

What is STRIBILD?

STRIBILD is a prescription medicine used to treat HIV-1 in adults who have never taken HIV-1 medicines before. STRIBILD can also replace current HIV-1 medicines for some adults who have an undetectable viral load (less than 50 copies/mL of virus in their blood) and whose healthcare provider determines that they meet certain other requirements. STRIBILD combines 4 medicines into 1 pill to be taken once a day with food. STRIBILD is a complete single tablet regimen and should not be used with other HIV-1 medicines.

STRIBILD does not cure HIV-1 infection or AIDS. To control HIV-1 infection and decrease HIV-related illnesses you must keep taking STRIBILD. Ask your healthcare provider if you have questions about how to reduce the risk of passing HIV-1 to others. Always practice safer sex and use condoms to lower the chance of sexual contact with body fluids. Never reuse or share needles or other items that have body fluids on them.

IMPORTANT SAFETY INFORMATION

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

STRIBILD can cause serious side effects:

- Build-up of an acid in your blood (lactic acidosis), which is a serious medical emergency. Symptoms of lactic acidosis include feeling very weak or tired, unusual (not normal) muscle pain, trouble breathing, stomach pain with nausea or vomiting, feeling cold especially in your arms and legs, feeling dizzy or lightheaded, and/or a fast or irregular heartbeat.
- Serious liver problems. The liver may become large (hepatomegaly) and fatty (steatosis). Symptoms of liver problems include 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, and/or stomach pain.

- You may be more likely to get lactic acidosis or serious liver problems if you are female, very overweight (obese), or have been taking STRIBILD for a long time. In some cases, these serious conditions have led to death. Call your healthcare provider right away if you have any symptoms of these conditions.
- Worsening of hepatitis B (HBV) infection. If you also have HBV and stop taking STRIBILD, your hepatitis may suddenly get worse. Do not stop taking STRIBILD without first talking to your healthcare provider, as they will need to monitor your health. STRIBILD is not approved for the treatment of HBV.

Who should not take STRIBILD?

Do not take STRIBILD if you:

- Take a medicine that contains: alfuzosin, dihydroergotamine, ergotamine, methylergonovine, cisapride, lovastatin, simvastatin, pimozide, sildenafil when used for lung problems (Revatio®), triazolam, oral midazolam, rifampin or the herbal supplement St. John's wort.
- For a list of brand names for these medicines, please see the Brief Summary on the following pages.
- Take any other medicines to treat HIV-1 infection, or the medicine adefovir (Hepsera®).

What are the other possible side effects of STRIBILD?

Serious side effects of STRIBILD may also include:

- New or worse kidney problems, including kidney failure. Your healthcare provider should do regular blood and urine tests to check your kidneys before and during treatment with STRIBILD. If you develop kidney problems, your healthcare provider may tell you to stop taking STRIBILD.
- Bone problems, including bone pain or bones getting soft or thin, which may lead to fractures. Your healthcare provider may do tests to check your bones.
- Changes in body fat can happen in people taking HIV-1 medicines.
- Changes in your immune system.
 Your immune system may get stronger and begin to fight infections.

Tell your healthcare provider if you have any new symptoms after you start taking STRIBILD.

The most common side effects of STRIBILD include nausea and diarrhea. Tell your healthcare provider if you have any side effects that bother you or don't go away.

What should I tell my healthcare provider before taking STRIBILD?

- All your health problems. Be sure to tell your healthcare provider if you have or had any kidney, bone, or liver problems, including hepatitis virus infection.
- All the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. STRIBILD may affect the way other medicines work, and other medicines may affect how STRIBILD works. Keep a list of all your medicines and show it to your healthcare provider and pharmacist. Do not start any new medicines while taking STRIBILD without first talking with your healthcare provider.
- If you take hormone-based birth control (pills, patches, rings, shots, etc).
- If you take antacids. Take antacids at least 2 hours before or after you take STRIBILD.
- If you are pregnant or plan to become pregnant. It is not known if STRIBILD can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking STRIBILD.
- If you are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed.
 HIV-1 can be passed to the baby in breast milk. Also, some medicines in STRIBILD can pass into breast milk, and it is not known if this can harm the baby.

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 Brief Summary of full Prescribing Information with **important warnings** on the following pages.

*STRIBILD is a combination of the medicines TRUVADA (emtricitabine and tenofovir disoproxil fumarate), TYBOST (cobicistat), and VITEKTA (elvitegravir).



STRIBILD is a prescription medicine used to treat HIV-1 in adults who have never taken HIV-1 medicines before. STRIBILD can also replace current HIV-1 medicines for some adults who have an undetectable viral load (less than 50 copies/mL of virus in their blood) and whose healthcare provider determines that they meet certain other requirements. STRIBILD does not cure HIV-1 or AIDS.

I started my personal revolution

Talk to your healthcare provider about HIV-1 treatment.

STRIBILD is a complete
HIV-1 treatment in 1 pill,
once a day that combines
the medicines in TRUVADA +
TYBOST + VITEKTA.*

Ask if it's right for you.

STRIBILD® |

elvitegravir 150mg/ cobicistat 150mg/ emtricitabine 200mg/ tenofovir disoproxil fumarate 300mg tablets

www.STRIBILD.com



Patient Information

STRIBILD® (STRY-bild)

(elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) tablets

Brief summary of full Prescribing Information. For more information, please see the full Prescribing Information, including Patient Information.

What is STRIBILD?

- STRIBILD is a prescription medicine used to treat HIV-1 in adults who have never taken HIV-1 medicines before. STRIBILD can also be used to replace current HIV-1 medicines for some adults who have an undetectable viral load (less than 50 copies/mL of virus in their blood), and have been on the same HIV-1 medicines for at least 6 months and have never failed past HIV-1 treatment, and whose healthcare provider determines that they meet certain other requirements.
- STRIBILD is a complete HIV-1 medicine and should not be used with any other HIV-1 medicines.
- STRIBILD does not cure HIV-1 or AIDS. You must stay on continuous HIV-1 therapy to control HIV-1 infection and decrease HIV-related illnesses.
- Ask your healthcare provider about how to prevent passing
 HIV-1 to others. Do not share or reuse needles, injection equipment,
 or personal items that can have blood or body fluids on them. Do not
 have sex without protection. Always practice safer sex by using a latex
 or polyurethane condom to lower the chance of sexual contact with
 semen, vacinal secretions, or blood.

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

STRIBILD can cause serious side effects, including:

- 1. Build-up of lactic acid in your blood (lactic acidosis). Lactic acidosis can happen in some people who take STRIBILD 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:
 - · feel very weak or tired
 - have unusual (not normal) muscle pain
 - · have trouble breathing
 - · have stomach pain with nausea or 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 STRIBILD. 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). Call your healthcare provider right away if you get 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 STRIBILD for a long time.

3. Worsening of Hepatitis B infection. If you have hepatitis B virus (HBV) infection and take STRIBILD, your HBV may get worse (flare-up) if you stop taking STRIBILD. A "flare-up" is when your HBV infection suddenly returns in a worse way than before.

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

Who should not take STRIBILD?

Do not take STRIBILD if you also take a medicine that contains:

- adefovir (Hepsera®)
- alfuzosin hydrochloride (Uroxatral®)
- cisapride (Propulsid®, Propulsid Quicksolv®)
- ergot-containing medicines, including: dihydroergotamine mesylate (D.H.E. 45°, Migranal°), ergotamine tartrate (Cafergot°, Migergot°, Ergostat°, Medihaler Ergotamine°, Wigraine°, Wigrettes°), and methylergonovine maleate (Ergotrate°, Methergine°)
- lovastatin (Advicor®, Altoprev®, Mevacor®)
- · midazolam, when taken by mouth
- pimozide (Orap[®])
- rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®)
- sildenafil (Revatio®), when used for treating lung problems
- simvastatin (Simcor[®], Vytorin[®], Zocor[®])
- triazolam (Halcion®)
- the herb St. John's wort

Do not take STRIBILD if you also take any other HIV-1 medicines, including:

- Other medicines that contain elvitegravir, cobicistat, emtricitabine, or tenofovir (Atripla®, Complera®, Emtriva®, Truvada®, Tybost®, Viread®, Vitekta®)
- Other medicines that contain lamivudine or ritonavir (Combivir®, Epivir® or Epivir-HBV®, Epzicom®, Kaletra®, Norvir®, Triumeq®, Trizivir®)

STRIBILD is not for use in people who are less than 18 years old.

What are the possible side effects of STRIBILD?

STRIBILD may cause the following serious side effects:

- See "What is the most important information I should know about STRIBILD?"
- New or worse kidney problems, including kidney failure. Your healthcare provider should do blood and urine tests to check your kidneys before you start and while you are taking STRIBILD. Your healthcare provider may tell you to stop taking STRIBILD if you develop new or worse kidney problems.
- Bone problems can happen in some people who take STRIBILD. Bone
 problems include bone pain, softening or thinning (which may lead to
 fractures). Your healthcare provider may need to do tests to check your bones.
- Changes in body fat can happen in people who take HIV-1 medicine.
 These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the middle of your body (trunk).
 Loss of fat from the legs, arms and face may also happen. The exact cause and long-term health effects of these conditions are not known.
- Changes in your immune system (Immune Reconstitution Syndrome)
 can happen when you start taking HIV-1 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 right away if you
 start having any new symptoms after starting your HIV-1 medicine.

The most common side effects of STRIBILD include:

- Nausea
- Diarrhea

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 STRIBILD. For more information, ask your healthcare provider.
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I tell my healthcare provider before taking STRIBILD?

Tell your healthcare provider about all your medical conditions, including:

- If you have or had any kidney, bone, or liver problems, including hepatitis B infection
- If you are pregnant or plan to become pregnant. It is not known if STRIBILD can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking STRIBILD.
 - There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry.
- If you are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed if you take STRIBILD.
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - Two of the medicines in STRIBILD can pass to your baby in your breast milk. It is not known if the other medicines in STRIBILD can pass into your breast milk.
 - Talk with your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements:

- STRIBILD may affect the way other medicines work, and other medicines may affect how STRIBILD works.
- Be sure to tell your healthcare provider if you take any of the following medicines:
 - Hormone-based birth control (pills, patches, rings, shots, etc)
 - Antacid medicines that contain aluminum, magnesium hydroxide, or calcium carbonate. Take antacids at least 2 hours before or after you take STRIBILD
 - Medicines to treat depression, organ transplant rejection, or high blood pressure
 - amiodarone (Cordarone®, Pacerone®)
 - atorvastatin (Lipitor®, Caduet®)
 - bepridil hydrochloride (Vascor®, Bepadin®)
 - bosentan (Tracleer®)
 - buspirone
 - carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®)
 - clarithromycin (Biaxin®, Prevpac®)
 - clonazepam (Klonopin®)
 - clorazepate (Gen-xene®, Tranxene®)
 - colchicine (Colcrys®)
 - medicines that contain dexamethasone
 - diazepam (Valium®)
 - digoxin (Lanoxin®)

- disopyramide (Norpace®)
- estazolam
- ethosuximide (Zarontin®)
- flecainide (Tambocor®)
- flurazepam
- fluticasone (Flovent®, Flonase®, Flovent Diskus®, Flovent HFA®, Veramyst®)
- itraconazole (Sporanox®)
- ketoconazole (Nizoral®)
- lidocaine (Xylocaine®)
- mexiletine
- oxcarbazepine (Trileptal®)
- perphenazine
- phenobarbital (Luminal®)
- phenytoin (Dilantin®, Phenytek®)
- propafenone (Rythmol®)
- quinidine (Neudexta®)
- rifabutin (Mycobutin®)
- rifapentine (Priftin®)
- risperidone (Risperdal®, Risperdal Consta®)
- salmeterol (Serevent®) or salmeterol when taken in combination with fluticasone (Advair Diskus®, Advair HFA®)
- sildenafil (Viagra®), tadalafil (Cialis®) or vardenafil (Levitra®, Staxyn®), for the treatment of erectile dysfunction (ED). If you get dizzy or faint (low blood pressure), have vision changes or have an erection that last longer than 4 hours, call your healthcare provider or get medical help right away.
- tadalafil (Adcirca®), for the treatment of pulmonary arterial hypertension
- thioridazine
- voriconazole (Vfend®)
- warfarin (Coumadin®, Jantoven®)
- zolpidem (Ambien®, Edlular®, Intermezzo®, Zolpimist®)

Know the medicines you take. Keep a list of all your medicines and show it to your healthcare provider and pharmacist when you get a new medicine. Do not start any new medicines while you are taking STRIBILD without first talking with your healthcare provider.

Keep STRIBILD and all medicines out of reach of children.

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

Issued: December 2014



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READERS POLL



JOURNALISM. INTEGRITY. HOPE.

JEFF BERRY

EDITOR-IN-CHIEF @PAeditor

"Thank you, Bob Munk, for your gifts, and for leaving the world a little bit better than the way you found it."

ENID VÁZQUEZ

ASSOCIATE EDITOR @enidvazquezpa

'We have limited space see ias2015.org for tons of medical information."

RICK GUASCO

CREATIVE DIRECTOR

@rickguasco

'There's a lot to know and stay on top of when you're living with HIV, but this issue should help sort things out."

JASON LANCASTER

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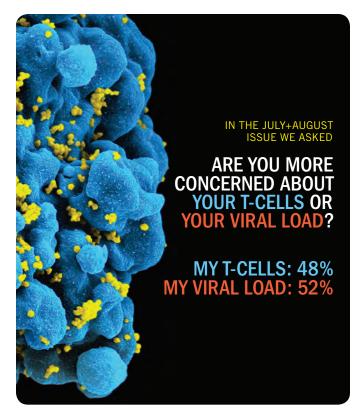
ADVERTISING **LORRAINE HAYES**L.Hayes@tpan.com

DISTRIBUTION AND SUBSCRIPTION SERVICES distribution@tpan.com

SINCE 1989. PUBLISHED BY

TPAN

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T-CELLS. They're your main line of defense.

VIRAL LOAD. That's what my doctor says, at least.

T-CELLS. My viral load is undetectable, but my T-cell count goes up and down.

VIRAL LOAD. Not even sure what T-cells are. Are they white blood cells? Mine are a little low, so somewhat concerned.

VIRAL LOAD. Having been positive since 1985, I am taking the long view.

VIRAL LOAD. CD4 counts are not a great indicator of disease progression or status; the viral load (regardless of CD4) is the most appropriate and accurate measure of HIV disease progression and overall health.

T-CELLS. My meds have helped get me undetectable but T-cell count is super slow in rising.

VIRAL LOAD. Because viral suppression is more important.

VIRAL LOAD. As long as the virus remains undetectable, I do not bother about my CD4.

T-CELLS. I've been on meds for over six years and have seen an undetectable viral load almost the entire time. Because of this, my greater concern is monitoring my T-cell count and ensuring I stay as healthy as possible.

VIRAL LOAD. Viral load concerns me more than T-cell count because more viral load means the virus can more likely be transmitted to someone else; also, it kills the T-cells you have left.

T-CELLS. Both are important. With an AIDS diagnosis, I worry about my T-cells dropping.

VIRAL LOAD. I am concerned about both. You should monitor both to stay virally surpressed (undetectable).

VIRAL LOAD. My T-cells are normal. An increasing viral load would indicate that my HIV is developing resistance to my medication.

VIRAL LOAD. Staying undetectable is very important to me.

THIS ISSUE'S QUESTION

Do you believe you will see an HIV cure in your lifetime?

VOTE AT POSITIVELYAWARE.COM

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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.

POSITIVELY AWARE

PTEMBER+OCTOBER 2015 VOLUME 27 NUMBER 6

VANCOUVER, IN BRITISH COLUMBIA, CANADA, IS A GATEWAY TO THE PACIFIC. THE CITY HOSTED THE CONFERENCE OF THE INTERNATIONAL AIDS SOCIETY. PAGE 36



IN EVERY ISSUE

4 READERS POLL

Are you more concerned about your T-cells or your viral load?

6 THE CONVERSATION

Gilead changes hepatitis C assistance.

7 EDITOR'S NOTE

This is dedicated to the one Bob Munk.

8 BRIEFLY

New hepatitis C drugs. WHO's transgender HIV recommendations. Olysio update. Updated HIV/AIDS strategy.

44 MY KIND OF LIFE

Ready for pickup.

ON THE COVER

WALDIE MURRAY, 27, LEARNED HE WAS HIV-POSITIVE IN JULY 2014. PHOTOGRAPHED BY SCOTT MURRAY.

FEATURES

14

HIV-THE BASICS

Tips for living healthier and better—whether you're newly diagnosed or not.

BY PETER SHALIT, MD

17 SMART MOVES

How to find a support group and other resources to help you plan your next step. BY ENID VÁZQUEZ

18 It's your move

How to find a provider, knowing your rights, and more.
BY ENID VÁZQUEZ

25 ADHERENCE ALL-STARS

Overcoming obstacles to adherence. BY DIANE PETERS

28

MICHAEL JOHNSON, HIV, AND MURDER

Disclosure and discrimination in the law.

BY CATHERINE HANSSENS

30

SHARED EXPERIENCE

Waldie Murray owns his HIV status, but he doesn't let it define him.
BY RICK GUASCO

41

THE RETURN OF ART+ POSITIVE

An HIV specialist with a passion for art rescues work long hidden away.

BY ENID VÁZQUEZ

42

SURVIVAL AIDS

Remembrance and art in the age of AIDS. BY ENID VÁZQUEZ

CONFERENCE UPDATE

36 IAS 2015-VANCOUVER

Cure or remission—what's in a word? Start treatment now. Doravirine in development. Switching to TAF. Young men and PrEP. BY JEFF BERRY AND ENID VÁZQUEZ

LET'S CONNECT All com-

munications (letters, email, online posts, etc.) are treated as letters to the editor unless otherwise instructed. We reserve the right to edit for length, style. or clarity. Let us know if you prefer we not use your name and city.

WRITE TO: POSITIVELY AWARE.

AWARE, 5050 N. Broadway St., Suite 300, Chicago, IL 60640-3016

EMAIL: inbox@ tpan.com

TWEET:





GILEAD CHANGES HEPATITIS C ASSISTANCE

The hepatitis C drug guide (July+August) looks better in person than I could have hoped for! I look forward to mailing them out to folks who call the H4H (Help for Hep) line and make sure they get spread all over.

One thing that has changed since we've gone to print: Gilead announced—very quietly and with no warning—that they are severely restricting access to the patient assistance programs for HCV. In a nutshell, if you have Medicaid or Medicare, you're out of luck. They won't cover you.

Suffice it to say, the advocacy community is not pleased.

-ANDREW REYNOLDS

HEPATITIS C EDUCATION MANAGER, PROJECT INFORM, SAN FRANCISCO AND AUTHOR OF THE THIRD ANNUAL HEPATITIS C DRUG GUIDE

EDITOR'S NOTE: According to a statement from Gilead Sciences, its Support Path Patient Assistance Program (PAP) is designed to help those with HCV in the U.S. who have high co-pays or who lack adequate insurance to access Sovaldi or Harvoni. The program will also no longer cover those who are insured, but who do not meet their payer's

coverage criteria (for example, due to fibrosis score restrictions or preference for a different therapy, such as Viekira Pak).

HEP C PATIENT RESOURCE

Hi, Andrew. I just read through the July+August issue of POSITIVELY AWARE you collaborated on and think it is superb. Congratulations on such a comprehensive and easy-to-follow informational resource for patients.

I am working on a patient app through the HepCure initiative (hepcure.org) with colleagues at Mount Sinai and wondered if you would allow us to incorporate some of the material in this issue of POSITIVELY AWARE into the Patient Resource Section of the app. The app will be free of charge.

—JEFFREY J. WEISS, PHD, MS

ASSOCIATE PROFESSOR,
ICAHN SCHOOL OF MEDICINE,
MOUNT SINAI; NEW YORK, NY

EDITOR'S NOTE: POSITIVELY AWARE and Project Inform are proud to be included in the outstanding hep C work of Jeffrey Weiss and Mount Sinai.

PrEP YES

I am a pharmacist and currently serving on the Kansas City PrEP Task Force. I was thrilled to see that the

latest issue of POSITIVELY AWARE (Summer 2015) was dedicated entirely to PrEP! As a health care professional I thoroughly enjoyed the special issue and see it as a conversational piece that gets the greater community talking about PrEP therapy. As a board member of the PrEP Task Force, I am trying to find effective ways to introduce and integrate PrEP as a health care measure that is acknowledged, accessible, and promoted in the community. The Task Force is focusing its attention on incorporating PrEP into common practice around the greater metropolitan

area of Kansas City and promoting its use and value among individuals in the area.

I would like to see if someone at POSITIVELY AWARE, a community organization in Chicago, David Evans, and/or Jim Pickett could provide recommendations or assistance to those here in Kansas City. As it was mentioned, smaller cities and towns that are less liberal have difficulty realizing PrEP's potential. We hope Kansas City changes its current practice and dialogue.

—ROD BASTANI, PHARMD, KANSAS CITY PREP TASK FORCE, KANSAS CITY, MO

Jeff Berry replies: Thanks so much for your email; I'm glad you liked the issue and found it useful. I would suggest one thing you can do immediately, if you're on Facebook and you're not already a member of the Facebook group PrEP Facts: Rethinking HIV Prevention and Sex, you may want to join. There you'll find over 7,000 researchers, community advocates, and people on PrEP who can answer questions and maybe offer assistance.

We and our clients enjoy your magazine very much. It is insightful and educational, as well as containing interesting articles ("Dr. No," "Not Alone in the Journey," Summer 2015). The more on PrEP, the better. We need to get this message out there and stop the stigma.

—CHRISTIAN S. BATTEY
AIDS PROJECT RHODE ISLAND (APRI)
PROVIDENCE, RI

Our staff and patients have appreciated PA for years. The PrEP issue came out just as we opened our PrEP clinic. Is there a way we can get more issues? Thanks so much for all you do and have done!

—SUE CARTER, MED, LPCC, LSW
RYAN WHITE PROGRAM
UNIVERSITY OF TOLEDO
HEALTH SCIENCE CAMPUS

Jeff Berry replies: Thank you, and yes, more copies of the PrEP issue are available upon request, free of charge. Email distribution@tpan.com.



SEPTEMBER+OCTOBER 2015 POSITIVELY AWARE



THIS IS DEDICATED TO THE ONE BOB MUNK

round 10 years ago when I became Editor of POSITIVELY AWARE magazine, I joined the AIDS Treatment Activists Coalition, and met many of the country's leading HIV/AIDS activists for the very first time. One of those activists was Bob Munk. Bob and I immediately hit it off and took a liking to one another, perhaps because we were similar in disposition, each of us having a dry sense of humor and sardonic wit (although his was much drier and wittier), but for me it was more likely because of that smile, that big grin that just sucked you right in.

I recall being so overwhelmed when I first started my job as editor that I approached him and asked, "How do you do it? How do you stay on top of everything?" He readily admitted it wasn't easy, but that he did a lot of reading and researching to keep up. I admired his honesty and ability to put me right at ease, and for being so gracious with his counsel and advice. We would go on to work together over the years, he as a recurring writer and guest editor for POSITIVELY AWARE, and both of us serving together on various advisory boards and committees.

One of my initial impressions of Bob was, Wow, what a sweet guy! And he really was, he was genuinely a sweet and lovable person with an incredible generosity of spirit. But there was another side to Bob I would see from time to time at meetings with pharmaceutical companies that would leave me in awe. Bob didn't always speak as much as some people did at these meetings, but when he did, he definitely had something to say. He could drive home a point with such deftness, and so swiftly and succinctly, that they wouldn't see it coming and were often left speechless and scrambling for a response. Bob would always fight for the underdog and underrepresented communities and populations, emphasizing that not only should a drug be studied in these groups, but made available to them after approval.

I last saw Bob at the United States Conference on AIDS in San Diego last fall. Bob's health had been in decline in recent years due to a debilitating neurological condition that eventually left him in a wheelchair. He would still make it to meetings and conferences even though he could no longer get around that easily. Bob and his husband, Enoch, have a place in San Diego and they had invited me to visit one afternoon after the conference. Enoch picked us both up at the convention center and we all rode back to their condo, where we shared some laughs and had an

enjoyable conversation over a drink or two. I will always cherish that memory.

This past July, feeling exhausted but exhilarated after a full day of crewing for TPAN's annual Ride for AIDS Chicago, I quickly checked Facebook, only to discover that Bob had just passed away. As I stood in a parking lot with other supporters and crew, cheering on riders as they arrived at camp, I struggled to fight back the tears, realizing I'd never see my friend and mentor again.

This issue of POSITIVELY AWARE on HIV basics is dedicated to the memory of Bob Munk. You see, Bob, probably more than any other person, helped to make HIV/AIDS information accessible and understandable to people in the U.S. and around the world through a website he created called AIDS Info Net. AIDSInfoNet.org continues to provide fact sheets filled with HIV/AIDS treatment information presented in a non-technical format at 8th or 9th grade reading level, and available in various languages. It required a lot of work to keep all of those fact sheets updated but Bob managed to do it, and did it well, until he decided a few years ago to entrust the project to those who he knew could continue the work, which I know he was grateful to be able to do.

I say all of this to remind us that we all have the ability and opportunity to help educate and inform each other by being honest, clear, concise, and most importantly, generous in our gifts to one another. Thank you, Bob Munk, for your gifts, and for leaving the world a little bit better than the way you found it.

Take care of yourself and each other.



Bob would always fight for the underdog and underrepresented communities and populations, emphasizing that not only should a drug be studied in these groups, but made available to them after approval.





NEW HIV TEST

In July, the FDA approved the Bio-Rad BioPlex2200 HIV Ag-Ab test, the first approved by the agency that can differentiate between HIV-1 antibodies, HIV-2 antibodies, and HIV-1 p24 antigen. HIV-2 is more common in resource-poor countries and HIV antigen can detect infection earlier, before HIV antibodies appear.

DAKLINZA AND TECHNIVIE APPROVED FOR HEP C

In July, the FDA approved two new medications for the treatment of hepatitis C virus (HCV).

Daklinza (dak-lin-za, generic name daclatasvir) was approved for use with Sovaldi (sofosbuvir) to treat HCV genotype 3 infections. In studies. the combination showed a cure rate of 98% in people without cirrhosis and 58% in those with cirrhosis. None of these patients had taken HCV treatment before. For those who had, the rates were 92% and 69%, respectively. The most common side effects for the combination were fatigue and headache.

Technivie contains ombitasvir, paritaprevir, and ritonavir and is to be used along with ribavirin for HCV genotype 4 in patients with no cirrhosis. In research, all 91 patients taking Technivie with ribavirin experienced a cure, compared to 91% of the 44 patients not taking ribavirin. The medications in Technivie are also available in Viekira Pak, a hep C therapy that includes a fourth drug, dasabuvir.

For more information, see the third annual Hepatitis C Drug Guide in the July+August issue of POSITIVELY AWARE.

U.S. HIV TREATMENT GUIDELINES UPDATED

Thanks to the results of two studies released at the International AIDS Conference in Vancouver in July (see page XX), U.S. treatment guidelines for HIV have been updated to strengthen the recommendation that everyone living with the virus be on antiviral therapy.

"With the availability of the START and TEMPRANO trial results, the Panel's overall recommendation remains the same: ART is recommended for all HIV-infected patients regardless of pre-treatment CD4 count," the Department of Health and Human Services (DHHS) reported in a press release. What has changed is the strength of the recommendation, upgraded to A1+ (indicating "strong recommendation based on data from randomized controlled trials"). Go to aidsinfo.nih.gov.

U.S. PERINATAL HIV GUIDELINES UPDATED

In August, the Health and Human Services panel on perinatal HIV guidelines made several updates. These included information on women born with HIV; hepatitis C co-infection; the use of HIV treatment and PrEP to prevent transmission in sero-different couples trying to conceive; reaffirmation of data showing no correlation between birth defects and the use of efavirenz (Sustiva, found in Atripla) in the first trimester; and the upgrading of boosted Prezista (darunavir/ritonavir) and also Isentress as preferred treatments for HIV-positive pregnant women taking antiviral therapy for the first time (boosted Reyataz remains a preferred therapy as well). Go to aidsinfo.nih.gov.

TIVICAY AND TRIUMEQ LABEL CHANGE

In August, the FDA added a side effect and drug interactions with carbamazepine (Tegretol) and metformin to the labels of Tivicay (dolutegravir) and Triumeq (dolutegravir/lamivudine/abacavir).

In the Triumeq label, under "Less Common Adverse Reactions Observed in Clinical Trials," was added "Psychiatric: Suicidal ideation, attempt, behavior, or completion. These events were observed primarily in subjects with a pre-existing history of depression or other psychiatric illness." The change was made to match the drug label of Tivicay (which is contained in Triumeq).

When taken with carbamazepine, Tivicay should be taken twice a day instead of once a day in people on HIV therapy for the first time or who have been on HIV therapy before but have not taken medication from the class of drugs to which Tivicay belongs (integrase inhibitors, or INSTIs—the other INSTIs are Vitekta, which is found in Stribild, and Isentress). Those who have previously taken an INSTI and have certain INSTI-associated drug resistance, or suspected resistance, should not use carbamazepine, but use an alternative to this medication instead.

If Triumeq is used with carbamazepine, add a dose of Tivicay 12 hours apart from the Triumeq.

When using either Tivicay or Triumeq with metformin, limit the daily dose of metformin to 1,000 mg a day. When stopping Tivicay or Triumeq, the metformin dose may need to be adjusted. Also, blood glucose should be monitored when someone begins taking the medications together and again if Tivicay or Triumeq is stopped.

GRAZOPREVIR/ELBASVIR FOR HEPATITIS C

In a study published in the Lancet HIV in July, good results were reported for patients co-infected with HIV and HCV with the combination of grazoprevir (MK-5172) and elbasvir (MK-8742). The C-Edge CO-INFECTION study looked at 218 patients with HCV genotypes 1, 4, or 6, with or without cirrhosis, and found a 98% sustained virologic response (SVR) at 12 weeks. Although SVR is normally considered a cure, seven patients (all without cirrhosis) relapsed, with two of them confirmed as having been re-infected with HCV. All 35 patients with cirrhosis achieved an SVR at week 12. The most common adverse events were fatigue, headache, and nausea.

OLYSIO UPDATE

In July, Janssen Therapeutics submitted a supplemental New Drug Application to the FDA to decrease the amount of time that the hep C medication Olysio can be taken. Based on the results of the Phase 3 OPTIMIST-1 and OPTIMIST-2 studies, Olysio (taken with Sovaldi) can be used for 12 weeks in patients on HCV therapy for the first time and for eight weeks in treatment-experienced patients. These patients had genotype 1 and no cirrhosis. Those with cirrhosis can take the treatment for 12 weeks, whether they are already treatment experienced or not.

SEPTEMBER+OCTOBER 2015 POSITIVELY AWARE

In July, the White House issued an updated version of the National HIV/AIDS Strategy (NHAS). According to AVAC, an organization dedicated to HIV prevention, "The updated NHAS has renewed the focus on those most affected by HIV: gay and bisexual men of all races, but especially black men, heterosexual black women and men, young people, people who inject drugs, and transgender women. There will be prioritization on places, like the southern U.S.—where nationally 50 percent of new infections now occur—and key metropolitan areas." The AIDS Institute, which maintains a policy office in D.C., reported that, "The updated Strategy continues a focus on reducing new infections, increasing access to care and treatment, reducing health disparities, and improving federal coordination. It also sets new outcome measures and considers new policy developments including the Affordable Care Act and scientific advancements such as treatment as prevention and pre-exposure [prophylaxis] (PrEP)." Go to aids. gov/federal-resources/national-hiv-aids-strategy/nhas-update.pdf.

WHO'S HIV TRANSGENDER RECOMMENDATIONS

The World Health
Organization in July
issued the policy brief
Transgender People and
HIV, noting available
data and listing recommendations. Go to who.
int/hiv/pub/transgender/
transgender-hiv-policy/
en/.



NATIONAL HIV/AIDS STRATEGY: UPDATED TO 2020

5 MAJOR CHANGES SINCE 2010

Since the first National HIV/AIDS Strategy was released in 2010, major advances have transformed how we respond to HIV, provided new tools to prevent new infections, and improved access to care. With a vision for the next five years, our National HIV/AIDS Strategy has been updated to leverage these achievements and look ahead to 2020.

Our prevention toolkit has expanded.

Pre-Exposure Prophylaxis (PrEP)

A daily pill to prevent HIV.

When taken consistently, can reduce the risk of HIV by up to



The Affordable Care Act has transformed health care access.



Millions more individuals now have affordable, quality health coverage.



Treatment as Prevention

The risk of HIV is reduced by



in those who have achieved viral suppression (they have very low levels of HIV in the body).

There is

There is no denial of coverage for pre-existing conditions, like HIV.

Preventive services are covered without co-pays, including HIV testing.



Protections against sex or disability discrimination in health care.

HIV testing and treatment are recommended.

Federal Guidelines now recommend routine HIV screening for people aged

15^{TO} 65



cDC updated recommendations for HIV testing to help labs detect infections earlier.

Federal HIV
treatment guidelines
now recommend
antiretroviral therapy
for all HIV-infected
individuals.

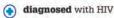
Improving HIV Care Continuum outcomes is a priority.

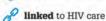
President Obama's

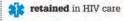
HIV Care Continum

Initiative directed

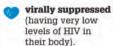
Federal departments to increase the number of individuals who are:

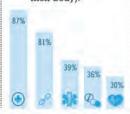












Research is unlocking new knowledge and tools.

- Evidence that starting HIV treatment early lowers the risk of developing AIDS or other serious illnesses
- New HIV testing technologies, including new diagnostic tests
- New HIV medications with fewer side effects, less frequent dosing, and a lower risk of drug resistance
- Continued investigation of long-acting drugs for HIV treatment and prevention, an HIV vaccine, and, ultimately, a cure.



LEARN MORE ABOUT THE NATIONAL HIV/AIDS STRATEGY: UPDATED TO 2020 AT AIDS.GOV/2020 #HIV2020



COMPLERA does not cure HIV-1 infection or AIDS.

To control HIV-1 infection and decrease HIV-related illnesses you must keep taking COMPLERA. Ask your healthcare provider if you have questions about how to reduce the risk of passing HIV-1 to others. Always practice safer sex and use condoms to lower the chance of sexual contact with body fluids. Never reuse or share needles or other items that have body fluids on them.

It is not known if COMPLERA is safe and effective in children under 18 years old.

IMPORTANT SAFETY INFORMATION

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

COMPLERA can cause serious side effects:

- Build-up of an acid in your blood (lactic acidosis), which is a serious medical emergency. Symptoms of lactic acidosis include feeling very weak or tired, unusual (not normal) muscle pain, trouble breathing, stomach pain with nausea or vomiting, feeling cold especially in your arms and legs, feeling dizzy or lightheaded, and/or a fast or irregular heartbeat.
- Serious liver problems. The liver may become large (hepatomegaly) and fatty (steatosis). Symptoms of liver problems include 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, and/or stomach pain.
- You may be more likely to get lactic acidosis or serious liver problems if you are female, very overweight (obese), or have been taking COMPLERA for a long time. In some cases, these serious conditions have led to death. Call your healthcare provider right away if you have any symptoms of these conditions.
- Worsening of hepatitis B (HBV) infection. If you also have HBV and stop taking COMPLERA, your hepatitis may suddenly get worse. Do not stop taking COMPLERA without first talking to your healthcare provider, as they will need to monitor your health. COMPLERA is not approved for the treatment of HBV.

Who should not take COMPLERA?

Do not take COMPLERA if you:

- Take a medicine that contains: adefovir (Hepsera), lamivudine (Epivir-HBV), carbamazepine (Carbatrol, Equetro, Tegretol, Tegretol-XR, Teril, Epitol), oxcarbazepine (Trileptal), phenobarbital (Luminal), phenytoin (Dilantin, Dilantin-125, Phenytek), rifampin (Rifater, Rifamate, Rimactane, Rifadin), rifapentine (Priftin), dexlansoprazole (Dexilant), esomeprazole (Nexium, Vimovo), lansoprazole (Prevacid), omeprazole (Prilosec, Zegerid), pantoprazole sodium (Protonix), rabeprazole (Aciphex), more than 1 dose of the steroid medicine dexamethasone or dexamethasone sodium phosphate, or the herbal supplement St. John's wort.
- Take any other medicines to treat HIV-1 infection, unless recommended by your healthcare provider.

What are the other possible side effects of COMPLERA?

Serious side effects of COMPLERA may also include:

- Severe skin rash and allergic reactions. Call your doctor right away if you get a rash. Some rashes and allergic reactions may need to be treated in a hospital. Stop taking COMPLERA and get medical help right away if you get a rash with any of the following symptoms: severe allergic reactions causing a swollen face, lips, mouth, tongue or throat which may lead to difficulty swallowing or breathing; mouth sores or blisters on your body; inflamed eye (conjunctivitis); fever, dark urine or pain on the right side of the stomach-area (abdominal pain).
- New or worse kidney problems, including kidney failure. Your healthcare provider should do blood tests to check your kidneys before starting treatment with COMPLERA. If you have had kidney problems, or take other medicines that may cause kidney problems, your healthcare provider may also check your kidneys during 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.
- Changes in liver enzymes: People who have had hepatitis B or C, or who have had changes in their liver function tests in the past may have an increased risk for liver problems while taking COMPLERA. Some people without prior liver disease may also be at risk. Your healthcare provider may do tests to check your liver enzymes before and during treatment with COMPLERA.
- Bone problems, including bone pain or bones getting soft or thin, which may lead to fractures. Your healthcare provider may do tests to check your bones.
- Changes in body fat can happen in people taking HIV-1 medicines.
- Changes in your immune system. Your immune system may get stronger and begin to fight infections. Tell your healthcare provider if you have any new symptoms after you start taking COMPLERA.

The most common side effects of COMPLERA include trouble sleeping (insomnia), abnormal dreams, headache, dizziness, diarrhea, nausea, rash, tiredness, and depression. Other common side effects include vomiting, stomach pain or discomfort, skin discoloration (small spots or freckles), and pain. Tell your healthcare provider if you have any side effects that bother you or do not go away.

What should I tell my healthcare provider before taking COMPLERA?

- All your health problems. Be sure to tell your healthcare provider if you have or had any kidney, mental health, bone, or liver problems, including hepatitis virus infection.
- 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. Keep a list of all your medicines and show it to your healthcare provider and pharmacist. Do not start any new medicines while taking COMPLERA without first talking with your healthcare provider.
- If you take rifabutin (Mycobutin). Talk to your healthcare provider about the right amount of rilpivirine (Edurant) you should take.
- If you take antacids. Take antacids at least 2 hours before or at least 4 hours after you take COMPLERA.
- If you take stomach acid blockers. Take acid blockers at least 12 hours before or at least 4 hours after you take COMPLERA. Ask your healthcare provider if your acid blocker is okay to take, as some acid blockers should never be taken with COMPLERA.
- If you are pregnant or plan to become pregnant. It is not known if COMPLERA can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking COMPLERA.
- If you are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed. HIV-1 can be passed to the baby in breast milk. Also, some medicines in COMPLERA can pass into breast milk, and it is not known if this can harm the baby.

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 Brief Summary of full Prescribing Information with **important warnings** on the following pages.





Brief Summary of full Prescribing Information COMPLERA® (kom-PLEH-rah)

(emtricitabine 200 mg, rilpivirine 25 mg, tenofovir disoproxil fumarate 300 mg) tablets

Brief summary of full Prescribing Information. For more information, please see the full Prescribing Information, including Patient Information.

What is COMPLERA?

- COMPLERA is a prescription medicine used as a complete HIV-1 treatment in one pill a day. COMPLERA is for adults who have never taken HIV-1 medicines before and who have no more than 100,000 copies/mL of virus in their blood (this is called 'viral load'). Complera can also replace current HIV-1 medicines for some adults who have an undetectable viral load (less than 50 copies/mL) and whose healthcare provider determines that they meet certain other requirements.
- COMPLERA is a complete HIV-1 medicine and should not be used with any other HIV-1 medicines.
- COMPLERA should always be taken with food. A protein drink does not replace food.
- COMPLERA does not cure HIV-1 or AIDS. You must stay on continuous HIV-1 therapy to control HIV-1 infection and decrease HIV-related illnesses.
- Ask your healthcare provider about how to prevent passing HIV-1
 to others. Do not share or reuse needles, injection equipment, or
 personal items that can have blood or body fluids on them. Do not have
 sex without protection. Always practice safer sex by using a latex or
 polyurethane condom to lower the chance of sexual contact with semen,
 vaginal secretions, or blood.

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

COMPLERA can cause serious side effects, including:

- 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:
 - feel very weak or tired
 - have unusual (not normal) muscle pain
 - have trouble breathing
 - having stomach pain with nausea or vomiting
 - feel cold, especially in your arms and legs
- feel dizzy or lightheaded
- have a fast or irregular heartbeat
- Severe liver problems. Severe liver problems can happen in people
 who take COMPLERA. 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). Call your healthcare provider right away if
 you get 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 for a long time.

- Worsening of Hepatitis B infection. If you have hepatitis B virus (HBV)
 infection and take COMPLERA, your HBV may get worse (flare-up) if you stop
 taking COMPLERA. 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 with your healthcare provider.
 - Do not run out of COMPLERA. 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 blood tests regularly to check your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking COMPLERA.

Who should not take COMPLERA?

Do not take COMPLERA if you also take any of the following medicines:

- Medicines used for seizures: carbamazepine (Carbatrol, Equetro, Tegretol, Tegretol-XR, Teril, Epitol); oxcarbazepine (Trileptal); phenobarbital (Luminal); phenytoin (Dilantin, Dilantin-125, Phenytek)
- Medicines used for tuberculosis: rifampin (Rifater, Rifamate, Rimactane, Rifadin); rifapentine (Priftin)
- Certain medicines used to block stomach acid called proton pump inhibitors (PPIs): dexlansoprazole (Dexilant); esomeprazole (Nexium, Vimovo); lansoprazole (Prevacid); omeprazole (Prilosec, Zegerid); pantoprazole sodium (Protonix); rabeprazole (Aciphex)
- Certain steroid medicines: More than 1 dose of dexamethasone or dexamethasone sodium phosphate
- Certain herbal supplements: St. John's wort
- Certain hepatitis medicines: adefovir (Hepsera), lamivudine (Epivir-HBV)

 Do not take COMPLERA if you also take any other HIV-1 medicines, including:
- Other medicines that contain emtricitabine or tenofovir (ATRIPLA, EMTRIVA, STRIBILD, TRUVADA, VIREAD)
- Other medicines that contain lamivudine (Combivir, Epivir, Epzicom, Triumeq, Trizivir)
- rilpivirine (Edurant), unless you are also taking rifabutin (Mycobutin) COMPLERA is not for use in people who are less than 18 years old.

What are the possible side effects of COMPLERA?

COMPLERA may cause the following serious side effects:

- See "What is the most important information I should know about COMPLERA?"
- Severe skin rash and allergic reactions. Skin rash is a common side effect
 of COMPLERA but it can also be serious. Call your doctor right away if you
 get a rash. In some cases, rash and allergic reaction may need to be
 treated in a hospital. Stop taking COMPLERA and call your doctor or get
 medical help right away if you get a rash with any of the following symptoms:
 - severe allergic reactions causing a swollen face, lips, mouth, tongue or throat, which may cause difficulty swallowing or breathing
 - mouth sores or blisters on your body
 - inflamed eye (conjunctivitis)
 - fever, dark urine or pain on the right side of the stomach-area (abdominal pain)
- New or worse kidney problems, including kidney failure. Your healthcare
 provider should do blood and urine tests to check your kidneys before
 you start and while you are taking COMPLERA. If you have had kidney
 problems in the past or need to take another medicine 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
- Change in liver enzymes. People with a history of hepatitis B or C
 virus infection or who have certain liver enzyme changes may have an
 increased risk of developing new or worsening liver problems during
 treatment with COMPLERA. Liver problems can also happen during
 treatment with COMPLERA in people without a history of liver disease.
 Your healthcare provider may need to do tests to check your liver
 enzymes before and during treatment with COMPLERA.
- 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 tests to check your bones.
- Changes in body fat can happen in people taking HIV-1 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-1 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 any new symptoms after starting your HIV-1 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.
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I tell my healthcare provider before taking COMPLERA?

Tell your healthcare provider about all your medical conditions, including:

- If you have or had any kidney, mental health, bone, or liver problems, including hepatitis B or C infection.
- If you are pregnant or plan to become pregnant. It is not known if COMPLERA can harm your unborn child.
 - There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of this registry 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.
- If you are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed if you take COMPLERA.
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - Two of the medicines in COMPLERA can pass to your baby in your breast milk. It is not known if this could 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 over-the-counter medicines, vitamins, and herbal supplements:

- COMPLERA may affect the way other medicines work, and other medicines may affect how COMPLERA works.
- 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-1 infection. The HIV-1 virus in your body may become resistant to COMPLERA or other HIV-1 medicines that are like it.
- Be sure to tell your healthcare provider if you take any of the following medicines:
 - Rifabutin (Mycobutin), a medicine to treat some bacterial infections.
 Talk to your healthcare provider about the right amount of rilpivirine (Edurant) you should take.
- Antacid medicines that contain aluminum, magnesium hydroxide, or calcium carbonate. Take antacids at least 2 hours before or at least 4 hours after you take COMPLERA.
- Certain medicines to block the acid in your stomach, including cimetidine (Tagamet), famotidine (Pepcid), nizatidine (Axid), or ranitidine hydrochloride (Zantac). Take the acid blocker at least 12 hours before or at least 4 hours after you take COMPLERA. Some acid blocking medicines should never be taken with COMPLERA (see "Who should not take COMPLERA?" for a list of these medicines).
- Medicines that can affect how your kidneys work, including acyclovir (Zovirax), cidofovir (Vistide), ganciclovir (Cytovene IV, Vitrasert), valacyclovir (Valtrex), and valganciclovir (Valcyte).
- clarithromycin (Biaxin)
- erythromycin (E-Mycin, Eryc, Ery-Tab, PCE, Pediazole, Ilosone)
- fluconazole (Diflucan)
- itraconazole (Sporanox)
- ketoconazole (Nizoral)
- methadone (Dolophine)
- posaconazole (Noxafil)telithromycin (Ketek)
- voriconazole (Vfend)

Know the medicines you take. Keep a list of all your medicines and show it to your healthcare provider and pharmacist when you get a new medicine. Do not start any new medicines while you are taking COMPLERA without first talking with your healthcare provider.

Keep COMPLERA and all medicines out of reach of children.

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

Revised: May 2015



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HIV: THE BASICS

TIPS FOR LIVING HEALTHIER AND SMARTER —WHETHER NEWLY DIAGNOSED OR NOT

BY PETER SHALIT, MD, PHD

et's say you just tested positive for HIV now what? We know that folks are healthier if their virus is treated and suppressed with medication, but not everyone is able to start treatment right away. Here are some questions you might consider before making the commitment to treatment.

QUESTION: What's in it for me? Why should I take medication for HIV?

comment: Studies are showing that people with HIV who take antivirals, regardless of their CD4 count or viral load, have fewer medical complications than those who leave their HIV untreated. In addition, successful treatment, with good suppression of the virus, makes it much less likely that a person will transmit their HIV infection to a

sexual partner or to their unborn child before or during childbirth.

Do I have a health care provider who is knowledgeable about HIV? And am I comfortable working with this person on my health?

When you first test positive, you may not already have a primary health care provider, or you may have one that is not an HIV expert. It's important to see an HIV expert for your care. In most

U.S. cities there are a number of physicians, nurse practitioners, and physician assistants who do high-quality HIV treatment, so you will probably have a choice. In rural areas it may be harder to find a suitable provider, so you may have fewer choices, and unfortunately you may have to travel some distance for health care.

Do I have health insurance that will pay the cost of medication and monitoring?

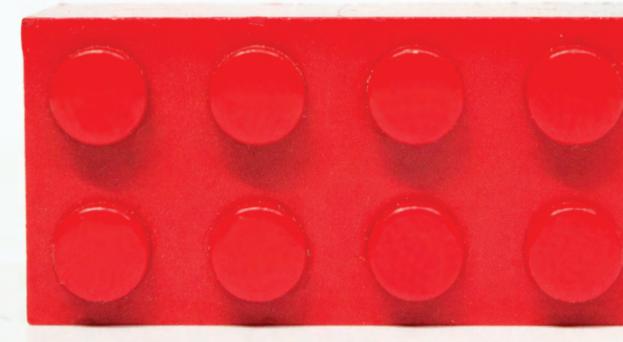
HIV treatment is expensive. It's important to have insurance that will cover the treatment. Your costs may still be high, but there are many programs that can help cover some of the costs. Since HIV treatment is a long-term commitment, it's important

that treatment not be interrupted by lack of insurance or inability to pay.

Is my life situation stable—are there issues in my life that would get in the way of taking medications every day?

Life complications such as an unstable living situation, difficult work situation, out-of-control substance use, or depression all can make it harder for a person to take medication every day.

If your ship of life is sailing through rough seas, you may want to find some calmer waters before starting on HIV treatment.



14 SEPTEMBER+OCTOBER 2015 POSITIVELY AWARE

I've heard there are so many drugs for HIV now, how do I decide what's the right treatment for me?

You can research different treatments yourself, but it's easy to get overwhelmed. That's why it's good to have a health care provider who you trust to sort through all the choices and recommend a treatment, or a few treatment choices, that may be best for you.

GENERAL HEALTH FOR FOLKS LIVING WITH HIV

Being healthy and HIV-positive is not only about having an undetectable viral load. All the standard advice about healthy living applies to people with HIV, but having the virus means there are a few extra considerations.

DIET: Whole books have been written about healthy diets. There's no special diet recommendation for people with HIV. There are a lot of fads out there, and even the research-based recommendations change from year to year. In general, though, unprocessed/fresh/raw foods tend to be healthier than heavily processed foods. Also, we're learning that excess carbohydrates (sugars, starches, and alcohol)

> contribute to weight

> > gain,

it's a good idea to avoid carbohydrate binges. There is no one study that definitively shows that multivitamin supplements have any particular health benefit for people with or without HIV; they are probably a waste of money. (Editor's note: Many advocates would argue otherwise.) The one supplement that may be beneficial is vitamin D, which is important for strong bones. Many Americans are low in vitamin D, and bone strength can be an issue for people with HIV, so a vitamin D supplement is not a bad idea (at least 2,000 IU per day).

EXERCISE: Some physical activity every day is important. There is no one right way to add exercise to your daily routine—there are many ways. Some people devote a special time each day for pure exercise, such as lifting weights at the gym, swimming at the Y. or taking a 2-mile run before breakfast. But you don't have to be one of those people to still include exercise as part of your life. You can build it into your day by walking or bicycling instead of driving or to the store; using

As the saying goes, "The best exercise is the one you do."

VACCINES: Folks with HIV should have all the same vaccines as everyone else, with some extra stipulations. In particular, everyone with HIV should be immunized for hepatitis A and B. There are now vaccines for HPV (the virus that causes warts and some cancers) but these are only approved for adolescents and people into their mid- to late 20s. Pneumonia vaccines are recommended for everyone with HIV. Your health provider can and should make sure you are up to date with your immunizations.

MENTAL HEALTH: Modern life is stressful. HIV can add additional stress. Especially the first weeks or months after getting an HIV diagnosis, you may need some help dealing with stress. There are many ways to do this. Exercise (see above) is a great way to burn off stress. It helps to have a confidant or advocate—a friend you can talk to about what you are experiencing, maybe accompany you to visits with your provider, and provide a hug when requested. Talking with a counselor or therapist can be helpful for some folks. Some cities have peer support groups for people with HIV. Spiritual practice is another way to reduce stress. If you find yourself struggling with stress and anxiety and you don't know where to turn, ask your health care provider.

RECREATIONAL DRUGS: Some mind-altering substances are okay in moderation. These include alcohol as well as cannabis (marijuana), which is now legal in some states. The key is moderation. Other drugs are too dangerous to ever be okay. These include tobacco as well as "street drugs" such as meth, cocaine, and heroin. The negative effects of these drugs outweigh any short-term pleasure they may provide. Two that can be

or taking the bus to work the stairs instead of the elevator; walking the dog; and so on. PHOTO: ISTOCKPHOTO particularly harmful for people SEPTEMBER+OCTOBER 2015 15 POSITIVELY AWARE

POSITIVELY AWARE



TESTING POSITIVE FOR HIV AND BEING AWARE OF YOUR STATUS ARE THE FIRST STEPS IN TAKING CHARGE OF YOUR HEALTH, AND PROTECTING YOUR PARTNER.

with HIV are tobacco and crystal meth. Tobacco is a major factor in many cancers (for example lung, throat, cervical, anal, and bladder) as well as heart and blood vessel disease, and people with HIV seem to be more susceptible to its effects. Tobacco is extremely addictive but there are ways to quit, and it's worth it. If you can't quit altogether, reducing the number of cigarettes you smoke each day is better than nothing. Crystal meth ruins lives, rots teeth, and damages brains, yet it can be very hard to stop once you get started. Better not to start in the first place, but if you have started and aren't yet ready to quit, there are places that can still help (such as a needle exchange or harm reduction program).

SEXUALITY: Often there is a lot of discomfort discussing sexuality, but it's an important part of being human. HIV can impact a person's sexuality in many ways. It can make dating complicated ("When do I tell the other person I'm positive? Will they reject me?"), and there are concerns about transmitting the virus during sex. We are learning that people whose HIV is well suppressed are very unlikely to transmit their virus. This is reassuring, but many people are not aware of this information, and so there is still much fear and potential rejection around serodiscordant matchups.

HIV can also impact hormone levels. Men with HIV sometimes develop testosterone deficiency. Lack of testosterone in a man can cause low energy, lack of interest in sex, and depression; it can also speed up the loss of calcium from the bones. It is common for men with low

testosterone to take testosterone replacement, given by shots or a daily application of testosterone-laced gel. This should be considered carefully because there are clues that testosterone replacement may increase a man's risk of a heart attack, and if a man develops prostate cancer while taking testosterone, the cancer may progress faster.

Erectile dysfunction is another common problem for men, and has many causes. Smoking is probably the single biggest factor against erections in men middle-aged or older, followed by diabetes. Interestingly, testosterone is not required for erections: many men with low testosterone have normal erections, while many men with erection problems have normal testosterone. Erectile dysfunction may be a barrier to safer sex, because condoms interfere with erectile function in some men. Medicines such as Viagra or Cialis can be very helpful in improving the quality and duration of a man's erection, and for some men it's the only way they can use a condom and still keep an erection.

Folks who are sexually active outside of a mutually monogamous relationship run the risk of sexually transmitted infections (STIs) such as syphilis, hepatitis C, gonorrhea, and chlamydia, so it's important to be screened regularly. In some cases (syphilis, hepatitis C) the infection can be worse if someone is HIV-positive. STI screening is an area where good communication with your health care provider is essential. It's also important to have a provider who is knowledgeable and nonjudgmental about the diagnosis and treatment of these conditions.

Reproductive health is a particular concern for many HIV-positive women and men. both straight and gay. It is now possible, and reasonable, for HIV-positive people to reproduce and have uninfected babies, but this must be done with the guidance of a knowledgeable health care provider. It is helpful if the pregnancy is planned, so that the viral load of the parent(s) is undetectable from the start, and so that if one parent is negative, the act of conception does not put them at risk of getting HIV. The chance of the baby turning out to be HIV-positive is extremely low if the mom's virus is well suppressed during the pregnancy.

OTHER MEDICAL CONDITIONS:

Folks with HIV are still susceptible to all the common conditions adults may get, such as high blood pressure, diabetes, heart disease, and cancer. The risk of some of these conditions is higher in people with HIV, so it is important to have regular monitoring, as well as preventive advice, by a primary care provider who is savvy about the health concerns of people with HIV. Two areas in particular are worth mentioning.

Cardiovascular disease is more common, and sometimes occurs earlier, in people with HIV. Heart attacks and strokes

can be prevented, or at least delayed, by working on lifestyle factors: exercise, careful diet, and not smoking. There are medicines that may be helpful for prevention as well.

Some cancers also occur earlier, or more commonly, in people with HIV. For women, breast cancer screening is the same whether the person has HIV or not, but cervical cancer screening recommendations are stricter for HIV-positive women, because the cancer can progress more rapidly. Screening for colon cancer starting at age 50 has been shown to benefit everyone. For other cancers, screening is not as well proven and is more controversial. This includes cancers of the lung, prostate, and anus. It's best to talk to your provider for advice on cancer screening and prevention, but remember that the single most important thing a person can do to prevent cancer is to not smoke.

CONCLUSION

Testing positive for HIV and being aware of your status is the first step in taking charge of your health, and protecting your partner. Knowing the right questions to ask, and exploring areas where there may be room for improvement, can give you the tools you need to live longer and stronger with HIV.



PETER SHALIT, MD, PHD, AAHIVS, FACP, attended college at Cornell University in Ithaca, New York, then moved to Seattle where he obtained his PhD in Genetics from the University of Washington in 1981. He graduated from the University of Washington Medical School in 1985, but his involvement in HIV care started in the early 1980s while still in medical school. He is Clinical Professor of

Medicine at the University of Washington School of Medicine and is involved in the training of health professionals and students in HIV care and the health care of sexual and gender minorities. He lives on Capitol Hill with his husband, Bob Clark.

16 SEPTEMBER+OCTOBER 2015

TAKE CARE **OF YOURSELF**

HIV is not just a chronic medical condition, like diabetes, but one that comes with a lot of social stigma. As such, it's even more imperative to take care of your emotional and mental well-being in addition to accessing medical care.

FIND A SUPPORT GROUP! It

helps to talk with someone who knows first-hand what you're going through. See resources on this page.

IF YOU SMOKE, STOP.

YOGA, MEDITATION, acupuncture, massage, and deep breathing techniques can help alleviate stress. (Just taking a couple of deep breaths can instantly calm you.) Alternative and complementary therapies have helped many people living with HIV.

SAY NO TO SHAME and guilt. Talk with someone you trust: find a therapist you like; write in a journal.

FIND A CREATIVE ACTIVITY that engages you, even if it's just a crossword puzzle.

'Oh, my God, your T-cells went up really high," nurse Keren Hahn told PA previously, "and they'll say, 'Oh, I got a new dog!'" Cats are good too. Having someone else to take care of can make you feel better.

You knew this was coming: use EXERCISE AND GOOD **NUTRITION.** Find something you like! Start with baby steps if you need to. When AIDS devastated his body decades ago, HIV-positive exercise and supplement guru Nelson Vergel started working out with cans of food, and look at him now;



THESE RESOURCES WILL HELP YOU PLAN YOUR NEXT STFP BY ENID VÁZQUEZ

ANNUAL PA HIV DRUG GUIDE

Includes a pull-out drug chart and a separate page for each drug with opinions from a doctor and an activist, including medications not yet on the market but expected to be approved within a year. Includes other charts and articles, such as co-pay assistance programs and the latest on treatment goals and news. Go to positivelyaware.com.

ASK THE EXPERT

Send your questions to TheBody.com, a website full of news, blogs, and experts to answer your concerns. HIV specialist Joel Gallant, MD, MPH, also answers questions at hivforum.tumblr.com.

BASICS

How does HIV affect your body? This manual may seem a little outdated and a little bit long, but will take you stepby-step-in short bites using simple and brief language and graphics—through pretty much everything you may want to know. Because only the British are cool like that. i-base.info/ english-treatment-trainingmanual.

FACTSHEETS

You can find easy to read yet

comprehensive factsheets at aidsinfonet.org. Factsheets are updated frequently to reflect advances in HIV treatment.

GOVERNMENT INFO

Snazzy and full of color, readable and easy to use, and so easy to remember: AIDS.gov. But there's much more from U.S. government agencies.

Like AIDS.gov, the CDC (Centers for Disease Control and Prevention) has an HIV Basics webpage in addition to a wealth of other HIV/AIDS information. Go to cdc.gov/hiv/basics.

From HIV symptoms and getting into care to living well and finding a social service provider, the CDC's Act Against AIDS campaign aims to inspire and assist people living with HIV to live healthy lives. Go to cdc.gov/ actagainstaids/campaigns/ hivtreatmentworks/index. html, or call 800-AID-AIDS (800-243-2437).

U.S. HIV treatment guidelines are regularly updated and produced by a panel of experts through the Department of Health and Human Services (DHHS). Pediatric, perinatal, and opportunistic infection

guidelines also provided. Go to aidsinfo.nih.gov.

The National Institutes of Health provides information in English and Spanish. Toll-free hotline: 800-HIV-0440 (800-448-0440). E-mail your questions to ContactUs@aidsinfo. nih.gov, or write to AIDSinfo, P.O. Box 4780, Rockville, Maryland 20849-6303.

SUPPORT GROUPS AND ASSISTANCE

Find a support group and learn of other resources near you. Go to aids.org/topics/ aids-factsheets/aids-hotlines for a list of hotline numbers for each state. Most hotlines operate 24/7. Also go to the CDC National Prevention Information Network's site npin.cdc.gov/ search/organization/testing for a list of organizations across the country that provide HIV services.

HIV HEALTH INFOLINE

A community-based information and support hotline from San Francisco's Project Inform. Operates Monday-Friday, 1 p.m.-7 p.m. (Eastern Time). Call 800-822-7422. Also operates the HELP-4-HEP (hepatitis C) hotline, 877-HELP-4-HEP (877-435-7443).

IT'S YOUR MOVE

HOW TO FIND A PROVIDER, KNOWING YOUR RIGHTS, AND MORE

BY ENID VÁZQUEZ

HIV PREVENTION

There are now more ways to prevent passing HIV on besides condoms and abstinence. Nothing is 100% guaranteed, however.

- You can reduce the risk of transmitting HIV to a sex partner by nearly 100% by being on antiviral therapy with an undetectable HIV viral load (called "treatment as prevention," or TasP).
- Choosing to have sex only with other people who have the same HIV status as you is a prevention strategy called serosorting.
- If you are HIV-positive, having HIV-negative sex partners who are on PrEP (pre-exposure prophylaxis) can greatly reduce the risk of transmission (with or without TasP).
- If there is sexual exposure to the virus, and the HIV-negative partner is not on PrEP, they can take a 28-day course of pills to prevent infection, called PEP (post-exposure prophylaxis).

5: INSURANCE

Just because you have health insurance doesn't mean that treatment is free. There are co-pays and other costs for medical care. (See the co-pay assistance chart in the PA Annual HIV Drug Guide at positivelyaware.com.) For those without insurance, go to healthcare.gov, or call (800) 318-2596.

2: FIND AN HIV SPECIALIST

HIV is a relatively new, and complicated, medical condition. Look for an HIV specialist. The American Academy of HIV Medicine and the HIV Medicine Association have a provider finder. Go to hivma.org and aahivm.org. Your local AIDS service organization knows the HIV specialists in your area, and can help point you in the right direction.

1: HIV TREATMENT

It's official: It's recommended that everyone with HIV be on antiviral therapy. It's been estimated that on treatment, people living with HIV will have a normal lifespan. Treatment also slows the progression from HIV infection to AIDS.

6: HIV AND THE ADA

How are people with HIV protected by the nation's disability law? Read the section on HIV from the Americans with Disabilities Act at ada.gov/archive/hivqanda.txt.

7: HIV ANTI-DISCRIMINATION LAW

The national Center for HIV Law and Policy protects human rights and covers several areas of concern (such as employment, housing, and immigration). Its website includes a link to organizations, by state, that can provide legal information to people living with HIV. Write the center at 65 Broadway, Suite 832, New York, NY 10006. Call (212) 430-6733. Go to hivlawandpolicy.org.

4: BASELINE

At diagnosis or soon thereafter, your clinic should check you for

- Other STIs
- HIV drug resistance
- Hepatitis B and C



3: MEDICAL CARE

Ideally, people with HIV should have a CD4+ T-cell count and HIV viral load measured every three to four months following suppression of HIV viral load with the use of therapy, although every six months and possibly yearly is generally accepted.

- The T-cell count is a measure of immune function.
- The viral load is a measure of viral function.
- Generally, the viral load is given greater weight.

ON SEPTEMBER 22ND, TAKE YOUR BEST SHOT AGAINST HIV!



A DAY WITH HIV is 9/22/2015. On that day, use your smartphone or digital camera to capture a moment of your day and share it with the world:

EMAIL IT to photo@adaywithhiv.com. **UPLOAD IT** at adaywithhiv.com. **POST IT** on social media with the hashtag #adaywithhiv.

Photo submissions will be featured in our online gallery. High-res images will be selected for publication in the November+December issue of POSITIVELY AWARE—and four will be chosen for four different covers of the magazine. Make sure to include the time and location of your picture, and the story behind your photo.

#adaywithhiv









ADHERENCE ALL-STARS

DESPITE 'CHAOTIC' LIVES, PEOPLE LIVING WITH HIV CAN OVERCOME OBSTACLES TO ADHERENCE

BY DIANE PETERS

y doctor says I'm her star patient,"
Dwight Barker brags. He's got a
right to: He takes his HIV meds like
clockwork and his viral load has
been undetectable for almost three
years. "No matter what, I take my
pills every day. It helps that as soon as I open my eyes I
can see the pill bottles on my night table and I take them
before I get out of bed."

Reaching star status has not been easy for Barker, who's 46. He was diagnosed with HIV in 2010, but suspects he contracted the virus the previous

summer when he was living in Vancouver [Canada] and injecting drugs.

Barker eventually moved to the Edmonton area to get

away from the Vancouver drug scene but he started using again. During a five-month relapse, he was unable to take his HIV meds for 12 days straight because someone stole his pills and he couldn't get to a doctor for a new prescription. But he was lucky: His high CD4 count and low viral load remained unchanged.

Before starting on HIV meds Barker's health was in decline, so he knows how bad things could get without them. He's seen friends get sick quickly after tossing their medications aside. And he's extra-motivated when he's dating someone—he does not want to pass the virus on to a sex partner and knows that when his viral load is low, his HIV transmission risk stays low, too.

Drug-free since 2014, Barker now has a part-time job and does peer support for HIV Edmonton. He still has his struggles with anxiety and with fractured relationships in his family, but his ability to stick to his meds through chaotic times is helping experts understand how people can stay adherent even when the odds are stacked against them.

WHAT'S YOUR SECRET?

University of Alberta School of Public Health instructor Megan Lefebvre conducted a unique study with the Northern Alberta HIV Program (NAHIV) to find out just why Barker and 12 others with self-described "chaotic lives" adhere so well to their meds.

The participants have indeed struggled with obstacles: homelessness, drug addictions, mental health issues, abuse, jail and co-infections. But NAHIV clinic staff had noticed that these clients were superstars when it came to adherence. Lefebvre decided to find out more. "The research always asks, what are the barriers?" she says. "We wanted to ask them: What's vour secret to success? How can you do this? We wanted to learn from them."

Lefebvre's community-based, participatory research project involved in-depth discussions with the 13 members of this group, who, along with clinic staff, helped develop the interview questions.

Working around the central question, "What is your secret for taking your HIV medication all the time?" Lefebvre learned about people's motivations and strategies for staying adherent. Common explanations included not wanting to die from HIV, family ties, wanting to protect others from the virus and having something to look forward to in the future. "I don't want to hurt the people that love me," confided one participant, while another stated simply, "I'm moving into a new apartment next month." Through these

interviews, Lefebvre discovered that what's considered a chore for many people with HIV is actually an opportunity for success and celebration for others.

It all boils down to a sense of control, according to Lefebvre. "These people felt they had little or no control over their daily lives. But by taking their HIV meds regularly, they could have control over something." Experiencing that sense of being in charge, in turn helped them make other positive life choices, such as renewing relationships with estranged family members or volunteering.

As a result of Lefebvre's research, clinical practices at NAHIV have changed. Lefebvre recounts how one of the clinic's nurses had remarked. "I didn't know about my client's families. I didn't ask about that. I believed I didn't have time." But, once staff understood the importance of family in motivating patients to stay adherent, they began to ask regularly about people's partners, kids, parents and siblings. If patients didn't have families, the clinic staff tried to act more like "family" to them, learning about patients' lives and goals, and keeping this conversation active from one visit to another. As a result, many in this group of adherence VIPs felt closely connected to their healthcare team and relished the support they got for their great adherence record. "Society often tells them negative things about themselves," Lefebvre says "but this is something they can do, and get recognized for."

SIMPLER HIV DRUG **REGIMENS**

Treatment for HIV gets better all the time. Today's medications are easier to take, cause fewer side effects and many

formulations require just one dose a day. But there's still a big catch: Adherence has to be high or the virus can start reproducing, leading to drug resistance, fewer treatment options and, eventually, illness. Studies from the past decade or so have indicated that an adherence rate of about 95 percent is ideal for achieving the best health outcomes. "That means if you take 30 pills a month, you can only miss two, not even," says Linda Robinson, an HIV clinical pharmacist in Windsor, Ontario.

Some of today's meds are longer acting, so if you miss a dose, there may still be enough drug in the body to keep the virus under control. "But it's a fine line," Robinson says-and experts don't know the precise point at which the drugs will stop working for an individual. People with existing drug resistance, co-infections or other underlying health conditions not related to HIV likely need to be more careful.

The bottom line is that getting into the routine of taking pills every single day exactly as prescribed and directed is still key and missing pills here and there can lead to drug resistance, health problems and the risk of HIV transmission.

BARRIERS TO ADHERENCE

Taking a pill once or twice a day may sound simple, but over a lifetime of pill-taking, it is a challenge, especially for those who face additional obstacles.

Research in the past decade has established that certain factors impact adherence rates. Between 2007 and 2010, British Columbia's LISA (Longitudinal Investigation into Supportive and Ancillary Health Services) cohort enrolled 566 participants with HIV who were taking

ADHERENCE TIPS

TAKE YOUR MEDICATION AT THE SAME TIME(S) EACH DAY.

USE THE ALARM ON YOUR CELL PHONE, A PAGER OR OTHER REMINDER DEVICE.

USE A PILL BOX TO TAKE EXTRA DOSES OF MEDICA-TIONS WITH YOU WHEN YOU ARE OUT.

GET YOUR PHARMACY TO PUT YOUR MEDICATIONS IN A WEEKLY DOSETTE OR BLIS-TER PACK.

KEEP BACKUP SUPPLIES OF YOUR MEDS AT PLACES WHERE YOU REGULARLY STAY (LIKE YOUR WORK-PLACE OR PARTNER'S HOME).

PLAN AHEAD FOR WEEK-ENDS, HOLIDAYS AND TRAVEL.

MAKE SURE YOU DON'T RUN OUT OF YOUR MEDICATIONS.

TALK TO OTHER PEOPLE WITH HIV AND LEARN FROM THEIR EXPERIENCES.

DEVELOP A SUPPORTIVE NETWORK OF PEOPLE WHO CAN HELP REMIND YOU TO TAKE YOUR MEDICATIONS.

antiretroviral therapy. Their research found that only 316 participants (55.8%) were "optimally adherent," or took their meds at least 95% of the time. In particular, they noted that women and people using injection drugs struggled most with adherence.

Depression and other mental health challenges can put people at risk for poor adherence. The BC study found that this was particularly so among women. Not surprisingly, going to jail can disrupt a medication schedule, as can moving from one province to another (and therefore one provincial medication coverage plan to another) or periods

26 SEPTEMBER+OCTOBER 2015

"PEOPLE'S CIRCUMSTANCES DICTATE THEIR ABILITY TO ADHERE. THAT, COMBINED WITH THEIR OWN PERSONALITY OR BEHAVIOUR PATTERNS. ADHERENCE IS A BEHAVIOUR."



of homelessness. "Where are you going to keep your meds?" asks Dr. Stan Houston, professor of medicine and public health at the University of Alberta and director of NAHIV. "Someone can steal your backpack at the shelter. But also, all your energy is devoted to what you are going to eat and where you are going to stay tonight. Taking pills may drop down on the priority list."

Immigrants and refugees in Canada who are living with HIV face considerable hurdles, including access to medications and privacy concerns that impact their ability to store and take meds. And, of course, HIV meds can cause unpleasant side effects—gas, fatigue or sleep problems— which can be real de-motivators to popping those pills.

NEW APPROACHES TO ADHERENCE

To address these issues, healthcare providers can offer extra help to reduce the barriers to taking medications. This may mean changing meds to avoid certain side effects, or creating a more convenient medication schedule. Dosettes and blister packs available through the pharmacy can help organize a complex medication schedule, as can assistive adherence apps.

But many HIV healthcare providers are beginning to look more closely at adherence as an acquired habit or behaviour. "People's circumstances dictate their ability to adhere," says pharmacist Linda Robinson. "That, combined with their own personality or behaviour patterns. Adherence is a behaviour."

Some people are creatures of habit and have a set routine, no matter what's going on in their lives. Others change what they do and how they do it daily.

Most people have points in their days that are more predictable than others. So the most successful approaches to adherence take into account the whole person with a very individualized adherence approach (see opposite page). "It's a question of figuring out a way of integrating a habit into your life," explains NAHIV's Dr. Stan Houston.

TACKLING SIDE EFFECTS

An individualized approach to adherence often starts with tackling side effects. Dr. Houston always questions his patients closely about side effects and how they are impacting their lives. "Ask. Never assume," he cautions. Some people don't mind digestive concerns while others, perhaps because of their work or living situation, really struggle to keep taking meds that cause these side effects. Again, these issues are so individual that doctors need to listen closely as their patients explain how certain aspects of their meds affect them and let that determine the next move.

ESTABLISHING MOTIVATION

Next, it's about establishing motivation. To help people grasp how their meds work and the benefits of sticking to their regimen, Robinson uses props like a balance scale to show how HIV drugs hold the viral load down and allow CD4 counts to rise.

Effective healthcare providers make sure their message is about teamwork and support, not judgment. "You have to be non-judgmental with your patients," Houston says. "You have to convey the idea that we both know adherence is important and it's part of both of our jobs to support it."

PLAYING PIGGYBACK

Then, it's on to finding a trick or technique that works. Some clinics send emails or text reminders to help patients adhere. But perhaps the ideal is to identify a daily routine on which to piggyback pill taking. One of Dr. Houston's patients with great adherence picks up his HIV meds every morning from the pharmacy on his daily trip to the liquor store.

SLIP, FALL AND GET BACK ON YOUR FEET

The best-laid plans can fail, and those taking meds for many years are at risk for slipping—particularly when life changes.

That's what happened to Alexandra de Kiewit. She took her HIV meds regularly for six years. Then, last fall, she started treatment for hepatitis C. A former injection drug user, de Kiewit was also working nights at a Montreal needle exchange. "The morning pill for HIV became so hard for me to take," she says. "Sometimes in the morning, I'd be fast asleep." Taking her evening pill, which she always did with dinner, stayed firmly entrenched in her routine.

Finally, six months later, she realized her medication schedule was not working and never would. A visit to her doctor resulted in a new regimen with a single HIV pill she could take at dinner.

Now, de Kiewit has been able to adhere well again, and is extremely motivated to keep it up, as she and her HIV-negative partner are trying to get pregnant. After discussions with the doctor, they both understand that de Kiewit's viral load has to be undetectable in order to have the best chance of conceiving naturally without her partner becoming positive. "At first I

took my medication for me, because I don't want to get sick," says de Kiewit, "but now I take it because of my relationship as well."

RESEARCH THAT KEEPS ON GIVING

Back in Edmonton, Megan Lefebvre's research became more than just a PhD thesis. She and six study participants decided to take what they discovered about superstar adherence and share it with others—healthcare workers, researchers and people who are HIV positive and struggling with medication adherence.

They made a video called Living with HIV and it's OK and screened it at HIV Edmonton at a series of pizza parties. Study participants acted as peer educators and HIV Edmonton clients enjoyed learning from "the celebrities" themselves. "It really humanized the issue of adherence," Lefebvre says. The pizza nights became so successful that the study participants continued to show this video and animate conversations about the importance of adherence throughout their communities.

DIANE PETERS is a Torontobased freelance writer, editor and teacher. She writes about health, business, parenting and other issues.

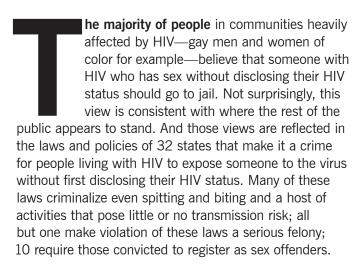
REPRINTED with permission from CATIE (Canadian AIDS Treatment Information Exchange) and *The Positive Side*.

TO WATCH MEGAN LEFEBVRE EXPLAIN HER RESEARCH AT THE NORTHERN ALBERTA HIV PROGRAM, CHECK OUT ADHERENCE AMONG CHAOS AT youtube.com/watch?v=P9VY13DOVI8.

POSITIVELY AWARE SEPTEMBER+OCTOBER 2015 27

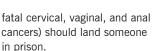
MICHAEL JOHNSON, HIV, AND MURDER

DISCLOSURE AND DISCRIMINATION IN CRIMINAL LAW BY CATHERINE HANSSENS



It is understandable that most people believe that if you are living with HIV, you have a responsibility to tell your sex partners. It is a serious, treatable but currently incurable disease.

If asked, most people also will say that those of us with herpes (incurable), syphilis, gonorrhea (god forbid if it's the treatment-resistant kind), chlamydia, and HPV (also incurable) have a responsibility to disclose our STIs to potential sex partners. The thing is, many people don't disclose some or any of this at least once and, for some, many times over the course of their sex lives. Yet few people would say that a failure to disclose HPV (the cause of most



Few among us have never hid or lied about some fact about ourselves that we feared would short-circuit a relationship or a hook-up. There are many things that a current or potential partner might consider very relevant to consenting to have sex or stay with us. And so we lie about having diseases, spouses, another partner, a job, a vasectomy, a desire to marry, an intention to divorce a spouse, and so on into near-infinity. These deceits all cause harm of varying degrees. Some of these lies are painful; some of them can have lifelong consequences.

So why the hang-'em-high response to discoveries of HIV non-disclosure?

The fact is that while most states also have laws that mandate disclosure or prohibit sexual contact when one has any STI,

partners, not criminal charges.

Those of us who haven't been living under a rock since becoming sexually active know that sex and intimacy come with risks. We may not know all the particulars—after all, we don't talk about it much in schools, and doctors are notoriously uncomfortable discussing sex with their patients of any age. But we know at least in general terms that diseases and heartache are part of the potential cost of sexual intimacy. Metaphorically speaking, there is no free lunch.

But let's say we don't really know the risks. Somehow we have managed to remain steadfastly ignorant. Let's say there

most of those laws are 1) minor misdemeanors and 2) rarely if ever enforced. Another fact is that people infected with other forms of STIs who decide to pursue legal recourse almost always file civil tort claims against their

really are gay men who use online hook-up sites or apps like Grindr who have no idea that having unprotected anal sex poses some risk of disease, be it HIV or gonorrhea or syphilis or herpes. Is ignorance a defense?

If this were a legal question, the answer would be no. No one charged with an HIV-related felony ever got off because they had no idea they could go to prison for decades for having HIV and sex. And in fact, studies show that most people are not familiar with the HIV law in the 32 states with HIV specific criminal laws or the other states (such as Texas and New York) that don't but prosecute people with HIV under general criminal laws like reckless endangerment or aggravated assault.

Someone can seek out his dream lover on a pick-up app like Grindr and have sex with a stranger and be treated as credible when he says, in testimony against the person he sought out for sex, I had no idea I was at risk for HIV. A recent sad example of this is the case of Michael Johnson.

Johnson, a 23-year-old former college wrestler who spent nearly two years in jail waiting for trial because he couldn't make the \$100,000 bail, was convicted of one class A felony and four class B felonies for having consensual sex without telling, or by deceiving, his partners about his HIV status (he says he did disclose at least part of the time). The complaining witnesses insisted they had no idea they were at risk for HIV by having condomless anal sex with Johnson. The one complainant whose case against Michael Johnson was dismissed is now selling a book describing his supposed victimization on Amazon.com (Kindle price: \$25).

On July 18th Johnson was sentenced to a total of 60.5 years, although with some of

the sentences running concurrently his actual sentence is 30.5 years, a sentence typically reserved for murder. If he were a repeat offender who killed someone while driving drunk, he would have received far less time.

This might make some sense if HIV were equivalent to anthrax. But nothing could be further from the truth. With treatment—and only one pill a day for most—a person living with HIV can expect to live as long and as productively as anyone else.

Also unlike anthrax, HIV is not an easy virus to transmit. Multiple studies over decades show that HIV is a lot harder to transmit than all those other potentially serious STIs. The average risk of contracting HIV through receptive anal intercourse, the riskiest behavior, is 138 in 10,000 exposures, meaning that transmission in the course of a single sexual contact does not occur, on average. 99% of the time. The risk from any form of oral sex is negligible to zero. The use of condoms reduces the risk of getting or transmitting HIV by another 80%. Using both condoms and antiretroviral therapy reduces the already small risk of getting HIV from sexual exposure by 99.2%, to zero or near-zero.

From the very outset of Michael Johnson's trial earlier this year, the prosecutor repeatedly stated that Johnson's actions were equivalent to driving while intoxicated (DWI). If you accept that analogy, you should know that under Missouri law, DWI is a class B misdemeanor. First offenders, if convicted, face a maximum penalty of six months in jail and most people get far less on an initial charge.

This is Webster dictionarydefined hysteria, the perfect storm of deeply ingrained

WE KNOW AT LEAST IN GENERAL TERMS THAT DISEASES AND HEARTACHE ARE PART OF THE POTENTIAL COST OF SEXUAL INTIMACY. **METAPHORICALLY** SPEAKING, THERE IS NO FREE LUNCH. THOSE OF US WHO HAVEN'T BEEN LIVING UNDER A ROCK SINCE **BECOMING SEXUALLY ACTIVE KNOW THAT** SEX AND INTIMACY COME WITH RISKS. WE MAY NOT KNOW ALL THE PARTICULARS— AFTER ALL. WE DON'T TALK ABOUT IT MUCH IN SCHOOLS, AND DOCTORS ARE NOTORIOUSLY UNCOMFORTABLE DISCUSSING SEX WITH THEIR PATIENTS OF ANY AGE.

homophobia, racism with all of the associated sexual stereotypes, and steadfast ignorance about HIV transmission routes, risks, and current-day realities.

Treating a positive HIV test as an element of a crime has done nothing to change anyone's sexual behavior or tendency to disclose his or her HIV or other STI diagnoses. The laws that do this have done nothing to keep people safe from disease, but they have ruined hundreds of lives.

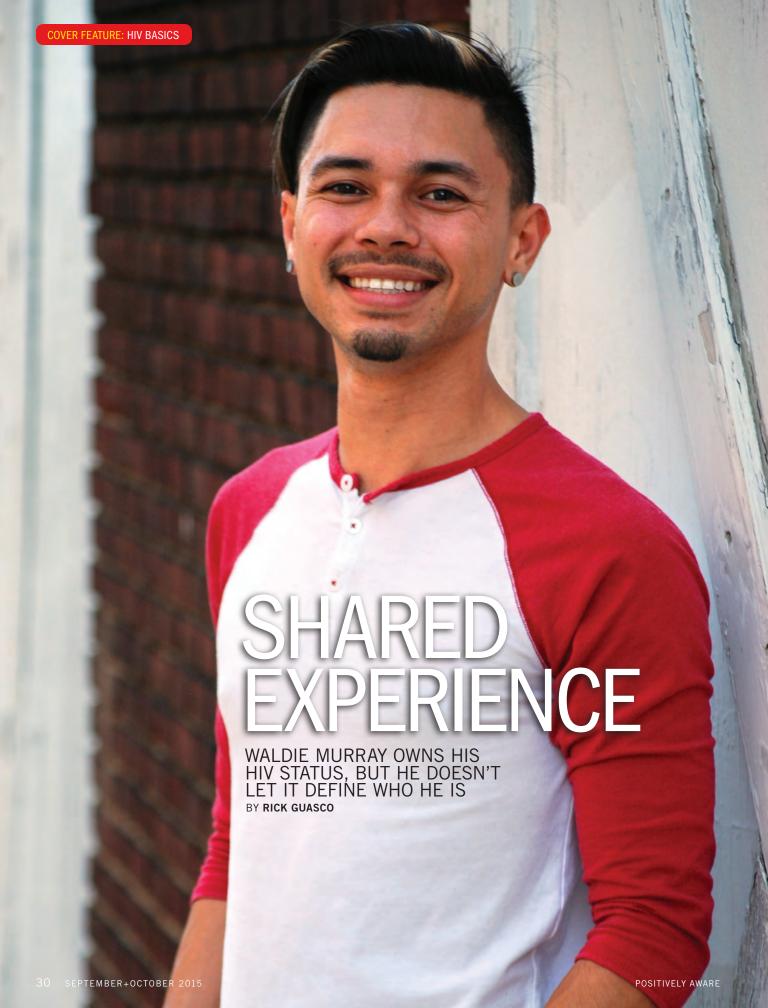
There may be no hard data on how these laws influence HIV testing behavior. But it would be foolish to ignore the implications of Michael Johnson's treatment for other young Black gay men, who see him facing decades behind bars because he is a young, handsome, openly gay, sexually active HIV-positive Black man.

CATHERINE HANSSENS,

Executive Director and Founder of the Center for HIV Law and Policy, has been active in HIV legal and policy issues since 1984. Previously, Hanssens was AIDS Project Director at Lambda Legal, where she led Lambda's HIV-related litigation and policy work. She also has been a visiting clinical professor at Rutgers University Law School-Newark and Director of the law school's Women and AIDS Clinic.

GO TO hivlawandpolicy.org
AND THE SITE'S HIV POLICY
RESOURCE BANK, A COMPREHENSIVE DATABASE OF
MATERIALS ON 37 TOPICS
OF IMPORTANCE TO PEOPLE
LIVING WITH HIV AND THEIR
ADVOCATES, INCLUDING
BRIEF SUMMARIES TO QUICKLY DETERMINE THE RELEVANCE OF EACH RESOURCE
TO YOUR SPECIFIC NEEDS.

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aldemar "Waldie" Murray found out he was HIV-positive in July 2014, on a day he had decided to take off from work, run some errands, and get his haircut. But that morning, something also told him to go get tested.

"I thought I should probably tend to my sexual health, because I couldn't even remember the last time I got tested," the 27-year-old says. "It was just an intuition that I should go."

Waldie's intuition was confirmed at Chase Brexton Health Services, an LGBT-friendly clinic in downtown Baltimore.

"This wasn't something I was expecting," he says. Waldie admits that he'd had condomless sex, but had never felt ill. (Seroconversion often comes with flu-like symptoms.) Taking a breath and sounding more resolute, he adds, "My first thought was, well, this is an experience that you're going to have, and it's going to be one you'll share with other people. I believe that we are meant to share our experiences with others. Sharing experiences is how we understand each other and have compassion for one another."

POSTING AS PROCESSING

While every person's reaction to learning they are HIV-positive is unique, and some people might not have the luxury of disclosing, Waldie's way of processing the news of his status was to be as open about it as possible.

Waldie went on Facebook—almost as soon as he had gotten home from the clinic.

"When I posted on Facebook, I was doing it for myself," Waldie says. "I wanted to let people know, but I didn't want anyone to feel sorry for me. I was doing it so that I felt I was in control of my situation. I'm going to say it to everyone, so that I didn't leave any room for gossip. The sooner I disclosed, the sooner the HIV 'label' would dissolve. The sooner people would just see me again as Waldie.

"I came at this from a very

self-empowered point of view, an emotionally strong place," Waldie adds. "As a result, most everyone accepted where I was with it."

Most everyone except his parents, at first. Waldie's mom had run into him while he had been running errands. He told her he was getting tested. When he came home, she asked him how it went, and Waldie gave her the news. She became very emotional and was unable to talk with him

But it was through Waldie's Facebook post that his father found out.

"My family isn't on Facebook, but one of my dad's friends must know someone who knows me, and so, I guess it popped up on his feed, or someone told him," Waldie says. "He contacted my dad to say how sorry he was to hear about me. My dad was like, 'What are you talking about?' He was caught off guard, obviously. He called my mom, was crying. I'd never known my dad to cry."

"I told my parents that this wasn't about blame, or getting upset, or even how it happened," Waldie adds. "The important thing now was how to take care of it."

Waldie already had begun to do his homework. In 2011, he had dated a guy who had recently tested HIV-positive. The guy was still trying to cope with his status and Waldie wanted to learn more about HIV. During the three months they dated, Waldie even accompanied his boyfriend to doctor appointments.

"At the time, PrEP was still new, so the doctor stressed that we use condoms, so we only had sex [with condoms]," Waldie says. "Having had that experience with him, I had educated myself about HIV. Fast forward to my own test results, I felt I was somewhat prepared."

However, Waldie didn't have

a doctor. "I always figured, I'm young, I'm fit, I feel healthy, so I'm good," he says. "Suddenly, I had to look for a physician."

Chase Brexton, the clinic where Waldie had gotten tested, offers healthcare services and case management. Within a week, he had a doctor's appointment and was seeing a case manager who helped connect him to HIV programs and services offered in Maryland.

But Waldie didn't immediately start treatment. It wasn't until four months later that he decided to go on meds.

"I wanted to make sure this was my decision," Waldie says, "and not because people were pressuring me to do it, because this was going to be a commitment I would be responsible for. But once I made the decision, I felt good about it."

'THREE AT 3'

Waldie's doctor put him on a three-pill-a-day regimen of Truvada, Norvir, and Prezista.

"Instead of a one-pill-a-day medication, my doctor said my regimen is more forgiving [of missed doses]," Waldie says. "If I forget to take one of my pills, at least I haven't missed a whole day's worth of meds. As a result, I have never completely missed a day. I don't remember the last time I forgot to take a pill. I take my meds at 3 p.m. every day. Three at 3, that's how I remember."

Waldie sets the alarm on his phone and takes his meds at his desk. The office where he has worked for five years is a familyowned, close-knit company, and he is very open about his sexuality and HIV status.

"Everybody at works knows," Waldie says. "When my alarm goes off, my coworkers will say, 'Is it 3 o'clock already? Waldie, take your pills.' I'm very lucky to be surrounded by people who really care about me.

"A former boss asked me if I was okay. I explained to her that there are medications for it, and she said, 'So, it's kind of like having diabetes.' I told her that HIV is controllable as long as you take your medication."

GO TO VIDEO

Soon after announcing his HIV status on Facebook, Waldie shot a video which he then posted.

"After I posted my status on Facebook, I thought people would wonder how I was really doing," Waldie says. "Even if I said I was fine, some people wouldn't believe it until they could see it. That's why I did the video. I wanted them to see I was alright. I had posted videos before; I found out my status on a Wednesday, I posted the video on Friday."

Waldie says he's been contacted by total strangers who found it after a Google search of keywords such as "HIV" and "video." Often, they're looking not so much for information about HIV as they are hopeful and encouraging words from people living with HIV.

"The people who are finding it, we have a connection," Waldie says. "We share a similar experience. Not everyone has the same support system I do or feel they can be as open. People have messaged me, saying they have felt empowered by my sharing my experience."

As he reached the one-year mark since learning his status, Waldie's viral load continued to be undetectable and he remained relentlessly upbeat and determined in his outlook.

"If I have any down days, it's because I'm having an off day, it's not because of HIV," Waldie says. "They're usually about, 'What am I going to do with my life?' Things like that.

"Living with HIV has become an experiential thing," Waldie adds. "It doesn't define me, it is just an experience, and I don't identify with the experience so strongly that I let it define me."

WATCH WALDIE'S VIDEO: youtube.com/ watch?v=ixwyZ3zdbPo.

WHAT IS PREZCOBIX™?

- PREZCOBIX[™] is a prescription HIV-1 (Human Immunodeficiency Virus 1) medicine used with other antiretroviral medicines to treat HIV-1 infection in adults. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). PREZCOBIX[™] contains the prescription medicines PREZISTA[®] (darunavir) and TYBOST[®] (cobicistat).
- It is not known if PREZCOBIX™ is safe and effective in children under 18 years of age.
- When used with other antiretroviral medicines to treat HIV-1 infection, PREZCOBIX™ may help:
 - o reduce the amount of HIV-1 in your blood. This is called "viral load."
 - increase the number of CD4+ (T) cells in your blood that help fight off other infections.
- PREZCOBIX™ is always taken in combination with other HIV medications for the treatment of HIV-1 infection in adults.
 PREZCOBIX™ should be taken once daily with food.
- PREZCOBIX[™] does not cure HIV-1 infection or AIDS, and you
 may still experience illnesses associated with HIV-1 infection.
 You must keep taking HIV-1 medicines to control HIV-1 infection
 and decrease HIV-related illnesses.
- Ask your healthcare provider if you have any questions on how to prevent passing HIV to other people.
- Please read the Important Safety Information below and talk to your healthcare provider to learn if PREZCOBIX™ is right for you.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about PREZCOBIX™?

- PREZCOBIX[™] may cause liver problems. Some people taking PREZCOBIX[™] may develop liver problems which may be life-threatening. Your healthcare provider should do blood tests before and during your treatment with PREZCOBIX.[™]
 - Chronic hepatitis B or C infection may increase your chance of developing liver problems. Your healthcare provider should check your blood tests more often.
 - Signs and symptoms of liver problems include dark (tea-colored) urine, yellowing of your skin or whites of your eyes, pale-colored stools (bowel movements), nausea, vomiting, pain or tenderness on your right side below your ribs, or loss of appetite. Tell your healthcare provider if you develop any of these symptoms.
- PREZCOBIX™ may cause severe or life-threatening skin reactions or rash. Sometimes these skin reactions and skin rashes can become severe and require treatment in a hospital. Call your healthcare provider right away if you develop a rash.
 - Stop taking PREZCOBIX™ and call your healthcare provider right away if you develop any skin changes with symptoms such as fever, tiredness, muscle or joint pain, blisters or skin lesions, mouth sores or ulcers, red or inflamed eyes like "pink eye" (conjunctivitis).
- PREZCOBIX,[™] when taken with certain other medicines, can cause new or worse kidney problems, including kidney failure.
 Your healthcare provider should check your kidneys before you start and while you are taking PREZCOBIX.[™]

Who should not take PREZCOBIX™?

 Do not take PREZCOBIX™ with any of the following medicines: alfuzosin (Uroxatral®), cisapride (Propulsid® Propulsid® Quicksolv), colchicine (Colcrys® Mitigare® if you have liver or kidney problems), dronedarone (Multaq®), dihydroergotamine (D.H.E.45® Embolex® Migranal®), ergotamine tartrate (Cafergot® Ergomar® Ergostat® Medihaler, Migergot, Wigraine, Wigrettes), methylergonovine (Methergine), lovastatin or a product that contains lovastatin (Altoprev, Advicor, Mevacor), lurasidone (Latuda), oral midazolam (Versed), pimozide (Orap), ranolazine (Ranexa), rifampin (Rifadin, Rifater, Rifamate, Rimactane), sildenafil (Revatio) when used for pulmonary arterial hypertension (PAH), simvastatin or a product that contains simvastatin (Simcor, Vytorin, Zocor), St. John's Wort (Hypericum perforatum) or a product that contains St. John's Wort, or triazolam (Halcion).

 Serious problems can happen if you take any of these medicines with PREZCOBIX™

What should I tell my healthcare provider before taking PREZCOBIX™?

- About all health problems. Tell your healthcare provider if you have liver problems, including hepatitis B or hepatitis C, have kidney problems, are allergic to sulfa (sulfonamide), have diabetes, have hemophilia, or have any other medical condition, are pregnant, breastfeeding, or plan to become pregnant or breastfeed. Tell your healthcare provider if you become pregnant while taking PREZCOBIX.™
- About all medicines you take. Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with PREZCOBIX.™ Keep a list of your medicines to show your healthcare provider and pharmacist. Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take PREZCOBIX™ with other medicines.

What are the possible side effects of PREZCOBIX™?

- The most common side effects of darunavir, one of the medicines in PREZCOBIX,™ include diarrhea, nausea, rash, headache, stomach area (abdominal) pain, and vomiting.
- Other possible side effects include:
 - High blood sugar, diabetes or worsening diabetes, and increased bleeding in people with hemophilia have been reported in patients taking protease inhibitor medicines, including PREZCOBIX.™
 - Changes in body fat can happen in people who take HIV-1 medicines. The exact cause and long-term health effects of these changes 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.

These are not all of the possible side effects of PREZCOBIX.™ For more information, ask your healthcare provider.

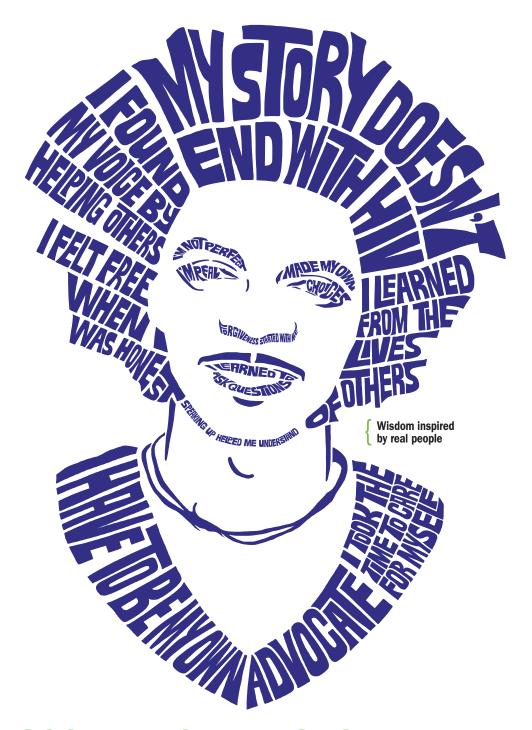
Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

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 accompanying full Product Information for more details.

Janssen Therapeutics,
Division of Janssen Products, LP





DISCOVER YOUR WISDOM WITHIN

Visit **PREZCOBIX.com** to hear wisdom inspired by experts and people like you living with HIV. **Ask your provider if Once-Daily*** **PREZCOBIX**™ **is right for you.**



PREZCOBIX.com

IMPORTANT PATIENT INFORMATION

PATIENT INFORMATION PREZCOBIX (prez-koe-bix) (darunavir and cobicistat) tablets

Please read this information before you start taking PREZCOBIX and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment. What is the most important information I should know about PREZCOBIX?

- PREZCOBIX may cause liver problems. Some people taking PREZCOBIX may develop liver problems which may be lifethreatening. Your healthcare provider should do blood tests before and during your treatment with PREZCOBIX. If you have chronic hepatitis B or C infection, your healthcare provider should check your blood tests more often because you have an increased chance of developing liver problems.
 Tell your healthcare provider if you have any of the below signs and symptoms of liver problems.
 - · dark (tea colored) urine
 - yellowing of your skin or whites of your eyes
 - pale colored stools (bowel movements)
 - nausea
 - vomiting
 - pain or tenderness on your right side below your ribs
 - · loss of appetite
- PREZCOBIX may cause severe or life-threatening skin reactions or rash. Sometimes these skin reactions and skin rashes can become severe and require treatment in a hospital. Call your healthcare provider right away if you develop a rash. Stop taking PREZCOBIX and call your healthcare provider right away if you develop any skin changes with symptoms below:
 - fever
 - tiredness
 - muscle or joint pain
 - · blisters or skin lesions
 - · mouth sores or ulcers
 - red or inflamed eyes, like "pink eye" (conjunctivitis)
- PREZCOBIX when taken with certain other medicines can cause new or worse kidney problems, including kidney failure. Your healthcare provider should check your kidneys before you start and while you are taking PREZCOBIX.

See "What are the possible side effects of PREZCOBIX?" for more information about side effects.

What is PREZCOBIX?

PREZCOBIX is a prescription HIV-1 (Human Immunodeficiency Virus 1) medicine used with other antiretroviral medicines to treat HIV-1 infection in adults. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

PREZCOBIX contains the prescription medicines PREZISTA (darunavir) and TYBOST (cobicistat).

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

When used with other antiretroviral medicines to treat HIV-1 infection, PREZCOBIX may help:

 reduce the amount of HIV-1 in your blood. This is called "viral load". increase the number of CD4+ (T) cells in your blood that help fight off other infections.

Reducing the amount of HIV-1 and increasing the CD4+ (T) cells in your blood may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

PREZCOBIX does not cure HIV-1 infection or AIDS. You must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others.

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

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

Who should not take PREZCOBIX?

Do not take PREZCOBIX with any of the following medicines:

- alfuzosin (Uroxatral®)
- cisapride (Propulside®, Propulsid® Quicksolv)
- colchicine (Colcrys®, Mitigare®), if you have liver or kidney problems
- dronedarone (Multag®)
- · ergot-containing medicines:
 - dihydroergotamine (D.H.E. 45®, Embolex®, Migranal®)
 - ergotamine tartrate (Cafergot®, Ergomar®, Ergostat®, Medihaler®, Migergot®, Wigraine®, Wigrettes®)
 - methylergonovine (Methergine®)
- lovastatin or a product that contains lovastatin (Altoprev[®], Advicor[®], Mevacor[®])
- lurasidone (Latuda®)
- midazolam (Versed®), when taken by mouth
- pimozide (Orap®)
- ranolazine (Ranexa®)
- rifampin (Rifadin®, Rifater®, Rifamate®, Rimactane®)
- sildenafil (Revatio[®]), when used for the treatment of pulmonary arterial hypertension (PAH)
- simvastatin or a product that contains simvastatin (Simcor®, Vytorin®, Zocor®)
- St. John's Wort (Hypericum perforatum), or a product that contains St. John's Wort
- triazolam (Halcion®)

Serious problems can happen if you take any of these medicines with PREZCOBIX.

What should I tell my healthcare provider before taking PREZCOBIX?

Before taking PREZCOBIX, tell your healthcare provider if you:

- have liver problems, including hepatitis B or hepatitis C
- have kidney problems
- are allergic to sulfa (sulfonamide)
- · have diabetes
- have hemophilia
- · have any other medical condition

IMPORTANT PATIENT INFORMATION

- are pregnant or plan to become pregnant. It is not known if PREZCOBIX will harm your unborn baby. Tell your healthcare provider if you become pregnant while taking PREZCOBIX.
 - Pregnancy Registry: There is a pregnancy registry for women who take antiretroviral medicines during pregnancy. The purpose of the registry 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 breastfeeding or plan to breastfeed. Do not breastfeed
 if you take PREZCOBIX.
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV to your baby.
 - It is not known if PREZCOBIX can pass into your breast milk.
 - 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 over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with PREZCOBIX. Keep a list of your medicines to show your healthcare provider and pharmacist.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with PREZCOBIX.
- Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take PREZCOBIX with other medicines.

How should I take PREZCOBIX?

- Take PREZCOBIX exactly as your healthcare provider tells you.
- Do not change your dose or stop taking PREZCOBIX without talking to your healthcare provider.
- Take PREZCOBIX 1 time a day with food.
- If you miss a dose of PREZCOBIX by less than 12 hours, take your missed dose of PREZCOBIX right away. Then take your next dose of PREZCOBIX at your regularly scheduled time.
- If you miss a dose of PREZCOBIX by more than 12 hours, wait and then take the next dose of PREZCOBIX at your regularly scheduled time.
- If a dose of PREZCOBIX is skipped, do not double the next dose. Do not take more or less than your prescribed dose of PREZCOBIX at any one time.
- If you take too much PREZCOBIX, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of PREZCOBIX? PREZCOBIX may cause serious side effects including:

- See "What is the most important information I should know about PREZCOBIX?"
- Diabetes and high blood sugar (hyperglycemia). Some people who take protease inhibitors including PREZCOBIX can get high blood sugar, develop diabetes, or your diabetes can get worse. Tell your healthcare provider if you notice an increase in thirst or urinate often while taking PREZCOBIX.
- Changes in body fat can happen in people who take HIV-1 medications. The changes may include an increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms, and face may also happen.

The exact cause and long-term health effects of these conditions are not known.

- Changes in your immune system (Immune Reconstitution Syndrome) can happen when you start taking HIV-1 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 right away if you start having new symptoms after starting your HIV-1 medicine.
- Increased bleeding for hemophiliacs. Some people with hemophilia have increased bleeding with protease inhibitors including PREZCOBIX.

The most common side effects of darunavir, one of the medicines in PREZCOBIX, include:

- diarrhea
- nausea
- rash
- headache
- stomach area (abdominal) pain
- vomiting

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

These are not all of the possible side effects of PREZCOBIX. For more information, ask your health care provider.

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

How should I store PREZCOBIX?

 Store PREZCOBIX tablets at room temperature between 68°F to 77°F (20°C to 25°C).

Keep PREZCOBIX and all medicines out of reach of children. General information about PREZCOBIX

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

If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about PREZCOBIX that is written for health professionals.

For more information call 1-800-526-7736.

What are the ingredients in PREZCOBIX?

Active ingredients: darunavir and cobicistat

Inactive ingredients: colloidal silicon dioxide, crospovidone, hypromellose, magnesium stearate, and silicified microcrystalline cellulose. The tablets are film-coated with a coating material containing iron oxide black, iron oxide red, polyethylene glycol, polyvinyl alcohol (partially hydrolyzed), talc, and titanium dioxide.

Manufactured by:

Janssen Ortho LLC, Gurabo, PR 00778

Manufactured for:

Janssen Therapeutics, Division of Janssen Products, LP, Titusville NJ 08560

Issued: January 2015

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027415-150108



CURE OR REMISSION—WHAT'S IN A WORD?

BY JEFF BERRY

rogress toward a cure continued at this year's International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment, and Prevention. Eradication of the virus from the body will be difficult if not nearly impossible to achieve, but remission (defined as HIV remaining in the body but viral load is undetectable in the absence of antiviral therapy, or ART), is possible and likely much more attainable. With one case of remission discovered in an HIV-positive teenager in Paris who has been off ART for 12 years and remains undetectable, research continues to adapt in this ever-evolving area of science.

In an outstanding plenary overview of cure research to date, Nicholas Chomont, Ph.D., outlined how HIV hides in reservoirs found in the brain, lymphatic system, gut, and genital tract even when a patient is on treatment and undetectable. Mechanisms of viral persistence include the active reservoir where there is residual replication such as in the tissue; the latent reservoir

found in memory CD4 T-cells; and T-cell proliferation, which is a major mechanism of viral persistence (proliferation, or increase, of T-cells is part of homeostasis, a process of the immune system which keeps the individual components in balance over a person's lifetime).

Chomont put forth two main cure strategies currently being pursued. The first would be to limit the establishment of the reservoir in the first place, such as with a vaccine prior to exposure or ART during early or acute infection. The second strategy would be to reduce or limit the reservoir in chronic infection, by either rendering the uninfected cells resistant to HIV; depleting the reservoir cells (such as with the drug auranofin); or flushing out the reservoir (shock and kill).

The latest strategy, which was presented at this conference, is silencing the reservoir or putting it into a deep sleep, so that it never awakens (as opposed to shock and kill).

In a study presented at CROI earlier this year, those treated early during infection had a



smaller active reservoir, which predicted a longer time to viral rebound once ART was stopped. This is important, and has been described by leading researcher Sharon Lewin and others as the holy grail of cure research. Being able to predict the time to viral rebound, and the ability to extend that, will be crucial when performing treatment interruptions in HIV-positive adults. A structured, or analytical, treatment interruption is so far the only way to measure whether or not the strategy or method you are testing is actually working in the absence of ART, which of course is the ultimate goal in HIV remission or cure—being and staying off ART while maintaining viral control. Combinations of treatments and/ or strategies will ultimately be needed to reach that goal.

At this conference there was one highly publicized case of prolonged remission in a young woman, 18 years old, who was born with HIV and has had undetectable virus (less than 50 copies) for 12 years after stopping therapy. She did experience a blip upwards measured at 515 when she was 12.

According to the IAS organizers the case, presented by Asier Sáez-Cirión of the Pasteur Institute in Paris, was "the first evidence that long-term HIV remission is possible in a perinatally infected child who received early treatment."

In their report, the researchers said this was the first evidence that "very long-term" remission was possible in these children. They also noted that the case study shows it's possible to have similar characteristics as reported in adult post-treatment controllers. Dr. Sáez-Cirión noted that the girl has none of the genetic factors typically associated with those who naturally control the virus.

The young woman's mother had uncontrolled virus with a very high viral load at the time of birth and the baby was given AZT for prevention. After she was found to have HIV herself, she was put on combination therapy at three months of age. Her family stopped her therapy, however, when she was around age six.

During the first 500 days of life the infant had several blips in her viral load. Is it possible that these blips could have induced or elicited a response from the developing immune system that contributed to her remission? Was it the treatment she received, her genetic profile, or because the child was still developing her immune system? While we can't know for sure, HIV physician and leading researcher Dr. Stephen Deeks stated during a press conference that we need to look at all of these possibilities.

The IAS is currently rewriting their Towards an HIV Cure Strategy, first introduced in 2012, and it will be presented at the International AIDS Conference in Durban, South Africa next year.

STARTING TREATMENT, NEW DRUGS, AND PREVENTION

BY ENID VÁZQUEZ

inal data from the SMART study confirmed previous results trumpeted around the world: starting HIV therapy sooner provides significant health benefits, regardless of how strong the person's immune system is (basically, how high their T-cell count). A person's chance of staying healthy and living longer more than doubles with immediate treatment. Moreover: if treatment is delayed, the risk of other diseases (cancer was the most common) doubles.

WHEN TO START? NOW

For years there's been debate about how soon to start therapy, but other data in addition to SMART have shown the benefits of starting earlier rather than waiting. Many experts—and treatment guidelines—have adopted the position that, in general, people should start treatment as soon as they've been diagnosed if they can—that is, have access to treatment, are ready to adhere to therapy, etc.

"IAS 2015 will be remembered as the definitive moment when the world agreed earlier initiation of treatment is the best way to preserve the health of people living with HIV, and one of the best tools we have to slow HIV transmission to others," said Julio Montaner, MD, in a press release. Dr. Montaner was the IAS 2015 Local Co-Chair and is Director of the British Columbia Center for Excellence in HIV/AIDS, "The new data presented [here] will inform HIV treatment guidelines worldwide, and inspire governments, funders, and health systems to act to save millions more lives."

TREATMENT PREVENTS TRANSMISSION

Serodiscordant couples—in which one partner is HIV-positive—were able to significantly reduce the risk of transmission out to 10 years when the positive partner had undetectable virus while on therapy, according to the large, landmark international study

HPTN 052. "The new data confirms the significant 'treatment as prevention' benefit to early ART [antiviral therapy] for HIV prevention that was previously reported in 2011," the IAS 2015 organizers noted in a press release. Although no linked transmissions were seen within the couples when the positive partner had undetectable viral load, researchers cannot put the risk at zero.

DORAVIRINE

An HIV medication still in development, doravine continued to do well in early 24-week results against efavirenz (Sustiva, which is contained in Atripla).

Both medications are from the same drug class, nonnucleoside reverse transcriptase inhibitors (NNRTIs). As a new drug, doravirine may still work for people who have developed resistance to efavirenz or rilpivirine. Rilpivirine (Edurant) is also an NNRTI, and is found in Complera.

Viral load results were the same for both groups, but there were fewer discontinuations in the study with doravirine: 4.6% of people given the newer drug vs. 12% for those on efavirenz.

The researchers noted that "the common NNRTIs are associated with suboptimal efficacy and/or safety profiles," with rilpivirine use restricted to people with lower viral loads (of less than 100,000) and efavirenz leading to "frequent CNS [central nervous system] adverse events," and neither

POSITIVELY AWARE SEPTEMBER+OCTOBER 2015 37



drug is recommended under current U.S. guidelines for first-time treatment of HIV.

MATURATION INHIBITOR BMS-955176

BMS-955176 is a secondgeneration maturation inhibitor, a drug class not yet on the market. Since synergy was seen with atazanavir (Reyataz) in the test tube, a small safety study of 28 individuals looked at combining the two drugs. The combination was well tolerated, with major drops in viral load. A similar early (Phase 2) study in treatment-experienced patients is planned. It's hoped that the combination can be used without a booster dose for Reyataz or a background of nucleoside medications, thereby simplifying treatment.

SWITCHING TO TAF

Once a new drug has been found to work as well as an old one, the question becomes: **Can you switch** from the old to the new?

The largest switch study to date in HIV looked at switching to a newer version of tenofovir DF (TDF, or Viread, found in Truvada). The study found that people had greater success with the new version, tenofovir alafenamide fumarate (or TAF). At the one year mark, they were significantly more likely to maintain suppression of their HIV viral load (to undetectable levels).

Specifically, the study compared Stribild to a newer version that contains TAF instead of TDF. The study also looked at switching to the new combo from Atripla (which contains TDF) or a regimen of Norvir-boosted Reyataz plus Truvada. Nearly 1,000 persons were switched and compared to nearly 500

who were kept on a TDF-containing regimen.

Switch participants also saw improvements in their spine and hip bone mineral density, as well as in proteinuria and other markers of kidney function, in addition to reductions in osteopenia and osteoporosis (both indications of loss in bone mass). Although tenofovir DF is considered very tolerable, TAF was created to overcome the medication's potential damage to the kidneys and bones, as seen by some patients.

"This is the first large study to demonstrate that switching from a TDF-based regimen to E/C/F/TAF can help improve patients' bone and kidney measures," said Tony Mills, MD, lead author of this advanced Phase 3 study and Medical Director of the Southern California Men's Medical Group in Los Angeles.

A separate switch study with 242 individuals also showed renal and bone improvements with TAF at 48 weeks.

A poster presentation (WELBPE13) also showed that the TAF regimen was able to maintain suppression of hepatitis B virus (HBV) in co-infected patients. (TDF is effective against HBV, as is emtricitabine, which is also found in Truvada. Patients who also have hepatitis B should generally be placed on HIV therapy that can also treat their hep B.)

The new single-tablet regimen containing TAF is awaiting FDA approval.

THAIS AND LOWER DOSE OF REYATAZ

Thai researchers reported that lower doses of Reyataz and Norvir were able to adequately suppress HIV in

Thais living with the virus when compared to standard doses. Pharmacokinetic data had previously found that the standard dose of boosted Reyataz (300 mg plus 100 mg Norvir) is associated with higher exposures in Thais, while a lower dose of 200 mg/100 mg led to adequate dosing with fewer side effects.

In the LASA study comparing the two doses among 500 patients, the higher drug levels also led to a greater number of treatment discontinuations.

The research group said that applicability to other ethnicities and larger body weights is not known, and that results are not generalizable to patients who are treatment-naïve or failing first-line therapy. Results are at one year, with patients who had undetectable virus levels for at least three months before entering the study.

YOUNG MEN AND PREP

Data from the PrEP Demonstration Project of the Adolescent Trials Network (ATN) were presented by Sybil Hosek, PhD, of Stroger Hospital in Chicago.

The ATN 110 study provided Truvada PrEP (pre-exposure prophylaxis) for HIV prevention to young men who have sex with men (MSM) ages 18 to 22, at 12 sites across the country.

The high level of risk behaviors seen when the young men entered the study continued throughout it. There was, however, a statistical trend for those who engaged in condomless sex to be consistently more adherent in taking their Truvada. Also, those who reported condomless receptive (bottom) anal sex had higher blood levels of Truvada, although there was no statistically significant difference.



PREP OVERVIEW

"Condom-based prevention is now insufficient to further reduce HIV incidence," reported Carlos F. Cáceres. MD. MPH. PhD. director of the Center for Interdisciplinary Research in Sexuality, AIDS and Society of Cayetano Heredia University in Lima, Peru. In his overview of combination prevention, he said, "The prevention paradigm has shifted from two decades of behavioral imperatives condoms, abstinence, and monogamy—to biomedical approaches: treatment as prevention and PrEP. ...We definitely have achievements [with the promotion of condoms], but we never achieved 100% condom use and with the rise of definitely lost." As usual with scientific advancements, there are barriers to overcome, including the attitudes of doctors and patients, and "even hostile responses," said Dr.

38 SEPTEMBER+OCTOBER 2015 POSITIVELY AWARE



White and Latino study participants (21% and 17% respectively of the total) took more than four doses of Truvada a week, which is considered to be very protective against HIV (the prevention pill is supposed to be taken every day). African American participants (53% of the total) and those self-identifying as mixed race (7% of participants) overall did not reach that level after 24 weeks in the 48-week study.

"Our African American participants, on average, did not reach the highly protective levels that PrEP can afford them at all across the study," Hosek said. Still, "The vast majority of participants had detectable drug throughout the course of the study, so they were all trying to take drug at some level," she said, and pointed out that all groups showed a drop-off in adherence at 12 weeks. It was at that point, she noted, that study visits changed from monthly to quarterly. More contact in person or mobile technology might help, the study team reported. Some groups went back up in adherence, but only whites had a higher adherence level at 48 weeks than when they began. Latinos also remained above the four-dose-aweek level.

There were four HIV infections during the study (out of 400 participants enrolled from more than 2,000 youths contacted), with two of the young men having been positive at study entry but testing HIV antibody negative, and none of the four having detectable blood levels of Truvada. Therefore, no drug resistance was found.

Given the high level of risk and STIs overall, the ATN

expected a higher level of HIV infections had the participants not been on Truvada PrEP. Also, the study noted that young MSM are at highest risk of HIV in this country.

In addition to looking at PrEP acceptability, patterns of use, adherence, and drug levels, ATN 110 also used evidence-based behavioral interventions (either Many Men, Many Voices, or 3MV; or Personalized Cognitive Counseling, or PCC) as well as provided information on the safety and efficacy of PrEP from prior studies (which may help improve adherence).

Data from ATN 113, which provides Truvada PrEP to young MSM ages 15 to 17, is expected next year.

Among its conclusions, the research team reported that the young men most at risk may be the most adherent, but called the results a "call to action for more in-depth understanding of the historical, societal, behavioral, and attitudinal barriers to PrEP access and adherence among those most impacted in the U.S.—black/African American young MSM."

"How can we dig deep to avoid growing the gap in disparities?" Hosek asked.

MORE ON YOUNG MEN AND PREP

A survey of young black MSM (YBMSM), looking at their knowledge and uptake of PrEP, was presented in a poster report by John A. Schneider, MD, of the University of Chicago Medicine and its Chicago Center for HIV Elimination.

According to the poster abstract, "In the United States, early evidence exists of racial disparities in PrEP knowledge, seeking behavior, and uptake. Young black MSM in particular have lower PrEP engagement when compared to other racial/ethnic groups, even in the context of increased health care access due to the Affordable Care Act."

More than 600 YBMSM participated. Half were younger than 22, and 28% were HIV-positive. Of the 252 respondents considered eligible for PrEP, only 40% knew about it and only 9% had used it.

Factors associated with knowledge of PrEP included completing college, having a medical provider, living with HIV, previously participating in an HIV prevention program, and membership in the House/Ball community. There was no significant

association found with closeness to the black or gay community, socializing in Boystown (Chicago's main gay neighborhood), or behavioral risk factors such as condomless sex with male partners and group sex.

"Several clinical factors were associated with PrEP knowledge suggesting that accelerating access to health care and HIV prevention programming may increase PrEP knowledge," according to the abstract's conclusion. "In addition some YBMSM sub-groups, such as the House/Ball community and HIV infected individuals, may be exposed more to PrEP information. Engaging YBMSM not engaged with HIV prevention/ clinical systems and those with sex behaviors associated with HIV risk is urgently required if PrEP uptake is to have public health impact on the U.S. HIV epidemic."

GO TO IAS2015.ORG TO VIEW WEBCASTS OF DR. CÁCERES' OVERVIEW AND OTHER PRESENTATIONS. SLIDES PRESENTED ARE AVAILABLE FOR DOWNLOAD, ALONG WITH THE ABSTRACT BOOK FOR THE CONFERENCE.

FOR A MAJOR SEAPORT, VANCOUVER REPORTED JUST 603,502 INHABITANTS IN THE 2011 CENSUS. YET, THE GREATER METROPOLITAN AREA ENCOMPASSES A POPULATION OF 2.4 MILLION, AND IS CANADA'S THIRD MOST POPULATED CITY. VANCOUVER IS RELATIVELY YOUNG—THE CITY WAS ESTABLISHED IN 1886 AS LITTLE MORE THAN A SETTLEMENT FOR LOGGERS, KNOWN AS GASTOWN. BUT VANCOUVER HOSTED THE 2010 WINTER OLYMPICS, AND WAS MOST RECENTLY RANKED THE THIRD MOST LIVABLE CITY IN THE WORLD, BY THE ECONOMIST MAGAZINE. YOU'VE PROBABLY SEEN VANCOUVER ON TV AND IN MOVIES WITHOUT EVEN REALIZING IT; PRODUCTIONS RANGING FROM CHER'S 1987 FILM MOONSTRUCK (DOUBLING AS NEW YORK CITY) TO COUNTLESS TV SERIES, ARE SHOT IN VANCOUVER BECAUSE OF LOWER PRODUCTION COSTS. IN 2014, VANCOUVER BECAME THE HOME OF THE TED (TECHNOLOGY, ENGINEERING AND DESIGN) CONFERENCE.





MUSICIAN AND ACTIVIST **RYAN LEWIS** POSES FOR A SELFIE WITH A DELEGATE.



'DIGITAL ORCA,' A 25-FOOT TALL SCULPTURE BY DOUGLAS COUPLAND, STANDS NEXT TO THE **VANCOUVER** CONVENTION CENTER, WHERE THE CONFERENCE WAS HELD.

> OCEAN VIEW FROM THE CONVENTION CENTER.





MAKING A VERY PERSONAL STATEMENT.

PHOTOS © MARCUS DAVIS AND STEVE FORREST-WORKERS' PHOTOS/IAS



- CHILINGS mmun



THE RETURN OF ART+ POSITIVE

AN HIV DOCTOR WITH A PASSION FOR ART RESCUES WORK LONG HIDDEN AWAY BY ENID VÁZQUEZ

or nearly two decades, the archives of ART+
Positive languished in a basement in Cincinnati.
The ACT UP affinity group was started in 1989
"to fight homophobia, AIDSphobia, and censorship in the arts."

Meeting notes, posters, flyers, letters, and art remained out of the public eye until earlier this year when HIV specialist Daniel S. Berger persuaded the collector to let him acquire the archives. That collector, who purchased the archives in 1996, had intended to showcase the work and ephemera, but never did. In June, Dr. Berger, founder and medical director of Northstar Medical Center in Chicago, along with artist John Neff, curated the art show "Militant Eroticism: The ART+ Positive Archives."

"Everyone went off the radar for 10 years," said Hunter Reynolds (see pages 42–43), who co-founded ART+ Positive. "We finally got a connection to the guy, and Dan spent months talking to him. He didn't return calls from others."

It is fitting that Dr. Berger brought the archives back to life. He is both an art collector who

runs a gallery as well as an M.D. who fresh out of medical school established Northstar at the start of the epidemic, renowned for aggressive action against the virus in times when little could be done.

"The artists of ART+ Positive expressed desperation, anger, and passion in a near hopeless situation," said Dr. Berger. "They were trying to create change in a very homophobic and AIDS phobic society. These artists and other activists were my collaborators working towards common goals, allowing patients to become equal partners with their providers, determining treatment choices and gaining early access to promising investigational treatment to save lives."

He has contacted museums and galleries around the country, and all have expressed interest in displaying the archives. He is also working on finding a permanent home for the material, but said it will only be donated to "the right institution that promises to display it, so that people can continue the discourse." He sees that early resistance against negative societal forces as a power that continues today and unites many struggles, such as Black Lives Matter. "I just feel honored to be sheltering the archives right now," Dr. Berger said.

"Demonstrate against
Homophobia and Censorship,"
reads a flyer for a protest at the
Metropolitan Museum of Art in
New York City. "Senator Jesse
Helms has proposed legislation
that would censor homoerotic art
and could lead to the removal
of much of the art in museums
across America. Helms wants to
tell us who to love, what kind of
sex to have, and what ideas we
can see and hear. Fight back!
Demonstrate!"

"Buttfuckers United Against Censorship!" declares another flyer. "Love between men is as precious as any other kind of love. ... Embrace homoeroticism! Speak out forcefully and honestly against this latest attempt to silence gay male expressions."

Artwork in the exhibit

included Equipped, photographs by Ray Navarro, first exhibited in the 1990 PS 122 exhibition An Army of Lovers: Combatting AIDS, Homophobia, and Censorship, in New York City. At the time, Navarro was sick and in the hospital, debilitated and blind due to AIDS complications. Artist Zoe Leonard assisted him in completing the work, depicting hospital equipment and using suggestive titles such as "Studwalk." According to the exhibit's website, "Equipped slyly mobilizes references to queer sex, AIDS medicine, and censored public speech." Navarro died on the day Army of Lovers opened.

That so much art and other fragile materials such as letters survived may be as much a stroke of luck as it is due to the passion for history of all those who had it in their possession. Now, in the age of the Internet, the archives are being scanned and have a much greater chance of not only being saved for posterity, but of being seen.

VIEW MILITANT EROTICISM AT icebergchicago.com.

SURVIVAL AIDS

PERFORMANCE AND ART INSTALLATION BLENDS THE PAST AND PRESENT BY ENID VÁZQUEZ

N SEPTEMBER, an AIDS protest comes to Expo Chicago (the International Exposition of Contemporary & Modern Art). Not a protest of the show, but of AIDS itself—its politics and its illness. Its death toll.

"Survival AIDS ACT UP Chicago—A Revolution" presents a mummification performance by gay and HIV-positive artist Hunter Reynolds along with three wall-sized panels where he collages photographs on scanned newsprint of articles on the epidemic, including material from POSITIVELY AWARE.

Here, he uses archival material from the ACT UP collection at the University of Chicago and the private collection of Chicago HIV specialist Dr. Daniel S. Berger (see previous page), part of his series entitled Survival AIDS.

One panel features a photo of Patina Du Prey, Reynolds' Shamanistic, gender fluid alter ego, wearing his AIDS Memorial Dress, created in 1993, silk-screened with 25,000 names of people who have died from HIV/AIDS.

"The sheer loss was the central theme of my work for 10 years in the '90s," said Reynolds. Patina Du Prey began in 1989 as "a way of dealing with the dragphobia in the gay community" and in the mid-'90s he used his studies in Sufism to perform with chanting and dervish dancing to express loss in the epidemic. He sensed a cathartic reaction from audiences and found himself at times "taking the energy" of their tears and their grief.

More recent are his mummification performances, like the one in Chicago, where his body is wrapped in cellophane and tape and he emerges as the "skin" is left on the floor. "Each one I do is about my body's transformation," said Reynolds, "transformation of life and survival." His work, he said, reflects his experiences as a gay man and as a person living with HIV, as well as AIDS activism. It's how he came to understand collage as a new form of artwork for him following a stroke in 2005 that left one side paralyzed for months, with only three T-cells and a fungal infection in his brain. In that period, he looked through the collection of news articles he clipped from 1989–1993, and found inspiration.

"I needed to reinvent my whole process of making art," he said. He has yet to regain the use of his right hand, or to paint again.

Reynolds hoped that the work might help "reignite interest" in the city's former ACT UP members and others. He said the Chicago panels are "another opportunity to tell a new story in another place from the same time frame."

"I always wanted to reflect sociopolitical issues," said Reynolds.

That political motivation came before the HIV epidemic. As an art student, he protested against nuclear proliferation. After moving to New York City in the mid-80s, he joined ACT UP as soon as it started, where he co-founded the affinity group ART+ Positive to push back against homophobia, "AIDSphobia," and censorship in the arts (see previous page). He later also became a member of Visual AIDS. He was still unaware of his own HIV-positive status, a diagnosis he wouldn't receive until 1989. Because he was part of a gay men's health study, however (which helped him obtain free medical care), he learned that he had actually become positive in 1984.

In his exhibit proposal, Reynolds wrote, "Through my layering of media and archives, I create historical and abstracted messages, infused with my own images to create a space within the work where experience and reporting, artist and audience, and present and past exist simultaneously."

(RIGHT) HUNTER REYNOLDS: SURVIVAL AIDS ACT UP CHICAGO—A REVOLUTION 2015 WITH MEMORIAL DRESS. PHOTO-GRAPHED BY MAXINE HENRYSON. ARCHIVAL C-PRINTS AND THREAD, 48 X 60 INCHES. COLLECTION DR. DANIEL BERGER. COURTESY PPOW GALLERY.

SURVIVAL AIDS MEDICATION REMINDER AT P.P.O.W GALLERY, NEW YORK CITY, SEPTEMBER 10-OCTOBER 17. OPENING RECEPTION THURSDAY, SEPTEMBER 10, 6-8 P.M.

SURVIVAL AIDS ACT UP CHICAGO—A REVOLUTION AT EXPO CHICAGO (AT NAVY PIER), SEPTEMBER 14–20.

SURVIVAL AIDS MUMMIFICATION

PERFORMANCE AT EXPO CHICAGO, SUNDAY, SEPTEMBER 20, 1–3 P.M. COLLABORATION WITH ELIJAH BURGHER AND STEVE REINKE. PERFORMANCE WILL BE VIDEOTAPED.

VISUAL AIDS TALK, BEGINNING AT PAVEL ZOUBOK GALLERY, NEW YORK CITY, AND ENDING AT P.P.O.W GALLERY, SATURDAY, OCTOBER 3, 3–5 P.M. WITH ERIC RHEIN.

ART AIDS AMERICA, INCLUDING A HUNTER REYNOLDS PIECE LOANED BY DR. BERGER, OPENS AT THE TACOMA ART MUSEUM, ON OCTOBER 3. MORE INFORMATION ABOUT THE EXHIBIT IS AT TACOMARTMUSEUM.ORG/ EXHIBIT/AAA.



August 19 1992

Doctor battles AI

Aggressive treatment is critical

Staff Writer

when Daniel Berger graces
ed from medical school is
planned a career in interm
medicine. But the training he received at St. Joseph's Hospit
gave his life new direction.
It was at the North Side med
cal center that he became is
creatingly aware of the AID

epidemic. Berger routinely say patients suffering from the de bilitating effects of HIV, and he wowed to make a difference. In the past three years he die exactly that, directing his own practice to help those afflictes with this modern-day plague

ly disease.

The Center for Special Imma nology, with its headquarters is Plorida, is a national network o centers dedicated to the treal ment and care of patients when the content of th

office - which opened in June of in the Sheffield Square Profes-

in the Sheffield Square Professional Center at 2835 N. Sheffield Are. — Berger talked of how the "team approach" is more effective in this fight for life.

Daley Agains



During an angry confrontation with Daley during a Feb. 20 Consentation on Hustel Buildings (CMR) baschage, activist Rick Carcia attempts to return his 1900 CMR page

Citizens for Lesbian

Concept. In or the designant generic but the technical and gay communities and with the technical and gay communities and arm for a facility of the control and the control and the control and the next set oncettle and the second of the spould so proud to present the fifth \$1,000 wants of Social Westerless.

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her own funds so front or currient of make significant money to organization. As a member of ACT UP/Chicago Acts was mulvious and took subservation position in runnersus demonstrations. Her of which related in the arrest and in the control of the control and the control of the control Nation/Chicago, she organized an participation of users in users and and the control that she began a long term solution user working busiless, another hotto our Chicago activits. The two of their are working busiless to hold society as are working busiless to hold society.

against queers.

Scout's credentals are many. She is an advisor for the youth group at Horzons Community Services, a member of the Lesbian and Gay Advisory Committee to the Chicago Police Department and has been Development Assistance.

cate for the AIDS Foundation of Chicago since 1988. In February of 1991, she was assured at the Chicago Campus of the University of Illinois and became the first person to fest the sexual preparation status of the Illinois

color crims limit.

South and Vibriero have engaged in impress alternot to lest inforcement of the Chrope Harman Regists. Offer about the Chrope Harman Regists. Offer about the Chrope Harman Regist Chron-the Armange Bagets Chrunch the Lord of them were physically assaulted and formby specied mit me waiting arms of golder because South attempted to ask a question against Caches Beeri Country stores and getting a country-wide human rights contained passed.

They both airs regional representatives of the 1995 March or Washigton for Lesbain. Gay, and Bisexually, and Rose and Ro

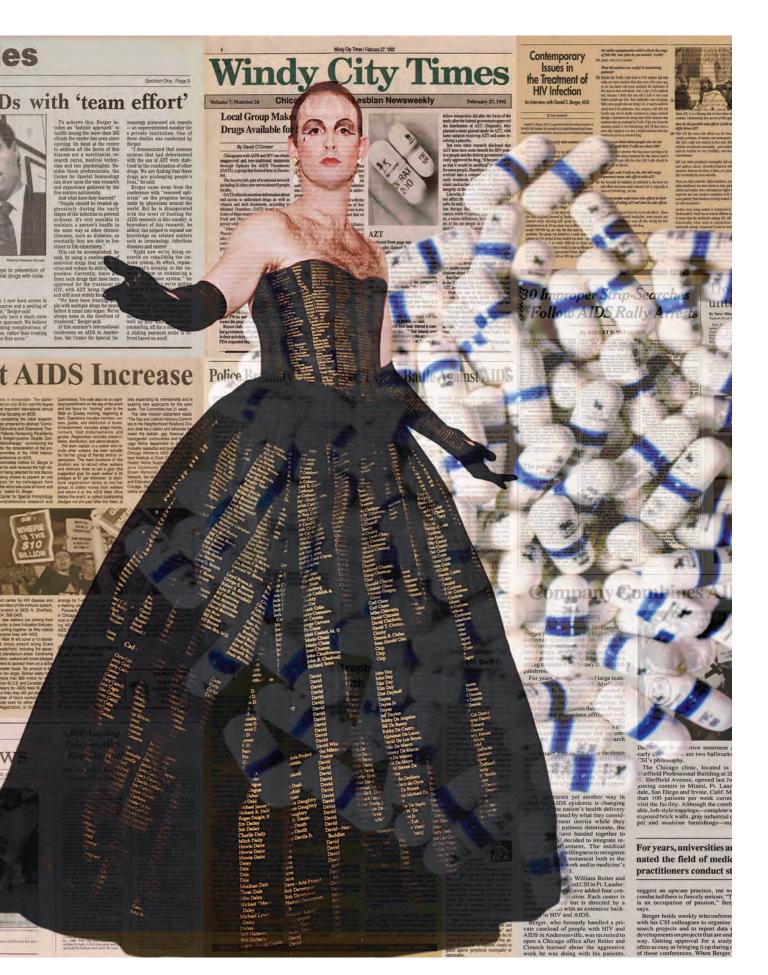
Chicago physician presented discussion at AIDS Conference cecaso - Daniel S. Berger, medical dispector of the Center for Special Immunology, present an oral discussion, entitled.

The New Hork Times

Metropolitan Ne



42 SEPTEMBER+OCTOBER 2015 POSITIVELY AWARE



POSITIVELY AWARE SEPTEMBER+OCTOBER 2015 43



READY FOR PICKUP

"Hello, this is your pharmacy calling to tell you that your medication is ready for pickup."

I hear this message at least once a month. When I do, I go pick up my prescriptions from the pharmacy. But some people, for a plethora of reasons, never pick up their meds. So what happens? Many unused, unopened, never picked up medications are destroyed when someone, somewhere could be using them to bring their HIV virus (or viral load) from uncontrolled to undetectable. If you refuse medication at the pharmacy level they can return it to stock, and if it's never picked up after two weeks it's also placed back in stock. However, this becomes tricky once the prescriptions are delivered to a person's home or a health care facility, and these are the medications that are going to waste. And this is a shame, because we tighten our belts and figure out a way to keep programs active; however, we can't work with gaping, bleeding wounds.

HIV medications have always been expensive and the newer once-a-day formulas that most people begin these days are even more costly. People employed full time should have health insurance through their employers and some can pay their own premiums, but many people have the "non-Cadillac" insurance that charges very high copays for HIV medications as well as other expensive ones such as those for hepatitis C and chemotherapy. Many are enrolled in the pharmaceutical manufacturer's Patient Assistance Program (PAP) and some of them still need to apply for the AIDS Drug Assistance Program (ADAP), which completely covers the cost of their HIV medications, and in some cases co-pays or premiums.

These programs ship medication to either the patient's house or their health care provider's office. The problem is that when patients do not pick up their medications they pile up and after a while either become expired or have to be destroyed. Some places link with aidforaids.org, and send the medications so they can be distributed to people who need them desperately in places like Africa.

While this is a wonderful way to not waste medications, it's too bad the patient the prescription was meant for is not on their HIV regimen. This is where the A-word comes in: adherence. Medications only work when taken properly, and this is adherence in its most basic form.

Can you take a red jelly bean once a day at the same time of the day for a month? I heard about this nifty little experiment years ago when providers asked people who never took medications if they could take a jelly bean candy of the same color at the same time daily for a month and then report their adherence to the provider. Many people found they couldn't do this, they were too consumed by their everyday life to stop their routine once a day at the same time and do something new and different. We all do something at or about the same time every day, and this is the best way to incorporate taking any medication into your daily routine. This can be a difficult task at first, and as difficult and burdensome as it may be, you may want to try the jelly bean tool—let's say for two weeks—to see if you can be adherent to your medication, before actually starting the real McCoy.

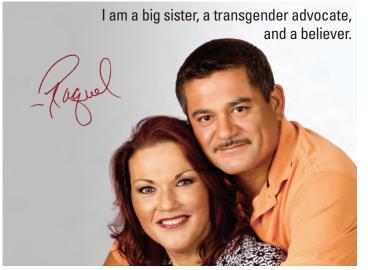
One of the main reasons many are adherent is because they are taking a once-a-day regimen in one pill, like Stribild or Complera; however, these pills are not one medication but three or four. Stribild is comprised of four separate medications, and Complera is made up of three. Further, these medications come from different classes of HIV drugs and if not taken as directed, daily and around the same time each day, one stands a chance of having their virus mutate, causing one or more of the medications to stop working for them.

There are many people living with HIV and other comorbidities like diabetes, cancer, or high blood pressure. Most of them are probably used to adhering to a daily routine to stay healthy by taking their medications on time, so they just add another pill to their existing regimen. However, diabetes doesn't mutate and HIV does. If a diabetic goes off their treatment they can usually restart their same medication.

Not true for HIV medications if you aren't adherent. When one stops taking the medication correctly, as prescribed (such as every day and with or without food), the HIV might begin to mutate, resistance mutations may develop, and these mutations will show up on a genotype test. Now the patient may need to take three, four, or perhaps five pills a day and believe me, this is much harder than a one-pill-a-day regimen. If possible consider trying the jelly bean trick for a couple of weeks and see how this works out before beginning HIV treatment. Once you know you're ready to start HIV medications and you can commit to being adherent, go for it.

We all do something at or about the same time every day, and this is the best way to incorporate taking any medication into your daily routine.

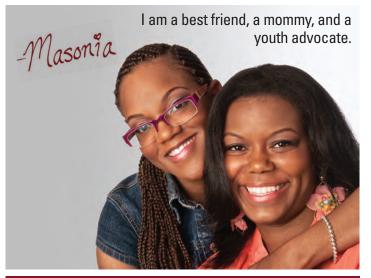
Let's stop HIV together."



Raquel has lived with HIV since 1992.



Jamar (left) has lived with HIV since 2006.



Masonia (right) has lived with HIV since 2010.



Chris (left) has lived with HIV since 2011.

More than one million people are living with HIV in the U.S.

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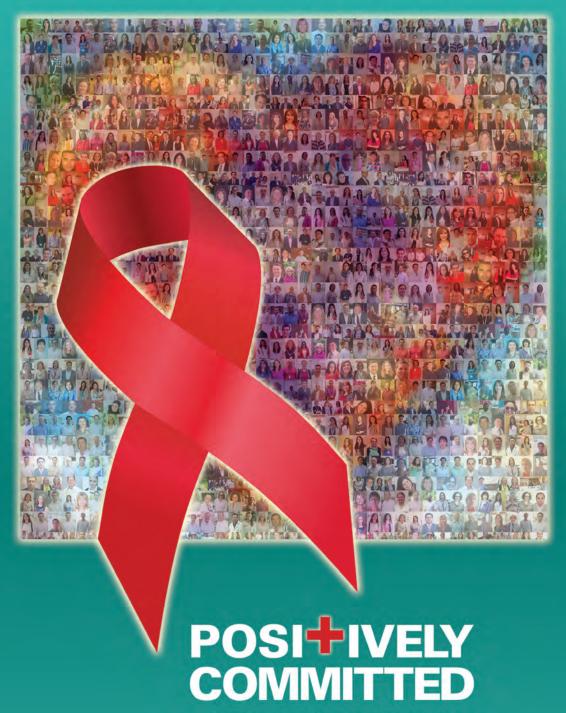












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