POSITIVELY AWARE
THE HIV TREATMENT JOURNAL OF TEST POSITIVE AWARE NETWORK
MAY+JUNE 2016

AIDSWATCH 2016

NEW PROBIOTICS STUDY

'MAGICAL THINKING' IN HIV

PLUS
CROI 2016 CONFERENCE UPDATE

STAYING IN THE GAME

OVERCOMING CHALLENGES TO CARE

BHUTTU MATTHEWS, 40, RUGBY PLAYER, AND HIV-POSITIVE SINCE 2004. HIS DEDICATION TO THE GAME HAS HELPED KEEP HIM IN CARE.

WHAT IS GENVOYA®?

GENVOYA is a 1-pill, once-a-day prescription medicine used to treat HIV-1 in people 12 years and older. It can either be used in people who are starting HIV-1 treatment and have never taken HIV-1 medicines before, or people who are replacing their current HIV-1 medicines and whose healthcare provider determines they meet certain requirements. These include having an undetectable viral load (less than 50 copies/mL) for 6 months or more on their current HIV-1 treatment. GENVOYA combines 4 medicines into 1 pill taken once a day with food. GENVOYA is a complete HIV-1 treatment and should not be used with other HIV-1 medicines.

GENVOYA does not cure HIV-1 or AIDS. To control HIV-1 infection and decrease HIV-related illnesses, you must keep taking GENVOYA. 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 GENVOYA?

GENVOYA may 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 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 and fatty. Symptoms of liver problems include your skin or the white part of your eyes turning 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, or have been taking GENVOYA for a long time. In some cases, lactic acidosis and serious liver problems have led to death. Call your healthcare provider right away if you have any symptoms of these conditions.
- **Worsening of hepatitis B (HBV) infection.** GENVOYA is not approved to treat HBV. If you have both HIV-1 and HBV and stop taking GENVOYA, your HBV may suddenly get worse. Do not stop taking GENVOYA without first talking to your healthcare provider, as they will need to monitor your health.

Who should not take GENVOYA?

Do not take GENVOYA if you take:

- **Certain prescription medicines for other conditions.** It is important to ask your healthcare provider or pharmacist about medicines that should not be taken with GENVOYA. Do not start a new medicine without telling your healthcare provider.
- **The herbal supplement** St. John's wort.
- **Any other medicines to treat HIV-1 infection.**

What are the other possible side effects of GENVOYA?

Serious side effects of GENVOYA may also include:

- **Changes in body fat,** which 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 GENVOYA.
- **Kidney problems, including kidney failure.** Your healthcare provider should do blood and urine tests to check your kidneys. If you develop new or worse kidney problems, they may tell you to stop taking GENVOYA.
- **Bone problems,** such as bone pain, softening, or thinning, which may lead to fractures. Your healthcare provider may do tests to check your bones.

The most common side effect of GENVOYA is nausea. 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 GENVOYA?

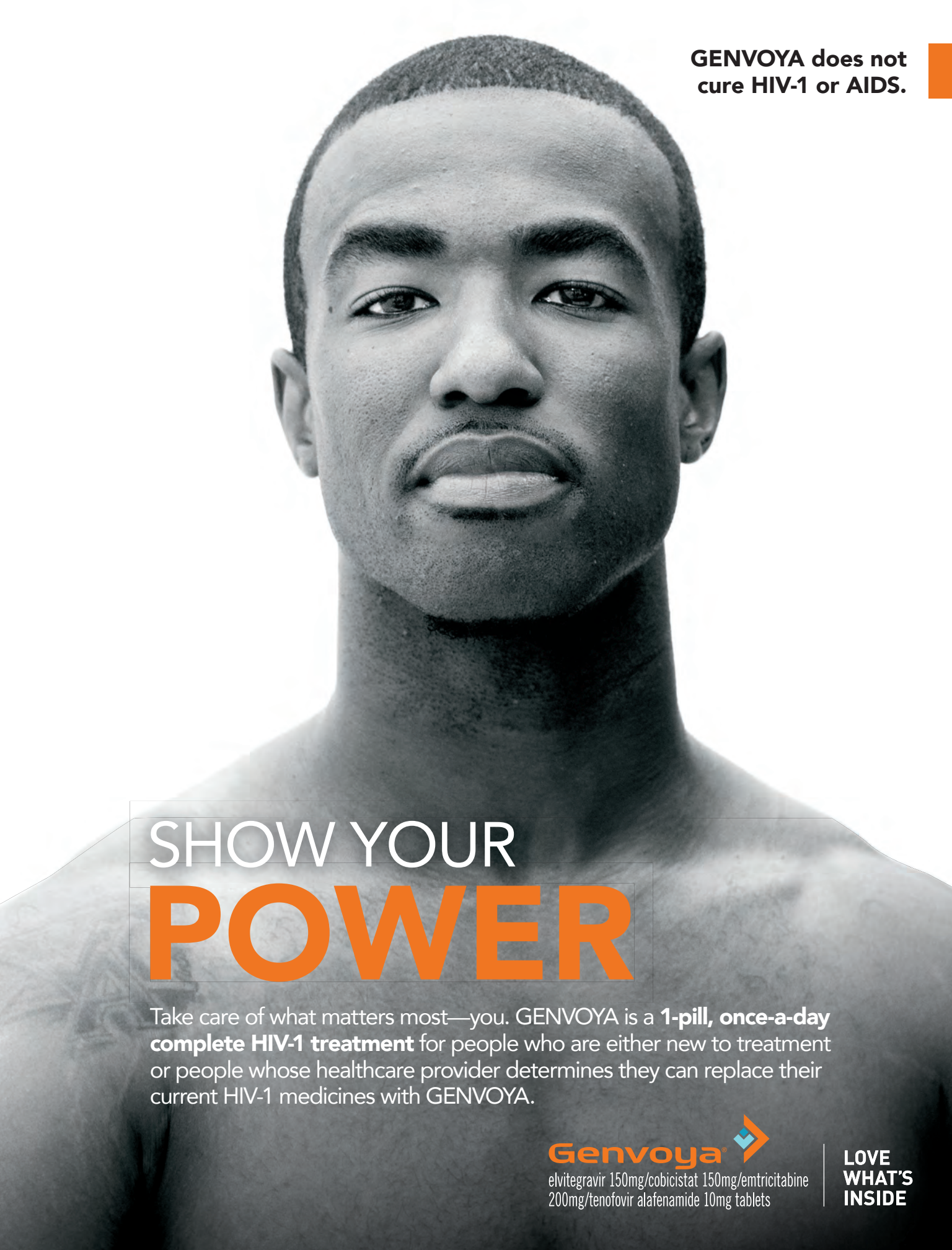
- **All your health problems.** Be sure to tell your healthcare provider if you have or have had any kidney, bone, or liver problems, including hepatitis virus infection.
- **All the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Other medicines may affect how GENVOYA works. Keep a list of all your medicines and show it to your healthcare provider and pharmacist. Ask your healthcare provider if it is safe to take GENVOYA with all of your other medicines.
- **If you take antacids.** Take antacids at least 2 hours before or after you take GENVOYA.
- **If you are pregnant** or plan to become pregnant. It is not known if GENVOYA can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking GENVOYA.
- **If you are breastfeeding** (nursing) or plan to breastfeed. Do not breastfeed. HIV-1 can be passed to the baby in breast milk.

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 Important Facts about GENVOYA including important warnings on the following page.

Ask your healthcare provider if GENVOYA is right for you, and visit GENVOYA.com to learn more.

GILEAD


GENVOYA does not cure HIV-1 or AIDS.
SHOW YOUR
POWER
Take care of what matters most—you. GENVOYA is a **1-pill, once-a-day complete HIV-1 treatment** for people who are either new to treatment or people whose healthcare provider determines they can replace their current HIV-1 medicines with GENVOYA.
Genvoya®
elvitegravir 150mg/cobicistat 150mg/emtricitabine 200mg/tenofovir alafenamide 10mg tablets
LOVE WHAT'S INSIDE

Genvoya®

elvitegravir 150mg/cobicistat 150mg/emtricitabine 200mg/tenofovir alafenamide 10mg tablets

(jen-VOY-uh)

IMPORTANT FACTS

This is only a brief summary of important information about GENVOYA and does not replace talking to your healthcare provider about your condition and your treatment.

MOST IMPORTANT INFORMATION ABOUT GENVOYA

Genvoya® may cause serious side effects, including:

- **Build-up of lactic acid in your blood (lactic acidosis),** which is a serious medical emergency that can lead to death. Call your healthcare provider right away if you have any of these symptoms: feeling very weak or tired, unusual 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.
- **Severe liver problems,** which in some cases can lead to death. Call your healthcare provider right away if you have any of these symptoms: 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.
- **Worsening of Hepatitis B (HBV) infection.** GENVOYA is not approved to treat HBV. If you have both HIV-1 and HBV, your HBV may suddenly get worse if you stop taking GENVOYA. Do not stop taking GENVOYA without first talking to your healthcare provider, as they will need to check your health regularly for several months.

You may be more likely to get lactic acidosis or severe liver problems if you are female, very overweight, or have been taking GENVOYA for a long time.

ABOUT GENVOYA

- GENVOYA is a prescription medicine used to treat HIV-1 in people 12 years of age and older who have never taken HIV-1 medicines before. GENVOYA can also be used to replace current HIV-1 medicines for some people 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 HIV-1 treatment, and whose healthcare provider determines that they meet certain other requirements.
- **GENVOYA does not cure HIV-1 or AIDS.** Ask your healthcare provider about how to prevent passing HIV-1 to others.

Do NOT take GENVOYA if you:

- Take a medicine that contains: alfuzosin (Uroxatral®), carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®, Tegretol-XR®, Teril®), cisapride (Propulsid®, Propulsid Quicksolv®), dihydroergotamine (D.H.E. 45®, Migranal®), ergotamine (Cafergot®, Migergot®, Ergostat®, Medihaler Ergotamine®, Wigraine®, Wigrettes®), lovastatin (Advicor®, Altoprev®, Mevacor®), methylergonovine (Ergotrate®, Methergine®), midazolam (when taken by mouth), phenobarbital (Luminal®), phenytoin (Dilantin®, Phenytek®), pimozide (Orap®), rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®), sildenafil when used for lung problems (Revatio®), simvastatin (Simcor®, Vytorin®, Zocor®), or triazolam (Halcion®).
- Take the herbal supplement St. John's wort.
- Take any other HIV-1 medicines at the same time.

POSSIBLE SIDE EFFECTS OF GENVOYA

GENVOYA can cause serious side effects, including:

- Those in the "Most Important Information About GENVOYA" section.
- Changes in body fat.
- Changes in your immune system.
- New or worse kidney problems, including kidney failure.
- Bone problems.

The most common side effect of GENVOYA is nausea.

These are not all the possible side effects of GENVOYA. Tell your healthcare provider right away if you have any new symptoms while taking GENVOYA.

Your healthcare provider will need to do tests to monitor your health before and during treatment with GENVOYA.

BEFORE TAKING GENVOYA

Tell your healthcare provider if you:

- Have or had any kidney, bone, or liver problems, including hepatitis infection.
- Have any other medical condition.
- Are pregnant or plan to become pregnant.
- Are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.

Tell your healthcare provider about all the medicines you take:

- Keep a list that includes all prescription and over-the-counter medicines, vitamins, and herbal supplements, and show it to your healthcare provider and pharmacist.
- Ask your healthcare provider or pharmacist about medicines that should not be taken with GENVOYA.

HOW TO TAKE GENVOYA

- GENVOYA is a complete one pill, once a day HIV-1 medicine.
- Take GENVOYA with food.

GET MORE INFORMATION

- This is only a brief summary of important information about GENVOYA. Talk to your healthcare provider or pharmacist to learn more.
- Go to GENVOYA.com or call 1-800-GILEAD-5
- If you need help paying for your medicine, visit GENVOYA.com for program information.

GILEAD

DRUG GUIDE CORRECTION

Your proofreader goofed! On page 46 of the March+April 2016 edition of Positively Aware, the Ziagen header incorrectly lists "tenofovir disoproxil fumarate" as the generic name instead of "abacavir." Thought you would want to know.

VICKIE ELIJAH, PHARM.D.

Editor Jeff Berry responds:

While POSITIVELY AWARE strives for accuracy, the generic name of Ziagen was misidentified in a heading in the 20th annual HIV Drug Guide. The generic name of Ziagen is abacavir sulfate. Also, the co-pay program for the drug Serostim covers up to $1,500 per prescription, with a lifetime maximum of 12 discounts; call (877) 714-AXIS (2947) for details. We regret the errors.

After the drug guide went to press, two new HIV medications were approved by the FDA, Descovy and Odefsey. Information about the new drugs can be found in Briefly on page 8.

PA'S BIGGEST COVER EVER.

THE BIG PICTURE

Thank you for the honor of having our members participate in the POSITIVELY AWARE cover photo [March+April, the 20th annual HIV Drug Guide]. About a dozen or so Being Alive members were able to participate in Louis Carr's wonderful photo shoot over three locations for PA's first-ever pullout cover. (Yeah, that's me in the teal dress shirt!) Thank you also to Rick Guasco for allowing us to participate. Everyone in the HIV field keeps this edition all year long as a reference guide. I know it was physically and emotionally demanding for some of our members, but you wouldn't know it from the photo. I love our Being Alive client members who are so engaged in their wellness.

GARRY GEORGE BOWIE
EXECUTIVE DIRECTOR
BEING ALIVE, LOS ANGELES

Bless you, Louis Carr, for taking such incredible pics for this magazine. You are one of my heroes! Love to all!

IRENE SODERBERG
WEST HOLLYWOOD, CALIFORNIA

Best cover! One of the issues I look forward to every year from any of the HIV mags.

@THOMASWIKJR
EAU CLAIRE, WISCONSIN

While at the dentist at Desert AIDS Project today, I went looking for the current POSITIVELY AWARE, and right there on the cover is my fabulous friend and chanteuse Irene Soderberg. I have known her since we both lived in Portland and she had red hair and I had, well, hair. What a great surprise! PA is very important to those who work in HIV/HCV prevention. Your drug guide is a go-to when talking to clients about meds.

SCOTT DAVIS
PALM SPRINGS

I need to get three copies of this issue, since my coworkers kept eyeing my 2015 one in my cubicle.

@JENNIETHAI
CHICAGO

KUDOS

Jeff Berry does a great, great job as editor of POSITIVELY AWARE. He's passionate, well informed, and knows how to make every issue both interesting and a learning experience. Huge kudos.

JIM O.
DETROIT

CONTINUED ON PAGE 6 >>

LET'S CONNECT

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All communications (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.

POSITIVELY AWARE

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MAY+JUNE 2016

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IN EVERY ISSUE

CONFERENCE UPDATE

ONLY ON POSITIVELYAWARE.COM

FEATURES

ON THE COVER AND ON THIS SPREAD
BHUTTU MATTHEWS, HIV-POSITIVE SINCE 2004. PHOTOGRAPHED BY JOHN GRESS.

LET'S CONNECT

>> CONTINUED FROM PAGE 3

REMEMBERING SPENCER COX

Just read the article about Spencer ["Spencer Cox: The Legacy of an Activist," March+April 2016]. I loved him so much. We met in '95 or '96, and even those first two days are memorable. He asked if he could borrow my blue velvet outfit (he borrowed the jacket). We both had artsy backgrounds, and he also probably felt sorry for me because when I first joined the ACTG community advisory group, I was really ignored or distanced from the "guys." He made sure I wasn't left totally alone. When he went back to school, I sent him a silly book bag and supplies like a kid. It is just heartbreaking to have lost such sweetness. I had spoken to him probably several months before he died, and now of course I wish I had been in touch constantly.

ALLEGRA CERMAK
ACTG COMMUNITY COORDINATOR

BLOCKING AWARENESS

I am an indigent inmate in the Arkansas Department of Corrections (ACD). Myself as well as others have tried to get your publication in the many units of the ADC, but have been denied. The reason for denial is as follows: "It is not the responsibility of the ADC to provide such publications," as well as "they promote homosexuality."

JASON D. STUMP
MARIANNA, ARKANSAS

GROWING AWARENESS

I recently had the opportunity to read your magazine via an inmate who is housed in the same unit as I am. I didn't even know that this magazine existed, let alone available to people such as myself who are living behind the fence, living positively *unaware*. The articles were very encouraging as well as informative. You have no idea how much of a difference your magazine can make in someone's life who is living positive in a place like this. Thank you for your great work.

JAMES WILSON
MALONE, FLORIDA

TALES FROM THE INSIDE

I'm an inmate living with hep C. I'm also an openly gay inmate. I was able to get my hands on a few of your magazines. It's good to know that you are out there supporting us living with HIV, AIDS, and hep C. I love the issues you are addressing in the LGBT community, and within the prisons. I'm a "legal aide" to my fellow inmates and I work within the medical dorms. Being openly gay, I come in contact with a lot of fellow inmates that open up more to me than others. Your magazine has given me a tool to help others as well as myself. The article "Tales from the Inside" [November+December 2015] by Chad Zawitz, MD, at Cook County Jail, was very inspiring to me as an inmate to step up and do more, and as a legal aide to reach out. I look forward to reading more of your magazine and using it to inspire and help others.

GARY D. NICHOLS
LA GRANGE, KENTUCKY

GET AND GIVE POSITIVELY AWARE.

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EDITOR'S NOTE

JEFF BERRY

Why care about the care continuum?

I have to be candid, whenever I'm sitting in a presentation and I hear the term HIV Treatment Cascade, my mind begins to wander and I start to think about waterfalls and TLC. Not the sexiest of terms, mind you, and the subject can tend to be a tad dry. But it's hugely important in the context of HIV medical care and ending the epidemic.

Just as there are five stages of grief (denial, anger, bargaining, depression, and acceptance), there are four or five stages along the HIV Treatment Cascade or HIV Care Continuum, depending on which model you use. The concept was first introduced in a 2011 paper by Dr. Edwin Gardner and colleagues, showing the five different stages of medical care that people living with HIV go through, from being diagnosed to achieving an undetectable viral load, and the percentage of people living with HIV in the U.S. that are engaged at each stage.

Why is this important? With around 50,000 new infections in the U.S. each year for the last decade or so, we need to understand why that figure has remained constant in order to reverse the trend. Understanding the HIV care continuum and applying it in real life situations helps us do that.

We now have simplified, one pill, once-a-day regimens for many people that have few or no side effects—shouldn't that be enough? Well it turns out, it's not. We can have the best medications available, but if people aren't using them or taking them every day as prescribed, then it doesn't really matter how good they are.

Once a person is diagnosed as HIV-positive, getting them referred into care, and keeping them there, has proven to be a big challenge. According to the latest data from the CDC, of the 1.2 million people living with HIV in the U.S. in 2011, 40 percent were engaged in HIV medical care, 37 percent were prescribed ART, and 30 percent had achieved viral suppression. In other words, only 3 out of 10 people living with HIV had their virus under control.

Now that we've heard these numbers repeatedly the last few years and they've been sufficiently drummed into our heads, a recent study suggests that we've actually been overestimating the number of people living with HIV in the U.S. (more like 820,000), and underestimating those who are in care (72 percent), on treatment (68 percent), and virally suppressed (55 percent). Whatever the exact numbers are, it's clear we still have work to do.

This issue of POSITIVELY AWARE looks at one point along the care continuum, engagement in care (also known as linkage to and retention in care). Chris Nguyen, PharmD, looks at what some people are saying about what's keeping them from accessing their health care; Kathleen Jacobs-McLoyd, RN, BSN, discusses several success stories at one clinic in Chicago; and Drew Gibson tells a fascinating story, "magical thinking in HIV," and how unrealistic thoughts keep some people with HIV away from medical care in the first place.

As I write this, I feel the need to acknowledge the fact that I have come from a place of privilege, in that I have had unfettered access to quality health care my entire life. That didn't stop me from getting HIV, but it certainly played a crucial role in my survival, and provided me with options that many others may not get, such as the ability to choose a preferred care provider. That is just not the reality for many people living with HIV who may be living in poverty, or are disenfranchised from the medical establishment, or who lack the ability to access culturally competent care.

The Affordable Care Act (ACA) ensured that one can no longer be denied medical coverage due to a pre-existing condition, which has allowed millions to get insurance who previously had none; but spiraling costs, escalating premiums, and tiered formularies are just some of the many barriers that have popped up since the ACA was enacted, and have become the new pre-existing conditions. We need to work to ensure that everyone has the same access to quality, affordable health care, to one day hopefully eliminate the cascade, and transform it into the HIV treatment plateau.

Take care of yourself, and each other.

We now have simplified, one pill, once-a-day regimens for many people that have few or no side effects—shouldn't that be enough? Well it turns out, it's not. We can have the best medications available, but if people aren't using them or taking them every day as prescribed, then it doesn't really matter how good they are.

@PAeditor

PHOTO: CHRIS KNIGHT

BRIEFLY

ENID VÁZQUEZ @ENIDVAZQUEZPA

Two new TAF-based meds approved

The FDA has recently approved two new HIV meds that contain TAF instead of TDF, reboots of Truvada and Complera.

For many years, TDF (tenofovir disoproxil fumarate) has been the most commonly used background drug in combination HIV therapy. TAF (tenofovir alafenamide), however, lessens the risk of kidney and bone toxicities seen with TDF.

Although TDF is available under the brand name Viread, it is most often taken as Truvada (emtricitabine/TDF, or FTC/TDF) or in various single-tablet regimens (STRs): Atripla, Complera, and Stribild.

The first HIV medication containing TAF to receive FDA approval was Genvoya, an STR, in November 2015. It is a new version of Stribild, switching out the TDF for TAF. A future medication with TAF that's anticipated is the first STR to contain a protease inhibitor drug, Prezista, in combination with cobicistat.

The new TAF formulations represent a shift in HIV therapy.

From TDF to TAF

TDF and TAF are actually prodrugs of tenofovir. A prodrug is a medication that becomes metabolized (processed in the body) into the active drug, in this case, tenofovir. Given by itself orally, tenofovir does not get properly absorbed by the body. Hence the need for a prodrug to ensure that tenofovir is effective.

TAF is easier on the kidneys and bones thanks to lower blood levels. Since tenofovir is eliminated through the kidneys, it creates a potential for renal toxicity. TAF was created to reduce the toxicity that TDF can have on the kidneys and bones. TAF allows for 90% less serum concentration of tenofovir compared to TDF; thus, there is less tenofovir to eliminate through the kidneys. The fact that the TAF dose is less than 10% of the TDF dose is also why pills containing TAF are smaller than their TDF-containing counterparts.

At the same time, there is more tenofovir in the target cells where it's needed, in the PBMCs (peripheral blood mononuclear cells, which include lymphocytes, monocytes, and macrophages).

This is also why there's a smaller TAF dose used than there is for TDF, 10 mg or 25 mg, compared to the 300 mg of TDF used in treatment. The 10 mg is used in several boosted single-tablet regimens (such as Genvoya and Stribild) and the 25 mg is used in the STR Odefsey and fixed-dose combination of Descovy, approved for use in both boosted and unboosted regimens (see "Descovy" below).

Descovy

On April 4, the FDA approved the new TAF version of Truvada, Descovy. Descovy (F/TAF) contains 200 mg of FTC and 25 mg of TAF. It can be taken by pediatric patients age 12 and older, and patients with moderate kidney disease (a creatinine clearance down to 30). Thanks to advocacy efforts of the Fair Pricing Coalition (FPC) Descovy is priced identical to Truvada, with a Wholesale Acquisition Cost (WAC) of $1,466 per month, or $17,841.69 per year (for 365 days). Initially it was thought that two different versions of F/TAF would be needed, one containing 10 mg TAF for boosted regimens and a 25 mg version for unboosted, but both Gilead and FDA saw value in simplification, and in studies using 25 mg TAF in those on boosted regimens, drug exposure was within acceptable ranges, efficacy was similar to 10 mg, and no safety signals (signs of toxicity) were seen. The Gilead Advancing Access program will cover Descovy the same as Truvada. Although Truvada has an FDA indication for HIV prevention, the new TAF version does not. Descovy should not be used for PrEP (pre-exposure prophylaxis) until research is done proving its effectiveness for prevention.

Go to positivelyaware.com/descovy for more information.

Odefsey

The new TAF version of Complera, Odefsey, was FDA approved on March 1. Complera and Odefsey are STRs. Odefsey contains the same medications as Complera but switches out the TDF for TAF. Odefsey is the second STR approved for patients with moderate kidney disease, down to a creatinine clearance of 30. (Genvoya was the first.) It is also the third STR, following Genvoya and Complera, that's approved for children age 12 and up—it's also the smallest STR pill. Of note, children's bones are still developing, so the TAF formulation may be especially useful vs. TDF. Odefsey has a switch indication—it can be taken by people switching from another regimen as long as they have had undetectable viral load (less than 50 copies) for at least six months prior to going on Odefsey, and no evidence of viral resistance to the medications in Odefsey. Like Complera, Odefsey should not be taken by people with less than 200 T-cells or more than 100,000 viral load. Besides FTC/TAF (both from Gilead Sciences), Odefsey (like Complera) contains rilpivirine, from Janssen Pharmaceuticals.

Go to positivelyaware.com/odefsey for more information.

NEW HEP C DRUG, ZEPATIER

On January 29, the FDA approved a new drug for the treatment of hepatitis C virus (HCV), Zepatier, specifically for genotypes 1 and 4. Zepatier consists of two medications, elbasvir and grazoprevir. A drug resistance test is recommended before taking Zepatier. Zepatier can be taken by patients on hemodialysis. Some patients may need to take it with ribavirin. See the POSITIVELY AWARE/Project Inform Hepatitis C Drug Guide online (July+August 2015).

DESCOVY AND ODEFSEY (SHOWN NOT TO ACTUAL SIZE) COURTESY OF GILEAD

TREATMENT RECOMMENDED FOR RECENTLY INFECTED

In January, U.S. HIV treatment guidelines strengthened their recommendation that all patients living with the virus be offered antiviral medication no matter what their CD4 T-cell count and added the words "including those with early HIV infection." The recommendation now has the highest grade possible, A1. It's based on two large studies (START and TEMPRANO) showing a 50% drop in death and illness for people who start treatment when they have more than 500 T-cells.

Although the studies did not include adolescents, the guidelines have extended the recommendation to this group "based on the expectation that they will derive benefits from early ART [antiretroviral therapy] similar to those observed in adults." The guidelines section on older adults "emphasizes that ART is especially important for older patients because they have a greater risk of serious non-AIDS complications and potentially a blunted immunologic response to ART." Go to aidsinfo.nih.gov.

STRIBILD LABEL UPDATE

On March 1, the FDA added a new drug interaction to the Stribild drug label. People taking the medication Seroquel (quetiapine) should consider taking other HIV therapy instead of Stribild. If taking both medications is considered necessary, the Seroquel dose should be reduced to one-sixth of its current dose to avoid increases in its exposure in the blood. It should be monitored for adverse reactions; see recommendations for monitoring on the Seroquel drug label. Seroquel is an antipsychotic medication used for the treatment of depression, schizophrenia, and bipolar disorder.

TWO-DRUG TREATMENT STUDIED

The AIDS Clinical Trials Group (ACTG) is looking to see if two drugs for treating HIV can be as good as three in treatment-naïve individuals. ACTG A5353 provides Tivicay (dolutegravir), a potent but tolerable HIV medication on the market, with Epivir (lamivudine). "Since some HIV medicines have side effects and are costly, there is interest in whether HIV can be successfully controlled with fewer than three HIV drugs," the group says on its website. The 28 sites participating in the study include clinics in Chicago, Los Angeles, New York City, San Francisco, and Puerto Rico. ACTG is also looking at switching people whose virus is suppressed on treatment to the simplified Tivicay + Epivir regimen. Go to actgnetwork.org.

COMPLERA NOW FOR PEDIATRICS

On March 1, the FDA approved the use of Complera, a single-tablet regimen, for use by pediatric patients ages 12 and up weighing at least 77 pounds. In a study of 36 children, however, depressive disorders were seen in 19.4% of them (seven of the 36), with one experiencing suicidal ideation and suicide attempt. Go to positivelyaware.com/complera for more information about the medication..

PEDIATRIC GUIDELINES RECOMMEND HIV TREATMENT FOR ALL CHILDREN

U.S. pediatric HIV treatment guidelines updated March 1 now recommend therapy for all children with HIV regardless of clinical symptoms, viral load, or CD4 T-cell count. "The strength of the Panel's recommendations varies by age and pretreatment CD4 cell count due to fewer available pediatric data regarding benefits and risks of therapy in asymptomatic HIV-infected children than in adults," the guidelines noted.

HIV medications now recommended as preferred for children include Norvir-boosted Prezista for ages 3 and up; Isentress for ages 2 to 12; and Genvoya and Tivicay for those age 12 and older.

The guidelines now use sexual maturity rating (SMR) rather than Tanner staging for determining treatment dosing in adolescents. More information has been added about the timing and selection of HIV therapy, adherence, and sexually transmitted infections in adolescents. There is also "additional guidance … to improve retention in care and minimize the risk of interruptions to ART [antiretroviral therapy]" during a transition from pediatric to adult health care settings. There is also more information about potential medication toxicities as well as drug-by-drug updates. The recommendation to use fourth-generation HIV tests in pregnancy has been strengthened. Read about all these and other updates at aidsinfo.nih.gov.

PHOTO: ISTOCKPHOTO

TRUVADA NOW FOR PEDIATRICS AT LEAST 37 POUNDS

The FDA in March updated the Truvada drug label to add pediatric patients weighing at least 37 lbs (17 kg) who are able to swallow a whole tablet. Also, Truvada (emtricitabine/tenofovir disoproxil fumarate, or FTC/TDF) now has three new pills available: 100 mg FTC/150 mg TDF; 133/200 mg; and 167/250 mg. Full-strength Truvada is 200/300 mg. In studies, pediatric patients experienced adverse reactions similar to those seen in adults, including kidney toxicity (reactions consistent with proximal renal tubulopathy) and decreases in bone density. See the drug label for more information.

BRIEFLY

ANTI-CRIMINALIZATION AND ADVOCACY TRAINING

HIV is Not a Crime II Training Academy will be held May 17–20, 2016 at the University of Alabama in Huntsville. The Training Academy consists of three days of workshops, state advocacy, grassroots organizing, criminalization reform messaging, and familiarity with the related legal, medical, media, and public health issues. Attendees include advocates living with HIV, community organizers, activists, and experts in public health, law, and public policy from across the country. The conference will unite and train advocates living with HIV and allies from across the country on laws criminalizing people living with and vulnerable to HIV and on strategies and best practices for repealing such laws. For more information go to hivisnotacrime.com.

SURVEY TARGETS OBTACLES TO WOMEN STAYING IN CARE

Poverty and transportation are two of the biggest hurdles HIV-positive women face in staying connected to care, according to a survey of 180 women by the Positive Women's Network-USA (PWN-USA). To learn more about the survey's results, go to pwnusa.wordpress.com.

ENGLAND'S NHS BACKS DOWN ON PREP

In March, England's National Health Service announced that it would fund "early implementer test sites" for two years covering Truvada PrEP (pre-exposure prophylaxis). Advocates criticized the agency's move away from a plan to provide the prevention pill on a much broader basis. The Terrence Higgins Trust issued a statement in which CEO Ian Green says, "By denying full availability of PrEP we are failing those who are at risk of HIV."

POZ CRUISE SETS SAIL OCTOBER 29

"There are 300 friends you haven't met yet, and they are sailing every year on the HIV Cruise Retreat," says a postcard for the 12th Annual Poz Cruise. "There is simply something powerful about having a thrilling vacation where your HIV status is not an issue. We draw support from each other." Cost starts at $629 plus $115 port tax. This year's cruise sails round-trip from Fort Lauderdale to Grand Turk, La Romana, Aruba, and Curacao, returning November 6. For more information, go to hivcruise.com.

LONG-TERM SURVIVORS SUMMIT SET FOR PHILLY

The Reunion Project heads to Philadelphia on Saturday, May 14, 2016.

This daylong summit at the William Way LGBT Community Center will bring together HIV long-term survivors to reconnect and share their experiences, while learning practical information about HIV and aging and long-term survival. For more information go to tpan.com/reunion-project, or email publications@tpan.com.

A POEM A DAY ABOUT HIV

I have seen the fire
Destroying everything
in its path
In its blazing wrath
—From *1996*,
by James Savik

HIV-positive poet Michael Broder created the online project "HIV Here & Now," posting a poem a day for one year leading up to the 35th anniversary of the first U.S. report on the epidemic (June 5), when the virus did not even have a name. Go to hivhereandnow.com.

GREG LOUGANIS GETS OWN BOX OF WHEATIES

Congratulations to Olympic Gold Medalist Greg Louganis on finally getting his image on a Wheaties box. On April 5, Louganis Tweeted, "Officially been welcomed into the Orange Box Club!" He told the *New York Times* he believed it was most likely homophobia that slowed down the honor of gracing the Breakfast of Champions for decades after his four Olympic gold medal wins in 1984 and 1988. He came out as gay in 1994 and a year later, his autobiography revealed that he was also living with HIV. Ever graceful, he was quoted as saying, "The times have changed so drastically and so fast," and praised two other Gold Medalists belatedly appearing on the cover of their own Wheaties box in a new "legends series." The honor came after an HBO documentary last year, *Back on Board: Greg Louganis* (nominated for a Sports Emmy Award, also in April), followed by a petition drive with 40,000 signatures asking that his photo be put on a Wheaties box. The boxes are expected to be available in stores from May through at least the end of summer. (Gosh, will General Mills be able to make enough for the demand?!)

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WHAT PEOPLE LIVING WITH HIV SAY ABOUT NOT COMING IN FOR HEALTH CARE

A CLINICIAN TALKS ABOUT LINKAGE AND RETENTION IN CARE

BY CHRISTOPHER M. NGUYEN, PharmD

HERE IN NEW YORK, only 66% of those living with HIV are linked to care and 57% are retained in care, according to the 2013 New York State HIV Care Continuum (or Treatment Cascade). The cascade also shows that only about half of people living with HIV in New York achieve viral loads less than 200.

We are all aware of the benefits of being on ART (antiretroviral therapy), and that persistent viremia (having detectable viral loads) can cause ongoing inflammation leading to negative consequences such as cardiovascular disease, yet many patients are not engaged in care and their virus controlled on medications.

Furthermore, not being on treatment and achieving undetectable viral load also increases the risk of transmitting HIV. In 2015, the CDC published a study estimating the number of HIV infections from people at each level of the Care Continuum in the U.S. According to the study, more than 90% of new infections in 2009 were attributable to people living with HIV who were not in medical care.

That means 9 out of 10 new infections could've been prevented by getting people tested and diagnosed early, linking and retaining them in care, and helping them achieve virologic suppression through ART.

So why are people lost to care? A number of individuals are never connected to care in the first place after an initial HIV diagnosis. Regular testing and early diagnosis are great, but

ILLUSTRATION: ISTOCKPHOTO/ HILCH

90%
OF NEW INFECTIONS IN 2009 WERE ATTRIBUTABLE TO PEOPLE LIVING WITH HIV WHO WERE NOT IN MEDICAL CARE.

it isn't very useful if nothing is done about it afterwards.

Some people who use home HIV testing kits may be reluctant to seek medical care after diagnosis due to stigma or fear. Others who test positive don't seek care because they feel healthy and don't want to get on meds, even though the current recommendation is to treat everyone regardless of CD4 count, the earlier the better.

THE VIEW FROM ONE CENTER

HERE AT Gay Men's Health Crisis (GMHC) where I practice, when an individual is diagnosed with HIV at our testing center, he/she is physically walked over by a staff member to a clinic to be connected immediately to care.

Once linked to care and put on ART, a number of individuals are not retained and engaged in care. According to studies, some demographic and clinical factors associated with missing clinic appointments include race (African American), younger age, low income, less education, lack of insurance, injection drug use, psychiatric issues, detectable viral loads, high CD4 counts, and CD4 counts less than 200 (AIDS diagnosis).

Sometimes when people don't feel sick they don't seek regular medical attention. But on the other hand, those that feel too sick may not have the energy to attend a medical appointment.

Patients have also identified social and cultural factors which cause them to miss appointments, including lack of child care, conflicting work schedule or social appointments, lack of transportation, family illness, stigma, fear, and cultural beliefs. Then there are those that simply forget. Some of my patients miss appointments because they live too far away from the clinic, yet others choose to travel long distances to see specific providers. Other common reasons that I see in my patients include being too sick, lack of transportation (or not enough money for public transit), forgetfulness, hindrance by bad weather, and simply because they didn't want to see the provider. I had a patient who disappeared for months, whom I later found out was incarcerated. This individual subsequently came back to see me after release.

IMPROVING RETENTION

WHAT CAN WE DO to improve retention? First, we have to truly understand the reasons why someone would miss appointments or is lost to care, especially the socio-cultural factors, and come up with individualized solutions. There have been different interventions used to help improve retention, such as appointment reminders, HIV education, social work and case management, verifying and updating the patient's contact information at each visit, and providing services for mental health, nutrition, housing, and substance abuse treatment. A multipronged approach seems to be the most effective, addressing different aspects of a person's daily life.

Here at GMHC, clients have access to a variety of supportive service programs such as care coordination, mental health support, food and nutrition, case management, advocacy, employment and legal services, and complementary wellness services such as massage and acupuncture.

Keeping those living with HIV in ongoing care can be a difficult process, but it should be a priority. Sometimes it is as easy as providing a subway pass to help patients keep their appointment. But oftentimes it really does take a village working together to keep someone engaged. Successful retention will result in improved HIV-related clinical outcomes, reduce the risk of treatment failure, and improve the relationship between patients and providers. PA

CHRISTOPHER M. NGUYEN, PharmD, AAHIVP is an HIV and hepatitis C specialty pharmacist for Walgreens/Duane Reade in New York City and currently provides care at Gay Men's Health Crisis. He works directly with clients on HIV-related issues such as adherence and medication management, and provides consults for local practitioners on drug interactions, dosing adjustments, and HIV and HCV regimen selection in co-infected patients. Dr. Nguyen served as the pharmacist for this year's POSITIVELY AWARE Annual HIV Drug Guide (March+April).

A SUCCESS STORY IN HIV LINKAGE TO CARE AND RETENTION

HOW HEALTH CARE NAVIGATORS LINK PEOPLE INTO CARE AT ONE CLINIC

BY KATHLEEN JACOBS-McLOYD, RN, BSN

HOW IMPORTANT IS LINKAGE AND RETENTION to primary medical care? What are the barriers that might prevent people to be linked and retained in care?

There are many barriers, and the solutions to these have to be numerous as well.

Barriers to care and retention have been identified as transportation problems, mental health issues, chemical dependency, homelessness, stigma, and lack of insurance, as well as many more. According to the CDC, "Improving the health of persons with HIV and reducing the number of new infections in the United States will depend on increasing access to HIV medical care and eliminating disparities in the quality of care received."

Offering services to help promote linkage and retention in care necessitates the partnerships of the entire care team. This includes medical providers, medical case managers, nursing, mental health, peer educators, benefits counselors, patient navigators, and others. Ideally, all new patients should receive appointments between one and two weeks after diagnosis in order to benefit from effective antiretroviral therapy (ART). Poor health outcomes for clients in our clinic are most often associated with late engagement into care as well as sporadic attendance at clinic appointments; in other words, those who are not rapidly engaged in care or who fall out of care after the first few months.

HELPING PATIENTS

HOW CAN WE as clinicians help our patients? At the CORE Center in Chicago our Ryan White Part A Early Intervention Services (EIS) Patient Navigators work diligently to link new patients into care, and conduct outreach for the purpose of re-engaging those individuals who have fallen out of care. We have helped patients navigate their system of care, while working very closely with the team. We have identified those barriers that could prevent patients from adhering to their clinic appointments. To date, problems with transportation remain the number one cause that prevents patients from coming to their appointments. Luckily, we are able to circumvent this as a barrier by providing transportation when needed.

How useful are well-being checks? What we found over the years was that our patients greatly appreciated having someone calling for the first few weeks to make sure that they were okay. How could well-being checks relate to overall better health outcomes? This little piece of care can sometimes be forgotten during the course of one's busy day. Our Linkage and

PHOTO: ISTOCKPHOTO/HILCH

IDEALLY, ALL NEW PATIENTS

SHOULD RECEIVE APPOINTMENTS BETWEEN ONE AND TWO WEEKS AFTER DIAGNOSIS IN ORDER TO BENEFIT FROM EFFECTIVE ANTIRETROVIRAL THERAPY.

Retention program recognized that well-being checks help to foster health and emotional well-being. It was equally as important as the need to educate or provide health literacy.

We've incorporated this approach as part of our daily routine, because we feel that overall it can increase appointment adherence and decrease the risk for noncompliance, and most importantly, helps with communication and promotes trust between the navigators and the patients.

Our Linkage and Retention program has had many successes with patients who are newly diagnosed and linked into care, reengaged, retained, or lost to care. The following patients are just two that we continue to monitor and support through the continuum of care.

A 52-YEAR-OLD AFRICAN AMERICAN MALE came to us in the fall of 2015 with multiple co-morbidities such as diabetes, blindness, hypertension, and a history of strokes. Due to his blindness, transportation was a huge barrier, as he couldn't rely on the services of others all the time. Our patient navigator provided cabs to and from his home for the appointments. A family member met him at home after he was seen. Over the course of time, the navigator was able to establish a relationship with the patient, and met him at the door each time he had a scheduled appointment. Follow-up well-being calls were made weekly for the first month. The navigator and the patient have now established a professional friendship which both hope will continue. Because of the face-to-face meetings and numerous well-being phone calls, the patient has been adherent to both clinical appointments and appointments to specialty clinics. To date, the patient remains undetectable (viral load less than 40 copies/mL), and his CD4 count remains over 1,000. His insurance is stable, he has a case manager in place, and now has a family member who brings him to the clinic. Whenever he is at the clinic, he asks to see his "special person," his navigator.

A 43-YEAR-OLD HISPANIC MALE met one of our navigators in the fall of 2015. This patient was an "old/new" who had returned after falling out of care for some time. When the navigator met him he was in a wheelchair due to the increased swelling of his lower extremities. He was diagnosed with Kaposi sarcoma (KS), unable to walk, drank a lot of alcohol, lived in a basement apartment, and basically had no help from family or friends. Our team quickly surrounded him, as he had some suicidal ideations. Our navigator immediately helped him through the system of care, which included his adherence to all appointments (including chemotherapy) and specialty clinics. Transportation was an issue because the patient could not walk. We provided him with cabs to his appointments, and an arrangement was made to have a friend help him in and out of the cab. There was a long and slow process to help him reverse the swelling in his legs and understand the need for medication adherence, along with addressing other issues. To date, the patient is in remission, he is able to walk to the bus to get to the clinic, has a part-time job, and has been attending his AA meetings. Our patient has been adherent to all clinical appointments thus far. His viral load is undetectable (less than 40 copies/mL) and his CD4 count is stable at 325. The patient has expressed his deep gratitude for the continued well-being checks and his navigator's involvement in his care.

These are just two of our success stories at the CORE Center. I can't stress enough the importance of navigators in the role of linkage and retention. As a medical team, we all must help support long-term retention across the continuum of care. If we hope to see a cure of HIV one day, we must all play a vital role in linkage and retention. PA

KATHLEEN JACOBS-McLOYD, RN, BSN, is presently working as the Linkage and Retention Project Coordinator at the Ruth M. Rothstein CORE Center in Chicago. Her past nursing experience includes 21 years at Children's Memorial Hospital working in the Pediatric Hematology/Oncology department. Kathleen wanted to expand her nursing career interest and decided to leave Children's and work primarily in the field of HIV/AIDS. She was hired at the RMR CORE Center in 2000 and began her journey in this specialty to her current position. She has worked in the community, given presentations, and worked on research demonstration projects. She is passionate about the work that she is doing both as a nurse and as a project coordinator.

MAGICAL THINKING IN HIV: MUCH MORE THAN DENIAL

HOW UNREALISTIC THOUGHTS KEEP PEOPLE AWAY FROM MEDICAL CARE

BY DREW GIBSON

TWO BARS. There have never been two bars before in the 200 or so HIV tests I had previously given.

About half an hour after an oral swab is taken, one red bar will show up, meaning the person tested negative for HIV. I tell people that they should get tested again in three months to make sure, since the test might not be able to pick up enough HIV antibodies to test positive if the patient contracted the virus in the last 90 days.

But this time there were two bars, meaning that there was a 99.98% chance that the person was HIV-positive based on this particular test.

As I walked to the curtained-off room in the ER where the patient was sitting, my mind played out possible reactions. Crying was fine. I could respond to crying and, hopefully, that flood of emotion would be coupled with acceptance of his HIV status and a willingness to get into medical care. Anger and denial were more negative responses, but I had been trained to deal with them. The concern wasn't that the patient would lash out, but that he might bolt out of the ER and away from care.

I didn't get any of the reactions I expected. Instead of tears or rage or disbelief, the young man responded nonchalantly, with a hint of disappointment. It was as if he had just lost $10 playing scratch-off lottery tickets at the gas station.

My supervisor, who had joined me when I delivered the results, asked the young man, who had already slung his backpack over his shoulder, if he had ever tested positive for HIV before. He said that he had—a couple of times. When I asked him why he had told us during our initial discussion that he had not previously tested positive, he answered, quite correctly, that it was because we wouldn't have given him the test if he told us that he had.

I was thoroughly confused. *Why*, I thought, *would a young man who had already been told on multiple occasions that he was HIV-positive go through all the trouble of hiding his status from us in order to take another HIV test when he knew what the results would be?*

My supervisor, however, had no trouble understanding the motivations behind the patient's actions. He had been living well with HIV for more than a decade and when first diagnosed, had done much the same thing this young man just did.

"He was probably just checking to see if it had gone away," my supervisor told me. "It happens more than you might think. When you're having trouble accepting the fact that you have HIV, your thoughts can take you all kinds of places. You go long enough after being diagnosed without any major problems and get to thinking that maybe you don't have what they say you have. Maybe the test was a false positive or your body got rid of the virus somehow. You can make yourself believe a lot of things when you don't want to have HIV."

THAT AFTERNOON, four years ago, was my first introduction to the power of magical thinking in HIV, and the ways it can disrupt the best laid plans to link people who are HIV-positive to medical care.

As the name suggests, magical thinking embraces objectively irrational or fantastic beliefs reinforcing the idea that the rules

PHOTO: ISTOCKPHOTO

'It happens more than you might think. When you're having trouble accepting the fact that you have HIV, your thoughts can take you all kinds of places.'

and scientific facts governing empirically validated experiences do not apply to one's self or, in some cases, to a loved one.

While HIV magical thinking is a form of denial, it is more complex than simply refusing to acknowledge a positive HIV test result. Those who refuse to accept the fact that they are HIV-positive are unlikely to engage with HIV health care providers after receiving their diagnosis, but people who get caught up in magical thinking appear at all stages along the continuum of care.

IN THE CASE of this young man, his magical thinking manifested itself in the belief—or perhaps the faint hope—that the HIV detected on multiple occasions would have somehow gone away between his last test and the one I gave him. >>

Without solid HIV outreach, post-test counseling, and linkage to care, it's not hard to see why tens of thousands of people get diagnosed and then vanish.

At first glance, it might seem as if the testing encounter was a waste of resources. However, the test we performed wasn't so much about the results as it was about giving us another opportunity to connect with someone who was on the edge of becoming willing to engage in care.

In fact, before he left the emergency room that day, my supervisor was able to schedule an appointment for him with an infectious disease doctor on the following day. I couldn't tell you if that young man ever showed up for that appointment or if he's in care now, but I can say that the encounter we had probably caused him to at least consider reevaluating his thinking around his HIV diagnosis and provided him with some tools with which to do so.

HIV-RELATED MAGICAL THINKING can be as prevalent among those who have been in care and on antiretroviral therapy as it is among those who choose not to seek help. The number of people who have been diagnosed with HIV, linked to medical care, and then lost to care is very similar to the number of people who were diagnosed but never linked, with each group representing roughly 1 out of every 5 HIV-positive people in the U.S., according to the CDC.

What this suggests is that it is just as hard, if not harder, to retain someone in HIV care as it is to get them connected to care in the first place. And, while there is a plethora of reasons why an HIV-positive person might be lost to care, I believe that one of the biggest reasons is this sort of magical thinking.

The most notable and bizarre public manifestation of HIV-positive magical thinking in recent years happened in January when actor Charlie Sheen followed up his public announcement that he was positive by going on *The Dr. Oz Show* and revealing that he had stopped taking his antiretroviral medication in favor of seeing a discredited doctor in Mexico. The doctor claimed to be able to cure HIV with goat milk and, allegedly, injected himself with Sheen's blood in front of him.

The combination of Sheen's celebrity, money, and history of mental health and substance abuse issues may have made his version of magical thinking more sensationalistic than most, but the impetus for his actions and his perception of risk probably weren't much different from that of thousands of HIV-positive people in the U.S. who think their way out of care each year.

I HAVE KNOWN PEOPLE living with HIV who were doing well, were adhering to their antiretroviral therapy, were virally suppressed and who then, for all intents and purposes, dropped off the face of the earth. And, a few months or a few years later, when I finally saw those people again, I found myself talking with someone who was sick, but refused to acknowledge it. They railed against Atripla and Truvada and Stribild as "poison" while telling me about the great new herbal therapies they were on. They said that they were cured or that the HIV test they took way back when was defective and that they had been HIV-negative all along. Others were in a serodiscordant relationship but had condomless sex with their partner because they were convinced that you couldn't contract the virus by sleeping with someone you truly loved.

All of these are examples of magical thinking. The reasons for the ubiquitousness of this sort of thinking are many and varied, but, ultimately, the simplest explanation for it is the fact that we're human.

UNTIL THERE IS A CURE for this virus, there aren't enough pharmacological advances in the world to alter the reality that living with HIV is hard. HIV is a chronic disease that takes a toll on both the mind and the body. Without a sound support network and a good relationship with an HIV service provider, it is all too easy for someone to drop out of touch and out of care.

Without solid HIV outreach, post-test counseling, and linkage to care, it's not hard to see why tens of thousands of people get diagnosed and then vanish. As it is with most things that cause us pain and distress, many of us would rather exhaust every illogical rationale and supposed silver bullet cure (denial and magical thinking) than accept not just a diagnosis, but the hard reality of the decisions that must be made in order to take care of ourselves once a diagnosis is accepted as being true.

AT PRESENT, two-thirds of HIV-positive individuals in the U.S. who have been diagnosed are currently not in care and, out of that two-thirds, I'm guessing that there is a sizable subgroup of people whose failure to get into and remain in care can be traced back, in part or in whole, to magical thinking.

Thus, the question arises: how do we go about eliminating these harmful thoughts and replace them with thinking patterns that promote consistent engagement with HIV service providers and healthy mechanisms to cope with the day-to-day realities of being positive?

There is no easy answer, but each and every time HIV providers have contact with someone who is positive, they have an opportunity to provide them with support and the reassurance that, regardless of where the person is at, they are willing to meet them there.

Should, as was the case with the young man I discussed earlier, an HIV provider encounter someone who is struggling to come to terms with the reality of their diagnosis, they need to do all they can to listen to and appreciate that person's concerns, no matter how fantastical they may seem. If giving an HIV test to someone who has already been diagnosed is the opening the person provides us to help them deal with their fears and reassure them about the benefits of being in care, then we need to give it because the cost of a seemingly superfluous OraQuick test is nothing compared to the cost of rejecting a client's roundabout invitation for us to help them.

IT IS EXCEEDINGLY DIFFICULT to disabuse a person of any sort of magical thinking with reason and fact alone, since those are the very things such thoughts were designed to deflect. Yes, it is vital that we equip people living with HIV with the knowledge and the resources to make the decisions that are best for their overall well-being. Sometimes, it's just as important to provide them with a safe space where they can verbalize and explore all of the magical thinking that might lead them to decisions that are not. PA

DREW GIBSON is a social worker and freelance writer based out of Cincinnati, Ohio. You can follow him on Twitter at @SuppressThis or visit his blog "Virally Suppressed," which covers a multitude of issues related to public health and social justice. (References available online.)

HAVING SIDE EFFECTS FROM HIV MEDS?

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Start the conversation by completing the checklist below.

Check all that apply to you:

When taking your HIV meds, have you noticed that you:

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- ☐ Have trouble sleeping
- ☐ Have frequent diarrhea
- ☐ Have frequent headaches
- ☐ Often feel dizzy or have an upset stomach
- ☐ Skipped taking medicine to avoid having to deal with a side effect

DEVIN,
diagnosed with HIV in 2012

WHAT'S NEXT?

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IMPORTANT: Tear this checklist out and share it with your healthcare team today.

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TAKING THE HILL

AN ADVOCATE LOOKS AT MAKING THE CASE TO CONGRESS FOR AIDS FUNDING, THEN AND NOW

BY VICTORIA NOE

THE LAST TIME I was in Washington, D.C., advocating for AIDS funding and legislation was 1990. A group of us gathered from across the country to advocate for the first Ryan White CARE Act. I'd lobbied in Springfield, Illinois and Chicago, but never on the Hill. It was intimidating and exhilarating and exhausting.

Even when I was in D.C. for the U.S. Conference on AIDS last September, I didn't plan to come back for AIDSWatch. Why should I? Can't someone else do it instead?

But there I was at the end of February, picking up my badge and feeling a little alone. The only people I knew were Ed Barron and Mark S. King. I knew no one else in my state delegation, for Illinois. I didn't feel alone for long.

The demographics were certainly different this time around. In 1990, most of the attendees were white gay men. As a woman, I definitely stood out. This time the diversity of over 350 attendees from 35 states, Washington, D.C., and Puerto Rico was exciting. Given the disproportionate impact of HIV on people of color and transgender women, it was inspiring to see these communities so well represented. The other difference was the diversity in the Illinois delegation. On my previous visit, Illinois was represented by Chicagoans. This time we had members from around the state.

Last fall I was at an author fair at the Princeton, Illinois, Public Library. Two people I spoke to at my table were involved in HIV/AIDS treatment. Yeah, in Princeton, just off I-80, due north of Peoria. Not Chicago, not even East St. Louis: Princeton. Rural representation at AIDSWatch was critical in many ways and I was pleased to see that "downstate" was not forgotten.

Monday, February 29, was spent getting everyone up to speed on why we were there. These were our four "asks":

1. **The Affordable Care Act (ACA), the Ryan White CARE Act, and ongoing health reforms:** Protect ACA and continue funding Ryan White; limit cost-sharing for specialty medications and require insurers to display or link their full formulary on marketplace websites including the true out-of-pocket costs; incentivize Medicaid expansion;

2. **The Housing Opportunities for People with AIDS (HOPWA) Program:** Modernize the HOPWA formula and increase funding by $40 million;

3. **Comprehensive Sexual Health Education:** Cosponsor HR 1706, the Real Education for Health Youth Act (REHYA); authorize the Personal Responsibility Education Program (PREP) beyond FY 2017; support increased funding for the Teen Pregnancy Prevention Program (TPPP) and the CDC Division of Adolescent and School Health (DASH); eliminate federal funding for abstinence-only-until-marriage (AOUM) programs by repealing the Title V state grant "Abstinence Education" program and the Competitive AOUM grant program;

4. **Funding for the Federal Response to the HIV Epidemic:** Adequately fund efforts to expand access to HIV prevention, treatment, and research; substantially increase funding by at least $100 million for HIV/AIDS research at the National Institutes of Health (NIH).

As you can see, very specific requests. For me, the last item—increased funding for NIH—is most important. You don't take your foot off the gas pedal when you're close to the finish line: you floor it. Pitting AIDS against cancer or Alzheimer's to compete for funding is immoral. We need to ensure that this epidemic doesn't last one day longer than it should. And if there's one thing the AIDS community is good at, it's putting pressure on the powers that be.

Every delegation had specific issues and ours was the impact of the state budget stalemate. For us in Illinois, federal funding has taken on a new urgency. Social services have already been gutted from lack of a state budget for the current year, so continued or increased federal funding is critical.

AIDSWatch is a partnership between AIDS United, the Treatment Access Expansion Project, and the U.S. People Living With HIV Caucus. On Monday night, after the training breakout sessions, a reception was held at the Rayburn House Office Building. AIDSWatch presented Positive Leadership Awards to Rep. Barbara Lee and the family of the late Senator Frank Lautenberg. The Elizabeth Taylor AIDS Foundation, presenting sponsor for this year's AIDSWatch, hosted the reception with Taylor's family members in attendance.

They were not just there for photo ops: they spoke to the media and headed up to the Hill the next day for their own appointments. The commitment of Taylor's grandchildren—and one great-grandchild—is impressive. I'm sure she'd be proud that they're determined to carry on her amazing legacy. And though I didn't get a chance to speak to any of them, I did have a lovely conversation with Kate Burton, her stepdaughter and one of the foundation's most passionate ambassadors. (See "Ambassador Kate," January+February issue.)

Unlike 26 years ago, when we scheduled our own appointments, AIDSWatch 2016 handled this. On Monday afternoon state delegations gathered to find out who we were meeting and when. The entire Illinois delegation met with aides to Illinois U.S. Senators Dick Durbin and Mark Kirk. Then we were placed in smaller groups for the numerous House representatives.

I was in the group to see Rep. Mike Quigley (my former Congressman) and Rep. Luis Gutierrez (whose district I was gerrymandered into). We were able to meet with both of them, though with Gutierrez we shared time with the Puerto Rican delegation. Unlike the comfort of Quigley's office, we all stood in the hallway (just like the original lobbyists). But we made our points.

I thought a lot about those

two days as I headed up to New York on the Northeast Regional Amtrak route. And I realized what the biggest difference was between 1990 and 2016: hope. In 1990 we were lobbying for the first Ryan White CARE Act, and to ensure that the new Americans with Disabilities Act (ADA) included people living with AIDS. In 1990, Senator Ted Kennedy explained he could not co-sponsor bills because there were senators who would vote against them just because his name was on them. Even one of my senators, Paul Simon, didn't want to vote for anything that would add to the national debt. I couldn't even get a meeting with one of Sen. Alan Dixon's aides.

I asked Erik Glenn, Executive Director of the Chicago Black Gay Men's Caucus about his impressions of AIDSWatch. "This was my first time being an advocate. This was my first time going to D.C. It was my first time going to AIDSWatch. As a new member of the Illinois Alliance for Sound AIDS Policy (Illinois ASAP), it was an eye-opening experience.

"All at once, we found ourselves surrounded by advocates whose stories described years of passionate discussions with elected officials at all levels, whose decisions affect the daily lives of Americans living with HIV or at risk for acquiring HIV.

"This was inspirational.

"By the time our Chicago delegation met with our congressional leaders, we were each ready to describe how important legislation is that funds essential HIV support services and ensures people living with HIV are free from institutional discrimination.

"We were greeted by an encouraging amount of support from our congressional leaders. Meeting after meeting, our officials and their staff reaffirmed their commitment to an AIDS-free generation."

Hope.

This time, I didn't feel the same kind of frustration I felt in 1990. Oh, I'm frustrated, all right, frustrated that we're still fighting the epidemic all these years later. But this time around we can see the light at the end of the tunnel. People are living with HIV and undetectable. Undetectable!

That wasn't something we dared dream about then, but today it's a reality. We're so close, so close to a cure, so close to an AIDS-free generation. But we can't do it alone.

We need to eliminate laws that criminalize HIV, and increase funding for research, education, and needle exchange programs and testing centers. In 1990 we had very few tools in the toolbox. Today it's overflowing. But we can't do it alone.

You don't need to spend two days in Washington to help. Follow AIDS United or your state's advocacy groups. Find out what's going on in your city, county, and state. Find out what committees your representatives serve on and e-mail or call them about bills coming before them.

Then, share what you've learned on social media. Talk to your friends and family and medical professionals. Write op-eds or letters to the editor. The battle to end AIDS should not be a secret. It should be shouted from the rooftops that we are so close to ending the epidemic.

Because today, more than ever, there truly is hope. PA

VICTORIA NOE is the author of the *Friend Grief* series and the forthcoming *Fag Hags, Divas and Moms: The Legacy of Straight Women in the AIDS Community* (coming in 2017). Her essays have appeared in *A&U Magazine* (2016 Christopher Hewitt Award for Creative Nonfiction), *Chicago Tribune*, *Windy City Times*, and *Huffington Post*. A former fundraiser in the AIDS community of Chicago, she is now an advocate and member of ACT UP/NY. Her website is victorianoe.com.

TOP PHOTO: ERIK GLENN, VICTORIA NOE, U.S. REP. MIKE QUIGLEY (D-IL), AND SURAJ MADOORI. **MIDDLE:** REP. LUIS GUTIERREZ (D-IL) (LEFT) LISTENS TO AIDSWATCH DELEGATES FROM ILLINOIS AND PUERTO RICO. **BOTTOM:** KATE BURTON AND VICTORIA NOE.

PHOTOS COURTESY OF AIDSWATCH

PAUL REVERE STATUE, DOWNTOWN BOSTON

NEWS FROM CROI 2016

SWITCHING TO TAF, LONG-ACTING INJECTABLE TREATMENT, AND MORE

BY JEFF BERRY AND ENID VÁZQUEZ

THE 23RD ANNUAL CROI (Conference on Retroviruses and Opportunistic Infections) took place in Boston February 22–25. In addition to abstracts (study summaries) and posters (research reports), many of the presentations, including some highlighted here, are available on video. Visit croiconference.org. Many sets of slides are also available at natap.org. Video capsule summaries are also available at accesshiv.org.

SWITCHING TO TAF

THE NEWEST HIV DRUG on the market, Descovy (FTC/TAF) (see Briefly), is a reboot of Truvada (emtricitabine/tenofovir disoproxil fumarate, or FTC/TDF).

Truvada is currently the most commonly used backbone drug in HIV therapy, and FTC/TDF is found in three of the six single-tablet regimens currently on the market. TDF is actually a prodrug of tenofovir, and a new prodrug of tenofovir is found in both of the two latest STRs to hit the pharmacy (Genvoya and Odefsey).

A prodrug is a medication that becomes metabolized (processed in the body) as the active drug, in this case, tenofovir. By itself, tenofovir does not get effectively used by the body.

The new version also contains emtricitabine, but changes out the TDF for tenofovir alafenamide, or TAF for short.

While TDF is associated with potential kidney and bone toxicity, TAF is known to be easier on kidneys and bones than TDF, thanks to lower blood levels.

As usual, data were presented that looked at how people living with HIV fare when they switch over to a new drug.

Participants in Study 311-1089 kept their viral load undetectable when they switched to a regimen containing FTC/TAF from one containing FTC/TDF. Previous switch studies with TAF only looked at switching to Genvoya (which contains TAF).

Half of the 660 participants in this study were kept on their FTC/TDF-containing regimen and half were switched to one with FTC/TAF. Through 48 weeks, most patients maintained virologic suppression (viral load under 50, or undetectable). Ninety-four percent of the TAF takers had undetectable viral load compared to 93% of those kept on TDF.

As expected, kidney and bone toxicities were less with TAF. Proteinuria measures improved and bone mineral density increased in the group taking F/TAF (as it was called in the presentation), but not for the participants kept on F/TDF.

PHOTO: ISTOCKPHOTO/ MARCIO SILVA

Similar results were seen earlier in Phase 3 studies on switching to Genvoya; there were fewer kidney and bone toxicities with TAF than with patients continuing to take TDF.

Participants switching to a boosted medication regimen (one containing cobicistat or ritonavir, such as Prezcobix or Stribild) used 10 mg TAF. Those not taking a booster drug used 25 mg of TAF.

Joel Gallant, MD, MPH, of the Southwest CARE Center in Santa Fe, presented the Study 1089 results. The study is continuing out to 96 weeks.

LONG-ACTING TREATMENT

A TWO-DRUG COMBINATION injected intramuscularly every 4 or 8 weeks successfully treated HIV in a clinical trial. Many patients and providers alike eagerly anticipate a medication like this that may help improve treatment adherence and results. Others are skeptical.

All 309 participants first received oral HIV therapy for 20 weeks with Epzicom plus cabotegravir, an integrase inhibitor still in development. At the end of the 20 weeks, they were put into one of three groups: either receiving an injection containing cabotegravir plus rilpivirine once every four or eight weeks or kept on the oral medications.

Rilpivirine is available under the brand name Edurant, and is found in Complera and the recently approved Odefsey (see Briefly).

As reported in the January+February Briefly (see link to press release for more information), 95% of the people given an injection every 8 weeks and 94% of those receiving an injection every 4 weeks maintained their undetectable viral load through 32 weeks. This compared to 91% of those kept on pills.

Injection site reactions,

DAVID A. MARGOLIS, MD

mostly pain, were common, seen in 92% of participants, but 99% of them were considered mild (82%) or moderate (17%). The reactions continuously decreased over time, and according to the presenter, 90% of them resolved (went away). When surveyed, patients reported a much higher level of satisfaction with the injection compared to the oral pill used in the induction phase of the study

There was a two-week flexibility in receiving an injection, either a week earlier or a week later than scheduled. There was also "oral bridging," in which injection participants could get pills at the pharmacy if they couldn't come in for a shot.

David A. Margolis, MD, presented the Phase 2b LATTE-2 study results on behalf of ViiV Healthcare, the maker of Epzicom, Tivicay, and Triumeq. Janssen Pharmaceuticals is the maker of Edurant.

VAGINAL RING HIV PREVENTION

FOR THE FIRST TIME, research showed that vaginal rings could protect women against HIV. These rings, made of silicone, are soft and flexible, and can be inserted by the women themselves.

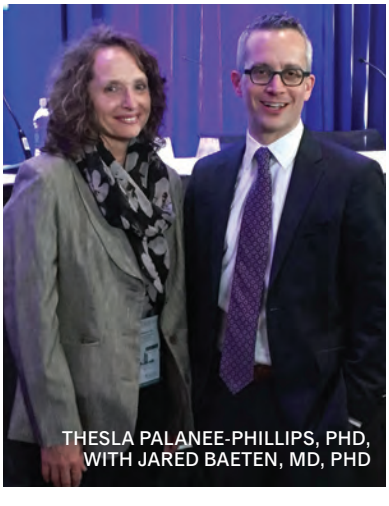
"The ASPIRE study is the first to demonstrate that a sustained drug delivery product that slowly releases an antiretroviral drug over time can offer partial protection from HIV," said Thesla Palanee-Phillips, PhD, of the Wits Reproductive Health and HIV Institute in Johannesburg, in a press release. She led the study along with presenter Jared Baeten, MD, PhD, of the University of Washington in Seattle.

The study found a 27% reduction in HIV infection overall, but a 56% reduction in women over 25 years of age.

A separate trial, The Ring Study, found a 31% reduction in HIV infections overall, but a slightly greater reduction, 38%, among women older than 21.

The two studies ran side by side to speed up commercial availability, if successful. The FDA requires two large, Phase 3 studies for approval. The National Institutes of Health (NIH) funds ASPIRE, conducted by the Microbicide Trials Network (MTN), while the Bill and Melinda Gates Foundation funds The Ring Study.

Both rings contained the anti-HIV medication dapivirine, which is only available in a research study. A ring was inserted once a month in the clinic and provided anti-HIV protection throughout the month.



THESLA PALANEE-PHILLIPS, PHD, WITH JARED BAETEN, MD, PHD

ASPIRE (**A S**tudy to **P**revent **I**nfection with a **R**ing for **E**xtended Use) enrolled 2,629 women in four African countries (Malawi, South Africa, Uganda, and Zimbabwe). In addition to a new ring, the women received HIV testing and risk reduction counseling each month. The average follow-up was 18 months, but some women had follow up as long as three years.

The Ring Study enrolled 1,959 women in South Africa and Uganda. At the time of the report, 761 women had completed two years of follow-up.

"HIV incidence was reduced by a third overall and by more than half among a subgroup of women who appeared to use the ring better," Baeten said in a press conference. "With the Ring Study, which replicates these results, these are important steps in developing new HIV prevention options for women."

For more information, go to the MTN website, mtnstophiv.org. MTN includes a link to the full ASPIRE study as published online in *The New England Journal of Medicine* (NEJM) on February 22.

A SINGLE CASE OF HIV INFECTION WHILE ON PrEP REPORTED

ADVOCATES AND PROVIDERS warn that HIV prevention with a pill "doesn't work if you don't take it." For the first time, there was a documented case of HIV infection in someone shown to be taking anti-HIV medication as directed. What happened?

The 43-year-old man in Toronto taking PrEP (pre-exposure prophylaxis) was found to be infected with HIV that was highly drug-resistant. It appears that this drug-resistant virus was able to overpower his Truvada, which is currently the only medicine available for HIV prevention.

PHOTO: LIZ HIGHLEYMAN

The virus that infected him, however, did not have the usual drug resistance pattern seen when the two drugs in Truvada can no longer control HIV. It did not contain the more important of the two mutations that most commonly confer resistance to the Truvada. Go to AIDSmap for an easy-to-read report on the complicated topic of drug resistance, as discussed in this case presentation; go to aidsmap.com/Almost-certain-case-of-PrEP-failure-due-to-drug-resistance-reported-at-CROI-2016/page/3039748/.

The transmission of drug-resistant HIV is not new. It's been discussed for more than a decade, often in the context of two people living with HIV—if one sex partner's drug-resistant virus is transmitted, could that cause the other partner's therapy to fail?

Yes and no. Mostly, this idea has ceased to be of major concern.

That's because researchers have found relatively few transmissions of drug-resistant virus.

Cases of highly-resistant virus being transmitted, fortunately, have been rare. This was one such case.

In addition to being rare, it's also fortunate that HIV drugs and drug classes approved in the last several years may be able to beat down drug-resistant viruses.

That's what happened with this patient. He was put on HIV treatment within two days of his infection being confirmed. Norvir-boosted Prezista and Isentress were added on top of his Truvada. His viral load was undetectable within three weeks.

Later, after tests came back from the lab that detailed the pattern of his virus's drug resistance, he was switched to another HIV regimen—Prezcobix, Tivicay, and Edurant. He has continued to be undetectable.

Obviously, however rare the acquisition of highly resistant virus may be, it can happen.

The Toronto patient reported "multiple acts of anal receptive sex with casual partners without the use of condoms" two and six weeks before his infection was found in May 2015 during routine HIV testing for his PrEP therapy. He had been HIV-negative at his last test in February 2015 and throughout his two years on adherent PrEP. He did not experience typical signs of HIV seroconversion, such as night sweats.

The Toronto patient told a reporter for *POZ* magazine, "PrEP didn't work for me, but I still think it's great." He also said that the man from whom he acquired HIV had told him he was HIV-negative. Read the interview at poz.com/article/meet-man-got-hiv-daily-prep.

View the presentation of Dr. David C. Knox, of the Maple Leaf Medical Clinic, on this case at croiwebcasts.org/console/.player/29737?mediaType=audio&.

HALF OF BLACK MSM PREDICTED TO ACQUIRE HIV

THE CENTERS FOR Disease Control and Prevention (CDC) provided estimated lifetime risk of HIV infection for both the general population as well as subpopulations.

Although the overall estimated risk of acquiring HIV infection has decreased from the agency's last report, increased risk was highest for black MSM (men who have sex with men): one in two.

Kristen Hess of the CDC reported that the new estimates were compiled from HIV surveillance, census, and mortality data collected from 2009 to 2013. The previous estimates were from a decade ago. Moreover, the CDC now has data from all 50 states, which it previously did not.

For the country as a whole, the risk of becoming infected with HIV is estimated to be 1 in 99 persons, as opposed to 1 in 78 individuals previously.

"However," said Hess in a press conference, "there are vast disparities that still persist. African Americans and Latinos face higher risks than whites. And MSM have a risk of 1 in 6. That's a much higher risk than heterosexual men, whose risk is 1 in 473. And black MSM are particularly high risk, with a risk of 1 in 2.

"It was already known that these groups account for the largest proportion of HIV diagnoses," Hess continued. "But presenting it in this manner can more effectively communicate the level of risk and large disparities to the general public. So this is a useful tool for clinicians, outreach workers, and policy makers."

The risk for Latino MSM is 1 in 4 and for white MSM, 1 in 11.

The CDC also reported risk on a state-by-state basis.

"As alarming as these lifetime risk estimates are, they are not a foregone conclusion. They are a call to action," said Jonathan Mermin, M.D., director of CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and Tuberculosis Prevention, in a press release. "The prevention and care strategies we have at our disposal today provide a promising outlook for future reductions of HIV infections and disparities in the U.S., but hundreds of thousands of people will be diagnosed in their lifetime if we don't scale up efforts now." Read the release at cdc.gov/nchhstp/newsroom/2016/croi-press-release-risk.html.

Estimated lifetime risk of HIV infection

1 IN 2 BLACK MSM
1 IN 4 LATINO MSM
1 IN 11 WHITE MSM

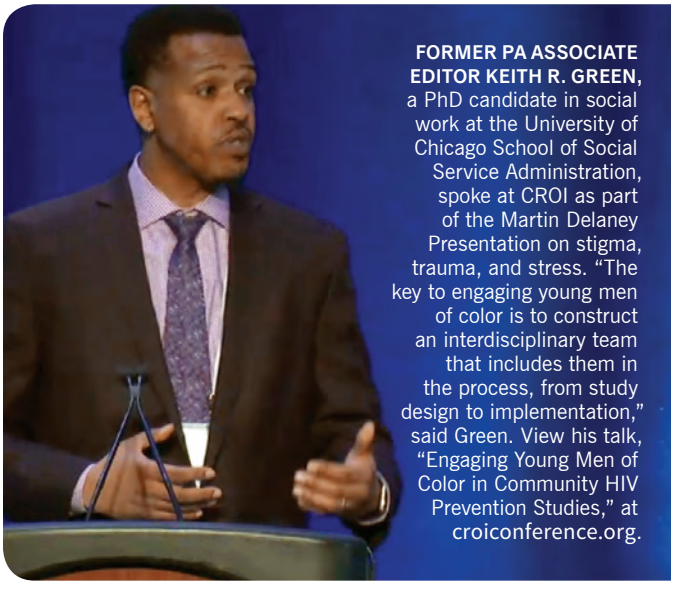
1 IN 62 MEN
1 IN 221 WOMEN

1 IN 19 BLACK MEN
1 IN 46 BLACK WOMEN

1 IN 47 HISPANIC/LATINO MALES
1 IN 214 HISPANIC/LATINA FEMALES

1 IN 127 WHITE MEN
1 IN 851 WHITE WOMEN

SOURCE: CDC



FORMER PA ASSOCIATE EDITOR KEITH R. GREEN, a PhD candidate in social work at the University of Chicago School of Social Service Administration, spoke at CROI as part of the Martin Delaney Presentation on stigma, trauma, and stress. "The key to engaging young men of color is to construct an interdisciplinary team that includes them in the process, from study design to implementation," said Green. View his talk, "Engaging Young Men of Color in Community HIV Prevention Studies," at croiconference.org.

HEPATITIS C AT CROI

BY ANDREW REYNOLDS

APPROXIMATELY 4,000 doctors, scientists, and advocates attended the Conference on Retroviruses and Opportunistic Infections (CROI) in Boston. Although HIV remains the major focus of this meeting, hepatitis C virus (HCV) has become increasingly covered at it as well, and this year was no exception. This article will provide a brief overview of some selected posters and presentations that are particularly relevant to MSM (men who have sex with men) living with HIV, with emphasis on **sexual transmission of HCV, treatment during the acute stage of HCV infection, and retreatment of HCV in HIV/HCV co-infected persons**.

SEXUAL TRANSMISSION OF HEP C: RISKS AND REINFECTION

OUR KNOWLEDGE of the dynamics and activities that lead to increased risk of sexual transmission of HCV continues to grow, and there were several poster presentations that further illuminated the sexual transmission of hepatitis C.

While blood and sexual fluids (semen and rectal fluids) have recently been demonstrated to have the potential to transmit HCV, it's more than sex alone that carries risk of transmission. There is often a confluence of risk factors that contribute to HCV transmission: drug use can lead to lessened inhibition that can lead to condomless sex and other high-risk activities, thus increasing risk of sexually transmitted ifections (STIs), including HCV.

In a review of HIV-positive MSM from the United Kingdom (England and Wales), Erica Pufall and colleagues presented data that highlights the role of substance use in the sex lives of HIV-positive MSM.

The study authors reviewed two sex phenomena with drug use: "chemsex," or the use of non-injectable drugs—amphetamines, GHB, crystal meth, and ketamine—to enhance sexual experience and decrease inhibitions, and "slamsex," a similar practice except the drugs are injected ("slamming").

The study, called "Positive Voices," is a computer-assisted self-interview (CASI) that collects information on behavioral and health needs. Of the 777 participants, 392 were sexually active, 105 (29%) of whom engaged in chemsex in the previous year, and 35 (10%) in slamsex. Of those who engaged in either of these practices, 50% reported a bacterial STI (gonorrhea, chlamydia, or syphilis) and 9.4% had been diagnosed with HCV. Significantly, the risk of HCV infection was significantly higher in both groups: 6 times greater in the chemsex group and 9 times greater in the slamsex group.

This research supports prior work that has shown that chemsex and slamsex lead MSM to take risks and engage in behaviors that place them at greater risk of HIV, STIs, and HCV. The study authors have found a clear association between chemsex and slamsex and risky sexual practices, and will do further research with larger numbers of MSM to deepen our understanding of these practices. The study authors conclude that interventions to HIV, STI, and HCV transmission among MSM who use drugs in a sexual context are needed. We know that harm reduction interventions can work to reduce sexual and drug using risk, and we know that gay men will use them. It is incumbent upon the medical and health education community to get these messages out to the community.

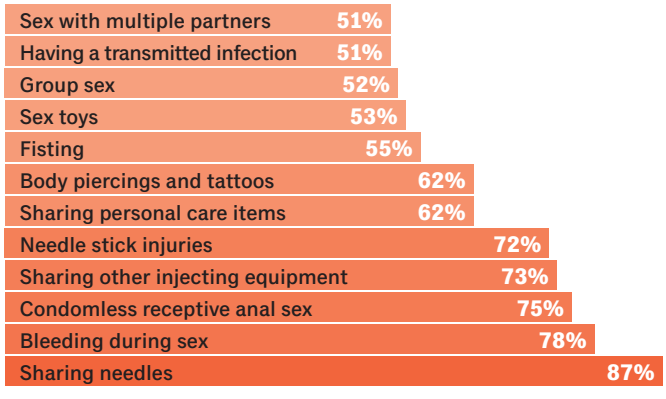
In a review of newly HCV-infected MSM living with HIV, Marianne Martinello and colleagues demonstrate that sexual transmission of HCV was more common in this group than transmission via injection drug use. The researchers reviewed a behavioral questionnaire that was completed by 218 HIV-positive MSM as a part of "The Control and Elimination within Australia of Hepatitis C from people living with HIV" (CEASE-D) study in Australia.

This study highlights a number of gaps in knowledge around transmission of HCV, and the need for service providers to provide better health education. The table below lists several potential risk factors for HCV transmission, and shows the percentage of respondents who were aware of them.

Of interest is the fact that while the majority of participants knew of the risk of HCV

Awareness of risk factors for hepatitis C transmission

A STUDY OF 218 HIV-POSITIVE MEN WHO HAVE SEX WITH MEN REVEALED GAPS IN THE MEN'S KNOWLEDGE OF ACTIVITIES THAT PUT THEM (AND THEIR PARTNERS) AT RISK FOR HEPATITIS C.



transmission from sharing syringes and other injecting equipment, as well as with condomless receptive anal sex, there are several risk factors that have been shown in prior research through the years to carry risk of which they were less aware: Co-occurring sexually transmitted infections, fisting, sharing of sex toys, sex with multiple partners, and group sex.

The study results also highlighted the challenges of HCV disclosure to sexual partners. While 73% of men reported that they "always" or "sometimes" disclose their HIV status to sexual partners, only 43% did the same for HCV. In fact, an additional 43% reported never disclosing their HCV status, compared to only 14% who never disclosed their HIV status.

Finally, only 73% of participants were aware of the risk of HCV reinfection, highlighting a gap in knowledge that needs to be addressed.

The study authors conclude that "limited knowledge around sexual transmission risk and HCV status disclosure is concerning. Awareness of sexual and drug use behavior in this population may help target health strategies and interventions."

AASLD/IDSA RECOMMENDATIONS

Genotype 1 HCV NS5A inhibitor treatment-experienced patients

Deferral of treatment is recommended, pending availability of data for patients with HCV genotype 1, regardless of subtype, in whom previous treatment with any HCV nonstructural protein 5A (NS5A) inhibitors has failed, who do not have cirrhosis, and do not have reasons for urgent retreatment.

Testing for resistance-associated variants that confer decreased susceptibility to NS3 protease inhibitors and to NS5A inhibitors is recommended for patients with HCV genotype 1, regardless of subtype, in whom previous treatment with any HCV nonstructural protein 5A (NS5A) inhibitors has failed, and who have compensated cirrhosis, or have reasons for urgent retreatment. The specific drugs used in the retreatment regimen should be tailored to the results of this testing as described below.

When using nucleotide-based (e.g., sofosbuvir) dual DAA therapy a treatment duration of 24 weeks is recommended, and weight-based RBV, unless contraindicated, should be added.

If available, nucleotide-based (e.g., sofosbuvir) triple or quadruple DAA regimens may be considered. In these settings treatment duration ranges from 12 to 24 weeks (see text), and weight-based ribavirin, unless contraindicated, is recommended.

EXCERPTED FROM: AASLD/IDSA. RETREATMENT OF PERSONS IN WHOM PRIOR THERAPY HAS FAILED. RECOMMENDATIONS FOR TESTING, MANAGING AND TREATING HEPATITIS C. HCVGUIDELINES.ORG/FULL-REPORT/RETREATMENT-PERSONS-WHOM-PRIOR-THERAPY-HAS-FAILED. ACCESSED MARCH 21, 2016.

HCV TREATMENT DURING ACUTE HCV IN HIV-POSITIVE MSM

WITH AN INCREASED awareness of the risks of HCV transmission faced by HIV-positive MSM, routine screening and detection becomes an important intervention to raise HCV status awareness and prevent further transmission. Additionally, prior to the direct-acting antiviral (DAA) era in HCV therapy, the detection and treatment of acute HCV (that is, in the first 6 months of infection) led to shorter and more effective treatment options with interferon-based therapies. There are currently no FDA-approved treatments for acute HCV, and neither are there recommendations from the current AASLD/IDSA HCV Treatment Guidance. Instead, the guidance recommends monitoring the person with periodic HCV viral load testing every 4 to 8 weeks for 6 months to a year in order to look for spontaneous clearance of the virus (approximately 20% to 50% of patients will clear the virus in the first 6 months of infection, with around 11% doing so at a later time), as well as to provide risk reduction counseling to protect the health of the liver and reduce the risk of transmission to others (see AASLD/IDSA information in the box below for a summary of these recommendations).

In an effort to find a shorter course of treatment with the current array of DAAs, researchers are beginning to study their effectiveness during the acute stage of infection. To that end, Jurgen Rockstroh and colleagues presented results from a small study looking at the effectiveness of 6 weeks of ledipasvir/sofosbuvir (Harvoni) in acutely infected HIV-positive MSM. The study comprised 26 men, 18 of whom were infected with genotype 1, and 8 with genotype 4, spread across 5 clinical sites in Germany and the United Kingdom. All but 1 were on HIV treatment, with an average CD4 count of 675 (ranging from 275 to 1,291). All 26 were acutely infected with HCV, and all were given Harvoni for 6 weeks.

In the first 4 weeks, 85% (22 of 26) achieved a sustained virologic response (SVR, an undetected viral load, which is the equivalent of a cure if it lasts for 12 weeks). Of the remaining 4 patients, 3 had a viral relapse and 1 was reinfected. At the 12 week follow-up, 77% (20 of 26) achieved an SVR12, or cure. In addition to the 4 men previously described, there were 2 who were lost to follow-up. The regimen was very well tolerated with mild to moderately severe side effects, with no one stopping treatment due to side effects.

Although the 77% SVR12 was far lower than what is achieved from the FDA-approved 12-week course of Harvoni, it is worth noting that individuals with a relatively low HCV viral load were all treated and cured successfully. This data is not strong enough to change any of our current recommendations for the care and treatment of acute HCV, but it does provide a foundation for future research studies looking at shorter and more effective, and thus more cost-effective, treatment options.

RETREATMENT OF HCV IN HIV/HCV CO-INFECTED PERSONS

THE AASLD/IDSA HCV Treatment Guidance provides recommendations for re-treating patients for whom both interferon-based and direct acting antiviral therapy did not work (treatment failures or viral relapse), but more information is needed on the

re-treatment of HIV/HCV co-infected persons.

Curtis Cooper and colleagues presented on the retreatment of 9 HIV/HCV co-infected persons who had previously failed 12 weeks of Harvoni. These 9 patients were GT 1 (7 were 1a and 2 were 1b). All were taking HIV medications, and had an average CD4 count of 785 (range 158 to 1,625).

All patients were retreated with 24 weeks of Harvoni + ribavirin. The average time from treatment failure to retreatment was 43 days (range from 34–70 days). With this course of treatment, 89% (8 of 9) achieved an SVR12. The regimen was well tolerated, with all patients reporting mild side effects, but no one needing to discontinue treatment. Similarly, no one experienced a worsening of their HIV disease.

The one patient who did not achieve a cure had some drug resistance related to Harvoni. This may have contributed to the treatment failure, but six other patients also had some drug resistance and were able to achieve a cure. Thus 86% (6 of 7) patients with NS5A (one of the drug classes in Harvoni) resistance achieved a cure. Further study is needed to come to a better understanding of retreatment of HCV in patients—both HCV mono-infected and HIV/HCV co-infected—and to manage HCV drug resistance and find the optimal regimen to cure this patient group (see AASLD/IDSA recommendations at right).

CONCLUSIONS AND FURTHER INFORMATION

THIS YEAR'S CROI continued to expand our knowledge of sexual transmission of HCV and treatment of HCV in HIV/HCV co-infected persons. The presentations and posters selected here for review highlight the need for further understanding of these issues, but also the need for health education to better serve people living with HIV around their risk for HCV.

If you're interested in learning more about these (and more) presentations from CROI, there are two excellent resources at your disposal. First, CROI makes available a number of presentations available to stream via webcasts. These can be found at croiwebcasts.org. There are a number of HCV presentations on original research, case studies, and lectures from this year's meeting, as well as archived ones from years past. The second resource is the National AIDS Treatment Advocacy Project (NATAP), found at natap.org. NATAP is an excellent site for primary sources on HIV and HCV conferences and journal articles. There are several presentations from CROI (as well as countless other conference presentations) available that otherwise would never be seen by the general public.

Finally, if you have any questions about HCV in general, including topics discussed here, call The Support Partnership's national toll-free hepatitis C phoneline, HELP-4-HEP (877-435-7443) and speak with a trained HCV counselor. The line is open Monday through Friday, 9 a.m.–9 p.m. EST.

ANDREW REYNOLDS is the Hepatitis C Education Manager at Project Inform, and serves as a counselor on the HELP-4-HEP phoneline.

AASLD/IDSA RECOMMENDATIONS
MANAGEMENT OF ACUTE HCV INFECTION

Recommended testing for diagnosing acute HCV infection

HCV antibody and HCV RNA testing are recommended when acute HCV infection is suspected due to exposure, clinical presentation, or elevated aminotransferase levels (ALTS, a liver function test).

Recommendations for medical management and monitoring in acute HCV infection

Regular laboratory monitoring is recommended in the setting of acute HCV infection. Monitoring HCV RNA (e.g., every 4 to 8 weeks) for 6 to 12 months is recommended to determine spontaneous clearance of HCV infection versus persistence of infection.

Counseling is recommended for patients with acute HCV infection to avoid hepatotoxic insults, including hepatotoxic drugs (i.e., drugs that can potentially damage the liver, such as high doses of acetaminophen) and alcohol consumption, and to reduce the risk of HCV transmission to others.

Referral to an addiction medicine specialist is recommended for patients with acute HCV infection related to substance use.

Recommended treatment for patients with acute HCV infection

If the practitioner and patient have decided that a delay in treatment initiation is acceptable, monitoring for spontaneous clearance is recommended for a minimum of 6 months. When the decision is made to initiate treatment after 6 months, treating as described for chronic hepatitis C is recommended.

If a decision has been made to initiate treatment during the acute infection period, monitoring HCV RNA for at least 12 to 16 weeks before starting treatment is recommended to allow for spontaneous clearance.

EXCERPTED FROM: AASLD/IDSA. MANAGEMENT OF ACUTE HCV INFECTION. RECOMMENDATIONS FOR TESTING, MANAGING, AND TREATING HEPATITIS C. HCVGUIDELINES.ORG/FULL-REPORT/MANAGEMENT-ACUTE-HCV-INFECTION. ACCESSED MARCH 21, 2016

New treatment for multi-drug resistance

Theratechnologies. and TaiMed Biologics announced in March a 12-year collaboration agreement to market and distribute ibalizumab in the U.S. and Canada, according to a press release. Ibalizumab is a novel CD4-directed HIV entry-inhibitor currently in a late-stage Phase 3 clinical trial, and will be evaluated under the FDA's priority review process, which is expected to be completed during the first half of 2017.

Ibalizumab was designated a "Breakthrough Therapy" by the FDA based on preliminary clinical evidence indicating that it may represent a substantial improvement over existing therapies on one or more clinically significant endpoints. In a Phase 2b study of 113 patients, it "significantly" reduced viral load in multi-drug resistant HIV-positive patients.

Ibalizumab is currently administered as a bi-monthly (once every two weeks) intravenous injection. TaiMed is conducting clinical trials with the same formulation for bi-monthly intramuscular injection (IM) and monthly IM administration.

Antibody-based prevention study opens

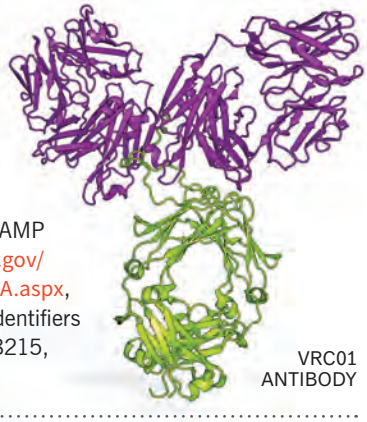
Enrollment has begun in the first of two multinational clinical trials of an intravenously delivered investigational antibody for preventing HIV infection, according to an April 7 NIH press release. Known as the AMP Studies, for antibody-mediated prevention, the trials will test whether giving people an investigational anti-HIV antibody called VRC01 as an intravenous infusion every 8 weeks is safe, tolerable and effective at preventing HIV infection. With a projected enrollment of 4,200 adults, the trials also are designed to answer fundamental scientific questions for the fields of HIV prevention and vaccine research.

"The AMP Studies could have a major impact on the future of HIV prevention and may be especially informative to HIV vaccine research," said NIAID Director Anthony S. Fauci, M.D. "Many scientists believe that if a vaccine were developed that elicited broadly neutralizing antibodies in healthy people, it would protect them from HIV infection. The AMP Studies will test this hypothesis by directly giving people the VRC01 antibody."

In addition, the studies could clarify what level of broadly neutralizing antibodies a vaccine or other long-acting HIV prevention method needs to achieve and maintain to provide sustained protection from the virus.

The AMP Studies are being conducted jointly by the NIAID-funded HIV Vaccine Trials Network (HVTN) and HIV Prevention Trials Network (HPTN). The National Institute for Drug Abuse and the National Institute of Mental Health, both part of NIH, also fund HPTN. The studies individually are known as HVTN 703/HPTN 081 and HVTN 704/HPTN 085.

More information about the AMP Studies is available at niaid.nih.gov/news/QA/Pages/AMP-Studies-QA.aspx, ClinicalTrials.gov under study identifiers NCT02716675 and NCT02568215, and at AMPstudy.org.



VRC01 ANTIBODY

First HIV-positive organ transplant

For the first time surgeons at Johns Hopkins University in Baltimore in April performed a liver and kidney transplant from an HIV-positive donor to two individual recipients living with HIV.

A law enacted in 1984 banned transplantation of organs from HIV-positive donors. For years, Johns Hopkins surgeon Dorry L. Segev "watched organs from HIV-positive donors being wasted, even as HIV-positive patients awaiting transplants died," according to a Johns Hopkins website. Segev worked to reverse the laws and helped draft the 2013 HOPE Act, which was signed by President Obama in 2013, making it possible for HIV-positive individuals to donate organs.

Illinois had passed legislation in 2004 to overturn the ban ahead of U.S. lawmakers, but it was unenforceable.

"The change in law and policy to catch up with what medicine can do for people, it's a huge step forward," said Hayley Gorenberg, deputy legal director for Lambda Legal, in an article in *The Baltimore Sun*. "The lives and the quality of life of hundreds will be affected every year."

Segev told the *Sun* he has more HIV-positive patients waiting for donors, and expects they'll now get needed organs sooner. His next move will be sharing Hopkins' protocols for choosing donors and recipients and ensuring safety with doctors at 30 other transplant hospitals.

BROOKS: WHITE HOUSE PHOTO

AIDS policy chief steps down

Douglas Brooks, the White House director of the Office of National AIDS Policy (ONAP) stepped down in late March after leading the division for two years.

According to the *Washington Blade* a "key component of Brooks' work was highlighting the potential role of PrEP, or pre-exposure prophylaxis medication, as a means to prevent people from contracting HIV. Under his leadership, the update to the National HIV/AIDS Strategy identified PrEP as a component of the plan to reduce the number of new HIV infections between 2015 and 2020 by at least 25 percent."

"Douglas' vision about the importance of improving access to PrEP was controversial in some circles at the time, but the growing body of scientific evidence is clear: PrEP is highly effective when taken daily at preventing HIV infection in the real world," said long-time friend and colleague Richard Wolitsky in a blog for AIDS.gov.

According to the White House, Brooks is taking time off before starting his next job in late spring, and Amy Lansky will serve as Acting Director of the Office of National AIDS Policy.

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THE 13TH
RIDE FOR AIDS CHICAGO
JULY 9–10, 2016

DETAILS AT RIDEFORAIDS.ORG

YOU'VE LOST THAT GUTSY FEELING, WHOA, THAT GUTSY FEELING

A NEW PROBIOTICS STUDY LOOKS AT BRINGING BACK THOSE CELLS THAT WERE GONE, GONE, GONE

BY ENID VÁZQUEZ

THE CD4 T-CELLS used by the immune system to protect health don't just exist in the blood. The gut has its own set of CD4 T-cells, separate from those in the blood plasma.

"Those CD4s that live in the gut get decimated right off the bat, very early, weeks or months after infection," said Brett Williams, MD, of Rush University Medical Center, in Chicago, "whereas the blood CD4 count doesn't go down until after a while, over years, and it looks like the gut CD4s don't seem to recover as well as blood CD4s. So even though I might measure someone's blood CD4 and it's up to a thousand, the gut CD4s don't seem to recover. Around the same time we were learning more about this, about 10 years ago, we started noticing that people with HIV had a leakier gut. So we check their blood and they had more bits of bacteria from the gut—bacterial DNA and bits of the bacterial cell walls—in their blood."

This "microbial translocation" as it applies to the gastro-intestinal (GI) mucosal cells is known more commonly as "leaky gut."

Dr. Williams, an HIV specialist, studies the microbiome. A "microbiome" is the environment in which a particular set of microbes live—germs, bacteria, viruses, and so forth. The gut has its own microbiome, which is more and more showing a critical relationship to disease.

Some microbes are like friends, promoting good changes. Others are more like enemies, causing harm. Most people have heard of the "good bacteria" provided by some yogurts, or of nutritional supplements called "probiotics."

There are thousands of kinds of microbes in the gut microbiome and there's a long way to go in identifying all of them and figuring out what they do. While some microbes living in the gut are friends, others have been associated with increased risk of heart disease, strokes, allergies, and even obesity.

"I love how it's all coming together from different sides, the effect of the gut microbes being seen in several diseases," said Dr. Williams. "Microbes play important roles in many organ systems, and we're just beginning to understand this physiology. It seems to have a greater effect in HIV."

He's a junior member of a team lead by Dr. Adriana Andrade at Johns Hopkins University and Dr. Turner Overton at the University of Alabama at Birmingham working on a study with the AIDS Clinical Trials Group (ACTG), expected to open soon, that will look at the effects of a probiotic. An earlier study had found that using this particular probiotic with HIV antiviral medicine in monkeys infected with SIV (the monkey version of HIV) improved gut CD4s more than using antiretrovirals by themselves. (The ACTG researchers are not receiving compensation from the company that produces the product.) A5350 will look for several effects including a reduced systemic level of immune activation and improved gut CD4 reconstitution.

Immune activation revs up the body like a roaring fire, creating wear and tear in the process. This results in damage which increases the risk of disease, much of it normally seen with aging.

A5352, which is a substudy of A5350, will give study participants a flexible sigmoidoscopy, a procedure usually used to check part of the colon for ulcers, polyps, and cancer. It's like a colonoscopy, but not as extensive. Biopsy (taking a tissue sample) would be done. The sub-study also looks at gut permeability – or leakiness—using something called a lactulose-mannitol test.

A separate Rush University study is evaluating the differences between the microbes of

THE HOPE IS THAT MICROBES CAN ALTER THE RISK OF HEART DISEASE, DIABETES, AND OTHER DANGERS.

individuals with HIV and their family members or roommates, to better determine the changes in the microbiome which are caused by HIV itself. Rush is recruiting participants who are just starting HIV medicine.

Explained Dr. Williams, "We have some evidence that some of the bacterial products, such as the short chain fatty acids butyrate and acetate—that these small molecules actually feed the gut cells and turn down inflammation. There are other bacteria that don't produce those and that may produce other molecules that are actually harmful. These findings are fairly well backed up by studies in people without HIV.

"Even people who've had undetectable viral load for years have a different microbiome. It doesn't get restored to HIV-negative status. That's what is disturbing to people—that even patients with suppressed viral load still seem to have extra morbidity and mortality not explained by other things like smoking. That's the driving force behind all these studies," he said. "Long-term survivors at our clinic who were in studies here long ago experience chronic diarrhea, or intermittent cramping, or chronic loose stools. That may be due to failure of the gut immune system to recover."

He and his Rush and Washington University colleagues also have a paper in the process of being published that reviews the microbiome studies in HIV which have already been published.

Some of the lack of immune rebound in the gut appears to be due to scarring, or fibrosis in the gut that happens with infection. If the walls of the gut fill in with fibrosis, there's not much room left for CD4s. This may also contribute to leaky gut, as fibrosis may disrupt the normal structure which evolved to prevent microbes from commuting into the bloodstream from the gut. The ACTG research will look for reduced scarring of the gut, as well as other markers (signs) of disease.

"What really got us interested in going after those leaky guts was two studies in HIV patients that came out in 2014 that showed that all these other diseases, diseases of aging—heart disease, stroke, cancer—were kind of linked to leaky gut," he said. "The immune activation we found in the blood related to translocation of gut bacteria was closely associated with bad outcomes. So it's not necessarily AIDS, but what we call non-AIDS morbidity and mortality. They looked back at blood samples from people who had events like heart attacks or strokes and found more evidence of leaky gut and the immune activation resulting from it, compared to those who didn't." So, the hope is that microbes can alter the risk of heart disease, diabetes, and other dangers.

Microbes seem to relate to behavior as well as medical conditions. At this year's CROI (see page 22), Muntsa Rocafort and colleagues reported that in MSM (men who have sex with men) with or without HIV, a positive HIV status had less of an effect on the gut microbiome than being MSM.

That research came about because intestinal "dysbiosis" was found to be different between SIV (the virus in non-human primates) and HIV, raising the question of an effect emanating from behavior. "Dysbiosis" is when the population of microbes is abnormal, such as when it is not diverse enough or when certain microbes are over or under represented.

Dr. Williams pointed to another study showing that when mice with signs of autism were given certain gut microbes, some of the abnormal behaviors went away, although he wondered how autism in mice related to autism in humans.

In two other studies, mice given certain microbes did not develop peanut allergies or they became obese. Microbes may also help control cancer, particularly melanoma.

In the meantime, his patients often ask about the benefits of taking probiotics.

"If people want probiotics, I generally tell them to try yogurt or kefir. People take these supplements every day. I'm not opposed to it, but I don't know if they will work. So that's why we've got to do a study so we can find out," he said. "Things like yogurt and kefir also have the added benefit of having the complex sugars that those bacteria need to make those beneficial molecules and to survive on themselves. Those are what we call prebiotics."

Dietary advice can be complicated, he said. He likes to pass on the suggestion from the activist writer Michael Pollan: "Eat food, not too much, mostly plants."

As for data on probiotics in HIV, he said none have been comprehensive and they have had mixed results. "Some have shown positive results, improved CD4 count, and reduced inflammation, and some have not really found any difference. They're all over the place. Some use Lactobacillus, some use Bifidobacterium, some use yeast called Saccharomyces. So it's a little bit of comparing apples to oranges to tomatoes."

He noted a lot of data showing the harmfulness of a molecule called TMA, which mostly occurs from the breakdown of animal products, and has been closely linked to heart disease and kidney failure. "After I learned that, I started eating a lot less meat," Dr. Williams said. Eating meat has also been shown to have a strong connection to colon cancer. In contrast, "the bacteria we think are the good guys break down plant matter and make the good molecules: butyrate, acetate—the short chain fatty acids."

"We think that if we can reduce leaky gut, we can reduce those bad outcomes: diabetes, strokes, heart attacks, and so on," said Dr. Williams. He notes, however, that these results, if possible, won't be immediately available. "It takes five years to do a trial like that. People don't just have heart attacks every other day, so you have to follow them for a long time to see a difference between treatments. It takes a long time to figure that out." PA

LOOK FOR INFORMATION on A5350 and A5352 at actgnetwork.org. Read about a CROI roundtable discussion on the gut and HIV at scientificamerican.com/article/how-gut-microbiota-impacts-hiv-disease. Watch a webcast of the roundtable at croiconference.org.

PROBIOTICS CAN BE FOUND IN KEFIR AND SOME NUTRITIONAL SUPPLEMENTS AND YOGURTS.

PHOTOS: ISTOCKPHOTO

RECONNECTING WITH HER COMMUNITY

PHOTO COURTESY OF TPAN

FEELING FREE WITH THE RIDE FOR AIDS CHICAGO

BY GARY NELSON

IT'S 9 P.M. on a Wednesday night in March, and Christina Joly is packing away a laptop, her notes, and the remaining transit cards not taken by members of her Treatment Education Adherence Management (TEAM) group. TEAM, a three-week-long educational course that covers HIV basics, HAART therapy, and managing diagnoses, is one of the four groups Christina facilitates at Test Positive Aware Network (TPAN), publisher of POSITIVELY AWARE. Despite being at the end of a long workday and group session she's energetic, which could be because she's missed a cycling class. In addition to Christina's groups and meeting weekly with 15 therapy clients, she's cycling with Team TPAN in the 2016 Ride for AIDS Chicago (RFAC).

"We hold TEAM quarterly. This session's in the evening to encourage participants from all walks of life to join us," Christina says as she straightens chairs. In the spring, that conflicts with RFAC's indoor training. "I miss spin, but this is more important."

Christina is precise in her word choice and considerate as she listens. She has the thoughtful composure of a therapist, though she is quick to break into good-natured laughter. In

JOLY (CENTER) WITH SOME COWORKERS AT TPAN'S NATIONAL WOMEN AND GIRLS HIV/AIDS AWARENESS DAY EVENT.

previous jobs and among friends, she was known for her ability to mediate conflict and serve as a go-between for people with differing opinions. Christina's work at TPAN is the right fit; it's also a return to a cause that's personal.

"I think I've been preparing for this for a long time without really knowing it," she said. Diagnosed with HIV in 1988 at the age of 15, Christina spent most of her teen years dedicated to HIV advocacy and educating others. "I was given 10 years to live when I was diagnosed, so, whatever I could do, I did." She threw herself into the HIV community with a determination to make a difference while she could, visiting schools with a group of HIV-positive youth and participating in drug trials: "Even if the drugs were toxic, I thought 'Who cares? I'm not going to be around and I'd rather be useful for whoever else is after me.'"

Finding herself still alive at the 10th anniversary of her diagnosis, and realizing she would continue to live, "was confusing. It was a bit of a shock and I pulled away from the community." She studied psychology in college and "planned on being a therapist, but felt I was so messed up at the time that that would be unethical. I was interested in doing it for me, to figure out my own problems rather than helping others."

Christina graduated college and took a sales job at a trading company where she advanced quickly. The corporate job came with a large salary and other perks, but, "I felt a big hole in my life. HIV and my participating in anything HIV-related was nonexistent. It was circumstantial, but also me not wanting to deal with my own status. I did read POSITIVELY AWARE and *POZ* when I saw them at the doctor's office, but I was completely isolated from other HIV-related things and people." After 13 years, the company closed and Christina faced a choice: go on to another unfulfilling sales job or take a risk on another career.

Christina found her answer in a Master's of Science in Counseling, a therapy internship at TPAN, and eventually a job at the Chicago agency. "I was looking for a way to put meaning into my life. I knew I didn't want to be just a therapist. I wanted to reconnect with my HIV community. In 13 years at my old job I only told one person I was HIV-positive. Thirteen years of working with people and I still didn't feel comfortable telling them. At TPAN, I knew there wouldn't be an issue with me telling people." That outlook of self-realization is central to Christina's therapy sessions with clients. "The ultimate goal of therapy, HIV-positive or not, is to support clients in finding the path to live their best life, whatever that means to them. Having therapy available at TPAN means they can expect a safe nonjudgmental space where they are able to explore and grow."

After an internship in 2014, Christina joined TPAN as a full-time therapist in 2015. In addition to TEAM, she leads herVoice and Future Focused, therapy groups focused on women living with HIV and those newly diagnosed. "It's not just being a therapist, but it's being a therapist in this particular field that's making it the most fulfilling thing I could imagine. That hole I was feeling years ago, this is what was missing."

Christina quickly learned about another way to participate in TPAN's mission: The Ride for AIDS Chicago. Held each year, RFAC is the agency's signature fundraising event, raising funds for HIV services, including TPAN's therapy programs, and combating the stigma associated with HIV/AIDS. Christina thought she "couldn't be at TPAN and not participate. The Ride felt like a natural evolution to me being here and being part of the HIV community. I was so happy with the response I got at TPAN to being open about my status, doing the Ride felt like the natural extension, not only to supporting other people but to supporting myself: I'm not going to live in the shadows any longer."

Christina rode in 2015 and described the experience as "overwhelming." An endurance athlete who had run marathons and completed several cross-Iowa bike rides, she said that RFAC was different. "It's not only a physical challenge, it's an emotional challenge. While I train and ride, I imagine all the people who didn't make it. I didn't know a ton of positive people when I was younger, but I definitely lost some friends. There are a lot of people who wanted to be here and aren't. I'm still here and I'm able to ride with their memories, or in their memory, whether I knew them or not. For me, it's not about raising money, although we are. It's about making a statement."

"Christina's range of advocacy is powerful," shared Jessie Mott, who co-facilitates TPAN's art therapy group with Christina. "She's soft-spoken with a strong presence. Many of the group members know that she also cycles 200 miles each year, which is so inspiring to all of us."

As she prepares for her 2016 ride, Christina reflects back on the most memorable portions of her first ride, the tradition of HIV-positive participants wearing orange bandanas to signify their status. "One of the things I've thought about my whole life, since I've been diagnosed most of my life, there's a part of me that wished I could just wear a button that says 'I'm HIV positive' and everyone would know and disclosure wouldn't be an issue. The orange bandana is kind of that button. Even though you're around a bunch of positive people and negative allies who aren't going to judge you, it's still very scary."

That fear speaks to the extent to which those who are positive have internalized HIV stigma. Events like RFAC strive to demonste that there is no shame in one's status. "For the first time in my life, 27 years of being positive, the Ride was the first time I felt I could be 100% myself. Even more than working at TPAN. To be able to walk around for two days wearing that bandana and to have everyone know, it was such a feeling of freedom that I'd never experienced before in my life. And you take part of that with you. You pack it back up and go back to your life. But I know I get to unpack it again this year. And I hope that each time unpacking it, it can stay out a little longer, or that I don't need to hide it again."

As it has for many other participants, the RFAC has become a vital part of Christina's life. "I couldn't not ride. I would miss the community and that big emotional hug; that's what it is, two days of emotional hugs. Imagine one of the best days of your life, that's the feeling you'll get out of doing this. I feel like I'm supposed to be there, and as long as I can do it, I will do it."

As Christina packs away the rest of her supplies she comments, with a smile, "this was the last meeting of this TEAM cohort. I'll be back at training next week." PA

THE 13TH ANNUAL RIDE FOR AIDS CHICAGO will be held July 9–10, 2016. To participate or sponsor a participant, go to rideforAIDS.org.

GARY NELSON is the Marketing and Communications Manager at TPAN.

STAYING IN THE GAME

A RUGBY PLAYER LEARNS TO OVERCOME OBSTACLES TO CARE AND TREATMENT

BY RICK GUASCO
PHOTOGRAPHY BY JOHN GRESS

FROM THE TIME he was a young boy in India, Bhuttu Matthews loved sports. An all-around athlete, he played soccer and volleyball and competed in track and field in school. He was much like his father, who was a boxer and track and field athlete.

"My first memory is of my dad teaching me how to hold a cricket bat," Matthews said. "Sports have always been a huge part of my identity."

All that was uprooted, however, after Matthews and his mother moved to the United States when he was 16, while his dad remained in India to preserve his retirement benefits. Matthews played soccer and swam while attending his new high school in Chicago, and then competed in martial arts while attending DePaul University. But he felt disconnected from a part of himself, and depression began to set in.

"Being closeted and coming from a culture that was very conservative and not accepting of gay people, it became an internal struggle that led to depression," Matthews said. "Sex was the only thing that made me feel good. The more I felt depressed about non-acceptance, the more I turned to sex. From the time I was 18, I was going to a bathhouse, and once the internet became popular, I was looking for sex online."

IN THE SPRING of 2004, Matthews tested HIV-positive. "Once I was diagnosed with HIV, I just threw caution to the wind," Matthews said. "It seemed only natural to me that I would continue on this path through artificial means."

Matthews began experimenting with crystal meth in the fall of 2005. By the following July, he was injecting it. "I would wake up in the morning and start thinking about when I could get high again," he said. "Once I had started doing it, I just wanted to keep doing it. Looking back at it now, I can recognize that I was an addict, but at the time, I did not think of my use in those terms."

His crystal meth use, Matthews says, did not affect his adherence to his "good drugs," his HIV meds. "What it did affect, however, was me going to work on time and paying my mortgage."

Matthews and his mother had just bought a condo together, where they both lived. It was an adjustable rate mortgage, with increasing monthly payments. Once Matthews started missing work—and

mortgage payments—it wasn't long before he and his mother faced foreclosure and homelessness.

Mother and son moved to Florida in the hopes of finding work and better prospects. Matthews no longer had insurance because he had missed a payment, and so was on the Illinois ADAP program. During this period of depression, drug use, and dealing with his HIV, Matthews had let his immigration status lapse. Matthews was now an undocumented immigrant, making him ineligible for Florida's ADAP.

Matthews was able to get a temporary supply of his HIV meds through a charity, but it was soon clear that he and his mother needed to return to Illinois. By this time, his mother's former employer had relocated to a distant Chicago suburb, which was where they moved. Matthews immediately picked up where he had left off with his drug and sex addictions. He started dating a guy he met at one of his party hook-ups.

JUST BEFORE Mother's Day 2008, Matthews and his mother were detained by the U.S. Immigration and Customs Enforcement (ICE) and were now facing imminent deportation. Matthews and his mother were being held in a detention facility in far southern Illinois, about a half hour's drive from the border with Missouri and Kentucky. To their credit, Matthews says, facility personnel understood the importance of his taking his HIV medication while he was locked up.

Deportation seemed unavoidable, however, until Matthews came out to his lawyer and disclosed his HIV status. U.S. immigration law allows for a person facing deportation to apply for asylum if they faced possible persecution or torture in their home country.

"My lawyer and I built up a pretty strong case—we had instances of people being attacked for their sexuality, people getting killed by their own family members because of their HIV status," Matthews said.

Matthews was allowed to stay in the U.S., after posting a bond. But because his mother is not a member of a protected class, she was sent back to India and banned from returning to the U.S. for 10 years.

Matthews abandoned the suburban apartment he had shared with his mother and moved in with the new boyfriend, although Matthews now only refers to him as his "ex." "Pretty soon, I found that this was not the ideal situation," Matthews said. "I would wake up early in the morning to the clanging of pots and pans in the kitchen. It was my ex, and he was high."

The situation eventually led to instances of physical violence. "That December, he attacked me," Matthews said. "He threatened that if I reported it to the police, he would revoke his status as my immigration bond holder. I knew that wasn't a real threat, and realized I no longer wanted to be in this relationship, so I started exploring options to become sober and living on my own.

"I realized that my drug use had gotten to the point where I was being attacked and unwilling to do anything about it. A week later, he threatened to throw my cat out the window. That's when I realized I could no longer stay in a relationship with him."

In January 2009, Matthews applied to a housing facility for people living with HIV that also provides support services. He also made contact with a therapist through another health services center and received a list of support group meetings.

"After I moved out of my ex's place, I attended my first support group meeting," Matthews said. "A few days later, I moved into a transitional housing facility, a sober living house that provides a four-month program." After successfully completing the sobriety program, his application was accepted by two housing facilities. That June, he moved into Bonaventure House, a supportive living residence and recovery home in Chicago specifically for people living with HIV/AIDS.

In the meantime, however, Matthews' ex-boyfriend began stalking him. Matthews was receiving email, voicemail and text messages from his ex, asking to reconcile, even as he claimed to not know what he had done wrong during their relationship. Matthews ignored the messages, refusing to respond.

"Unfortunately, what I'd forgotten to do was change the passwords to all my email and social media accounts," Matthews said. "Suddenly, my brother and friends I hadn't seen since my high school days in India started letting me know they were receiving strange emails saying that I was HIV-positive, injecting crystal meth, and having condomless sex with strange men in bathhouses. I knew it was my ex who was doing this, so I got an order of protection from him."

WHILE LIVING AT the housing facility, Matthews began an internship at Sweet Misgivings, a bakery operated by Chicago House. That soon led to a job lead at Access Living, a non-profit organization that advocates for and empowers people living with disabilities.

"My job has been as an external relations coordinator to the general public and the disability community," Matthews said. "A call might come in, searching for resources for someone with disabilities. Maybe they're facing homelessness or they need home modifications done or they might need assistive technology. I'll help them find resources to address those needs."

"I have loved my job because I've gotten to interact with the public and promote the message of disability inclusion and how important it is for people to live inclusive lives," Matthews said.

AS SATISFYING as his work is, Matthews' source of stability and strength to overcome his challenges remains what it's always been—rugby.

"I started rugby the same month I found out I was HIV-positive," Matthews said. March 2004 was a critical time for Matthews—just as he was preparing to graduate from Chicago's DePaul University, he discovered he was HIV-positive. At the same time, a gay men's rugby team was forming, the Chicago Dragons. Wanting to play competitively, Matthews wasn't sure if the new team was more a social group instead. However, he kept tabs on the Dragons. As soon as he had finished his final exams, he introduced himself to the coaches at the team's first game. By the following week, he was attending practice.

"I OFTEN SAY that rugby saved my life, because along with my medications, I always knew that there was this big commitment in my life," Matthews said. "I had a commitment to my teammates to show up and be ready to play."

Matthews' role has changed. He's been serving as referee since 2010, and began coaching in 2014. He found the competition that he thrives on, but something more.

"I coach college rugby, and I have found nothing but acceptance from the team," Matthews said. "The Dragons are a gay team, but my college team is not, and they don't care. I have a lot of acceptance and respect from them."

"I call myself an 'old boy,'" Matthews said. "An 'old boy' is a rugby term. The rule in rugby is that you never let your team play a man down, so you always show up, ready to play. It doesn't matter how old you are or what shape you're in, if they need you, you step in. Your days of playing in every game might be over, but you never quit the game." PA

Brief Summary of Patient Information about ODEFSEY

ODEFSEY (oh-DEF-see)
(emtricitabine, rilpivirine and tenofovir alafenamide) tablets

Important: Ask your healthcare provider or pharmacist about medicines that should not be taken with ODEFSEY.

There may be new information about ODEFSEY. This information is only a summary and 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 ODEFSEY?

ODEFSEY can cause serious side effects, including:

- **Build-up of lactic acid in your blood (lactic acidosis).** Lactic acidosis may happen in some people who take ODEFSEY or similar 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
- **Severe liver problems.** Severe liver problems may happen in people who take ODEFSEY. In some cases, these liver problems can lead to death. Your liver may become large and you may develop fat in your liver.

  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
  - nausea
  - pain, aching, or tenderness on the right side of your stomach area
- **You may be more likely to get lactic acidosis or severe liver problems if you are female, very overweight (obese), or have been taking ODEFSEY or a similar medicine for a long time.**
- **Worsening of Hepatitis B virus (HBV) infection.** ODEFSEY is not approved to treat HBV. If you have HBV and take ODEFSEY, your HBV may get worse (flare-up) if you stop taking ODEFSEY. A "flare-up" is when your HBV infection suddenly returns in a worse way than before.
  - Do not run out of ODEFSEY. Refill your prescription or talk to your healthcare provider before your ODEFSEY is all gone.
  - Do not stop taking ODEFSEY without first talking to your healthcare provider.
  - If you stop taking ODEFSEY, 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 ODEFSEY.

What is ODEFSEY?

ODEFSEY is a prescription medicine that is used to treat HIV-1 in people 12 years of age and older:

- who have not received HIV-1 medicines in the past and have an amount of HIV-1 in their blood ("viral load") that is no more than 100,000 copies/mL, **or**
- to replace their current HIV-1 medicines in people who have been on the same HIV-1 medicines for at least 6 months, have a viral load that is less than 50 copies/mL, and have never failed past HIV-1 treatment.

It is not known if ODEFSEY is safe and effective in children under 12 years of age or who weigh less than 77 lb (35 kg).

When used to treat HIV-1 infection, ODEFSEY 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).

ODEFSEY 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.

Ask your healthcare provider about how to prevent passing HIV-1 to others. Do not share or re-use 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.

Who should not take ODEFSEY?

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

- carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®, Tegretol-XR®, Teril®)
- dexamethasone (Ozurdex®, Maxidex®, Decadron®, Baycadron™)
- dexlansoprazole (Dexilant®)
- esomeprazole (Nexium®, Vimovo®)
- lansoprazole (Prevacid®)
- omeprazole (Prilosec®, Zegerid®)
- oxcarbazepine (Trileptal®)
- pantoprazole sodium (Protonix®)
- phenobarbital (Luminal®)
- phenytoin (Dilantin®, Dilantin-125®, Phenytek®)
- rabeprazole (Aciphex®)
- rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®)
- rifapentine (Priftin®)
- the herb St. John's wort or a product that contains St. John's wort

What should I tell my healthcare provider before taking ODEFSEY?

Before taking ODEFSEY, tell your healthcare provider if you:

- have liver problems including hepatitis B or C virus infection
- have kidney and bone problems
- have had depression or suicidal thoughts
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if ODEFSEY can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking ODEFSEY.

Pregnancy registry: there is a pregnancy registry for women who take HIV-1 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.

- are breastfeeding or plan to breastfeed. Do not breastfeed if you take ODEFSEY.
  - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  - At least one of the medicines in ODEFSEY can pass to your baby in your breast milk. It is not known if the other medicines in ODEFSEY 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.

Some medicines may interact with ODEFSEY. **Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.**

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

How should I take ODEFSEY?

- Take ODEFSEY exactly as your healthcare provider tells you to take it. ODEFSEY is taken by itself (not with other HIV-1 medicines) to treat HIV-1 infection.
- Take ODEFSEY 1 time each day with a meal.
- Do not change your dose or stop taking ODEFSEY without first talking with your healthcare provider. Stay under a healthcare provider's care when taking ODEFSEY.
- Do not miss a dose of ODEFSEY.
- If you take too much ODEFSEY, call your healthcare provider or go to the nearest hospital emergency room right away.
- When your ODEFSEY supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to ODEFSEY and become harder to treat.

What are the possible side effects of ODEFSEY?

ODEFSEY may cause serious side effects, including:

- **See "What is the most important information I should know about ODEFSEY?"**
- **Severe skin rash and allergic reactions.** Skin rash is a common side effect of ODEFSEY. Rash can be serious. Call your healthcare provider right away if you get a rash. In some cases, rash and allergic reaction may need to be treated in a hospital. **If you get a rash with any of the following symptoms, stop taking ODEFSEY and call your healthcare provider right away:**
  - fever
  - skin blisters
  - mouth sores
  - redness or swelling of the eyes (conjunctivitis)
  - swelling of the face, lips, mouth or throat
  - trouble breathing or swallowing
  - pain on the right side of the stomach (abdominal) area
  - dark "tea-colored" urine
- **Depression or mood changes.** Tell your healthcare provider right away if you have any of the following symptoms:
  - feel sad or hopeless
  - feel 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 ODEFSEY. Liver problems can also happen during treatment with ODEFSEY 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 ODEFSEY.
- **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.
- **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 ODEFSEY. Your healthcare provider may tell you to stop taking ODEFSEY if you develop new or worse kidney problems.
- **Bone problems** can happen in some people who take ODEFSEY. Bone problems may include bone pain, softening or thinning (which may lead to fractures). Your healthcare provider may need to do tests to check your bones.

The most common side effects of rilpivirine, one of the medicines in ODEFSEY, are depression, trouble sleeping (insomnia), and headache.

The most common side effect of emtricitabine and tenofovir alafenamide, two of the medicines in ODEFSEY, is nausea.

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

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

For more information, call **1-800-445-3235** or go to **www.ODEFSEY.com.**

Keep ODEFSEY and all medicines out of reach of children.

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Odefsey™
emtricitabine 200mg/rilpivirine 25mg/
tenofovir alafenamide 25mg tablets

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Odefsey™

emtricitabine 200mg/rilpivirine 25mg/
tenofovir alafenamide 25mg tablets

New Odefsey® is now available

Actual Size
(15.4 mm x 7.3 mm)

One small pill contains rilpivirine, emtricitabine, and tenofovir alafenamide (TAF).

Ask your healthcare provider if ODEFSEY is right for you.

To learn more visit **ODEFSEY.com**

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Please see Brief Summary of Patient Information with important warnings on the adjacent pages.