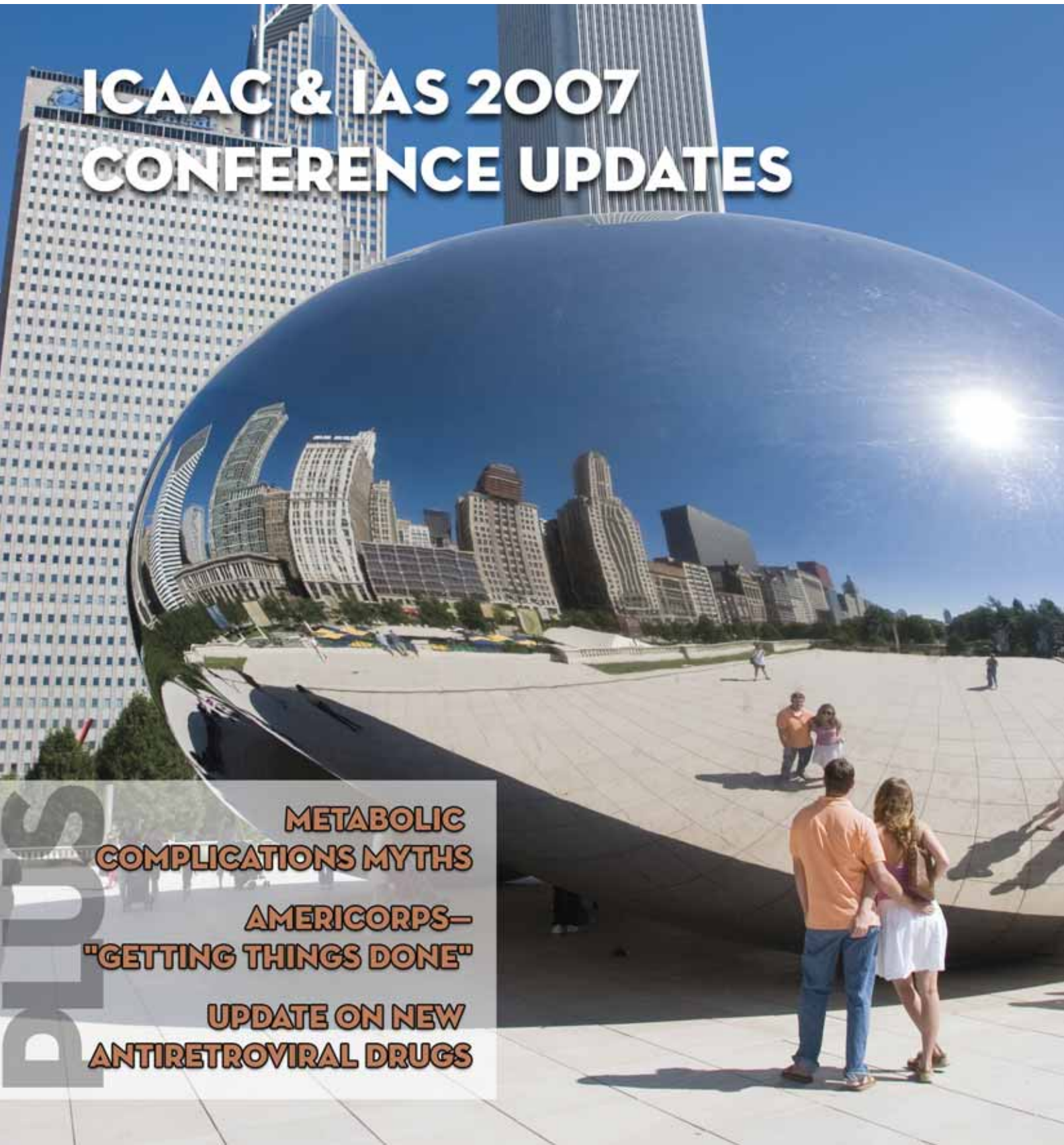
November / December 2007

Positively Aware

The Journal of Test Positive Aware Network



ICAAC & IAS 2007 CONFERENCE UPDATES

PLUS

METABOLIC COMPLICATIONS MYTHS

AMERICORPS– "GETTING THINGS DONE"

UPDATE ON NEW ANTIRETROVIRAL DRUGS

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

You control your life. Take an

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 ATRIPLA™, VIREAD®, EMTRIVA®, Combivir®, Epivir®, Epivir-HBV®, Epzicom™, or Trizivir®.**

USE OF TRUVADA:

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

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

GILEAD

active role in your HIV treatment.

Ask your doctor about TRUVADA® taken once 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

TRUVADA is the #1 Prescribed HIV Med*

- 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. **Please see Patient Information on the next page.**

*Based on data from PHAST retail monthly data, April 2006–February 2007, 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** (build up of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital. **Call your healthcare provider right away if you get the following signs or symptoms of lactic acidosis.**
  - You feel very weak or tired.
  - You have unusual (not normal) muscle pain.
  - You have trouble breathing.
  - You have stomach pain with nausea and vomiting.
  - You feel cold, especially in your arms and legs.
  - You feel dizzy or lightheaded.
  - You have a fast or irregular heartbeat.
- **Some people who have taken medicines like TRUVADA have developed serious liver problems called hepatotoxicity,** with liver enlargement (hepatomegaly) and fat in the liver (steatosis). **Call your healthcare provider right away if you get the following signs or symptoms of liver problems.**
  - Your skin or the white part of your eyes turns yellow (jaundice).
  - Your urine turns dark.
  - Your bowel movements (stools) turn light in color.
  - You don't feel like eating food for several days or longer.
  - You feel sick to your stomach (nausea).
  - You have lower stomach area (abdominal) pain.
- **You may be more likely to get lactic acidosis or liver problems** if you are female, very overweight (obese), or have been taking nucleoside analog medicines, like TRUVADA, for a long time.
- **If you are also infected with the Hepatitis B Virus (HBV),** you need close medical follow-up for several months after stopping treatment with TRUVADA. Follow-up includes medical exams and blood tests to check for HBV that could be getting worse. **Patients with Hepatitis B Virus infection, who take TRUVADA and then stop it, may get "flare-ups" of their hepatitis. A "flare-up" is when the disease suddenly returns in a worse way than before.**

What is TRUVADA?

TRUVADA is a type of medicine called an HIV (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.
- Do not take TRUVADA if you are already taking ATRIPLA™, Combivir (lamivudine/zidovudine), EMTRIVA, Epivir or Epivir-HBV (lamivudine), Epzicom (abacavir sulfate/lamivudine), Trizivir (abacavir sulfate/lamivudine/zidovudine), or VIREAD because these medicines contain the same or similar active 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:

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

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

How should I take TRUVADA?

- Take TRUVADA exactly as your healthcare provider prescribed it. Follow the directions from your healthcare provider, exactly as written on the label.
- The usual dose of TRUVADA is 1 tablet once a day. TRUVADA is always used with other anti-HIV 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 does not stop you from passing the HIV infection to others.
  - **Do not share needles or other injection equipment.**
  - **Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.**
  - **Do not have any kind of sex without protection.** Always practice safer sex by using a latex or polyurethane condom or other barrier to reduce the chance of sexual contact with semen, vaginal secretions, or blood.
- ATRIPLA, Combivir (lamivudine/zidovudine), EMTRIVA, Epivir or Epivir-HBV (lamivudine), Epzicom (abacavir sulfate/lamivudine), Trizivir (abacavir sulfate/lamivudine/zidovudine), 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 approved 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 effect 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, 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 TRUVADA at room temperature 77 °F (25 °C).
- Keep TRUVADA in its original container and keep the container tightly closed.
- Do not keep medicine that is out of date or that you no longer need. If you throw any medicines away make sure that children will not find them.

General information about TRUVADA:

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

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

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

What are the ingredients of TRUVADA?

Active Ingredients: emtricitabine and tenofovir disoproxil fumarate

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

℞ Only

May 2007

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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 www.tpan.com

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Volume 18 Number 6

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All photos of IAS 2007 Conference courtesy of International AIDS Society

Articles

47th ICAAC—Chicago Conference Update

IAS 2007—Sydney Conference Update

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

Programs and Meetings

Programs and Meetings at TPAN

- Support Groups
- Rapid HIV Testing
- Yoga, Reiki and Massage
- Needle Exchange Program
- Buddy Program
- Access Medical Clinic at TPAN
- PULSE, an HIV-positive Weekly Social
- TEAM (Treatment Education Advocacy Management)
- Positively Aware Party at Hydrate
- SMART Sex—Prevention and Outreach Program
- TRADE (Teachin', Reachin', Advocatin', Demonstratin', Empowerin')— Prevention and Outreach Program
- Monthly Educational Forums and Trainings

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

TPAN Events

TPAN Events Calendar

- Chicago Takes Off, Sat., Feb. 9th, 2008 (See ad page 21)
- Ride for AIDS, June 7–8, 2008, visit www.rideforAIDS.org
- Other Special Events

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

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In My Own World AIDS

During a recent trip to San Francisco, I had the opportunity to visit the National AIDS Memorial Grove in Golden Gate Park. My partner and I rented bikes, and spent several hours riding through the park. It was a perfect day, and in addition to the bike ride, we walked through the rose garden, sat by the lake, and took in the sights. We stopped at Ocean Beach, ate lunch, and on our way back, we happened upon the Grove.

The Grove is situated in a beautiful section of the park known as de Laveaga Dell, which had once fallen into a state of disrepair. According to their website, it was "conceived in 1989 by a small group of San Francisco residents representing a community devastated by the AIDS epidemic, but with no positive way to express their collective grief. They envisioned a serene place where people would come alone or in groups to hold memorial services, to remember among the rhododendrons and redwoods. It was to be a place dedicated to all lives touched by AIDS."

In 1996, Congress and President Clinton passed the National AIDS Memorial Grove Act, marking it as the first national AIDS memorial. It is a place for people to remember, to grieve, and to honor those whose lives have been touched by HIV/AIDS, without fear of stigma or reprisal.

I peered over the tops of the trees, and down into the dell. I was caught off guard as tears began to suddenly well up in my eyes, and I briefly reminisced about a few of my friends who I have lost to this disease.

I thought of my friend Eugene. His dreams of becoming a dancer were cut short by AIDS. I remember his wide grin, his salty humor—even his voice, which to this day I can still hear, clear as a bell. I wondered why I didn't make more of an effort to go visit him after he became really sick.

I thought of my friend Ian. It was the 1980's, and it was one of the last times I visited him in the hospital. I remember he was sitting up in bed, his body riddled with KS lesions. He had by that time become bitter and angry, and rightfully so— back then there were virtually no treatments that might have helped him. Feeling helpless, in my infinite wisdom, along with my unique sense of timing, I suggested he might want to borrow one of my Louise Hays books. I was startled when he snapped back that he "didn't believe in that *crap*."

I thought of my friend Carl. There couldn't have been a sweeter guy than Carl. Always soft-spoken, he could at once charm you and put you at ease with his sexy, southern, Kentucky drawl. He never had a bad word to say about anybody, not that I recall anyway. Why did he have to die so young?

I thought of my friend Larry. Larry was a gifted, dedicated and hardworking individual, who came to TPAN as a volunteer in the agency's resource center. Although he suffered from constant pain due to his neuropathy, he rarely complained about it. He insisted that he never once had unprotected anal sex, and was adamant that he had gotten HIV through oral sex. He was estranged from his family, and died in a hospice not far from my house, alone. I had left his side only hours earlier.

I thought of my friend Lou. Lulu was a dear friend, and my mentor. He taught me pretty much everything I know about music, deejaying and working a crowd. I moved to Chicago because he had offered me a job. By the time he developed AIDS, I was one of only two people he would allow to come to his home to visit and care for him. He shut himself off from his entire circle of friends, for whatever reason—fear, stigma, stubbornness. He came to me in a dream the other night, and he looked healthy, whole and happy. I guess he wanted me to be sure I knew he was all right.

So many more friends, and yet there was so little time to reflect upon them all. It was getting late, and we had to get back to the hotel and pack our bags. While we could not stay at the Grove for very long, I left feeling a sense of renewal, and vowed to revisit the Grove the next time I was in San Francisco.

I am proud to live in a country where there is such a beautiful, living memorial, a safe space where we can pay tribute to those who we've lost to HIV/AIDS. I only wish I could have had more time.

Take care of yourself, and each other.

Jeff Berry
Editor
publications@tpan.com

To learn more about the Grove, visit www.aidsmemorial.org.

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.

Write to: *Positively Aware*,
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E-mail: readersforum@tpan.com

Don't Miss Out!

PA E-mail Updates

Sign-up today for our new *Positively Aware* e-mail newsletter and receive timely updates on up-to-date HIV treatment news and information.

Visit www.tpan.com and click on Subscribe to TPAN E-mail Updates, enter your e-mail address and click submit. Once you recieve a confirmation e-mail, you can update your TPAN profile to include "*Positively Aware* Updates."

HIV 101

I have had a subscription to *Positively Aware* for over 10 years. I share it with clients and volunteers and have found it very useful. The September/October issue, "Everything you always wanted to know about HIV," is outstanding and I know will be very useful for my new volunteers and those recently diagnosed.

Marge Mazza Schumann, Director,
HIV/AIDS Ministry, Catholic Charities,
Stevens Point, WI

Sero-sorting

In Jack Degnan's excellent article in the September/October issue of *Positively Aware*, he refers to "sero-sorting" as a prevention method. I am not clear just what this term means. Could you clear this up? Thanks.

Brian McNamara, Marlborough, MA

Editor's note: Sero-sorting is a term that refers to the practice of choosing one's sexual partners based on their HIV status, generally used as a prevention tool. For instance, an HIV-positive individual may choose to have sex with only other HIV-positive partners, while an HIV-negative person may choose only negative partners. However, it is by no means a fool-proof method for those who are negative to stay that way. There is a window period of up to six months after an unsafe encounter before antibodies to HIV may show up in a blood test.

Could you let Jack know I really enjoyed his piece on serosorting? It was a nice combination of personal feelings and information. I wrote a similar piece in *ACRIA Update's* Summer issue, so I know how he feels. See www.acria.org/treatment/treatment_edu_summerupdate2007_ub2.html. If enough of us keep speaking, maybe the word will finally get out!

Mark Milano, New York City, via the Internet

Remembering Chris Clason

TPAN produced a short video for the recent 20th anniversary celebration and as a result, we heard from a long-ago member who saw it through his work with the AIDS Treatment Activists Coalition (ATAC). The "guy named Chris" he refers to was our founder, Chris Clason. I just think it's a testament to his work, and to the work that we all do. Chris Clason passed away in 1991, but his work lives on. Among other things, it was his mimeographed and photocopied newsletter that became Positively Aware, *and the vital support groups continue to be strong.—JB*

When I lived in Madison, in the late 80's (1987 maybe) right before I started treatment and when Madison did not have a good support group—or access to the support group was guarded by the case manager from the local start-up ASO [AIDS service organization]—I drove down to Chicago a few times and met with the guy who started TPAN and several others. We were all in "it's a time to revolt" mood because we felt the larger ASOs viewed us as a commodity they owned and did not give us access to leadership roles or even a say in the services they delivered. We felt we were supposed to get sick and die with beatific smiles of gratitude as our "buddies" guided us to the light; maybe provide a photo op or two also. I think this guy's name was Chris, and I liked him, and I hope he was part of your 20-year anniversary.

Pat, via the Internet

November / December 2007
PA Online Poll

Do you plan to do anything special this year in commemoration of World AIDS Day?

Give your answer at www.tpan.com

Living With(out) Crystal Meth

I just found this article online [July/August 2005] and was very moved by it. My son is a crystal meth addict, and his story is so much like Eddie Young's. He actually entered treatment at Pride Institute in Eden Prairie, Minnesota, July 3 of last year; after four relapses and several short stays in treatment again, he was finally approved by insurance for 60 days of Extended Care. He has now been sober for almost 5 ½ months. Apparently Pride Institute is one of the very, very few drug and alcohol treatment centers for the GLBT community, and I applaud them for their work. This is a fierce illness, and crystal meth has gripped that community with a death grip, but it can't win. Truth, love, recovery—those are all stronger than this drug. My son calls quite often and tells me about the meetings he attends as well as the importance of his sponsor in his recovery. He is working full time again and is getting back on top of his finances. Eddie's story is typical as well as unique. I know that each person has a story, a history, a sadness, and of course happiness too. Sometimes the joy has been forgotten and left behind, but it's still there, waiting to be found again. The most important thing is to believe, really believe, that recovery *will* happen. Eddie's story helps in that regard, and I see in my own son's story that even though it is the hardest work he's ever done, he really wants to do it for the result he's seeing. He's back into life again, and in life, there is joy. I urge families, loved ones, friends to get their own help as they try to help the addicts in their lives recover. It's only when we realize ways in which we may have unconsciously contributed (enabling behavior, you know) to the continuation of this disease that we can let go of our feeble attempts to "control" or "fix" our loved one and begin our own path to recovery. And from our experience, our recovery has helped our son to gain control over his own life and stop using excuses. Thank you for publishing the story online.

Jan, Vermont, via the Internet

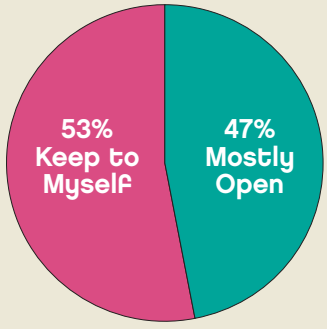
Losing a loved one

I've been reading *Positively Aware* for several years now and have wanted to write several times. The editor's note from September/October 2006, "Who Will be There for Us?" was timely and so well written. Many thanks to Jeff Berry for writing such a powerful and sensitive piece. The paragraph that really got me was: "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." Yours was a wonderful note—the universal theme of losing a loved one. I've re-read your story multiple times as well, partly for my connection with my mother and Claudia (my birth mother—I was adopted) and my partner, who are all alive. I read your story knowing that there are difficult times ahead of me, and I ask myself if I have the strength to get through loss. I tell my mom and Claudia that I love them. I love my partner and support him in his decisions, even when some of them seem counter to being and staying healthy. I'm almost 40, HIV-negative, and fairly healthy—the hardest, yet most profoundly wonderful thing I have ever experienced was choosing into a relationship with a man who is HIV-positive. When it comes down to it, HIV is a non-issue—I love the man, regardless. Your words help me appreciate each and every day and not see life through a lens of loss or potential loss. I'm not always graceful about it, but at least I'm aware. Thanks again for being so brave and writing such strength through vulnerability.

Donavan, via the Internet

September / October 2007 PA Online Poll Results

Other than your sexual partners, are you mostly open about your HIV status, or is it something you keep to yourself?



September / October 2007 PA Online Poll comments

- The only place I won't disclose is in the workplace. My family and many of my close friends know of my status. Without their support, the trip with HIV would definitely have been a tougher one to handle. I am glad I disclosed!
- I tell everyone who needs to know.
- I live in a small town with narrow minds.
- I definitely analyze every relationship prior to disclosing my HIV status. My health issue is really my business.
- I am always open with any sexual encounter. I am also open with friends and family, but not casual acquaintances.
- My reason for sharing with others is because I want them to be aware that it can happen to them also.
- One way I deal with it is to be honest with people, and by telling them right off. It is a way I weed out the people I do not need in my life.

News Briefs

by Enid Vázquez

New HIV drug on the market, Selzentry

The U.S. Food and Drug Administration (FDA) in August granted accelerated approval for Selzentry (maraviroc). Selzentry is a CCR5 inhibitor (or antagonist). It blocks HIV from entering a CD4 immune cell by blocking a co-receptor called CCR5 that lies on the surface of some immune system cells. (See the *Positively Aware* Annual HIV Drug Guide in January/February for more information.) It is approved for people who've already taken HIV medications and who have detectable levels of HIV in their blood (viral load). A blood test called Trofile is needed before taking Selzentry, because Trofile helps determine whether a person has HIV that uses the CCR5 co-receptor.

The FDA reported that, "The product label includes a boxed warning about liver toxicity (hepatoxicity) and a statement in the Warnings/Precautions section about the possibility of heart attacks. …The most common adverse events reported with maraviroc were cough, fever, upper respiratory tract infections, rash, musculoskeletal symptoms, abdominal pain, and dizziness."

Unfortunately, excitement over the drug may be somewhat waning as questions over the measurement of CCR5-tropic virus and effects of CCR5 co-receptor blocking continue. In early 24-week data, about twice as many people taking Selzentry had undetectable viral load compared with those with optimized background therapy alone (number of individuals and viral load levels not given). Research continues, including further developments with the CCR5 test.

New HIV drug on the way, Isentress

An advisory panel to the U.S. Food and Drug Administration (FDA) in September recommended accelerated approval for a new HIV drug, Isentress (generic name raltegravir). Final FDA approval was expected in October, after *Positively Aware* went to press. (See also Get Sharp on page 12)

Isentress is an HIV integrase inhibitor, an entirely new class of medication to fight the virus. As such, it does not have cross-resistance with other HIV drugs already in the pharmacy.

But more importantly, Isentress has achieved tremendous stature in the eyes of treatment advocates for the results they have seen in people taking it during studies, and for the data produced by the research.

Like other new (or newer) antiviral drugs, Isentress was developed to help people on longtime HIV therapy who, for one reason or another, need a new treatment option. There are already several options for most people who are taking HIV medication for the first time. It's the people who've already been on therapy, especially those on antiviral treatment for a long time or who've used multiple drug combinations, who need a new drug the most. They are more likely to have drug complications requiring a change; have developed resistance patterns to the medications; and developed treatment fatigue that negatively affects their ability to take medication, among other difficulties. Isentress was studied in people whose HIV has already developed resistance to three HIV drug classes.

In testimony before the FDA panel hearing, TPAN Director of Education and Advocacy Matt Sharp said, "I added Prezista and Truvada to raltegravir in the EAP [Expanded Access Program]. I achieved an undetectable viral load in less than two weeks and have experienced almost a doubling of CD4 cells, maintained now for almost a year. It appears my immune system is gaining ground as my T-cells are higher than they have been in 16 years… and recalcitrant cutaneous warts have started to literally dry up and fall off."

For more information, see also the Annual HIV Drug Guide (January/February).

AAHIVM selects new executive director

The American Academy of HIV Medicine (AAHIVM) in September selected a new executive director, James M. Friedman, a former longtime official with the U.S. Department of Health and Human Services (DHHS). Among its many good works, the Academy partners with TPAN and *Positively Aware* to answer questions from people with HIV (see Ask the HIV Specialist on page 14). The Academy, based in Washington, D.C., is an independent organization of HIV medical providers dedicated to advancing excellence in HIV/AIDS care. Through advocacy and education, AAHIVM is committed to supporting HIV clinicians and to ensuring better care for those living with HIV disease.

Friedman was with DHHS from 1973-1996, serving as Deputy Assistant Secretary for Health Planning and Evaluation (acting) as well as Deputy Director of that office. More recently, Friedman headed the health team at Hill & Knowlton Public Affairs in Washington, D.C. and served as Deputy Executive Director of The Alliance for Aging Research, a not-for-profit education and advocacy organization. He is married and has two adult children.

Vaccine bites the dust

In mid-September, Merck and Co., Inc. and the HIV Vaccine Trials Network (HVTN) announced that vaccination in a phase 2

Photo © Russell McGonagle

study of Merck's experimental HIV vaccine is being discontinued. A scheduled interim efficacy analysis of the study found it to be ineffective at preventing new HIV infection and at reducing the amount of virus in those who became infected.

The trial, known as STEP, was an international "test of concept" trial involving 3,000 uninfected volunteers in Australia, the Americas and the Caribbean who are at high risk for acquiring HIV. Enrollment and vaccination in another phase 2 study of the vaccine that was being conducted in South Africa, known as Phambili, and two additional phase 1 trials have also been discontinued.

"This is a huge disappointment for all of us who have been involved in the search for an HIV vaccine," said Glenda Gray, M.D., principal investigator of the HVTN-sponsored Phambili trial. "HIV is ravaging our communities, and all the scientists, participants and communities involved in HIV vaccine studies have been affected by this epidemic. The scientific community must continue the race to find a vaccine to help secure an HIV-free generation for the future."—*Keith R. Green*

Pregnancy category upgraded for Viramune

Viramune (nevirapine), an anti-HIV medication from a class of drugs known as non-nucleoside reverse transcriptase inhibitors (NNRTIs), was recently upgraded to be included in pregnancy Category B from Category C—making it the only NNRTI to achieve such status. Viramune is also the only NNRTI recommended by the U.S. Department of Health and Human Services for use in pregnant women.

Pregnancy category is one of many treatment considerations for discussion by HIV-positive women and their health care providers. Category titles range from Category A-D and Category X, with drugs in Category A considered to be the safest for pregnant women, and those in Category X considered to be completely dangerous and not recommended at all.

It is important to note, however, that life-threatening and fatal liver toxicity has occurred in patients taking Viramune, and that the drug is not recommended for women with CD4 counts with greater than 250 cells—the group considered to be at greatest risk for such toxicity. Therefore, it is still recommended that Viramune be used in this group only if the potential benefits justify the potential risks.—*KRG*

Mr. Sharp Goes to Washington

Advocating for a new drug before the FDA

by Matt Sharp

I was recently flown to Washington, D.C. by the AIDS Treatment Activists Coalition (ATAC) to present open public testimony at a Food and Drug Administration (FDA) hearing for the approval of Isentress (raltegravir), an integrase inhibitor, which is a new HIV drug class (see also News Briefs on page 10). This is the first integrase inhibitor that had reached this far in drug development and I was to be giving my own personal history about this drug to the FDA and Merck, the drug's maker, and an unbiased panel of experts. The purpose of the hearing was to scrutinize the available data and recommend or not recommend approval.

It wasn't like the testimonies you see before Congress on CNN, those distressed people pleading for some issue before the legislative twangs and glasses-hanging-off-noses, representing various constituencies from across the country. But I felt in somewhat of a twilight zone, amazed that so much history had passed since HIV drugs have been in development. At least for me, I felt passionate and sure about this new drug, and I was committed to telling my story.

I had testified in front of the FDA before, and had appeared on the "panel of experts" in the community role. But this was different as I was telling my story about a new HIV drug that was actually helping to keep me alive. I have come a very long way with this disease called AIDS and it was surreal that I was even alive to be there at all.

As an activist I also felt conflicted about this experience as I never want to appear as if I am "promoting" or favoring one drug over another. But this was different and I was happy to tell my story in order that others could share my experience, and hopefully support the panel in a favorable vote to approve the drug.

This new drug was the first in a long time to work to bring treatment-experienced people to undetectable and out of the woods, especially if they added another new drug they had not used before.

For about three hours the FDA Antiviral Advisory committee grilled Merck about particular points as the myriad of study data was presented. The company rebutted with a repertoire of over a thousand slides at their disposal, confidently poised and answering in the shortest responses possible.

Clearly the clinical trial data for this new drug spoke for itself and it was clear that the road was paved for approval. At that point I wasn't sure what my testimony would add to the day. This new drug was the first in a long time to work to bring treatment-experienced people to undetectable and out of the woods, especially if they added another new drug they had not used before. It is the highlight of a new treatment phenomenon in HIV.

There were no clear safety issues and few drugs that would interact with Isentress. In speaking on behalf of this drug, knowing that I had remained undetectable for over a year on it—for the first time in 20 years living with HIV—I felt no qualms about its approval, and knew that my story would bring a personal affect to the hearing, a face to the story, a period at the end of a sentence.

I was given a place to sit in front of the general audience for the "open public hearing," where I was allowed two minutes to give a five-minute speech I had prepared a few weeks beforehand. When the time came I was nervous, despite the fact that public speaking is my specialty. Speaking about myself, in front of scientists and government officials, cameras and even reporters, especially for the approval of a drug that will hopefully save thousands with few options, was a bit intimidating. My mouth was dry, and I couldn't catch my breath. I had my reading glasses on to see the written speech but that prevented me from seeing the audience. I was looking at a bunch of bureaucratic blurs.

I finished in my time allotment without the federal officer hauling me off the microphone and felt relieved once again that I could do my two cents to help save a few lives. It was a relief knowing my point had been made.

The vivid evidence that this new drug was one of the brightest lights in the last several years of HIV drug development was just too compelling for the panel. Despite some issues about the final wording on the indication, and some valid concerns around malignancies reported early on in the studies, the panel voted unanimously to approve.

I had followed the development of Isentress since before it even had a name. I waited for access knowing I needed this new drug, and I anticipated success like so many times before when the drugs ended up failing. Speaking in Washington to simply tell it like it is was icing on the cake, because after all these years of struggling to survive I was actually a part of the success.

See, advocacy is not that hard at all.

Photo © Russell McGonagle

AAHIVM HIV SPECIALIST™

Ask the HIV Specialist™

This month's Specialist

Craig Hutchinson, M.D., AAHIVS, Correctional Medical Services, East Lansing, MI

Dr. Hutchinson is an internist and infectious diseases physician who has been providing care—including HIV care—to prisoners of the Michigan Department of Corrections for eight years. Visit www.aahivm.org.

Megace, hep C in prison

I am a 32-year-old inmate in Texas. I am HIV-positive and HCV-positive. As you can imagine, medical information that is accurate is hard to come by in here. I have two questions.

One, I've been HIV-positive for 14 years and am currently on Atripla, doing well. Due to difficulty gaining and maintaining weight, I've been placed on megestrol (Megace) 40 mg twice a day, as an appetite stimulant. I am aware that this is a progesterone and am wondering how long I can take this safely?

Two, I underwent interferon treatment in 2004 and did well to "clear" it from my system. I am genotype 3. I am wondering if it is possible to be re-infected with a different genotype?

Michael, Dallas, TX

Treatment of men with HIV-associated decreased appetite with megestrol has been associated with reduced testosterone. Additionally, most of the weight gain is fat. This and the expense of this medication has made it less popular. Testosterone deficiency itself is a significant cause of being underweight in men with HIV. In general, it is best to identify and correct the specific cause for the loss of appetite or weight.

Infection with more than one genotype of hepatitis C is rare but has been reported. Infection with different genotypes, one after the other, has also been reported in a few children who received multiple transfusions before the careful testing of the blood supply was begun. Even though this is unusual, you should still be very careful to avoid exposing yourself to any blood-borne infections.

Chewing tobacco

I was standing with this person who was chewing tobacco. While talking he spit and some of it went into my eye, about the size of a rice grain. I almost immediately wiped my eye from outside with a cloth and found a tiny browninsh spot. I have heard that these guys often have bleeding gums and assuming that his spit contained saliva mixed with blood, is it capable of transmitting HIV? Although there was no burning sensation and I washed my eye thoroughly after 15 minutes, I am getting stressed out thinking about the possibility of HIV.

Karl, Greenbelt, MD

According to the U.S. Centers for Disease Control and Prevention (CDC), "HIV has been found in the saliva and tears of some persons living with HIV, but in very low quantities. It is important to understand that finding a small amount of HIV in a body fluid does not necessarily mean that HIV can be transmitted by that body fluid. HIV has not been recovered from the sweat of HIV-infected persons. Contact with saliva, tears, or sweat has never been shown to result in transmission of HIV."

Saliva without obvious blood is saliva, so you don't need to be concerned about bleeding gums unless you actually saw the blood.

Hep C treatment side effects

Does hepatitis C treatment with interferon or ribavirin damage the immune system? Many of the people I know who have done the treatment experienced big drops in their CD4 counts. This seems to indicate that it could be very dangerous for persons with HIV. Have there been any studies on this?

Also, how harmful are antibiotics to the immune system?

Joe, Oakland, CA

Treatment of hepatitis C with pegylated or standard interferons usually causes a drop in the CD4 counts of patients with HIV co-infection. Because of this, and also because the hepatitis C treatment does not work as well with CD4 counts below 300-400, it is best to start the hepatitis C treatment with the CD4 as high as possible. Sometimes that means treating the HIV first, until the CD4 peaks, before beginning hepatitis C treatment.

Certain HIV medication combinations can be used along with the hepatitis C treatment in some patients. My preference is to avoid this if possible, but sometimes the CD4 drops enough that I have to use the HIV medications during the hepatitis C treatment. It is important to follow the CD4 count and percentage closely during the hepatitis treatment.

Most antibiotics do not damage the immune system. However, your body's defenses against misbehaving microbes go beyond the immune system. Antibiotics can change the balance among the many types of microbes on your skin as well as in your mouth and gut. This can allow overgrowth and even toxin production by microbes that are usually kept in check by competition and by the immune system. A common example is the yeast (fungus) infection in the mouth or vagina that occasionally occurs in people with normal immunity when they take an antibacterial antibiotic. In addition to killing the bacteria it was prescribed for, it can kill many other harmless bacteria that normally compete with the yeasts. On your body, just like in any marketplace, a monopoly is a bad thing.

ICAAC Update

From the 47th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), held in Chicago in September

by Enid Vázquez

One year of Isentress

After one year on Isentress (formerly known as MK-0518), 54% of study participants taking it had less than 50 viral load, compared to 9% of the people taking a placebo (dummy pill).

All participants started the study with more than 5,000 viral load, with half of them having more than 50,000 viral load. All had HIV that was drug-resistant to at least three classes of antiviral medication. They had an average of nine years on HIV therapy.

This study of 178 individuals tested three doses of Isentress against placebo, all in combination with optimized background therapy (OBT), the best drug combination that could be put together for them. Halfway through the study, everyone—including the placebo group—was put on 400 mg of Isentress twice a day. The researchers concluded that, "In patients with limited treatment options, MK-0518 at all doses had potent and durable antiretroviral effect through week 48, and was generally well tolerated."

Does Selzentry change HIV?

Looking at results with almost 800 individuals in studies of Selzentry (maraviroc), Pfizer company researchers concluded that persons for whom the drug stops working may experience reversible suppression of CCR5-tropic viruses.

Selzentry is FDA approved for use in people with CCR5-tropic HIV. CCR5 is a protein on some cells that HIV uses to enter the cell and infect it. There is another protein, however, that HIV can also use, CXCR4. People with CXCR4-tropic HIV generally have more advanced disease. Thus there is concern that by suppressing CCR5 virus, CXCR4 virus can emerge and even dominate. The results of this study, therefore, are welcome news. They indicate that the more gentle CCR5 virus can come back if treatment with Selzentry fails.

Moreover, T-cell increases were higher in the people taking Selzentry compared to the control group even when there was emergence of CXCR4 virus. The researchers also reported that CXCR4-using virus was not associated with Category C events.

TMC-125

Drug resistance information was presented for the still-experimental but coming soon non-nucleoside drug TMC-125 (it's in the same class of drug as Sustiva and Viramune). Thirteen genetic mutations in HIV were associated with a smaller chance that TMC-125 (etravirine) would work, along with other non-nucleoside mutations. (Mutations are changes in a person's HIV that makes a drug less likely to be effective.) People with three or more mutations in their virus had the least success with therapy. This group made up 15% of the people taking TMC-125. The presentation combined 24-week results from the DUET-1 and DUET-2 studies, with more than 1,200 participants altogether.

The rash associated with TMC-125 occurred in 17% of people taking it, was usually Grade 1 or 2 (meaning mild), began within two weeks, went away while treatment continued, and was limited to the skin, not to other organs. It was found to be more common in women.

A year of Selzentry

After a year on Selzentry (maraviroc) along with an optimized background regimen, more than half of the people on therapy had less than 400 viral load (undetectable), compared to 22% of the people taking only placebo (dummy pill) plus optimized therapy.

Results are from the MOTIVATE-1 study, which tested once-a-day and twice-a-day Selzentry in people who were highly treatment experienced and whose HIV had extensive drug resistance. They all had more than 5,000 viral load. The presentation reported that treatment safety was about the same for all three groups in the study. At ICAAC, presenter Jay Lalezari, M.D., reported that those people taking Fuzeon for the first time had an added benefit from their therapy.

Prezista vs. Kaletra

Kaletra is one of those drugs to beat, and the newer Prezista is no wallflower. But is it as good as Kaletra? A two-year study comparing the two, called ARTEMIS, provided results from one year.

Prezista boosted with Norvir was found to be non-inferior to Kaletra. In people taking therapy for the first time, 84% of the boosted Prezista folks had less than 50 viral load (undetectable on an ultra-sensitive test) compared with 78% of those on Kaletra. Presenter Edwin DeJesus, M.D., reported, however, that a different analysis could not find that Prezista was superior. Still, not bad results for Prezista at all, especially when you consider the notorious Kaletra gastrointestinal (GI) side effects, like diarrhea. Both the tablet form of Kaletra as well as the older capsule formula were used.

Almost half of the people on Kaletra experienced GI effects (47%), compared with 23% (almost one in four) of the people taking Prezista. The Prezista group also had fewer lipid elevations, another side effect associated with Kaletra (as well as other of the HIV protease inhibitor drugs).

The report also noted that people who started therapy with more than 100,000 viral load or less than 200 CD4 T-cells did better on Prezista. Everyone in this study (about 700 participants) received Truvada in addition to their Kaletra or Prezista. (See also IAS report on page 16.)

For more information, visit www.icaac.org, www.thebody.com, and www.clinicaloptions.com.

Updates from IAS

News from the International AIDS Conference

by Jeff Berry

Positively Aware magazine first reported on the 4th IAS Conference on HIV Pathogenesis, Treatment and Prevention in our last issue (see News Briefs, September/October). In our following continuing coverage we take a look at further important findings from the conference, which took place over four days in Sydney, Australia, in late July. For additional information visit www.ias2007.org, www.kaisernetwork.org/ias2007, www.aidsmap.org, and www.thebody.com. Webcasts, podcasts and transcripts are available.

The Sydney Declaration

This year's conference organizers announced a global sign-on letter, the Sydney Declaration, inviting all stakeholders including clinicians, researchers, policymakers, and those living with HIV, to join together in urging governments and donors to allocate "no less than 10% of all resources dedicated to HIV programming for research." Individuals can sign on to the declaration at www.iasociety.org.

Dual vs. triple-drug therapy in naives

A study from Italy in 152 treatment-naïve individuals looked at Kaletra (lopinavir/ritonavir) in combination with one or two nucleosides. Around half of the participants received Kaletra plus Viread (tenofovir), and the other half received Kaletra plus two nukes. CD4+ T-cell (T-cell) increases were higher in the dual group (250) than in the group receiving triple-drug therapy (152). A trend toward lower lipid elevations was also seen in the dual group. Viral load reductions were similar in both groups, suggesting a boosted protease inhibitor (PI) regimen may not always require the use of two nucleosides in some individuals.

To boost or not to boost

Two studies which looked at Reyataz (atazanavir) boosted with Norvir (ritonavir) compared to unboosted Reyataz showed similar results to previous findings. 96-week data from one study of 200 treatment-naïve individuals randomized to receive either boosted or unboosted Reyataz plus 3TC and d4T found comparable viral load reductions and T-cell increases in both groups, however there were more virologic failures and more resistance mutations in those failing unboosted Reyataz. No one in the study receiving boosted Reyataz developed phenotypic resistance to it or any PI, suggesting that when you can, it's better to boost.

Lexiva vs. Reyataz

48-week data from the ALERT study with 106 participants looked at two groups, one using a regimen containing Lexiva (fos-amprenavir) boosted with a lower dose of Norvir (100 mg) compared to another group using boosted Reyataz, both in combination with Truvada (Viread/Emtriva), and found similar efficacy in both groups. There was some reduction in renal function, although about the same in both groups, and lipid changes were also similar. The frequency of grade 2-4 adverse events was higher in the Reyataz group, but this difference was largely explained by elevated levels of unconjugated bilirubin (this is a blood test result that generally has no side effects except possibly some skin darkening). The current recommended boosting dose of Norvir is 200 mg when used with Lexiva. This was a small study in treatment-naïve individuals, and while it may be too soon to tell, it does suggest that at some point it may be possible to use a lower dose of Norvir to boost Lexiva.

Prezista vs. Kaletra

TITAN is a phase 3 study of 595 treatment-experienced individuals comparing boosted Prezista to Kaletra, both in combination with an optimized background regimen (OBR). Based on a primary endpoint of viral load less than 400 at 48 weeks, it showed that Prezista/r was non-inferior to Kaletra. Both Prezista/r and Kaletra were taken at the twice-daily dose. Adverse events were similar in the two groups, with a higher incidence of diarrhea in the Kaletra group. The old gel-capsule formulation of Kaletra was used during the study.

Aging, or AIDS?

Monday's plenary session included an enlightening presentation on HIV and aging by Brian Gazzard, M.D. of Chelsea Westminster Hospital. One-third of all adults who are HIV-positive in the U.K. are 55 or older, a "quite staggering statistic," and his talk sought to address the intersecting relationships between aging, HIV, and the effects of highly active antiretroviral therapy (HAART). Gazzard explained that older people tend to have a poor immune response, and the immune response to HAART is reduced in older people. On the other hand, studies have shown that people over 50 tend to better adhere to therapy, with over 95% adherence. Chronic diseases that are usually associated with aging, such as liver failure, chronic liver disease, and loss of bone mineral density, are more common in those with HIV. So there is, in his words, "a changing perception that many of the diseases of old age will kill us, and they will more likely kill us if we're HIV-positive than if we're HIV-negative."

The D:A:D study has shown that after adjusting for NNRTI exposure there is an incrementally increased risk each year of

All photos of IAS 2007 Conference courtesy of International AIDS Society

developing cardiovascular disease for those on HAART. But one of the interesting things Gazzard pointed out in his talk was that the relative risk goes down each year, "so the longer you've been exposed to these drugs, actually the relative risk seems to be diminishing that you will get cardiovascular disease." He went on to add that looking at additional findings from the recently halted SMART study, one could surmise that "HIV itself is associated with a very big increase in cardiovascular risk that is reduced enormously by antiretroviral drugs, but not actually completely back to normal. [A] very different idea [from] those that we had before."

Gazzard pointed out that large numbers of HIV-positive individuals are dying prematurely of cancers that are not necessarily classic cancers that we associate with AIDS, especially the older you get and the lower your T-cell count.

Regarding dementia, although Gazzard says he has not observed it as much in his own practice, he did say that the changes can be more subtle than we realize. HAART itself may actually increase the risk of dementia, while HIV may contribute to Alzheimer's disease. He ended with the grim prediction that there may be a whole new epidemic of dementia in store for us.

Finishing the talk on a somewhat more upbeat note, Gazzard encouraged those in the audience who were younger to remember how important it is to continue to do research in this area, and that it is a very exciting time. "Please make it simple," said Gazzard. "I'm a great believer that people who get the Nobel Prize have simple answers to complicated problems, not complicated answers that nobody understands."

Complications in HIV treatment

TB and co-infection news from IAS

by Bill Farrand

TB/HIV: Still a deadly combination

Several studies examined the role of tuberculosis (TB) co-infection as the leading cause of death for those with HIV disease worldwide as well as new approaches to treatment.

One study of 155 individuals in Cambodia looked at the incidence of Tuberculosis-associated Immune Reconstitution Inflammatory Syndrome (TB-IRIS), a significant complication of early antiretroviral therapy (ART) in high TB incidence settings. The study aimed to characterize TB-IRIS and the potential role of simple tests in the diagnosis of TB-IRIS and discovered a correlation with increased PPD-specific T-cell responses detected by a blood test.

PPD is the skin test that is given to detect the presence of TB by a small welt at the pin-prick site as an immune response in those with a normal immune system. In patients with compromised immune systems, no reaction appears, so these findings show that an immune response to PPD can be detected through a blood test that measures the release of interferon-y as an immune response, rather than the skin inflammation reaction that a person with a normal immune system would have. These findings may prove useful in the early diagnosis of TB-IRIS for those starting ART so that proper treatment for TB can be initiated at the same time.

Also presented were findings on dosing protocols of Viramune (nevirapine) for patients with HIV and tuberculosis co-infection as part of ART in conjunction with rifampicin in resource-limited settings where the TB burden is high. In studies prior to the introduction of ART, the use of Viramune in conjunction with rifampicin was shown to reduce plasma levels of Viramune by up to 20%. However, it was concluded that overall immunological results were comparable between 400 mg and 600 mg Viramune regimens when accompanied by ART and rifampicin.

A study out of Brazil, where there is free access to ART, compared mortality rates between patients who had HIV/TB co-infection and patients with TB who are HIV-negative, and found the incidence of death from TB to be over seven times higher for the HIV-positive group than the HIV-negative group.

Cancer and HIV

Meta-studies of HIV-positive transplant recipients have associated a higher rate of mainly infection-related cancers than was previously thought. Infection-related cancers are caused by previous viral infections and express in specific types of cancers. The study revealed higher incidence of Hodgkins lymphoma associated with prior infection of the Epstein-Barr virus; oral, anal, and genital cancers associated with human papillomavirus (HPV); and liver and stomach cancers associated with hepatitis B and C.

Another study has shown the usefulness of HPV DNA screening in addition to

Pap smears for HIV-positive males as an indicator of the need for further or more frequent testing for anal cancers. This outcome has significant implications for long-term care of HIV patients and standards of care.

On the positive side, a second study on HPV in men has shown potential for use of the HPV vaccine recently approved for use in females in the prevention of cervical cancer, and has been found to be well tolerated and to show increased immune response even in cases of severe immune suppression. These findings will need further studies to determine the efficacy of the vaccine against progression to these anal cancers for men with prior HPV infection.

Routine screening for skin cancers other than Kaposi's sarcoma are called for by the findings of yet another study, which showed a higher incidence of basal cell carcinomas and melanomas in an HIV-positive cohort than in the general population.

A study in the U.S. aimed at the incidence of non-AIDS defining cancers found an increased risk of seven types of cancer, further confirming the need for more effective routine screening as part of long-term HIV care.

Hepatitis B and C

In another analysis from the SMART study, HIV treatment interruption in patients co-infected with either hepatitis B or C was found to increase the risk of death.

Highlights of biomedical prevention strategies

Methods to prevent HIV from the angle of biology offer hope

by Keith R. Green

A significant portion of this year's International AIDS Society Conference was devoted to current developments in the area of HIV prevention—specifically, those that have come to be known as biomedical prevention. Unlike traditional prevention strategies, such as the promotion of condom use and the knowledge of one's own HIV status, biomedical prevention generally involves strategies that are more deeply rooted in medical science, requiring more rigorous and heavily scrutinized study in clinical trials before they are approved for use among the general population.

In addition to discussion about recent trials involving HIV vaccine candidates (the original attempt at biomedical prevention, which have been slow coming and often disappointing in their development), the IAS Conference this year focused on four other emerging and innovative technologies that are gaining momentum around the world—pre-exposure prophylaxis (PrEP), male circumcision, microbicides, and HSV-2 (herpes simplex virus type-2) suppression.

PrEP

Clinical trials that are currently exploring the safety and efficacy of PrEP involve the use of currently approved anti-HIV medications—Viread (tenofovir) in particular. In these studies, antiretrovirals are prescribed to high-risk HIV-negative people in an effort to prevent the onset of the virus in the event of actual exposure.

Trials are presently underway in several countries, including Thailand, Botswana, Peru, Ecuador, and the United States, most of which are safety trials. The study in Thailand, which is specifically looking at the use of PrEP in intravenous drug users, appears to be furthest along, with preliminary data projected to be available in the spring of next year and a final analysis expected the following year. There is also a safety trial being developed in that country which explores the use of Viread as an alternative prevention strategy for women.

The trial in Botswana is looking at both heterosexual men and women, while trials in Peru and Ecuador are exploring the use of PrEP in men who have sex with men (MSM).

Researchers are very optimistic about these trials for a number of reasons. "Number one," explains Dawn Smith, M.D., MS, MPH, a principle investigator for PrEP clinical trials conducted through the U.S. Centers for Disease Control and Prevention (CDC), "is that there is biological plausibility.

"We know that these drugs have concentrated levels in the genital tract, which is where the majority of the world's transmission occurs. We know that it works in animal models. We know that PrEP works for post-exposure prophylaxis [after exposure to the virus]. And we know that safety was demonstrated in the FHI [Family Health International] trial that has already been completed."

Smith stressed the importance of preparing for the implementation of PrEP even before trial results are in because, she says, we've never had a biomedical prevention method such as this one in the U.S. Therefore, she explains, the CDC will need adequate time to prepare for it. And even if by some small chance these trials prove to be ineffective, this planning will still be useful for "the next biomedical intervention, whether that be microbicides or vaccines," she said. "So it's not a wasted exercise in that event."

Smith argues that the most important advantage to PrEP, aside from the fact that

it may work for more than one type of exposure, is that it is the first opportunity to get high risk people in for periodic risk reduction counseling and HIV testing.

Microbicides

Hope for an effective prevention method that women, in particular, can control was dampened at the conference when news regarding the failure of a once promising microbicide was presented. Data from two studies showed that Ushercell, a microbicide containing 6% cellulose sulphate, did not protect women against sexually transmitted HIV infection, and suggested that it may have even contributed to an increased risk of HIV acquisition.

Microbicides are anti-HIV substances, in the form of creams or gels, that can be applied to the vaginal or rectal areas in an effort to prevent HIV infection. There are currently no microbicides approved for use, however, there are a number of them being studied in clinical trials.

Ushercell showed no signs of potential harm in pre-clinical testing, and was considered to be acceptable to the women in the studies, causing minimal side effects when used vaginally.

A large-scale phase 3 study of the microbicide that was being conducted in Benin, South Africa, Uganda, and India was stopped in January 2007, however, when an interim analysis revealed that more women who were actually using the gel had become infected than those using a placebo gel. These findings also led to the pre-mature termination of Ushercell trials in Nigeria, though upon analysis of these studies, the women enrolled in this country were experiencing an opposite effect (which researchers did not deem statistically significant).

Scientists are still uncertain as to what may have been the cause of these disappointing findings, but speculate that there may have been inflammatory reactions to the gel, and/or localized immune dysfunction or disruption of the normal vaginal flora as a result of frequent cellulose sulfate use. Extensive testing is currently being done to accurately determine the cause of failure.

Male circumcision

Three randomized controlled trials conducted in Africa have shown that male circumcision reduces the risk of HIV acquisition in heterosexual men. However, because circumcision is not a universally feasible or acceptable prevention strategy for various reasons, the promotion of genital hygiene—which includes washing the uncircumcised penis after vaginal intercourse—has been suggested as an alternative.

A study of 2,552 uncircumcised men conducted in Rakai, Uganda, however, showed that cleaning the penis after vaginal sex does not protect men from HIV infection. In fact, the study found that the men who washed with soap, as well as those who washed a few minutes after having sex, were at highest risk for acquiring HIV.

Dr. Fredrick Makumbi, a researcher from the Makerere University Institute of Public Health in Uganda who presented the study at the conference, believes that this could be for two reasons: 1) failure to thoroughly dry the penis after washing with soap results in wetness of the mucosal area, which increases the likelihood of cells becoming inflamed making the uncircumcised man more vulnerable to HIV infection, and 2) washing the penis too soon after sex could remove enzymes found in vaginal fluid that help to neutralize HIV.

And, while circumcision as a prevention strategy has not been a popular topic among MSM, interesting data was presented about the use of the procedure among this high-risk population. On the one hand, a study that explored the willingness of MSM living in South America to participate in circumcision trials yielded a favorable response (meaning they were willing to go through with it), but a separate study conducted in Sydney, Austrailia found no difference in the risk of becoming infected with HIV between circumcised and uncircumcised MSM. So, the verdict is still out on the benefit of circumcision for MSM.

Finally, an additional study that examined the adverse effects of circumcision on HIV-positive and HIV-negative men in Uganda found the procedure to be equally safe in both populations, though more of the HIV-positive men had not fully healed 30 days out from the operation. This difference could be the result of weaker immune systems among HIV-positive men.

HSV-2 suppression

Data presented from a 30-month randomized study conducted in Tanzania by researchers from the London School of Hygiene and Tropical Medicine showed that treatment with acyclovir, a medication used to treat HSV-2 (also known as genital herpes) infection, does not protect women against HIV.

These findings came as a shock to many, including the researchers themselves, considering that the relationship between HSV-2 infection and the risk of acquiring HIV has been well established. In fact, a recent study found that HSV-2 infection increased the risk of HIV acquisition by three-fold. The National Institutes of Health (NIH) also estimates that nearly half of the people in the U.S. who are living with HIV are also co-infected with HSV-2.

We also know that HSV-2 outbreaks in HIV-positive people tend to last longer

and have more severe symptoms than in HIV-negative people. Studies have shown that HSV-2 infection is also associated with an increase in HIV viral load in the genital fluids.

This particular study recruited 820 "high-risk," HIV-negative women who were infected with HSV-2 into a placebo controlled trial using a daily oral dose of 400 mg of acyclovir. The women were randomized to either acyclovir or placebo and followed up with at three monthly intervals, during which time they were provided with further study treatment packs, condoms, safer sex counseling, and HIV testing.

There was no significant difference in the HIV incidence between the women in the two arms, and researchers also found only modest decreases in the amount of HIV present in the genital secretions of these women on long-term therapy with acyclovir.

Though adherence was monitored through pill counts and random urine tests to check acyclovir levels, and information about the importance of adherence was given to the women, researchers suggested that poor adherence was likely the cause of the disappointing results. The data showed that only about 50% of the women in the treatment arm had 90% or better adherence to acyclovir, with only 19% taking between 75-90% of their doses.

Also presented during this session was a study conducted by the U.S. military, which revealed a high prevalence of HSV-2 among U.S. military personnel, and a strong association between HSV-2 and the risk of HIV infection among those studied.

Recurring themes and discoveries

It is important to note here that many researchers at different periods throughout the conference made reference to a couple of critical discoveries about HIV prevention in general, that have come as a result of the process for developing these biomedical interventions.

The first of these is that in order for effective research and implementation of biomedical prevention technologies to take place, there must emerge a stronger relationship between the world of science that is behind them and the community-based organizations that have their hands on the pulse of the people for whom they will benefit most.

This realization comes as more and more physical scientists begin to collectively understand what social scientists have been saying about HIV for years—it is just as much a social problem as it is a biological one. In fact, HIV infection is usually directly related to one or more social problems, including but not limited to disparate access to quality health care, poverty, homophobia, sexism, and racism.

Dr. Smith from the CDC put it this way, "If we fail to plan to deal with the disparities (associated with HIV infection) and the causes of these disparities, then we will have much less impact on the epidemic than we might have otherwise."

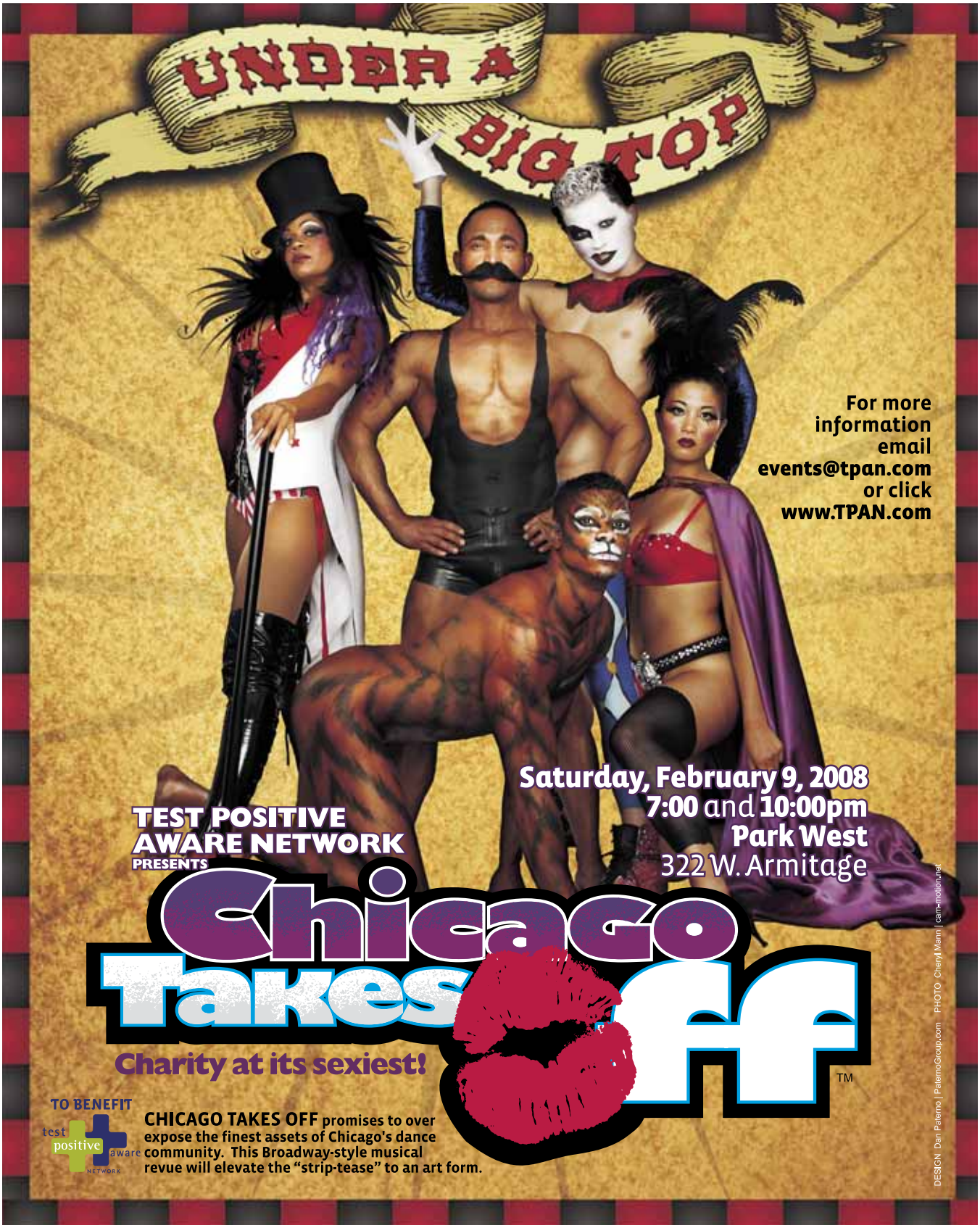
Further support for this idea is provided by Dr. Somyot Kittimukona of the Thailand Bureau of AIDS, TB and STIs, Department of Defense in her discussion of PrEP.

"Unlike a vaccine, which might be reasonably offered to the general public, PrEP is only going to be cost effective if it can be targeted successfully to high-risk individuals," she says, "and these are individuals who are HIV negative. They are not self-identifying as patients, they are self-identifying as members of the community…and I think it's going to be our community-based organizations that will have the best information, the most sophisticated information, about where these people can be found, how they can be identified, and how best to counsel them."

The other finding of medical researchers, as more clinical trials are developed for proposed biomedical prevention strategies, is that an integration of several proven strategies must become common practice.

So, for instance, if a consenting adult male in Uganda undergoes circumcision in order to reduce his risk for HIV infection, he should still be encouraged to make condom use during intercourse a part of his regular sexual routine. By the same token, women who understand that their risk of contracting HIV decreases when their male partners are circumcised, should be encouraged to also use microbicides when they are made available.

This leads us back to our primary recurring theme of the conference—the importance of the relationship between scientist (both medical and social) and community-based organization, because it is mostly the work of the CBO's to debunk myths and promote prevention.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Update on New Antiretroviral Drugs

An interview with Harold Kessler, M.D.

by Matt Sharp

Harold Kessler, M.D., is a professor of Medicine, Immunology/Microbiology at Rush University Medical Center in Chicago, where he has an HIV practice, and is a supervising clinician at the CORE Center, a joint venture between Cook County and Rush University Medical Center for the treatment of HIV patients. He is a nationally-known and well-respected researcher and clinician who has worked in the field since the early days of the epidemic.

Matt Sharp: We seem to be having a resurgence in treatment success today, especially in people who have run out of options, people like me who have been treated for many years from the beginning of the epidemic and have been treated sub-optimally due to HIV resistance. I know you see patients like me. Are you seeing success with patients in your clinic?

Harold Kessler: Absolutely. I think you correctly pointed out we see two types of patients who have failed prior antiretroviral [ARV] regimens.

The first are those who are long-term survivors who were treated early in the epidemic, and who unfortunately through our ignorance at the time, were treated with a series of monotherapy treatments. Obviously we started with AZT or other nucleoside [NRTI] options as they became available, then we began to explore the use of combinations, dual [NRTIs] which seemed to be superior to monotherapy treatment. We then moved into the era of NNRTIs [non-nucleosides] and PIs [protease inhibitors] and began to develop a true appreciation of the need to use multiple classes of drugs, not just multiple drugs, to effectively treat HIV disease.

The second group of patients are those who have had failures of their prior antiretrovirals who have not been able to take their medications on a consistent basis. This happens for a variety of reasons, the two most common of which are either side effects of the medications, which make it impossible for them to take them on a reliable basis, or individuals who have challenges in their life which have made adherence difficult. Either situation which leads to poor adherence can result in the failure of the ARV regimen.

So that's really what we are faced with today in our clinic. As you pointed out there are patients like you who were treated very early in the epidemic, with what is referred to now as sequential monotherapy, and who subsequently developed viruses which are resistant to multiple medications and multiple classes of medications. It has been difficult to construct effective regimens for these patients. This has significantly changed in the last 12-18 months with the development of two exciting new classes of compounds, the entry inhibitors, such as enfuvirtide [T-20] and the CCR5 inhibitor maraviroc [Selzentry], and the first of the integrase inhibitors, raltegravir [Isentress] and elvitegravir.

The first drug in the new classes of drugs, T-20 [Fuzeon], made a significant difference for patients with multiple-resistant HIV, especially if we could partner it with another active drug. We know now that to be effective in treating any type of HIV infection—whether it's naïve [never before on therapy] or failing [treatment] infection—we have to put together at least two active drugs, preferably two or more in order to effectively suppress HIV replication. T-20 came along at a time when we really didn't have highly effective second agents to partner it with to get a fully suppressive regimen. Now we really are in a situation where we have these newer classes of drugs which are making it much easier for us to develop regimens with two or more active agents, which has really changed the entire paradigm for treating failure.

As you might be aware, the guidelines to reflect these significant changes were changed in the last 12 months in terms of what our goals should be for treating a failing patient—now we have our primary objective to get the virus suppressed to less than 50 copies—and I think thankfully now with the two new classes of drugs we seem to be there. And the good news is that these new drugs are much more tolerable in terms of their side effects pro-

files, and they are pharmacologically more friendly in terms of their dosing schedules.

MS: Okay, if you had a patient now who came to you who needed to get their virus under control and had not used T-20 but yet had options to not use T-20, I guess you would think of them individually, but what is your decision about using T-20 in these patients?

HK: There is nothing magical about T-20. It's a perfectly excellent drug and we have to think about it like we would think about any other drug to which the virus is not susceptible. The first cut on our decision-making is to think about the drugs that are available to us that are active against this virus. The next issue we have to come up with is that we have two or more of those drugs to utilize in a regimen, and third is what the tolerability and the effects on the activities of daily living are for this particular individual when designing that next regimen. If T-20 needs to be used to be one of the active drugs, then I would not hesitate to use it. If we can design a regimen which is a completely oral regimen with relatively well tolerated drugs then it doesn't have to include T-20. I don't want to think about T-20 any differently than any other drug, other than the fact that it has to be injected.

MS: Some of the most exciting recent data showed that use of Prezista and T-20 with Isentress showed up to 98% undetectable viral load responses. How would you balance the decision to treat to maximize response based on all these new drugs? Or would you weigh on the side of practicality?

HK: The first cut is always to get the most potent regimen, and the second is to evaluate that regimen and make sure the patient can tolerate it. Therefore if I have to use a drug that's injectable I'll use it, otherwise if I have oral drugs I'll use them first. I think the fact that we now have PIs such as darunavir [Prezista] and tipranavir [Aptivus] which have an expanded resistance profile, in other words a greater likelihood that virus will be susceptible to [these drugs] than it is to the other PIs, along with maraviroc, along with T-20, along with raltegravir, which is available through expanded access, we start to think now about new regimens which may not even include drugs from the older classes. The other drug that we may be remiss in not mentioning is etravirine, or TMC-125, the new NNRTI which also looked excellent in combination with darunavir [DUET study] in a highly-resistant patient population. So it's quite exciting and we really need to think about not only the drugs we talked about but etravirine as a new expanded spectrum NNRTI in designing our new regimens.

MS: The understanding is that etravirine is nearing FDA approval.

HK: As far as I know, raltegravir is nearing final approval and etravirine will be following close behind.

MS: Okay. Let's talk about maraviroc. There has been some concern about the safety of this compound, but the data thus far shows that it's pretty safe. I guess there is unknown concern with the tropism shift and if it's real. Would you expand upon what we understand and what your feeling is about maraviroc.

HK: The first concern is that this is a drug that targets the host, not the virus—it's a totally different paradigm in thinking about the drugs. It inhibits the CCR5 receptor on human cells, not on the virus. The receptor is an important target in relationship to normal immune function, so some of the concerns have been about using a drug which theoretically could have immunosuppressive properties, which would be counterintuitive [for] use in treating an infection which causes immune suppression. In fact, from the earliest stages of the development of maraviroc, at least looking at *in vitro* assays to determine its effect on immune function, it was not shown to be immune suppressive. Studies in mice suggested that maraviroc may have some impact on normal host defenses against herpes virus infection. In humans there has been a suggestion that for individuals who are deficient in part of the CCR5 molecule, there may be an increase in risk of symptomatic West Nile virus. But beyond that we really don't have many current data suggesting long-term adverse outcomes with maraviroc. On the other side of the coin, we are very early in our clinical experience with use of the drug. There continues to be some caution in the infectious disease and HIV-treating community in getting longer term safety data on the use of maraviroc. But so far, as you point out, the safety profile is excellent, and there has been quite extensive scrutiny by the FDA on the current data which suggests it is very safe. So I think maraviroc is a very important drug for us to be using in patients with multi-drug resistant virus. The question is whether maraviroc should be used in naïve patients. Based upon one data set that we have available it did not seem to perform as well in naïve patients when compared to a Sustiva-containing regimen. Some of the difference may have had to do with the way the study was designed in terms of non-inferiority. That's kind of a statistical technicality that we'll have to take into consideration.

One of the key aspects of the use of maraviroc is that we have to determine that the virus that we're going to treat utilizes exclusively the CCR5 co-receptor to gain access to cells. The assay that's currently available to do that is called the Trofile test developed by Monogram Biosciences. It's an assay which uses a technology similar to the phenotype resistance test. One of the concerns about the assay is that it's very expensive—somewhere between $1,700 and $1,900, and the assay suffers from limitations in sensitivity, just like the phenotype test. We know that the phenotype assay does not recognize small sub-populations of virus which are resistant to HIV drugs, something less than 10% of the whole population of all the viruses in the body. Those can be missed by the assay. It looks like the Trofile assay may be missing 8% of small sub-populations which are not CCR5 virus [and] therefore are resistant to maraviroc. In some cases we may do the Trofile assay and place the patient on maraviroc and not see the result that we'd hoped to see because we probably missed some of these sub-populations. Monogram is working on an enhanced sensitivity assay, but for now we have to use the drug with the knowledge that 8-10% of the time we may not succeed with maraviroc because of these minority sub-populations, much in the same way we may not always succeed in choosing our next regimen based upon the result of a phenotypic assay, because we may be missing sub-populations which are resistant in the assay.

MS: Are you having issues in reimbursement for the Trofile assay?

HK: I haven't because I haven't ordered one yet. In terms of third-party payment, I believe that it's being covered. I'm not quite sure of the status of public aid. My guess is it will also pay for it, but that will have to be verified.

MS: Let's talk about HIV resistance with raltegravir and maraviroc. What do we know thus far?

HK: The resistance to maraviroc we know very little about at this point in time. It's more a question of whether a virus is CCR5-using.

In terms of the resistance to the integrase inhibitors, it appears resistance can take one of two different resistance pathways. One pathway seems to be more common for raltegravir and the other for elvitegravir based on *in vitro* data. It seems to require more than one mutation to develop resistance to one of the integrase inhibitors, but it may take as few as two mutations to become resistant.

There was a recent small study designed to determine if patients who had become resistant to elvitegravir could be treated with raltegravir to look at cross resistance in this class. Based on *in vitro* data the hope was that you could treat patients who were resistant to elvitegravir with raltegravir. Unfortunately, after the first two patients in this small pilot study were enrolled it was shown that neither one of them had any meaningful antiviral response so the study was stopped. It looks like we're going to be dealing with significant cross-resistance within this class, at least with the first two drugs in this class.

MS: Are there other integrase inhibitors in development that you're aware of?

HK: Yes, I know that Merck and Gilead have follow-up compounds, and I'm sure there are some other ones out there that I don't know about. There was an integrase inhibitor being developed by GSK [GlaxoSmithKline] that didn't pan out.

MS: Can you comment on the safety profile on the two new classes, besides what we mentioned already with maraviroc?

HK: You can talk about both the tolerability and safety, as they go hand in hand. Both of the new classes seem to be extremely well tolerated, and when you look at safety compared to the comparator arms they are either identical or better. Importantly, the newer drug classes seem to have very favorable lipid profiles, which of course is always a concern for us in terms of long-term potential cardiovascular effect. We do not have long-term safety data so we have to remain diligent in continued monitoring for any as of yet unrecognized adverse events.

MS: Right, and if the safety and efficacy hold out in these drugs and if there are more studies looking at them in naïve populations, would you foresee both of these drugs being used in first-line therapy?

HK: I think there is every likelihood that we may get to a situation that we get to a NRTI regimen, for example. The combinations are endless. You can talk about TMC-125, in combination with darunavir. There's a compound coming along called rilpivirine [TMC-278] which is another NNRTI that is a companion drug to 125. The difference is that rilpivirine is going to be a once-a-day drug compared to etravirine, which requires twice-a-day dosing. Therefore, you have a once-a-day NNRTI with a higher genetic barrier to resistance than efavirenz [Sustiva], which you could combine with a once-a-day PI, such as the new data on darunavir 800 mg boosted with 100 mg ritonavir, which could be a highly effective regimen without having to use NRTIs. You could also have new triple-combination compounds like Atripla, because you could potentially co-formulate ABC+3TC [Ziagen plus Epivir, or Epzicom] with one of these new drugs like rilpivirine, or combining with a PI such as atazanavir [Reyataz]. I think the combination potential is quite promising. These new drugs will not only have an impact on patients failing their antiretroviral therapy, but also the naïve population down the road.

MS: One of the things that struck me at ICAAC in reviewing the posters on new drugs was that I became aware that there are more new drug developments in the co-receptor and integrase realm. It kind of shows us where we're at with drug development today.

HK: Yes, it's all good news. Recently, I wrote a blog on clinicalvillage.com, which is a website for HIV treaters. It's a wonderful site for treaters to interact with their colleagues. It's kind of like a MySpace for HIV treaters. The blog was titled, "Do we really need any new HIV drugs?" Again, I think we're at a point in time where it's wonderful to have these new drugs. We need them because there are individuals who are going to be challenged in taking their drugs, and are going to have the potential to develop resistance. But in reality we have enough new drugs now that if we get them to the people who really need them, and work hard with those individuals and choose those individuals carefully to take the existing drugs, we probably have the drugs available to treat 98% of HIV-infected people.

I think it's gratifying that we're continuing to see developments of new drugs, because the rewards to the pharmaceutical indusctry in terms of the return on their investment is becoming much more challenging. As there are more and more drugs, and as people are doing better for longer periods of time on their initial regimens, the potential market for these newer drugs become smaller and smaller. Thankfully, the pharmaceutical companies continue to forge ahead to investigate new classes of drugs and new drugs from existing classes. So I think the news is all very good for us.

MS: In the early days we had only one or two drugs to consider, and it's clear today we've come a long, long way.

HK: It's phenomenal, it really is!

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

Metabolic Complications Myths

Some misunderstandings about treatment

by David Alain Wohl, M.D.

Introduction

One of the greatest drags on the success of potent antiretroviral (ARV) therapy has been the fear of metabolic complications associated with these medications. Disfiguring body shape changes including the loss of fat in the face, as well as unhealthy cholesterol and triglyceride levels and pre-diabetes are troublesome counter-balances to the euphoria that arose when these drugs arrived and people stopped dying. Even as ARVs have become more user-friendly—less pills, less frequent dosing, less diarrhea and nausea—the specter of metabolic problems can still overshadow these advances, leading those in need of therapy to hesitate when ARVs are recommended. For those already on treatment, metabolic disorders may prompt a change in therapy or lead to the prescription of even more medication and can raise the volume of the little voice that says it is okay to skip doses.

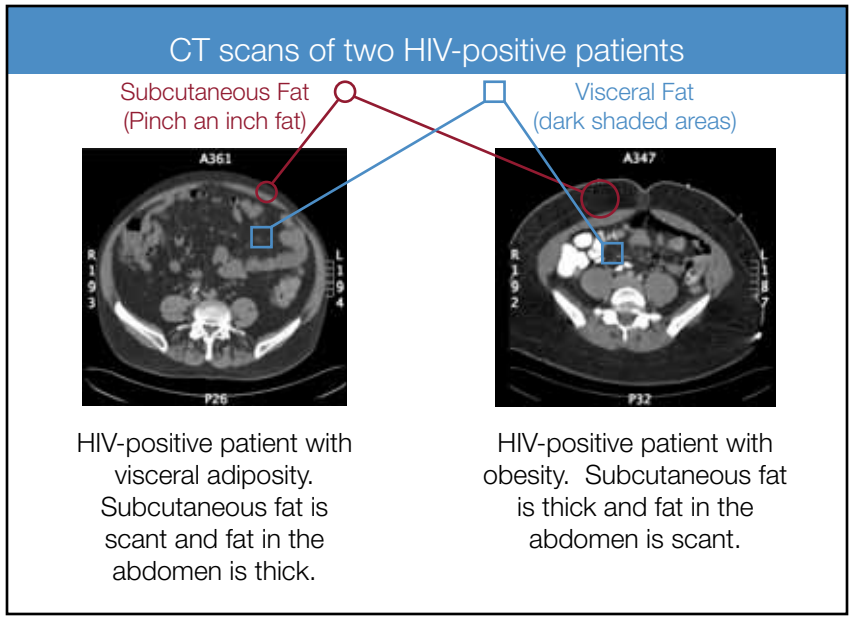
A major frustration for people living with HIV and their health care providers has been a lack of information regarding the cause of metabolic problems during HIV infection and ways to prevent and treat them. The field of metabolic complications of HIV and its therapies is relatively young and much has been learned during a short period of time but some conclusions have been reached with little supportive data. Below is a list of some of the most common of these metabolic complications myths. Myths that emerged in a data vacuum and that even people in the "HIV-know" often still accept. Fortunately, over the past few years a slew of studies has painted a clearer picture of these changes and together suggest that some of our closely-held beliefs about the risks for metabolic complications have been wrong. Understanding that these assumptions are no longer valid, and why, is essential if people living with this infection and their health care providers are to make informed decisions about their care.

Myth #1: Protease inhibitors are responsible for the increases in belly fat.

Like many myths, this one is based on a truth that has been stretched to extremes. People taking protease inhibitors *can* see an increase in their belly fat, both the deep down fat that surrounds our internal organs and the surface, pinch-an-inch fat so abundant in our land of amber waves of grain. But protease inhibitors hold no monopoly on an ability to expand trunk fat. Studies of efavirenz (Sustiva) have shown that people taking this non-nucleoside also tend to have increases in belly fat. In fact, increases in waist size have been seen in studies of every HIV regimen in which body shape has been objectively measured. For example, in a federally funded AIDS Clinical Trials Group (ACTG) clinical trial called study A5142 comparing the popular HIV medications lopinavir/ritonavir (Kaletra) and efavirenz, trunk fat was seen to increase in participants regardless of which drug they were assigned. Similarly, a Bristol-Myers Squibb sponsored head-to-head study of efavirenz and another protease inhibitor, atazanavir (Reyataz), in patients who were starting HIV therapy also found that both drugs when combined with zidovudine and lamivudine (Retrovir and Epivir, also Combivir) tended to increase abdominal fat over time. Interestingly, a recent Abbott Laboratories study that looked at using

lopinavir/ritonavir by itself (i.e. monotherapy) in patients started on this protease inhibitor and zidovudine/lamivudine found that these patients experienced increases in belly fat to the same extent as a control group of patients who were maintained on zidovudine/lamivuine and efavirenz. Therefore, it looks like both protease inhibitors and, at least, the non-nucleoside efavirenz can lead to gains in belly fat.

A problem for most all of these studies is that they rely on a special type of scan called a DEXA to measure abdominal fat. This scan, commonly used to also measure bone density, cannot tell the difference between the deep and surface fat. So, one therapy could be causing accumulation of the deeper fat while another could be associated with surface fat. CT and MRI scans, however, can differentiate deep and surface fat. Unfortunately, we do not have much data regarding the relative changes in fat in deep and surface fat for most HIV regimens. Clearly, more studies need to be done on other regimens, including those that contain newer drugs, and should use CT scans when possible but one thing is clear: when it comes to increasing belly fat, protease inhibitors are not unique.



Myth #2: People who get bigger bellies on HIV meds typically also lose fat in their arms and legs.

As if a big spare tire was not bad enough, some people taking HIV medications also experience loss of fat of the arms, legs, and face. The image of an apple-shaped body with skinny limbs is a frightening one that further turns many people off to HIV therapy. However, it has become clear that most people on HIV medications do not develop this body shape. In fact, a couple of studies of people starting a variety of HIV regimens have found that for most people limb and belly fat tend to increase or decrease together. That is, if someone experiences a gain in belly fat then they are more likely to also experience a gain rather than a loss in limb fat. In one study, only a quarter of people experienced a loss of arm and leg fat while gaining abdominal fat.

Most studies suggest that overall fat gain is a major problem for HIV-positive people. As in the general population, being overweight and obese is common. In a study of HIV-infected patients receiving care in Philadelphia, rates of being overweight and obesity were more of a problem than weight loss. As people with HIV infection look to decades of living with their infection, the problem of obesity is likely to take its toll since obesity increases the risk of diabetes, heart disease and death.

Myth #3: Loss of limb fat during HIV therapy only occurs when stavudine (d4T) is included in the treatment regimen.

The profound loss of fat within the arms, legs and especially the face among people on HIV medication cocktails that was seen in the mid-1990s was quickly associated with one drug, stavudine (Zerit). The link between such disfigurement and this drug was so obvious that use of stavudine in the U.S. and Europe quickly fell and is now rarely prescribed (unfortunately, stavudine is still commonly used in developing nations as it is easy to make and, thus, cheap).

The drop in stavudine use was followed by a dramatic reduction in new cases of severe fat loss of the face and limbs. However, over time some doctors and their patients noticed a slower but undeniable depletion of fat in these same areas of the body. But, as these changes were slow to develop and DEXA, CT, and MRI scans are not routinely performed in clinics to measure and follow body fat changes, it was unclear whether these changes were real and, if so, what caused them. What was clear was that these people seemed to be losing limb and face fat but had never taken stavudine.

Some answers came from clinical trials that incorporated DEXA scans into their design. One study done several years ago by the ACTG found that people starting HIV therapy who took the protease inhibitor nelfinavir (Viracept) were more likely to lose limb fat—as measured by DEXA scans—than those taking efavirenz, even when the other medication taken was limited to zidovudine/lamivudine (Combivir). This meant that people on zidovudine/lamivudine were experiencing fat loss and that this was accelerated with nelfinavir use. Another study comparing zidovudine/lamivudine with tenofovir/emtricitabine (Truvada) when both were taken with efavirenz found that there was a progressive loss of fat among those assigned to zidovudine/lamivudine while those taking tenofovir/emtricitabine gained limb fat over time.

The ACTG study A5142 looking at people new to HIV medications also performed DEXA scans before HIV medications were

initiated and then at regular intervals after starting the drugs. This was a large study of almost 750 people who were assigned to one of three different study treatments: a.) lopinavir/ritonavir plus two nucleosides, or b.) efavirenz plus two nucleosides, or c.) lopinavir/ritonavir plus efavirenz alone without nucleosides. Those taking nucleosides could use only lamivudine plus either stavudine, zidovudine or tenofovir (Viread). The study is very important as efavirenz and lopinavir/ritonavir are two of the most popular medications used to treat HIV infection yet, had never been compared before. The results of this trial have shaken the field of body shape changes during HIV treatment. Those taking stavudine had, as expected, the greatest loss of limb fat and those taking tenofovir had the least. But, zidovudine fell in between. This alone indicated that some people experienced limb fat loss even when not receiving stavudine and that zidovudine was capable of doing this to a greater extent than many had thought. In addition, the study found that no matter what nucleoside was used, efavirenz was more likely to cause significant fat loss compared to lopinavir/ritonavir. That is, efavirenz seemed to add to the fat loss that was associated with the nucleosides. The good news is that few of those on tenofovir lost significant amounts of limb fat at 96 weeks of study, even when on efavirenz, so fear of fat loss should not be a major concern for those who are taking or considering use of tenofovir plus efavirenz (two of the three medications in Atripla).

A remarkable number of intelligent men and women arrive at their clinic visits complaining of increases in belly fat, and are frustrated that endless sit-ups have done nothing to reduce their mid-body girth.

Taken together, these data indicate that fat loss of the arms and legs is not limited to stavudine and that other drugs can also produce these changes. Zidovudine appears to be worse than tenofovir (or abacavir [Ziagen]), albeit it is not as bad as stavudine. Additionally, efavirenz seems to be able to dial-up the fat loss effect of nucleosides to a greater extent than lopinavir/ritonavir. Unfortunately, there is not much information regarding face fat from any of these studies.

Myth #4: Sit-ups can spot reduce belly fat.

This myth falls into the same category as the belief that going out with wet hair will increase your risk for a death of a cold and that too much time spent self-pleasuring can wreak havoc on your visual acuity. A remarkable number of intelligent men and women arrive at their clinic visits complaining of increases in belly fat, and are frustrated that endless sit-ups have done nothing to reduce their mid-body girth.

Sit-ups, when done properly, can increase strength in the abdominal muscles. This leads to firmer muscles and an increase in core strength but will not melt away fat in that one area. Fat is lost when more energy is expended than taken in. While sit-ups require energy, they do not preferentially draw that energy from the deposit of fat cells found in those love handles. A better approach is to combine sit-ups with aerobic exercises that require heavy breathing and sweating for prolonged periods of time like running, cycling, stair climbing, rope jumping, etc. Small studies have shown decreases in abdominal fat when HIV-positive people followed a program of aerobic exercise and weight lifting several times a week.

Diet can also play a role here and a smart approach would be to limit simple sugars and the highly caloric fats that make up most of the so-called comfort foods of our society. For most people dietary modification need not be very complicated and can be summed up with a recommendation to greatly increase daily intake of fruits and vegetables, the latter preferably raw or lightly steamed. These are foods that are not packed with excess calories, contain cholesterol-lowering fiber and are filling—leaving less room for the fatty, super-size-me foods at the root of many of our health problems.

In addition to eating like a Buddhist monk and joining a gym there are other interventions that have been studied to reduce excess fat. Unfortunately, few have panned out. Growth hormone is an injectable agent that has been found to reduce fat in the belly and buffalo hump and some people have benefited from this therapy. However, this is an expensive drug that is not usually covered by insurance carriers for the treatment of excess fat. Also, at the doses studied for the treatment of excess fat, growth hormone has been plagued by a number of troublesome side effects including worsening glucose levels, muscle and joint aches, and feet swelling. Interestingly, exercise is known to increase the body's own production of growth hormone.

Testosterone and other androgens ("male hormones") have also been studied as treatments for fat accumulation in people with HIV infection. These hormones, like growth hormone, can pop fat cells but in another ACTG study were found to preferentially reduce the surface fat and not the deep fat that made for most of the enlargement of the belly. Androgens can also worsen limb and face fat loss. Therefore, although beloved by many, the data suggest that androgens may do little to reduce abdominal girth and can aggravate loss of fat beyond the trunk.

A few drugs used for the treatment of diabetes have also been studied for fat accumulation, including metformin, rosiglitazone, and pioglitazone. Most of the data informing the use of these drugs in people with HIV come from small studies. Suffice to say that

their effects, if present at all, seem to be mostly limited to those with diabetes or a pre-diabetes condition. The underwhelming study results and the toxicities of these medications have diminished any enthusiasm for dedicated use of these drugs to treat fat changes in people with HIV infection.

Myth #5: People with HIV infection have higher cholesterol levels than people without HIV.

Take a survey of people living with HIV or even their docs and ask whether HIVers have higher cholesterol levels than those without HIV. Chances are most would respond that those who are HIV-positive would, on average, have higher levels than those who are uninfected. Actually, at least a couple of studies have found that people with HIV infection tend to have *lower* levels of LDL cholesterol, the "bad" cholesterol that has been strongly linked to heart disease, than people in general; this finding holds even when including those who are on HIV medications.

This does not mean that those with HIV infection have a better lipid profile than uninfected folks. A major problem is that levels of the "good" cholesterol, HDL cholesterol, are also lower in HIV-positive people. HDL cholesterol has been found to offer protection from heart disease and a low level is an independent risk factor for cardiovascular problems. Exercise and modest alcohol (not just red wine) intake can safely raise HDL cholesterol in some people. In addition, a little appreciated fact is that certain HIV medications also raise HDL cholesterol levels. The non-nucleosides efavirenz and nevirapine [Viramune] and the protease inhibitor atazanavir alone or in combination with ritonavir [Norvir] and most all other protease inhibitors that are boosted with ritonavir have all been found to raise HDL cholesterol levels.

Triglyceride levels, though, are a different story. Triglycerides are broken down in the body from fat and can be found floating free in the blood or in a complex with other lipids and proteins in the form of cholesterol. The more triglycerides in the cholesterol complex, the more dangerous it is in terms of cardiovascular risk with LDL cholesterol having more triglycerides than HDL cholesterol. Fasting triglyceride levels are, on average, higher in people with HIV infection and increases further with HIV therapy. While in some people the level of triglycerides can skyrocket to very concerning levels (greater than 500 mg/dL) most people with HIV infection have levels that are high but not alarming. In addition, by itself the level of triglycerides measured in the blood is not considered as nearly big a risk for cardiovascular disease as high LDL or low HDL cholesterol. Most all HIV regimens can raise triglyceride levels. The ritonavir-boosted protease inhibitors are a bit worse in this regard than efavirenz, and most studies suggest that lopinavir/ritonavir and fos-amprenavir/ritonavir (Lexiva/Norvir) may raise triglyceride levels a bit more than other commonly-used boosted protease inhibitors, but the clinical significance of these modest differences is not clear.

Overall, the data suggest that people with HIV may be at greater risk of cardiovascular problems like heart attacks due to their low HDL cholesterol levels and possibly increases in LDL cholesterol and triglyceride levels during HIV therapy. Additionally, there may be other factors such as inflammation caused by the virus that can lead to chemical changes in the body that can prompt clogging of the arteries. However, it is almost certain that smoking adds much more to the risk of cardiovascular disease than these other HIV-related factors and that of all the things a person with HIV infection could do to survive and thrive, beyond taking HIV medications when necessary, the most significant is to stop smoking.

New investigations have revealed the accuracy and inaccuracy of previous assumptions and allow us opportunities to better choose among our options.

Summary

Clinicians and their patients do not tolerate ambiguity well. Gaps in knowledge of a disease demand to be filled and when the research data come up short it is difficult not to extrapolate. In the 25 years since the AIDS pandemic ignited, much has been learned about HIV and the crowning achievement of the scientists, clinicians, and advocates dedicated to this disease has been the dramatic reversal of the lethality of this disease. However, in HIV, as in medicine in general, it has been difficult to not jump to conclusions when data are conflicting or just plain not in existence.

In the case of metabolic complications of HIV and its treatments, we have learned to learn. New investigations have revealed the accuracy and inaccuracy of previous assumptions and allow us opportunities to better choose among our options. The trick is we have to be willing to let go of our old beliefs and embrace findings that rigorously challenge these concepts. The old mantra that knowledge=power still holds, but we have to accept that *better* knowledge=*even more* power.

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GETTING THINGS DONE

AmeriCorps program offers invaluable training while providing service to HIV/AIDS community

l to r: AmeriCorps volunteers Shawn, Valencia, Jenna and Shannon

by Leslie Anderson

The year was 1993, and Bill Clinton was in office putting into law legislation that created the Corporation for National and Community Service. This legislation in turn created AmeriCorps, a new addition to national service programs already in place, such as VISTA (Volunteers in Service to America) and the National Civilian Community Corps (NCCC).

Since then, the motto for AmeriCorps members has been "Getting Things Done"—whether those "things" may be painting an old recreational center or volunteering with the mentally ill. There are literally hundreds of programs that people can get involved with based on their personal service interests.

Just one of these many programs is the National AIDS Fund AmeriCorps/Caring Counts Program, the first program to focus exclusively on HIV care, education, and prevention. The National AIDS Fund (NAF) Program has been around since 1994, and is generously supported by the Corporation for National and Community Service and the MetLife Foundation. In addition, NAF currently has AmeriCorps sites in seven cities around the U.S.—Chicago; Indianapolis; Detroit; Washington, D.C.; Tulsa, Oklahoma; Charlotte, North Carolina; and new in 2007, Albuquerque/Santa Fe, New Mexico—each having 5-12 members.

Goals

One of the main goals of the NAF Program is to recruit and retain young, motivated, energetic people to the field of HIV. More than 25 years after the virus made its first appearance in the U.S., funding for prevention and treatment has shrunk painfully, and the sense of urgency and panic has often faded into feelings of ambivalence and indifference outside of the HIV community. All of this in the face of a pandemic that does not show any signs of slowing down. So when the activists of the early days are no longer able to fight the battles necessary to win the war against AIDS, and the most influential generations of the future (Gen. X, Y & Z) are being seduced by the worlds of dot-coms and pharmaceuticals, who will be left to carry the messages of the more than 40 million people worldwide fighting for their lives? Hopefully the NAF Program has some practical solutions to this problem.

The preceding is one of the long-term goals of the program, but there is also a very real and immediate impact that the program was forged to accomplish—filling service gaps that have resulted from the drastic cuts in U.S. funding, both private and federal, over the past decade. Very simply, for each AmeriCorps member, this means "giving up" 11 months of your life for service, but for some agencies on the brink of closure, this translates into one more year of providing service to forgotten populations. I use the term "giving up" because many people from my generation (the generation that sees life in terms of résumé builders and 401k's) see service to another, especially coupled with little money and typically no recognition, as a waste of time. I hope that after you read this article, especially if you are under the age of 35, you will no longer see it that way, but rather will view it as an opportunity to have a hand in ending this public health crisis.

Stipend

Enough of the soap box—and on to the benefits of being an AmeriCorps member! Most AmeriCorps members receive a modest living allowance, and all members completing a full-time term of service are eligible to receive a $4,725 AmeriCorps Education Award. Additional benefits include health insurance, child care

Photos courtesy of Leslie Anderson

coverage, and forbearance of student loans. Luckily (or unfortunately) this means that after taxes, members fall below the federal poverty limit, which entitles you to certain government benefits such as food stamps, which last year in Chicago amounted to approximately $152 per month.

Professional development

For those of you who are unapologetic résumé builders, here's a perk for you—unless you have a degree in social work or the like, you will likely never have the opportunity to do this type of work on a paid or unpaid basis. People in this program perform a range of duties including HIV testing and counseling, case management support services, and community outreach, just to name a few, and are entitled to training opportunities to the tune of 340 hours throughout their service. This training includes an HIV 101 certified training provided to you at the pre-service meeting, where you will travel (courtesy of the MetLife Foundation) to meet the other 40-plus members across the nation doing the same type of work. So if you have ever been frustrated with being told you do not have enough experience to get a job, but without a job you cannot gain experience, this program effectively solves both problems.

Clockwise from top left: Jenna, Clinton, Shawn, Leslie, Valencia and Shannon

"You must be the change
you wish
to see in the world"
—Mahatma Gandhi

Just in case you are still skeptical, I spent the last two years of college knowing that I wanted to work in HIV, but having no clue as to how I was going to convince people to give me a chance. All I had was a degree in an unrelated field, and passion (not enough these days as many of us know all too well). After two years of service and training, I am currently employed by the State of Wisconsin's HIV/AIDS Program, helping to coordinate the ADAP (AIDS Drug Assistance Program) and Insurance Subsidy Program.

Okay, so one person "made it," big deal. On the contrary, in recent years, members have been able to leave this AmeriCorps program and walk into case management jobs, non-profit coordinator jobs, academic labs studying various effects of HIV, and professional programs all over the country. At the end of the day, the NAF Program *is* a résumé building tool, complete with practical training and professional development. But there is also the added bonus of walking away from your 11 months of service with something you may not have expected—a greater sense of social consciousness.

My story

For the past two years, I have been a member of Team Chicago. During my second year in the program I was placed with an agency that most of you will be familiar with if you have read the cover of this magazine, Test Positive Aware Network (TPAN). My year with them was their first as a National AIDS Fund AmeriCorps/Caring Counts Program host agency, and with the help of an inspiring supervisor and a steep learning curve, you can be sure they will be around for a long time with this program.

Four days a week I spent working with clients, coordinating a positive buddy program and conducting HIV test counseling, among other duties. On the "fifth day" of the work week, the seven-member team ventured into the broader community, volunteering with other CBO's (community-based organizations) not necessarily in the field of HIV. The team mentality of the NAF Program is part of what sets it apart from most other AmeriCorps Programs, which place individuals in a volunteer position with no other AmeriCorps members on site.

Besides the obvious rationale of team member support, the model also benefits the community in a significant and lasting way. Team members work collaboratively to imagine, design, and implement a long-term project that promotes volunteerism and raises community awareness of HIV/AIDS.

This most recent year, Team Chicago's brainchild was a latex and leather fashion show and prevention event called Project Latex. With the support of local area leather and specialty shops, we put on a fashion extravaganza with over 20 models and more than 40 designs. In addition to the fashion, we also had condom demonstrations, spoke about risk reduction, and hopefully put a new spin on prevention that uses humor in place of conventional fear. With the success of the pilot year, there are future projects currently in the works that will continue to spread messages of hope and education through a non-traditional medium.

Years ago as a college student embedded deep in democratic (and sometimes socialist) culture, I spent hours on end debating, complaining, and threatening revolution. One day, instead of just listening, a professor of mine who had spent a good portion of the '70's protesting the Vietnam War said very quietly and prophetically, "Action is the language of change."

Leslie lives with her husband in Madison, Wisconsin, and works for the State of Wisconsin as an HIV Client Eligibility Specialist for the State ADAP and Insurance Programs. Prior to her AmeriCorps service, she graduated from Lyman Briggs College at Michigan State University with a bachelor's degree in Human Physiology and minors in Bioethics and History/Philosophy of Science. She is originally from Toronto, Ontario.

To learn more, go to www.aidsfund.org/AmeriCorpsCaringCounts. To become part of AmeriCorps, visit www.americorps.org, where you can search for specific programs such as the NAF program, or choose a program based on your personal interests. Contact the National AIDS Fund directly to get more information about the application process for program year 2008-2009 (rolling admissions begin January 2008). E-mail Maggie Cunha at mcunha@aidsfund.org or call (202) 408-4848, extension 202.

Deliverance

Deeply disturbed

by Jim Pickett

So, where were we?

On the fairy-flip-out, Sissy Asylum, Hard Time for Henrietta storyline I last recounted to you about my bipolar-lite odyssey into mental illness a couple of issues ago (July/August), we left off with the harrowing scene in which I was playing docile, obedient patient to Evil Counselor Queen (ECQ) who had made abundantly clear in a drawl right out of *Deliverance* that he was deeply disturbed that I was intent on exiting the facility sooner rather than later.

Do you remember?

I had been chillaxin in the "lounge"on Day 2 with some of my fellow bipolar, substance abusing, depressed, disturbed pals playing another game of UNO when I was summoned into my chambers by ECQ for a little heart-to-heart and I guess you could say, "tough love"—but without the love.

He had been reviewing my chart and saw that on my first morning in the facility, I had marched my ass to the front desk and stridently informed the staff on duty that I was going to leave. This did not go over well, and there was a bit of an argument about my rights, and their responsibilities, and yadda yadda. It seems there is some liability with allowing suicidal patients out too soon—and while I had admitted myself, I was not in the position to say when the ride was over and fit to re-enter society. However, I did have the legal right to sign what is called a "5-Day" which says that they can't force me to farm funny past five days if I no longer pose a hazard to myself and/or others at that time. I signed that baby, and it was noted in my chart and next to my name on the dry erase board in the nurse's station.

"How dare you! You are meeeeyentalleeee eeeyelll. I don't want you representin' me in D.C. or anywhere with an untreated meeeeyental eeeyelllnyess," hissed ECQ . He proceeded to berate me, telling me how fucked up and wrong I was to think I was better than anyone else, that basically I was a real asshole for not allowing myself the help I needed to get better. And that I would be going out into the world of HIV/AIDS, gay men's health advocacy a *sick man* and no good could come of that for anybody. He was convinced that it was all about me doing the time, a *lot* of time. A mere five days was not nearly enough in his opinion.

He made me cry.

I was not about to let on that I was actually planning on leaving *before* 5 days, and had talked to my shrink (named after the planet of love) about such a potential early withdrawal and she was *all over it*, thank you very much. I mean, I did have only one outfit—the sweatshirt and jeans I checked in with, and it was clear that the look was not holding up very well over the days. But La Shrink—one of the few staff who seemed to understand me—was only in our wing for a short visit each day, and the rest of the time I, like my other disturbed, captive pals, was left under the supervision of the counselors and other staff, several of whom were clearly raised by wolverines, and in the case of ECQ, obviously the youngest in a litter birthed by the bitter, brutish alpha-bitch who starred in Satan's canine patrol back in the '60's. Really. Google it, you'll see.

ECQ, like all the staff, had the ability to note unfavorable comments in my paperwork—about how recalcitrant or uncooperative I was, if I engaged in a lot of sass or back talk, or if I was late to group, or didn't participate in group, or said that I felt "fine" during group check-in ("how dare you say you feel fine, you wouldn't be here if you felt fine") or if I didn't draw crazy drawings or paint crazy paintings during art therapy, or if I argued about how mentally ill I was or wasn't…

I did not want to add any documentary "proof" that could keep me in the pen, that would indicate I remained an unbalanced hazard and therefore should not be set free, so I essentially agreed with his assessment, only taking to task his notion that I felt my supposed A-list-ness precluded me from anything but a short-term stint. It was like he was mad at me because I kept saying I had a job, and an important conference to attend the following week and I wanted to get out to prepare for it, and that if I didn't get to go this conference, then I would *really* be a depressed, bipolar-lite mess.

He took all that to mean I thought my boogers were spun from gold, sternly reprimanding me. Even someone as snoot-snoot tooty and siddity as me needed to be there for at least a week, maybe two, to get the care and treatment necessary to get a handle on this meeeeyental eeeyelllnyess. Everyone else needed two weeks, and most insurance covered that amount of time, so who the flippin' flap did I think I was to even suggest my spa days were numbered any less?

I played my cards as best I could.

Ya know, it might have been nice to be able to stay a few extra days. Seriously. I could have used some more time, and was sort of getting into the routine of groups (all the sharing!), med-times, chow-times, UNO and hanging out with the smokers during breaks in one of the stinkiest rooms I have ever encountered. Good times. Alas, they were not meant to last. I had places to go and things to do and my journey to mental stability would simply have to continue on the outside sooner rather than later.

I was set loose three days after checking myself in. All my buddies said goodbye to me in a sort of ceremony the last afternoon that was really touching and misty and made me want to hang out one more night. But instead I got my Blackberry and my keys returned and made a bee-line for Starbucks and, all nice and caffeinated bussed up to Walgreens to have my Lexapro anti-depressant scrip filled.

Ah, Lexapro, how I began to love thee…

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