



**POSITIVELY AWARE**  
HIV Treatment and Health

**YOU'RE GETTING  
OLDER & BETTER!**

## **AGING WITH HIV**

**PLUS:**

**HOW TO HAVE STRONGER,  
HEALTHIER BONES**

**JULES LEVIN ON  
HIV-AGING RESEARCH**

**CROI 2009**

HIV treatment advocate  
**Nelson Vergel**  
"Going Beyond Survival"

MAY / JUNE 2009  
THE JOURNAL OF TEST POSITIVE AWARE NETWORK

## IMPORTANT INFORMATION ABOUT REYATAZ® (atazanavir sulfate)

**INDICATION:** REYATAZ is a prescription medicine used in combination with other medicines to treat people who are infected with the human immunodeficiency virus (HIV). REYATAZ has been studied in 48-week trials in both patients who have taken or have never taken anti-HIV medicines.

**REYATAZ does not cure HIV or help prevent passing HIV to others.**

### IMPORTANT SAFETY INFORMATION:

**Do not take REYATAZ if you are allergic to REYATAZ or to any of its ingredients.**

**Do not take REYATAZ if you are taking the following medicines:** rifampin, Camptosar® (irinotecan), Versed® (midazolam) when taken by mouth, Halcion® (triazolam), ergot medicines, Propulsid® (cisapride), St. John's wort (*Hypericum perforatum*), Mevacor® (lovastatin), Zocor® (simvastatin), Orap® (pimozide), Crixivan® (indinavir), or Viramune® (nevirapine).

**Speak with your healthcare provider before taking the following medicines if you are taking REYATAZ:** hormonal contraceptives such as birth control pills or contraceptive patch, Viagra® (sildenafil), Levitra® (vardenafil), Cialis® (tadalafil), Vfend® (voriconazole), AcipHex® (rabeprazole), Nexium® (esomeprazole), Prevacid® (lansoprazole), Prilosec® (omeprazole), Protonix® (pantoprazole), Axid® (nizatidine), Pepcid AC® (famotidine), Tagamet® (cimetidine), or Zantac® (ranitidine), Advair® (fluticasone propionate and salmeterol inhalation powder), Flonase® or Flovent® (fluticasone propionate), or Sustiva® (efavirenz).

**The above lists of medicines are not complete. Discuss all prescription and non-prescription medicines, vitamin and herbal supplements, or other health preparations you are taking or plan to take with your healthcare provider.**

Tell your healthcare provider right away if you have any side effects, symptoms, or conditions, including the following:

- **Mild rash** (redness and itching) without other symptoms sometimes occurs in patients taking REYATAZ, most often in the first few weeks after the medicine is started, and usually goes away within two weeks with no change in treatment.
- **Severe rash** has occurred in a small number of patients taking REYATAZ. This type of rash is associated with other symptoms which could be serious and potentially cause death. **If you develop a rash with any of the following symptoms, stop using REYATAZ and call your healthcare provider right away:**
  - Shortness of breath
  - General ill-feeling or “flu-like” symptoms
  - Fever
  - Muscle or joint aches
  - Conjunctivitis (red or inflamed eyes, like “pink-eye”)
  - Blisters
  - Mouth sores
  - Swelling of your face
- **Yellowing of the skin and/or eyes** may occur due to increases in bilirubin levels in the blood (bilirubin is made by the liver).
- **A change in the way your heart beats** may occur and could be a symptom of a heart problem.
- **Diabetes and high blood sugar** may occur in patients taking protease inhibitor medicines like REYATAZ.
- **If you have liver disease**, including hepatitis B or C, your liver disease may get worse when you take anti-HIV medicines like REYATAZ.
- **Kidney stones** have been reported in patients taking REYATAZ. Signs or symptoms of kidney stones include pain in your side, blood in your urine, and pain when you urinate.
- **End stage kidney disease** managed with hemodialysis.
- **Some patients with hemophilia** have increased bleeding problems with protease inhibitor medicines like REYATAZ.
- **Changes in body fat** have been seen in some patients taking anti-HIV medicines. The cause and long-term effects are not known at this time.

**Other side effects** of REYATAZ taken with other anti-HIV medicines include: nausea, headache, stomach pain, vomiting, diarrhea, depression, fever, dizziness, trouble sleeping, numbness, and tingling or burning of hands or feet.

You should take REYATAZ once daily with food (a meal or snack). You should take REYATAZ and your other anti-HIV medicines exactly as instructed by your healthcare provider.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

# On REYATAZ,

Wednesday  
Mary's  
birthday  
party

Thursday  
5:30  
Choir  
practice

Buy new  
shoes  
for Latisha

  
**REYATAZ**®  
(atazanavir sulfate) 200 mg/300 mg capsules  
Fight HIV your way.

Please see Important Patient Information about REYATAZ on the adjacent pages.

# how you spend your time is up to you.



Individual results may vary.

## Once-daily REYATAZ can help fight your HIV.

### REYATAZ, a protease inhibitor (PI), in HIV combination therapy:

- ◆ Can help lower your viral load and raise your T-cell (CD4+cell) count
- ◆ Has a low chance of diarrhea (shown in clinical trials)\*
- ◆ Is taken once a day with a snack or meal

\* REYATAZ in combination therapy had a 1%-3% rate of moderate-to-severe diarrhea.

REYATAZ is one of several treatment options your doctor may consider.

Ask your healthcare team about REYATAZ [www.REYATAZ.com](http://www.REYATAZ.com)

REYATAZ does not cure HIV, a serious disease, and has not been shown to reduce the risk of passing HIV to others.

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Prescription Assistance

## FDA-Approved Patient Labeling Patient Information

Rx ONLY

**REYATAZ**® (RAY-ah-taz)  
(generic name = **atazanavir sulfate**)  
**Capsules**

**ALERT: Find out about medicines that should NOT be taken with REYATAZ (atazanavir sulfate).** Read the section “What important information should I know about taking REYATAZ with other medicines?”

Read the Patient Information that comes with REYATAZ before you start using it and each time you get a refill. There may be new information. This leaflet provides a summary about REYATAZ and does not include everything there is to know about your medicine. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

### What is REYATAZ?

REYATAZ is a prescription medicine used with other anti-HIV medicines to treat people who are infected with the human immunodeficiency virus (HIV). HIV is the virus that causes acquired immune deficiency syndrome (AIDS). REYATAZ is a type of anti-HIV medicine called a protease inhibitor. HIV infection destroys CD4+ (T) cells, which are important to the immune system. The immune system helps fight infection. After a large number of (T) cells are destroyed, AIDS develops. REYATAZ helps to block HIV protease, an enzyme that is needed for the HIV virus to multiply. REYATAZ may lower the amount of HIV in your blood, help your body keep its supply of CD4+ (T) cells, and reduce the risk of death and illness associated with HIV.

### Does REYATAZ cure HIV or AIDS?

**REYATAZ does not cure HIV infection or AIDS.** At present there is no cure for HIV infection. People taking REYATAZ may still get opportunistic infections or other conditions that happen with HIV infection. Opportunistic infections are infections that develop because the immune system is weak. Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium* complex (MAC) infections. **It is very important that you see your healthcare provider regularly while taking REYATAZ.**

**REYATAZ does not lower your chance of passing HIV to other people through sexual contact, sharing needles, or being exposed to your blood.** For your health and the health of others, it is important to always practice safer sex by using a latex or polyurethane condom or other barrier to lower the chance of sexual contact with semen, vaginal secretions, or blood. Never use or share dirty needles.

### Who should not take REYATAZ?

#### Do not take REYATAZ if you:

- **are taking certain medicines.** (See “What important information should I know about taking REYATAZ with other medicines?”) Serious life-threatening side effects or death may happen. Before you take REYATAZ, tell your healthcare provider about all medicines you are taking or planning to take. These include other prescription and nonprescription medicines, vitamins, and herbal supplements.
- **are allergic to REYATAZ or to any of its ingredients.** The active ingredient is atazanavir sulfate. See the end of this leaflet for a complete list of ingredients in REYATAZ. Tell your healthcare provider if you think you have had an allergic reaction to any of these ingredients.

### What should I tell my healthcare provider before I take REYATAZ?

#### Tell your healthcare provider:

- **If you are pregnant or planning to become pregnant.** It is not known if REYATAZ can harm your unborn baby. Pregnant women have experienced serious side effects when taking REYATAZ with other HIV medicines called nucleoside analogues. You and your healthcare provider will need to decide if REYATAZ is right for you. If you use REYATAZ while you are pregnant, talk to your healthcare provider about the Antiretroviral Pregnancy Registry.
- **If you are breast-feeding.** You should not breast-feed if you are HIV-positive because of the chance of passing HIV to your baby. Also, it is not known if REYATAZ can pass into your breast milk and if it can harm your baby. If you are a woman who has or will have a baby, talk with your healthcare provider about the best way to feed your baby.
- **If you have liver problems or are infected with the hepatitis B or C virus.** See “What are the possible side effects of REYATAZ?”
- **If you have end stage kidney disease** managed with hemodialysis.
- **If you have diabetes.** See “What are the possible side effects of REYATAZ?”
- **If you have hemophilia.** See “What are the possible side effects of REYATAZ?”
- **About all the medicines you take** including prescription and nonprescription medicines, vitamins, and herbal supplements. Keep a list of your medicines with you to show your healthcare provider. For more information, see “What important information should I know about taking REYATAZ with other medicines?” and “Who should not take REYATAZ?” Some medicines can cause serious side effects if taken with REYATAZ.

### How should I take REYATAZ (atazanavir sulfate)?

- **Take REYATAZ once every day exactly as instructed by your healthcare provider.** Your healthcare provider will prescribe the amount of REYATAZ that is right for you.
  - For adults who have never taken anti-HIV medicines before, the dose is 300 mg once daily with 100 mg of NORVIR® (ritonavir) once daily taken with food. For adults who are unable to tolerate ritonavir, 400 mg (two 200-mg capsules) once daily (without NORVIR®) taken with food is recommended.
  - For adults who have taken anti-HIV medicines in the past, the usual dose is 300 mg plus 100 mg of NORVIR® (ritonavir) once daily taken with food.
- Your dose will depend on your liver function and on the other anti-HIV medicines that you are taking. REYATAZ is always used with other anti-HIV medicines. If you are taking REYATAZ with SUSTIVA® (efavirenz) or with VIREAD® (tenofovir disoproxil fumarate), you should also be taking NORVIR® (ritonavir).
- **Always take REYATAZ with food** (a meal or snack) to help it work better. Swallow the capsules whole. **Do not open the capsules.** Take REYATAZ at the same time each day.
- **If you are taking antacids or didanosine (VIDEX® or VIDEX® EC),** take REYATAZ 2 hours before or 1 hour after these medicines.
- **If you are taking medicines for indigestion, heartburn, or ulcers such as AXID® (nizatidine), PEPCID AC® (famotidine), TAGAMET® (cimetidine), ZANTAC® (ranitidine), AcipHex® (rabeprazole), NEXIUM® (esomeprazole), PREVACID® (lansoprazole), PRILOSEC® (omeprazole), or PROTONIX® (pantoprazole),** talk to your healthcare provider.
- **Do not change your dose or stop taking REYATAZ without first talking with your healthcare provider.** It is important to stay under a healthcare provider’s care while taking REYATAZ.
- **When your supply of REYATAZ starts to run low,** get more from your healthcare provider or pharmacy. It is important not to run out of REYATAZ. The amount of HIV in your blood may increase if the medicine is stopped for even a short time.
- **If you miss a dose of REYATAZ,** take it as soon as possible and then take your next scheduled dose at its regular time. If, however, it is within 6 hours of your next dose, do not take the missed dose. Wait and take the next dose at the regular time. Do not double the next dose. **It is important that you do not miss any doses of REYATAZ or your other anti-HIV medicines.**
- **If you take more than the prescribed dose of REYATAZ,** call your healthcare provider or poison control center right away.

### Can children take REYATAZ?

Dosing recommendations are available for children 6 years of age and older for REYATAZ Capsules. Dosing recommendations are not available for children from 3 months to less than 6 years of age. REYATAZ should not be used in babies under the age of 3 months.

### What are the possible side effects of REYATAZ?

The following list of side effects is **not** complete. Report any new or continuing symptoms to your healthcare provider. If you have questions about side effects, ask your healthcare provider. Your healthcare provider may be able to help you manage these side effects.

### The following side effects have been reported with REYATAZ:

- **mild rash** (redness and itching) without other symptoms sometimes occurs in patients taking REYATAZ, most often in the first few weeks after the medicine is started. Rashes usually go away within 2 weeks with no change in treatment. Tell your healthcare provider if rash occurs.
- **severe rash:** In a small number of patients, a rash can develop that is associated with other symptoms which could be serious and potentially cause death.
  - **If you develop a rash with any of the following symptoms stop using REYATAZ and call your healthcare provider right away:**
    - shortness of breath
    - general ill feeling or “flu-like” symptoms
    - fever
    - muscle or joint aches
    - conjunctivitis (red or inflamed eyes, like “pink eye”)
    - blisters
    - mouth sores
    - swelling of your face

- **yellowing of the skin or eyes.** These effects may be due to increases in bilirubin levels in the blood (bilirubin is made by the liver). Call your healthcare provider if your skin or the white part of your eyes turn yellow. Although these effects may not be damaging to your liver, skin, or eyes, it is important to tell your healthcare provider promptly if they occur.
- **a change in the way your heart beats (heart rhythm change).** Call your healthcare provider right away if you get dizzy or lightheaded. These could be symptoms of a heart problem.
- **diabetes and high blood sugar (hyperglycemia)** sometimes happen in patients taking protease inhibitor medicines like REYATAZ (atazanavir sulfate). Some patients had diabetes before taking protease inhibitors while others did not. Some patients may need changes in their diabetes medicine.
- **if you have liver disease** including hepatitis B or C, your liver disease may get worse when you take anti-HIV medicines like REYATAZ.
- **kidney stones** have been reported in patients taking REYATAZ. If you develop signs or symptoms of kidney stones (pain in your side, blood in your urine, pain when you urinate) tell your healthcare provider promptly.
- **some patients with hemophilia** have increased bleeding problems with protease inhibitors like REYATAZ.
- **changes in body fat.** These changes may include an increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these conditions are not known at this time.

Other common side effects of REYATAZ taken with other anti-HIV medicines include nausea; headache; stomach pain; vomiting; diarrhea; depression; fever; dizziness; trouble sleeping; numbness, tingling, or burning of hands or feet; and muscle pain.

**Gallbladder disorders** (which may include gallstones and gallbladder inflammation) have been reported in patients taking REYATAZ.

**What important information should I know about taking REYATAZ with other medicines?**

**Do not take REYATAZ if you take the following medicines (not all brands may be listed; tell your healthcare provider about all the medicines you take). REYATAZ may cause serious, life-threatening side effects or death when used with these medicines.**

- Ergot medicines: dihydroergotamine, ergonovine, ergotamine, and methylergonovine such as CAFERGOT®, MIGRANAL®, D.H.E. 45®, ergotrate maleate, METHERGINE®, and others (used for migraine headaches).
- ORAP® (pimozide, used for Tourette's disorder).
- PROPULSID® (cisapride, used for certain stomach problems).
- Triazolam, also known as HALCION® (used for insomnia).
- Midazolam, also known as VERSED® (used for sedation), when taken by mouth.

**Do not take the following medicines with REYATAZ because of possible serious side effects:**

- CAMPTOSAR® (irinotecan, used for cancer).
- CRIVIVAN® (indinavir, used for HIV infection). Both REYATAZ and CRIVIVAN sometimes cause increased levels of bilirubin in the blood.
- Cholesterol-lowering medicines MEVACOR® (lovastatin) or ZOCOR® (simvastatin).

**Do not take the following medicines with REYATAZ because they may lower the amount of REYATAZ in your blood.** This may lead to an increased HIV viral load. Resistance to REYATAZ or cross-resistance to other HIV medicines may develop:

- Rifampin (also known as RIMACTANE®, RIFADIN®, RIFATER®, or RIFAMATE®, used for tuberculosis).
- St. John's wort (*Hypericum perforatum*), an herbal product sold as a dietary supplement, or products containing St. John's wort.
- VIRAMUNE® (nevirapine, used for HIV infection).

**Do not take the following medicine if you are taking REYATAZ and NORVIR® together:**

- VFEND® (voriconazole).

**The following medicines may require your healthcare provider to monitor your therapy more closely:**

- CIALIS® (tadalafil), LEVITRA® (vardenafil), or VIAGRA® (sildenafil). REYATAZ may increase the chances of serious side effects that can happen with CIALIS, LEVITRA, or VIAGRA. Do not use CIALIS, LEVITRA, or VIAGRA while you are taking REYATAZ unless your healthcare provider tells you it is okay.
- LIPITOR® (atorvastatin) or CRESTOR® (rosuvastatin). There is an increased chance of serious side effects if you take REYATAZ with this cholesterol-lowering medicine.
- Medicines for abnormal heart rhythm: CORDARONE® (amiodarone), lidocaine, quinidine (also known as CARDIOQUIN®, QUINIDEX®, and others).
- VASCOR® (bepridil, used for chest pain).
- COUMADIN® (warfarin).

- Tricyclic antidepressants such as ELAVIL® (amitriptyline), NORPRAMIN® (desipramine), SINEQUAN® (doxepin), SURMONTIL® (trimipramine), TOFRANIL® (imipramine), or VIVACTIL® (protriptyline).
- Medicines to prevent organ transplant rejection: SANDIMMUNE® or NEORAL® (cyclosporin), RAPAMUNE® (sirolimus), or PROGRAF® (tacrolimus).
- The antidepressant trazodone (DESYREL® and others).
- Fluticasone propionate (ADVAIR®, FLONASE®, FLOVENT®), given by nose or inhaled to treat allergic symptoms or asthma. Your doctor may choose not to keep you on fluticasone, especially if you are also taking NORVIR®.

**The following medicines may require a change in the dose or dose schedule of either REYATAZ (atazanavir sulfate) or the other medicine:**

- INVIRASE® (saquinavir).
- NORVIR® (ritonavir).
- SUSTIVA® (efavirenz).
- Antacids or buffered medicines.
- VIDEX® (didanosine).
- VIREAD® (tenofovir disoproxil fumarate).
- MYCOBUTIN® (rifabutin).
- Calcium channel blockers such as CARDIZEM® or TIAZAC® (diltiazem), COVERA-HS® or ISOPTIN SR® (verapamil) and others.
- BIAXIN® (clarithromycin).
- Medicines for indigestion, heartburn, or ulcers such as AXID® (nizatidine), PEPCID AC® (famotidine), TAGAMET® (cimetidine), or ZANTAC® (ranitidine).

**Talk to your healthcare provider about choosing an effective method of contraception.** REYATAZ may affect the safety and effectiveness of hormonal contraceptives such as birth control pills or the contraceptive patch. Hormonal contraceptives do not prevent the spread of HIV to others.

**Remember:**

1. **Know all the medicines you take.**
2. **Tell your healthcare provider about all the medicines you take.**
3. **Do not start a new medicine without talking to your healthcare provider.**

**How should I store REYATAZ?**

- Store REYATAZ Capsules at room temperature, 59° to 86° F (15° to 30° C). Do not store this medicine in a damp place such as a bathroom medicine cabinet or near the kitchen sink.
- Keep your medicine in a tightly closed container.
- Keep all medicines out of the reach of children and pets at all times. Do not keep medicine that is out of date or that you no longer need. Dispose of unused medicines through community take-back disposal programs when available or place REYATAZ in an unrecognizable, closed container in the household trash.

**General information about REYATAZ**

This medicine was prescribed for your particular condition. Do not use REYATAZ for another condition. Do not give REYATAZ to other people, even if they have the same symptoms you have. It may harm them. **Keep REYATAZ and all medicines out of the reach of children and pets.**

This summary does not include everything there is to know about REYATAZ. Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Remember no written summary can replace careful discussion with your healthcare provider. If you would like more information, talk with your healthcare provider or you can call 1-800-321-1335.

**What are the ingredients in REYATAZ?**

**Active Ingredient:** atazanavir sulfate

**Inactive Ingredients:** Crospovidone, lactose monohydrate (milk sugar), magnesium stearate, gelatin, FD&C Blue #2, and titanium dioxide.

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US Patent Nos: 5,849,911 and 6,087,383

 **Bristol-Myers Squibb**  
Princeton, NJ 08543 USA

## TPAN PROGRAMS AND MEETINGS

- Support Groups
- Rapid HIV Testing
- Meditation, Reiki, Yoga, and Massage
- Needle Exchange Program
- Buddy Program
- Case Management
- Access Medical Clinic at TPAN
- PULSE, an HIV-positive Weekly Social
- Positively Aware Party at Hydrate
- POWER (Positive Outcomes for Wellness, Education, and Recovery)
- TEAM (Treatment Education Advocacy Management)
- SMART Sex—Prevention and Outreach Program
- Monthly Educational Forums and Trainings

For detailed descriptions of programs, including dates, times, and locations, visit [www.tpan.com](http://www.tpan.com) and click on Client Services, or call (773) 989-9400.

## TPAN EVENTS

- Ride for AIDS  
June 6-7, 2009  
[www.rideforaids.org](http://www.rideforaids.org)
- SAVE THE DATE  
2009 Aware Affair Gala  
September 12, 2009



For detailed descriptions of these and other TPAN events visit [www.tpan.com](http://www.tpan.com) and click on Events, or call (773) 989-9400.



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

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Treatment advocate Nelson Vergel, see article on page 24. Photo by Evin Thayer

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## The Graying Epidemic



When I was younger, *much* younger, I used to daydream about what my life would be like once I reached 50. I imagined I would have a successful career, own a big, white house with a picket fence, be “settled down” and perhaps have started a family, boast a wide circle of friends, and of course I would, above all, be immensely happy and satisfied.

I was almost certain that my hair would prematurely turn shock white—as did my father’s—before the ripe age of 30, and that, as I aged, I would not necessarily appear “old,” but, rather, I would be “distinguished-looking,” as men my age are often described. And as a child, in my mind’s eye, my adult self exuded an air of supreme confidence, and people flocked to me for advice, or at the very least, when they needed a shoulder to cry on.

Well, as we all know, life doesn’t always end up exactly the way we planned.

I suppose one could say that I have achieved a moderate level of success in my life, both personally and professionally. I have an immensely rewarding career, one that pays the bills and then some, which has allowed me to journey to faraway lands and meet some interesting folks I might otherwise never have met. But instead of a big, white house, my partner and I own a condominium. Our family, made up of two gay men along with our two cats, is what would be considered by many to be non-traditional. I have a small group of extremely close, lifelong friends (thankfully), who are there for me just as much as (if not more than) I am for them. And my hair never did turn white, but instead became silvery-gray.

For me, these realities are a metaphor for what aging is like for many of us living with HIV. As my virus and I both approach our sunset years together, hand in hand, I look back at a life full of uncertainties and lowered expectations, disappointments and challenges, regrets and missed opportunities. At the same time, my life has often been extremely rewarding and gratifying. But one thing is for sure—it was never what I expected.

Getting older with HIV is, at times, a double-edged sword. Yes, I am certainly grateful for having survived this long. But at a time in our lives when we should still be *creating* memories, many of us now suffer from early memory loss, either due to the effects of HIV, or sometimes from the medications we take to control the virus.

As a youngster, I can remember cringing when ordinary conversations at family gatherings would invariably morph into a litany of everyone’s recent ailments, impending surgeries, hospitalization horror stories, and deteriorating health. But nowadays, and in an

ironic twist of fate, the snap, crackle, and pop of bones made brittle by HIV and ARVs makes for titillating dinner conversation with friends.

Depression, stigma, neurocognitive impairment, non-AIDS malignancies, osteoporosis, liver failure, kidney and cardiovascular disease—the list goes on and on. Weren’t these supposed to be our golden years? Is there ever going to be light at the end of the tunnel, or do we just resign ourselves to the fact that we’ll be “walking towards the light,” and at a very early age?

Happily, the answer to the latter is no. During the course of researching this issue, I learned that there may indeed be light at the end of the tunnel—we just may need to put on our granny glasses in order to see it. Researchers are only now beginning to uncover some of the mechanisms that may be responsible for early aging in people with HIV, including inflammation and advanced aging of the immune system brought on by the virus itself. Understanding just how and why these effects occur may not only help those with HIV, but also those with other diseases. It may one day even help tackle some of the problems associated with the effects of aging for everyone.

Unfortunately, research is taking place at a snail’s pace. According to most estimates, over half those who are HIV-positive in the U.S. will be over the age of 50, in just a few short years. Not only will this create a tremendous burden on our present health care system—one that we are ill-prepared for—it will also demand of us an innovative and forward thinking response to address the needs of this ever-growing population.

A special thanks to Nelson Vergel, Jules Levin, and Dr. Victor Valcour for their contributions to this issue of *Positively Aware*. It is only through the continued efforts of advocates and researchers like them that we will continue to bring much needed attention to the unique issues that are part of the graying epidemic.

Take care of yourself, and each other.

Jeff Berry  
Editor  
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## Important Information

### INDICATION

ATRIPLA® (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate [DF] 300 mg) is a prescription medication used alone as a complete regimen or with other medicines to treat HIV-1 infection in adults.

**ATRIPLA does not cure HIV-1 and has not been shown to prevent passing HIV-1 to others. See your healthcare provider regularly.**

### IMPORTANT SAFETY INFORMATION

**Contact your healthcare provider right away if you experience any of the following side effects or conditions associated with ATRIPLA:**

- **Nausea, vomiting, unusual muscle pain, and/or weakness. These may be signs of a buildup of acid in the blood (lactic acidosis), which is a serious medical condition.**
- **Light colored stools, dark colored urine, and/or if your skin or the whites of your eyes turn yellow. These may be signs of serious liver problems.**
- **If you have HIV-1 and hepatitis B virus (HBV), your liver disease may suddenly get worse if you stop taking ATRIPLA. Do not stop taking ATRIPLA unless directed by your healthcare provider.**

**Do not take ATRIPLA if you are taking the following medicines because serious and life-threatening side effects may occur when taken together:**

Vascor® (bepidil), Propulsid® (cisapride), Versed® (midazolam), Orap® (pimozide), Halcion® (triazolam), or ergot medications (for example, Wigraine® and Cafergot®).

**In addition, ATRIPLA should not be taken with:**

Combivir® (lamivudine/zidovudine), EMTRIVA® (emtricitabine), Epivir® or Epivir-HBV® (lamivudine), Epzicom® (abacavir sulfate/lamivudine), SUSTIVA® (efavirenz), Trizivir® (abacavir sulfate/lamivudine/zidovudine), TRUVADA® (emtricitabine/tenofovir DF), or VIREAD® (tenofovir DF), because they contain the same or similar active ingredients as ATRIPLA.

Vfend® (voriconazole) or REYATAZ® (atazanavir sulfate), with or without Norvir® (ritonavir), should not be taken with ATRIPLA since they may lose their effect and may also increase the chance of having side effects from ATRIPLA. Fortovase® or Invirase® (saquinavir) should not be used as the only protease inhibitor in combination with ATRIPLA.

Taking ATRIPLA with St. John's wort or products containing St. John's wort is not recommended as it may cause decreased levels of ATRIPLA, increased viral load, and possible resistance to ATRIPLA or cross-resistance to other anti-HIV drugs.

**This list of medicines is not complete. Discuss with your healthcare provider all prescription and nonprescription medicines, vitamins, or herbal supplements you are taking or plan to take.**

**Contact your healthcare provider right away if you experience any of the following side effects or conditions:**

- **Severe depression, strange thoughts, or angry behavior** have been reported by a small number of patients. Some patients have had thoughts of suicide and a few have actually committed suicide. These problems may occur more often in patients who have had mental illness.

- **Dizziness, trouble sleeping or concentrating, drowsiness, unusual dreams, and/or hallucinations** are common, and tend to go away after taking ATRIPLA (efavirenz 600 mg/emtricitabine 200 mg/tenofovir DF 300 mg) for a few weeks. Symptoms were severe in a few patients and some patients discontinued therapy. These symptoms may become more severe with the use of alcohol and/or mood-altering (street) drugs. If you are dizzy, have trouble concentrating, and/or are drowsy, avoid activities that may be dangerous, such as driving or operating machinery.

- **Kidney or liver problems.** If you have had kidney or liver problems, including hepatitis infection or take other medicines that may cause kidney or liver problems, your healthcare provider should do regular blood tests.

- **Pregnancy: Women should not become pregnant while taking ATRIPLA and for 12 weeks after stopping ATRIPLA.** Serious birth defects have been seen in children of women treated during pregnancy with one of the medicines in ATRIPLA. Therefore, women must use a reliable form of barrier contraception, such as a condom or diaphragm, even if they also use other methods of birth control.

- **Breast-Feeding: Women with HIV-1 should not breast-feed** because they can pass HIV-1 through their milk to the baby. Also, ATRIPLA may pass through breast milk and cause serious harm to the baby.

- **Rash** is a common side effect that usually goes away without treatment, but may be serious in a small number of patients.

- **Seizures** have occurred in patients taking a component of ATRIPLA, usually in those with a history of seizures. If you have ever had seizures, or take medicine for seizures, your healthcare provider may want to switch you to another medicine or monitor you.

- **Bone changes.** If you have had bone problems in the past, your healthcare provider may want to check your bones.

- **If you have ever had mental illness or use illegal drugs or alcohol.**

Changes in body fat have been seen in some people taking anti-HIV-1 medicines. The cause and long-term health effects are not known.

**Other common side effects** of ATRIPLA include tiredness, headache, upset stomach, vomiting, gas, and diarrhea. Skin discoloration (small spots or freckles) may also happen.

You should take ATRIPLA once daily on an empty stomach. Taking ATRIPLA at bedtime may make some side effects less bothersome.

ATRIPLA is one of several treatment options your doctor may consider.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

**Patient model.  
Individual results may vary.**

If you or someone you know needs help paying for medicine, call 1-888-4PPA-NOW (1-888-477-2669). Or go to [www.pparx.org](http://www.pparx.org)



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Please see Patient Information on the following pages.



**“ATRIPLA has all my HIV meds  
in one pill daily, and helps  
me take charge of my HIV.”**

*Steven*  
on ATRIPLA for 2 years

**ATRIPLA is the #1 prescribed HIV regimen.\***

- Only ATRIPLA combines 3 HIV medications in 1 pill daily.
- Proven to lower viral load to undetectable<sup>†</sup> and help raise T-cell (CD4+) count to help control HIV through 3 years of a clinical study.

**Talk to your doctor to see if ATRIPLA is right for you.**

Your doctor may prescribe ATRIPLA alone or with other HIV medications.

**ATRIPLA**<sup>®</sup>  
(efavirenz 600 mg/emtricitabine 200 mg/  
tenofovir disoproxil fumarate 300 mg) Tablets

To learn more, visit  
[www.ATRIPLA.com](http://www.ATRIPLA.com)

Please see Important Safety Information, including information on **lactic acidosis, serious liver problems, and flare-ups of hepatitis B virus (HBV)** on adjacent page.

\*Synovate Healthcare Data; US HIV Monitor, Q3 2008.

<sup>†</sup>Defined as a viral load of less than 400 copies/mL.

## FDA-Approved Patient Labeling

### Patient Information

#### ATRIPLA® (uh TRIP luh) Tablets

#### ALERT: Find out about medicines that should NOT be taken with ATRIPLA.

Please also read the section “MEDICINES YOU SHOULD NOT TAKE WITH ATRIPLA.”

Generic name: efavirenz, emtricitabine and tenofovir disoproxil fumarate (eh FAH vih renz, em tri SIT uh bean and te NOE' fo veer dye soe PROX il FYOU mar ate)

Read the Patient Information that comes with ATRIPLA (efavirenz/emtricitabine/tenofovir disoproxil fumarate) before you start taking it and each time you get a refill since there may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. You should stay under a healthcare provider's care when taking ATRIPLA. **Do not change or stop your medicine without first talking with your healthcare provider.** Talk to your healthcare provider or pharmacist if you have any questions about ATRIPLA.

#### What is the most important information I should know about ATRIPLA?

- **Some people who have taken medicine like ATRIPLA (which contains nucleoside analogs) have developed a serious condition called lactic acidosis** (build up of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital. **Call your healthcare provider right away if you get the following signs or symptoms of lactic acidosis:**
  - You feel very weak or tired.
  - You have unusual (not normal) muscle pain.
  - You have trouble breathing.
  - You have stomach pain with nausea and vomiting.
  - You feel cold, especially in your arms and legs.
  - You feel dizzy or lightheaded.
  - You have a fast or irregular heartbeat.
- **Some people who have taken medicines like ATRIPLA have developed serious liver problems called hepatotoxicity**, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). **Call your healthcare provider right away if you get the following signs or symptoms of liver problems:**
  - Your skin or the white part of your eyes turns yellow (jaundice).
  - Your urine turns dark.
  - Your bowel movements (stools) turn light in color.
  - You don't feel like eating food for several days or longer.
  - You feel sick to your stomach (nausea).
  - You have lower stomach area (abdominal) pain.
- **You may be more likely to get lactic acidosis or liver problems** if you are female, very overweight (obese), or have been taking nucleoside analog-containing medicines, like ATRIPLA, for a long time.
- **If you also have hepatitis B virus (HBV) infection and you stop taking ATRIPLA, you may get a “flare-up” of your hepatitis. A “flare-up” is when the disease suddenly returns in a worse way than before.** Patients with HBV who stop taking ATRIPLA need close medical follow-up for several months, including medical exams and blood tests to check for hepatitis that could be getting worse. ATRIPLA is not approved for the treatment of HBV, so you must discuss your HBV therapy with your healthcare provider.

#### What is ATRIPLA?

ATRIPLA contains 3 medicines, SUSTIVA® (efavirenz), EMTRIVA® (emtricitabine) and VIREAD® (tenofovir disoproxil fumarate also called tenofovir DF) combined in one pill. EMTRIVA and VIREAD are HIV-1 (human immunodeficiency virus) nucleoside analog reverse transcriptase inhibitors (NRTIs) and SUSTIVA is an HIV-1 non-nucleoside analog reverse transcriptase inhibitor (NNRTI). VIREAD and EMTRIVA are the components of TRUVADA®. ATRIPLA can be used alone as a complete regimen, or in combination with other anti-HIV-1 medicines to treat people with HIV-1 infection. ATRIPLA is for adults age 18 and over. ATRIPLA has not been studied in children under age 18 or adults over age 65.

HIV infection destroys CD4<sup>+</sup> T cells, which are important to the immune system. The immune system helps fight infection. After a large number of T cells are destroyed, acquired immune deficiency syndrome (AIDS) develops.

ATRIPLA helps block HIV-1 reverse transcriptase, a viral chemical in your body (enzyme) that is needed for HIV-1 to multiply. ATRIPLA lowers the amount of HIV-1 in the blood (viral load). ATRIPLA may also help to increase the number of T cells (CD4<sup>+</sup> cells), allowing your immune system to improve. Lowering the amount of HIV-1 in the blood lowers the chance of death or infections that happen when your immune system is weak (opportunistic infections).

#### Does ATRIPLA cure HIV-1 or AIDS?

**ATRIPLA does not cure HIV-1 infection or AIDS.** The long-term effects of ATRIPLA are not known at this time. People taking ATRIPLA may still get opportunistic infections or other conditions that happen with HIV-1 infection. Opportunistic infections are infections that develop because the immune system is weak. Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium complex* (MAC) infection. **It is very important that you see your healthcare provider regularly while taking ATRIPLA.**

#### Does ATRIPLA (efavirenz/emtricitabine/tenofovir disoproxil fumarate) reduce the risk of passing HIV-1 to others?

ATRIPLA has not been shown to lower your chance of passing HIV-1 to other people through sexual contact, sharing needles, or being exposed to your blood.

- **Do not share needles or other injection equipment.**
- **Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.**
- **Do not have any kind of sex without protection.** Always practice safer sex by using a latex or polyurethane condom or other barrier to reduce the chance of sexual contact with semen, vaginal secretions, or blood.

#### Who should not take ATRIPLA?

Together with your healthcare provider, you need to decide whether ATRIPLA is right for you.

Do not take ATRIPLA if you are allergic to ATRIPLA or any of its ingredients. The active ingredients of ATRIPLA are efavirenz, emtricitabine, and tenofovir DF. See the end of this leaflet for a complete list of ingredients.

#### What should I tell my healthcare provider before taking ATRIPLA?

##### Tell your healthcare provider if you:

- **Are pregnant or planning to become pregnant** (see “What should I avoid while taking ATRIPLA?”).
- **Are breast-feeding** (see “What should I avoid while taking ATRIPLA?”).
- **Have kidney problems or are undergoing kidney dialysis treatment.**
- **Have bone problems.**
- **Have liver problems, including hepatitis B virus infection.** Your healthcare provider may want to do tests to check your liver while you take ATRIPLA.
- **Have ever had mental illness or are using drugs or alcohol.**
- **Have ever had seizures or are taking medicine for seizures.**

#### What important information should I know about taking other medicines with ATRIPLA?

ATRIPLA may change the effect of other medicines, including the ones for HIV-1, and may cause serious side effects. Your healthcare provider may change your other medicines or change their doses. Other medicines, including herbal products, may affect ATRIPLA. For this reason, **it is very important to let all your healthcare providers and pharmacists know what medications, herbal supplements, or vitamins you are taking.**

#### MEDICINES YOU SHOULD NOT TAKE WITH ATRIPLA

- The following medicines may cause serious and life-threatening side effects when taken with ATRIPLA. You should not take any of these medicines while taking ATRIPLA: Vascor (bepidil), Propulsid (cisapride), Versed (midazolam), Orap (pimozide), Halcion (triazolam), ergot medications (for example, Wigraine and Cafergot).
- ATRIPLA also should not be used with Combivir (lamivudine/zidovudine), EMTRIVA, Epivir, Epivir-HBV (lamivudine), Epzicom (abacavir sulfate/lamivudine), Trizivir (abacavir sulfate/lamivudine/zidovudine), SUSTIVA, TRUVADA, or VIREAD.
- Vfend (voriconazole) should not be taken with ATRIPLA since it may lose its effect or may increase the chance of having side effects from ATRIPLA.
- **Do not take St. John's wort (*Hypericum perforatum*), or products containing St. John's wort with ATRIPLA.** St. John's wort is an herbal product sold as a dietary supplement. Talk with your healthcare provider if you are taking or are planning to take St. John's wort. Taking St. John's wort may decrease ATRIPLA levels and lead to increased viral load and possible resistance to ATRIPLA or cross-resistance to other anti-HIV-1 drugs.

It is also important to tell your healthcare provider if you are taking any of the following:

- Fortovase, Invirase (saquinavir), Biaxin (clarithromycin); or Sporanox (itraconazole); **these medicines may need to be replaced with another medicine when taken with ATRIPLA.**
- Calcium channel blockers such as Cardizem or Tiazac (diltiazem), Covera HS or Isoptin (verapamil) and others; Crixivan (indinavir); Methadone; Mycobutin (rifabutin); Rifampin; cholesterol-lowering medicines such as Lipitor (atorvastatin), Pravachol (pravastatin sodium), and Zocor (simvastatin); or Zolof (sertraline); **these medicines may need to have their dose changed when taken with ATRIPLA.**
- Videx, Videx EC (didanosine); tenofovir DF (a component of ATRIPLA) may increase the amount of didanosine in your blood, which could result in more side effects. **You may need to be monitored more carefully** if you are taking ATRIPLA (efavirenz/emtricitabine/tenofovir disoproxil fumarate) and didanosine together. Also, the dose of didanosine may need to be changed.
- Reyataz (atazanavir sulfate) or Kaletra (lopinavir/ritonavir); these medicines may increase the amount of tenofovir DF (a component of ATRIPLA) in your blood, which could result in more side effects. Reyataz is not recommended with ATRIPLA. **You may need to be monitored more carefully** if you are taking ATRIPLA and Kaletra together. Also, the dose of Kaletra may need to be changed.
- Medicine for seizures [for example, Dilantin (phenytoin), Tegretol (carbamazepine), or phenobarbital]; your healthcare provider may want to switch you to another medicine or check drug levels in your blood from time to time.

**These are not all the medicines that may cause problems if you take ATRIPLA (efavirenz/emtricitabine/tenofovir disoproxil fumarate). Be sure to tell your healthcare provider about all medicines that you take.**

Keep a complete list of all the prescription and nonprescription medicines as well as any herbal remedies that you are taking, how much you take, and how often you take them. Make a new list when medicines or herbal remedies are added or stopped, or if the dose changes. Give copies of this list to all of your healthcare providers and pharmacists **every** time you visit your healthcare provider or fill a prescription. This will give your healthcare provider a complete picture of the medicines you use. Then he or she can decide the best approach for your situation.

#### How should I take ATRIPLA?

- Take the exact amount of ATRIPLA your healthcare provider prescribes. Never change the dose on your own. Do not stop this medicine unless your healthcare provider tells you to stop.
- You should take ATRIPLA on an empty stomach.
- Swallow ATRIPLA with water.
- Taking ATRIPLA at bedtime may make some side effects less bothersome.
- Do not miss a dose of ATRIPLA. If you forget to take ATRIPLA, take the missed dose right away, unless it is almost time for your next dose. Do not double the next dose. Carry on with your regular dosing schedule. If you need help in planning the best times to take your medicine, ask your healthcare provider or pharmacist.
- If you believe you took more than the prescribed amount of ATRIPLA, contact your local poison control center or emergency room right away.
- Tell your healthcare provider if you start any new medicine or change how you take old ones. Your doses may need adjustment.
- When your ATRIPLA supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to ATRIPLA and become harder to treat.
- Your healthcare provider may want to do blood tests to check for certain side effects while you take ATRIPLA.

#### What should I avoid while taking ATRIPLA?

- **Women should not become pregnant while taking ATRIPLA and for 12 weeks after stopping it.** Serious birth defects have been seen in the babies of animals and women treated with efavirenz (a component of ATRIPLA) during pregnancy. It is not known whether efavirenz caused these defects. **Tell your healthcare provider right away if you are pregnant.** Also talk with your healthcare provider if you want to become pregnant.
- Women should not rely only on hormone-based birth control, such as pills, injections, or implants, because ATRIPLA may make these contraceptives ineffective. Women must use a reliable form of barrier contraception, such as a condom or diaphragm, even if they also use other methods of birth control. Efavirenz, a component of ATRIPLA, may remain in your blood for a time after therapy is stopped. Therefore, you should continue to use contraceptive measures for 12 weeks after you stop taking ATRIPLA.
- **Do not breast-feed if you are taking ATRIPLA.** The Centers for Disease Control and Prevention recommend that mothers with HIV not breast-feed because they can pass the HIV through their milk to the baby. Also, ATRIPLA may pass through breast milk and cause serious harm to the baby. Talk with your healthcare provider if you are breast-feeding. You should stop breast-feeding or may need to use a different medicine.
- Taking ATRIPLA with alcohol or other medicines causing similar side effects as ATRIPLA, such as drowsiness, may increase those side effects.
- Do not take any other medicines, including prescription and nonprescription medicines and herbal products, without checking with your healthcare provider.
- **Avoid doing things that can spread HIV-1 infection** since ATRIPLA does not stop you from passing the HIV-1 infection to others.

#### What are the possible side effects of ATRIPLA?

**ATRIPLA may cause the following serious side effects:**

- **Lactic acidosis** (buildup of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital. **Call your healthcare provider right away if you get signs of lactic acidosis.** (See "What is the most important information I should know about ATRIPLA?")
- **Serious liver problems (hepatotoxicity)**, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). Call your healthcare provider right away if you get any signs of liver problems. (See "What is the most important information I should know about ATRIPLA?")
- **"Flare-ups" of hepatitis B virus (HBV) infection**, in which the disease suddenly returns in a worse way than before, can occur if you have HBV and you stop taking ATRIPLA. Your healthcare provider will monitor your condition for several months after stopping ATRIPLA if you have both HIV-1 and HBV infection and may recommend treatment for your HBV.
- **Serious psychiatric problems.** A small number of patients may experience severe depression, strange thoughts, or angry behavior while taking ATRIPLA. Some patients have thoughts of suicide and a few have actually committed suicide. These problems may occur more often in patients who have had mental illness. Contact your healthcare provider right away if you think you are having these psychiatric symptoms, so your healthcare provider can decide if you should continue to take ATRIPLA.

- **Kidney problems.** If you have had kidney problems in the past or take other medicines that can cause kidney problems, your healthcare provider should do regular blood tests to check your kidneys.
- **Changes in bone mineral density (thinning bones).** It is not known whether long-term use of ATRIPLA (efavirenz/emtricitabine/tenofovir disoproxil fumarate) will cause damage to your bones. If you have had bone problems in the past, your healthcare provider may need to do tests to check your bone mineral density or may prescribe medicines to help your bone mineral density.

#### Common side effects:

Patients may have dizziness, headache, trouble sleeping, drowsiness, trouble concentrating, and/or unusual dreams during treatment with ATRIPLA. These side effects may be reduced if you take ATRIPLA at bedtime on an empty stomach. They also tend to go away after you have taken the medicine for a few weeks. If you have these common side effects, such as dizziness, it does not mean that you will also have serious psychiatric problems, such as severe depression, strange thoughts, or angry behavior. Tell your healthcare provider right away if any of these side effects continue or if they bother you. It is possible that these symptoms may be more severe if ATRIPLA is used with alcohol or mood altering (street) drugs.

If you are dizzy, have trouble concentrating, or are drowsy, avoid activities that may be dangerous, such as driving or operating machinery.

Rash may be common. Rashes usually go away without any change in treatment. In a small number of patients, rash may be serious. If you develop a rash, call your healthcare provider right away.

Other common side effects include tiredness, upset stomach, vomiting, gas, and diarrhea.

#### Other possible side effects with ATRIPLA include:

- Changes in body fat. Changes in body fat develop in some patients taking anti-HIV-1 medicine. These changes may include an increased amount of fat in the upper back and neck ("buffalo hump"), in the breasts, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these fat changes are not known.
- Skin discoloration (small spots or freckles) may also happen with ATRIPLA.

Tell your healthcare provider or pharmacist if you notice any side effects while taking ATRIPLA.

Contact your healthcare provider before stopping ATRIPLA because of side effects or for any other reason.

This is not a complete list of side effects possible with ATRIPLA. Ask your healthcare provider or pharmacist for a more complete list of side effects of ATRIPLA and all the medicines you will take.

#### How do I store ATRIPLA?

- **Keep ATRIPLA and all other medicines out of reach of children.**
- Store ATRIPLA at room temperature 77 °F (25 °C).
- Keep ATRIPLA in its original container and keep the container tightly closed.
- Do not keep medicine that is out of date or that you no longer need. If you throw any medicines away make sure that children will not find them.

#### General information about ATRIPLA:

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use ATRIPLA for a condition for which it was not prescribed. Do not give ATRIPLA to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about ATRIPLA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about ATRIPLA that is written for health professionals.

Do not use ATRIPLA if the seal over bottle opening is broken or missing.

#### What are the ingredients of ATRIPLA?

**Active Ingredients:** efavirenz, emtricitabine, and tenofovir disoproxil fumarate

**Inactive Ingredients:** croscarmellose sodium, hydroxypropyl cellulose, microcrystalline cellulose, magnesium stearate, sodium lauryl sulfate. The film coating contains black iron oxide, polyethylene glycol, polyvinyl alcohol, red iron oxide, talc, and titanium dioxide.

## Rx ONLY

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# READERS FORUM



## DRUG GUIDE CORRECTION: REYATAZ AND SUSTIVA

A dosage of 400 mg Reyataz/100 mg Norvir should be used in combination with Sustiva, not 300 mg Reyataz/100 mg Norvir as listed on the Sustiva page of the Annual HIV Drug Guide (March/April). Also, HIV treatment-experienced people should not use Reyataz with Sustiva at all. When rifabutin is taken with Reyataz, it is recommended that rifabutin dose and frequency be reduced to 150 mg every other day or three times a week. Sustiva was approved in 1998, not 2002. The manufacturer contact for Bristol-Myers Squibb, makers of Reyataz and Sustiva, is 1-800-321-1335. *Positively Aware* apologizes for the errors.

## DRUG GUIDE ONLINE

I found the March/April 2009 issue with the 13<sup>th</sup> Annual Drug Guide online, but can't find the 2009 HIV Drug Chart. Has it been posted on the site yet or am I just missing it?

Tom, via the Internet

*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. Please advise if we can use your name and city.

Write to: *Positively Aware*,  
5537 North Broadway  
Chicago, IL 60640

Fax: (773) 989-9494

E-mail: readersforum@tpan.com

*The link to the HIV drug chart was inadvertently overlooked and therefore not in place on the website. The correct link, which is now on the website, is [http://positivelyaware.com/2009/09\\_02/drug\\_chart.pdf](http://positivelyaware.com/2009/09_02/drug_chart.pdf).*

*We apologize for any confusion this may have caused, and thanks for bringing this to our attention!*

## "HOW IT IS"

I enjoyed reading the January/February issue of *Positively Aware*. That was my first time ever laying eyes on the magazine or ever knowing anything about it. I liked Jim Pickett's article. Why? Because I feel a lot like him, in more ways than one. I'm 23 years old and was diagnosed with HIV in September 2007, one week before delivering my second child. Plus, I was in the county jail on my way to prison, where I am presently. My child is not positive. We tested my lover who also had it, but had had it and didn't tell me. He didn't give me the opportunity to say I wanted in on it or I didn't and he didn't think about my child. Truth be told, it took me awhile to let it all sink in, but when it did I couldn't hold it inside anymore. In prison, I heard people talking about it and I couldn't be quiet, I had to let someone know. So when I told people, they were like, "No, man, you don't look like you got that." But that's the point—HIV/AIDS doesn't have a "look." When I found out, that's how I coped with having HIV, by letting people know. It doesn't bother me at all. I'd rather tell someone than let it eat me up inside. So when I meet people, I tell them and just watch the shock cross their face—the "too much information" look. A lot of people think TMI, but I felt I was making them aware that it's out there and it doesn't discriminate against anyone.

Well, I'm happy, no medication in my life, undetectable and healthy as a dog. One

day I want to be an advocate, an educator and I am a "scared little girl, an angry queen and a bitch!" So there it is, life goes on and that's how it is.

Name withheld by request

## MS "READY FOR THE WORLD"

Dear Mr. Berry,

Hello—I receive your magazine every month. I am a 23-year-old White female in prison in Georgia. I have been HIV-positive for almost five years. In this past year, I started HIV medications for the first time, but they were unable to get a genotype on me, so they just put me on Kaletra and Truvada, hoping it would work. Since I started my meds, I have been sick and I really don't like it. I am at the point of giving up on the medication. I'm hoping you can put my name and address in your next issue so that I might get some input and help from others.

I also have a few questions I would like to ask. First, is it easier for a female to give HIV to another female or to a male? Second, if my husband and I have never had protected sex and I am HIV-positive and he isn't, what is the chance of him still contracting it? And, last, will I ever have a normal sex life again? I ask that because I feel like I've lost everything.

Well, thank you for your magazine and for taking the time to read this.

Sincerely,

Theresa Yount #1204504  
Metro State Prison  
1301 Constitution Rd. SE  
Atlanta, GA 30316

Dear Theresa,

*I'm sorry to hear that you're having such a hard time with your meds. You didn't mention if you've had any tests to see how well*

*they're working. I think it's safe to say that people starting these medicines for the first time are rarely prepared for the side effects they experience. I can easily understand how you would be so frustrated with feeling sick that you would question the validity of continuing to take the meds. But I urge you to think long and hard about the consequences of discontinuing them. Many times the nausea, headaches, fatigue, and other effects you feel when you first begin go away within a short period of time. The virus, however, doesn't go away, though these medications can keep it from getting out of control. Talk to your doctor or medical provider about all the medications you are taking, and report your side effects. Ask what you can expect regarding them, and try to find out if there may be ways to minimize the side effects (such as taking immodium for diarrhea).*

*As for your other questions, transmission is always a risk, whether it's female-to-female or female-to-male, though the risk of female-to-female is considered to be lower, especially when using a female condom or dental dam. If you are still having unprotected sex with your husband, he is at risk for contracting it, no matter how long he has managed to stay negative. He should be tested regularly every three months and a condom should be used from this point on. A "normal" sex life is certainly possible, as long as you and your partner take precautions to protect yourselves.*

*In closing, I encourage you to realize that while this disease can change your life, it is totally up to you to decide between being controlled by the disease or doing what you can to control it. I wish you the best of luck!*

Best regards,  
Jeff Berry  
Editor, *Positively Aware*

## **BEHIND THE FENCE**

I'm currently in Taylor Correctional Institution, so I'm writing to all those who are behind the fence, as well as in the free world. I'm daunted by the way the media labels us as being horrible, stupid, or unchanging. We, like any other human being, are in the process of growing, learning, and healing. The media won't tell you about the bodies they bag up and wheel out of here due to poor health care behind prison bars.

My advice to readers of *PA*—live your life. Ask yourself, "Am I living how I would want to live if this was the last month of my life?" We own our blueprint; let's start using it. I know there are a lot of people dead today who listened and lived out their doctor's orders in prison. The truth is that as long as we have access to information from sources like *Positively Aware* and others, we can learn of treatments and options that can keep us alive longer.

I want to extend a special thanks to all who make it possible at *Positively Aware*. I have very little family and no outlet beyond these prison walls. If you could add my name and address, I'd welcome all responses.

Respectfully yours,  
Edward Perez #426775  
Taylor Correctional Institution  
8515 Hampton Spring Rd.  
Perry, FL 32348, H4 106

## **LONG OVERDUE**

I am long overdue with this letter to you and to the others who make *Positively Aware* possible. *PA* has been such a valuable resource to me over the years and I do want to share that with you and with your readers.

I am director of Samaritan Ministry, an ASO connected with a Baptist church

in Knoxville, Tennessee. In 2004 we made our first foray into the HIV activist world with a trip to USCA in Philadelphia. It was during that visit that we became acquainted with TPAN. I believe it was Keith and Carlos that we met at your booth, and there began our long-standing relationship with *PA* magazine.

I have finally finished a thorough reading of the 13<sup>th</sup> Drug Guide issue. Thanks again for such a thoughtful and thorough issue on HIV meds.

As I am privileged to work with many who are living with HIV in our community and across the country, it is through the trusted eyes of *PA* that I try to keep myself educated on HIV issues. Many of your past issues have been important to me and to our clients and we do receive bulk issues to distribute during our two support groups, and occasionally to mail out when an issue really strikes us as important. I especially liked "HIV 101," "Systems Check," and "Everything You Always Wanted to Know," among others.

Reading the Martin Delaney tribute was meaningful to me, also, as I was privileged to hear him speak about Atripla and the new drugs of 2007 at a TAPWA forum in Nashville a couple of years ago. Rarely do I feel greatness in the room, but I felt it that evening. I hope I have been able to "infect" our clients with some of Martin's hopeful enthusiasm for all of these exciting new treatments.

Thanks, Jeff, for the work all of you do at TPAN. Just wanted you to know how much I personally rely on *PA* to be sure that I am guiding those we serve with accurate, up-to-date, and reliable information.

Best regards, Wayne ☩

# NEWS BRIEFS



by Enid Vázquez

## CDC UPDATES OI GUIDELINES

The U.S. Centers for Disease Control and Prevention (CDC) in March released updated guidelines for opportunistic infections (OIs) in people with HIV. Major changes and updates to the guidelines include:

- additional emphasis on the importance of anti-HIV treatment for the prevention and treatment of OIs
- information on the diagnosis and treatment of IRIS (immune reconstitution inflammatory syndrome, sometimes seen after the beginning of antiviral therapy)
- information on interferon-gamma release assays (IGRAs) for the detection of latent (existing but not active) *Mycobacterium tuberculosis* (TB) infection
- updated information on drug interactions with rifamycin TB drugs
- addition of a section on hepatitis B virus (HBV) infection
- a new section on malaria



So-called opportunistic infections prey on weakened immune systems and, before the arrival of strong HIV treatments, were frequently the cause of major illness and death. To see the guidelines, visit [www.aidsinfo.nih.gov](http://www.aidsinfo.nih.gov). An updated OI guidelines for pediatrics is expected in the near future.

## SAY NO TO ZIAGEN SKIN PATCH TEST

In March, the U.S. Food and Drug Administration (FDA) cautioned health care providers not to use a skin patch test to check for hypersensitivity reaction to Ziagen (abacavir, ABC), which is also found in the fixed dose medications Epzicom and Trizivir. The FDA stated that, “The use of skin patch testing is difficult to justify as the basis for rechallenging a patient with ABC [going back on the medication], given the risk for a fatal systemic reaction.” The agency explained that, “Several research reports have described using skin patch testing to confirm suspected cases of abacavir hypersensitivity immunologically. However, data suggest that skin patch testing may miss cases of true hypersensitivity reaction or provide false positive results. The FDA points out that the accuracy of skin patch testing is unknown, and that using skin patch testing to confirm cases of abacavir hypersensitivity has not been validated clinically.”



Given that rechallenging a patient with a suspected hypersensitivity reaction could be fatal, these reactions must continue to be diagnosed clinically.”

## NEW FEMALE CONDOM

Also in March, the FDA approved a new female condom. It is a lower-cost version from the Female Health Company, which had the only women’s condom to date. The condom is expected to sell for about 30% less, or about 70 cents to the Reality condom’s approximate one dollar cost. Instead of polyurethane, like the old version, it is made of a synthetic rubber called nitrile.



## NEW STUDY, START, EXPLORES WHEN TO BEGIN HIV TREATMENT

For people with HIV, the best time to begin treatment for the virus is not conclusively known (see also story on page 44). A very large study would be needed to help answer the question. The START Study is designed to be that clinical trial. START, for Strategic Timing of AntiRetroviral Treatment, is being planned by INSIGHT, the offshoot of a research organization that’s no longer in existence, the CPCRA (Community Program for Clinical Research on AIDS). INSIGHT expects to begin with the enrollment of 900 individuals from 22 countries later this year. Individuals must have more than 500 CD4+ T-cells and have never taken HIV therapy before. For more details, visit <http://insight.cabr.umn.edu/start>. See also the Fall 2008 RITA! at [www.centerforaids.org](http://www.centerforaids.org).

Photo © Russell McGonagle

## TWICE AS MANY POSITIVE PEOPLE WITH TB

Around the world, tuberculosis (TB) is a greater problem than it is here in the United States. Now, the World Health Organization (WHO) has found that one out of four TB deaths was related to HIV infection, twice as many than was previously estimated. According to the WHO, the greater numbers came from better reporting methods and increased HIV testing in people with TB. As of 2007, there were an estimated 1.37 million new cases of TB, and 456,000 deaths from the disease, among HIV-positive individuals. The 2009 global TB report was released in March. It listed TB/HIV co-infection and multi-drug-resistant TB as the greatest challenges in controlling the disease, but also discussed concerns over funding.

## JACK MACKENROTH JOINS POZ I AM INTERNET RADIO SHOW

Fashion designer Jack Mackenroth of Project Runway fame (season four) is the new co-host of the POZ I AM Internet radio show, joining its founder, Robert Breining. The show includes interviews on news in the HIV community. According to Mackenroth's website, "Jack has always been very open about his HIV positive status. Since his diagnosis in 1990, he has tried to combat the stigma associated with HIV by living honestly and being a role model through his professional and athletic achievements. He believes that public visibility educates and eventually saves lives." Mackenroth also works with Merck & Co. on the Living Positive by Design campaign. POZ I AM airs Wednesdays at 2 p.m. EST. Visit [www.blogtalkradio.com/poziam](http://www.blogtalkradio.com/poziam) and [www.jackmackenroth.com](http://www.jackmackenroth.com).

## CARIBBEAN CRUISE AND RETREAT

The combined gay and hetero Caribbean Positive Cruise is scheduled for October 10–18, and expects to sell out in early June. There are separate, as well as combined, activities for the two groups. The cruise sails for eight nights, beginning at Ft. Lauderdale on Saturday, October 10, with stops in St. Thomas, Antigua, Tortola, and Nassau. Rates begin at \$535 per person, plus taxes. The annual cruise, which also serves as a fundraiser for HIV organizations, provides educational forums in addition to social activities, and starts out with a Celebration of Life Ceremony. This year's speakers include Dr. Michael Wohlfeiler and treatment activist Nelson Vergel (whose photograph graces this issue's cover). For more information,



visit [www.hivcruise.com](http://www.hivcruise.com) for the gay group and [www.positivecruise.com](http://www.positivecruise.com) for the heterosexual group.

## NEW TPAN EXECUTIVE DIRECTOR

In March, the Board of Directors of Test Positive Aware Network (TPAN), publisher of *Positively Aware*, announced that Bruce Weiss has been named Executive Director.



Weiss has provided leadership to the HIV/AIDS community in Washington, D.C., for more than a decade. He served for several years as the executive director of SMYAL (Sexual Minority Youth Action League), overseeing major growth in their programs, staffing, and funding. He later became the director of the Whitman-Walker Clinic of Northern Virginia, a community health clinic focused on HIV and LGBT (lesbian, gay, bisexual, and transgender) health care. Most

recently, he was Director of Community Health at D.C.'s Whitman-Walker Clinic. In 2006, he was a recipient of the *Capital Pride Hero Award* honoring LGBT leaders.

"Bruce is that rare combination of experienced leadership and unbridled enthusiasm," stated TPAN Board President Condon McGlothlen. "Everyone at TPAN is excited about his arrival."

Weiss has an exceptional knowledge of fundraising, board development, and programmatic activities, and holds a Masters in Social Work from the University of Pennsylvania, and a graduate certificate in non-profit management from Georgetown University.

"I feel very fortunate to be joining such a vibrant organization," said Weiss. "Chicago is a great city and the TPAN staff, board of directors, and volunteers inspired me with their energy and passion the moment I walked through the front door. It is a remarkable organization providing important HIV prevention and care services."





## You're Not Getting Any Younger

*Embrace it!*

by Matt Sharp

**T**urning 50 two years ago was not an easy birthday, yet it was, in a way, as transformative as it can be for anyone, HIV-positive or -negative. I thought that, due to the fact that I am a 20-year survivor of HIV, reaching the ripe mid-century mark would somehow be more celebratory—and it was, on paper—but there were many mixed emotions. I worried about an unsure future with a broken immune system and a community that increasingly discriminates against older people. I worried I would die single. I don't know, perhaps, all in all, I'm just a whiner. But I heard from a lot of people who felt my pain.

The research on aging with HIV/AIDS is starting to bear some fruit since some of us old geezers have stayed around long enough to: 1) get infected with HIV in the first place; 2) live through the early experimental age of antiretroviral therapy; and 3) actually be considered "aged." We have lived long enough to die of "natural causes." What is less understood is the evidence that could definitively prove that HIV exacerbates the aging process and all the complications thereof—it most likely does. Or that living to an older age makes HIV worse, which is less clear. Cumulative drug therapy, immune dysfunction, and immune capacity most surely will have a long-term effect on most of us who live long enough to see our golden years. We also understand that while constant inflammation is a natural immune response, it most certainly will have long-term negative consequences. We know that stopping HIV drugs will increase mortality due to the inflammation that occurs when HIV has been allowed to cut loose. But assuredly, we now know that antiretroviral medicine is allowing us a much longer life than we ever thought possible.

Unfortunately, HIV exacerbates the aged appearance in most long-term survivors. In the past two years, one of the biggest bees in my bonnet has been the ageism I see and have experienced within the HIV-positive, gay male population. My HIV-pos-

itive women friends also express to me their feelings about the ageism they deal with. In reality, discrimination against older people is pervasive in America. We treat our elders like s\*\*t. HIV/AIDS survivors now have to bear yet another stigma—old age.

Moving to San Francisco in July probably made AIDS ageism all the more apparent, due to the fact that there is a larger ratio of HIV-positives to gay men here. But I cannot understand the old paradigm of people within their own race/gender/ethnicity/sexual orientation and HIV serostatus who discriminate against themselves. After all we've been through, and all the outside discrimination we experience, it has been a rude awakening to witness stigmatization among my HIV-positive brothers.

Where does this stigmatization come from? Maybe it's the attractiveness factor, which is also pervasive in our society, gay or straight, positive or negative. Our society thrives in "looks-ism". Gay men have that creative gene that perpetuates beauty and perfection, yet at the same time, we are loving and supportive. No denying I get excited when I see an attractive man! But it's tragic to witness obvious avoidance of older people with HIV, strictly on sight. Blatant ageism based on wrinkles, grey hair, and a belly is just plain idiotic, and is really dividing our community.

I'm all for *choice*, but what I'd love to see is younger and older positive people talking, socializing, and networking together. Through survival, we too often grow old only to experience isolation and depression because our own are turning us away. As a poz community, let's not make each other live through the painful discrimination other social groups sometimes perpetuate among themselves—skin tone in people of color; body weight and shape in women; socioeconomic status in everyone.

Older people with AIDS will probably suffer a multitude of social problems, as many have families or old friends who rejected them long ago due to discrimination. They are left with few choices, but in many cases, can survive fairly well on our

HIV social services system. However, I would argue that, in many instances, staying in this entitlement life leads to isolation, which can lead to depression and overall poor health, including substance abuse. Sadly, some have no choice, as they simply cannot work, or they do not have savings or insurance caps have long ago been met, leaving them uninsured. Much of any money they had was spent on just staying alive.

Ever consider getting back to work? Work provides great stabilization in our society. I have held jobs most of the time I've been positive even though I went on disability for awhile. But I eventually went back to work at the ripe old age of 48—when I was not out of the woods in terms of my antiretroviral drug choices. Sure, HIV has caused me to have "bad days" while working, but I'm still a strong advocate for going back to work. Working will help stave off isolation and at the same time bring in a salary. It provides a social framework and foundation. If we now see ourselves living to older age, we should at least be looking at going back to work if it is physically and mentally possible. Also, if full-time work isn't an option, try a part-time job or volunteering! For me, having a daily routine makes me feel so much more alive than staying home, cashing disability checks, and sitting on the couch watching reruns of "Sex in the City." It's just healthier.

Despite my HIV and age, I am damn fortunate to have all that I do: stable health, a great new job, and a supportive and loving companion—16 years my junior—who brings me boundless joy. I never thought I'd get here when I was first diagnosed 20 years ago. The clock ticks and we get older living with what was once considered to be an untreatable virus. You can celebrate every positive, healing moment. Time adds to the knowledge and understanding about AIDS, and just maybe as we survive more years, a cure will be in the works. You can consider growing older as a challenge, or you can find your own ways to embrace it and look forward to many more years. ☪

Photo © Russell McGonagle

ASK THE  
AAHIVM  
HIV  
SPECIALIST™

This issue's specialist:  
Sharon Valenti, M.D., N.P., AAHIVS



DEAR HIV SPECIALIST,

My partner started on Atripla at the same time I did (one year ago) and both of us are now suffering from right breast engorgement with pain. Is this a common side effect?

Signed, In Pain

DEAR IP,

The condition of breast enlargement or engorgement in men is called *gynecomastia* (guy-na-ko-mass-tee-a). It is a benign (not cancerous) condition and represents an increased amount of ductal tissue in the breast, along with an increase of connective tissue supporting the ducts. This can happen in one breast or both. Gynecomastia is confirmed by a mammogram and biopsy. There is another benign condition, called lipomastia, which is an accumulation of fat in the breast. This condition may be controlled or eliminated with diet and exercise. Both conditions, however, must be evaluated by mammography. Rarely, certain cancers, such as lymphoma, may be the cause of breast enlargement.

Highly Active Antiretroviral Therapy (HAART) has been implicated in the development of gynecomastia and lipomastia in HIV-positive men. Interestingly, it was not until the initiation of HARRT, in the mid- to late 90s, that more and more cases of gynecomastia were reported. The use of drugs in the protease inhibitor class of antiretrovirals have most often been implicated, but other clinical trials have found the use of nucleoside analogs and non-nucleoside analogs may also contribute to the condition of lipomastia. Atripla is made up of a non-nucleoside (efavirenz) and two nucleosides (emtricitabine and tenofovir).

In the case of true gynecomastia, it is important to understand that there are other drugs and physical conditions that may be the cause. Drugs, such as those used to treat cardiovascular conditions or gastric ulcer diseases, have been implicated, as well as long-term use of marijuana. Other chronic conditions, such as hepatitis and kidney disease, may also produce the symptoms of breast enlargement. It is important that your physician evaluate your condition to determine the precise cause of your breast enlargement in order to provide the best treatment for you. ☒

SUBMIT YOUR QUESTIONS FOR ASK THE HIV SPECIALIST TO  
AAHIVM@TPAN.COM

IS YOUR PROVIDER AN AAHIVM-CREDENTIALLED HIV SPECIALIST™?

If you are living with HIV, you have a lot of choices to make when seeking care and treatment. One of your most important choices is your health care practitioner—so why not choose someone who is knowledgeable about HIV and experienced in its treatment?

The American Academy of HIV Medicine (AAHIVM)'s HIV Specialist™ credentialing program is the first and only clinical credentialing program offered domestically and internationally to physicians (MDs and DOs), nurse practitioners, and physician assistants specializing in HIV care. HIV care providers become designated HIV Specialists™ after meeting experience and education requirements, and successfully completing a rigorous exam on HIV-specialized care. Look for the letters "AAHIVS" after their name.

LOCATE AN HIV SPECIALIST™

Your search for an HIV Specialist™ is easy with AAHIVM's online Find-A-Provider directory at [www.aahivm.org](http://www.aahivm.org). Just click on the "Find-A-Provider" window on the homepage, key in your location and click on the search button for a list of HIV Specialists™ near you.

Due to space limitations, not all submitted questions can be answered in this column, but every effort is made to ensure you receive the information you have requested. For more information about AAHIVM, call 202-659-0699 or visit [www.aahivm.org](http://www.aahivm.org).

## USE OF TRUVADA:

TRUVADA is a type of medicine called an HIV-1 (human immunodeficiency virus) nucleoside analog reverse transcriptase inhibitor and combines EMTRIVA® (emtricitabine) and VIREAD® (tenofovir disoproxil fumarate [DF]) in one pill. TRUVADA is always used with other anti-HIV-1 medicines to treat adults with HIV-1 infection.

TRUVADA® does not cure HIV-1 infection or lower your chance of passing HIV-1 to others. **TRUVADA should not be used with ATRIPLA®** (efavirenz 600 mg/emtricitabine 200 mg/tenofovir DF 300 mg), VIREAD®, EMTRIVA®, Combivir® (lamivudine/zidovudine), Epivir® or Epivir-HBV® (lamivudine), Epzicom® (abacavir sulfate/lamivudine), or Trizivir® (abacavir sulfate/lamivudine/zidovudine) because these medicines contain the same or similar active ingredients. TRUVADA should not be used with HEPSERA® (adefovir dipivoxil).

## IMPORTANT SAFETY INFORMATION:

**Contact your healthcare provider right away if you experience any of the following side effects or conditions while taking TRUVADA:**

- **Nausea, vomiting, unusual muscle pain, and/or weakness. These may be signs of a buildup of acid in the blood (lactic acidosis), which is a serious medical condition**
- **Light colored stools, dark colored urine, and/or if your skin or the whites of your eyes turn yellow. These may be signs of serious liver problems (hepatotoxicity), with liver enlargement (hepatomegaly), and fat in the liver (steatosis)**
- **If you have HIV-1 and hepatitis B virus (HBV) and stop taking TRUVADA, your liver disease may suddenly get worse. Your healthcare provider will monitor your condition for several months**
- If you have had kidney problems or take other medicines that can cause kidney problems, your healthcare provider should do regular blood tests to check your kidneys
- Lab tests show changes in the bones of patients treated with VIREAD, a medicine in TRUVADA. If you have had bone problems in the past, talk to your healthcare provider before taking TRUVADA. Also, bone pain and softening of the bone (which may contribute to fractures) may occur as a consequence of kidney problems.

Changes in body fat have been seen in some people taking TRUVADA and other anti-HIV-1 medicines.

If you notice any symptoms of infection soon after you start HIV treatment, talk to your doctor right away.

The most common side effects of the medicines in TRUVADA when taken with other anti-HIV-1 medicines are diarrhea, dizziness, nausea, headache, fatigue, abnormal dreams, sleeping problems, rash, depression, and vomiting. Additional side effects are kidney problems (including decline or failure of kidney function), inflammation of the pancreas, inflammation of the liver, allergic reaction, shortness of breath, pain, fatty liver, stomach pain, weakness, indigestion, and intestinal gas. High volume of urine and thirst, muscle pain and muscle weakness due to kidney problems have been reported. Skin discoloration (spots and freckles) may also happen with TRUVADA.

**Discuss all medicines you take with your healthcare provider and be aware:** Your healthcare provider may need to follow you more closely or adjust your therapy if you are taking Videx® or Videx® EC (didanosine), Reyataz® (atazanavir sulfate), or Kaletra® (lopinavir/ritonavir) with TRUVADA.

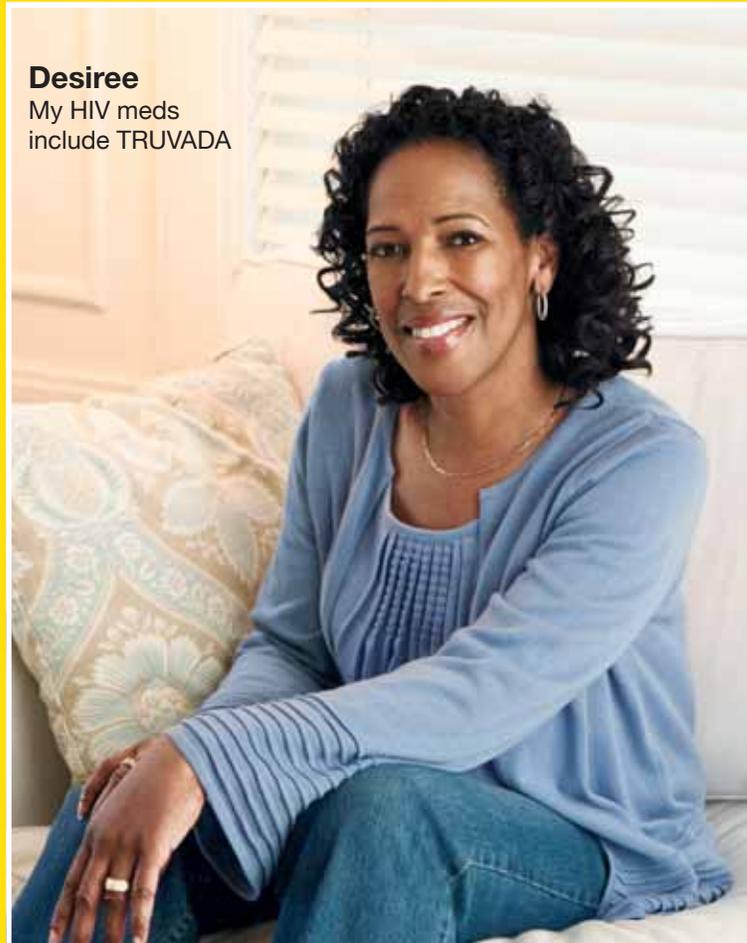
Please see Patient Information on next page, including **“What is the most important information I should know about TRUVADA?”**.

**You are encouraged to report negative side effects of prescription drugs to the FDA.**

**Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

# HIV doesn't have

**Desiree**  
My HIV meds  
include TRUVADA



**In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults**

**References: 1.** Based on data from PHAST retail monthly data; September 2005-October 2008; Wolters Kluwer Health.

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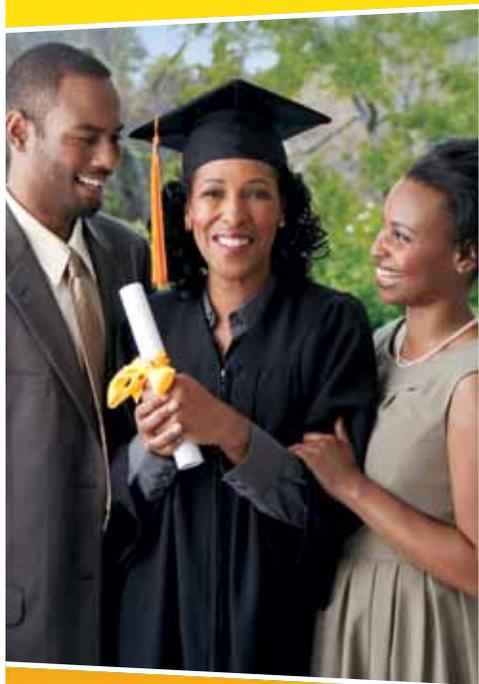


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#1

prescribed HIV  
med by doctors<sup>1</sup>

to change the  
hopes and dreams I have now.



Individual results may vary.

With *once a day* TRUVADA for my HIV, I can plan for long-term success.

- Proven over the long term to reduce viral load to undetectable (<400 copies/mL) and increase CD4 cell count in 3 years of a clinical study
- Established long-term safety and tolerability

TRUVADA does not cure HIV-1 infection or prevent passing HIV-1 to others.

Ask your doctor about TRUVADA and go to [www.TRUVADA.com](http://www.TRUVADA.com).

  
**Truvada**<sup>®</sup> 

200 mg emtricitabine · tenofovir disoproxil fumarate 300 mg

*Think long term.\* Starting now.*

\* Through 3 years of a clinical study.

## Patient Information

### TRUVADA® (tru-VAH-dah) tablets

Generic name: emtricitabine and tenofovir disoproxil fumarate  
(em tri SIT uh bean and te NOE' fo veer  
dye soe PROX il FYOU mar ate)

Read the Patient Information that comes with TRUVADA before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. You should stay under a healthcare provider's care when taking TRUVADA. **Do not change or stop your medicine without first talking with your healthcare provider.** Talk to your healthcare provider or pharmacist if you have any questions about TRUVADA.

#### What is the most important information I should know about TRUVADA?

- **Some people who have taken medicine like TRUVADA (nucleoside analogs) have developed a serious condition called lactic acidosis** (build up of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital. **Call your healthcare provider right away if you get the following signs or symptoms of lactic acidosis.**
  - You feel very weak or tired.
  - You have unusual (not normal) muscle pain.
  - You have trouble breathing.
  - You have stomach pain with nausea and vomiting.
  - You feel cold, especially in your arms and legs.
  - You feel dizzy or lightheaded.
  - You have a fast or irregular heartbeat.
- **Some people who have taken medicines like TRUVADA have developed serious liver problems called hepatotoxicity**, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). **Call your healthcare provider right away if you get the following signs or symptoms of liver problems.**
  - Your skin or the white part of your eyes turns yellow (jaundice).
  - Your urine turns dark.
  - Your bowel movements (stools) turn light in color.
  - You don't feel like eating food for several days or longer.
  - You feel sick to your stomach (nausea).
  - You have lower stomach area (abdominal) pain.
- **You may be more likely to get lactic acidosis or liver problems** if you are female, very overweight (obese), or have been taking nucleoside analog medicines, like TRUVADA, for a long time.
- **If you are also infected with the Hepatitis B Virus (HBV)**, you need close medical follow-up for several months after stopping treatment with TRUVADA. Follow-up includes medical exams and blood tests to check for HBV that could be getting worse. **Patients with Hepatitis B Virus infection, who take TRUVADA and then stop it, may get "flare-ups" of their hepatitis. A "flare-up" is when the disease suddenly returns in a worse way than before.**

#### What is TRUVADA?

TRUVADA is a type of medicine called an HIV-1 (human immunodeficiency virus) nucleoside analog reverse transcriptase inhibitor (NRTI). TRUVADA contains 2 medicines, EMTRIVA® (emtricitabine) and VIREAD® (tenofovir disoproxil fumarate, or tenofovir DF) combined in one pill. TRUVADA is always used with other anti-HIV-1 medicines to treat people with HIV-1 infection. TRUVADA is for adults age 18 and older. TRUVADA has not been studied in children under age 18 or adults over age 65.

HIV infection destroys CD4+ T cells, which are important to the immune system. The immune system helps fight infection. After a large number of T cells are destroyed, acquired immune deficiency syndrome (AIDS) develops.

TRUVADA helps block HIV-1 reverse transcriptase, a chemical in your body (enzyme) that is needed for HIV-1 to multiply. TRUVADA lowers the amount of HIV-1 in the blood (viral load). TRUVADA may also help to increase the number of T cells (CD4+ cells). Lowering the amount of HIV-1 in the blood lowers the chance of death or infections that happen when your immune system is weak (opportunistic infections).

**TRUVADA does not cure HIV-1 infection or AIDS.** The long-term effects of TRUVADA are not known at this time. People taking TRUVADA may still get opportunistic infections or other conditions that happen with HIV-1 infection. Opportunistic infections are infections that develop because the immune system is weak. Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium complex* (MAC) infection. **It is very important that you see your healthcare provider regularly while taking TRUVADA.**

**TRUVADA does not lower your chance of passing HIV-1 to other people through sexual contact, sharing needles, or being exposed to your blood.** For your health and the health of others, it is important to always practice safer sex by using a latex or polyurethane condom or other barrier to lower the chance of sexual contact with semen, vaginal secretions, or blood. Never use or share dirty needles.

#### Who should not take TRUVADA?

- Do not take TRUVADA if you are allergic to TRUVADA or any of its ingredients. The active ingredients of TRUVADA are emtricitabine and tenofovir DF. See the end of this leaflet for a complete list of ingredients.
- Do not take TRUVADA if you are already taking ATRIPLA® (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), Combivir (lamivudine/zidovudine), EMTRIVA, EpiVir or EpiVir-HBV (lamivudine), Epizcom (abacavir sulfate/lamivudine), Trizivir (abacavir sulfate/lamivudine/zidovudine), or VIREAD because these medicines contain the same or similar active ingredients.

- Do not take TRUVADA (emtricitabine/tenofovir disoproxil fumarate) to treat your HIV infection if you are also taking HEPSERA® (adefovir dipivoxil) to treat your HBV infection.

#### What should I tell my healthcare provider before taking TRUVADA?

##### Tell your healthcare provider if you:

- **are pregnant or planning to become pregnant.** We do not know if TRUVADA can harm your unborn child. You and your healthcare provider will need to decide if TRUVADA is right for you. If you use TRUVADA while you are pregnant, talk to your healthcare provider about how you can be on the TRUVADA Antiviral Pregnancy Registry.
- **are breast-feeding.** You should not breast feed if you are HIV-positive because of the chance of passing the HIV virus to your baby. Also, it is not known if TRUVADA can pass into your breast milk and if it can harm your baby. If you are a woman who has or will have a baby, talk with your healthcare provider about the best way to feed your baby.
- **have kidney problems or are undergoing kidney dialysis treatment.**
- **have bone problems.**
- **have liver problems including Hepatitis B Virus infection.**

**Tell your healthcare provider about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take:

- Videx, Videx EC (didanosine). Tenofovir DF (a component of TRUVADA) may increase the amount of Videx in your blood. **You may need to be followed more carefully if you are taking TRUVADA and Videx together.** Also, the dose of didanosine may need to be reduced.
- Reyataz (atazanavir sulfate) or Kaletra (lopinavir/ritonavir). These medicines may increase the amount of tenofovir DF (a component of TRUVADA) in your blood, which could result in more side effects. You may need to be followed more carefully if you are taking TRUVADA and Reyataz or Kaletra together. TRUVADA may decrease the amount of Reyataz in your blood. If you are taking TRUVADA and Reyataz together, you should also be taking Norvir (ritonavir).

Keep a complete list of all the medicines that you take. Make a new list when medicines are added or stopped. Give copies of this list to all of your healthcare providers and pharmacist **every** time you visit your healthcare provider or fill a prescription.

#### How should I take TRUVADA?

- Take TRUVADA exactly as your healthcare provider prescribed it. Follow the directions from your healthcare provider, exactly as written on the label.
- The usual dose of TRUVADA is 1 tablet once a day. TRUVADA is always used with other anti-HIV-1 medicines. If you have kidney problems, you may need to take TRUVADA less often.
- TRUVADA may be taken with or without a meal. Food does not affect how TRUVADA works. Take TRUVADA at the same time each day.
- If you forget to take TRUVADA, take it as soon as you remember that day. **Do not take more than 1 dose of TRUVADA in a day. Do not take 2 doses at the same time.** Call your healthcare provider or pharmacist if you are not sure what to do. **It is important that you do not miss any doses of TRUVADA or your anti-HIV-1 medicines.**
- When your TRUVADA supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to TRUVADA and become harder to treat.
- Do not change your dose or stop taking TRUVADA without first talking with your healthcare provider. Stay under a healthcare provider's care when taking TRUVADA.
- If you take too much TRUVADA, call your local poison control center or emergency room right away.

#### What should I avoid while taking TRUVADA?

- **Do not breast-feed.** See "What should I tell my healthcare provider before taking TRUVADA?"
- **Avoid doing things that can spread HIV infection** since TRUVADA does not stop you from passing the HIV infection to others.
  - **Do not share needles or other injection equipment.**
  - **Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.**
  - **Do not have any kind of sex without protection.** Always practice safer sex by using a latex or polyurethane condom or other barrier to reduce the chance of sexual contact with semen, vaginal secretions, or blood.
- ATRIPLA (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), Combivir (lamivudine/zidovudine), EMTRIVA (emtricitabine), EpiVir or EpiVir-HBV (lamivudine), Epizcom (abacavir sulfate/lamivudine), Trizivir (abacavir sulfate/lamivudine/zidovudine), or VIREAD (tenofovir disoproxil fumarate).

#### TRUVADA should not be used with these medicines.

- TRUVADA should not be used with HEPSERA.

#### What are the possible side effects of TRUVADA?

**TRUVADA may cause the following serious side effects** (see "What is the most important information I should know about TRUVADA?"):

- **Lactic acidosis** (buildup of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital. **Call your doctor right away if you get signs of lactic acidosis.** (See "What is the most important information I should know about TRUVADA?")





- **Serious liver problems (hepatotoxicity)**, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). Call your healthcare provider right away if you get any signs of liver problems. (See “What is the most important information I should know about TRUVADA?”)
- **“Flare-ups” of Hepatitis B Virus infection**, in which the disease suddenly returns in a worse way than before, can occur if you stop taking TRUVADA (emtricitabine/tenofovir disoproxil fumarate). Your healthcare provider will monitor your condition for several months after stopping TRUVADA if you have both HIV-1 and HBV infection. TRUVADA is not approved for the treatment of Hepatitis B Virus infection. If you have advanced liver disease and stop treatment with TRUVADA, the “flare-up” of hepatitis B may cause your liver function to decline.
- **Kidney problems**. If you have had kidney problems in the past or take other medicines that can cause kidney problems, your healthcare provider should do regular blood tests to check your kidneys.
- **Changes in bone mineral density (thinning bones)**. Laboratory tests show changes in the bones of patients treated with VIREAD (tenofovir disoproxil fumarate), a component of TRUVADA. If you have had bone problems in the past, your healthcare provider may need to do tests to check your bone mineral density or may prescribe medicines to help your bone mineral density. Additionally, bone pain and softening of the bone (which may contribute to fractures) may occur as a consequence of kidney problems.

Other side effects with TRUVADA when used with other anti-HIV-1 medicines include:

- Changes in body fat have been seen in some patients taking TRUVADA and other anti-HIV-1 medicines. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms and face may also happen. The cause and long term health effect of these conditions are not known at this time.
- In some patients with advanced HIV infection (AIDS), signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body’s immune response, enabling the body to fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please inform your doctor immediately.

The most common side effects of EMTRIVA (emtricitabine) or VIREAD when used with other anti-HIV-1 medicines are: diarrhea, dizziness, nausea, headache, fatigue, abnormal dreams, sleeping problems, rash, depression, and vomiting. Additional side effects are lactic acidosis, kidney problems (including decline or failure of kidney function), inflammation of the pancreas, inflammation of the liver, allergic reaction, shortness of breath, pain, fatty liver, stomach pain, weakness, indigestion, intestinal gas, and high volume of urine and thirst caused by kidney problems. Muscle pain and muscle weakness, bone

pain, and softening of the bone (which may contribute to fractures) as a consequence of kidney problems have been reported. Skin discoloration (small spots or freckles) may also happen with TRUVADA (emtricitabine/tenofovir disoproxil fumarate).

These are not all the side effects of TRUVADA. If you have questions about side effects, ask your healthcare provider. Report any new or continuing symptoms to your healthcare provider right away. Your healthcare provider may be able to help you manage these side effects.

**How do I store TRUVADA?**

- **Keep TRUVADA and all other medicines out of reach of children.**
- Store TRUVADA at room temperature 77 °F (25 °C).
- Keep TRUVADA in its original container and keep the container tightly closed.
- Do not keep medicine that is out of date or that you no longer need. If you throw any medicines away make sure that children will not find them.

**General information about TRUVADA:**

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use TRUVADA for a condition for which it was not prescribed. Do not give TRUVADA to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about TRUVADA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about TRUVADA that is written for health professionals. For more information, you may also call 1-800-GILEAD-5 or access the TRUVADA website at [www.TRUVADA.com](http://www.TRUVADA.com).

Do not use TRUVADA if seal over bottle opening is broken or missing.

**What are the ingredients of TRUVADA?**

**Active Ingredients:** emtricitabine and tenofovir disoproxil fumarate

**Inactive Ingredients:** Croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and pregelatinized starch (gluten free). The tablets are coated with Opadry II Blue Y-30-10701 containing FD&C Blue #2 aluminum lake, hydroxypropyl methylcellulose 2910, lactose monohydrate, titanium dioxide, and triacetin.

**Rx Only**

November 2008

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**SAVE THE DATE!**  
**AWARE AFFAIR**  
**9-12-2009**

# Nelson Vergel:

## Going Beyond Survival



In 1986 Nelson Vergel was only 27 years old when he learned he had HIV. At the time, he wasn't sure he'd make it to 30, let alone to one day see 50. At the recent Retrovirus conference in Montreal in February, he invited a large group of friends to dinner to share his fiftieth birthday with him.

"Being 30 was a big milestone, 40 was a huge one, and now 50...I never even thought, three or four years ago, I was going to be 50," says Vergel. "It was a big miracle for me, which I was able to enjoy with my friends."

A native of Venezuela and former chemical engineer, Vergel is a 25-year survivor of HIV who has, by necessity, become a leading treatment advocate for people with HIV. Vergel has developed multi-drug resistance (MDR), rendering his HIV essentially resistant to every commercially available HIV drug, but you'd never know it by looking at him. Vergel is the picture of perfect health—fit, toned, and tanned—and even though on disability, probably works harder than most people with a full-time job. And while he claims he's dealing with it, he says it sometimes makes him feel like he's not going to live that much longer. "Yet," he laughs, "I've been around forever."

His number one issue right now? "Fatigue," says Vergel, without hesitation. "People think I'm a hyperactive person, I lecture around the country, and yet when they see me is when I'm at my best. I would say that 80% of the time I'm struggling to get to the point where I have enough energy. I have severe fatigue—it's cyclic, it comes and goes—but most of the time I have it, and I have to find ways to deal with it."

Vergel, an international speaker on HIV treatments

Photo © Evin Thayer

## A leading advocate's thoughts on getting the most out of life

by Jeff Berry

and side effect management, and co-author of the book *Built To Survive*, says that the people who come to his lectures are aging and long-term survivors who, like himself, experience fatigue, as well as gastrointestinal (GI) problems. "We used to blame Norvir—well, I haven't taken Norvir for three years, and I still have some diarrhea and bloating, so that's my number two," jokes Vergel.

"I'm 50 years old, I exercise, I look pretty good, and I try my best to keep my body in shape and not fall apart with lipodystrophy or wasting. But at the same time, I wonder if this is the way a healthy 50-year-old feels. And I'm almost sure that the answer is no."

Vergel says he is on a constant search for the answer to fatigue, through research, reading and consuming HIV information on a daily basis—to the point where it's almost become a full-time job. Curiously enough, a recent e-mail from HIV advocate Jules Levin, founder of the National AIDS Treatment Advocacy Project (NATAP, see article on page 36), gave Vergel his first glimpse into why some people with HIV are experiencing so much fatigue.

"They conducted a study where they performed functional MRIs of the brain, and they found a section of the brain that, when compared to healthy HIV-negative subjects, produced less creatine, which is a metabolite for energy production. So already there's something going on in our brain that is causing us to have fatigue. Some people also blame, of course, side effects of medications we're taking. Fatigue is occurring not only in people like me who are dealing with MDR, but it's also occurring in people with undetectable viral load. So I'm always searching for 'What is it?' and 'How can we treat it?'"

To treat it, Vergel takes testosterone by injection every two weeks, which keeps his testosterone hormone levels within normal range. He also takes vitamin supplements, including B vitamins, for the reason that B-6 and B-12 deficiencies have been correlated to fatigue.

"Another drug that's becoming popular is Provigil [modafinil]," says Vergel, "It's actually been studied in people with HIV at Sloan-Kettering in New York, with great results." He cautions, though, that the drug is metabolized through the same P450 pathway in the liver which many HIV drugs use, and therefore more drug-drug interaction studies are needed. Vergel states, however, that many are now taking Provigil once or twice a day to battle fatigue and depression.

**"I tell them we have to go beyond getting our T-cells up and getting our viral load down to undetectable."**

He said doctors have also been prescribing Adderall, which is a stimulant composed of mixed amphetamine salts, and is thought to work by increasing the amount of norepinephrine and dopamine in the brain. It's used to treat Attention Deficit Hyperactivity Disorder (ADHD) and narcolepsy (a chronic sleep disorder), but, on the downside, it may become habit-forming.

"There's green tea, and some people take ginseng—I've tried that too," says Vergel. "So there are some of us in this constant search for what we call a pseudo-normal life, either through medications or other things to increase our energy level, because without energy, there's no life. When I'm tired, not only do I not produce, I don't write, I don't help others, I feel depressed, everything collapses. I cannot deal with stress, I don't want to pay my bills, I'm too tired for that, or to deal with phone calls. So energy and fatigue really, really affect everything in life, even adherence—but we need more studies."

Another big issue, says Vergel, is undiagnosed sleep apnea, which he has a mild case of. He says that some of us wake up more tired, sometimes, than when we went to bed. But according to Vergel, most people are not referred to sleep labs, because many doctors feel that if you're HIV-positive, you're expected to feel fatigued. Some individuals may have sleep disorders that are either induced by weight or by things they aren't even aware of, including side effects from drugs such as Sustiva or Atripla, which may be causing a disruption in their sleep patterns.

It's often a struggle, says Vergel, to have a really good quality of life. "I tell people that survival doesn't mean anything unless you have a good quality of life. I mean, if you're going to stick around

# “It’s really important that all of us, even those who are HIV-negative, deal with the acceptance of aging.”

in this world, and yet you’re tired all the time and you’re depressed, your body’s falling apart, and you’re actually not keeping yourself in good health, then what’s the point, really, of surviving? I tell people that we have to go *beyond* survival.”

And it just so happens that going beyond survival is the subject of Vergel’s next book, which he says is two-thirds complete and due out later this year. It’s a compilation of 25 years of what he calls “collective health wisdom,” which is a tremendous amount of information he has learned while moderating his list serve (pozhealth at Yahoo! Groups) as well as from e-mails he’s received from people with HIV all over the world.

“People ask me, ‘How do you know so much?’” says Vergel. “I’m reading e-mails from other people who’ve tried different things. There’s this collective wisdom that we have as long-term survivors. I think we also know a lot in HIV as we age, more than any other disease, we’ve learned so much and, yes, we keep it to ourselves and it’s time to share that. For instance, what we have learned about hormones, we’ve been using them for 20 years, before anyone else did; what we have learned about exercise; what we have learned about nutrition, supplements, things that help with energy, depression, and sexual function—*that’s* something *nobody* wants to talk about.”

Vergel says he sees the younger generation of HIV-positives only worrying about taking their pill and moving on with life and while he thinks that’s good, he tells them to go beyond that. “Thinking about HIV all day isn’t very good for you anyway,” says Vergel. “I tell them we have to go beyond getting our T-cells up, getting our viral load down to undetectable—there are other issues

that come up. We’re now having concerns about bone density. We seem to be losing bone more than healthy people—are we going to have fractures in a few years? And most of us are taking Truvada or Viread—is it really going to end up affecting our kidneys? Our liver—some of us, like myself, have hepatitis B or C—is cirrhosis going to affect us at the end? I wonder about liver, kidney problems, bone density—and there are bigger issues that I think are coming up in most studies, such as cancer, including anal cancer. They say a little education is needed for doctors and patients about how to diagnose problems that lead to anal cancer; how to catch it early; Pap smears—what does that mean? Should we all be getting that?

“People say, ‘You’re so obsessed with health.’ Well, I’m obsessed with life! I want to live a good life! I love my life. I think having a good quality of life so that I can travel and lecture is very important, so I have to be aware of all these things. Are we going to have a shitty older life? I don’t know, I don’t think so. Maybe some of us are, some of us may not—some of us may reach a very healthy 80-year-old age. I think some people forget that, people with HIV, yes, we may have more health issues, but we also go to the doctor 10 times more frequently than any other person out there. We go to the doctor every three months—they check our lipids, they check our blood sugar, our kidneys, our liver, chemistry, all that. Very few people in this country go to the doctor every three months. Most Americans don’t go to the doctor for years, until something happens to them. So yes, we may have some issues, but we keep an eye on them more than anyone else, so that’s a good thing. It makes us a little bit more, I won’t say obsessed, but focused, on numbers than anyone else. Are we sicker than most people? Maybe, maybe not. But we’re definitely being monitored more frequently than any other people in the United States.”

Vergel says it breaks his heart that a lot of the younger folks who come to his lectures are completely clueless. “There is this vast amount of information we have as a community, and yet we weren’t able to really package it so that we could say, ‘Here—read this, and hopefully you’ll learn what a lot of us old folks have dealt with. Without scaring them, of course—I don’t want to scare the new, naïve patients because, as I said, they’re going to have it easier than we did. They have drugs that are a lot more friendly and don’t cause lipodystrophy or lipoatrophy, and they don’t have to take high doses of Norvir anymore. But yet, I think they’re going to have issues—they may not be as severe as ours, but there will be things that probably bother them, like CNS problems with Sustiva, some bone density issues, some kidney toxicity eventually, or even cancers that may flare up later in life.”

The stigma associated with being HIV-positive is a continuing problem, admits Vergel, which contributes to feelings of loneliness and depression, especially in older adults. While he doesn’t see it going away any time soon, he does believe there’s reason to hope.

“Women with HIV who are heterosexual, they’re stigmatized horribly,” he says. Vergel goes on the Hetero Poz Cruise Retreat each year (See News Briefs on page 16), where he speaks to more than 60 heterosexual individuals, and is able to spend the entire week with them on a cruise. “We think we have it bad in the gay community, but we don’t have it as bad as the heterosexual community with HIV, where they’re terrified of how people treat them in the straight world, too. So it’s not only the gays, it’s the straight people with HIV, especially the women, who have a lot of issues around stigma.”

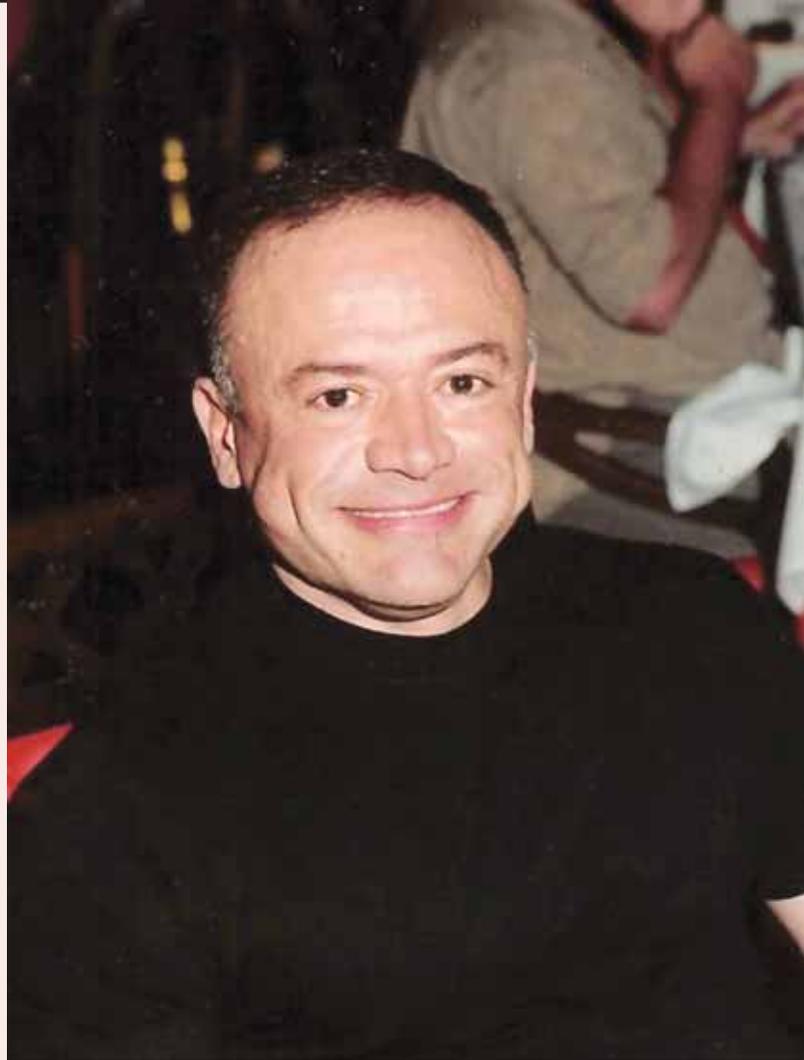
In order to be able to start to change people’s perceptions, Vergel believes we need to begin with the younger generation. “I think I’m seeing a trend for them to be more open-minded, more accepting of what’s different. Stigma really is a fear of what’s different. Most people stigmatize because they don’t understand certain things, so they’re afraid of them and they discriminate against them.” Vergel thinks HIV is always going to have some stigma associated with it since many of us acquire it through sexual transmission, and because many are stigmatized for being gay.

“But I have seen an openness in that generation—they have straight/gay alliances in most schools, and kids are able to come out earlier than we did. Most of us were in the closet until we were 20-something, so I really think the world’s going to be a better place in 10 or 15 years, when a lot of the older generation that has grown up with a lot of stigma, misconceptions, racism, homophobia, and HIV-phobia are going to be moving a ways back. We have to generate a lot of programs at the college level, the high school level, where we can teach these kids, hey, it’s okay, these people are not evil, HIV doesn’t discriminate, it’s just a virus. I think we’re going to get there, I really think so.

“I may not be alive to see the day,” says Vergel, “But I think the next generation that comes through is going to be more accepting of people who are different, who are not what we call the ‘norm.’ ”

Vergel says he’s very out about his own HIV status and being gay, and that even being an immigrant from South America with a Spanish accent hasn’t caused him to suffer as much stigma as most. “Is it because I am very out about it and I feel actually proud of all the differences I have? Or maybe it’s the fact that I live in a more isolated, bubble kind of world, that doesn’t expose me to people who are really anti-HIV, anti-gay, anti-female, anti-immigrant, and all the other ‘anti’ things we have in the world,” laughs Vergel.

One final thing that Vergel stresses is that it’s really important that all of us, even those who are HIV-negative, deal with the acceptance of aging. “You know, when we look at ourselves in the mirror, we’re not looking like we did 20 years ago. Some of us may still be single and looking for dates, or sex, and some of us may be getting rejected because we are older. For some of us who have been positive for a long time and getting older, we’re not really preparing ourselves. I think we’re in pseudo-denial of the fact that we’re ever



going to get a day older because we were not going to be around for that long, or so we thought.”

While Vergel says that we’re never going to be that person we were a few years ago, especially with concerns around lipoatrophy and facial wasting, we have to find ways to love ourselves. “Think of the things we’ve gone through and yet, we’re *here*, most of us are not falling apart, having productive lives. We’re survivors of a horrible thing that happened, and is still happening, and often we have friends and lovers die around us, and we have to take care of ourselves.”

Vergel was recently involved in an anti-stigma campaign in Houston, and says that early next year they will be holding what he believes to be the area’s first conference focusing specifically on HIV and aging, and bringing in experts to talk about the physical and mental aspects of aging with HIV. “It’s hard,” explains Vergel. “I don’t want to preach about it, because I deal with it too, but somebody needs to look at that. I’d like to see a study, a cohort, observing people who are aging with HIV and what our main issues are.

“I think it’s time.” ☒

*For more information on Nelson Vergel and PoWeR, visit [www.powerusa.org](http://www.powerusa.org). For more information on the Hetero Poz Cruise Retreat, see page 16 or visit [www.positivecruise.com](http://www.positivecruise.com).*

# Where Are They Now?

## Whatever happened to Compound Q and the rest of them?

by Sue Saltmarsh



**R**emember Compound Q? AL721? Did you ever grow a Kombucha mushroom in your basement and pass a “baby” onto someone else?

In the process of settling into my new position on the staff of *Positively Aware*, I’ve had the pleasure of reading the very first issues of *TPA News*, from which *PA* evolved into the international publication it is today. Definitely “low-tech,” this grassroots newsletter was, at the time of its inception, one of the very few sources available for information on the treatment of HIV, much of which was what would now be called “complementary” or “alternative.” Like indigenous cultures throughout human history who found themselves facing the invasion of new germs, viruses, and diseases, early HIV-fighters turned to Nature, ancient traditions, and innovation to arm themselves against this disease.

As an herbalist in 1992, just starting to work with HIV-positive clients, I was firm in my conviction that if there was ever to be a cure, it would be a combination of botanical/natural and pharmaceutical, the most perfect, harmonious marriage of science and Nature, and the scientists, herbalists, nutritionists, and docs would work together in altruistic efforts to create that cure. Yeah, sure! I proceeded along the course of that conviction until I could no

longer deny that The Cocktail was here to stay, so effective in controlling the virus and so profitable for the pharmaceutical companies that no further investigation of herbs, vitamins, minerals, and other natural substances would occur—at least not here in the U.S. In Europe, India, South America, Asia, even Israel, where capitalism does not have the stranglehold on health care that it has here, research into these kinds of treatments existed before HIV/AIDS and goes on to this day.

I thought it might be interesting to find out whatever happened to a handful of these early treatments. A self-admitted Luddite when it comes to computer literacy, I got some tutoring on how to do Internet research (thanks, Brad!) and, while Jeff and Enid were soaking up information at CROI, I gave myself over to Google.

### COMPOUND Q

Remembering my first days at the AIDS Alternative Health Project, I started with Compound Q (or GLQ223), an extract of Chinese cucumber that many of my clients had taken. The fact that it had “toxicity issues” didn’t seem to deter anyone from trying it and, indeed, there was a wave of con-

trovery involved with the study of its effects. As federally-approved Phase 1 toxicity trials were taking place at San Francisco General Hospital Medical Center, Martin Delaney and his Project Inform activists were consulting with doctors to design a protocol for an underground trial, thus challenging the FDA’s usually slow process for testing urgently needed, potentially life-saving drugs. Preliminary results of the “guerilla” trial concluded that, while many of the trial’s volunteers showed a marked decrease in activity of HIV, there were also those who suffered adverse events and Compound Q could not be considered a cure. Seen through the lens of historical perspective, perhaps the most important result of Compound Q’s short-lived fame was the pressure Delaney and other activists were able to put on the FDA, which now has accelerated approval procedures that allow promising drugs to get to the people who need them the most.

### KOMBUCHA MUSHROOMS

Next on my list was the fungus known as Kombucha mushrooms. Benefits included boosting the immune system, increasing digestion and appetite, and improving skin and nails. This was taken in the form of a

drink made by adding a pancake-shaped mass of bacteria and yeast to tea and sugar. The mixture ferments to produce the liquid that is imbibed. Even though these things were gross to look at and the taste was definitely an acquired one (I tried it once and had to spit it out!), there was a certain positive psychological effect in that, similar to people passing on their sourdough starter to friends, networks of people were formed that exchanged “babies” used to start their own mushrooms. This coming together of community may have been the best result of the Kombucha phase, since the home grown variety later had toxicity of its own, including instances of anthrax contamination, metabolic acidosis, and lead poisoning (from being brewed in a ceramic pot painted with lead-based paint). There is now commercially brewed kombucha, much safer, standardized, and popular for its probiotic properties, including certain bacteria known to have beneficial effects on digestion. Dr. Brent Bauer, director of the Complementary and Integrative Medicine Program at the Mayo Clinic, believes it may have legitimate value but says, “My own philosophy is, we better wait for clinical trials.”

#### EGG LECITHIN

In the early editions of *TPA News*, there was much discussion about egg lecithin, also known in commercial form as AL721. First available in Israel, AL721 was a combination of three lipids, derived from egg yolks, which purportedly made cell receptor sites resistant to viral attachment. Anecdotal evidence existed in abundance, citing almost-miraculous improvement in T-cell counts, cessation of diarrhea and weight loss, great improvement in skin conditions and no more fevers or night sweats. So what could be the problem with this, I wondered?

As it turns out, AL721 was licensed in 1985 to Praxis Pharmaceuticals, and in a report from September 1985, Praxis believed it would be at least four years before the FDA would consider allowing any commercial sales. According to *AIDS Treatment News*, January 1986, “clinical tests of AL721 against AIDS are being planned, but have not received final approval.” As far as I could determine, those trials never took place and nothing further has been heard about AL721. In the process of researching it, I found several instances in different AIDS publications of people sharing their

recipes for homemade AL721. Perhaps, like Kombucha, it provided a solidifying of the HIV/AIDS community. *AIDS Treatment News* called for accountability in what it called “a major failure of public policy in the AIDS epidemic—lack of commitment to modify business as usual when necessary to save lives.”

#### SELENIUM

Just as I began to resign myself to cynicism about the impossibility of a pharmaceutical/natural treatment ever being developed, I read a posting on our community forum (thanks, Elise!) about a 2007 study of the effects of selenium on HIV. It seems to indicate that when selenium levels are increased, viral loads tend to be lower and the number of CD4 cells increase. Researchers from the University of Miami conducted a double-blind, randomized, placebo-controlled trial of selenium supplements in 262 patients with HIV. Patients were randomly divided into two groups to take either a capsule containing 200 micrograms of high-selenium yeast or a sugar pill daily.

Nine months later, each patient underwent a comprehensive physical exam, and results showed that the patients taking daily selenium supplements had lower levels of the virus in their bloodstream and increased T-cell counts compared to patients who took a placebo pill.

Anecdotal evidence abounds about the benefits of selenium, starting with the simple geographical fact that the nation of Senegal, with its unusually selenium-rich soil, has only a 1.77% incidence of HIV while its neighbor, Zimbabwe, which has low levels of selenium in the soil, has a 26% incidence. There is an almost identical pattern of risky sexual behavior in both countries.

There is an ongoing five-year, double-blind study on selenium being done in Africa which will come to an end this year. Could it prove that augmentation of this mineral for HIV-positive people would

make it possible to decrease dosages of the more toxic pharmaceutical drugs now being used? Could there finally be that convergence of the scientific with the natural that I used to dream about? Obviously, more studies like the African one need to be done before any such marriage of selenium and anti-retrovirals is cemented and becomes an accepted treatment option.

#### HOPE

Little glimmers of hope appear in other areas as well. There is currently an ongoing study of a Chinese herbal blend, ViraPhyte, which could serve to delay the need for drug treatment, as well as to provide a “bridge” therapy for those experiencing treatment interruptions. In 2006, FIAR (the Foundation for Integrative AIDS Research) helped investigators Fred Blair and Mark Kuebel to benefit from a grant from NCCAM (the National Center for Complementary and Alternative Medicine), a division of the National Institutes of Health, to enable clinicians in a non-pharmaceutical system of medicine to research their methods of treating HIV. George Carter, of FIAR and the New York Buyer’s Club, confirms my belief that research on alternative/complementary therapies in the U.S. must find a way to conform or compare to the scientific model of double-blind, placebo-controlled, randomized studies before they will be considered seriously by the scientific and medical communities. Though the study is progressing slowly due to several challenges (New York readers, consider participating!), perhaps the work that these men do will blaze the trail for a future melding of allopathic and alternative methods. I remain ever hopeful. ✚

For more information on the study, visit [www.hivherbs.org](http://www.hivherbs.org)

For information on other research, visit [www.fiar.org](http://www.fiar.org)

## COULD THERE FINALLY BE THAT CONVERGENCE OF THE SCIENTIFIC WITH THE NATURAL THAT I USED TO DREAM ABOUT?



*The following information was presented at the 16<sup>th</sup> Conference on Retroviruses and Opportunistic Infections (CROI) in Montreal this past February.*

*For more information, including webcasts and interviews with doctors, visit [TheBody.com](http://TheBody.com), [aidsmeds.com](http://aidsmeds.com), or [retroconference.org](http://retroconference.org).*

#### **HIV A HEART RISK ALL BY ITSELF**

At HIV medical conferences, the same doctors usually get to present on their pet specialties. For HIV and heart disease, Carl Grunfeld, M.D., Ph.D., of the University of California, San Francisco, often reports on the latest information. What did the Grunfeld have to say this year?

“It’s clear—HIV is an additional risk factor,” Grunfeld said. “It is virtually the same” as being male, a smoker, or a diabetic, he reported. “What’s clear from our study is that HIV itself is bad on your atherosclerosis.”—Enid Vázquez

#### **HEART DISEASE WITH ZIAGEN AND OTHER MEDS**

A previous report from the D:A:D cohort study (Data Collection on Adverse Events of Anti-HIV Drugs) found an increased risk of heart attack in people taking Ziagen or Videx. In an updated report, there was also a higher risk of heart attack in people taking Crixivan or Kaletra. As usual, the risk was higher in those people who already had risk factors, such as smoking, high cholesterol, or older age. The report noted that, “As with any observational study, our findings must be interpreted with caution given the potential for confounding [unknown factors influencing the findings].” Although the relative risk was higher, the actual number of heart attacks in this large cohort (approximately 33,000 individuals) was very low.—EV

#### **BYE, BYE, NORVIR?**

Norvir started out as an HIV drug, one of the “savior” protease inhibitors (PIs) to come out in the mid-1990s. It was hard to stomach, however, and was saved only when it was found useful, in small doses, for boosting the blood levels of other PI drugs, cutting the doses of those meds (and their side effects) while maintaining or improving their power.

That’s nice, but Norvir became a villain when manufacturer Abbott Laboratories raised its price 400%, which compensated for its smaller dosage and took advantage of its wide-spread use. That’s why advocates for HIV treatment, including doctors, have been waiting for years to kick Norvir to the curb. Now that end appears to be in sight.

Not just one but two drugs in development are expected to boost the blood levels of HIV protease inhibitors.

GS-9350 matched Norvir’s boosting of the drug midazolam, meeting proof-of-concept criteria for continued research. In test tube studies, GS-9350 has less of an effect on triglycerides, cholesterol, and insulin resistance (related to diabetes) than does Norvir. GS-9350 also has co-formulation potential, so that it can be given in a pill with the medications it boosts, not just taken separately. Having met these criteria, it went into research as a quad tablet—four medications in one. The three other meds are Viread and Emtriva (which are also available together, known as Truvada) and

Photos © Enid Vázquez

# CROI ROUND-UP

NEW INFORMATION  
ON THE HEART,  
PLUS A POSSIBLE  
ALTERNATIVE TO  
NORVIR AND MORE



THE COSTLY STUDIES MAY EVENTUALLY  
LEAD TO DEEPER UNDERSTANDING OF  
THE IMMUNE SYSTEM.

the experimental elvitegravir, which is an HIV integrase inhibitor drug. With a successful Phase 1 (safety study) behind it, the quad tablet now moves into Phase 2 study, being tested against Atripla, a triple drug in one (Sustiva, Viread, and Emtriva). GS-9350 will also be tested as a booster of the protease inhibitor Reyataz.

GS-9350 is from Gilead Sciences, considered a small company, but one with the blockbuster HIV drugs Viread and Truvada, as well as Emtriva, and which received high praise for working with another pharmaceutical company (Bristol-Myers Squibb) to create Atripla.

The other potential PI booster still in research is SPI-452. In test tube studies, it boosted three protease inhibitors. In an early study, it also caused no increase in triglycerides or LDL (the “bad” cholesterol) compared to a placebo (sugar pill), and has potential for co-formulation. SPI-452 is being developed by Sequoia Pharmaceuticals.—EV

#### **IL-2 FAILS TO DEMONSTRATE CLINICAL BENEFIT IN TWO LARGE TRIALS**

Results from two large, randomized trials of IL-2 (interleukin-2), in which significant increases in CD4 T-cells were seen in those taking IL-2 injections in combination with antiretroviral therapy (ART), unfortunately did not translate into any clinical benefit, and showed no difference in rates of AIDS diagnoses or death for the IL-2 group versus those on ART alone.

Data from the two studies, ESPRIT and SILCAAT, were presented. Together, the two studies monitored around 6,000 individuals over a 7-year period. In one study, those taking IL-2 were found to be at greater risk for life-threatening adverse events (AEs), including DVT (deep vein thrombosis). While it is not yet clear exactly why the CD4 increases did not confer any benefit, some possible explanations offered were that the adverse events offset any benefit, or that the kind of T-cell being affected by IL-2 differs in function from the type of CD4 which is normally boosted when taking ART. The costly studies, while disappointing, may eventually, following further planned analyses, lead to deeper understanding of the immune system.—*Jeff Berry*

#### **INDEVUS' PRO 2000 BECOMES FIRST MICROBICIDE TO DEMONSTRATE EFFICACY**

Research on an experimental microbicide known as PRO 2000 has demonstrated that the vaginal gel provides a small amount of protection against HIV in women, according to a study that was presented at CROI.

PRO 2000, manufactured by Indevus Pharmaceuticals, works by binding up HIV and preventing it from attaching to certain white blood cells. This preliminary study, designed to test the safety of the gel, found it to be 30% effective at preventing the onset of infection. These findings miss the mark of statistical significance

by three percentage points; however, the study itself is the first to demonstrate the potential for microbicides to be effective.

Conducted by the Center for AIDS Program of Research in South Africa, and funded by the U.S. National Institutes of Health (NIH), the study divided 3,000 women from the U.S. and four different regions in Africa into four groups. One group used the PRO 2000 gel, another used a different microbicide gel produced by Reprotect known as BufferGel, a third group used a placebo gel, and the remaining group used no gel at all. Comprehensive sex education was also provided to the women, and condom use was encouraged.

At the end of the study, 194 women had contracted HIV, 36 of whom were from the PRO 2000 group, 54 from the BufferGel group, 51 from the placebo group, and 53 from the group that used no microbicides.—*Keith R. Green* 🏠



ADVOCATES OF  
HIV TREATMENT, INCLUDING DOCTORS,  
HAVE BEEN WAITING FOR YEARS TO  
KICK NORVIR TO THE CURB.



Please read Important Safety Information below, and talk to your healthcare professional to learn more about PREZISTA.

### ABOUT PREZISTA

PREZISTA® (darunavir) is a prescription medicine. It is one treatment option in the class of HIV (human immunodeficiency virus) medicines known as protease inhibitors.

PREZISTA is always taken with and at the same time as ritonavir (Norvir®), in combination with other HIV medicines for the treatment of HIV infection in adults. PREZISTA should also be taken with food.

- The use of other medicines active against HIV in combination with PREZISTA/ritonavir (Norvir®) may increase the likelihood of your overall treatment response. Your healthcare professional will work with you to find the right combination of other HIV medicines
- The long-term effects of PREZISTA therapy are unknown at this time. It is important that you remain under the care of your healthcare professional

PREZISTA does not cure HIV infection or AIDS, and does not prevent passing HIV to others.

### IMPORTANT SAFETY INFORMATION

- PREZISTA, together with Norvir® (ritonavir), has rarely been observed to cause liver problems that may be life-threatening. It was not always clear if PREZISTA caused these liver problems because some patients had other illnesses or were taking other medicines. Your healthcare professional should do blood tests prior to initiating combination treatment including PREZISTA. If you have chronic hepatitis B or C infection, your healthcare professional should check your blood tests more often because you have an increased chance of developing liver problems

Talk to your healthcare professional about the signs and symptoms of liver problems. These may include yellowing of your skin or whites of your eyes, dark (tea-colored) urine, pale-colored stools (bowel movements), nausea, vomiting, loss of appetite, or pain, aching or sensitivity on your right side below your ribs

- Skin rashes have been reported in patients taking PREZISTA. Rarely, PREZISTA has been reported to cause a severe or life-threatening rash. Contact your healthcare professional if you develop a rash
- Taking PREZISTA with certain medicines could cause serious and/or life-threatening side effects or may result in loss of its effectiveness. Do not take PREZISTA if you are taking the following medicines: dihydroergotamine (D.H.E.45®, Migranal®), ergonovine, ergotamine (Wigraine®, Ergostat®, Cafergot®, Ergomar®), methylergonovine, cisapride (Propulsid®), pimozone (Orap®), oral midazolam, triazolam (Halcion®), rifampin (Rifadin®, Rifater®, Rifamate®), indinavir (Crixivan®), lopinavir/ritonavir (Kaletra®), saquinavir (Invirase®), lovastatin (Mevacor®), pravastatin (Pravachol®), simvastatin (Zocor®), or products containing St. John's wort
- Before taking PREZISTA, tell your healthcare professional if you are taking sildenafil (Viagra®), vardenafil (Levitra®), tadalafil (Cialis®), atorvastatin (Lipitor®), atorvastatin/amlodipine (Caduet®), or rosuvastatin (Crestor®). This is not a complete

# Belief

in myself  
in my doctor  
in my care



PREZISTA now offers **ONCE-DAILY** dosing for adults taking HIV meds for the first time.

PREZISTA must be taken with and at the same time as ritonavir (Norvir®) and with food.

PREZISTA must be taken in combination with other HIV meds.

Talk to your doctor to see if PREZISTA is right for you.



Please visit [www.PREZISTA.com](http://www.PREZISTA.com)

**list of medicines. Be sure to tell your healthcare professional about all the medicines you are taking or plan to take, including prescription and nonprescription medicines, vitamins, and herbal supplements**

- Tell your healthcare professional if you are taking estrogen-based contraceptives (birth control). PREZISTA might reduce the effectiveness of estrogen-based contraceptives. You must take additional precautions for birth control, such as condoms
- Before taking PREZISTA, tell your healthcare professional if you have any medical conditions, including allergy to sulfa medicines, diabetes, liver problems (including hepatitis B or C), or hemophilia
- Tell your healthcare professional if you are pregnant or planning to become pregnant, or are breastfeeding
  - The effects of PREZISTA on pregnant women or their unborn babies are not known. You and your healthcare professional will need to decide if taking PREZISTA is right for you
  - Do not breastfeed if you are taking PREZISTA. You should not breastfeed if you have HIV because of the chance of passing HIV to your baby
- High blood sugar, diabetes or worsening of diabetes, and increased bleeding in people with hemophilia have been reported in patients taking protease inhibitor medicines, including PREZISTA
- Changes in body fat have been seen in some patients taking HIV medicines, including PREZISTA. The cause and long-term health effects of these conditions are not known at this time
- As with other protease inhibitors, taking PREZISTA may strengthen the body's immune response, enabling it to begin to fight infections that have been hidden. Patients may experience signs and symptoms of inflammation that can include swelling, tenderness, or redness
- The most common side effects related to taking PREZISTA include diarrhea, nausea, headache, and abdominal pain. Uncommon but severe side effects such as inflammation of the pancreas and increased blood fat levels have also been rarely reported. This is not a complete list of all possible side effects. If you experience these or other symptoms, talk to your healthcare professional. Do not stop taking

PREZISTA or any other medicines without first talking to your healthcare professional

- Please refer to the ritonavir (Norvir®) Product Information (PI and PPI) for additional information on precautionary measures

**For adults taking HIV meds for the first time: PREZISTA 800 mg (two 400-mg tablets) must be taken at the same time with 100 mg Norvir® once daily every day. PREZISTA must be taken with food.**

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

**Please see Important Patient Information on the next page for more information, or visit [www.PREZISTA.com](http://www.PREZISTA.com).**

**If you or someone you know needs help paying for medicine, call 1-888-4PPA-NOW (1-888-477-2669) or go to [www.pparx.org](http://www.pparx.org).**

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# IMPORTANT PATIENT INFORMATION

## FDA-Approved Patient Labeling

### PREZISTA® (darunavir) Tablets

Patient Information about

#### PREZISTA (pre-ZIS-ta)

for HIV (Human Immunodeficiency Virus) Infection  
Generic name: darunavir (da-ROO-nuh-veer)

**ALERT: Find out about medicines that should NOT be taken with PREZISTA.** Please also read the section "Who should not take PREZISTA?".

Please read this information before you start taking PREZISTA. Also, read the leaflet each time you renew your prescription, just in case anything has changed. Remember, this leaflet does not take the place of careful discussions with your doctor. You and your doctor should discuss your treatment with PREZISTA prior to the first time you take your medicine and at regular checkups. You should remain under a doctor's care when using PREZISTA and should not change or stop treatment without first talking with a doctor.

### WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT PREZISTA?

PREZISTA, together with NORVIR® (ritonavir), has rarely been observed to cause liver problems which may be life-threatening. It was not always clear if PREZISTA caused these liver problems because some patients had other illnesses or were taking other medicines. Your healthcare professional should do blood tests prior to initiating combination treatment including PREZISTA. If you have chronic hepatitis B or C infection, your healthcare professional should check your blood tests more often because you have an increased chance of developing liver problems. Please also read the section "What are the possible side effects of PREZISTA?".

Rarely, PREZISTA has been reported to cause a severe or life-threatening rash. Contact your healthcare provider if you develop a rash. Your healthcare provider will advise you whether your symptoms can be managed on therapy or whether PREZISTA should be stopped.

### WHAT IS PREZISTA?

**PREZISTA is an oral tablet used for the treatment of HIV (Human Immunodeficiency Virus) infection in adults. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).** PREZISTA is a type of anti-HIV medicine called a protease (PRO-tee-ase) inhibitor.

### HOW DOES PREZISTA WORK?

PREZISTA blocks HIV protease, an enzyme which is needed for HIV to multiply. When used with other anti-HIV medicines, PREZISTA can help to reduce the amount of HIV in your blood (called "viral load") and increase your CD4 (T) cell count. HIV infection destroys CD4 (T) cells, which are important to the immune system. The immune system helps fight infection. Reducing the amount of HIV and increasing the CD4 (T) cell count may improve your immune system and, thus, reduce the risk of death or infections that can happen when your immune system is weak (opportunistic infections).

PREZISTA is always taken with and at the same time as ritonavir (NORVIR®), in combination with other anti-HIV medicines. PREZISTA should also be taken with food.

### DOES PREZISTA CURE HIV OR AIDS?

PREZISTA does **not** cure HIV infection or AIDS. At present, there is no cure for HIV infection. People taking PREZISTA may still develop infections or other conditions associated with HIV infection. Because of this, it is very important for you to remain under the care of a doctor. Although PREZISTA is not a cure for HIV or AIDS, PREZISTA can help reduce your risks of getting illnesses associated with HIV infection (AIDS and opportunistic infection) and eventually dying from these conditions.

### DOES PREZISTA REDUCE THE RISK OF PASSING HIV TO OTHERS?

PREZISTA does **not** reduce the risk of passing HIV to others through sexual contact, sharing needles, or being exposed to your blood. For your health and the health of others, it is important to always practice safer sex by using a latex or polyurethane condom or other barrier method to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions, or blood. Never re-use or share needles.

Ask your doctor if you have any questions on how to prevent passing HIV to other people.

### WHAT SHOULD I TELL MY DOCTOR BEFORE I TAKE PREZISTA?

**Tell your doctor about all of your medical conditions, including if you:**

- are allergic to sulfa medicines.
- have diabetes. In general, anti-HIV medicines, such as PREZISTA, might increase sugar levels in the blood.
- have liver problems, including hepatitis B and/or C.
- have hemophilia. Anti-HIV medicines, such as PREZISTA, might increase the risk of bleeding.
- are pregnant or planning to become pregnant. The effects of PREZISTA on pregnant women or their unborn babies are not known. You and your doctor will need to decide if taking PREZISTA is right for you. If you take PREZISTA while you are pregnant, talk to your doctor about how you can be included in the Antiretroviral Pregnancy Registry.
- are breastfeeding. Do not breastfeed if you are taking PREZISTA. You should not breastfeed if you have HIV because of the chance of passing HIV to your baby. Talk with your doctor about the best way to feed your baby.

### WHO SHOULD NOT TAKE PREZISTA?\*

Together with your doctor, you need to decide whether taking PREZISTA is right for you.

#### Do not take PREZISTA if you:

- are allergic to darunavir or any of the other ingredients in PREZISTA
- are allergic to ritonavir (NORVIR®)
- take any of the following types of medicines because you could experience serious side effects:

#### Type of Drug

Ergot Derivatives  
(to treat migraine and headaches)

Gastrointestinal Motility Agent  
(to treat some digestive conditions)

Neuroleptic  
(to treat psychiatric conditions)

Sedative/hypnotics  
(to treat trouble with sleeping and/or anxiety)

Herbal Product  
HMG-CoA Reductase inhibitors  
(also known as statins)  
(to lower cholesterol levels)

Antimycobacterial  
(to treat tuberculosis or *Mycobacterium avium* complex)

#### Examples of Generic Names (Brand Names)

dihydroergotamine (D.H.E. 45®, Migranal®)  
ergonovine  
ergotamine (Cafergot®, Ergomar®)  
methylergonovine  
cisapride

pimozide (Drap®)

oral midazolam  
triazolam (Halcion®)

St. John's wort (*Hypericum perforatum*)  
lovastatin (Mevacor®, Altoprev®, Advicor®)  
simvastatin (Zocor®, Simcor®, Vytorin®)

rifampin (Rifadin®, Rifater®, Rifamate®, Rimactane®)

### CAN PREZISTA BE TAKEN WITH OTHER MEDICATIONS?\*

Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements. PREZISTA and many other medicines can interact. Sometimes serious side effects will happen if PREZISTA is taken with certain other medicines (see "Who should not take PREZISTA?").

Tell your doctor if you are taking estrogen-based contraceptives (birth control). PREZISTA might reduce the effectiveness of estrogen-based contraceptives. You must take additional precautions for birth control such as a condom.

Tell your doctor if you take other anti-HIV medicines. PREZISTA can be combined with some other anti-HIV medicines while other combinations are not recommended.

Tell your doctor if you are taking any of the following medicines:

#### Type of Drug

Antiarrhythmics  
(to treat abnormal heart rhythms)

Anticoagulants  
(to treat and prevent blood clots)

Anticonvulsants  
(to treat epilepsy and prevent seizures)

Antidepressants  
(to treat depression)

Anti-infectives  
(to treat bacterial infections)

Antifungals  
(to treat fungal infections)

Antimycobacterials  
(to treat tuberculosis or *Mycobacterium avium* complex)

β-Blockers  
(to treat high blood pressure, heart attack, or heart failure or to lower pressure in the eye)

Benzodiazepines  
(to treat anxiety and/or trouble with sleeping)

Calcium Channel Blockers  
(to treat heart disease)

Corticosteroids  
(to treat inflammation or asthma)

HMG-CoA Reductase Inhibitors  
(also known as statins)  
(to lower cholesterol levels)

#### Examples of Generic Names (Brand Names)

bepridil  
lidocaine (Lidoderm®)  
quinidine  
amiodarone (Cordarone®)  
digoxin (Lanoxin®)  
flecainide (Tambocor®)  
propafenone (Rythmol®)  
warfarin (Coumadin®)

carbamazepine (Tegretol®, Carbatrol®)  
phenobarbital  
phenytoin (Dilantin®, Phenytek®)  
trazodone (Desyrel®)  
desipramine (Norpramin®)  
clarithromycin (Biaxin®)

ketoconazole (Nizoral®)  
itraconazole (Sporanox®)  
voriconazole (Vfend®)  
rifabutin (Mycobutin®)

metoprolol (Lopressor®, Toprol-XL®)  
timolol (Betimol®, Combigan®, Istalol®, Cosopt®, Timoptic®)

midazolam administered by injection

felodipine (Plendil®)  
nifedipine (Adalat®)  
nicardipine (Cardene®)

dexamethasone  
fluticasone propionate (Advair Diskus®, Cutivate®, Flonase®, Flovent Diskus®)

atorvastatin (Lipitor®)  
pravastatin (Pravachol®)  
rosuvastatin (Crestor®)

## IMPORTANT PATIENT INFORMATION

Type of Drug	Examples of Generic Names (Brand Names) (cont.)
Immunosuppressants (to prevent organ transplant rejection)	cyclosporine (Sandimmune®, Neora®) tacrolimus (Prograf®) sirolimus (Rapamune®)
Narcotic Analgesics (to treat narcotic withdrawal and dependence)	methadone
Neuroleptics (to treat schizophrenia or bipolar disorder)	risperidone (Risperdal®, Risperdal® Consta®, Risperdal® M-TAB®) thioridazine
PDE-5 Inhibitors (to treat erectile dysfunction)	sildenafil (Viagra®) vardenafil (Levitra®) tadalafil (Cialis®)
Selective Serotonin Reuptake Inhibitors (SSRIs) (to treat depression, anxiety, or panic disorder)	paroxetine (Paxil®) sertraline (Zoloft®)

Tell your doctor if you are taking any medicines that you obtained without a prescription.

This is **not** a complete list of medicines that you should tell your doctor that you are taking. Know and keep track of all the medicines you take and have a list of them with you. Show this list to all of your doctors and pharmacists any time you get a new medicine. Both your doctor and your pharmacist can tell you if you can take these other medicines with PREZISTA. Do not start any new medicines while you are taking PREZISTA without first talking with your doctor or pharmacist. You can ask your doctor or pharmacist for a list of medicines that can interact with PREZISTA.

### HOW SHOULD I TAKE PREZISTA?

Take PREZISTA tablets every day exactly as prescribed by your doctor. You must take ritonavir (NORVIR®) at the same time as PREZISTA.

- For adults who have never taken anti-HIV medicines, the usual dose is 800 mg (two 400 mg tablets) of PREZISTA, together with 100 mg (one 100 mg capsule) of ritonavir (NORVIR®), once daily *every day*.
- For adults who have taken anti-HIV medicines in the past, the usual dose is 600 mg (one 600 mg tablet or two 300 mg tablets) of PREZISTA, together with 100 mg (one 100 mg capsule) of ritonavir (NORVIR®), twice daily *every day*. Do not take PREZISTA once daily if you have taken anti-HIV medicines in the past.

PREZISTA and ritonavir (NORVIR®) should be taken together at the same time every day. If you have questions about when to take PREZISTA and ritonavir (NORVIR®), your doctor can help you decide which schedule works for you.

Take PREZISTA and ritonavir (NORVIR®) **with food**. Swallow the whole tablets with a drink such as water or milk. Do not chew the tablets.

Continue taking PREZISTA and ritonavir (NORVIR®) unless your doctor tells you to stop. Take the exact amount of PREZISTA and ritonavir (NORVIR®) that your doctor tells you to take, right from the very start. To help make sure you will benefit from PREZISTA and ritonavir (NORVIR®), you must not skip doses or interrupt therapy. If you don't take PREZISTA and ritonavir (NORVIR®) as prescribed, the beneficial effects of PREZISTA and ritonavir (NORVIR®) may be reduced or even lost.

#### Patients taking PREZISTA once daily

If you miss a dose of PREZISTA or ritonavir (NORVIR®) by more than 12 hours, wait and then take the next dose of PREZISTA and ritonavir (NORVIR®) at the regularly scheduled time. If you miss a dose of PREZISTA or ritonavir (NORVIR®) by less than 12 hours, take your missed dose of PREZISTA and ritonavir (NORVIR®) immediately. Then take your next dose of PREZISTA and ritonavir (NORVIR®) at the regularly scheduled time.

#### Patients taking PREZISTA twice daily

If you miss a dose of PREZISTA or ritonavir (NORVIR®) by more than 6 hours, wait and then take the next dose of PREZISTA and ritonavir (NORVIR®) at the regularly scheduled time. If you miss a dose of PREZISTA or ritonavir (NORVIR®) by less than 6 hours, take your missed dose of PREZISTA and ritonavir (NORVIR®) immediately. Then take your next dose of PREZISTA and ritonavir (NORVIR®) at the regularly scheduled time.

You should always take PREZISTA and ritonavir (NORVIR®) together with food.

If a dose of PREZISTA or ritonavir (NORVIR®) is skipped, do not double the next dose. Do not take more or less than your prescribed dose of PREZISTA or ritonavir (NORVIR®) at any one time.

### WHAT ARE THE POSSIBLE SIDE EFFECTS OF PREZISTA?

Like all prescription drugs, PREZISTA can cause side effects. The following is **not** a complete list of side effects reported with PREZISTA when taken either alone or with other anti-HIV medicines. Do not rely on this leaflet alone for information about side effects. Your doctor can discuss with you a more complete list of side effects.

PREZISTA, together with NORVIR® (ritonavir), has rarely been observed to cause liver problems which may be life-threatening. It was not always clear if PREZISTA caused these liver problems because some patients had other illnesses or were taking other medicines. Your healthcare professional should do blood tests prior to initiating combination treatment including PREZISTA. If you have chronic hepatitis B or C infection, your healthcare professional should check your blood tests more often because you have an increased chance of developing liver problems.

Talk to your healthcare professional about the signs and symptoms of liver problems. These may include yellowing of your skin or whites of your eyes, dark (tea colored) urine, pale colored stools (bowel movements), nausea, vomiting, loss of appetite, or pain, aching or sensitivity on your right side below your ribs.

Rash has been reported in 10.3% of subjects receiving PREZISTA. In some patients, PREZISTA has been reported to cause a severe or life-threatening rash. Contact your healthcare provider if you develop a rash. Your healthcare provider will advise you whether your symptoms can be managed on therapy or whether PREZISTA should be stopped.

Other relevant severe side effects reported at an uncommon or rare frequency were inflammation of the liver or pancreas, increased blood fat levels, diabetes, and changes in body fat.

Some side effects are typical for anti-HIV medicines in the same family as PREZISTA. These are:

- high blood sugar (hyperglycemia) and diabetes. This can happen in patients taking PREZISTA or other protease inhibitor medicines. Some patients have diabetes before starting treatment with PREZISTA which gets worse. Some patients get diabetes during treatment with PREZISTA. Some patients will need changes in their diabetes medicine. Some patients may need new diabetes medicine.
- increased bleeding in patients with hemophilia.
- changes in body fat. These changes can happen in patients taking anti-HIV medicines, including PREZISTA. The changes may include an increased amount of fat in the upper back and neck, breast, and around the back, chest, and stomach area. Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these conditions are not known.
- immune reconstitution syndrome. In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment, including PREZISTA, is started. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms.

The most common side effects include diarrhea, nausea, headache, and abdominal pain.

Tell your doctor promptly about these or any other unusual symptoms. If the condition persists or worsens, seek medical attention.

### WHAT DO PREZISTA TABLETS LOOK LIKE?

PREZISTA 300 mg tablets are orange, oval-shaped, film-coated tablets mentioning "300" on one side and "TMC114" on the other side.

PREZISTA 400 mg tablets are light orange, oval-shaped, film-coated tablets mentioning "400" on one side and "TMC" on the other side.

PREZISTA 600 mg tablets are orange, oval-shaped, film-coated tablets mentioning "600" on one side and "TMC" on the other side.

### HOW SHOULD I STORE PREZISTA TABLETS?

Store PREZISTA tablets at room temperature (77°F (25°C)). Short-term exposure to higher or lower temperatures [from 59°F (15°C) to 86°F (30°C)] is acceptable. Ask your doctor or pharmacist if you have any questions about storing your tablets.

**This medication is prescribed for your particular condition. Do not use it for any other condition or give it to anybody else. Keep PREZISTA and all of your medicines out of the reach of children. If you suspect that more than the prescribed dose of this medicine has been taken, contact your local poison control center or emergency room immediately.**

This is a brief summary of information about PREZISTA. If you have any questions or concerns about either PREZISTA or HIV, talk to your doctor.

For additional information, you may also call Tibotec Therapeutics at 1-877-REACH-TT or 1-877-732-2488.

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# HIV Accelerates Aging

A call for investigation  
by Jules Levin

**T**his CROI focused more on aging than any previous conference, but this serious concern is not receiving adequate attention from our research community. Preliminary research is demonstrating that HIV-positive individuals are aging more quickly than HIV-negative individuals and that the HIV virus, itself, is a major culprit in causing this. As a result, we have been seeing increases in non-AIDS-related co-morbidities and consequent deaths—is there a risk this could explode soon?

We have known for a while that immune activation is caused by HIV; this revs up the immune system to deal with HIV but, at the same time, wears it down. So, as we get older, the immune system is weaker than that in HIV-negative individuals, and this can reduce our ability to fight off cancers, diabetes, and diseases of the kidneys, heart, brain, and bones.

Also, HIV gets into parts of the body soon after initial infection. Apparently, highly active antiretroviral therapy (HAART) improves, but does not reverse, immune activation. We are uncertain how this affects the infected person 30 years into the future, although it appears that it causes premature aging and a weakened immune system. Numerous studies conducted in the past two years find that inflammation and premature aging of T-cells appear to be caused by HIV. The SMART Study, among others, finds that inflammation increases when patients take antiretroviral therapy (ART) treatment interruptions, and that the prevalence of non-AIDS-related co-morbidities and consequent deaths increases due to the inflammation resulting from treatment interruptions.

These findings are not new to HIV. For years, the published literature has been full of articles and research finding that inflammation is associated with co-morbidities like cognitive impairment, diabetes, heart disease, and kidney disease. Hepatitis C is also associated with causing kidney disease and perhaps cognitive impairment. On a particularly troubling note, two studies at CROI found that the brains of HIV-positive individuals had characteristics of HIV-negative individuals 15-20 years older. And metabolic abnormalities, including elevated triglycerides and diabetes, were associated with brain damage.

Researchers have become aware of such concerns only over the past year, but we hope that now they will respond by quickly conducting the right research to help us address the concerns. What is the issue? Isn't it okay for HIV-positive individuals to get older just like everyone else, even if they do age faster? After all, we can't have the fountain of youth, some people say. Nonsense.

The point is that HIV accelerates aging, and the consequences of this acceleration in HIV-positive individuals are troublesome, if not dire. About 20% of HIV-positive individuals are over 50 years old, a percentage that has increased by 25% in the past few years, and this trend is on the upswing, so perhaps in several years, as many as 40% will be over 50.

Obviously, this is likely to create a tremendous burden on patients but, less obvious, is that it will create a tremendous burden on the HIV care system in the U.S., which is already tremendously overburdened. We have not spent very much money in recent years to improve the HIV care system and it is straining at the seams. The

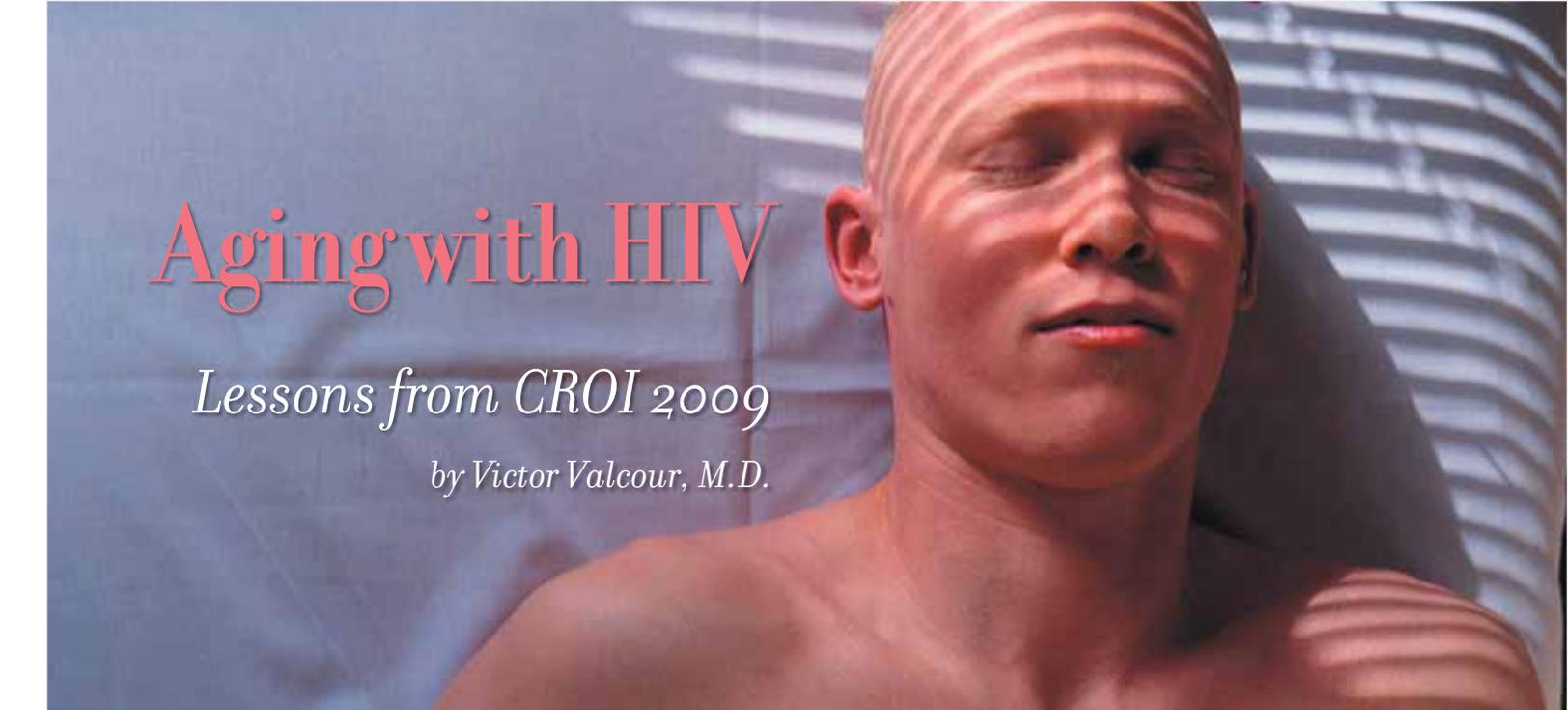
economic demands of providing services related to the aging population have been overlooked. One study at CROI reported that the cognitive impairment rate among patients over 60 years old was 50%. Bone studies report 50% osteopenia rates and 5-20% osteoporosis rates at the stunningly young age of an average in the mid-40s. Osteoporosis is associated with increased frailty and mortality. A recent study has reported that HIV-positive individuals are much more "frail" than HIV-negative individuals. This can also lead to premature morbidity and mortality concerns.

This is arguably the number one issue for HIV-positive individuals in care in the Western world, but it will occur for the developing world as well, and perhaps be considerably worse for them. This problem cannot be ignored, but so far, it is not getting adequate attention. For years, we have all been giddy about the success of HAART, but the luster may be wearing off now and we might be facing, within a few years, more serious problems, as we age, than we've imagined thus far.

On a personal level, HIV-positive individuals should start a dialogue with their clinician about this problem, if they haven't already. Screening and monitoring can be used to evaluate the development of co-morbidities. A bone DEXA is performed quickly, is inexpensive, and can detect bone loss, for which taking calcium and vitamin D supplements might help. Simple blood tests can monitor lipids, sugar, the kidneys, and the cardiovascular system. Blood tests for inflammation markers are easily available (hsCRP, IL-6, etc.). Monitoring, prevention, and timely treatment are crucial to stave off these complications.

In the meantime, the HIV research community cannot ignore the problem. I hope they will not! We need timely and good research to look for the mechanism of action by which HIV causes immune activation, senescence (aging), and inflammation; and we need to find treatment interventions now. ☩

*Jules Levin is the founder and director of the National AIDS Treatment Advocacy Project (NATAP), which educates individuals about HIV and hepatitis treatments, and advocates on behalf of people living with HIV/AIDS and HCV. See accompanying article, "Aging with HIV" by Victor Valcour, M.D. on page 37. Visit [www.natap.org](http://www.natap.org).*



# Aging with HIV

## Lessons from CROI 2009

by Victor Valcour, M.D.

**S**ome of the world's leading HIV researchers converged on Montreal in February of this year for the 16<sup>th</sup> Conference on Retroviruses and Opportunistic Infections (CROI). This year's conference continued to document the unfolding world-wide access to antiretroviral therapy, with large advances noted, despite some set-backs. These accomplishments rightly find their place centrally in the agenda for this premier international conference. The conference also relayed new findings on the risk factors for HIV and non-HIV-related complications. Presentations related to new therapies were less frequent and research related to vaccines continued to detail great challenges.

Attendees interested in emerging issues related to aging with HIV infection would be largely disappointed, as the emphasis on aging was notably scant. Despite many papers describing age-related vulnerability and a general agreement that this population is rapidly expanding, there continues to be a large gap in research specifically addressing this population. This is quite disappointing to clinicians who are witnessing the graying of their clinic populations across the U.S. while they have few guidelines by which to direct specialized care. Even resource-limited settings will soon be facing the challenges related to the management of chronic HIV in populations that will inevitably age with infection, as was noted in data presented by researchers in Senegal.<sup>1</sup>

In the U.S., the prevalence of HIV in people who are over 65 years of age has increased more than 10-fold in the past decade.<sup>2</sup> In some regions, more than half of HIV patients are currently over 50 and it is broadly acknowledged that this distribution is likely to be noted nationwide by 2015. Numerous articles have already been published demonstrating a detrimental effect of aging on HIV and non-HIV outcomes, rendering the age-related findings from many of the 16th CROI papers to be confirmatory rather than enlightening as to underlying mechanisms. There were no papers (and probably little-to-no data) that tried to address the controversy related to age-specific treatment recommendations, despite nearly universal detrimental outcomes associated with age. This striking deficit may reflect the relative infancy of this topic in the minds of researchers, and we can only hope it will change in the years ahead.

With few exceptions, aging was considered as a potential modifying factor in models for clinical studies presented at the 16th

CROI. Depressingly, the impact is almost universally unfavorable, which was brought quickly to light in large studies, such as that presented in abstract #145.<sup>3</sup> (Visit [www.retroconference.org](http://www.retroconference.org).) With the occasional outlier (two papers suggest a signal that prostate cancer rates may be lower than anticipated in HIV compared to age match controls, #30, 178)<sup>4, 5</sup> older HIV patients can typically anticipate higher rates and worse outcomes for nearly all complications. These poorer outcomes should be worrisome enough, but become even more striking when one considers that most participants in these trials are not old. Typically, the reported mean age is in the mid- to upper 40s, representative of the HIV epidemic in resource-rich countries, in general. Thus, outcomes for truly old HIV populations remain under-studied and largely unknown.

What follows is a brief synopsis of papers that highlight aging or complications with particular relevance to the aging HIV population.

### CARDIOVASCULAR DISEASE

Over the past decade, it has become increasingly clear that cardiovascular complications are frequent among patients treated for HIV. Accordingly, the 16th CROI included a broad array of papers on the topic. HIV infection was confirmed to be an independent risk factor for cardiovascular disease based on data from the FRAM study;<sup>6</sup> but promising data were noted from the California Kaiser Permanente database, where rates of myocardial infarction (MI) decreased in recent years and are now similar to background rates, possibly owing to aggressive management of risk factors.<sup>7</sup> Risk for cardiovascular outcomes and intermediate markers of cardiovascular change can be predicted with the Framingham risk scores;<sup>8</sup> however, HIV-specific changes (not necessarily associated with traditional risk factors) are also noted. One study identified changes in endothelium-dependent vasodilatation (a measure of cardiovascular risk) in treatment-naïve HIV patients to the extent that would be anticipated in HIV-negative controls who were 25 years older, suggesting vascular (blood vessel) changes akin to accelerated aging.<sup>9</sup>

While age negatively impacts cardiovascular outcomes, several papers also identified modifiable risk factors that influence cardiovascular (as well as all-cause) mortality, including intravenous drug use, smoking, hypertension, and diabetes.<sup>3, 10</sup> The relationship

between abacavir use and cardiovascular outcomes was discussed in several papers with some,<sup>11-13</sup> but not all,<sup>14</sup> studies identifying associations. This controversy is beyond the scope of this review, but was the subject of paper #152, for readers interested in more information on the topic.<sup>15</sup>

### **OSTEOPOROSIS AND RENAL DISEASES**

Osteoporosis is largely a disease associated with age in HIV-negative populations, but has also been demonstrated to be more frequent with HIV<sup>16, 17</sup> (50% osteopenia in HIV and 5-20% osteoporosis at the average age of 45). Some of this risk is explained by hypogonadal status in HIV-infected men.<sup>18</sup> As with other complications, the presence and pattern of osteoporosis may suggest age-related changes,<sup>19</sup> such as its association with increased markers of T-cell senescence (when cells lose the ability to divide).<sup>20</sup>

Renal function decreases with age, regardless of HIV status, often requiring medication adjustments. One paper identified that the rate of decline is increased with HIV and this increase is not arrested by control of viral load.<sup>21</sup> Age was also shown to increase risk for renal tubular disease in association with tenofovir (Viread) use.<sup>22, 23</sup> New advances in medications that may eventually replace ritonavir (Norvir) as a boosting agent were presented and are thought to have improved gastrointestinal profiles compared to ritonavir, a factor likely to greatly impact quality of life for HIV elders.<sup>24, 25</sup>

### **MALIGNANCIES AND MORTALITY**

Cancer rates are elevated with HIV and with age. The California Kaiser Permanente database identified a rate of 29.7/10,000 person-years for infection-related non-AIDS-defining cancers in HIV-positive people compared to a background rate of 4.4/10,000 (RR = 6.8).<sup>4</sup> This rate has remained essentially unchanged in the last decade. Cancers found to be elevated in HIV include anal cancer, Hodgkin's lymphoma, head and neck cancers, gynecological cancers, and kidney, lung, and skin melanomas. The notable exception was prostate cancer, where the authors noted an early signal of decreased relative risk (0.7).<sup>4</sup> This trend was noted by another group as well.<sup>5</sup>

Although aging is associated with increased mortality, modifiable risk factors, such as smoking, also predict morbidity and mortality, providing opportunities to potentially decrease risk.<sup>10, 26</sup> These studies and others mark the need to address non-AIDS-related mortality risk in order to reduce rates in HIV patients. An evaluation of 13 cohort studies identified non-AIDS-related causes of death to be more frequent than AIDS-related deaths.<sup>27</sup> Some leading causes include non-AIDS-related malignancies and/or infections, renal failure, violence, liver disease, and cardiovascular disease.

### **IMMUNOLOGY**

The debate on initiating ARV (antiretrovirals) at a higher CD4 count continued at CROI 2009. While not specifically addressed in presentations, it was noted that both age and starting ARV at less than 500 CD4s negatively impacted survival.<sup>28</sup> Another group noted that age impacts the beneficial effects seen when HAART is initiated during primary HIV infection.<sup>29</sup> Two groups presented evidence demonstrating altered immunological responses associated with age and HIV infection, independently, as measured by IL-7 responsiveness of memory CD4 cells in poster #315<sup>30</sup> and T-cell activation in poster #407.<sup>31</sup> These findings could inform future research designed to determine if age-specific treatment recommendations would improve outcomes for older HIV-positive individuals.

### **COGNITIVE IMPAIRMENT**

Dementia and milder degrees of cognitive impairment have obvious implications for older individuals, given the strong predisposition for dementia associated with age in seronegative populations. Although dementia affects less than 1% of HIV-negative individuals younger than sixty, nearly one-half of HIV patients in this age group can expect to experience cognitive impairment. At the 16th CROI, investigators from the CHARTER study evaluating over 1,000 individuals confirmed cognitive impairment in nearly 50% of enrollees (the mean age of the CHARTER cohort is only 43.2 years).<sup>32</sup> Despite optimism that HAART would eradicate cognitive impairment, this group confirmed that the prevalence rates have not changed with HAART. Specifically, they note rates of mild, moderate, and severe impairment in the CHARTER that are strikingly similar to past University of California—San Diego HIV cohorts evaluated before antiretroviral medications were available. They further note that co-morbidity frequently confounds cognitive diagnoses. Since many of these confounds are modifiable, there is hope that future work may identify treatment options for individuals with impairment.

Perhaps one of the first studies to report on cognition in patients over 60 years of age, the Neurosigma study from France reported that half of subjects over 60 had neurocognitive impairment despite sustained response to antiretroviral therapy.<sup>33</sup> As with the CHARTER group, co-morbidities (other diseases) were common in these impaired subjects, including diabetes (27%), hypertension (49%), and dyslipidemia (43%). This study and the CHARTER findings confirm previous work published from the Hawaii Aging with HIV Cohort, identifying metabolic disturbances in HIV as a correlate to cognitive impairment, providing a possible framework for intervention trials in the era of HAART.<sup>34</sup> The CHARTER group also identified a risk for neuropathy associated with diabetes and age; the latter was also noted in resource-limited settings.<sup>35-37</sup>

The presence of co-morbidities may partially explain the puzzling report that the presence of HIV brain pathology at autopsy

does not correlate to pre-death cognitive impairment, based on specimens in the National NeuroAIDS Tissue Consortium.<sup>38</sup> Despite this phenomenon, HIV brain pathology remains frequently identified at autopsy and correlates to CD4 nadir count and plasma HIV RNA. More work is needed to clarify clinical-pathological correlations, an area of great importance to informing treatment opportunities.

Two papers are particularly noteworthy in relation to aging. Ances and colleagues evaluated cerebral blood flow within the visual cortex of HIV compared to non-HIV cases, noting that both age and HIV factors influence cerebral blood flow.<sup>39</sup> In their models, the slope of change in cerebral blood flow by age is similar for HIV cases and HIV-negative controls, but HIV appears to add 10-15 years, displacing the slope to the right. Stated in a different way, their findings suggest that cerebral blood flow in HIV-positive individuals appears similar to that of HIV-negative individuals who are 10-15 years older. This finding, if confirmed, would add credence to a concern for accelerated brain aging in HIV. A second paper by Kallianpur and colleagues identified an interaction effect between CD4 nadir, a factor shown in several cohorts to relate to dementia, and the presence of an apolipoprotein ε4 allele, a marker known to be associated with Alzheimer's disease.<sup>40</sup> This paper and another note a relationship between posterior corpus callosum (the part of the brain which connects the left and right hemispheres) volume and cognitive impairment, a relationship that was not described in the pre-HAART era.<sup>40,41</sup> These findings suggest a possible change in phenotype of cognitive impairment in HIV and may suggest a risk for neurodegenerative processes.

#### CLOSING REMARKS

One need look no further than a typical HIV clinic in the United States to recognize the graying of the HIV population. However, we will have to look beyond the 16th CROI to develop tools specific to this aging population, since many of the age-related presentations at this conference do not successfully transition from correlations of detrimental outcomes in aging to mechanism-related discovery of modifiable targets. This finding likely exposes the infancy of HIV-aging research and uncovers a need to move beyond the recognition that aging detrimentally impacts a broad and diverse set of outcomes, to determining precise underlying mechanisms whereby aging exerts its impact.

This work should not be considered solely an HIV issue, as papers presented at the 16th CROI suggest that HIV may be a model of accelerated aging. Thus, much of the information gained is likely to impact older Americans regardless of serostatus. For example, new knowledge relating to immune system senescence (and, perhaps, accelerated senescence with HIV) will largely inform the aging process in general and aging-related susceptibility to poor outcomes in non-HIV infections. Likewise, uncovering

## AGING-HIV RESEARCH MUST PROVIDE MEANINGFUL, INFORMATIVE, MECHANISM-BASED REPORTS THAT WILL OFFER TREATMENT OPTIONS

mechanisms by which inflammation may accelerate atherosclerosis or neurodegeneration may have broad non-HIV implications. In other words, findings from the 16th CROI lend credence to HIV as a model of accelerated aging, suggestive that findings from this population may have broad applicability.

The mandate is clear. The unprecedented successes of HIV treatments and the incessant process of aging have had the inevitable and welcome result of HIV-infected populations who are now in their seventh, and older, decade of life. Without better information regarding the potential interactions between aging and HIV to inform treatment options, clinicians will have to approach older patients with inadequate tools. Aging-HIV research must transition from confirmatory observations of detrimental outcomes to meaningful, informative, mechanism-based reports that will offer researchers and clinicians treatment options aimed to improve these outcomes.

*(Referenced footnotes available online)*

*Victor Valcour, M.D. is an adjunct clinical instructor at the Memory and Aging Center at the University of California, San Francisco; Associate Professor of Geriatric Medicine at the University of Hawaii, Manoa; and Director of the Office of Neurology and Aging Research (ONAR), which is part of the Hawaii AIDS Clinical Research Program (HACRP) at the Pacific Center for AIDS Research in Honolulu. Reprinted with permission from [www.natap.org](http://www.natap.org).*

# Break No Bones About It

*HIV itself—as well as medications and traditional causes—may increase the risk of fracture*

*by Enid Vázquez*

Everyone's heard about elderly people falling and breaking their hips, but for a while, there were stories about much younger HIV-positive people with brittle, breaking bones. Some were even having hip replacements (see "I couldn't cross at the light" on page 43). What was going on?

As suspected, the life-saving HIV medications that were still relatively new at that time played a role—but they were only partially to blame, it turned out.

Providing an overview on the matter at this year's CROI was Todd T. Brown, M.D., Ph.D., of Johns Hopkins University. Yes, HIV medications may negatively affect bone health, but there is also the effect of HIV itself, as well as the usual suspects like cigarettes and alcohol. (See the half-

hour presentation at [retroconference.org](http://retroconference.org), Wednesday sessions, "Long-term Non-AIDS Complications," 4–6 p.m.)

In 2006, Brown and colleagues published a report in the medical journal *AIDS* showing that a large number of people with HIV (15%) had osteoporosis. Osteoporosis is a loss of bone tissue that makes fractures more likely. They found that compared to HIV-negative control groups, people with HIV were three-and-a-half times more likely to have osteoporosis. They gathered those numbers after analyzing 11 HIV studies that included data on bone mineral density (BMD).

But if HIV and the medications used to treat it combine with traditional risk factors to make for brittle bones, the Titans clash over what to do about it. As with many

conditions, you can decide to be aggressive with screening and treatment, or not.

## MANY ROLES

Several studies have clarified the role of HIV medications. (See sidebar on page 42.)

Many other things, however, affect people with HIV and the chance to keep their bones intact.

First there's HIV itself. Later on, the role of HIV came to light. The virus has proteins that, in a variety of ways, weaken bone mass.

Then there's the immune system. "Many cross-sectional studies have shown an association between low CD4 cell counts and lower bone mineral density," Brown said, adding that this information is still being investigated "to figure out what exactly is going on."

Other personal attributes are "very important to pathogenesis [the cause of disease]," said Brown. "We know that there are a variety of traditional osteoporosis risk factors that may be higher in prevalence in our HIV patient population," Brown said. He listed the following:

- low body weight
- smoking
- alcohol use
- opiate use
- hypogonadism (impaired sexual hormones)
- low vitamin D levels
- physical inactivity
- hepatitis C co-infection

The use of steroids, often prescribed in the treatment of disease, can also negatively affect bones.

Brown suggested that patients with reduced bone mineral density be checked

*continued on page 42*

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## BODY OF BONE EVIDENCE

After the era of HAART (highly active antiretroviral therapy) began with the HIV medications called protease inhibitors in late 1995 and early 1996 (and soon with other powerful medications called non-nucleoside analogues), deaths due to AIDS dropped greatly, but side effects began to take a toll. Among the problems seen were bone fractures in people with HIV who weren't yet 50.

Todd T. Brown, M.D., Ph.D., of Johns Hopkins University, took his audience at this year's CROI back to the 7th conference, in 2000, with the presentation of two studies that were the first in the post-HAART era to look at bone mineral density (BMD) in people with HIV. Adequate BMD is needed for bones to resist fracture. It's also known to reduce with age and menopause.

Both studies showed a high prevalence of reduced bone mineral density in people with HIV, which was associated with the use of protease inhibitors.

Later, there were four different studies comparing PIs to non-PIs (the non-nucleosides). "What we can say is that, at least for some PIs, there appears to be an added risk of reduced bone mineral density. It's unclear exactly which PIs are indicated," Brown said.

Later, in 2006, Brown and his colleagues published a meta-analysis in the journal *AIDS*, that looked at 11 HIV studies which included BMD data. They found that people with HIV were three-and-a-half times more likely to be at risk of osteoporosis compared to HIV-negative groups. Then there were concerns about bone problems with Viread (generic name tenofovir, a nucleotide analogue HIV drug that's also found in Truvada and Atripla). Study 903, comparing Viread to Zerit (both taken with Epivir and Sustiva) found decreased spine BMD with both treatment regimens, but a significantly higher reduction in bone mineral mass with the Viread group of the study.

There was also a statistically significant difference in bone health between Truvada and Epzicom in a report from the STEAL study at this year's CROI. (STEAL stands for Simplification with fixed dose Tenofovir/Emtricitabine or Abacavir/Lamivudine.)

"This is clearly an effect of tenofovir on bone mineral mass, but the etiology [cause] is unclear," said Brown.

The large, international SMART study, comparing positive people who were on therapy with those who weren't, found that the people maintained on HIV medication had a greater reduction in bone mineral mass than the people taken off their HIV meds. These results were from a four-year observational period, reported in the fall of last year.

"The picture is quite different in the drug conservation group, those who stop antiretroviral therapy," said Brown. "What you see in the hip is a preservation of bone mineral density, but what you see in the spine is an increase in bone mineral density in the [same] period ... again arguing for the fact that there is something about antiretroviral therapy that is detrimental in its effect on bone."

Brown then listed six studies of antiretroviral therapy (ART) initiation that included BMD data. "What has been remarkable in the studies that have looked at antiretroviral initiation is the consistency of a drop in BMD over 48 to 96 weeks," Brown said. "It's really unclear whether or not there is clinical significance, and none of these trials have shown an increase in fractures. What we can say is that the 2.5 to 3% decrease you see with antiretroviral therapy initiation is similar to what you might see with two years of menopause.

"Still," said Brown, "with the exception of the viral suppression group in the SMART study, most other longitudinal studies that have looked at bone mineral density have shown either stability or an actual increase in bone mineral density over time. There is something about antiviral [HIV] therapy that is detrimental to bone mineral density." Brown continued, "The good news is that [this is] over 48 to 96 weeks [approximately one to two years], then it levels out."—*Enid Vázquez*

for the following secondary causes of BMD, as a "minimal work-up":

- vitamin D deficiency (25 OH vitamin D)
- hyperparathyroidism (PTH, Ca++)
- subclinical hyperthyroidism (TSH)
- hypogonadism (males—testosterone, females—menstrual history)
- phosphate wasting (serum phosphate)
- idiopathic hypercalciuria (24-hour urinary calcium)
- celiac sprue (tissue transglutaminase)
- multiple myeloma (serum protein electrophoresis)
- mastocytosis (serum tryptase)
- Cushing's syndrome (24-hour urinary free cortisol)

To help prevent bone loss, patients have several options. First are calcium and vitamin D supplements. Then there's weight-bearing exercise; smoking cessation and alcohol reduction; and treatment of secondary causes of reduced BMD.

Brown noted that the level of vitamin D deficiency in the general U.S. population is "exceedingly high" and suggested supplementation of 1,000 to 1,200 IU vitamin D for everyone, no matter their level of bone mineral density. During the question-and-answer section, however, he admitted that's a standard recommendation that he, like many providers in the audience, thinks is too low. He said he usually recommends 50,000 IU of herbal calciferol twice a week for eight to 12 weeks in patients with low levels of vitamin D.

There are also the common sense measures doctors tell their patients who are at risk for falling or breaking a bone. This includes the many people with HIV suffering from the nerve damage of peripheral neuropathy, making them unsteady on their feet. Take care of loose rugs and clutter on the floor. Keep wires behind furniture. Add night lights to help you watch your step. Avoid slippery or uneven surfaces. Beware of drinking excess alcohol. Wear sturdy shoes.

Also at higher risk are those people with HIV who have lipoatrophy, or fat loss and thinning. Hips with less fat cushioning them are at greater risk of breaking in a fall.

Cognitive or visual impairment, sedative use, and muscle weakness resulting from hypogonadism are also osteoporosis risk factors.

Boys with HIV seem to be another group at risk. At the lipodystrophy conference in London in November, the Pediatric ACTG (AIDS Clinical Trials Group) reported that of children with HIV, boys failed to reach peak bone mineral mass, while girls didn't. This puts those boys at greater risk of fracture.

Brown said the development of bone mineral mass peaks around age 30 and goes downhill from there. For anyone to be osteoporotic at 65, Brown said, means that they lost bone mineral density quickly after 30, or they failed to reach peak bone mineral density in the first place, or a combination of the two. "[This report] suggests that, at least in males, there's failure to reach bone mineral mass and there are obvious ramifications later on in life."

### BROKEN?

"We talk about BMD in HIV, but what we really want to know is about fractures," Brown said. "This data is beginning to emerge. The risk of fracture is higher in HIV patients, particularly as age advances. So, we know that osteoporosis is common. We know that there's an increased risk of fracture in HIV-infected patients. We also know that the etiology is multifactorial. So the issue that comes up is what to do about it, how to screen for it, and how to treat it."

Brown concluded that although osteoporosis is common in HIV, he doesn't recommend universal screening, but that aggressive screening and treatment in people over the age of 50 would be good.

Daniel S. Berger, M.D., of Northstar Medical Clinic in Chicago, said, "I take issue with screening [only] for people over 50. [There should be a] bone DEXA [scan] for everyone diagnosed with HIV." Brown said he agrees with a universal DEXA in "a world of endless resources." He called the relative risk of fracture high, but the actual risk very low, and he would rather put a patient on biphosphonate therapy for osteoporosis when the patient is 55 and best able to benefit from treatment. Otherwise, patients with low bone mineral density who are in their 30s or 40s should start taking calcium supplements, cut down on their drinking, stop smoking, and take other steps to improve their bone status.

In response to another question from the audience, he said he thinks HIV-positive women on Depoprovera should definitely take calcium and vitamin D.

Even though the virus and its medications may be attacking your bones, Brown said you may not want to rush to take bone meds. He said there is a theoretical concern with biphosphonates, which make up first-line treatment of osteoporosis. "[There is a] question on whether this very potent effect on bone turnover is actually a good thing. We require bone turnover to repair micro-

fractures that occur all the time with regular wear and tear." It's unknown what effect this would have on younger patients taking the medications for a longer period of time. Currently, he said, doctors recommend a holiday from the treatment every five or 10 years. These medications include Actonel (risedronate), Fosamax (alendronate), ibandronate, and zoledronic acid. ☒

### "I COULDN'T CROSS AT THE LIGHT"

Five years ago, at age 47, while living in Chicago, Doug Ferguson noticed he was developing a fast growing pain in his left knee. The man who played tennis several times a week, worked out at the gym regularly, and darted through airport concourses each week for business suddenly found himself hobbling in pain with a noticeable limp.

"The pain got so severe that I could only move at a snail's pace," said Ferguson. "Stairs and street intersections became my enemies. If I didn't start to cross the street right when the light turned green, I'd get stuck in the middle of the street when the light turned red. Cars would be honking at me, but I could barely move."

Early diagnosis was a torn meniscus of the left knee. After arthroscopic surgery, Ferguson did physical therapy, but the situation only got worse. It was the physical therapist who figured out the real problem. She could see that the problem with walking was not in his knees, but in his hips.

X-rays had not revealed the actual problem, but now an MRI did. Ferguson was diagnosed with Stage 3 osteonecrosis (also called avascular necrosis or AVN) in his left hip and Stage 1 in his right. Osteonecrosis is a fairly rare disease where blood flow is restricted inside the bones (especially the long bones, like the femur), resulting in brittleness, fractures, and bone decomposition. The exact cause is unknown, but experts have pointed to alcoholism, steroid use, and sickle-cell anemia as contributors and, since the late 1990s, HIV has also been included on the list of possible causes.

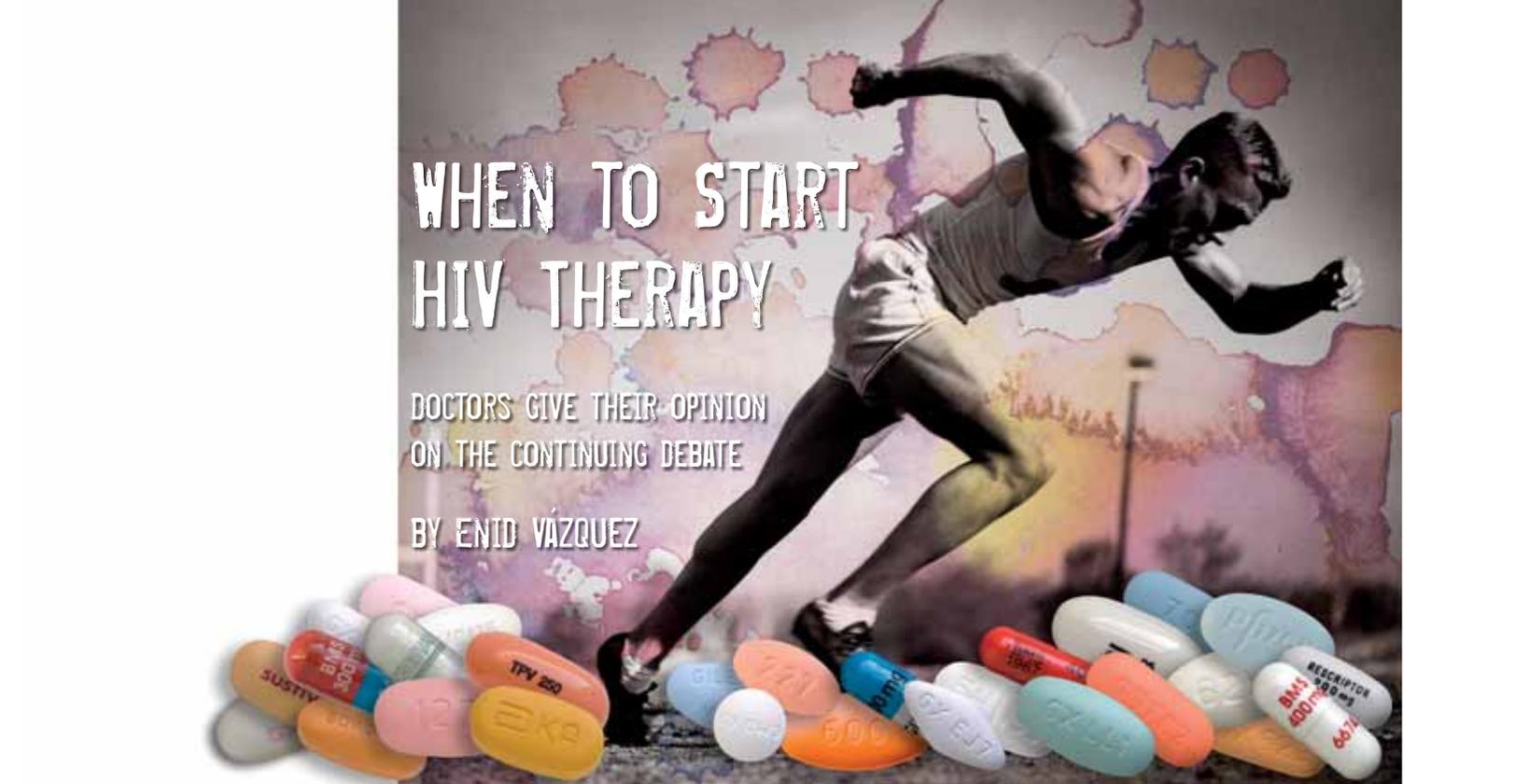
Fearful that the left hip could collapse, Ferguson opted, within a week, to have surgery on both hips. Because his T-cells were low, doctors wanted to avoid hip replacement and the high risk of infection. A new procedure called core decompression was recommended. The surgery involves drilling into the thigh through the femur and "coring out" the inner bone wall to allow for development of new blood vessels and rebuilding of healthy tissue.

Ferguson found a friend who had had the same procedure and who warned him not to walk or put any pressure on the legs for eight weeks after surgery. The friend had, unfortunately, rushed his recovery period and ended up with a leg fracture, requiring repeat surgery. For Ferguson, however, the procedure was a success and, within a year, he was competing on the tennis court and tearing through airports again.

Jokingly, Ferguson refers to being part of an elite "Senior Class of HIV" with 20-plus years of being "poz." Within this class of long-term survivors, he's found others who've experienced AVN and other knee, hip, and bone problems.

Related medical studies are few and inconclusive, but Ferguson (along with many HIV specialists) thinks long-term use of HIV drugs may be a key contributor to AVN, versus the HIV disease itself.

"No one knows if the AVN can return," says Ferguson. "I certainly hope not, but I do suspect that the 'senior varsity class' of HIV survivors will be prone to a different set of illnesses that are possibly compounded by extensive med therapy over the long haul. Given the fact that I've been on meds for so long and I'm still strong and healthy, I will deal with whatever comes my way." —Enid Vázquez

A composite image featuring a runner in mid-stride, a world map, and various HIV medications. The runner is in the foreground, wearing a white tank top and shorts, running towards the right. The background is a stylized world map with a purple and pink color scheme. In the foreground, there are several large, colorful pills and capsules, including brands like Sustiva, TPV 250, and Rescriptor. The text 'WHEN TO START HIV THERAPY' is overlaid on the top left of the image.

# WHEN TO START HIV THERAPY

DOCTORS GIVE THEIR OPINION  
ON THE CONTINUING DEBATE

BY ENID VÁZQUEZ

When is the best time for people with HIV to start therapy?

No one knows for sure, but the estimate has gone up and down over the years. Now at CROI, and previously at ICAAC (see the January/February *Positively Aware*), a large study continues to show that you have a greater chance of survival if you start HIV therapy earlier, when you have more than 500 T-cells.

According to a revision of U.S. HIV treatment guidelines in December 2007, the suggested time for starting therapy is when T-cells drop to 350. Previously, the guidelines suggested that therapy begin when T-cells drop to 200. There are circumstances when it's recommended that a person without symptoms begin therapy before reaching 350, for example, during pregnancy or in the presence of kidney disease or hepatitis. (Visit [www.aidsinfo.nih.gov](http://www.aidsinfo.nih.gov).)

The NA-ACCORD study (North American AIDS Cohort Collaboration on Research and Design) found a 60% greater survival rate for people who started anti-HIV treatment above 500 T-cells, compared to those who waited. This survival rate was determined after the study adjusted for potential confounding factors, such as viral load or hepatitis C infection. An observational study like NA-ACCORD is prone to confounding—real life issues that can make its statistics invalid. The study excluded, however, injection drug users. The observational period was 10 years. The study was published in the April 1 issue of *The New England Journal of Medicine* (NEJM). According to an accompanying editorial, “The strengths of the study notwithstanding, the results of the NA-ACCORD study cannot be considered definitive evidence that everyone with HIV should start receiving antiretroviral therapy.”

Another observational study presented at this year's CROI, the ART Cohort Collaboration (“ART” stands for antiretroviral therapy), also found a larger survival benefit to starting therapy earlier. The benefit, however, only went up to 400 T-cells. Beyond that, there was no difference in survival. (The Collaboration looked at increases of 50 T-cells at a time, while NA-ACCORD only compared individuals in the 350 to 500 T-cell range, and then those people above 500.)

There's a lot to consider, however. Mari Kitahata, M.D., of NA-ACCORD, noted that, as research continues to show the negative effect of HIV on the body, such as inflammation and permanent damage to the immune system, the hope that earlier therapy can increase survival continues to grow.

At the same time, newer HIV drug combinations are much more tolerable, making them less of a problem for starting therapy in the first place.

With all the complications of this scenario, *Positively Aware* polled HIV specialists for their take on data pointing towards earlier treatment. See also News Briefs on page 16 for a new study, START, designed to help answer this question, and the Fall 2008 issue of *RITA!* at [www.centerforaids.org](http://www.centerforaids.org).

## ROSS SLOTTEN, M.D., KLEIN & SLOTTEN MEDICAL ASSOCIATES, CHICAGO

I believe in earlier treatment. HIV is one of the few treatable diseases where we choose to wait to treat rather than treat as soon as someone is diagnosed with the infection. For example, if someone is found to have syphilis, we don't advise the person to return in six months to see what happened without treatment. Similarly, we should not delay treating HIV infection, at least in theory. The development of lipodystrophy has been the main obstacle to early treatment. However, newer combinations, especially those without AZT and Zerit, do not appear to be associated with this terrible syndrome. What we don't yet know is what other long-term side effects might arise from antiretroviral therapy. The fact that abacavir may be associated with an increased risk of coronary artery disease is a real concern. Nevertheless, it is unlikely that any side effect will ever surpass the deadly consequences of untreated HIV infection. Moreover, treating HIV also reduces transmission of the virus to uninfected people, which is another potent argument for initiating therapy early in the course of the disease.

**FRANK M. GRAZIANO, M.D., PH.D., UNIVERSITY OF WISCONSIN HOSPITAL AND CLINICS, MADISON**

I have always believed the following.

1. If there is someone who comes to me and has found out he/she has been infected within the last 2-3 months, I will always start them on therapy (I don't find very many of these).
2. If someone comes to me and tells me they want therapy no matter what their CD4 count or viral load is (high or low) or no matter what I say, I will start them as long as we do enough education to ensure they understand what they are getting into. I figure they know something I don't know (not many ask for this).
3. If someone comes in with a rapidly falling CD4 count (even 900 going down to 500) over a relatively short period of time, I will start them.
4. Same with viral load. I feel uncomfortable with someone having a viral load greater than 100,000 for a long time.
5. Basically, I make a decision based upon each individual who is sitting in front of me (not just guidelines).

All of this does not answer the question. Based on the recent data from the *new* pathogenesis of HIV and the role of inflammation in this process, I believe that we should be starting patients (with some of the newer HIV drugs) within the first few times we see them—whether high or low CD4 count. I wish I could tell you that I do this. The thing that stops me is the uncertainty of what will happen with long-term use of the drugs. I believe that there are side effects with every drug we use (it is just the severity of the problem seen). We need more clinical studies *now* to see how to approach this problem. My honest feeling is that I will soon start having patients on HIV medications at much higher CD4 counts than what we have now.

I am uncertain I answered the question scientifically. It comes more from 28 years of experience with treatment.

*Dr. Graziano provided the doctor's perspective in this year's Annual Positively Aware HIV Drug Guide.*

**JOEL GALLANT, M.D., M.P.H., JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE, BALTIMORE**

We know from both observational and clinical trial data that people should be treated if they have AIDS, severe HIV-related symptoms, or CD4 counts below 200 cells/mm<sup>3</sup>. More recently, observational studies led guidelines committees to recommend therapy at CD4 counts of 350 cells/mm<sup>3</sup>. Now, we have data from the NA-ACCORD cohorts showing a 70% lower all-cause mortality in people who started treatment at CD4 counts between 350 and 500 cells/mm<sup>3</sup> compared to those who waited until their CD4 counts fell below 350 cells/mm<sup>3</sup>, and a later analysis from the same study showing a 60% lower mortality in those who started with CD4 counts above 500 cells/mm<sup>3</sup> vs. those who waited until their CD4 count had fallen below 500 cells/mm<sup>3</sup>. NA-ACCORD may be the most important observational study to help answer the question of when to start, but as with any observational study, it has potential weaknesses: most importantly, that people who start therapy early may live longer for reasons that have nothing to do with when they started. They may be the type of people who are less likely to die simply because they keep themselves healthy.

Many HIV experts feel we need a large randomized trial to answer this question. However, such a trial would be expensive and

would take years to complete. During the course of the trial, changing practices and guidelines might make it impossible to enroll. In the end, it might help to answer the question of whether the best CD4 threshold is 350 or 500 cells/mm<sup>3</sup>, but how important is that distinction? For a newly diagnosed 25-year-old, starting therapy at 500 might mean 1–2 years more treatment than starting at 350, but that's 1-2 years out of 4-5 decades of treatment over a lifetime.

In addition, it's possible that our focus on CD4 thresholds is misguided. Some of the problems caused by HIV infection are present from the first day of infection, regardless of CD4 count. There is evidence of heightened levels of inflammation, immune activation, and tendency to develop blood clots, and these problems are more closely related to viral load than to CD4 count. These changes could help explain the increased risk of so-called "non-AIDS-related events," such as cancers, heart attacks, and liver disease, that are now getting so much attention.

AS RESEARCH CONTINUES TO SHOW THE NEGATIVE EFFECT OF HIV ON THE BODY, THE HOPE THAT EARLIER THERAPY CAN INCREASE SURVIVAL CONTINUES TO GROW.

If you ask most HIV experts what they would do if *they* were infected, they usually say, "I'd start treatment regardless of CD4 count and viral load." I believe that antiretroviral therapy should be considered in *every* patient. Some people should wait: mainly those who simply aren't ready, willing, or motivated to take and be adherent with therapy. Some would argue that long-term non-progressors should wait, although we know that despite their high CD4 counts and low viral loads, non-progressors still have higher levels of inflammation and immune activation than people with undetectable viral loads on ART.

HIV infection is unique among infectious, transmissible diseases in that, despite being treatable but fatal if left untreated, our approach has been *not* to treat until there is evidence to support treatment. For any other such disease, the "default" would be to treat, and the burden of proof would be on those who wanted to wait. How did we end up with such a backwards approach to therapy? The reasons are historical: we began with no treatment at all; then we had fairly ineffective therapy; then we had effective but difficult and toxic therapy. Finally, in the third decade of the epidemic, we developed effective, well tolerated, and fairly non-toxic treatment. Had we begun with the treatment we have today, we probably wouldn't be spending so much time arguing about when to start. ☒

*Dr. Gallant is the author of 100 Questions & Answers About HIV and AIDS and a frequent contributor to TheBody.com. He is also editor-in-chief of the HIV Guide for Johns Hopkins, which includes an interactive forum. Visit [www.hopkins-hivguide.org](http://www.hopkins-hivguide.org).*

**Jeff Berry:** I wanted to go over the Isentress studies presented at this year's CROI, including the cancer data.

**Joe Eron:** The results of the 96 weeks of BENCHMRK are very encouraging. What we saw is that for the proportion of individuals whose viral loads were suppressed to less than 50 at 48 weeks, that proportion persisted quite well through 96 weeks. Given the high level of resistance that many of these patients had, many of us were concerned that the suppression wouldn't be sustained. Many of the things we learned from the 48-week data were reinforced; for example, people who had two additional active drugs had the highest level of suppression and that high level of suppression was sustained. The other worthwhile point is there were no really surprising new toxicities that emerged between week 48 and week 96.

There was also a poster here presented by Jeff Lennox, on the STARTMRK data, that looked at multiple different sub-analyses of the 48-week data. STARTMRK is the study that looked at raltegravir compared to efavirenz [Sustiva], both with Truvada in treatment-naïve patients. Again, I think that study's very easy to summarize—they looked at many, many different baseline characteristics such as age, race, gender, and area of the world, and really showed that there were very, very similar results regardless of how you stratified the data. They also included stratifications for baseline CD4 cell count and baseline viral load, and in all of the analyses the proportion that suppressed on the raltegravir arm was very, very similar compared to efavirenz.

You mentioned the cancer study. Originally, when the results of the BENCHMRK study came out, there was a suggestion of numerically more cancers in those patients treated with raltegravir. The cancers occurred relatively early, which would make you think it was a little bit harder to figure out anything causal. We also observed diverse cancer types, and if you talked to oncologists, all those different cancers have different mechanisms, so you would think that the relationship probably wasn't due to the drug. But there

## One-on-One with Joe Eron, M.D.

*An update  
on Isentress  
(raltegravir) data,  
including some  
unexpected results*

*Interview by Jeff Berry*

were numerically more and people were concerned.

Now that Merck has even more data from BENCHMRK, now they have all the data from STARTMRK, and they have long-term follow-up from their Phase 2 study of raltegravir in treatment-experienced patients, I think now they have very convincing data that raltegravir is not associated with malignancies.

The SWITCHMRK study is actually two identical studies, just like BENCHMRK. I think that's the harder one to discuss and explain because it doesn't have a simple answer and in part because, literally, we just got the data right before Christmas on one of the two studies, and we didn't get the data on the second study until between Christmas and the presentation.

Each SWITCHMRK study had about 350 patients, so a total of 700 patients, and they were randomized, double-blind, placebo-controlled studies where patients who were stable on a lopinavir/ritonavir [Kaletra]-containing regimen and [nucleoside] reverse transcriptase inhibitors [NRTIs], were randomized—remember,

in a blinded fashion—to either stay on their lopinavir/ritonavir plus [NRTIs], or switch to raltegravir while obviously continuing [NRTIs]. So the only substitution that was made was raltegravir for lopinavir/ritonavir in a randomized way.

If we cut to the chase, the patients who switched to raltegravir had an improvement in multiple different lipid values: total cholesterol, non-HDL cholesterol, and triglycerides. This was one of the primary end points at 12 weeks and this was good.

On the other hand, if one looked at the proportion of individuals who had their viral load suppressed at week 24, which was the second primary end point, fewer patients were suppressed at week 24 on the raltegravir arm. The numbers were slightly different between the two studies—in the one study that was done mostly in Europe and the U.S., it was 87% remaining suppressed on the lopinavir/ritonavir arm vs. 81% on the raltegravir arm, so a difference of about 6%. In the other study, it was 94% remaining suppressed on lopinavir/ritonavir vs. 88% on raltegravir, so again about 6% difference.

The numbers are slightly rounded, but on average, it was about a 6% difference in suppression and what we can say, if you look at the two studies independently, is that raltegravir was *not* non-inferior to lopinavir/ritonavir in that setting and, as was pointed out during the questioning, if you actually put the studies together, then the difference approaches superiority for lopinavir/ritonavir. So that prompted us to ask, "Well, why is that?"

We thought we had so much positive data about raltegravir and it turns out that, if you look carefully at the study design, it's very different from previous switch studies. The study design was such that patients could've had multiple previous treatment regimens, they could've even had multiple previous virologic failures. In fact, some of the patients had been on treatment on the order of 16-20 years, so we know those patients had received single and dual nucleosides because we didn't have HAART 20 years ago. So when we looked at the patients who had virologic failure on the raltegravir arm, we found that for 84% (or 27 out of the 32 failures

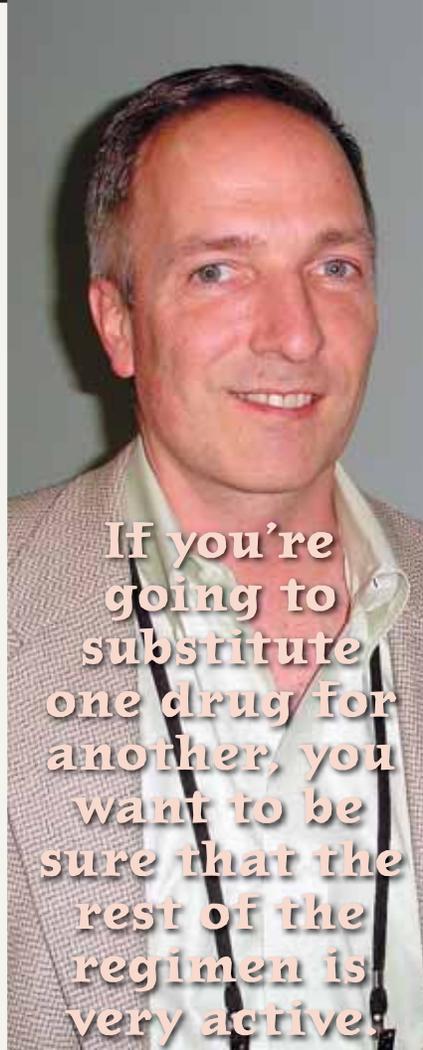
combined on the two studies), the Kaletra regimen they were on at the start of the study was not their first regimen. So then, if you look at those 27 where it wasn't their first regimen, two-thirds of those patients actually had documented previous virologic failure on previous regimens, obviously not on lopinavir/ritonavir, but on previous regimens. Now, the analysis suggests that the reason we saw more virologic failure on the raltegravir arm is because these patients with previous virologic failure were likely to have nucleoside resistance.

**JB:** What does it show you as far as it not being a good idea to just substitute one drug for another?

**JE:** I think what it tells you is that if you're going to substitute one drug for another, especially if you're taking a drug that has a very high genetic barrier, like the protease inhibitors, and you have another drug that you know is very potent, but may not have as high a genetic barrier, you want to be sure that the rest of the regimen is very active.

So, for example, there were other studies presented here and at ICAAC [in October], and at the AIDS meeting last summer where raltegravir was substituted for T-20 and those studies all show a very good result. In fact, there was a randomized study presented here by the French ANRS group showing an excellent result with people randomized to either stay on T-20 or switch to raltegravir. I think the reason for that is that if T-20 is working—and on average, those patients were on T-20 for 2-2.2 years—if T-20 has been working for somebody for 2.2 years, probably the rest of the drugs in that regimen are contributing something, so switching the T-20, the enfuvirtide, for raltegravir maintains suppression.

If I had to guess, and I'm trying to be helpful clinically here, I'm not speaking for Merck or the study or anything but as a clinician—I think if a patient is on their first regimen, and you know, for example, that the nucleosides are fully active because you have a baseline resistance test when the patient has been suppressed, I



**If you're going to substitute one drug for another, you want to be sure that the rest of the regimen is very active.**

think it's likely that substituting raltegravir would be fine. Anecdotally, many of the investigators on these studies have come up to me and said, "Well, at our site we only looked at people who were on their first regimen and it's our experience that the patients have done very well."

That's a little bit biased, right? Because 88% of the patients on raltegravir did fine, so if you only have 10 patients at your site, your impression is going to be that both raltegravir and lopinavir/ritonavir over time did well, so I think you have to be a little bit careful about that bias.

In general, I think if you have uncertainty about the strength of the partner drugs, that you shouldn't be switching out one drug. The other lesson, I think, is that these were people who were very stable on lopinavir/ritonavir. They didn't have hyperlipidemia, they couldn't be on statins or other lipid-lowering agents. 83% of the patients had been on the lopinavir/ritonavir therapy for a year or more, so these people were tolerating the regimen really well and didn't really have any major toxicities from the regimen.

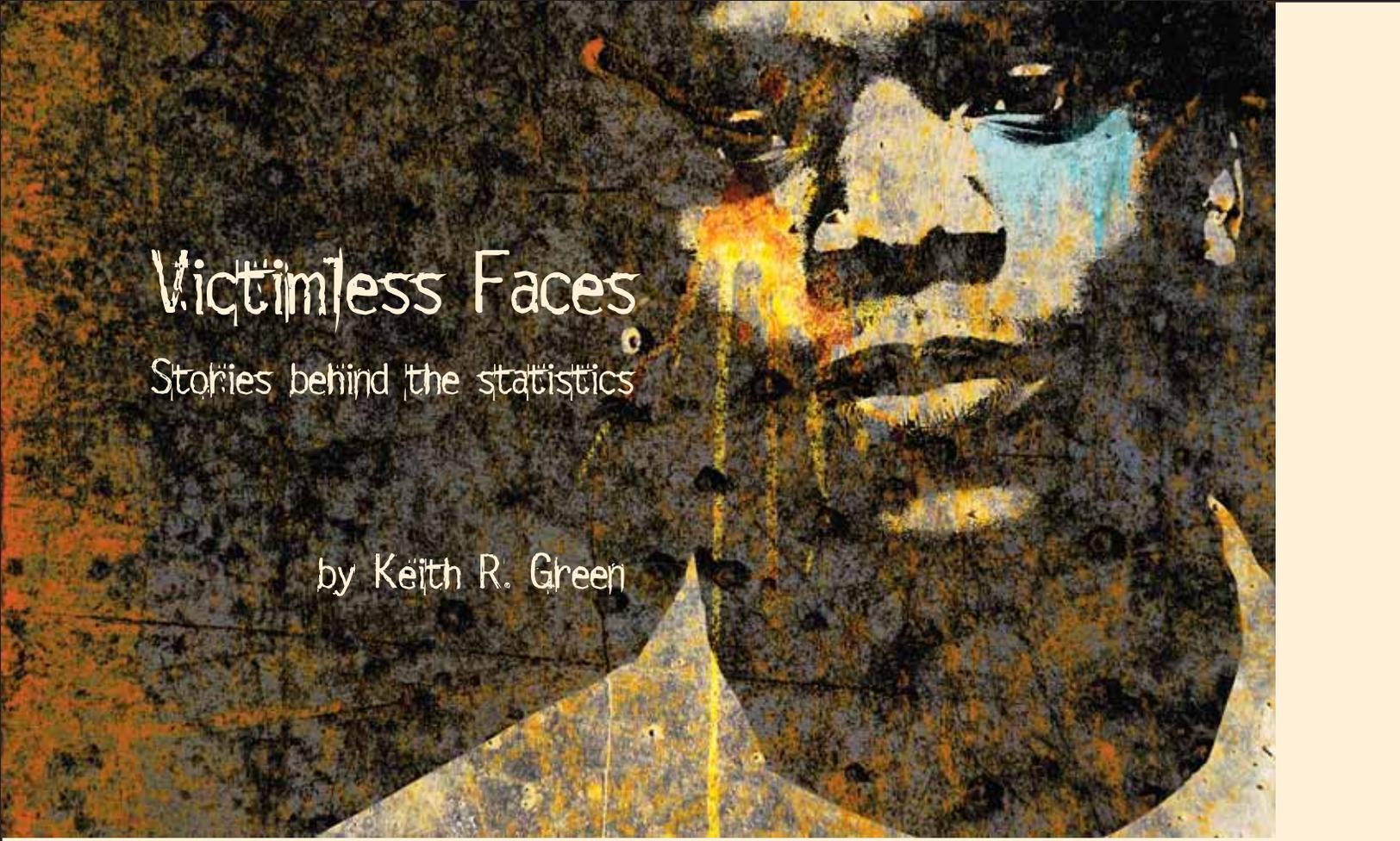
So, again, I think one has to balance

what you're doing—if something's working pretty well and it doesn't have a lot of side effects, the impetus for change should be less. On the other hand, if you have a patient on their first regimen of boosted PI and their triglycerides are sky high and they are having GI trouble or diarrhea or something, then that's probably a different situation.

**JB:** So the basic premise is not that switching from a drug that had a high barrier to resistance to one that had a lower one was the issue.

**JE:** No. There have been studies where people have switched boosted PIs to nevirapine [Viramune]. Nevirapine has a very low genetic barrier, much lower than raltegravir, and those studies, many of them published, have been successful. Or there've been switch studies, like the SWAN study for example, where individuals on a boosted PI have been switched to atazanavir [Reyataz] unboosted, clearly going from a higher genetic barrier to a lower genetic barrier, but in those studies, the partners, the other drugs in the regimen were likely to be very active. Most of the drugs that we use are pretty potent drugs, but the key is combining potent drugs. The one exception to that rule is the boosted PI, where we know you can give boosted PI monotherapy and get 75% of people suppressed. That's different than any other drug. I think they are special drugs, and the boosted PI is a special combination. It has downsides, so you have to weigh the upsides and downsides. ☒

*Joe Eron is a Professor of Medicine at the University of North Carolina at Chapel Hill. He has been the Director of the UNC AIDS Clinical Trials Unit for 4 years and was the Associate Director for seven years prior to becoming the Director. He is also the Director of the UNC Center for AIDS Research Clinical Core and the Associate Director of the General Clinical Research Center at UNC.*



# Victimless Faces

Stories behind the statistics

by Keith R. Green

*In 2006, Black gay and bisexual men between the ages of 13 and 29 accounted for more new HIV infections among gay and bisexual men than any other race or age group. And more than half, or 52 percent, of all Black gay and bi men infected that year were under 30 years old.—Black AIDS Institute, Making Change Real: The State of AIDS in Black America, 2009*

**O**ftentimes in our discussions about HIV and aging, we tend to speak strictly to the physical effects that the virus has on the inevitable process of growing older. Rarely do we connect these concepts with the concurrent psychosocial impact, particularly as it relates to those who become infected as very young adults, or even as youth.

The aforementioned data regarding young Black gay and bisexual men is staggering. Not only will a vast majority of this new breed of America's youth never know an adult life without HIV (and all that comes along with being infected), but they must somehow manage to juggle their status with the everyday struggles of coming into adulthood as a racial and sexual minority. The truth of the matter is that HIV gets compounded by a whole host of other factors.

## HUDSON

Hudson Kelly may be an extreme example of this, but it is quite likely that his story is a common one.

A native of Flint, Michigan, Hudson was taken from his mother at the age of 18 months due to child abuse issues. His younger sister,

who suffered from spinal meningitis, died when she was thrown into a wall by their mother's heroin-addicted boyfriend, allegedly because she wouldn't stop crying.

Governmental efforts at keeping families together saw Hudson reunited with his mother when he was in his early teens, only to feel as if he was reliving his early childhood all over again. Though he was not a heroin addict, at least, Hudson's mother's new boyfriend stood six-feet tall, 220 pounds, and took pleasure in regularly beating her and her children.

"I got so numb to it at 14, it didn't matter anymore," he says matter-of-factly. "My brothers and sisters would just take it, but I was like, 'No!' My mom even told me that if I would just sit there and take it, he would probably stop. But because I wouldn't, it was like he had to break me."

A cousin's girlfriend recognized the strength in him and allowed Hudson to stay with them so that he could finish high school safely. He went on to college in Ann Arbor and stumbled upon a gay bar. As he says, that's where he found himself.

A kid of the eighties, he has vivid memories of the many conflicting misnomers that emerged about the virus (many of which still linger to this day). He remembers how President Reagan pushed monogamy as the only sure way to remain HIV-free. He'd heard his uncles and other relatives declare it a "gay disease" that only the "white boys" were susceptible to. He did what he thought he needed to do to avoid HIV. Therefore, when he entered into his first monogamous relationship at 18 years old, with an older gentleman who had recently migrated to the U.S. from Spain, Hudson assumed that he had escaped the risk of being infected with HIV.

For nine years, Hudson lived the life of a prince. His partner, who made a very nice living as an accountant with a large brokerage house, spoiled him with the finest of everything, while at the

Photoillustration © Russell McGonagle

same time sheltering him from the rest of the world around them. It wasn't until Hudson began to grow up and come into his own that he started to realize that, outside of this man, he had no life.

In an effort to establish an identity of his own, he decided to join the Navy. His partner warned him that, in doing so, he would find out something about himself that he would not be able to handle. Hudson assumed his mate was implying that, at five feet, four inches tall and weighing 119 pounds, he wasn't strong enough for the Navy, but he was determined to face that kind of challenge. It was when they pulled him into the little white room after his physical, that his whole world came tumbling down. Being diagnosed with HIV ended Hudson's plans for life in the military. He later learned that his partner had known that he was HIV-positive all along. He told Hudson that he had contracted it from a blood transfusion while living in Europe, and that his family sent him away to the U.S. A friend would later tell Hudson that he had seen his partner chopping up pills and putting them into a hamburger patty that he was making for Hudson, his fruitless effort at protecting him.

From Michigan, Hudson moved to Los Angeles and then to Atlanta, where he found a welcoming Black gay community where stigma surrounding status was almost non-existent. When he learned that his mother was ill, he left Atlanta to be closer to her, only to realize that not much had really changed in her life at all.

He's 31-years old now and living in Chicago. "I didn't start facing the stigma until I moved to Chicago," he says. "And the racial tension here is so thick that it's almost combustible. It's like, 'It's okay for you to be here, because we're not racist and this is not the South or whatever, but just know that we're not really going to include you.'"

He's found refuge in volunteering with Test Positive Aware Network, and his image and story are currently being used in the organization's citywide prevention campaign called SmartSex (an adaptation of the Community Promise model).

He recently completed the agency's treatment education program, and is planning to get more deeply involved by going back to school for a degree in social work or human resources. He also maintains a Yahoo360 blog, which has chronicled his journey with HIV.

## RAYMOND

Raymond Berry became the man of his household when he started working at the local White Castle at the age of 16. His parents had split when he was 10 or 11. What little support his father provided after the separation wasn't enough, and had to be supplemented through welfare assistance. When Raymond became old enough to work, his father cut him and his two sisters off altogether.

"It felt like he thought he had been trapped in marriage, but that he didn't really want to be bothered," says Raymond. "And I took it personally, thinking he didn't care about me. I just associated him with money, as a provider, and he barely did that."

Raymond feels that being abandoned by his father has greatly influenced the relationships that he has had with other men since.

"He conditioned me to believe that men leave when you need them, and that maybe I needed to do something to make them stay," he says. "Whether it's to give money or sex or be submissive, I believed that I needed to do something. I couldn't just be myself. There was something that I needed to give beyond me, and so I was wearing this mask that kept changing."

Although he's known that he was somehow different since the crush he developed on another boy in the third grade, Raymond has never told his family that he is gay. Deeply rooted in the Black church, they kept it the secret that everybody knew, but nobody would talk about, until they were forced to.

While working to earn his bachelors degree in fine arts at the University of Chicago, Raymond came down with what he thought was a cold that he could not shake. He went to the emergency room and was admitted with a diagnosis of pneumonia. When he confided in the doctor that he was gay, an HIV test was immediately ordered.

"Though I wasn't expecting [a positive result], I certainly thought about the inevitability of it," says Raymond. "I had been tested before and I was negative, so that became my excuse to go right back out there and do whatever I was doing. I didn't see that as a sign from the universe saying, 'Okay, you're negative, slow down.'"

"For my family, it just kind of confirmed every stereotype that was associated with my lifestyle," he continues. "And when my twin sister came to pick me up from the hospital she asked me, 'With all that we know, with all that you know—how could you let this happen?' And I didn't know what to say."

"I was a little bit sad, a little bit confused, and a little bit angry," he says. "But I don't think I dealt with it until I started writing about it."

Though he endured extreme loneliness from lack of a solid support system following his diagnosis, and admits to contemplating suicide on more than one occasion, Raymond credits his ancestors with pulling him back from the brink of death.

"I believe that I was put on this Earth because the ancestors chose me to continue what was started before me. Essex, Marlon, Joseph, and Melvin. They chose me. It's almost priestly. I have work to do. I have to try to prevent this from happening to anyone else."

Raymond went on to obtain a masters degree in fine arts and, at 29, is currently in Chicago teaching a college course on African American literature. His first book, entitled *Diagnosis*, is being published by Vintage Press and will be available July 1st. It is a collection of poetry that chronicles his physical, mental, and emotional journey after being diagnosed.

"I convinced myself that I am not supposed to have a personal life," he continues. "I don't date. I'm not sexually active. If one day that person comes along, cool. But I'm not looking for it. I haven't been sexually active since 2004, and I haven't dated since 2005."

"I can honestly say that I am stable," he says. "I'm not going to off myself, although I think I already have. Not necessarily physically, you know, but anytime you shut down, you lose those socialization skills. You punish yourself by thinking that you are not worthy of relationships. But how do you come to the realization that you're worthy or deserving of them?"

## AGAINST THE ODDS

Compared to many, Hudson and Raymond are success stories. They have each, in their own way, faced the combined, destructive forces of childhood abuse, homophobia, betrayal, stigma, self-judgment, and on top of all of that, HIV. But both have found purpose and value in their lives. Both will one day, no doubt, become part of the class of "elders" that others who contract the disease in their youth will look to for help, guidance, and inspiration. ☪

# THE BUZZ



## The HAND that Rocks the Cradle

*Neurocognitive disorders occurring in patients treated for HIV*

*by Daniel S. Berger, M.D.*

**W**e know that the survival rate of HIV-positive individuals has improved through better treatment, and people are living longer. What follows, of course, is a rapid current of normal aging within the population of treatment-experienced patients. Until relatively recently, the health problems in HIV-positive patients that traditionally surfaced during their disease course were often only HIV-related. As our patients get older, we now see a plethora of aging-related medical issues that require attention.

At least some of these complications can be attributed to the natural course of aging, which we also know is true in normal, HIV-negative individuals. However, there's the big question of whether long-term treatment-experienced individuals, who now show signs of these non-HIV-related medical complications, may in fact be experiencing them prematurely. We know definitely, for example, that bone loss occurring in a 30- or 40-year-old HIV-positive person is untimely.

This article is about the phenomenon of long-treated patients suffering from subtle, or sometimes obvious, cognitive dysfunctions. There is increasing evidence that HAND (HIV-associated neurocognitive disorders), is not uncommon and probably more progressive than expected with normal aging.

Individuals who are being treated with effective anti-HIV medications achieve undetectable viral loads in the blood. However, the mistaken belief is that their cerebrospinal fluid (CSF), the fluid that cushions the brain, should have comparable findings to the blood or have undetectable virus in the brain. Although we cannot perform brain biopsies on patients, by the use of very sensitive assays for viral load from the CSF that surrounds the brain, we do have an indirect way of measuring virus in the central nervous system (CNS). Conventionally used viral load tests detect HIV down to 50 copies/ml, but some tests are

more sensitive. These more sensitive assays detect down to 2 copies/ml. This testing is being used for research purposes and studies investigating whether there is detectable virus in the CSF.

### STUDIES

During the recent Conference on Retroviruses and Opportunistic Infections, held in Montreal (February 2009), several studies relating to neurocognitive impairment were presented. I believe that clinicians were surprised to hear some of the statistical results. In the CHARTER study, 1555 HIV-positive patients, from six sites around the U.S., participated; their average age was 43 years. The group was mostly male (77%); 49% were African American, 39% non-Hispanic white, and 9% Hispanic; 58% were from the MSM (men having sex with men) population. Average CD4 counts were about 420 cells and CD4 nadir (lowest level during their disease course, usually before starting treatment) was 174 cells. The vast majority were on antiviral therapy.

Overall, 45% of the patients in this study were shown to have some neurocognitive impairment (NCI), based on the comprehensive testing that was done, which increased when individuals had other illnesses (co-morbidities) present. Also, when there was minimal co-morbidity, patients with AIDS diagnoses and lower CD4 nadirs had higher rates of NCI. Reasonably, this would indicate that starting treatment early, when the nadir of CD4 counts is still high, might have a positive impact on preventing HAND from occurring. Also, agents that have better penetration of the blood brain barrier may be an effective tool for helping avoid HAND down the road.

Of antiviral medications that penetrate the brain, nevirapine (Viramune) has long been understood to be an agent achieving the highest CSF levels. One poster in Montreal showed that efavirenz (Sustiva or EFV) and FTC (Emtriva) penetrate the CSF better than was originally thought, however,

Dr. Scott Letendre, a lead researcher in the field, pointed out (in a personal communication) that EFV levels are very low in CSF compared with blood (about 0.5%), but in most samples (about 95%) seem to exceed the IC50 (half maximal inhibitory concentration). [IC50 is a measure of the effectiveness of a medication in inhibiting biological or antiviral activity.] The extent to which the levels exceed the IC50 is similar to the better protease inhibitors, but still not as good as nevirapine (up to 100-fold over the IC50). When you combine the lower-than-nevirapine levels and the CNS side effects of EFV, Dr. Letendre believes that it's a good idea to avoid EFV in people with HIV and cognitive impairment.

Other interesting presentations delved into the surrounding issues. A subset of patients participating in the CHARTER study had paired samples of blood and CSF collected; 300 subjects taking antiretrovirals with undetectable viral loads (<50 copies) in both blood and CSF were investigated here. Using the assay that detects HIV down to 2 copies/ml, 41% of these individuals had detectable virus in their CSF. At least 25% of individuals have detectable HIV solely in their CSF, but not in their blood. These patients have much worse cognitive performance. The authors concluded that the cognitive impairments may be the result of incomplete effectiveness of treatment of HIV in the CNS.

### IN THE CLINIC

From a very clinical standpoint, I find that symptoms of HAND can be identified by asking patients some simple questions.

"Can you remember phone numbers the way you once used to?"

"Do you remember the name of the last movie you saw in the theatre, or the TV program watched the night before?"

"Is forgetting keys, wallet or phone, becoming more noticeable?"

Photo © Russell McGonagle

“Have there been increasing difficulties with simple addition or tasks related to numbers?”

These are questions I use in the exam room looking for suspected HAND. Although these kinds of changes are seen often, most physicians, under our current economic conditions and medical system, may not have the time to examine patients this way. From the patient’s perspective, most learn how to adapt to their impairments, continuing in their daily routines and job responsibilities. I often suggest some helpful exercises to patients facing these issues, such as learning how to write things down more often, or practice utilizing and sharpening their short-term memory.

I believe it’s possible for patients that do not show signs of severe HAND to improve their cognitive abilities by exercising the mind, so to speak. Here are a few examples of what I’ve suggested to patients. I think that learning new skills, specifically ones that require the use of memory, such

as learning a new language or computer program, are helpful. Also, it may be useful to practice daily reading of articles from a newspaper or magazine and then close the article or newspaper and practice recalling what was just read. Newspapers and magazines contain crossword puzzles as well, another mind game that could also be fun. Admittedly, I’m not able to site references or studies that confirm my suspicions about these suggestions, but some of my patients have improved their cognitive skills this way. After all, we do know that patients with other diseases, such as strokes, have been able to regain neurologic functions with the help of therapy.

#### CONCLUSION

Although treatment with HAART has been successful in major ways, an area that needs more attention is HAND. If the treatment pendulum is swinging back to starting therapy at higher CD4 counts, this may result in some patients eventually avoiding some of these neurocognitive issues, now

coming to light. If other antiretroviral agents are developed that have superior CNS penetration, they may become handy tools, as these issues are rapidly gaining importance.

*Dr. Daniel S. Berger is a leading HIV physician in the U.S. and is Clinical Associate Professor of Medicine at the University of Illinois at Chicago. He is founder and medical director of NorthStar Healthcare, the largest private HIV treatment and research center in the Greater Chicago area. Dr. Berger has published extensively in such prestigious journals as The Lancet and The New England Journal of Medicine and serves on the Medical Issues Committee for the Illinois AIDS Drug Assistance Program and the AIDS Foundation of Chicago. Dr. Berger has been honored by Test Positive Aware Network with the Charles E. Clifton Leadership Award. Dr. Berger can be reached at DSBergerMD@aol.com and www.NStarMedical.com*

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# WHOLISTIC PICTURE



## Quantity vs. Quality

*Is longer necessarily better?*

by Sue Saltmarsh

I've worked with and along-side HIV-positive people for the last seventeen years. I've watched them decline in health and I've lost too many. I've watched them rally miraculously when they were expected to die. I miss the ones I've lost and am grateful for the ones I've found and can embrace. But nothing really brought home the reality of the life and death see-saw they're on until I had my own run-in with the specter of life-altering illness.

Granted, diabetes is nowhere near as destructive as HIV and the dangers of imminent death are fewer, but, as I've discussed with Jeff and other colleagues, after 52 years of pharmaceutical-free living, I can now understand better what a life-changing thing it is to be dependent on a pill, to be constantly aware of the precarious balancing act going on inside my own body. And it has brought me closer to my own mortality and consideration of the possibilities of *how* I am going to die.

is a true healer and puts up with my incessant questions, doubts, resistance, and weirdness, knowing that I am nothing if not determined to maintain my right and power to decide my own fate. I feel sorry for him sometimes, because even though I think he sort of enjoys me and my irascibility, I will never be an "easy" patient. I struck a compromise with him today—I'll try the statin he wants me to take, as long as he understands that if it makes me feel nauseous or achy or tired, I'm going to quit taking it, accepting the risk that comes with that choice. It really is OK with me if a heart attack or stroke is the way I'm going to go, but I also know I have more to do around here before the time comes, and I don't want to feel crappy every day until then. Unfortunately, my HIV-positive friends and colleagues have a harder choice than mine, since the risk of quitting their meds is more life-threatening than mine.

So when I read about the side effects of most of the AIDS meds (and after proofing the Drug Guide, they're vivid in my mind!) I am infinitely grateful that I don't have to weigh quantity vs. quality concerning them. Watching friends suffer through chemo and radiation makes me grateful that I don't have to make that choice either. What would I do? If you don't take the treatment, you might die too soon, and not pleasantly. What if a cure is right around the corner? What if there never is a cure? What if it's something we already know about but haven't used in the right way yet? What if it's something that has yet to be discovered?

## THESE THINGS HAVE MADE ME THINK ABOUT THE TIME I HAVE LEFT AND HOW I WANT TO LIVE IT

I joked with a friend on my birthday that it would be a great way to go if I ate so much birthday cake that I went into a diabetic coma and never woke up. But I don't think suicide-by-cake is the best approach! I know that when the time is right, the "how" won't really matter. It'll be good, whatever it is. Death is something that has never scared me, but dealing with the input of all the medical people I've interacted with since August, adjusting to the fact that I now have to do math (something I HATE!) every time I even consider eating, missing the sugar in my coffee; all of these things have made me think about the time I have left and how I want to spend it, in short, the quality vs. the quantity of my life.

I am so very grateful to have found my doctor, Dr. David Moore—as with any hard lesson, I believe he is one of the reasons all this happened, since I might never have met him otherwise. He

I've always thought I'd die when I was 82—old enough to have seen my nieces grow up, to have driven a car fueled by water, to have seen Israel and Palestine become a united country at peace, to have seen health care become a birthright, not a privilege for the wealthy few, and yet still together enough to continue to write Oscar-winning screenplays, cheer the Bears to victory in Super Bowl LXXIII, and celebrate the 50th anniversary of *Positively Aware* with Jeff, Enid and Keith (who will be President by then!). Whether Metformin and Pravachol get me there or not, the important thing to me is that I love the steps along the way. I hope that whatever treatment options you choose make that possible for you, too!

Breathe deep and live long (and well!). ☸

Photo © Russell McGonagle

# PICKETT FENCES



## Beyond Ripe

*But hanging in there!*

by Jim Pickett

**A**s is my custom these days, I have been in full-tilt-boogie procrastination mode on this column. I have already received a week extension, and I am—at 11 pm on the Monday when it was/is/was due—just now firing up the ‘puter to tippy tap this thing out.

It’s like I am still in college. I’m behaving in the exact same manner that led me to drop out after three and a half years, seven majors, and a lot of time lying on dorm room floors in caffeine-induced crazes, laughing and smoking (Salem Lights and pot, thanks) and cranking “Purple Rain” at 2 am instead of writing that term paper on “Shoah.” Or Cliff Noting more than one word of “Henry VI.” Or perusing twelve geology chapters for the final in the morning.

Why the hell did I take that class? Perhaps I still have time to drop? Maybe the lecture hall will be on fire tomorrow.

You’d think the past 22 years since my last college course, when I was at Marquette University majoring in, um, theater, would have taught me a few things. Given me, uh, wisdom through experience. But you’d be wrong on a number of counts.

I haven’t grown up in so many ways.

The words moist, slacks, salve, butter, whiskers, slender, beaver and beige continue to make me laugh. Go ahead. Whisper “whiskers” to me at a funeral and see what happens. It’ll be your fault. You, in those crushed velvet bell-bottom slacks and that poly blouse.

I still love 80’s music—dammit, it’s my defining decade. I remember going to Papagallo for New Wave Thursdays and to Park Avenue for Gay Sundays and shimmying in my shoulder pads, spiked hair, and many, many rubber bracelets to the Thompson Twins, INXS, Duran Duran, Bananarama, Adam Ant, Frankie Goes to Hollywood, The Cure, Depeche Mode, Flock, Tina, Cyndi, Michael Jackson before the troubles, and on and on... And I only realize how old that actually makes me when I realize I can’t name more than two current bands, or

when some booger-nosed brat underscores how she was crapping her pants when Madonna was banging Sean Penn, a historical fact of which she is clueless.

“I don’t feel like eighty. I guess you never think you’re the age you are, and, as long as you don’t look in the mirror, you aren’t,” Frank Gehry, of Pritzker Pavillion fame, recently told *The New Yorker*, remarking on his 80th birthday.

While I never think I am the age I am, I’m different than Frank. First of all, while I am indeed more than halfway there, I ain’t 80. Second, I look in the mirror and think, “Yeah, young and fresh.” It’s only when I see pictures of myself—contemporary or vintage, bloated or wisp-o-the-will—that I’m startled into awareness. “Oh, heavens,” I say. Hand me the goggles.

**I LOOK IN  
THE MIRROR  
AND THINK,  
“YEAH, YOUNG  
AND FRESH.”**

The Middle Ages. Yes, I have become one of those people who says, squinting through his bifocals and strategically aligning candles, “It is so dark in here, I can’t read the menu.”

Yes, I am now someone who just wants to be able to sit. Who wishes it weren’t so loud, “so we could at least have a decent conversation.” Who nods off before the end of the ten o’clock storm center update on a

Saturday night. Who declares, “They don’t make sitcoms like they used to.”

Yep.

“And in the end, it’s not the years in your life that count,” said Abe Lincoln. “It’s the life in your years.”

All my kvetching aside, I am happy I made it to 43. Fourteen years ago, when I found out I was HIV-positive, the drama queen in me had me burned up in a vase before 40. I truly didn’t think I would have this time, or if I did, I would be three feet in at this point. And never mind HIV, some of the stunts I pulled as a wild child should have either killed me, maimed innocents, or landed me in prison. I squeezed a lotta life out of those earlier decades.

I would not go back a decade, one year or one day. It is a delight to be 43, verging

on permanent crank, in a sort of Alzheimer’s-lite fog much of the time (better for not remembering) with crampy legs and random aches. Really, I love it. As long as I can crawl out of my crypt every morning, there is still a lot for me to do in my sensible shoes. And I intend to get on with it. ☘

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# THIS ISSUE'S POLL

## THIS ISSUE'S QUESTION

**What do you think is the most important issue for women regarding HIV?**

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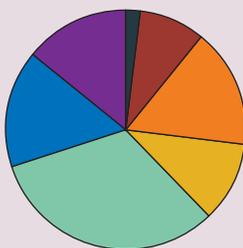
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## MARCH/APRIL 2009 POLL RESULTS

**How long have you been living with HIV?**

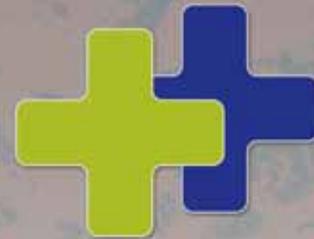


2%	Less than a year
9%	1-2 years
16%	3-5 years
11%	6-10 years
32%	11-20 years
16%	More than 20 years
14%	I am not HIV-positive

## COMMENTS

- I seroconverted in March of 1981. I was part of a CDC-funded hep B vaccine study in San Francisco. Less than 1 in 10 of the 5,000 gay men who participated in the study are still alive.
- 11 years from the time when I know I was infected. Looks like I'm about to go on therapy soon.
- I celebrated 20 years being HIV-positive on March 14, as well as my 55th birthday!
- Tested positive October 1984; asymptomatic for 25 years for any AIDS-defining illnesses; started AZT out of fear in 1988, have taken three 18-month drug holidays and viral load has never been higher than 115,000; T-cells to date 541, viral load undetectable for over 10 years.
- Diagnosed with AIDS September 2002; however, the advanced stage of the disease indicates to me that the answer is truly more than 20 years.
- It's been a struggle, but I'm still kicking!

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