It's not about change. It's about becoming.
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Sabel Samone-Loreca, photographed by Louis Carr at Venice Vintage Paradise in Venice, California. Special thanks to proprietors Jeanie Reynolds and Sal Torres; @venicevintageparadise.

ON THE COVER FLAP
Sam Lenser, photographed by John Gress along Lake Michigan.

ON THIS SPREAD
Transgender youth, photographed by John Gress for Howard Brown Health in Chicago.
THE CONVERSATION

Got my first copy of POSITIVELY AWARE today. Thank you for my subscription. By far my favorite HIV-related magazine!

BILLY EUGENE WILLIS III
VIA FACEBOOK

This is the seventh month since I’ve been diagnosed with HIV. This is the third time that I have been reading your magazine. It helps me with some of the things I’m going through. This month you let me know about the meds I’m on. I have been taking Genovaya for six months now. I am undetectable. But it still doesn’t make me any happier inside. Just have to get out to a world that feels that you can give them or your family something by just being around them. It hurts very much. Jeff Berry, you said trauma makes you strong. Let me find meaning in life now. That way I can keep going. Thank you. I’m trying to learn to love me for me.

VINCE HUDSON
CHINO, CALIFORNIA

I want to thank your fine publication, for the positive and inspiring stories you do for us long-term survivors. I tested positive in 1983. Lost my partner of many years in 1989. I’ve been through the lean years of losing many friends to the times when great advancements in meds and research has kept us all going. Through alcoholism and mistakes I ended up in the Texas prison system. But I fight on and persevere, with your help and guidance. Thank you for all you do to help in this fight!

Longtime reader,

DANNY BURKS
RASHARON, TEXAS

I would like to request a copy of your most recent HIV drug chart and any new issue of PA pertaining to prison and incarceration. A big issue/concern that we are experiencing at this unit in Texas is that we are forced to pay a medical copay of $100 (which is subject to increase in the very near future), but we cannot be involved in the selection or choice of our HAART regimen.

In a nutshell, due to the high cost of HIV meds, we have no other choice than to take a “cocktail” of five pills as opposed to a simpler regimen. Yet, we are required to pay an annual medical co-pay. I would like to find some information regarding this particular issue, if any is currently available. Thank you for your services. They are invaluable.

DUSTY HERNANDEZ
TENNESSEE COLONY, TEXAS

Our colleagues at A&U —Art and Understanding magazine posted this picture of the HIV magazines on display alongside the various community publications at The LGBTQ Center of Long Beach. Seeing everyone’s work presented in such a winning manner compelled us to share their photo.

As a prisoner who will always be eternally grateful for your magazine and the help it has provided for me. I would also like you to know it’s an education tool for peer education here at this prison. I am HIV-negative, but am currently advocating and involved in activism about the HCV treatment and policies here in prison, along with peer education advancements. As a successful litigator I can express how your magazine has helped in my communication with health care officials on my behalf and that of others. Without your magazine I would not be able to have successfully obtain Harvoni here in prison. Thank you.

IGNACIO COTA
IONE, CALIFORNIA

THE LISTING FOR MYTESI in the copay and patient assistance chart of the 2017 POSITIVELY AWARE HIV Drug Guide (March+April) contained incorrect information. Mytesi’s manufacturer, Napo Pharmaceuticals, offers a copay program which can be reached by calling 877-336-4377; for the patient assistance program call 888-527-6276; also, go to mytesi.com. POSITIVELY AWARE regrets the error.
THE FORGOTTEN

It’s been nine years since POSITIVELY AWARE’s first issue on transgender people and HIV, and a lot has changed during that time. The title of my Editor’s Note in the July + August 2008 issue, “A Decade Delayed,” sprang from my interview with researcher Walter Bockting, PhD, and was a reference to how far we lagged behind when it came to the research and data (10 years behind, in fact). In that interview Bockting used terms such as transsexual (which has since fallen out of favor) and bi-gender (which has now morphed into gender non-binary). What a difference a decade makes.

The title of this Editor’s Note comes from my profile of Sam Lenser on page 28, and a comment from Sam’s friend Lee Dewey about the need to broaden our thinking when addressing prevention and care in populations that are especially vulnerable to HIV, to include not only gay men and transwomen, but also transmen and gender non-binary individuals (trans people who do not identify as male or female, or identify as both).

When I approached Asa Radix, MD (Director of Research and Education at Callen-Lourde Community Health Center in New York City), to be a part of this issue (see “PrEP and Transgender People,” page 16), Asa expressed to me how vitally important it is to include the voices of transgender people. In addition to the profile of Sam, we get to hear Sabel Samone-Loreca’s phenomenal story of resilience and perseverance, in the face of tragedy and despair; and you can read my second interview (almost a decade later!) with the extraordinary actress and advocate Alexandra Billings, whose character Davina in the award-winning hit TV show Transparent is HIV-positive. We discover why Davina’s character mirrors the real life Alex in many ways, and we also get a hint of what may be coming in season four.

For transgender people there is some good news, as we learn in Tonia Poteat’s article “The Importance of Gender-Affirming Care.” Transgender people living with HIV are likely to be retained in care the same as cisgender people, and since 2011 there has been a 12% increase in viral suppression among transgender women; but the not so good news is that transgender women were less likely to have a suppressed viral load.

For transmen there is little to no data, and indeed here we still are a decade delayed. We need to continue to advocate for more research and data on HIV in transmen and gender non-binary individuals, and push for more culturally competent education and training for providers to ensure that they are asking the right questions, so that they don’t assume someone’s behavior and vulnerability to HIV and other STIs by how they present themselves outwardly.

Stigma and discrimination continue to plague transgender people and are linked to other issues such as mental health, substance abuse, lack of housing, and survival sex, as you’ll read about in the article on “How Stigma and Discrimination Hurt Transgender Health Care” by Enid Vázquez, on page 32.

When I look back over the last nine years I’m encouraged by the many advances we’ve made in transgender rights and awareness, and I’m struck by how far we’ve come; but it sometimes feels like two steps forward, one step back. In late March North Carolina lawmakers “repealed” H.B. 2, the so called “bathroom bill” which restricted which public restrooms transgender people could use, but kept in place until 2020 the part of the bill which bans local governments from protecting LGBT people. In April the Trump administration released the questions to be included in the 2020 census that included questions about sexual orientation and gender identity, only to have them quickly removed, with the Census Bureau announcing that they had inadvertently released an incorrect version.

Those who have been forgotten must stand up and be counted, and fight for the right to be recognized and seen. But there are also those who would choose to see us erased altogether, and we can’t allow that to happen. There have been those within our own community who have questioned why the T is part of the LGB. As Alexandra Billings so eloquently points out in her interview, “There’s problems in our own community, but look, if we cannot meet in the middle, if we, the LGBT tribe cannot meet in the center of who we are, how do we expect other people outside the tribe to do that?”

Take care of yourself, and each other.
P

eople living with HIV (PLWH) who receive government disability checks have previously received that income without going through reviews.

As of March 1, the Social Security Administration (SSA) began requiring that PLWH prove they are still disabled. Like others receiving disability payments, they will have to go through a Continuing Disability Review (CDR). These are conducted every one to seven years.

There are exceptions. Not subjected to a CDR are those with HIV who have

- Multicentric Castleman disease,
- primary central nervous system lymphoma,
- primary effusion lymphoma,
- progressive multifocal leukoencephalopathy, or
- pulmonary Kaposi sarcoma.

“The big take-away here: if you are receiving disability benefits, it is very important to stay in medical care. Document every symptom and have your doctor note them. Document, document, document,” said Marina Kurakin of the Legal Council for Health Justice, in Chicago, who wrote “Money Trail” in the November + December 2016 issue of POSITIVELY AWARE.

She said that one of the biggest concerns now is those who received disability based on mental health status but are not currently seeing a therapist and individuals who are working part-time while receiving disability benefits.

Previously, PLWH were screened out of CDRs. That simply means that they did not have to undergo the reviews. Today, some of those people are actually very healthy. A review may put their disability income at risk.

It’s not yet known when CDRs are expected to begin for people living with HIV. Legal advocates for PLWH, however, point out that the Social Security Administration moves slowly. If there are staff and budget cuts, SSA can be expected to move even more slowly.

Said Bashirat Osunmakinde, Director of Care for the AIDS Foundation of Chicago, in an e-mail to area providers, “The important take-away for HIV-positive folks on disability is this: do your best to keep up with your medical appointments, get all the care you need, and make sure your doctor/nurse/PA/therapist knows everything that’s going on with you. If you do not have ongoing medical records, then when your CDR comes up you won’t have much evidence that you are still disabled. Do not tell your doctor, ‘I’m fine,’ if in fact you are having a lot of trouble with diarrhea and fatigue and neuropathy. Many clients have been so used to their long-standing symptoms that they do not even talk about them with their medical providers anymore, and when they do not communicate their ongoing, longstanding problems to their providers, those problems disappear from the medical record, and thus no longer exist in the eyes of Social Security.”

Osunmakinde also strongly advised Social Security disability recipients to stress to their providers the need to chart everything. “Often, providers will not note in medical records the longstanding, unchanging problems, because they are not actively treating them,” he wrote.

The SSA change came about after the agency revised its criteria for evaluating HIV as a disability on January 17.

See “Yes, SSA Disability Just Made a Slight Change for HIV-Positive Recipients; No, You Shouldn’t Freak Out” at thebody.com. Information about the SSA change, while a little technical, can be found at secure.ssa.gov/apps10/reference.nsf/links/02282017105458AM.
Hep C drug interactions and side effects

Gilead Sciences awards $22 million for HIV cure research
Pharmaceutical Gilead Sciences early this year announced the recipients of grants for HIV cure research, totaling $22 million. The money will support 12 new cure research projects. Gilead produces the bestselling HIV drugs Truvada and Genvoya, among other antiretrovirals. Read the company’s press release on this commitment at bit.ly/2jsiNSB.

HIV activists seek development of immune drugs
A coalition of HIV activists called for the development of immune enhancement drugs for people with suboptimal immune reconstitution despite years of being on treatment. They called these individuals “immunologic non-responders,” or INRs. The group advocates that scientists, biotech, and pharmaceutical companies pursue therapeutic candidates for INRs. “For example, while gene and anti-inflammatory therapies are being assessed in the context of cure research, there is also evidence that they may have potential to promote immune reconstitution and reduce markers associated with risk of morbidity and mortality in INR patients,” the coalition stated in a press release. Read it at treatmentactiongroup.org/press/hiv-activists-seek-accelerate-development-immune-enhancing-therapies.

Having a baby—Enter the HIVE
HIVE has created a new series of patient materials on safer conception for all persons living with HIV who want to have a baby, including transgender people and gay male couples. Many of the “Thinking About Having a Baby?” materials are available in Spanish. HIVE, formerly known as BAPAC (the Bay Area Perinatal AIDS Center), has also several videos on a YouTube page; go to youtube.com/channel/UC-hwrTcCe_EQ-yjgcFpALVQ. Materials are available for providers as well. Go to hiveonline.org.

WHO publishes hepatitis guidelines
Last November, WHO (World Health Organization) published its first guidelines on testing for chronic hepatitis B and C. According to WHO, “Testing and diagnosis of hepatitis B (HBV) and C (HCV) infection is the gateway for access to both prevention and treatment services, and is a crucial component of an effective response to the hepatitis epidemic.” For more information, go to bit.ly/2ocuP9n. Read the guidelines at bit.ly/2ocixh1.

WHO updates information on HIV and hormonal contraception
In March, WHO updated its guidance on hormonal contraception. “The recommendations for use of progestogen-only injectables among women at high risk of HIV changed from category 1 to category 2, with an accompanying clarification…” WHO reported. “Women at high risk of acquiring HIV can also use progestogen-only injectables (norethisterone enanthate [NET-EN] and depot medroxyprogesterone acetate [DMPA, intramuscular or subcutaneous]) because the advantages of these methods generally outweigh the possible increased risk of HIV acquisition (MED category 2).” Read the guidance at who.int/reproductivehealth/publications/family_planning/hc-and-HIV-2017/en. See also avac.org/blog/who-updates-guidance-hormonal-contraception-and-hiv. AVAC also conducted a webinar to explain the changes.

Heart study enrolling
Enrollment continues for the REPRIEVE study. REPRIEVE is looking at the use of the cholesterol drug pitavastatin (brand name Livalo) to see if it can prevent heart disease in people living with HIV. According to a study brochure, “Men and women with HIV are 50–100% more likely to develop heart disease.” To qualify for the study, individuals must be between 40 and 75 years of age; on anti-HIV therapy for at least six months; have no history of cardiovascular disease (including heart attack or stroke); and are not currently using a statin medication. The study also provides guidance on nutrition, exercise, and smoking cessation.

June 5 marks 4th annual HIV Long-Term Survivors Awareness Day
“HIV-Resilient” is the theme of this year’s fourth annual HIV Long-Term Survivors Awareness Day (HTLSAD) taking place June 5, according to a press release by Let’s Kick ASS – AIDS Survival Syndrome. This year’s commemoration marks the 36th anniversary of the U.S. Centers for Disease Control and Prevention (CDC) report on June 5, 1981 about five cases of a rare pneumonia affecting young gay men living in New York and California. It was the beginning of what would later come to be known as HIV/AIDS.

HTLSAD co-founder Tez Anderson is looking for people to share stories of survival and resilience on social media using images, words, and videos to illustrate how many years they have been living with the virus. “Given the current political climate, when our healthcare is being threatened by a new administration, it’s vital that we hear the stories of survivors of the worst epidemic of the modern age,” says Anderson.

People are encouraged to post on social media using the hashtags #HIVResilient, #HTLSAD2017, and #LongTermSurvivors. For additional information, go to HTLSAD.org.
“F*ck without Fear, PrEP Here” campaign

Early this year, the Los Angeles LGBT Center kicked off its new PrEP campaign, “F*ck without Fear, PrEP Here.” The asterisk is designed in the shape of five blue tablets, representing the blue Truvada for PrEP HIV prevention pill. “The Center’s sex-positive F*ck w/out Fear campaign uses raw, real language to get people’s attention and spur conversation. It also combats misconceptions about the safety and effectiveness of PrEP and the belief that it’s unaffordable,” the organization reported in a press release. “Those most at risk of HIV are gay and bisexual youth of color and transgender women, but a recent study by APLA Health of young gay and bisexual men revealed that Latino and African-American youth are the least likely to know about PrEP and less than 10 percent are using it. Those who do know about PrEP frequently have misconceptions about it, including the belief that it’s not effective or safe and that it’s unaffordable.”

“For more information or to book a free online consultation, visit PrEPHere.org.”

Consensus statement on lipodystrophy

An international panel of HIV treatment experts published a consensus statement on “the recognition and management of obesity and lipohypertrophy in HIV” in the February 24 issue of Clinical Infectious Diseases. The panel writes that excess fat is related to both the virus and the drugs to treat it. “The metabolic and inflammatory consequences of excess adiposity are critical drivers of non-AIDS events in this population,” they wrote. A discussion of available treatments, including Egrifta and metformin, is included. Read the paper at positivelyaware.com.

New trial for Michael Johnson

A new trial has been ordered for college wrestler Michael Johnson, with the Missouri Court of Appeals determining that important information for the defense had been withheld by the prosecution. In April, the Missouri Supreme Court upheld the decision, and the St. Charles County Prosecutor could retry the case as early as when this issue went to press, according to The Center for HIV Law and Policy, in New York. Johnson had been sentenced to more than 60 years in prison for not informing sex partners that he was HIV-positive, with sentences running concurrently for 30 years. Funds are being raised for his adequate defense. As Plus magazine pointed out in its coverage, “Johnson’s lawyer’s opening words to the jury were apparently, ‘You have to consider my client guilty until proven otherwise.’ The judge reportedly corrected the public defender by saying, ‘I believe you meant to say ‘innocent.’” Go to fundedjustice.com/freemichaeljohnson. See also “Michael Johnson, HIV, and Murder: Disclosure and discrimination in criminal law” in the September + October 2015 POSITIVELY AWARE.

Gilead launches new HIV prevention campaign

Gilead Sciences reports that, “In response to community feedback to be more involved in educational efforts to support HIV prevention, and as part of our ongoing commitment to the HIV community, we are pleased to announce Gilead has launched Healthysexual, a new disease awareness campaign focused on generating meaningful conversations among at-risk individuals and their healthcare providers about healthy sexual behaviors, including getting tested, practicing safer sex, and understanding HIV prevention options.” Gilead is the maker of the only HIV prevention pill currently available, Truvada for PrEP. The PrEP pill was FDA approved in 2012. Advocates have long been urging the company to promote the prevention pill. Go to healthysexuals.com.

Harvoni and Sovaldi approved for children

In April, the FDA approved two hepatitis C medications for use in pediatrics: Sovaldi (sofosbuvir) and Harvoni (ledipasvir and sofosbuvir). The medications were approved for children ages 12 to 17 or weighing at least 77 pounds (35 kg). According to the FDA, “These approvals provide pediatric treatment options for six major genotypes, or strains, of the HCV virus.” Harvoni is to be used with genotype 1, 4, 5, or 6 in children without cirrhosis or with compensated cirrhosis. Sovaldi is to be used in combination with ribavirin, in genotype 2 or 3 in children also without cirrhosis or with compensated cirrhosis. For more information, talk with your child’s medical provider. Go to fda.gov.

VIDEO CAPSULE SUMMARIES of news from CROI 2017 by AccessHIV are available at youtube.com/channel/UCQ72ynMDDfXCVK2E0LmUHvA, including the annual HIV Treatment Update by POSITIVELY AWARE Editor Jeff Berry, pictured here with Jonathan Li, MD, and Rick Elion, MD. Read more about CROI in this issue, beginning on page 41.
AIDSWatch 2017

MORE THAN 600 ACTIVISTS from across the country arrived in the nation’s capital for AIDSWatch 2017, held March 27 and 28. AIDSWatch brings people living with HIV and their advocates to the Capitol to meet with members of Congress and educate them on the issues affecting the HIV-positive population. According to AIDS United, one of the event’s organizers, “We now have the knowledge and tools to end AIDS in America. We can successfully treat those living with HIV and stop new infections. However, meeting this goal will require substantial scale-up of solutions, removal of barriers, and real leadership.” AIDSWatch is presented by the Elizabeth Taylor AIDS Foundation.

PHOTOS COURTESY OF AIDS UNITED, SEAN BLACK, HARRY C. HOPKINS, AND ROY FERGUSON
Experts estimate that there are about 25 million transgender people globally, and 1.4 million transgender-identified people live in the United States. A growing body of research indicates that transgender people are more likely to be living with HIV compared with the overall population. In 2015, the National Center for Transgender Equality led a survey of over 27,000 transgender people in the U.S. The survey asked about HIV status: 1.4% of respondents reported living with HIV, about 5 times the estimate for the general population of the United States (0.3%).

Not surprisingly, HIV impacted some transgender communities more than others. The prevalence of HIV among transgender men matched the overall estimate for the U.S. (0.3%). Gender non-binary individuals had a prevalence of 0.4%; and transgender women had a prevalence of 3.4%. Nearly one in 5 (19%) of black transgender women reported living with HIV—13 times higher than the overall prevalence of HIV in the study.

This self-reported information on HIV status from so many transgender people is incredibly important. However, not everyone knows their HIV status or is willing to report it on a survey. So, data from studies that include HIV testing provide important information for understanding the epidemic. The Centers for Disease Control and Prevention (CDC) have reported data on CDC-funded testing events across the U.S. from 2009–2011. Of the 2,047 HIV testing events among transgender men, 0.4% resulted in positive tests; and of the 11,771 testing events among transgender women, 2.9% were positive. Among transgender women, African Americans were most likely to have an HIV-positive testing event (54%), followed by Latina (30%) and white (7%) transgender women.

The CDC also supports the National HIV Surveillance System which collects data on newly diagnosed HIV infections across the country. From 2009–2014, they received over 2,000 reported cases of HIV in transgender people: 1,974 among transgender women and 361 among transgender men. Consistent with other data, African Americans made up over half the people diagnosed with HIV. Most transgender people diagnosed with HIV were living in the South, and about one in four were diagnosed with AIDS within three months of their HIV diagnosis. In other words, they were diagnosed late in the disease.

These numbers make it clear that there’s a great need for accessible, culturally appropriate, medically competent HIV care for transgender people, particularly transgender women of color. The Ryan White HIV/AIDS Program provides public funding for HIV care services across the country, and collects data on all recipients of Ryan White services. Almost 6,000 transgender individuals received Ryan White services in 2015, including 5,553 transgender women and 327 transgender men.
Transgender women of color who were on hormone therapy were more likely to engage in care and have an undetectable viral load if their HIV care provider was also the person who prescribed their hormones.

Transgender people were similarly likely to be retained in care (79% vs. 81%), but transgender women, specifically, were less likely to have a suppressed viral load (77% vs. 83%) compared with cisgender people. The good news is that this represents a 12% increase in viral suppression for transgender women compared with 2011. Among all transgender people receiving Ryan White services, retention in care was lowest for individuals who were younger and who had unstable housing. Viral suppression was lowest for individuals younger than 24 years old, African American or black, and with unstable housing.

As part of their Medical Monitoring Project (MMP), the CDC has published information on over 5,700 transgender women living with HIV receiving medical care in the U.S. They did not report on transgender men due to low numbers. In their analysis, they found no difference between transgender women and cisgender people in the percentages of those who were prescribed antiretroviral therapy. However, a significantly lower percentage of transgender women had 100% antiretroviral dose adherence (78% vs. 87%) and durable viral suppression (51% vs. 61%).

It is likely that these differences in adherence and viral suppression are driven by social and economic marginalization of transgender women of color. In the MMP, they found that more than 80% of transgender women were African American or Latina, and had an annual income less than $20,000; more than 20% reported homelessness; and over 30% did not have any health insurance. These rates of poverty, housing instability, and lack of insurance were significantly more common among transgender women than cisgender people. As would be expected, this resulted in a greater proportion of transgender women who needed supportive services.

Unfortunately, needs for basic services like food and housing were less likely to be met for transgender women compared with cisgender people. These findings suggest that unmet basic needs impede transgender women’s ability to effectively engage in and benefit from HIV care and treatment. In fact, preliminary baseline data from a project designed to improve engagement of transgender women of color in HIV care found that homelessness and lack of transportation were associated with poor adherence, and that transience and lack of transportation were associated with lack of viral suppression. Importantly, transgender women of color who were on hormone therapy were more likely to engage in care and have an undetectable viral load if their HIV care provider was also the person who prescribed their hormones.

The U.S. Transgender Survey was released at the end of 2016, and provided data from transgender participants living with HIV. Eighty-nine percent had seen a health care provider for HIV care in the last 12 months. Reasons given for not receiving HIV care included not having health insurance, not being able to afford HIV care, not knowing where to go for HIV care, not feeling sick enough to seek care, relying on a higher power, and only recently finding out about their HIV status.

The vast majority (82%) of transgender people living with HIV reported that they had CD4 count and viral load testing within the previous six months. Eighty-seven percent of participants living with HIV had been prescribed antiretroviral therapy. Eighty-one percent reported currently taking their ART medications. Of those who had been prescribed antiretroviral therapy, nearly two-thirds (64%) reported taking it as prescribed all the time. Nearly half (45%) of respondents who were not taking their antiretroviral therapy medication all the time reported forgetting as the main reason. Other reasons included not being able to afford the medication, not having health insurance, concerns about interactions with other medications, concerns about weight gain, and simply not wanting to take their meds.

The Transgender Law Center led a national needs assessment specifically for transgender people living with HIV. When participants were asked to identify their top five health priorities, gender-affirming and non-discriminatory care topped the list followed by hormone therapy and its effects, while antiretroviral therapy was fifth. The study also found that a higher percentage of transgender people had suppressed virus when their providers were supportive of their gender identity rather than hostile—or even neutral. Reported viral suppression was also lower when medical providers restricted access to hormone therapy based on adherence to antiretroviral medications. In other words, when a provider required a transgender person to be adherent to antiretroviral medication before providing access to hormone therapy, the transgender person was less likely to achieve viral suppression.

Clearly, the evidence supports the importance of gender-affirming medical care in promoting engagement in HIV care and suppression of viral load among transgender people and the need to address concerns about drug-drug interactions with hormone therapy. Importantly, transgender people, particularly transgender women, may have even greater challenges with housing, income, and food security than other people living with HIV; and it is more likely that these needs are not met. Recent experiences of violence have also been associated with lack of viral suppression among transgender women.

The difficult circumstances that lead to challenges with HIV care engagement do not occur in a vacuum. Widespread stigma, discrimination, and violence against transgender people (transphobia) are critical barriers to care engagement. Low educational attainment due to school bullying, limited employment opportunities due to discrimination and poor education, and often breathtaking risk of physical and sexual violence all contribute to the poverty, homelessness, and psychosocial trauma that drive poor HIV outcomes. In the first three months of 2017, there have already been eight reported murders of transgender women of color in the U.S. It is likely that countless other murders and non-lethal violence went unreported.

It’s not hard to imagine that immediate survival and management of chronic trauma would trump engagement in HIV care. Health care environments that incorporate gender-affirming, trauma-informed, culturally and medically competent HIV care are most likely to successfully engage transgender populations and reduce the disparities we currently see in HIV outcomes.

CITATIONS AT positivelyaware.com.

Dr. Tonia Poteat is an Assistant Professor in the Department of Epidemiology at Johns Hopkins Bloomberg School of Public Health, whose research focuses on LGBT Health and HIV. She is a certified HIV Specialist by the American Academy of HIV Medicine and has provided primary care for transgender individuals since 1996.
Over the past decade, transgender and gender non-binary (TGNB) individuals (i.e., people whose gender identity does not conform to their sex assigned at birth) have become more and more visible. There are currently about 1.4 million TGNB people living in the U.S. Unfortunately, many face discrimination in employment, education, housing, and healthcare as well as facing high rates of verbal, physical, and sexual violence. The HIV epidemic disproportionately affects the community, but awareness of prevention efforts using PrEP have been inadequate for this particularly vulnerable group.

Rates of HIV among TGNP people

THOUGH NOT UNIFORMLY COLLECTED, current data show that transgender women are disproportionately affected by HIV. A meta-analysis published in 2013 revealed that about one in four transgender women worldwide is living with HIV and they are almost 50 times more likely to be HIV-infected than the general population. The recent U.S. Transgender Survey (USTS) that studied over 28,000 TGNB people found that the rate of HIV infection among transgender women was 3.4%, which is nearly 10 times the overall rate in the country. The rate was much higher among transwomen of color. One in five African American transwomen (20%) reported being HIV-positive. Although rates were lower among transgender men and non-binary people (0.3% and 0.4%), there is an increased risk of infection among transgender men who have sex with cisgender (non-transgender) men.

PrEP research and TGNB people

IN 2015 JUST OVER 39,000 PEOPLE in the U.S. were diagnosed with HIV infection, a significant drop in new infections over the preceding decade. This decline is due to the success of public health programs that have promoted testing and early treatment of those who are newly diagnosed, but may also be due to the rollout of pre-exposure prophylaxis (PrEP). PrEP is a daily pill (brand name Truvada) approved by the FDA in 2012, containing two medicines (tenofovir DF and emtricitabine), that greatly reduces the risk of HIV infection. Despite the increased risk of HIV among transgender women, TGNB people are still not designated as a priority population for PrEP by the CDC, which prioritizes sexually active MSM, heterosexuals at substantial risk for HIV, and injection drug users.

The largest PrEP study, called iPrEx, enrolled about 2,500 HIV-negative gay men and transgender women from six countries. They took either a placebo (inactive pill) or Truvada. The study showed that the rate of HIV infection was reduced by 44% in people who were assigned to take Truvada. When people took their pills consistently they had even greater protection against HIV, over 92%.

A subanalysis that only looked at the 339 (14%) transgender women in the iPrEx study showed that there was no difference in the rates of new infections among those assigned to take Truvada and those assigned to take the placebo; i.e., the drug did not appear to be effective. Further investigations showed that transgender women who seroconverted while assigned to take Truvada had no evidence of the drug in their blood. The investigators concluded that adherence may be more difficult for transgender women who may be dealing with structural barriers to care and psychosocial issues, such as homelessness,
Transgender people on PrEP

BEFORE STARTING PrEP, people are screened for HIV infection, hepatitis B, and STIs and evaluated for kidney problems. While on PrEP, testing for HIV, STIs, and kidney function is usually repeated every 3 months. For transgender men who start PrEP, it is important to remember that they will also need to be regularly screened for pregnancy if they are having frontal (vaginal) sex with cisgender men, even if they are on testosterone, since this doesn’t completely protect against pregnancy. Other differences also exist for transgender men. Those who take testosterone will have an increase in muscle mass, which can elevate the serum creatinine. Since the creatinine level is used to evaluate kidney function, transgender men on testosterone should have their values interpreted using the usual male range of test results. Although PrEP is thought to reach adequate levels in rectal tissue after 7 days, it may take up to 20 days for maximum levels in vaginal tissue. Transmen who have vaginal sex will need to know that they may not be fully protected against HIV until they have been on PrEP for about 3 weeks.

Some TGNB people may have had gender-affirming surgeries, including genital reconstruction. For transgender women who have had vaginoplasty surgery, the vagina is usually created using scrotal and penile tissue. Although the skin is thought to be more resistant to infections than mucosal tissue, the neovagina does not naturally lubricate, and may be prone to small tears, ulcers, and abrasions, which may theoretically increase susceptibility to HIV and STIs. Transgender men may decide to have genital reconstruction to create a phallus (phalloplasty) or to extend the clitoris (metoidioplasty) and can choose to retain or remove the vagina, uterus and ovaries. It is important for providers to ask questions about surgeries and sexual behaviors in order to give appropriate information on HIV and STI risks, screening, and prevention. There is not a lot of information about the best ways to screen for STIs in those who have had genital surgeries, but the general rule is that testing should be based on the existing anatomy and the sexual behaviors that people engage in. We also do not have information about how these surgeries impact the tissue concentrations of PrEP drugs.

Implementing PrEP

EVEN WITH THE PUBLICITY following the iPrEx results, knowledge about PrEP remains low among communities at risk, especially among transgender people. In San Francisco a survey conducted in 2013 among transgender women showed that less than 14% had heard about PrEP. This occurred even though many of the women had risk factors for HIV infection, and would have benefited from using it. The lack of knowledge about PrEP is likely due to many things. Transgender people are often neglected in public health campaigns. Even more important is the fact that transgender people face many barriers when trying to access comprehensive primary care and sexual health services. The USTS showed that about 1 in 3 transgender people had at least one negative experience with a health care provider, such as being denied care or facing verbal and physical harassment or not being able to find a provider knowledgeable about transgender health concerns. These access issues are even worse for transgender people of color and those who have disabilities or who are sex workers. About a quarter of transgender people avoid healthcare services altogether due to fear of being mistreated, which lessens their chance of getting tested for HIV or learning about HIV prevention measures, including PrEP. Providers often have little experience talking to transgender people about their bodies and sexual health, and may not properly assess their risk factors for HIV and other STIs. They may also make assumptions, e.g., that transgender men are not at risk for HIV and fail to offer appropriate screening or HIV prevention.

Additional barriers

PrEP IS EXPENSIVE, costing about $1,200 a month as well as the added costs of testing and office visits. Cost can be a real barrier for transgender people, who may be unemployed or lack insurance, and who may be unaware that there are patient assistance programs to cover these costs. Difficulties also arise when TGNB people have identification or insurance cards with names or gender markers that do not match their gender presentation, including denial of medical care, verbal harassment, and physical assault. Name changes require a court order in many jurisdictions, which may...
be unaffordable for many. Transgender women might also worry that Truvada can negatively affect their hormones. The good news is that interactions are unlikely to happen between estrogens and the agents that make up PrEP.

Scaling up

**PreP IS AN EXTREMELY IMPORTANT ADDITION** to HIV prevention services, but is underutilized by TGNB people. There needs to be a realistic understanding of the barriers to its use in these communities and innovative approaches to improving access. Educational campaigns and materials need to be redesigned to ensure these are trans-inclusive, not only in words but in images that resonate with TGNB people. Future studies on PrEP implementation and trials evaluating new agents need to include TGNB people to ensure questions on efficacy, tissue concentrations, and drug-drug interactions are properly addressed.

Scaling up PrEP will require that health settings are safe and affirming of TGNB people, especially for those who may have had previous negative experiences. This includes allowing people to register under their preferred name, that staff ask about and use pronouns correctly and consistently, and that people are able to use public accommodation, such as restroom facilities, without harassment. Providers should improve their knowledge about transgender people, and ensure they are appropriately trained to conduct sexual health interviews that are respectful and affirming of trans-identities and that empower people to make informed decisions about risk and prevention.

**ADDRESSING STRUCTURAL BARRIERS** to care through provision of legal services (e.g., assisting with name changes, housing, and employment discrimination), drug assistance programs for the under- and uninsured, wrap-around services to aid adherence, risk-reduction efforts, and programs that address mental health and substance use are all other important areas to consider.

**WHAT TRANS PEOPLE NEED TO KNOW ABOUT PreP**

**Thinking about PrEP?**

When taken daily, PrEP reduces the risk of getting HIV by up to 99%!

**Is PrEP right for me if I am TGNB?**

People of all different gender identities and gender expressions can take PrEP.

**Will hormones interfere with PrEP?**

No! PrEP works just as well for people who are using hormones, but you must take it as prescribed, one pill every day. PrEP also does not interfere with your hormones.

**I've only seen transgender women on PrEP. Does it work for transgender men?**

Yes! If you have frontal (vaginal) sex you will need to take PrEP for 3 weeks before you are fully protected. It takes this long for the drug levels to reach the right concentrations in vaginal tissue.

**How will I pay for PrEP?**

You can use your health insurance. If you do not have insurance, your provider can help you to apply to a patient assistance program that will cover the costs of PrEP. There are also programs to help cover the co-pays. See projectinform.org/pdf/PrEP_Flow_Chart.pdf.

**Where can I find a provider to prescribe PrEP?**

Many LGBT health centers have providers who are knowledgeable about transgender health issues and also do HIV testing and prescribe PrEP. There is also a national PrEP provider database: greaterthan.org/get-prep/.

**How can I find out more about PrEP?**

Go to avac.org/resource/transcending-barriers-safer-pleasure.

**How can I find out more about TGNB sexual health?**


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**Dr. Asa Radix** is the Director of Research and Education and an infectious disease physician at the Callen-Lorde Community Health Center in New York City. Asa has 20 years experience working with transgender clients and is the clinical associate editor of Transgender Health.
"I understand that we are adopting new vocabulary, that we are taking terminology and turning it upside down, but language is malleable," says Alexandra Billings, transgender actress and co-star of the TV series Transparent, in an interview (see page 37). Here’s a primer on some of the changing language to describe gender, identity, and sexuality:

**Biological Sex:** Sex refers to our biological and physical anatomy. Biological sex is used to assign gender at birth. For most people, biological sex and gender are aligned. However, many variables can factor into one's biological sex; for example, a person's chromosomal or anatomical configurations. These and other factors can combine in such a way as to make biological sex much more complex than two distinct categories.

**Cisgender** (often abbreviated as cis): A term for people whose gender identity matches the sex that they were assigned at birth.

**Gender Identity:** Unlike biological sex—which is assigned at birth and based on physical characteristics—gender identity refers to a person’s innate, deeply felt sense of being male or female (sometimes even both or neither). While it is most common for a person’s gender identity to align with their biological sex, this is not always the case. A person’s gender identity can be different from their biological sex.

**Gender Expression:** In contrast to gender identity, gender expression is external and is based on individual and societal conceptions and expectations. It encompasses everything that communicates our gender to others: clothing, hairstyles, body language, mannerisms, how we speak, how we play, and our social interactions and roles. Most people have some blend of masculine and feminine qualities that comprise their gender expression, and this expression can also vary depending on the social context i.e., attire worn at work rather than play, hobbies or interests, etc.

**Sexual Orientation:** A term that refers to being romantically or sexually attracted to people of a specific gender. Our sexual orientation and our gender identity are separate, distinct parts of our overall identity. Although a child may not yet be aware of their sexual orientation, they usually have a strong sense of their gender identity from a very early age.

**Gender Variance/Gender Non-Conformity:**

- **Gender Fluidity:** Gender fluidity conveys a wider, more flexible range of gender expression, with interests and behaviors that may even change from day to day. Gender fluid people do not feel confined by restrictive boundaries of stereotypical expectations of women and men. For some people, gender fluidity extends beyond behavior and interests, and actually serves to specifically define their gender identity. In other words, a person may feel they are more female on some days and more male on others, or possibly feel that neither term describes them accurately. Their identity is seen as being gender fluid.
- **Transgender:** This term refers to an individual whose gender identity does not match their assigned birth sex. For example, a transgender person may self-identify as a woman but was born biologically male. Being transgender does not imply any specific sexual orientation (attraction to people of a specific gender). Therefore, transgender people may additionally identify as straight, gay, lesbian, or bisexual. In its broadest sense, the term transgender can encompass anyone whose identity or behavior falls outside of stereotypical gender norms.
- **Genderqueer:** This term is growing in usage, representing a blurring of the lines surrounding society’s rigid views of both gender identity and sexual orientation. Genderqueer people embrace a fluidity of gender expression that is not limiting. They may not identify as male or female, but as both, neither, or as a blend. Similarly, genderqueer is a more inclusive term with respect to sexual orientation. It does not limit a person to identifying strictly as heterosexual or homosexual. (NOTE: This term is not typically used in connection with gender identity in pre-adolescent children.)

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The Transgender Pride flag was created in 1999 by transwoman Monica Helms, and displayed the following year at a pride parade in Phoenix. Describing her design, Helms said, “the stripes at the top and bottom are light blue, the traditional color for baby boys. The stripes next to them are pink, the traditional color for baby girls. The stripe in the middle is white, for those who are intersex, transitioning or consider themselves having a neutral or undefined gender. The pattern is such that no matter which way you fly it, it is always correct, signifying us finding correctness in our lives.

Although it’s the most commonly used flag, various transgender communities have come up with their own versions.
Sabell Samone-Loreca is statuesque and captivating, with an abundance of tattoos, piercings, and a radiant smile. A self-described loner, she can be shy and introverted. She also can be very vocal when advocating for the rights of HIV-positive transwomen.

“If living in your authentic self is more important than anything else; if you can’t eat; if you can’t sleep; if you can’t do anything but think about living in your authentic self—then fuck whatever anyone else says, and live who you want to be,” says Sabel.

Sabel has bravely survived her HIV diagnosis, pneumonia (PCP), racism, multiple suicide attempts, rapes, a hate crime in 2013, hepatitis C, rectal cancer, addiction, and homelessness. On March 15, 2017, at the age of 49 and after being interviewed for this article, she finally underwent gender confirming surgery (GCS), which she describes as “a lifelong goal” that she thought would never happen.

Originally from Tampa, Florida, Sabel struggled with her gender identity and sense of self, especially in the religious African American community where her family lived. In the churches where she was raised, God was judgmental and punishing. While assigned male at birth, she had feminine mannerisms and had what they call in the South, “a little sugar in the tank.” She wasn’t sure what exactly she was and turned to the trusty red and beige family encyclopedia (if you grew up in the 1970’s your family probably had a set of these encyclopedias also!) for answers. The books had listings for “gay” and “hermaphrodite,” neither of which rang true for her. She “wasn’t in the book”, which was “very weird” for her, since “the book” was full of all of the information you would ever need.
Skin color was also an issue. "Even in my own African American culture, I was judged for my skin color. If I wasn't light enough then I didn't get certain things. The darker skinned you are in African American culture, the less valued you are." At the tender age of 10, she was sexually assaulted for the first time. She was sexually assaulted again in her teens—this time at a mental health facility. With cruel irony, but not uncommonly, the rapist was a staff member at the facility.

When she was in her late teens, she snuck into gay clubs where she saw a striking Asian woman who was somehow “different.” Later, Sabel saw her out of the club environment, behind a makeup counter at a Tampa department store. It turned out that this particular woman was transitioning and already had breast implant surgery. This was Sabel’s first experience of a transwoman and it resonated deeply. "She was what I was looking for... I hadn’t seen this in my community."

However, she still struggled with her identity and attempted suicide a shocking and saddening 10 times between eighth and 12th grade. She calls some of those attempts “cries for help”, but others were real. Following her last attempt, a nurse told her that if she tried to kill herself again, she would be involuntarily committed to a Florida state mental institution. Atlanta offered escape and a chance to start over—and possibly self-discovery.

Atlanta had a thriving drag scene, which Sabel joined with enthusiasm. She performed at local drag clubs in Midtown but also had mainstream jobs in offices, restaurants, and in the beauty industry. Sabel began to embrace her androgynous look and she started dressing like a woman.

She started dating and, in 1987, felt that “there was something not right with her relationship” and she went to get tested for HIV—at the Centers for Disease Control (CDC)—which can only be described as an intimidating experience. The CDC is a huge white building with lots of doors and cubicles. The testing area had four cubicles and if you stood, you could see who was on the other side of the wall—hardly a confidential environment. There she was asked “900 questions” about her sex life, given a number on a piece of paper, and told to return in two weeks. Two weeks later, very early in the morning, she went back for her results. An uncompassionate test counselor told her that her HIV test result was positive. At that point Sabel literally could not hear any more. Everything else the counselor said sounded to her just like the adults in "Charlie Brown" cartoons: “whaaah, whaaah, whaah.” She wiped her tears, pulled herself together, and went and worked a 24-hour shift at her job. Her then-boyfriend also tested positive for HIV.

Asked if she considered suicide again after her HIV diagnosis she said, “No, I was already dead.” In 1987, people living with HIV were expected to live only three years—and only two of those were “good years.” Sabel numbed herself with alcohol, drugs (when asked what was her drug of choice: “anything that was around”), and travel, which eventually brought her to California.

Before heading to the West Coast, she started taking AZT. At one point, she was taking pills four times a day—for a total of 30 pills daily. In addition to HIV medications, she also took anti-nausea pills, an antidepressant, and an appetite stimulant.

In 1993, Sabel and four other trans friends from Atlanta decided to go on vacation to California and jumped on a bus to Los Angeles. The vacation became permanent for Sabel—she never returned to Georgia. The group did not like L.A. at the time,” said Sabel. Local gang activity involving the Crips and Bloods was quite frightening (especially for vulnerable transwomen), so they headed north to San Francisco and ended up in the Tenderloin.

San Francisco was both a wonderful and horrible time. Sabel and her friends lived in the Ambassador Hotel (it was cheaper than renting apartments) and partied. She fell deeper into addiction and the hustle. If there was “coin” to be made, she was going to make it. “I didn’t give a fuck about myself and certainly didn’t give a fuck about anyone else.”

Things changed in 1994 when she began taking hormones. She credits her doctor and social worker at the South of Market Health Center for encouraging her to get off drugs and to get clean. They saw beyond her addiction and recognized her potential to make an impact in the community. But, in order to get hormone treatments, she had to test clean for street drugs and take her HIV medications. And she stayed clean for a while.

Also in San Francisco, she legally changed her name to Sabel Samone, and that name is listed on her birth certificate, identification card, and Social Security card. Sabel chose not to reveal her previous name or discuss her early life experiences other than what is included in this article. “That part of me is gone;” she stated emphatically.

Sabel started working at Californians Helping Alleviate Medical Problems (CHAMP) and Central City Hospitality House (with transwomen). However, even with her support system, the clinic and her meaningful jobs, drugs were difficult to escape. She moved to Los Angeles to “run away from drug addiction.” Much to her surprise, she met a man who soon became her husband, Luis A. Loreca.

Luis and Sabel met at a People Assisting The Homeless (PATH) shelter in Hollywood. Luis was also HIV-positive. The attraction was instant but they felt shy and awkward. It took a while for them to get past subtle glances and smiles. Eventually Sabel cooked a meal for Luis, and the old adage proved true: the way to a man’s heart really is through his stomach. They became inseparable. Luis saw Sabel helping and supporting other PATH residents with their HIV diagnoses and encouraged her to get a job in the community. She began working at Minority AIDS Project (MAP) and with the HIV Stops With Me campaign, where she publicly came out about her HIV status in 2004.

The two were married in 2005 and Sabel became the first known transwoman in California to legally...
marry. Tragedy struck just a few months later when Luis was diagnosed with cancer and died suddenly. A picture of the happy couple remains on her wall to this day, a testament to what might have been.

**2005 was also the year** Sabel took her next step in her transition journey when she had an orchiectomy, otherwise known as surgical castration (the benefits of an orchiectomy include loss of body hair, muscle mass, and increased body fat). In 2008, she received breast implants. In 2016, she started prepping for gender confirming surgery (GCS), which involved painful electrolysis treatments. In the same year, she was cured of hep C and was also diagnosed with and treated for rectal cancer.

Her thoughts about GCS are mixed. A medically savvy woman, she purposefully does not want to know the surgical details of the vaginoplasty. She just wanted “to wake up and have it be over.” She thinks that the surgery will build her confidence but is worried about post-operative pain. After a month, she hoped to take walks around Los Angeles and return to the gym in three months. Sexual activity is permitted after six months. It will take a full year for her to heal from the surgery. She will have to dilate her new vagina for the rest of her life (dilation is necessary to keep the vagina at the depth and width that was created during surgery).

**Today, she only takes one pill a day** to control her HIV as opposed to 30 pills a day in the late ’80s and early ’90s. Sabel is now sober and no longer actively using. And she holds a coveted Consumer Seat (in Service Planning Area 4) on the Los Angeles County Commission on HIV.

A vocal spokeswoman for HIV-positive transwomen, she hopes that her story about both her HIV diagnosis and her transition will help the community. Her advice to other transwomen? “Everybody, young or old should live their life the way they need to be. Living my life as Sabel was a life or death moment…it would have been easier to be dead than walking this earth killing myself slowly, with drugs…not taking care of my health.” In other words, be true to yourself.

She turns 50 in August and hopes to celebrate this milestone birthday with a trip to Hawaii. Like many people who have had HIV for a long time, she didn’t expect to live this long. She didn’t expect to live at all.

Sabel may not have a listing in an encyclopedia, as the internet has replaced those dusty reference books. If you Google Sabel, you will find links to numerous articles about her and interviews. Sabel is finally “in the book,” and we can look forward to many more riveting chapters in her life. And, as Sabel says, “There’s a lot to me.”

Writer Michelle Simek works at an HIV/AIDS research and treatment clinic in Los Angeles. She is also an actor, freelance writer, and literary editor. In her spare time, she knits, goes to punk rock shows, and pets her cat, Baxter.
WHAT IS GENVOYA®?

GENVOYA is a 1-pill, once-a-day prescription medicine used to treat HIV-1 in people 12 years and older and weigh at least 77 lbs. It can either be used in people who are starting HIV-1 treatment and have never taken HIV-1 medicines before, or people who are replacing their current HIV-1 medicines and whose healthcare provider determines they meet certain requirements. These include having an undetectable viral load (less than 50 copies/mL) for 6 months or more on their current HIV-1 treatment. GENVOYA combines 4 medicines into 1 pill taken once a day with food. GENVOYA is a complete HIV-1 treatment and should not be used with other HIV-1 medicines.

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

IMPORTANT SAFETY INFORMATION

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

GENVOYA may cause serious side effects:

- **Build-up of an acid in your blood (lactic acidosis)**, which is a serious medical emergency. Symptoms of lactic acidosis include feeling very weak or tired, unusual muscle pain, trouble breathing, stomach pain with nausea or vomiting, feeling cold (especially in your arms and legs), feeling dizzy or lightheaded, and/or a fast or irregular heartbeat.

- **Serious liver problems.** The liver may become large and fatty. Symptoms of liver problems include your skin or the white part of your eyes turning yellow (jaundice); dark “tea-colored” urine; light-colored bowel movements (stools); loss of appetite; nausea; and/or pain, aching, or tenderness in 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 GENVOYA for a long time. In some cases, lactic acidosis and serious liver problems have led to death. Call your healthcare provider right away if you have any symptoms of these conditions.

- **Worsening of hepatitis B (HBV) infection.** GENVOYA is not approved to treat HBV. If you have both HIV-1 and HBV and stop taking GENVOYA, your HBV may suddenly get worse. Do not stop taking GENVOYA without first talking to your healthcare provider, as they will need to monitor your health.

Who should not take GENVOYA?

Do not take GENVOYA if you take:

- **Certain prescription medicines for other conditions.** It is important to ask your healthcare provider or pharmacist about medicines that should not be taken with GENVOYA. Do not start a new medicine without telling your healthcare provider.

- **The herbal supplement** St. John’s wort.

- **Any other medicines to treat HIV-1 infection.**

What are the other possible side effects of GENVOYA?

**Serious side effects of GENVOYA may also include:**

- **Changes in body fat,** which can happen in people taking HIV-1 medicines.

- **Changes in your immune system.** Your immune system may get stronger and begin to fight infections. Tell your healthcare provider if you have any new symptoms after you start taking GENVOYA.

- **Kidney problems, including kidney failure.** Your healthcare provider should do blood and urine tests to check your kidneys. If you develop new or worse kidney problems, they may tell you to stop taking GENVOYA.

The most common side effect of GENVOYA is nausea. Tell your healthcare provider if you have any side effects that bother you or don’t go away.

What should I tell my healthcare provider before taking GENVOYA?

- **All your health problems.** Be sure to tell your healthcare provider if you have or have had any kidney or liver problems, including hepatitis virus infection.

- **All the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Other medicines may affect how GENVOYA works. Keep a list of all your medicines and show it to your healthcare provider and pharmacist. Ask your healthcare provider if it is safe to take GENVOYA with all of your other medicines.

- **If you take antacids.** Take antacids at least 2 hours before or after you take GENVOYA.

- **If you are pregnant** or plan to become pregnant. It is not known if GENVOYA can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking GENVOYA.

- **If you are breastfeeding** (nursing) or plan to breastfeed. Do not breastfeed. HIV-1 can be passed to the baby in breast milk.

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

Please see Important Facts about GENVOYA including Important Warnings on the following page.

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

GILEAD
Take care of what matters most—you. GENVOYA is a 1-pill, once-a-day complete HIV-1 treatment for people who are either new to treatment or people whose healthcare provider determines they can replace their current HIV-1 medicines with GENVOYA.
Do NOT take GENVOYA if you:
- Take a medicine that contains: alfuzosin (Uroxatral®), carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegeotlo®, Tegretol-XR®, Teril®), cisapride (Propulsid®), Propulsid Quicksolv®, dihydroergotamine (D.H.E. 45®, Migranal®), ergotamine (Cafergot®, Migergot®, Ergostat®, Medihaler Ergotamine®, Wigraine®, Wigrette®), lovastatin (Advicor®, Altoprev®, Mevacor®), lurasidone (Latuda®), methylmergolovine (Ergotrate®, Methergine®), midazolam (when taken by mouth), phenobarbital (Luminal®), phenytoin (Dilantin®, Phenytek®), pimozide (Orap®), rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®), sildenafil when used for lung problems (Revatio®), simvastatin (Simcor®, Vytorin®, Zocor®), or triazolam (Halcion®).
- Take the herbal supplement St. John’s wort.
- Take any other HIV-1 medicines at the same time.

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

Care of the Transgender Patient with HIV Infection
hivguidelines.org/adult-hiv/transgender

Protocols for the Provision of Hormone Therapy
From the Callen-Lorde Community Health Center, New York.
callen-lorde.org/transhealth

OTHER RESOURCES

Frontline: Growing Up Trans
This 2015 documentary follows the stories of transgender children and adolescents. It also looks at the new world of pediatric transgender clinical treatment.
pbs.org/wgbh/frontline/film/growing-up-trans

“How important is age in transitioning?”
Interview in the Windy City Times with pediatrician Robert Garofalo, MD, who specializes in the treatment of transgender children and adolescents.
windycitymediagroup.com/lgbt/How-important-is-age-in-transitioning/58624.html

HIV Among Transgender People
Fact sheet from the CDC.
cdc.gov/hiv/group/gender/transgender

“How Improving the Lives of Transgender Older Adults”
Publication by Services & Advocacy for GLBT Elders (SAGE) and the National Center for Transgender Equality that addresses the concerns of transgender older adults on issues such as financial security,

WPATH (World Professional Association for Transgender Health)
The WPATH Standards of Care are “based on the best available science and expert professional consensus.” wpath.org

UCSF Center of Excellence for Transgender Health
Comprehensive source for information on transgender health and care, including HIV.
transhealth.ucsf.edu

WPATH (World Professional Association for Transgender Health)
The WPATH Standards of Care are “based on the best available science and expert professional consensus.” wpath.org

National Center for Transgender Equality
Social justice advocacy organization that works at the local, state, and federal level to change laws, policies and society.
transequality.org

Transgender Law Center
National organization dedicated to advancing the rights of transgender and gender nonconforming people through litigation, policy advocacy, and public education. This year the center published two reports based on national surveys of transgender and gender non-conforming people living with HIV: “Some Kind of Strength: Findings on health care and economic wellbeing” and “See Us As People: Findings on state and interpersonal violence.” transgenderlawcenter.org

“Out and Visible: The Experiences and Attitudes of Lesbian, Gay, Bisexual and Transgender Older Adults, Ages 45–75”
This report by SAGE examines the values, needs, wants, and lifestyle preferences of LGBT older people.
sageusa.org/resources/outandvisible.cfm
A PATH
Sam Lenser first found out about TPAN and its annual Ride for AIDS Chicago separately, when a friend of a friend had a heroin addiction and was at extremely high risk for overdosing. Sam went to TPAN, the Chicago AIDS service organization that publishes POSITIVELY AWARE, for Narcan (naloxone), the injection that reverses the overdose. “She’s okay,” says Sam of the friend. “I utilized you guys for that resource, which is phenomenal and super accessible.”

Sam, 32, who identifies as genderqueer trans masc and prefers the pronouns they/them/their, learned about the Ride from one of Sam’s best friends, Piper, who wanted them to crew.

“I remember last year crewing and everyone else had gone to bed, because they’d ridden a hundred miles, and I was up at nine o’clock at night by myself just walking around the camp,” says Sam. “I had a really deep moment where I realized why it’s so upbeat, and why it’s such a tight-knit community, because the issue is so serious, and so devastating—the cause that we’re working towards. At that point I decided I really wanted to start riding, and started riding my bike after that.”

Sam came out as trans at the age of 15, but then went back in the closet for 12 years after meeting a guy who “wanted to do the hetero-normative, wifey thing.” Sam says it wasn’t sustainable, and after the relationship ended moved from the Chicago suburbs into the city.

“The more I was exposed to queer culture, and reminded of it, the more I started to engage in it again, and realized what path I was on. I started really presenting masc—masculine—for a while. Then in 2015 on Halloween, I went as a male character, and I really couldn’t figure out whether I was male or female, and I thought, ‘Wow, this feels like I’m not in costume for the first time in a long time.’”

Since then Sam says, “I came out, got top surgery—gender-affirming surgery—in January of this year, and I’ve gotten a lot more involved in the queer community and community organizing.”

Sam started hooking up and engaging in “affirming casual sex” even before the surgery. “It’s my personal experience and I think a shared experience among a lot of
trans folks, and why we run a higher risk too, for HIV, is seeking out sex to affirm our gender. So if I hook up with a gay male, if I hook up with someone who sees me more genuinely and can affirm [my identity through sex]—that’s an affirming component. Because we’re more sensitive and newer to engaging in different dating pools, whether it be the lesbian community, or the gay male community, there are a lot of educational aspects, and vulnerability, so unprotected sex is a lot more common with us.”

Sam, who is HIV-negative, started taking PrEP about a year ago. Through getting involved in the trans masculine community in Chicago, Sam realized the risk factors for HIV are so much higher, and learned about PrEP from best friend Lee Dewey, who is HIV-positive. Say Sam, “I think a lot of trans masc folks are unaware of the social risk factors, but also that T [testosterone] causes atrophy in [their] walls, so tearing is more probable [making them more vulnerable to HIV]. Some doctors aren’t aware of that too.”

Sam and Lee are the two co-organizers of Community Cave Chicago, which Lee describes as “a community group for anyone assigned female at birth and identifies as anything other than cisgender.” The group meets regularly at Center on Halsted in Chicago, and recently changed its name from Man Cave Chicago to intentionally be more inclusive of allies and other populations in some of their programs. Lee, 34, identifies as gender non-conforming trans, and tested positive for HIV about two years ago.

“I tested regularly every three to six months since my early 20s. I’d test in a variety of locations, every time somebody showed up with free testing I would test. The platform of my advocacy is around the fact that nobody ever suggested Truvada for PrEP to me, even though I was testing regularly at a wide variety of locations and very open about my sex life, and that it involved people of different genders, and there were sometimes occasional risks where condoms didn’t get used, so I was at risk and having sex with gay men. It’s unfortunate that nobody ever brought up PrEP to me.”

Lee was waiting to see their doctor and saw a pamphlet for PrEP, and realized it was available and probably free. “I’d also been experiencing some weird flue symptoms, and [my doctor] was suspicious that I was poz, newly exposed, and she was correct. I was still testing negative on the quick test, but she did a full blood panel and it came back positive. I’d kind of heard of Truvada, but I didn’t realize that it was accessible, and that I could afford it, so the day that I learned that I could actually qualify for this thing that I thought I was the perfect candidate for, I found out that it was too late.”

Lee now advocates to make sure that the same thing doesn’t happen to anyone else.

“I’m surprised because I tested at such a variety of locations, and talked about HIV and AIDS activism, and talked about testing. I was already an ally. I wish I’d done my homework better.”

Lee says their provider was sort of surprised at the same time that Lee didn’t realize how accessible it was, and she’d been their doctor for a while, so it was sort of like a light bulb went off for both of them—“this is so preventable.”

“I talked to her about it not being recommended, and she’d taken that forward and probably does at least mention it [now]. It’s kind of tricky, because do you push it on people when they’re talking about it? But they talk about safer sex practices, they talk about condoms, why not also talk about PrEP? I feel like they do to some populations, and then not to others, and it seems like an obvious and logical leap—but some people didn’t see the gap,” says Lee.

Since Sam’s top surgery last year, their doctor gave the green light in January to begin riding again, so Sam started training for Ride for AIDS Chicago, which this year takes place July 8–9. [As this issue of POSITIVELY AWARE went to press, Sam had to pull back from this year’s Ride due to health reasons not related to the surgery, but will continue to support the Ride.]

“Last year when I was helping for training was the first time I really got on a bike,” says Sam. “I looked a little ridiculous showing up in an Uber to help people at 6 a.m. when they were going to ride 60 miles doing training rides. When that
was all done in July when the Ride wrapped up, I started riding to work and back, and then quit my job and started doing bike order stuff. So all through winter until my surgery I was riding for a living. I did the math, and you can actually figure out how many miles you can do a marathon for, and I could actually do 200 miles in a weekend. So that was last October, and I was like, 'Okay, cool!'"

Between training, working, and community organizing, Sam keeps pretty busy, and is grateful for the community that has been so welcoming and accepting when Sam first came out.

“There are different struggles that each generation has to face, and I think that this is a big one that the LGBTQ community is coming up towards, just advocating for the trans struggle in general. I've felt overwhelmingly included and welcomed in the gay male community—it was a total shock to me. I feel that there is a lot to gain from learning the different perspectives that we have. Like at that moment when I realized the tremendous history that I luckily missed out on, but there is a lot of road ahead, and [we share] similar struggles.”

Lee agrees that we have our work cut out for us. “The community at large...a lot of older, white gay men, don’t know anything about trans and non-binary people. Maybe there has been some buy-in with transmen, because we have Buck Angel to look at in porn. He is sort of a bridge; he’s not the end goal. Understanding that there are trans people that are masculine, that are binary, that look and act and screw just like gay men, but that also there is this larger community of non-binary and genderqueer people that were either assigned male or assigned female at birth who have sex with all kinds of people in all kinds of ways, and that we’re also at risk.

“We all need to think about how we can do better as a community to take care of each other and recognize that while we have a lot of different backgrounds and unique characters, we all experience a lot of the same things in a lot of the same ways, and have a lot of the same riskiness. Just sort of opening the mind so that when you think about HIV not just thinking about gay men. Or not just thinking about black transwomen, who absolutely need to be a focus...black transwomen are at one of the highest risks. But there’s also the forgotten population, and we often need that conversation to start because we need providers to see us as being at risk. Even when we’re telling them we’re at risk often they don’t hear it, and they won’t test, or they won’t suggest, or they won’t prescribe, because we haven’t really caught up.”

Lee points out that we don’t need anybody else’s spotlight, because the communities that are in focus need to remain in focus, but we have enough room to add more.

Asked if there is anything they would want some young person who is transitioning or questioning to know, Sam says, “That there is this really vibrant community that I wasn’t aware of, before I reached out, and how warm and welcoming we are. Because I was just terrified, really, for over six months, to come out, and completely isolated. I think there is support in the community at every stage, not just coming out; if you’re testing poz, if you’re looking for resources, or want to explore your thing.”

Lee adds, “Test often, practice safer sex, love yourself, and if you come up positive—realize that life isn’t over.”

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Lee adds, “Test often, practice safer sex, love yourself, and if you come up positive—realize that life isn’t over.”
The clinic sees indigent patients, many homeless or dealing with addiction. The transgender patients, however, too often face even more difficulties and even greater discrimination. All of this makes it that much more difficult for those who are also living with HIV to take care of their health.

“THERE’S A HUGE amount of stigma that transgender people have to deal with in general—look at all the political aspects with bills floating around federally and statewide—then you add on top of that the stigma that comes with being HIV-positive. I think you can wreak havoc on people’s psyche and their ability to function, and with that there’s a lot more mental health issues, and issues around substance abuse,” Dr. Nguyen says. “So I see people who are really more desperate. When you throw both stigmatizations on there, I think it’s really hard for patients to cope. And I think that makes it harder for me to take care of them, because being HIV-positive and being stable and under control requires a lot of things to be in place that they just may not have access to.”

“IT’S ABOUT MUCH more than hormones and surgery”

BY ENID VÁZQUEZ

Across the Bay in the TransVision program, researcher Erin Wilson, DrPH, also of the SFDPH, conducts some of her work with transgender individuals to look at their needs. “I think we often lump transgender folks together,” she says. “But the reality is that racial/ethnic minority transwomen, particularly black and Latina, are the ones really facing the breadth of the epidemic in the community. Having done work with lots of different groups of folks living with HIV, I’ve never seen the multiple disparities that transwomen of color face. As providers we need to think critically about developing models where we can adequately serve people, which is not going to be a 15-minute visit in a one-every-six-months check-in. It needs to be more intensive, and it needs to be trauma-informed.”

One of her colleagues recently published a paper looking at “multiple minority stress” that’s helping to lead the work on trans research. That paper found that in a cohort of transgender women followed in the study, those from racial or ethnic minority groups were less likely to live with their family of origin while growing up. “So there are some disadvantages at an early age, due to racial and ethnic identity with more residential segregation and poorer schools,” Wilson says, “and then that gets compounded with facing discrimination and transphobia over the course of their lives both from family and peers, and from society. I think human beings only have a capacity to deal with so much and I think transwomen of color take the breadth of everything that’s wrong in our society and adapt and cope with it.”
Oddly but appropriately, the East Bay clinic Wilson works with has added legal services to its care. “I’m doing interviews with transgender women of color there who are getting legal services to help them engage in their HIV care, which is kind of a radical thought,” says Wilson. “We don’t think of HIV care as providing legal services. But this legal clinic we have for participants has been radically life-changing. We have these issues where people have a traffic ticket that turns into a warrant, that turns into a car being impounded, which turns into a three-hour commute to work and from work every day, which then becomes untenable and people can’t even make an appointment. Something like this gets addressed and all of a sudden there’s a light at the end of the tunnel. One of our participants said, ‘It’s wild. You never make a connection between a legal issue and my care, but until my housing is dealt with, until my legal issues are dealt with, until I have transportation, until I have food security, I can’t possibly come to a doctor appointment on some regular basis and be expected to stay on my meds and keep my prescriptions up to date.’

Although those types of legal issues are related to poverty rather than being transgender, being transgender—especially for persons of color—leads to job discrimination and thus greater risk of poverty. Dr. Nguyen says many of his transgender patients trade sex for food, money, or a place to sleep. “So, survival sex, right?” he points out. He says it’s harder for these patients to ensure their safety from violence or from infection by insisting on the use of condoms, or that clean syringes be used when sharing drugs. Moreover, messages around HIV prevention with the use of PrEP tend to bypass transgender women, he says.

HEALTH CARE FOR THOSE WHO ARE LIVING WITH HIV

“IN TERMS OF being HIV-positive, I don’t think there’s a huge difference between someone who’s transgender or not in terms of the effectiveness of the medications,” says Dr. Nguyen. “Obviously, there are some drug-drug interactions that you must always be on the lookout for, especially for patients who are on hormones and how the HIV medication might influence those. Once you account for that, the medications work very, very well for transgender patients ... if they’re able to take them on a regular basis.

“Again, those issues around stigma, the issues around homelessness and everything that I’ve mentioned, really wreak havoc on the ability of patients, especially transgender patients, who are trying to stay adherent to their HIV medication,” he continues. “All this really affects mostly transgender women, much more so, because they’re way more affected than transgender men when it comes to HIV.”

HEALTH CARE FOR TRANSGENDER PATIENTS

“BE EMPATHETIC and just listen,” says Dr. Nguyen. “We teach this in medicine. You need to individualize care. Not everybody is the same, and everybody has different issues in their lives both medically and psychosocially. Be willing to hear the stories of the patients and just be there in a very non-judgmental way. After that you can explore options.

“It’s also really important to make sure you use the right pronoun. One of the first things I do when I have a new transgender patient, at the initial appointment, is I ask these two questions: ‘What was the sex you were assigned at birth? What gender do you identify with right now?’ Keep it very neutral because they can answer male, female, or none of the above. Gender non-conforming? It’s really up to them. Then I would also ask how they would like to be addressed. ‘For me I’m a he, him, his. How would you like me to address you?’ And if you make a mistake, just apologize and move on. Don’t make a big deal out of it. Because people make mistakes.

“The one thing that I have really learned in my work with transgender patients is to really treat them as they see themselves. Then allow the relationship to just mature to the point where they trust you, and make sure that you give them access to services as much as you can.”

Drug interactions

NOTE: This is not a comprehensive list.

HORMONES USED FOR TRANSGENDER THERAPY have not been tested in the lab for interactions with other drugs. Instead, the much lower dose of ethinyl estradiol (a form of estrogen) in birth control pills is used as a guide. Hormone therapy for transwomen, whether tablets, patches, or injections, requires a much higher dose of estrogen than that used in birth control pills. An increase in blood levels of a drug generally increases the risk of a side effect. A decrease in blood levels generally decreases the efficacy of a drug. Hormone dosage that is increased due to HIV medication needs to be reduced immediately upon discontinuation of the HIV drug (or drugs) due to dangerously high levels when off the HIV therapy.

Levels of ethinyl estradiol are INCREASED by:

- Edurant (rilpivirine)
- Crixivan (indinavir)
- Reyataz (atazanavir)
- Intelence (etravirine)

Levels of ethinyl estradiol are DECREASED by:

- Prezista/Norvir (darunavir/ritonavir)
- Strivil (elvitegravir/cobicistat/tenofovir DF/emtricitabine)

Has NO EFFECT on levels:

- Isentress (raltegravir)
- Tivicay (dolutegravir)
- Truvada (tenofovir DF/emtricitabine)
- Selzentry (maraviroc)
- Viread (tenofovir DF)

NO DATA available:

- Evotaz (atazanavir/cobicistat)
- Prezax (darunavir/cobicistat)
- Ziagen (abacavir)

SPECIAL THANKS to Andrew Macdonald, PharmD, AAHIVP, of Community, a Walgreens Pharmacy, in Oakland, California, for reviewing and updating this drug chart.

See the “HIV Drug Interaction Checker” from the University of Liverpool, an invaluable resource for anyone living with HIV, at hiv-druginteractions.org. The checker quickly looks up known drug interactions between HIV medications and other drugs. It is updated every one to two weeks. Some dosing recommendations given. Free app available for Android and Apple smartphones.

See also a PDF of “A Transgender Therapy Primer” from the July/August 2008 issue of POSITIVELY AWARE at positivelyaware.com.

1. Hormone therapy for HIV-positive transgender patients should be prescribed according to the same standards of care regardless of if they are receiving antiviral therapy or not.
2. In diabetic patients on testosterone, blood sugar decreases, requiring adjustments in dose of their diabetic medication.
3. Testosterone may also potentiate the blood thinner warfarin (Coumadin).
4. There are no published pharmacokinetic studies looking at drug-drug interactions with HIV medications and spironolactone (brand name Aldactone) or finasteride (brand name Proscar).
5. It is important to monitor liver function.
6. Clinicians should monitor hormone levels while patient is on ART in order to assess for elevated or subtherapeutic levels, as well as ongoing viral load monitoring.
7. Clinicians should also be aware of possible increase in cardiovascular disease and osteoporosis among HIV-positive patients on hormones.
8. More research is needed on interactions between oral, injectable, and transdermal hormones and ART medications.
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.

DESCOVY.com
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- 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.
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- 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.
**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.

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**MOSTIMPORTANT 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.

**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.

**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.

**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.

**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.
We first spoke with Alexandra Billings in POSITIVELY AWARE’s issue on transgender people and HIV in 2008. We recently caught up with the co-star of the Emmy-winning Amazon TV series Transparent to talk about the show, the shifting terminology around identity, and how Co-Ed Prison Sluts may have changed the course of her life.

JEFF BERRY:
So much has changed in the nine years since I first interviewed you for POSITIVELY AWARE—marriage equality is now the law of the land; there’s an increased awareness in the general public around issues facing transgender people; PrEP has been approved for HIV prevention; you’re in a hit TV show! So what do have to say about all of that?

ALEXANDRA BILLINGS:
I think what’s great is the transgender community’s identity and how specific it’s now become, because it’s no longer an idea or a philosophy, it’s actual, and it means something now. Ten years ago, it was true, but it wasn’t practiced. And now it is. That’s largely due to the political movements, the size of the revolution, awareness of the LGBTQ community at large, and it also has to do with the acceptance of our allies, our straight allies, and our parents and our grandparents and the people who come along with us. So really I feel very hopeful, even in the climate that we’re in right now, with Mr. Trump at the helm, that poor, lost, sad soul. I feel great hope. I also want to say, without saying too much—our show is dealing with the transgender community and the onslaught of the HIV virus [Season four premiers in Fall 2017]. Our community has always been hit very hard by this virus, especially among trans people of color, and we’re starting to look at that, in a sort of black comedy kind of way. So the advances of medical science are catching up with the advances of our spiritual science as well, so I’m very hopeful.

Back to the show in a minute, but in terms of increasing awareness around transgender and gender non-binary people, the terminology can be confusing for some, and it keeps changing so rapidly. [Gender non-binary actress] Asia Kate Dillon was on Ellen recently, and even Ellen seemed to stumble a bit. I’ve even found myself struggling when interviewing people for this issue. Have you ever found yourself in the same situation? Because there’s almost a generational kind of difference. >>
Well, you’re exactly right. The problem is not the terminology; the problem is fear of change. Even in our own community, we have generations fighting generations. That’s always been true, since the dawn of consciousness, since we’ve decided, “I’m going to dress this way, and you’re going to dress that way, and it’s going to stay the same forever!” Since that was sort of decreed, we’ve all been resistant to anything upsetting the apple cart, so to speak. I’ll tell you what I have a real problem with, anyone—I don’t care where they sit on which side of the fence—who flat out refuses to attempt something new, simply because they don’t like it. That’s where my problem lies. I understand that we are adopting new vocabulary, that we are taking terminology and turning it upside down, but language is malleable. That’s always been true. Language is musical; it’s the music of the universe. I mean all of us have been singing the same song for generations, we just do it in different keys. That’s why there are different languages. So people who have specific problems and refuse to use certain words, simply because they feel some kind of ownership to them, are working from a place of fear and ignorance. That’s very different than, “I don’t understand this, it doesn’t make any sense, help me through it.” I’m not on the gender binary, I consider myself a transgender female, I do not consider myself female, I never have. I married a female. But that’s just the way I identify. But I have friends who are on the binary, who consider themselves either gender fluid or genderqueer, and they prefer the pronouns they/them, and some of them prefer the word it.

I had a conversation with a really good friend of mine who said, “Well I’m not going to call anybody ‘it.’” And I said, “Yes, but that’s not really up to you.” And they said, “Well I’m just not going to use it. They need to find a different word.” And I said, “Well, okay, but until they do, why don’t we just acquiesce? Why don’t we just surrender, give in, allow their terminology, so they can begin to blossom? Why don’t we just do that first, before we say no?”

That’s great advice. I think it’s about us all educating each other.

I started transitioning when I was 20 years old in 1980. I’ve been living this way for many decades, I’ve been around LGBT people all my life, my father was in the theater, so I’ve been around queer people since I was seven years old. So that’s my tribe, these are my humans, and I understand them, and I love them. And there are problems in our own community, but look, if we cannot meet in the middle, if we, the LGBT tribe, cannot meet in the center of who we are, how do we expect other people outside the tribe to do that?

Good point.

If someone says to you, “call me ‘they,’” I don’t understand what the problem is. If someone says, “I’m Sam, in the afternoon, and then at night when I go to work and put a wig on, I’m Jacqueline,” I don’t understand the problem. It’s just something that doesn’t make sense to me.

I think for some people it’s...okay, I’ll just say it, for me, sometimes I get a little nervous and get tongue-tied, and I’m like, “Oh, I’m going to get this wrong.” I’m the type of person, when I have my current partner and my former partner in the same room, I’ll call them by the opposite...the wrong name. Every time. It never fails.

Yeah, but that’s different. That’s you being nervous, or working perhaps from a place of apprehension, and needing to please, I mean, who knows. But that’s very, very different than a flat out refusal to even make the attempt to allow someone to live in what is their truth. Those are very different things. If you make a mistake, someone should be kind enough to correct you. And it really depends on how I’m misgendered. If I’m misgendered and it’s used as a weapon, then you’ll get a very specific response. I just went to McDonald’s, and I have a voice that can be mistaken for male or female sometimes depending on the time of day, and if I’m sick, or limping, and it didn’t bother me. I drove up, she looked at me, and she didn’t really say anything, and I didn’t say anything, because there was no point. Which is very different from walking up to me when I’m at an awards show in a gown with jewels, lashes, and lipstick, and carrying a purse, and saying, “Hey, mister, can you hand me that glass of water?” That’s very different. It really is about approach, and about attempt, and about willingness.

I love that. So about that hit show.
The fact that I can walk into a meeting of Hollywood people, and... You know, I've lived on this planet for a long time, over half a century, and I've battled this disease for a very long time. We're in desperate need of our community to pick up an enormous amount of space. I don't have time, or the patience anymore, or the willingness, to compromise my own well-earned set of principles. And by that I mean my principles in my transgender life. I'm not going to be marginalized anymore, I'm not going to be fetishized, I'm not going to be de-sexualized, or devalued in any way, anymore, on screen or on film. I will not be a part of it. Because I don't have to. I'm not a 20-year-old desperate actress yearning to take any role so that I can win an Oscar, that's just not who I am. So I'm working from a place of great peace in my life, to be honest.

You know this thing happened because Jill Soloway, who's amazing, and who is the creator, director, [and] producer of Transparent, and her sister Faith Soloway, who's one of the head writers, as well as an executive producer, they worked with the Annoyance Theatre in Chicago, and were there for many years, and they scored—they wrote the music and the lyrics—for a show called Co-Ed Prison Sluts. This was in the '80s, and I was in a show coincidentally across town at the Torso Theater called Cannibal Cheerleaders on Crack. This is when late night was hopping, late night Chicago theater was on fire. Cannibal Cheerleaders started at 9:30 or 10, and Co-Ed Prison Sluts started at 11 or something. One month Susan Messing, who is a great actress, and a great teacher, who was playing one of the characters in Co-Ed Prison Sluts had to miss the show. Mick Napier who runs and owns the theater called and said, "She's gotta go [for a few weeks], can you step into the role?" I said, "Mick, I'm in another show." And he said, "Yeah, but she doesn't come in until the second act. So you could actually do one act, and run over and still make your show." So that's what I did, I went and did one act of Co-Ed Prison Sluts and then I would take a cab and drive to the other theater to do Cannibal Cheerleaders on Crack, and did that for a couple of weeks. And that's how Jill, Faith, and I met. Then, a hundred years later, out of the blue, I'm on Facebook, and I get this message from Faith Soloway, and she said, "Listen, we're doing this little itty bitty TV show that nobody's ever going to see, but it's very dear to us, because our parent just transitioned. We want to know if you want to be involved in this little project that we're taking to Amazon." I remember writing her back and going, "Amazon?! You mean the place that sells books? Why are you doing a TV show for a place that sells books, I don't understand what you're doing." Because this was a long time ago, and they were like, "Yeah, but they want to do TV shows." And I go, well, nobody's going to see it and I love these guys, they're brilliant, and I love that they're doing something that's true and that's actually happening in their family, so I'd love to be a part of it. So I auditioned, and Jeffrey Tambor and I hit it off immediately, he is a genius, and so funny, and kind, and they cast me, and we did it, and all hell broke loose.
In Season three we’re introduced to Shea, the character played by Trace Lysette. Can you talk a little about the character for those who don’t know?

The great thing I can tell you, and this is a testament to Trace and her miraculous gifts, is that she was supposed to be the yoga teacher for five seconds in season one; you were only supposed to see her in this little itty bitty scene teaching yoga, and us going out to dinner afterwards, and that was it. She was such a strong presence, that the producers and writers said, “No, no, no, we gotta bring her back, we gotta flesh her out, she’s interesting.” She’s a friend of Davina, and she’s the other trans character in the show, and she represents a whole other trans generation. She’s a younger generation than I am, and I think that that voice is important. So in season three you get to learn a little bit more about her, and what happens to us as we fall in love, and as we are loved. A lot of our community, the trans females anyway, are idolized, because of the way we look, and the way we act, the way we speak, and we’re not humanized. That is not only Shea’s experience, but feels—I don’t know if this is true or not—a lot like it’s Trace’s experience too. So she brings that into Transparent. I think it’s important for people to see us that way; that we’re human beings, we’re not dolls.

I’ve been enjoying your Facebook live posts and the letters that you get from young trans kids, as well as your response to the occasional haters. I just read the one from the guy who hated your rendition of Radiohead’s Creep.

That was a female, actually. People think they’re mostly men, and weirdly, most of the mail that I get that is unkind is from women, which I always think ironic.

Have you ever thought about writing a book?

I am writing a book, I’m writing my autobiography as we speak. It’s slow going for me, I’m taking my time, I’m not in any rush, and I want to make sure I tell a full story, in the sense that I’ve lived through a lot of our LGBT history, and so I want to get the history correct, and my place in the history correct. Funny you should ask.

You’re writing is so profound, and moving, and funny, and sad, it’s everything that you are, it comes through so strong in your writing.

Thank you, Jeff, that means a lot to me, I appreciate that. Thank you.

I don’t know if you remember, but in [our first] interview I asked you where you thought you’d be 10 years from now, and you said, hopefully not getting any more Botox, and that you try not to look ahead, but that you hoped you’d be working, happy, and well. So, dreams really do come true?

Look at that, it worked out—don’t you love it when it works out?

It’s just amazing to me that it’s been that long, do you want to look ahead into the crystal ball 10 years from now?

Well, you know, I hate to repeat myself, [but] if I’ve learned anything in my life it’s to notice where I am, and to be grateful for where I am; so 10 years, maybe we should do this! Maybe this should be a decade check-in, with Alex Billings. I want to be living in my joy, I want to be healthy, and I think if I were going to add anything I would like to be in service to others as much as I possibly can. If those three things are true, everything else will fall into place.

Thanks again for taking the time, it’s nice catching up with you.

Of course, love; that made me happy.
Dispatches from the Emerald City

BY ENID VÁZQUEZ

TRAVEL BAN
“CROI and [co-organizer] International AIDS Society-USA (IAS-USA) strongly oppose arbitrary travel restrictions based solely on religion or national origin,” the conference organizers said in a press release.

“These restrictions threaten to interrupt the exchange of scientific research information that is vital to the global response to health threats such as HIV/AIDS, Ebola, Zika, and many other infectious diseases,” said Susan P. Buchbinder, MD, of the San Francisco Department of Public Health and chair of this year’s CROI.

“As a consequence, the restrictions endanger rather than protect the health and wellbeing of Americans and people all over the world.”

The declaration came in response to a presidential Executive Order signed January 27 that temporarily bans travel to the U.S. by citizens of seven Middle Eastern countries. The order may have affected travel to CROI by medical providers and scientists from the Middle East.

More than 4,000 individuals attended CROI this year.

TIVICAY/EDURANT
For many years now, researchers looked to see if HIV treatment could continue to be effective when using fewer medications. Currently, therapy consisting of three HIV drugs continues to dominate therapy, even if taken as only one or two pills.

It was in the spirit of treatment simplification that a two-drug regimen of Tivicay (dolutegravir) and Edurant (rilpivirine) was studied in virally suppressed (undetectable) individuals being switched from the HIV therapy they were using.

Results were good, since nearly all individuals remained undetectable on the new combo, but providers had mixed responses to such a switch.

One prominent doctor questioned the thrill of hooking up a tolerable, easy-to-take drug like Tivicay with a medication that needs to be taken with a meal and can’t be used with proton pump inhibitors (like Prilosec OTC) or H2 blockers (like Zantac).

The combination also consists of two pills, when Tivicay is available in the single-tablet regimen of Triumeq (which, like most HIV drugs, has issues of its own). A fixed-dose tablet of Tivicay/Edurant, however, is expected to be approved this year or next.

Others, however, point to the potential benefit of eliminating the nucleoside analog drug class as a background for an HIV therapy. Called “nukes” for short, the class is the oldest in HIV drug treatment.

Although better nucleosides became available over the years (such as TAF), eliminating them altogether may further reduce the risk of their potential side effects. These include potential kidney toxicity and bone problems.

POSITIVELY AWARE editor Jeff Berry switched to Tivicay/Edurant years ago when he wanted to stop taking Reyataz due to the yellowing that it caused, harmless though it probably was to his health. He takes the medications with his breakfast and loves his therapy.

A Chicago nurse specializing in HIV pointed out, however, that, “Jeff knows where his next meal is going to come from. You have to be real deliberate about your calories with rilpivirine. The food requirement is a real thing. Some people don’t know when their next meal is coming. [Moreover], for people who are controlled [undetectable], I say ‘why?’ Three drugs seems to be the charm.”

The research team noted in their report that rilpivirine was used successfully in previous switch studies. They also pointed to the high barrier to drug resistance from dolutegravir, which can help keep the drug working for much longer times compared to those with a low barrier to resistance. To date, in fact, drug resistance to dolutegravir has rarely been seen.

For those who meet the requirements of rilpivirine, it has the “safety, tolerability, and efficacy [that] make it an optimal partner” for dolutegravir, the research team noted.

They concluded that, “A dolutegravir + rilpivirine two-drug regimen offers the potential for reduction in cumulative ART [antiretroviral therapy] exposure, without an increased risk of virologic failure.”

Josep M. Llibre, MD, of Barcelona, presented the results (see webcast), noting that, “Therapy is lifelong, so we’re looking to reduce medications needed. This opens the door to new two-drug strategies.”

In fact, some providers are looking forward to seeing more results with Tivicay/3TC (brand name Epivir, also available generically).

This Phase 3 research looked at combined results from the SWORD-1 and SWORD-2 studies. A total of 513 patients switched to DGT/RPV and 511 stayed on their original therapy. For people in both arms of the study, 95% were undetectable. Unlike most HIV treatment studies, there was a high number of women (21% and 24%) and more people over age 50 (about 30%). The majority of participants (70%) had more than 500 T-cells.

Rilpivirine cannot be used by people with more than a 100,000 viral load or less than 200 T-cells, but that did not matter here because this was a switch study with people whose virus was under control and who had more than 200 T-cells.

DORAVIRINE VS. DARUNAVIR
Doravirine, an HIV drug in development, was found to...
be non-inferior to darunavir (brand name Prezista) at 48 weeks. Darunavir is the only protease inhibitor medication recommended for first-time use by U.S. HIV treatment guidelines. Darunavir is a non-nucleoside medication, a drug class that includes efavirenz (brand name Sustiva, found in Atripla). A co-formulation with the generic versions of Viread and Epivir is in the works, which should help bring down price. On the other hand, darunavir has not been compared to an integrase inhibitor (INSTI), which are the drugs to beat in HIV treatment today (aside from the protease inhibitor Prezista, found in Prezobix).

In this study, the treatment-naive individuals in the study were 80% (darunavir group) and 84% (darunavir group) undetectable (less than 50 copies viral load). That’s a lower success rate than is expected in HIV treatment today, but was thought to be affected by the number of people who quickly dropped out of the study when they saw how many pills they had to take. Those drop-outs were counted as virologic failures.

**BICTEGRAVIR**
The INSTI drug class dominates HIV treatment today. A new INSTI in development, bictegravir (BIC), looked comparable to dolutegravir (DTG, brand name Tivicay, found in Triumeq).

Unlike other INSTIs on the market, both bictegravir and dolutegravir are unboosted (they don’t require another medication to raise their blood levels). Moreover, they were studied with a background of emtricitabine (FTC) plus tenofovir alafenamide (TAF), not the previous standard nucleoside med, tenofovir disoproxil fumarate (TDF).

These early results are reported as a potential new antiviral drug class. The capsid inhibitors have the potential for long-term parenteral (non-oral) use.

Winston C. Tse, PhD, of Gilead Sciences reported that a 10-week single dose they examined provided proof of concept for possible efficacy against HIV with this type of medication. “We’re very excited that this has potential for long-acting activity,” he said.

“While HIV capsid (CA) plays an essential role in multiple stages of the viral life cycle, it remains an unexplored target for antiretroviral (ARV) therapy,” reported the researchers from Gilead in their abstract.

In this test tube research, it also appeared that some of the capsid inhibitors may work against some drug-resistant HIV.

**OTHER DRUGS IN DEVELOPMENT**
A host of HIV drugs in development were presented in the session titled “I Want A New Drug” (webcast available).

Judith S. Currier, MD, of UCLA, and CROI vice chair, said at the opening press conference, “It’s really important and encouraging to see data on new drugs for HIV. While we have good drugs, there’s room for improvement.”

**END OF MONOTHERAPY**
A study of dolutegravir used by itself increased the risk of treatment failure and the development of drug resistance.

The poor results of the study seemed to put the final nail in the coffin for this simplification strategy in the minds of many. Previous attempts at HIV therapy with a single drug have also failed. “Although DTG monotherapy was non-inferior to cART [continued antiretroviral therapy] at week 24, virologic failure continued to occur after week 24 and led to DTG resistance in three [patients],” the researchers wrote in their abstract. “The genetic barrier of DTG monotherapy is insufficient to allow for maintenance monotherapy.”

**TRUVADA FOR PREP IN WOMEN**
Bacteria found in the vagina may have a negative impact on the absorption of tenofovir when used in the form of a gel or film. However, it did not seem to affect doses of the drug when taken orally. Tenofovir is used for HIV prevention in the form of the drug Truvada. Gel and film formulations with tenofovir, which are placed inside the vagina, are still in the experimental stages. (Webcast available.)

**A PrEP FAILURE**
A gay Amsterdam man became HIV-infected despite adequate adherence to PrEP, according to a report from that city. After eight months of taking the HIV prevention pill, he had an indeterminate result on the best HIV test available today, a fourth-generation HIV antibody/antigen test. He later seroconverted to HIV-positive with a 40,000 viral load. HIV treatment was successful in bringing his viral load to undetectable levels and his virus showed no sign of drug resistance.

In his Really Rapid Review of CROI (go to thebodypro.com), Dr. Paul Sax said that, “The case illustrates the likely importance of ‘inoculum’ in PrEP failure—the person had a very high number of potential exposures. It’s worth looking at the full poster presentation [Hoornegorg, #953], as the clinical and laboratory manifestations of acute HIV infection were unusual, possibly influenced by being on TDF/FTC [Truvada].”
If you’re living with HIV, you may face another clinical challenge to healthy aging

Help Curb Excess Abdominal VAT

Visceral adipose tissue (VAT) isn’t regular fat. VAT is a hard fat that surrounds organs, may be associated with serious health issues, and can be difficult to control with diet and exercise alone.

**EGRIFTA®** (tesamorelin for injection) is the only FDA-approved treatment for excess HIV-related abdominal VAT

*EGRIFTA®* was shown to reduce VAT in 2 clinical trials of 816 total adult patients who received 2 mg of *EGRIFTA®* or placebo (26-week Main Phase and 26-week Extension Phase).a

**Trial 1:** 18% average reduction. **Trial 2:** 14% average reduction.

*EGRIFTA®* is not indicated to treat health issues beyond the reduction of excess abdominal VAT.

**SELECTED RISK INFORMATION**

**What is **EGRIFTA®?**

- *EGRIFTA®* is an injectable prescription medicine to reduce the excess in abdominal fat in HIV-infected patients with lipodystrophy. The impact and safety of *EGRIFTA®* on cardiovascular health has not been studied.
- *EGRIFTA®* is not indicated for weight loss management.
- It is not known whether taking *EGRIFTA®* helps improve compliance with anti-retroviral medications.

**EGRIFTA®** may cause serious side effects including:

- Serious allergic reaction. Stop using *EGRIFTA®* and get emergency help right away if you have symptoms such as a rash over your body, hives, shortness of breath or trouble breathing, swelling of your face or throat, fast heartbeat, and feeling of faintness or fainting.

**Swelling (fluid retention).** *EGRIFTA®* can cause swelling in some parts of your body.

- Increase in glucose (blood sugar) intolerance and diabetes.
- Injection-site reactions. Change (rotate) your injection site to help lower your risk for injection-site reactions. The following symptoms around the area of the injection site can occur: redness, itching, pain, irritation, bleeding, rash, and swelling.

**The most common side effects of **EGRIFTA®** include:** joint pain, pain in legs and arms, swelling in your legs, muscle soreness, tingling, numbness and pricking, nausea, vomiting, rash, and itching.

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

Please see brief summary of full Important Patient Information on next page.

Learn more at EGRIFTA.com
IMPORTANT PATIENT INFORMATION

The following is a brief summary only. See complete Prescribing Information at EGRIFTA.com or request complete Prescribing Information by calling 1-844-347-4382. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is EGRIFTA® (tesamorelin for injection)?

- **EGRIFTA®** is an injectable prescription medicine to reduce the excess in abdominal fat in HIV-infected patients with lipodystrophy. The impact and safety of EGRIFTA® on cardiovascular health has not been studied.
- **EGRIFTA®** is not indicated for weight loss management.
- It is not known whether taking **EGRIFTA®** helps improve compliance with anti-retroviral medications.

Do not use **EGRIFTA®** if you:

- have pituitary gland tumor, pituitary gland surgery or other problems related to your pituitary gland.
- have active cancer or are receiving treatment for cancer
- are allergic to tesamorelin or mannitol.
- are pregnant or become pregnant. If you become pregnant, stop using **EGRIFTA®** and talk with your healthcare provider.

Talk to your doctor to find out if **EGRIFTA®** is right for you.

How should I use **EGRIFTA®**?

- **Read the detailed “Instructions for Use”** that comes with **EGRIFTA®** before you start using **EGRIFTA®**. Your healthcare provider will show you how to inject **EGRIFTA®**.
- **Use EGRIFTA®** exactly as prescribed by your healthcare provider.
- Inject **EGRIFTA®** under the skin (subcutaneously) of your stomach area (abdomen).
- Change (rotate) the injection site on your stomach area (abdomen) with each dose. Do not inject **EGRIFTA®** into scar tissue, bruises or your navel.

**EGRIFTA®** may cause serious side effects including:

- Serious allergic reaction. Some people taking **EGRIFTA®** may have an allergic reaction.

Stop using **EGRIFTA®** and get emergency help right away if you have any of the following symptoms:

- a rash over your body  
- hives  
- swelling of your face or throat  
- shortness of breath or trouble breathing  
- fast heartbeat  
- feeling of faintness or fainting  
- Swelling (fluid retention). **EGRIFTA®** can cause swelling in some parts of your body. Call your healthcare provider if you have an increase in joint pain, or pain or numbness in your hands or wrist (carpal tunnel syndrome).
- Increase in glucose (blood sugar) intolerance and diabetes. Your healthcare provider will measure your blood sugar periodically.
- Injection-site reactions. Change (rotate) your injection site to help lower your risk for injection-site reactions. Call your healthcare provider for medical advice if you have the following symptoms around the area of the injection site:

  - redness  
  - itching  
  - pain  
  - irritation  
  - bleeding  
  - rash  
  - swelling

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

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

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

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

You may also report side effects to **EGRIFTA ASSIST** toll-free at 1-844-EGRIFTA (1-844-347-4382).

For more information about **EGRIFTA®**, go to www.EGRIFTA.com or contact **EGRIFTA ASSIST** toll-free at 1-844-EGRIFTA (1-844-347-4382).

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Dr. Demetre Daskalakis, Acting Deputy Commissioner of Disease Control for the New York City Department of Health and Mental Hygiene, delivered the morning plenary on the last day of the conference, and as they say, they saved the best for last. Daskalakis is one of the architects of the Ending the HIV Epidemic (EtE) in New York State, along with TAG’s Mark Harrington, Housing Work’s Charles King, and others.

Daskalakis pointed out in his excellent presentation that they realized they have the technology to end the epidemic through treatment as prevention (TasP), the use of condoms, and PrEP, and that there are three pillars to their plan to end the epidemic in New York:

- Test everyone;
- Linkage, retention, and viral load suppression; and
- Make PrEP a public health intervention.

In 2014 New York Governor Mario Cuomo formed a task force with input from community activists, community-based organizations, the Health Department and other key stakeholders, and the state plan was released in 2015. New York City Mayor Bill DeBlasio approved $23 million to implement the city-wide plan on World AIDS Day 2015.

In New York City they began to treat HIV as an emergency and an outbreak, says Daskalakis, and by combining the political will, biological interventions, and harm reduction “you can get to zero” new infections. He also spoke of the importance of acknowledging pleasure in the plan, and using “a population-wide strategy” to end disparities.

Daskalakis outlined six points in the implementation strategy:

1. Transform STD clinics into destination clinics for sexual health services.
2. Make sexual health clinics a gateway for HIV treatment and prevention by launching same-day starts for PrEP (pre-exposure prophylaxis) and antiretroviral therapy (ART), and 28 days of PEP (post-exposure prophylaxis), no questions asked.
3. Support NYC community providers of HIV prevention in the launch of PrEP, while repairing the nPEP (non-occupational post-exposure prophylaxis) delivery system. (PEP supports condom use, says Dr. D, but currently the system is a mess; they are creating PEP centers of excellence, using an urgent care model, with immediate starts of PEP regardless of insurance, and linkage to PrEP.)
5. Take NYC viral suppression from good to excellent.
6. Make NYC a “status neutral” (stigma-free) jurisdiction.

Throughout the process he noted that HIV activists turned into rabid activists for sexual health, so that a visit to the STD clinic becomes the point where people get right onto treatment or PrEP, using delivery systems for different types of health care that are community appropriate.

Using EtE funding to expand services and hours to make sexual health clinics destination clinics, he stated that as of last week (early February), “STD clinics are dead. No more disease, only health.”

—JEFF BERRY

TO VIEW THE FULL SESSION GO TO croiwebcasts.org.
Conference Update
CROI 2017: Seattle

HIV cure research and basic science

By Richard Jefferys, Treatment Action Group

CROI 2017 offered a dizzying parade of new data. Webcasts of presentations and PDF files of posters were rapidly placed online and are accessible via the CROI website. The following is adapted from the full report available online at treatmentactiongroup.org.

A fillip for kick & kill

On the cure research front, the results that drew the most attention related to a small trial combining a latency-reversing agent (the HDAC inhibitor romidepsin) with therapeutic vaccination—a strategy commonly referred to as “kick & kill.”

Presented by Beatriz Mothe from IrsiCaixa in Barcelona, the crux was that five out of 13 recipients of the interventions have since interrupted ART and displayed control of viral load to low levels for several months (the longest a little over six months). None of the five have yet met the study criteria for restarting ART, which is a viral load over 2,000 copies/mL; the other eight participants quickly rebounded to levels above this cutoff and resumed ART.

Contrary to a slew of erroneous headlines in the mainstream media, none of the five individuals are “virus-free” based on the slide presentation, three appear to have viral loads below the limit of detection of the assay used (20 copies/mL); whereas the other two are oscillating between the limit of detection and about 2,000 copies/mL.

The study represented a rollover from a prior trial that administered two therapeutic vaccines to 24 people who had started ART within three months of HIV infection. The vaccine vectors were based on a chimpanzee adenovirus (ChAdV63) and modified Vaccinia Ankara strain (MVA), both encoding antigens designed to focus T-cell responses on highly conserved parts of HIV, including elements from the Gag, Pol, Env, and Vif proteins. In a poster presented at last year’s CROI, Mothe reported that receipt of these vaccines shifted HIV-specific T-cell responses toward the intended conserved targets but did not have a measurable effect on the size of the HIV reservoir.

A total of 15 participants from this original trial then agreed to enroll in a follow-up study, which provided booster immunizations with the MVA vector before and after three infusions of romidepsin. Eight weeks after the final MVA dose, all participants interrupt ART, and so far 13 individuals have reached this stage and contributed data to Mothe’s report at CROI 2017.

Although the numbers are small and follow up still relatively short, Mothe noted that the frequency of viral load containment in the cohort (approximately 38%) is higher than has been observed in any studies involving early initiation of ART (where rates have varied from 0–15%). Ongoing analyses are exploring potential correlates of control, with Mothe suggesting there are hints of links between the induction of T-cell responses to the conserved HIV antigens, lower HIV DNA levels, and the achievement of post-ART viral load control.

The contribution of romidepsin is unclear due to the lack of any control group, but the drug did not have a measurable effect on the size of the HIV reservoir when levels before and after administration were compared. There was evidence of blips in HIV viral load after each romidepsin dose, consistent with a latency-reversing effect. Mothe pointed out that blips also occurred after the MVA immunizations in 60% of the participants, indicating that the vaccine may have activated latently infected CD4 T-cells specific for HIV antigens (a number of studies have reported that HIV-specific CD4 T-cells can contain a substantial proportion of the latent HIV reservoir).

Romidepsin infusions were associated with an array of side effects known to be caused by HDAC inhibitors—primarily grade 1 and grade 2 headaches, fatigue and nausea—and the drug also caused precipitous but transient declines in peripheral blood CD4 T-cell counts of around 300 cells. One participant developed the serious complication of sepsis after the final romidepsin dose.

Additional follow up will be required before the significance of the study can be fully assessed, but it represents the first time that any kick & kill strategy has been associated with an increased frequency viral load control after ART interruption. There is an important caveat that applies to all studies reporting maintenance of low viral load in the absence of ART: while most news coverage assumes that the health benefits of viral load suppression will be the same regardless of whether the suppression is being mediated by immune responses or ART, that assumption remains unproven.

Based on studies of elite controllers, it is possible that even low level viral load may be associated with a slight increase in the risk of morbidity and mortality compared to the stricter control of HIV replication imposed by ART. If post-ART control of viral load can eventually be induced in more significant numbers of people, there will be opportunity to more carefully investigate this issue by comparing clinical outcomes between post-ART controllers and study participants who restart or continue ART.

Complete suppression of HIV replication by ART

The question of whether low-level HIV replication persists despite ART has been a major issue of debate in the cure research field.

The balance of evidence has favored the conclusion that ART typically completely prevents HIV from reproducing in adherent individuals, but some studies have challenged this view, including a paper published last year in Nature which argued that cryptic replication occurs in lymphoid tissues.

At CROI 2017, Mary Kearney from the National Cancer Institute addressed the question with an analysis of HIV evolution in ten children who started ART early (mostly within a few months of birth) and were followed for at least seven years.

Two of the children experienced some lapses in suppression of viral load and served as positive controls, while the remaining eight showed no evidence of any viral load blips during follow up.

Kearney found that the evolution of HIV genetic sequences was readily
apparent in the two individuals whose viral load was not continually suppressed. In stark contrast, no evidence of HIV evolution was detectable in the other eight participants, supporting the idea that ART completely stymies viral replication. Kearney suggested that differences in the types of tools used to analyse HIV evolution may explain some of the conflicting results that have been reported, noting that the Bayesian approach employed in last year’s Nature paper may mistakenly suggest that the virus has been evolving because the timing of sample collections influences the outcome of the analysis.

Kearney’s results were buttressed by a poster presentation from Morgane Rolland of the U.S. Military HIV Research Program (US MHRP).

Rolland studied eight individuals who initiated ART at Feibig I, an extremely early stage of infection estimated to represent the period 10–17 days after HIV acquisition. After an average of around three years, ART was interrupted as part of a protocol assessing whether HIV remission might occur. All eight participants experienced a viral load rebound within a median of 26 days, and Rolland compared the re-emerging HIV genetic sequences with those sampled at the pre-ART baseline. These analyses, like Kearney’s, revealed no evidence of HIV evolution during ART.

Jintanat Ananworanich also described the results of this U.S. MHRP clinical trial in detail in a separate oral presentation.

CELLULAR AND GENE THERAPY IN CANCER AND HIV

Carl June from the University of Pennsylvania gave a plenary talk on the dramatic advances that have occurred in the cancer field involving genetically modified T-cells. These approaches typically extract T-cells from an individual, genetically modify them in the laboratory to target the desired antigen, then expand and reinfuse the cells, which are described as “chimeric antigen receptor” (CAR) T-cells. Impressively, results have been obtained against a variety of cancers, although serious safety issues have also emerged in some cases due to the potential for excessively vigorous immune reactions to cause inflammation and pathology.

June highlighted that many different clinical trials of this type of approach are currently underway across the globe in cancer, but none are occurring in HIV. June advocated for the development of combination approaches that both engineer HIV resistance in CD4 T-cells (such as the Sangamo approach, which June has been involved in studying) and modify CD8 T-cell antigen receptors to better target HIV-infected cells for elimination.

He also stressed the need to foster engineering innovations to make this type of therapy cheaper, scalable, and globally accessible.

END THE EPIDEMIC BY 2030?

John Ward, Director of Viral Hepatitis at the Centers for Disease Control and Prevention (CDC), delivered a presentation with the provocative title of “Hepatitis C Virus: Gone by 2030?” The World Health Organization (WHO) has called on all nations to initiate HCV elimination plans, and the United States has embarked on developing one. Elimination is a public health term that seeks to achieve a 65% reduction in HCV-related mortality (death) and a 90% reduction in HCV transmission.

With current HCV treatments, we can reduce HCV related deaths. Through employing and expanding harm reduction services (such as syringe access and clean injection equipment, opioid substitution therapy, and other drug treatment services), or even interventions that have yet to be employed in the U.S. such as safe injection facilities) we can reduce by over 70%. The more testing and more treatment that is done, the greater the impact on prevention. It won’t be easy, and there are many barriers to overcome. But as Dr. Ward states in his abstract: “With strong societal commitment and support for implementing comprehensive HCV prevention, testing, care, and treatment, HCV can be eliminated as a public health threat in the U.S.”

TREATING PEOPLE WHO INJECT DRUGS IN SYRINGE EXCHANGE PROGRAMS

Hepatitis C will never be eliminated if we don’t treat people who inject drugs (PWID).

A central tenet of harm reduction in the provision of services to PWID is to “meet them where they’re at,” that is, to provide services to people who use drugs in a way that is culturally competent as well as in a low-threshold environment that is both effective and accessible. “Low-threshold environments” are harm reduction programs offering services without making a lot of demands on clients, such as meeting a certain level of drug usage. Syringe access programs, or needle exchange sites, are one such area where PWID can be met where they’re at, and offered care and treatment. To that end, Benjamin Eckhardt and colleagues presented on a small pilot study looking at providing HCV treatment in PWID in a needle exchange program in New York City.

HEPATITIS C OVERVIEW FROM CROI

Eliminating HCV and more

BY ANDREW REYNOLDS, PROJECT INFORM

More than 4,000 doctors, clinical scientists, and advocates converged on Seattle on February 13–17 to attend the Conference on Retroviruses and Opportunistic Infections (CROI) and its affiliated meetings. CROI has become a highly anticipated conference for new research on hepatitis C (HCV), and this year was no exception with dozens of HCV-related abstracts for posters and oral presentations. This brief review will highlight a selection of key presentations on the prospects of eliminating HCV, with emphasis on HCV prevention and treatment.
This study enrolled 45 people, with 34 who were able to have a prescription for HCV treatment submitted. Due to insurance restrictions, 26 of these people were approved, and 22 of them, or 85%, were cured. Although the numbers were relatively small, this study demonstrated that community-based HCV treatment at needle exchange sites can be done, and they will result in the cure of many PWID.

In addition to community settings, HCV treatment at community clinics will be an important site for any HCV elimination program. Sophy Wong and colleagues demonstrated the impact that primary care providers can have on HCV treatment in Federally Qualified Health Centers (FQHCs), achieving high cure rates in populations that are traditionally thought of as “hard-to-reach,” including those with substance use disorders, mental health conditions (depression, anxiety, psychotic or organic brain disorder), and other co-occurring medical problems.

Data was reviewed from 5 FQHCs from January 2015 to December 2016, and the researchers found that 190 of 199, or 96%, of those treated for HCV were cured (SVR12). The following chart displays the cure rates in patients with various behavioral health (BH) characteristics:

<table>
<thead>
<tr>
<th>PATIENT DIAGNOSES AND SVR12 CURE RATES</th>
<th>All treated patients: 96%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients without behavioral health diagnoses: 92%</td>
<td></td>
</tr>
<tr>
<td>Patients with 1+ behavioral health diagnoses: 97%</td>
<td></td>
</tr>
<tr>
<td>Patients with 2+ behavioral health diagnoses: 98%</td>
<td></td>
</tr>
<tr>
<td>Patients with mental health diagnosis: 96%</td>
<td></td>
</tr>
<tr>
<td>Patient with substance or alcohol diagnoses: 98%</td>
<td></td>
</tr>
<tr>
<td>Chronic pain diagnoses: 97%</td>
<td></td>
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</tbody>
</table>

This study demonstrates that patients who have traditionally been left out of HCV treatment can be successfully cured.

**Hepatitis C reinfection: Dispelling myths**

Reinfection of HCV, particularly among at-risk groups such as sexually active HIV-positive MSM and PWID, has been reviewed in the medical literature, and the assumption is that the rates are high. These assumptions are often cited as a rationale to deny treatment to PWID: Why treat them with these expensive drugs if they are only going to get reinfected later?

Patrick Ingiliz and colleagues reviewed the medical charts of 1,483 participants in the German Hepatitis C Cohort (‘GECCO’), a group of HCV-monoinfected and HIV/HCV infected patients from nine clinics across Germany. After removing individuals who did not get cured (N=66, or 3.6%), there were 1,417 individuals, of whom 24 (1.7%) were reinfected. Of these 24, 5 were PWID, 14 were HIV-positive MSM, and the remaining 5 were MSM who inject drugs.

While the overall rate of reinfection is low, this study shows that it can and does happen in individuals who engage in ongoing risk behaviors. HIV-positive MSM remain at greatest risk of reinfection, thus highlighting the importance of ongoing HCV screening and risk reduction counseling after the cure.

**Cure as prevention**

There are many benefits of HCV treatment and cure for the individual infected with the virus, including but not limited to improved liver functioning, reduced risk of death, and better quality of life. In addition to these benefits of cure, there is great potential to prevent new infections to others. To that end, Anne Boerekamps and colleagues looked at the incidence of acute hep C (that is, new HCV infections) in HIV-positive MSM before and after the rollout of new direct acting antivirals (DAAs). In 2014, the year before DAAs were widely available to HIV-positive people, there were 93 acute HCV infections documented across 18 health centers spread across the Netherlands. By 2016, one year after the introduction of DAAs, there were only 49 acute HCV infections, which is a reduction by 52%.

This marks the first real-life data to show that treating and curing HCV can prevent new infections. Expanding treatment to at-risk populations is an essential element to any elimination plan we employ.

**Screen for HCV before starting PrEP**

Any effort at HCV elimination must include effective monitoring of potential new outbreaks and populations that could be impacted by infection. In general, HCV is not efficiently transmitted sexually in HIV-negative individuals. Since the year 2000, we have recognized that HCV can be sexually transmitted by HIV-positive MSM, but rates of infection among HIV-negative MSM have been low. Continued monitoring of HCV rates in HIV-negative MSM is important, and this includes those on PrEP.

Elkke Hoornenborg and colleagues presented a poster on the HCV prevalence of HIV-negative MSM who start PrEP in the Amsterdam PrEP (“AMPReP”) project. Of the 375 MSM in AMPReP, 19 (4.8%) were infected with HCV at their first PrEP intake visit. The reported risk factors that these HIV-negative MSM reported were similar to the risk factors we know HIV-positive MSM have: Condomless receptive anal sex, use of drugs during sex (“chem sex”), an STD (rectal gonorrhea, chlamydia, or syphilis), and injection drug use.

The researchers were able to study the HCV strains in these MSM, and found that they were similar to the strains that were found in HIV-positive MSM in Amsterdam. We still do not know the risk of infection of sexual transmission of HCV in MSM while on PrEP, but both the CDC and AASLD/IDSA HCV Guidance recommend that everyone who starts PrEP should be screened when they start. These study results reinforce that recommendation, and call for on-going HCV awareness and risk reduction counseling around sexual transmission of HCV. It also serves as an important early warning that screening for HCV in HIV-negative MSM should potentially be considered. At minimum, those who have condomless anal sex with known HCV-infected partners should be screened.

**Conclusion**

This year’s CROI has provided compelling evidence that dispels the myths that PWID cannot be successfully treated and cured of HCV, and has deepened our understanding of the sexual transmission of HCV. If we are to reach the goal of eliminating HCV by 2030, we must trust in the science and evidence of HCV prevention and treatment to end outbreaks in PWID and raise awareness of sexual transmission to avoid new, emerging outbreaks before they begin.
CROI MOMENTS: A street pole offers an affirming message. Ace Robinson, Executive Director of the C.A.R.E. Program at St. Mary Medical Center in Long Beach, California. C.A.R.E. launches a program specifically for transgender people this summer. Winston Tse, PhD, reported on a potential new class of antiviral drugs. At a press conference, Paul Sax, MD, discusses bicetegravira, a new drug in development. Coinciding with CROI, A Day without Immigrants political street protest sweeps past the conference.

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