POSITIVELY AWARE

COMMEMORATING **30 YEARS** PUBLISHED BY TPAN
JAN+FEB 2020

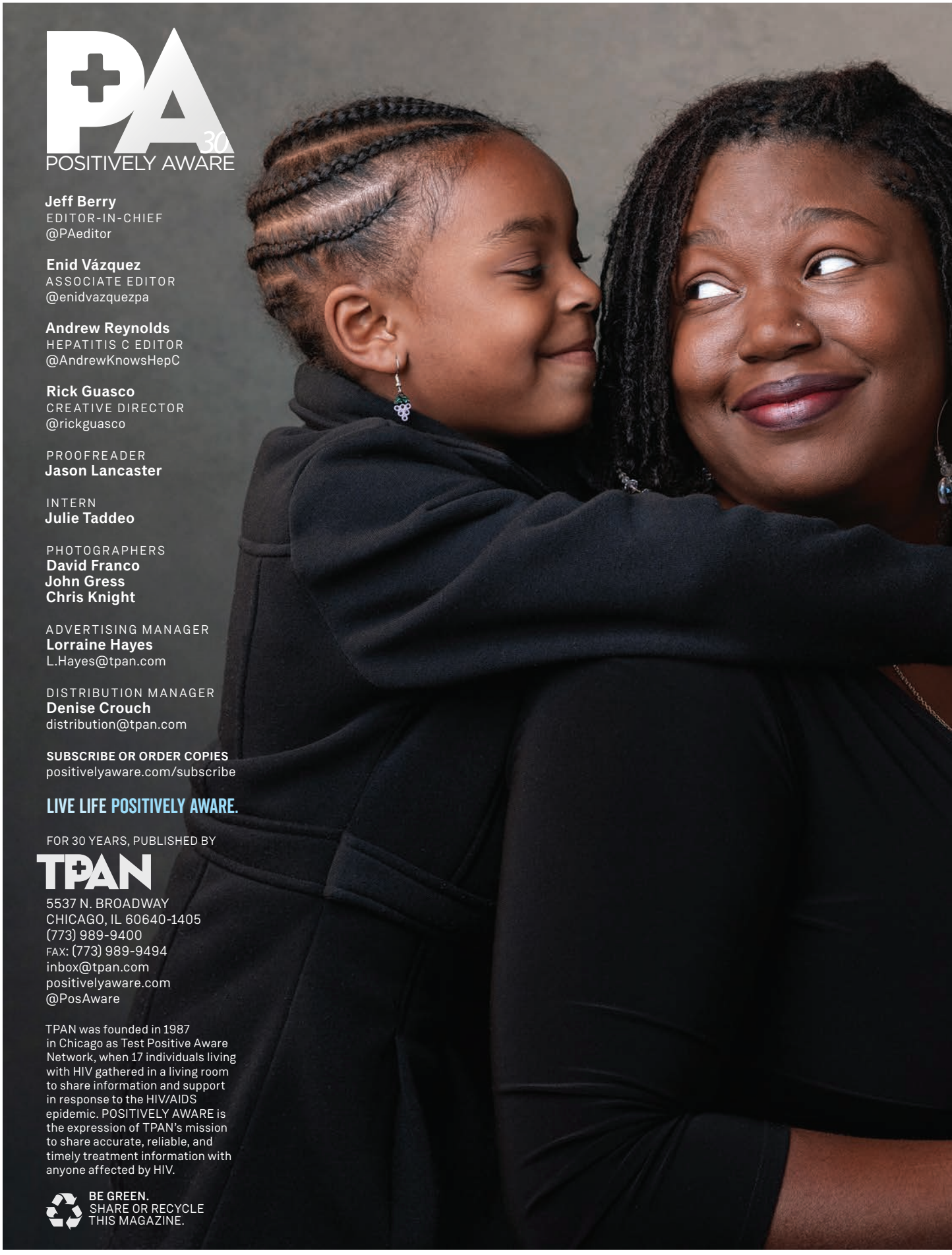
SCENES FROM THE BNAB REVOLUTION

TIRED OF THE WAY THINGS ARE

HONORING LONG-TERM SURVIVORS

BORN FREE

LYNNEA LAWSON was born with HIV, and gave birth to a daughter who is HIV-negative



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TPAN was founded in 1987 in Chicago as Test Positive Aware Network, when 17 individuals living with HIV gathered in a living room to share information and support in response to the HIV/AIDS epidemic. POSITIVELY AWARE is the expression of TPAN's mission to share accurate, reliable, and timely treatment information with anyone affected by HIV.

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JAN+FEB 2020

VOLUME 30 NUMBER 1 positivelyaware.com @posaware

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TIRED OF THE WAY THINGS ARE
Former associate editor **KEITH R. GREEN** notes that while much in the world of HIV/AIDS has changed since another editor's passing, a lot has not. Plus, a 2001 Editor's Note from the late PA editor Charles E. Clifton.

ON THE COVER AND ON THIS SPREAD: **LYNNEA LAWSON** AND DAUGHTER **NAE'LYN** BY LOS ANGELES-BASED PHOTOGRAPHER **DAVID FRANCO**.

THE CONVERSATION

A reader's own 'Note to my younger self'

I HAVE JUST received my copy of the September + October 2019 issue. Like I do with every issue, I always go to the Editor's Note first. This one put tears in my eyes. "Note to my younger self"—wow, if only I could have been able to do that!

I have struggled with alcohol and drug use since I was 13, which is also when I drank my first beer and smoked my first joint. Little did I know then that I would later become an alcoholic and drug addict, live in and out of jail (mostly in), and become HIV and hepatitis C positive—at the same time! All of the hurt, all of the pain, all because of drinking and drug use. If I were able to go back, I need not to tell you what I would have said to that kid. Since 1990, I have only lived about three years on the street (closest I've come to having a home). Now, I just turned 53 and will have been in prison most of my adult life.

I was tested in in 2005 because of a rash that I developed. The skin irritation began in the summer, so my cellmate and I thought it must have been a heat-rash. Turns out that the rash was actually shingles. The nurse put me on quarantine and said that it usually occurs when there is a breakdown in the immune system. So there I was in prison, alone in a cell, with nothing and no one, thinking, "What the ----?"

After a couple of weeks, I was escorted to the dispensary. I was pushing 40 and scared and nervous as hell. The possibility of getting hepatitis C and HIV never crossed my mind. I was thinking it might have been skin cancer.

I was taken to a room with a big table and five people dressed in white medical scrubs were crowded around it. Now I'm really freaking out. Two doctors I had never seen before were accompanied by two nurses from the jail, and with them was the psychologist I had been seeing regularly for mental health.

"Now, Michael, we have some news that may cause a great deal of alarm and anxiety. We are sorry, but your blood tests came back positive. You have hepatitis C and HIV," they said.

July 2005 was when my world caved in on me, Jeff. You said that yours came "crashing down around you" and that you felt "alone and full of shame"—just as I do!

I read your note over and over and it took me back to nearly 15 years ago. I was already feeling alone and shameful for the thefts, now feeling even more alone, with the shame continuing to amplify. I couldn't help recalling how I was molested as a young boy, considering the prostitution I was involved in, reflecting on the men I had been with while incarcerated, and thinking about my drug use with needles. Just a flood of thoughts of everything I did and everything that was done to me.

I was so overwhelmed with these erupting thoughts, memories, flashing faces, places, and everything in between, I felt shame, embarrassment, insecurity, and humiliation. I became so very isolated and hurt, even angry.

The doctors told me that I needed treatment right away. My CD4 was 209 (borderline), and my viral load was over a million. They said that starting HIV treatment was the first priority; hepatitis C could wait a little while.

I was put on Sustiva and Truvada for 10 years. I then switched to Atripla, a single, daily pill. I now take Triumeq, a different single and daily pill. My viral load has been undetectable since 2008—took three years. My CD4 has been rising, but it fluctuates. It has been as high as 1,407; however, last check was only 986, and before that it was 1,113. Every 90 days I have my blood drawn; hopefully, I will see better results over the next few weeks. I'm hepatitis C free, as I went through 48 weeks of pegylated interferon (an old form of treatment).

I have a court hearing that I hope will get me treatment via the Maryland Department of Health and Mental Hygiene. The Third Circuit Court judge for Baltimore County, Nancy M. Purpura, understands that I need help. I suffer from PTSD, anxiety, and depression, so I want to get mental health treatment. I am hoping to get into a long term inpatient program that treats dual diagnoses.

As you say and have said, Jeff, "Hope has sustained me this far, and so it will continue to do so." I will never, ever give up hope. Hope is all that I have.

Jeff, thank you for being the inspiration in my life, as I'm sure you are in many. Together, we can continue on with our fight.

—MICHAEL BARNHOUSE
HAGERSTOWN, MARYLAND

EDITOR JEFF BERRY RESPONDS: I'm glad to hear you are doing so well, Michael, and honored to be a source of inspiration for you. Most now agree that viral load suppression is a more important marker than T cell function, so I wouldn't worry too much about the fluctuation, especially with such high numbers. It sounds like you are getting good medical care, not everyone in your situation does. I hope that you are able to get into the long-term inpatient program, and continue to keep hope alive.

CORRECTION

IN "THE FUTURE IS ALREADY HERE" in the November + December issue, a reference to cabotegravir long-acting plus rilpvivirine long-acting had raltegravir incorrectly listed in place of rilpivirine. POSITIVELY AWARE regrets the error.

JOIN IN THE CONVERSATION

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EDITOR'S NOTE

JEFF BERRY

A chronicle of the epidemic, 30 years in the making

This year marks 30 years of POSITIVELY AWARE (PA) magazine. What started out as TPA News, a local newsletter for TPAN (the HIV service organization that publishes PA), became POSITIVELY AWARE and went national with the launch of the November 1990 issue.

As someone who accessed services at TPAN a few years after testing positive in 1989, I would get the magazine in the mail. There were things about PA that I immediately identified with. I loved the campiness of the illustrations (see page 41), and the fact that it was sex positive. Even though death was all around us in those early days of the epidemic, PA somehow made it less morbid and depressing. This was still the pre-protease inhibitor (and pre-internet) era, but it opened up my thinking and made me believe that I could still live a "normal" life. I loved that PA covered every aspect of people's lives—spirituality, sex, stress, disclosure—and all in a very approachable way. I came to understand through the imagery and content of PA that I could still have a fulfilling life, and sex life, in the age of AIDS, which is very important to someone who has been handed what at the time was a death sentence. It was fun to read the magazine, despite the serious topic.

We've seen many changes in POSITIVELY AWARE over the years, going from a local newsletter to a national monthly magazine putting out 16 issues a year, including four quarterlies that were customized for 10 different cities, another quarterly publication in Spanish that ran for several years, and ongoing special focus issues on topics such as pharmacokinetics, HIV and aging, and PrEP. We've always remained dedicated to our highest purpose, and that is to deliver cutting-edge information to people living with and affected by HIV, in a way that's easy to understand.

This year as we mark our 30th anniversary of publishing, we'll be looking back at some of the stories and people who helped make POSITIVELY AWARE what it is today: a vital resource for so many. In this issue you'll hear from former associate editor Keith R. Green as he introduces a reprint of a very personal Editor's Note from the late Charles Clifton, written in the days following 9/11. Author and sociology professor Celeste Watkins-Hayes reflects on her time at TPAN in 2005 when she began her research on women living with HIV that culminated in her new book, *Remaking A Life: How Women Living with HIV/AIDS Confront Inequality*. And you'll see some of those campy images and covers from previous issues.

While some things have changed, many remain the same. Prevention of vertical (mother-to-child) transmission of HIV, one of the biggest successes of HIV treatment in the history of the epidemic, is the subject of our cover story "Born Free," by Michelle Simek. The story is a very personal account of one woman born with HIV who gave birth to a child who is HIV-negative.

For the October 1993 issue (right) our staff needed someone to stand in for the cover shoot at the last minute, so I volunteered. I posed with Gina, who let me borrow her loafers because I had worn white tennis shoes that day (hey, it *was* the '90s)—hence the white socks. Gina, now a long-term survivor, was one of the success stories and a participant in the ACTG 076 study which showed that giving AZT to pregnant women with HIV was effective in preventing transmission of the virus to the infant. Her son, who was born HIV-negative, is now a healthy and thriving young man.

Publishing is a collaborative process, and this magazine would not be possible without the contributions of many writers who donate their services, and the talented POSITIVELY AWARE team including Associate Editor Enid Vázquez, Creative Director Rick Guasco, Advertising Manager Lorraine Hayes, Hepatitis C Editor Andrew Reynolds, and proofreader Jason Lancaster.

I never expected a volunteer position to turn into a career and my life's work, but somehow it did and for that I'm grateful. I love the work that I do, and the people I work with. I'm proud of how we've always been able to accomplish so much with so little. And the best moments are when we occasionally get a letter or a note from someone thanking us for a story or for something that we wrote, and how it touched or helped them in their life. That is what makes it all worthwhile.

Take care of yourself, and each other.

BEFORE HE BECAME EDITOR-IN-CHIEF, JEFF BERRY WAS A COVER BOY, APPEARING IN THE OCTOBER 1993 ISSUE OF POSITIVELY AWARE (ABOVE).

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BRIEFLY

ISTOCKPHOTO

As a pregnancy precaution, FDA updates dolutegravir label

The U.S. Food and Drug Administration (FDA) updated the dolutegravir drug label in October 2019, based on final results of the Tsepamo Study in Botswana.

The FDA said there were five cases of neural tube defects (NTDs) reported out of 1,683 deliveries (0.3%) among women exposed to an HIV regimen containing dolutegravir around the time of conception. The popular HIV antiretroviral is sold under the brand name Tivicay, and is found in Dovato, Juluca, and Triumeq.

In comparison, the rate of this birth defect was lower for women with HIV who were not taking dolutegravir (0.1%; 15 out of 14,792 deliveries). But it was higher for HIV-negative women (0.8%; 70 out of 89,372 deliveries).

The Baylor College of Medicine reported last July on a laboratory study conducted with dolutegravir following the preliminary findings in Tsepamo. As has been known for a long time, the Baylor researchers found that the nutritional supplement folate acid protects embryos against NTDs.**GO TO** bit.ly/2YAbCjA.

The FDA advises against taking dolutegravir around the time of conception and throughout the first trimester. Switching to a different regimen during the first trimester would depend on a number of considerations. **READ** the FDA announcement at bit.ly/2O9D7KP.

New HIV med on the way: fostemsavir

ViiV Healthcare submitted a New Drug Application (NDA) to the Food and Drug Administration (FDA) for fostemsavir, **a medication for adults with extensive HIV treatment experience who have multidrug-resistant HIV and are unable to form a suppressive regimen due to resistance, intolerance, or safety considerations**.

Fostemsavir has been granted FDA Fast Track and Breakthrough Therapy Designations. A breakthrough designation requires preliminary clinical evidence indicating that the drug may demonstrate substantial improvement on clinically significant endpoint(s) over available therapies.

Fostemsavir is an oral attachment inhibitor that works differently than another currently on the market, Trogarzo. See the fostemsavir page in the POSITIVELY AWARE HIV Drug Guide: positivelyaware.com/drug-guides/fostemsavir.

"Fostemsavir may provide an important treatment option for the group of people living with HIV who, for a variety of reasons, are not able to suppress their virus with other medicines and could be left with few or no treatments available to them. In keeping with our mission of leaving no person with HIV behind, we have overcome many barriers to bring this important new medicine to people living with HIV, including investing in what is a very complex manufacturing process," said Deborah Waterhouse, ViiV's CEO, in a December 2019 press release announcing the NDA. The company is solely devoted to HIV therapy and cure.

BRIEFLY

DRUG LABEL UPDATE

Efavirenz and nervous system toxicity

The FDA in October added information about neurotoxicity to the drug labels of medications containing the HIV antiviral efavirenz—Sustiva, Atripla, Symfi, and Symfi Lo. The FDA said neurotoxicity may occur months to years after starting therapy with efavirenz. Called "late-onset neurotoxicity," adverse events include ataxia (poor coordination) and encephalopathy (disease, damage, or malfunction of the brain). The agency said the effects have been seen in people who have a genetic trait called "CYP2B6." This trait is associated with increased levels of efavirenz despite standard dosing.

"Patients presenting with signs and symptoms of serious neurologic adverse experiences should be evaluated promptly to assess the possibility that these events may be related to EFV [efavirenz] use, and whether discontinuation is warranted," the FDA reported.

READ the FDA announcement: bit.ly/37sK8Ow.

OI GUIDELINES UPDATE

Kidneys, pneumonia, and more

The U.S. guidelines on opportunistic infections (OIs) in HIV were updated in October and November.

Tables relating to medications for OIs were updated, including dose adjustments needed for people with kidney problems.

Key changes were made to the section on community-acquired pneumonia.

The section on talaromycosis has been updated.

READ "What's New in the Guidelines": bit.ly/updatedHIVguidelines2019-11-21.

Mail order testing yields results

Free home HIV testing kits provided through mail order to men who have sex with men (MSM) offered an effective strategy for getting people into care, according to a study conducted by the Centers for Disease Control and Prevention (CDC).

Using banner ads on social media and music websites, 2,665 men were recruited for the 12-month-long study. Half were sent four free HIV testing kits, with the option to order more—many of them did, sharing the kits with friends. The other half only got a link to local testing services. All participants completed quarterly surveys and had access to online HIV resources and telephone counseling upon request.

Among those who received testing kits, 25 men learned they were living with HIV, as did 11 from the other group. And from the home tests shared with friends, another 34 men were diagnosed.

More than 70 percent of participants who tested positive sought treatment.

"Self-testing is an important option for some people and in some situations, it saves time, offers privacy, and reaches people who may not be able to or willing to access existing testing services," said Robin MacGowan, the study's lead author and a researcher at the CDC in a statement.

The study used the OraQuick saliva test, the only approved and available over-the-counter home HIV test, and a finger stick blood test, which was sent

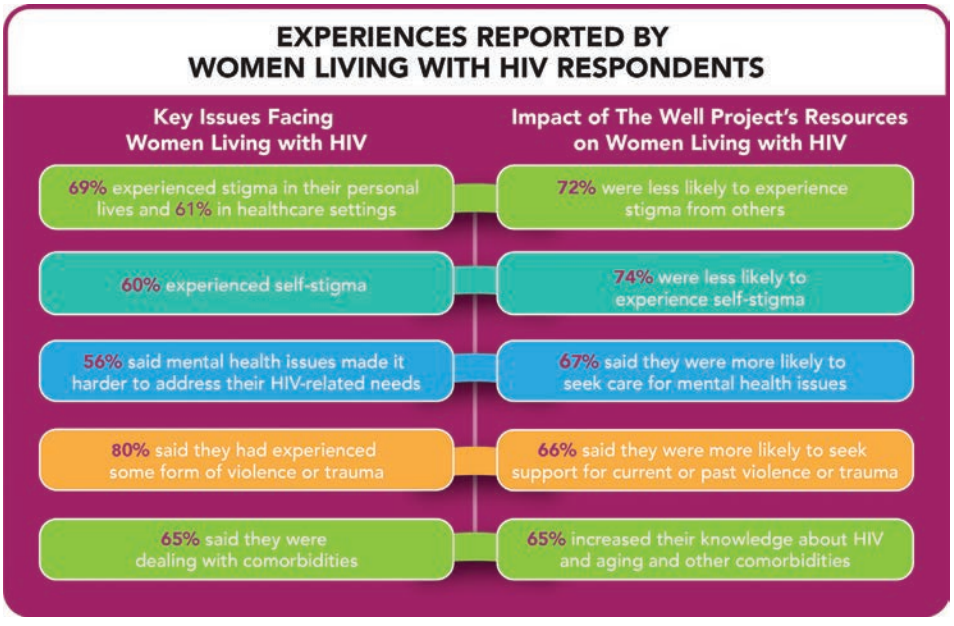
Survey assesses the needs of women living with HIV

Results of a new survey conducted by The Well Project offer insight into the experiences and needs of women living with HIV. The report, *Together We Are...Making an Impact*, highlights the need to look beyond viral suppression (undetectable viral load) as an indicator of quality of health.

The report is the result of a survey of 239 respondents, two-thirds of whom identified either as cisgender or transgender women living with HIV, and points out that there remain numerous opportunities to improve the lives of women living with HIV, including:

- Implementing educational programs to reduce stigma experienced by women living with HIV in healthcare settings and their personal lives
- Normalizing mental and behavioral health issues, including current or past violence and trauma, and encouraging women living with HIV to seek the care they need
- Emphasizing the need for education for healthcare providers about the stigma-reducing messages of U=U (Undetectable Equals Untransmittable)
- Driving research on and increasing attention to the numerous issues around living with HIV over the long-term (including co-morbidities)
- Continuing to promote opportunities for women living with HIV to connect with one another

Established in 2002, The Well Project is a leading resource for women living with HIV: thewellproject.org.



INFOGRAPHIC: THE WELL PROJECT

to a lab. The men were given up to $90 for participating if they reported test results and completed the surveys.

New York City, Los Angeles, and the states of New York and Arizona are among those that have home testing programs. Arizona's program is administered by Aunt Tina's Foundation, a nonprofit based in Phoenix.

Home testing helps extend access to large rural areas, but is also useful for people living in urban areas and the suburbs, said Glen Spencer, executive director of Aunt Tina's. "It's also helpful in communities of color, where stigma can be more pronounced," he added. "Many aren't comfortable from a cultural standpoint in going to an HIV testing facility, but still want to know their status."

In addition to the home tests, Aunt Tina's provides online resources statewide. People who test negative can get information about PrEP. Arizona resources are available at hivaz.org, and in Spanish at vihaz.org. After taking an online survey, Arizona residents can order a free home testing kit at mysterykit.org, or order in Spanish at mipaquete.org.

Second reported case of HIV transmission during vaccine study

A second case of HIV transmission to a partner from someone who had temporarily stopped their HIV treatment to participate in a cure study has been reported. **The report has renewed discussion about whether HIV-negative partners of people in cure studies should be offered PrEP.**

The search for an HIV cure involves analytical treatment interruptions (ATIs)—it's the only way to determine if a potential strategy will work. People living with HIV participating in a cure study may agree to an ATI, temporarily going off their HIV medication so that researchers can see if the virus becomes detectable again, how quickly, and at what viral load.

The first case of a sexual partner acquiring HIV during a cure study took place in France in November 2014, and was first reported in February 2019 in the *Journal of Infectious Diseases*.

A second reported case of ATI-related transmission occurred in Spain during a study that started in 2016 and concluded in May 2019. The study participant was a gay man in his forties who had been diagnosed with HIV 12 years earlier, and on suppressive therapy for four years. He became detectable four weeks into the ATI after reporting symptoms similar to acute HIV infection, and was restarted on his previous ART regimen four weeks later.

Prior to the partner's ATI for the study, the couple had been counseled on HIV prevention methods, including condom use and PEP (post-exposure prophylaxis). At the time, PrEP was not available in Spain, but could be purchased online. PrEP did not become widely available in Spain until November 2019.

In an interview with the British HIV website aidsmap.com, study co-author Dr. Lorna Leal of Barcelona General Hospital said, "finding the best option to prevent secondary transmission is mandatory, since ATI remains the most frequently recommended intervention to analyse the impact of cure-related strategies."

THIS REPORT drew from a number of online sources, primarily from aidsmap: bit.ly/2pNT687.

Court clears way for safe injection site

After political struggles that climaxed in a court battle, Safehouse, **the first safe injection site in the United States** was set to open in Philadelphia. As this issue went to press, the facility was scheduled to open on January 1, pending a final ruling.

Available in other parts of the world, these sites allow people to use drugs under the supervision of trained harm reduction personnel to help prevent or treat an overdose. Additional services would include on-site initiation of Medically Assisted Treatment (MAT), recovery counseling, education about substance use treatment, basic medical services, and referrals to support services such as housing, public benefits, and legal services.

Co-founders Ronda B. Goldfein, executive director of the AIDS Law Project of Pennsylvania, José A. Benitez, executive director of Prevention Point, a local nonprofit, and Ed Rendell, the former Democratic governor of Pennsylvania, wrote an essay about the need for places like Safehouse, which appeared October 15 in the *Washington Post*: bit.ly/Safehousecommentary.

VIRAL HEPATITIS BRIEFLY
BY **ANDREW REYNOLDS**

Hepatitis D drug development guidance

The FDA has announced the draft guidance for development of antiviral drugs to treat chronic hepatitis D (HDV). Hepatitis D, also called "delta hepatitis," can only be acquired by people who have hepatitis B (HBV); HDV cannot replicate itself without HBV. HDV is transmitted from blood-to-blood contact, and can be either acute (short-term) or chronic (long-term). To date, there are no treatments nor is there a vaccine for HDV. Overall, it is rare in the United States; according to the CDC, there've been approximately 357,000 people with past or chronic HDV, but rates of infection are higher among Asian immigrants and other foreign-born individuals where both HBV and HDV are more endemic. HDV can lead to serious liver problems such as cirrhosis, liver failure, and liver cancer. Developing treatments and cure for this overlooked disease is a very important intervention, and **the guidance and support provided by the FDA is an important first step toward a cure**. Announcement of the draft guidance came November 1. **SOURCE:** bit.ly/HVDdraftguidance.

Baraclude treatment updates for hepatitis B

Changes to the label of Baraclude (entecavir), an antiviral used for treating chronic hepatitis B (HBV), were approved by the FDA on November 8. The changes are the result of a five-to-10-year observational study of 12,378 people, in which approximately half took Baraclude, and the other half took other HBV medications. Patients were monitored every six months, focusing on a variety of clinical issues including malignant tumors (neoplasms), liver-related HBV disease progression, liver cancer, and death. The **study found that Baraclude was not associated with increased risk of tumors when compared with other HBV medications**. Similarly, Baraclude was not associated with lower rates of HBV-related disease progression or death when compared to other HBV treatments. To date there is no cure for HBV, and while not everyone with chronic HBV needs treatment, research like this helps patients and medical providers make important choices about which treatment is right for them.

BRIEFLY

The AIDS Quilt finds a new home

The 50,000-panel National AIDS Memorial Quilt is headed to the Bay Area under **an agreement that hands over care and management of the quilt from the Names Project to the National AIDS Memorial Grove** in San Francisco.

In a report by the Bay Area Reporter (BAR), Names Project CEO Julie Rhoad, president and CEO of the Names Project, told the publication that the nonprofit will transfer its operations to the AIDS grove and that The Names Project "will close and cease operations," shutting down by the end of the year.

The Names Project was established in 1987 in San Francisco as custodian of the quilt, which was conceived in memory of people who had died as a result of HIV/AIDS. In 2001, the nonprofit moved to Atlanta, along with the quilt. The agency had also organized various displays and educational events across the country and throughout the world.

The quilt will be relocated early this year to a warehouse near Oakland International Airport, said AIDS grove CEO John Cunningham in an interview with the BAR. The AIDS grove plans to build a new facility in San Francisco, the Center for Social Justice, which will house the quilt.

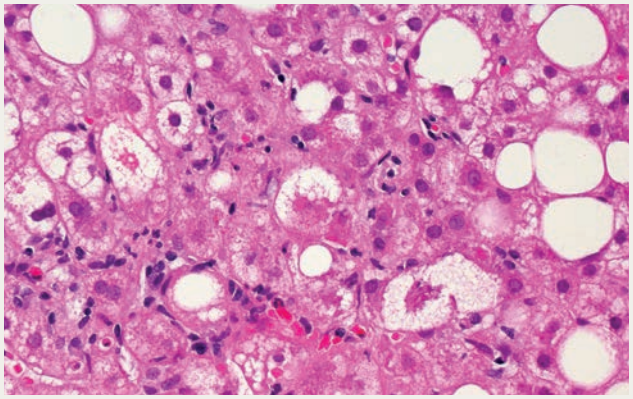
An archive of more than 200,000 items—personal letters, photographs, and biographical records related to people memorialized in the quilt, along with a sewing machine that was used to stitch together part of the quilt—will be contained at the Folklife Center of the Library of Congress, in Washington, D.C.

Comprised of more than 50,000 sewn panels measuring 3 feet by 6 feet, honoring 105,000 people, the quilt weighs 52 tons.

MORE INFORMATION:
AIDSmemorial.org and LOC.gov.

JULIE RHOAD, CEO OF THE NAMES PROJECT, AND NATIONAL AIDS MEMORIAL CEO JOHN CUNNINGHAM AT THE LIBRARY OF CONGRESS, ANNOUNCING THE TRANSFER OF THE AIDS QUILT AND ITS ARCHIVES.

BRIEFLY EXTRA BY JULIE TADDEO



LIVER TISSUE AFFECTED BY NON-ALCOHOLIC FATTY LIVER DISEASE; THE LARGE AND SMALL WHITE SPOTS ARE EXCESS FAT DROPLETS FILLING LIVER CELLS (HEPATOCYTES).

Tesamorelin reverses non-alcoholic fatty liver disease in people living with HIV

Tesamorelin (Egrifta) may be an effective agent for reducing liver fat and preventing fibrosis in people living with HIV, according to a study released in October by the National Institute of Allergy and Infectious Diseases (NIAID) and the National Cancer Institute.

Tesamorelin, an injectable growth-hormone-releasing synthetic hormone, was approved in 2010 by the FDA to reduce visceral fat in people with HIV. A potential complication of HIV, antiretroviral therapy, or both may be changes in the distribution of adipose tissue (fat), otherwise known as lipodystrophy. Abdominal lipohypertrophy (a form of lipodystrophy) is the accumulation of excess visceral adipose tissue (VAT)—deep belly fat surrounding the liver, stomach, and other abdominal organs. Visceral fat is directly associated with liver inflammation and fibrosis, which can help lead to non-alcoholic fatty liver disease (NAFLD). "Because tesamorelin proved effective in treating abnormal fat build-up in the abdomens of people in the context of HIV and related medication use, we hypothesized that the drug might also reduce fat that accrues in the liver and causes damage in a similar population," explained one of several lead investigators, Steven K. Grinspoon, MD, chief of the Metabolism Unit at Massachusetts General Hospital.

NAFLD affects 25% of people living with HIV in the developed world.

"Many people living with HIV have overcome significant obstacles to live longer, healthier lives, though many still experience liver disease," said NIAID director Anthony S. Fauci, MD, in a press statement. "It is encouraging that tesamorelin, a drug already approved to treat other complications of HIV, may be effective in addressing non-alcoholic fatty liver disease."

Of the 61 participants from the double-blind, randomized study, 43% had at least a mild case of fibrosis and 33% had the more severe subset of NAFLD called nonalcoholic steatohepatitis (NASH). Participants were randomly divided into two groups: 31 received 2 mg injections of tesamorelin daily and 30

LIVER TISSUE: DR. DAVID KLEINER, NATIONAL CANCER INSTITUTE
QUILT: SHAWN MILLER, LIBRARY OF CONGRESS

were given placebo injections. All participants were given nutritional counseling and instruction on how to self-administer the injections. Liver health was examined in both groups at baseline and 12 months later.

Participants who were given tesamorelin had better liver health than those who received the placebo. A healthy hepatic fat fraction (HFF, or fat to liver ratio) was achieved by 35% of the participants who received tesamorelin, while only 4% of those who were given placebo were able to do the same with nutritional advice alone. Additionally, nine placebo participants experienced onset or worsening of fibrosis, while only two from the tesamorelin group reported the same.

According to the study results, tesamorelin reduced the risk of developing NAFLD by 37%. Aside from joint pain, skin irritation, and stomach pain around injection sites, the drug was well tolerated overall. Several blood markers associated with inflammation and liver damage (including the enzyme alanine aminotransferase) also decreased more among participants taking tesamorelin, specifically those who had increased levels upon entering the study.

Investigators suggest that the indication for tesamorelin be expanded to include people living with HIV and diagnosed with NAFLD. They recommend that further research into the long-term effects of tesamorelin as protection against serious liver disease in people without HIV. "Our hope is that this intervention may help people living with HIV, as well as benefit HIV-negative people with liver abnormalities," said Colleen M. Hadigan, MD, senior researcher at NIAID's Laboratory of Immunoregulation.

PHOTO COURTESY OF CHARLES SANCHEZ

SAGE conference focuses on LGBT senior housing

Elderly members of the LGBT community face far more barriers finding adequate housing than their heterosexual counterparts, according to SAGE, an advocacy and services organization for LGBT seniors. SAGE reported that when applying for housing, 48% of same-sex couples are subjected to discrimination. This was the focus of a SAGE conference. Sponsored by Citi Community Development, the conference was held in Washington, D.C. at the National Community Reinvestment Coalition. The event brought together nonprofits, housing developers, and policy experts from around the country to discuss LGBT housing and to collaborate on strategies to combat the disparities within it.

Finding safe, affordable housing is a common concern for many older people; addressing that challenge, while also facing discrimination from property owners, residents, and company representatives, can make the entire process feel futile. In a press release, Bob Annibale, Global Director of Citi Community Development, said that, "**The LGBT population age 50 and above is expected to grow from three to seven million over the next decade**, yet there are only about 600 units of affordable housing that are equipped with the appropriate training and services to meet their unique needs." Additionally, there are currently 26 states with laws which allow property owners and providers to evict or refuse prospective residents based on who they are or who they love.

This conference was held as a part of SAGE's National LGBT Elder Housing Initiative. By creating a platform for housing experts and LGBT advocacy organizations to exchange information and ideas, SAGE hopes to establish new partnerships and identify collaborative solutions to ensure that elderly LGBT members have improved access to culturally competent housing.

'Merce' returns for a second season

Put off by the outdated and tragic portrayals of HIV often depicted in the media, Charles Sanchez, a writer/performer living with HIV, **attempts to break the misconceptions with his award-winning musical web series, *Merce***. The show centers on the adventures of Merce, a single, middle-aged, gay man living with HIV in New York City, and comically follows his journey to find love and self-acceptance. What makes the show unique is Merce's optimistic, cheerful, and energetic attitude, proving that, "life can be positive, even when you're HIV+." The show is intended to inspire and represent the modern life of a person living with HIV.

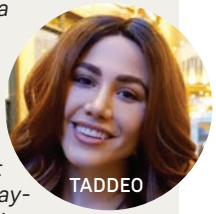
SANCHEZ

The second season of the series has been renewed by Skipping Boyz Productions and is scheduled to launch January 2020 with eight new episodes. Director Tyne Firmin shares how the success of the first season allowed them to raise the production budget for the second. "I think the audience is going to love the hilarious world we've created," Frimin exclaims. Two new composers, Rob Hartmann and Adam J. Rineer, will also be joining the production crew. Season two will continue its bawdy humor while addressing important topics such as serodifferent relationships, comorbidities, U=U, PrEP, stigma, and marriage equality.

In anticipation of the release, producers are leaking musical numbers from the second season. **LISTEN** to music from the first episode composed and written by Rob Hartmann: bit.ly/348TVqS. **WATCH** the second season of Merce: bit.ly/2XLt028.

REFLECTIONS FROM OUR INTERN

As I near the end of my internship, I leave POSITIVELY AWARE having met so many people living with HIV with a renewed and deeper appreciation of life. I'll admit, as a 24-year-old, it's easy to get caught up in day-to-day trivialities.



TADDEO

But the gratitude for life that I have seen among people with HIV is inspiring. Many find purpose in community involvement or advocating for something larger than themselves. These are principles that I too can find value in pursuing. —**JT**

BORN FREE

Lynnea Lawson was born with HIV, and gave birth to a daughter who is HIV-negative

BY **MICHELLE SIMEK** · PHOTOGRAPHY BY **DAVID FRANCO**

"I have taught my daughter how to not let what other people think affect her. After I learned that myself, that is when I started to love me. I am HIV-positive and if you can't deal with that, you don't deserve me in any aspect."

—**LYNNEA LAWSON**, LOS ANGELES, CALIFORNIA

LYNNEA LAWSON FOUND OUT that she has HIV when she was seven years old—she had acquired HIV at birth. Her HIV status was outed when she was a teenager and she had to switch high schools due to serious stigma. Her self-esteem was low. She thought she was ugly and worthless. For a while, she even adopted an "alter ego" that had nothing to do with HIV/AIDS and enabled her to live a second life in denial of her diagnosis. Now, at 34 years old, she is both an HIV activist and the proud mother of a daughter who is HIV-negative. Lynnea—like the knowledge that we have today about HIV and pregnancy—has grown tremendously.

IN THE 1980S AND EARLY '90S, most women living with HIV were actively discouraged from having children due to fear, stigma, and concern that they would not live long enough to raise their children or would transmit HIV to their babies. Moreover, some women living with HIV who became pregnant were pushed to terminate their pregnancy—an option that many ignored, and thus had to fight for their right to bear their child. Some were pushed into having cesarean deliveries (C-sections) to help prevent HIV transmission during labor.

In 2020 (and since the 1990's), women living with HIV can and do have babies who are virus free, not only in the U.S. and Europe but also in Africa and other continents. However, there are guidelines to prevent vertical transmission (also known as mother-to-child transmission, or MTCT):

- If the expectant mother is not on HIV therapy, she needs to start right away.
  - She should take a regimen that contains two nucleoside reverse transcriptase inhibitors (NRTIs, or nukes) plus one other HIV medication from another drug class
  - Treatment should be individualized for each mother, taking into account her circumstances, potential side effects, opportunistic infections, or other co-morbidities (most especially hepatitis)
- If the expectant mother gets her viral load down to undetectable—and keeps it there—the risk of transmitting HIV to her unborn baby is virtually nonexistent.
- If the expectant mother is already taking anti-HIV medication and her viral load is undetectable, she should continue taking it as long as it is safe for both mother and child (see sidebar about dolutegravir).
- Women who are pregnant and living with HIV can have vaginal deliveries! C-sections are no longer recommended but can be scheduled electively two weeks prior to the due date.
- Mothers who are living with HIV in the U.S. and Western Europe should not breastfeed. (Guidelines are different in some resource-limited countries in the southern hemisphere, where the risk of using contaminated water for formula is more dangerous than HIV due to the risk of other life-threatening infections such as cholera, dysentery, and other water-born illnesses.)
- Newborns take liquid pediatric doses of AZT for 4–6 weeks after birth as an added preventive measure (the time frame depends on whether the mother took HIV medications or not).

Growing up

A LOS ANGELES NATIVE, Lynnea is a seasonal tax preparer and self-described "lifelong AIDS activist." When she became pregnant, she followed the guidelines listed above, and her five-year-old daughter, Nae'lyn, is HIV-negative.

The very first HIV test (ELISA) was approved in April 1985, but Lynnea was born the month before, so neither she nor her mother were tested. As she got older, one of her sisters, Keisha, was very inquisitive and kept asking their mother why Lynnea had so many medical visits. "I was the only one out of four kids who kept going to the doctor and having blood drawn." Keisha was relentless with her questioning and their mother, Patsy, eventually revealed the truth although "it wasn't in my mother to disclose." Patsy told Keisha that Lynnea had HIV but instructed her not to say anything about

it to her sister. Lynnea remembers being outside playing while Keisha was with her, keeping quiet while she was deep in thought. Finally Keisha asked, "'Did you ever wonder why you kept getting stuck with those needles?'" Lynnea said, "I had never thought about it until she brought it up. I had never asked. I had complete trust in my mother. If my mom said I needed to take this medication, I knew I'd be okay."

Keisha's next words were: "You have HIV."

"I had no idea what that meant. I just saw HIV in passing. Like Ryan White and Magic Johnson." But it still "stuck out to me like something bad. Magic is gonna die because of it. The only thing I thought was that I was gonna die too." When Lynnea saw her mother, she asked, "Why didn't you tell me I was gonna die?" Patsy's response? "As long as I'm okay, I will take care of you. I have AIDS and AIDS is worse than HIV."

Patsy did not know that she had HIV while she was pregnant with Lynnea or while pregnant with Lynnea's little brother Raymond, who was born both premature and HIV-positive. Patsy took him home and "prayed that he would live long enough to wear the new baby clothes that were bought for him." Baby Raymond did wear the baby clothes, but died shortly after. "His life was short so that ours could be long. No telling if my mom ever would have been tested for HIV. Then she got all the kids tested."

Already a shy child, Lynnea became even quieter, although she dreamt of one day becoming a model and being in fashion shows. But when stigma hit, it hit hard. A "random kid" at Jefferson High walked behind her and said, "Someone told me you have HIV." He used his drumsticks to drum on her backpack and sang "HIV girl" behind her all the way down the school hallway. She went home in tears and talked to her mother. "After that, I didn't go back. When that happens, you don't want to go back to school. I wasn't learning anything anyway. I had to leave Jefferson and transfer to Fremont High." At Fremont, Lynnea kept to herself, not sharing her HIV status or her secret plans to be a model. "I was a loner and very shy with low self-esteem. I was a sponge and liked what everyone else did and didn't speak to anyone. Anyone else's opinion was my opinion." To this day, she has no idea how the "random kid" at Jefferson found out her HIV status.

After Fremont High, Lynnea intentionally took on an "alter ego" named "Angel Doll." "I didn't know how to act and didn't think I was good enough. I didn't matter. I never mattered. I copied what everyone else did and didn't have my own opinion. I always had this double life kind of thing. I was a wonderful person in one setting, in the next setting I just wanted to be a normal person." That is, a person without HIV. Lynnea was interviewed by the *Los Angeles Times* about HIV/AIDS and the story identified her by her real name. "If someone Googled my name, it [the story] would come up. So, I just stopped telling people my real name." And Angel Doll was not shy like Lynnea. Angel Doll was "very outgoing, flirtatious, spontaneous, and free." This alter ego existed until her late 20's when Lynnea "intentionally killed off Angel Doll. It was very freeing. I had realized that I could have my own opinion."

All grown up

ONCE SHE FELT freer to be herself, she came up with an idea called "Positively Beautiful," her passion project. When Lynnea was younger, she figured that she would never be able to model. She decided that no one thought that she was beautiful because of "all of the horrible things" that were said about people living with HIV/AIDS (PLWHA). After her "Angel Doll" years, she realized and accepted that HIV was "never part of her outward appearance." In 2006, thanks to a friend from the Los Angeles HIV/AIDS community and the National Association of People with AIDS (NAPWA), Lynnea co-created and participated in her first fashion show. The Positively Beautiful fashion show took place during the Positive Youth Institute as part of the Ryan White National Youth Conference. The show took place during one of the many conference-related social events that attendees were invited to. Lynnea gathered together PLWHA who were willing to model and gave them t-shirts. The models decorated their own shirts with words that described themselves that "they wanted other people to see." The PLWHA models then walked the "Ryan White runway." But the ultimate goal of Positively Beautiful is to have a fashion show that includes models who are both HIV-positive and HIV-negative—and the audience won't know who is who. "They will just know that they all look good." Lynnea was finally given a beauty pageant sash as part of her peer award from the Los Angeles HIV/AIDS Women's Task Force. But she still wants the full runway fashion show, even as a mom.

Desire for a child

EVENTUALLY, Lynnea started thinking about motherhood and having her own child. "I was at a point in life when I was almost ready to have a kid." But her desire to be a mother intensified when one of her best friends became pregnant and asked her to be godmother. Lynnea's friend said, "You have a health condition that won't allow you to be a mom, so I'm gonna share my baby with you." After the baby girl was born Lynnea felt that "it was the nail in the coffin. I loved that baby so much and wanted one so badly that I would have picked one up at the store if I could have." Thanks to her activism and education about HIV, she knew that she could potentially have a child who was HIV-negative.

When the home pregnancy test turned out positive, she "got what I wanted. I was happy and also very nervous. Can I do this? Am I about to ruin someone else's life?" In addition to worries about her mothering abilities and HIV, she worried (and still does) about having an African American child in the U.S. "What about having a child in this world? Where, if you are black, you are not encouraged to be 100% who you are. I have limited options. I'm not married or traditional, so things are not set up in an ideal way. I don't own a home, have money, have a good career, or a husband. And I'm not in a position to not worry about money." Also, her brother, Danny, had served nine years in prison for robbery as a result of his involvement with an "urban gang violence thing." He spent his 21st birthday in prison, but Danny is no longer incarcerated and is "on the right track now with a good job."

The dolutegravir issue

SINCE 2018, there has been conflicting and concerning information about Tivicay (dolutegravir) and pregnancy and neural tube defects (NTDs—birth defects of the brain, spine, or spinal cord). According to results from the Tsepamo study in Botswana, there were five cases of NTD out of 1,682 deliveries to women who took dolutegravir. On October 25, 2019, the Food and Drug Administration (FDA) approved new labeling to dolutegravir and medications containing it: Triumeq, Juluca, and Dovato. The new labeling states that HIV-positive women should not take dolutegravir or any drugs containing dolutegravir starting at the moment of conception through the first trimester. According to the FDA, dolutegravir can be used in the second and third trimesters of pregnancy, but only if "the expected benefit justifies the potential risk to the pregnant woman and the fetus" and if the expectant mother decides to take it. (SEE *Briefly.*)

'I TOOK THE STEPS AND DID THE RESEARCH. MY SELF-ESTEEM IS NOT THE BEST, BUT **I HAD CONFIDENCE IN THAT MOMENT**. AND THAT MOMENT OF CONFIDENCE CARRIED OVER INTO OTHER ASPECTS OF CHILD REARING, LIKE MY ABILITIES AS A MOTHER.'
—LYNNEA LAWSON

Prevention

WHILE PREGNANT, Lynnea took Odefsey (entricitabine/rilpivirine/tenofivir alafenamide). Labor had to be induced and the clinic gave Nae'lyn a pediatric dose of AZT in an IV drip. And the AZT doses continued via bottle when Lynnea took her Nae'lyn home. "I cried. That was the hardest part. I know how bad AZT is and I had to give it to her right after birth." And of course her sister Keisha was full of questions: "What are you giving to the baby? Are you sure about that? Do you know how bad it is?" Patsy had chosen not to give Lynnea AZT when she was a child because she didn't trust it. She thought it was harsh and toxic (1980's dosing of AZT was, indeed, too high and caused severe side effects). And watching *Dallas Buyers Club* at home alone while giving Nae'lyn pediatric AZT certainly didn't help. The film got in her head. "I worried about AZT's reputation. I worried that it would cause harm and side effects." She had to make sure to focus on the outcome and what her doctors told her, both throughout her own life and during her pregnancy and labor (Lynnea receives her own HIV medical care at the University of Southern California's Maternal Child and Adolescent/Adult Center for Infectious Diseases and Virology [MCA] and went for prenatal care at MCA as well). After all, "they had many years to get it right." Lynnea turned to her faith for strength and support. "I had to pray about it. I prayed, 'God, if this is not going to be good, please make the bottle [containing AZT] spill over.' But the bottle never spilled over and I prayed that prayer every day. I would still cry as I gave it to her. It was a process." She told her daughter, "Mommy is only giving this to you because it will make you be healthy."

Lynnea took Nae'lyn to MCA approximately every two months, for wellness checks, immunizations, and HIV tests. The nurse at MCA (who had also taken care of Lynnea when she was a child) didn't specifically mention the HIV testing or the test results. "They didn't tell me, and I didn't ask. It was just normal blood work." When Nae'lyn was one-and-a-half years old, she tested negative for the last time. "That time, they told me that this would be the final HIV test and that she had tested negative until now. I was pretty confident that she would really be HIV-negative." When the test results came back, Lynnea "wasn't excited and it wasn't a cause for celebration. It was like 'tell me something I don't know!' I took the steps and did the research. It was good! My self-esteem is not the best but I had confidence in that moment. And that moment of confidence carried over into other aspects of child rearing, like my abilities as a mother."

Growing up, Part 2

CURRENTLY, LYNNEA and her story are part of an interactive exhibition at UCLA's Fowler Museum called "Through Positive Eyes," and Nae'lyn is thriving in kindergarten. "If you ask Nae'lyn if her mom has HIV, she might say 'yes.' She's been around while I do my advocacy work. She has heard my story. I don't alter the world for my child. I explain it to her the way that it is. I let her experience it as it is and explain it in a way so that she can understand it for herself." And Lynnea is not worried that her daughter will feel ashamed that HIV

is part of the family. "I have given her enough information to banish stigma."

Asked what she wants for her daughter, Lynnea says, "I want my daughter to be a well adjusted, happy, and healthy person. Whatever that looks like for her, well, I'm fine with that. I want to expose her to everything in the world. I want to encourage her to find her own gifts—and a lot of people don't get that opportunity." Compared to Lynnea, Nae'lyn is most definitely not shy. "She is a ball of fire but still sensitive to the needs of others." Recently her daughter deliberately missed her lunch break to check in on her kindergarten teacher who was suffering from a migraine and having a tough day.

When Lynnea concludes her portion of "Through Positive Eyes," she always finishes with the same description about her daughter: "She's a happy, healthy, HIV-negative, little girl. She's sassy, spunky—quite the opposite of me as she's not shy at all! She sings at church and she remembers everything. She's very loving yet full of attitude. She wants everything her own way. She's a handful."

And now that she has become a mother, what's next for Lynnea? "I want to use my voice to fight HIV. I let myself be an example. I want to teach others how to be an ally to the HIV community. And how to be a friend to us. There is no place for judging or shaming." And of course she still wants to work on her passion project, Positively Beautiful, and that real runway show. With models of all shapes, sizes, and serostatuses. PA

MICHELLE SIMEK has worked in HIV/AIDS for more than 20 years. She currently works at the UCLA Center for Clinical AIDS Research and Education (CARE) and is a popular HIV/AIDS presenter, both locally and nationally. In her downtime, she is an avid reader and concert goer and proud mom of Baxter, her five-year-old rescue cat.

Another potential way to prevent vertical transmission?

EACH YEAR, 180,000 infants worldwide acquire HIV via breast milk. However, using water potentially contaminated with cholera or dysentery in baby formula is dangerous. Additionally, the use of formula instead of breast milk can be very stigmatizing for new mothers who are living with HIV, especially in cultures where breastfeeding is the norm. Results of a new study show promise that may change this infection paradigm. Published on November 4, 2019 in the *Journal of Infectious Disease*, the study indicates that use of broadly neutralizing antibodies (bNABs) may help reduce MTCT transmission. bNABs are a type of antibody that can recognize and block HIV from entering healthy cells. They may also activate (turn on) other white blood cells to help destroy HIV-infected cells. (SEE page 32.)

This was a phase 1 safety study of a bNAB called VRC01. Babies who were exposed to HIV during pregnancy in the U.S. and Africa were given a single dose of VRC01 subcutaneously (under the skin). Infants who were being breastfed were given 40 mg after birth and then 20 mg monthly. Anti-HIV medication was also given to all babies in the study. Other than some mild-moderate skin reactions (reddening at the injection site), the experimental drug was deemed to be safe in the study infants. More research is needed to see if VRC01 is effective in preventing HIV transmission.

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TWIN EPIDEMICS

Vertical transmission of hepatitis C and congenital syphilis: What you need to know for prevention, treatment, and maternal and child health

BY **ANDREW REYNOLDS**

IN RECENT YEARS, we have seen a dramatic rise in vertical (also known as mother-to child) transmission of hepatitis C (HCV) as well as increases in perinatal syphilis, both of which are tied to opioid and other drug use, poor access to prenatal healthcare, stigma, and lack of access to reproductive health, including contraception. These, when combined with other structural factors like poverty and health inequality, have created a perfect storm for an increase in infectious disease transmission overall and from mother to child in particular.

Vertical transmission of HCV is on the rise in the United States. Approximately 29,000 women living with HCV give birth each year, making it the leading cause of pediatric HCV. As the opioid crisis rages on, we have seen increases in HCV as a growing number of younger women of childbearing age acquire the virus. From 2011 to 2016, there has been a 39% increase in HCV-positive pregnant women and a 13% increase in HCV-positive children.

Congenital syphilis rates are also dramatically on the rise. Since 2013, the rates of congenital syphilis have more than doubled, and these rates appear to be increasing. From 2016 to 2017 rates increased by 44%. In 2017 alone, over 900 cases of congenital syphilis were reported to the Centers for Disease Control and Prevention (CDC), the highest number of cases in more than 20 years.

Screening for HCV and congenital syphilis are essential components of prenatal care. This article will provide an overview of both mother-to child transmission of HCV and congenital syphilis to help people understand each condition and help make informed choices for the health of the mother and baby.

What is vertical transmission of hepatitis C?

JUST AS HIV and hepatitis B can be transmitted from mother to child during pregnancy, so too can HCV. However, unlike HIV and hepatitis B, HCV is not routinely screened for in pregnancy, so it is often missed. The American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD/IDSA) HCV Guidelines call for routine HCV screening for all pregnant women, ideally at the initial visit.

The rate of vertical transmission of HCV is approximately 5.8% among persons with HCV mono-infection, though some studies have found it as high as 15%. There do not appear to be any clear risk factors that increase the chance of transmission, though a higher HCV viral load and HIV/HCV co-infection do appear to play a role in higher rates of infection.

Hepatitis C's impact on pregnancy outcomes

PREGNANCY does not appear to make HCV worse, but there is some evidence that HCV can lead to some problems during pregnancy. Pregnant women with HCV have higher rates of preterm labor and delivery; their babies may be smaller and have lower birthweight, too. There is some debate over whether these effects are the result of HCV or other lifestyle issues, but these problems are found in women even when maternal age, tobacco, alcohol, and drug use are taken into account.

Preventing vertical transmission of HCV

ALTHOUGH there are safe and effective ways to prevent vertical transmission of HIV and HBV, there are no recommended interventions to reduce the risk of transmission of HCV from mother to child. Hepatitis C direct-acting antiviral (DAA) treatment cannot be used to prevent it. An elective cesarean section is not recommended, as it does not decrease the risk of transmission. It is recommended to avoid certain medical procedures such as fetal scalp monitoring during labor, prolonged rupture of membranes, and episiotomies. Avoiding the use of forceps during delivery is also recommended.

BOTH INFECTIOUS DISEASES ARE ON THE RISE IN THE U.S.,

but with proper screening and health education, we can help reverse this trend.

Pregnancy and hepatitis C treatment

DIRECT-ACTING antivirals (DAAs) are the current medications for the treatment and cure of HCV. While they are safe and effective to take overall, and there is reason to think that they can be safely taken during pregnancy just like HIV and HBV medications can, they have not been studied for safety for use during pregnancy, so as such they are not recommended at this time.

Ribavirin, a medication that was used more frequently with previous HCV treatment regimens but is rarely used today, cannot be safely taken during pregnancy. Ribavirin can cause serious birth defects or death.

There have been cases where women on HCV treatment became pregnant, or pregnant women were accidentally treated with DAAs, and in these few cases the women have been cured with no negative outcomes for the pregnancy associated with the treatment. This offers hope for treatment options, but more study is needed before recommendations can be made.

Hepatitis C and breastfeeding

BREASTFEEDING IS SAFE to do for mothers living with HCV, as it is not a risk for transmission of the virus. That said, as HCV is transmitted from blood-to-blood contact, mothers who breastfeed should monitor their nipples for bleeding and should not breastfeed if they are cracked and bleeding.

Just as it is not recommended that pregnant women be treated for HCV, it is not recommended that women who breastfeed be treated with DAAs.

What is congenital syphilis?

ALSO CALLED perinatal syphilis, congenital syphilis occurs when a mother who has syphilis passes the infection on to her newborn. It is a very serious infection that can lead to a wide range of health problems for the baby. Congenital syphilis can lead to stillbirth (a baby born dead) or a miscarriage (losing the baby during pregnancy) in up to 40% of pregnancies. In addition, congenital syphilis can cause:

- Premature birth
- Low birth weight
- Deformed bones
- Anemia
- Brain and nervous system problems, including blindness or deafness
- Meningitis
- Enlarged liver and/or spleen

Not all babies born with congenital syphilis will show signs of infection, so testing for it and providing treatment are essential medical interventions to prevent serious problems for the baby.

Testing for syphilis

TESTING FOR SYPHILIS during pregnancy is routine: All women should be tested at their first prenatal visit. Depending upon risk factors and certain conditions, women may get tested more frequently. The CDC recommends that syphilis testing should also occur in the third trimester and again before getting discharged from the hospital. Both the mother and newborn infant should be evaluated for syphilis infection before release.

Treatment for syphilis

SYPHILIS IS TREATED with antibiotics. In pregnancy, only penicillin is recommended for the treatment of syphilis. If the woman is allergic to penicillin, she will need to be desensitized to it and then treated.

As syphilis is highly contagious between sexual partners, it is also important that all sex partners get evaluated, tested, and preventatively treated for syphilis.

The treatment for syphilis is safe for the unborn child, and indeed it is essential to minimize the risk of complications during pregnancy and to improve the long-term health of the baby.

After treatment is administered, both mother and child should be monitored and tested for at least one year to make sure that both have been cured.

Conclusions

ALTHOUGH vertical transmission of HCV cannot be prevented, universal screening should occur as it is a means of finding HCV in women, and it allows for the proper monitoring and follow-up of babies born to mothers with HCV. Congenital syphilis is preventable, and the timely testing and treatment will have a dramatic impact on the health outcome for the baby. Both infectious diseases are on the rise in the U.S., but with proper screening and health education, we can help reverse this trend, and improve the health of both mother and baby. PA

What is hepatitis C?

HEPATITIS C (HCV) is a viral infection of the liver. It is transmitted by blood-to-blood contact, and it can lead to long-term liver damage over time as it leads to more and more scarring, eventually resulting in cirrhosis. HCV can be an acute infection or chronic, and it is usually asymptomatic. When there are symptoms, they include fever, fatigue, nausea/vomiting, joint pain, or jaundice (yellowing of skin and eyes). HCV can be cured, with newer HCV treatments curing 90–100% of people with mild side effects in as little as 8–12 weeks. For more information about HCV, check out the POSITIVELY AWARE Hepatitis Drug Guide and our "FAQs of Hepatitis C" article at positivelyaware.com/articles/faqs-hepatitis-c.

What is syphilis?

SYPHILIS IS a sexually transmitted disease. It is passed when someone comes into contact with a syphilis sore during oral, vaginal, or anal sex. It has several stages—primary, secondary, latent, and tertiary—each with different symptoms. These symptoms include, but are not limited to, a painless sore, a rash (especially on the palms of hands and soles of feet), swollen lymph nodes, patchy hair loss, and fatigue. That said, it is easy to miss these symptoms, so the only way to know if you have it is to test for it. If it goes untreated, a person can live with it for years before serious health problems can arise. Fortunately, syphilis is relatively easy to treat with antibiotics such as penicillin. For more detailed information about syphilis, check out cdc.gov/std/syphilis/stdfact-syphilis.htm.

PrEP battles for the vagina

Research for cisgender women and adolescent girls is underway to help determine vaginal protection with Descovy for PrEP

BY **ENID VÁZQUEZ**

What's the deal with the Food and Drug Administration (FDA) approving Descovy as a new HIV prevention pill, except for "receptive vaginal sex"?

First of all, that's a nice way of acknowledging that some transmen still have a vagina. Or, as many prefer, "front hole" (sounds less feminine that way).

But it also says other things. For one, there is evidence that the way the drug affects the vagina might matter.

And for another, in the words of the FDA, that "Descovy is not indicated in individuals at risk of HIV infection from receptive vaginal sex because the effectiveness in this population has not been evaluated."

For now, there's a highly effective and safe HIV prevention drug already available that does cover vaginas—Truvada. Descovy for PrEP (pre-exposure prophylaxis, or prevention) was only studied in cisgender men who have sex with men (MSM) and transgender women.

To a great extent, the vaginal exclusion points to a problem across different medical conditions: research is being conducted mostly in cisgender men.

It also points to issues surrounding the extrapolation of research laboratory measures.

In the final analysis, everyone from the activist community to the FDA agrees that both medications now on the market for preventing HIV are effective (except for that one exclusion) and generally safe.

Oh, and research for cisgender women and adolescent girls is underway to help determine vaginal protection with Descovy.

"It is not new that cisgender women are greatly overlooked when it comes to HIV prevention research, and frankly, for most sexual and reproductive justice matters," said Dázon Dixon Diallo, founder and CEO of SisterLove, in Atlanta, in a press release about the agency's 30th anniversary gala in October. "We look forward to working with Gilead [maker of Truvada and Descovy] to conduct these trials in important locales, and in accordance with the needs and desires of populations of cisgender women in all our diversities."

At press time, SisterLove was set to convene a meeting in early December at the International Conference on AIDS and STIs in Africa (ICASA 2019) in Kigali,

LORADO-ISTOCKPHOTO

Two PrEP studies of cisgender women found much lower levels of tenofovir in their vaginal tissue compared to the levels (concentrations) in their rectal tissue.

Rwanda, to provide the company with a set of recommendations and expectations going forward.

The test tube vs. the body

Monica Gandhi, MD, MPH, told parts of the story behind Truvada and Descovy for prevention in a webinar held by community advocates in October just a couple of weeks after Descovy received FDA approval for PrEP. Dr. Gandhi is director of the Center for AIDS Research as well as the Ward 86 HIV Clinic, both part of the University of California, San Francisco.

She pointed out how measurements of drug levels in the body taken during a study may indicate something that turns out not to be the case in real life.

Although Descovy is a newer version of Truvada, they operate differently. Both drugs started out as HIV treatment before being studied and approved for HIV PrEP.

One of the differences between Descovy and Truvada is drug levels in the body. This is because the tenofovir in each drug works and is absorbed differently. Descovy contains tenofovir alafenamide (TAF), and Truvada contains tenofovir disoproxil fumarate (TDF); both contain a second drug, emtricitabine (FTC).

So, how about genital levels? For prevention of a sexually transmitted infection like HIV, researchers wanted to see how a medication works in what they clinically call "genital compartments."

Two PrEP studies of cisgender women found much lower levels of tenofovir in their vaginal tissue compared to the levels (concentrations) in their rectal tissue. This suggested that PrEP might not be as effective for vaginal sex. That, plus actual disappointing results indicating ineffectiveness, led to a concern about PrEP for this "compartment."

One idea arising from the different studies of Truvada and Descovy was that maybe men only need to take PrEP four times a week, while women need perfect adherence, taking a PrEP pill every day.

But then, at the International AIDS Conference in Mexico City last July, two demonstration studies of cisgender women reported effectiveness in the real world without perfect adherence, said Dr. Gandhi.

How did that good news happen?

Pharmacokinetics vs. pharmacodynamics (or, the test tube vs. the body)

The contradiction started with two studies that looked at Truvada PrEP for cisgender women, FEM-PrEP and VOICE, Dr. Gandhi said.

Unlike other PrEP studies that also had thousands of participants but which found Truvada was effective in preventing HIV in cisgender women (Partners PrEP, TDF2, and the Bangkok FTV Study), FEM-PrEP and VOICE were stopped because they weren't going to be able to show a high level of protection against HIV.

"It was surprising when FEM-PrEP and VOICE closed early," said Dr. Gandhi.

To help figure out what went wrong, the studies compared self-reports of drug adherence to actual blood levels of the drug, which would suggest just how adherent participants actually were.

The women reported high levels of adherence, saying they took more than 90% of their Truvada doses. The drug levels in their blood samples, however, were low, indicating that adherence was actually less than 30%.

Then it was found that the tenofovir (TFV) levels from Truvada were 30 times higher in rectal tissue of the cisgender women compared to the levels found in their vaginal tissue.

There was an even greater difference in the level of tenofovir diphosphate (TFV-DP), the active metabolite of tenofovir. Let's just say that an interesting thing about TFV-DP is that it indicates the level of drug adherence over several weeks. You can't just pop a pill before going in to get blood drawn to show that you've been taking your meds.

So, for TFV-DP (drumroll, please): the level in the rectal tissue was 120 times higher than in the vaginal tissue.

Researchers then arrived at a logical question. They already knew that cisgender men were being protected against HIV by taking Truvada only four days a week. (The FDA-approved PrEP dose is one pill a day.) Given the discrepancy in genital tissue and the disappointing lack of protection in FEM-PrEP and VOICE, might cisgender women need better drug adherence to PrEP to achieve prevention against HIV?

Maybe not. The two PrEP demonstration studies in cisgender women reported in Mexico City (HPTN 082 and the 3P study) found high levels of HIV prevention with—surprise—drug levels indicating four Truvada doses a week.

This continued a question raised by PrEP research over the years—how much do genital drug levels matter? The answer remains uncertain.

The doctor explains

It's a case of findings in the lab (pharmacokinetics) vs. findings in real bodies (pharmacodynamics), Dr. Gandhi said.

"It was a combination of those surprising findings of FEM-PrEP and VOICE and the pharmacokinetic data that led to a relatively long period of time where we have the dogma that women had to take higher frequency of TDF/FTC [Truvada] doses than men," said Dr. Gandhi. "And so, that idea that there were lower levels of tenofovir in the cervical/vaginal tract compared to the rectal tract led to a modeling study that said probably women need higher doses, and higher number of doses, of TDF/FTC than men do for the same amount of efficacy. And modeling in the iPrEX OLE study showed, for men at least, that probably four doses a week was okay for PrEP efficacy. And the relative dogma was that women needed seven doses per week for efficacy—full daily adherence—for this to work."

Instead, "It's when you study a drug in trials or in real life or in demonstration projects—that's when you get closer to the truth than some of our [mathematical] models.

"There was very high PrEP uptake in HPTN 082 and, very importantly, very low incidence of HIV despite the fact that women were taking around four doses a week. At three, six, and 12 months, there are low levels of tenofovir diphosphate [as measured] in dried blood spots, but

Kidney and **bone safety**

THE SIDE EFFECTS of most concern with tenofovir have been the potential for bone and kidney toxicities. (That's in addition to the potential for a hepatitis B reactivation upon stopping medication—it's important to know your hep B status before starting.)

The DISCOVER study that brought Descovy to market for PrEP showed an increased eGFR (a marker for, or sign of, kidney dysfunction) for Descovy compared to a decreased eGFR for Truvada. The lower the eGFR, the worse the kidney functioning is.

At one year, the median change in eGFR was an increase of 1.8 mL/min for people on Descovy and a decrease of 2.3 for those on Truvada (a 4.1 mL/min difference).

The long-term clinical significance of changes in eGFR, however, is not known.

There was a greater difference for people who started the study with Truvada but switched to Descovy when they were allowed to in the trial (after one year in the study). The increase was 3.9 for those who switched to Descovy vs. a decrease of 0.6 for those staying on Truvada (a 4.1 mL/min difference).

There was also a difference between the two PrEP drugs in terms of bone mineral density (BMD). From baseline to one year, there was an increase of 0.5% in lumbar spine measurement for Descovy vs. a 1.1% decrease for Truvada. There was an increase of 0.2% in hip BMD with Descovy vs. a 1.0 decrease for Truvada.

Again, the long-term clinical significance is unknown.

"It's not a claim that something was safer, but there was significantly less impact on BMD. This is what we saw," said Calita Mathole, the senior community liaison in the Chicago area for Gilead Sciences, the maker of both drugs, in a presentation for the staff of TPAN, publisher of POSITIVELY AWARE. "I wouldn't say safer on kidneys," she added.

The Gilead slides do note, however, that individuals under 25 years of age are still experiencing bone growth. Meaning, you wouldn't want to risk harming that growth.

The medical take

FOR HIV TREATMENT, Descovy is approved for people with greater kidney dysfunction (CrCl less than 30) compared to Truvada (CrCl less than 50). In fact, Descovy recently received an indication from the U.S. Food and Drug Administration (FDA) for use in dialysis patients with a CrCL under 15.

Gilead has to exercise caution in not overplaying a safety card for Descovy. That's been a bone of contention for activists, some of whom have heard evidence to the contrary.

For medical providers, however, the differences are important to weigh for their patients.

"TAF [in Descovy] is considered safer than TDF [in Truvada] for renal and bone safety," said Eric Farmer, PharmD, HIV clinical pharmacist at the Indiana University Health LifeCare Clinic at Methodist Hospital in Indianapolis. "The net safety difference depends on the patient. If you have a 16-year-old male whose bones are still developing, then perhaps it is better to go with TAF vs. TDF so you don't have any inhibitory effect on bone growth. If you have a 60-year-old male who has fallen and broken a hip before, TAF is likely safer again because of the lack of effect on bone.

"If a 50-year-old man with diabetes has an eGFR of 50 mL/min and you put him on Truvada and decrease his eGFR to 40 mL/min, this is clinically significant because you decreased the eGFR by 20%," he said. "Versus if you put a 25-year-old patient with an eGFR of more than 120 mL/min on Truvada and it decreases the eGFR by 10 mL/min to 110 mL/min, the percent change is much smaller—8%—and much less clinically significant.

"My professional opinion is there is indeed a safety difference that is demonstrated in clinical studies between TAF and TDF, but that difference may not be large enough or clinically significant enough to justify using TAF in every single patient," said Dr. Farmer. "Some patients can use TDF safely."

—ENID VAZQUEZ

Blood levels and vaginal tissue concentrations are just two of the many differences that surround Truvada vs. Descovy for PrEP.

importantly, there were very few seroconverters," she said.

"The same finding occurred in the 3P study ... high-risk young population with STIs and partners suspected of having other partners. And again, the PrEP adherence as assessed by tenofovir diphosphate concentrations in dried blood spots was not seven doses a week. It was more like four doses a week. And importantly, there were no HIV seroconversions here as well," she said. "And I'm building this argument because, again, the studies were not done with TAF/FTC [Descovy], but maybe we need the host [human] studies before we extrapolate from pharmacokinetic data." There was one seroconversion in 3P.

"Any extrapolation that we want to make for women or men from the pharmacokinetics for TAF and FTC vs. TDF/FTC may not tell us what eventually happens in the real world with men and women, just like those two demonstration projects told us different things from the pharmacokinetics and what happened in demonstration projects," said Dr. Gandhi. "And it is important to say that women are still underrepresented in clinical trials."

Summary

There are many ways to compare PrEP using either Truvada or Descovy. Like cost issues, side effects, and pharmacological workings (fentamoles, anyone?).

Blood levels and vaginal tissue concentrations are just two of the many differences that surround Truvada vs. Descovy for PrEP. Descovy is now being put to the test for vaginal protection against HIV—in real bodies. In the meantime, there's protection with Truvada.

And hey, Truvada may avoid the weight gain suspected of HIV treatment containing Descovy.

But that's another story out of the many involved.

"What we have shown is that women can be enrolled in clinical trials," said Dawn Averitt, founder of The Well Project, an organization focusing on women and HIV. PA

DR. GANDHI WALKS YOU THROUGH her slides in the recorded webinar from AVAC, the Treatment Action Group (TAG), The Well Project, and the Women's Research Initiative (WRI) at avac.org/event/webinar-advocates-debrief-science-daily-ftaf-vs-tdfftc-prep. **READ** the FDA briefing document of August 7, 2019 that includes a discussion of tenofovir levels throughout the body at fda.gov/media/129607. **READ** a comprehensive and powerful essay on PrEP research, "Where were the Women? Gender Parity in Clinical Trials" by Robert H. Goldstein, MD, PhD, and Rochelle P. Walensky, MD, MPH, published online October 30 in the *New England Journal of Medicine*: nejm.org/doi/full/10.1056/NEJMp1913547.

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FOCUSING ON THE TARGET

Viral hepatitis treatment access, elimination, and patient and provider advocacy

BY **ANDREW REYNOLDS**

This article will provide a brief overview of two selected presentations—one for HCV and another for HBV—from an affiliate event organized by the National Viral Hepatitis Roundtable: "Viral Hepatitis Elimination and Advocacy in the U.S." held November 12, 2019.

Viral hepatitis—hepatitis B and C—is a leading cause of suffering and death worldwide. It is estimated that as many as 325 million people—or four percent of the world's population—lives with viral hepatitis, leading to over 1.34 million deaths a year. In the United States, where at least 2.4 million people live with HCV, deaths from this disease exceed deaths of the next 59 infectious diseases combined. The suffering, death, and resulting social and economic burden caused by viral hepatitis is the backdrop from which the World Health Organization (WHO) called on all member nations to eliminate HBV and HCV by the year 2030. Hepatitis C elimination is defined as reaching a 90% reduction in new infections, a 65% reduction in liver-related deaths, and 90% of HCV diagnosed with 80% of people treated and cured.

The U.S. is not on target to reach this 2030 goal; one analysis showed that the U.S. would not achieve it until well after the year 2050, if at all.

At the 2019 Liver Meeting, held in Boston last November, the National Viral Hepatitis Roundtable (NVHR) brought together a group of patients, advocates, and physicians to discuss the prospects and needs to achieve HCV elimination in the U.S. There is a long way to go, but as Lauren Canary, Director of NVHR stated: "We have the tools to eliminate viral hepatitis in the U.S., but we need the willpower. My hope with this session was to call attention to the many opportunities providers have to partner with their patients and drive elimination, whether by advocating for expanded treatment access, informing the public health response, or appealing to their elected officials for increased viral hepatitis funding."

No elimination with treatment restrictions

Robert Greenwald, a clinical professor at Harvard Law School and Faculty Director of the Center for Health Law and Policy Innovation (CHLPI), delivered a presentation called "The Path Towards HCV Elimination: Addressing Discriminatory Barriers to HCV Treatment," where he provided an overview of HCV treatment access restrictions imposed by both public and private insurance providers.

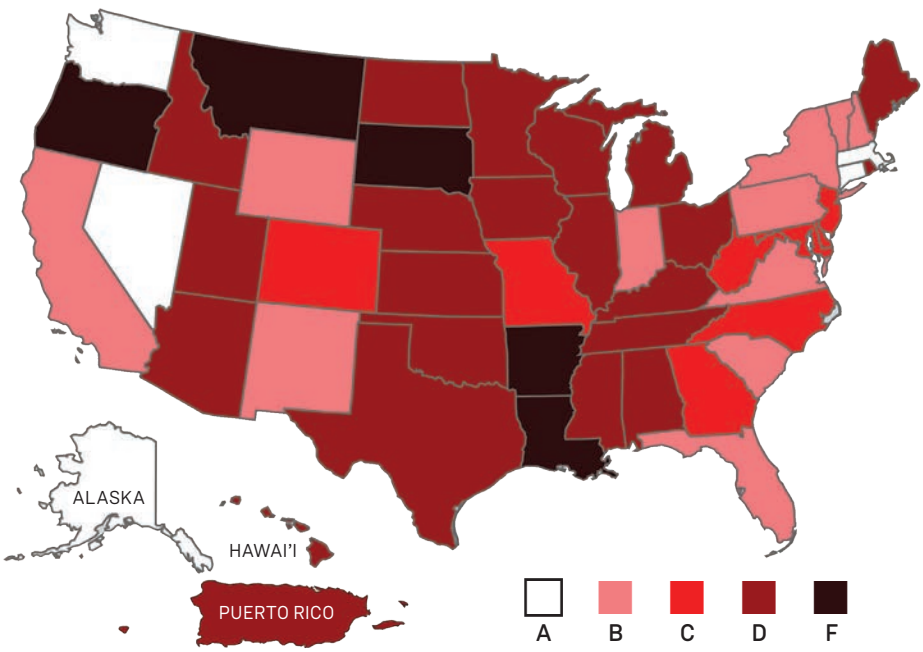
With the development and FDA approval of new medications called direct-acting antivirals (DAAs) for the treatment and cure of HCV came much excitement for the prospect of improved health for people living with HCV. The excitement was tempered by what Greenwald calls "unprecedented restrictions" on access to DAAs.

Many public and private insurance payors limited access to treatment based on disease severity, sobriety, and prescriber specialty. To raise awareness and help consolidate advocacy efforts, CHLPI partnered with NVHR to produce a document entitled "Hepatitis C: The State of Medicaid Access" (StateofHepC.org) that breaks down access and restrictions on a state-by-state basis (including Washington, D.C. and Puerto Rico) and gives each state a grade of A through F.

In 2015, the Centers for Medicare and Medicaid Services (CMS) issued guidance on HCV DAAs calling on all states to cover all medications with no restrictions. Still, many of these states ignored the guidance, so lawsuits or the threat of lawsuits, were used to lift barriers and increase access. States such as Washington, Colorado, and Michigan reached settlements during litigation, while many more states made changes before any lawsuits were needed. Similarly, there has been much prison litigation to improve access to HCV treatment and cure for people who are incarcerated.

There has been much progress and success for reducing HCV treatment

STATE OF MEDICAID ACCESS



GRADES ARE BASED UPON MEDICAID PROGRAMS' CURATIVE HEPATITIS C TREATMENT RESTRICTIONS RELATED TO THREE AREAS: 1) LIVER DISEASE PROGRESSION (FIBROSIS), 2) SOBRIETY/SUBSTANCE USE REQUIREMENTS, AND 3) PRESCRIBER LIMITATIONS. GRADES IN THIS MAP DO NOT REFLECT THE PLUSES OR MINUSES GIVEN TO SOME STATES IN THE FULL REPORT.

access restrictions, but there is more work to do. Many states still have treatment restrictions that prevent access to HCV cures, and without access to the cure, HCV elimination cannot be achieved. There is optimism that we will get there, as Greenwald states: "The law is clear, and we will continue with advocacy and litigation campaigns until all discriminatory HCV treatment access restrictions are eliminated."

Hepatitis B elimination

Su Wang, Medical Director for the Center for Asian Health and Viral Hepatitis Programs at Saint Barnabas Medical Center, provided a roadmap to guide the U.S. towards HBV elimination.

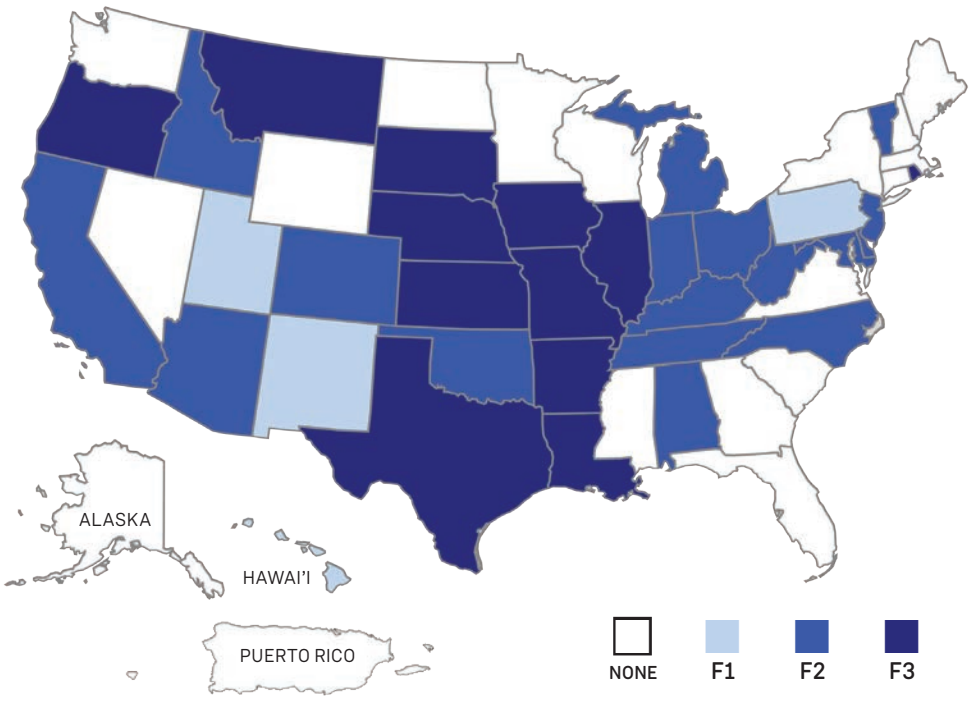
With over 257 million people living with HBV and no cure on the horizon, achieving elimination is daunting. That said, with a safe and effective vaccine to prevent new infections, and medications that can treat HBV and slow down liver disease progression, achieving elimination is not impossible.

As Wang states, however, we can't get there without first getting adequate funding and resources devoted to HBV. HIV and HCV receive over 66 times and twice the funding that HBV receives, respectively.

In addition to increases in funding, there is a need for improved screening and prevention programs. Vertical transmission of HBV is a problem worldwide, and in the U.S., there are 800–1,000 babies born with HBV each year. Preventing perinatal transmission through improved HBV birth dose vaccinations should be prioritized. Innovative models of HBV screening, such as automated screening in the ER combined with linkage to care using HBV "patient navigators" will improve health outcomes for people living with HBV and HCV. With improved awareness, vaccinations and prevention, elimination of HBV can get within reach.

THE CLOCK IS TICKING and 2030 is not that far off. The U.S. has far to go to get there, but with policy and practice changes, the goal of viral hepatitis elimination can be achieved. With leadership from advocates like the National Viral Hepatitis Roundtable and the Center for Health Law and Policy Innovation, as well as the collective actions from medical providers and patients alike, the U.S. will get there. PA

LIVER DAMAGE RESTRICTIONS



MAPS: STATEOFHEPC.ORG

A RISING TIDE LIFTS ALL BOATS

Some hep B targets for elimination planning

A HIGHLIGHT of the entire session was a single slide from Dr. Su Wang that set targets and goals for HBV elimination. To get there, we need to:

- **Prevent perinatal transmission:** Increase the HBV birth dose vaccine rates across hospitals
- **Integrate HBV and HCV testing:** People at risk for HCV are also at risk for HBV, so we should Include HBV testing with HCV testing in at-risk groups and integrate linkage to care for both infections
- **Work with health department on surveillance:** There are gaps in our knowledge of HBV epidemiology due to acute vs. chronic case reporting definitions
- **Align efforts with those that reach at-risk communities:** There is a need to partner with community-based organizations that work with immigrant communities across diseases like HIV and TB, as well as with cancer prevention and others who work in health equity and minority health
- **Increase HBV vaccination for adults:** And don't forget hepatitis A, as outbreaks of this disease are occurring throughout the country

As HCV advocates fight for better services and increased funding for elimination, they would do well to include and align their efforts to include HBV, too.

WANT TO GET INVOLVED?

If you're interested in becoming more involved in viral hepatitis advocacy, you can join the NVHR "Voices4Hep" Advocacy Network at voices4hep.org. This group will connect you to other advocates, keep you up to date on funding and policy news and actions and access resources to strengthen your impact.

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How has living with HIV affected YOUR DESIRE TO HAVE A FAMILY?

That was the question we put to our followers on Facebook, Instagram, and Twitter, and they shared their feelings and experiences.

"After having been diagnosed with PCOS [polycystic ovary syndrome] at a young age I was told it would be hard to conceive. So most of my life I went on thinking how hard it would be to have children. After being diagnosed with HIV at age 26, still no children, I figured any glimmer of hope was now out the window. Even my family not knowing the facts didn't think it was wise for me to try to have children. I've told myself I didn't want kids because it was easier with everything that seemed to be against me but deep down and knowing the little chance of passing HIV to my child I say why not! I know the love and wisdom I can pass on, so I absolutely welcome the possibility of one day being called mom!"

MARISSA GONZALEZ
FORT MYERS, FLORIDA

"I've said for years that when I was born, I skipped the 'fathering' gene. I have never once in my life, not even for a nano-second, wanted to have a child. And I'm glad I missed that gene—it's been difficult enough just to take care of myself, let alone taking full responsibility for raising another human being for at least 18 years. My having HIV has only intensified my aversion to having a 'family.'"

HANK TROUT
SAN FRANCISCO, CALIFORNIA

"I was married and had an 18-month-old son when I was exposed to HIV. Four and a half months later, I was given my HIV diagnosis in 1994. I opted to start meds right away to keep my immune system healthy as long as possible. My husband and I gave up the idea of having another child. Taking protease inhibitors meant an increase in blood pressure and type 2 diabetes, further making a second child seem an impossible dream. In 2000, I found myself pregnant and made an appointment with my HIV doc to decide whether to terminate the pregnancy, as my husband insisted. My doc said at age 34 I had a higher percent chance of a baby with Down syndrome than HIV, since I had been virally suppressed for so long. Happy to say she is 19 and HIV-negative."

XIO MORA-LOPEZ
WEST NEW YORK, NEW JERSEY

"I acquired HIV after having my last born in 2000. Currently, I am an HIV/AIDS counselor based in Kenya for the past 20 years. In my interaction with HIV-positive patients, many don't want to give birth as they believe the kids may die immediately. And some are always depressed in such a way they don't want to hook up. But since then my wife and I went for counseling therapy and we have been living together happily. I even quit my job to become a permanent professional HIV counselor in my area."

JOHN MRIMA TSUMA

"Having HIV absolutely affected my decision to have a family. It doesn't matter if you are defined or labeled as gay or straight or other. A family is a precious thing as long as there is compassion, love, and understanding. I decided not to have a family as I was diagnosed early on, and adoption for me was not possible. Now in my fifties, I see positive people thriving as good parents, and I'm proud of them."

KATHLEEN HARTMAN

"This is a very timely question, as my partner and I are about to complete our classes to become certified foster parents. Very early on in my relationship with my partner, we discussed what our long-term goals were, including having children. And, fortunately, we both shared the same goal of one day growing our family.

Our goal to become certified foster parents is to eventually adopt. And my HIV was not an obstacle when we decided to pursue this goal. Instead, as a person who has been living with HIV for over a decade, I believe I am better equipped at loving, accepting, and supporting a child who may also suffer from a stigmatized illness.

Lastly, at the beginning of our relationship, I decided to disclose my HIV status to my partner. We made it a goal since to get routinely checked and make sure we both stay healthy. And to this day, I still maintain my undetectable status and he is still HIV-negative. As a result, this has allowed us to have peace of mind to plan ahead and go after big goals; in this case, adopt!"

JOSUÉ E. HERNÁNDEZ
ORANGE COUNTY, CALIFORNIA

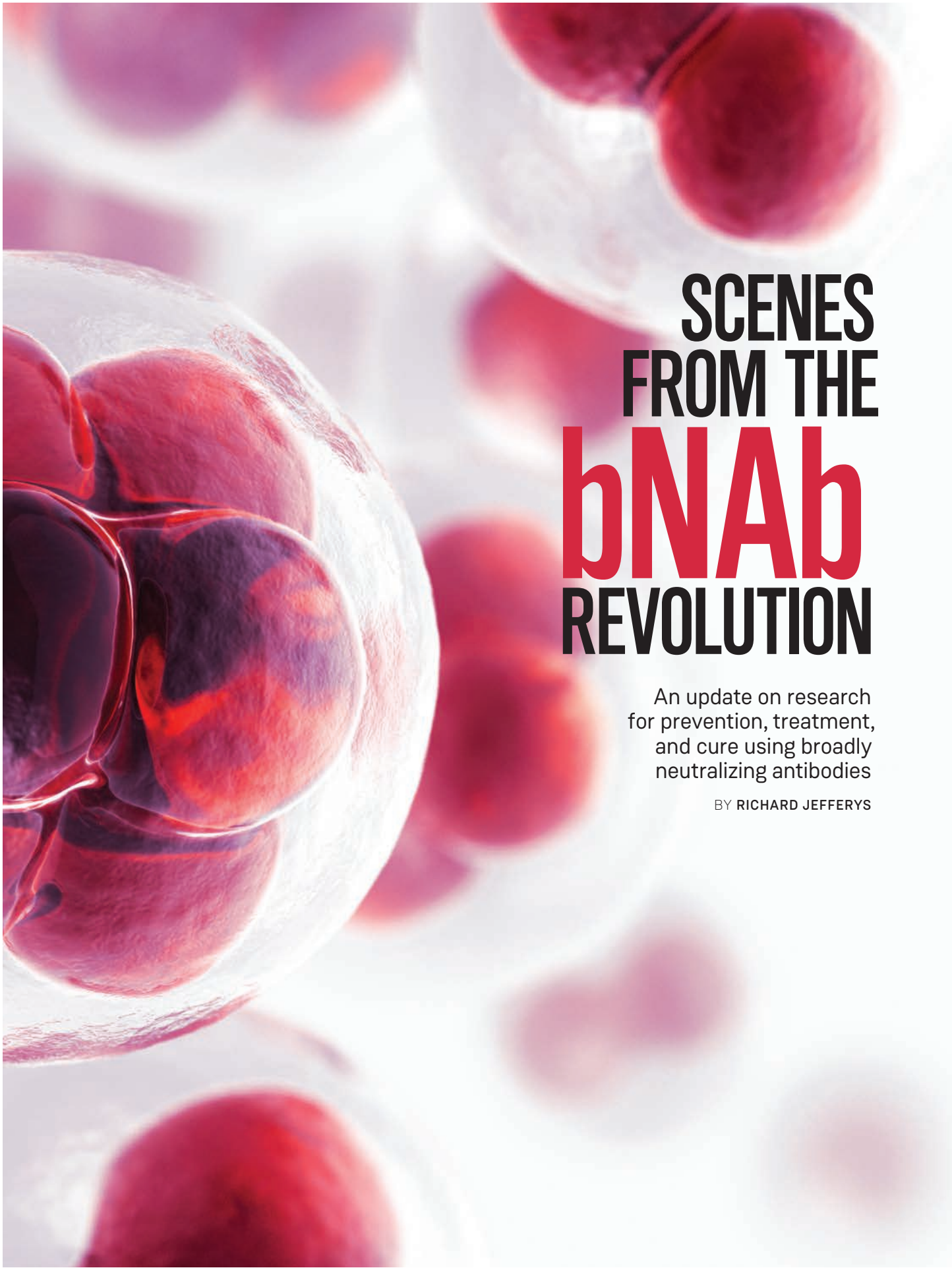
"As a gay man in my 20s, I was approached by my lesbian friends to father a child, but after I tested positive back in 1994, I didn't want to transmit the virus to a child or a female for that matter, so I just learned to cope with the idea that I wouldn't father any kids, and I bought pet fishes and birds as my companion. But I'm approaching 50, and kids aren't on my radar, especially in these trying times."

JACK R. MILLER
NEW YORK, NEW YORK

"It has affected me very much. I was diagnosed in 1984, and prospects for the future were not good. So I decided to not take the risk, fearful of transmitting the virus to the father or to a baby. Today, I see many beautiful families of people living with HIV. I adore seeing this, and wish I had done it. Well, that's life."

ARLETTE CANALES
GRAUBUNDEN, SWITZERLAND

SABEL SKAYA/ISTOCKPHOTO



SCENES FROM THE bNAb REVOLUTION

An update on research for prevention, treatment, and cure using broadly neutralizing antibodies

BY **RICHARD JEFFERYS**

Up until a decade ago, only a few antibodies had been identified as capable of significantly inhibiting HIV, and their activity was limited compared to antiretroviral drugs.

Antibodies are one of the more familiar components of the immune system, known for playing an important role in the body's fight against many infections. HIV, like a number of other pathogens, has evolved mechanisms to fend off antibody attacks. In particular, HIV cloaks itself in a protective cloud of sugar molecules called glycans, which serves as a shield against antibody-mediated neutralization.

In most people with HIV, the immune system generates many antibodies against the virus—they are used as the basis for the HIV antibody test—but they are ineffective in blocking viral replication.

Over time, however, this area of research has been transformed by new technologies that greatly enhance the ability of scientists to discover and characterize rare antibodies with strong anti-HIV effects (**SEE BOX:** bNAb Discovery).

The upshot is that at the start of 2020, we have an ever-expanding family of antibodies capable of potently neutralizing a broad array of diverse HIV strains from around the world. They have been named broadly neutralizing antibodies (bNAbs). bNAbs are now being tested for HIV prevention, treatment, and even cure.

The current landscape of bNAb research

AN ANTIBODY is a Y-shaped protein generated by B cells (a type of white blood cell that is part of the immune system). Their primary job is to bind to infectious agents, thereby neutralizing them and facilitating their elimination from the body. In some cases, antibodies also have the capacity to attach to cells infected with viruses or other pathogens, flagging the cell for destruction.

As the research progresses, bNAbs of increasing potency and breadth are being discovered. Potency refers to the amount of the antibody needed to inhibit HIV—the lower the amount of antibody required, the higher the potency. Breadth refers to how many different HIV variants can be inhibited. The virus is notorious for its ability to mutate and there are multiple different regional HIV subtypes (also called clades).

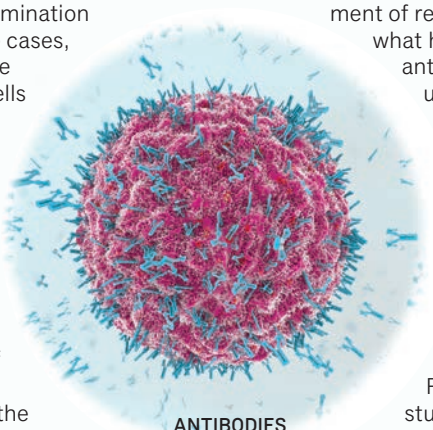
There are currently several threads to bNAb-related research in HIV (**SEE ALSO** trial tables on following pages):

- The discovery, development and manufacture of bNAbs for delivery into the body, either singly or in combinations. This approach is being used to evaluate the ability of bNAbs to prevent, treat, or contribute to curing HIV when delivered via infusion, subcutaneous injection, or gene-based delivery systems.

- The development of preventive HIV vaccine candidates that aim to induce the production of bNAbs by the vaccine recipient's B cells. This effort is at an early stage and is being guided by research into how bNAbs are generated by the immune system, as well as structural studies assessing how bNAbs interact with the parts of HIV that they target.

In experiments involving macaque monkeys and simian equivalents of HIV—either simian immunodeficiency virus (SIV) or SIV/HIV hybrids called SHIVs—bNAbs have demonstrated both protection against infection and an ability to significantly lower viral load.

The main Achilles heel is the development of resistance, similar to what has been seen with antiretrovirals when used alone. The future of bNAbs is therefore likely to involve combinations, particularly for therapeutic use.



ANTIBODIES ATTACKING A VIRUS

The largest ongoing human bNAb trials are the Antibody-Mediated Prevention (AMP) studies, which are evaluating whether bimonthly infusions of VRC01—one of the first bNAbs to be discovered—can prevent HIV acquisition in people at high risk of exposure. At the current time, individual bNAbs are mostly still known by the codenames assigned by their discoverers, making for a pipeline populated by candidates such as VRC01, 3BNC117, 10-1074, PGDM1400, N6 and PGT121. The shared feature of these bNAbs is that they are able to target sites of vulnerability on HIV's outer envelope.

The AMP research is jointly sponsored by the HIV Vaccine Trials Network (HVTN) and the HIV Prevention Trials Network (HPTN), and the aim is to demonstrate "proof of concept" that bNAbs can offer significant protection against HIV.

The AMP studies comprise:

- **HVTN 704/HPTN 085**, which includes men and transgender individuals who have sex with men at sites in Brazil, Peru, Switzerland and the United States.

- **HVTN 703/HPTN 081**, which has recruited sexually active women at sites in Botswana, Kenya, Malawi, Mozambique, South Africa, Tanzania and Zimbabwe.

On June 21, 2019, HVTN announced that both trials had fully enrolled, with a total of 4,625 participants.

Even if efficacy is observed in the AMP studies, VRC01 probably won't be advanced toward licensing for prescription because bNAbs with greater potency and breadth have since been discovered, and longer-acting formulations that offer less frequent dosing are also in the works (antibody names with "LS" added have been structurally modified to enhance their persistence

bNAb Discovery

THE TECHNOLOGIES that have facilitated the discovery of bNAbs allow researchers to sample huge numbers of B cells from an individual, and then analyze the anti-HIV effects of the antibodies being made by each individual B cell.

Sampling B cells from people with HIV has led to the discovery that some people generate rare antibodies with the capacity to strongly inhibit the virus. In most cases the antibodies are not of benefit to the sample donor, because they're present in only small amounts and are essentially overwhelmed by the virus.

Researchers can pinpoint the genetic code of the B cell that acts as a blueprint for producing the bNAb, and then use that code as a means to manufacture the antibody in large quantities.

in the body). The research aims to move the science forward by discovering how much bNAb needs to be present in the blood in order to achieve protection against HIV infection.

Several of these potentially improved bNAbs are in smaller, earlier phase trials both alone and in combinations. Delivery methods are typically either intravenous infusions or subcutaneous injections.

Researchers are also creating single antibodies capable of recognizing two or three different HIV targets, which are described as bi-specific or tri-specific—essentially a combination approach with one antibody. Both HIV-negative and HIV-positive individuals are being enrolled in studies due to the interest in exploring bNAbs in the preventive and therapeutic contexts.

Cure

FOR RESEARCHERS working on attempting to develop curative interventions, there is interest in the potential for bNAbs to trigger destruction of HIV-infected cells and/or enhance immune responses against the virus.

The main mechanism for promoting killing of infected cells is

bNAb HIV treatment and cure-related clinical trials

GO TO clinicaltrials.gov AND ENTER THE TRIAL REGISTRY NUMBER TO LEARN HOW TO TAKE PART IN THE STUDY

SHADED ENTRIES INDICATE INCLUSION OF AN ANALYTICAL TREATMENT INTERRUPTION (ATI).

SEE "BRIEFLY" ON PAGE 9 FOR AN UPDATE ON THE RISK OF HIV TRANSMISSION RELATED TO ATIs.

AGENT(S)	ADDITIONAL DESCRIPTION	TRIAL REGISTRY IDENTIFIER(S)
PGT121, VRC07-523LS, PGDM1400	Broadly neutralizing antibodies + long-acting broadly neutralizing antibody	NCT03721510
VRC01	Broadly neutralizing antibody in infants	NCT03208231
VRC01LS, 10-1074	Long-acting broadly neutralizing antibody + broadly neutralizing antibody in early-treated children	NCT03707977
10-1074-LS, 3BNC117-LS	Long-acting broadly neutralizing antibodies	NCT03554408
10E8.4/iMab	Bi-specific broadly neutralizing antibody	NCT03875209
3BNC117, 10-1074	Broadly neutralizing antibodies	NCT03571204
3BNC117, 10-1074	Broadly neutralizing antibodies	NCT03526848
3BNC117-LS	Long-acting broadly neutralizing antibody	NCT03254277
AAV8-VRC07	Broadly neutralizing antibody delivered by adeno-associated virus (AAV) vector	NCT03374202
Elipovimab (formerly GS-9722)	PGT121-derived broadly neutralizing antibody	Not listed in clinicaltrials.gov
PGDM1400, PGT121, VRC07-523LS	Broadly neutralizing antibodies	NCT03205917
SAR441236	Tri-specific broadly neutralizing antibody	NCT03705169
VRC01, 10-1074	Broadly neutralizing antibodies	NCT03831945
VRC01LS, VRC07-523LS	Long-acting broadly neutralizing antibody	NCT02840474 (closed to enrollment)
VRC01	Broadly neutralizing antibody in acute HIV infection	NCT02591420
Combinations including bNAbs		
ROADMAP: romidepsin, 3BNC117	HDAC inhibitor + broadly neutralizing antibody	NCT02850016 (closed to enrollment)
TITAN: lefitolimod, 3BNC117, 10-1074	TLR9 agonist + broadly neutralizing antibodies	NCT03837756
eCLEAR: romidepsin, 3BNC117	HDAC inhibitor + broadly neutralizing antibody	NCT03041012
iHIVARNA, MVA vector HIV vaccine, 10-1074, romidepsin, HIVACAR01	Therapeutic vaccines, broadly neutralizing antibody, HDAC inhibitor	NCT03619278 (not yet open for enrollment)
IMPAACT P1115 v2.0: Very early intensive treatment of HIV-infected infants to achieve HIV remission	ART +/- VRC01	NCT02140255
N-803, haNK, VRC07-523LS, PGT121	Recombinant human super agonist interleukin-15 complex, haploidentical natural killer cells, broadly neutralizing antibodies	NCT04144335 (not yet open for enrollment)
3BNC117, 10-1074, peginterferon alfa-2b	Antiretroviral therapy +/- broadly neutralizing antibody	NCT03588715 (not yet open for enrollment)
VRC07-523LS + vorinostat	Long-acting broadly neutralizing antibody + HDAC inhibitor	NCT03803605

ADAPTED FROM TREATMENT ACTION GROUP'S REGULARLY UPDATED RESEARCH TOWARD AN HIV CURE LISTING: treatmentactiongroup.org/cure/trials

antibody-mediated cellular cytotoxicity (ADCC). ADCC involves bNAbs binding to virus proteins displayed on the outside of a stricken cell and thereby attracting other immune system players such as natural killer cells to destroy the infected cell. Enhancement of immune responses against HIV could theoretically occur by bNAbs binding to HIV proteins and forming bundles called immune complexes, which can stimulate T cell immunity.

The enthusiasm for exploring these activities is reflected by the number of cure-related trials that are testing bNAbs or combinations of bNAbs with other interventions.

Several trials are attempting to target the reservoir of HIV that persists despite antiretroviral therapy (ART) by marrying bNAbs with strategies intended to awaken dormant or latent HIV, which would otherwise be invisible to the immune system. The hope is that these latency-reversing strategies will prompt virus-infected cells to reveal themselves by displaying HIV proteins on their surface, which can then be glommed onto by bNAbs, ultimately promoting destruction of the cell via ADCC.

MANUFACTURER/SPONSOR(S)	LOCATION(S)	PHASE
International AIDS Vaccine Initiative (IAVI)	USA	Phase 1/2a
NIAID	Botswana, Brazil, Malawi, South Africa, USA, Zimbabwe	Phase 1/2
NIAID	Botswana	Phase 1/2
Rockefeller University	USA	Phase 1
Aaron Diamond AIDS Research Center	USA	Phase 1
NIAID	USA	Phase 1
Rockefeller University	USA	Phase 1
Rockefeller University	USA	Phase 1
NIAID	USA	Phase 1
Gilead Sciences	USA	Phase 1
IAVI	USA	Phase 1
NIAID	USA	Phase 1
NIAID	USA	Phase 1
NIAID	USA	Phase 1
NIAID	Kenya, Tanzania, Thailand, Uganda	Phase 1
Rockefeller University	Denmark, Germany, USA	Phase 2a
University of Aarhus	Denmark, Australia, USA	Phase 2a
Aarhus University Hospital	Denmark	Phase 2
David Garcia Cinca	Spain	Phase 1/2a
IMPAACT	Argentina, Brazil, Haiti, Kenya, Malawi, South Africa, Tanzania, Thailand, Uganda, USA, Zambia, Zimbabwe	Phase 1/2
University of Minnesota	USA	Phase 1b
Wistar Institute	USA	Phase 1
University of North Carolina, Chapel Hill	USA	Phase 1

HIV treatment interruption

THE ABILITY of bNAbs to maintain HIV viral load suppression during an ART interruption is another area of study. In some cases, the aim is to enhance the ability of the immune system to control HIV, but researchers are also assessing if ongoing intermittent bNAb administration could serve as a less burdensome means of maintaining viral load suppression compared to daily pill taking.

So far single bNAbs have shown limited activity after ART interruption and the development of resistance has been common, but in a small study with nine participants the dual combination of 3BNC117 and 10-1074 maintained viral load suppression for as long as dosing was continued. There were no cases of resistance developing to both bNAbs. Two of the participants continued to display suppressed viral loads until the end of the study period, 24 weeks after the last dose of the bNAbs, perhaps hinting at some enhancement of immune responses against HIV—this possibility is now being explored in additional trials.

AAV-based bNAb delivery

ONE ONGOING TRIAL is assessing whether it might be possible to avoid intravenous or subcutaneous injection of bNAbs by using a delivery method drawn from gene therapy. The genetic code for the bNAb VRC07 is inserted into a harmless adeno-associated virus (AAV), which is administered by a single injection. The idea is for the AAV to persist in the body and act as a factory that produces a constant supply of the bNAb. A similar strategy has been used with some success to deliver factor IX to hemophiliacs. However, an initial study in HIV-negative volunteers sponsored by the International AIDS Vaccine Initiative (IAVI) found that the body generated antibodies against the bNAb encoded by the AAV, preventing the achievement of detectable bNAb levels—this problem will need to be overcome in order for the approach to be successful.

bNAb HIV prevention trials

GO TO clinicaltrials.gov AND ENTER THE TRIAL REGISTRY NUMBER TO LEARN HOW TO TAKE PART IN THE STUDY

AGENT(S)	ADDITIONAL DESCRIPTION	TRIAL REGISTRY IDENTIFIER(S)	MANUFACTURER/ SPONSOR(S)	PHASE
VRC01	Broadly neutralizing antibody administered intravenously	NCT02716675 (HVTN 704/HPTN 085) NCT02568215 (HVTN 703/HPTN 081)	NIAID/HVTN/HPTN	Phase 2b
PGT121, VRC07-523LS, PGDM1400	Broadly neutralizing antibodies administered intravenously	NCT03721510	IAVI	Phase 1/2a
3BNC117-LS-J, 10-1074-LS-J	Long-acting broadly neutralizing antibodies administered subcutaneously or intravenously	NCT04173819	IAVI	Phase 1/2
VRC01, VRC01LS, VRC07-523LS	Broadly neutralizing antibody administered subcutaneously to HIV-exposed infants	NCT02256631	NIAID	Phase 1
VRC07-523LS	Long-acting broadly neutralizing antibody administered intravenously	NCT03387150 NCT03735849	NIAID	Phase 1
3BNC117-LS	Long-acting broadly neutralizing antibody administered intravenously	NCT03254277	Rockefeller University	Phase 1
10-1074-LS, 3BNC117-LS	Long-acting broadly neutralizing antibodies administered subcutaneously or intravenously	NCT03554408	Rockefeller University	Phase 1
PGDM1400, PGT121	Broadly neutralizing antibodies administered intravenously	NCT03205917	IAVI	Phase 1
N6LS	Long-acting broadly neutralizing antibody administered subcutaneously or intravenously	NCT03538626	NIAID	Phase 1
PGT121, PGDM1400, 10-1074, VRC07-523LS	Broadly neutralizing antibodies + long-acting broadly neutralizing antibody administered intravenously	NCT03928821	NIAID	Phase 1
10E8.4/iMab	Bi-specific antibody administered subcutaneously or intravenously	NCT03875209	Aaron Diamond AIDS Research Center	Phase 1
VRC07-523LS, PGT121	Long-acting broadly neutralizing antibody + broadly neutralizing antibody administered subcutaneously	PACTR201808919297244 (CAPRISA 012A)	Centre for the AIDS Programme of Research in South Africa	Phase 1

ADAPTED FROM TREATMENT ACTION GROUP'S ANNUAL HIV VACCINES, PASSIVE IMMUNIZATION, AND ANTIBODY GENE TRANSFER PIPELINE REPORT: treatmentactiongroup.org/pipeline-report

Safety

NO SIGNIFICANT safety issues associated with bNAb administration have been documented to date among several thousand recipients, with one exception.

In a trial involving HIV-negative volunteers, subcutaneous delivery of the bNAb 10E8VLS prompted injection site reactions, including quite severe skin reddening and irritation (erythema), along with fever and malaise. Researchers suspect that the adverse events may be linked to the way this specific bNAb interacts with lipid molecules on the surface of cells, and this is being investigated (the trial has been suspended).

Production challenges

IN THE IDEAL scenario in which bNAbs are able to demonstrate sufficient efficacy to justify licensure—whether in the preventive or therapeutic realms—the next challenge will be to ensure that they are affordable and globally accessible.

Manufacturing antibodies is significantly more complex than the production of most pharmaceutical drugs. The process is expensive, involving the use of cell lines to churn out the antibodies in vast steel tank bioreactors. Estimates suggest production costs of around $100 per gram of bNAb, and this would need to be drastically reduced to around $3 per gram to ensure equitable access.

Efforts are underway to address the problem. IAVI is collaborating with the Serum Institute of India, an established vaccine manufacturer, to explore strategies for reducing production costs. In parallel, researchers are continuing to work on increasing the potency and persistence of bNAbs in order to reduce the amount that would need to be administered.

At least two large pharmaceutical companies are in the bNAb mix. Gilead Sciences licensed the rights to the bNAb PGT121 and are now testing a modified version, which has the distinction of being the first to be given a name: elipovimab (formerly GS-9722). More recently, ViiV Healthcare announced that they have acquired the rights to commercially develop the bNAb N6LS for HIV treatment and prevention.

The future for bNAbs

FOR A LONG TIME, it was thought that HIV might essentially be invulnerable to antibodies. The technological revolution of the last decade has overturned that pessimistic assumption, leading to the alphabetical and numerical soup of bNAbs now in clinical trials. Progress to date suggests that even more potent and broadly active bNAbs are likely to be on the horizon.

Until additional results become available, the role that bNAbs will play in the future of HIV prevention and treatment is uncertain. But there are reasons to be optimistic about their potential to add new, relatively user-friendly options to the current array of interventions. PA

RICHARD JEFFERYS began working in the field of HIV/AIDS in 1993 as a volunteer at the nonprofit AIDS Treatment Data Network in New York City. He joined Treatment Action Group (TAG) in 2001, and directs TAG's Basic Science, Vaccines, and Cure Project.

Long-acting and vaccine research moves forward

New options for prevention and treatment

BY **LIZ BARR**

ATAC (AIDS Treatment Activists Coalition) is a national coalition of AIDS activists—many of whom are living with HIV/AIDS. ATAC works to end the AIDS epidemic by advancing research on HIV.

Members of ATAC's Drug Development Committee (DDC) met in Philadelphia in May 2019 with representatives from the Janssen pharmaceutical company to discuss the firm's HIV research program and drug pipeline. Janssen is active in the areas of HIV vaccine research and creating antiretroviral treatments, including long-acting formulations. Here are some highlights of our conversation.

Long-acting formulations of antiretroviral treatments

IN AN EFFORT to provide more options for HIV treatment, improve adherence, and simplify regimens, Janssen is working with the HIV-focused drug company ViiV Healthcare to develop a long-acting regimen that may require only monthly or even less frequent dosing. At our meeting, we talked about preliminary market research Janssen has conducted concerning providers' and patients' attitudes to various forms of long-acting drugs, such as injections and/or implants, and found that long-acting options certainly have appeal. While not there yet with options in late-stage development, long-acting therapies that could be self-administered are attractive, and regardless, less frequent dosing could improve medication adherence over time. Not having to keep medications in the home could also alleviate anxiety around HIV-related stigma (less risk of someone seeing your pills in the bathroom).

ATAC members stressed that—as with contraceptive methods—the more options and choices available to the user, the better. While many people will prefer sticking with daily pills, many others may prefer using a long-acting method of treatment—and among those folks, some may prefer an implant to an injection and vice versa.

It will be important for Janssen and ViiV to maintain robust community and provider engagement as they continue to develop and market long-acting regimens. DDC members also stressed that price and ease of access will be key components of usability and user-friendliness of these new formulations. The ongoing research into long-acting treatments will reveal much about what works and what doesn't in providing these new options—and it will be crucial that Janssen and ViiV clearly communicate the lessons that are learned.

HIV preventive vaccine research

THE GOAL of Janssen's HIV vaccine program is development of a broadly acting, multi-clade vaccine for HIV-1 prevention. Janssen's vaccine program uses what's called a "mosaic vaccine"—meaning that the actual vaccine is made up of snippets from multiple clades of HIV-1 joined to a modified, non-replicating cold virus (adenovirus). Varying clades of HIV-1 are found in different geographic regions, so addressing multiple clades with a vaccine should help make it more universally effective.

Our discussions focused on the APPROACH, TRAVERSE, and Imbokodo trials. APPROACH and TRAVERSE were phase 1 and 2a studies intended to determine which vaccine formulation and regimen will move to a phase 2b, proof-of-concept study. In APPROACH, HIV-negative adults in the U.S., Rwanda, Uganda, South Africa, and Thailand were randomized to different mosaic-based vaccine regimens. That study identified one vaccine regimen that appeared to maintain an antibody response one year after the last vaccination. (Full results from APPROACH were presented at AIDS 2018). The TRAVERSE study compared a vaccine with a tetravalent mosaic vector (combining four adenovectors expressing HIV mosaic proteins) to one with a trivalent mosaic vector (combining three) in HIV-negative people in the U.S. and Rwanda. Early data from TRAVERSE (which were presented at the 2018 Research for Prevention Conference in Madrid) showed that not only was the tetravalent vaccine well tolerated, but it also appeared to enhance volunteers' immune responses more than the trivalent vaccine (**GO TO** bit.ly/MosaicStudyResults).

Based on the results from APPROACH and TRAVERSE, Janssen identified a vaccine candidate for the Imbokodo study (HVTN 705/HPX2008), which enrolled around 2,600 cisgender women in Southern Africa. During our meeting, ATAC members asked a number of questions about safety monitoring, plans for reservoir sampling from participants who acquire HIV, how endpoints were determined, and what happens to women who acquire HIV during the Imbokodo study (Answer: they are immediately linked to care). Janssen reiterated that all participants in their vaccine trials receive standard of care prevention methods and education.

We concluded our discussion of Janssen's vaccine research with Mosaico (HVTN 706/HPX3002), a phase 3 efficacy study for cisgender men, transgender individuals who have sex with cisgender men or transgender individuals, or transgender individuals who are at increased risk, which was planned to start before the end of 2019 and is now underway. ATAC raised questions about the study's design—for example, how is "high risk" defined, is a placebo arm necessary, and how will the study be implemented?

ATAC also reminded Janssen that outreach and engagement will be crucial if they want this product to have an impact for those who need it most, particularly black and Latinx people. In light of rising HIV incidence in older individuals, ATAC suggested Janssen reconsider the current upper age limit of 60 for this study. Janssen acknowledged this point, which could potentially be addressed in future studies. ATAC members stressed the importance of developing an HIV preventive vaccine for all populations, including cisgender women, and also urged Janssen to include women in sufficient numbers in trials so as to perform sex-disaggregated analyses. The Imbokodo study is evaluating the mosaic vaccine in this population.

ATAC members asked Janssen to remain in conversation with our group and other community stakeholders as Janssen conducts the Mosaico study and finalizes its plans for licensure.

New trials being considered for HIV treatment

WE CONCLUDED our meeting talking through other potential trials under consideration at Janssen. The bulk of this discussion was bound by nondisclosure agreements, however, we can report the company is considering a trial of re-engagement strategies that would benefit people who've had previous issues with adherence. Janssen is also considering the issue of weight gain, particularly for people taking integrase inhibitors. ATAC members provided input on key populations to include in studies of weight gain, and on the importance of distinguishing between integrase inhibitor-related weight gain and non-integrase inhibitor-related weight gain.

There were 13 ATAC members in attendance at this meeting as well as one from the EATG. For more information about the AIDS Treatment Activists Coalition, **GO TO** AIDStreatmentactivists.org.

LIZ BARR is a member of ATAC and former member of the AIDS Clinical Trials Group (ACTG) Community Scientific Subcommittee.

Q&A WITH **CELESTE WATKINS-HAYES**

Hope and Redemption

Research on women points to the importance of safety nets for everyone

STARTING IN 2005, Northwestern University professor Celeste Watkins-Hayes spent a decade documenting the lives of over 100 women living with HIV/AIDS in Chicago and beyond. Much of her work started at TPAN, the nonprofit HIV/AIDS service organization that publishes POSITIVELY AWARE. She finds something unexpected—not despair, but a story of the profound power of personal and political transformation, all of which she chronicles in her groundbreaking new book Remaking a Life: How Women Living with HIV/AIDS Confront Inequality (University of California Press; July 2019). Following is a brief Q&A with the author.

You interviewed over 100 women living with HIV/AIDS. When did you realize that this book would have a great sense of hope and redemption?

Sometimes the best research uncovers something surprising and unexpected. Talking with women living with HIV/AIDS for more than a decade, I heard many stories about trauma and struggle, perhaps not surprising given the devastation wrought by the epidemic and the dynamics that fuel it. But I also heard stories of transformation. Women in my research talked about following a trajectory that began with dying from HIV/AIDS and took them to living with and even thriving despite HIV. I became deeply curious as more and more women's stories followed this pattern.

My book does not downplay or romanticize the devastation of the epidemic or the other struggles women are facing. Rather, it's about how women take those circumstances and reinvent themselves. And in the process, they develop new tools and strategies to cope with and confront what I call the injuries of inequality. How do people gather the courage to stand up to forces that can destroy them, and how do they make radical changes in their lives in the process? How do people do this with limited resources or with a highly stigmatizing condition? Those are the questions that I explore in the book.

What I came to realize is that this experience applies not only to women living with HIV/AIDS but to individuals confronting a variety of challenges produced by the inequalities that operate in our lives.

Is there an individual woman you spoke with whose experience is most representative of the book's broader themes?

There are so many women with fascinating and diverse stories in the book that it's hard to point to one. I talked to women of significant economic resources who never imagined that their lives would take this turn and to women who have been economically and socially marginalized all of their lives who told me that the HIV diagnosis was not the worst thing that's ever happened to them. The women who probably intrigued me the most were those who had such radical life changes that it was as though they had two lives. I'm thinking of HIV/AIDS activist Gina Brown, who describes her history of childhood sexual trauma, drug addiction, and living on the streets of New Orleans. Gina is now one of the most inspiring and effective HIV/AIDS activists in the country. She is a community organizer, earned a masters degree in social work, and served on the President's Advisory Council on HIV/AIDS during the Obama administration. In the HIV/AIDS community, Gina and many others found an unexpected place to create their lives anew.

You discuss the difference between "dying from," "living with," and "thriving despite." Can you elaborate on the differences?

"Dying from" is a state of extreme distress. What I discovered is that the women I interviewed were dying not just from the health condition that is HIV/AIDS but also from the shame, stigma, and trauma. Many were also dying from addiction, early sexual abuse, untreated mental health issues, and economic and social conditions like homelessness and poverty.

"Living with" is a place whereby women are gathering the tools to live with HIV as a chronic illness rather than as a death sentence. It's about managing their health and addressing the psychological hurdles like shame and social isolation that can accompany an HIV diagnosis. But it is also about developing new strategies to navigate the economic and social inequality that may have put women more at risk for HIV acquisition in the first place. It's about finding stable housing, income, and social support so that there are fewer ongoing crises that can distract from taking care of one's health.

"Thriving despite" takes place when women take a leadership role in their communities, building strong families, and significantly improving their physical and mental health. It happens when they become politically and civically engaged, speak out about HIV and health care access, and educate those around them. "Thriving despite" is about turning those past hurts, struggles, and traumas into fuel to make change.

What can organizations like TPAN do to advance the struggle for equity and justice in the fight against HIV/AIDS?

People living with HIV have opportunities to teach to break down barriers, to confront stigma, and to help us end this epidemic.

The HIV movement has always focused on equity and justice, but there has been an ongoing tension within the movement around the question of "Equity and justice for whom?" The public face of the HIV movement was often that of white gay men, but we know that a much more diverse group of people were affected by HIV and involved in the fight in various ways. Many gay men of color and cisgender and transgender women were instrumental in the fight, even if their faces didn't always show up in media depictions of AIDS activism. But they were there, working within activist and advocacy organizations and putting their bodies on the line, working within the walls of mainstream institutions to provide services and shape policy, and working independently or in small collectives to shape the cultural understanding of the epidemic through artistic or political work.

What organizations like TPAN can do is to continue to be a space that convenes, centers, and puts institutional resources behind the people and the issues that are most negatively impacted by societal inequity and injustice. The HIV safety net is at its best when it provides four things to people living with HIV and communities most affected by the epidemic: access to health care, robust social support, tools to help people survive economically, and an on-ramp to political and civic engagement so that people can leverage what they know to help others and to shape policy. Those are social justice resources that TPAN can offer until we are able to make the structural changes necessary to get at the root causes of inequity and injustice: racism, sexism, homophobia, transphobia, and unchecked greed.

What role did activism and private charities play in providing a safety net for these women once they got sick? What do private charities do that government can't or fails to do?

The extraordinary conversion of HIV/AIDS from an inevitable death sentence to a manageable chronic illness in well-resourced countries like the United States is one of the most noteworthy medical achievements of the past 35 years, as well as a significant social achievement. This mobilization of activists brought about an extensive HIV/AIDS safety net offering four vital things: access to healthcare, modest economic assistance, extensive social support, and a path to political and civic engagement. The HIV safety net functions through a

A backstory of shame and struggle can become a testament to the ability that we all possess to remake our lives in the wake of life's traumas.

three-sector partnership (public, private, and nonprofit). Private charities can get to know communities on the ground and often have more flexibility to experiment with innovative programs. From small community-based organizations to large national and international entities, they are critical partners in HIV/AIDS work.

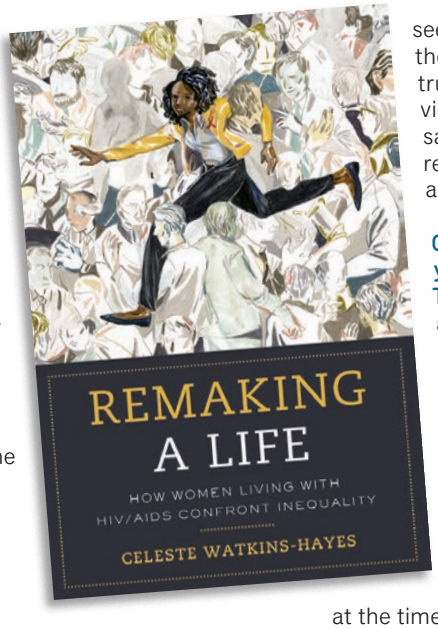
If you could give politicians one take-away from the book, what would it be?

If the policy goal of ending the HIV epidemic by 2030 is going to be reached, we must ensure that the HIV safety net is an integral part of the strategy. It is that safety net—the health care services, social support services, drug and alcohol rehabilitation services, and other assistance—that provides the crucial support system for people living with HIV to thrive. People will not utilize the very effective medications if they are derailed by stigma, mental health challenges, addiction, or economic instability. The solution to ending the epidemic is not just biomedical, it's also social.

We have ample evidence demonstrating that services funded by the Ryan White Care Act, the Housing Opportunities for People Living with HIV/AIDS Program, and other programs in the HIV safety net are highly effective. We have to continue to support them.

Can you explain how "successful transformative projects" these women enact often include community organizing and activism? Why is this such an important component to move into "thriving despite"?

Community organizing and activism enjoys a long history in the HIV/AIDS epidemic. It's about using the power of storytelling to shape attitudes, behaviors, and policies. Women realize that they have a voice and something to contribute. A backstory of shame and struggle can become a testament to the ability that we all possess to remake our lives in the wake of life's traumas. Civic and political engagement is about using gifts and talents that may have been previously ignored in the service of the greater good. People living with HIV have opportunities to teach, to break down barriers, to confront stigma, and to help us end this epidemic. They have the potential to make major contributions to our world because that community has already done so time and time again. And they inspire us to think about what other hidden and underutilized voices are out there.



How does *Remaking a Life* fit into the discussion of our American healthcare system and the debates around social services today?

The HIV system of care offers some valuable lessons. The Ryan White Care Act passed with bipartisan support in 1990 and it still continues to enjoy bipartisan support. Republican and Democratic presidents have made important contributions to the HIV safety net in the U.S. and abroad. In the wake of our opioid crisis, Senator Elizabeth Warren and [the late] Congressman Elijah Cummings introduced legislation to help communities grappling with opioid epidemics that was modeled off the Ryan White Care Act. President Trump has now declared that he would like to see an end to the epidemic in the U.S. by the year 2030.

That doesn't mean that politicians haven't put their own ideological spin on HIV/AIDS policy, sometimes in ways that were contrary to the scientific evidence. But my hope is that this issue continues to have bipartisan support focused on ending the epidemic. My hope is that we can think of the broader healthcare system in similar ways.

In the book, I grapple with the unfortunate irony of my analysis and its policy implications. Many women who were struggling with poverty and other serious issues did not receive assistance until after their HIV diagnosis. That says that our societal safety net has been perversely shaped to intervene only when people are already deeply injured or assumed to pose a threat to public health. The fire had to be raging before we installed the fire extinguisher.

So, I also hope that we challenge the idea that social services and safety nets are inherently problematic. Because of political rhetoric, we've been conditioned to believe that every form of assistance is a handout that serves as a hammock rather than a ladder. I've seen in my research that the opposite is often true. The services provided through the HIV safety net offer critical resources for survival and stability.

Could you tell us how you got connected to TPAN in the first place, and started your research by interviewing women here for the book?

When I began conducting interviews with women living with HIV in 2005, I was connected to Barb Marcotte, who at the time was running TPAN's Women's Support Group. She was extremely supportive of the project and very passionate about the need to hear the voices of women in the epidemic. I rented out a small office in TPAN to conduct interviews, and Barb and [POSITIVELY AWARE Associate Editor] Enid Vázquez helped me get the word out. Many of the women who I interviewed had connections to TPAN, attending support groups and serving as peer educators.

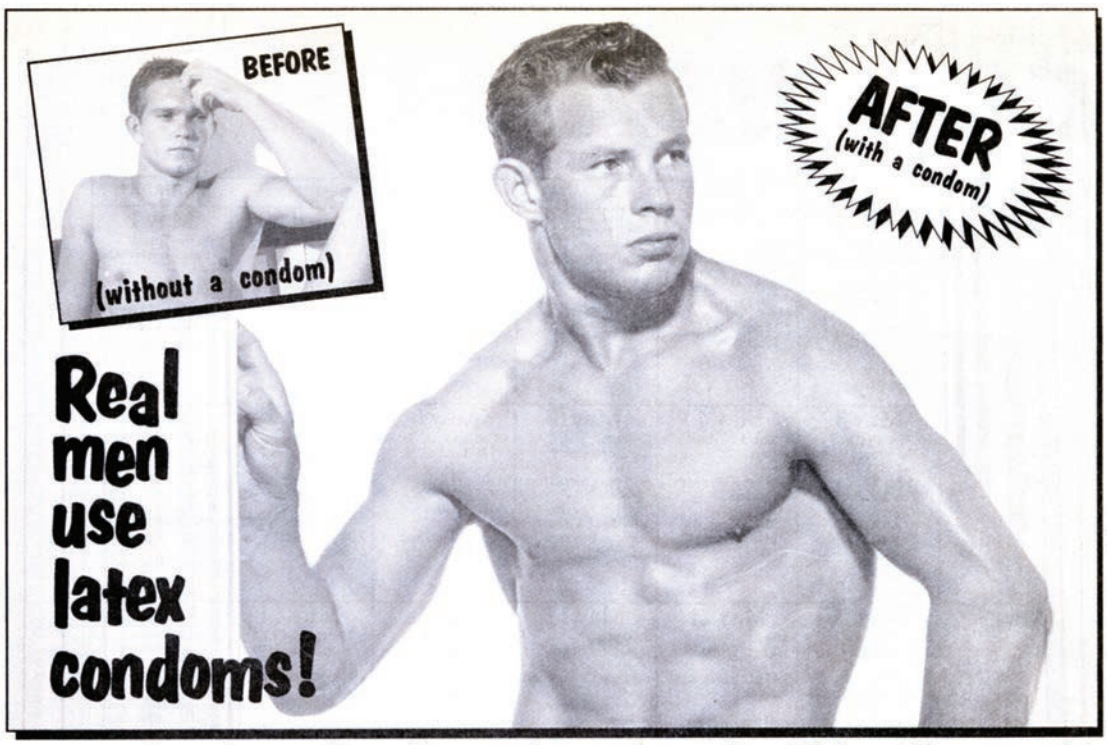
Anything else you might want to share about TPAN for POSITIVELY AWARE's 30th anniversary?

TPAN's support was absolutely critical to me as I wrote *Remaking a Life: How Women Living with HIV/AIDS Confront Inequality*. It wasn't simply about TPAN providing the physical space where I could conduct interviews and hang my recruitment flyers. TPAN welcomed me into the HIV community. The organization helped me to understand the issues, made it okay to ask questions, and signaled to me that I belong in this conversation. For that, I am eternally grateful, and may the organization continue to do those things in the community for years to come. PA

CELESTE WATKINS-HAYES, PHD, is a professor of sociology and African American studies and faculty fellow at the Institute for Policy Research at Northwestern University.

CAMP HUMOR, 1993

Turning scarcity into a virtue, POSITIVELY AWARE had few resources for photos, and so applied a camp sensibility, using retro images to promote the use of condoms to prevent HIV. Times have changed—the imagery is different, and public health messaging now includes U=U and PrEP.



PHOTOS FROM THE GEORGE HARVEY COLLECTION

Tired of the way things are

Former POSITIVELY AWARE associate editor **Keith R. Green, PhD, MSW** notes that while much in the world of HIV/AIDS has changed since an editor's passing, a lot has not

It's been 15 years since the passing of POSITIVELY AWARE editor Charles Edward Clifton, and it still baffles me how a man I only knew for a short period of time could have such a lasting impact on my life.

I'd volunteered with POSITIVELY AWARE under Charles' leadership for over a year before accepting a part-time position in April of 2004. Four months later, Charles was gone. Shortly thereafter, his Editor's Note from the September+October 2001 issue of POSITIVELY AWARE titled "The Past, The Present, and The Future" was reprinted on TheBody.com. Prior to reading this piece, no one could have convinced me that the burden Charles was carrying was so incredibly heavy. Charles' presence exuded a sense of vibrancy and passion that was incongruent with the revelations of this particular writing. His sudden passing robbed those of us who so deeply respected and admired him of the opportunity to demonstrate that we had his back in the same way that he so selflessly had ours.

I, for one, wholeheartedly believe that I would not be alive and thriving without the divine intervention that came by way of Charles. Literally. His example as an openly gay and HIV-positive Black man, coupled with the nurturing environment that he fostered at POSITIVELY AWARE and its parent organization, TPAN, unshackled me from the burdens of stigma and shame that I'd been carrying around since my own diagnosis 10 years prior.

I'd walked into TPAN dying of AIDS, with a T cell count of 30 inside of a woefully emaciated six-foot-four frame. Under Charles' leadership, the people there provided me with the kind of unconventional social support that I needed to believe that I could follow my dreams. They also instilled in me the knowledge necessary for gaining and maintaining control of HIV. TPAN helped to nurse me back to health and Charles made it clear to everyone in the organization (including my beloved Jeff Berry, who was my immediate supervisor) that education was to be my priority. Because education is what I told him I wanted.

Long after Charles' passing, the folks at TPAN continued to support my pursuit of education. I earned both a bachelor's and a master's degree while working there. After earning a doctoral degree in social service administration, I'm now an assistant professor at Loyola University Chicago. My research is focused on how community-based organizations like TPAN ensure access to antiretroviral-based HIV prevention and treatment approaches, while equally emphasizing critical social service interventions that are also necessary to ensure that people living with HIV both live and thrive.

As I write this, I can relate more to the tiredness that Charles speaks of in "The Past, The Present, and The Future" than ever before. While so much in the world of HIV/AIDS has changed since Charles' passing, a lot has not. The work continues to be mentally and emotionally taxing and I too carry my burdens in silence for the most part. Maybe that's something I picked up from Charles. And perhaps revisiting this piece will prompt me to somehow proceed differently...

CHARLES E. CLIFTON'S EDITOR'S NOTE (ABOVE) FROM THE NOV+DEC 2001 ISSUE, DESIGNED BY THEN-ART DIRECTOR RUSSELL McGONAGLE.

KEITH R. GREEN, PhD, MSW, is an assistant professor in the School of Social Work at Loyola University in Chicago. He was formerly an associate editor of POSITIVELY AWARE before becoming Director of Federal Affairs at the AIDS Foundation of Chicago. He is an award-winning spoken word artist and was inducted into the Chicago LGBTQ Hall of Fame in 2012.

CHARLES E. CLIFTON

The Past, The Present, and The Future

POSITIVELY AWARE editor Charles E. Clifton died suddenly in 2004. This Editor's Note by Charles first appeared in the November+December 2001 issue; it is presented here as it might appear today in the magazine. Note that this editorial was written years before the Swiss Statement and the era of U=U.

I'm tired from "tops" who believe they can't contract HIV. I'm tired from "bottoms" who continue to roll the dice. I'm tired from irresponsible HIV-positive barebackers. I'm tired from irresponsible HIV-negative barebackers. I'm tired of the belief that barebackers are always gay men. I'm tired, because it ain't true. I'm tired of condoms. I'm tired for everyone waiting for the results to come back from an HIV test. I'm tired.

I'm tired for intravenous drug users who share contaminated needles. I'm tired for men who refuse to use a condom. I'm tired for the women and men forced to have sex with men who refuse to use a condom. I'm tired for sex workers who can't use a condom. I'm tired for young people who don't have sex education. I'm tired of prevention that doesn't seem to work. I'm tired.

I'm tired from individuals who promote conspiracy rather than care. I'm tired from those who don't believe in re-infection. I'm tired from medications that make people sick rather than well. I'm tired from people who could, but don't adhere. I'm tired for everyone in America, Africa, Asia, and Eastern Europe who would adhere, but can't. I'm tired from a system that profits from homelessness, hunger, and mental illnesses. I'm tired from illiteracy. I'm tired.

I'm tired from some that believe women and children, the incarcerated, and drug users don't deserve our attention. I'm tired because some believe that gay men don't deserve our attention. I'm tired from blacks that blame whites. I'm tired from whites that blame blacks. I'm tired from men who blame women. I'm tired from women who blame men. I'm tired from MSMs, SAMs, "trade," and "on the down-low." I'm tired of categories. I'm tired.

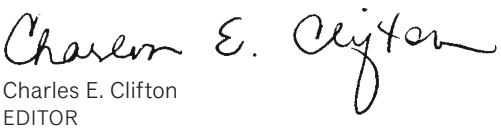
I'm tired of incompetent negatives. I'm tired of unqualified positives. I'm tired of bureaucracy. I'm tired of cynics. I'm tired of the hypocrites. I'm tired of the dishonesty. I'm tired because I don't know what to do. I'm tired of being stressed, depressed, and overwhelmed. I'm tired because I don't have time to do more. I'm tired because I don't feel like doing more. I'm tired.

I'm tired from Slavery. I'm tired from Emancipation. I'm tired from Jim Crow. I'm tired from Civil Rights, Women's Rights, Gay/Lesbian Rights, and now Healthcare Rights. I'm tired from prejudice and hatred. I'm tired from ignorance. I'm tired that mistakes from the past continue to be repeated. I'm tired.

I'm tired from John F. Kennedy, Martin Luther King, Jr., Robert Kennedy, and my father. I'm tired from the events of September 11, 2001. I'm tired for this nation. I'm tired for this world. I'm tired for everyone who has ever lost someone to a senseless act of violence. I'm tired for everyone who will lose a loved one in the coming days, weeks, and months.

I'm tired of grieving. I'm tired of remembering. I'm tired of wondering. I'm tired that I still grieve the death of Antonio, who died 15 years ago on October 8th. I'm tired of marking the anniversary of his death. I'm tired of wondering what might have been. I'm tired of hoping. I'm tired of coping. I'm tired of dates that always remind me of how tired I am. I'm tired of wondering what's next, who's next. I'm tired of this road.

I'm just tired.



Charles E. Clifton
EDITOR

I'm tired from John F. Kennedy, Martin Luther King, Jr., Robert Kennedy, and my father. I'm tired from the events of September 11, 2001. I'm tired for this nation. I'm tired for this world.

Connecting past to future

Long-term survivors share their stories, discuss strategies for the year ahead

BY **JD DAVIDS**

Since 2015, The Reunion Project (TRP) has opened space for vital conversations between and among long-term survivors of HIV. Now, after nearly five years, as they are poised to expand their work, they reached out to the community through a webinar, an online video meeting that reported back on their activities and inviting them to join in the year ahead.

'The importance of a sense of belonging to community and their experience, knowing that our experiences are being honored and that our suffering has meaning as a part of that community... We will not lose that essence, as we move forward, as we stabilize, we will deepen and we will expand.'

Like many of TRP's programs, the webinar offered a warm welcome along with a mix of report-backs from leaders, opportunities to reflect, and an invitation to work together to move forward. The virtual gathering allowed the groups' leaders to share their newly-adopted roadmap for developing the organization so they can build successful strategies for living and supporting one another, today, and into the future.

And they also launched their call for expanded leadership: They invited people to consider applying for their steering committee, which will increase from seven to a body of 15–21 people, or to one of the work groups on communication, fundraising, network-building, and programs that are open to all community members.

Facilitator Vanessa Johnson, who was diagnosed with HIV in 1990, opened up the webinar, which was titled "Honoring Our Past, Envisioning Our Future: Mobilization Through Our Stories of Survival," thanking the seven-member steering committee that has shepherded the group as a national alliance of HIV survivors, and introducing Matt Sharp of Oakland, California, who co-founded the group with Jeff Berry of TPAN and POSITIVELY AWARE.

Sharp explained that The Reunion Project was inspired by initial town meetings in San Francisco that revealed an eagerness for connection and discussion—not just about the biological or medical issues that affected their lives as they aged with HIV, but the psychosocial issues, including loneliness and isolation, grief and fear, that many were facing.

The Reunion Project expanded this town meeting model in events around the country, finding several groups eagerly hosted subsequent events, allowing the momentum of those first town meetings to continue. They also presented workshops at the United States Conference on AIDS (USCA), held a national roundtable forum, and released a groundbreaking report, *Unintended Consequences of HIV Survival*.

Their initial efforts garnered much praise and some funding (though not as much as may be perceived at times in the HIV community, they are quick to clarify); they've directly reached over 800 people in seven cities, inspiring many more as the impact of the sessions resonated across the lives of the participants. In addition, in the last year they entered into a three-year collaboration with TPAN, "Positively Aging," which allows TPAN to increase direct services for older persons living with HIV in Chicago, The Reunion Project to expand its national support network, and information about the project and issues surrounding aging with HIV to be shared with POSITIVELY AWARE's national audience.

"Most of 2019 has been around restructuring and strategies to make sure that we have a model that's going to be sustainable," explained steering committee member Waheedah Shabazz-El of Philadelphia.

"We like hearing from you. We need your feedback. We honor your feedback and stories," she added, referring to over 30 interviews that the group conducted this year with program

ISTOCKPHOTO

participants and community leaders. "Because we don't want to be talking to each other—we want to be talking to you. We want to deepen our funding, our partnerships, and resource expansion."

Ultimately, the group adopted a roadmap (disclosure: I worked with fellow consultant Susan Wolfson to draft and present the roadmap to the group) that will allow them to increase their leadership to sustain and then expand their programs and national network.

Steering committee member Louis Spraggins offered a variety of quotes from the interviews, explaining that the broad range of input emphasized how each long-term survivor has a unique experience to share—and that these voices will continue to guide TRP as it moves forward.

"The untold stories are profoundly important for us," he said. "The importance of a sense of belonging to community and their experience, knowing that our experiences are being honored and that our suffering has meaning as a part of that community... We will not lose that essence, as we move forward, as we stabilize, we will deepen and we will expand."

Towards the end of the gathering, Jeff Berry led a moment of reflection and goal setting, asking everyone to imagine that they were standing at the center of the year 2019:

On one side, each person was held up by a mantra or slogan, an individual person, or a program, group, or organization that supported them over the year. On the other side, they held someone else who they are helping or mentoring, or even just supporting with a smile.

As each person envisioned themselves as supported while also being a source of support, Berry asked them to consider the year ahead: What will be the opportunities and challenges?

In typical Reunion Project fashion, the answers were as inspiring as they were varied, striking a balance between the need to face what may come to pass in the 2020 elections while continuing to grow in self-knowledge and unity across our communities.

It was time to close the call—but Shabazz-El offered to stay on the call late, to give space for folks who needed more time to talk, just like those lingering at the end of a town meeting. PA

JD DAVIDS is a longtime HIV and social justice activist who now runs JD Strategy: liberating possibilities for power and justice. In 2019, he served as a strategic advisor to The Reunion Project as well as other networks of people living with HIV, and in and across transgender communities.