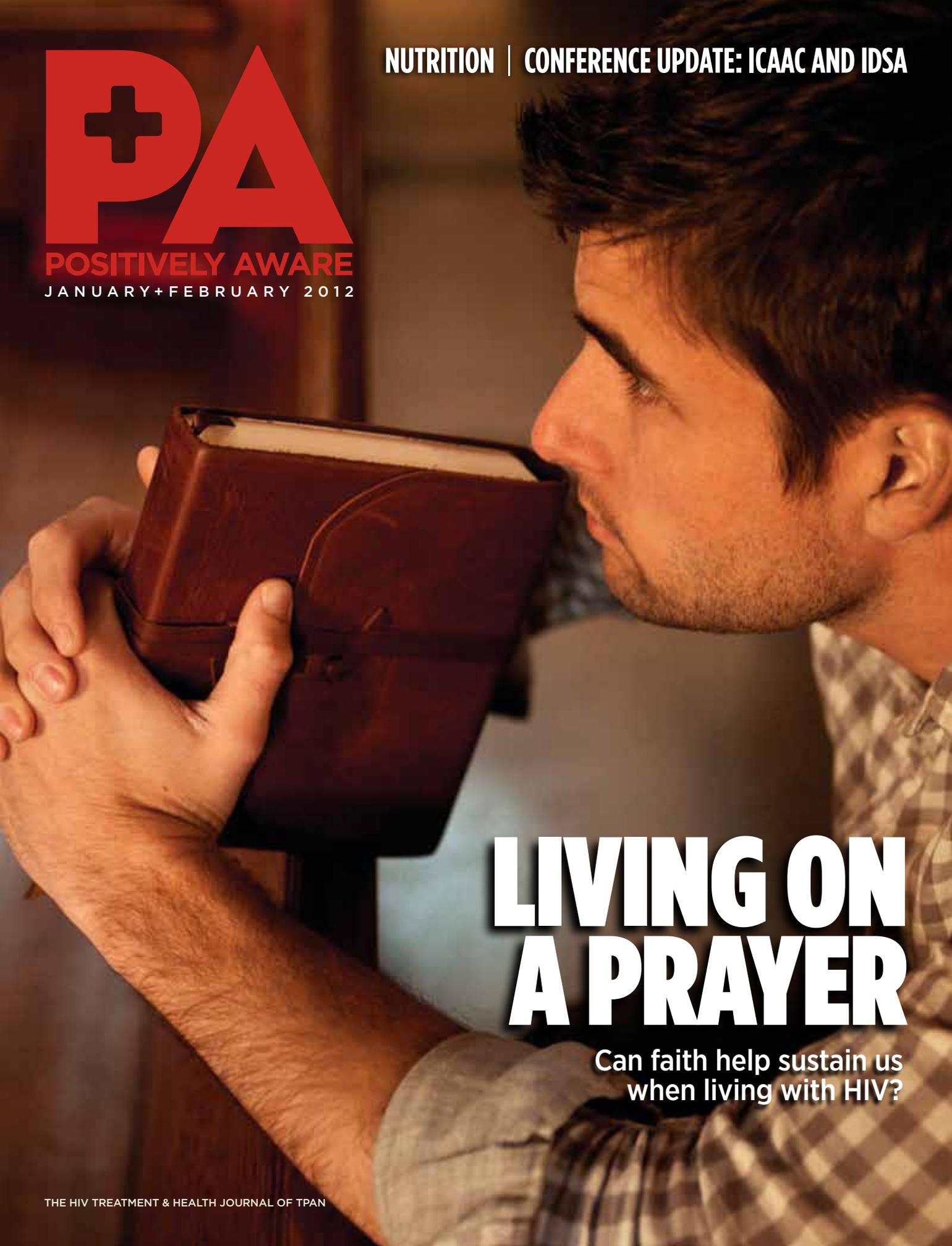


NUTRITION | CONFERENCE UPDATE: ICAAC AND IDSA

PA
POSITIVELY AWARE
JANUARY + FEBRUARY 2012



LIVING ON A PRAYER

Can faith help sustain us
when living with HIV?



The one for me

Patient model. Pill shown is not actual size.

INDICATION

COMPLERA® (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir disoproxil fumarate 300 mg) is a prescription HIV medicine that contains 3 medicines, EMTRIVA® (emtricitabine), EDURANT™ (rilpivirine), and VIREAD® (tenofovir disoproxil fumarate) combined in one pill. COMPLERA is used as a complete single-tablet regimen to treat HIV-1 infection in adults (age 18 and older) who have never taken HIV medicines before.

COMPLERA does not cure HIV and has not been shown to prevent passing HIV to others. It is important to always practice safer sex, use latex or polyurethane condoms to lower the chance of sexual contact with any body fluids, and to never re-use or share needles. **Do not stop taking COMPLERA unless directed by your healthcare provider. See your healthcare provider regularly.**

IMPORTANT SAFETY INFORMATION

Contact your healthcare provider right away if you get the following side effects or conditions while taking COMPLERA:

- Nausea, vomiting, unusual muscle pain, and/or weakness. These may be signs of a buildup of acid in the blood (lactic acidosis), which is a serious medical condition
- Light-colored stools, dark-colored urine, and/or if your skin or the whites of your eyes turn yellow. These may be signs of serious liver problems (hepatotoxicity), with liver enlargement (hepatomegaly), and fat in the liver (steatosis)
- If you have HIV-1 and hepatitis B virus (HBV), your liver disease may suddenly get worse if you stop taking COMPLERA. Do not stop taking COMPLERA without first talking to your healthcare provider. Your healthcare provider will monitor your condition

COMPLERA may affect the way other medicines work, and other medicines may affect how COMPLERA works, and may cause serious side effects.

Do not take COMPLERA if you are taking the following medicines:

- other HIV medicines (COMPLERA provides a complete treatment for HIV infection.)
- the anti-seizure medicines carbamazepine (Carbatrol®, Equetro®, Tegretol®, Tegretol-XR®, Teril®, Eptol®), oxcarbazepine (Trileptal®), phenobarbital (Luminal®), phenytoin (Dilantin®, Dilantin-125®, Phenytek®)
- the anti-tuberculosis medicines rifabutin (Mycobutin), rifampin (Rifater®, Rifamate®, Rimactane®, Rifadin®) and rifapentine (Priftin®)
- a proton pump inhibitor medicine for certain stomach or intestinal problems, including esomeprazole (Nexium®, Vimovo®), lansoprazole (Prevacid®), omeprazole (Prilosec®), pantoprazole sodium (Protonix®), rabeprazole (Aciphex®)
- more than 1 dose of the steroid medicine dexamethasone or dexamethasone sodium phosphate
- St. John's wort (Hypericum perforatum)
- other medicines that contain tenofovir (VIREAD®, TRUVADA®, ATRIPLA®)
- other medicines that contain emtricitabine or lamivudine (EMTRIVA®, Combivir®, Epivir® or Epivir-HBV®, Epzicom®, Trizivir®)
- rilpivirine (Eduvant™)
- adefovir (HEPSERA®)

In addition, also tell your healthcare provider if you take:

- an antacid medicine that contains aluminum, magnesium hydroxide, or calcium carbonate. Take antacids at least 2 hours before or at least 4 hours after you take COMPLERA
- a histamine-2 blocker medicine, including famotidine (Pepcid®), cimetidine (Tagamet®), nizatidine (Axid®), or ranitidine hydrochloride (Zantac®). Take these medicines at least 12 hours before or at least 4 hours after you take COMPLERA
- the antibiotic medicines clarithromycin (Biaxin®), erythromycin (E-Mycin®, Eryc®, Ery-Tab®, PCE®, Pediazole®, Ilosone®), and troleandomycin (TAO®)
- an antifungal medicine by mouth, including fluconazole (Diflucan®), itraconazole (Sporanox®), ketoconazole (Nizoral®), posaconazole (Noxafi®), voriconazole (Vfend®)
- methadone (Dolophine®)

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

COMPLERA is a prescription medicine used as a complete single-tablet regimen to treat HIV-1 in adults who have never taken HIV medicines before. COMPLERA does not cure HIV or AIDS or help prevent passing HIV to others.

New COMPLERA

A complete HIV treatment in only 1 pill a day.

Ask your healthcare provider if it's the **one** for you.

Before taking COMPLERA, tell your healthcare provider if you:

- have **liver problems**, including **hepatitis B or C** virus infection
- have **kidney problems**
- have ever had a **mental health problem**
- have **bone problems**
- are **pregnant or plan to become pregnant**. It is not known if COMPLERA can harm your unborn child
- are breastfeeding; **women with HIV should not breast-feed** because they can pass HIV through their milk to the baby

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

Serious side effects associated with COMPLERA:

- **New or worse kidney problems** can happen in some people who take COMPLERA. If you have had kidney problems in the past or take other medicines that can cause kidney problems, your healthcare provider may need to do blood tests to check your kidneys during your treatment with COMPLERA
- **Depression or mood changes** can happen in some people who take COMPLERA. Tell your healthcare provider right away if you have any of the following symptoms: feeling sad or hopeless, feeling anxious or restless, or if you have thoughts of hurting yourself (suicide) or have tried to hurt yourself
- **Bone problems** can happen in some people who take COMPLERA. Bone problems include bone pain, softening or thinning (which may lead to fractures). Your healthcare provider may need to do additional tests to check your bones
- **Changes in body fat** can happen in people taking HIV medicine. 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
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider if you start having new symptoms after starting your HIV medicine

Common side effects associated with COMPLERA:

- trouble sleeping (insomnia), abnormal dreams, headache, dizziness, diarrhea, nausea, rash, tiredness, and depression

Other side effects associated with COMPLERA:

- vomiting, stomach pain or discomfort, skin discoloration (small spots or freckles), and pain

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of COMPLERA. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Take COMPLERA exactly as your healthcare provider tells you to take it

- **Always take COMPLERA with a meal.** Taking COMPLERA with a meal is important to help get the right amount of medicine in your body. A protein drink does not replace a meal
- **Stay under the care of your healthcare provider during treatment with COMPLERA and see your healthcare provider regularly**

Please see Patient Information for COMPLERA on the following pages.



COMPLERA[®]
emtricitabine 200mg/rilpivirine 25mg/
tenofovir disoproxil fumarate 300mg tablets

Learn more at www.COMPLERA.com

FDA-Approved Patient Labeling

Patient Information

COMPLERA® (kom-PLĒH-rah)

(emtricitabine, rilpivirine and tenofovir disoproxil fumarate) Tablets

Important: Ask your doctor or pharmacist about medicines that should not be taken with COMPLERA. For more information, see the section “What should I tell my healthcare provider before taking COMPLERA?”

Read this Patient Information before you start taking COMPLERA 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.

What is the most important information I should know about COMPLERA?

COMPLERA can cause serious side effects, including:

1. Build-up of an acid in your blood (lactic acidosis). Lactic acidosis can happen in some people who take COMPLERA or similar (nucleoside analogs) medicines. **Lactic acidosis** is a serious medical emergency that can lead to death.

Lactic acidosis can be hard to identify early, because the symptoms could seem like symptoms of other health problems. **Call your healthcare provider right away if you get any of the following symptoms which could be signs of lactic acidosis:**

- feeling very weak or tired
- have unusual (not normal) muscle pain
- have trouble breathing
- have stomach pain with
 - nausea (feel sick to your stomach)
 - vomiting
- feel cold, especially in your arms and legs
- feel dizzy or lightheaded
- have a fast or irregular heartbeat

2. Severe liver problems. Severe liver problems can happen in people who take COMPLERA or similar medicines. In some cases these liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis) when you take COMPLERA.

Call your healthcare provider right away if you have any of the following symptoms of liver problems:

- your skin or the white part of your eyes turns yellow (jaundice).
- dark “tea-colored” urine
- light-colored bowel movements (stools)
- loss of appetite for several days or longer
- nausea
- stomach pain

You may be more likely to get lactic acidosis or severe liver problems if you are female, very overweight (obese), or have been taking COMPLERA or a similar medicine containing nucleoside analogs for a long time.

3. Worsening of Hepatitis B infection. If you also have hepatitis B virus (HBV) infection and you stop taking COMPLERA, your HBV infection may become worse (flare-up). A “flare-up” is when your HBV infection suddenly returns in a worse way than before. COMPLERA is not approved for the treatment of HBV, so you must discuss your HBV therapy with your healthcare provider.

- Do not let your COMPLERA run out. Refill your prescription or talk to your healthcare provider before your COMPLERA is all gone.
- Do not stop taking COMPLERA without first talking to your healthcare provider.
- If you stop taking COMPLERA, your healthcare provider will need to check your health often and do regular blood tests to check your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking COMPLERA.

What is COMPLERA?

COMPLERA is a prescription HIV (Human Immunodeficiency Virus) medicine that:

- is used to treat HIV-1 in adults who have **never** taken HIV medicines before. HIV is the virus that causes AIDS (Acquired Immunodeficiency Syndrome).
- contains 3 medicines, (rilpivirine, emtricitabine, tenofovir disoproxil fumarate) combined in one tablet. EMTRIVA and VIREAD are HIV-1 (human immunodeficiency virus) nucleoside analog reverse transcriptase inhibitors (NRTIs) and EDURANT is an HIV-1 non-nucleoside analog reverse transcriptase inhibitor (NNRTI).

It is not known if COMPLERA is safe and effective in children under the age of 18 years.

COMPLERA may help:

- Reduce the amount of HIV in your blood. This is called your “viral load”.
- Increase the number of white blood cells called CD4+ (T) cells that help fight off other infections.

Reducing the amount of HIV and increasing the CD4+ (T) cell count may improve your immune system. This may reduce your risk of death or infections that can happen when your immune system is weak (opportunistic infections).

COMPLERA does not cure HIV infections or AIDS.

- Always practice safer sex.
- Use latex or polyurethane condoms to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions, or blood.
- Never re-use or share needles.

Ask your healthcare provider if you have any questions about how to prevent passing HIV to other people.

Who should not take COMPLERA?

- Do not take COMPLERA if your HIV infection has been previously treated with HIV medicines.
- **Do not take COMPLERA if you are taking certain other medicines.** For more information about medicines that must not be taken with COMPLERA, see “**What should I tell my healthcare provider before taking COMPLERA?**”

What should I tell my healthcare provider before taking COMPLERA?

Before you take COMPLERA, tell your healthcare provider if you:

- have liver problems, including hepatitis B or C virus infection
 - have kidney problems
 - have ever had a mental health problem
 - have bone problems
 - are pregnant or plan to become pregnant. It is not known if COMPLERA can harm your unborn child
- Pregnancy Registry.** There is a pregnancy registry for women who take antiviral medicines during pregnancy. Its purpose is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.
- are breast-feeding or plan to breast-feed. The Centers for Disease Control and Prevention recommends that mothers with HIV not breastfeed because they can pass the HIV through their milk to the baby. It is not known if COMPLERA can pass through your breast milk and harm your baby. Talk to your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

COMPLERA may affect the way other medicines work, and other medicines may affect how COMPLERA works, and may cause serious side effects. If you take certain medicines with COMPLERA, the amount of COMPLERA in your body may be too low and it may not work to help control your HIV infection. The HIV virus in your body may become resistant to COMPLERA or other HIV medicines that are like it.

Do not take COMPLERA if you also take these medicines:

- COMPLERA provides a complete treatment for HIV infection. Do not take other HIV medicines with COMPLERA.
- the anti-seizure medicines carbamazepine (CARBATROL®, EQUETRO®, TEGRETOL®, TEGRETOL-XR®, TERIL®, EPITOL®), oxcarbazepine (TRILEPTAL®), phenobarbital (LUMINAL®), phenytoin (DILANTIN®, DILANTIN-125®, PHENYTEK®)
- the anti-tuberculosis medicines rifabutin (MYCOBUTIN®), rifampin (RIFATER®, RIFAMATE®, RIMACTANE®, RIFADIN®) and rifapentine (PRIFITIN®)
- a proton pump inhibitor medicine for certain stomach or intestinal problems, including esomeprazole (NEXIUM®, VIMOVO®), lansoprazole (PREVACID®), omeprazole (PRILOSEC®), pantoprazole sodium (PROTONIX®), rabeprazole (ACIPHEX®)
- more than 1 dose of the steroid medicine dexamethasone or dexamethasone sodium phosphate
- St. John’s wort (*Hypericum perforatum*)

If you are taking COMPLERA, you should not take:

- other medicines that contain tenofovir (VIREAD®, TRUVADA®, ATRIPLA®)
- other medicines that contain emtricitabine or lamivudine (EMTRIVA®, COMBIVIR®, EPIVIR® or EPIVIR-HBV®, EPZICOM®, TRIZIVIR®)
- rilpivirine (EDURANT™)
- adefovir (HEPSERA®)

Also tell your healthcare provider if you take:

- an antacid medicine that contains aluminum, magnesium hydroxide, or calcium carbonate. Take antacids at least 2 hours before or at least 4 hours after you take COMPLERA.
- a histamine-2 blocker medicine, including famotidine (PEPCID®), cimetidine (TAGAMET®), nizatidine (AXID®), or ranitidine hydrochloride (ZANTAC®). Take these medicines at least 12 hours before or at least 4 hours after you take COMPLERA.
- the antibiotic medicines clarithromycin (BIAXIN®), erythromycin (E-MYCIN®, ERYC®, ERY-TAB®, PCE®, PEDIAZOLE®, ILOSONE®), and troleandomycin (TAO®)
- an antifungal medicine by mouth, including fluconazole (DIFLUCAN®), itraconazole (SPORANOX®), ketoconazole (NIZORAL®), posaconazole (NOXAFIL®), voriconazole (VFEND®)
- methadone (DOLOPHINE®)

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine. Your healthcare provider and your pharmacist can tell you if you can take these medicines with COMPLERA. Do not start any new medicines while you are taking COMPLERA without first talking with your healthcare provider or pharmacist. You can ask your healthcare provider or pharmacist for a list of medicines that can interact with COMPLERA.

How should I take COMPLERA?

- **Stay under the care of your healthcare provider during treatment with COMPLERA.**
- **Take COMPLERA exactly as your healthcare provider tells you to take it.**
- **Always take COMPLERA with a meal.** Taking COMPLERA with a meal is important to help get the right amount of medicine in your body. A protein drink does not replace a meal.
- Do not change your dose or stop taking COMPLERA without first talking with your healthcare provider. See your healthcare provider regularly while taking COMPLERA.
- If you miss a dose of COMPLERA within 12 hours of the time you usually take it, take your dose of COMPLERA with a meal as soon as possible. Then, take your next dose of COMPLERA at the regularly scheduled time. If you miss a dose of COMPLERA by more than 12 hours of the time you usually take it, wait and then take the next dose of COMPLERA at the regularly scheduled time.
- Do not take more than your prescribed dose to make up for a missed dose.
- When your COMPLERA supply starts to run low, get more from your healthcare provider or pharmacy. It is very important not to run out of COMPLERA. The amount of virus in your blood may increase if the medicine is stopped for even a short time.
- If you take too much COMPLERA, contact your local poison control center or go to the nearest hospital emergency room right away.

What are the possible side effects of COMPLERA?

COMPLERA may cause the following serious side effects, including:

- **See “What is the most important information I should know about COMPLERA?”**
- **New or worse kidney problems** can happen in some people who take COMPLERA. If you have had kidney problems in the past or take other medicines that can cause kidney problems, your healthcare provider may need to do blood tests to check your kidneys during your treatment with COMPLERA.
- **Depression or mood changes. Tell your healthcare provider right away if you have any of the following symptoms:**
 - feeling sad or hopeless
 - feeling anxious or restless
 - have thoughts of hurting yourself (suicide) or have tried to hurt yourself
- **Bone problems** can happen in some people who take COMPLERA. Bone problems include bone pain, softening or thinning (which may lead to fractures). Your healthcare provider may need to do additional tests to check your bones.
- **Changes in body fat** can happen in people taking HIV medicine. 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.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider if you start having new symptoms after starting your HIV medicine.

The most common side effects of COMPLERA include:

- trouble sleeping (insomnia)
- abnormal dreams
- headache
- dizziness
- diarrhea
- nausea
- rash
- tiredness
- depression

Additional common side effects include:

- vomiting
- stomach pain or discomfort
- skin discoloration (small spots or freckles)
- pain

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of COMPLERA. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 (1-800-332-1088).

How do I store COMPLERA?

- Store COMPLERA at room temperature 77 °F (25 °C).
- Keep COMPLERA in its original container and keep the container tightly closed.
- Do not use COMPLERA if the seal over the bottle opening is broken or missing.

Keep COMPLERA and all other medicines out of reach of children.

General information about COMPLERA:

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use COMPLERA for a condition for which it was not prescribed. Do not give COMPLERA to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about COMPLERA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about COMPLERA that is written for health professionals. For more information, call (1-800-445-3235) or go to www.COMPLERA.com.

What are the ingredients of COMPLERA?

Active ingredients: emtricitabine, rilpivirine hydrochloride, and tenofovir disoproxil fumarate

Inactive ingredients: pregelatinized starch, lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, povidone, polysorbate 20. The tablet film coating contains polyethylene glycol, hypromellose, lactose monohydrate, triacetin, titanium dioxide, iron oxide red, FD&C Blue #2 aluminum lake, FD&C Yellow #6 aluminum lake.

This Patient Information has been approved by the U.S. Food and Drug Administration

Manufactured and distributed by:

Gilead Sciences, Inc.

Foster City, CA 94404

Issued: August 2011

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202123-GS-000 02AUG2011 CON11252 11/11



JAN+FEB 2012

VOLUME 24 NUMBER 1



ARTICLES OF FAITH

In times of crisis, many people turn to religion, church, or prayer. Can faith help sustain us when living with HIV?

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POSITIVELY AWARE

5537 N. BROADWAY ST.

CHICAGO, IL 60640

PHONE: (773) 989-9400

FAX: (773) 989-9494

publications@tpan.com

www.positivelyaware.com

EDITORIAL

EDITOR-IN-CHIEF JEFF BERRY

ASSOCIATE EDITOR ENID VÁZQUEZ

COPY EDITOR SUE SALTMARSH

WEB MASTER JOSHUA THORNE

ART & DESIGN DIRECTOR RICK GUASCO

PROOFREADERS

JASON LANCASTER, CAMILLE SMITH

CONTRIBUTING WRITERS

KEITH R. GREEN, LIZ HIGHLEYMAN,

SAL IACOPELLI, LAURA JONES,

JIM PICKETT, MATT SHARP

PHOTOGRAPHERS

JOHN GRESS, CHRIS KNIGHT,

JOSHUA THORNE

MEDICAL ADVISORS

DANIEL S. BERGER, MD

GARY BUCHER, MD

MICHAEL CRISTOFANO, PA

JOEL GALLANT, MD

SWARUP MEHTA, PHARM D

ADVERTISING & DISTRIBUTION

ADVERTISING INQUIRIES

LORRAINE HAYES

l.hayes@tpan.com

DISTRIBUTION COORDINATOR

BRADLEY P MAZZIE

distribution@tpan.com



POSITIVELY AWARE
IS PUBLISHED BY
TEST POSITIVE AWARE NETWORK

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EXCLUSIVELY ON POSITIVELYAWARE.COM

The 'Plan B' question

Are we prepared for when health care reform fails?

www.positivelyaware.com/2012/12_01/planb.shtml

Getting to the bottom of anal health, Part II

High-resolution anoscopy and treatment of anal cancer.

www.positivelyaware.com/2012/12_01/anal.shtml

Grocery list for healthy eating

Use this list for nutrition that packs a healthy punch.

www.positivelyaware.com/2012/12_01/grocery.shtml

DIGITAL EDITION

Read the print version of POSITIVELY AWARE on your computer.

<http://issuu.com/positivelyaware>



EDITOR'S NOTE
JEFF BERRY

Keeping the faith

I FONDLY REMEMBER, FROM WHEN I WAS GROWING UP AND AS a young boy, visits with my mom's parents during family gatherings. My grandfather, Daniel, was a Methodist minister (and his mother was also a Methodist minister, which was uncommon for a woman in those days). He would tell me from time to time that he hoped I would follow in his footsteps and become a minister myself one day. He apparently saw something in me that I didn't, and which suggested to him that I had been "called."

I was petrified and at the same time a bit curious—I was intrigued by the idea of ministering to others, but I somehow knew that a life in the church just wasn't for me. Since I never really had the heart (or was it the guts?) to tell him so, I would just smile and kind of nod my head whenever he would bring it up in conversation.

I had forgotten all about this piece of my childhood until the other day, when I was going through some old papers of mine that my brother had passed along to me during a recent visit. I came across an old birthday card from my grandfather with the words "I'm counting on you!" that he had scrawled along the bottom. It got me thinking about the different ways in which we minister to others, and the meaning of faith, and how it plays a role in our day-to-day lives.

This issue of POSITIVELY AWARE delves into the topic of faith and HIV, with a specific focus on religion, and encompassing, as one writer puts it, "The Good, the Bad, and the Ugly." It's hard for many people to separate the concepts of faith and religion—for some the two go hand in hand. Unfortunately, these days I think many people have been disillusioned with

the standard dogma and tenets of modern religion. There are the ongoing scandals of child sexual abuse at the hands of priests, and the cover-ups by those in authority that took place afterwards which allowed it to continue. And there is the fire-and-brimstone mentality of those who take the gospel word for word, and use it against those whose lifestyles or sexual orientation they either don't agree with or can't even attempt to understand.

It's no wonder that people have lost faith. But faith is much more than brick and mortar or words on the page of a book.

My parents would make us go to church every Sunday when I was growing up, and I came to dislike it and would sometimes pretend I was sick just so I wouldn't have to go. But I look back at it now and I'm grateful for those experiences, because it instilled in me a faith in something greater than myself, something beyond this world and this realm of experience, which became unshakeable. I stopped attending church years ago, but my faith in a higher power remained firm—it's something that I believe lies within me, and within all of us. I have also come to believe that, regardless of the circumstances in our lives, we are

always presented with a choice in how we perceive what is happening in the world around us. And that choice gives us the power, and the strength, to create change, or at least a change in perception.

So here I am, all these years later, a minister of sorts, I guess. I feel extremely privileged and grateful to be able to do work which allows me to have a voice, to reach out with a message of hope and inspiration about living and thriving with HIV, and provide information and support to help people live healthier and more productive lives in the face of HIV/AIDS.

I know from experience it's important to hear these messages of hope. My mom told me years ago, not long after I tested positive, that she somehow just knew that I was going to be okay. I believed her, and it turns out she was right. That was 1989, over 22 years ago. She gave me the faith to carry on, even while she was fighting her own struggle with metastatic breast cancer. Even though she eventually lost her battle, she fought bravely and valiantly, and I now feel a sense of responsibility to share my own story in the hopes of helping others—and to try to be as authentic as possible while doing so. Hey, I'm by no means perfect, and I make mistakes just like everyone else. But I do believe I'm in the right place, at the right time, doing exactly what I need to be doing. And that's what keeps me going. I have faith that Grandpa, and Mom, would both be proud.

Take care of yourselves, and each other.

POSITIVELYAWARE.COM

PHOTO: CHRIS KNIGHT

Reading as self-empowerment

I JUST GOT MY LATEST COPY OF YOUR magazine and wanted to write and let you know that it helps.

I am a 36-year-old, mostly gay man locked up on a four-year term in Chino, California. I was diagnosed positive in 2006 and have had to make a lot of decisions about life without any up-to-date information.

I find myself trying to advocate to the very people who are the hardest to reach because, in a very real way, they too live with HIV on a daily basis.

I am very out and very loud about the fact that I am positive. It's weird, though—all people want to know is why or when or how I got it, and the way I see it, those things pale in comparison to the fact that I'm positive and what choices I make now. People who don't know better freak out about having social contact with me and it gets really hard.

Thank you for your help.

Jeremy Riley
CHINO, CA

FAITH TO FIGHT

I'M A 29-YEAR-OLD MAN WHO'S BEEN living with HIV for about 12 years. I've been in prison for the past 10 years and, on several occasions, have run across issues of your magazine.

I really enjoy reading about the new meds out there and how people are able to deal with this monster of a virus that we fight every day. In 1999, I started treatment with Ziagen and Combivir, but due to an allergic reaction, was put on Reyataz,



Epivir, and Viread. After about a year, lots of bilirubin built up in my liver and my eyes and skin turned yellow. I then took a three-year "vacation" before starting Atripla. Wow! It's amazing—I've been on the treatment for almost four years now and I haven't had any problems yet!

Thanks for providing information and support and giving me faith in this fight. It's a daily struggle

dealing with the depression, stress, and fear, but I know I can make it—I only have four years left.

—*Matthew G.*
BUFORD, GA

MARKING "A DAY"

I'D LIKE TO ORDER A COPY OF THE 2010 Nov.+Dec. edition. My photo was one selected for that first "A Day with HIV in America" spread. Look for my Miss Noon in Miss America stance with official wave on a red carpet. I've since subscribed to POSITIVELY AWARE, but could not get my hands on a hard copy of the 2010 edition.

I'm happy to see my rear end at 9:37 a.m. in 3-D on the Internet slide

show [www.adaywithhiv.com]. I got a \$1,000 hormone shot on the official ADWHIA shoot day—Lupron—for prostate cancer treatment. Then three gold markers were inserted inside my prostate for radiation treatments to find the walnut during radiation zaps for 8 weeks, 5 days a week. Testosterone range is 7.2 - 24.0. Guess my count—0.2! Can't stop singing "I'm EVERY Woman!"

Cheers for the great work you do; especially Rick on this project!

Mark A. Davis
PHILADELPHIA, PA

A DAY WITH HIV IN AMERICA WAS A VERY engaging photo essay project created by POSITIVELY AWARE. The idea behind the project was to broaden the way people understand what it means to live with HIV today and to combat the overwhelming stigma associated with the disease. The result was an exciting photo collage of the experiences of various people with HIV in this country.

Styx bassist Chuck Panozzo was one of the judges charged with the considerable undertaking of narrowing down the submitted photos. Mr. Panozzo, a co-founder of the legendary rock band, is also openly gay and HIV-positive. He's extremely proud to be out and open about who he is and feels he has "a responsibility to send a message to the audience." He added, "How can we expect others to respect us if we can't respect ourselves?"

This photo project is an excellent instrument to help people gain more respect for themselves and their communities, and the outspoken Panozzo was a perfect fit for it. There are still very few artists and entertainers who are out about their HIV status, so Panozzo stands out as someone bold enough to speak about what it means to have HIV today. One of his goals is to educate people about what it's like to live with this disease and he says, "Being out and being open is the best form of education."

It's refreshing to encounter a performer

CONTINUED ON PAGE 8 >>

DO THE WRITE THING

POSITIVELY AWARE treats 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. Unless you tell us not to, we will use your name and city.



POSITIVELY AWARE 5537 N. Broadway St., Chicago, IL 60640
E-MAIL: readersforum@tpan.com

IN BOX

>> CONTINUED FROM PAGE 7

who isn't shy about expressing an opinion or speaking candidly about his life experience. Panozzo's life experience of living with HIV for over 20 years and still touring demonstrates how dramatically the world of HIV has shifted and that people who have AIDS can now flourish.

If there were a theme for the Day with HIV in America project, it would be something like "thriving." Of course, people still endure the challenge of living with HIV in America, and economic disparities and social injustice make HIV a profound struggle. We have a ways to go, but our

community has never been stronger and better prepared to meet these challenges.

Today, HIV is a story of having survived the worst to now have the opportunity to thrive. When I look at the various photos in the project and when I think of Chuck Panozzo, I see a community that is thriving and working hard to fight stigma, organizing to protect the rights of people with HIV, and establishing a culture for people whose days in America are impacted by HIV but no longer destroyed by it.

—from a blog post by Alex Garner

EDITOR-AT-LARGE
FRONTIERSLA.COM



Jayson Conner submitted this picture for A Day with HIV in America. (photograph by Jeffrey L. Newman)

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A model, photographer, or author's HIV status should not be assumed based on their appearance in POSITIVELY AWARE, association with TPAN, or contributions to this journal.

Distribution of POSITIVELY AWARE is supported in part through an unrestricted grant from ViiV Healthcare.

READERS' POLL

Do you think the new health care reforms will help, hurt, or not affect the fight against HIV in the U.S.?

RESULTS FROM THE READERS' POLL IN THE NOVEMBER+DECEMBER ISSUE:



YOUR COMMENTS:

"I fear that the Ryan White program will cease to exist."

"It will have no effect at all... I would think whatever changes that will be made, HIV-positive people won't be included."

"There will end up being no benefit to anyone since the Republicans will never let it be enacted and funded."

"Hurry and Wait and Hope for Help! What?"

"With the current political environment, extending Ryan White seems nearly impossible and with the efforts toward repealing the Affordable Care Act, it appears we will soon be up the creek. Advocates must begin to get a consistent voice, know who and for what we are voting for, and get behind efforts to fight for health care."

THIS ISSUE'S POLL QUESTION:
Is religion and/or spirituality important to you in maintaining your health?

CAST YOUR VOTE AT
POSITIVELYAWARE.COM



ASK THE HIV SPECIALIST

FATHER DREW A. KOVACH, MD, MDIV, ABFM, AAHIVS



For what ails the soul

Q: I RECENTLY FOUND OUT THAT I'M HIV-POSITIVE. SO FAR I haven't told anyone except my best friend and just thinking of people finding out I'm gay and have HIV makes me want to crawl into a cave! I was raised in a religious family and my faith community, which is very important to me, is very conservative.

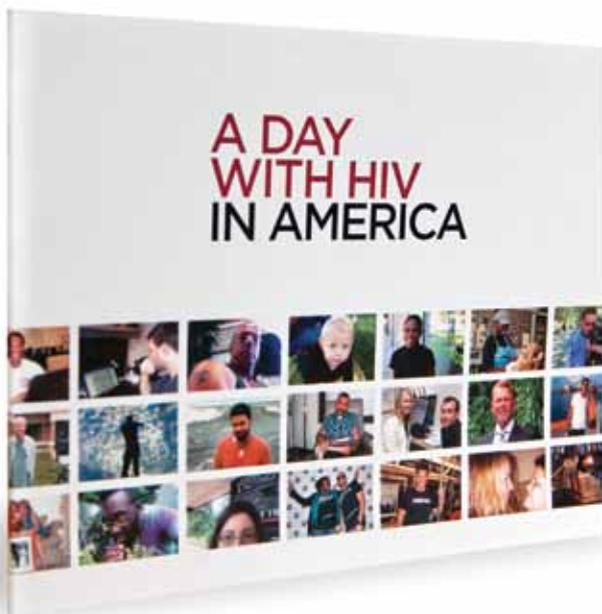
Over the years, I've heard them condemn homosexuals and theorize that AIDS is God's punishment for being gay. Now is a time when I need my faith and I feel like that, as well as my health, has been taken from me and I'm really depressed about it all. I have a friend who's some sort of pagan and he talks about how important the mind/body/spirit connection is to your health and well-being—I believe that may be true, but I just can't abandon what I've always believed in for something that's not true for me. I've prayed and prayed and haven't gotten any clarity. What do you think? How important is my faith to my health?

A: Faith and a solid spiritual foundation is essential in living well with HIV. HIV affects the mind, the body, and the spirit and all must be in balance to be whole and well. Religion is a man-made construct to try to understand God. God loves all of us, no matter that we are gay, lesbian, bisexual, or transgender, or if we have HIV! Disease is never a punishment from God. In the Christian belief, Jesus turned no one away and healed all who came to him. He wants us to be well, whole, and holy. Religion is simply a vehicle to things spiritual. No more, no less. As a physician and a priest and as a gay man taking care of HIV patients now for over 30 years, I know

how conflicted one can be about such matters of sexual preference and what religion has to say about such things. God the Creator is bigger than religion. Again, let it be clear, God loves us just the way we are and for who we are.

THE REVEREND FATHER DREW A. KOVACH, MD, MDIV, ABFM, AAHIVS is an ordained Episcopal/Orthodox priest, as well as a board certified Family Medicine Physician, an HIV/AIDS Specialist, and Director of HIV Services at Kaiser Permanente Hawaii.

SEARCH FOR AN HIV SPECIALIST™
Finding an HIV Specialist™ is easy with AAHIVM's Referral Link at www.aahivm.org. Enter your ZIP code on the home page, and click on the "Go" button for a list of HIV Specialists™ near you.



Seize the Day.

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To order, go to www adaywithhiv.com/book



BRIEFLY

REPORTED BY ENID VÁZQUEZ

New all-in-one HIV drug, the Quad, goes before FDA

Good news for HIV treatment options: in October, **Gilead Sciences submitted a New Drug Application (NDA)** to the Food and Drug Administration (FDA) for approval of the “Quad,” a complete single-tablet HIV regimen. The other two such complete medications on the market are Atripla and Complera.

All three medications contain Truvada (Viread and Emtriva) from Gilead Sciences as the background drug. Atripla also contains Sustiva, from Bristol-Myers Squibb, while Complera’s third drug is Edurant, from Tibotec Therapeutics (now Janssen Therapeutics). Both Sustiva and Edurant are from the drug class called non-nucleoside reverse transcriptase inhibitors, or NNRTIs.

The Quad would be different in that its principle drug is elvitegravir, an HIV integrase inhibitor medication like Isentress. The Quad also contains the new drug level-boosting medication called cobicistat, which allows for once-daily use of elvitegravir. Therefore, the Quad is taken as one pill once daily, as are Atripla and Complera.

The NDA is based on results from two Phase 3 (advanced) studies showing non-inferiority (an FDA standard) at 48 weeks of research compared to either Atripla or boosted Reyataz. Both drugs are recommended by U.S. HIV treatment guidelines for first-time therapy.

Drug makers sign agreements on new fixed-dose combo pills

Kudos to **Bristol-Myers Squibb (BMS) and Tibotec (now Janssen) Therapeutics for signing a commercial agreement with**

Gilead Sciences to get that company’s new boosting medication, cobicistat, into a fixed dose pill with BMS’s Reyataz and Tibotec’s Prezista. The two HIV protease inhibitors, along with a booster medication, are the two PIs recommended for first-time antiviral therapy by U.S. treatment guidelines. Currently, Reyataz and Prezista use Norvir as a boosting agent, but that medication can be very intolerable. While the agreement with BMS is for a boosted Reyataz pill, the agreement with Tibotec is for a complete HIV regimen in one tablet that includes Prezista, cobicistat, Emtriva, and Gilead’s GS-7340, a pro-drug (an inactive substance that metabolizes into active form in the body) of its popular Viread (tenofovir, also found in Truvada, Atripla, and Complera).

HIV treatment guidelines updated

On October 14, the Department of Health and Human Services (DHHS) **updated its HIV treatment guidelines.**

The revised guidelines can be found at www.AIDSinfo.nih.gov. Many changes were made by the panel of experts that updates the guidelines. These changes, listed below, all apply to the recommendations of what to use for people going on HIV therapy for the first time.

- The new HIV non-nucleoside drug Edurant (rilpivirine, in the same class as Sustiva) was added as an acceptable option; a number of tables, such as the drug interactions table, also had Edurant information added.
- Prezista plus Epzicom, and Isentress plus Epzicom were upgraded to an “alternative regimen” from previously being considered “acceptable, but more definitive data are needed.”
- Combivir (the combination of AZT [zidovudine] plus lamivudine) was downgraded from an “alternative” to “acceptable” dual nucleoside

background because it has twice-daily dosing and greater toxicity than the medications Truvada and Epzicom. However, Combivir remains preferred for the treatment of pregnant women due to its demonstrated ability to stop HIV transmission to infants.

- Lexiva has been removed as a protease inhibitor (PI) option because of inferior potency and the potential for developing resistance to Prezista, a recommended PI for first-time therapy.
- Virmune (nevirapine), a non-nucleoside, is now considered “acceptable” (but not “recommended” or “alternative”) for first-time therapy (depending on the sex and beginning T-cell count of the patient); see the guidelines for its upgrading and downgrading information.
- Videx or Videx-EC plus Epivir were removed as an option for dual nucleoside background because they have the least study data and greater toxicity than other background drugs available.

Ziagen and the heart

The updated HIV treatment guidelines (see above) also **expanded the discussion of a possible risk of heart attack with abacavir** (Ziagen, also found in Epzicom and Trizivir). This association was first noted years ago, leading various groups of researchers around the world to try to confirm or eliminate the risk factor. The guidelines added an update on all this work, explaining that of the several studies looking at this issue, some have found an association while others haven’t. Additional studies have also looked at possible mechanisms of action for such an association, without success. All in all, the latest version of the guidelines

states that “to date, no consensus has been reached either on the association of [abacavir] use with MI [myocardial infarction, or heart attack] risk or a possible mechanism for the association.”

New side effect warnings for Isentress

The FDA added warnings in November to the package insert for the popular HIV drug Isentress (raltegravir). Although known for tolerability, the following adverse reactions have been seen with Isentress.

The “Warnings and Precautions” section now includes “severe skin and hypersensitivity [allergic] reactions.” Also added was rash with eosinophilia (elevated levels of a specific type of white blood cells), systemic symptoms [those that occur throughout the body, such as fever], and cerebellar ataxia, which is sudden, uncoordinated movement due to disease or injury of the cerebellum (part of the brain).

According to the updated information, “Delay in stopping Isentress treatment or other suspect agents after the onset of severe rash may result in a life-threatening reaction.” The new information also states that, “Patients should be advised to immediately contact their healthcare provider if they develop rash. Instruct patients to immediately stop taking Isentress and other suspect agents, and seek medical attention if they develop a rash associated with any of the following symptoms as it may be a sign of a more serious reaction such as Stevens-Johnson syndrome, toxic epidermal necrolysis, or severe hypersensitivity: fever, general ill feeling, extreme tiredness, muscle or joint aches, blisters, oral lesions, eye inflammation, facial swelling, swelling of the eyes, lips, mouth, breathing difficulty, and/or signs and symptoms of liver problems

(e.g., yellowing of the skin or whites of the eyes, dark or tea colored urine, pale colored stools/bowel movements, nausea, vomiting, loss of appetite, or pain, aching or sensitivity on the right side below the ribs). Patients should understand that if severe rash occurs, they will be closely monitored, laboratory tests will be ordered, and appropriate therapy will be initiated.”

Prezista label adds longer-term data

The Food and Drug Administration (FDA) in October approved a label update to the HIV protease inhibitor Prezista (darunavir) to add new 192-week data.

“Since its launch in 2006, Prezista has become one of the most prescribed antiretroviral agents in the protease inhibitor class,” said Vanessa Broadhurst, the president of Janssen Therapeutics, in a press release. “Having data showing the efficacy, safety, and tolerability of Prezista over 192 weeks should give added confidence to healthcare providers who are considering Prezista as an option for their patients who are starting treatment for the first time.”

Prezista showed superiority to Kaletra at 192 weeks in the ARTEMIS study of people on HIV therapy for the first time (Prezista is always boosted with Norvir and Kaletra has Norvir boosting in it). Seventy percent of the 343 individuals taking Prezista achieved undetectable viral load (less than 50 copies per mL) compared to 61% of the 346 people taking Kaletra. Virologic failure (not maintaining undetectable viral load) was 12% for Prezista vs. 15% for Kaletra.

The most common adverse reactions of moderate intensity (greater or equal to grade 2, with 5 being the highest) were diarrhea (9% for Prezista and 16% for

Kaletra), headache (7% vs. 6%), abdominal pain (6% for each), and rash (6% vs. 7%).

Prezista was developed by Tibotec (now Janssen) Therapeutics. It is one of two protease inhibitors recommended by U.S. HIV treatment guidelines for people taking antiretrovirals for the first time.

AMA supports research on HIV organ transplants

The American Medical Association (AMA) voted in November to support amending a federal law that bars clinical research of organ donations from HIV-positive donors, calling such research “a potentially lifesaving measure for people living with HIV infection.”

Indeed, according to an AMA press release, “Advances in the medical management of HIV infection coupled with improvements in transplant outcomes could make organ transplantation a viable clinical option for many HIV-infected patients. Despite these scientific advances, the Federal National Organ Transplant Act of 1984 precludes donations of HIV-infected organs, thereby prohibiting investigational studies on a source of organs for HIV-infected patients. It is estimated that there are approximately 500-600 potential HIV-infected kidney and liver donors per year in the United States. Organs from these donors have the potential to save the lives of approximately 1,000 HIV-infected patients each year.”

The release goes on to quote AMA Board Member Ardis D. Hoven, MD. “Research is needed to fully evaluate the clinical risks and benefits of organ transplantation between HIV-infected individuals,” said Dr. Hoven. “The new policy adopted today extends the AMA’s support for a change in federal law that will permit the necessary scientific investigation.”

BRIEFLY

COMPILED FROM THE WEEKLY E-NEWS

First clinical trial of ARV vaginal ring underway

In the first clinical trial of a vaginal ring combining two antiretroviral (ARV) drugs, researchers from the Microbicide Trials Network (MTN) are collaborating with the International Partnership for Microbicides (IPM) to evaluate whether the ring is safe for use in women. If the ring does prove to be safe, it could be considered for further testing, and **eventually be evaluated for its effectiveness as a microbicide for protecting women against HIV** infection through vaginal sex.

The study, which is funded by the National Institutes of Health and goes by the name MTN-013/IPM 026, is evaluating a ring that contains dapivirine, a non-nucleoside reverse transcriptase inhibitor (NNRTI) and the entry inhibitor Selzentry (maraviroc). The dapivirine-maraviroc ring is the first combination microbicide to enter clinical trials. It is also the first vaginal microbicide containing an entry inhibitor. The belief is that combining the two drugs, which act at different points in the HIV life cycle, may provide greater protection against HIV than a single drug alone.

The ring was developed by IPM, a non-profit product development partnership headquartered in Silver Spring, Maryland, in collaboration with Queens University Belfast (Belfast, Northern Ireland).

Globally, women comprise half of the 34 million people living with HIV. In most cases, women acquire HIV through unprotected heterosexual sex with an infected partner. Because the use of condoms is often not an option, there is an urgent need for effective prevention strategies that women can control themselves. To that end, vaginal microbicides in the form of a gel or a ring are being developed to provide women with new tools to protect themselves against HIV.

MTN-013/IPM 026, which is now

screening potential participants, will enroll 48 healthy, HIV-negative women ages 18–40 at the University of Pittsburgh, Fenway Institute in Boston and the University of Alabama at Birmingham. Researchers will evaluate the ring's safety and how well women like or are willing to use the ring. In addition, different tests will be performed to help determine how much of each drug is taken up by the cells usually targeted by HIV and whether drug levels are sustained throughout the four weeks the ring is worn. Women will wear their assigned ring for 28 days. Different tests and procedures will be conducted during this time as well as during a 24-day follow-up period.

"IPM has been a pioneer in developing vaginal rings for delivery of antiretrovirals. Our collaboration marks an important juncture for the field as we begin to explore drugs with different mechanisms of action and methods that we hope will give women new, easy-to-use options for preventing HIV," remarked MTN principal investigator Sharon Hillier, PhD, who is professor and vice chair for faculty affairs, and director of reproductive infectious disease research in the department of obstetrics, gynecology, and reproductive sciences at the University of Pittsburgh School of Medicine.

"Our partnership with MTN on the first combination microbicide to enter clinical trials is an important milestone for the HIV prevention field," said Zeda F. Rosenberg, ScD, IPM chief executive officer. "With extensive pre-clinical data on both drugs to support the combination ring's development, we hope this product will one day expand women's HIV prevention options and open the door to developing other combination HIV prevention methods."

Next year, the MTN will launch a Phase 3 effectiveness trial of the dapivirine-only ring. The study, called ASPIRE—A Study to Prevent Infection with a Ring for Extended Use—will enroll approximately

3,475 women at sites in five African countries.

As part of IPM's strategy to license the dapivirine ring, IPM will conduct The Ring Study (IPM 027), which will be done in parallel with ASPIRE, and collect long-term safety and efficacy data about the ring among approximately 1,650 women at multiple research centers in Africa.

Capsaicin patch for neuropathy gets FDA review

NeurogesX, Inc., a biopharmaceutical company focused on developing and commercializing novel pain management therapies, announced on November 14 that the Food and Drug Administration (FDA) has accepted for review the company's supplemental new drug application (sNDA) for Qutenza (capsaicin) for the management of neuropathic pain caused by HIV-associated peripheral neuropathy (HIV-PN). The FDA has granted Qutenza a priority six month review classification.

"The FDA's filing and priority review of our sNDA for Qutenza in HIV-PN is a significant achievement for NeurogesX as we seek to expand our pain management franchise," said Anthony DiTonno, president and CEO of NeurogesX in a press release. "This takes us another step forward in our effort to provide lasting relief from one of the most challenging chronic pain conditions. We look forward to our continued discussion with the FDA during the review of this application."

The Qutenza sNDA seeks approval for a 30-minute application for the treatment of neuropathic pain associated with HIV-PN. Qutenza is currently FDA approved as a 60-minute application for the management of neuropathic pain associated with postherpetic neuralgia (PHN). If approved, the company believes

that Qutenza would be the first and only product approved to treat HIV-PN in the United States.

Early trial suggests rectal microbicide is safe, effective

A topically applied microbicide gel containing a potent anti-HIV drug has been found to **significantly reduce infection when applied to rectal tissue that was subsequently exposed to HIV in the laboratory**, according to a new study by the UCLA AIDS Institute. The gel was also found to be safe and acceptable to users.

The Phase 1 clinical trial of the rectal HIV-prevention drug known as UC781, a non-nucleoside reverse transcriptase inhibitor, is described in the current edition of the online journal PLoS ONE.

While anal-receptive intercourse is known to be the main route for new HIV infections in men who have sex with men, far more women than men worldwide practice anal intercourse. The risk of HIV infection, per sex act, is anywhere from 20 to 2,000 times greater with receptive anal sex than receptive vaginal sex — particularly if there are other infections present, such as herpes, gonorrhea or chlamydia, according to the study's lead author, Dr. Peter Anton, a professor of medicine in the division of digestive diseases at the David Geffen School of Medicine at UCLA, and a member of the UCLA AIDS Institute.

"While the main goal of this trial was also to evaluate safety, these new tests enabled us to evaluate, indirectly, whether this drug and route of delivery might potentially reduce new HIV infections," said Anton. "Of course, it is very gratifying that the results were so impressive. This approach reflects the kind of intensive analyses these dedicated participants in these early trials are willing to tolerate to help us evaluate a

drug's potential earlier in the pipeline of drug development."

In the trial, researchers tested a formulation of the gel that was created for vaginal use in human trials and that contained two concentrations of UC781. They enrolled 36 male and female subjects at UCLA who were not infected with HIV, and they collected blood and rectal tissue samples at baseline, before participants were randomized to either a placebo group or to receive one of two concentrations of UC781. All participants were given the placebo or active drug as a single exposure by the team's clinicians, with research samples collected 30 minutes later for analysis.

After two to three weeks, the participants resumed the second part of the trial by applying the gel or placebo once daily over seven days on their own at home. Afterwards, they returned to the clinic for another collection of samples. All participants completed the study once they were enrolled. In-depth interviews with each participant assessed their acceptability of the current form of the product.

Though the microbicide used for this study was formulated for vaginal use, the same team of researchers has also developed a rectal-specific microbicide gel, which they plan to start testing in a clinical trial in January 2012.

Another setback for women's HIV prevention

In the November/December issue of PA, it was reported that the VOICE study had stopped the use of Viread (tenofovir) tablets in its investigation of HIV prevention for women because it proved to be no better than a placebo.

In December, news came that an

independent Data and Safety Monitoring Board (DSMB) recommended stopping the 1% tenofovir gel being studied because it was also no more effective than placebo (fake substance). The women given either the gel or the placebo had the same incidence of acquiring HIV from their sex partners, 6% in each group.

Tenofovir 1% gel was found to be effective in preventing HIV in women in the landmark CAPRISA 004 study, and it continues to be studied for prevention in FACTS 001, an advanced Phase 3 study.

VOICE, which stands for Vaginal and Oral Interventions to Control the Epidemic, will continue to study the daily use of Truvada pills for prevention. The study is being carried out by the Microbicide Trials Network (MTN) in 15 sites throughout Uganda, South Africa, and Zimbabwe, and has enrolled more than 5,000 women.

In a press release, AVAC, a U.S. organization working on global advocacy for HIV prevention, reported, "The announcement that the 1% tenofovir gel arm of a large-scale HIV prevention trial known as VOICE will stop early is disappointing but is not the end of the road for tenofovir gel or antiretroviral (ARV)-based microbicides."

"This is a blow to the HIV prevention field but is not the definitive answer about whether 1% tenofovir gel is an effective HIV prevention product for women," said Mitchell Warren, AVAC executive director.

15.9
MILLION
women are living with
HIV/AIDS worldwide.
SOURCE: AVERT.ORG



Model

INDICATIONS

ISENTRESS is a medicine used to treat the human immunodeficiency virus (HIV). ISENTRESS must be taken with other HIV medicines to improve your chances of fighting the virus. You must remain under your doctor's care.

ISENTRESS has not been studied in children.

ISENTRESS will not cure HIV or reduce your chances of passing it on to others.

IMPORTANT RISK INFORMATION

A condition called Immune Reconstitution Syndrome can happen in some patients with advanced HIV infection (AIDS) when anti-HIV treatment is started. Signs and symptoms of inflammation from opportunistic infections may occur as the medicines work to treat the HIV infection and strengthen the immune system. Call your doctor right away if you notice any signs or symptoms of an infection after starting ISENTRESS.

Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness while taking ISENTRESS. This is because on rare occasions muscle problems can be serious and can lead to kidney damage.

When ISENTRESS has been given with other anti-HIV drugs, side effects included nausea, headache, tiredness, weakness, trouble sleeping, stomach pain, dizziness, depression, and suicidal thoughts and actions. Mild rash occurred more often in patients taking ISENTRESS plus *Prezista* than with either drug alone.

I am a go-getter. I am romantic. I am a world traveler. I am HIV positive.

You are special, unique, and different from anyone else. And so is your path to managing HIV. When you're ready to start HIV therapy, talk to your doctor about a medication that may fit your needs and lifestyle.

In clinical studies lasting 96 weeks, patients being treated with HIV medication for the first time who took ISENTRESS plus *Truvada*:

- ◆ Had a low rate of side effects
 - The most common side effect of moderate to severe intensity (that interfered with or kept patients from performing daily activities) was trouble sleeping
 - This side effect occurred more often in patients taking ISENTRESS plus *Truvada* (4%) versus *Sustiva* plus *Truvada* (3%)
- ◆ Experienced less effect on LDL cholesterol ("bad" cholesterol)
 - Cholesterol increased an average of 7 mg/dL with ISENTRESS plus *Truvada* versus 21 mg/dL with *Sustiva* plus *Truvada*
 - When they began the study, the average LDL cholesterol of patients on ISENTRESS plus *Truvada* was 96 mg/dL versus 93 mg/dL for those on *Sustiva* plus *Truvada*

Ask your doctor about ISENTRESS.

Not sure where to start? Visit isentress.com/questions

People taking ISENTRESS may still develop infections, including opportunistic infections or other conditions that occur with HIV infection.

Tell your doctor about all of your medical conditions, including if you have any allergies, are pregnant or plan to become pregnant, or are breast-feeding or plan to breast-feed. ISENTRESS is not recommended for use during pregnancy. Women with HIV should not breast-feed because their babies could be infected with HIV through their breast milk.

Tell your doctor about all the medicines you take, including prescription medicines like rifampin (a medicine used to treat infections such as tuberculosis), non-prescription medicines, vitamins, and herbal supplements.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For more information about ISENTRESS, please read the Patient Information on the following page.

Need help paying for ISENTRESS? Call 1-866-350-9232

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Prezista is a registered trademark of Tibotec, Inc.



ISENTRESS[®]
raltegravir tablets

Patient Information

ISENTRISS® (eye sen tris) (raltegravir) Tablets



Read the patient information that comes with ISENTRESS[®] before you start taking it and each time you get a refill. There may be new information. This leaflet is a summary of the information for patients. Your doctor or pharmacist can give you additional information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

What is ISENTRESS?

- ISENTRESS is an anti-HIV (antiretroviral) medicine used for the treatment of HIV. The term HIV stands for Human Immunodeficiency Virus. It is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). ISENTRESS is used along with other anti-HIV medicines. ISENTRESS will NOT cure HIV infection.
- People taking ISENTRESS may still develop infections, including opportunistic infections or other conditions that happen with HIV infection.
- Stay under the care of your doctor during treatment with ISENTRESS.
- The safety and effectiveness of ISENTRESS in children has not been studied.

ISENTRISS must be used with other anti-HIV medicines.

How does ISENTRESS work?

- ISENTRESS blocks an enzyme which the virus (HIV) needs in order to make more virus. The enzyme that ISENTRESS blocks is called HIV integrase.
- When used with other anti-HIV medicines, ISENTRESS may do two things:
 1. Reduce the amount of HIV in your blood. This is called your “viral load”.
 2. Increase the number of white blood cells called CD4 (T) cells.
- ISENTRESS may not have these effects in all patients.

Does ISENTRESS lower the chance of passing HIV to other people?

No. ISENTRESS does not reduce the chance of passing HIV to others through sexual contact, sharing needles, or being exposed to your blood.

- Continue to practice safer sex.
- Use latex or polyurethane condoms or other barrier methods to lower the chance of sexual contact with any body fluids. This includes semen from a man, vaginal secretions from a woman, or blood.
- Never re-use or share needles.

Ask your doctor if you have any questions about safer sex or how to prevent passing HIV to other people.

What should I tell my doctor before and during treatment with ISENTRESS?

Tell your doctor about all of your medical conditions. Include any of the following that applies to you:

- You have any allergies.
- You are pregnant or plan to become pregnant.
 - ISENTRESS is not recommended for use during pregnancy. ISENTRESS has not been studied in pregnant women. If you take ISENTRESS while you are pregnant, talk to your doctor about how you can be included in the Antiretroviral Pregnancy Registry.
- You are breast-feeding or plan to breast-feed.
 - It is recommended that HIV-infected women should not breast-feed their infants. This is because their babies could be infected with HIV through their breast milk.
 - Talk with your doctor about the best way to feed your baby.

Tell your doctor about all the medicines you take. Include the following:

- prescription medicines, including rifampin (a medicine used to treat some infections such as tuberculosis)
- non-prescription medicines
- vitamins
- herbal supplements

Know the medicines you take.

- Keep a list of your medicines. Show the list to your doctor and pharmacist when you get a new medicine.

How should I take ISENTRESS?

Take ISENTRESS **exactly** as your doctor has prescribed. The recommended dose is as follows:

- Take only one 400-mg tablet at a time.
- Take it twice a day.
- Take it by mouth.
- Take it with or without food.

Do not change your dose or stop taking ISENTRESS or your other anti-HIV medicines without first talking with your doctor.

IMPORTANT: Take ISENTRESS exactly as your doctor prescribed and at the right times of day because if you don't:

- The amount of virus (HIV) in your blood may increase if the medicine is stopped for even a short period of time.
- The virus may develop resistance to ISENTRESS and become harder to treat.
- Your medicines may stop working to fight HIV.
- The activity of ISENTRESS may be reduced (due to resistance).

If you fail to take ISENTRESS the way you should, here's what to do:

- If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do NOT take two tablets of ISENTRESS at the same time. In other words, do NOT take a double dose.
- If you take too much ISENTRESS, call your doctor or local Poison Control Center.

Be sure to keep a supply of your anti-HIV medicines.

- When your ISENTRESS supply starts to run low, get more from your doctor or pharmacy.
- Do not wait until your medicine runs out to get more.

What are the possible side effects of ISENTRESS?

When ISENTRESS has been given with other anti-HIV drugs, side effects included:

- nausea
- headache
- tiredness
- weakness
- trouble sleeping
- stomach pain
- dizziness
- depression
- suicidal thoughts and actions

Other side effects include: rash, severe skin reactions, feeling anxious, paranoia, low blood platelet count, diarrhea, liver failure.

A condition called Immune Reconstitution Syndrome can happen in some patients with advanced HIV infection (AIDS) when combination antiretroviral treatment is started. Signs and symptoms of inflammation from opportunistic infections that a person has or had may occur as the medicines work to treat the HIV infection and help to strengthen the immune system. Call your doctor right away if you notice any signs or symptoms of an infection after starting ISENTRESS with other anti-HIV medicines.

Contact your doctor promptly if you experience unexplained muscle pain, tenderness, or weakness while taking ISENTRESS. This is because on rare occasions, muscle problems can be serious and can lead to kidney damage.

Rash occurred more often in patients taking ISENTRESS and darunavir together than with either drug separately, but was generally mild.

Tell your doctor if you have any side effects that bother you.

These are not all the side effects of ISENTRESS. For more information, ask your doctor or pharmacist.

How should I store ISENTRESS?

- Store ISENTRESS at room temperature (68 to 77°F).
- **Keep ISENTRESS and all medicines out of the reach of children.**

General information about the use of ISENTRESS

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets.

- Do not use ISENTRESS for a condition for which it was not prescribed.
- Do not give ISENTRESS to other people, even if they have the same symptoms you have. It may harm them.

This leaflet gives you the most important information about ISENTRESS.

- If you would like to know more, talk with your doctor.
- You can ask your doctor or pharmacist for additional information about ISENTRESS that is written for health professionals.
- For more information go to www.ISENTRESS.com or call 1-800-622-4477.

What are the ingredients in ISENTRESS?

Active ingredient: Each film-coated tablet contains 400 mg of raltegravir.

Inactive ingredients: Microcrystalline cellulose, lactose monohydrate, calcium phosphate dibasic anhydrous, hypromellose 2208, poloxamer 407 (contains 0.01% butylated hydroxytoluene as antioxidant), sodium stearyl fumarate, magnesium stearate. In addition, the film coating contains the following inactive ingredients: polyvinyl alcohol, titanium dioxide, polyethylene glycol 3350, talc, red iron oxide and black iron oxide.

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ICAAC & IDSA

BY JEFF BERRY & ENID VÁZQUEZ

Reports from the 51st Interscience Conference on Antimicrobial Agents & Chemotherapy (ICAAC), which met in Chicago, and the 49th Annual Meeting of the Infectious Diseases Society of America (IDSA), held in Boston.

COMPLERA AND ATRIPLA NEWS

Last summer, 48-week data won FDA approval for Complera (see the November+December 2011 Briefly for the complicated details). At IDSA, 96-week data were presented from the ECHO and THRIVE studies that pitted the new Complera against Atripla. **Complera continued to be non-inferior to Atripla, but also continued to have more virologic failure** in people who started therapy at viral loads greater than 500,000.

There was bad news for people who began Complera with a viral load of greater than 100,000, as well. The researchers conducted a so-called “snapshot” analysis, looking at viral load measurements made between 96 and 103 weeks. Here, the virologic failure was almost twice as high for Complera: 22% vs. 12% for Atripla. Moreover, virologic failures leading to treatment discontinuation were also higher with Complera: 12% vs. 4% for Atripla.

On the plus side, Complera also continued to be more tolerable. The treatment

discontinuation rate for adverse events was 4% for Complera compared to 9% for Atripla, a statistically significant difference. These figures were about double those of week 48 (2% vs. 5% respectively).

As leading HIV specialist and researcher Cal Cohen of the Community Research Initiative of New England said, “For the right person, Complera is a good drug, and it’s important to consider for those who want the benefit of taking a single tablet once daily, and for whom Atripla isn’t the right choice.”

SWITCHING FROM ATRIPLA TO COMPLERA

Now that the best-selling Atripla has a real competitor, an important question becomes, **can people switch from Atripla to the new Complera?**

While switching to a new and improved drug or regimen is common, there was a concern about switching here because of the way these drugs act in the body. The Sustiva in Atripla activates the

protein (or enzyme) CYP34A. This is the same enzyme that the body uses to metabolize the Edurant in Complera. Sustiva has a long half-life and therefore drops the blood levels of Edurant; because there’s too much metabolism of Edurant going on, the body eliminates it.

That interaction was recognized thanks to an earlier study that found a drop in Edurant blood levels of about 25% for approximately four weeks in volunteers switching from Sustiva to Edurant.

Fortunately, an HIV study presented at both ICAAC and IDSA has now shown that patients were able to maintain undetectable viral loads when switching from Atripla to Complera, out to three months. There was only a small temporary drop in Edurant blood levels.

At ICAAC, Dr. Tony Mills of Los Angeles made a poster presentation on the 49 patients switching from Atripla to Complera because of problems with tolerability. Atripla was their first HIV regimen and they had been taking it for at least three months (the average was 2.5 years). At week 12 after the switch, all 49 still had undetectable viral loads of less than 50 copies per mL.

The study did see lower than expected blood levels of Edurant at week one, but not at the other weeks in which bloodwork was collected (2, 4, 6, 8, and 12). The study concluded that “brief [Sustiva] inductive effects on [Edurant] metabolism may not

be clinically relevant in suppressed patients [those with undetectable viral loads],” since all viral loads were undetectable at 12 weeks. The study also reported that Complera was well tolerated.

ISENTRESS FOR FOUR YEARS

The longest-term data on Isentress to date, presented at IDSA, show better virologic (viral load) and immunologic (T-cell count) results than Sustiva, out to 192 weeks (nearly four years).

STARTMRK is a non-inferiority study, but was able to demonstrate **virologic superiority over Sustiva** at 192 weeks based on pre-specified data standards.

At 192 weeks, 76.2% of the 281 people on Isentress vs. 67% of the 282 individuals taking Sustiva had undetectable viral load of less than 50 copies per mL. The Isentress group also saw a greater increase in their CD4+ T-cell counts, 361 vs. 301 for those on Sustiva.

Isentress was also more tolerable, with 50% of the people taking it experiencing a “drug-related clinical adverse event” compared to 80% of those taking Sustiva. Discontinuations due to adverse events were also lower with Isentress: 5% vs. 8.2% for Sustiva. In terms of what’s called “serious adverse events,” there was a similar rate: 17.8% for Isentress and 18.4% for Sustiva.

ICAAC & IDSA

BY JEFF BERRY & ENID VÁZQUEZ

Isentress, like Sustiva, is one of the medications recommended by the Department of Health and Human Services HIV treatment guidelines for people taking antiviral therapy for the first time.

RISKY BUSINESS AND PrEP INTEREST IN CHICAGO STI CLINIC

Chicago researchers surveyed patients at a clinic treating sexually transmitted diseases about condom use, perception of HIV risk, and acceptance of PrEP (pre-exposure prophylaxis, the use of medication to prevent HIV infection).

At ICAAC, they presented **an analysis of 359 heterosexuals deemed at high risk for HIV infection and found that the vast majority (84%) saw themselves as being at no or low risk of HIV infection.**

The two risk factors that were significantly different between the men and the women were having ever been in a jail or prison (55% of men and 23% of women) and having ever exchanged sex for money or drugs (6% of men and 15% of women).

HIV specialist Dr. Kimberly Y. Smith of Rush University Medical Center, one of the leaders of this study, said that women may not recognize that incarceration increases the risk of HIV for their male sex partners and in turn, for the women themselves. The women don't want to believe

that their male partners are engaging in sex with other men while incarcerated, whether consensual or not, nor do they recognize other incarceration risk factors such as sharing needles for drug use or tattooing.

Dr. Smith said that when talking with heterosexual or bisexual men who have been incarcerated or have HIV, they will often have kept their sexual contact with other men or their HIV infection a secret from female sex partners.

According to U.S. government data, the prevalence of AIDS among U.S. prisoners is three times that of the general population, and approximately one in five people with HIV will be incarcerated at some point. A factsheet from the Centers for Disease Control and Prevention (CDC), states that incarceration risk factors of unsafe tattooing, sex, and drug use "coupled with the sexual relationships and socioeconomic consequences faced by persons with histories of incarceration, make prisons a risk factor for HIV infection."

The majority of the individuals surveyed in Chicago were people of color (75% black and 15% Latino). In this public clinic (CORE Center), there was a high level of poverty: nearly half (45%) had household incomes of less than \$499 a month. Only a third of them were employed and 79% had only a high school education or less.

Half of the 234 men in this study had two or more sex partners in the month before

being surveyed, including at least one new sex partner in that time period.

The majority of participants also reported high levels of inconsistent condom use (81 to 96%), with both vaginal and anal intercourse. One-fifth (21%) of both men and women reported having had anal intercourse.

Other risk factors included drinking alcohol or using drugs at least half of the time when having sex, and having a sexually transmitted infection (STI) within the past year.

Some risk factors were based on a partner's behavior (STI within past year; ever exchanging sex for money or drugs; drug use within past 30 days; and ever being in jail or prison).

When asked about taking medication for the prevention of HIV, 83% of the participants said they would take a pill for PrEP. Their preference for taking PrEP was lowest for daily use (63%) and 75% preferred taking it an hour before sex, a day before sex, or a week before sex.

Among the audience at the presentation were doctors who thanked the researchers for reminding everyone that women engage in anal sex and who pointed out that surveys of gay and bisexual men have also found low perceptions of HIV risk in the face of risky behavior or actual infection. One audience member questioned the perception of low risk in light of the fact that these individuals were being seen in an STI clinic.

Presenter Dr. Thana Khawcharoenporn said the participants showed a disassociation between their high level of knowledge of risk factors and the assessment of their own risk.

Included in the presentation was information on an earlier study by Denise Dion Hallfors and colleagues that found blacks in the U.S. are at higher risk of HIV despite normative (the same) behavior as whites, that they perceive themselves to be at low risk based on their own actions instead of the risk behaviors of their sex partners, and that the perception of low risk may be associated with ongoing risky behavior and lack of prevention strategies.

Kudos to the researchers at Rush, CORE Center, and Stroger Hospital (Chicago's public hospital) for gathering this information.

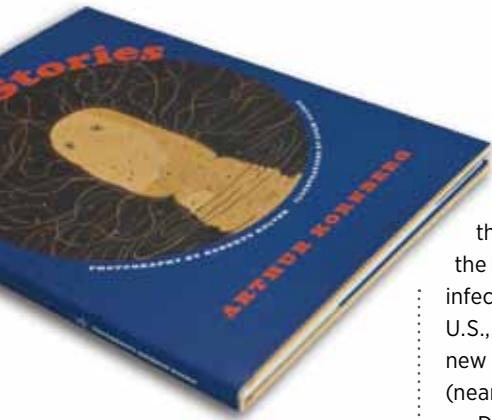
GERM STORIES —A CHILDREN'S BOOK

The organizer of ICAAC, the American Society for Microbiology, took on a very different project by lending photographs by Roberto Kolter to be used in a **children's picture book called *Germ Stories***, by Nobel Prize-winning enzymologist Arthur Kornberg. Cute illustrations by Adam Alaniz round out the photos and text.

The HIV germ story centers on a schoolboy named Bill who has hemophilia.

The very short story goes





on to explain how unlikely the virus is to be transmitted at school, and how medication keeps Bill well. Other germs visit other children—yeast and food poisoning, pneumonia, and more.

Unfortunately, AIDS is referred to as “acute immunodeficiency syndrome” instead of “acquired.” And “dread disease” is an unfortunate reference. But did you know that “a measly grain of sand is 8,000,000,000 times bigger than a single particle of HIV”? All in all, the book is a dynamic combo of rhyme and science, which may or may not delight any particular child.

REACHING YOUNG GAY MEN THROUGH GRINDR

Raphael J. Landovitz, MD, of UCLA said he was going to show “how to meet a gay man in five easy steps—GRINDR 101.” The greater purpose of his presentation, however, was to give the results of a **survey of young gay men using the social networking app and discuss how it might be useful for HIV prevention.** In Los Angeles, as in the United States, he said, men who have sex with men (MSM) acquire the majority of new HIV infections, with

those age 20–29 having the higher incidence (new infections) in that city. In the U.S., the majority of MSM with new infections are ages 13–29 (nearly four out of 10).

Dr. Landovitz reported that GRINDR boasts two million users worldwide, with 8,000 more joining each day and 280,000 logged on at least daily. GRINDR allows its users to locate each other geographically by using GPS functionality. An example put up on the screen was of a 27-year-old Latino located 81 feet away. He was single and looking for “dates, friends, and networking.”

“Some of you may not be familiar with GRINDR,” Dr. Landovitz said. “Some of you may be logged on to it right now,” at which the audience broke out laughing.

In one slide, Landovitz pretended to show two audience members logged on. He presented their exchange on the screen.

“Hey—you’re hot [referring to the person’s profile photo]!”

“Thanks! U2. Where u at?”

“ICAAC.”

“No way. Me too!”

“Presentation on GRINDR. Interesting, but the presenter is a dork.”

They make arrangements to meet up later.

According to the research group’s abstract, “Young MSM (YMSM) in Los Angeles

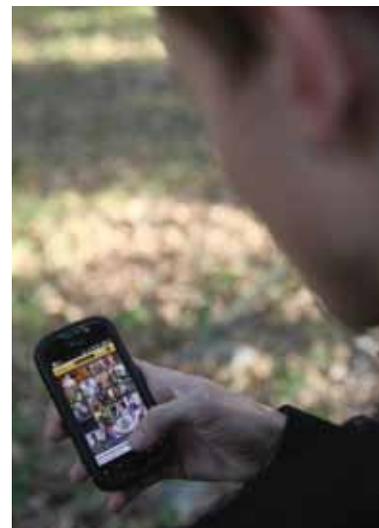
age 20–29 have the highest HIV incidence rates of any age-risk population segment in the city. YMSM are technology savvy and use GPS-based social networking ‘apps,’ such as GRINDR, to facilitate sexual partnering. GRINDR has more than [two] million users and more than 46,500 users in L.A. GRINDR may be a tool to access hard to reach communities.”

Was it? In their abstract conclusion, they report that, “GRINDR was a feasible and acceptable method to recruit a sample of YMSM. Most complied with CDC-recommended annual HIV testing. Prevalence of self-reported HIV was similar to data from other recruitment techniques in YMSM; this suggests little bias by HIV status in this sample. With high rates of reported STIs and risk behavior, the sample is at high risk for HIV acquisition. On GRINDR, fewer HIV-positives inquired about partners’ HIV status than HIV-negatives, suggesting less serosorting [picking partners of the same HIV status]. GRINDR may be a mechanism for providing HIV prevention messaging and interventions.”

The research group used areas of Los Angeles frequented by young MSM. GRINDR members identified as 18 to 29 years of age were eligible for the survey. Of 4,808 contacts made over five months, only 375 individuals (7.8%)

were recruited into the survey. Their age ranged from 22 to 27. The greatest number of them were white (42.4%), followed by Latinos (33.6%), Asian (14.1%), and African Americans (6.4%).

Of these, 83.2% had been tested for HIV in the past year, with 4.3% reported having never been tested for the virus. The men reported having had gonorrhea (17.9%), Chlamydia (13.6%), and syphilis (9.1%). The average number of partners for anal sex in the previous year was 10. More than half (56%) had found a sex partner through GRINDR in the previous three months and 41% reported inconsistent condom use for receptive anal sex. While 98% reported sex with men in the previous year, 10% reported having sex with women in that time period, two reported sex with transgender women, and one reported sex with a transgender male.



Cruising for prevention information?

www.egrifta.com



Actual patient living
with HIV since 2000

YOU HAVE YOUR HIV UNDER CONTROL. NOW, ON TO HIV-RELATED EXCESS BELLY FAT.



In two separate clinical trials of HIV-infected people with lipodystrophy, each lasting 6 months, *EGRIFTA*[®] reduced HIV-related excess belly fat by an average of 18% in the first trial, and 14% in the second trial.

This reduction in excess belly fat resulted in an approximate 1-inch reduction in waist size. Individual results may vary. On average, patients on *EGRIFTA*[®] did not lose weight.

Like HIV, HIV-related excess belly fat is a chronic condition. In clinical studies:

- People who used *EGRIFTA*[®] continuously for 1 year maintained their results over this time period
- People who stopped taking *EGRIFTA*[®] after 6 months had their HIV-related excess belly fat come back

EGRIFTA[®] is believed to work with your own body to produce natural growth hormone to reduce your excess belly fat.

Indication:

EGRIFTA[®] is a daily injectable prescription medicine to reduce the excess in abdominal fat in HIV-infected patients with lipodystrophy.

Limitations of use:

- The impact and safety of *EGRIFTA*[®] on cardiovascular health has not been studied
- *EGRIFTA*[®] is not indicated for weight-loss management
- It's not known whether taking *EGRIFTA*[®] helps improve compliance with antiretroviral medications
- *EGRIFTA*[®] is not recommended to be used in children

Important Risk Information:

Do not use *EGRIFTA*[®] if you:

- Have pituitary gland tumor, pituitary gland surgery or other problems related to your pituitary gland
- Have or had a history of active cancer (either newly diagnosed or recurrent)
- Are allergic to tesamorelin or any of the ingredients in *EGRIFTA*[®], including mannitol or sterile water
- Are pregnant or become pregnant

Before using *EGRIFTA*[®], tell your healthcare provider if you:

- Have or have had cancer
- Have diabetes
- Are breastfeeding or plan to breastfeed
- Have kidney or liver problems
- Have any other medical condition
- Take prescription or non-prescription medicines, vitamins, or herbal supplements

EGRIFTA[®] may cause serious side effects, including:

- Serious allergic reaction. Stop using *EGRIFTA*[®] and get emergency help right away if you have any of the following symptoms: rash over your body, hives, swelling of your face or throat, shortness of breath or trouble breathing, fast heartbeat, feeling of faintness or fainting
- Swelling (fluid retention). *EGRIFTA*[®] can cause swelling in some parts of your body. Call your healthcare provider if you have an increase in joint pain, or pain or numbness in your hands or wrist (carpal tunnel syndrome)
- Increase in glucose (blood sugar) intolerance and diabetes

- Injection-site reactions, such as redness, itching, pain, irritation, bleeding, rash, and swelling. Change (rotate) your injection site to help lower your risk for injection-site reactions

The most common side effects of *EGRIFTA*[®] include:

- joint pain
- pain in legs and arms
- swelling in your legs
- muscle soreness
- tingling
- numbness and pricking
- nausea
- vomiting
- rash
- itching

EGRIFTA[®] will NOT cure HIV or lower your chance of passing HIV to others.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see Consumer Brief Summary of *EGRIFTA*[®] on following page.

Ask your healthcare provider if *EGRIFTA*[®], the first and only FDA-approved medicine for HIV-related excess belly fat, may be right for you.

For more information, visit www.egrifta.com or call the AXIS Center at 1-877-714-AXIS (2947).



Consumer Brief Summary for **EGRIFTA**® (tesamorelin for injection)

EGRIFTA® (eh-GRIF-tuh)

(tesamorelin for injection) for subcutaneous use

Read the Patient Information that comes with **EGRIFTA®** before you start to take it and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is **EGRIFTA®?**

- **EGRIFTA**® is an injectable prescription medicine to reduce the excess in abdominal fat in HIV-infected patients with lipodystrophy. **EGRIFTA**® contains a growth hormone-releasing factor (GRF).
- The impact and safety of **EGRIFTA**® on cardiovascular health has not been studied.
- **EGRIFTA**® is not indicated for weight loss management.
- It is not known whether taking **EGRIFTA**® helps improve compliance with antiretroviral medications.
- It is not known if **EGRIFTA**® is safe and effective in children. **EGRIFTA**® is not recommended to be used in children.

Who should not use **EGRIFTA®?**

Do not use **EGRIFTA**® if you:

- have pituitary gland tumor, pituitary gland surgery or other problems related to your pituitary gland
- have or had a history of active cancer (either newly diagnosed or recurrent)
- are allergic to tesamorelin or any of the ingredients in **EGRIFTA**®. See the end of this leaflet for a complete list of ingredients in **EGRIFTA**®
- are pregnant or become pregnant. If you become pregnant, stop using **EGRIFTA**® and talk with your healthcare provider. See "What should I tell my healthcare provider before using **EGRIFTA**®?"

What should I tell my healthcare provider before using **EGRIFTA®?**

Before using **EGRIFTA**®, tell your healthcare provider if you:

- have or have had cancer
- have diabetes
- are breastfeeding or plan to breastfeed. It is not known if **EGRIFTA**® passes into your breast milk. The Centers for Disease Control and Prevention (CDC) recommends that HIV-infected mothers not breastfeed to avoid the risk of passing HIV infection to your baby. Talk with your healthcare provider about the best way to feed your baby if you are taking **EGRIFTA**®
- have kidney or liver problems
- have any other medical condition

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. **EGRIFTA**® may affect the way other medicines work, and other medicines may affect how **EGRIFTA**® works. Know the medicines you take. Keep a list with you to show your healthcare provider and pharmacist when you get a new medicine.

How should I use **EGRIFTA®?**

- **Read the detailed "Instructions for Use"** that comes with **EGRIFTA**® before you start using **EGRIFTA**®. Your healthcare provider will show you how to inject **EGRIFTA**®.
- Use **EGRIFTA**® exactly as prescribed by your healthcare provider.
- Inject **EGRIFTA**® under the skin (subcutaneously) of your stomach area (abdomen).
- Change (rotate) the injection site on your stomach area (abdomen) with each dose. Do not inject **EGRIFTA**® into scar tissue, bruises or your navel.
- Do not share needles or syringes with other people. Sharing of needles can result in the transmission of infectious diseases, such as HIV.

What are the possible side effects of **EGRIFTA®?**

EGRIFTA® may cause serious side effects including:

- Serious allergic reaction. Some people taking **EGRIFTA**® may have an allergic reaction. Stop using **EGRIFTA**® and get emergency help right away if you have any of the following symptoms:
 - a rash over your body

- hives
- swelling of your face or throat
- shortness of breath or trouble breathing
- fast heartbeat
- feeling of faintness or fainting

- Swelling (fluid retention). **EGRIFTA**® can cause swelling in some parts of your body. Call your healthcare provider if you have an increase in joint pain, or pain or numbness in your hands or wrist (carpal tunnel syndrome).
- Increase in glucose (blood sugar) intolerance and diabetes. Your healthcare provider will measure your blood sugar periodically.
- Injection-site reactions. Change (rotate) your injection site to help lower your risk for injection-site reactions. Call your healthcare provider for medical advice if you have the following symptoms around the area of the injection site:
 - redness
 - itching
 - pain
 - irritation
 - bleeding
 - rash
 - swelling

The most common side effects of **EGRIFTA® include:**

- joint pain
- pain in legs and arms
- swelling in your legs
- muscle soreness
- tingling, numbness and pricking
- nausea
- vomiting
- rash
- itching

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of **EGRIFTA**®. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. To report side effects, contact EMD Serono toll-free at 1-800-283-8088 ext. 5563. You may report side effects to FDA at 1-800-FDA-1088.

Keep **EGRIFTA® and all medicines out of the reach of children.**

General information about the safe and effective use of **EGRIFTA®:**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use **EGRIFTA**® for a condition for which it was not prescribed.

Do not give **EGRIFTA**® to other people, even if they have the same symptoms you have. It may harm them.

Do not share your **EGRIFTA**® syringe with another person, even if the needle is changed. Do not share your **EGRIFTA**® needles with another person.

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

For more information about **EGRIFTA**®, go to www.EGRIFTA.com or contact the AXIS Center toll-free at 1-877-714-2947.

What are the ingredients in **EGRIFTA®?**

Active ingredient: tesamorelin

Inactive ingredients: mannitol and Sterile Water for Injection

EMD Serono
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WHAT'S GOIN' ON?
KEITH R. GREEN

Faith without works is dead —James 2:17

Black men moving from faith to action

A COUPLE OF YEARS AGO, I HAD THE HONOR OF INTERVIEWING actress and comedian Mo’Nique for a POSITIVELY AWARE cover story. I was genuinely moved by how deeply connected she was to the impact that HIV/AIDS has had and is having on African American communities. There was one thing that she said during the interview, however, that’s been stuck in my mind ever since.

When speaking about the government response (or the lack thereof) to the epidemic among black people, Mo’Nique made it clear that if a solution is ever to be realized, it would have to come from within.

“When has the government ever said ‘we’re gonna help black people?’” she asked. “So now, because we have this disease, did we really think the cavalry was going to come in?”

Mo’Nique’s rhetorical question speaks to an elephant in the room that many in the HIV/AIDS service sector have ignored for far too long. Though significant progress is being made in the era of the Obama administration’s National HIV/AIDS Strategy (NHAS), the real impact is yet to be realized. And, truth be told, public policy interventions are all for naught if the communities which they are designed to help are unwilling or unable to align themselves with their goals and work collaboratively to create change.

We have faith that since our country finally has a National HIV/AIDS Strategy, “a change is gonna come” for the people most impacted by this disease. The iPrEx trial and HPTN 052 have given us faith that using antiretrovirals as prevention will lead us to the end of the epidemic. And we have strong faith that full implementation of healthcare reform in 2014, if that ever happens, will allow unfettered access to the aforementioned

treatment-as-prevention strategies for people who need them most.

Faith without works, however, is dead! Acting on faith, advocates fought like hell to make policies such as the NHAS and the Affordable Care Act a reality. With strong faith, researchers poured their blood, sweat, and tears into the scientific advances that continue to demonstrate the possibility of stopping HIV in its tracks.

But at the end of the day, if the people who could benefit most from all of these exciting developments do not believe that the buck stops with them and then govern themselves accordingly, it’s all in vain. Faith in the end of HIV is dead in the absence of action!

This revelation became exceptionally clear to me during a roundtable discussion with African American service providers at the 2011 United States Conference on AIDS. Miquel Brazil, who is Director of Prevention Programming at the AIDS Taskforce of Greater Cleveland, questioned whether the reason for lack of success with young black gay and bisexual men is because they do not feel connected to the progress that’s been made over the years.

They don’t know that it wasn’t just white gay men who “acted up” in the middle of the streets of San Francisco and Philadelphia when President Reagan wouldn’t even mention the word “AIDS.” They don’t know that black gay men like Phill Wilson and Cornelius Baker, still

wildly respected leaders in the fight, were involved in advocacy that helped change the way drugs are brought to the market in this country...or that they got involved because they saw too many brothers die.

And they don’t know these things because, from what I heard from them, a solid sense of community is lacking among black gay men. Community fellowship, for reasons other than giving its members an opportunity to shake their asses or hear more bad news about how disproportionately impacted by disease they are, is practically non-existent. Communities share their history and pass on legacies. Communities mentor their young, and their young accept mentoring (and the occasional loving correction that comes with it).

But then, this issue is not unique to HIV/AIDS. I hear my elders say the same thing about my generation being ungrateful for the many privileges that they fought so hard for, which we now take for granted.

At what point do we actually stop complaining and wishing for change, and begin to facilitate the process of not simply passing but sharing the torch? When do we realize that the “government” isn’t going to do anything for us that we aren’t willing to do for ourselves? WE, THE PEOPLE... Who else are we waiting on?

I was glad to hear that this particular group of brothers has faith that they can make a difference, and have created blueprints for a plan of action to be revisited at the African American MSM Leadership Conference taking place January 19–22 in New Orleans.

I have faith that we’re heading in the right direction. And I’ll be right there with them as they get down to action.



FAITH-BASED ORGANIZATIONS AND AIDS

The Good, the Bad, and the Ugly

BY JACQUI PATTERSON

“COME UNTO ME ALL YE THAT LABOR AND ARE HEAVY LADEN and I will give thee rest.” As a Christian and a proponent of social justice for all, I have some questions regarding churches’ response to AIDS.

I’ve enjoyed ten years of working in faith-based organizations (FBOs) that fight AIDS, and have seen much to inspire, educate, and horrify me. I’ll base my comments on human rights and love, both of which are biblical principles, even if “human rights” isn’t stated in those terms in the Bible.

There is a lot that is compelling about the work of FBOs in AIDS and a lot that, while compatible in theory, is quite contradictory and damaging in practice. Because FBOs have received millions of dollars from the U.S. and other nations, and from other funding sources such as the Global Fund to Fight AIDS, it is critical to examine how they are working and what their impact is on nations, communities, families, and individuals.

WHY ARE FAITH-BASED ORGANIZATIONS ENGAGED IN AIDS WORK?

The Bible offers a clear mandate to care for people in need of help and to attempt to balance the scales of justice. Matthew 25:40 says, “Whatsoever you do unto the



PHOTO: JOSHUA THORNE

least of these, you do unto me”; Micah 6:8 states, “What do I require of you...to live justly”; and 1 John 3:17 asks, “If anyone has enough money to live on and sees a brother or sister in need and refuses to help, how can God’s love be in that person?”

So it is not surprising that in sub-Saharan Africa, Latin America, and the Caribbean, FBOs provide up to 40% of all health care, and churches are present in many communities. At times, there is no other health institution of any sort. In the U.S., there are also many faith-based health centers and other HIV service providers. The sheer presence and capacity of FBOs puts them in a good position to offer a range of services. Also, in many communities in Africa, Latin America, the Caribbean, the U.S., and, to some extent, Asia, there are very high percentages of Christians—so the influence that FBOs and faith leaders have in the community is significant, for better or worse.

WHAT HAS WORKED?

My first entrée to global work in AIDS was

through an FBO. I was focused on supporting home-based care and hospices through Interchurch Medical Assistance World Health and its member organizations (a variety of mainline Protestant churches). The reach of these churches and FBOs into communities was tremendously helpful—outreach workers were there for families and individuals in need of support and comfort in their final months. I also witnessed how the spiritual component offered great comfort, resulting in a peaceful death for many.

I’ve also seen churches have a very positive influence in the policy arena. The United Methodist Church, Lutheran Church, Church World Service, and others have invested significant resources in policy analysis and mobilizing their congregations to advocate for increased funding for AIDS, as well as related issues like debt cancellation, which afforded countries the flexibility to assign more resources to health programs.

Similarly I’ve seen the establishment of the African Network of Religious Leaders Living with AIDS, which has worked to destigmatize HIV by having religious leaders speak out, offering messages of love and compassion, without judgment. Cristo Greyling and Gideon Byamugisha have encouraged language such as “The Body of Christ has AIDS” to signify that when one of us is infected, we all are, and that we need to address AIDS as a community issue—not singling people out for blame.

In the last two years of my work with IMA World Health, I managed the organization’s PEPFAR (President’s Emergency Plan for AIDS Relief) treatment program. In theory, this should have gone well. FBOs have the reach, health facilities, relationships, and understanding of communities—all of which should lead to a successful endeavor.

Indeed, the infrastructure afforded by the extensive networks of faith-based hospitals, clinics, and mobile units was a fantastic resource. Several of our partners were already successfully running treatment programs using generic drugs. At first the glut of resources and the prospect of being able to serve hundreds of thousands in need of treatment was all very exhilarating. But those of us who were concerned about nuance came into conflict with the

restrictions on reproductive health services, the inability to use generic drugs, and the “Anti-Prostitution Loyalty Oath,” which restricts how organizations can use their funds to engage in speech or programs related to sex work. I found that many FBOs were not ready to buck the system on behalf of those they were supposed to serve. This strongly interfered with my ability to work, and I found myself in constant conflict. So, hundreds of thousands are receiving treatment through FBOs, and that’s a good thing. But I put this on the cusp of the “What Hasn’t Worked” section because I still ask, “At what cost?” and “Could we have done it better?”

WHAT HASN’T WORKED?

In their AIDS response, churches have clearly been constrained by judgment and dogma. Kay Warren of the Saddleback Church rightfully pointed out, “The Church is more known for what it is against than what it is for.” A friend of mine, Dazon Dixon Diallo of SisterLove in Atlanta, once said she wants to make a bumper sticker that reads, “Jesus, Please Come Back and Save Us from Your Followers!” The words of Martin Luther King, Jr. are also very apt: “Yes, I see the Church as the body of Christ. But, oh! How we have blemished and scarred that body through social neglect and through fear of being nonconformists.”

On one hand there has been judgment regarding people with HIV and rhetoric around “the wages of sin equal death” and “you reap what you sow.” At the 2008 Ecumenical Advocacy Alliance in Mexico City, one religious leader spoke of the condemnation and judgment she has faced since declaring her HIV status. There has also been stigma around certain high-risk populations, leading to damaging programs or outright neglect.

There are many examples of the influence of conservative Christian ideology and personalities on policy development. When PEPFAR was being designed, there were multiple forces influencing its policies, such as the Institute for Youth Development and the Children’s AIDS Fund, which had an ideology rooted in conservative Christianity. This challenge to the separation of church and state should have been revealed early on and dealt with head on. Instead, it led to

My purpose here is not to sway those in the church who find a biblical basis to oppose homosexuality, but rather to **question their application of biblical principles.**

policies that didn't follow the scientific literature or the actual experience of gender inequality and other dynamics. Ideological policies masqueraded as evidence, like the Anti-Prostitution Loyalty Oath and the emphasis on HIV prevention through abstinence and fidelity to the exclusion of the proven effectiveness of condoms.

The gender inequality in many churches also permeates the societies where they are influential. This has played out in messages stating that being faithful is protection against HIV, when for many married women this is a death sentence. Both partners have to be HIV negative and monogamous for this to be effective. Yet people are offered simple messages without caveats. Church-based instruction on submission to one's husband has led women to stay in relationships with unfaithful husbands and to suffer violence at their hands. Often, churches do not offer guidance on the protection of women, focusing instead on the "sanctity of marriage" and "'til death do us part," regardless of the risk to the often powerless woman.

At the 2008 Ecumenical Pre-Conference in Mexico City, I appreciated the dialogue around gender, and specifically patriarchy, in the church. But there was no space in the program for the LGBT community and its issues—unfortunate, given the early and continued epidemiology of HIV as well as the continued discrimination against LGBT people. How can there be an entire HIV conference without space for LGBT matters when we have had activists like Sizekele Sigasa and Salome Moosa, champions for HIV justice, who were murdered in South Africa in a vicious hate crime? When we have Solomon Adderly Wellington, a noted gay HIV activist in the Bahamas, murdered? When we have the President of Gambia vowing to lop off the heads of gay people and criminalize any who offer safe harbor? When we have Steve Harvey, a gay HIV activist from the Jamaica Support Services, slain in a country where there are more churches per capita than anywhere in the world? (Jamaica is my country of origin, yet

I'm embarrassed to say that I would warn my gay friends about even visiting there, knowing that they risk life and limb due to homophobia.) And when we now have Uganda attempting to pass a law similar to that in Gambia, with the instigation of this legislation allegedly resting at the feet of certain U.S. evangelical churches.

Where are the voices of churches on these issues? Where is the high-profile public statement condemning such heinous hate crimes? Instead, there is much condemnation of same-sex relationships, and the intensity of Christian leaders' words, deeds, and attitudes seem to indicate that they are more concerned about these acts of love than acts of hate. One colleague spoke about being invited to dinner and learning mid-meal that his host was gay. He said, "There I was eating the food..." And this is a person who is in charge of HIV programs for his denomination! A participant in a workshop I facilitated stated that many in the church are only ready to embrace people who are "like us" by whatever notion of self-proclaimed sanctity "we" in the church define ourselves. My purpose here is not to sway those in the church who find a biblical basis to oppose homosexuality, but rather to question their application of biblical principles. I ask them, what would Jesus do?

At Rick Warren's 2006 Saddleback Church conference, an awkwardly titled session, "Loving Homosexuals as Jesus Would?" led to hopes that this evangelical leader was questioning attitudes toward LGBT people. Instead, it was a panel of speakers from the "ex-gay" movement, not a workshop offering guidance on how churches could be safe spaces that welcome all and uphold justice within a range of beliefs. They went beyond many churches in even holding such a workshop, but they need to take it further.

Does being known more for condemnation of individuals (and cozying up to big pharma and other questionable allies) instead of fighting for justice and human rights match the scene of Jesus in the temple overturning the tables of

the money changers? Does it fit with the image of Jesus embracing and blessing a sex worker? His directive to her was to "go and sin no more." Repentance wasn't a precursor for his embrace. His championship of justice was not selective.

One of the conflicts I experienced in my work with the AIDS Relief Consortium was the need to include prevention programs with the treatment work we were doing, as it makes little sense to be doing treatment alone. That would be like trying to plug holes in a dam while more spring open. A group that was in charge of \$330 million of AIDS funding was constrained in the prevention resources it could provide. The restrictions came from the ideologically driven PEPFAR guidelines, which mandate how much funding can be used for treatment and what emphasis must be placed on abstinence and fidelity. In addition, the organizational policies of Catholic Relief Services don't allow condom distribution or a full range of reproductive health services.

Many in the church refer to the AIDS pandemic as an "opportunity for evangelism." Ken Isaacs of Samaritan's Purse stated "AIDS has created an evangelism opportunity for the body of Christ unlike any in history." Community Health Evangelism offers a presentation entitled "HIV/AIDS in Asia: A Window of Opportunity for Community Health Evangelism." This is troubling on at least two levels. First, there's the notion that people could be celebrating such a dread disease—as if it was sent so that they could save more souls. Second, the idea of "bread in one hand and the Bible in the other" could lead to the coercion of people who are in a vulnerable position.

RECOMMENDATIONS

There are critical roles for FBOs that contribute substantially to the well-being of communities, families, and individuals with HIV. Some FBOs have used their influence to advocate for needed policies, including debt cancellation and universal access to treatment. Religious groups have also used their reach in communities to ensure



PHOTO COURTESY OF ACHIEVE

that there is a comprehensive web of support for people with HIV. I applaud these efforts and hope that these initiatives persist and multiply.

But FBOs should establish guiding principles so that everyone knows where each organization stands. I pushed for the establishment of such principles and values at the Pan African Christian AIDS Network. All were enthusiastically in favor. But when we completed the process, it included a clause saying, "Marriage should only be between a man and a woman." I decided then that it was time to bid adieu, as I am an uncompromisingly staunch ally of LGBT rights.

People within organizations should expose the underlying forces driving their agendas, and organizations operating in coalition should be encouraged to offer up a statement of principles so that hidden biases can be revealed.

Advocacy conducted by FBOs should be based on principles of human rights. If this is the guideline, the automatic corresponding principle is "do no harm." The judgment-based advocacy that has resulted in such policies as the Anti-Prostitution Loyalty Oath and hateful anti-gay legislation such as that being discussed in Uganda that proposes the death penalty for loving persons of the same sex would not pass the "do no harm" test.

There is a role for abstinence in HIV prevention. It's possible to choose abstinence and it's good to have support in adhering to that choice. But doctrines and societal edicts are not enough if someone makes another choice or if people find themselves in situations where they have little or no choice. People who are in these circumstances need to know the options for keeping themselves as safe as possible.

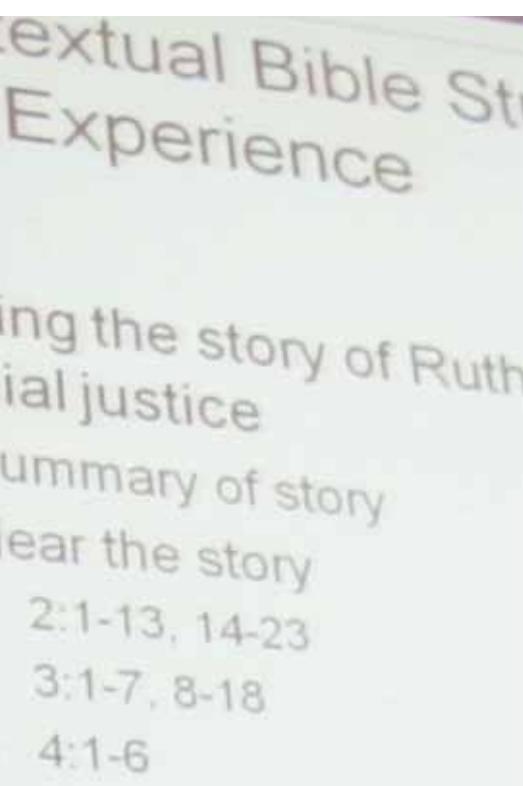
Finally, let's reward those FBOs that are doing good work, replicate their practices, and emphasize these positive models. There are churches that have articulated biblical bases for supporting women's rights and gay rights, and who promote a broad range of social justice issues. There are others who have devoted themselves to treatment, the care of orphans and vulnerable children, economic development, peace work, and hospice care through highly effective work. We need many more like them. ✚

JACQUI PATTERSON is an activist and policy analyst working on women's rights, racial justice, and public health globally.

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Cheryl B. Anderson, of the Garrett-Evangelical Theological Seminary, leads clergy through an example of contextual bible study—looking at its stories from the perspective of social justice.





OF FAITH AND COMPASSION

Black leaders urge the church to tend to its people

BY ENID VÁZQUEZ

PERNESSA C. SEELE GREW UP IN THE SMALL, ALL-BLACK TOWN of Lincolnton, South Carolina, where she witnessed firsthand the power of the church to help people. She saw the love and respect her family had for the church and its leaders, and it fostered in her a lifelong passion for faith leadership.

Growing up and moving to New York, Seele and her new church in Brooklyn became involved in the HIV epidemic before the terms “HIV” or “AIDS” had been created. They tended to a sick parishioner, the director of their choir, whom they dearly loved. It was church members who went to his home and found his body.

But later, working at Harlem Hospital, she saw patients with HIV who were not visited by either their families or their churches, who had been left alone, and in those days, often dying.

“All of these experiences created this passion for what I believe the work of the church should be: to be there for people,” Seele said.

And so in 1989, she founded The Balm in Gilead, beginning her efforts with the Harlem Week of Prayer for the Healing of AIDS, now a national project.

Today, after more than 20 years of bringing together the worlds of faith and HIV, she says the black church is no more homophobic than any other religious institution, despite accusations that are regularly raised in prevention work. “The black church has taken a bad rep on homophobia,” she said. “Because I have traveled the world and I’ve traveled

this country, I know that those African American churches that preach homophobia are no more homophobic than any other—white churches, Korean churches, Hispanic churches, and so on.”

At the same time, Seele is acutely aware of the harmful effects of the homophobia that does exist. “People still want to believe the myth that homosexuality causes HIV, and because they’re against homosexuality, therefore, they do not speak about HIV. That myth has created a big problem in the African American community,” she said. In her blog, she spoke more forcefully: “The lingering myth that homosexuality causes AIDS continues to mislead and misguide people to their death or destruction.”

But she says that 30 years into the epidemic, she and The Balm in Gilead “do not have time to beat [these churches] over the head,” when what they see more often is religious leaders wishing to address HIV, but not knowing how. “The Balm in Gilead wants the church to be a center of HIV prevention, of education and advocacy, and compassionate care,” she said. “We work to mobilize these churches and build their capacity to do that.”

Seele also believes churches don’t

PHOTO BY GREGORY TROTTER; COURTESY OF THE AIDS FOUNDATION OF CHICAGO

“It’s amazing to me in how many instances people feel like they are personally threatened by the fact that a person’s sexual orientation is different from their own.”

get credit for just how much they do, especially from the media. People who are not members of the congregation, or otherwise involved, don’t realize that a lot of work is actually being done, including housing and case management.

And, she says, they’re in a perfect position to do the work. “The African American church is the only institution that black people completely own,” said Seele. “It is the second largest employer of black people in this country, and it is the only institution that black people trust. It is the place where people come and gather for information. We may hear ‘Well, I don’t trust the pastor’ or ‘I don’t trust this or that,’ but every Sunday morning folks are gathering at the church. My critics say, ‘Pernessa, there are a lot of people who don’t go to church.’ That’s very true. But I say to you that everybody in the black community knows someone who’s going to church next Sunday. And those people who go bring back the information and disseminate it throughout the community.

“The church is unique,” she continues. “It’s unique in that it provides support in all areas—physical, spiritual, and emotional. That’s different from CBOs [community-based organizations]. CBOs do great work, but the church becomes very inclusive. They will go with you to the doctor’s office and to the hospital. If you have children, they support your children. They embrace your entire family. And they believe in the power of prayer.”

WHOSOEVER

Like Seele, the Rev. Edwin C. Sanders II of the Metropolitan Interdenominational Church in Nashville saw death in his congregation before anyone had heard of HIV or AIDS. He decided then and there that his church should get involved in this new reality.

Rev. Sanders promotes the concept of “Whosoever,” that congregations should be inclusive and affirming, including people of all sexual orientations. Churches that are accepting of homosexuality are called

“radically inclusive.” He explains that just as there are multiple interpretations of the Bible, the topic of sexuality is no different. A homophobic interpretation is not one that all churches adhere to. Rather, he believes churches should follow the notion that all humans are divinely created, and that all life is sacred and worthy of respect and affirmation.

Under his leadership, the Metropolitan Interdenominational Church established the Technical Assistance Network, or MICTAN, through a grant from the Centers for Disease Control and Prevention (CDC), nearly two decades after the church began working on HIV awareness and outreach. MICTAN has provided an extensive series of seminars around the country to mobilize faith leadership in the black community around HIV/AIDS work, and will continue to mobilize them to work together. The promotion of HIV testing and awareness is a priority, but so much of the work depends on the spirit in which it is conducted, and it is that the reverend preaches about. When people tell Rev. Sanders he’s preaching to the choir, he replies, “In my experience, the choir needs preaching to.” In promoting mutual assistance, he has found homophobic church leaders become transformed by working with gay and bisexual church members. Many such experiences continue to inspire him to promote HIV ministry.

In Chicago last fall, he asked a group of black faith leaders, “Who do you say is not welcome?” He was referring to item number one on a list of six ways to begin HIV work (be welcoming). “Stop and think what that means for the life of your congregation. Anything you deny, anything you hold as a secret will kill you. And we have a community where hiding is killing us. If we end up being guilty of perpetuating that, it is ethically unconscionable.

“A part of my passion around this whole business of HIV/AIDS,” he continued, “is that I’m convinced if we do this work right, it has implications that go way beyond this disease. We’ll address not just

HIV, but all the things that keep us from being the people we need to be in our communities. Housing, education, economic development, sexism, homophobia—all of it ends up being part of the equation of dealing with HIV.”

Other speakers in the MICTAN series of seminars included Gail Wyatt, PhD, a clinical psychologist, sex therapist, and professor in the Department of Psychiatry and Biobehavioral Science at UCLA; Cheryl Anderson, PhD, of the Garrett-Evangelical Theological Seminary in Evanston, Illinois; Mindy Thompson Fullilove, MD; and her husband Robert E. Fullilove, PhD, of Columbia University, who discussed rebuilding and empowering decimated black communities.

Although Wyatt discussed sexual health and knowledge within the context of black history, Rev. Sanders took on the job of urging faith leaders to become comfortable discussing sexuality as it relates to their own history. He said, “We need to have the ability to talk about any aspect of human sexuality openly, honestly, and competently. We have to have the ability to accept the sexual preference and activities of others without feeling personally threatened and without *moralizing* or being judgmental.

“It’s amazing to me in how many instances people feel like they are personally threatened by the fact that a person’s sexual orientation is different from their own,” he continued. “And in this instance, it goes way beyond the whole issue of same gender-loving people or the whole issue of how the relationship between two men or two women manifests itself. In our communities especially, I’m always intrigued by people who go around talking about ‘what we don’t do [in a harsh, hard tone]. We don’t do that. That’s what the other folk do.’ It’s very interesting because I find that most of that is guilt-bound moralizing to feel more comfortable with themselves.”

Pernessa Seele agrees with that. “We have many faith leaders who take the position that their congregations don’t

“We need to appreciate the fact that sexuality is a gift from God, that needs to be celebrated and needs to be respected and understood that it’s good.”

do anything [considered wrong], and we all know that’s not true. We all know that every church is full of people living their everyday lives. A church is not a place where only the holy and the righteous go. They’re all people living their lives to the best of their ability.” She remembers that her mother wouldn’t allow their pastor to see her smoke, even though the pastor himself was a smoker, so she understands that people may hide their true selves where their church is concerned.

“I think that if I had to make one simple statement about how we talk about sexuality in the context of the church it’s to simply say sexuality is a gift from God,” said Rev. Sanders to the faith leaders. “One of the things that has happened to the church is that we have come to interpret sexuality in a way that has put it outside the realm of what we are used to thinking of as a gift. But we need to appreciate the fact that it is a gift from God, that needs to be celebrated and needs to be respected and understood that it’s good. That will help us get beyond the blinders that we have let get in the way of what we can learn and what we can do to understand ourselves as sexual beings. It’s something that can no longer be peripheral, but rather becomes the subject matter of the sermon that we preach, of Sunday school lessons that we teach, whenever we come together for any reason for fellowship and spiritual growth.

“I think that until we do that we’re going to find ourselves in a place where the things that are not being talked about are the things that are going to harm us, and are going to harm us in ways that will continue to perpetuate this disease and the impact that it has on our community. This begins where I think we need to start, and that is, are you comfortable with your sexuality? People don’t easily move to talk about and think about and deal with the ways their own experiences as sexual beings have evolved. And if they do, in many instances, it’s associated with things that are not necessarily positive. It’s often

framed in a way that is negative. I have a feeling we might not be here if we were comfortable in a way we need to be with this issue.”

FAITH IN ACTION

A postcard from Faith Responds to AIDS, established by the AIDS Foundation of Chicago, puts it more bluntly, “Do or Die.” The card lists the statistics affecting African Americans and what churches can do to promote testing, treatment, and awareness, as well as scriptural evidence supporting the foundational concept of God’s love of all

people. At its website (www.aidschicago.org), the project offers a manual of how churches can do work around HIV, including a chapter on homophobia, stigma, and discrimination.

“We are living in interesting times,” said Pernessia Seele, “and every person of faith—every person of faith—whether they are a member of a church or not, or part of any institution, has the responsibility to address HIV and the suffering that we are seeing in this country. That’s what people of faith should be about—the compassionate business of the whole and not just the one. That’s faith that works, faith in action.” ✚

ARE YOU COMFORTABLE WITH YOUR SEXUALITY?

From MICTAN training for faith leaders, taken from *The Theology of Sexuality*, of the United Methodist Church.

Sexually comfortable people:

- Have examined their own personal sexual history
- Have explored their own sexual attitudes and confronted their own limitations and biases about sexuality
- Have listened to the beliefs of others about sexuality, which are different from their own
- Have the ability to speak openly, honestly, and confidently about any aspect of human sexuality
- Have the ability to accept the sexual preference (the way they choose to identify themselves) and activities of others without feeling personally threatened and without moralizing and being judgmental
- Have the ability to discuss sex with the young, middle aged, and elderly
- Have the ability to interact with people of all genders, ages, and sexual orientations in respectful and appropriate ways
- Are knowledgeable or seek to increase their knowledge about human sexuality, including sexual behaviors, sexual response, sexual and gender orientation, and relationships
- Will have up-to-date, science-based, factual knowledge
- Will have knowledge of different sociocultural and religious beliefs about human sexuality

EDITOR’S NOTE: The ability to engage in open discussion does not include being forced into conversations where you are uncomfortable. In such cases, listen to your gut feelings, and know you have the right to walk away.

THE HIDDEN PEOPLE

Courage and brotherhood bring the Muslim community into the light

BY SUE SALTMARSH

WITH THE HEAVY EMPHASIS CURRENTLY PLACED ON THE Christian response to HIV/AIDS, especially in the black community, the subject of how the Muslim community has dealt with it is intriguing, if not compelling. At the U.S. Conference on AIDS in Chicago in November, a workshop entitled “The Homophobia and Stigma Endured with being Gay, Muslim, and Living with HIV” addressed this very issue.

The three presenters, Shadeed Sadeeq Jenkins, Imaad Hafiz Boyd, and Karim Ishmael Rush, were dressed in, as one attendee put it, “full Muslim gear”—the izar, an oversized, tube-style waist cloth, and the kufi, a knit cap. They met with POSITIVELY AWARE before their workshop to talk about their experiences being gay and Muslim. Their soft-spoken articulateness and gentle smiles lent credence to their stories of struggle, unity, and commitment to both their religion and to finding a way to spread the message of acceptance within their somewhat rigid faith community.

LEADING A DOUBLE LIFE

The rules and expectations placed on a devout Muslim are daunting and, just as with other religions, are often unrealistic and unattainable by the average human being. Boyd admitted that he “needs help” with the restriction on cursing and foul language. But that is nothing compared to “avoid

yawning in a gathering as much as possible,” “mix with people and put up with their insults” or “check customs and habits against Islamic standards.” And then there is the praying or salah. As obligatory and complicated as Catholic mass can be, salah has many more rules and ritual procedures, including the requirement to pray at certain times of the day. Being Muslim is not easy to begin with—being gay makes it even harder.

When asked to speak about how their faith has affected them as gay and/or HIV-positive men, Karim Rush began with the simple truth that “Being gay and Muslim is...difficult.” It was like leading a “double life,” and he felt uncomfortable going to his masjid (mosque) until he found someone else who was going through the same thing, which is how he met Shadeed Jenkins. “It’s been a lot easier since then,” said Rush.

“I was raised Muslim,” explained Jenkins, the only one of the three who was raised in a Muslim family (the others



Karim Rush, Shadeed Jenkins, and Imaad Boyd at

converted from Christianity) and who is HIV-positive. “From an early age, it [homosexuality] wasn’t condoned.” The internal battle that raged within him between his faith and his Truth led Jenkins to fall away from practicing his religion and get caught in a downward spiral of drug addiction. Like Rush, he has greatly benefitted by having his gay “brothers in faith” around him who can identify with his struggles and who know the feeling of being surrounded by people and still feeling lonely. And he has encountered people in the Muslim community who’ve found out about his sexuality and actually told him “there is no such thing as a gay Muslim,” a common experience he and his friends have helped each other through.



the U.S. Conference on AIDS, in Chicago.

PHOTO: JOSHUA THORNE

SPEAKING OUT

This was not the first presentation the three have given at an HIV conference. Their friend, Don Ransom, originally encouraged Jenkins to submit an abstract for such a presentation so the HIV community would be aware of the challenges that Muslim gay men face. He spoke about the reaction at other conferences when people saw “those three Muslim brothers” walking around and wondered what they were doing at a conference having to do with gay men and HIV. “I realized then that we as black, gay men had excluded the Muslim community,” said Ransom. Evidently their presence caused enough curiosity because their first workshop and those that followed have been

great successes. Certainly, the engagement and enthusiasm of the audience later that day was evidence that, though Muslims are hardly ever mentioned in either the HIV community in general or in any of the goals set by agencies to reach out to “communities of color,” the time is right for their presence and their message to be acknowledged.

Have they started a movement? They all laughed, but then mentioned that there is a movement already going on with such organizations as Muslims for Progressive Values, with an LGBT outreach program led by Daayiee Abdullah, an openly gay imam (religious leader) in Washington, D.C. Like any movement for social change, progress is not quick to happen.

It’s an uphill battle against an entrenched attitude that makes open discussion about homosexuality taboo among most Muslims. In fact, almost the same words of condemnation that appear in the Bible also appear in the Quran. Boyd acknowledges that the judgment and rejection can be “really psychologically damaging.” Just having someone with whom to talk about it openly is a great relief. Ransom, who is an HIV counselor and sees Muslims totally closed off and resistant coming into his agency to get tested, said, “As soon as I’d show them into a counseling room and shut the door, they’d open up and start telling me about their struggles.”

Jenkins, who has come out to his

MUSLIMS HAVE NO RESOURCES WITHIN THEIR INSULAR COMMUNITIES—NO MUSLIM HIV TESTING AND TREATMENT CENTERS—SO THE IMPORTANCE OF FEELING WELCOMED BY NON-MUSLIM PROVIDERS IS KEY TO ANY PREVENTION OR TREATMENT EFFORT.

Muslim parents, said that while they didn't take it well at first ("My mother cried and my father asked me if I was going to start wearing dresses."), now they've learned that just because he's gay doesn't mean he's a different person than the son they know. Unfortunately, his sexuality remains a taboo subject among some other family members and even his parents don't discuss it with other members of their religious community.

"You have to understand," said Jenkins, "Some of the mentality and the retaliation within the Islamic community can be really barbaric at times." The "double-barrel blast" of being Muslim in the U.S. post-9/11, as well as being marginalized in one's own community, has led to an even heavier burden for many.

"It's a whole deeper level of discrimination," said Jenkins, "I've talked to them a lot, gotten a lot of backlash—I'm kind of in the forefront..."

"Forefront? He's kicking down doors and taking New Jersey by storm!" Boyd interjects.

Jenkins continues with a sad smile, "I've actually questioned not going back to serve houses of worship because of the retaliation and not feeling comfortable."

Boyd spoke up to share his experience of converting from Christianity and finding that Muslim women had no problem with his sexuality. "They were willing to have more discussions with me, to talk about issues with me more so than the men."

Rush has had the opposite experience, though. "We don't cross the rules. It's not even permissible to talk to the females where I go, everything's totally separated."

When speaking about the "bigger picture" of their work, Jenkins says that it's not just about an alternative lifestyle or a religion, but that their hope is also to get people to take a look at themselves, and take an "inventory" of their own perceptions and reactions. All three talk about the automatic wall that goes up when people

see them, whether they're in an airport or an HIV/AIDS agency. From what Jenkins says, it's not just the knee-jerk reaction of bigotry, but there's a stigma attached to him even before people know he's HIV-positive. And such a reaction causes distrust and resistance to seeking help from Muslims who may experience it at places they go to for services. "It goes both ways, though," said Jenkins, acknowledging that, in many cases, Muslims themselves create negative situations by seeming unapproachable or defensive. According to Boyd, "When you walk into an agency, you walk in with your defenses already up, because you know you're being instantly judged."

Muslims have no resources within their insular community—no Muslim health clinics, certainly no HIV testing and treatment centers, no programs run for Muslims by Muslims, so the importance of feeling welcomed by non-Muslim service providers is key to any prevention or treatment effort.

During their presentation, which was to a full house, they rightly called out the HIV community, asking them to "open eyes, ears, minds, and hearts to the reality that there is a population within the MSM/HIV-positive community that is being ignored, abused, and not shown the same respect as other MSM," as well as to "better understand how their own biases and treatment affect this population mentally, physically, emotionally, and spiritually." Boyd says care providers, "underestimate themselves and the impact they can have on the community."

HIDDEN IN PLAIN SIGHT

No statistics are available about the HIV infection rate among Muslims. Boyd points out that many men convert to Islam while in prison and may not be aware of their infection, and thus take the virus with them back to the community where they may transmit HIV to their partners, both male and female. In this case, silence does indeed equal death.

At the presentation, a social worker asked what could be done to open up lines of communication to the Muslim community regarding MSM and HIV/AIDS education and prevention. All three of the men shook their heads and said, "Nothing." But then Jenkins theorized that perhaps one way to get a foot in the door would be to frame HIV and other STDs in terms of health disparities, minimizing the association with sex. People might respond better if they thought about it as a fight for health care equality.

The workshop was indeed the actively engaged, sometimes boisterous, experience that Rush had predicted. "There's always lots of questions – honestly, if we didn't have a curriculum and just did a Q&A session, it'd be almost endless." There were several people in the audience who were Muslim and thanked the three men for their efforts to educate people and advocate for a population that remains, for the most part, hidden.

One woman admitted being cynical, perhaps, but what she said was true—that until Muslims become a "targeted population," the way African Americans and Hispanics are now, programs aimed at them will not be funded and until there's money involved, not much attention will be paid. Ironically, since many Muslim MSM are black, they could already fit into programs created for that population, but as long as they feel threatened by the prospect of being outed or by possible negative reactions from agencies, they will stay hidden.

Rush says there are always other Muslims who identify themselves during or after their presentation and are grateful that the presentation is bringing their story to the forefront. "I think it's good," he says. "I think it's a good thing that people are starting to talk and step up a little bit more, because that just means that the message is continuing to grow and more and more people are going to begin to be more open and comfortable."

There is still plenty of work to be done by these brave young men. No doubt they will be familiar faces at future HIV conferences, including the World AIDS conference in Washington next year. In the words of Mohammed, "A Muslim who meets with others and shares their burdens is better than one who lives a life of seclusion and contemplation." ﷻ

We are TPAN.



Celebrating a quarter century of service to Chicago's HIV community.

Test Positive Aware Network (TPAN) began in 1987 when a small group of HIV-positive people gathered in a Chicago living room, drawn together by a desire to share experiences, exchange information, and to provide and accept support from one another. These founders were living with HIV. This is the heart of TPAN.

In 2012, thanks to the generosity of supporters like you, TPAN will celebrate 25 years of providing services, information, and hope to those whose lives are impacted by HIV/AIDS.

Nearly 25,000 come to TPAN for information and support every year, and more than 100,000 receive it through POSITIVELY AWARE, TPAN's HIV treatment and education journal.

TPAN aims to raise \$25,000 before January 31st to kick off our 25th anniversary. Please consider supporting our work by donating to our anniversary campaign with a one-time or monthly donation. Simply visit us online at www.tpan.com.





OUTSMARTING HIV WITH **HEALTHY EATING**

LIVING WITH A CHRONIC ILLNESS LIKE HIV CAN PRESENT certain nutritional challenges. Without effective HIV medication treatment, replicating virus can tax the body, destroying lean body mass and impairing immune function and quality of life.^{1,2}

While this destruction of lean tissue can be controlled with effective HIV antiretroviral combination therapy, other challenges like fat accumulation and increases in lipids (cholesterol and triglycerides) and/or insulin resistance may arise in some patients after treatment initiation.³ Although limited research has been done on the effects of nutritional approaches on pre- and post-HAART (highly active antiretroviral therapy) metabolic issues, general suggestions can be extracted from studies regarding

other conditions like diabetes, cardiovascular disease, and obesity. These suggestions are aimed at helping the body deal with the effects of HIV or its medications on metabolism, body shape, and quality of life as we live longer with HIV.

THE COMPONENTS OF WHOLE FOOD

Foods are made up of many different components—some are “micro” or smaller quantity nutrients, like vitamins, and some

are “macro” or larger quantity nutrients. The three macro groups that compose the majority of our diets are carbohydrates, proteins, and fats. These three units are the basic materials that fuel our activities and metabolism and maintain body composition. Selecting the best sources and amounts of these three macronutrients may help to minimize metabolic disorders (such as high cholesterol and blood sugar) and prevent loss of lean body mass and accumulation of body fat.^{4,5,6}

THE BEST CARBOHYDRATES

Carbohydrates provide our body’s main source of quick energy. After carbohydrates are digested and after some processing by the liver, they are released into

Mixing carbohydrates with protein, fiber, and good fats is one way to reduce their problematic effect on blood sugar and insulin.

the bloodstream as a sugar called glucose to be delivered to the cells.

Throughout the majority of the last million years of our evolution, the human diet consisted of animal carcasses, some seeds, nuts, and fibrous vegetable and fruit carbohydrate sources that are generally nutrient-rich with lots of water, but are not calorie-dense like processed foods of today. The majority of these carbohydrate sources are vegetables, leaves, roots, and fruits (all rich in fiber). Because vegetable fiber tends to slow down digestion, a majority of the carbohydrates in these foods are absorbed relatively slowly, inducing less blood sugar (glucose) and insulin spikes than processed sweets that contain no fiber. Some people call these “slow carbs.”

It was only after the advent of agriculture that human beings were introduced to higher intakes of grains as carbohydrate sources. Higher intakes of grains deliver lots of calories. Additionally, some grains deliver their sugar energy relatively quickly, especially if the grain is milled (which removes the fiber that slows down sugar absorption), as are the grains in breads and pasta. Unless you are very active and exercise enough to metabolize nutrients more rapidly, this quick glucose release into the bloodstream can create a dysfunctional hormonal environment that can ultimately promote obesity, cardiovascular disease, and diabetes. This hormonal shift also has a profound effect on lean body mass and fat metabolism, and possibly immune function.^{7,8,9} The key hormone involved in this problem is called insulin, produced by an organ called the pancreas.

INSULIN AND INSULIN RESISTANCE

The hormone insulin is produced by the pancreas to control blood sugar and store it in muscles for later use as glycogen. Insulin's main job in the body is to promote the delivery of sugar energy as glucose to cells. When a small amount of glucose is delivered into the bloodstream, a small

amount of insulin is produced by the pancreas to accompany it. When there is a large amount of glucose, the pancreas works to produce a large amount of insulin to facilitate its delivery so that cells can take in as much glucose as possible. Extra glucose that cannot be taken in by the cells circulates in the bloodstream and can be toxic to brain cells, so under normal circumstances, most of it is soon converted into triglycerides (fat) in the liver to be stored for later use. But we have to be careful with high blood levels of triglycerides, since they are what feed fat cells.

The correct amount of carbohydrate sources will provide enough sugar to give a healthy amount of glucose to the cells, but not too much at once. Thus, levels of glucose and insulin in the bloodstream are not unusually elevated for any long period of time. The pancreas works, but it is not overworked trying to keep up with an unusual demand for insulin.¹⁰ However, in the U.S., much of the diet consists not only of large amounts of high-calorie carbohydrate sources, but also of carbohydrates from sweets and sodas, which are very concentrated sources of sugar. The net effect that intake of these calorie-dense carbohydrate foods creates is a bloodstream that is occasionally flooded with large amounts of glucose, a pancreas that is overworked, and large amounts of insulin and triglycerides circulating in the bloodstream. Note that excess insulin causes increased production of cholesterol.

Over time, these occasional glucose, triglyceride, and insulin floods can cause a decrease in the sensitivity of the cells' response to insulin, which reduces the cells' ability to take in glucose. Insensitivity to insulin is called insulin resistance, and it is a serious consideration in HIV because we are now seeing it as one of the core components of lipodystrophy and metabolic problems.¹¹ Some HIV medications can worsen insulin resistance, so we need to be aware of nutritional considerations that can help. Ways to decrease insulin resistance are to exercise, choose more metabolic-friendly

HIV medications, and follow a proper diet. For instance, a prominent study from Tufts School of Medicine found that HIV-positive people consuming an overall high-quality diet, rich in fiber and adequate in energy and protein, were less likely to develop fat deposition.¹² This is why it is best to select the majority of your carbohydrate intake from fiber-rich, slow-releasing carbohydrate sources that do not contain an excessive amount of calories. And these good carbs should be accompanied by good sources of protein and fats.

COMBINING CARBOHYDRATES WITH PROTEIN, FIBER, AND FAT

Protein, fiber, or fat will slow the absorption into the blood of glucose from carbohydrates, which helps to reduce the rise in blood sugar and insulin spikes. So, mixing carbohydrates with protein, fiber, and good fats is one way to reduce their problematic effect on blood sugar and insulin. Ensure that every meal and snack you consume has a mix of these three macronutrients. But what are the best fats, protein, and high-fiber carbohydrates sources out there?

Fats and oils. There are a number of different kinds of fats. There is motor oil, there is butter, and there are essential fatty acids. The most important oil to keep a Honda running right is not the kind with essential fatty acids (EFAs), but if you want to help your body stay healthy and your immune system operating at its best, you had better consider getting these EFAs on a daily basis. They are called “essential” because your body cannot manufacture them, and must obtain them from an outside source, like food or supplements. These oils are necessary for every critical function in your metabolism, including building lean body mass and fighting infections.

The main point is that since we need EFAs and other fats for health, we should be getting them in our diets from fresh, high-quality sources. A proper diet reduces the amount of starchy carbohydrates while

Recent data have shown that mono-unsaturated fats decrease the risk of certain cancers, and have an anti-inflammatory effect. Since AIDS is an inflammatory disease, **mono-unsaturated fat intake is a factor in managing AIDS, too.**

maintaining a certain amount of healthy fats so that there is a different macronutrient balance than the old high-carbohydrate, high-protein, low-fat diets contained. This means striving to get fatty acids from several sources, the least of which are the saturated fats in butter or animal fat. Understand that saturated fats are not the demons we have been led to believe. When we realize that we evolved getting a certain amount of saturated fat from foods in the wild, it is only logical that they would have a place in a healthy diet. One recent study showed that dietary saturated fat and mono-unsaturated fat were associated with healthy testosterone production in humans, while EFAs had no effect. So it appears that we need a little saturated fat for optimal hormonal health. However, most people get far too much saturated fat, which promotes insulin resistance and metabolic problems, and not enough EFAs, which are needed for healthy cells and immune function.¹³

The other important kind of fat that we should consciously include in our daily diet is mono-unsaturated fat, which we get from foods like olive oil. Recent data have shown that mono-unsaturated fats decrease the risk of certain cancers, and have an anti-inflammatory effect.¹⁴ AIDS is an inflammatory disease, so mono-unsaturated fat intake logically has a place of importance in managing AIDS, too.

Fatty acid recommendations. EFAs include the omega-3 and omega-6 fatty acids. Most people get an imbalance of these two by consuming too small an amount of omega-3 fats, which have anti-inflammatory properties, and relatively too large an amount of omega-6 fats, which tend to promote inflammation when out of balance.¹⁵ To get more omega-3s, eat more fish, including salmon, tuna, sardines, anchovies, mackerel, rainbow trout, and herring. Omega-6s are contained in common vegetable oils, like sunflower, safflower, and corn oils. Try to reduce your intake of these.

Oils and cooking. Olive oil is one of the

best oils to cook with. You can also cook with high-oleic sunflower oil, avocado, canola, macadamia, or any oil that is high in mono-unsaturated fatty acids.

Avoid cooking with oils made from corn and sesame. These oils contain more omega-6 fats, and less mono-unsaturated fats, so they have a higher potential for spoiling and turning to trans-fats, which are bad for the immune system. Try to avoid any intake of these oils when they are not absolutely fresh.

Also, choose oils that are minimally processed. Most of the clear oils in supermarkets are stripped of some of their natural components to make them more suitable for sitting on store shelves for long periods of time without spoiling. Do not use these stripped oils. When you do cook, do not overheat the oil so that it smokes, which causes the formation of carcinogens and destroys the beneficial fatty acids.

Avoid margarine, hydrogenated fats, or processed oils. Do your best to avoid processed fats or oils, as they have negative effects on cellular health, overall metabolism, and your immune system. Look out for the words hydrogenated and partially-hydrogenated. These kinds of manipulated fats probably do increase the risk of cancer and heart disease. They also weaken healthy cellular immune metabolism, which means that they might increase HIV progression. Lastly, they are also likely to promote high lipid levels and insulin resistance.

Protein, food for the immune system. Dairy protein fractions, such as casein (contained in milk curd) and whey, are at the top of the list of proteins that optimally feed lean body mass growth. In dairy products, the amino acid balances, insulin-raising potential, and overall growth factor content add up to one thing: milk proteins were created to make mammals grow bigger. While there is a lot of hoopla related to which dairy protein fractions are best, there is more misinformation than reality in this area. Those with lactose intolerance

should be careful in their selection of milk-based products. Aged cheeses and yogurt may be more tolerable for those who cannot digest lactose.

Egg protein. Next on the list are egg proteins. The important thing to remember is that whole egg is probably somewhat better than egg white for lean body mass growth and overall health effect, because the yolk is a rich nutrient source, and its protein content complements the protein in the egg white. Together they are a better source of protein.

Meat protein. While real food like meat often seems to take a back seat to protein powders because of a mindset created by slick advertising, professional athletes know the value of real food related to lean body mass growth. If you do not make real food and meat fundamentals in your diet, you will not grow lean body mass tissue as well. Fish, chicken, turkey, and beef are vitally important foods, not only because of their protein content, but because they contain numerous other nutritional components that are important for a healthy metabolism. The message is: eat real food, then supplement food with protein powder drinks if you need them.

Lean red meat is a superior source for lean body mass growth and blood-building nutrients. These include creatine, carnitine, phenylalanine, conjugated linoleic acid (CLA), and heme- (blood) iron, the most absorbable form of iron. And meat, in general, is less likely to cause allergic reactions than eggs or dairy proteins, like casein and whey. The only caution about red meat is that the high amount of saturated fat most commercial red meat contains could promote metabolic problems. So be moderate about including it in your diet and choose leaner meats if you do.

Important details on meat: cooking kills bacteria in meats. Stewed meat is better for digestion (chicken soup, beef stew). Roasting is okay. Try not to fry or barbecue with charcoal. Charred foods are associated with increased risk of gastrointestinal

Vegetarian or vegan diets present a challenge to people with HIV or AIDS who need a full spectrum of amino acids and micronutrients. Unless you are vegetarian for ethical reasons, consider eating eggs and fish.

system cancers. Any cooking of meat or vegetable protein that causes the formation of a hard outer skin renders the protein that becomes the skin to be much less digestible because it cross-links the protein.

VEGETARIAN DIETS

It is very difficult to gain lean muscle weight on a vegetarian diet. In fact, it is almost impossible for most people, especially when they are fighting infections that burn lean body mass. While I know a very few HIV-positive people who can do well adhering to a vegetarian regime, I find that the vast majority cannot do it and keep their lean body mass. Additionally, vegetarian diets increase the potential for anemia because of a lack of blood-building components such as highly absorbable heme-iron and vitamin B12.

If you do choose a vegetarian diet, your best protein sources are beans, seeds and nuts. Digestion of nuts and seeds will be improved by soaking them overnight to reduce the enzymes they contain that inhibit digestion of proteins. If you can eat them without digestive problems, many nuts and seeds are ideal foods because they contain protein, healthy fat, and complex carbohydrates in a very good balance for overall health. They also make a great snack between meals. However, the amino acid balances in these proteins do not appear to be optimum for lean body mass growth for humans. Again, vegetarian or vegan diets present a challenge to people with HIV or AIDS who need a full spectrum of amino acids and micronutrients. Unless you are vegetarian for ethical reasons, consider eating eggs and fish.

Caution: People who are on HIV medications like tenofovir (in Viread, Truvada, Atripla, Complera, and the Quad), which may affect kidney function in some patients, should be careful about increasing their protein intake too high (over 1 gram per pound of body weight per day), as this can increase the potential for kidney problems. Ask your doctor if you are taking kidney burdening medicines, and, if so, only eat a higher protein diet under

your doctor's direction. Those who have liver problems need good protein intake for the repair of liver tissue, but should also be careful about higher protein intake, and should also do so only under a doctor's supervision.

CALCIUM AND VITAMIN D—TWO IMPORTANT MICRONUTRIENTS

Bone loss has been reported in several HIV studies. It seems to be caused by the effect of the virus on the body. Certain medications like tenofovir (Viread) may make this problem worse. We also seem to have a high incidence of vitamin D deficiency due to potential HIV medication effects or metabolism issues. We know that calcium and vitamin D help to strengthen bone. Many of us chose to take calcium plus vitamin D supplements, but there are also foods that are rich in these nutrients. Calcium-rich foods include milk, cheese, spinach, fortified orange juice (be careful with the sugar, though!), fish, eggs, and beans. Vitamin D-rich foods include milk, most fish, and eggs. However, most of us do not consume the 1000 mg and 2000 IU needed per day for calcium and vitamin D, respectively, and need to take over-the-counter supplements. One word of caution: do not take your calcium supplements with your HIV medications since they may interfere with their absorption (at least two hours before or after is okay).

MISCELLANEOUS NUTRITION TIPS

If diet, weight loss, and exercise fail to lower your LDL cholesterol and triglycerides, ask your doctor for a prescription for lipid-lowering agents (statins, fibrates, etc.) or to switch your meds to a more lipid-friendly HIV medication combination.

For your food, shop mostly in the outer part of the grocery store where the fresh produce, meats, and milk products/eggs are. Avoid overly processed canned or packaged foods, except for frozen vegetables. Read the labels and avoid products with many preservatives and additives. Trans-fats and hydrogenated oils, high fructose corn syrup, and high

sugar should be on your radar when reading labels. Watch this funny video for more details on healthy eating: www.youtube.com/watch?v=peuLPHuvq1Y.

Try to eat several smaller balanced (protein + good carbs + good fats) meals or snacks instead of two to three large ones. Smaller meals/snacks are more easily digestible, keep blood sugar and insulin more constant through the day, and keep you from binge eating late at night.

Eat more almonds, walnuts, pecans and pistachios (good cholesterol-lowering fats). Twice a day, snack on such nuts to get your good fats and fiber. If you wish, mix them with some dried fruit. Research has shown that people who eat nuts tend to have lower LDL cholesterol.

Avoid junk and fast food. The best way to do this is to have enough food at home and to bring lunch to work. Cook a lot of food on weekends and freeze meals in small containers you can heat up later.

Do not sabotage yourself by bringing sweets and junk into your home. Watch your cravings at night, when most people find it the most difficult to avoid overdrinking alcohol or eating ice cream, cookies, and comfort foods.

Eat a large breakfast, a moderate lunch, and a small dinner. Skipping breakfast makes you more prone to overcompensate by eating more calories late in the day. Your body has spent several hours without food and is starved for nutrients in the morning. Do not feed it sugar and white flour products at this important time. Eggs, oatmeal (the type that has no added sugar, and you can add whey protein powder to it!), Greek-style yogurt with nuts and fiber supplements, low-fat cottage cheese with fruit, almond butter on multigrain (high-fiber) bread, and fruit are all good choices for breakfast.

For lunch have some soup and a glass of water first and wait 10 minutes to trick your body into feeling full faster. Grilled chicken with vegetables, tuna salad over greens and nuts, a Greek salad with sliced steak, and any Mediterranean food choices are good.

For dinner, fill yourself with stir-fried

Consuming sugar daily can affect your metabolism, create insulin resistance, make you fat, and have all kinds of negative health consequences.



(use olive oil!) vegetables and lean meats. Two hours before bed, you can have half an almond butter sandwich or yogurt with fruit. You will not be hungry and desperate with this diet!

Eat fruits and vegetables of all colors. Each has a different antioxidant profile. The produce section of the market is basically a fresh vitamin department and a medicine chest. Some foods like garlic, onions, and ginger have genuine therapeutic effects. Eating the widest variety of fresh produce on a daily basis assures you of getting all the ingredients that nature provides that can help keep your body strong enough to handle bacteria and viruses so that you stay healthy.

Avoid sodas, sweet drinks, and fruit juices (fruit sounds healthy, but juice contains too much sugar and no fiber to slow down its absorption into the blood).¹⁶ Consuming sugar daily can affect your metabolism, create insulin resistance, make you fat, and have all kinds of negative health consequences. The suggested pecking order of carbohydrate food sources that support your health without increasing insulin resistance follows. Best are vegetables in their many forms. Next are beans and peas. These deliver more calories than vegetables, but the carbohydrates release much more slowly than grains. Next are whole grains, which are calorie-dense but contain carbohydrates that, in general, release somewhat slowly. At the bottom, and the most likely to promote body fat problems, are carbohydrates from milled grains, like wheat and corn. Whole grains are marginally better

than processed grains, but when they are milled into flour the difference is not that great. The very worst carbohydrate sources are sweets, like candies, which can deliver as many as 2,000 calories per pound. Try to eat from the first group of slow-release carbohydrate sources most of the time, and if you are relatively healthy, you can have small amounts of milled wheat products or sweets once in awhile.

Drink lots of water. Six to eight glasses a day is a good goal. If you get thirsty, you are already dehydrated!

Eat a high-protein, complex carbohydrate-rich meal after workouts. Examples: chicken salad with nuts, cottage cheese or yogurt and nuts/fruit, celery sticks and hummus (chickpea butter), etc.

Manage your intake of caffeine (it reduces appetite but can increase anxiety). Do not have any caffeine after 4 p.m., since it can impair your sleep.

Minimize hidden sugars like high fructose corn syrup. Read the labels of food you buy. Diet sodas tend to make your brain crave sweets in general, so they are not good substitutes for sugary drinks. Water, water, water!

If you do not consume at least 20 grams of fiber a day, add to your intake supplements like Citrucell or Benefiber, purchased in any grocery store. Fiber improves insulin sensitivity, makes you feel full longer, keeps your gut healthy (friendly gut bacteria that produce vitamins love fiber), keeps you regular and reduces diarrhea, and can lower the chances of getting colon cancer.¹⁷

Eating healthy is eating smart, and it

does not mean that you should starve yourself. Hopefully, this information has shed some light on healthy food sources and how they can affect health and the body. Now that we are living longer, food choices can determine how well we do as we age with HIV. So, take charge of your health and take care of your body. It is the only one you have. ☒

GO TO POSITIVELYAWARE.COM for references and an example of a healthy shopping list.

NELSON VERGEL, a chemical engineer from Venezuela, has been HIV-positive since 1983, and is a leading treatment advocate on HIV disease. He created the Program for Wellness Restoration (PoWeR) and founded the Body Positive Wellness Center in Houston. Nelson has lectured extensively around the country and overseas, and with his research partner, Michael Mooney, co-authored the book *Built to Survive*. In 2010, he wrote and published *Testosterone: A Man's Guide—Practical Tips for Boosting Physical, Mental and Sexual Vitality*.

He is currently a member of the DHHS Panel on Antiretroviral Guidelines, the AIDS Treatment Activists Coalition, and moderates PozHealth, one of the largest HIV health discussion listservs online.

Read posts from Nelson's blog, "Surviving HIV," at <http://survivinghiv.blogspot.com/>

Read Nelson's blog, "Outsmarting HIV: A Survivor's Perspective," at www.thebody.com/content/art60473.html

COME RIDE WITH US

Gearing up for the 2012 Ride for AIDS Chicago

BY RICHARD CORDOVA



AS A FUNDRAISING EVENT, THE RIDE FOR AIDS CHICAGO (RFAC) raises money. As an endurance event, it changes lives. The two-day, 200-mile bicycling event produced by Test Positive Aware Network (TPAN) raises funding for TPAN and other partner agencies.

Since its inception in 2004, the Ride for AIDS Chicago has returned over \$1.5 million to TPAN and partner agencies. The 2012 Ride will mark its 10th anniversary and promises to be bigger and better than ever. After raising over \$525,000 in 2011 alone, the 2012 Ride aims to raise over \$750,000 to support HIV services in the Chicago area.

The Ride begins in Chicago on a Saturday morning for the journey into Wisconsin, along the shores of Lake Geneva, and then into camp on Green Lake, part of the Lauderdale Lakes chain. After arriving at camp, riders and crew members enjoy a hot meal, lounge with friends, and celebrate the accomplishment of making it halfway. With 100 miles behind them, they get a good night's sleep in preparation for the return home.

Riders and crew members can register as part of a team, or as individuals. Riders are required to raise a minimum of \$1,000 and crew members are encouraged to set a modest goal of \$500. Team captains

and other team leaders help ensure that participants are successful in their training and fundraising.

The months of training and fundraising are nothing compared to the challenges HIV-positive people face, but they are challenges nonetheless. Early morning training rides, expensive equipment, sore legs (and other body parts), and relentless requests for donations are just some of the ways Ride participants commit to this event. Many of the riders and crew members are themselves living with HIV.

Here is what some participants have to say about the Ride for AIDS Chicago:

Renee DeMann, 2011 Rider, 2012 Team Co-Captain:

"I had no idea what to expect. It was the most difficult, challenging, strenuous experience of my life, and I was in labor with my child for 13 hours and pushing for three! Can't wait 'til next year!"

Shannon Cunningham, 2011 Rider and Team Co-Captain, 2012 Fundraising Co-Chair:

"The idea that I could challenge myself to ride 200 miles was the primary reason I signed up for the Ride for AIDS Chicago 2011.

"I ended up raising almost \$4,000, making amazing friends, and realizing I do have the ability to change someone's life... and I did get to ride all 200 miles.

"I'm returning this year to help others learn how strong they are, both physically and mentally, and how the sum of our entire efforts not only changes a community, it creates one. See you on the Ride!"

Lauren Kirby, 2010 and 2011 Rider:

"The Ride meant learning a small part of the endurance and strength it takes to live with HIV/AIDS. I learned this by being passed by people living with HIV/AIDS and knowing that those people were just as strong as me, if not more!

"In addition, the Ride was in the face of a 14-year-old boy who was raised by conservative Catholics saying, "I teared up when that guy [Richard] talked, I've never felt that way before. It makes me want to think differently of people." The Ride to

The Ride's capacity to inspire and transform lives is one of the many rewards experienced by those who participate in the Ride for AIDS Chicago.

me is changing people's attitudes about those living with HIV/AIDS."

Jeremiah Miles, 2010 and 2011 Rider, 2012 Training Co-Chair:

"For me, RFAC started out as something to 'do.' Then it became a selfish addiction: more training, more donations. Now I have a selfless passion of involvement and awareness."

Shaine Wynsma, 2007 to 2011 Rider; 2008 to 2011 RFAC Co-Chair; and 2012 RFAC Chair:

"What has the Ride done for me? The Ride has allowed that part of me that can conquer anything set in my path to come forward, and it gave me the strength to 'come out' about my own status.

"What does it do for the community? Several things. It keeps the crisis in plain sight, it gives the crisis a face. It shows the community that people who are HIV-positive are not bedridden, waiting to die.

"Why do I continue to participate? I have an addiction to seeing the new riders become empowered and overcoming what they thought was a weakness."

Bill Farrand, TPAN Executive Director, 2007 -2010 Crew Member and 2011 Rider:

"After having extremely rewarding experiences as an RFAC crew member over the previous four years, I made a commitment to myself to ride in 2011 to mark and celebrate my 50th birthday, as well as 27 years being HIV-positive. By doing so, I was able to fully understand that we are only limited by the constraints we place upon ourselves through our negative beliefs and preconceptions. By doing the Ride, I proved to myself that a positive outlook—and a little training—are the keys to surviving and thriving. It was an experience that has changed my life, and if I can do it, I believe anyone can."

Unlike other rides of this kind, Ride for AIDS Chicago is committed to returning nearly 100% of the money raised back to the beneficiaries. Through corporate sponsorship, registration fees, and the help of dedicated participants, we are able to keep that commitment. In 2011, 97 cents of every dollar raised went to help support HIV services in the community.

The Ride's capacity to inspire and transform lives is one of the many rewards experienced by those who participate in the Ride for AIDS Chicago. The impossible becomes the possible. Hard-earned successes become memories of a lifetime.

The 2012 Ride for AIDS Chicago will take place on July 14 and 15. Registration opened on December 1, 2011. For more information, visit www.RideForAIDS.org. Additional questions may be directed to Richard Cordova, Athletic Events Director at r.cordova@tpan.com.

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THE BUZZ
DANIEL S. BERGER, MD

THE PATH TO A CURE

The pathway to an HIV cure and other treatments in the pipeline

IS CURING HIV POSSIBLE? I BELIEVE THAT THE ANSWER IS A resounding YES! The proof of concept for a cure is derived from the famous Berlin patient, Timothy Ray Brown, who many now believe has been “cured.” Also, at least two small pharmaceutical companies are researching gene therapy, of which the upshot may be to mimic the same effects observed in Mr. Brown.

At the time of this writing, it has been more than five years since Brown’s bone marrow transplant and he continues to demonstrate clearance of HIV from blood and other tissues. The transplanted cells were from a donor who harbored the delta 32 variant gene. Moreover, there are some individuals who already have this rare genetic alteration; they do not need a “cure” because they were born with and harbor this same delta 32 genetic variant. These individuals cannot become infected by exposure to HIV.

To be clearer, HIV requires bonding at two sites in order to gain entry into human cells: the CD4 receptor site and a chemokine receptor site, most commonly CCR5. When a person has both genes (homozygous) carrying the delta 32 variant, it results in a deletion of the gene that, under normal circumstances, selects for the CCR5 chemoreceptor. In other words, it results in them lacking CCR5, a protein on the surface of immune cells that HIV uses to gain entry. In this situation, HIV is disabled from gaining entry or infecting human cells. Roughly 1% of Northern Europeans possess this abnormality. Other individuals that are heterozygous and have the genetic modification in only one gene are not protected.

At least two pharmaceutical companies

are involved in looking at gene therapy. Their focus is to mimic the individuals who are naturally born with this genetic variation by causing the deletion of the gene that selects for CCR5. While this may be merely a sketch of the possible pathway to a cure, it is certainly a new road of research for HIV disease treatment.

Brown suffered from a leukemic disease as well as HIV. When treating leukemia, patients often undergo stem cell transplants after all their diseased cells are destroyed by chemotherapy. This form of chemotherapy is dangerous, wiping out many immune system cells as well, and carries with it a 50% mortality rate due to severe infections that can arise with a severely crippled immune system. However, during the post-chemo phase, where there should be no evidence of host cell disease, donor stem cells are infused into the patient with the hope of repopulating and replacing the cell lines with the new healthy donor cells. Five years ago, Mr. Brown’s physician had the vision to treat his HIV and leukemia at the same time by using donor cells from someone with the delta 32 variant. Timothy Ray Brown is currently the only living example of a possible HIV cure.

Enter a new possible approach

to treating HIV: gene therapy being researched by Sangamo Biosciences which collaborated with Sigma Life Science, a company which has made zinc finger technology widely available. Other scientists are looking at Sangamo’s example of how to best use this technology for creating new cell lines and new proteins to help fight additional disease states. Sangamo, with a viral vector (carrier), has created a method of using zinc finger nucleases to clip both strands of DNA that selects for the CCR5 co-receptor. In HIV-positive individuals, replacing genes with this deletion could potentially prohibit any HIV from infecting those cells. The altered CD4 cells that lack the co-receptor, known as SB-728-T, are multiplied in a laboratory and infused back into the same patient.

Recent data from Sangamo’s trial were presented at the 51st ICAAC in Chicago in September. Cohorts from the West Coast (nine patients) and East Coast (six patients) had undergone the procedure of altering the cells to become SB 728-T-modified CD4 cells during a Phase 1 trial.

The nine patients from the West Coast had baseline undetectable viral loads and median CD4 counts of 384 cells/mm³ (384 cells are felt to be suboptimal CD4 recovery after ART). The study participants, median age of 50 years, had been HIV-positive for an average of 20 years. Results showed that the modified cells persisted for a median of 337 days, with the maximum duration being 561 days. The presence of the CCR5 deletion was shown in 25% of the patients and all had CD4 increases of an average of 163 cells. Also, the CD4 cells had normal migrating

Since approval, clinicians have been switching selected patients to Complera. This occurs more commonly when patients have been enduring side effects from Atripla, containing Sustiva.

properties. Side effects were minimal and short lived, with flu-like symptoms occurring for 24 hours after their infusion.

The East Coast cohort underwent a 12-week ART interruption starting four weeks after receiving SB-728-T-modified CD4 cells. The subjects with CCR5-deleted genes who also had higher CD4 values showed lower viral loads and as much as a .08 to 2-log viral load drop. One of the subjects who had the heterozygous form of the delta 32 gene achieved undetectability during the treatment.

Sangamo is now considering investigation into treating patients by adding small doses of chemotherapy prior to infusing the zinc finger (SB-728-T)-modified CD4 cells, with the aim of achieving a higher turnover towards CCR5-deleted CD4 cells and thus further progress at arriving at a functional cure.

NEW SINGLE-PILL COCKTAILS

Let's move on to a discussion of two new single-pill regimens, each containing triple drug therapy in one pill. Complera, recently approved, contains the new non-nuke rilpivirine (Edurant) plus Truvada (Viread plus Emtriva). Another pill, nicknamed the Quad, is undergoing Phase 3 studies but has filed a New Drug Application (NDA) with the Food and Drug Administration (FDA) for approval. If successful, it may become available by April 2012. The Quad contains the integrase inhibitor elvitegravir boosted by cobicistat, plus Truvada.

Since approval, clinicians have been switching selected patients to Complera. This occurs more commonly when patients have been enduring side effects from Atripla, containing Sustiva (such as sleep disorders, morning lethargy, and anxiety), but also when side effects of some protease inhibitor regimens persist. Also, some patients are being transitioned to Complera merely for the sake of treatment simplification.

Some clinicians have been more reserved, not confident of Complera's potency due to higher failure rates

observed in naïve patients of the Phase 3 trials, who had baseline viral loads greater than 100,000 copies/ml. Thus, physicians are split between using Complera now, vs. waiting for the Quad to become approved. However, in present real-world situations, patients who have already reached undetectability, being stable on other regimens, are undetectable at this baseline when switching; concerns regarding the effectiveness of Complera should at least be on par with the overall data of non-inferiority compared to the standard of care, Atripla. Of note is that higher levels of rilpivirine are achieved within the single pill Complera than were observed in the original Phase 3 trials, in which rilpivirine was administered as a separate pill. Of course, prior to any switch, clinicians should review their patients' previous genotypic history, ensuring that no underlying rilpivirine and Truvada resistance is present.

During the ICAAC conference, new data on Complera were presented by Dr. Tony Mills. In this study, 49 patients who were undetectable on Atripla switched to Complera. All 49 patients remained undetectable at 12 weeks.

Also, two more studies are ongoing to better define Complera's use. In one trial, Complera is being pitted against Atripla in a study of nearly 800 treatment-naïve patients. The second, which enrolled approximately 500 patients, is studying treatment-experienced patients on boosted protease inhibitors, who were randomized to either stay on their original regimen or be switched to Complera. I currently serve as principle investigator for all three trials at Northstar Healthcare, while seeing many of our patients on these studies. It gives me great pleasure to be observing patients improve their quality of life while contributing to research and our knowledge base as they are offered these new advances in treatment.

NEWEST NUKE, GS-7340

GS-7340 is a pro-drug of tenofovir (Viread) (pro-drugs get metabolized

within the body, or *in vivo*, which improves bio-availability). 7340 has been thought to have great antiviral activity at low doses, also penetrating tissues at 20-100 times that of other drugs. At Northstar, we have recently completed a Phase 1 dose-finding, 10-day monotherapy study, comparing several low doses of the drug. We expect data to be released from this study in the near future. Also, Gilead has reported that they plan to formulate yet another single-tablet regimen, to contain GS-7340 plus Emtriva and the cobicistat-boosted integrase inhibitor elvitegravir.

SUMMARY

2012 is expected to be an exciting year for development of HIV therapeutics. Various single-pill regimens will eventually overtake older regimens where previous treatment-naïve patients were started on quantities of three or four pills. Many treatment-experienced patients will also be eligible to have treatment simplified towards one-pill therapy. Further down the road, a completely new approach in treatment is underway—one that may have the potential to be a functional cure of HIV infection. However, challenges still remain in the attempt to retard the premature development of complications associated with the aging HIV population.

DR. DANIEL S. BERGER is a leading HIV physician in the U.S. and is Clinical Associate Professor of Medicine at the University of Illinois at Chicago. He is founder and medical director of Northstar Healthcare, has published extensively in such prestigious journals as *The Lancet* and *The New England Journal of Medicine*, and currently serves as principle investigator at Northstar Healthcare. Dr. Berger has been honored by Test Positive Aware Network with the Charles E. Clifton Leadership Award. Dr. Berger can be reached at DSBergerMD@aol.com and www.Nstarmedical.com.



SALIENT RAMBLINGS
SAL IACOPELLI

“It is wanting to know the end that makes us believe in God, or witchcraft... to believe, at least, in something.”

—*Other Voices, Other Rooms, Truman Capote*

WHEN STUDYING HISTORY, ONE WILL NOTE THE ROMAN CATHOLIC Church has a dark history of being wrong on many issues. Consider their view on Galileo’s work or St. Paul advising slaves to be obedient to their masters. Each time science and knowledge has advanced, the Church fought to hang on to ignorance.

Medical science and mental health knowledge have concluded that homosexuality is a normal phenomenon contrary to the Church’s 13th century teachings on “natural law.” Rather than admit that calling gays “inherently disordered” and worse is simply wrong, an explanation is offered as to why condemning gays is still morally acceptable: the Devil causes a supposed malfunction in fetal development in the womb and so, a gay child is born.

My biggest dissension with Christianity is that it is based on fear. There are liberal clergy preaching a gospel of love; yet to do so, they ignore the bulk of Christian teachings and Christian history. Throughout much of its existence, Christianity focused on fear of the devil and of hell. Even today, the existence of the devil and hell are cardinal doctrinal tenets of almost all Christian creeds. Many fundamentalist preachers still openly resort to terrorizing followers with lurid, sadistic portraits of the suffering of nonbelievers after death.

For over a millennium Christianity arrested the development of science. From the time of Augustine until the Renaissance, systematic investigation of the natural world was restricted to theological investigation and the interpretation of biblical passages. There was no direct observation and interpretation of natural processes because that was considered a useless pursuit, as all knowledge resided

in scripture. Scientific knowledge barely advanced in over 1,000 years from the rise of orthodox Christianity in the fourth century to the 1500s.

Not bad enough? Misogyny is fundamental to the writings of Christianity. In passage after passage, women are encouraged, indeed commanded, to accept an inferior role and to be ashamed of themselves for the simple fact that they are women. From the New Testament we find “Wives, submit yourselves unto your own husbands, as unto the Lord. For the husband is the head of the wife, even as Christ is the head of the church...” (Ephesians 5:22-23) and “These [redeemed] are they which were not defiled with women...” (Revelation 14:4). From the Old Testament we find “How then can man be justified with God? Or how can he be clean that is born of a woman?” (Job 25:4).

Finally, Christianity from its beginnings has been markedly homophobic. The biblical basis for this homophobia lies in the story of Sodom in Genesis, and in Leviticus. Leviticus 18:22 reads: “Thou shalt not lie with mankind, as with womankind: it is abomination,” and Leviticus 20:13 reads: “If a man lie with mankind as he lieth with a woman, both of them have committed an abomination: they shall surely be put to death; their blood shall be upon them.” Leviticus declares many other “abominations” and prescribes

the death penalty for several other acts. Leviticus 17:10-13 prohibits the eating of blood sausage; Leviticus 11:6-7 prohibits the eating of “unclean” hares and swine; Leviticus 11:10 declares shellfish “abominations”; Leviticus 20:9 prescribes the death penalty for cursing one’s father or mother; and Leviticus 20:10 prescribes the death penalty for adultery. Clearly, Leviticus had some issues. Maybe he’d also been “visited” by the Devil in the womb.

Few realize the history of the world is filled with same-gender-loving spirituality. Ancient civilizations, tribes, and sects revered homosexuals as spiritual guardians. As religion became more organized, millions of these shamans, priests, and priestesses were exiled, brutalized, and even killed by the church.

For centuries, in many societies, sex was undifferentiated. Sexual choice was merely a matter of taste. In the Middle East, many non-monotheistic gods and goddesses presented an image of sexual ambivalence and bisexuality. As late as 600 AD, even in Europe, love, friendship, sex, and pleasure were considered interconnected, while marriage was specifically for the purpose of procreation. However, as the church, prejudiced by strict Biblical interpretation, became a monolithic political force in the West, gay people and gay spirituality were brutally denied any contribution to human history, and forced to go underground for hundreds of years. The term “homosexuality” wasn’t even coined until late in the 19th Century.

If I were not gay, would I be so wary of Christianity? Indeed. As a thinking being, there are myriad reasons to at least question, if not shun, its teachings.



**DECIDING
MOMENT:
"HAVING THE
SUPPORT OF
MY FAMILY."**

EVA

I'm a mother, a grandmother and a nurse. I am also HIV positive. My family means everything to me. By staying consistent with my treatment and using protection, I am making sure my fiancée stays HIV negative and we can be here for our kids. I love my family and I love my life.

I AM EVA AND I AM GREATER THAN AIDS.

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