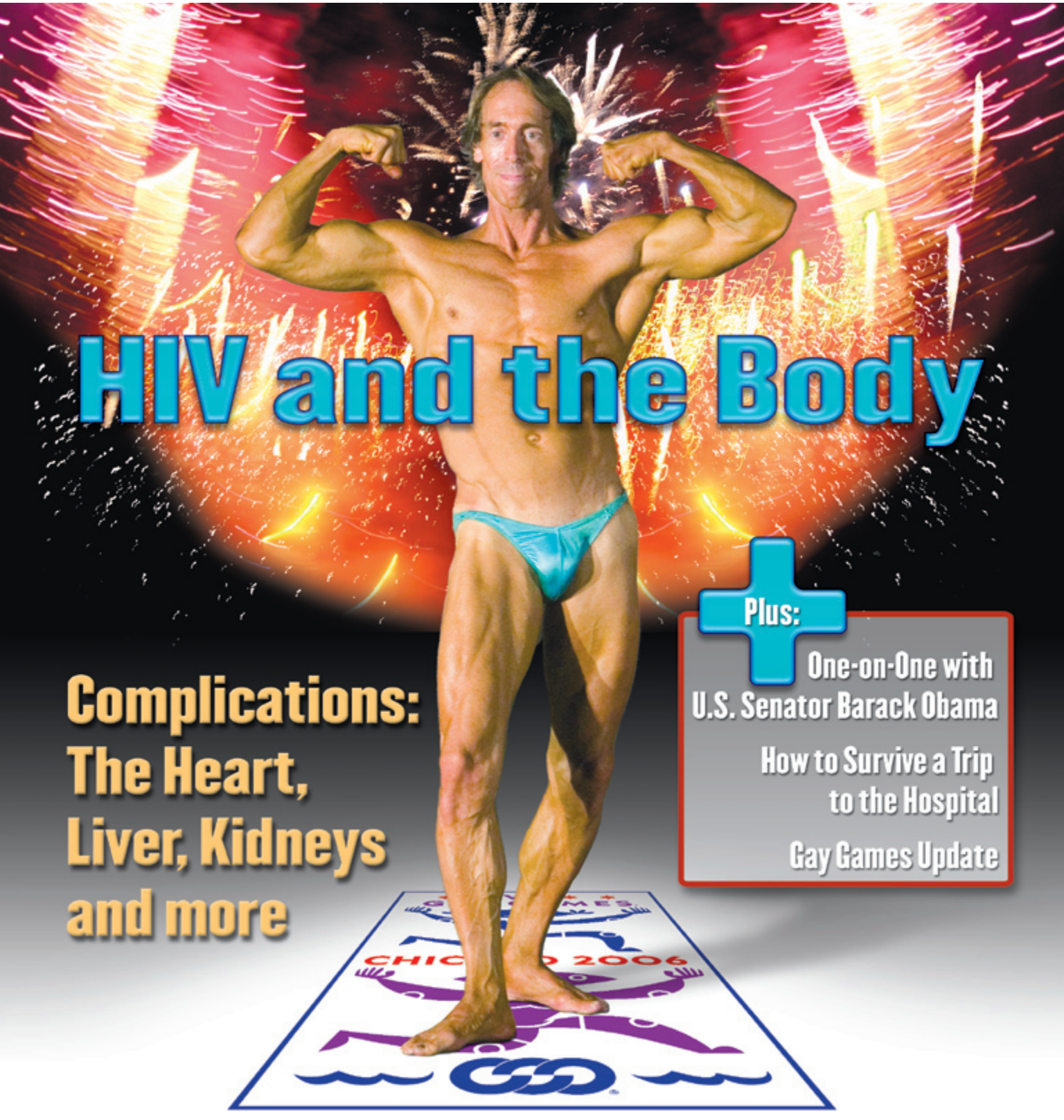
September / October 2006

Positively Aware

The Journal of Test Positive Aware Network



HIV and the Body

Complications: The Heart, Liver, Kidneys and more

Plus:

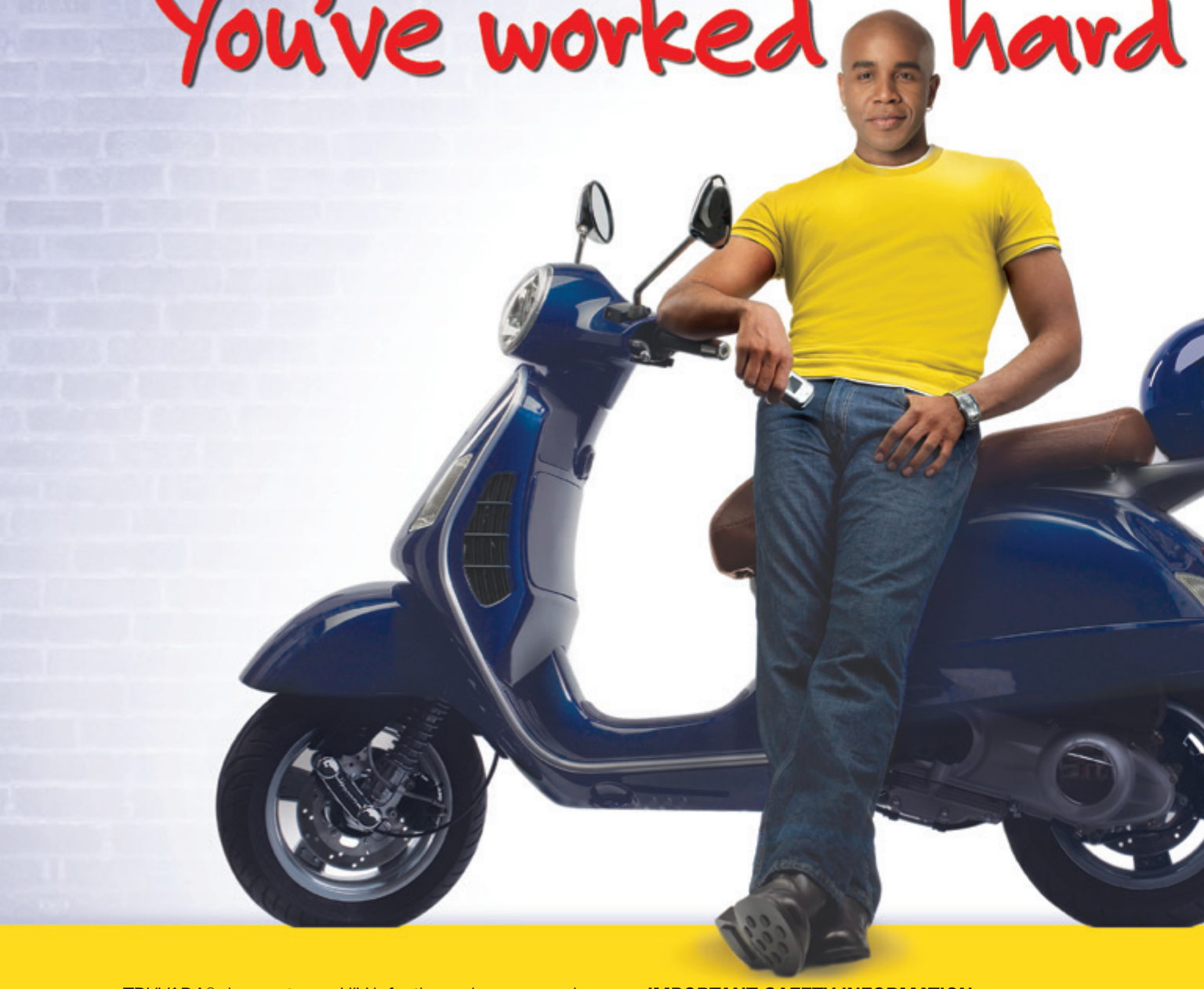
One-on-One with U.S. Senator Barack Obama

How to Survive a Trip to the Hospital

Gay Games Update

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

You've worked hard



TRUVADA® does not cure HIV infection or lower your chance of passing HIV-1 to others and must be used as part of combination therapy. **TRUVADA should not be used with VIREAD®, EMTRIVA®, Combivir®, Epivir®, Epivir-HBV®, Epzicom™, or Trizivir®.**

USE OF TRUVADA:

TRUVADA is indicated in combination with other antiretroviral agents (such as nonnucleoside reverse transcriptase inhibitors or protease inhibitors) for the treatment of HIV-1 infection in adults.

GILEAD

IMPORTANT SAFETY INFORMATION:

- **Lactic acidosis** (a buildup of acid in the blood) can be a medical emergency and may need to be treated in the hospital. Call your healthcare provider right away if you have nausea, vomiting, unusual muscle pain, and/or weakness
- **Serious liver problems** (hepatotoxicity), with liver enlargement (hepatomegaly) and fat in the liver (steatosis), may occur. **Call your healthcare provider right away** if you have light colored stools, dark colored urine, and/or if your skin or the whites of your eyes turn yellow
- **Flare-ups of hepatitis B virus (HBV) infection:** If you have HIV and HBV, your liver disease may suddenly get

to get where you are.

So why settle for an HIV med that's twice a day?

Once-a-day TRUVADA® can help get you to undetectable and keep you there. As part of an HIV regimen, the meds in TRUVADA:

- Can be taken with or without food
- Reduce viral load and increase CD4 cell count

Ask your doctor how TRUVADA can be part of a complete once-a-day regimen.

Truvada®

200 mg emtricitabine · tenofovir disoproxil fumarate 300 mg

Move On With Life

TRUVADA is the #1 Prescribed HIV Med*

worse if you stop taking TRUVADA. Do not stop taking TRUVADA unless directed by your healthcare provider

- **Kidney problems:** 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
- **Bone changes:** It is not known whether long-term use of TRUVADA causes damage to your bones. If you have had bone problems in the past, talk to your healthcare provider before taking TRUVADA

Changes in body fat have been seen in some people taking anti-HIV medicines. The most common side effects of TRUVADA when taken with other anti-HIV medicines are dizziness, diarrhea, nausea, vomiting, headache, abdominal pain, depression, rash, and gas. Skin discoloration (spots and freckles) may also occur.

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®, Videx® EC, Reyataz®, or Kaletra® with TRUVADA

For more information, please visit **www.truvada.com** or call **1-800-GILEAD-5 (1-800-445-3235)** and select option 2. **There is additional information about TRUVADA on the next page.**

*Based on data from PHAST retail monthly data; April 2006–June 2006; Wolters Kluwer Health.

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** (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 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.
- **TRUVADA is not for the treatment of Hepatitis B Virus infection.** Patients infected with both HBV and human immunodeficiency virus (HIV) who take TRUVADA 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 (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 medicines to treat people with HIV 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 reverse transcriptase, a chemical in your body (enzyme) that is needed for HIV to multiply. TRUVADA lowers the amount of HIV in the blood (viral load). TRUVADA may also help to increase the number of T cells (CD4 cells). Lowering the amount of HIV 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 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 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 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.

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:

- COMBIVIR®, EMTRIVA, EPIVIR®, EPIVIR-HBV®, EPZICOM™, TRIZIVIR®, or VIREAD. **TRUVADA should not be used with those medicines.**
- Drugs that contain didanosine (VIDEX®, VIDEX EC®). 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.**
- 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.

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 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 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 doesn't 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.
- COMBIVIR, EMTRIVA, EPIVIR, EPIVIR-HBV, EPZICOM, TRIZIVIR, or VIREAD. **TRUVADA should not be used with these medicines.**

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. Your healthcare provider will monitor your condition for several months after stopping TRUVADA if you have both HIV and HBV infection. TRUVADA is not for the treatment of Hepatitis B Virus infection.
- **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 TRUVADA 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.

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

- Changes in body fat have been seen in some patients taking TRUVADA and other anti-HIV 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 effects of these conditions are not known at this time.

The most common side effects of EMTRIVA or VIREAD when used with other anti-HIV medicines are: dizziness, diarrhea, nausea, vomiting, headache, abdominal pain, depression, rash, and gas. Skin discoloration (small spots or freckles) may also happen with TRUVADA.

These are not all the side effects of TRUVADA. This list of side effects with TRUVADA is **not complete** at this time because TRUVADA is still being studied. 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 at room temperature up to 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.

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

What are the ingredients of TRUVADA?

Active Ingredients: emtricitabine and tenofovir DF

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, hypromellose, lactose monohydrate, titanium dioxide, and triacetin.

Rx Only

January 2005

GILEAD

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Distribution of *Positively Aware* is supported in part through grants from AIDS Foundation of Chicago, GlaxoSmithKline and Abbott Laboratories.

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Volume 17 Number 5

Departments

On the cover:
Douglas Graham Bates, who took home a silver medal in the Physique competition at this year's Gay Games (see page 30).

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

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

Articles

Programs and Meetings

Programs and Meetings at TPAN

- Support Groups
- Rapid HIV Testing
- Reiki and Massage
- Needle Exchange Program
- Individual Counseling
- Peer Support Network/Buddy Program
- Speakers Bureau
- Access Medical Clinic at TPAN
- PULSE, an HIV-positive Weekly Social
- TEAM (Treatment Education Advocacy Management)
- Positively Wired—A Free Basic Computer Skills Workshop

For detailed descriptions of programs, including days, times and locations, go to http://www.tpan.com/client_services/clientservices.shtml or visit www.tpan.com and click on Client Services, or call (773) 989-9400

TPAN Events Calendar

TPAN Events Calendar

- Educational Forums and Trainings
- Special Events

For detailed descriptions of upcoming TPAN events go to http://www.tpan.com/events/events.shtml or visit www.tpan.com and click on Events, or call (773) 989-9400

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Who Will Be There For Us?

I am not I.
I am this one
Walking beside me whom I do not see.
Whom at times I manage to visit,
And whom at other times I forget.
Who remains calm and silent while I talk.
And forgives, gently, when I hate.
Who walks where I am not.
Who will remain standing when I die.

—Juan Ramon Jimenez

In the summer of 1976, my father died at home after battling lung cancer. I, along with other members of my family, knelt by his side, holding his hand as he drew his last, labored breath. A tear rolled down my cheek and landed on his arm. It was sad and excruciatingly beautiful all at the same time. It was his wish that he die at home, and we were able to be there for him, to grant him that one, last wish.

In the summer of 1998, my mother died at home after a lengthy struggle with breast cancer. My mom had collapsed five days earlier and was rushed to the hospital. When I received the call, I jumped in the car and raced 180 miles home to find her on life support, unresponsive, and in a coma. My brother, sisters, and I remained by her side for the next five days, taking shifts, as the doctors ran every conceivable test. We talked to her, played her favorite music, sang to her, and cried. When the doctors determined that there was no chance of recovery, the decision was made to bring her home, and to get her out of that dreary hospital room, so that she could spend the last few moments of her life surrounded by those she loved, in the home my dad had helped to build, and where I had spent my entire childhood.

As hospital rules dictated, they had to remove my mom from life-support while still at the hospital, so there was a chance that she might not have survived the ambulance ride home. My mom, bless her heart, lived another 18 hours. We were by her side the next morning, as the sky began to lighten, and the birds began to sing, one of her favorite songs, "Morning Has Broken," was playing on the tape machine, and she drew her last breath.

She was a brave soul, as were both my parents, but I learned a lot from my mom about death and dying during the last few months of her life. When my dad died, I was only seventeen, and I was young and impatient, and not nearly as close to him as I was to my mom.

Mom had been battling breast cancer for nearly 20 years; she had had two radical mastectomies, a botched implant that was later removed, several reconstructive surgeries, and suffered severe pain for many years once the cancer metastasized and spread to her bones. She underwent toxic chemotherapy treatments to keep the cancer under control, and opiates to help numb the constant pain, but she went on living more than five years, far surpassing any of the doctor's predictions.

She never really complained or said, "Why me?" But I remember one day when she suddenly broke down in tears because she was unable to make me a tuna sandwich for lunch. She probably had the final realization that life was becoming too hard; her little body was starting to give out, and she was losing control.

The rest of my immediate family, who were with her day in and day out, they were the ones who had the hardest part. Mom required constant care, and we even had a hospital bed put in the living room, once she could no longer walk up the stairs to her bedroom. A nurse would come by for a few hours a day, and that helped out somewhat. But I had the luxury, I guess, of being able to go and visit, and then at the end of the weekend I would head back to Chicago.

I was seeing a therapist at the time (thank God) and he encouraged me during those last few months to let my mom know what she meant to me, and to ask her what I meant to her. So every chance I could, I would make the three-hour drive to Michigan, and we would spend quality time together playing cards, talking or just sitting, but I never really knew how I would broach the subject of saying goodbye.

One day when we were alone together, I finally got up the nerve and just spoke from the heart. Among other things, I told her how much I loved her, and asked her if she knew how much she meant to me. I asked her if she knew what a good mother she was. She looked deep into my eyes, and for an instant we connected as though we were one, and she told me no, that she didn't know that, but that she had always *felt* it, from the moment she had first held me as a baby.

How do you say that final goodbye to someone you love? As I was leaving the last time I visited my mom, several days before she died, and I pulled the front door shut behind me, I paused and turned to smile and wave at her through the porch window. She waved back at me from her bed, and had this big, beautiful smile on her face, as if to say, "See you next time!" I didn't know that that would be the last time we would ever communicate, but it is something that I will never forget, and will cherish forever.

Take care of yourselves, and each other.

Jeff Berry
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publications@tpan.com

Photo © Russell McGonagle

Readers Forum

Positively Aware will treat all communications (letters, faxes, e-mail, etc.) as letters to the editor unless otherwise instructed. We reserve the right to edit for length, style or clarity. Please advise if we can use your name and city.

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Chicago, IL 60640
Fax: (773) 989–9494
E-mail: readersforum@tpan.com

Metabolic complications

I am a practicing registered dietitian in an outpatient clinic dealing with HIV and AIDS patients. I appreciate you tackling a subject with a paucity of research, particularly from the diet and lifestyle perspective [HIV Treatment Series, "Early Intervention for Metabolic Complications of HIV," March/April 2006]. However, I must say that I was taken aback by many of your proposed food recommendations. Why all the organic food choices? Most of the patients who I see can hardly afford regular foods. It seems that you may have allowed your personal preferences to govern your recommendations rather than keeping at heart the socioeconomic status of many of the people infected with HIV. Secondly, to my knowledge, there have been no clear-cut studies demonstrating that "organic foods" are any better nutritionally than their conventionally grown counterparts. Although I do agree that there are definitely better choices when it comes to carbohydrates, using the glycemic index to classify foods as "good" or "bad" is highly controversial. In a patient population that often falls short on meeting their nutritional needs, *all* foods, even in the context of metabolic complications of HIV, have a place in a well-balanced meal plan.

Jeffrey Luckring, MS, RD

Carla Heiser responds: Borrowing from the well-designed endocrine and cardiology literature, data regarding insulin resistance and metabolic syndrome dates back to the 1970's. Certainly diet and lifestyle information that gets translated to consumers is confusing—with mixed messages and new spins for the "in-style" diet du jour. I will counter the reference to a paucity of research though. For example, a quick search of "glycemic index" at www.pubmed.com reveals 831 articles, 112 of which are randomized, controlled studies in humans.

As for organic and hormone-free food, we need to be responsible in our counseling of clients with a variety of income levels. Organic food selection becomes a personal choice, based on preferences for taste, quality, and cost effectiveness. We recommend shifting from fast food and junk food to eating a balanced diet consisting of "real, whole food." We encourage avoiding processed, canned, and pre-prepared foods, as well. Depending on individual factors, however, a serving of canned fruit and nuts is more nutritious than "Pop-Tarts and soda or juice."

When there are clinical issues with hormone imbalance in particular, impacting a majority of our HIV-positive patients, selecting hormone-free foods can be a sensible and practical first-line approach. When possible, we prioritize hormone-free dairy, eggs, meat, and poultry. Outlets like Trader Joe's (owned by Aldi's) are promoting more affordable health food selections. The other good news is that mainstream supermarkets and price competitive venues like Walmart will be introducing organic foods, if they are not already available. It becomes our job to help with consistent messages that impact health outcomes effectively. Organic sugar is still sugar. [References available on www.tpan.com.]

Jeffrey Luckring responds: Thank you for your attention to my comments and the detailed response. I would like to clarify a few things, if I may. My reference to "paucity of research" deals specifically with the fact that the authors of the article dealt with the HIV patient population. Unfortunately, randomized controlled trials with HIV patients on any topic concerning nutrition are few and far between. I am well aware of the voluminous amount of data concerning the glycemic index and the general population. However, most would agree that you cannot make inferences based on data from one population to another, especially taking data from individuals without disease or even those with insulin resistance and transferring it to a population with a myriad of complex metabolic manifestations such as lipodystrophy. Secondly, although I would agree that the glycemic index has some utility when considering optimal foods for athletic performance/recovery, most individuals do not consume a solitary food item when they sit down for a meal. That is why the glycemic index is relatively useless for meal planning and has garnered little if any merit from the American Diabetes Association. The glycemic load, on the other hand, would be much better as it has the potential to predict an individual's glycemic response to an entire meal. Again, it is unfortunate that we are left with this conundrum, for it would be exhausting, if not impossible, to calculate or even predict the glycemic load for the hundreds and thousands of food combinations available. We are definitely in accord regarding our desire to steer our patients towards healthier foods. However, I am still having a lot of trouble with your recommendations for organic and hormone-free foods. HIV patients certainly can have a number of hormonal imbalances, but I find it hard to believe that eating a "hormone-free egg" or "hormone-free chicken" is going to have any positive benefit, especially when there is no current data to support that recommendation. Until proven otherwise, my contention will continue to be that organic foods are no better nutritionally than conventionally grown. I appreciate this forum and I do enjoy Positively Aware. *I look forward to reading more articles on nutrition and HIV in the future.*

Carla Heiser responds: I disagree about making inferences from the general medicine literature. In our practice we see hundreds of patients with various levels of health. Clinically, when we limit sugar and refined carbohydrates, replacing them with complex carbs, using lean protein, and good fats and oils, we see remarkable results.

New York prisons and hepatitis C

At the moment, I continue to serve as the inmate program coordinator of Marcy

Correctional Facility; our program here is for AIDS counseling and education. We always rely on outside help with information to educate ourselves. Without this assistance we are unable to educate the inmate population.

I have been HIV-positive now for 18 years, and hepatitis C-infected for well over 20 years. I am currently on the hepatitis C treatment, and in three months of treatment I was able to bring my hepatitis C viral load from one million down to undetectable levels, which is a blessing for a person with cirrhosis. I will soon write about my experience while on treatment; both my doctor and I were amazed with the results.

Most people with genotype 2B do well, but with cirrhosis it does become difficult to reach the goal of undetectable levels. I have been on the treatment since December 2005 and it was a challenge here in New York State Corrections to receive the treatment because of the policy in place. However, Corrections was forced to change the policies in order to benefit us all. Corrections is always interested in saving a penny rather than saving lives. They did not want to treat those with hepatitis C without their participation in a substance abuse program and wouldn't treat those with less than 15 months before release. Also, the substance abuse program in New York City's DOC [Department of Corrections] gets you into the program within two years of your earliest release, so the new changes did make a big difference in many people's lives. The new policy changes consist of your encouragement to participate in a substance abuse program, and it does not matter the amount of time left on your release date. Furthermore, it will be linked to a hospital or clinic upon release.

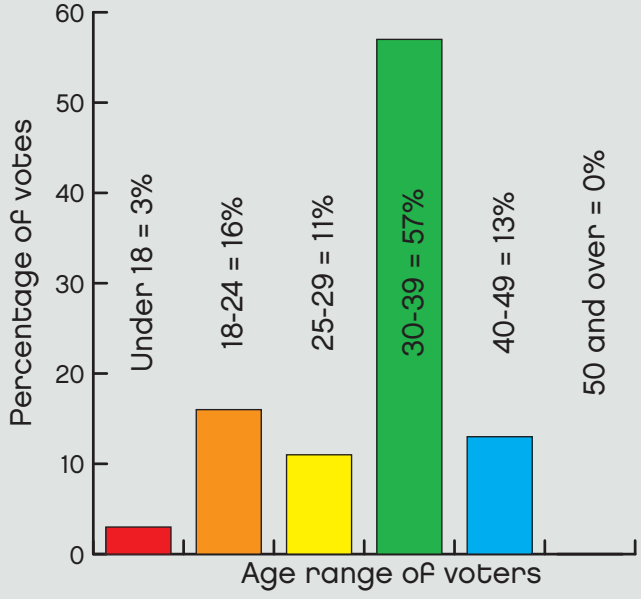
William Lopez, 0414146, Coordinator,
P.A.C.E., Marcy Correctional Facility,
Box 3600, Marcy, N.Y. 13403–3600

Treatment options

I have a tricky treatment question: Do I have any options other than my current regimen besides Fuzeon? My history: saquinavir [Invirase], AZT [Retrovir], and 3TC [Epivir] in 1996. I dropped saquinavir and added Crixivan in '97. My doctor suggested dropping AZT in '99 due

July / August
PA Online Poll Results

At what age did you test positive for HIV?



Comments:

- I got my positive results the day after my 28th birthday. My first appointment at the clinic every nurse, aide and doctor I had to see gave me this long sad look. Those were crazy days—my partner at the time and I had tested three months prior at our family doctor's office. My partner came back pos and I came back neg. That doctor said "get your affairs in order, quit your job and relax as much as possible" to my partner. To me he said "you'll be positive in a few weeks, do the same as him." Those are direct quotes—you don't ever forget what a doctor said when he tells you something like that. Although we broke up a month after that doctor visit, 18 years later we are both still alive and kicking.
- About 5 months ago, at the age of 23
- I tested positive at 16, on June 9, 1996. I freaked out in silence...just cried. I felt the world was over and I would try to commit suicide. I told my mom and my best friend, and they always stood by my side, but we never talked about it. When I turned 24, I ended up in the hospital quite a few times, not to mention my drug abuse (crack cocaine). I then decided to start on meds and accept reality. I am taking Sustiva and Truvada. I do not smoke cigarettes any longer and I definitely don't do drugs. I feel free now. I am positive and sure of my self. You choose what you want.

September / October
PA Online Poll:

Have you ever avoided HIV treatment because you were concerned about facial/body changes?

Give your answer at www.tpan.com

continued from page 9

to fatigue, so I used Crixivan, d4T [Zerit] and 3TC until 2001 (undetectable viral load and high T-cells—600–800). Facial and limb atrophy prompted me to switch to Trizivir in 2002. Trizivir was stopped due to fatigue in mid-2002. A genotype test in '02 indicated "susceptible" to all [protease inhibitors] and NNRTIs [non-nucleoside reverse transcriptase inhibitors]; high level resistance to 3TC, abacavir [Ziagen, one of the drugs in Trizivir], and AZT; intermediate level resistance to d4T, ddC [Hivid], and ddI [Videx] (K70R, M184V, M41L, T215Y/F mutations). Viracept, d4T, and ddI were tried and dropped due to stomach problems in '02. No HIV meds from August '02 to September '03. My T-cells fell to 309 (22%) and viral load climbed to 250,000 in that time. I started Viramune, ddI, Viread, and 3TC (later Truvada), which brought my viral load down to undetectable, but T-cells declined to low 200s (lowest ever; %'s around 20) in '04. In '04 and '05 I got stabbed 12 times (ultimately, more a mental than physical impact), experienced wasting syndrome, balance problems, peripheral neuropathy in my feet, depression, and anxiety. In March '05, I dropped ddI and Viread and started Kaletra, Viramune, and 3TC (then dropped 3TC). In '06, my neuropathy is slowly improving, and I have gained my weight back. However, Kaletra caused much diarrhea, bloating, and gas. Two weeks ago, I switched to Lexiva, Norvir, and Viramune to see if that makes any difference. No difference. I know that "protocol" indicates that PI-experienced folks do not use Lexiva without Norvir, but what do you think my chances would be on Lexiva and Viramune? What about Lexiva and Viramune, and Norvir at night (100 mg), but not in the a.m. (the daytime dose seems to be the primary culprit)? Crixivan and Viramune? Are there any other alternatives besides Fuzeon? Should I get another genotype test? My doctor is great, but not very sympathetic to the mentally and socially debilitating effects of chronic GI [gastrointestinal] problems. I am trying to dig myself out of depression and anxiety, and the stomach problems only add to them. I am also on acyclovir, Klonapin, Pilocarpine, Avapro, Vicodin (for chronic pain from a botched anal wart laser surgery), Fentanyl (for neuropathy), and Lexapro. I smoke pot semi-regularly, but not in great quantities. I drink two or three drinks every night, which I am working to reduce. Any insight would be greatly appreciated.

Name withheld, via the Internet

Dr. Dan Berger responds: I will comment on some particulars of your history. We now know that ddI plus Viread when combined in a non-nuke regimen (in your case, Viramune) is associated with T-cell deterioration and should not be used. Also, there is a new protease inhibitor called darunavir (TMC-114) [see "New HIV drug: Prezista," p. 13]. It is effective against most protease inhibitor mutations and will likely be very effective for you. Finally, I would like to see a phenotype with the genotype (not a virtual phenotype) so that we can get a clear picture of what can be added with TMC-114 and Viread, and to see if Fuzeon is truly necessary. From the sound of it, and if you are still susceptible to an NNRTI, that can also be used in concert. Current data suggests that you need only at least one other susceptible agent with TMC-114 to get a significant response. All of my above stated options should not worsen neuropathy nor lipoatrophy. Thus, I highly doubt that Fuzeon is absolutely necessary for your situation at this time.

The Dating Game in the Real World

I just finished reading your article "Living With It: The Dating Game," [March/April 2004]. My best friend came across it and sent me the link. I was awe-struck. It read like the conversations *we* have had! I'm 52 and he just turned 51. I'm poz and he's got AIDS. My ex-boyfriend of three years is named Ken! *Wow!* Imagine that!

I just want to say bravo to the writer… and I wonder if my telephone conversations were "tapped!" Seriously speaking, it tugged at my heart in such a way that I wish there was a place/organization/group etc. here in Atlanta where I could have this conversation with others in my/that situation.

Thanks again for such a compelling and insightful article. I'm also glad to have found a new HIV/AIDS website.

Name withheld, via the Internet

Youth and prison

I am writing to tell you thank you on behalf of the peer education program here at the Price Daniel Unit of the Texas Department of Criminal Justice prison system. Your journal has really been a very useful tool in helping to teach offenders how to protect themselves from HIV/AIDS and how or what to do in case of infection. Every time I get a new issue from you, people start lining up wanting to read it. People in here always want good, updated information on HIV/AIDS, and you do a really good job of providing this in your journal.

I am also writing you to ask for an address at which I can contact the Hope's Voice organization (July/August 2006). You provided a Web address but no mailing address. Hope's Voice sounds like a very good program, and I'd love to see more programs like this. In Texas we have a lot of young adults being locked up for long periods of time. It's a sad but true fact and it seems to be getting worse as time goes on. Most of them are between the ages of 18–28 years old and come from lower income families. One good thing is they do seem to be the most interested group of people who want to take the peer education's "Wall-Talk" class on disease prevention. They want to learn how to be safe in prison and when released. I was wondering if the Road to Hope Tour ever thought about possibly going in to a prison and talking to the offenders? To me this would be a great way to help a lot of young people, hopefully, become aware of HIV/AIDS and help them be more responsible upon release. Also, the article mentioned a video documentary of the tour—is there any way we could get a copy for our class?

Name withheld, Snyder, TX

Enid Vázquez responds: As of press time, Hope's Voice did not answer an e-mail request for answers to your question (and there is no address listed on the organization's Website).

one out of Two

men with HIV/AIDS
have low testosterone...
Could you be one of them?

If you are HIV positive, there are real reasons why you might not feel your best... Low Testosterone (Low T) doesn't have to be one of them.

Ask your doctor about Testim.
Testim provides significant, lasting results:
- **Increased lean body mass**
- **Decreased Fat Mass**
- **Increased bone mineral density**

Testim®1%
(testosterone gel) Ⓒ

The Power of T.

Adverse Events

Adverse events reported in controlled clinical studies with Testim were redness/irritation (1%) at the application site and increased red blood cells (increased hematocrit/hemoglobin (2%)

Contraindications and Warnings

Contraindications: Testosterone should not be used by men with known or suspected cancer of the prostate or breast. Testim is not indicated for use in women, has not been evaluated for use in women, and must not be used in women. *Warning:* Older patients treated with male hormones may be at greater risk of cancer of the prostate or enlargement of the prostate.

References

1. Dobs AS, Dempsey MA, Ladenson PW, Polk BF. Endocrine disorders in men infected with immunodeficiency virus. Am J Med. 1988 (3pt2):611-616 **2.** Wagner G, Effects of Testosterone Replacement Therapy on Sexual Interest, Function, and Behavior in |HIV + men. The Journal of Sex Research, Vol. 34,p.27, 1997
3. Annapoorna N, et al, An increased Risk of Osteoporosis During Acquired Immunodeficiency Syndrome, International Journal of Medical Sciences. 2004 1(3):152-164

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0406-006.a

Testim® 1%
(testosterone gel) ℞

The Power of T.

Brief Summary:
Before prescribing Testim®, please see full prescribing information.

INDICATIONS AND USAGE: Testim® is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: 1. Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone levels and gonadotropin (FSH, LH) above the normal range. 2. Hypogonadotrophic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum levels but have gonadotropins in normal or low range. Testim® has not been clinically evaluated in males under 18 years of age. **CONTRAINDICATIONS:** Androgens are contraindicated in men with carcinoma of the breast or known or suspected carcinoma of the prostate. Testim® is not indicated for use in women, has not been evaluated for use in women, and must not be used in women. Pregnant and nursing women should avoid skin contact with Testim® application sites on men. Testosterone may cause fetal harm. Testosterone exposure during pregnancy has been reported to be associated with fetal abnormalities. In the event that unwashed or unclothed skin to which Testim® has been applied comes in direct contact with the skin of a pregnant or nursing woman, the general area of contact on the woman should be immediately washed with soap and water. Testim® should not be used in patients with known hypersensitivity to any of its ingredients, including testosterone USP that is chemically synthesized from soy. **WARNINGS:** 1.Testim® should not be applied to the abdomen. 2. Prolonged use of high doses of orally active 17-alpha-alkyl androgens (e.g., methyltestosterone) has been associated with serious hepatic adverse effects (peliosis hepatitis, hepatic neoplasms, cholestatic hepatitis, and jaundice). Peliosis hepatitis can be a life-threatening or fatal complication. Long-term therapy with testosterone enanthate, which elevates blood levels for prolonged periods has produced multiple hepatic adenomas. Transdermal testosterone is not known to produce these adverse effects. 3. Geriatric patients treated with androgens may be at an increased risk for the development of prostatic hyperplasia and prostatic carcinoma. 4. Geriatric patients and other patients with clinical or demographic characteristics that are recognized to be associated with an increased risk of prostate cancer should be evaluated for the presence of prostate cancer prior to initiation of testosterone replacement therapy. In men receiving testosterone replacement therapy, surveillance for prostate cancer should be consistent with current practices for eugonadal men (see PRECAUTIONS: Carcinogenesis, Mutagenesis, Impairment of Fertility and Laboratory Tests). 5. Edema, with or without congestive heart failure, may be a serious complication in patients with preexisting cardiac, renal, or hepatic disease. In addition to discontinuation of the drug, diuretic therapy may be required. 6. Gynecomastia occasionally develops and occasionally persists in patients being treated for hypogonadism. 7. The treatment of hypogonadal men with testosterone may potentiate sleep apnea in some patients, especially those with risk factors such as obesity or chronic lung diseases. **PRECAUTIONS:** Transfer of testosterone to another person can occur when vigorous skin-to-skin contact is made with the application site. (See Clinical Studies) The following precautions are recommended to minimize potential transfer of testosterone from Testim® treated skin to another person: Patients should wash their hands thoroughly and immediately with soap and water after application of Testim®. Studies of handwashing show that Testim® is effectively removed from the skin surface by thorough washing with soap and water. Patients should cover the application site(s) with clothing after the gel has dried (e.g. a shirt). Prior to any situation in which direct skin-to-skin contact is anticipated, patients should wash the application sites thoroughly with soap and water so as to remove drug residue. In the event that unwashed or unclothed skin to which Testim® has been applied does come in direct contact with the skin of another person, the general area of contact on the other person should be washed thoroughly with soap and water as soon as possible. Changes in body hair distribution, significant increase in acne, or other signs of virilization of the female partner should be brought to the attention of a physician. **General:** The physician should instruct patients to report any of the following: Too frequent or persistent erections of the penis, any changes in skin color, ankle swelling or unexplained nausea and vomiting, breathing disturbances, including those associated with sleep. **Information for Patients:** Advise patients to carefully read the information brochure that accompanies each carton of 30 Testim® single-use tubes. **Advise patients of the following:** Testim® should not be applied to the scrotum, penis, or abdomen. Testim® should be applied once daily at approximately the same time each day to clean dry skin of the shoulders and/or upper arms. Washing or swimming may lessen testosterone levels; however, when washing occurs two or more hours post drug application, serum testosterone levels remain within the normal range. Testim® may be transferred to another person by vigorous contact with the application site. Potential for transfer may be avoided by washing hands thoroughly with soap and water prior to any direct skin-to-skin contact. **Laboratory Tests:** 1. Hemoglobin and hematocrit levels should be checked periodically (to detect polycythemia) in patients on long-term androgen therapy. 2. Liver function, prostate specific antigen (PSA), cholesterol, and high-density lipoprotein (HDL) should be checked periodically. 3. To ensure proper dosing, serum testosterone concentrations should be measured (See Dosage and Administration). **Drug Interactions:** Oxyphenbutazone: Concurrent administration of oxyphenbutazone and androgens may result in elevated serum levels of oxyphenbutazone. Insulin: In diabetic patients, the metabolic effects of androgens may decrease blood glucose and, therefore, insulin requirements. Propranolol: In a published pharmacokinetic study of an injectable testosterone product, administration of testosterone cypionate led to an increased clearance of propranolol in the majority of men tested. It is unknown if this would apply to Testim®. Corticosteroids: The concurrent administration of testosterone with ACTH or corticosteroids may enhance edema formation; thus these drugs should be administered cautiously, particularly in patients with cardiac or hepatic disease. **Drug/Laboratory Test Interactions:** Androgens may decrease levels of thyroxin-binding globulin, resulting in decreased total T4 serum levels and increased resin uptake of T3 and T4. Free thyroid hormone levels remain unchanged, however, and there is no clinical evidence of thyroid dysfunction. **Carcinogenesis, Mutagenesis, Impairment of Fertility: Animal Data:** Testosterone has been tested by subcutaneous injection and implantation in mice and rats. In mice, the implant induced cervical-uterine tumors, which metastasized in some cases. There is suggestive evidence that injection of testosterone into some strains of female mice increases their susceptibility to hepatoma. Testosterone is also known to increase the number of tumors and decrease the degree of differentiation of chemically induced carcinomas of the liver in rats. **Human Data:** There are rare reports of hepatocellular carcinoma in patients receiving long-term oral therapy with androgens in high doses. Withdrawal of the drugs did not lead to regression of the tumors in all cases. Geriatric patients and other patients with clinical or demographic characteristics that are recognized to be associated with an increased risk of prostate cancer should be evaluated for the presence of prostate cancer prior to initiation of testosterone replacement therapy. In men receiving testosterone replacement therapy, surveillance for prostate cancer should be consistent with current practices for eugonadal men. **Pregnancy Category X (see Contraindications) – Teratogenic Effects:** Testim® is not indicated for women and must not be used in women. Testosterone may cause fetal harm. **Nursing Mothers:** Testim® is not indicated for women and must not be used in nursing mothers. **Pediatric Use:** Safety and efficacy of Testim® in patients <18 years old has not been established. **ADVERSE REACTIONS:** In a controlled clinical study, 304 patients were treated with Testim® 50 mg or 100 mg or placebo for up to 90 days. Two hundred-five (205) patients received Testim® 50 mg or 100 mg daily and 99 patients received placebo. Patients with adverse events that were possibly or probably related to study drug and reported by ≥1% of the Testim® patients and greater than placebo are: application site reactions, benign prostatic hypertrophy, blood pressure (diastolic) decreased, blood pressure increased, gynecomastia, headache, hematocrit/hemoglobin increased, hot flushes, insomnia, lacrimation increased, mood swings, smell disorder, spontaneous penile erection and taste disorder. The following adverse events possibly or probably related to Testim® occurred in fewer than 1% of patients but were greater in Testim® groups compared to the placebo group: activated partial thromboplastin time prolonged, blood creatinine increased, hemoglobin abnormal, prothrombin time prolonged, appetite increased, sensitive nipples, and acne. In this clinical trial of Testim®, six patients had adverse events that led to their discontinuation. These events included: vertigo, coronary artery disease, depression with suicidal ideation, urinary tract infection/pneumonia (none of which were considered related to Testim® administration), mood swings and hypertension. No Testim® patients discontinued due to skin reaction. In one foreign Phase 3 trial, one subject discontinued due to a skin-related adverse event. In the pivotal US and European Phase 3 trials combined, at the 50 mg dosage strength, the percentage of subjects reporting clinically notable increases in hemoglobin or hematocrit were similar to placebo. However, in the 100 mg dose group, 2.3% and 2.8% of patients had a clinically notable increase in hemoglobin (≥19 g/dL) or hematocrit (≥58%), respectively. In the combined ongoing US and European open label extension studies, approximately 140 patients received Testim® for at least 6 months. The preliminary results from these studies are consistent with those reported for the US controlled clinical trial. **DRUG ABUSE AND DEPENDENCE:** Testim® contains testosterone, a Schedule III controlled substance as defined by the Anabolic Steroids Control Act. Oral ingestion of Testim® will not result in clinically significant serum testosterone concentrations due to extensive first-pass metabolism. **OVERDOSAGE:** There were no reports of overdose in the Testim® clinical trials. There is one report of acute overdosage by injection of testosterone enanthate: testosterone levels of up to 11,400 ng/dL were implicated in a cerebrovascular accident. **DOSAGE AND ADMINISTRATION:** The recommended starting dose of Testim® is 5g of gel (one tube) containing 50 mg of testosterone applied once daily (preferably in the morning) to clean, dry intact skin of the shoulders and/or upper arms. Morning serum testosterone levels should then be measured approximately 14 days after initiation of therapy to ensure proper serum testosterone levels are achieved. If the serum testosterone concentration is below the normal range, or if the desired clinical response is not achieved, the daily Testim® dose may be increased from 5g (one tube) to 10g (two tubes) as instructed by the physician.

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by Enid Vázquez

Two new HIV drugs

The U.S. Food and Drug Administration (FDA) approved two new HIV drugs this past summer. Atripla is a combination in one pill of three drugs from two different HIV drug classes (the non-nucleoside Sustiva and the nucleosides Emtriva and Viread, which are also available as a two-in-one combination pill called Truvada). Prezista is an HIV protease inhibitor that must be taken with another HIV drug, Norvir.

Atripla

Atripla is one of the greatest achievements of HIV therapy. Atripla is a complete HIV regimen in one pill. And you only have to take it once a day. Other HIV treatment combinations are once daily, but never before just one pill. In addition, the three drugs in Atripla are all heavy hitters in the world of HIV, potent and tolerable. They are all among the drugs listed in U.S. treatment guidelines as "preferred" for first-time therapy. The achievement also overcame two important barriers: the scientific problem of getting the drugs to combine in the same pill (an earlier formulation failed), and the reluctance of pharmaceutical companies to work together. Here, Bristol-Myers Squibb (Sustiva) and Gilead Sciences (Truvada) did just that. Moreover, the two companies agreed to do what advocates requested—make the drug cost neutral. In this case, that means that the new drug does not cost more than the drugs (Sustiva and Truvada) taken separately (approximately $1,000 a month), despite the greater convenience, single co-pay, and development cost. Kudos to BMS and Gilead for their outstanding work. (One cynical medical provider, however, suggested that the formula had been approved much earlier, but was held up by company lawyers hammering out profit shares.)

While Emtriva and Viread are extremely tolerable drugs, Sustiva has a long list of potential central nervous system and psychiatric side effects, including vivid dreams or nightmares, insomnia, dizziness, and depression. Nevertheless, people have said it's like taking candy compared to other anti-HIV meds, and those who do experience side effects may see them go away after a few months. Sustiva may also cause people to test positive for marijuana (a confirmatory test is needed), and it cannot be taken by women if there's a chance of becoming pregnant. Because it is very important to take HIV drugs as directed, to prevent the virus from mutating and thus getting beyond the grasp of medications, treatment advocates want people to remember something simple about the once-a-day Atripla: Take… each… dose.

Prezista

Prezista (formally known as TMC-114) was created to work for people with drug resistance to the HIV protease inhibitors (as stated above, this is when the virus mutates and gets beyond the grasp of one or more medications). The drug has long created excitement for its effectiveness in this hard-to-treat group. In *Positively Aware's* 2006 HIV Drug Guide, Dr. Dan Berger, a Prezista-funded researcher, wrote, "The take home message should be that TMC-114 has shown very good safety and tolerance… It has also shown to be highly active against a wide range of resistance mutations or multi-drug resistant strains that was unprecedented, compared to other drugs studied for patients with advanced disease or resistance. Finally, a significant increase in CD4 T-cell counts were also seen in the studies of patients on TMC-114."

As with other new protease inhibitor drugs on the market, Prezista (generic name darunavir), was studied against other PI combinations. All PIs were boosted with a small dose of Norvir, and Prezista doses must be taken with that drug. The FDA reported that approval was based on two studies, in which 70% of people on Prezista "achieved a virologic response [greater than one log drop in viral load]," compared to 21% of the study participants on the other drug combinations. Forty-five percent had undetectable (less than 50) viral load compared to 12.1% for the other groups, and T-cell increases were 92 vs. 17. Results are from 24 weeks of study, which is still early in research. The most common side effects of Prezista/Norvir were diarrhea, nausea, and headache. In addition, about 7% experienced skin rashes ranging from mild to serious (Prezista is a sulfa drug). In addition to the usual continuing study of drugs brought to market under accelerated approval, Prezista will be studied for pediatric use, drug-drug interactions, and appropriate doses in people with liver impairment. Prezista, discovered and developed by Tibotec Pharmaceuticals, is the first HIV drug to be marketed by Johnson & Johnson.

Prezista price a win

The AIDS Treatment Activists Coalition (ATAC) applauded Tibotec Pharmaceuticals for not pricing Prezista higher than the two most recently approved HIV protease inhibitor drugs. The

group said that the $25 a day cost is $9 less than that of Aptivus and only 25 cents higher than Reyataz. Tibotec originally planned to price the medication at $34 a day, said the group in a press release. ATAC noted that, "The price of prescription drugs has gone up radically over the last ten years. In 1996, when the first highly effective anti-HIV combination therapy became available, treatment for a single individual cost at least $12-15,000 a year per person for a typical 3-drug cocktail. Today, a single drug can cost this much or even twice this amount."

Longtime ATAC member Lynda Dee said in the release that, "Tibotec's decision to do the right thing is a good first step that must be copied by other drug companies. …Tibotec has tried very hard to work in partnership with the patient community. We're elated they have taken our suggestion and reversed the upward spiral of unconscionable new life-saving drug prices. While ATAC would still prefer even lower drug prices as the price point achieved here is still far from inexpensive, we believe this represents real progress." Visit www.atac-usa.org.

Warning on Aptivus

The FDA in July updated the black box warning on Aptivus, the strictest warning a drug can have. Of 6,840 people on the drug, 13 experienced intracranial hemorrhage (ICH), and eight died. The majority of the 13 had other medical conditions (CNS lesions, head trauma, recent neurosurgery, coagulopathy, hypertension, or alcohol abuse) or drugs (anticoagulants and antiplatelet medications) that could also cause bleeding. The median time on Aptivus before ICH was 525 days. The warning is for caution in people with the risk of increased bleeding. The FDA said in a press release that, "No pattern of abnormal coagulation parameters were observed in patients receiving Aptivus in general, or preceding the development of ICH. Routine measurement of coagulation parameters is not currently indicated in the management of patients on Aptivus. However, in *in vitro* experiments, tipranavir was observed to inhibit human platelet aggregation at levels consistent with exposures observed in patients receiving Aptivus/ritonavir." See a PDF copy of a Dear Healthcare Provider letter, including contact information for complications, at http://www.fda.gov/medwatch/safety/2006/Aptivus-tipranavir_DHCP.pdf. According to the letter, "In preclinical studies in rodents, Aptivus treatment induced changes in coagulation parameters (increased prothrombin and activated partial thromboplastin times). At higher doses and in extreme cases, these changes led to bleeding in multiple organs and death. The mechanism for this effect is unknown. This effect was not seen in preclinical studies with dogs." See the updated Aptivus label at http://www.fda.gov/medwatch/safety/2006/Aptivus_PI.pdf.

Aptivus study stopped

A study of Aptivus in people taking anti-HIV medication for the first time was stopped due to inferior performance at 60 weeks. An Aptivus combination was being compared to a Kaletra combination. Earlier, at 48 weeks, Aptivus was found to be non-inferior (an FDA-established goal) to Kaletra. Aptivus came to market based on effectiveness seen in people who were heavily treatment-experienced, with drug resistance.

New HIV test

The FDA in June approved EHIV, a test for all known types of HIV: HIV-1, HIV-2, and a subtype of HIV-1. Previously, people with HIV-2 were testing negative in the U.S. because tests only looked for HIV-1, the vast majority of types in the country. HIV-2 is primarily found in West Africa. The company behind the test, Bayer, reported that EHIV is also the first fully automated HIV test, eliminating manual lab work.

Guidelines update

In July, the U.S. Department of Health and Human Services (DHHS) updated its perinatal treatment guidelines. A section devoted to drug resistance was added. Care needs to be taken with HIV drugs during pregnancy to avoid limiting future treatment options for both the mother and child (if necessary). To see the guidelines, visit www.AIDSinfo.nih.gov. Call 1-800-HIV-0440 (448-0440) or write AIDSinfo (or "Guidelines"), P.O. Box 6303, Rockville, MD 20849-6303 to request a free copy.

Condoms work

Advocates have long pointed out that condom usage helps lower the risk—but not completely—of the very common sexually transmitted infection HPV (human papilloma virus), which can lead to cancer. The virus can be transmitted from skin-to-skin contact, as from the unprotected testicles. People infected with abstinence madness, however, pushed for stringent wording on condom packages and government Web sites to the effect that really, condoms don't work against HPV. That's why a recently published study in the prestigious *New England Journal of Medicine* (NEJM) gathered so much press attention. The study in the June 22 edition reported that young women engaging in condom-protected sex for each intercourse were 70% less likely to get HPV than women whose partners used condoms less than 5% of the time.

HPV vaccine

Meantime, the FDA also approved the first vaccine to protect against HPV, Gardasil, for use in girls and women ages 9 to 26, preferably before intercourse has taken place. The abstinence folks are against this too.

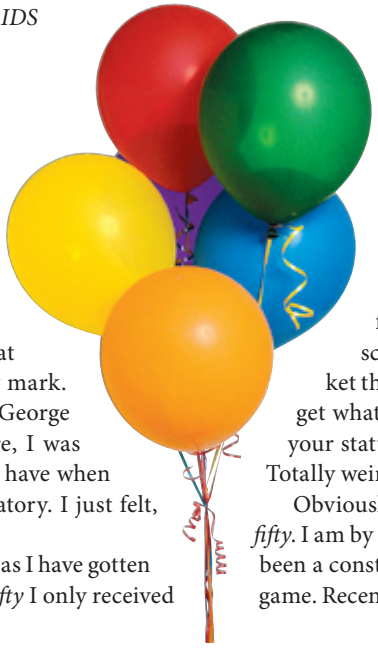
Getting meds free

If you need a medication and can't get it through any private or public form of insurance, contact the company that makes the drug. Almost all companies have programs called "Patient Assistance Program" or something similar that provides their drugs free for people who can't afford them. Call 1-888-477-2669 or visit www.pparx.org for a list of patient assistance programs. You may also refer to the annual *Positively Aware* HIV Drug Guide (January/February). These programs often say they serve people below a certain income level, but if you are above that level and still can't afford the medications, don't hesitate to apply anyway. Most programs offer considerable flexibility.

Half Century

Turning fifty hasn't detracted from surviving AIDS

by Matt Sharp



My *fiftieth* birthday came and went with no particular symphonic fanfare or 4th of July fireworks that one expects when they reach the half-century mark. Besides the mood of my day being tainted by George Bush's creepy sixtieth birthday the day before, I was expecting those feelings a PWA is supposed to have when they reach *fifty*. But I felt anything but celebratory. I just felt, well…old.

Cards and gifts have been less forthcoming as I have gotten older, but it didn't make me feel better that at *fifty* I only received one card, one gift, one belated e-birthday card and a well-intentioned dinner party where half the invitees didn't show. Where was the Mediterranean villa with tubs of champagne and caviar? I got no dancing boys at *fifty*! At any rate, the casual attitude didn't make me feel it was supposed to be a special birthday.

Several people tried encouraging me by saying that I am fortunate to have survived to *fifty*. But I wasn't encouraged much that day. My feelings were more about aging than a victory in surviving AIDS for 18 years. I'd probably be having a much better *fifty* had I not had AIDS in the first place. Truth is, my perspective on turning *fifty* was screwed up because of my near quarter century of fighting AIDS. I wasn't quite prepared to reach this milestone.

Don't get me wrong, I never thought I would reach forty when I tested positive in 1988 at the ripe old age of 32. I should be dead, according to the testing counselor who gave my ill-fated result. Still, every day I mourn my community of brothers and sisters who didn't live to see 28 AIDS drugs and HAART (highly active antiretroviral therapy). Now that I have survived at *fifty* I can reflect on life as a half-centurion as almost any person would, AIDS or not. I can turn *fifty* now and know that I will most likely lead a normal lifespan of wrinkles, gray hair and a failed social security system. Yech.

Being *fifty* and HIV-positive is no joyride in our society, where young looks and good health reign supreme. As a single gay man it is even more challenging trying to meet guys when everything is based on "disease free" and "18-45 only." (Oops, five years over.) The whole Internet-based scene is a scam anyway, as so many people lie in order to market themselves, especially for sex. People say anything to get what they want online. Guys reject you if you disclose your status when you could just lie and they'd never know. Totally weird and dangerous!

Obviously, HIV is not over for me simply because I turned *fifty*. I am by no means out of the woods. My 18 years of HIV has been a constant battle staying ahead of the antiviral resistance game. Recently, I missed out on a new drug trial that was my last best hope of controlling my rampant, resistant virus. The university stalled too long and the study never began. Now I have to wait another two months for the expanded access program to open. So staying ahead of a resistant virus will always be my agenda, but will a cure come before I die?

First I had to grow up, then I tested positive, and now I'm old.

The newer drugs are appearing to be better for treating resistant HIV and there are hints that at least people like me will live to the old age of…sixty? Who knows? All the pitfalls of turning fifty and beyond can at least be celebrated because of the miracles of research into HIV and activists who have fought and died and never had the chance to reach *fifty*. For those who did not survive I will celebrate my fifty in their memory.

But I'm not sure how I'm supposed to feel anymore turning older. First I had to grow up, then I tested positive, and now I'm old. It has been a long fight for me to survive HIV, but perhaps I am taking survival for granted now that I have been lucky enough to reach *fifty*.

Reaching this age has led me to think about new prospects on living and getting some real perspective as to why I am still here. Surviving with AIDS to 50 and beyond will take more guts, more fortitude, and more commitment. Turning *fifty* hasn't detracted from surviving AIDS, it just created a new opportunity to reflect, stay strong, and gain steam for the next 50 years. An old ACT UP comrade of mine helped to keep the struggle of survival in perspective by saying, "Keep Your Eye on the Prize."

Photo © Russell McGonagle

The Tingling of My Heart

Little did I know I had a cardiac condition

by Laird Petersen

I never thought that after living with HIV for more than 20 years that I would have to worry about Coronary Artery Disease (CAD).

But there I was, in March of 2004, thinking that I had dodged the HIV bullet after many combinations of therapy, my T-cells stable and viral load undetectable, working at a job I loved, in a long-term relationship of 10 years and pretty happy with my life.

Then one Sunday, I noticed what I thought to be a re-occurrence of peripheral neuropathy (PN), only this time it was affecting my hands and arms. I thought to myself, "You beat it in your legs, so you can do so in your arms."

Except there was a difference this time. It was not constant, and I was feeling the tingling and numbness more in my left arm than the right arm.

Now, I had been through enough health crises over the last 22 years that I pretty much knew, or I thought I did, how to handle most anything that came my way. In 1998 I was reduced to using a cane or wheelchair for months due to the PN in my legs, had been through numerous other neurological episodes, a scare with a lump on my breast, asthma, COPD [Chronic Obstructive Pulmonary Disease, often referred to as emphysema]—the list could go on forever.

Yet, I was feeling good except for the tingling. After three days of hounding by my partner, I called my doctor's office to get an appointment, described the symptoms to the receptionist, and all of a sudden one of the other docs in the office was on the phone, asking all sorts of questions that I don't even remember now. He wanted me to go right to the emergency room. I assured him that this was not urgent, as it had been going on for so many days, so reluctantly, I was given an appointment for later that afternoon.

After the conversation with the doc, I was a bit worried about what was happening, but continued with my work and left the office a little early to make the appointment.

After my doc examined me and determined that my pulse was normal and blood pressure was good, he decided to do an EKG, which also was normal. After a few minutes, he reappeared with a nitroglycerin tablet, and asked me to put it under my tongue and let it dissolve, and told me to relax and lay down for about five minutes.

When he came back into the room, I was amazed that I felt much better, the tingling was gone, and I felt as though I had regained my usual energy level. The doctor was not as happy as I was. He told me that I needed to go to the emergency room for further blood work and a few tests, and even gave me cab fare, so I wouldn't waste time looking for an ATM to get some cash.

Not thinking this could really be a heart attack, as I had seen plenty of them on TV and knew the tell-tale signs (crushing chest pain, collapse, etc.), I had the cab drop me off in front of the hospital instead of at the emergency room, so I could have a cigarette and call my partner. When I reached him he was about an hour away, coming home from work, so I suggested that by the time he could get to the hospital, I would be finished, and we could go out for drinks and dinner. Call me a denialist!

By the time he arrived, I had been poked and prodded by so many people I was losing count, but it was clear that we wouldn't be going out for dinner.

Within a couple of hours, I was wheeled into a catheterization laboratory, and when all was said and done, we were told that I had 100% blockage in one vein, 80% in two, and 60% in two others,

in addition to 80% in a vein in my leg, and would be undergoing quintuple bypass surgery the next morning.

I must say that I am a little foggy about the next two days, but was walking and visiting with family and friends 24 hours after surgery, which was a great relief. The cardiac surgeon told us that I was his third HIV-positive case in as many months.

We were home in less than a week, but I almost had a relapse after opening the mail and seeing the hospital bill…over $300,000 for a five-day hospitalization, not including doctors' fees! Since I had three unrelated surgeries earlier in the year, my only out-of-pocket costs were prescription co-pays. Thank God!

If you smoke cigarettes, you should begin the sometimes long process of quitting!

The recovery was pretty easy for me, though I was extremely weak. I walked a lot to build up strength and then began a cardiac rehabilitation program at the hospital, which I must say, was geared for 70–80 year old patients, not 46-year-old ones, but I kept pushing the limits and was back doing work via e-mail in a week and back at the office in a month.

Fortunately, six months later I was able to have a stent placed in my leg to correct the other blockage, which was by now blocked 100%.

I spent a great deal of time doing my own research, to understand if this was a trend with long-term HIVers, or just the luck of the draw genetically and have yet to come to any conclusions, though surely my smoking didn't help.

I am heartened, nonetheless, to see that there are many studies, such as the MACS study, looking at the issue of increased lipids as a result of HIV protease inhibitor drugs and the effect they have on hardening of the arteries, and a possible increase in incidence of heart attacks among people who are on HAART (highly active antiretroviral therapy). Researchers are also looking at what effect HIV has on hardening of the arteries. Many healthcare providers prescribe statin drugs to reduce your cholesterol levels.

Since many protease inhibitors raise lipid levels, it is critically important that HIV-positive individuals who are on HAART raise this issue with their providers. Regular monitoring of cholesterol is key to assessing cardiovascular risk factors for developing coronary artery calcification, so that you and your provider can take steps to reduce the risk of arteriosclerosis (hardening of the arteries) and reduce your risk of heart attacks. My cholesterol was very low prior to taking Kaletra and has been controlled by Lipitor since 2001. It is now 171, and the LDL (bad cholesterol) level is 92, so it's pretty good. Monitor your triglycerides as well.

If you smoke cigarettes, you should begin the sometimes long process of quitting!

Also, as HIV is now thought by many to be a chronic disease, we need to think about how our bodies are changing, and yes, aging. Cardiac artery disease and heart attacks are more common than we would like to think in people over 40, and the relationship of HIV infection and HAART therapy and hardening of the arteries has not been fully determined yet because longer-term studies need to be done.

Following are a few of the diagnostic tools that your healthcare provider may use:

- Regular cholesterol screenings
- Blood level of C-reactive proteins, which measures the level of general inflammation, may correlate with the risk of heart attacks
- Ultrasound imaging of the carotid artery
- Electron beam computed tomography (EBCT), which you should discuss with your healthcare provider.

The significance of findings from ultrasounds, heart scans, and EBTCs should be discussed and evaluated by a cardiologist.

We have lost too many of our friends and colleagues to HIV and AIDS over the last 25 years, so we need to be vigilant about watching out for other health issues that have also taken the lives of many of our friends too early.

All too often when our bodies are reacting to changes, we only think of HIV-related issues, and look at all the side effects and adverse reactions to the drugs we take. Sometimes, we need to look beyond those easy solutions and take a more aggressive approach, and ask our healthcare providers for more diagnostic tests. You should also demand that your provider provide a comprehensive set of tests to determine your baseline, and then monitor progression to avoid unnecessary health crises in the future.

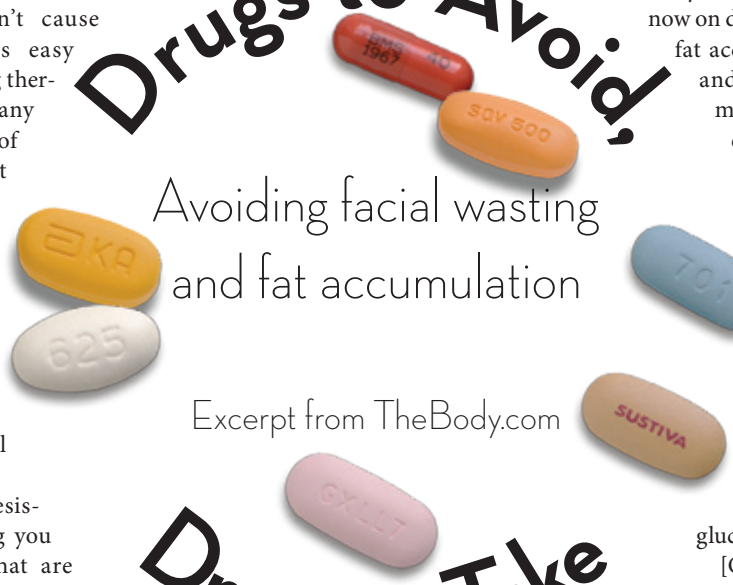
Laird Petersen is Chief of Staff for Illinois State Representative Larry McKeon, an openly gay and HIV-positive legislator.

It's easy to weigh down medical information in a lot of mumbo-jumbo, but HIV specialist Dr. Joel Gallant, of Johns Hopkins University School of Medicine, has a knack for putting things in short, simple words. Without listing all the studies involved, he explained which HIV drugs cause problems and which ones don't in a lipoatrophy chat last November for TheBody.com. Lipoatrophy is thinning of the face, arms, and legs, which can be caused by HIV medications. Following is a shortened version of Gallant's answers to the people who attended the chat. Most of the generic drug names have been removed.—Enid Vázquez

Drugs to Avoid, Drugs to Take

Avoiding facial wasting and fat accumulation

Excerpt from TheBody.com



The best thing you can do is to take medications that don't cause lipoatrophy, which is easy enough to do if you're starting therapy for the first time, without any drug resistance. I have lots of patients with lipoatrophy, but they're all people who've been on therapy since back in the 20th century. I'm not seeing new development of lipoatrophy anymore, because we now have better treatment options. Don't let the fear of lipoatrophy dissuade you from taking antiretroviral therapy if you need it!

If you have no drug resistance and can take anything you want, then combinations that are unlikely to cause body shape changes would be either Truvada or Epzicom *plus* either Sustiva, Viramune, or Reyataz (preferably boosted with Norvir). However, you're unlikely to get lipoatrophy with any protease inhibitor, as long as you're using Truvada or Epzicom, as the association between fat accumulation and protease inhibitors is not as direct as the association between lipoatrophy and thymidine analogs (like AZT [brand name: Retrovir; also known as zidovudine] and d4T [brand name: Zerit; also known as stavudine]).

The drugs that are known to cause lipoatrophy are [Zerit], AZT (whether it is in the form of Retrovir, Combivir, or Trizivir), and possibly also [Videx]. Drugs that are *not* believed to cause it are [Epivir], [Emtriva], tenofovir (whether it is in the form of Viread or Truvada), and abacavir (whether it is in the form of Ziagen or Epzicom). Because you're [the person asking the question] on Combivir, you could still be losing fat due to AZT. If your resistance pattern (or lack of it) will allow you to switch to Truvada or Epzicom, that could help a lot.

We have head-to-head trials that show a clear difference. For example, after three years, people on [Zerit] got lipoatrophy, while those on [Viread] didn't. And we also know that switching from [Zerit] or AZT to either [Viread] or [Ziagen] allows fat to return, which makes it pretty unlikely that either of those drugs causes lipoatrophy.

If you've switched from Zerit to either Viread or Ziagen (rather than to AZT), then your fat should start coming back, but it can take a long time, and there's no guarantee that it will be completely restored. If you've got the money, Sculptra injections seem to be the most effective way to deal with facial fat loss.

It *may* be the case that you regain fat at about the rate that you lost it.

It sounds like you [the person asking the question] need to get off the AZT, if you can do so without jeopardizing your virologic [viral load] response. Everyone knows now that [Zerit] causes lipoatrophy, but we often forget that AZT does it too, but just at a slower rate. Getting off AZT won't make everything all right again, but it could halt further loss of fat, and may allow fat to return… slowly. You're now on drugs that are less likely to cause fat accumulation [Viread, Combivir, and Viramune], but that doesn't mean that what happened to you on previous regimens will go away.

With fat accumulation, the things to do are to (1) eat a low-fat diet; (2) exercise regularly, especially with aerobic exercise; (3) keep your lipids, and especially triglycerides, under control; and (4) treat insulin resistance, if you have it. Insulin resistance is diagnosed by fasting insulin levels and/or glucose tolerance tests.

[Question: Is eating too much sugar a contributing factor to lipo?] It could definitely contribute to fat accumulation, but probably not to lipoatrophy. If you have fat accumulation, you need to avoid insulin resistance and hyperglycemia [high blood sugar] if possible.

The link between antiretrovirals and fat accumulation isn't as strong as the link with lipoatrophy, but drugs that cause high triglycerides and insulin resistance may be the ones that cause the problem the most. Protease inhibitors cause those problems, but Reyataz seems to be an exception, so the regimen they're recommending [Reyataz/Trizivir] is probably pretty safe from a fat accumulation perspective.

We don't have a lot of information on Videx, because for many years it was usually combined with other drugs that cause lipoatrophy (AZT and d4T). However, there is reason to believe that Videx *could* cause lipoatrophy. In addition, there are several concerns about combining Viread and Videx, including CD4 decline and easy selection of resistance, especially when combined with Viramune or Sustiva. So you have several reasons to discuss this with your doctor.

We know that lipoatrophy is reversible if you stop the drugs that cause it. The reversibility is slow and may not be complete, but that's better than nothing.

Editor's Note: TheBody.com has a lipodystrophy section, www.thebody.com/lipo/index.html.

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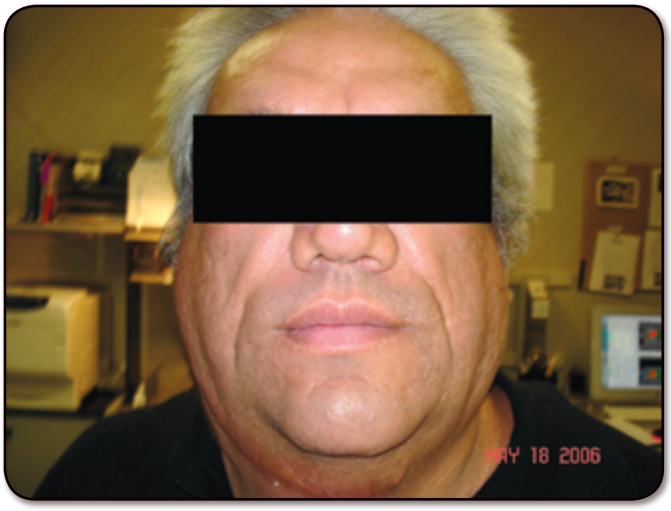
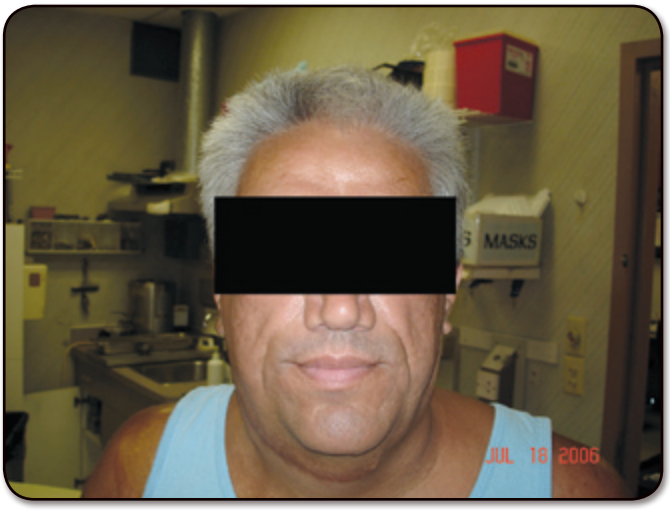




Banishing Chipmunk Cheeks and Bullfrog Neck

Treating these and other body changes from HIV drugs

by Enid Vázquez

Some people experienced facial wasting as a result of HIV treatment, others got a fat face. Nelson Vergel had the swollen glands on the side of his face that made it look bigger.

Vergel, a treatment activist who started as an advocate of exercise and anabolic steroids to treat loss of lean body mass in people with HIV, lectures all over the world on how to live well with the virus. Still, he found nothing by the way of research discussing the problem of inflamed parotid glands in HIV. Then he got a call from a friend in Los Angeles, Dr. Tony Mills. Mills found a local cancer doctor successfully treating the condition.

Vergel sought the radiation treatment from Dr. Patricia Gordon and raved about the results on his blog, http://survivinghiv.blogspot.com. "It's been four years now (as of March 2006) and they are still normal! I had no significant side effects besides redness for a few days, no beard for a month (which I liked), and a temporary loss of normal saliva production. All returned to normal after a month or so." He thought that a temporary small dip in his T-cells also resulted from the treatment, but couldn't be sure.

"These cheeks can become massive."

The chipmunk cheeks, the bullfrog neck, the buffalo hump, the protease paunch—there are treatments for these distressing body changes brought on by HIV medications. That doesn't mean that getting back to where you started is easy. It does mean that options exist.

Chipmunk cheeks

Minutes after I e-mail Dr. Gordon about her amazing work with HIV patients experiencing facial abnormalities, she calls me. That's a dedicated doctor.

"My patients are always looking for ways to get the word out," she tells me.

"I treat lung, prostate, and breast cancer, but my passion is HIV," Gordon continues. Treating 1,500 AIDS patients with Kaposi's sarcoma (KS) during the late '80s was tremendously satisfying for her. Parotid enlargement is not cancer," she says, "but low doses of radiation have been highly successful in eliminating the swelling, getting rid of the chipmunk look and restoring the normal angle of the jaw line."

"Kaposi's sarcoma went away with antiviral therapy, and then we saw the horrible side effects of lipodystrophy," Gordon explains about her new HIV work. "Lipodystrophy" refers to body fat abnormalities related to HIV medications, as well as metabolic complications such as elevated cholesterol.

She provides several treatments of low-dose radiation, over three weeks, to shrink the glands back to normal, and says she's had no trouble getting reimbursement from Medicaid and private insurance. That's because "it's painful," she says of the condition. "These cheeks can become massive. Some of these guys are so grateful they cry. Some wouldn't go out of the house because it was so grotesque looking." The treatment "greatly reduces, and in most cases, eliminates, the swelling," she says of the 400-plus HIV patients she has treated. She can be reached at 1-310-201-6739 or 1-310-659-6770. Her clinic has a hotel rate for patients.

Bullfrog neck

I recently saw a prominent woman with HIV, a motivational speaker, still slim and beautiful after all these years. But on her neck, directly under her face, there was about five or 10 pounds of fat, so large and abnormal that anyone seeing her would know something was wrong.

"I can fix that," says plastic surgeon Dr. Joseph Romano, whose clinic is in San Francisco. Vergel refers people to Romano: "He's doing great work. He uses ultrasound-assisted liposuction, so that the ultrasound breaks down the fat before liposuctioning it out. It goes down with weight loss, but some people need liposuction."

Romano can be reached at 1-415-981-3911 or via his Website, www.jromano.com. Remember that plastic surgery is expensive, and not covered by insurance, unless it can be tied to pain-related issues or sleep apnea.

Facial wasting

"I see someone with sunken cheeks," says Vergel, "and I just want to talk to them: 'Listen, there's a patient assistance program [for Sculptra]—you don't even have to pay for it. I can show you how.'" Vergel says his lectures and Internet work makes it easy for him to talk about Sculptra treatments because it allows people to come to him. Vergel's Website is www.powerusa.org.

Also see back issues of *Positively Aware* for personal stories of surgery for facial wasting. The November/December 2004 issue covers Bio-Alcamid, available in a Tijuana clinic with a large number of HIV patients, for both facial wasting and buttock enhancement—look for an upcoming article on the latter. Call 1-619-298-0657 or visit www.clinicestetica.com. It is also now available in Canada; visit www.facialwasting.org. The May/June 2002 issue has a story on Sculptra.

Protease paunch

Vergel swears that the so-called "protease paunch" associated with antiviral therapy can be reversed, but few people can do what it takes: diet and exercise.

"First, improve your insulin sensitivity by choosing only low-glycemic index carbs (like oatmeal, fruits, and vegetables)," he says. "Lower your simple carbs. White is bad, color is good—it's not a racist thing!" jokes Vergel, who's from Venezuela. "No sugar, no white flour, no pasta, no tortillas, no chips. Lots of lean meats, nuts, eggs, low-fat cheese. Don't drink soda pop, just water. Watch bottled juice—some have more sugar than pop. I think all these problems are sugar related. Dr. [Donald] Kotler showed that visceral obesity [the enlarged belly] is associated with glucose intolerance, and that many people with normal blood sugar have metabolic symptoms years before it shows up in the blood." [See Vergel's interview with Dr. Kotler at www.nelsonvergel.com.]

Vergel points out that a fasting blood sugar test is very different from a glucose tolerance test. The glucose tolerance test is simple, but very inconvenient. It consists of giving someone a glucose solution to drink and then having them sit around for hours waiting to be tested for their blood glucose response to see if there is glucose intolerance. Said one prominent HIV specialist, "Patients hate taking the test, and we hate giving it."

For those people with both obesity and severe glucose intolerance, the use of metformin (Glucophage), says Vergel, has been shown in a small study to decrease belly fat, especially if used along with cardiovascular exercise. Other insulin sensitizers like Actos [pioglitazone] and Azandia [rosiglitazone] don't seem to work as well in reducing belly fat, he says.

A low-carb diet would "shed all that fat" (although he's not a fan of the Atkins diet), but people find it hard to stay on them, Vergel continues.

Liposuction cannot be used for protease paunch—what in other groups of people, such as alcoholics or diabetics, is called metabolic syndrome or Syndrome X—because the fat lies internally, directly on the organs. This type of belly tends to be hard, not blubbery.

Vergel talked about a Tufts University study showing that in HIV-positive people, those with a higher intake of soluble fiber (fruits and vegetables) had a trend towards lower incidence of lipodystrophy-related abdominal fat, and so did the ones who exercised. "This makes sense," says Vergel, "since soluble fiber slows down the absorption of glucose into the blood stream and may give insulin a better chance to work properly. Exercise also makes insulin work better to help the body use glucose for energy. I tell people, if you can't do anything else, walk everywhere you can, avoid processed sweets and starches, and eat more fruits and vegetables. It is interesting to me that I see less obesity among the people in New York and in European cities—they walk everywhere.

"We're not eating enough soluble fiber or exercising, and the PIs [protease inhibitor HIV medications] make it much worse, and we're all aging," Vergel concluded.

Internet resources

www.thebody.com/metabolism/contents.html
www.medibolics.com

Losing the fat, in brief

The editors of *AIDS Treatment Update*, in London, put together these weight loss tips from Nelson Vergel in their December 2005 issue. Visit www.aidsmap.com.

- Cut calories and fill yourself up with fruits, vegetables, grains, and lean meats. Eat small frequent meals.
- Exercise with weights/machines 3–4 times a week for an hour, and also do cardiovascular exercise (fast walking, light jogging, etc.) for at least 30 minutes a day after weight training. Make sure that you sweat!
- Ask you doctor to check your hormone levels and your thyroid function since low levels of testosterone or thyroxin can make you prone to gaining more fat.
- Get your lipids and blood sugar under control with a healthy diet, regular exercise, and medicines if necessary.
- Beware of companies that claim their weight loss/appetite suppressant supplements or "growth hormone precursors" work. They don't. Most weight loss supplements have stimulants that can affect mood and increase blood pressure and cardiovascular risks.

Living with HIV and Hepatitis C

What you need to know, in brief

by Tracy Swan

"Knowing about HCV helps you make decisions on how to take care of yourself."—Beri Hull

Beri Hull was diagnosed with hepatitis C in 1992 and HIV in 1993. After seeing her co-infected friends die of liver disease, even though they had high CD4 cell counts and low HIV viral loads, Hull started learning about hepatitis C virus (HCV).

"Being in denial, and not knowing much about hepatitis C makes it more frightening," said Hull, who is the Global Advocacy Officer at The International Community of Women Living with HIV and AIDS (ICW). Her advice: "Don't panic; a lot of people don't need HCV treatment, but co-infected people need to be more on top of the situation. Learn as much as possible about HCV and get a biopsy."

Hull went on HCV treatment in 1999. Although her hepatitis C virus became undetectable after five months of treatment, the side effects—depression, fatigue, anemia, and weight loss—were severe, and she stopped treatment at the end of six months. Unfortunately, her hepatitis C viral load resurfaced within weeks.

Hull is planning to have a second liver biopsy to see if she can delay re-treating her hepatitis C. She is hoping to wait until better HCV treatment is available. "Since I'm African American, and have HCV genotype 1, it is unlikely that I will respond to pegylated interferon and ribavirin. If my liver can hold up, I'll hold on."

Hull offered some practical suggestions for people dealing with HIV and hepatitis C:

- Find a doctor who is willing to deal with both your hepatitis C and your HIV.
- Try to line up insurance coverage for your HCV treatment.
- If you are considering treatment, be very aware of the side effects and talk to people who have been on HCV treatment.
- Consider taking an antidepressant before starting treatment.
- Know your energy level will be compromised while you're on treatment, and be ready to adjust your life to lower stress and demands on your energy.

HIV doctors are beginning to focus on hepatitis C co-infection, but many remain reluctant to deal with the problem. Hepatitis C may go undiagnosed or untreated until after serious liver disease has developed. Even when people are promptly diagnosed, there are significant barriers to HCV treatment: access is limited, HCV treatment is less effective for HIV-positive people, and side effects tend to be particularly severe. Many clinicians are reluctant to treat drug users and people with a history of depression, even when they are stable, willing to go on treatment, and it is medically necessary.

Co-infected people with concomitant diagnoses have been successfully treated for hepatitis C through a multidisciplinary model incorporating medical and mental health care, peer support, education, and services for drug users.

Hepatitis C diagnostics

Hepatitis C testing is recommended for all HIV-positive people, since as many as 30% of people with HIV may be co-infected with HCV. Often, people don't have any symptoms until they have had HCV for many years and serious liver damage has already developed.

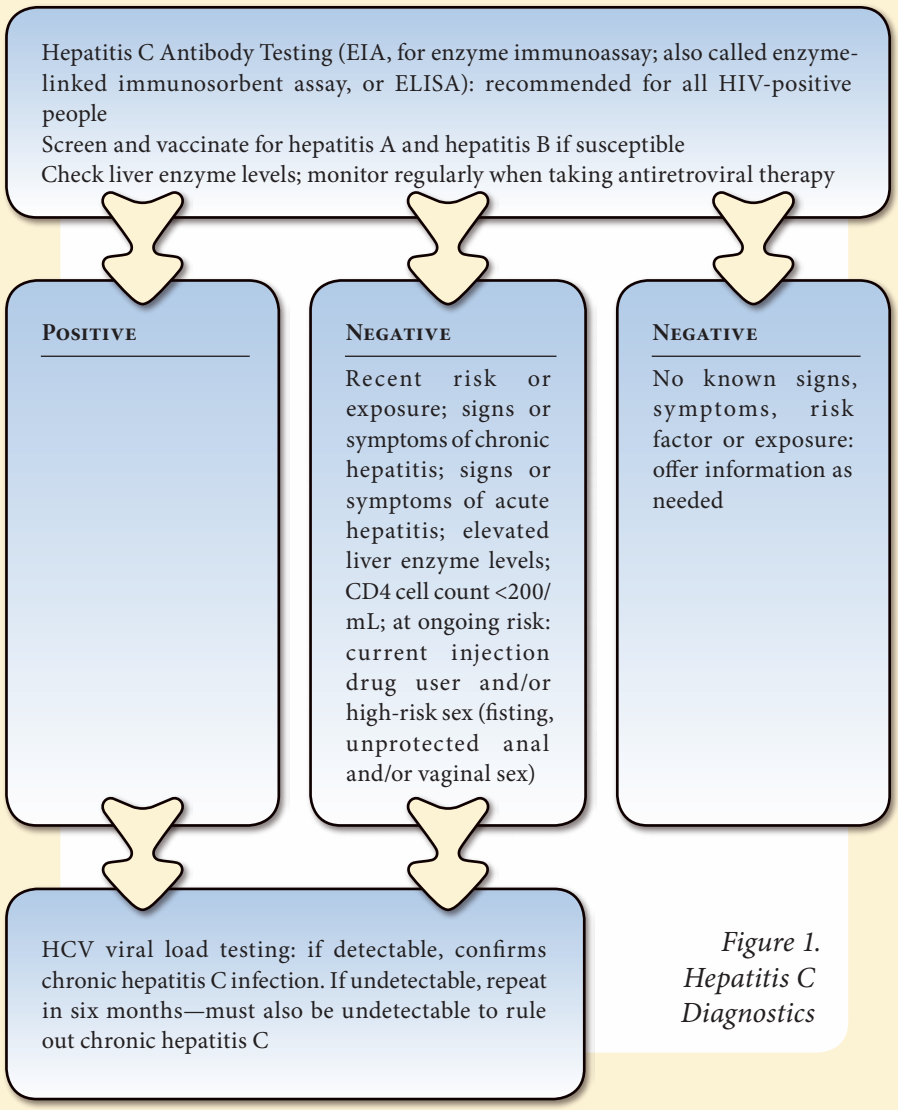


Figure 1. Hepatitis C Diagnostics

Hepatitis C does not always develop into a chronic infection. Some people clear the virus without treatment, although they remain antibody-positive for hepatitis C. HIV-negative people are more likely to clear HCV without treatment than HIV-positive people. A negative hepatitis C antibody test doesn't always rule out chronic HCV infection. An HCV viral load test is needed to diagnose chronic hepatitis C infection (see Figure 1, Hepatitis C Diagnostics).

With hepatitis C, the viral load does not indicate or predict disease progression. A low hepatitis C viral load is less than two million copies or 800,000 international units, unlike HIV. People with low hepatitis C viral loads are more likely to respond to hepatitis C treatment.

Finding out which hepatitis C genotype you have is important, because genotype helps to predict response to HCV treatment. There are at least six different genotypes of hepatitis C and many subtypes. In the United States, genotype 1 is most common. Unfortunately, hepatitis C treatment is not as effective for genotype 1 as it is for genotypes 2 and 3.

Having liver enzymes checked regularly is especially important for co-infected people taking ARVs (antivirals). Some HIV medications are metabolized by the liver; elevated liver enzyme levels may signal difficulty with a particular drug or combination of drugs. Unfortunately, liver enzyme levels cannot be used to predict hepatitis C disease progression, or to reveal liver damage.

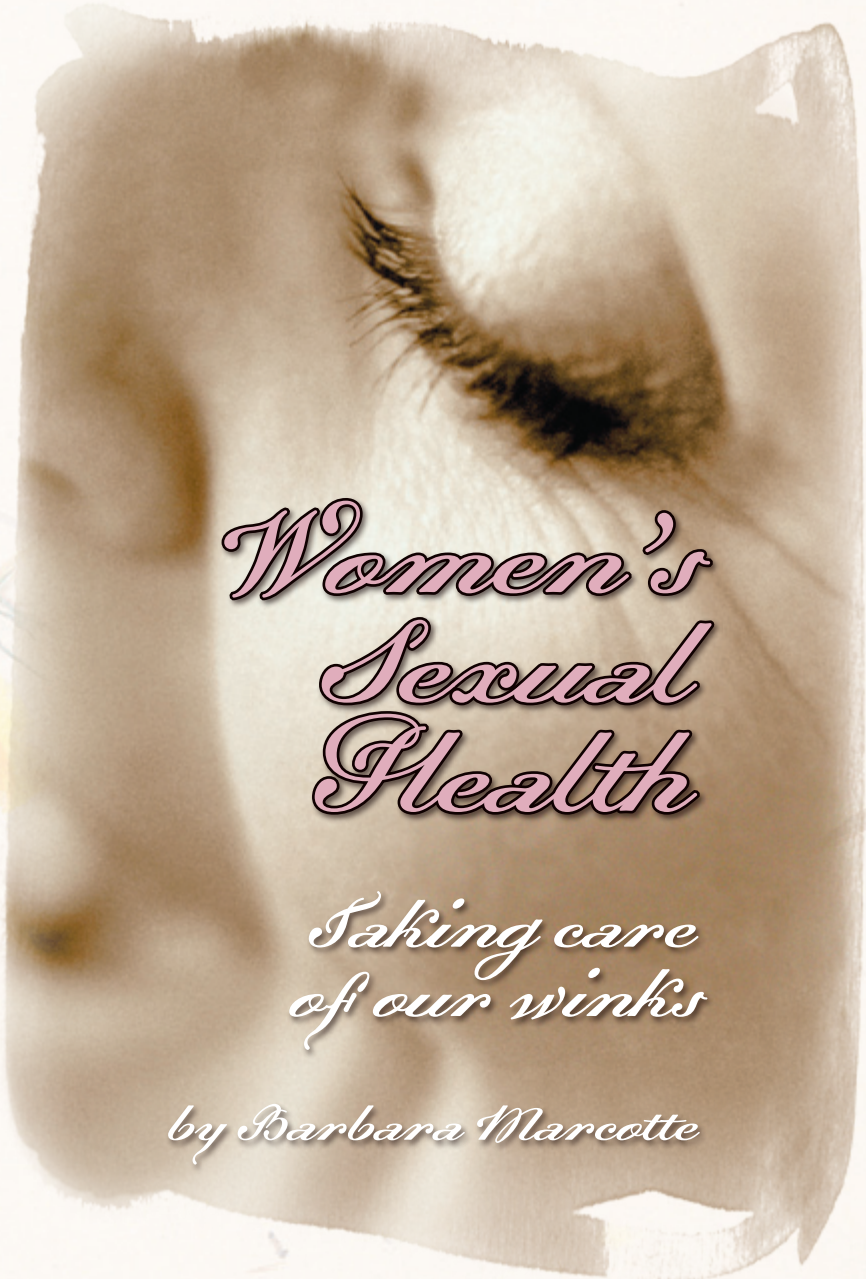
Hepatitis C does not always need to be treated, depending on the extent of liver damage—and other key factors, such as willingness/readiness to treat, access to treatment, and eligibility. A liver biopsy is sometimes referred to as the CD4 cell count of hepatitis C. Biopsy is the best way to assess liver scarring (stage) and inflammation (grade). Research on less invasive alternatives is underway, but biopsy remains the gold standard, although it is painful, and there is a very small risk of serious complications.

Last words

"My experience with HIV helped me to deal with hepatitis C," says Hull. "Activism and advocacy—working with people—have been a very powerful and spiritual incentive, and have improved my life."

Tracy Swan is Coinfection Project Director at Treatment Action Group, New York City.

Having liver enzymes checked regularly is especially important for co-infected people taking ARVs (antivirals).



Women's Sexual Health

Taking care of our winks

by Barbara Marcotte

Tatas, goodies, kitty cat, taco, pussy, melons, coochie, butterfly, cat, posey, suzy, tootie, hot box, privates, muff, pearl, clam shell, pie, peach, cha-cha, cooty, front door, poontang, girl parts, poonani, garage, nookie, snapper, sideways smile, beaver, cameltoe, boulders, bearded clam, my girl, love box, donut, squeeze box, pink taco, roses, Pus-say.

And my personal favorite given to me by my parents: wink.

When I was a little girl, my parents told me that I had a wink and my brother had a pee-pee. We were doing some cross-country traveling when I was about five or six and stopped for dinner. I ordered my kid's meal when the waitress asked me what I wanted to drink. I asked her what my choices were. She says, "We have Coke, Tab, 7-UP, Orange Crush, and Wink." You can only imagine the shocked look on my face. My parents really enjoyed that one… but I could go on and on about the stories my father liked to tell me, and my future confusions because of them.

For most of us, our thoughts of our own sexuality began when we were very young. Funny how these memories can affect us throughout the rest of our life. A healthy image of one's "girl parts" is formed or not in these early stages of our development and can affect how well we take care of these parts into our adulthood. Women with HIV may have varying self images of their sexuality depending on where they are in the scheme of acceptance of their HIV, and how active they are in their own personal health care.

Who knew?

In 1990 I had a yeast infection that just would not go away. This was before the age of over-the-counter medication for yeast infections. I went to the doctor and got a prescription, used the yucky medicine, and still had a yeast infection. I called the doc and he gave me a refill, but still it would not go away. After several months of this terrible infection, I became embarrassed and decided to just ignore it. This yeast infection continued. I found out that I was HIV-positive the following year.

After finding out that I was positive, I discussed the issue with my gynecologist. I asked him why he did not think to offer or discuss an HIV test with me. His response was that I was in a monogamous relationship and that I did not fit the "demographics" for those at risk. I am a white female and I was in my early 20's at that time. We all know that there are populations determined to be at higher risk for HIV, but I ask

> Those of us with HIV can not always predict when, if or for how long the flow will began or end.

you, if you have unprotected sex, aren't you at risk? Anyway, I believe my doctor learned from my situation and I continued with him for treatment through the next 10 years. He really took it upon himself to gather information and educate himself about HIV-specific issues.

The number of women with HIV has increased steadily around the globe. By the end of 2005, according to the World Health Organization (WHO), 17.5 million women worldwide were infected with HIV. Globally, women represent half of all people living with HIV/AIDS. Astonishingly, AIDS is the number one cause of death for African American women aged 25–34.

Most women do not enjoy a visit to the gynecologist, but it is necessary for our overall health and well-being. Women with HIV need to pay attention to taking good care of our "Girl Parts." With HIV comes greater risk of other female health problems. Women with HIV experience specific gynecologic problems more frequently than women who are HIV-negative. Let's look at some of those issues.

Yeast

Vaginal yeast infections can be more frequent, persistent, and difficult to treat successfully for women with HIV. Today, women with HIV are commonly treated with a round of fluconazole, an anti-fungal medication. There is a new study that suggests weekly doses of fluconazole can be used to prevent vaginal yeast infections without resulting in drug resistance. For women with lower T-cell counts and higher viral loads, fluconazole may be given as a prophylactic (preventative) medication.

STIs

Other vaginal infections can occur more frequently and with greater severity in HIV-positive women. Women with HIV may experience more frequent bouts of bacterial vaginosis and sexually transmitted infections such as gonorrhea, Chlamydia, and trichomoniasis.

Herpes

Herpes simplex virus (HSV) can be severe for women with HIV. Women with HIV who have herpes can have severe ulcerations that are sometimes unresponsive to standard therapy, such as acyclovir. This can really affect one's quality of life, as the ulcerations can be quite painful. In people with HIV, herpes recurrences tend to be more frequent, more severe, and longer lasting. Sometimes the lesions can become infected with other bacteria or fungi. An HIV-positive person who has herpes ulcers which last for four weeks or longer is diagnosed as having AIDS.

Herpes infections are treated with acyclovir (Zovirax). Other treatments for herpes include valaciclovir (Valtrex), and famciclovir. Acyclovir has very few side effects. It cannot eliminate HSV in nerve cells, so herpes attacks may recur after an attack has been treated. Salt baths can be a good remedy for relieving the pain of genital herpes lesions.

Idiopathic genital ulcers

There is also a strange little thing sometimes confused with herpes called idiopathic genital ulcers. These ulcers can be bumps or sometimes like pimples around or within the vaginal areas. The cause of idiopathic genital ulcers is unknown. Idiopathic genital ulcers are a unique manifestation of HIV and have no proven treatment. Researchers are evaluating the effect of the drug thalidomide (proven effective in treating mouth ulcers in patients with HIV) on idiopathic genital ulcers in HIV-positive women. The drug, however, is infamous for causing birth defects.

HPV

Human papilloma virus (HPV) is common in women with HIV and can also be very serious if not treated. HPV causes genital warts (anal and/or vaginal) and can lead to cervical or anal cancer. A precancerous condition associated with HPV, called cervical dysplasia, is also more common and more severe in HIV-infected women, and more apt to recur after treatment. HPV treatment can be effective, but positive women may need multiple treatments.

Once you have HPV, you will always have it. It is always possible that HPV can flare up and it is also possible to transmit it to others. Studies have found that HIV-positive women with low CD4 counts or viral loads rising above 10,000 copies have a higher risk for abnormal Pap smear results and developing HPV-related disease. Screening, monitoring and managing HPV infections are crucial for women living with HIV. While there is a lack of consensus in the medical community for treatment and management of HPV infection, there is an effort to establish guidelines to better serve women living with HIV.

The Centers for Disease Control (CDC) recommends HIV-positive women receive two Pap smears a year within the first month of diagnosis. If the results are abnormal, colposcopy or biopsy is suggested. One treatment is cryotherapy or cryocaterization, the application of liquid nitrogen applied to the affected area using an instrument called a cryoprobe. This treatment freezes and kills the abnormal cells. According to doctor recommendations, multiple treatments may be required. Some pelvic pressure or menstrual-like cramps can occur. This procedure may also cause cervical scarring and make it difficult for doctors to view the cervix during exam.

Another form of treatment for dysplasia is laser vaporization, an intense light stream used to kill abnormal cells. This can also cause cervical scarring and the

> Women with HIV need to pay attention to taking good care of our "Girl Parts."

procedure is performed in the hospital under local or general anesthesia.

Electrocauterization, also known as a LOOP or LEEP procedure, uses a small wire with an electric current to burn or destroy abnormal tissue. A local anesthetic is sometimes used during this procedure and you may experience cramping for up to 24 hours after the procedure.

When a woman has recurrent dysplasia and suspected cancer, a cone biopsy is used to both diagnose and remove abnormal tissue. A cone-shaped tissue sample is removed from the cervix. This procedure is done in the hospital and usually under a general or spinal anesthesia.

HPV is a serious situation and can lead to cancer, so the bottom line is make sure you receive monitoring and treatment for dysplasia as recommended by your doctor. Ask questions or seek a second opinion if your doctor does not take action to have these abnormal cells removed.

Menstruation

The menstrual cycle is one of my favorite topics. My boyfriend particularly enjoys the irregularities of my PMS (bitchy, moody, unpredictable outbursts, chocolate and/or salt feeding frenzies) associated with being HIV-positive. Yes, that is correct, women. Those of us with HIV can not always predict when, if or for how long the flow will begin or end. These abnormal changes may include heavier, lighter, more or less frequent, or more painful periods.

Some studies have contested these findings, showing no connection between HIV and the menstrual cycle. But you know, I need to have something to blame that PMS on, please!

It should also be noted that some of the antiretroviral medications we take can affect our cycle and the reliability of the birth control pill. Protease inhibitors with potential interactions include Norvir, Viracept, and possibly Lexiva —use of additional or alternative methods of birth control are recommended with these drugs. It is always important to ask your doctor or pharmacist about medications that may affect the reliability of birth control pills.

Pregnancy

When I found out that I was HIV-positive, we (my fiancé and I) were told that children were completely out of the question. Today life is different. Women with HIV are giving birth to normal happy and healthy infants. Women who are HIV-positive are marrying and having families. For many of us who survived the early days of HIV, this is a dream come true.

The current risk of transmission from mother to child with the appropriate treatment is less than 2%. If a woman does not know her status, risk is still in the minority, 25–30%. If you are HIV-positive and considering pregnancy, then you need to think about some of the normal issues such as age, other medical conditions such as diabetes and high blood pressure, etc. Talk with your doctor about how to best prepare your body and when it would be a good time to start trying to get pregnant.

Currently it is known that pregnancy does not make your HIV disease worse. There is a normal drop in CD4 cell counts that usually rebound after birth to pre-pregnancy levels. This is normal for all women regardless of HIV status. If your CD4 count does fall below 200, you are at a higher risk for opportunistic infections. Overall health during pregnancy is important regardless of HIV status. Make sure you get proper nutrition, exercise, and rest, quit smoking if you smoke, and avoid caffeine, street drugs, and alcohol. Most importantly, find a health care team that supports your decision to have a baby and work with an obstetrician who has experience working with HIV-positive women.

Wink positive

As an HIV-positive woman, it is important to stay on top of your health. Women with HIV need to be aware of the issues that affect our sexual health.

- See your gynecologist at least once a year or as recommended.
- Get a yearly pap smear.
- If you have an abnormal pap smear, follow up with appropriate treatment.
- Use condoms to protect yourself from other sexually transmitted infections.

Women tend to be the caretakers; we tend to think of the husband, boyfriend, children, and family first before we think of ourselves. I encourage you to find the time to spend a portion of each day reflecting on yourself, your needs, your health, and your desires. Try to do one thing each day just for you. Form friendships with other women who are HIV-positive. This can be a great way to stay in touch with current treatment information as well as receiving support from one another. Be an active participant in your health. Stay informed regarding new treatments and developments for positive women. Women with HIV are living—we are working, loving, giving birth, growing old, marrying, and going on with a life that some of us thought would never be. Realize this is your life and you are in charge of your destiny and well-being. Take care of your winks!

Barb Marcotte is Director of Programs at TPAN.

How to Survive a Trip to the Hospital

The intern who takes your history just graduated from medical school

by Jim Schniepp, PharmD.

So, you take care of your mind, body, and whatever else is in need of maintenance, and you time your meds by the bleep of the atomic clock and never miss a dose. Good for you. Who would think that going to the hospital for your face-lift or appendectomy or brain transplant could be a threat to all of that hard work and discipline.

Blessedly, few people living with HIV/AIDS need to be hospitalized these days compared to the bad old days. A by-product of this success is that most interns (doctors in training), pharmacists, and nurses who work in hospitals don't have much experience with HIV meds. They may have heard something about "cocktails" and AZT and how easy things are now, but they may not know how drugs are combined or realize the importance of taking every dose on time or that it's not okay to skip one drug out of your combination.

So guess who gets to be the expert? *You*! Yes, you are a medical expert when it comes to your therapy, and it is up to you to make sure things don't get messed up.

The intern who takes your history just graduated from medical school six months ago and she's really busy and you're only the second person she's seen on HIV meds and it took her a while to enter your orders and the pharmacy is all the way downstairs and they don't know if they have that one med and now it's midnight and you totally fell asleep and didn't get your meds.

So what can you do?

1. Most importantly, *know* what meds you're on, how much you take (the number of milligrams *and* the number of pills), and how often and when you take them. It's scary how many people are admitted to the hospital and can only recall that there's "a blue pill with a D on it that I used to take, but now I think it's a pink one."
2. *Write* down your meds and allergies on a wallet card like the one with this article. (You can also print the wallet card from the PDF of this issue at www.tpan.com.) If you don't have a list handy, do not hesitate to call your pharmacy or doctor's office. Either one can speak to the hospital doctor and help you keep your therapy on track.
3. *Take* a 2-day supply of meds with you to the hospital. Even though all meds that you take in the hospital should come from the pharmacy, they may not have a supply of new or seldomly used drugs. It can also take a while to get your orders processed and filled. Bring each drug separately in a labeled bottle from the pharmacy. Showing an unlabeled pillbox to your nurse is just going to add to the confusion.
4. Most hospital pharmacies don't stock Fuzeon, so definitely bring enough to last your entire stay in the hospital.

Medication	Dose	Schedule	Comment

Name:_____ **Allergies:**_____

Physicians:

Name:_____ **Phone:**_____

Name:_____ **Phone:**_____

Pharmacy:_____ **Phone:**_____

test positive aware NETWORK

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Chicago, IL 60640-1405
T:773-989-9400
F:773-989-9494
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Remember to take charge of your meds, don't be afraid to speak up to get them, and enjoy your stay in the hospital. It's the most you will ever pay for bad food.

Jim Schniepp is an HIV specialty pharmacist currently working at Rush University Medical Center in Chicago. He can be contacted at James_R_Schniepp@rush.edu.

one on one:

U.S. Senator Barack Obama (D-IL)

The Politics of HIV

Interview by Jeff Berry

In our continuing coverage leading up to the November elections, U.S. Senator Barack Obama (D-IL) responds to our questions on HIV/AIDS. We still have not heard back from a Republican—any takers?

Jeff Berry: What are your priorities on your agenda for national HIV/AIDS issues for 2006?

Barack Obama: This past June, the world paused to commemorate the passing of 25 years since the first AIDS case was identified. Over this time, the epidemic has evolved from one primarily afflicting the white, homosexual community to one that impacts all populations, regardless of race, ethnicity or socio-economic status. The epicenter is shifting towards women and children, and African Americans continue to experience the highest rates of new infections and deaths from HIV/AIDS compared to all other patient groups. For African American women aged 25-34 in the United States, HIV/AIDS is the leading cause of death.

The tragedy and irony of these statistics is that HIV/AIDS is a preventable disease. To that end, I believe that the most critical AIDS issue facing our nation is the need for prevention. We have not adequately educated ourselves and each other about this disease, nor have we identified effective ways to empower individuals to change their sexual practices to protect themselves from HIV infection.

Until we have an open and honest dialogue about what we need to do, or do better, we will not be able to stop the silent but deadly spread of this disease. This is not an easy task, and given that the HIV/AIDS epidemic continues to evolve, what may seem logical today may not be a top priority tomorrow. Additionally, successful eradication is unlikely without a comprehensive, large-scale societal investment in improving the educational and economic opportunities of our most vulnerable populations, which are disproportionately affected by this disease.

That being said, the following are some of the general policy priorities for my HIV/AIDS agenda.

Expansion of coverage for HIV/AIDS treatment and services. A number of programs, particularly those offered under the Ryan White CARE Act, have been instrumental in getting individuals the care they need to remain healthy and live longer. Yet too many individuals continue to fall through the cracks, and the overall federal investment is inadequate given the scope and magnitude of the epidemic. And the care we do provide must be comprehensive. Having the correct medications will not be of much benefit to an individual battling AIDS who lacks a decent meal and a place to sleep.

Promotion of screening for HIV/AIDS. Studies indicate that about one-fourth of Americans infected with HIV are unaware of their status. If we expect these individuals to make healthy decisions, seek care, and discontinue activities contributing to the transmission of this deadly infection, these individuals first need to be educated and tested. And if we expect to gain ground on the epidemic, we need to educate the public about prevention. While there have been several national public education campaigns in the U.S., many would argue that our efforts have been surpassed by those in other countries. For example, walking down the streets of Kenya, you cannot help but notice the prevention advertisements. The U.S. should follow in the steps of other countries in which public advertisements regarding education and testing are popular, prominent, and effective. Until we do, fear, stigma, ignorance, and transmission will persist.

Strengthening of the public health infrastructure. The federal government's investment in prevention is minimal compared to its investment in medical care and treatment, and is yet another example of this Administration being "penny-wise and pound-foolish." We must increase our investment in the federal and state public health agencies, as well as in our community-based organization partners —the foot-soldiers in this war against AIDS.

Support for treatment and drug research. HIV has continued to mutate, hampering vaccine development efforts and rendering many current treatments ineffective.

The federal government must expand and accelerate research for the development of effective medications and treatments. In particular, we must act expeditiously to support the development of microbicides, which hold tremendous promise for HIV prevention for women.

Provision of comprehensive sex education. Promotion of abstinence from sex outside of monogamous relationships must be part of any successful HIV prevention strategy, but it cannot be the entire strategy. Raising awareness of the virtues of abstinence cannot be a substitute for providing truthful, medically accurate, and age-appropriate information about contraception, sexually transmitted diseases, and reproductive health in general. Information about condoms and other effective tools must be made readily available. We are losing the battle against the HIV/AIDS epidemic, and we cannot allow partisan politics to trump sound, scientific policies.

Berry: What is the current state of affairs with support for HIV/AIDS care and prevention today and how do you see it becoming affected in mid-term 2006 and general 2008 elections?

obama: I believe that health care issues on the whole will receive greater attention during the election seasons, and that has the potential to be a very good thing. I am constantly disappointed that the issues my Illinois constituents tell me they are most concerned with —issues such as health care, energy costs, and education—get put on the back burner in favor of divisive social issues such as gay marriage or a constitutional amendment to ban flag burning. My hope is that the elections will fuel sound debate on health issues on the Hill, which will translate to greater action on HIV/AIDS care and prevention concerns.

Berry: What is your policy on harm reduction and what is your perception of the crystal meth problem?

obama: There is no denying the link between HIV transmission and injection drug use. I believe that harm reduction and law enforcement are not mutually exclusive methods of reducing drug abuse and its health consequences. In April 2005, the U.S. Department of Health and Human Services reported that 18% of users shared their needle with others after use and 13% used a needle they suspected or knew someone else had previously used. Only 56% of users claimed to use needles purchased from a pharmacy or provided through a needle exchange program.

I understand the controversial nature of implementing harm reduction methods on a national level. However, this is not a novel concept. Many developed nations rely on harm reduction as part of the solution to control the spread of HIV/AIDS. We can either acknowledge the potential public health benefits of harm reduction, while continuing to strengthen law enforcement efforts in the war on drugs, or we can choose to allow the drug world to be a breeding ground for HIV/AIDS, hepatitis, and so many other preventable diseases.

Crystal meth use in Illinois and across the nation is skyrocketing, with no signs of improvement. According to the 2004 National Survey on Drug Use and Health conducted by the National Institutes of Health, 12 million Americans have tried methamphetamine. Abuse of crystal meth leads to a host of serious problems, including high-risk sexual behavior which increases risk for HIV/AIDS. As a U.S. Senator, I have fought for more funding for law enforcement efforts to combat meth use. However, this is not only a law enforcement issue but also a health and public health issue. A greater investment in prevention, treatment, and rehabilitation programs is long overdue. In Illinois, we have several programs, including those sponsored by the Women's Treatment Center and the Haymarket Center, which have been quite effective at using family-centered models to treat women with meth addiction, helping them to stay out of jail and with their families, and assisting them with employment training and other needs. We should support similar programs on a national level.

Berry: Who would be your choice for a pro-AIDS care president in 2008?

obama: As I stated earlier, I expect health care to be one of the major issues in the 2008 Presidential campaign. I will not support any candidate who has not demonstrated a serious commitment to improving health and health care broadly and combating the HIV/AIDS epidemic more specifically.

Berry: Where do you see AIDS research funding in 2006? Are you committed to continued funding for OAR (Office of AIDS Research)?

obama: Federal agencies will spend approximately $21.1 billion this year on HIV/AIDS programs. Of this funding, only 14% is directed for research. The President requested $22.8 billion for FY07 [Fiscal Year 2007] HIV/AIDS activities. Despite the 8.3% overall increase requested by the President, funding for research was reduced by 0.05% to $2.6 billion. While we certainly should not reduce funding for prevention, treatment, and international efforts, I think most would agree that continued investment in HIV/AIDS research is critical to making progress against this epidemic.

The Office of AIDS Research has been quite effective in directing HIV/AIDS related research at NIH, and should continue to receive full support.

Berry: Are you committed to being a leader in keeping the CARE Act strong and intact for the future?

obama: The Ryan White Care Act (RWCA), which is up for reauthorization, has provided vital support for those suffering from HIV/AIDS. An important component of this statute is, of course, medical treatment. However, comprehensive and effective care must include housing, transportation, and food. RWCA was crafted with multifaceted care in mind, and that is the reason for its success. During reauthorization, we must be certain to strengthen, not jeopardize, this comprehensive approach. Additionally, in order to provide this comprehensive care, Congress must allocate adequate funding. We cannot put service providers in a position of providing care to a greater number of clients with fewer resources.

A number of contentious issues are still being discussed and negotiated by House and Senate members, including determining a fair proxy method for funding allocation, defining "core medical services," and balancing the needs of urban and rural populations, just to name a few. I have and will continue to voice my support or concerns regarding the proposed legislation, and hope the Congress will work through policy and political differences to pass a good bill this year.

Gay Games Athletes Are All Winners

Profiles of three positive contenders

by Jeff Berry

Douglas Graham Bates, 50, of Newark, Delaware, featured on the cover of this issue, came to Chicago in July to compete in this year's Gay Games. Last October, Doug fell ill with a severe case of salmonella, and his weight dropped to a mere 125 lbs. Last week Doug took home a silver medal in the Men's Masters Physique Competition, age 50–59. I spoke with him several days before the opening of the Games.

Doug looks upon his return to health and his trek to the Gay Games as his "journey to wellness." In June he took part in Broadway Bares at Roseland in New York City (see picture above), an event which this year raised more than $650,000 for Broadway Cares/Equity Fights AIDS.

Doug, who says he's always been very spiritual, stated that he was "New Age before New Age was New Age!" But last year before he became sick, he had gotten off of meds, and was in denial, and his health was declining. He says he was suffering from dementia, and had four T-cells—so few that he could have named them. He ended up in the hospital, and moved back in with his parents shortly thereafter. "I was really lovely to be with," he says.

During his slow recovery he would play Scrabble with his dad, who was an avid player and would always beat Doug at the game. One day the words started coming together for Doug, and all the pieces began falling into place, literally. "I not only won, I trounced him!" he laughs.

That's when he knew he was starting to get better, and he began lifting weights at home. He convinced his parents that he needed to get back to the gym. "The gym is my sacred space," says Doug almost religiously. "It saved my life." He was soon up to working out two-and-a-half hours per day, six days a week, but was told by a trainer that he was in fact over-training, and cut back to one hour per day, five days a week. His exercise routine included yoga as well.

Doug decided he wanted to participate in the Gay Games. A friend of his had competed during the Sydney Games in 2002, and it had served as an inspiration to Doug at the time. "My mission is to be a catalyst and to inspire others," says Graham, "and I can't do that through darts."

Since he was living on Social Security, he didn't have enough money to make it to the Games without some help. And so, with the assistance of the folks at AIDS Delaware, a fund was set up to help him get to the Games.

Doug was determined to win a medal, and his story, like hundreds of other Gay Games athletes living with HIV, reminds us that even those of us living with the virus should strive to be the best that we can be.

Update on James Ballard

James Ballard, profiled in the May/June issue of *Positively Aware*, sent us the following e-mail shortly before the Games began.

"My hopes of competing in Chicago have gone down in flames, as my old med regimen collapsed and my health sailed through Dante's Inferno. The news is not all bad, though, as I brush off the ash and drag my training suit back into the pool, for my body is responding to a new 'summer cocktail' and I am thrashing less and less in the water. It will take time, however, to get back water rhythm and of that there is simply not enough to scale the blocks and launch.

"I know that I will miss the start and the finish, but most of all, I will miss the memories which will be taken home by everyone who has the fortune to participate. I wish all well and hope that everyone takes home gold, at least in their heart."

Craig Goodman—no pain, all gain

I spoke with Craig Goodman several days after the Games concluded. Goodman was also featured in the May/June issue of *Positively Aware*, and said that his experience at the Games was awesome. "Chicago was so friendly and accommodating. I was kind of disappointed that it got political and some of the countries weren't able to attend."

Craig (pictured below) competed in the bowling competition as part of one of his local leagues, "The Classics," which hails from a suburb of Los Angeles, Conaga Park. "I was with 15 women, and 13 of them went home with medals. Unfortunately, I didn't.

"The camaraderie [of the Games] is indescribable—it's overwhelming, and very humbling. The people I was with, we became closer and closer throughout the week.

"When those lights went off [during opening ceremonies] and we saw [the lighted rainbow flag] on the giant screens, it was a rush.

"For those 10 days, I was just another athlete. I was not someone living with HIV—it was the farthest thing from my mind. I live with neuropathy, but during the week, I had no pain at all. Getting to the Games was one of my goals, one of my living goals. Now, my next goal is [Cologne] Germany [site of the 2010 Gay Games].

"When we would run into people on the street in Chicago, they would see our badges and ask us how we were doing in our category—one lady, who had her baby with her, came up and asked us where she could get tickets to go see the athletes compete.

"Thank Chicago for us, it's a really beautiful city, right there on the lake. I never imagined so much color!"

At Game's End

Participation, Inclusion, and Personal Best. These are the ideals that Tom Waddell, founder of the Gay Games, challenged athletes to strive for during the first Gay Games in San Francisco in 1982. It was also the theme for this year's "Gaymes," which just wrapped up here in Chicago.

30,000 people packed Soldier Field for the spectacular opening ceremonies, and nearly as many attended the festive closing party at Wrigley Field. Between the two, and all week long, a huge array of sporting competitions, cultural activities, parties and events filled field houses, sporting venues, bars, clubs, and restaurants throughout the Chicago area with athletes from all across the world.

Highlights of the opening ceremonies included performances by Margaret Cho, Andy Bell, Jody Watley, Heather Small, and Matthew Cusick, the performer booted from Cirque du Soleil because of his HIV-positive status, who subsequently sued and won. Chicago Mayor Richard Daley delivered a rousing welcome to the athletes and the audience alike.

George Takei, who played Sulu in Star Trek, gave a stirring and inspirational speech, and spoke of the barbed-wire fences that surrounded internment camps here in the U.S. for Japanese-Americans during World War II. He said that this country has abolished slavery and granted women the right to vote, but that there still exists "an invisible barbed-wire fence" for gay Americans who are not allowed to marry.

"America is a land of shining ideals, but it has not always lived up to them," stated Takei. "I am a proud, gay American, and a runner in the Gay Games, and we will tear down these invisible barbed-wire fences, because we are Americans."

As nearly 10,000 athletes from around the world poured out onto the field, Team Chicago, one of the largest contingents with 2,500 athletes, was the last to enter. It took fifteen minutes for them to finish filling the field, much to the delight of the roaring "home" crowd. The Wyoming contingent of two, with one woman holding a flag bearing Matthew Shepard's name, brought tears to my eyes, and the crowd to its feet. The Ugandan team with one, lone athlete brought with him the realization that as separate as we may be geographically, we can stand together in unison as a community.

When the last athletes lined up, the lights came down, and 10,000 glow sticks instantly created a gay rainbow flag on the grass of Soldier Field, truly a sight to behold. A male streaker lightened up the evening as the program dragged into the third of four-plus hours, which culminated in a dizzying rainbow fireworks display which circled the perimeter of the stadium toward evening's end.

All in all, the Games were deemed a success. They were a once-in-a-lifetime opportunity for many people from all walks of life to come together and celebrate their differences, while affirming that which we have in common, and reminding us all of how far we've come, yet how far we have to go.—*Jeff Berry*

Abbott Virology

The HIV Treatment Series is sponsored in part by an unrestricted grant from Abbott Virology.

HIV and the Kidneys

How to know when something is wrong, and why it is important

by Lynda Anne Szczech, MD, MSCE, FASN

Knowledge of your kidney function and kidney health is important for both HIV-infected and non-HIV-infected persons. It has been known for approximately 20 years that HIV may result in kidney failure[1]. Given that the specific types of kidney diseases seen among HIV-infected persons have a tremendous predilection for Black Americans[2], the focus to date has been on screening and prevention of kidney disease in people of color. This focus, however, needs to be expanded to all persons with HIV-infection regardless of race, given recent understanding that the risk associated with abnormalities of kidney tests identifies persons at a greater risk of illness and death.

Put simply, everyone with HIV infection should be aware of their kidneys.

How do you test kidney function?

Kidney function can be assessed by simple blood and urine tests. The two methods to assess kidney function complement each other and should both be performed as the presence of an abnormality in one, the other or both tests provides clues to the type and severity of the kidney disease. In addition, a couple of different mathematical measurements help turn these two test results into a clearer picture of health.

Detection of kidney disease relies almost entirely on the performance of blood and urine tests. While infrequently, clues to the onset and presence of kidney disease—such as swelling of the legs or face and changes in urinary habits—may occur, generally symptoms associated with a decreased ability of the kidneys to clear waste products from the blood are vague, including fatigue and loss of appetite, occur only after the majority of kidney function has been lost, and may be confused with other causes.

Table 1: Equations to estimate kidney function using creatinine

Name of formula	Measure of kidney function provided	Equation	On-line calculator
Cockcroft-Gault[3]	Creatinine clearance	$CrCl\ (mL/min) = \frac{(140-age) \times weight\ in\ kg}{(sCr^* \times 72)}$ Multiply by 0.85 if calculating for a woman	www.nephron.com
MDRD (Modification in Diet in Renal Disease Study Equation)[4]	GFR (Glomerular filtration rate)	$GFR\ (mL/min\ per\ 1.73\ m^2) = 186 \times sCr^{-1.154} \times Age^{-0.203} \times (0.742\ if\ female) \times (1.210\ if\ black)$	www.kidney.org/professionals/tools

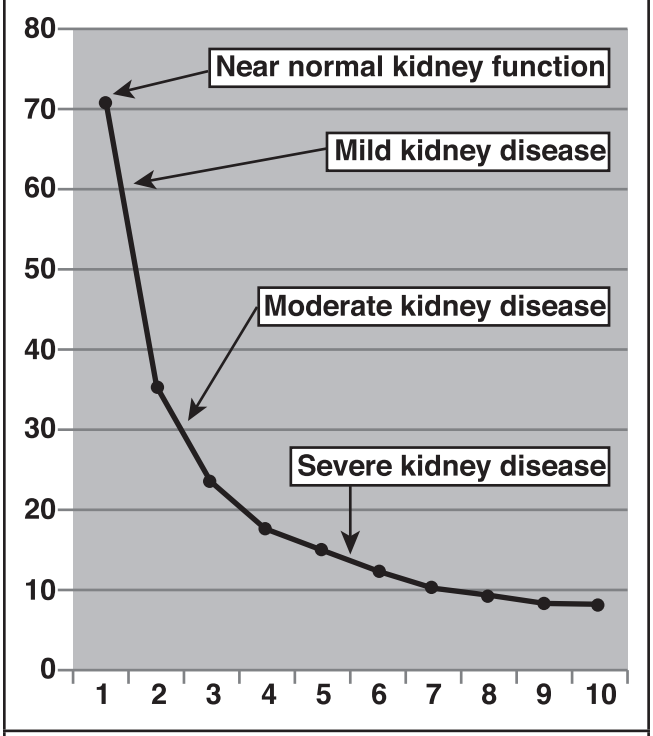
* blood creatinine level

A urine analysis can provide a tremendous amount of information on the presence and activity of diseases in the kidneys. The presence of small amounts of the protein albumin (albuminuria) or larger amounts of protein (proteinuria) can be assessed using a dipstick of a small amount of urine. Albuminuria or proteinuria usually indicates the presence of kidney disease and may be seen early even prior to loss of kidney function.

A measurement of the creatinine level in the blood can subsequently provide an estimate for the ability of the kidneys to clear the blood of waste products. Creatinine is a molecule excreted by muscle cells on a continuous basis. When the kidneys function well, it is filtered effectively out of the blood, and the blood levels are low. As kidney function declines due to kidney disease, it is less effectively cleared out of the blood, and its blood level rises.

To truly understand how this simple blood test is translated within an individual to the amount of kidney function they have, the level of creatinine must be manipulated. Because the absolute level of creatinine is related not only to kidney function but also

Figure 1: The association between creatinine and kidney function.



(This figure plots the amount of kidney function as calculated by the Cockcroft-Gault formula for a 55-year-old white male.)

Table 2: Kidney diseases described with HIV infection[5,6]

HIV-associated nephropathy (a kidney disease related to a direct infection of kidney cells by HIV)
Mesangial glomerulonephritis (IgA and HSP) (a disease where the kidney has a lot of inflammation related to certain types of antibodies that are trapped in the areas where filtering occurs)
Lupus-like glomerulonephritis (a disease where the kidney has a lot of inflammation related to certain types of antibodies that are trapped in the areas where filtering occurs)
Minimal change disease (a type of kidney disease where little is seen on kidney biopsy but the person has a lot of protein in their urine)
Membranous nephropathy (a kidney disease where certain types of antibodies are trapped in areas where filtering occurs leading to the loss of a lot of protein in the urine and the potential loss of kidney function requiring dialysis)
Membranoproliferative glomerulonephritis type 1 (a disease where the kidney has a lot of inflammation related to certain types of antibodies that are trapped in the areas where filtering occurs)
Paraprotein nephropathies: light chain/amyloid/fibrillar (a kidney disease where abnormal proteins in the blood of an individual with a chronic disease such as HIV can be trapped in the kidney, affecting the function)
Thrombotic thrombocytopenic purpura/Hemolytic uremic syndrome (a disease where the inside of blood vessels are severely damaged, resulting in kidney failure and sometimes seizures)
Acute tubular necrosis (a kidney disease where a sudden loss of kidney function occurs due to things such as medication toxicities or extreme changes in blood pressure)
Allergic interstitial nephritis (a kidney disease that is caused by an allergic reaction to medications)
Crystal-induced nephropathy (a kidney disease that is caused by the precipitation of medications inside the kidney)
Fanconi syndrome (a problem with kidney function that may be caused by changes in the functioning of the kidney with loss of important minerals and salts from the kidney in the urine)
Kaposi's sarcoma (a cancer related to immune dysfunction), infiltrative

to the amount of muscle a person has, for it to really reflect the amount of kidney function it must be converted using a mathematical formula. This is essential to avoid two common and dangerous misconceptions. The first is that a smaller or older individual does not have significant kidney disease simply because their creatinine falls into a "normal range" for a laboratory.

As an example, a 55-year-old Caucasian male may have a creatinine of 1.3 mg/dL, which is technically within normal limits for the ranges that many laboratories provide (usually normal is listed as less than 1.4 mg /dL). His estimated kidney function (using the Cockcroft-Gault formula in Table 1) is 54.5 cc/min. Given that "normal" is in the range of 90 to 110 cc/min, this represents a reduction in his kidney function of approximately 45% that would have gone unnoticed had it not been calculated.

The second misconception is that a "small" elevation in creatinine is not a matter of concern. This misconception that a small elevation in creatinine should not result in an investigation of the causes is due to the fact that as kidney function decreases with disease, creatinine doesn't rise at a constant rate accordingly. As with any disease, however, the earlier the diagnosis and treatment, the more likely the cure. This is especially true of kidney disease. In the case of kidney disease early diagnosis may translate to either avoiding or delaying kidney failure, with the subsequent need to start dialysis, a painful, expensive, and complicated procedure.

Early in the course of kidney disease, as creatinine goes from the normal for that individual upwards to the value of 2 mg/dL, that person has likely lost half of their kidney function. Later on in the course of the kidney disease, as the individual's creatinine rises from 4 to 5 mg/dL the loss is much less pronounced. This is shown in Figure 1, plotting the amount of kidney function on the vertical axis against the level of creatinine on the horizontal axis. In this graph, the rate of loss of kidney function is considerably more steep when creatinine rose from 1 to 2 as compared to its decline when creatinine rose from 4 to 5 mg/dL. The key message here is that any elevation needs to be evaluated, and the earlier the better.

The forest and the trees

There is an old cliché that warns not to miss the forest for the trees. In this analogy, it is appropriate to consider the trees as the kidneys and the forest the person who owns them. The warning here is based on the fact that kidney disease puts an individual at risk of events even worse than declining kidney function and the prospect of dialysis. This article will first describe the risk of kidney disease to kidney function and then go on to describe the risk of kidney disease to the life of the person him or herself.

The trees: the risk of progressive kidney disease

A person with HIV-infection may get many types of kidney diseases, including those related to the virus and those related to conditions such as hypertension or diabetes. The types of kidney diseases that have been described among persons with HIV are listed in Table 2.

If a person has an abnormal kidney test (abnormal urine dipstick or elevated serum creatinine), the only definitive way to determine the exact type of kidney disease that he or she has is by kidney biopsy. While a kidney biopsy is relatively low risk, the risk of bleeding does exist. Therefore, it makes sense to only perform a kidney biopsy on those persons in whom knowledge of the exact type of kidney disease will affect the therapy chosen.

Since many therapies are beneficial to the person overall (such as good blood pressure control in a person with high blood pressure and tight blood sugar control in a person with diabetes), it is not always necessary to perform a kidney biopsy initially. Discussion of whether or not a particular individual needs a biopsy should be held with a health care provider specializing in the care of kidney disease, such as a nephrologist. If a kidney biopsy is not initially pursued, that decision should be re-examined periodically, based on the course of the kidney disease and how the person responds to the therapy instituted.

Table 3: Potential interventions for kidney disease

Kidney disease	Potential interventions
All kidney diseases	Good blood pressure control (goal below 130/80) Lipid control [cholesterol and triglycerides] Specific attention to cardiovascular risk reduction Anemia management Prevention of bone disease related to kidney disease
HIVAN	Anti-HIV therapy Angiotensin converting enzyme [ACE] inhibitors or angiotensin receptor blockers medications Corticosteroids (role uncertain)
Diabetes	Angiotensin converting enzyme [ACE] inhibitors or angiotensin receptor blockers medications Tight blood sugar control Low protein diet (somewhat controversial)
Hypertension	Good blood pressure control (goal below 130/80)
Glomerulonephritis (a type of kidney disease where the kidney has a lot of inflammation)	No proven therapies among persons with HIV infection. Immunosuppressive therapy has been attempted. Angiotensin converting enzyme [ACE] inhibitors or angiotensin receptor blockers medications may be used. Antiretroviral therapy may be utilized.

Risk factors

The type of kidney disease someone is likely to have can be influenced by multiple factors. The most influential of these factors, however, is clearly race. Black Americans without HIV infection are pre-disposed to most kidney diseases as compared to Caucasians[2]. Black Americans with HIV infection also have a greater risk of kidney disease[2]. Among persons with HIV infection and kidney disease, the types of kidney disease are also quite different among Black and Caucasian Americans[5, 6, 7]. Kidney diseases more likely to be associated with HIV, such as HIV-Associated Nephropathy (HIVAN), are significantly more common among Black Americans, whereas Caucasians are more likely to experience kidney diseases related to their concurrent illnesses, such as hypertension and diabetes. The risk associated with race for developing HIVAN is so great that it is exceptionally rare to diagnose a Caucasian with it, and such a diagnosis would be written up as a case report in a medical journal.

Treatment of kidney disease should be directed at the type or suspected type of kidney disease a person is likely to have. Table 3 represents a partial list of the types of kidney diseases and potential recommended interventions to stop, slow, or reverse the effects of the disease on the kidneys. The goal of treatment is to halt or at least slow the progression of kidney disease to delay or perhaps avoid the need for the institution of dialysis.

The trees: the association between kidney disease and the risk of illness and death

It has long been known that among persons without HIV infection, such as those with diabetes, heart disease, the elderly, and those with high blood pressure, the presence of kidney disease is associated with an even greater risk of death[8]. It should therefore not be surprising this association is also present among patients with HIV.

Importantly, this is not only true for persons with elevated serum creatinine levels (and therefore decreased kidney function), but also for individuals whose kidney function is normal but who merely have a little protein in their urine.

Several studies demonstrate that persons with HIV-infection and protein in their urine and/or elevated creatinine have an increased risk of hospitalization and death[9, 10], and that these increases in risk are not subtle. A person with either protein in their urine or elevated creatinine is at a 70% increased risk of hospitalization due to new AIDS-defining illness and a 50% increase in risk for overall hospitalization.

Looked at separately, protein in the urine and an elevated creatinine have equally concerning associations with new AIDS-defining illness and risk of death. In the absence of antiretroviral therapy, the presence of protein in the urine is associated with a 31% increased risk of new AIDS-defining illness (ADI) and a 35% increase in risk of death[11]. This latter finding is underscored by the fact that a person without proteinuria and a CD4 lymphocyte count of 350 cells/ml3 has a lower risk of death than a person with a CD4 lymphocyte count of 500 who has protein in their urine. This important finding was noted in a study looking at women followed in the Women's Interagency HIV Cohort Study (WIHS), a study of over 2,500 women with HIV.

Initiation of antiretroviral therapy may affect this risk among persons with kidney abnormalities, but improvement in lowering the risk is not tremendous. Even following the initiation of antiretroviral therapy, a person with protein in their urine is at a 121% increased risk of death and a person with an elevated creatinine is at a 42% increased risk of a new ADI.

One of the mechanisms behind these elevated risks may be due to a less vigorous response to the initiation of therapy among people with kidney disease. A single study suggests that individuals with proteinuria may be less likely to respond to antiretroviral therapy with a non-detectable viral load. Clearly a greater understanding of whether or not these findings should result in stronger recommendations than simply starting individuals with kidney disease on antiretroviral therapy early is paramount.

What do we know, what do we think we know, what do we need to know, and what should you do?

Our knowledge of HIV and how it affects the kidneys is still relatively rudimentary. Significant work remains to be begun to truly understand who is susceptible to kidney disease and why. At present, it would appear that while the overwhelming burden of kidney disease occurs within the Black American community, subtle abnormalities in kidney tests may be a risk factor for increased risk of AIDS-defining illness and death among all HIV-positive persons.

Given the ability of early screening to provide a greater likelihood of prevention and treatment, screening is imperative. Screening as simple as a urine analysis and a serum test for creatinine should be employed in every person with HIV. Guidelines from the Infectious Diseases Society of America (IDSA) currently suggest that all persons with HIV infection get screened for kidney disease at least once[12]. If screening results in no apparent abnormalities, persons at increased risk for increased kidney disease should be re-assessed at least yearly. Persons with abnormal screening tests should have further evaluation by their health care provider and potentially be referred to a nephrologist. When given your lab results, if you don't hear anything about your kidneys, it doesn't hurt to ask: "How is my kidney function?"

When it comes to kidney disease the adage "What you don't know can't hurt you" couldn't be less applicable. Please—remember to pee in the cup!

[1–12] *References available at www.tpan.com.*

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Shit Storm

Treatment trauma with no umbrella

by Jim Pickett

Okay, it's official. I can now say with complete confidence that I have at the tender and vulnerable age of 40, experienced the most humiliating, degrading event of my life. And hon, there's plenty of embarrassing competition for that honor.

As of this writing, I am back on meds after a year-and-a-half holiday. The regimen I had been on for a couple years was wonderful, no side effects, stratospheric T-cells, decimated viral load. But one day, it just stopped working. I couldn't bear facing a new drug cocktail so I decided I would take a break, give my body a rest. I had done this before, I would do it again.

I pushed it a bit too far this time, and am kind of shocked with myself at how far I let things slip. The whole first half of this year I've suffered from extraordinary fatigue, now that I look back on it, really major league exhaustion. The kind where you go to bed at 7 p.m. and sleep straight through the night 'til 5 a.m. the next morning. But instead of thinking, "Hmmmm, HIV progression?" or pondering, "Hmmmm, should I maybe go back on meds?" I instead chalked up my debilitating energy levels to an intense work schedule and lots of running through airports, lots of projects, lots of commitments. I was giving tons of my energy to work, there just wasn't much left for anything else. Even a viral load of over 300,000 in April didn't really faze me. I had a major conference on microbicides in Cape Town to attend and numerous exciting and gratifying projects to finish, and start, and finish, and start… I was going to be doing the AIDS Marathon Training Program again, and I had a triathlon for the Gay Games in Chicago to prepare my mind and body for. There was no time for drug-related nausea, diarrhea or those annoying rashes that kill you.

Well, a series of health issues, including severe strep throat and a middle ear infection in both my ears (on-going) beginning in early June, coupled with a blood test that indicated I was now slightly anemic (actually HIV-related fatigue), startled me into a major reality check. Time to go back on meds, Missy. Vacation over. You have been slipping, your T-cells are sliding toward the "Danger, Will Robinson" zone… do you enjoy feeling like a train wreck every day?

As depressed and worried as I was about the notion of being ball-and-chained to pill bottles once more, returning to the stark, toxic realities of treatment also theoretically offered sweet, sweet relief from the Coma Coma Coma chameleon I had become. They would be dispatched to trample the virus and bump up those T's, give me back my energy so I could accomplish everything in my Outlook.

And huzzah, they have done just that.

But with the price I indicated earlier.

So it's the middle of June and I am in Washington, D.C. for meetings and Hill visits to push for the reauthorization of the Ryan White CARE Act. I've just begun my new regimen (Kaletra and Invirase) and have had just a few moments of intense nausea and some "loose stools" in the morning. No biggie. Yum, yum, yummy, I got love in my tummy.

It's Sunday morning and I am running late for a meeting in the god-awful Crystal City suburb. I take a small bit of half a donut from the free (and a little scary) hotel breakfast "buffet" and down my dose running out the door. Continued very poor decision-making leads me to purchase a sweetened iced coffee on the way to the Metro, but it's hellacious hot and I do need some caffeine. My stomach starts to gurgle ever so slightly at my train connection, but I think, "Oh, I can make it to Crystal City, I will use a restroom at the mall there when I exit." The train is scheduled to arrive in three minutes as a few more insistent gurgles call for my attention. I now realize that I will have to exit the station here and just be a little more late for my meeting than I already am. Sorry. I head for the escalators when it becomes very, very, adrenaline,

Photo © Russell McGonagle

deer-in-the-headlights clear that I better start running, fast. As fear sweat pours down my back, I sprint towards the second set of escalators and with no other warning, no pushing back, no fight whatsoever, the shit storm breaks and my light tan, slightly snug Capri Culottes start to fill with the spicy chicken, guacamole and bean super burrito from yesterday, the half donut, and the sweetened iced coffee.

I have had close calls, I have had near misses, I have been forced to take dumps next to dumpsters in full view of passenger rail lines, wiping my ass with newspaper from the ground, but never have I been in a situation as awful as this. It has to be noticeable to others. I can certainly smell what is happening, and besides, I swear flies are swarming around the enormous brownish, green dripping mess that is the back of my light tan, slightly snug Capri Culottes.

Full panic. Try to hold my backpack behind me to hide the aftermath, look totally idiotic, fooling nobody, flies too smart. Dripping. Brown and green. I am in Chinatown, everything is closed. No! There's a McDonalds, and an open bathroom, the kind designed just for one person, with a sink. Hallelujah. What luck. But God, I am a disaster. I don't know where to begin and what I am going to do with the destruction I have caused, and the shame of it all, the shame. I am barely into assessing next steps when the insane, obsessive compulsive employee begins to pound insistently on the door, wanting to clean the bathroom *now*. I say, "Gonna need a minute." And she pounds some more. This routine goes on for a quarter hour as I desperately try to clean myself up and say goodbye to my favorite pair of going-on-a-date Diesel pantaloons.

After rushing past McOCD and returning to my hotel after another quarter hour trying to hail a cab, showering and dressing anew, I am a little later for my meeting than I had intended. But the shit storm that is national AIDS advocacy takes my mind off the depths I had sunk to just hours ago.

My T-cells went up 100% the first month, my viral load down to 1,000. My energy and then some has returned, and yesterday, at 7:48 a.m., I completed my first triathlon, swimming a half mile, biking twelve and running three along the beautiful Chicago lakefront with hundreds of other lovely gay men and women from all over the world.

I treated myself to some cute new under things while I was still in D.C. The light tan, slightly snug Capri Culottes washed up just fine.

Looking into the Future of Antiretroviral Regimens

An educated speculation

by Daniel S. Berger, M.D.

We do not have a crystal ball. And most of us have not been given the skills of Johnny Smith, who after a near-fatal car crash leaving him in a deep coma in the Dead Zone, regained consciousness with the discovery that he had the ability to predict the future by touching an individual or a possession. These amazing psychic powers are not common among medical doctors, but based on an insider's view and experience in research, one can try to provide educated speculation in predicting the future of antiviral treatment.

Being involved in conducting research does have its perks. Physically observing patients on investigational compounds while studying preclinical data of proof-of-principle and Phase I studies can often be an eye-opening and inspirational experience, not to leave out fascinating. It makes coming to work sometimes better than watching *Deep Space Nine* or *House*.

While peering ahead into the future of HIV treatment, the next three to five years will incorporate new classes of drugs that are presently being studied. Taking into account toxicities and impracticalities of existing medications still in use, one can easily see substitutions in the making. This article is not meant to be gospel nor a treatise on virology, but rather speculation serving as an appetizer for what is to come. Let's start with discussing the less useful medications; this is going to be a harsh reality for some to digest and a completely different scene from what some in the industry would like to hear. We will then move on to bandying about newer agents or constructing treatment cocktails of the not-so-distant future.

Shifting tides in medication usage

As we learn more about existing meds, coupled with the emergence of better treatments, there should be a natural tendency for thoughtful HIV specialists to consider different preferences as they become available. This is the natural progression.

Nucleosides, historically the oldest class of antivirals, have been used as a backbone and are combined with more potent protease or non-nuke reverse transcriptase inhibitor (NNRTI) drugs. However, nucleosides do bear some of the greatest toxicities, including lipoatrophy (fat loss in the face, buttocks, legs, and arms), lactic acidosis, neuropathy, anemia, and a host of constitutional symptoms.

As newer, safer, and more potent agents become approved, it has become clear that drugs such as Zerit (d4T) are moving towards extinction (if not already there). Additionally, we now understand that combining Videx-EC (ddI) together with Viread (tenofovir) or Truvada for certain regimens are a concern: T-cell decreases have been described in several studies. There will be less use of ddI, and truthfully it has its own additional baggage. Finally, one needs to mention study GS-934, in which AZT was essentially compared to Viread (Combivir vs. Truvada). AZT has been shown to be associated with more lipodystrophy (body habitus changes) and constitutional symptoms and anemia.

Thus, in the nucleoside class we are generally left with more favored combination agents such as Truvada (Viread/Emtriva) and Epzicom (Ziagen/Epivir) or their individual components. With better formulations and upcoming agents discussed later in this article, the older treatments associated with various problems begin disappearing from the treatment map.

Scrutinizing the entire class of approved protease inhibitors, at first glance it appears there are many drugs, but from the standpoint of resistance there may not be as many. The older agents have cross-resistance and difficult side effects. One only needs to remember full-dose Norvir (ritonavir) or its liquid formulation. For those of you who weren't unfortunate enough to experience it, taking liquid Norvir was akin to drinking a mixture of gasoline fluid and Drano. Also recall the frequent kidney stones observed with the once ever popular full-dose (unboosted) Crixivan (indinavir).

Thus, with all fairness, Invirase (saquinavir), Crixivan, and Viracept (nelfinavir) will not have much of a presence in the future. While the antiviral efficacy of Kaletra continues to be well proven, in the experience of many clinicians, its problems with lipids, or elevated blood fat (cholesterol and triglycerides), lipodystrophy, and diarrhea are issues that are not going away for many patients. Moreover, some patients have not experienced the purported change in toilet schedules that was expected with the new formulated tablets. Consequently, several newer alternatives such as Reyataz (atazanavir), Lexiva (fos-amprenavir), and Prezista (darunavir) are promising choices that provide inroads for reducing complications and side effects for some individuals.

Reyataz is important as a once-daily protease inhibitor, without significant elevated lipids. Lexiva has been better tolerated with less diarrhea for some patients and may prove to be equally as effective as Kaletra (KLEAN Study). Prezista (see page 13) has an outstanding and unprecedented efficacy and tolerability that was observed in experienced patients with high degrees of resistance to other antivirals. Other Prezista studies are still pending, including one

in treatment-naïve patients with once-daily dosing and another comparing it to Kaletra. These newer alternatives to the older medications appear more patient friendly and put some older protease inhibitors into the no-fly zone.

Last year Aptivus (tipranavir) became approved and was developed for treatment of patients with resistance to other protease inhibitors. Unfortunately, Aptivus requires a doubling of the standard Norvir boosting dose. Also, there have been concerns with liver toxicity and more recent reports of intracranial hemorrhage. With the approval of Prezista being significantly superior, not to mention the upcoming integrase inhibitors, Aptivus will become less used by clinicians for first salvage.

Interestingly, a pharmaceutical company has taken up the challenge in attempting to develop a Norvir alternative for protease inhibitor boosting. One hears whispers that Tibotec has a candidate compound which, if successful, may be a cost-cutting, safer alternative that eventually replaces Norvir. Norvir's astonishing price increase (not forgotten) combined with associated elevated blood lipids (cholesterol and triglycerides) has served as a good motivating factor for this line of research.

Fuzeon, the first drug developed to block HIV's ability to fuse onto T-cells, has been an important step in providing multiclass resistant patients with an alternative for treatment (TORO I & II, RESIST, and TMC114-C202). From a practical standpoint, however, it's a drawback to have patients be required to self inject themselves twice daily. Also, its cost stands out as the most expensive antiviral on the market, making it an easy target for searching for alternatives. Currently there are other classes of drugs, as well as new entry inhibitors in development, orally administered and one with intravenous application, that may each replace Fuzeon.

Cocktails of the future

This next section is based on the definite trend to expand diversity and efficacy of HIV treatment. Two integrase inhibitors rapidly developing are MK0518 and GS-9137. There are also new non-nukes, TMC-125 (etravirine) and TMC-278, the entry inhibitor maraviroc (as well as another CCR5 antagonist, vicriviroc), the maturation inhibitor PA-457, and several other compounds for a list too long to provide here. If these all become available, there will be much to conjecture about the future of antiviral therapy.

Naturally, one does not yet know all possible drug interactions or the complete efficacy and safety of many new candidate treatments, but if one were to design the optimal cocktail, one could potentially conceive of several superpower regimens. A particular regimen may involve one boosted integrase inhibitor (GS-9137 at once-daily dosing) plus a once-daily co-boosted protease inhibitor (Reyataz or Prezista), and perhaps an entry inhibitor administered once every two weeks intravenously in the clinic (TNX-355). Or substitute TNX-355 with either Truvada, Epzicom, or a maturation inhibitor or maraviroc. These are but a few examples.

Integrase inhibitors utilize a new antiviral enzyme target and are moving quickly in development; they block HIV's ability to integrate itself into the human cell's DNA (genetic protein). At Northstar Healthcare in Chicago, we are currently conducting trials with the two lead agents in development. We learned only a few years ago that boosting blood levels of protease inhibitors was a major advance in treatment because it builds a pharmacokinetic wall opposing viral resistance. If the model of boosting holds true with integrase inhibitors, GS-9137 may demonstrate similar durability and efficacy.

For those individuals intolerant of Norvir, MK-0518 used with TMC-125 or TMC-278 and perhaps an entry inhibitor are also a possibility.

Also, one knows that the 2-log drop in viral loads observed early in Phase II for both integrase inhibitor candidates, GS-9137 and MK-0518, shows very strong potency. With multiple agents having similar effect, we can design superior cocktails with each antiviral being more potent than the last. Thus, one could expect that those antivirals providing only .5 to 1 log drop in HIV RNA eventually become un-preferred.

TMC-278 is a new potent non-nuke that may be effective against previous non-nucleoside RT resistance. Currently in Phase II, it is a very small or tiny-dosed medication that has the potential of being easily combined with many different antivirals, including Truvada, Epzicom, or Prezista. Just as Truvada and Sustiva became formulated into one Atripla pill (see page 13), one hopes that other pharmaceutical companies follow this lead and spur the development of other easily administered regimens. The single pill, once-daily Atripla, can be implemented as a complete cocktail for some patients. Consider combining TMC-278 with other treatments. While optimal dosing has not been finalized, the possibilities of combinations with a maturation inhibitor (PA-457), an integrase inhibitor, or another protease inhibitor are tantalizing and not to be scoffed at.

Finally, consider TNX-355, an entry inhibitor which is being studied and administered in clinical trials intravenously once every two weeks. If this treatment makes it through all the hoops to approval, what will we be combining it with? Could other treatments be administered less frequently, such as another fusion inhibitor? TNX-355 contains genetically engineered antibodies, known as monoclonal antibodies, that bind to the CD4 receptor on T-cells, preventing the virus from infecting healthy cells.

Conclusion

Articles in this column usually deal with fact, backed up by studies and experience. But the aim of this article is not about stating facts or predicting "how it will be." One hopes that the ideals and futuristic treatment speculated on here provide for interesting discussion about the long-term outlook. Inspiration and spring-boards are hope for a better quality-of-life and the intent of this commentary. Notice that "cure" is never mentioned. Many older and familiar HIV medications once used or sometimes still current do not always fit the equations modeled here. It is impractical for pharmaceutical companies or physicians to expect the continuous re-cycling of medications to infinity. New targets and better, more effective treatments are steadily budding so that many HIV-positive individuals can hope to live long, productive lives.

Daniel S. Berger, MD, is Medical Director and full-time practitioner at NorthStar Healthcare, in Chicago.

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