POSITIVELY AWARE
HIV TREATMENT, PREVENTION, AND SUPPORT FROM TPAN
JANUARY + FEBRUARY 2017

BOOK EXCERPT
IN THE EYE OF THE STORM
One doctor's 30-year journey through the AIDS epidemic

POSITIVE SUPPORT
Gay men support themselves and each other as they confront HIV

OLDER, WISER, STRONGER
Living well as you age with HIV

HEPATITIS C AWARENESS
What gay men need to know

BACK TO THE FUTURE
When old meds have failed

Descovy®
emtricitabine 200mg/
tenofovir alafenamide 25mg tablets

YOU MATTER AND SO DOES YOUR HEALTH

That's why starting and staying on HIV-1 treatment is so important.

What is DESCOVY®?

DESCOVY is a prescription medicine that is used together with other HIV-1 medicines to treat HIV-1 in people 12 years and older. DESCOVY is not for use to help reduce the risk of getting HIV-1 infection. DESCOVY combines 2 medicines into 1 pill taken once a day. Because DESCOVY by itself is not a complete treatment for HIV-1, it must be used together with other HIV-1 medicines.

DESCOVY does not cure HIV-1 infection or AIDS.

To control HIV-1 infection and decrease HIV-related illnesses, you must keep taking DESCOVY. 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 DESCOVY?

DESCOVY may cause serious side effects:

- **Buildup 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; nausea; and/or pain, aching, or tenderness on the right side of your stomach area.
- **You may be more likely to get lactic acidosis or serious liver problems** if you are female, very overweight, or have been taking DESCOVY 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.** DESCOVY is not approved to treat HBV. If you have both HIV-1 and HBV and stop taking DESCOVY, your HBV may suddenly get worse. Do not stop taking DESCOVY without first talking to your healthcare provider, as they will need to monitor your health.

What are the other possible side effects of DESCOVY?

Serious side effects of DESCOVY 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 DESCOVY.
- **Kidney problems, including kidney failure.** Your healthcare provider should do blood and urine tests to check your kidneys. Your healthcare provider may tell you to stop taking DESCOVY if you develop new or worse kidney problems.
- **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 DESCOVY is nausea. Tell your healthcare provider if you have any side effects that bother you or don't go away.

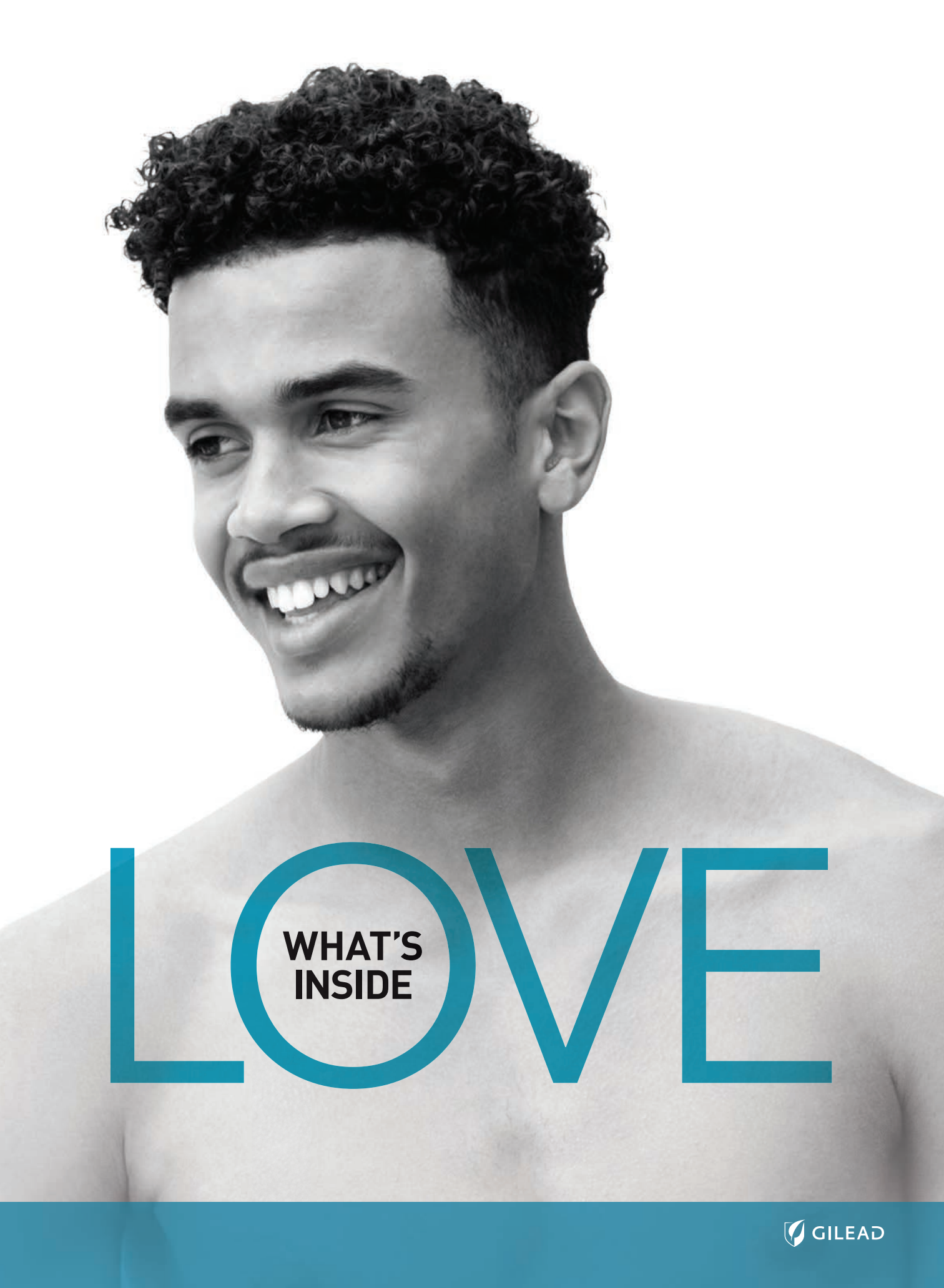
What should I tell my healthcare provider before taking DESCOVY?

- **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 DESCOVY 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 DESCOVY with all of your other medicines.
- **If you are pregnant** or plan to become pregnant. It is not known if DESCOVY can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking DESCOVY.
- **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 DESCOVY, including important warnings, on the following page.

Ask your healthcare provider if an HIV-1 treatment that contains DESCOVY® is right for you.


LOVE
WHAT'S
INSIDE
GILEAD

Descovy®
emtricitabine 200mg/
tenofovir alafenamide 25mg tablets

(des-KOH-vee)

IMPORTANT FACTS

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

MOST IMPORTANT INFORMATION ABOUT DESCOVY

DESCOVY may cause serious side effects, including:

- **Buildup 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; loss of appetite; light-colored bowel movements (stools); nausea; and/or pain, aching, or tenderness on the right side of your stomach area.
- **Worsening of hepatitis B (HBV) infection.** DESCOVY is not approved to treat HBV. If you have both HIV-1 and HBV, your HBV may suddenly get worse if you stop taking DESCOVY. Do not stop taking DESCOVY 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 DESCOVY or a similar medicine for a long time.

ABOUT DESCOVY

- DESCOVY is a prescription medicine that is used together with other HIV-1 medicines to treat HIV-1 in people 12 years of age and older. DESCOVY is **not** for use to help reduce the risk of getting HIV-1 infection.
- **DESCOVY does not cure HIV-1 or AIDS**. Ask your healthcare provider about how to prevent passing HIV-1 to others.

HOW TO TAKE DESCOVY

- DESCOVY is a one pill, once a day HIV-1 medicine that is taken with other HIV-1 medicines.
- Take DESCOVY with or without food.

POSSIBLE SIDE EFFECTS OF DESCOVY

DESCOVY can cause serious side effects, including:

- Those in the "Most Important Information About DESCOVY" 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 DESCOVY is nausea.

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

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

BEFORE TAKING DESCOVY

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 DESCOVY.

GET MORE INFORMATION

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

GILEAD

TO LIVE OR NOT TO LIVE

PA readers respond to one reader's decision to give up

"I'm tired and don't want to deal with it," wrote one reader whose letter appeared in the November+December issue. "All my friends gone—my lover, too. Take care, God bless all my family at TPAN and all around the world!" With that, he had seemingly given up. The Conversation is usually the forum for readers to respond to articles in the magazine, but that letter prompted a number of PA readers to react, sharing their own experiences and offering messages of hope. What follows are readers' responses, in the order in which we received them.

Sometimes I think somebody is talking to me through your magazine. I read The Conversation on Hughes Unit in Gatesville, Texas ["Don't want to deal with it," November+December 2016]. I was there. Not in Texas, but where he is in the way he was thinking. I too wanted to give up.

I also lost many people that I cared about through the years. In 2011 I lost Doris, the mother of my son. I saw her in a hospital in the Bronx. I could not recognize her. I tell you this: You really don't want to die. What I think you are trying to say is "I want to live." Many of us lost someone who we cared about. We feel the void. Who will replace that empty spot in my life? Nobody. I too wanted to stop taking my meds. I felt alone too. Right now I'm in prison, not my first time. I'm not proud of things I've done that led me here. But one thing is for sure. I want to live. That you ever thought about telling someone your story—do you know you may save someone because of it? You have a purpose in this world, so do it. Help someone else by sharing your story. Stay alive, be alive. You just made someone look at you—*me*. You are not alone. I would like for you to consider this. Honor your loss by giving some hope to others to live life. Maybe you can become a speaker of some kind, but how would you know if you just give up? I will honor Doris by helping others. I'm a peer educator here at Collins and it's very hard to reach this population, but I don't quit because it's hard. I want to help others because by doing so I am also helping me. So, I hope and pray that you take a new look at the way you think.

I was diagnosed with AIDS in 1994. I recently found out that I have Stage 4 cirrhosis and dementia due to HIV and alcohol, among other things. I refuse to let this take me to the grave. I will fight for my life to help someone else not to go through this. That is my purpose right now. Become educated to educate others on prevention. Hope this will change your mind, my friend. Yes, my friend. So now you have a new friend, okay? You are not alone and won't be. The Editor's Note [in response to the letter] is right on point. I don't want you to die. I want you to live and enjoy life. Whatever time you have, use it in a positive way. Become a new person who won't just give up. Try it. It works.

—RICHARD LAFLOWER
COLLINS, NEW YORK

I must comment on the letter titled "Don't want to deal with it." I also, after 20-plus years on our wonderful meds, am ready to throw in the towel! I have been on monotherapy, then the protease inhibitors, and now on Stribild—not bad but not good. I believe most damage was done years ago.

I live in the middle of Trump/Pence Land, two hours south of Chicago in Indiana, the most discriminatory place in the world. There is no transportation for people here on disability. It costs me $110 to get to my doctor. Now I have a shrink trying to take me off my Paxil, Ritalin, and Ativan because I'm not depressed!The last time he did this, my head went into "No Meds Land." I miss my husband (whom I cared for alone), my dog, and my real life. I buried the three most important people in my life within three months of each other. Once again I am considering stopping all meds—last time I was put on life support. I have a DNR [Do Not Resuscitate order]. No more comas to recover from, especially being totally alone.

Sorry to ramble on, but to "Don't Want to Deal"—I get you! God bless your journey. Peace be with you.

P.S. In 1996 I was given nine months to live. Now, at almost 60, I am so over it!

—NAME WITHHELD
LOGANSPORT, INDIANA

I am enclosing a letter I would like you to forward to the person who wrote "Don't Want to Deal with It." I don't know what kind of policy you have regarding forwarding mail, but I hope that in this matter you will see that my letter gets mailed to them. The tone of their letter left me feeling a need to reach out and offer a small comfort without preaching the need to change the decision they had made. I only offer up my own story and hope that that will encourage them to stay healthy, no matter how they do it. I can't imagine that I am the only person who reads your publication who has been encouraged to reach out to this person, and I hope if several others have, that you will forward

CONTINUED ON PAGE 6 >>

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POSITIVELY AWARE
JOURNALISM. INTEGRITY. HOPE.

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ON THE COVER AND THIS SPREAD **Photographed by Louis Carr on Santa Monica Beach, California.** FROM LEFT: **Anthony Braga**, 50; diagnosed with AIDS in 1999, a peer support advocate in Ventura County, and volunteer at Being Alive Los Angeles. **Dontá Morrison**, 44; HIV-positive since 1999, co-founder of 6in10.org, host of *The Dontá Show* on Blogtalk Radio, and a program coordinator at APLA Health. **Steven Campa**, 23; diagnosed with HIV in 2014, prevention training specialist at APLA Health. **Chris Wilson-Smith**, 30; diagnosed with HIV 10 years in January, prevention and care manager at the Black AIDS Institute and a project coordinator at ETR Associates. **Greg Wilson**, 34; diagnosed with HIV in February 2005, manager of the Positive Images program at the Los Angeles LGBT Center, author of *Metamorphosis of a Heart*.

JAN+FEB 2017

VOLUME 27 NUMBER 1

IN EVERY ISSUE

FEATURES

IF IT WASN'T FOR YOU, I DON'T KNOW WHAT I WOULD DO.
Yes, I've had a change of heart. Thank you!
—JIMMY LEE

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>> CONTINUED FROM PAGE 3

our letters. Thank you for your continued diligence in making HIV/AIDS awareness a top priority and a place for those of us to reach out to when the need arises.

—THOMAS S. FORD
MIAMI, FLORIDA

This is the most heart-wrenching letter I have ever read. This sounds like my partner. The author's pain hits me in the gut. The response to people in this situation is so horribly inadequate at every level and for so long. They are the forgotten soldiers still fighting and fully engaged in the fight. Is no one reaching out. This is making me cry, I can't forget this voice.

—NAME WITHHELD

The writer of the letter that started it all wrote a follow-up himself...

Hello, TPAN and Mr. Jeff Berry. Well, after reading the November+December issue, I saw the letter I wrote you and the Editor's Note, and I want my family there and around the world to know that when I see my doctor in January, I'm getting on a different regimen of medication. Because I know you guys care about me and people around the world would want me to fight the fight with you all too. Right now I'm on standby; I'm trying to see her before January because I'm not feeling too well. I'm having staph infections and outbreaks. This is because my T-cell count is so low. If it wasn't for you, I don't know what I would do. Yes, I've had a change of heart. Thank you!

—JIMMY LEE
GATESVILLE, TEXAS

MY COUSIN, LEW KATOFF

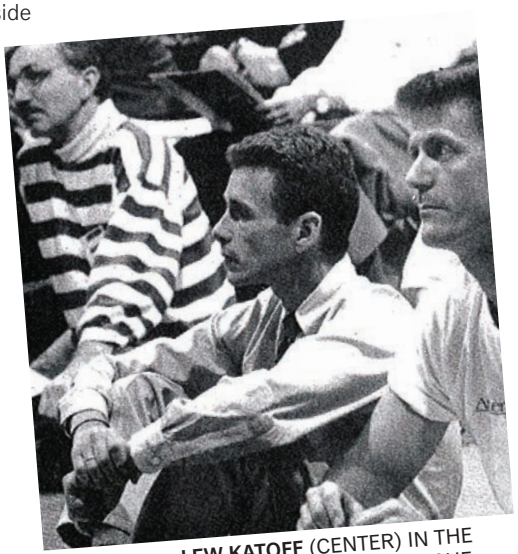
I am the gay first-cousin-once-removed of HIV/AIDS clinical researcher Lew Katoff. Lew died when I was 11, and was my only LGBT relative on my mom's side of the family. He was my mom's first cousin in a tight-knit Brooklyn Jewish family.

I have spent big chunks of time over my life trying to learn more about Lew, because I didn't know him very well (I was very young) and by the time I came into my own sexuality, he was gone. I have listened to some of the tapes where he interviewed long-term AIDS survivors, but have seen or heard little of his own voice.

I recently learned that a speech Lew gave was adapted for publication in the October 1991 issue of POSITIVELY AWARE. I would be willing to pay for the costs that would be associated with retrieving a copy from the archives, if possible. I would appreciate any assistance you could render in my quest to better know my too-soon-departed gay cousin.

—BRAD ROSEN
brad.evan.rosen@gmail.com

NOTE FROM ASSOCIATE EDITOR ENID VÁZQUEZ: When we received Brad's message, a copy of Lew Katoff's article was actually on my desk. Of the thousands of articles written in POSITIVELY AWARE in more than 25 years of publication, his—"Psychology of Long-Term Survivors"—was the only one at my fingertips (read it at positivelyaware.com). Because we had recently written so much about long-term survivors, I wondered what the term meant in 1991 after I came across the story. Brad has also applied for permission to access Lew's documents in the Special Collections office of the New York Public Library. I urge anyone who knew Lew or has anecdotes about him, or who has documents mentioning him, to contact Brad.



LEW KATOFF (CENTER) IN THE OCTOBER 1991 ISSUE.

PHOTO: CHRIS KNIGHT

EDITOR'S NOTE
JEFF BERRY

NO WORDS

On the evening of November 8, my partner Stephen and I went with our friend Doug to dinner at this great little Mexican restaurant in the neighborhood, and enjoyed a good meal, a pitcher of margaritas, and great conversation. The television screen in the background displayed early results of the election with Trump leading, but only three states at that point had been called, so I wasn't too worried. But after arriving home and as the night wore on, I started to get worried. Then scared—really scared. And then I became downright angry.

In subsequent days people talked about how they privately wept (some for days, curled up in fetal positions), or became physically ill, at the realization that Trump had been elected, but my reaction was one of anger. I was pissed at those who voted for him, and mad at the Democratic Party for not mounting a better campaign, but mainly I was angry at the media for their complicity in helping to get him elected.

So I stopped watching. Cold turkey. It used to be a part of my everyday ritual to turn on one of the morning news shows as I started about my day, and then again the evening news when I returned home, in addition to reading the newspaper. But I just stopped viewing the next day, and have pretty much not watched ever since, because I didn't want to listen to those same people who helped get him elected now pontificate on and on about what happened and why. I also stopped for my own sanity. I needed a break. And I didn't want the visuals. I wanted to control how and when I received the information, and just take some time to breathe, and gather my thoughts.

It's going to be a long four years, so we need to learn to pace ourselves. I had read somewhere recently that you should set aside some time each day, preferably the same time, and do something for yourself for 10 or 15 minutes, such as meditation, yoga, reading, or some other exercise or ritual that helps you to clear your mind of the clutter, and focus on the here and now. It's really helped me to stay more grounded and centered, and be less anxious. Now I start each day off with something I look forward to, rather than flipping on the TV and all the attendant noise and chatter that comes along with it.

Each day the news seems to only get worse. The anti-gay and anti-abortion Cabinet choices. The calls for repealing and replacing the Affordable Care Act (and with what?). Medicare and Medicaid potentially being put on the chopping block. Possible cuts to funding for HIV research at the National Institutes of Health (NIH). The list goes on and on. And when no one was watching, the 21st Century Cures Act was pushed through Congress in December, so now new drugs in development may not have to actually be proven to be effective to get approved. What can we possibly do in the face of all this madness?

Well, I have a theory. Remember, this is how he got elected, constantly throwing stuff out there, changing his tune every five minutes with ever more absurd or ridiculous claims and/or statements. That won't change, only this time it will take the form of appointments of people who are going to make decisions that have lasting effects. There are going to be many targets and they will keep shifting, so we will have to remain focused in our efforts, and keep our eyes on the prize.

There are already leaders in the HIV community who are coming together to mobilize and strategize the next plan of attack, and preparing for when the transition occurs so they can come armed with facts, figures, and arguments as to why, for instance, it's cheaper in the long run to keep certain provisions of the ACA such as covering those with pre-existing conditions, or keeping the individual mandate and the expansion of Medicaid.

There are things that we can do individually as well. Find what interests you most, and get involved. Call an HIV organization in your area and see if they need help or volunteers. Participate in advocacy or peaceful demonstrations. When you get those requests for individual or organizational sign-ons, or calls to members of Congress about legislation, take part and participate! Check out the great new resource #ActivistBasics from our friends at TheBody.com.

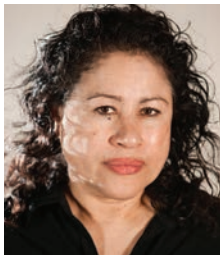
Veteran LGBTQ activist Michelangelo Signorile, in a recent interview on *Huffington Post*, said there are four key messages he'd like young queer people to adopt, which can apply to all people: Don't wait; recognize the importance of intersectionality; protest creatively; and remain intergenerational in our resistance.

Lastly, in the words of activist Jennifer Johnson Avril, it may not be so much about asking yourself what you can do, but "who will I become?"

Take care of yourself, and each other.

It's going to be a long four years, so we need to learn to pace ourselves. I had read somewhere recently that you should set aside some time each day, preferably the same time, and do something for yourself for 10 or 15 minutes, such as meditation, yoga, reading, or some other exercise or ritual that helps you to clear your mind of the clutter, and focus on the here and now.

@PAeditor



BRIEFLY

ENID VÁZQUEZ @ENIDVAZQUEZPA

Smoking is worse than HIV

"HIV-positive individuals who smoke cigarettes may be more likely to die from smoking-related disease than the infection itself," according to a press release on a study published in November 2016 in the *Journal of Infectious Diseases* (JID). "**The study, which analyzed men and women with HIV who take their treatments as prescribed, found that smoking reduces life expectancy by about twice as much as HIV**. Now that HIV treatments are so effective against the virus, this research highlights the need to make smoking cessation a priority among this patient population—which has smoking rates more than double that of the general U.S. populations."

Study author Krishna P. Reddy, MD, of Massachusetts General Hospital and Harvard Medical School, and her colleagues used a computer simulation model of HIV disease and treatment to project estimations of life expectancy.

Reductions in life expectancy for smokers were twice as high as reductions from HIV. Again, this was for people who adhere well to their HIV treatment.

"It is well-known that smoking is bad for health, but we demonstrate in this study just how bad it is," Dr. Reddy said in the release. "A person with HIV who consistently takes HIV medicines but smokes is much more likely to die of a smoking-related disease than of HIV itself."

According to the Centers for Disease Control and Prevention (CDC), more than 40% of people living with HIV in the U.S. smoke, compared to 15% of adults in the general population. The discrepancy has long been recognized. Medical providers are urged to ask patients living with HIV about smoking and provide assistance in achieving smoking cessation.

According to the mathematical modeling study, smoking would still equal the cuts in life expectancy—for men—as would be seen with HIV alone for those with imperfect taking of HIV treatment and missed follow-up health care.

As one example, the research team reported that men starting HIV care at age 40 who continued to smoke lost 6.7 years of life—women lost 6.3 years—compared to those living with HIV who never smoked.

On the other hand, if they stopped smoking at age 40, men would gain 5.7 years of life, and women would gain 4.6 years. Basically, they would almost even the score, as if they had never smoked.

But Dr. Reddy said that even people who smoked until age 60 and then stopped "have a substantial increase in their life expectancy compared to those who continue to smoke. So it's never too late to quit."

The research team used data from studies of people living with HIV for their findings. The study was funded by the National Institute of Allergy and Infectious Diseases and Massachusetts General Hospital.

PHOTO: GUNNERL/ISTOCKPHOTO

NEW HEP B PILL—VEMLIDY: The **FDA approved tenofovir alafenamide (TAF) as a treatment for hepatitis B** virus (HBV), as a medicine called Vemlidy. TAF is also an HIV treatment in the combination pill Descovy and other fixed-dose combinations. Vemlidy was approved by the FDA on November 10, 2016.

HIV perinatal guidelines

The U.S. Department of Health and Human Services (DHHS) updated the guidelines for perinatal HIV treatment, recommending that HIV therapy should start as early in pregnancy as possible.

"The Panel now recommends that—based on the preponderance of studies indicating no difference in rates of birth defects for first-trimester compared with later ARV [antiviral] exposures—women can be counseled that **ART [antiretroviral therapy] during pregnancy generally does not increase the risk of birth defects**," DHHS reported.

This includes the use of efavirenz (found in Atripla), in accordance with guidelines from the World Health Organization and the British HIV Association, despite the birth defect warning that remains on the drug label. Efavirenz, however, was reclassified from a "Preferred" HIV drug to take in pregnancy to "Alternative" due to its neurological effects. Women who tolerate it well should continue to use it.

However, the relatively new medication tenofovir alafenamide (TAF), which is found in Descovy, Genvoya, and Odefsey, cannot be recommended for pregnant women at this time, due to lack of safety and pharmacokinetic data.

In addition, the section on initial assessment of HIV-positive pregnant women was updated to include intimate partner violence-related screening and supportive care. There is also referral information for HIV testing of sexual partners plus information on the use of PrEP (pre-exposure prophylaxis, or prevention) for the partners.

Among the other updates and changes:

- **References to expedited HIV testing**, preferably using fourth-generation antigen/antibody rapid tests
- **Expanded information on drug interactions** between HIV medications and hormonal contraceptives
- **Counseling information on the use of Truvada** for prevention in HIV-negative partners of women living with HIV

The "What's New in the Guidelines" section is long, listing 17 items covering such issues as pregnancy for women born with HIV and medicines to prevent HIV in infants born to women living with the virus. The perinatal guidelines were updated October 26, 2016. Go to aidsinfo.nih.gov.

Selzentry approved for children

The U.S. Food and Drug Administration (FDA) has approved Selzentry (maraviroc) for children who are at least two years old and weigh at least 22 pounds (10 kg). **The HIV medication was also approved in a new formula and in new pills**: a 20 mg/mL oral solution plus 25 mg and 75 mg tablets. Previously, Selzentry consisted only of 150 mg, 300 mg, and 600 mg tablets. The oral solution and the tablets with smaller doses better suit the medication needs of children. The FDA created a table of Selzentry doses for children, based on weight and other medications being taken. Selzentry is taken twice a day.

Read the extensive FDA press release on this approval, including pediatric data, at content.govdelivery.com/accounts/USFDA/bulletins/170a8a2/. You can also go to positivelyaware.com/selzentry for information about the drug. Approval of Selzentry for children came November 4, 2016.

HIV can cause cancer

Not only is HIV a serious illness, it can also cause cancer. DHHS reports that **an immune system weakened by HIV "is thought to increase a person's risk of getting several cancers caused by other viruses**, including non-Hodgkin's and Hodgkin's lymphomas; anogenital cancers, including penile, vaginal/vulvar, cervix, and anal; Kaposi sarcoma; and possibly oral-related cancers; and liver cancer. It also increases the risk of other types of cancers, including non-melanoma skin cancer, eye cancer, and possibly lung cancer." Four other viruses were also among the carcinogens added to the list—human T-cell lymphotropic virus type 1, Epstein-Barr virus, Kaposi sarcoma-associated herpesvirus, and Merkel cell polyomavirus. Read the release and report at ntp.niehs.nih.gov/pubhealth/roc/index-1.html.

More STDs

Bad news from the CDC: "**Total combined cases of chlamydia, gonorrhea, and syphilis reported in 2015 reached the highest number ever**, according to the annual Sexually Transmitted Disease Surveillance Report," released October 19, 2016. "There were more than 1.5 million chlamydia cases reported (1,526,658), nearly 400,000 cases of gonorrhea (395,216), and nearly 24,000 cases of primary and secondary (P&S) syphilis (23,872)—the most infectious stages of the disease. The largest increase in cases reported from 2014 to 2015 occurred in P&S syphilis (19 percent), followed by gonorrhea (12.8 percent) and chlamydia (5.9 percent). Chlamydia, gonorrhea, and syphilis are the three most commonly reported conditions in the nation and have reached a record high level." Read the report at cdc.gov/nchhstp/newsroom/2016/std-surveillance-report-2015-press-release.html.

Paying for lipodystrophy care

In August 2016, the state of Massachusetts passed a law requiring insurance coverage for lipodystrophy in people living with HIV. Although increases in cholesterol and triglycerides are part of the lipodystrophy syndrome and covered by insurance, **disfiguring aspects of the condition are considered cosmetic and not eligible for care and reimbursement.** For more information, go to glad.org/tlc.

WEBSITE NAME CHANGE: In a sign of the times, aids.gov, **the federal government's HIV information website, has changed its name** to hiv.gov. While AIDS has not gone away, the U.S. Department of Health and Human Services says, "today, people with HIV who are diagnosed early, linked to care, start antiretroviral therapy (ART), and take it as prescribed, can achieve life-long viral suppression that prevents HIV infection from progressing to AIDS."

New HIV vaccine approach

In the long road to a "functional cure," in which people living with HIV can keep their virus in check with a vaccination instead of taking medications on a daily basis, **researchers have found promise with the combination of new compounds**. They presented pre-clinical (very early) data in 36 non-human primates with SIV (a virus similar to HIV) over a two-year period.

Among the findings: the combination of an experimental medication called a TLR7 agonist, which stimulates the immune system, and an experimental therapeutic vaccine worked better than either given alone at lowering HIV "set point." This is the lowest level of virus reached by an individual. The nine primates given the combination also had less viral load and a longer time to viral rebound (detectable viral load).

Combining the two methods represents a new approach at a functional cure.

Read more about the results published in the November 9, 2016 edition of *Nature* in a press release at jnj.com/media-center/press-releases/new-therapeutic-vaccine-approach-in-non-human-primates-shows-potential-as-functional-cure-for-hiv-1.

More functional cure potential

In more research looking into a functional cure, researchers reported that the compound **VRC01, a broadly neutralizing antibody (bNAb),**

EXONERATING 'PATIENT ZERO'

In the early days of the AIDS epidemic, Canadian flight steward Gaétan Dugas was branded "Patient Zero." However, more recent scientific findings discredit this claim, saying **Dugas could not have possibly started the U.S. epidemic**. The report in the Spring 2014 *Bulletin of the History of Medicine*, written by Richard A. McKay, is a fascinating account of AIDS panic, sensationalism, and stigma.

In his introduction, McKay notes that, "[This] article also traces how [Randy] Shilts's highly selective—and highly readable—characterization [in his book *And the Band Played On*] of [Gaétan] Dugas rapidly became embedded in discussions about the need to criminalize the reckless transmission of HIV." McKay is a Wellcome Trust research fellow in the Department of History and Philosophy of Science at the University of Cambridge. His book on this story is due for publication this year by the University of Chicago Press. Go to ncbi.nlm.nih.gov/pmc/articles/PMC4046389/#f40. The *New York Times* published a lengthy article on the findings on October 26, 2016; read it at nytimes.com/2016/10/27/health/hiv-patient-zero-genetic-analysis.html?smid=fb-share.

MIRROR MEMOIRS PROJECT: Mirror Memoirs is a nationwide project looking for **stories and leadership of LGBTQ people of color in the emerging movement to end child sexual abuse**. Founder Amita Swadhin writes that, "The project builds an audio archive of at least 50 survivors' stories, will release a report aimed at service providers, philanthropists, and advocates, and will convene survivors and allies together in 2017 (in conjunction with the California Coalition Against Sexual Assault)." Childhood sexual assault is a known risk factor for acquiring HIV infection later in life. For more information, go to mirrormemoirs.com.

stopped signs of HIV replication for four weeks after the 24 study participants stopped taking their antiviral regimen. Because the virus did return to detectable levels, the scientists reported that further study is needed, as well as studies that combine bNAbs. Get more information at medicalxpress.com/news/2016-11-antibody-suppresses-hiv-infected-individuals.html, which includes a link to the report published in the *New England Journal of Medicine* (NEJM).

Accelerating immune therapies

According to Treatment Action Group and the Program for Wellness Restoration, "A coalition of HIV/AIDS activists are calling for renewed attention to HIV-positive people termed immunologic non-responders (INRs), who experience sub-optimal immune system reconstitution despite years of viral load suppression by antiretroviral therapy. Studies have shown that **INR patients remain at increased risk of illness and death** compared to HIV-positive people who have better restoration of immune function on current drug therapies." Read the press release at webnewswire.com/2016/11/30/hiv-activists-seek-to-accelerate-development-of-immune-enhancing-therapies-for-immunologic-non-responders/.

New hep C STR on the way

In December, Gilead Sciences applied for a New Drug Application (NDA) from the FDA for a new single tablet regimen for hepatitis C. The new drug consists of sofosbuvir and velpatasvir, which are already available in the pharmacy, plus a new medication, voxilaprevir (see page 28). According to a company press release, Gilead submitted data supporting the use of the regimen for 12 weeks of treatment for patients with genotypes 1–6 with either cirrhosis or compensated cirrhosis. These patients had experience with direct-acting antivirals for hepatitis C. Read the release at gilead.com/news/press-releases/2016/12/gilead-submits-new-drug-application-to-us-food-and-drug-administration-for-the-investigational-single-tablet-regimen-sofosbuvirvelpatasvirvoxilaprevir.

CDC'S "FABULOUS" GAY DANCE VIDEO

"The Centers for Disease Control and Prevention (CDC) has taken the unprecedented step of producing **a music video to educate gay men about the many HIV prevention options available** to them, and it is foot-stomping fabulous," writes Mark S. King, in his blog, *My Fabulous Disease*. "The song, *Collect My Love*, was released last year by The Knocks, and features vocals by the inimitable Alex Newell, the young gender-bending singer who rose to fame by stealing season three of the television series, Glee. (His rendition of *Boogie Shoes* on the show is a one-way ticket to my happy place.) The CDC invited Newell to participate in a new music video for the song, and it's a perfect fit for their outreach to young gay men of color." Read more at marksking.com/my-fabulous-disease/cdcs-gay-dance-video-hiv.

'Fear and Discrimination'

The new documentary *HIV Criminalization: Masking Fear and Discrimination* tells the story of unjust laws used against people living with the virus, which SERO Project executive director Sean Strub called "a defining moral issue" for HIV activists. The SERO Project, a U.S.-based network of people living with HIV and their allies, released the film on World AIDS Day, December 1, 2016. The network fights stigma and injustice facing people living with HIV, particularly in unjust criminal prosecutions. The film is directed by Christopher Kind and produced by Mark S. King. Go to seroproject.com.

Report on long-term survival with HIV/AIDS

On World AIDS Day 2016, the first chronicle of its kind describing a series of unique health and psychosocial challenges in HIV/AIDS survivors was released. *The Unintended Consequences of AIDS Survival* is **a 24-page status report that calls attention to the lives of long-term survivors**, who feel their psychosocial needs are not prioritized in the AIDS landscape. This, added to earlier physiologic aging now widely studied in survivors with years of traumatic stress and unprocessed grief, has essentially become the rallying cry for a new HIV movement. Written by long-time activist and survivor Matt Sharp, the report details the history of the epidemic and its lasting effects on those who have been HIV-positive for decades. Special needs and challenges for long-term survivors are examined, along with community responses from around the country. The report was funded by Bristol-Myers Squibb. Go to tpan.com/sites/default/files/Unintended_final.pdf.

WHAT IS ODEFSEY®?

ODEFSEY 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, have never taken HIV-1 medicines before, and have an amount of HIV-1 in their blood ("viral load") that is no more than 100,000 copies/mL; or in 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. ODEFSEY combines 3 medicines into 1 pill taken once a day with a meal. ODEFSEY is a complete HIV-1 treatment and should not be used with other HIV-1 medicines.

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

ODEFSEY may cause serious side effects:

- **Buildup 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; loss of appetite; light-colored bowel movements (stools); nausea; and/or pain, aching, or tenderness on the right side of your stomach area.
- **You may be more likely to get lactic acidosis or serious liver problems** if you are female, very overweight, or have been taking ODEFSEY or a similar medicine 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 virus (HBV) infection.** ODEFSEY is not approved to treat HBV. If you have both HIV-1 and HBV and stop taking ODEFSEY, your HBV may suddenly get worse. Do not stop taking ODEFSEY without first talking to your healthcare provider, as they will need to monitor your health.

Who should not take ODEFSEY?

Do not take ODEFSEY 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 ODEFSEY. 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 ODEFSEY?

Serious side effects of ODEFSEY may also include:

- **Severe skin rash and allergic reactions.** Skin rash is a common side effect of ODEFSEY. Call your healthcare provider right away if you get a rash, as some rashes and allergic reactions may need to be treated in a hospital. Stop taking ODEFSEY and get medical help right away if you get a rash with any of the following symptoms: 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, and/or dark "tea-colored" urine.
- **Depression or mood changes.** Tell your healthcare provider right away if you: feel sad or hopeless, feel anxious or restless, have thoughts of hurting yourself (suicide) or have tried to hurt yourself.
- **Changes in liver enzymes.** People who have had hepatitis B or C or who have certain liver enzyme changes may have a higher risk for new or worse liver problems while taking ODEFSEY. Liver problems can also happen in people who have not had liver disease. Your healthcare provider may do tests to check your liver enzymes before and during treatment with ODEFSEY.
- **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 ODEFSEY.
- **Kidney problems, including kidney failure.** Your healthcare provider should do blood and urine tests to check your kidneys. Your healthcare provider may tell you to stop taking ODEFSEY if you develop new or worse kidney problems.
- **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 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 effects that bother you or do not go away.

What should I tell my healthcare provider before taking ODEFSEY?

- **All your health problems.** Be sure to tell your healthcare provider if you have or have had any kidney, bone, mental health (depression or suicidal thoughts), 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 ODEFSEY 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 ODEFSEY with all of your other medicines.
- **If you 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.
- **If you are breastfeeding** (nursing) or plan to breastfeed. Do not breastfeed. HIV-1 can be passed to the baby in breast milk.

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

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.

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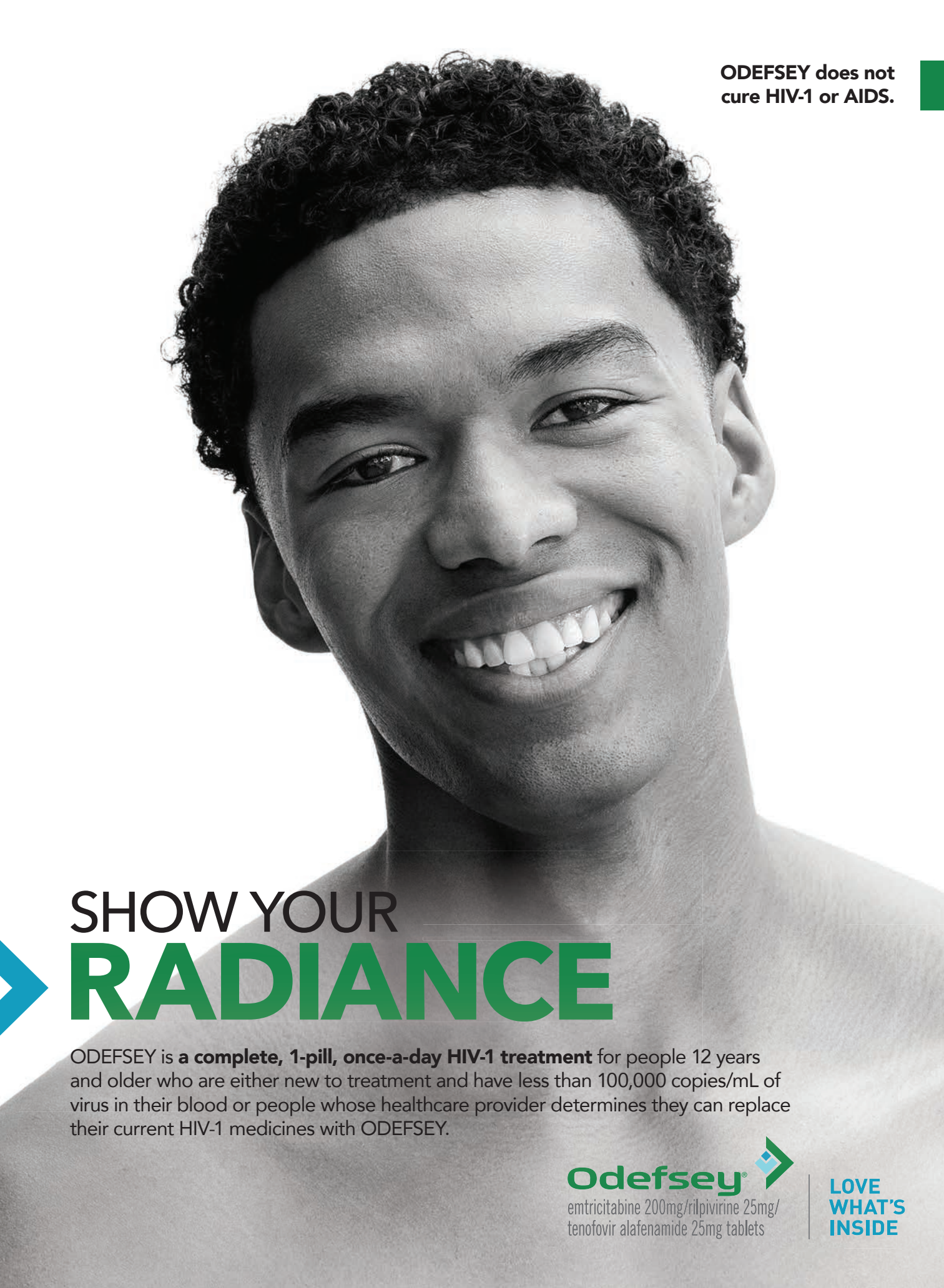
Please see Important Facts about ODEFSEY including important warnings on the following page.


ODEFSEY does not cure HIV-1 or AIDS.
SHOW YOUR
RADIANCE
ODEFSEY is **a complete, 1-pill, once-a-day HIV-1 treatment** for people 12 years and older who are either new to treatment and have less than 100,000 copies/mL of virus in their blood or people whose healthcare provider determines they can replace their current HIV-1 medicines with ODEFSEY.
Odefsey®
emtricitabine 200mg/rilpivirine 25mg/
tenofovir alafenamide 25mg tablets
LOVE
WHAT'S
INSIDE

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

(oh-DEF-see)

IMPORTANT FACTS

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

MOST IMPORTANT INFORMATION ABOUT ODEFSEY

ODEFSEY may cause serious side effects, including:

- **Buildup 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; loss of appetite; light-colored bowel movements (stools); nausea; and/or pain, aching, or tenderness on the right side of your stomach area.
- **Worsening of hepatitis B (HBV) infection.** ODEFSEY is not approved to treat HBV. If you have both HIV-1 and HBV, your HBV may suddenly get worse if you stop taking ODEFSEY. Do not stop taking ODEFSEY 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 ODEFSEY or a similar medicine for a long time.

ABOUT ODEFSEY

- ODEFSEY 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 and who have an amount of HIV-1 in their blood ("viral load") that is no more than 100,000 copies/mL. ODEFSEY can also be used to replace current HIV-1 medicines for some people who have an undetectable viral load (less than 50 copies/mL), have been on the same HIV-1 medicines for at least 6 months, have never failed HIV-1 treatment, and whose healthcare provider determines that they meet certain other requirements.
- **ODEFSEY does not cure HIV-1 or AIDS.** Ask your healthcare provider about how to prevent passing HIV-1 to others.

Do NOT take ODEFSEY if you:

- 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®), or rifapentine (Priftin®).
- Take the herbal supplement St. John's wort.
- Take any other HIV-1 medicines at the same time.

POSSIBLE SIDE EFFECTS OF ODEFSEY

ODEFSEY can cause serious side effects, including:

- Those in the "Most Important Information About ODEFSEY" section.
- Severe skin rash and allergic reactions.
- Depression or mood changes.
- Changes in liver enzymes.
- Changes in body fat.
- Changes in your immune system.
- New or worse kidney problems, including kidney failure.
- Bone problems.

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.

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

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

BEFORE TAKING ODEFSEY

Tell your healthcare provider if you:

- Have or have had any kidney, bone, mental health (depression or suicidal thoughts), 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 ODEFSEY.

HOW TO TAKE ODEFSEY

- ODEFSEY is a complete 1-pill, once-a-day HIV-1 medicine.
- Take ODEFSEY with a meal.

GET MORE INFORMATION

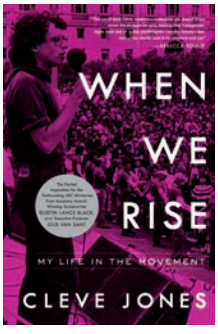
- This is only a brief summary of important information about ODEFSEY. Talk to your healthcare provider or pharmacist to learn more.
- Go to ODEFSEY.com or call 1-800-GILEAD-5
- If you need help paying for your medicine, visit ODEFSEY.com for program information.

GILEAD

SOUNDS OF LIFE
ACT UP'S SILENCE = DEATH AIR HORN PROTEST, FROM *HOW TO SURVIVE A PLAGUE*

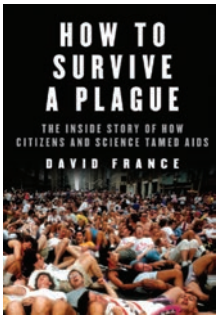
NOW HEAR THIS—RECOMMENDED READING

Two new releases, and one essential guide from 2015, round out our list of must-reads for the New Year



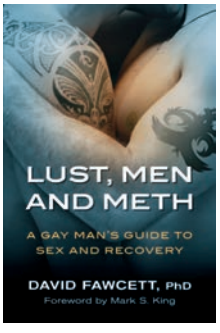
When We Rise: My Life in the Movement
by Cleve Jones
Hachette Books, 2016.

Cleve Jones, the co-founder of the NAMES Project AIDS Memorial Quilt and the San Francisco AIDS Foundation, recounts his remarkable life story in this new memoir written entirely in his own words. From his early childhood growing up being bullied in school first in a suburb of Pittsburgh, and then when his family moved to Phoenix, Arizona, to the gay liberation movement of the 1970s in San Francisco, and then within the grim epicenter of the AIDS epidemic of the '80s and '90s, Jones captures a moment in time and a movement that resonates even more today. With a number of funny and tender moments and a slew of unforgettable characters woven throughout, you will find it difficult to put this one down. *When We Rise* is the partial inspiration for the forthcoming ABC television miniseries of the same name, from Academy Award-winning screenwriter Dustin Lance Black, and executive producer Gus Van Sant. clevejones.com



How to Survive a Plague: The Inside Story of How Citizens and Science Tamed AIDS
by David France
Alfred A. Knopf, 2016.

Written by the creator of the Oscar-nominated documentary of the same name, *How to Survive a Plague* is the riveting story of the grassroots movement of activists, many of them in a life-or-death struggle, who seized upon scientific research to help develop the drugs that turned HIV from a mostly fatal infection to a manageable disease. David France describes the founding of ACT UP and TAG (Treatment Action Group), and the activists who helped forge the way for treatments that saved the lives of 16 million people living with HIV. Drawing upon his own experiences as a young gay man in New York, and with unparalleled access to this community, France honors previously unknown activist heroes, and even more importantly, ensures that the victims of the plague years won't be forgotten. davidfrance.com



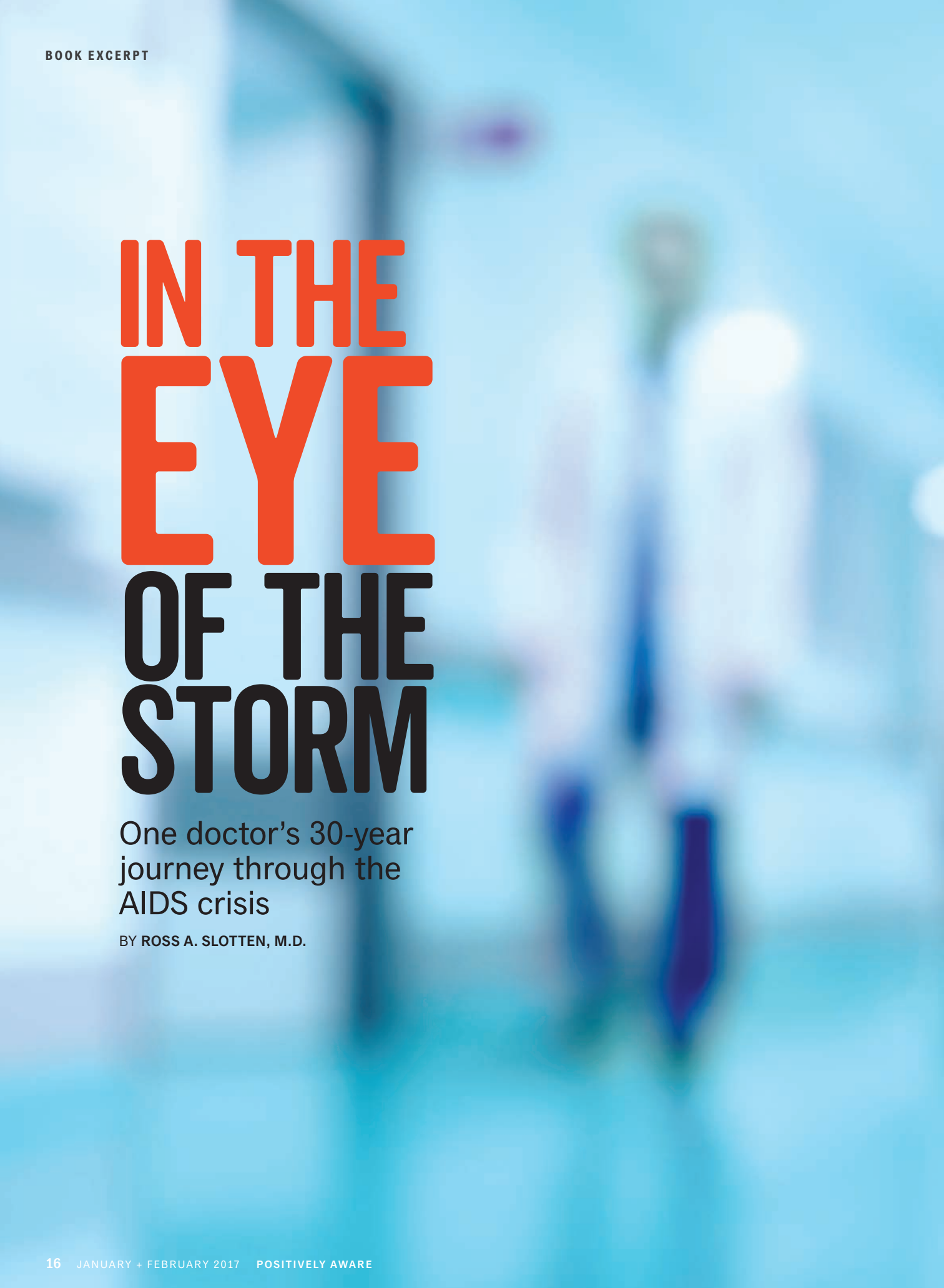
Lust, Men and Meth: A Gay Guide to Sex and Recovery
by David Fawcett, PhD
Healing Path Press, 2015.

David Fawcett provides the first practical resource for recovery from methamphetamine and the restoration of healthy sex and intimacy. Based on over a decade of clinical experience and research, Dr. Fawcett outlines the seductive appeal of methamphetamine and its impact on high-risk behaviors and sexual desire, resulting in the fusion of meth and sex in the brain. Such patterns of use quickly lead not only to a devastating addiction but sexual dysfunction as well.

Illustrated with examples from dozens of cases, this book outlines a path toward healing, describing the phases of physical, emotional, and sexual recovery and provides a broad range of supportive tools from managing triggers to mindfulness. david-fawcett.com

AVAILABLE AT a bookstore near you and online booksellers

ACT UP: RICK GERHARTER



IN THE EYE OF THE STORM

One doctor's 30-year journey through the AIDS crisis

BY **ROSS A. SLOTTEN, M.D.**

A couple of years ago, I reread some journals I'd kept during the worst years of the AIDS epidemic. I hadn't looked at them in more than a decade and was surprised not only by their vividness but also by the rawness of their content. They brought back memories of a time I'd almost forgotten or, rather, repressed because of the intense sadness they evoked. As a doctor, I was taught to keep an emotional distance from my patients. Too much emotion clouds one's judgment. But how does one keep an emotional distance from men who were like me at the time, young and gay and who ought to have had more tomorrows than yesterdays?

It took me many years to look at those journals again. So much had changed in the interval. Having HIV was no longer a death sentence, at least in the United States. A universally fatal disease had become a chronic one. It was possible, and likely, that my HIV-infected patients could live a normal lifespan. What a medical miracle! Enough time had passed that I wondered if I could turn these journals into a book. But how could I create something original?

There have been many books on AIDS, most written before 1995 when the first life-saving and life-restoring medication regimens became available. As time passed and more people survived than died, the story of AIDS seemed to end there. Other diseases began to terrorize the public, like Ebola, SARS, and now Zika. Writing about AIDS is passé, some people think. But HIV hasn't vanished. Every year, 40,000 to 50,000 new cases of HIV infection occur in the U.S., the majority among gay men and now primarily in men of color. PrEP may dent the numbers, but until there is a vaccine or cure, HIV/AIDS is here to stay.

I decided to write a memoir, because my career has been defined by the AIDS epidemic. It has followed the arc of the epidemic, from the first recognition of the virus to the present era. That's what makes my book unique. In 1981, I was an intern in family practice at Saint Joseph Hospital in Chicago. Thirty-five years later, I'm still here treating people with HIV/AIDS. The challenges I confronted in the '80s, '90s, and early 2000s differ from the challenges I face today. At first, I tried to prevent my patients from unduly suffering because preventing death was impossible; then I helped them live a few years longer than expected with the hope that a successful treatment would save them. Later, that treatment arrived. Now, the challenge is to keep the vulnerable from getting infected and to be a cheerleader for those infected who might become complacent and less compliant with their medications.

Although it is unlikely, HIV can wipe out another generation again. All it takes is a failure of resolve, especially from politicians who might deny access to life-saving treatments, whether through the termination of programs that fund the AIDS Drug Assistance Program or by allowing health care premiums to become unaffordable. I'm not predicting that scenario, but the lives of many depend on the kindness of strangers. My book serves as a cautionary tale for those who've forgotten or are ignorant of the ravages of one of the worst epidemics in human history.

—ROSS SLOTTEN

***"It is a wondrous tale** that I have to tell: if I weren't one of many people who saw it with their own eyes, I would scarcely have dared to believe it, let alone write it down, even if I had heard it from a completely trustworthy person ..."*

—GIOVANNI BOCCACCIO, *THE DECAMERON*

CHAPTER 1: **NO END IN SIGHT (1992)**

To the casual visitor, the west wing of the 11th floor of St. Joseph Hospital didn't look like hell. The elevator let people off into the solarium, a light-filled semicircular space with a panoramic view of Lincoln Park and Lake Michigan. In the distance, facing east, a few sailboats plied the placid waters beyond the stream of traffic on Lake Shore Drive; in the foreground, runners jogged along the tree-shaded paths. Northward, fashionable high rises lined the park's perimeter; to the south, one glimpsed the iconic skyscrapers of downtown Chicago. And to the west, not visible from this vantage point, was Boystown, the city's gayest neighborhood, a jumble of bars, restaurants, sex shops, and cheap apartments—the epicenter of the AIDS epidemic in Chicago. It was September 1992 and the city brimmed with life, in stark contrast to our AIDS Unit, where death reigned.

Occasionally a patient sat in a chair admiring the scenic vista or reflecting on his own mortality, his back in silhouette and body connected to an intravenous line that snaked from a plastic bag atop a metal pole and disappeared into an invisible arm. If the patient were someone I couldn't deal with at that early morning hour because of an intractable medical problem or difficult personality, I'd try to sneak by and speak to him later, when I had only minutes to spare before fleeing to my office two miles away. It was harder evading his family or lover, who waited anxiously for me to give them an update on their loved one's condition or to ask questions I often couldn't answer. These uncomfortable encounters foreshadowed my visits to the sick and dying patients in their rooms on the ward. Despite the cheerful urban vista 11 stories below, I was never deceived: 11 West, as we referred to our AIDS Unit, was a kind of inferno, with no one but I to guide me down to its deepest circles.

On several floors, including the 11th, three wings—north, south, and west—converged onto a solarium, a configuration that shaped St. Joseph Hospital into an enormous cross thirteen stories tall. It was a Catholic institution after all, administered by the Daughters of Charity, an order that once commanded the largest nonprofit fleet of hospitals in the United States. The Daughters soft-pedaled their religion. There were, of course, the requisite crucifixes in strategic places for all to see. But everyone was welcome, regardless of religious belief (or non-belief), race, gender, or sexual orientation. In my darkest moments, when I battled unsympathetic colleagues or struggled with internal demons, I sometimes forgot that St. Joe's was a refuge of tolerance. Otherwise, I could never have practiced there.

I'd exited the two elevators on the 11th floor so many times

PHOTO: SUDOK1 /ISTOCKPHOTO

A sick person wants to see strength in his doctor, not weakness, although too much suppression makes the

during the past four years since we'd established the AIDS unit that I rarely bothered to look out the floor-to-ceiling windows. I was usually in a hurry and took the view for granted. Pushed and pulled in many directions, I had a lot to accomplish in the two or three hours I could dedicate to hospital rounds. Whether one turned right or left from one of the two embankments, 11 West laid straight ahead, its gleaming linoleum floors forming an elongated, truncated triangle in perfect perspective. From the patient rooms emanated rectangular splashes of light, if all the doors happened to be open. It was like a runway or stage. But the drama rarely occurred in the hallways. It was on the sidelines, in each room, where a tragedy unfolded. Dreading this, I procrastinated at the nurse's station, gossiping with the unit secretaries, nurses, and other attending physicians, as if I were at a pre-performance party and not in the grim confines of a hospital. Then I got down to business and thumbed through the charts, catching up on the previous day and night's events, and reviewing the notes of the interns, residents, and consultants or searching for important lab and x-ray results.

With an impression of the patients' current conditions in mind, I took a deep breath and walked onto that stage, like an improvisational actor, uncertain of what my audience would demand of me. Dressed in my doctor costume—a long gray frock with a pen and penlight clipped into a breast pocket; a stethoscope stuffed into one side pocket; and a prescription pad into the other—I exuded the confidence of a seasoned performer, although I felt anything but self-confident. That lack of self-confidence stemmed not from inexperience or inability—I'd been a licensed physician since 1981 and had treated people with AIDS for a decade—but from the impossible expectations that patients placed on me, and that I placed on myself.

Doctors are often referred to as healers, or as practitioners of the healing arts. I thought of the two Dr. B.'s on our staff, cardiovascular surgeons, who performed life-saving procedures like cardiac bypass surgery to stave off heart attacks; or my orthopedic friends, who fixed hips and repaired other fractures that in a distant era would have left their patients crippled or deformed for the rest of their lives. But on the AIDS ward I wasn't healing anyone. I was ministering to my patients, as doctors once did in the pre-antibiotic era, doling out bad news, holding a hand in sympathy, or expressing my condolences in response to an incurable, fatal disease. Under such conditions I felt more like a failure than a success, even though HIV-infected gay men flocked to me from the city and suburbs or from neighboring states because of my expertise and reputation.

As my shoes clicked on that glistening surface, the pungent odors of sanitizer, shit, and urine—a smell unique to hospitals and nursing homes—wafted unpleasantly into my nose. And from some of the rooms emanated sounds of suffering: groans, cries in varying intensities, hacking coughs, or vomiting. If I heard laughter I suspected dementia or an inappropriate response to illness, for there was little to laugh about on 11 West. Rounding on terminally ill patients filled me with overwhelming sadness and wasn't something I looked forward to, for my performance didn't matter to those too sick to care; and to those in an earlier stage of their disease, I feared I might stumble over or forget my lines. They hung on every word and gesture, as if what I said or how I said it held the key to their salvation or pointed the way to their demise. It was a pressure almost too much for me to bear.

The first room I entered that morning was that of my patient Tony, only twenty-eight years old. Although he identified himself as African-American, he was light-skinned and sallow, his hair shaved down to the scalp. A nice looking man with a pleasant personality, he'd become my patient not long after testing positive for HIV. In such circumstances, when a person grapples with a life-threatening disease, he and the doctor either bond, or don't, as on a first date. We bonded, in part because we shared one important trait: we were both gay. This mutual knowledge shattered the barrier that often arises between doctor and patient. Although I didn't share details of my personal life with him, we spoke the same language and could understand each other on a human level, which increased his trust in me, and my comfort with him. One week earlier I'd sat on the side of his bed holding his hand as we talked about how he'd get out of the hospital and resume a normal life for a while. I'd been treating him with intravenous antibiotics for an intractable sinus infection, but each day I watched him descend deeper into a depression as he spent more time in bed, clutching the left side of his head in pain.

It wasn't long before his depression began to grate on me. Why didn't he want to go home, I wondered? On the day he was supposed to be discharged, I asked him to stand up after examining him in bed and finding nothing obviously wrong. Not believing that he was as ill as he claimed to be, I wanted proof that he was incapable of managing on his own. Bracing himself on the handrails as he rose from the bed, he took a few steps forward and staggered, which startled me. With my hands on his shoulders to stabilize him, I guided him gently back to bed, as it finally dawned on me that he wasn't exaggerating his symptoms, but suffering from something more serious than sinusitis or depression. And he was. The next day, he had a seizure and lost consciousness. A CAT scan of his brain showed multiple tumors; diffuse disease of the white matter; and swelling of the brain—images suggesting that his death was imminent. I'd not suspected the diagnosis, so convinced was I that something more benign caused his headaches and fatigue. But miraculously he improved after I prescribed high doses of steroids, which alleviated pressure on the part of the brainstem that controlled his vital functions.

On this particular September morning, several days after the seizure, I found Tony alert but debilitated by severe neurological deficits. Invariably, his room was dark except for a television that blasted inanities. Passing the bathroom, I glimpsed him in the flickering artificial light lying on his back with his neck twisted to the left ("looking at the brain lesions," as the consulting neurologist explained his awkward posture) like someone who'd had a stroke. His lower lip protruded outward and he breathed through his mouth, but both lips were scaly and cracked from an inability to moisten them. His face glistened with oil, and he smelled of urine and sweat, despite the nurses' best efforts to keep him clean. How much had changed in so short a time, I thought! A once vibrant young man seemed to have aged fifty years. A

doctor seem cold and uncaring. Finding the right balance between compassion and aloofness was something I struggled with.

fleeting feeling of pity passed through me as I approached the bedside, but as a doctor, one learns to suppress emotions, for unbridled emotions can cloud clinical judgment and lead to faulty decisions. A sick person wants to see strength in his doctor, not weakness, although too much suppression makes the doctor seem cold and uncaring. Finding the right balance between compassion and aloofness was something I struggled with each time I confronted a dying patient, or any patient for that matter.

Pulling up a chair, I sat down beside the head of the bed and called Tony's name. "Hello," he responded in a garbled voice, unable to turn his head toward me. The muscles on the right side of his neck appeared deceptively muscular, because of the strain on the left. With his neck bent in such a vulnerable way, he reminded me of a sacrificial lamb waiting to be slaughtered. An impairment of his eye muscles prevented him from looking at me directly. And even if he could look, each eye roved separately, without coordination. Although he squeezed my fingers in his left hand when I asked, indicating higher cognitive function, he couldn't move the rest of his arm. I asked myself if this was the best he'd ever be. Probably, I concluded. What a nightmare! I should never have tried to treat him, I lamented. It would have been best to let him die, rather than to leave him here in the hospital to languish in such a dependent state for the remaining days or weeks of his life. Of course, I didn't tell him this because it was my job to give some degree of hope even in the most hopeless situations. Yet given the severity of his disability, it wasn't possible to have a meaningful conversation with him. All I could do was pat him on the shoulder, grope for a few reassuring, if meaningless words, and move on.

The two other patients I rounded on that morning were faring no better than Tony, and both were destined to die in the near future. One had a partner who cried when I gave him that cruel prognosis. He wasn't ready to let his lover go. I hugged him as he sobbed into my coat, while I fought off my tears, unable to imagine how I would react if my own partner were on the verge of death. In normal circumstances, we'd be elderly, our sorrow no less painful but mitigated by the knowledge that we'd lived a long life and our times had come. But we were all too young to be dealing with such monumental issues.

I marvel how people *can hold on to the thinnest thread of hope when the only outcome, death, is obvious,* I reflected in my journal that night. My partner Kevin had already fallen asleep in the bedroom of our home, but sleep eluded me. I sat in bed by the lamplight and scribbled down whatever thoughts came to mind without attempting to interpret what I'd experienced that day.

It's as if a person is clinging to a cliff. You clutch both hands but one hand slips away. As you tighten the grip on the other, it too slips away. In desperation you grab a piece of clothing, but that piece rips off. The person falls screaming and all you're left with is a fragment of cloth. And still you believe the person is somehow alive. All three of the patients are cloth fragments, I think. You can't classify them as living. They breathe; they sweat; they urinate; they shit—the only evidence of life. Otherwise, they're in the land of the dead. They reek of death—from the skin, from the breath, from the rectum, from the interstices of their human shell. They stink of AIDS, which stinks like no other disease I know. Each death from a particular disease has its own stink. AIDS patients rot from the inside out, though they often rot from the outside in. When they breathe, the rot pours out, like the smell of waste from a sewer. Their bodies are sewers. Death from them is rarely peaceful or beautiful. It's a relief!

But whose relief was I referring to: the patients', the families' and friends'—or my own? I felt so weary, in some ways as helpless as Tony on the day I penned those observations. I was a caregiver who shepherded his patients from the land of the living to the land of the dead, like the boatman Charon, ferryman to Hades—hardly the role I'd envisioned as an enthusiastic, idealistic twenty-seven-year old man with the newly minted initials "M.D." after his name when he graduated from medical school in June 1981. And now more than ten years had passed since the first cases of AIDS had been identified in the United States. I'd been immersed in AIDS since its initial recognition, when I began my internship in July in Family Medicine at St. Joseph Hospital. Two weeks earlier, in late June 1981, the Center for Disease Control in Atlanta, Georgia, published the first report of a strange, lethal infection among a cohort of gay men in Los Angeles. I read the report in the hospital library wondering what it meant. As a gay man, was this something I was supposed to worry about? As a young doctor, would I ever see a case? I had no clue that the disease would soon kill friends, former lovers, colleagues, and patients; devastate tens of millions of people and their families worldwide; and consume my entire professional life and half my chronological one.

After opening a practice with my partner Tom in 1984, we became one of a small group of openly gay, regional experts dealing with this horrific disease. By 1992, when I made the entries about those three AIDS patients, I had the dubious distinction of having signed more death certificates in the city of Chicago—and probably in the entire state of Illinois—than any other physician. How many deaths had I witnessed? How many more could I withstand before breaking down?

I had no answers to such questions. In fact, such questions barely entered my mind that morning when I finished my rounds, recorded my observations and recommendations in my patients' charts, and returned to the bank of elevators without any acknowledgment of the beautiful urban landscape outside the windows. Lost in thought about my upcoming day, I descended to the first floor, stored my grey coat in a locker in the doctors' lounge, exited the hospital for the garage, slipped into my car, and headed to my office, Hell's waiting room. PA

PHOTO COURTESY OF ROSS SLOTTEN

ROSS SLOTTEN is a physician in Chicago who has been treating people with HIV/AIDS since 1982 (before it was known as AIDS). He has an M.D. from Northwestern University and a master's degree of public health from the University of Illinois at Chicago. In 2014, he was inducted into the Chicago Gay and Lesbian Hall of Fame for his work serving the Chicago gay community. He lives with his husband Ted.

A SECOND CASE OF INFECTION

Following reports of another patient acquiring HIV while on PrEP, **Damon L. Jacobs** talks with **Dr. Howard Grossman**, a leading HIV specialist, for answers and why he believes 'the pill is still the most effective tool for HIV prevention'

On October 18 at the 2016 HIV Research for Prevention (HIVR4P) conference in Chicago, longtime HIV clinician and primary care provider Howard Grossman, MD, shared data on a patient who acquired HIV despite having a lab test indicating consistent use of Truvada (tenofovir/FTC) as pre-exposure prophylaxis (PrEP).

PrEP use has increased rapidly in the past year in the United States. During a period in which Grossman estimates around 100,000 people worldwide have been on PrEP, this is only the second reported case of apparent HIV acquisition by a person adherent to PrEP. The first report was released in February at CROI 2016.

Grossman, who has written of his own decision to take PrEP, spoke with Damon L. Jacobs, an HIV prevention expert for TheBody.com, to explain the specifics of this case. He says that, with just two cases to date of documented HIV acquisition from PrEP-adherent people, PrEP remains the most effective HIV prevention technology available.

(Jacobs also spoke with **Dr. Bob Grant**, lead investigator for the iPrex study, the first clinical trial that first conclusively demonstrated the power of PrEP for HIV prevention, to learn more about how to discuss this new case.)

As with the first case, the new patient was infected with a very rare mutated form of HIV that is resistant to the drugs in Truvada (as well as a range of other HIV medications). Grossman reports that this time, however, his patient's likely risk was through insertive anal sex (topping), a sexual position with lower risk of HIV acquisition than receptive sex (bottoming).

—**JD Davids,** TheBody.com

DAMON L. JACOBS: What happened in this case?

A man on PrEP since December 2015 came in for his routine follow-up and had a positive fourth generation HIV test. His partner is male and HIV-positive but undetectable since soon after seroconversion in 2012. The patient had condomless insertive sex with this partner, but used a condom when receptive. On further questioning, they added that they'd played with

PHOTO: TIM HORN

two other people. Both times the person on PrEP who acquired HIV was on top.

Only one part of the HIV test was positive—the HIV qualitative test, which is a nucleic acid amplification test. [In other parts of that test and other tests], there were no signs of antigen or antibody and no viral load.

This is the second time we've learned of an HIV infection while someone adhered to PrEP. Does this mean that PrEP doesn't work as well as we thought?

Two cases out of perhaps 100,000 people is a very low failure rate. PrEP is still the most effective tool for HIV prevention we have ever had. Every scientific paper on PrEP has shown it to be less than 100% effective. Even in the Partners PrEP study, where no one got infected over the course of the study, mathematical modeling predicted up to a 4% infection rate if patients were followed for 10 years. Scientists have consistently held that PrEP is not 100% effective. It is people in the community who have put out the message that it is foolproof.

Why didn't PrEP prevent HIV infection in this person?

He was infected with a multi-drug resistant virus. It has resistance mutations for most of the nucleosides and some NNRTIs [non-nucleoside reverse transcriptase inhibitors]. There is no reason PrEP would work in the face of HIV that is resistant in this way.

How do you know this person was adherent to Truvada?

We got blood spot analysis and did hair analysis, much as they did for the iPrex trial. Both confirmed good levels that indicate long-term adherence. Neither test is commercially available.

We've always believed that being the insertive partner (or "top") put someone at less risk of acquiring HIV. Has that changed?

Well, this is the first documented case. There is no reason to doubt the patient or his partner. They have been very forthcoming. Just as there is a myth that tops can't get HIV, it would appear that those who say it is impossible for a top on PrEP to get infected are wrong. Still it is obviously a rare event to date. Nothing is ever impossible in medicine.

Does this change what we know about an undetectable HIV-positive partner being non-infectious?

Absolutely not. That would have been our fear if the virus appeared to come from his partner but we know it did not. So being HIV positive and undetectable continues to be an incredibly important prevention tool.

Now that this person has HIV, will HIV treatment work for him?

He has never had a viral load and is still HIV antibody negative. He remained on Truvada while we were trying to figure out what was going on, and once it became clearer that he was probably infected, we intensified with dolutegravir [Tivicay]. Then we got the results of resistance analysis done on proviral DNA (again a research test), showing resistance to all the nucleoside analogue drugs. So, we intensified again with Prezcobix, cobicistat-boosted darunavir. He is still undetectable. We kept the Truvada in his regimen as it has been shown that, even in the face of resistance, patients may do better with drugs containing nucleoside analogues in the mix.

Are there ways for people with HIV to find out if PrEP would not work for their partners, due to the possibility that they may have this type of resistant virus?

These are the key questions. If a partner is HIV positive who is not undetectable as there is negligible risk of HIV transmission when a person has undetectable HIV viral load, he or she can get resistance testing to determine what, if any, mutations exist. If that person's virus shows resistance to tenofovir and emtricitabine, the components of Truvada, then PrEP will not work to protect their negative partner. Again, for a known partner, it is more likely that this information exists.

If one is having condomless sex with a known partner who does not have undetectable HIV viral load, then the risk can be substantially reduced. With unknown partners of unknown HIV status who might not be well controlled and might have a resistant virus—there's the risk.

What other issues does this case bring up for you?

The other key issue this case raises is that our current testing algorithm for HIV may not be appropriate for those on PrEP. In this case, we would never have been able to assess the patient the way we did, determine his adherence, determine that his virus was genetically different from his partner's, or determine what resistance mutations existed without the intervention of folks in labs at Rockefeller, University of California San Francisco, the National Institutes of Health, and in Colorado. Most clinicians are not going to have those resources.

We only got the Western blot information because Marty Markowitz's lab at Rockefeller could run it. Commercial labs no longer do that test. We need to rethink whether a Western blot test could be helpful and should be put back into the commercial mix. It also raises the question of how we decide what to treat these people with, since the kind of resistance testing we got from Markowitz's lab [that identified additional mutations] is not readily available to clinicians.

Based on the new evidence in this case, will this significantly change the way you teach or talk to your patients about PrEP?

I have always said that I think there is an increased risk once the sex is with an unknown partner. There is absolutely no reason why PrEP will protect against a virus already resistant to these drugs, so having sex with people who could potentially be infected with a resistant virus and not know it—or who may be non-adherent with medication and have high viral levels—carries a risk. Sex with a known partner, either HIV-positive or -negative, carries far less risk to my way of thinking.

That said, obviously the odds are still good for most people. PA

DAMON L. JACOBS is a licensed marriage and family therapist; he is also the founder of the "PrEPFacts: Rethinking HIV Prevention and Sex" page on Facebook.
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What is TRUVADA for PrEP (Pre-exposure Prophylaxis)?

TRUVADA is a prescription medicine that can be used for PrEP to help reduce the risk of getting HIV-1 infection when used together with safer sex practices. This use is only for adults who are at high risk of getting HIV-1 through sex. This includes HIV-negative men who have sex with men and who are at high risk of getting infected with HIV-1 through sex, and male-female sex partners when one partner has HIV-1 infection and the other does not.

Ask your healthcare provider if you have questions about how to prevent getting HIV-1. 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 TRUVADA for PrEP?

Before taking TRUVADA for PrEP to reduce your risk of getting HIV-1 infection:

- **You must be HIV-negative.** You must get tested to make sure that you do not already have HIV-1 infection. Do not take TRUVADA for PrEP to reduce the risk of getting HIV-1 unless you are confirmed to be HIV-negative.
- **Many HIV-1 tests can miss HIV-1 infection in a person who has recently become infected.** If you have flu-like symptoms, you could have recently become infected with HIV-1. Tell your healthcare provider if you had a flu-like illness within the last month before starting TRUVADA for PrEP or at any time while taking TRUVADA for PrEP. Symptoms of new HIV-1 infection include tiredness, fever, joint or muscle aches, headache, sore throat, vomiting, diarrhea, rash, night sweats, and/or enlarged lymph nodes in the neck or groin.

While taking TRUVADA for PrEP to reduce your risk of getting HIV-1 infection:

- **You must continue using safer sex practices. Just taking TRUVADA for PrEP may not keep you from getting HIV-1.**
- **You must stay HIV-negative to keep taking TRUVADA for PrEP.**
- **To further help reduce your risk of getting HIV-1:**
  - Know your HIV-1 status and the HIV-1 status of your partners.
  - Get tested for HIV-1 at least every 3 months or when your healthcare provider tells you.
  - Get tested for other sexually transmitted infections. Other infections make it easier for HIV-1 to infect you.
  - Get information and support to help reduce risky sexual behavior.
  - Have fewer sex partners.
  - Do not miss any doses of TRUVADA. Missing doses may increase your risk of getting HIV-1 infection.
  - If you think you were exposed to HIV-1, tell your healthcare provider right away.
- **If you do become HIV-1 positive, you need more medicine than TRUVADA alone to treat HIV-1**. TRUVADA by itself is not a complete treatment for HIV-1. If you have HIV-1 and take only TRUVADA, your HIV-1 may become harder to treat over time.

TRUVADA can cause serious side effects:

- **Too much lactic acid in your blood (lactic acidosis)**, which is a serious medical emergency. Symptoms of lactic acidosis include weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, nausea, vomiting, stomach-area pain, cold or blue hands and feet, feeling dizzy or lightheaded, and/or fast or abnormal heartbeats.
- **Serious liver problems.** Your liver may become large and tender, and you may develop fat in your liver. Symptoms of liver problems include your skin or the white part of your eyes turns yellow, dark "tea-colored" urine, light-colored stools, loss of appetite for several days or longer, nausea, and/or stomach-area pain.
- **You may be more likely to get lactic acidosis or serious liver problems** if you are female, very overweight (obese), or have been taking TRUVADA for a long time. In some cases, these serious conditions have led to death. Call your healthcare provider right away if you have any symptoms of these conditions.
- **Worsening of hepatitis B (HBV) infection.** If you also have HBV and take TRUVADA, your hepatitis may become worse if you stop taking TRUVADA. Do not stop taking TRUVADA without first talking to your healthcare provider. If your healthcare provider tells you to stop taking TRUVADA, they will need to watch you closely for several months to monitor your health. TRUVADA is not approved for the treatment of HBV.

Who should not take TRUVADA for PrEP?

Do not take TRUVADA for PrEP if you already have HIV-1 infection or if you do not know your HIV-1 status. If you are HIV-1 positive, you need to take other medicines with TRUVADA to treat HIV-1. TRUVADA by itself is not a complete treatment for HIV-1. If you have HIV-1 and take only TRUVADA, your HIV-1 may become harder to treat over time.

Do not take TRUVADA for PrEP if you also take lamivudine (Epivir-HBV) or adefovir (HEPSERA).

What are the other possible side effects of TRUVADA for PrEP?

Serious side effects of TRUVADA may also include:

- **Kidney problems, including kidney failure**. Your healthcare provider may do blood tests to check your kidneys before and during treatment with TRUVADA for PrEP. If you develop kidney problems, your healthcare provider may tell you to stop taking TRUVADA for PrEP.
- **Bone problems**, including bone pain or bones getting soft or thin, may lead to fractures. Your healthcare provider may do tests to check your bones.
- **Changes in body fat**, which can happen in people taking TRUVADA or medicines like TRUVADA.

Common side effects in people taking TRUVADA for PrEP are stomach-area (abdomen) pain, headache, and decreased weight. Tell your healthcare provider if you have any side effects that bother you or do not go away.

What should I tell my healthcare provider before taking TRUVADA for PrEP?

- **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.
- **If you are pregnant or plan to become pregnant**. It is not known if TRUVADA can harm your unborn baby. If you become pregnant while taking TRUVADA for PrEP, talk to your healthcare provider to decide if you should keep taking TRUVADA for PrEP.
  Pregnancy Registry: A pregnancy registry collects information about your health and the health of your baby. There is a pregnancy registry for women who take medicines to prevent HIV-1 during pregnancy. For more information about the registry and how it works, talk to your healthcare provider.
- **If you are breastfeeding** (nursing) or plan to breastfeed. Do not breastfeed. The medicines in TRUVADA can pass to your baby in breast milk. If you become HIV-1 positive, HIV-1 can be passed to the baby in breast milk.
- **All the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. TRUVADA may interact with other medicines. Keep a list of all your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.
- **If you take certain other medicines** with TRUVADA for PrEP, your healthcare provider may need to check you more often or change your dose. These medicines include ledipasvir with sofosbuvir (HARVONI).

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 TRUVADA for PrEP including important warnings on the following page.

Have you heard about

TRUVADA for PrEP™?

The **once-daily prescription medicine** that can help reduce the risk of getting HIV-1 when used **with safer sex practices**.

- TRUVADA for PrEP is only for **adults who are at high risk of getting HIV through sex**.
- You **must be HIV-negative** before you start taking TRUVADA.

Ask your doctor about your risk of getting HIV-1 infection and if TRUVADA for PrEP may be right for you.

visit **start.truvada.com**

Truvada®

200 mg emtricitabine · tenofovir disoproxil fumarate 300 mg

Truvada®

200 mg emtricitabine - 300 mg tenofovir disoproxil fumarate

(tru-VAH-dah)

IMPORTANT FACTS

This is only a brief summary of important information about taking TRUVADA for PrEP (pre-exposure prophylaxis) to help reduce the risk of getting HIV-1 infection. This does not replace talking to your healthcare provider about your medicine.

MOST IMPORTANT INFORMATION ABOUT TRUVADA FOR PrEP

Before starting TRUVADA for PrEP to help reduce your risk of getting HIV-1 infection:

- **You must be HIV-1 negative.** You must get tested to make sure that you do not already have HIV-1 infection. Do not take TRUVADA for PrEP to reduce the risk of getting HIV-1 unless you are confirmed to be HIV-1 negative.
- **Many HIV-1 tests can miss HIV-1 infection in a person who has recently become infected.** Symptoms of new HIV-1 infection include flu-like symptoms, tiredness, fever, joint or muscle aches, headache, sore throat, vomiting, diarrhea, rash, night sweats, and/or enlarged lymph nodes in the neck or groin. Tell your healthcare provider if you have had a flu-like illness within the last month before starting TRUVADA for PrEP.

While taking TRUVADA for PrEP to help reduce your risk of getting HIV-1 infection:

- **You must continue using safer sex practices. Just taking TRUVADA for PrEP may not keep you from getting HIV-1.**
- **You must stay HIV-1 negative to keep taking TRUVADA for PrEP.**
- **Tell your healthcare provider if you have a flu-like illness while taking TRUVADA for PrEP.**
- If you think you were exposed to HIV-1, tell your healthcare provider right away.
- **If you do become HIV-1 positive, you need more medicine than TRUVADA alone to treat HIV-1.** If you have HIV-1 and take only TRUVADA, your HIV-1 may become harder to treat over time.
- **See the "How to Further Reduce Your Risk" section for more information.**

TRUVADA may cause serious side effects, including:

- **Buildup 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: weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, nausea, vomiting, stomach-area pain, cold or blue hands and feet, feeling dizzy or lightheaded, and/or fast or abnormal heartbeats.
- **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, dark "tea-colored" urine, light-colored stools, loss of appetite for several days or longer, nausea, and/or stomach-area pain.
- **Worsening of hepatitis B (HBV) infection**. If you have HBV and take TRUVADA, your hepatitis may become worse if you stop taking TRUVADA. Do not stop taking TRUVADA 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 TRUVADA for a long time.

ABOUT TRUVADA FOR PrEP (PRE-EXPOSURE PROPHYLAXIS)

TRUVADA is a prescription medicine used with safer sex practices for PrEP to help reduce the risk of getting HIV-1 infection in adults at high risk:

- HIV-1 negative men who have sex with men and who are at high risk of getting infected with HIV-1 through sex.
- Male-female sex partners when one partner has HIV-1 infection and the other does not.

To help determine your risk, talk openly with your doctor about your sexual health.

Do NOT take TRUVADA for PrEP if you:

- **Already have HIV-1 infection or if you do not know your HIV-1 status.**
- Take lamivudine (Epivir-HBV) or adefovir (HEPSERA).

POSSIBLE SIDE EFFECTS OF TRUVADA FOR PrEP

TRUVADA can cause serious side effects, including:

- Those in the "Most Important Information About TRUVADA for PrEP" section.
- New or worse kidney problems, including kidney failure.
- Bone problems.
- Changes in body fat.

Common side effects in people taking TRUVADA for PrEP include stomach-area (abdomen) pain, headache, and decreased weight.

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

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

BEFORE TAKING TRUVADA FOR PrEP

Tell your healthcare provider if you:

- Have or have had any kidney, bone, or liver problems, including hepatitis infection.
- Have any other medical conditions.
- Are pregnant or plan to become pregnant.
- Are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed if you become HIV-1 positive 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 TRUVADA for PrEP.

HOW TO TAKE TRUVADA FOR PrEP

- **Take 1 tablet once a day, every day**, not just when you think you have been exposed to HIV-1.
- Do not miss any doses. Missing doses may increase your risk of getting HIV-1 infection.
- You **must** practice safer sex by using condoms and you **must** stay HIV-1 negative.

HOW TO FURTHER REDUCE YOUR RISK

- Know your HIV-1 status and the HIV-1 status of your partners.
- Get tested for HIV-1 at least every 3 months or when your healthcare provider tells you.
- Get tested for other sexually transmitted infections. Other infections make it easier for HIV-1 to infect you.
- Get information and support to help reduce risky sexual behavior.
- Have fewer sex partners.
- Do not share needles or personal items that can have blood or body fluids on them.

GET MORE INFORMATION

- This is only a brief summary of important information about TRUVADA for PrEP to reduce the risk of getting HIV-1 infection. Talk to your healthcare provider or pharmacist to learn more, including how to prevent HIV-1 infection.
- Go to start.truvada.com or call 1-800-GILEAD-5
- If you need help paying for your medicine, visit start.truvada.com for program information.

GILEAD

Version date: April 2016

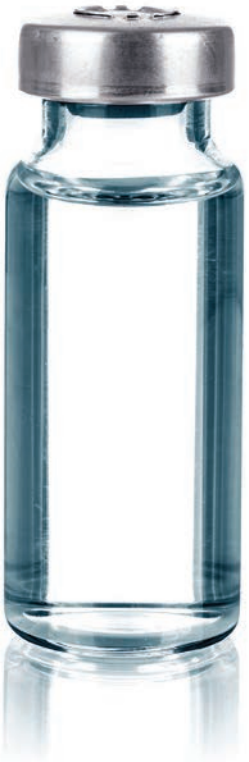

PHOTO: ROSE CARSON/ISTOCKPHOTO

BACK TO THE FUTURE

A new HIV medication offers hope to those who've exhausted their options

BY **ENID VÁZQUEZ**

In a way, the story of ibalizumab is a time travel tale back to 1994, before any protease inhibitor drugs were approved, bringing with them the era of powerful HIV combination therapy, of "Lazarus rising from the dead."

That breakthrough came at a cost—the drugs produced side effects that made people stop taking treatment. HIV drug development then continued its uphill climb, searching for newer and better medicines that people could easily tolerate. Fast forward to the present, and today's HIV medications are amazing in comparison.

But there are patients from the early years for whom most drugs soon failed regardless of side effects.

That's why the IDWeek report on a new treatment in development, ibalizumab (IBA), was so important. It was shown to work well for people who have no viable HIV treatment options left.

IBA could be approved by the U.S. Food and Drug Administration as early as this summer, and is actually available now to people who need it. It has virtually no side effects and no drug interactions.

But it comes with one big hurdle: it has to be given via IV infusion every two weeks. The infusion takes about 40 minutes. There are hopes of creating a subcutaneous injection formula.

Another great difficulty will be cost. If this is effective therapy for a relatively small group of people—however lifesaving—how can the cost be controlled?

Victims of success

Ten years after advocating for salvage therapies for people who have run out of effective HIV treatments, activist Nelson Vergel was fortunate to enter a study with ibalizumab. His CD4+ T-cells jumped from 220 to 483. Within a period of about three weeks, his HIV viral load was undetectable for the first time after more than two decades of living with the virus. The other four patients in his Houston doctor's office who were also in the study are also undetectable.

"Salvage" sounds so ugly. Yet there it was. Many people, for one reason or another, could no longer benefit from HIV medications. They had developed multi-drug resistant (MDR) virus. Their virus could no longer be controlled by medications. But HIV viral load needs to be suppressed to help people live and be healthy.

"Most of us, including me, who have multi-drug resistant virus volunteered for two or three studies in our lives and every study—because we had no other option—exposed us to functional monotherapy," he said.

They developed MDR virus in part because they put their bodies on the line in the search for HIV treatment at a time when it was not yet known that HIV drugs must be taken in combination in order to work best. They went on one drug after another, in one study after another. That's monotherapy, instead of the combination therapy needed to bring down HIV viral load.

"So we should be treated as veterans of the clinical trials," he said. "We got other drugs approved, but we sacrificed our health in the search for treatment."

'The most vulnerable'

"The issue of multi-drug resistant virus in HIV is not a huge problem in that we see the continued success of combination therapy, one pill once a day," said Jacob Lalezari, MD, the lead researcher on the ibalizumab study—TMB-301—presented at IDWeek, in an online video discussion about the IBA findings. Lalezari is the medical director of Quest Clinical Research, in San Francisco. "Most of the patients in our clinic are doing fine. This drug is really about addressing the needs of those left behind, the most vulnerable people .... In many ways they are the victims of the success of HIV drug development, because these once-a-day therapies are working so well and the bar is set so high that it's very difficult for

companies to bring new molecules with new mechanisms of action into the clinic."

Of note, the 40 patients in this study needed to have at least one other medication they could take that was active against their virus—one to which their HIV was not resistant.

For half of the study participants, that second active compound was another treatment which acts in the same area of viral infection that IBA does, at the cell entry stage. This one treatment on the market is Selzentry (maraviroc; see also page 9). Although both IBA and Selzentry are HIV entry inhibitors, they work in different ways. Selzentry is a CCR5 inhibitor and IBA is a monoclonal antibody.

Starting with two new therapies active against their virus keeps people from the functional monotherapy of just adding ibalizumab to a combination of HIV drugs to which they are already resistant.

Looking to meet FDA requirements for bringing ibalizumab to market, this was the first phase 3 study—the last step before FDA approval—in HIV history that didn't use the standard randomized trial design in which different people receive different therapies. Instead, everyone received IBA, because of the need to speed up the process in getting to approval. This new study design was created by the FDA to facilitate testing of new HIV medications for patients with limited treatment options.

The research team documented treatment failure (a detectable viral load) for their patients at Day 1 and Day 7. On Day 7, study participants were given a 2,000 mg loading dose of ibalizumab, via IV. At Day 14, the researchers optimized the therapy with a new drug. Thereafter, participants received an IV infusion of IBA once every two weeks, except now they were given a lower maintenance dose of 800 mg, as part of their treatment regimen.

At two weeks (Day 14), 83% of patients (33 out of 40) had experienced an HIV viral load drop of greater than half a log. (A "log" is simply a mathematical measure for dealing with extremely high numbers.) This is important, said Lalezari, because a half-log reduction of virus has been shown in other studies to be associated with a 33% decrease in mortality.

Better still, 17 of the 40 patients (55% of them) had a full one-log drop in their viral load.

These results were no easy feat. The study participants were, as one medical provider said, "at the very end of sustainability." A third of them had fewer than 10 T-cells. The patients were so ill that four of them died before the 24-week study ended. The cause of death included cirrhosis and Kaposi sarcoma. None of the deaths were related to ibalizumab.

The average time of living with HIV was 21 years and the average T-cell count was 161. Nearly one-third of them (28%) had taken more than 10 previous HIV medications.

Last chance?

"So, very significant antiviral activity with ibalizumab in this most difficult and vulnerable population," Dr. Lalezari said in the video. "Not enough to stop the virus as a single agent, but definitely an important new tool with which to cobble together a new regimen—potentially the last regimen—for a patient to both get their virus under control and then prevent the spread of that virus to someone else. It's the first of long-acting treatments that are changing the treatment paradigm towards a less frequently dosed regimen for a subset of patients. But the importance today is for a unique mechanism of action active against multi-resistant virus."

It's possible that IBA may be the "last chance" for some people, Lalezari said during a press conference at IDWeek. "It's very good and may be all we have right now."

Lucky

"I've been lucky to have five years of health," Vergel said. He and the others in the study were able to continue on ibalizumab after the 24-week study concluded when IBA went into expanded access, a process created for those who are urgently in need of new treatments that have not yet received FDA approval.

When the small company behind ibalizumab, TaiMed Biologics USA, started having financial difficulties in developing IBA, Vergel urged them to apply for orphan drug status as a way to cut the time and money needed to bring it to market. Orphan drug status is justified for populations of under 200,000 patients. The population of patients with MDR HIV fit into this requirement. In addition, the FDA granted a Breakthrough Therapy designation to IBA.

"I want to thank the FDA for agreeing to allow this to be an orphan drug because that was the only way the company could continue to work on getting it approved," said Vergel. "They didn't have enough funding to proceed. Without the drug my viral load would bounce back up. I would be lost. There's nothing else out there.

"Different people will tell you different things about the size of the multi-drug resistant population," Vergel said. "There's definitely less than 50,000 of us and probably less than 20,000 of us, so obviously the FDA said yes to the request. It will be the first orphan drug to be approved for HIV in history."

Vergel said that's both good and bad. It's good because it brings IBA to market faster and helped TaiMed to raise more money for its development. The bad part is that orphan drugs are priced very high because of their limited market.

Like Dr. Lalezari, he found the results encouraging and an opening for other therapies in the future.

It's possible that IBA may be the 'last chance' for some people, Lalezari said during a press conference at IDWeek. 'It's very good and may be all we have right now.'

WATCH the short video of Dr. Lalezari explaining the IBA study at bit.ly/2f2b37j. For more information on the TMB-311 expanded access study of ibalizumab, go to clinicaltrials.gov.

MORE NEWS FROM IDWEEK

These reports are but snapshots of findings presented at **IDWeek, held October 26–30, 2016, in New Orleans**. Search for research abstracts and poster presentations from IDWeek at idsa.confex.com/idsa/2016/webprogram/meeting2016-10-27.html.

SCREENING FOR ANAL CANCER

"Anal cancer is a common cancer among HIV-infected men who have sex with men (MSM), and studies have suggested an increasing incidence in this population," reported Mark Freedman, DVM, MPH, and colleagues. "To date, there are no national guidelines recommending anal cancer screening and no population-based estimates of screening rates among HIV-infected MSM."

Researchers found that, "**Between 2009 and 2012, only 11% of HIV-infected MSM in care were screened for anal cancer**, and significant disparities in screening by various characteristics were observed." The group noted that there are no federal guidelines for anal cancer screening in HIV-positive men. Information for this report came from the Medical Monitoring Project (MMP). They hope it can be used to guide decisions and screening, noting that guidelines for cervical cancer screening have reduced the rates of death and illness in women living with HIV.

RECRUITING POSITIVE GAY MEN ONLINE

Online intervention was more likely to keep HIV-positive gay men in care, on treatment, and virally suppressed, a research team discovered.

Richard Teran, MPH, and colleagues at the Columbia University Mailman School of Public Health reported in their poster presentation, "**Recruiting men online provides an additional avenue for researchers and clinicians** to (1) study HIV-positive MSM sexual behavior by reaching thousands of HIV-positive men, (2) identify men disengaged from HIV-related care, and (3) implement behavioral interventions to improve HIV-related care and outcomes."

They also concluded that, "Similar to CDC's estimates, our analysis identified younger and ethnic/racial minority MSM to be less likely to achieve viral suppression."

DOCTORS AGAINST MEDICINE

PrEP (pre-exposure prophylaxis) still faces an uphill challenge among some health care providers. **An anonymous survey of health care providers at the University of Maryland School of Medicine looked at experience, knowledge, and attitude towards HIV prevention with the use of medicine**. Despite general comfortableness with the biomedical prevention strategies, 15% of respondents (7 out of 47) said that PrEP should not be discussed with people requesting an HIV test.

Sarah Schmalzle, MD, and colleagues reported that requests for nPEP (non-occupational post-exposure prophylaxis) and PrEP happened rarely or never among the providers taking the survey. Providers had little awareness of patient assistance programs (for financial help) and noted barriers, "but most did think that both nPEP and PrEP were feasible and could be provided quickly."

The poster, packed with information, is available online.

TRAINING DOCTORS ON PrEP

Although the CDC recommends pre-exposure prophylaxis (PrEP) for those at high risk for HIV, **few primary care providers (PCPs) are willing to prescribe it**, reported Natalie Mariam Salas, MD, and colleagues in a poster.

"We discovered a lack of awareness of PrEP among PCPs in a metropolitan area in New Mexico. However, providers previously uncomfortable with prescribing PrEP became willing to do so after our educational intervention."

DISCLOSURE DISCUSSION DIFFICULT

Heather Farthing, BS, and colleagues from the University of Miami Miller School of Medicine and Jackson Memorial Hospital (in Miami) reported that of 71 HIV-positive patients surveyed (83.1% heterosexual, 80.3% African American, and 22.5% Latino), many said they had sex in the past year with someone who was HIV-negative or had unknown status. Of these 40.8% of survey respondents, 17.2% said they "never" disclose their HIV status to sexual partners.

"**Frequency of and comfort with discussions about HIV/AIDS and sex with friends, family, and partners may impact PrEP awareness** and should be considered when devising strategies to offer PrEP to discordant partners," the team reported in its conclusion.

HIV OUTBREAK IN INDIANA

An emergency syringe exchange program (SEP) established during an HIV outbreak in Indiana in 2015 reduced risks for transmitting the virus.

"Among clients enrolled during the first two months of an emergency SEP, many injection-related risk behaviors declined significantly," reported Monita R. Patel, PhD, MPH, and colleagues from the CDC. "**Emergency SEPs can rapidly reduce risk behaviors** capable of transmitting HIV in an outbreak setting."

HCV OUTBREAK IN INDIANA

Back in 2011, Indiana experienced an increase in acute (new) hepatitis C virus (HCV) infections among people with "a history of illegal drug use." The Indiana State Department of Health (INDH) decided to evaluate the use of a test called pooled NAAT (nucleic acid amplification test) that finds early-acute HCV cases. Cases found were later confirmed when the patients seroconverted, which showed the efficacy and benefit of this testing strategy.

The pilot program was discontinued in 2013 due to time and money constraints, but re-instituted during the 2015 HIV outbreak.

INDH found six cases that were NAAT-positive that had tested negative using the traditional HCV antibody test).

This number represented 2.11% of the antibody negative tests, but that was a higher detection rate than was found during the 2013 statewide pilot program (0.1%).

"**These data demonstrate the efficacy of pooled NAAT testing for the detection of acute HCV infection** in a high risk population," INDH reported. "In the future, acute-HCV screening through pooled NAAT may be seen as a useful barometer for the assessment of injection drug usage and risk of HIV acquisition throughout Indiana."

—ENID VÁZQUEZ

WHY CO-INFECTION MAY NO LONGER

Hepatitis C treatment for HIV/HCV co-infected people, sexual transmission of HCV, and other news from the **AASLD Liver Meeting held November 11–15, 2016, in Boston**

BY **LIZ HIGHLEYMAN**

This year's AASLD Liver Meeting featured several presentations on promising advances in treatment for hepatitis C, including for HIV-positive people with hepatitis C virus (HCV) co-infection. But sexual transmission of HCV and re-infection after being cured remain a concern.

Hepatitis C treatment for co-infected people

Direct-acting antiviral therapy has made hepatitis C treatment shorter, better tolerated, and much more effective than the old interferon-based therapy.

Interferon did not work as well for HIV-positive people as it did for HIV-negative people with hepatitis C, but fortunately this is no longer the case with direct-acting antivirals. Most clinical trials have shown that people with HIV respond just as well to these new drugs—so much so that experts no longer consider co-infected people a "special population."

But it is important to confirm these findings in real life, since participants in formal clinical trials are carefully selected and may receive more intensive monitoring and support.

Susanna Naggie, MD, from Duke University and colleagues compared the effectiveness of Harvoni (sofosbuvir/ledipasvir) for HIV/HCV co-infected people in clinical trials and in real-world medical practice.

The comparison included three clinical trials with a combined total of about 440 participants and four real-world cohorts with about 730 people, all with HCV genotype 1—the most common type in the U.S. A majority had not been previously treated for hepatitis C and did not have liver cirrhosis. They took Harvoni for 12 or 24 weeks. Pooling the results, the overall cure rates were 97% in the clinical trials and 94% in the real-world groups.

Juan Gonzalez-García, MD, reported findings from another study, from Spain, which found that more than 90% of HIV-positive people—including many with liver cirrhosis—were cured with direct-acting antivirals in clinics and hospitals in Madrid. Few people stopped treatment early due to side effects.

Together, these studies show that **real-life treatment for HIV/HCV co-infected people can match the very good outcomes seen in clinical trials**.

New treatment options for hepatitis C

Approved interferon-free direct-acting antiviral regimens have overall cure rates above 90%, but **there is still room for better options for harder-to-treat patient groups**. Combining more drugs that target additional steps of the HCV viral life cycle offers the potential for shorter and more effective treatment.

Gilead Sciences' POLARIS trials tested an experimental combination pill that combines three drugs: sofosbuvir (an HCV polymerase inhibitor), velpatasvir (an HCV NS5A inhibitor), and voxilaprevir (an HCV protease inhibitor). Unlike Harvoni, which is most effective against HCV genotype 1, the new combination is pangenotypic, meaning it is active against all genotypes, including the most difficult-to-treat genotype 3.

These studies showed that the combination taken for eight weeks cured 95% of previously untreated people with all HCV genotypes, while a 12-week regimen cured up to 97% of people who experienced prior treatment failure with older direct-acting antivirals.

AbbVie is testing a dual combination of glecaprevir (an HCV protease inhibitor) and pibrentasvir (an NS5A inhibitor), both of which are pangenotypic. This combination taken for eight or 12 weeks cured at least 98% of people with HCV genotypes 1, 2, 4, 5, or 6. It even cured almost everyone in the hardest-to-treat group, those with genotype 3, previous treatment experience, and advanced liver disease.

Finally, Merck is evaluating a three-drug combination pill containing grazoprevir (a protease inhibitor), ruzasvir (an HS5A inhibitor), and MK-3682 (a polymerase inhibitor). This

GRAHAM FOSTER PRESENTED RESULTS OF THE POLARIS-3 STUDY.

PHOTO: LIZ HIGHLEYMAN

BE 'SPECIAL'

During the interferon era, when treatment was poorly tolerated, many patients and providers preferred to wait and see if natural HCV clearance would occur. But with direct-acting antivirals, there may be little reason to wait other than the cost of the drugs.

regimen taken for 12 weeks cured 97% to 100% of people with genotypes 1, 2, or 3. This combination was also highly effective as re-treatment for people who relapsed on earlier direct-acting antivirals.

These new drug studies did not include many HIV/HCV co-infected participants, but prior experience with direct-acting antivirals suggests that co-infected people are likely to respond as well as those with HCV alone.

Hepatitis C among gay men

Starting in the early 2000s researchers in the U.K. and elsewhere in Europe began reporting clusters of apparently sexually transmitted acute HCV infection among HIV-positive gay and bisexual men in large cities; similar outbreaks followed in cities in the U.S. and Australia.

A number of risk factors have been implicated—including condomless anal sex, fisting, group sex, other sexually transmitted infections, and non-injection drug use—but these have not been consistent across studies. HCV sexual transmission remains rare among HIV-negative men who have sex with men.

Antoine Chaillon, MD, and colleagues from the University of California at San Diego looked at new HCV infections among gay and bi men in San Diego. To date, most studies of HCV sexual transmission in the U.S. have come from New York City and San Francisco.

Out of 2,396 men seen at the city's largest HIV clinic who started with a negative HCV antibody test, 149 became HCV-positive, for an incidence rate of 1.19 per 100 person-years. HCV incidence rose over time, from just 0.36 new infections per 100 person-years in 2000-2003 to 1.52 per 100 person-years in 2012–2015.

New HCV infections were identified an average of 11 years after HIV diagnosis and nearly four years after the first negative HCV test. Newly infected men were more than twice as likely as uninfected men to have injected drugs (18% vs 7%)—but still most said they had never done so. However, the newly infected men were also significantly more likely than uninfected men to report methamphetamine use (82% vs 58%). HCV infections occurring among gay men who do not inject drugs adds to the evidence for sexual transmission.

"These findings suggest that HCV incidence is increasing among HIV-positive [men who have sex with men] in San Diego," the researchers concluded. "These rates are similar to London and other major European cities."

Dr. Chaillon's team also compared the incidence of primary (first-time) HCV infection and re-infection following successful hepatitis C treatment at the same San Diego clinic.

About a quarter of people get rid of HCV naturally and many more can be cured with treatment. But unlike some diseases, having been infected with HCV in the past does not provide immunity that protects against future infections.

Out of 1,092 HIV-positive men seen at the clinic between 2008 and 2016, there were 40 HCV seroconversions, for overall primary HCV incidence rate of 1.16 per 100 person-years.

Forty-three men received hepatitis C treatment and were cured; 29 of them remained in care and were periodically re-tested for HCV re-infection. Three of the men treated successfully became re-infected, for a rate of 2.89 per 100 person-years. Two reported sharing drug injection equipment, but the third did not report any history of drug use and was assumed to have been re-infected through sex.

"HCV re-infection incidence among HIV-infected MSM in San Diego is two- to three-fold higher than primary HCV incidence," the researchers concluded, recommending increased efforts to prevent post-treatment re-infection.

Acute HCV infection

Due to a growing awareness of sexual transmission of HCV, gay men are more likely to be tested soon enough to catch it during the acute phase of infection, when it is easier to cure. Many pre-exposure prophylaxis programs, for example, test men on PrEP at least annually and some do so more often.

Katja Deterding, MD, from Hannover Medical School in Germany reported results from an acute hepatitis C study that evaluated Harvoni taken for six weeks—half the usual 12-week course recommended for most people with chronic or long-term infection.

This pilot study enrolled 20 participants with new HCV infection within the past six months. All had HCV genotype 1 and none were HIV-positive. Some had very high ALT liver enzyme levels and jaundice (yellowing of the skin and eyes due to high bilirubin).

This short regimen cured 100% of study participants. People with high baseline HCV levels took longer to achieve viral suppression, but all had undetectable HCV viral load by the end of treatment. They also experienced steep declines in ALT and bilirubin, reaching normal levels by the end of treatment.

The effectiveness of this regimen for acute hepatitis C needs to be confirmed for other HCV genotypes and for HIV/HCV co-infected people, who make up a substantial proportion of people diagnosed during acute HCV infection.

Earlier this year researchers reported that in another small study the same six-week Harvoni regimen cured all co-infected people with low baseline HCV viral load, but there were some relapses among people with high viral levels, suggesting that some HIV-positive people with acute hepatitis C might benefit from longer treatment.

During the interferon era, when treatment was poorly tolerated, many patients and providers preferred to wait and see if natural HCV clearance would occur. But with direct-acting antivirals, there may be little reason to wait other than the cost of the drugs.

The HepNet researchers encouraged prompt treatment of acute HCV—rather than waiting for possible spontaneous clearance—because it rapidly improves acute hepatitis symptoms, prevents onward transmission of HCV, and could even be cost-saving when compared to longer treatment during chronic infection.

LIZ HIGHLEYMAN (liz@black-rose.com) is a freelance medical writer based in San Francisco and editor of HIVandHepatitis.com.

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HEPATITIS C AWARENESS FOR GAY MEN

HCV educator **Andrew Reynolds** tells you what you need to know

Hepatitis C (HCV) is the most common blood-borne infection in the United States, with at least 3.5 million people living with it. Of this group, about 25% are co-infected with HIV and HCV. In recent years there's been increased attention to HCV as new medications have been developed and cure rates have improved for nearly all people living with the disease. With the fast pace of drug development and the blur with which treatment guidelines change, it can be hard for medical providers and people living with HCV to keep up.

Using information from current research and "Recommendations for the Testing, Managing and Treating of Hepatitis C," put out by the American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA), this article will provide a basic overview of HCV testing, prevention, and treatment overall, with information that is specific for gay men.

Hepatitis C testing

There is nothing specific or unique about HCV risk for gay men. That is to say, gay men aren't at any greater risk for HCV than anyone else. With HCV, it's the risk factors that matter: It's the things we do regardless of sexual orientation or gender that determine if one should be tested for it.

Historically we've not done a very good job of

HIV-positive gay men are at higher risk of sexually acquired HCV than other groups. That said, it can still be complicated when you start to break it down. We know that HCV is transmitted from blood-to-blood contact, but what about sexual fluids? There are some small studies that have found HCV in semen and non-bloody rectal fluids, while others have not. Whether or not it's in semen or other fluids, we know it's in blood, and sexual practices that can lead to blood carry risk for HCV transmission.

SHOULD YOU GET TESTED?

AASLD/IDSA HCV TESTING RECOMMENDATIONS

One-time HCV testing is recommended for anyone born between 1945-1965, without the need to do a risk assessment.

Anyone who injects or has ever injected drugs (including anyone who may have injected only once or those who did so many years ago).

Anyone who uses non-injectable, intranasal drugs (snorting from straws).

Anyone who has ever received a blood transfusion, blood products, or an organ transplant before 1992.

Anyone who has been on long-term hemodialysis;

Anyone who has gotten a tattoo in an unregulated setting.

Anyone who is incarcerated or has a history of incarceration.

Anyone born to an HCV-infected mother.

Anyone with HIV.

Anyone who has unexplained chronic liver disease.

Solid organ donors.

SOURCE: HCVGUIDELINES.ORG

testing for HCV. We're getting better, and we have clear recommendations for who should be screened and how frequently that screening should occur (see the box). If you are at ongoing risk through injection drug use and/or are living with HIV and sexually active, you should test for HCV at least once per year.

Hepatitis C is not routinely screened for during annual physicals or other medical provider visits. In fact, while many people just assume that HCV gets screened during STD exams, it rarely does. If you think you need a test, you should ask for it. Your medical provider may ask you some questions and do a risk assessment so they can justify the ordering of the test and provide you with proper care and health education.

How do they do HCV testing?

Hepatitis C testing can be pretty complicated. It's a two-step process: First, you take an HCV antibody test; and second, if the antibody test is positive, you take an HCV viral load test (also called HCV RNA or HCV PCR) to confirm that you are chronically infected with HCV.

The most important thing to remember here is this: If you test positive on the HCV antibody test, you have to confirm it with that viral load test.

If you're told "you are positive for hepatitis C because you tested positive for the antibody test," then you should follow up with the question "Are you sure? Did you confirm that antibody result with an HCV viral load?" If they didn't do a viral load test, ask for one. Seriously: You'd be surprised how frequently this gets missed by medical providers.

Why the two types of tests?

As with HIV, if you get infected with HCV, your body will respond by making antibodies (protein from your immune system). You'll have these antibodies for the rest of your life. The thing that's important to remember: Some people clear the virus within six months of infection, that is, there is no more virus in your body doing damage to your liver. This happens about 25% of the time (1 out of 4 people).

When you clear the virus, you will test positive for the antibodies, but not have the virus in you. Therefore, to know if you're chronically infected or not, you need to confirm that positive antibody test with a viral load test.

Hepatitis C prevention

Hepatitis C (HCV) is mainly transmitted from blood to blood contact when someone shares a syringe or other injecting equipment with someone infected with the virus. The gold standard of HCV prevention is using a new syringe and unused injection equipment each and every time you inject, and you never have to share anything. This is easier said than done: Sometimes you have no other option but to re-use a syringe. When faced with this situation,

PHOTO: MIHAILO MILOVANOVIC/ISTOCKPHOTO

there are things you can do to help prevent infection.

The primary way in which HCV infection occurs is through the sharing of syringes: That's where the most blood is and that is the most direct way for HCV to get into a person. That said, the sharing of other injecting equipment—cookers, cotton, water—can lead to HCV infection, too.

The best way to prevent HCV infection while injecting drugs is to use a new syringe and unused injecting equipment each time you inject. If you have to re-use a syringe, try to mark it as your own so as to avoid accidentally using someone else's syringe.

If sharing a syringe is the only option available, rinse the syringe with bleach to try to disinfect it and kill off any HCV that may be in there. (Remember to rinse it well afterwards.) A recent study has found that bleach was highly effective in killing HCV, but it's important to note that it's not a guarantee to prevent infection. From a harm reduction perspective, it's better than nothing, but again, the gold standard for preventing HCV is to use a new syringe for each injection you do.

Sexual transmission of HCV

Sexual transmission of HCV is a complicated topic. HIV status appears to be the single greatest risk factor for gay men (see page 29). Rates of HCV in HIV-negative gay men are much lower than in HIV-positive gay men. Research has shown that HIV-negative gay men are at low risk of HCV, and,

WHILE MANY PEOPLE JUST ASSUME
that HCV gets screened during STD exams, it rarely does. If you think you need a test, ask for it.

as with non-injection drug using, HIV-negative heterosexuals, routine screening for HCV is not warranted. This research flies in the face of what many people assume: Gay men have anal sex and anal sex can lead to bleeding. Since blood can transmit HCV, many assume that anal sex will transmit the virus. While the data suggests little risk, the concerns and anxiety about the risk remain high.

HIV-positive gay men are at higher risk of sexually acquired HCV than are other groups. That said, it can still be a little complicated when you start to break it down. For example, we know that HCV is transmitted from blood-to-blood contact, but what about sexual fluids? There are some small studies that have found HCV in semen and non-bloody rectal fluids, while others have not. Whether it's in semen or not, we know it's in blood, and sexual practices that can lead to blood carry risk for HCV transmission.

In studies that have looked at possible risk factors associated with sexual transmission of HCV, several behaviors have been identified: condomless anal sex, group sex, fisting, and so on. So, what accounts for the higher rates in this population? One possible explanation is sero-sorting, or the practice of only having sex with men who have the same positive HIV status. Many positive gay men have taken to this practice to prevent transmission to HIV-negative sex partners. Gay men may be aware of their partner's HIV status, but not

HOW TO REDUCE YOUR RISK FOR HEPATITIS C

These tips are geared toward HIV-positive gay men, but the risk reduction tips and activities are applicable to anyone concerned about sexual transmission of HCV

1. Test for HCV routinely. Testing for HCV alone is not prevention, but knowing your status so you can seek treatment and prevent transmitting it to others is very important. You should test at least once per year, but might consider more frequent testing depending upon your level of risk.

2. Talk to your partner(s) about hepatitis C. If he is HCV-positive, or does not know his HCV status, you might consider doing things that are less risky such as oral sex, masturbation, or wearing a condom for anal sex. Communication and awareness of your sex partner's status is especially important if you are sero-sorting and only having sex with other HIV-positive men.

3. Wear a condom for anal sex. Both tops and bottoms are at an increased risk for sexual transmission of HCV. Condoms can provide an effective barrier to prevent blood contact during anal sex. Use water-based lube to make sex smoother and minimize the chance for micro tears and bleeding.

4. Practice safer fisting. As with anal sex, both tops and bottoms are at increased risk for sexual transmission of HCV. Check your hands for any cuts or bleeding cuticles. Wear latex gloves and change into new, unused ones for each new partner. HCV is a tough virus and can live in water for up to 21 days, so although we may not know how long it can live in lube, it's good practice to not share lube between partners, either.

5. Sequence your sex play. Avoid receptive anal sex after fisting or vigorous sex toy play that may have caused tearing and bleeding in the rectum, or you could be the top for anal sex.

6. Keep your sex toys clean. Cover your dildos and vibrators with condoms and change them for new ones with each partner. Do not use toys with more than one person before fully washing them.

7. Take a break from anal play. If you recently had anal warts removed, or had a case of hemorrhoids, take a break from bottoming to give yourself a chance to heal. The same is true following any type of receptive anal sex, especially if you see any blood or feel any discomfort or pain.

8. If you use drugs during sex, don't share anything. Whether you use injectable or non-injectable drugs, don't share anything. HCV can live for a very long time in syringes, on surfaces, and in drug-using equipment, and anything with HCV-infected blood on it can transmit the virus.

9. Screen for STDs regularly. Routine screenings for STDs that can cause sores—primary syphilis, herpes, anal warts, etc.—are an important part of your sexual health. If you are sexually active, aim for STD testing every 3–6 months. Give yourself self-exams, too, and check for any sores (especially if you have a history of herpes or anal warts). If you see something, check with your medical provider or go to an STD clinic to get it checked out. If you feel any rectal discomfort or see any rectal bleeding or other discharge, do the same.

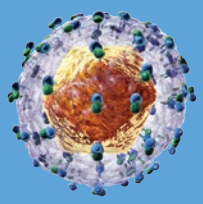
10. Stay HIV-negative. Screen routinely for HIV and know your status. If you test positive, get into care, screen for HCV, and talk about HIV care and treatment. If you test HIV negative, continue to practice safer sex and safer drug use, screen for STDs regularly, and talk to your medical provider about PrEP.

11. Stay HCV-negative. If you clear HCV—either naturally or through treatment—remember that you can get re-infected with the virus if you get exposed to it again. Continue to use the practices above to stay negative, and remember: If you cleared the virus, you will always test HCV antibody positive, so your follow-up testing going forward must be viral loads to look for the virus directly.

UNDERSTANDING YOUR TEST RESULTS

HCV antibody result	HCV viral load result	What it means...
Negative	Negative	You don't have HCV.
Positive	Negative	You do not have HCV: You have cleared the virus, through treatment and cure, or as one who naturally cleared the virus.
Negative	Positive	You have early HCV infection and haven't had time to make antibodies, or your immune system cannot produce enough HCV antibodies. More follow-up tests should occur.
Positive	Positive	You have chronic hepatitis C.

If you're testing within the window period for developing chronic infection, work with your medical provider or testing site to re-test later.



THE HEP C VIRUS CAN SURVIVE

ON SURFACES AND IN INJECTING EQUIPMENT ("WORKS" LIKE COOKERS, COTTON, AND WATER)

SYRINGES
UP TO 63 DAYS

SURFACES
UP TO 6 WEEKS

WATER
UP TO 21 DAYS

COTTON FILTERS
24 HOURS—48 HOURS IF WRAPPED IN FOIL

their HCV one, and if they practice condomless anal sex (or fisting) their risk for HCV is higher.

What is the role of HIV itself and the risk of HCV acquisition from sex? It certainly makes sense that a weaker immune system can make one more vulnerable to HCV infection. Research is limited, but there may be a relationship between lower CD4 counts and increased risk of HCV acquisition. Additionally, rates of HCV were higher in HIV-positive gay men with lower CD4 counts even when they had fewer risk factors for HCV. We do not yet know what the protective factor of taking anti-HIV medications might provide against sexual transmission of HCV, but we do know all of the health benefits it provides otherwise. Regardless of CD4 count, you want to minimize your risk of blood contact to minimize the risk of HCV transmission. The following section reviews the risk factors for sexual transmission of HCV that have been identified in a variety of studies looking at HIV-positive gay men.

Hepatitis C re-infection

You can get hepatitis C more than once. This is weird and can be a little confusing, and there is a lot of misinformation out there among both patients and medical providers about this.

With many viruses (like the herpes virus that causes chicken pox) or even other types of hepatitis viruses (like hep A and hep B), you can get it and your body makes antibodies and immunity to fight off any future infection. In other words, if you get it once, you're not going to get it again.

When you get infected with HCV, your body produces antibodies in an effort to fight the infection. As stated above, it's the antibody test that used to detect a possible infection. If this test is positive, then we follow it up with a viral load test to look for the actual virus.

About 1 in 4 (25%) people clear HCV in the first six months of infection on their own. A person who clears it will always have HCV antibodies but no more virus to do any damage to their liver. These antibodies don't protect them from a future infection, and they can still get re-infected and get HCV again. Again, the person can get HCV and clear the virus again (or even multiple times), but there's always a risk that the next time will lead to chronic infection.

Hepatitis C re-infection occurs when a person has detectable HCV virus in their blood after he or she has either been cured through treatment or after they have spontaneously cleared the virus on their own.

If you are one of those 25% of people who cleared it naturally, or you were treated and cured, you're going to have HCV antibodies. You'll still want to do all you can to stay HCV negative and avoid re-infection. Additionally, if you're one of these people and you have ongoing risk for re-infection, you want to test regularly—at least annually—by doing a HCV viral load test as the antibody test won't tell you anything about a new infection.

Hepatitis C treatment

If you talked to someone who was treated for HCV as little five years ago, you would likely hear horror stories of a year of treatment, complete with weekly injections of a medication that would make a person feel as though they had the worst flu of their life. For all of the misery, only about 50% of people would be cured. The treatments were so bad and the options so poor that many people chose not to test at all as they didn't want to know if they had it since they would never take (or, in the case of some medical providers, would never prescribe) the medications available.

Today, hepatitis C can be cured in just about everybody with 12 (in some cases 24) weeks of pills (no injections!) and very tolerable side effects.

Let that sink in for a moment.

With the effectiveness and relative ease of treating and curing all people with HCV, the AASLD/IDSA HCV Guidance Panel recommends HCV treatment for all people living with the virus, except in the few circumstances where a person has a very low life expectancy where said treatment won't make a difference.

ILLUSTRATION: WIKIPEDIA

It gets better. We can treat people with very advanced liver disease—cirrhosis—and we can treat people who are both on the liver transplant list or who have received a liver transplant. It's complicated, but with a liver specialist to manage care and treatment, successful cures are possible for even the most advanced of cases.

Hepatitis C treatment in HIV/HCV co-infected persons

HIV/HCV co-infection is a serious medical issue. As discussed above, there is increased risk of sexual transmission of HCV in this population, but HIV also appears to speed up HCV-related liver disease. For these reasons and more, the AASLD/IDSA HCV Treatment Guidance recommends treatment for all HIV/HCV co-infected persons, just as they recommend it for all HCV-mono-infected persons. Similarly, all co-infected persons can be treated with almost all of the available regimens that a person without HIV can take. It can get complicated, and you want to make sure that your HIV provider and HCV provider (if they are not one and the same) are in regular communication with one another and each knows what the other is prescribing to avoid any drug-drug interactions. See the PA Annual Hepatitis C Drug Guide (July+ August 2016).

Conclusions

We are in a remarkable time for the care and treatment of hepatitis C. In theory, we can treat and cure everyone and eradicate the virus from the planet. We have a long way to go, but increasing education and awareness, testing for the virus as needed, preventing primary infection and re-infection, and engaging in medical care will get us there. PA

ANDREW REYNOLDS is the Hepatitis C Education Manager at **Project Inform**, and facilitates several support groups in the San Francisco Bay Area. He's also a counselor on the HELP-4-HEP phoneline.

FOR MORE INFORMATION about hepatitis C and one-on-one support, call the HELP-4-HEP phoneline at (877) HELP-4-HEP, (877) 435-7443.

SEE "Can Hepatitis C Be Sexually Transmitted?" in the November + December 2014 issue of PA.

PrEP AND HEP C

Does taking PrEP place one at greater risk for sexual transmission of HCV? The CDC recommends that everyone gets tested for HCV before starting PrEP, but there are no recommendations for ongoing screening.

There has been little research on this, so we can't say for sure. We know that HCV rates are low in non-injecting, HIV-negative gay men. There is one brief published report from Kaiser San Francisco, where two HIV-negative men on PrEP got infected with HCV. Neither men reported any injection drug use or other potential HCV risks like unsterile tattoos or other blood exposures.

There were, however other potential risk factors: One of the men had rectal gonorrhea and chlamydia plus two cases of syphilis while on PrEP, and reported condomless receptive anal sex with a partner who had a penile piercing, as well as condomless receptive anal sex with multiple partners in a group setting. The second man also had syphilis (once) and multiple rectal STDs: three cases of chlamydia and two of gonorrhea while on PrEP. His sexual history was not described in the Kaiser letter.

Is this definitive proof that these two men became infected through condomless sex? Not necessarily, but it's still considering. As we know, in studies of HIV-positive men who have been diagnosed with HCV through sexual transmission, several risk factors have been identified (see chart at right).At least a couple of these factors were present for these two men, and although more research is warranted to determine the HCV risks for gay men on PrEP, it certainly is good practice to educate them about these potential risk factors while we wait.

Some may conclude from this report that PrEP has increased the risk of HCV transmission. In fact, it's too early to tell and it would be wise to not jump to conclusions. We don't know what rates of HCV would be found in HIV-negative gay men who were not taking PrEP, but were getting routinely screened in sexual health settings. Perhaps it would be the same. The key is we don't yet know, so it would be incorrect to assume that taking PrEP leads to higher rates of sexually acquired HCV than we would find in men who are not taking PrEP, but engaging in the same risk behaviors.

Finally, it's worth noting that none of the 485 men taking PrEP tested positive for HIV, and ultimately, that is what PrEP is: an HIV prevention intervention. In this respect, it is a remarkable success. Routine prevention counseling, screening, and treatment of STDs are important components of PrEP service delivery. This Kaiser report, although small in numbers, suggests that we should do the same for HCV.

—ANDREW REYNOLDS

IN STUDIES OF HIV-POSITIVE MEN who have been diagnosed with HCV through sexual transmission, **several risk factors have been identified:**

- condomless receptive anal sex
- group sex
- fisting
- non-injection drug use during sex
- presence of an STD
- limited awareness of your partner's HCV status

PHOTO: JOSHUA THORNE

AGING, AND THRIVING, WITH HIV

TPAN forum brings together long-term survivors

STORY AND PHOTOS BY **ENID VÁZQUEZ**

Older. Wiser. Stronger. This was the theme of an educational and community-building event, "Living Well as You Age with HIV," held in October by TPAN, the HIV service organization that publishes POSITIVELY AWARE. TPAN was built on the self-help model of support groups, providing information and having people living with HIV share their experiences with one another. Houston activist Nelson Vergel delivered the program's keynote address.

Of special interest in this era of powerful HIV medications that bring with them longer life are the long-term survivors who were here at a time when medications were often ineffective and toxic. It's long been expected that by 2015, more than half of people living with HIV would be over the age of 50. Now that figure is expected to reach 70% by 2020.

Although many of those over 50 have not been living with HIV for a long time, others have been positive for decades. They live with scars from the early days of the epidemic. Some long-term survivors are HIV-negative, who experienced the death of friends, family, lovers, and patients. Some are young, having been born with HIV or infected through tainted blood products as children and lived all their lives with the virus.

"There have been a number of different definitions for long-term survivors over the years," POSITIVELY AWARE editor and TPAN Director of Publications Jeff Berry said during his talk. Jeff has been leading TPAN's national efforts to address the needs of long-term survivors since helping to create The Reunion Project two years ago.

In the mid-1980s, long-term survivors were those who survived three years post-diagnosis, when median survival was 18–20 months. In the '90s it was sometimes used to refer to long-term non-progressors. For the purposes of Jeff's presentation, the definition he used was those individuals who were diagnosed with HIV before 1996 and the dawn of protease inhibitors.

By definition, he said, many in this group of people living with HIV experienced multiple losses of friends along with repeated trauma.

"There are also those who went through the dark days of the epidemic and suffered great loss, but didn't seroconvert until after 1996, sometimes many years later," said Jeff. "HIV-negative people are also survivors in their own right, and we need to remember that doctors are survivors too."

There are people who don't like the word "survivor," said Jeff, "which I understand." He said some prefer the word "thriver."

There are many groups with a variety of needs and issues. Some, like himself, have never received an AIDS diagnosis. Some are still young. And so on.

Then too there will be a new wave of long-term survivors who did not experience the early traumas and difficult medications, but will share many of the same issues around aging with HIV, he said.

In 2014, in response to a PA survey, one reader wrote, "I've already had both hips replaced, at age 52, from Crixivan and have kidney failure from Truvada ... what next?"

Continuing side effects include metabolic syndrome and disfiguring fat redistribution, peripheral neuropathy, chronic kidney disease, osteopenia and osteoporosis, and multi-drug resistance resulting from sequential monotherapy—when there was only one drug to take at a time.

Other clinical issues include HIV-associated neurocognitive disorders (HAND), effects of long-term chronic inflammation, increased risk for cardiovascular disease and non-AIDS cancers, and co-morbidities and co-infections.

While these are concerns that need to be understood and addressed, Jeff pointed to the concept of resiliency, of strength in the face of adversity. There's emotional self-empowerment to be found in it.

One of the biggest issues is societal: stigma, affecting everyone living with HIV, even if newly infected. HIV stigma has been shown to keep people from learning their positive status and from seeking treatment and staying in care.

The physical side effects experienced by many long-term survivors also fuel the stigma they face.

"They're also getting older, so there's the stigma of aging and, for many, of being gay," said Jeff.

He pointed to recent documentaries addressing the early years of the epidemic and looking at long-term survivors—*How to Survive a Plague*, *Desert Migration*, *Last Men Standing*. He thinks enough time has passed and enough good has come about that we as a society can revisit those difficult times and deal with the harsh realities many survivors face. Even a few years ago, these films would have been too painful, he said.

Participants in The Reunion Project (TRP), which organizes day-long summits around the country to bring together long-term survivors of HIV, discuss needs, and look at resources and how to find support. The Reunion Project is supported by Bristol-Myers Squibb. The next summit will be held in Fort Lauderdale on January 28. Another is planned for Atlanta later this spring. "The idea is to create an ongoing support network," Jeff said.

Jeff also highly recommended the HIV Long-Term Survivors group on Facebook, a source of support and information, as well as other closed groups like The Reunion Project and the 55-Plus HIV Support Network.

"I truly believe that we can overcome a lot of these challenges if we try to understand them and take them into consideration when planning services and designing studies," Jeff said. "I think that any work being done in the area of HIV and aging needs to take a holistic approach and take into account the psychosocial and other issues facing long-term survivors. We need to identify successful models of resiliency, and begin to think about resiliency as a teachable skill."

Jeff being Jeff (one veteran activist described him as "all Zen"), he concluded his talk with a slide containing a smiling image of and quote from David Bowie, which said, "Aging is an extraordinary process whereby you become the person that you always should have been." He said he included it because, "A), I love David Bowie, and B), I think we sometimes forget about the positive aspects of aging. This topic can be a real downer, and so I think it's good to try to remember to strike a balance, just as in real life."

Additional challenges facing long-term survivors

- **Many have no support systems** in place, as they've lost friends and lovers, or are estranged from families.
- **Post-traumatic stress disorder** (PTSD), depression, isolation, loneliness, suicidal ideation, substance abuse disorders, survivor's guilt—why did I live when better people died?
- **Few medical providers are trained** in HIV and geriatrics. Assisted living, nursing

EMPOWER YOURSELF!

ADVICE FROM JEFF TAYLOR OF THE REUNION PROJECT:

- Make sure that your health care providers address all of your health issues, not just HIV. We're more than just our viral load and T-cell counts.
- Eat a healthy, common-sense diet.
- Exercise! No need to run marathons, but keep moving.
- Make sure you get enough, good quality sleep.
- Keep mentally healthy—minimize stress, address any depression or anxiety, etc.
- Be happy! Don't isolate yourself. Socialize and engage.

homes, and hospice staff may have no formal training and little experience.
- **Financial difficulties** for many who never thought they had a future to plan for.
- **The disability trap**—those whose work disability plans will soon run out resulting in loss of income, but who have been out of the workplace for years.
- **Independent living** may become more difficult as housing costs increase.
- **Special issues** for women, transgender individuals, people infected in childhood, and people of color, such as cervical cancer and culturally competent care.

Although established for training health care providers, the new HIV and Aging Toolkit from SAMHSA (Substance Abuse and Mental Health Services Administration) is also helpful for those living with the virus. Go to hivmentalhealth.edc.org/toolkits/hiv-and-aging-toolkit.

'I think that any work being done in the area of HIV and aging needs to take a holistic approach and take into account the psychosocial and other issues facing long-term survivors. We need to identify successful models of resiliency, and begin to think about resiliency as a teachable skill.'
—JEFF BERRY

Nelson Vergel: Cookies and testosterone

Twenty years ago, activist Nelson Vergel was dying with AIDS. He had lost a great amount of his weight and strength. But the former chemical engineer fought his way back to health after becoming aware of the life-giving benefits of weight-training and hormonal therapy. He made it his mission in life to pass it on, to help others struggling for life and health.

"I became obsessed with hormones in '92 because I was wasting and most of my friends were dying," Nelson said during his keynote speech, "but I saw the bodybuilders living and doing well."

He became an expert on the use of testosterone and other methods for regaining strength and wellness for people living with HIV. As might be expected for an engineer, his vast knowledge was technical and complicated. He wrote two books and established the websites ExcelMale.com and powerusa.com (Program for Wellness Restoration).

He was good, however, at making it all relatively simple for the average Joe and Jill. He was also good at helping people find the resources to enable them to live more healthy lives. More recently, he started the business DiscountedLabs.com to help people obtain the hormonal treatments they need by offering discounted lab tests.

Along with these more complementary approaches, Nelson strongly believes in antiviral therapy. While medications also helped him survive (see page 25), as a long-term survivor he saw them begin to lose their effectiveness. It was then that he became a leader in the struggle for salvage therapy, new and improved medications, and other therapies for those whose virus has developed resistance to HIV drugs. He built the PozHealth Facebook group for conversations about what works and what doesn't work, and also answers questions at TheBody.com.

Over time, however, Nelson grew more disillusioned with the depressing news from the world of medical research. Having survived into his 50s, he found it difficult to hear nothing but bad news about premature aging associated with HIV, heart disease and dementia at an earlier age, and other conditions. As always, he wanted solutions.

"I won't read about aging with HIV anymore," he said. And his slides showed it.

He started out with a more emotional slide, his **Seven Cardinal Rules in Life**:

- **Make peace** with your past, so it won't screw up the present.
- **What others think** of you is none of your business.
- **Time heals** almost everything; give it time.
- **Don't compare** your life to others and don't judge them. You have no idea what their journey is all about.
- **Stop thinking** too much. It's alright not to know the answers. They will come to you when you least expect it.
- **No one is in charge** of your happiness, except you.
- **Smile.** You don't own all the problems in the world.

They are hard-won lessons that helped him overcome the trauma of long-term survival with HIV since the early dark days.

"I experienced trauma with the death of 50 friends," said Nelson. "I dealt with it by not feeling it." There's also, he said, "the grief of our loss in our own health." For him that included a bout with cancer two years ago.

"Have compassion for yourself. If you have lived to your 50s with HIV, you have skills . . . and you have resilience. Not only have you taken your medications, but you've developed wisdom," Nelson told the audience.

Mindfulness, the practice of keeping your attention in the present, is a skill he learned that helps him to cope with anxiety.

Pushing back against stigma is another important skill, he said. "I think we are all anti-stigma activists. Every time we come out, we decrease stigma."

What about cookies?

Nelson said he is known as the Cookie Man at his doctor's office, because he brings cookies for the staff when he's there. It's just another way to get to know his clinic staff better and encourage a better working partnership with them.

VIEW NELSON'S SLIDES, including more technical information on hormonal therapy, on the PozHealth Facebook group.

GO TO positivelyaware.com for more from Living Well as You Age with HIV: A panel discussion by social workers Hugh Cole and Tom Hunter and activist Rae Lewis-Thornton; and audience comments on long-term survival with HIV, including Social Security information.

PHOTO COURTESY OF BENJAMIN DI'COSTA

THE POWER OF BEING POSITIVE WITH AN HIV-NEGATIVE STATUS

The struggle continues, says **Benjamin Di'Costa**, with his generation

So, chances are you are feeling some kind of way about the title to this article. But now that I have your attention, I want to tell you my story of how I turned being an HIV-negative youth activist into a positive and powerful thing.

According to the CDC the rates of new HIV infections among young gay men ages 13–24 are skyrocketing at alarming rates, especially within black and brown communities.

You might be quick to assume that these rates somehow equate to the amount of sex we are having, or that we are somehow anti-condoms. But we must first look at sexual and reproductive health education in the schools.

I am a child of homeschooling; my parents, who are evangelical pastors, removed me from fourth grade after the Columbine shooting out of fear of attacks on Christians. So growing up I never was given the "Birds and the Bees" talk, and didn't know what HIV or an STD was. All I knew was that condoms prevented pregnancy and that abstinence until marriage is the only way of life. It wasn't until 2010 when I met my first partner that HIV was introduced to me.

It was the day of Orlando Pride at around 7 a.m.; my partner who was 20 years old at the time had been in the hospital with serious co-infections. Aside from dealing with the typical LGBT discrimination within the healthcare system, my partner experienced something I had never seen before: HIV discrimination at the time of his diagnosis.

When my partner was diagnosed, the doctor walked in and said, "We're sorry, we made a mistake on your HIV test, you actually are HIV-positive," then proceeded to walk out of the room. No compassion. No counseling. My partner turned to me immediately with tears in his eyes and said, "You're going to leave me, aren't you?" At that moment I made a promise to him to get educated about HIV and support him through this journey.

He was one of those rare individuals, less than 1% of those who are positive, who was able to control the virus without using medication; however, current recommendations state that people who test positive for HIV should consider starting treatment right away. Eventually our relationship dissolved for other reasons, but I still had a fire inside me about making sure other young people like him do not have to go through such a traumatic experience.

Throughout the past six years I have wondered what my role in HIV is since I am a 26-year-old, white-passing, and cisgender queer male who happens to be HIV-negative.

Throughout the past six years I have wondered what my role in HIV is since I am a 26-year-old, white-passing, and cisgender queer male who happens to be HIV-negative. But there is power (and privilege) in your HIV status. I've learned being HIV-negative is a privilege but staying HIV-negative should be afforded to all regardless of socio-economic status, race, or gender identity. After the outcome of the recent presidential election, it is apparent that we as a community who are no strangers to adversity and activism must continue to fight for funding and continued research for HIV/AIDS.

Lastly, I want to challenge young people to take note from people like Paul Kawata, Cecilia Chung, Ryan White, Peter Staley, and Pedro Zamora, to name a few. These are leaders who have paved the way for us through community organizing to have adequate HIV programming. Now more than ever is the time for our generation to rise up and continue the fight to see HIV infections get to zero.

BENJAMIN DI'COSTA (@BenjaminDiCosta) is a nationally recognized HIV activist based out of Chicago. He recently was awarded the Pedro Zamora Young Leaders Scholarship by the National AIDS Memorial Grove to continue his work with youth.

FACING STIGMA

A Day with HIV participants open up about stigma

BY **DAVID DURÁN**

Stigma is as much a part of HIV as ever. That's the point made by **A Day with HIV**, POSITIVE AWARE's anti-stigma campaign. Launched in 2010, A Day with HIV is a single 24-hour period in September during which everyone, regardless of HIV status, is encouraged to capture a moment of their day with a picture and caption. The images and stories are shared on social media, using the hashtag #adaywithhiv, and featured on the campaign's online gallery at adaywithhiv.com.

This past September 22, nearly 200 photos were submitted from participants in 11 countries on four continents. The various images told one common story, however—living with HIV often means having to confront stigma and ignorance. Following is a look at three long-term survivors who shared their story.

Mark Holmes, who is 63, and shared a photo of him mid-fall while skydiving (after learning how to last year and now having done so more than 120 times), wanted to inspire younger HIV-positive gay men with his submission. "I wanted to show folks, particularly other HIV-positive guys, that there are no limits to the life you can live while positive," he said. "I also wanted to show that age isn't a barrier either, to those who want to live their dreams. I'm 63 and wanted to show both my peers and younger positive guys that being HIV-positive is certainly not a death sentence, and when managed well, can actually make your life better, and that HIV doesn't hold you back from doing anything that anyone else can do."

Holmes hasn't had any recent encounters with stigm, but explained that's mostly because he faces disclosure head-on when starting a new relationship and is very open about his status. "I've experienced some stigma from others early on, particularly after 1991, when my physical appearance changed," he said. "I remember being at a family dinner for my parents' 60th wedding anniversary when a man at another table began pointing me out to his friends with disdain and laughter. My brother and father heard it and got into a fist fight with them after I boldly announced, 'I've got AIDS and my family doesn't appreciate your comments,' which put an end to that." Holmes says that he never really paid much attention to HIV stigma because "it was just a disease and their reactions were due to ignorance."

Since then, Holmes has used rejection in his personal life as a teaching moment. "I never felt offended when someone didn't want to sleep with me due to my HIV, and would let them know about my undetectable status and what that means—and how I'm probably one of the safest people they could play with." Holmes is referring to instances in which others might lie or not know their status; the Swiss cohort study has shown that people living with HIV who are undetectable virtually cannot transmit the virus.

ALL IN A 'DAY': RALPH THURLOW (ABOVE, LEFT) WITH HUSBAND DAVID SPIHER. HANK TROUT.

David Spiher, who has been HIV-positive since December 1985 and has had AIDS since 1989, shared a photo of himself and his husband Ralph Thurlow, who has had AIDS for 15 years and has had an HIV/AIDS dementia diagnosis for three years, insisted that there was no inspiration behind his photo submission. "It's how we are living today, it is what it is," he said. In the photo's caption, Spiher says, "Ralph's home healthcare worker wasn't able to show up or call in time to arrange other plans, so Ralph is at my office as I do my development job." It was a snapshot of their hurdle that day, and how they just dealt with the realities of life.

"I'm now out as having HIV and came out in a very public way when I was featured in [the] documentary [*Last Men Standing*] by the *San Francisco Chronicle*," he said. "Stigma comes from a fear of the unknown. Is this news? We have known this since the beginning of the epidemic... people living with HIV don't feel safe enough to be visible and that invisibility means our communities don't 'know' us. Being out about your 'status' means you just might end up broke, and alone, with a lot of health problems as you age—this is especially true if you live outside of arge cities."

Spiher also voiced concern about support centers and networks in cities. "We don't even run them, services are provided for us." After November's election results, Spiher is also concerned about future health coverage. "With the repeal of Obamacare/Ryan White looming, I actually am rethinking my own decision to come out publicly as having HIV—it may mean that my husband or I may not be able to get the health coverage we need in the near future."

Hank Trout, a 27-year long-term survivor and HIV columnist submitted a smiling photo of himself this year. "When I first heard about the A Day with HIV project, I jumped at the chance to participate," he said. "Having lived with HIV since before my diagnosis in 1989, I've learned that the only way to combat the stigma that attaches to being HIV-positive is to normalize being positive—to say, this is what a 63-year-old HIV-positive man looks like; I'm not scary, I'm not to be feared, I'm no threat to you—I am a healthy, life-loving, active member of my community with much to offer."

Trout has been in a monogamous relationship with his fiancé for 15 years, but understands the kinds of stigma he knows others have experienced on dating apps and in person from other gay men. "Before this relationship began, when I was still cruising, I frequently found myself not only rejected but vilified by HIV-negative men, online and in person, and not only by potential sex partners. For instance, I used to wrestle quite a lot, and I've known potential opponents, other gay men, who refused to wrestle me because of my status, assuming, I guess, that any contact with me would infect them."

When it came to the root of stigma with the gay community, Trout agreed with the other men that it stemmed from ignorance and fear. "Our community is certainly not immune to that ignorance and fear. We've done a decent job of teaching HIV-positive men how to live with the virus, but we've not done as well at teaching HIV-negative men how to live with HIV-positive men. To verify that, we need only look at the online personal ads that are still full of phrases like 'I'm clean, U B 2,' implying that anyone who is HIV-positive is 'dirty,' or 'Drug-and-Disease-Free Only'—when AIDS first hit us in the 1980s, 'DDF' became the new 'whites only' in our personal ads. Fear and ignorance lead to prejudice of this sort," he said.

Asked about his thoughts on what could be done to overcome this stigma within the gay community, Trout said, "*Education*! As a community, we need to redouble our efforts to educate our own. For instance, how many HIV-negative men understand that having a viral load that is 'undetectable' means that we HIV-positive folks cannot transmit the virus to anyone else? The only antidote to fear—and ignorance-based stigma—is education to erase that fear and ignorance." PA

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PHOTOS AND CAPTIONS submitted to A Day with HIV are on display at adaywithhiv.com. A traveling exhibit of images from PA's antii-stigma campaign is co-sponsored by the Centers for Disease Control and Prevention. For more information, email photo@adaywithhiv.com.

PHOTOS FRM A DAY WITH HIV SUBMITTED BY MARK HOLMES, DAVID SPPIHER AND HANK TROUT