky. Do not leave the pharmacy without anti-diarrhea medication available without a prescription, such as Imodium. Take a change of clothes with you when you leave home for the first several weeks. Try Solgar oat bran tablets, psyllium husk fiber bars, calcium supplements (including Tums or Rolaids) and pancreatic enzymes (all with meals). First protease inhibitor choice for children who cannot swallow capsules or tablets, but solution tastes horrible and requires a large amount for mixing into food. It's preferable to crush adult tablets for use in children. Do not mix with acidic drinks because of bitter taste.



Brand Name:
Viracept

Common Name:
nelfinavir

Manufacturer

Viracept, in combination with other antiretroviral agents, is indicated for the treatment of HIV infection. Viracept's potency, durability, and unique resistance profile make it an important first line treatment option for patients wanting to preserve their future treatment options. At 48 weeks of triple combination therapy, Viracept lowered the amount of HIV in the blood to levels below the limit of detection and substantially increased CD4 cell counts in the majority of people being studied. Viracept is well-tolerated; diarrhea is a common side effect, but manageable in most cases. Approved in March 1997, Viracept is currently available in film-coated tablets or powder formulation for the treatment of adults and children (ages 2-13 years). Twice daily dosing of Viracept was approved in November 1999. Viracept should be taken with a light meal or snack. For more information on Viracept, call toll-free 1-888-VIRACEPT (1-888-847-2237) or access the website at: <http://www.viracept.com>.

—Agouron Pharmaceuticals

Doctor

Nelfinavir is a potent protease inhibitor commonly used as a first line agent. It is taken with meals either as three 250-mg tablets three times a day and or as 5 tablets twice a day. Most patients prefer the latter for convenience of dosing. Other than its effectiveness against HIV, another major reason for its popularity as a frontline agent is because once HIV develops resistance to nelfinavir, it remains susceptible to most other protease inhibitors, thus allowing for more choices for salvage therapy. The most common side effect is diarrhea, but most patients are able to remedy this using over the counter preparations like Imodium, calcium or Metamucil. Increased blood cholesterol, diabetes and lipodystrophy have been seen in a few patients treated with protease inhibitors in general. Studies are currently ongoing to determine the exact relationship between these drugs and the above-mentioned metabolic derangements, and the appropriate therapies.

—Dr. Allan Tenorio

Activist

If it weren't for the diarrhea that is so common with this drug, Agouron would have cornered the PI market. The fact that the new twice-a-day dose, and Agouron's price hikes make it the highest priced of all the PIs shows that the company sure thinks it's a hot property. Agouron also argued that it was better to start with Viracept, since this would leave the other PIs as options in case of resistance, but this has never been proven to my satisfaction, at least. Viracept is a potent and popular PI, as long as you can get the diarrhea under control. Try Imodium, of course, and Metamucil. Ultrase, a pancreatic enzyme, has also reported some encouraging results, but I've heard mixed reports about its usefulness in the real world. I once asked a friend who had lived with Viracept diarrhea for years how he did it, and he said, "I was almost dead before I started it, so I'm quite happy to deal with some dirty underwear now and then."

—Mark Milano

Brand Name:

Fortovase

Common Name:

saquinavir soft-gel



Class: HIV protease inhibitor

Standard dose: Six 200 mg soft-gel capsules three times a day with food, or within two hours after a meal. If you miss a dose, take the next dose as soon as possible. Do not double the next dose.

Wholesale cost: \$7,702/yr., \$642/month

Patient assistance number: 1 (800) 910-4687, www.fortovase.com

AIDS Treatment Information Service: 1 (800) HIV-0440

Potential side effects:

Diarrhea, nausea, abdominal discomfort or pain, flatulence (gas), indigestion, headaches, insomnia, fatigue, and taste alteration. Seen with all protease inhibitors are: high blood levels of cholesterol and triglycerides (fats) and perhaps associated heart disease, lipodystrophy (body fat changes, including thinning of the face, arms and legs, with or without fat accumulation in the stomach, breasts and sometimes the upper back), worsening or new cases of diabetes (symptoms include increased thirst and hunger, frequent urination, unexplained weight loss, fatigue, and dry itchy skin; see your doctor immediately) and increased bleeding in hemophiliacs.

Potential drug interactions:

Do not use Zocor or Mevacor lipid-lowering drugs; suggested alternatives are Lipitor, Lescol, Baycol, and Pravachol (looks best on paper for protease inhibitors). Alternatives should still be used with caution because of potential for liver toxicity. Increased blood levels with Crixivan, Norvir and Viracept. Blood levels decreased significantly by Sustiva, but can be taken together if Norvir is included. Fortovase should not be taken with rifampin or Mycobutin. Other drugs that may also reduce Fortovase blood levels are Decadron and Tegretol, Dilantin, and phenobarbital. Do not take with Halcion, Versed, sedatives/hypnotics, ergot derivatives (such as Wigraine and Cafegot, in any form—serious interactions seen with dilation during gynecological

exams), Seldane and Hismanal. High incidence of liver problems, and severe ones, when taken with Rescriptor. Protease inhibitors increase blood levels of Viagra (sildenafil citrate), and Viagra dose should be started at 25 mg and increased as needed and tolerated. It's recommended that people do not exceed 25 mg in a 48 hour period because of potential for fatal reaction. Mycobutin (rifabutin), phenobarbital, phenytoin dexamethasone and carbamazepine (Tegretol and others), Viramune and Sustiva decrease Fortovase levels (but the last two can be taken if Norvir is added). Rescriptor, Crixivan, Norvir and Viracept all significantly increase Fortovase plasma concentrations, but Crixivan may be antagonistic. The side effects of calcium channel blockers, clindamycin, dapsone and quinidine may be increased if taken with saquinavir.

Tips:

Must be taken with food or within two hours after a meal. Keep capsules at room temperature if they will be used up within three months. Zantac, Pepcid, Tagamet or antacids may be necessary to treat Fortovase heartburn (which is common). Refrigerated (36-46° F or 2-8° C) capsules remain stable until the expiration date printed on the label. Once brought to room temperature capsules should be used within 3 months. Avoid direct sunlight. Long popular when taken twice a day with Norvir (both 400 mg each). Potential for once a day dosing at 1600 mg with 100 mg Norvir, being studied. Older version of saquinavir, Invirase, is rarely used.

Manufacturer

Fortovase (saquinavir soft gel capsules), approved in November 1997, is a second-generation formulation of saquinavir that offers significantly improved efficacy over the original formulation, Invirase. Fortovase, when used in combination with other anti-retroviral agents, slows the replication of HIV in the body to reduce viral load. Ongoing clinical trials are testing once-daily and twice-daily dosing of Fortovase in combination with a mini dose (100 mg) of the protease inhibitor ritonavir. Side effects associated with Fortovase include diarrhea, nausea and headaches. Additionally, an exacerbation of chronic liver dysfunction has been reported in patients taking Fortovase. Other side effects may include hyperglycemia or diabetes, and spontaneous bleeding in patients with hemophilia associated with the use of protease inhibitors.
—Roche

Doctor

Soft gel saquinavir is an improved version of the old saquinavir (Invirase) in that it is better absorbed and more potent against HIV. However, the drug is taken as six 200 mg pills three times a day with meals. Other than the pill burden, saquinavir is well tolerated. Most side effects are mild and include abdominal discomfort or pain, nausea, and diarrhea. Saquinavir is also commonly used in combination with zidovudine, two 200 mg pills of the former with four 100 mg pills of the latter twice a day. Ritonavir boosts the blood levels of saquinavir so that less saquinavir pills are required. This combination is more tolerable and slightly more convenient to take, and is increasingly being used as part of salvage regimens. As with nelfinavir, increased blood cholesterol, diabetes and lipodystrophy have been seen in some patients taking saquinavir.
—Dr. Allan Tenario

Activist

The comeback kid. The first protease inhibitor approved, and the first disappointment. Roche rushed an early version of this drug to market (Invirase), with a dose that was too low and not well-absorbed. Worse, they set the benchmark for the high prices of PIs, according to most activists. Roche corrected the problem a few years later, with the introduction of Fortovase, a form of saquinavir that is far better absorbed by the body. But increasing the dose meant increasing the pill count to 18 pills a day! Most people use Fortovase in combination with Norvir or Viracept, which reduces the number of pills dramatically. Watch out for GI problems initially—diarrhea, nausea, gas, etc.
—Mark Milano

Class: HIV protease inhibitor

Standard dose: Eight 150 mg (1200 mg) soft gelatin capsules twice a day, with or without food. Take a missed dose as soon as possible, but do not double the next dose. Approved for children ages 4 and older. Grape, bubblegum, peppermint flavored liquid. Adults should not use liquid if possible.

Wholesale cost: \$7,613/yr., \$634/month

Patient assistance number: 1 (800) 722-9294, www.agenerase.com

AIDS Treatment Information Service: 1 (800) HIV-0440

Potential side effects:

Nausea, vomiting, abdominal pain, taste disorders, fatigue, headache, rash, anemia, colitis, bruising easily, prolonged bleeding, depressive or mood disorders, circumoral paresthesia (tingling or numbing around the mouth) and peripheral paresthesia. Gaseous symptoms are common and may be severe. Taking with food may help, but check for pancreatitis when there is severe stomach pain. Seen with all the other protease inhibitors are high blood levels of cholesterol and triglycerides (fats) and perhaps associated heart disease, lipodystrophy (body fat changes, including thinning of the face, arms and legs, with or without fat accumulation in the stomach, breasts and sometimes the upper back), worsening or new cases of diabetes (symptoms include increased thirst and hunger, frequent urination, unexplained weight loss, fatigue, and dry itchy skin; see your doctor promptly) and increased bleeding in hemophiliacs.

Potential drug interactions:

Do not use Zocor or Mevacor; suggested alternatives are Lipitor, Lescol, Baycol, and Pravachol (looks best on paper for protease inhibitors). Alternatives should still be used with caution because of potential for liver toxicity. Rescriptor and Viracept greatly increase Agenerase blood levels (and usually stomach discomfort) and pre-

scriber may need to adjust dose accordingly. Sustiva has been shown to significantly reduce blood levels of Agenerase unless also taken with Norvir mini-dose. Interacts with several antihistamines, sedatives, and antifungal drugs. Do not use with rifampin. Dose reduction of Mycobutin is necessary. Increased blood levels and drug activity are seen with dapsone, erythromycin, Sporonox, Xanax, Tranxene, Valium, flurazepam, Cardene, Procardia or Adalat CC and Nimotop. Each capsule contains vitamin E, so avoid taking with other blood thinners, such as Coumadin (warfarin), clotting factor, vitamin K, and low-dose daily aspirin, as well as herbs such as ginger, garlic, feverfew, ginseng and ginkgo biloba. Ibuprofen (Advil) can also be problematic. Do not take extra vitamin E. Protease inhibitors increase blood levels of Viagra (sildenafil citrate), and Viagra dose should be started at 25 mg and increased as needed and tolerated. It's recommended that people do not exceed 25 mg in a 48 hour period because of potential for fatal reaction.

Tips:

Huge number of horse pills a major drawback. Cut that huge dose with Norvir. Four Agenerase capsules (600 mg) with one capsule of Norvir (100 mg) twice a day equals the full Agenerase dose. Norvir significantly increased cholesterol and triglycerides. These preliminary results are from only 14 people. Agenerase has the potential for good central nervous system (CNS) penetration, which may help prevent or treat neurological damage (such as dementia). May also penetrate the lymph nodes, where virus can hide out. Severe rash can be life-threatening (see Viramune). Avoid taking with food high in fat. Should not be used by pregnant women, because of fetal toxicity seen in animals. Warning issued last year on Agenerase liquid for certain populations (including women and children).



Brand Name:
Agenerase

Common Name:
amprenavir

Manufacturer

Agenerase (amprenavir), approved April 1999, is an HIV protease inhibitor that, in clinical studies, has appeared to have significant antiviral activity when used in a variety of two-, three-, and four-drug combination regimens. Agenerase has been studied clinically in combination with numerous approved and investigational antiretroviral therapies, including nucleoside analogue reverse transcriptase inhibitors, non-nucleoside RTIs and protease inhibitors. In clinical trials to date, Agenerase appears to have an acceptable safety profile with few treatment-limiting adverse events. The most commonly reported adverse events in clinical studies have included nausea, diarrhea, headache, fatigue, vomiting, rash and perioral parasthesia.

—Glaxo Wellcome

Doctor

Amprenavir has been shown to have potent activity in both PI-naïve and PI-experienced patients due to a relatively unique resistance pattern. The major side effect of Agenerase is nausea (particularly when combined with AZT). A mild rash is rare. There is some suggestion that patients treated with Agenerase may be less likely to develop elevated cholesterol and triglycerides and fat redistribution than those treated with other PIs. The most unfavorable aspect of Agenerase is the pill burden. Full dose Agenerase requires eight large capsules (1200 mg) twice per day. Recently more clinicians are using Agenerase combined with low-dose ritonavir to boost Agenerase levels, increase its potency and lessen the pill burden (when combined with 100 mg of ritonavir, Agenerase dose can be reduced to 600 mg—4 pills—twice per day). The manufacturer is presently working on an amprenavir pro-drug with lower pill burden and improved potency.

—Dr. Kimberly Y. Smith

Activist

Glaxo seems to have developed Agenerase largely to have a PI in their catalog of drugs, perhaps with the intention of making a single pill that combined it with their two other drugs, AZT and 3TC. But the large size and number of pills required each day ("16 horse pills," as one friend who took the drug describes them), makes that impossible. It is similar to Crixivan in effectiveness for first-line therapy, but if you are resistant to other PIs, don't get your hopes up. Be careful when combining this drug with NNRTIs like Sustiva and Rescriptor, since they affect its blood levels. It contains sulfa, so if you're allergic to Bactrim, watch for a reaction. Also be sure your vitamin K levels are normal before starting. Side effects include diarrhea, and GI problems, gas, etc.

—Mark Milano

Brand Name: **Kaletra**

Common Name: **lopinavir/ritonavir**



2x

Class: HIV protease inhibitor

Standard dose: Three soft-gelatin capsules (133.3 mg lopinavir and 33.3 mg ritonavir each) twice a day, preferably with food; liquid formula available. Take missed dose as soon as possible, but do not double dose.

Wholesale cost: \$8,125/yr., \$677/month

Patience Assistance Number: 1 (800) 637-2400, www.kaletra.com

AIDS Treatment Information Service: 1 (800) HIV-0440

Potential side effects:

Rash in children. Loose stools, diarrhea, nausea, headache, muscle weakness, and increased cholesterol, triglycerides (fats in the blood) and AST/ALT (liver function tests, a sign of liver damage). These were not fasting samples, needed for the most accurate results. Seen with all older protease inhibitors (except Agenerase) are high blood levels of cholesterol and triglycerides (fats) and perhaps associated heart disease, lipodystrophy (body fat changes, including thinning of the face, arms and legs, with or without fat accumulation in the stomach, breasts and sometimes the upper back), worsening or new cases of diabetes (symptoms include increased thirst and hunger, frequent urination, unexplained weight loss, fatigue, and dry itchy skin; see your doctor promptly) and increased bleeding in hemophiliacs.

Potential drug interactions:

Dosage of methadone may need to be increased when taken with Kaletra. Dose increase to 4 capsules twice a day with food recommended when using with Sustiva or Viramune in people who previously took HIV drugs, especially protease inhibitors. May lower levels of Retrovir and Ziagen. Do not use Zocor or Mevacor; suggested alternatives are Lipitor, Lescol, Baycol, and Pravachol (looks best on paper for protease inhibitors). Alternatives should still be used with caution because of potential for liver toxicity. Protease inhibitors increase blood levels of Viagra, and Viagra dose should be started

at 25 mg (half the normal dose) and increased as needed and tolerated. It's recommended that people do not exceed 25 mg in a 48 hour period because of potential for fatal reaction. Phenobarbital, phenytoin (Dilantin and others) or carbamazepine (Tegretol and others) may lower blood levels of Kaletra. Reduces effectiveness of birth control pills; use alternative contraceptive. Oral solution contains alcohol, so do not use with Antabuse or Flaygl. Do not take with flecainide, propatenone, Hismanol, Seldane, rifampin, ergot derivatives (such as Cafetrate, Cafergot, Wigraine and Methergine, in any form—serious interactions seen with dilation during gynecological exams), D.H.E. 45, St. John's Wort, pimozide, Versed and Halcion. (Also dihydropyridine calcium channel blockers.) Videx should be given an hour before (or two hours after) Kaletra is taken with food. Rifabutin dose must be lowered.

Tips:

Doctors and patients report that the newest protease inhibitor is honest-to-God very tolerable; although one guy used Depends for weeks. Great viral load results out to 72 weeks (significant) in people on their first HIV regimen. Good results also seen in heavily treatment-experienced children and adults, even those with protease inhibitor resistance. However, drug-experienced people also used a non-nuke, which may mean that three classes of HIV drugs are needed for them, and which limits future options. Then again, some people don't have many options. Expected to successfully control HIV that no longer responds to other meds due to drug resistance, but cross-resistance has already been seen. Has Norvir's yucky taste and taste aversion—one guy said his beer tasted like soap. There is hope for once a day dosing. Preliminary (24 weeks) results indicate that Kaletra is just as effective for people with high viral loads (more than 100,000).

Manufacturer

Abbott developed Kaletra to fulfill an unmet need for a different PI which combines power and tolerability for patients across the spectrum of HIV, including those new to, and experienced with, HIV therapy. Kaletra's enhanced pharmacokinetic profile is the key to its strength and durability. Kaletra can be maintained at much higher levels in the blood than any other protease inhibitor. Elevated levels create a high barrier to viral mutations and may prevent resistance. Data from ongoing Phase II and Phase III trials show that genotypic resistance to Kaletra has not developed yet in treatment naive patients. At 48 weeks, data also show that Kaletra continues to be more effective than nelfinavir at suppressing viral load below undetectable levels in a significant portion of patients and is better tolerated, with only 2% of patients discontinuing due to Kaletra-related adverse events. Doses: 3 capsules BID; 4 capsules BID when combined with efavirenz for highly experienced patients.

—Abbott Laboratories

Doctor

Kaletra is a combination tablet of lopinavir and low dose ritonavir that has demonstrated superior efficacy in a twice daily regimen compared to a three times daily nelfinavir-based regimen. Equally important, this drug has demonstrated substantial efficacy in combination with efavirenz (Sustiva) for patients with extensive protease inhibitor experience. Clinicians have been anxious to gain access to new agents with activity against PI resistant viruses and Kaletra appears to be one of the best options to come along in some time. Further information on resistance that may develop following Kaletra therapy will help clinicians define the best uses for this exciting new agent.

—Dr. Kimberly Y. Smith

Activist

It looks like Abbott has found what many people with HIV have been looking for: a PI that can work for people who have become resistant to the approved PIs. Kaletra is combined with a small amount of Norvir to boost its levels in the blood. For people who are treatment experienced, this is not a concern, but those who are thinking of Kaletra as first-line therapy should consider the fact that they could become resistant to two drugs (Kaletra and Norvir), which may make switching to another PI more difficult. Side effects seem to be tolerable, since the amount of Norvir in each capsule is small.

—Mark Milano

Class: experimental protease inhibitor
Standard dose: Dose not yet established because of experimental drug status
Wholesale cost: Not yet established because of experimental drug status
Manufacturer Contact:
www.boehringer-ingleheim.com
AIDS Clinical Trials Information Service:
1 (800) TRIALS-A (874-2572)
Potential Side Effects:
Diarrhea, loose stools, nausea, vomiting and fatigue.
Potential Drug Interacts:
Not yet reported.

Tips:
Hopes to be effective against drug-resistant HIV, but that's manufacturer hype that rarely pans out. In studies, cross-resistance has been seen. Still, as the only non-peptidic protease inhibitor (a different chemical structure), should not be cross-resistant to other protease inhibitors. And significant viral load decrease has been seen in people with protease inhibitor resistance who took tipranavir by itself (for less than a month). Dose can become as many as 30 large pills a day, but using with small amounts of Norvir could cut this. Tipranavir is being studied at a twice-a-day dose.

Photo not available because of experimental drug status.

Brand Name:
Not Yet Established

Common Name:
tipranavir

Manufacturer

Tipranavir is an investigational compound currently in Phase II clinical trials. It is the first in a new class of non-peptidic protease inhibitors (PI)—with a molecular structure different from other peptidic PIs. The key benefit of the drug, shown by early *in vitro* data, is that it retains activity against virus which has become resistant to the currently available PIs (insufficient data is available for amprenavir and lopinavir). As with other PIs, it works at the last stage of the virus reproduction cycle by preventing HIV from being assembled and released from infected CD4+ cells. Researchers are currently studying its safety profile, possible drug interactions and dosing regimen. BI acquired the worldwide development, production and marketing rights to tipranavir in January 2000.

—Boehringer-Ingelheim

Doctor

Tipranavir is new protease inhibitor currently in Phase II studies. This agent has demonstrated antiretroviral activity in dose ranging studies and new reports suggest that this agent may also have potent activity against PI resistant viruses. Importantly however, this agent may have pharmacokinetic issues (it acts as both a substrate and inducer of the cytochrome p-450 system) that may require it be used in combination with ritonavir to boost its blood levels.

—Dr. Kimberly Y. Smith



Activist

Tipranavir is a new type of protease inhibitor, and in the test tube, it has activity against virus that is resistant to other PIs—maybe against some of the most resistant viruses we've seen. Whether this will be the case in people remains to be seen (whenever I see the word "promising" in a press release, I always see "untested"). The drug was recently purchased by Boehringer-Ingelheim from Pharmacia-Upjohn, which slowed its development somewhat. BI was forced to go back to square one: finding the right dose, particularly because they have decided to combine tipranavir with ritonavir to improve blood levels. Along with doing drug interaction studies, this delays a large-scale efficacy study until the Fall of 2001. Activists have pressured for an expanded access program to open simultaneously with that trial—we'll see if BI comes through. Side effects include diarrhea and nausea, and it looks like the drug will be dosed twice a day.

—Mark Milano

Brand Name:

Not yet established

Common Name:

T-20, pentafuside

Class: experimental fusion inhibitor

Standard dose: Taken as self-administered, twice-daily subcutaneous injections. Dose not yet established because of experimental drug status.

Wholesale cost: Not yet established because of experimental drug status

AIDS Clinical Trials Information Service:

1 (800) TRIALS-A (874-2572)

Potential Side Effects:

Irritation or infection at site of injection, fever, and headache.

Potential Drug Interactions:

Not yet reported.

Tips:

Prevents HIV from attaching to T-cells. Two shots twice a day (as used in one study for people who've taken many antivirals) creates the potential for four painful injections, and infection or irritation. No major problems with this seen so far. Because of injections, tested in people who've already taken HIV drugs, since people using antivirals for the first time have more convenient options. Some say shots won't scare people off (especially if they have limited options), others think that's a joke. Showed good viral load decrease when added to a stable antiviral combination in heavily treatment-experienced people, including those with protease inhibitor-resistant virus and those who've taken all three current drug classes. All in all, viral load came down from about 70,000 to around 10,000. On the minus side, only 40 out of 71 people who entered the study stayed on T-20 for the 48 weeks (not all drop outs were due to adverse events, which were actually few). Because it's in a new drug class, T-20 is not expected to have cross-resistance with other HIV medicines. T-20's peptide structure may be recognized by the body as a foreign object, and then antibodies may be created to fight it. But this potential problem (not seen with other HIV drugs) has not

occurred. Because peptides are big molecules, they cannot be taken orally and must be injected. The size is another reason why T-20 might be recognized as a foreign object. Manufacturer has another fusion inhibitor in development that may work as resistance to T-20 develops. May be able to penetrate lymph system, where most of the body's HIV hides. Very expensive to manufacture, and perhaps very difficult as well, limiting supply. Discoverer Trimeris already has a second generation fusion inhibitor in the works (T-1249). Visit www.rocheusa.com.

Photo not available because of experimental drug status.

Manufacturer

T-20, an investigational anti-HIV compound, is the first in a new class of drugs called fusion inhibitors which is being co-developed by Roche and Trimeris. Fusion inhibitors block fusion of HIV with host cells before the virus enters the cell and begins its replication process. Currently in Phase III clinical trials, T-20 received "fast track" designation from the U.S. FDA in February 1999. Phase II trial results collected from patients who had failed an average of 10 HIV medications and entered with high viral load show that T-20 in combination with other agents achieved either a 1 log viral suppression or levels of HIV less than 400 copies/mL in 33 percent (23/70) of patients (Intent to Treat). Side effects associated with T-20 include fever, headache and lymph node abnormalities, in addition to local irritation resulting from the subcutaneous injection.

—Roche

Doctor

T-20 is the first of several fusion inhibitors currently in clinical development. As the name implies, these antiretroviral agents attach to the virus, preventing it from drawing near, and fusing with, the human cell. The first studies of T-20 indicated substantial antiretroviral activity with reductions in viral load of approximately 1.5 log. However when used as monotherapy resistance developed rapidly. Studies of T-20 in combination with other antiretroviral agents have been more promising with viral load reductions of 1-1.5 log observed over 48 weeks in highly antiretroviral experienced individuals. The major drawback of T-20 and similar agents is that in their current formulation they require subcutaneous injection and they can cause local irritation at injection sites.

—Dr. Kimberly Y. Smith

Activist

Research on this salvage therapy seems to finally be picking up speed, and some form of expanded access should open by this summer. This will certainly not be a first-line therapy, since most people will want to avoid twice-daily subcutaneous injections, but reports are that people who have used up their options and need this drug do not have a problem with the shots. Since it is the first in an entirely new class of drugs, no one should have any resistance to it. As part of combination therapy, results in people who are multi-drug resistant have been good, not great (in one trial, 60% of patients had their viral load drop more than 1 log, while only 36% had VLs below 400), but if you've used up your options, it's definitely worth checking into if you're not scared of needles. And if you are—get over it! Side effects appear minimal, other than some irritation at the injection site for some patients.

—Mark Milano

Class: A cancer drug commonly used as an HIV anti-viral

Standard dose: One 500 mg Hydrea capsule twice a day. Droxia available in 300 mg and 400 mg capsules.

Wholesale cost: \$920/yr., \$77/month

Patient assistance number: 1 (800) 272-4878

AIDS Treatment Information Service: 1 (800) HIV-0440

Potential side effects:

Bone marrow suppression (anemia, low white blood cell counts, low platelet counts, and/or leukopenia, the loss of white blood cells, which are needed to fight infections), gastrointestinal symptoms (nausea, vomiting, anorexia, and diarrhea), constipation, fatigue, hair loss, drug-induced hepatitis and paresthesia (pins and needle sensation). Potential for severe anemia requiring blood transfusion or hospitalization when used with Retrovir (AZT). May cause birth defects. May increase risk of pancreatitis from Zerit or Videx.

Potential drug interactions:

A combination with other bone marrow suppressive drugs like Retrovir (AZT, which is also a cancer drug) and ganciclovir (Cytovene and Vitrasert) may lead to severe anemia and possibly the need for a blood transfusion or hospitalization. The combination of Retrovir, Hivid or Videx with hydroxyurea will increase the effect of the antiviral.

Tips:

Hot a couple of years ago, but now rarely used. Too toxic. Its potential came from report of the Berlin patient, who started hydroxyurea and Videx within weeks of his infection, then had to stop both drugs, went back on them, stopped again and did not have detectable viral load for years afterwards. The two drugs together may increase the risk of pancreatitis. A very few other people who started hydroxyurea extremely early in their infection were also able to maintain undetectable viral load after stopping treatment. Avoid taking with Retrovir (AZT),

because both drugs can deplete white blood cells and thus may require a blood transfusion. Does not raise T-cells, and may even decrease them. Avoid prolonged exposure to sunlight because of the potential for photosensitivity, or use an SPF-15 or higher sunblock. The drug is inexpensive because it is off-patent, which means that the developer no longer has an exclusive right to sell it. May cross the blood-brain barrier to a useful degree, which may treat or prevent neurological damage (such as dementia).

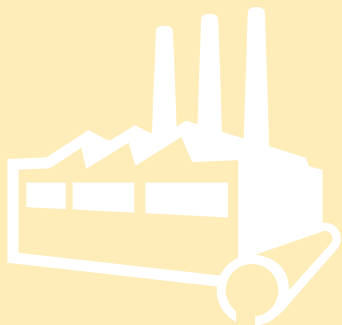


2x

Brand Name: **Hydrea, Droxia**
Common Name: **hydroxyurea**

Manufacturer

Bristol-Myers Squibb withholds comment because Hydrea is not FDA-approved for the treatment of HIV.



Doctor

Hydroxyurea is a drug which has primarily been used for treatment of sickle cell disease. It is not FDA approved for the treatment of HIV disease. However it has been used by several clinicians and investigators for treatment of HIV disease due to its synergistic activity when combined with ddI (didanosine, Hivid). Hydroxyurea inhibits cellular ribonucleotide reductase resulting in decreased intracellular deoxynucleoside triphosphates that are required for DNA synthesis, thus resulting in impaired viral replication. Recently hydroxyurea has fallen out of favor with many clinicians due to concerns that it may contribute to mitochondrial toxicity that has been associated with ddI and other nucleoside analogue antiretroviral agents. The major side effects observed in subjects on hydroxyurea are peripheral neuropathy and blunted CD4 cell response.

—Dr. Kimberly Y. Smith

Activist

Personally, I would approach hydroxyurea carefully, since it lowers white blood cells and does not seem to improve CD4 counts. But it is quite effective at lowering viral loads (in one study of 24 people, every person achieved a viral load below 400 copies, and of course there's that famous German guy who took a combo containing HU and has remained undetectable for years after stopping all therapy). A more recent study found that adding HU to d4T/ddI/Sustiva did not add any benefit in lowering viral load, at least in patients who are naive to treatment. There was a benefit for experienced patients, however. The study was stopped early for the naive patients due to an increase in peripheral neuropathy and other side effects. Also, those not taking HU saw CD4 increases while those who took it did not. If you've used up your options, you might consider HU if your WBC and CD4 counts are good. Just watch carefully how you react to it.

—Mark Milano

Combination Drug Chart

Chart by Glen Pietrandoni

Text by Enid Vázquez

When combining protease inhibitors and non-nucleoside analogues, standard dosages usually need to be changed. Check the chart to make sure your combo is right.

"Mini-Dose" Norvir

Taking one or two capsules of Norvir twice a day with another protease inhibitor is becoming more and more popular. It allows Crixivan to be taken twice a day and with food, but with greater risk of Crixivan side effects, including kidney stones (drink even more water). Taking with food is preferable to decrease risk of nausea and diarrhea. Norvir cuts the huge number of Agenerase capsules. Downside of mini-dose: increased GI (gastrointestinal) distress (nausea, vomiting, diarrhea) as well as triglyceride and cholesterol levels.

Crixivan vs. Viramune

Preliminary results show that the two are comparable, although Crixivan is in a supposedly more potent drug class. A small Spanish trial (50 people) reported its 32 weeks results at the International AIDS Conference in South Africa last July. People with viral loads above 100,000 also did equally well. Another non-nucleoside analog, Sustiva, has already proven its equivalency to Crixivan.

Mega-HAART

That's Highly Active Anti-Retroviral Therapy. According to Medscape: "Studies have found that between 30–59% of patients on mega-HAART regimens achieve viral load below 20 copies, but the majority of these individuals were non-nucleoside RTI-naïve. Disadvantages of mega-HAART include increased cost and toxicity problems...prolonged treatment is likely to be problematic." Generally, at least five drugs is considered mega-HAART, and is used for people who've already taken several regimens.

Switching PI to NN

The MAINTAVIR Study reported in September that of the 63 of 73 people (86%) who switched their protease inhibitor for a non-nuke remained undetectable (under 400 viral load) for at least a year. Other studies have found similar results. People generally switch because of side effects.

Sustiva vs. Viramune

A tiny retrospective British analysis suggests that either of these two drugs combined with Ziagen is a good "salvage" regimen when protease inhibitors stop working. Ziagen is the most potent nuke. ☩

Ritonavir, Norvir

Nelfinavir, Viracept	750 NFV/400 RTV TID
Indinavir, Crixivan	400 IDV/400 RTV BID 800 IDV/100 RTV BID 800 IDV/200 RTV BID
Saquinavir, Fortovase	400 SQV/400 RTV BID 800 SQV/200 RTV BID 1000 SQV/100 RTV BID 1600 SQV/100 RTV QD 800 SQV BID/100 RTV BID/600 EFV QD

Amprenavir, Agenerase	600 APV/100 RTV BID 1200 APV BID/200 RTV BID/600 EFV QD
Efavirenz, Sustiva	600 EFV QD/500 RTV BID 600 EFV QD/100 RTV BID/800 SQV BID 600 EFV QD/200 RTV BID/1200 APV BID

Nevirapine, Viramune	200 NVP/600 RTV BID
Delavirdine, Rescriptor	600 DLV/300 RTV BID

Nelfinavir, Viracept

Indinavir, Crixivan	1200 IDV/1250 NFV BID
Saquinavir, Fortovase	1200 SQV/1250 NFV BID 800 SQV/750 NFV TID
Amprenavir, Agenerase	750 or 800 APV/750 NFV TID 1200 APV/1250 NFV BID

Efavirenz, Sustiva	600 EFV QD/1250 NFV BID
Nevirapine, Viramune	200 NVP/1250 NFV BID
Delavirdine, Rescriptor	600 DLV/1250 NFV BID

Indinavir, Crixivan

Saquinavir, Fortovase	SQV/IDV Antagonistic <i>in vitro</i>
Amprenavir, Agenerase	750 or 800 APV/800 IDV TID
Lopinavir/ritonavir, Kaletra	400-100 LPV-r/600 IDV BID
Efavirenz, Sustiva	600 EFV QD/1000 IDV q8h
Nevirapine, Viramune	200 NVP BID/800 IDV q8h
Delavirdine, Rescriptor	600 DLV/1200 IDV BID

Saquinavir, Fortovase

Amprenavir, Agenerase	750 or 800 APV/800 SQV TID
Lopinavir/ritonavir, Kaletra	400-100 LPV-r/800 SQV BID
Efavirenz, Sustiva	600 EFV QD/800 SQV BID/100 RTV BID
Delavirdine, Rescriptor	600 DLV/1600 SQV BID 400 DLV/1200 SQV TID

Amprenavir, Agenerase

Lopinavir/ritonavir, Kaletra	400-100 LPV-r/750 APV BID
Efavirenz, Sustiva	600 EFV QD/1200APV BID/200 RTV BID

Lopinavir/ritonavir, Kaletra

Efavirenz, Sustiva	600 EFV QD/533-133 LPV-r BID
Nevirapine, Viramune	200 NVP/533-133 LPV-r BID

Efavirenz, Sustiva

Nevirapine, Viramune	400 NVP/800 EFV QD
Delavirdine, Rescriptor	Limited data on NNRTI combo

Nevirapine, Viramune

Delavirdine, Rescriptor	Limited data on NNRTI combo
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Abbreviations

RTV	Ritonavir, Norvir	NVP	Nevirapine, Viramune
NFV	Nelfinavir, Viracept	DLV	Delavirdine, Rescriptor
IDV	Indinavir, Crixivan	QD	Once a day
SQV	Saquinavir, Fortovase	BID	Twice a day
APV	Amprenavir, Agenerase	TID	Three times a day
LPV-r	Lopinavir/ritonavir, Kaletra	q8h	Every eight hours
EFV	Efavirenz, Sustiva		

Drug Tips

by Enid Vázquez

- Ask for a copy of all your lab results. They are free, but your doctor's office may charge you a small fee for sending a copy elsewhere. Laboratory testing should be performed before starting therapy and then at periodic intervals or if any clinical signs or symptoms occur. Try to have a fasting measure taken (do not eat or drink anything but water for at least 12 hours prior to the blood draw).

- Never get overly concerned over one high viral load result. Always wait for the results of a second test, especially before changing therapy.

- Pharmacists are usually much more readily available than doctors, and probably more helpful. Ask them all your questions.

- When HIV mutates under pressure from drug therapy, it isn't as fit as wild-type HIV (the original one people have with a new infection). The mutations hurt its ability to reproduce. So, you're still benefiting from treatment, even with detectable viral load.

- To monitor mother and child outcomes of pregnant women exposed to HIV drugs, the Antiretroviral Pregnancy Registry has been established. Physicians are encouraged to register patients by calling (800) 258-4263.

- Testing blood levels of uric acid can monitor for a condition called hyperuricemia. This condition can also be a sign of kidney problems. Symptoms of hyperuricemia are joint pain and arthritis. Several studies have reported these problems in people taking strong HIV combination therapy.

- Nail down your doctor and pharmacist on potential side effects and how

to handle them. Also remember that side effects can pop up after years without a problem. Remember: it's better to be seen by an HIV specialist.

- A good doctor will review how the drugs fit your lifestyle. Research suggests that the best predictor of adherence is the amount of time a doctor or other healthcare provider spends discussing the drugs with you.

- Writer Michael Mooney, nutritionist Chester Myers, and Lark Lands, complementary health guru, have made the following recommendations to prevent or reverse heart damage and fat redistribution being seen with drug therapy: progressive resistance exercise (weight-bearing) to improve insulin resistance; testosterone replacement where needed (women included) to fight insulin resistance and build muscle; high-potency multivitamin and mineral supplement; glutathione-boosting nutrients daily (600–1,200 mg alpha lipoic acid; 1,500–3,000 mg N-acetyl-cysteine, or NAC; 2,000–3,000 mg vitamin C; 1,200 IU vitamin E distributed throughout the day; and 5–10 gm glutamine, or 30–40 in cases of severe muscle loss); a GTF (glucose tolerance factor) formula with 200–300 mcg chromium three times a day (also helps increase insulin sensitivity) and 500–1,000 mg magnesium for glucose metabolism (sugar control).

- For a free copy of the U.S. Department of Health and Human Services guidelines for HIV treatment for adults, children, and pregnant women (as well as principles of HIV therapy), call (800) HIV-0440, visit www.hivatis.org, or write ATIS, P.O. Box 6303, Rockville, MD 20849-6303. Available in Spanish.



Glossary

Compiled by Laura Jones

Acute HIV Infection: The 4 to 7 weeks following HIV infection, during which time the body begins to mount an immune response to HIV virus. About 30% to 70% of people experience flu-like symptoms (fever, malaise, headache, swollen lymph nodes, and/or rash) during this time period. Also called Primary Infection.

ADAP: AIDS Drug Assistance Program. State-based programs providing HIV medications, opportunistic infection treatments, and therapy-administration devices for little or no cost. Funded in part by Title II of the Ryan White CARE Act. Eligibility criteria and covered medications/therapies are determined at the state level, and therefore vary from state to state.

Antibodies: Proteins, manufactured by the immune system, that mark, attack or destroy disease-causing organisms like bacteria and viruses. Also called Immunoglobulins.

Antiretrovirals: Medicines that stop or slow the replication and activity of HIV and other retroviruses. Includes NNRTIs, nucleoside analogues, and protease inhibitors.

Branched DNA Assay: Test that measures the amount of HIV or other virus in blood by creating a luminescent reaction to viral

RNA and measuring the brightness of the reaction. Used to evaluate HIV disease progression and effectiveness of drug treatments; not approved for diagnosing HIV infection. Also called bDNA Test.

CD4+ Cells: Special white blood cells that coordinate the immune response to fight bacterial and viral infections. In HIV medicine, the CD4+ count is a marker for measuring immune-system health—normal CD4+ count is between 500 and 1500 per cubic milliliter of blood. HIV infection plus a CD4+ count below 200 is considered an AIDS diagnosis.

Clinical Trial: Investigative study, administered to humans, in order to determine an experimental treatment's safety, effectiveness and potential complications (side effects, interactions, toxicity, etc.) before approving the treatment for widespread use.

ELISA Test: Enzyme-Linked Immunosorbent Assay. Common diagnostic test used to detect HIV antibodies in a blood or saliva sample. If two ELISA tests are positive for HIV antibodies, a Western Blot test is done in order to confirm HIV infection.

HAART: Highly Active Antiretroviral Therapy. Aggressive HIV treatment involving a combination of protease inhibitors, NNRTIs, and nucleoside analogs. HAART

works by disrupting the virus at all stages of replication; the goal is to reduce HIV viral load to “undetectable” levels. Sometimes referred to as “the cocktail”.

HIV Disease: The whole spectrum of HIV infection, including initial infection, seroconversion, asymptomatic HIV infection, symptomatic HIV disease/ARC, and AIDS. However, the term “HIV disease” is frequently used to refer specifically to Symptomatic HIV Disease, previously known as ARC (AIDS Related Complex).

HIV-1: Human Immunodeficiency Virus Type 1. The retrovirus most commonly associated with HIV disease. HIV-1 is currently the most common strain of HIV virus, accounting for the majority of global HIV infections.

HIV-2: Human Immunodeficiency Virus Type 2. Another strain of HIV virus, considered less virulent and less widespread than HIV-1. HIV-2 infection is found primarily in West Africa and Southeast Asia.

Limit of Detection/Limit of Quantification: The level at which a diagnostic test is no longer sensitive enough to accurately measure the substance it is designed to detect. “Limit of Detection/Quantification” is the reason

why a person's HIV viral load will be "undetectable", even though there is still virus present in the body fluid sample.

Long-Term Nonprogressor: A term used to describe HIV+ people, positive for at least 7 years, who have stable CD4+ cell counts over 600 and no HIV-related opportunistic infections despite having never used antiretroviral therapy.

Microbicide: Protective substance containing bacterial/viral-killing agents that can be applied to the vagina, rectum, mouth, or other skin. If developed, vaginal and anal microbicides could be used by both women and men to protect against HIV and STD infections, especially in situations where a male or female condom can't or won't be used.

NNRTI: Non-Nucleoside Reverse Transcriptase Inhibitor. Antiretroviral medication that works to stop HIV replication in the beginning stages by binding to reverse transcriptase, preventing RNA from converting into DNA. Examples: Viramune, Sustiva, and Rescriptor.

Nucleoside Analogue: Antiretroviral medication that becomes part of HIV DNA after it's converted from RNA, creating incomplete DNA that can't replicate. Examples: AZT, Ziagen, Efavir, Hivid, Zerit, Videx, and Combivir.

OI: Opportunistic Infection. An illness or condition that occurs when the immune system is too weak to keep it in check. Examples of HIV-related OIs include PCP, Kaposi's sarcoma, shigellosis, toxoplasmosis, and HPV-related cervical cancer in women. The presence of HIV infection and one or more OIs is diagnostic of AIDS.

PCR: Polymerase Chain Reaction. Laboratory test that measures the amount of HIV virus in a blood sample or lymph node by rapidly replicating a sample piece of DNA. Helpful in monitoring the progress of HIV disease and the impact of antiretroviral medications on HIV replication. Not approved for diagnosing HIV infection because of high false-positive and false-negative rates.

PEP: Post-Exposure Prophylaxis. Antiretroviral drug treatment administered after possible exposure to HIV (e.g., needle-stick accidents), in the hope of preventing HIV infection by stopping HIV replication before the virus has a chance to fully set up shop in the body.

Protease Inhibitor: Antiretroviral medication that prevents new HIV virus from being properly assembled and released after replication. Examples: Crixivan, Norvir, Viracept, Fortovase and Kaletra.

Retrovirus: A virus that stores its genetic information in RNA instead of DNA. During replication, the virus uses reverse transcriptase enzyme to make a DNA copy of the information contained in the RNA. The DNA can then become part of the host cell's genetic material, and force the cell's reproductive mechanisms to make more retrovirus. Example: HIV virus.

Reverse Transcriptase: The enzyme used by retroviruses to make DNA copies of genetic information stored in RNA.

Seroconversion: The development of a detectable amount of antibodies to a particular infectious agent. HIV seroconversion may take anywhere from a few weeks to six months, depending on the individual.

Viral Load: Amount of measurable HIV virus found in blood or other body-fluid sample.

Western Blot: Sensitive laboratory test that detects the presence of HIV antibodies in a blood or saliva sample. Western Blot tests are used as final confirmation for reactive ELISA tests—if the Western Blot is also reactive, the test is considered "positive" for HIV infection.



Rituals and Regimens 2001

Life after Diagnosis

by Sanford E. Gaylord

It has been three years, although it seems much longer, that I've been taking Highly Active Anti-retroviral Therapy (HAART). It wasn't that long ago that I pondered the thought of life after diagnosis, and the reality of popping pills to sustain myself for the rest of my life. In order to get through that period, I had to build myself up mentally before beginning what would become a daily ritual.

I have the honor of calling myself a "long-term survivor" in my own personal war with HIV. In my case, my identity as a seronegative same-gender-loving man of African decent was cut short at the age of twenty-four. I received a seropositive diagnosis by phone in 1989. In person, I was told to get my affairs in order; that I could either get into a clinical trial or start taking a new drug, AZT, to prolong my life.

My life shattered at the news—shattered as well was my denial about who was most at risk for infection. Since 1990, it is documented that the proportion of AIDS cases occurring in people of African decent surpassed cases among Whites. It took some time to pull myself together, but I did so with

the help of brothas who were standing on the frontlines, waging war against HIV. A good part of the foundation I have as a warrior comes from Brothers United in Support (BUS), a program of Test Positive Aware Network here in Chicago, as well as from reading journals like *Positively Aware*. Flashing back, at that time I couldn't imagine seeing thirty. Now I'm looking forward to thirty-six.

It was in the seventh year of my HIV-positive diagnosis that another physician, after reviewing the results of a blood draw, informed me that I should consider HAART. I however decided to wait and see how my labs would turn out with the next draw. Over the course of a year I researched anti-retroviral therapies, and went power shopping for a holistic approach in preparation for what I felt was to come.

When the physician and I spoke again, my undetectable viral load without meds had skyrocketed and CD4 count had dropped significantly. We discussed treatment options and formulated a plan for my therapeutic armamentarium. It consisted of a HAART regimen of Viramune (nevirap-

ine), Zerit (d4t) and Videx (ddI). Even with all of the research that I prepared myself with, due to fear, the pills sat on my dresser for a month before I decided to take them. They were the first thing I saw every morning.

Overcoming the fear of making the meds a part of my daily rituals was ultimately my greatest challenge. Popping pills would be a constant daily reminder that I was living with HIV. When I did take them, it was with breakfast. I got a large glass of water and began what was to become a daily ritual. I took the Videx, supposedly as having a wonderful citrus flavor, which must be taken on an empty stomach or at least two hours after eating. It tasted more like chalk to me. The food made me feel full, but the meds made me feel empty.

The first few weeks were like a nightmare turned into reality. I felt nauseated, especially after taking Videx. And my thought was that the meds were much too expensive to throw up and have to retake. This led to my not having much of an appetite and forcing myself to eat.

The most degrading aspect of this ritual was the diarrhea. Walking down the street,

...my identity as a seronegative same-gender-loving man of African decent was cut short at the age of twenty-four.

thinking you've got gas, defecating on yourself and being a long way from home. In my case, the humiliation was intensified because I had to take public transportation home after the incident. I cursed the damn meds that were supposed to help me in this battle and prolong my life. I also cursed the cruel creature at the root of the problem—my ignorance of so many years ago about HIV/AIDS.

After what felt like an eternity, I made it home. I peeled out of my clothes and cried during my two showers. I called my brothas from BUS for advice and much needed support. I was informed that my body needed to adjust to the meds, and that the symptoms I was experiencing were the casualties of war; that they were probably related to Videx and would or should pass. [Editor's Note: The new formulation, Videx EC, eliminates the diarrhea problem.]

By the third week of taking meds I couldn't take the side effects any longer. I phoned my physician. We had an emergency appointment to talk about new treatment options. I was cautioned that once beginning anti-retroviral therapy it must be strictly adhered to, otherwise it could possibly lead to HIV mutating and developing resistant strains. The good thing is that I have always made a point of having open communication with my physicians and chose to be proactive about my healthcare as I battle HIV. I received a new prescription for Efavir (3TC) to replace Videx. By the end of the week, I started coming back to focus. My appetite returned and the other side effects dissipated.

I still follow my rituals with my regimen, adhering to the daily dosing regimen until there is a cure for HIV/AIDS and we're still nowhere near a cure. After living with HIV for the past 11 years I seem to be managing very well for now, and haven't had to change my regimen. However, there is always an amount of anxiety that I experience after bloodwork to determine my CD4 count and viral load. Every three months my mind fixates on what the magic number will be this time. There are still times that I dread going

to my medicine cabinet for my evening dose or packing my meds for the next day.

More so, I cringe when I hear that people think HIV/AIDS is over, or worse that it's a "manageable disease." The miseducation of our youth, the exploitative anti-HIV drug ads, and an absence of accurate media coverage of HIV/AIDS reinforces this way of thinking. Yes, HIV positive people are living longer lives, and the progression to AIDS has slowed. However, the reality is that the rates of new infection are growing essentially, especially among people of color. And yes, people are still dying from AIDS (3 brothas from BUS, including founding member Michael J. and 7 TPAN members were lost in 2000).

People are living longer because of biomedical research of HIV and anti-retroviral therapy that has advanced tremendously since the dark eighties (1980s). What I have learned about my daily rituals with my regimens is that you need to be prepared and focused. You've got to be a fighter in order to survive. You owe it to yourself to do some research and actively participate with your physician in your healthcare management. If there's a safe space where you can talk to other long-term survivors who practice daily rituals with regimens, treat yourself to their stories. Some of those warriors have many battle scars and

helpful tales of survival. There is life after diagnosis. It's a battle, but isn't any life a battle to some degree? ☸

Sanford Gaylord is a member of Chicago's premiere lesbian/gay/trans performance group A RealRead, and a columnist for BLACKlines.



Complementary Therapies for People Living with HIV*

Complementary therapies have been attractive, and a necessity of life for PWAs since the beginning of the HIV epidemic. Positively Aware is committed to providing easy-to-understand health information—including complementary therapy—to help people living with HIV make informed choices in regard to their treatment. As more anti-retroviral therapies become available it is important for people living with HIV to remember that we, also, have to learn more about complemen-

tary treatments to ease the side effects associated with HIV therapy. The following is a brief excerpt of many complementary therapies used by PWAs, as compiled by CATIE (Community AIDS Treatment Information Exchange). As some complementary therapies can interact with your drug regimen, it is important to remember to discuss therapy decisions with your health care provider.

Homeopathy

Homeopathy involves specialized remedies to treat the whole person rather than a diagnosed condition. Homeopathic remedies are chosen by matching the remedy to the unique physical, emotional and mental characteristics of the individual being treated. Hundreds of homeopathic remedies are available, and all are prepared from dilute extracts of animals, plant and mineral substances.

Homeopathy is popular in Europe, where a number of clinical trials have looked at homeopathic methods. A recent paper in the prestigious British journal, *The Lancet*, concluded that the effects of homeopathy could not be attributed to the placebo effect and urged further clinical study. Although some people living with HIV use homeopathy to treat particular HIV-related infections or symptoms, very little has been published about the experiences of HIV-positive people with homeopathy, and few studies have examined the usefulness of homeopathy in HIV.

Homeopathic combination remedies are sold in some drug and health food stores. These over-the-counter remedies are not carefully matched to specific symptoms. Instead, they contain combinations of dif-

ferent remedies that are most commonly prescribed for particular illnesses. Despite this broad-spectrum approach, these remedies carry little risk of side effects because they are so dilute. For treatments specifically targeted to symptoms, visit a qualified homeopath.

Naturopathy

Naturopathy uses natural substances and the body's own healing powers to treat and prevent illness. Naturopaths view the symptoms of illness as warnings of lifestyle flaws or imbalances in the body. Naturopathic treatments are specific responses to extensive reviews of an individual's lifestyle and nutritional requirements. Naturopaths are trained in many of the healing practices including acupuncture, herbal treatments, massage and homeopathy as well as nutritional counseling. Naturopaths are the generalists of the complementary medicine world, employing methods derived from a variety of different systems. Visiting a naturopath may help you decide which complementary therapies are right for you.

Traditional Chinese Medicine and Acupuncture

Traditional Chinese medicine (TCM) is a complete medical system with its own unique philosophy, diagnostics and treatment methods. The goal of TCM is to balance the yin (vital function) and the yang (vital essence). One analogy describes yang as the gear and yin as the grease that allows the gear to run smoothly. An excess of yang leads to the consumption of yin and the formation of heat, much as a gear that works too hard burns away the grease and builds up heat. The balancing of yin and yang stabilizes as person's energy, otherwise known as qi (pronounced chee). The purpose of TCM is fu-zheng, which means to support the true or righteous qi to inhibit diseased qi from progressing.

Acupuncture is a component of TCM widely used by HIV positive people. It stimulates the flow of qi in specific organs or areas through the insertion of needles at designated points on the body.

Acupuncture can be used to treat generalized symptoms, such as fatigue, and may be useful for localized symptoms, such as neuropathy (tingling or burning sensation in

the hands and feet). Neuropathy, which may be a side effect of antiretroviral drug treatment or a direct result of HIV infection, is notoriously hard to treat. Although different approaches work for different individuals, many reports indicate that neuropathy symptoms and pain decrease for PHAs treated with acupuncture.

Several other forms of Chinese medicine focus on acupuncture points. Through massage, acupressure stimulates the acupuncture points without the use of needles. In moxibustion the acupuncture points are warmed by applying burning herbs to protected skin. The herb used is mugwort (*Artemisia vulgaris*). Fat cigar-shaped bundles of the herb wrapped in rice paper are most commonly used. Moxibustion is frequently used to treat digestive complaints such as diarrhea, but it should be avoided if you are experiencing fever, numbness or neuropathy.

Herbal Therapies

Herbal therapies are medically active substances harvested from plants. They may come from any part of the plant but are most commonly made from leaves, roots, seeds or flowers. They are eaten, drunk, smoked, inhaled or applied to the skin.

Herbal medicines are often viewed as a balanced and moderate approach to healing. Pharmaceutical drugs derived from plants are made by isolating the chemicals that have a medical effect and concentrating them in the medication. Herbal therapies, on the

other hand, contain all the chemical components of a plant, as they occur naturally. This important part of herbal medicine may explain why some herbs—used by experienced practitioners for centuries—have not performed well in modern clinical trials when their active chemicals were isolated from the rest of the plant.

Herbal medicines are often promoted as a gentle and non-toxic approach to good health. This does not mean health therapies never cause side effects or never interact with other pharmaceutical and herbal treatments. Learn enough about any herbal therapy to ensure that the dose is safe and effective. Learn about possible side effects and watch for signs of drug interactions.

Juicing

Juicing creates liquid foods, which the body can easily assimilate and absorb. It allows the vitamins and other nutrients in fresh fruits and vegetables to be easily consumed—even by people who have no appetite. Raw foods provide abundant energy. They supply the body with optimum nutrition in the form of vitamins, food enzymes and fiber. Juicing is often used if a PHA's health is compromised by weak digestion or malabsorption and if a person has difficulty chewing.

Most fruits have a cleansing effect on the body's system. Their high water content flushes the digestive tract and kidneys. Juicing is used to flush the kidney, liver and gastrointestinal system of toxins. For PHAs

dealing with the side effects of antiretrovirals, juicing may assist in removing the toxic by-products of the drugs. These enzymes are naturally present in fruits and vegetables. Proponents of juicing believe that enzymes are destroyed when food is processed or heated. Our own bodies produce enzymes that digest food and incorporate it into the cells of our bodies. Juicing allows us to ingest the enzymes of fruits and vegetables, which may make digestion easier.

The freshest produce will give you the most enzymes. So choose fruits that are in season. To avoid ingesting pesticides, peel the skin of the fruit or vegetable and do not ingest the pulp. Fresh juices are a concentrated form of food. Be moderate in your consumption. Fruit juices are high in fruit sugar. Think of juice as a meal.

Doing Your Own Research On Complementary Therapies

Although the use of complementary therapies is becoming increasingly common, [however] depending on where you live, you may have difficulty finding some of the therapies.

Here are ten questions to ask yourself to guide your investigation into any new therapy, either complementary or conventional.

- What am I hoping to get out of this therapy?
- Is this therapy used by other PHAs?
- Am I able to talk to any of these PHAs about their experiences?

- Is there any research or additional information about this therapy?
- What are the side effects of this therapy, if any?
- What sort of commitment do I have to make to use this treatment?
- Where can I get this treatment, and will it be regularly available?
- How much of this treatment is too much and what are the early signs of taking too much?
- Does this treatment interact with anything else I'm taking?
- How much does it cost?

Red Flags (things that should make you cautious about complementary therapy information)

- The information source discourages you from consulting others or belittles the information you have received.
- The source claims that the treatment can be used for a long list of illnesses without any explanation of how results vary depending on the condition or how the conditions are related.
- The information focuses on the treatment's popularity or financial success, not on how it works.

- The information relies exclusively or predominantly on testimonials from past users.
- The information is all about comparisons with other similar products.
- The qualifications of the practitioners or promoters aren't offered.
- Studies of the product referred to in promotional literature haven't been published or are published only in a newsletter owned by those selling the product.
- The source's focus is on payment, not information.
- Opinions and facts are mixed together in the information.
- The treatment is unjustifiably expensive and no clear explanations are given.

When you start a new treatment, it is wise to keep a journal. This applies to any new treatment, complementary or conventional. A journal allows you to record your experiences so that, in a few weeks or months (depending on the time commitment required), you can decide if the treatment is working. In the journal, record how you feel each day and what changes, if any, you think can be attributed to the new treatment. Record when you feel ill or when you think

this treatment is interacting with another or with food. If you're experimenting with dosage, you should record the various amounts and your observations. If you get the treatment when you see a practitioner, note the date and time of your appointments. A journal will allow you to evaluate the treatment more fairly. It is a more reliable record than your memory, which often remembers only the most dramatic experiences, good and bad. A journal will help you determine whether changes in your life are associated with a particular treatment. It will give you a record of your treatments, which you can use in discussions with your doctor or practitioner. This type of record-keeping is particularly useful if you are trying a number of treatments. The journal is also a good source of information for PHAs who ask you about your experiences. ☩

** This information was provided by the Community AIDS Treatment Information Exchange (CATIE). For more information, contact CATIE at 800-263-1638 or on the web at <http://www.catie.ca>*

Introduction written and resource list compiled by Charles E. Clifton.

Resources for Complementary Therapies and HIV

BOOKS

Healing HIV: How to Rebuild Your Immune System, by Jon Kaiser, MD. (Mill Valley, CA: Health First Press).

You Don't Have to Die: Unraveling the AIDS Myth, by Leon Haitow, ND, DO, and James Strohecker with The Burton Goldberg Group. (Puyallup, WA: Future Medicine Publishing).

Nutrition and HIV: A New Model for Treatment, by Mary Romeyn, MD. (San Francisco: Jossey-Bass Inc. Publishers).

The HIV Wellness Sourcebook: An East-West Guide to Living Well with HIV/AIDS, by Misha Ruth Cohen, OMD, LAC, with Kalia Doner. (New York: Henry Holt).

Directory of Complementary and Alternative Therapies in HIV/AIDS, by National AIDS Manual. (London: NAM).

Encyclopedia of Nutritional Supplements, by Michael Murray, ND. (Rocklin, CA: Prima Publishing).

Prescription for Nutritional Healing A-To-Z Guide to Supplements, by James F. Balch, MD, and Phyllis A. Balch. (East Rutherford, NJ: Avery Publishing Group/East Rutherford).

WEBSITES

AEGIS

www.aegis.com

The New Mexico AIDS InfoNet

www.aidsinfonet.org

The Body

www.thebody.com/treat/altern.html

CATIE

www.catie.ca

Critical Path AIDS Project

www.critpath.org/alt.htm

Healing Well

www.healingwell.com

Herb Research Foundation

www.herbs.org

Project Inform

www.projinf.org

University of California, San Francisco

www.hivinsite.ucsf.edu

Understanding HIV/AIDS Drug Resistance Assays*

by Andrea Ho-Kean, PharmD.

HIV/AIDS drug resistance is a frequent cause of HIV/AIDS medication failure and presents a major challenge for physicians as they try to effectively suppress viral load to an undetectable level. In the past, physicians have had limited guidance in selecting the most effective combination of medications for a patient with HIV. Research studies suggest that new technologies such as phenotypic and genotypic HIV drug-resistance assays (lab tests) may assist physicians in making better treatment decisions. It is likely that these assays may become routine laboratory tests in the near future. The following information may help you better understand these resistance assays and their future roles in treatment decisions. (Note: It is important to understand the concepts of viral resistance and resistance mutations in order to fully appreciate

how the resistance assays work. The recommended readings at the end of this article provide background information on viral resistance.)

What are antiretroviral drug-resistance assays and why are they important?

Drug-resistance assays are unique laboratory tests used by HIV/AIDS specialists to determine whether the virus infecting a patient is likely to respond to specific antiretroviral medications.

What types of resistance assays are available and is one better than the other?

Currently, there are two types of resistance assays used in clinical practice and in research: phenotypic and genotypic assays.

Genotypic resistance testing detects the presence of specific genetic mutations that are thought to cause drug-resistance, such as the M184V mutation associated with lamivudine (Epivir) therapy. Phenotypic resistance testing directly measures the ability of a patient's virus to grow in the presence of known blood concentrations of antiretroviral drugs. There are distinct advantages and disadvantages associated with each test and there has been no consensus among experts as to whether one is better than the other. (see table)

In the past, phenotypic assays were criticized for a lack of sensitivity in detecting drug-resistant minor species (viruses that exist as a smaller sub-population of the wild type viruses) and the fact that it took a longer time (four to six weeks) to get results. However, PhenoSense™ HIV, a new test by

continued on page 59

Assays	Advantages	Disadvantages
Phenotypic Assays: 1. PhenoSense™ HIV, ViroLogic (South San Francisco, CA) (800) 777-0177 2. Antivirogram™ Virco (Mechelen, Belgium) (800) 533-0567	<ul style="list-style-type: none"> • Direct measure of susceptibility of patients' HIV to antiretroviral drugs • Physician-friendly—easier to interpret than genotypic assays • Turn-around time for results is better • Reproducible results • Reliable results with repeated tests • Evaluates susceptibility to all available antiretroviral drugs • Can be modified to evaluate new class(es) of HIV drug 	<ul style="list-style-type: none"> • Not available at all labs • May not detect all minor and subspecies of virus • Potential exists for false negative results, because patient's sample may contain a mixture of drug-sensitive and resistant viruses • Results from the assays made by different manufactures may not be comparable • Cost per test: \$700-1,000
Genotypic Assays: 1. VircoGen™, Virco (Mechelen, Belgium) (800) 533-0567 2. TRUGENE™ HIV-1 Applied Sciences/Visible Genetics (Toronto, ONT) (770) 734-9872 3. Genotypic resistance testing (ABI/PE Biosystem, Foster City, CA) Stanford Hospital and Clinic, Microbio/Virology Lab (650) 723-6671	<ul style="list-style-type: none"> • Available at many commercial and academic labs • Technically less demanding; therefore, results are available in days • Results from assays made by different manufacturers are easier to compare 	<ul style="list-style-type: none"> • Indirect measure of drug sensitivity • May not detect all minor and subspecies of virus • Potential for false positive or false negative results (i.e., may over-estimate and under-estimate drug resistance) • Difficult to interpret the results because of complex interactions between types of mutations (e.g., M184V mutation associated with lamivudine reverses the resistance to zidovudine) • Cost per test: \$400-600

continued from page 56

ViroLogic offers significant improvements in the ability to detect minor species that comprise as little as 10 percent of the total viral population. In addition, the results from this test are now available within two weeks.

From a practical sense, the ideal test should be accurate, easy to use, readily available, sensitive to minor viral species, without restrictions on viral load requirement for test accuracy, and reasonably priced. There are some physicians who prefer the phenotypic assay because it is a direct measure of drug sensitivity against the virus, and it is easy to use and interpret. Others may select the genotypic assay for its ability to predict the likelihood of drug resistance. Still others believe that both tests may actually complement each other in treating and monitoring HIV/AIDS patients. Hopefully, further research will address the appropriate use of these two tests together in enhancing patient care.

How are these assays currently used?

The resistance assays are beginning to be used routinely in patient care. This may increase, since an International AIDS Society (IAS)-USA Panel has recently published Drug Resistance Testing Guidelines to assist clinicians in better use of the resistance tests (for additional info see: www.IASUSA.org). The ISA-USA panel *recommends* the following criteria for the use of the HIV-resistance assays:

- Pregnancy—to optimize maternal treatment and prevention of HIV in the unborn infant
- First drug regimen failure—to identify the drug(s) to which there is resistance and help guide future drug selection
- Multiple-drug regimen failures—to assist in selecting active drugs in the next regimen and eliminate those that are ineffective

The panel *suggests* that resistance testing be considered in the following situations:

- Primary HIV infection—to detect transmission of drug-resistant viruses and to modify therapy to maximize drug response and main-

tain HIV-specific immune responses. However, treatment should not be delayed while awaiting results.

- Established HIV infection before starting an initial regimen—to possibly detect prior transmission of drug-resistant HIV. The panel warns of careful use and interpretation of the resistance assay results since prior transmission of drug-resistant HIV may be difficult to determine.

The ISA-USA panel points out that the resistance assays should not be used as the sole criterion for deciding when to *initiate* or *change* therapy. Physicians are urged to consider other important factors such as: patient's drug history, viral load, tolerance, adherence, concomitant medications and diseases prior to adding or eliminating a drug.

What are the potential future implications of these assays?

The resistance assays offer scientifically sophisticated tools for physicians. Early studies suggest they are useful in improving short-term patient outcomes by allowing better selection of the most effective antiretroviral medications. In addition, earlier switching to a more sensitive medication guided by these tests may have an invaluable impact on preserving a patient's immune system, minimizing unnecessary side effects and costs, and most importantly, the development of drug resistant mutations. Despite this optimism, physicians and patients are still presented with complex questions such as: Which test is best suited for a given clinical condition? What are the long-term health benefits for patients? What are the long-term economic benefits associated with these assays? Which insurance companies are covering the assays? Future studies should address these concerns. In the meantime, most physicians agree that proper use of the resistance assays may actually reduce long-term costs associated with treating and monitoring HIV/AIDS patients. ☞

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Glossary

Gene or gene mutation: a change in the genetic code. Think of genetic code like letters in a word. If you change the order of the letters, the word doesn't make sense anymore. These changes in the code happen randomly as HIV reproduces. Sometimes, antiviral medications can't make sense of the changes; therefore, they can't work against the virus. In an attempt to survive and fight back, the virus will continue using the mutation against the drug and drug resistance occurs.

Genotype: genetic information or the genetic code that determines a specific genetic trait (e.g., the color of your eyes or hair). In HIV, if the virus has normal genetic information, it will most likely be sensitive to antiviral medications. If the virus has mutated genetic information, it may be resistant to an antiviral medication.

Phenotype: an observable characteristic or behavior (e.g., the personality of an individual). In HIV, phenotype normally refers to drug resistance or susceptibility.

Resistance: reduction in an organism's sensitivity to a particular drug. In other words, the virus is no longer vulnerable to a particular antiviral medication. Viral resistance is thought to be the result of genetic mutations.

Resistance assay: a laboratory test used to see if a drug would work against a virus or bacteria. In the case of HIV, the current resistance tests need the patient to have a particular viral load in order to work. They also need a resistant minor species to make up a particular amount of the virus in order to find it.

Wild type virus: naturally occurring virus that is circulating before drug resistance develops.

Recommended Readings:

1. Horn, Tim; Cox, Spencer and Richman, Douglas. *A No-Nonsense Guide to HIV Drug Resistance Testing*. University of California, San Diego.
2. Resistance: www.projinfo.org/pub/29/resistance.html April 2000
3. Geno- and Phenotypic Resistance Tests. www.projinfo.org/fs/GenoPheno.html March 2000.



Thank God for Women's Health Activists!

by *Laura Jones*

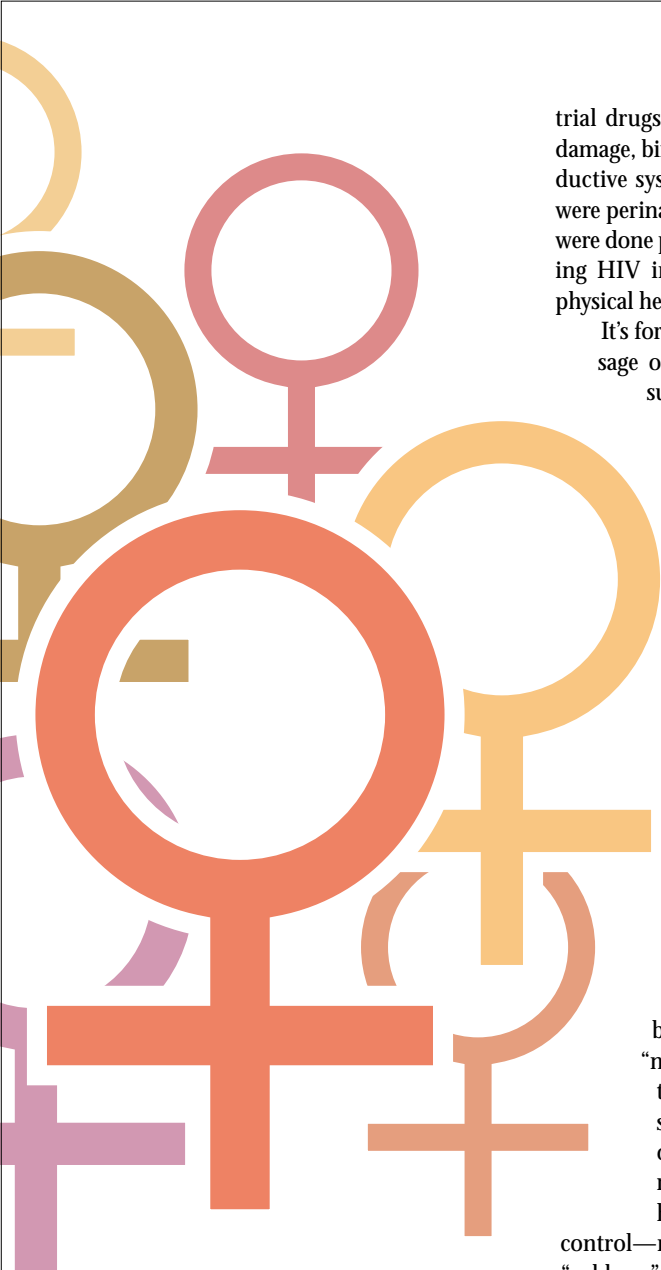
Since the beginning of the AIDS epidemic, women's HIV care has been largely determined by the same factors that have affected all our healthcare needs: getting info and medical care that's appropriate for our "not-man" bodies, but which does not focus solely on our ability to make babies. HIV infection and disease are no exception. On one hand, there's Treatment: Women are still largely unable to find straight answers to gender-specific medication concerns, and researchers have yet to

prioritize the studies that would fill this knowledge gap. While we are all relieved that the risk of perinatal transmission has been so dramatically reduced, too many questions remain unanswered for nonpregnant women.

On the other hand, there's Prevention: Millions of women at risk for HIV infection have no reliable protection method that doesn't require partner cooperation... something the majority of the world's women can't count on. Add to this the fact that both

male and female condoms, when used properly, also keep women from becoming pregnant—which is great if a pregnancy isn't wanted, but not when it is.

Year 2000 saw one major victory on the Treatment Front (passage of the Clinical Hold Rule) and increased activity on the Prevention Front (microbicide research activism). There's still tons of work to be done, but for right now let's take our hats off to the activists involved in this progress—you deserve cake, and so much more!



trial drugs were later found to cause fetal damage, birth defects, or harm to the reproductive system. The exceptions, of course, were perinatal transmission trials. But those were done primarily for the benefit of reducing HIV infection in infants, not for the physical health benefit of women.

It's for these reasons that the FDA's passage of the Clinical Hold Rule in the summer of 2000 is one of the biggest recent activist victories for HIV-positive women. In short, the Clinical Hold Rule allows the FDA to delay or suspend any clinical trial that's found to be excluding women (or men) because of its "reproductive potential." Therefore, passage of the Clinical Hold Rule dramatically increases the opportunity for women with HIV and other potentially life-threatening conditions to take advantage of drug trials and other treatment research.

Prevention: Microbicides

Us vaginal people think it'd be great if we could all enforce the "no glove/no love" rule every single time, but very few of us can (and some of us don't want to). Some of our penile friends have also realized that it'd be kinda cool to have other options for infection control—mainly something a little less "rubbery." Wouldn't it be great if there was some kind of...I dunno...cream or gel we could put on or in ourselves to protect us from HIV and bacterial infections? Something we could carry around discreetly, and apply before sex...something we could control ourselves, without discussion or hassle from a partner?

Something like...microbicides?

Fortunately, activists are working hard to get microbicides some of the attention—and funding—they so richly deserve. Advocates from organizations such as the International Center for Research on Women (ICRW), Alliance for Microbicide Development (AMD), and the Center for Health and Gender Equality (CHANGE) have already laid the groundwork for coordinated efforts to get microbicides some fed-

eral and institutional money. Microbicide activists like Anna Forbes, Polly Harrison, Megan Gottemoeller and Lori Heise have been educating the public and private sectors about the amazing potential inherent in the products microbicide researchers and developers such as Anne-Marie Corner, Deborah Anderson, Julie McGrath, Zeda Rosenberg and Sharon Hillier are trying to get made, tested, and available.

If you want to join in microbicide activism yourself:

(1) Call your state representative and/or senator and encourage them to support the **Microbicides Development Act of 2000**. This bill seeks to increase the National Institutes of Health (NIH) funding for microbicide research from its current \$25 million/year level to \$50 million in 2001, \$75 million in 2002, and \$100 million in 2003. To reach your senator or state rep, call 800-648-3516.

(2) **The Global Campaign for STI/HIV Prevention Alternatives** has put together an Activist Packet for anyone interested in raising microbicide awareness and furthering the fight for microbicide research funding. Anyone who wants to join this activist effort can get more information, sign a petition, or obtain educational materials about microbicides by calling 301-270-1182 or checking out the Gender Health website at <http://www.genderhealth.org>

Much as we're all happy about the advances in perinatal transmission protection, we need care above and beyond what affects our potential offspring. We need to know more about how women's HAART experience differs from men's, and how to get the most from all our meds. We need protection methods that are under OUR control, not reliant upon our ability to convince a partner to "do the right thing." And we need a safe way to try for a pregnancy when we would otherwise not risk baby-making.

That's not too much to ask. So let's make it happen. ☛

Microbicide information was taken largely from POZ articles "The Jelly Revolution" (3/2000, Deb Schwartz) and "Micro Money" (11/2000, Anna Forbes). Both these women do amazing work—thank you, Deb and Anna!

Laura Jones is a sexual health activist and teacher, and is also a counselor for the Illinois AIDS/HIV & STD Hotline, operated by TPAN.

Treatment: Clinical Hold Rule

Currently, women comprise only about 9% to 20% of all clinical trial participants—a shockingly small number, given the obvious need for gender-specific clinical information. But even more upsetting is the main reason why the number of female trial participants is so low: until very recently, *women who could possibly become pregnant could be (and were) legally barred from participating in clinical research trials*. Although women were present among the earliest cases in the AIDS epidemic, the available trials from the early 1980's until now have largely excluded female participants "of childbearing potential"—primarily out of fear that women would sue pharmaceutical companies if the

Five Steps to Effective AIDS Advocacy

And Why Getting Involved Can Make All the Difference

By Sara Schmitt

You have programs to run, presentations to make, and condoms to distribute. The volunteer program needs attention and a grant proposal is due. Considering all you do in the fight against AIDS, AIDS public policy may seem complicated, far removed from your client's lives or better left to the AIDS advocates and lobbyists. What difference could your voice make in the political arena?

One voice, *yours*, is a powerful force. History shows us that individual activism is a powerful force for change—just think of the enormous social and political contributions made by Rosa Parks, Harvey Milk, and Ryan White, to name just a few. In ways large and small, individuals have countless opportunities to make a difference, a lesson aptly illustrated by the recent presidential election. As President Clinton said, “No American will ever be able to seriously say again, ‘My vote doesn’t count.’”

Individuals concerned about and affected by HIV/AIDS have a critical role to play in shaping America's response to the epidemic. Public funding for HIV/AIDS programs and services is increasingly insecure. Meanwhile, the need for such programs continues to grow as the number of people living with HIV—or at high risk for infection—expands relentlessly. Lawmakers need to be informed about the realities of HIV/AIDS and the challenges it is creating in the communities they represent.

AIDS advocacy may seem complicated, but getting involved can be easy, fun, and rewarding. With a little effort, you can benefit the communities you serve by facilitating policies and laws that help stop the spread of HIV and prevent discrimination against HIV-positive people.

based AIDS Action Council at (212) 986-1300 or www.aidsaction.org, and the San Francisco-based Project Inform at (415) 558-8669 or www.projectinform.org. These organizations provide members with regular news on pressing AIDS advocacy issues, as well as information on quick and effective ways to make a difference. As an affiliate, you can focus on your daily tasks, yet stay informed on current issues and ways to promote sound AIDS public policy.

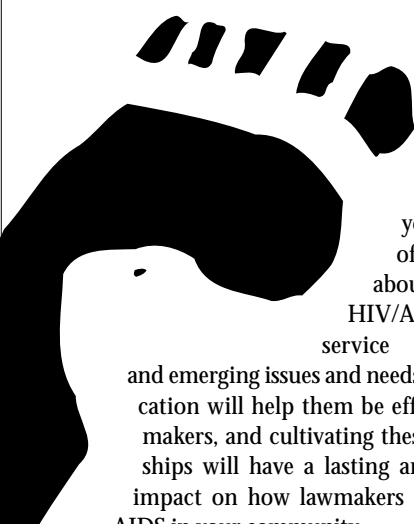
The next step is to know your elected officials

Most AIDS advocacy organizations will gladly help you identify your representatives in Congress, the state legislature, and city hall. In most states, the board of elections, secretary of state's office, and/or county clerk's office have information on state legislators and city council officials, or check out AIDS Action's website. Identify your district's elected officials and the people who represent the AIDS organizations you are affiliated with.

The first step to AIDS advocacy is information

Groups in Washington, DC and in every state monitor Congress, state legislatures, and other government offices on HIV-related issues. By joining one of these groups, you can keep up to date on national, state, and local AIDS advocacy issues. Most groups offer their services free of charge and registration is simple. If your agency is located in Illinois, call the AIDS Foundation of Chicago at (312) 922-2322 or visit their website at www.aidschicago.org. Outside of Illinois, contact the DC-

Individuals concerned about and affected by HIV/AIDS have a critical role to play in shaping America's response to the epidemic.



Talk to your elected officials about

HIV/AIDS, local service providers, and emerging issues and needs. This education will help them be effective lawmakers, and cultivating these relationships will have a lasting and positive impact on how lawmakers respond to AIDS in your community.

The third step: Take action

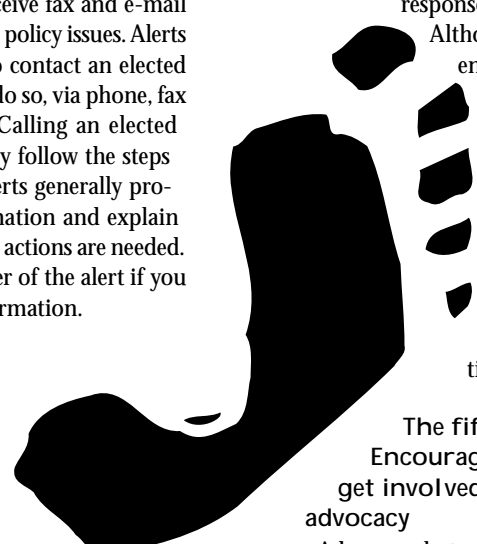
Once you are affiliated with AIDS advocacy groups, you will receive fax and e-mail "alerts" on pressing AIDS policy issues. Alerts generally instruct you to contact an elected official, and you should do so, via phone, fax or email, immediately. Calling an elected official is painless: simply follow the steps outlined in the alert. Alerts generally provide background information and explain what and why the certain actions are needed. Always contact the sender of the alert if you need any additional information.

The fourth step: Involve those organizations with whom you are affiliated

On important issues, contact your agency's legislators as well as those in your home district.

When you call, tell the person on the phone who you are and why this issue is important to your community—lawmakers want to know how these issues will impact their constituents. Remind co-workers and clients they will not be quizzed on the phone about the issue, nor will they be asked about their HIV status. Generally the person answering the phone will note your comment and may ask for your name and address in order

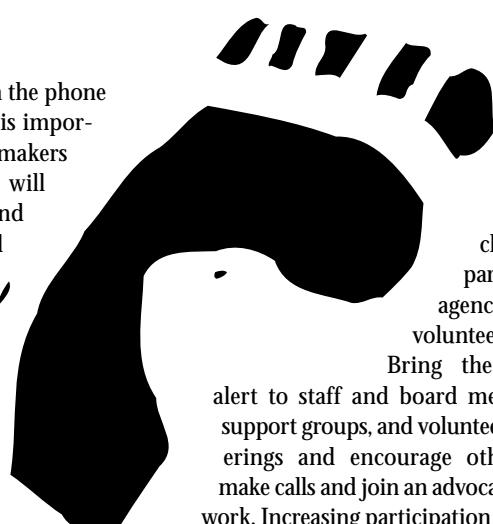
to send you a response.



Although the entire process rarely lasts five minutes, these simple efforts help produce better policies and programs for HIV-positive individuals.

The fifth step: Encourage others to get involved in AIDS advocacy

Advocacy alerts can be useful tools in your local efforts to fight AIDS. Share AIDS advocacy information with friends,



clients, partner agencies and volunteers.

Bring the latest alert to staff and board meetings, support groups, and volunteer gatherings and encourage others to make calls and join an advocacy network. Increasing participation among staff and clients in your agencies will make your advocacy efforts more effective, and will show legislators the strength and number of those concerned about the epidemic. If contacting elected officials seems daunting, remember that public officials were elected to serve constituents just like you. Once you've made some calls, you'll find that most officials appreciate hearing from their constituents. Thank you letters for a job well done also helps improve and strengthen a commitment to our cause.

Getting involved in HIV/AIDS public policy advocacy is as easy as joining a network and making some phone calls—things you do all the time, already. With a little time and effort, you will make a huge difference.



Sara Schmitt is the statewide advocacy network coordinator for the AIDS Foundation of Chicago.

Pickett Fences

Slip Sliding Away

by Jim Pickett

A couple months ago I attended the U.S. Conference on AIDS in Atlanta with over 3,000 other members of royalty known as AIDS, Inc. It was another highlight in my never-ending quest to achieve the rapture—AIDS starlet-dom.

And it was hot. There were hordes of AIDS activists and advocates, educators and prevention specialists, front line workers, policy wonks and administrators. And tons of gorgeous, beautiful men. Gorgeous, beautiful gay men, sexy HIV-infected men, delicious AIDS-ridden men—everywhere, crawling out the woodwork and swinging out from the chandeliers, and many on the make. Including me.

Recently un-partnered, it was exciting to be horny amidst this randy group, where HIV status was no big deal and would send no one fleeing for the exits. So I worked my voodoo at the opening night function held at City Hall, and met up with a lovely long distance runner and prevention worker from Houston.

While decidedly not being impressed with the food, I bump into him in a chow-line. Somehow we just start talking, and somehow I'm saying witty, bright, and clever things, or so he, and the wine, leads me to believe. He laughs easily, giggly like a little boy, huge smile, crinkly eyes, energy just pouring out of his small frame. He's delightful, and he has AIDS, and I am smitten.

I pay him a visit in his room that night. On his wisp of a balcony he shares a joint he's smoking in preparation for his nauseating meds. We get high and silly, he medicates, we get naked and roll around the bed. His body is perfect—long distance running

clearly does very good things. Somehow I don't feel intimidated with my carcass, one that only runs for the train, next to his... and on top of his, beneath his.

Soon we're in position. He wants to fuck me, I want him to fuck me.

His dick is pushing at my ass, and it goes in for a hot second, just a little bit. He doesn't have a rubber on, and for a hot second,

It was exciting to be horny amidst this randy group, where HIV status was no big deal and would send no one fleeing for the exits.

an interminably long, hot second I want to do it just that way. I want to feel his naked dick all the way inside me.

In the same second—like I said it was very long—I think about these 6 things concurrently, in no order:

1. Here we are, two boys working it for AIDS Inc., both “specializing in prevention,” at the U.S. Fucking Conference on AIDS, and we're about to have “unsafe sex.” We're gonna “bareback.”

2. But, so? We're both already infected.

3. So? But we may have different strains.

4. So? He has AIDS and I don't yet.

5. So? We've both done a lot of meds—I don't wanna be resistant to his before I even use them, I don't want that possibility for him.

6. But God it feels good, God it's gonna feel good. God I wanna do it.

And we do...with a condom. The second passes, I ask, and he doesn't hesitate. He's got plenty lying around—so many free samples doncha know—and when it's on, and he's in me, it's incredible.

Looking back I kind of freaked out that I had come so close to doing the verboten. I was simply caught up in the moment. My fears that surface with negative men were simply not there. And it wasn't just the fear of harming somebody, infecting somebody with this awful crap, that was missing. It was somehow the fear of judgment also. Mine, and his. Its absence, and the lack of shame, was as tangible and fulfilling as his body in mine. I didn't feel dirty and diseased and unworthy with him—I did feel the deep, unspoken understanding we have from being in a war together. We're different in many ways, but there, in his Hyatt king-sized, we were equals.

Upon returning to Chicago, I decided to finally catch the wave and put a profile on AOL to chase boys around the schoolyard and chat rooms with. I wanted to meet boys and not have to drink five slushies to do it. I had always made wicked, condescending fun of people who click-clicked for dick, and now I was gonna be one of them. If you can't beat 'em, fuck 'em.

In my profile, I have made it very clear that I am HIV-positive, and consequently, many other positive men have responded. And to my rather naive surprise, I discovered that most want to have sex without latex. They're looking for other positives expressly for that purpose.

Even though I like to think I was never one to demonize the so-called “barebackers,”



it again kind of freaked me out. It felt naughty, it felt wrong, and I was not comfortable doing something that has been pounded into me as being a deadly sin. I was not going to do the thing that got me here in the first place.

But guess what? I did. I have recently succumbed to temptation with two different positive men, and fucked, and got fucked, without a condom. And I loved it. And I'm gonna do it again.

My two boundaries are—never doing this with a negative man, and no one coming inside anyone else—other than that, with me and another consenting positive man, it's slip sliding away. While many will justify this behavior by proclaiming it's a way to be more connected with the person, to be more intimate, to share in some deep spirituality, I say no such thing. Being intimate with someone has nothing to do with or without a latex barrier. This condom-free zone is about the physical feeling for me, not about falling in love for a second or forever, but about the wonderful way it feels. And yes, though we are encouraged not to say so, it feels fantastic and liberated to fuck without a condom—plain and simple. It is hotter, and juicier, and let's face it, more natural. The act is not so much about brotherhood for me as

it is about animal.

Condoms suck—I think we need to say that. Many of us feel that way, and many of us, both positive and negative, in fact, don't use them on a regular basis, though we're not likely to talk too loudly about it. Until we have effective microbicides, condoms are what we are left with to protect ourselves when it comes to fucking. We need to be honest about why we do and don't use them, and we need to push for other methods of prevention so we can have the natural, animal sex we all want to have (and do) and still contain, and halt, the epidemic.

The epidemic will never end unless we are very clear and communicate about what we like and don't like, and what our actual behaviors are, not what they "should" be. ☞☜

Condoms suck—I think we need to say that. Many of us feel that way, and many of us, both positive and negative, in fact, don't use them on a regular basis.

Drug Holidays & Lipodystrophy: Ongoing Controversies and Research

By Daniel S. Berger, MD

This is the first installment of “The Buzz”, a column that is scheduled to appear in every issue of *Positively Aware*. I hope to provide our readers with an inside perspective on treatment issues and community concerns that are at times controversial, and commentary on topics being whispered or bandied about by clinicians, researchers or industry. I’d like to thank the editors, Charles Clifton and Enid Vázquez for asking me to contribute in this way and becoming part of the *Positively Aware* family and staff.

A “treatment interruptions think tank” recently took place, as 80 researchers from around the world gathered in Chicago. Martin Delaney, founder and executive director of Project Inform (San Francisco), remarked that a major consensus emerged among the attendees, which included many conservatives and old hat researchers. What Martin has been saying for years, most now seem to agree upon—that “life-long treatment with antivirals is not a viable option.” While current treatments have been life saving measures for HIV-positive individuals, it is time for researchers to focus more attention on addressing the drug side effects and toxicities. As an approach to long-term treatment, perhaps treatment interruptions may be part of the solution for patients having to deal with these concerns.

Another issue discussed at this meeting was “reversal of resistance,” which may be accomplished through treatment interruption. Wild type virus, the viral population

that is usually present during initial infection with HIV, is stronger and usually dominates over the presence of resistant virus. To invoke the emergence of wild type virus, HIV drug therapy may be placed on hold. As wild type begins to replicate it keeps down resistant strains. This method is now increasingly being investigated.

One example of how reversal of resistance occurs in practice is demonstrated with an anecdotal report. One of my new patients, who came in from another clinic, had viral loads approaching 7 million copies (one of the highest that I’ve ever seen) despite taking a “kitchen sink” regimen of five antivirals including T-20, a fusion inhibitor, and one of the newest treatment breakthroughs. I stopped all the antiviral medications and placed the client on a six-month strategic treatment interruption (drug holiday). Since restarting treatment with a new drug regimen, the client’s viral load has dropped to very low levels and CD4+ T-cells have tripled. This probably occurred because wild type virus recurred and suppressed the resistant HIV strains. This approach to treatment is investigative. Many safety questions regarding this approach remain unanswered, and individuals should not attempt this without physician guidance.

While Martin tells me not to call these interruptions “drug holidays,” *holiday* seems to be the “buzz” in the field. And it is increasingly clear that many clients are interested in alternatives to treatment that involve interruptions or holidays. While there remains much uncertainty, if an individual is faced

with the pressures of treatment toxicity or multiple failures due to drug resistance, drug holiday or strategic treatment interruption should be on the table as a viable option.

While attending the International Workshop on Lipodystrophy in Toronto, September 2000, it was refreshing to observe more progress in this area. Two institutions presented groundbreaking research regarding genetically engineered rat models of lipodystrophy. The Department of Molecular Genetics, University of Texas at Southwestern Medical Center has genetically engineered mice that are deficient in fat, similar in many ways to the HIV patients who demonstrate lipodystrophy. The NIH Diabetes Branch has also genetically developed a mouse model that lacks various types of adipose (fat) tissue. Because these mice have a high tendency to develop insulin resistance and diabetes, the researchers conclude that it is the lack of fat that results in various metabolic abnormalities that occur with lipodystrophy. Many HIV impacted individuals have lipoatrophy, a condition that refers to a loss of fat from the face, buttocks, and/or extremities. With these fat-redistribution changes, these individuals often have diabetic symptoms as well as elevated cholesterol or triglycerides. Having an animal model to study lipodystrophy should improve our knowledge and lead to further developments in this field.

What drives scientific research at competitive pharmaceutical companies?

During the International Workshop on Lipodystrophy, Jim Lenhard's group, from the diabetes branch of research at Glaxo-Wellcome, presented results from a recent study. The researchers examined the effects of antioxidant vitamins on metabolic aberrations that occur after treatment with nucleoside reverse transcriptase inhibitors (NRTI, or nukes). In this study mice were the research subjects. The immune competent (HIV-negative) mice were treated with nukes, Retrovir (AZT) or Zerit (d4T) given at 5mg/kg (lower dose) or Zerit at a much higher dose of 50 mg/kg. This resulted in the mice developing many of the metabolic changes associated with lipodystrophy, seen in HIV-treated patients. The abnormalities included elevated lactic acid and lipid levels, as well as increased liver weight. The Zerit treated animals (although at very high doses), developed greater metabolic abnormalities. Subsequently these same study mice were then treated with ascorbate (vitamin C) and tocopherol (vitamin E), which then reversed many of the objective changes. The reversal of metabolic complications of nucleosides by anti-oxidant vitamins holds many implications for further research.

However, during the presentation, many in the largely scientific audience ques-

tioned the possibility of marketing bias in the design of the study, since Zerit is a competitor of Glaxo's product, Retrovir. The mice were indeed treated with higher doses of Zerit than their Retrovir counterparts. The "buzz" included cynicism in regards to the design of the study. However, after dis-

...if an individual is faced with pressures of treatment toxicity or multiple failures...drug holiday or strategic treatment interruption should be on the table as a viable option.

cussing the results with Dr. Lenhard, he claimed that the focus of the study was not to place Retrovir against Zerit, but to examine the effects of the vitamins on oxidative stress. Toxicology studies with animals traditionally involve the administration at much higher doses, Lenhard stated, since they metabolize drugs more quickly than humans do. It was crucial to realize the metabolic toxicities of the nucleosides, in order to enable testing the effects of antioxidants against those toxicities.

Finally, a word of caution: while the results show that antioxidant vitamins can potentially be helpful, one should not overstate the conclusions of this study and

attempt to take high doses of antioxidants without discussion and supervision by one's physician. Normal doses of vitamin C are okay and high doses are rarely toxic, however high doses of vitamin E can be toxic—and should not be used as a supplement by people taking Agenerase. While the results of this study are interesting and positive, one should not assume that these effects would be reproducible in HIV-positive humans. Further studies at GlaxoWellcome are being planned.

On the local news front in Chicago, continuing a trend of all too frequent big business takeovers, Advocate Healthcare has assumed control of Illinois Masonic Medical Center. Illinois Masonic was the first hospital in the Chicago area to have a dedicated HIV unit and has long been a pillar of in-patient hospital care for the community. It is a place where HIV-positive patients that needed hospitalization could always depend on for the highest quality care. While many ensuing changes are sure to occur, we hope the quality of care continues. ☸

Daniel S. Berger, MD is Medical Director for NorthStar Medical Center, Clinical Assistant Professor of Medicine at the University of Illinois at Chicago and editor of AIDS Infosource (www.aidsinfosource.com). Of recent, he is a medical consultant for Positively Aware.

Positively Aware 2000 Index

Compiled by Jeff Berry

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TPAN Calendar of Events

January 2001

All events are held at TPAN offices unless otherwise indicated.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	New Years Day Office Closed					
	1	2	3	4	5	6
gam Sunrise AA						
7	8	9	10	11	12	13
gam Sunrise AA	M L King Day Office Closed	7 pm TPAN Board of Directors Meeting; TPAN Members invited				
14	15	16	17	18	19	20
gam Sunrise AA		6:30 pm * HIV Treatment Update at Woodson Regional Library, sponsored by GlaxoWellcome				
21	22	23	24	25	26	27
gam Sunrise AA						
28	29	30	31			

* For additional information on these events please contact Keith Waltrip, Program Director at (773) 404-8726.

February 2001

All events are held at TPAN offices unless otherwise indicated.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
				* Fireball Gala, Sponsored by Hearts Foundation		
				1	2	3
8th Annual Conference on Retroviruses and Opportunistic Infections, Chicago. 4th-8th For registration: www.retroconference.org						
9am Sunrise AA						
4	5	6	7	8	9	10
9am Sunrise AA		5 pm Clinical Trial Update with AIDS Research Alliance			* Fireball Weekend 16th, 17th, 18th Sponsored by Hearts Foundation; volunteers needed www.fireball.com	
11	12	13	14	15	16	17
* Fireball Weekend		7 pm TPAN Board of Directors Meeting; TPAN members invited		6:30 pm Retrovirus Conference update with Forum Advisory Council		
9am Sunrise AA						
18	19	20	21	22	23	24
9am Sunrise AA			9 am * HIV Prevention Planning Group (HPPG) at the Chicago Bar Association			
25	26	27	28			

* For additional information on these events please contact Keith Waltrip, Program Director at (773) 404-8726.

Programs and Meetings

All meetings held at TPAN offices unless otherwise indicated: 1258 W. Belmont Ave., Chicago.
Office hours: Monday–Thursday, 9 am–8 pm. Friday, 9 am–6 pm
phone: (773) 404-TPAN • fax: (773) 404-1040 • e-mail: tpanet@aol.com • www.tpan.com

Discussion and Support Groups (Call 773-404-8726)

Beyond Basics: Getting on with Life

A group for those who have lived with HIV for several years. Thursdays at 7:30 pm.

Brothers United in Support (BUS)

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

Chicago Help

A group for those infected with an STD or their partner. Focus on education, support, and resources. Second Thursday at 7:00 pm. Call Chicago Help (773) 660-0416.

Family AIDS Support Network (FASN)

A group for family, friends, and caregivers. Call Betty Stern at (773) 404-1038.

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.

Newly Diagnosed

A group for newly diagnosed individuals. Mondays at 7:30 pm.

Negative Partners

The Negative Partners of Positive People group meets every 2nd and 4th Tuesday at 7:30 pm. The group is dedicated to helping those who are dealing with issues surrounding the HIV positive status of their significant other as well as their own HIV-negative status.

Positive Progress

A group for HIV positive people in recovery. Tuesdays at 7:30 pm.

Straight Talk

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

TPAN Daytimers

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

transDiva

transDiva is a transgender “safe space” for youth and young adults (ages 13–24) to get together and discuss issues important to them. Fridays 5:00 pm–9:00 pm.

transGenesis

A group for HIV-affected transgender individuals. Mondays at 6:00 pm.

T.R.I.B.E.

An educational discussion group for Gay Men of Color focused on maintaining a healthy lifestyle. 2nd and 4th Monday at 7:00 pm.

Women’s Group

A group for HIV positive women. Women supporting each other in dealing with HIV and overcoming other issues. Created for positive women by positive women. Call Sylvia for more information.

Health and Fitness

Medical Clinic

Free medical care provided by a physician’s assistant. 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. Fridays 2:00 pm–5:00 pm.

Needle Exchange Program

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

Wellness Wednesday

Free alternative therapies (massage, Reiki, Shiatsu, Structural therapy). This program is offered by AIDSCare. Wednesdays 12:00 pm–3:00 pm. Call for an appointment.

Yoga

Wednesdays at 7:30 pm.

Resources

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 or Keith.

Chris Clason Resource Center

Find the latest news in the Chris Clason Resource Center. Open Monday through Thursday 9:00 am–8:00 pm., Friday 9:00 am–6:00 pm.

Social

Berlin HIV positive Social Hour

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

Buddy Programs

Peer Support Network

Provides one-on-one support for recently diagnosed individuals. Volunteers provide support, information and referrals. Call Angelo to get a buddy!

Positive Buddy

Provides individuals living with HIV/AIDS one-on-one emotional/physical support. Volunteers provide the support that each HIV positive individual has often lost. Call Angelo to get a buddy!

Legal issues

HIV-Related Legal Clinic

First and third Thursdays, 4:00–6:00 pm at 1258 W. Belmont Ave.; second and fourth Wednesdays, 2:30–4:30 pm at 310 South Michigan Ave.; by appointment only. Call Katy at (773) 404-8726.

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