POSITIVELY AWARE

HIV TREATMENT, PREVENTION, AND SUPPORT FROM **TPAN**
JAN+FEB 2019

NEW HORIZONS

JARED BAETEN, MD, PHD is among the physicians, researchers, and advocates working on new strategies for HIV treatment and prevention

LONG-ACTING INJECTABLES COMING SOON

THE NEXT GENERATION OF LONG-TERM SURVIVORS

INNOVATIVE PREVENTION AND CARE PROGRAMS

BREAKING THE OPIOID CRISIS IN THE U.S.

REDUCING HIV RISK FOR TRANS WOMEN

POSITIVELY AWARE

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POSITIVELY AWARE
JOURNALISM. INTEGRITY. HOPE.

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LIVE LIFE POSITIVELY AWARE

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TPAN was founded in 1987 in Chicago as Test Positive Aware Network, when 17 individuals 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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I just got POSITIVELY AWARE in the mail today and was at first apprehensive to read [the NOV+DEC 2018 issue] as it was themed around faith. I'd had a horrible experience with the evangelical church when I came out and became an atheist. However, you balanced the positive coverage of faith experiences with the not-so-positive, which really made me appreciate PA all the more!

—**BARRY WEISS** LOS ANGELES, CALIFORNIA

MYSTERIOUS WAYS

"Amazing Grace or Highway to Hell?" (NOV+DEC 2018) started by saying, "When you think of HIV/AIDS and God or religion, the following images may come to mind: 'God Hates Fags' lining the streets at the local AIDS walk." This type of hatred is exactly what I experienced recently when I decided to share my HIV status with a family member. Ten years since my diagnosis, I felt ready to come out of the closet for the second time and share my HIV status.

I contacted Michelle SImek, who wrote the article, to share this negative experience. As a result of her interview with me, I told her that I had decided to start contacting family and friends to share my HIV status before her article would appear in PA. Although most of my family's reactions were positive and supportive, one family member reacted negatively.

This family member told me that it was my fault for becoming infected. They said that I had chosen this "gay lifestyle" and, so I was suffering the consequences. Additionally, they said that my diagnosis was a sign that the end of times was coming—Armageddon—and that I was going to die.

Fast forward to earlier this week: An elder from a congregation on the East Coast contacted me, reminding me of God's love and to assure me that I was not alone. He added that he had read Michelle's article, and prayed to God about it; ultimately, he felt compelled to call me directly to demonstrate his support. Additionally, he will be mailing some reading materials for me to go over where, he assured me, I will find some support. These are the same reading materials where he found hope and support after receiving negative feedback from his family after sharing his sexual orientation.

God works in mysterious ways, and I have found the love and support that I need to keep going. Thank you.

—**JOSUÉ E. HERNÁNDEZ**
BREA, CALIFORNIA

'SHARING OUR EXPERIENCES'

As a long term HIV/AIDS survivor, I found Michelle Simek's article, "Amazing Grace or Highway to Hell?" not only well written, and informative, but refreshing as well. It was wonderful to see faces and hear stories as diverse as HIV/AIDS itself. I also loved the common thread of spirituality that seemed to run throughout her article; regardless of whether one is atheist, Baptist, Catholic, Jewish, Lutheran, or Methodist, without some sort of spiritual practice, none of us would've survived. It also reminded me of how connected we all are by this disease. HIV/AIDS does not discriminate. It doesn't matter if you're male or female; gay or straight; black, brown or white; young or old; doctor or housewife; or rich or poor. It affects all of us, as humans, and draws us closer to one another. Sharing our experiences with others, and hearing their stories in return, is a part of the healing process for all of us. Bravo to Ms. Simek and POSITIVELY AWARE for this wonderfully inspirational article!

—**PAMELA YELSKY**
LOS ANGELES, CALIFORNIA

CORRECTION

IN THE PRINT EDITION of the NOV+DEC 2018 issue, a photo accompanying "Amazing Grace or Highway to Hell?—God, spirituality, and HIV" incorrectly identified Andrea de Lange (appearing above, fourth from left). POSITIVELY AWARE regrets the error, which has been corrected in digital and online versions of the issue.

PHOTO: JOHN GRESS

EDITOR'S NOTE

JEFF BERRY

Old barriers, new horizons

Each New Year offers us hope, the chance to start anew, and the opportunity to make resolutions that we may or may not keep. 2019 marks the 30th year since I tested positive for HIV. Many amazing breakthroughs in HIV treatment and prevention have occurred over the last three decades, and what's interesting is that even more are on the horizon. Warren Tong's article on page 15 will give you a small taste of what's to come, including long-acting injectable agents. POSITIVELY AWARE will continue to keep you updated in future issues about the innovative ways in which researchers are looking at how to, as the old activist saying goes, get drugs into bodies, including once weekly or monthly oral treatment, and new classes of drugs.

Of course all of this is great in a perfect world where every person has access to adequate health care that they can afford, is stably housed, and can get to a provider who is culturally competent and specializes in trauma-informed care. Barriers including stigma, discrimination, intimate partner violence, transphobia, gender differences, income inequality, and any number of other obstacles to care continue to thwart our best efforts. Biomedical breakthroughs in treatment and prevention are only one piece of the puzzle—we also require advances in how we deliver services and provide care. On page 20, Michelle Simek takes a look at three organizations and how they designed innovative programs to reach those most in need.

As I write this, I learned of another friend living with HIV gone too soon. Lately the losses seem to have been occurring more frequently. Maybe part of that is what happens as you get older, but for those of us who lost multiple friends, family members, and co-workers decades ago at the height of the epidemic, it feels like we are on the precipice of a new tsunami of unanticipated grief. Add this to our already unresolved grief and survivors' guilt, PTSD, loneliness and the isolation that can come as a result, and the outcome could prove devastating. It can all be so overwhelming and seem too much at times. We need to prepare ourselves as an entire generation of long-term survivors enters this new phase of their lives, and develop tools and resources to support them on their journeys. Newer generations of survivors will have their own unique journeys, and on page 26 David Durán talks about his story of survivorship.

Giving the gift of life as a living organ donor is possible for people living with HIV, but many aren't aware of it. Activist Nina Martinez shows us how you can become a donor by describing and sharing with us her own story on page 28. Nina tells us how she came to her decision, and then set about actually doing something about it.

Each of these horizons is an opportunity for a new day, and new beginnings in the fight against HIV. None of them are the only answer, and there is no magic bullet or one size fits all. What seemed unthinkable only a few years ago, such as a pill to prevent HIV, is now a reality. The fact that you can't pass on the virus sexually to someone if you are HIV positive and on suppressive antiretroviral therapy is one of the biggest breakthroughs of all. We are limited only by our own imaginations, and our ability, or inability, to think outside the box.

I hate to admit it but recently I missed a dose of my meds. Not just my HIV meds. Everything! My meds for high blood pressure, triglycerides, vitamins—all of them. And I'm probably the most adherent person you'll ever meet (well clearly not *the* most, since I missed one). But we are not perfect human beings, and stuff happens. Wouldn't it be nice if I could take a shot every other month, or every three months? Every six? And how great if I could just stop at the pharmacy on the way home from work to get my shot! Or even better, to be able to self-administer at home. I used to think not, since there are other medications I have to take. But missing those other meds every now and again, at least in my case, is not as serious as missing my HIV meds and developing resistance to them. If getting a shot was really convenient, it might be nice to not have that daily reminder of HIV. Maybe.

All of these things could be in our not-so-distant-future, and the future is indeed looking bright. But alongside developing these new and innovative treatments and interventions, we need to double down our efforts and focus on getting them into the populations who need them the most, including marginalized and underserved populations and communities of color. That is truly the new horizon I long for.

Take care of yourself, and each other.

@PAeditor

Each of these horizons is an opportunity for a new day, and new beginnings in the fight against HIV. None of them are the only answer, and there is no magic bullet or one size fits all.

ENID VÁZQUEZ @ENIDVAZQUEZPA

BRIEFLY

- HIV meds during pregnancy
- Black AIDS Institute's new CEO
- New off-patent nuke co-forumulation
- Two-drug single-tablet regimen coming
- Highlights from the International Congress on Drug Therapy in HIV Infection

Updates to HIV treatment guidelines

New medications get their recommendation; plus, pregnancy updates and more

HIV TREATMENT GUIDELINES from the U.S. Department of Health and Human Services (DHHS) were updated in October. A one-page section called "What's New in the Guidelines" lays out the changes for you. Some highlights:

Pregnancy: Last year, preliminary data from Botswana showed a possible connection between dolutegravir and birth defects in infants whose moms were on the medication around the time of conception (see also page 7). The guidelines now provide guidance, including a table, on the use of dolutegravir and other INSTIs (integrase strand transfer inhibitors) in patients who could become pregnant. Dolutegravir (brand name Tivicay) is also found in Juluca and Triumeq. The other INSTIs on the market are raltegravir (Isentress and Isentress HD), bictegravir (found in Biktarvy), and elvitegravir (found in Genvoya and Stribild).

At the same time, there is **new information on why dolutegravir may be the only treatment option for some people experiencing virologic failure** (when viral load is no longer undetectable). Information on this option includes pregnancy considerations.

Note: There were reassuring data presented at the International Congress on Drug Therapy in HIV Infection, held in Glasgow in October. Read Keith Alcorn's report, "Neural tube defects and integrase inhibitors: studies show no further evidence of increased risk," at aidsmap.com.

What to use when starting HIV treatment: Three medications approved by the FDA last year are now rated "recommended initial regimen for most people with HIV" (the highest recommendation there is): Pifeltro when taken with Descovy, along with the single-tablet regimens Biktarvy and Delstrigo. Pifeltro is the brand name of the non-nucleoside reverse transcriptase inhibitor doravirine. Biktarvy contains the INSTI bictegravir plus emtricitabine (FTC) and tenofovir alafenamide (TAF). Like Biktarvy, Delstrigo is a single-tablet regimen. It combines doravirine with lamivudine (3TC) and tenofovir DF (TDF).

Genvoya and Stribild have been downgraded from that highest recommendation and are now "recommended initial regimens in certain clinical situations." According to the guidelines, this change was made due to the many drug interactions associated with cobicistat, the booster medication found in Genvoya and Stribild, and because the primary drug in these single-tablet regimens, elvitegravir, has a lower barrier to drug resistance than bictegravir or dolutegravir.

The combination of dolutegravir and 3TC (brand names Tivicay and Epivir) may now be considered when abacavir, TDF, or TAF "cannot be used or are not optimal." This two-drug therapy is expected to receive FDA approval as a single-tablet regimen later this year. Look for its drug page in the POSITIVELY AWARE Annual HIV Drug Guide in the upcoming March+April issue.

A review of data on Trogarzo (ibalizumab), approved by the FDA last year, has also been added. According to the guidelines, "Patients with ongoing detectable viremia [detectable viral load] who lack sufficient treatment options to construct a fully suppressive regimen [get to undetectable viral load] may be candidates for the recently approved CD4 post-attachment inhibitor ibalizumab."

More new information: There are also updates on HIV/HCV co-infection; drug-related adverse events; drug interactions; drug resistance testing; average monthly cost of the most commonly used HIV medications; and use of treatment when there are kidney or liver problems.

GO TO aidsinfo.nih.gov.

PREGNANT WOMAN: LAFLOR/ISTOCK; COPELAND COURTESY OF BAI

HIV meds during pregnancy

LATE LAST YEAR, the FDA made several changes related to the use of HIV drugs during pregnancy.

Rilpivirine (brand name Edurant, found in Complera and Odefsey) has been shown to have lower exposure levels during pregnancy, which possibily makes it less effective at controlling the virus. Therefore, **pregnant women taking rilpivirine who have undetectable viral load should have their viral load monitored closely** to make sure it remains undetectable. The FDA reported that the lower rilpivirine levels are not, however, considered clinically relevant.

Genvoya and Stribild are not recommended during pregnancy due to "substantially lower exposures" with elvitegravir and cobicistat (both found in Genvoya and Stribild) during the second and third trimesters. Switching to an alternative HIV therapy during pregnancy is recommended.

Moreover, Tybost (cobicistat) taken with either darunavir (Prezista) or atazanavir (Reyataz) is also not recommended in pregnancy, for the same reason. Note, there are co-formulated medicines with these drugs, Prezcobix and Evotaz.

Updates to perinatal HIV treatment guidelines

Updated in December were the U.S. HIV perinatal treatment guidelines. As with the adult and adolescent guidelines, there's an introduction to the changes. Go to aidsinfo.nih.gov. Among the highlights:

Dolutegravir (Tivicay, found in Triumeq and Juluca): Dolutegravir is not recommended during the first trimester of pregnancy or in someone trying to become pregnant. It is recommended after the first trimester, when it is actually a preferred medication from the drug class of integrase strand transfer inhibitors (INSTIs). Counseling points about whether or not to switch to a different HIV regimen are provided for those who are in their first trimester.

The concern about using dolutegravir during the first trimester come from a surveillance study in Botswana suggesting a possible increased risks of neural tube defects (NTDs) in infants born to mothers taking dolutegravir at the time of conception. "However," the guidelines state, "other data from this study and others support the safety and efficacy of dolutegravir when it is initiated during pregnancy."

Not recommended during pregnancy: The following medications were added to the list of HIV drugs not recommended for use during pregnancy: Evotaz, Prezcobix, and elvitegravir/cobicistat (found in Genvoya and Stribild).

Not enough data for use in pregnancy: New HIV medications that do not have enough data at this time to be recommended for use in pregnancy are bictegravir (found in Biktarvy), doravirine (Pifeltro, found in Delstrigo), and ibalizumab (Trogarzo).

Hepatitis C: Due to the low level of testing for hepatitis C in babies exposed to that virus *in utero*, medical providers are urged to counsel parents about the important of testing exposed children for hep C during the first few years of life.

Recommended medicine for infants: It is now recommended that infants exposed to HIV *in utero* who >>

New era, new leader for Black AIDS Institute

THE BLACK AIDS INSTITUTE (BAI) starts the new year with a new CEO. Longtime staff member **Raniyah Copeland became BAI's new president and CEO** on January 1, succeeding founder Phill Wilson.

Copeland's selection was announced following a 10-month national search from among 20 candidates. In 2015, Wilson had announced he would step down from BAI at the end of 2018. Copeland joined the organization in 2008 as training and capacity building coordinator; most recently, she had been serving as Director of Programs.

RANIYAH COPELAND

"I have grown from planning the details of one of our largest programs to leading the strategic direction of all of BAI's programming, including our newest entry into providing HIV direct services," Copeland says. "In my tenure with the Institute I have had the pleasure of developing seasoned and meaningful relationships with significant individuals and institutions from federal leaders, to community organizers, and key funders. I have led our growth to currently having the largest staffed and skilled programs team we have had in 10 years."

Copeland earned a Bachelor of Arts degree in African American Studies at the University of California, Berkeley, and has a Master's in Public Health from Charles Drew University of Medicine and Science. She is married to Bryce Copeland, a business manager for Sony Pictures Entertainment. They are the parents of two children.

"As a Black cis-woman and mother, my intersectionality informs how I center people living with HIV, queer people, Black trans women, and folks in the Black communities who are marginalized because of who they are," says Copeland.

>> are at a higher risk of becoming infected be treated with the triple drug combination of zidovudine plus lamivudine plus raltegravir.

Other recommendations have been added based on higher or lower risk of infection to an infant.

Genvoya now for dialysis

Thanks to new 48 week safety data on Genvoya in patients with end stage renal (kidney) disease (ESRD), the FDA updated the drug's label in December. **Adults with ESRD (creatinine clearance, or CrCl, below 15 mL per minute) who are receiving chronic hemodialysis can now take Genvoya, but on the days of dialysis, it must be taken after the dialysis is over.** Previously, individuals needed a CrCl of at least 30 mL per minute to receive Genvoya. Genvoya is not recommended, however, for those with ESRD who are not on dialysis, nor for individuals with severe renal impairment (estimated CrCl between 15 to below 30 mL per minute). Genvoya is the only single-tablet regimen that can be given to people with ESRD on chronic dialysis.

New off-patent nuke co-formulation

THE FDA in November approved a co-formulation of lamivudine and tenofovir DF, or 3TC/TDF, for HIV therapy. The new Temixys was approved based on bioavailability data showing that it has similar exposure levels as the two brand name drugs it is based on, Epivir (lamivudine) and Viread (TDF). There is already another new co-formulation on the market, Cimduo, which like Temixys also uses the 3TC/TDF combination. Lamivudine is often used interchangeably with emtricitabine for treatment of HIV, which in combination with TDF is sold under the brand name Truvada; however neither Temixys nor Cimduo are approved for use in PrEP. **Because Cimduo and Temixys are based on drugs that have gone off patent, they should be lower in cost.**

CLAUDIA DIBBS AND ZAKK MARQUEZ IN SOUTH AFRICA DURING MTV'S STAYING ALIVE FOUNDATION GRANTEE WORKSHOP.

'Sex Ed Is Lit'

Claudia Dibbs and Zakk Marquez became 2018 grantees of the MTV Staying Alive Foundation, tasking themselves to build a multimedia platform which harnesses the power of technology, peer support, honesty, and humor to communicate truths about sexual health and allied topics.

Literally Sex Ed is poised to be a new tool to **foster awareness and educate young audiences** around key components and the intersectional forces of sexual health like STI risk, HIV, and consent through short videos, memes, gifs, and graphics while leveraging the hyper-connectivity among folks via social media. "The idea is," Marquez says, "if we talk about sexual health in a light-hearted and humorous way, we can have deep, sustained conversations. We have to be able to talk about things like gender, sexuality, and race in order to talk about HIV."

The mission of Literally Sex Ed is to help people, especially youth, on their journeys to self-love though sex education, because, says Marquez, "it is this kind of love that can change the world."

Two-drug single-tablet regimen coming

VIIV HEALTHCARE, an offshoot of pharmaceutical giant GlaxoSmithKline devoted solely to HIV, filed a New Drug Application (NDA) with the FDA back in October for a combo pill of two of its HIV meds already on the market: **dolutegravir (brand name Tivicay) and 3TC (brand name Epivir)**. The two meds would be contained in one pill as a single-tablet regimen, meaning that's all someone would take.

Two-drug therapies have certain advantages, and these two meds have some advantages as a single regimen. Look for its drug page in the upcoming POSITIVELY AWARE Annual HIV Drug Guide, the March + April issue. FDA approval is expected sometime this year.

Two years with Biktarvy or Symtuza

AT TWO YEARS (96 weeks) of taking Biktarvy, individuals in Study 1490 continued to have **non-inferior results compared to those taking Tivicay plus Descovy**. The Phase 3 study results were presented at the International Congress on Drug Therapy in HIV Infection in Glasgow in October. Biktarvy is one of the newest single-tablet regimens (STRs) for HIV on the market, and quickly gaining ground in sales for a variety of reasons.

Also presented at Glasgow were two-year data with Symtuza, another new STR on the market. The Phase 3 AMBER study found that 85% of people put on Symtuza maintained an undetectable viral load at week 96—this was 308 of the 362 individuals taking Symtuza. U.S. HIV treatment guidelines recommend darunavir (contained in Symtuza) for people with suboptimal adherence, who may develop drug resistance as a result, and for individuals who need to start treatment right away before drug resistance test results are in.

Landmark report documents challenges of older adults living with HIV in San Francisco

"OLDER ADULTS LIVING with HIV in San Francisco face staggeringly high rates of mental health issues and levels of loneliness, as well as experience a dire need for regular social connections and health care coordination," according to a landmark new report by the ACRIA Center on HIV and Aging at GMHC

PHOTO COURTESY OF ZAKK MARQUEZ

[formerly Gay Men's Health Crisis] in New York City, released in October. This is **the first report from the multi-site Research on Older Adults with HIV (ROAH) 2.0 project.** The report "demonstrates in stark terms that living with HIV as an older adult presents a unique set of challenges—and requires a complex set of coordinated solutions," says a GMHC press release.

"Though most participants reported that their HIV is well managed and that their health is 'excellent' or 'good,' 41% reported that their health is 'fair,' 'poor,' or 'very poor.' They also reported a high burden of physical symptoms and diseases other than HIV," GMHC continued. "Furthermore, survey participants said that they contend with hunger, low income, and burdensome housing costs. Many also said they lack ways to get help with the activities of daily living or care should they fall sick or be injured."

GO TO bit.ly/2Sloaop to read the report.

Lambda Legal victory over Michigan prisons

THE MICHIGAN DEPARTMENT OF CORRECTIONS (MDOC) settled a lawsuit filed by Lambda Legal and Michigan Protection & Advocacy Services over **excessive punishment of an inmate based solely on his positive HIV status**. After John Dorn and another incarcerated man were accused of engaging in consensual sex, Dorn was immediately taken from the lowest-level security facility to the highest and placed in solitary confinement. He was kept there for 21 months, while in contrast, the other inmate (who is HIV negative) lost 30 days of privileges. MDOC's settlement includes substantial changes to its policy allowing disproportionate punishment of inmates with HIV, and a monetary settlement of $150,000.

"I lost over 21 months of my life to solitary confinement for no good reason because of the prior MDOC policy directive," Dorn said in a Lambda press release. "No human being should have to endure that type of punishment. In my case, the directive that led to nearly two years of isolation was based on old science. It was also based on a presumption that did not consider the actual risk of transmission. I am proud that I survived to tell my story. I am also satisfied that I was able to fight for changes in the system that will help other incarcerated people living with HIV in Michigan not experience what I, and others, have."

Discriminatory policies hurt LGBT healthcare, says statement

THREE HEALTH ASSOCIATIONS teamed up to issue an anti-discrimination policy statement on behalf of the LGBTQ community. The statement, released in October, reads:

"The Infectious Diseases Society of America (IDSA), the HIV Medicine Association (HIVMA), and the Pediatric Infectious Diseases Society (PIDS) oppose laws and policies that discriminate against Lesbian, Gay, Bisexual and Transgender (LGBT) individuals. Such laws and policies harm individual and public health and impede the response to the HIV and STD epidemics. **We affirm the rights of all individuals**, regardless of their gender orientation or sexual identity, to access quality competent health care services free from stigma and discrimination. We emphasize that all health care providers have an ethical and professional obligation >>

CONFERENCE UPDATE

INTERNATIONAL CONGRESS ON DRUG THERAPY IN HIV INFECTION
GLASGOW, SCOTLAND OCTOBER 28–31, 2018

FOLLOWING ARE brief items from the conference. The community-based NAM (formerly the National AIDS Manual) from the United Kingdom is the official reporter of the conference. Read their reports at aidsmap.com. For more information, including research abstracts, go to hivglasgow.org.

■ **No increased risk** of serious side effects was seen with Truvada for PrEP, according to a meta-analysis of PrEP studies (looking at a combination of trials). Of note, there were no adverse events in kidney or bone outcomes (side effects associated with Truvada) for either the PrEP takers or the individuals given a placebo. After their analysis of 13 randomized studies with 15,678 individuals, the researchers concluded that, "The safety profile of [Truvada] would support more widespread use of PrEP in populations with a lower risk of HIV infection."

■ **Using two drugs** instead of a triple-drug combination is part of the wave of the future. Another meta-analysis, this time looking at seven randomized trials of dual-drug HIV therapy, concluded that "dual therapy was non-inferior to triple therapy by U.S. FDA criteria, with significantly fewer discontinuations for adverse events." More importantly, perhaps, was the fact that results were good in both people with HIV treatment experience as well as those taking HIV therapy for the first time, who usually do the best with HIV medication. Results are from 1,624 patients, at one year out in their study, looking at the dual combos of a ritonavir-boosted protease inhibitor plus 3TC *or* tenofovir DF (TDF). Drop the extra drug, drop the extra cost and the extra side effects.

■ **Researchers in Warsaw** confirmed previous reports that a chronic infection with hepatitis C virus (HCV) is a risk factor for preterm births. In one analysis, the following were associated with preterm birth in the women who were also living with HIV: the use of a nucleoside reverse transcriptase inhibitor (NRTI medication), dolutegravir, drug use, and the previously mentioned hep C infection. The research team stressed that the risk with dolutegravir be viewed with caution due to limited number of individuals in the analysis.

■ **New findings suggest** the need for greater awareness of the risk for type 2 diabetes and poorly controlled blood sugar levels among people living with HIV. Nearly one-third of people living with HIV receiving care at three large HIV clinics in south London had diabetes or pre-diabetes.

Type 2 diabetes is one of the most common chronic health conditions in older adults. Doctors at King's College Hospital and Guy's and St. Thomas's Hospitals reviewed the prevalence of elevated glucose levels and type 2 diabetes in 338 individuals with HIV receiving care at their clinics. The sample reflected the demographics of those receiving care at the clinics: 49% were Caucasian, 31% Black African, and 17% Black Caribbean. Median age was 49 years; 74% were male.

Among patients tested, 15% had diabetes (fasting glucose >7.0 mmol/L), and 17% had pre-diabetes (6.0–6.9 mmol/L). While 14% of patients ages 40–49 had diabetes, 17% had pre-diabetes; those who were ages 60–69 and 70–79 saw rates of 33% for diabetes and 25% for pre-diabetes.

Echoes of rage from the early years of AIDS

AIDS ACTIVIST David Wojnarowicz was a prominent artist out of the New York East Village arts scene in the 1980s who wrote and painted and sculpted and photographed and collaged and created video and music, until his death due to AIDS in 1992 at the age of 37. The Whitney Museum of American Art presented a retrospective of his work last year, with concurrent exhibits in New York City.

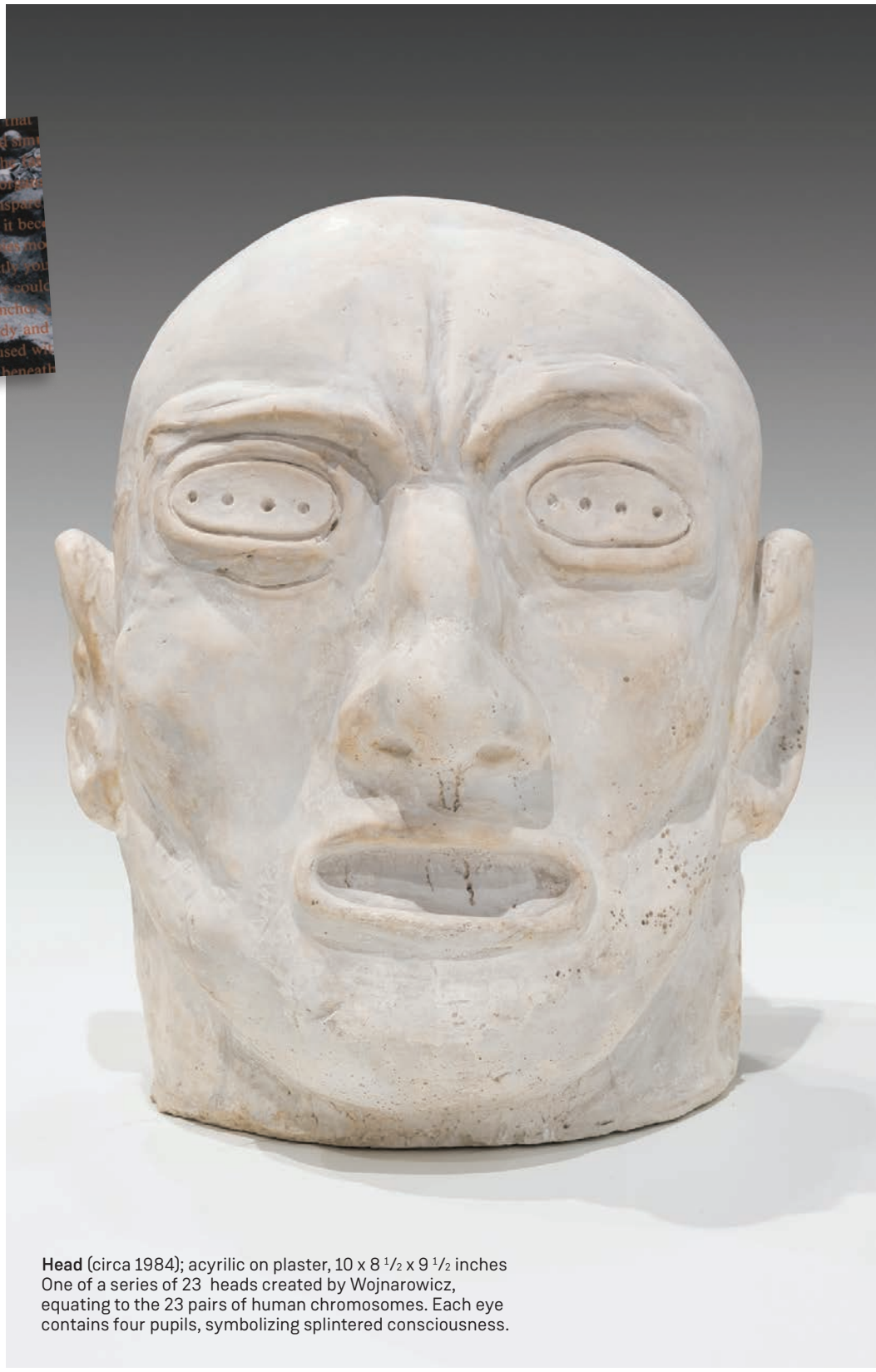
David Wojnarowicz: Flesh of My Flesh comes from last summer's exhibit of the same title at Iceberg Projects in Chicago, and is the title of the second book from HIV specialist and art curator and collector Daniel S. Berger, MD. It follows his first book, "Militant Eroticism: The Art+ Positive Archives," also the title of the exhibit at Berger's Iceberg Projects gallery, which included Wojnarowicz's work, as he was part of the ACT UP affinity group.

In his afterword, Dr. Berger writes, "The rage Wojnarowicz expressed echoed my own rage during the early years of the AIDS crisis, when challenges were all-consuming."

The book includes historic photographs, essays by P.P.O.W co-founder Wendy Olsoff and artist Elijah Burgher, and a transcript of a conversation between Dr. Berger and gallery director Barry Blinderman.

"By the late 1980s David happened to be without a gallery, and P.P.O.W was in the right place at the right time," writes Olsoff. "By this period David's work had become razor focused on the AIDS crisis, driven by the death of his mentor Peter Hujar and many other friends, by his own HIV-positive diagnosis, and by the censorship wars and Christian right-wing politics, which refused to acknowledge the epidemic's existence."

Flesh of our flesh indeed.



Head (circa 1984); acyrilic on plaster, 10 x 8 ½ x 9 ½ inches
One of a series of 23 heads created by Wojnarowicz, equating to the 23 pairs of human chromosomes. Each eye contains four pupils, symbolizing splintered consciousness.

>> to provide all patients with humane and competent medical care and treatment."

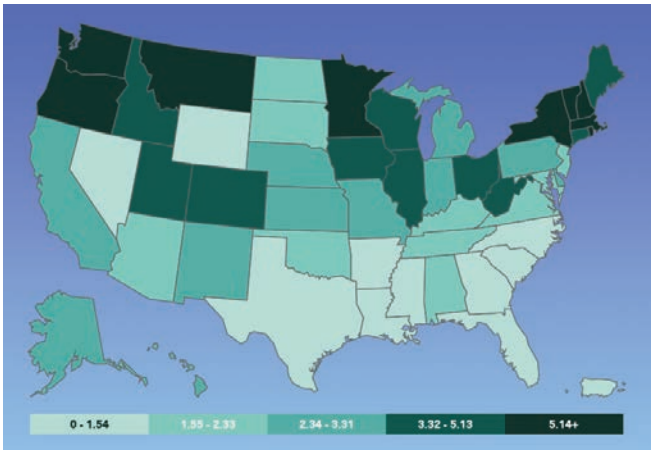
In addition to their statement, the three organizations discuss research findings on the effects of discrimination on LGBTQ health and provide references. Read the findings at idsociety.org, hivma.org, or pids.org.

Fentanyl and tramadol interactions with Genvoya and Stribild

The FDA added fentanyl and tramadol to the narcotic analgesics (pain medication) section of the drug labels for Genvoya and Stribild late last year. "Careful monitory of therapeutic and adverse effects of fentanyl (including potentially fatal respiratory depression) is recommended with coadministration. A dose decrease may be needed for tramadol with concomitant use."

Police charged in AIDS activist's death

FOUR ATHENS POLICE officers were charged in the beating death of Greek AIDS activist Zak Kostopoulos, 33, in September, as reported in POSITIVELY AWARE's November + December 2018 issue. **Also charged was the owner of a store** where Kostopoulos had broken in, seeking shelter from a street brawl, his friends say. Hundreds of people attended a memorial rally following his death. The charges filed were of inflicting "fatal bodily harm," which his family has asked be upgraded to murder. The beating was caught on camera.



PrEP data online

AIDSvu.org—the website that provides interactive maps and data visualization of HIV statistics in the U.S. by county—now offers similar state-level information about PrEP usage. Local HIV testing and services and PrEP providers can also be located by ZIP Code.

Using data from the Centers for Disease Control and Prevention and state and local health departments, AIDSVu's interactive maps illustrate the prevalence of HIV based on race/ethnicity, gender, age, education, and income. The site is optimized for Chrome, Edge, and Firebox web browsers. AIDSVu also operates a similar interactive site for hepatitis C information, HepVu.org.

OPPOSITE PAGE: IMAGES COURTESY OF DAN BERGER, MD

POSITIVELY AWARE

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Jared Baeten, MD, PhD
PROFESSOR AND VICE CHAIR OF THE DEPARTMENT OF GLOBAL HEALTH, UNIVERSITY OF WASHINGTON, IN SEATTLE

PHOTO: BRIAN WELLS

EMERGING OPTIONS

Doctors and advocates discuss treatment and prevention breakthroughs on the horizon

BY **WARREN TONG**

People living with HIV can live long, healthy lives with current antiretroviral therapy (ART). By taking just one pill a day, HIV has become for many a chronic, manageable condition. However, even with these lifesaving medications, a pill a day can lead to pill fatigue and serve as a daily reminder of HIV.

On the prevention front, our options have never been better. We currently have daily oral PrEP (pre-exposure prophylaxis), condoms, and U=U (undetectable equals untransmittable). But what if we could make HIV prevention even more accessible and easier to take? We spoke with a few providers and experts to see what's currently on the horizon for HIV treatment and prevention.

LONG-ACTING INJECTABLES

Perhaps the most exciting option and the closest to becoming available to people living with HIV, long-acting injectables are seen as the future of HIV treatment and prevention. For many living with HIV, not having to take pills every day would be liberating. Imagine going to the doctor's office once every month or two for an injection. No more daily pills. That may soon be a reality.

There are currently two Phase 3 studies in progress evaluating the safety, efficacy, and tolerability of switching from a pill regimen to long-acting cabotegravir (an integrase inhibitor) plus long-acting rilpivirine (a non-nuke).

"The things that are furthest in testing are long-acting injectables, both for treatment and for prevention," said **Jared Baeten, MD, PhD**, professor at the University

While the idea of receiving injectable treatment once every one or two months sounds like

of Washington's Department of Global Health. "It's the same product—cabotegravir is being tested for both. To speak from more of a prevention point first, it offers another option for potentially effective HIV prevention. Of course, it's still in testing, but what everyone needs are more choices so they can choose what's going to work for them."

How close are we to having long-acting injectables on the market?

Both Phase 3 studies recently reported non-inferiority results, showing that the two-drug long-acting injectable regimen did not perform worse than a standard oral three-drug regimen. The next step would be submitting these drugs to the U.S. Food and Drug Administration (FDA) for approval.

"Both trials hit that non-inferiority margin, which is really important because it means that they will probably be FDA approvable," said **W. David Hardy, MD**, Adjunct Professor of Medicine at Johns Hopkins University School of Medicine in the Division of Infectious Diseases.

Updated results of these two studies are anticipated at the CROI conference in March. If the data are good and the drugs are submitted to the FDA for approval, we could have long-acting injectables on the market very soon.

"For many, many years while the studies were being slowly recruited, it was always talked about 'into the future, into the future,' but now the future is pretty close," said Hardy. "I think the good news is that the reality of patients being able to access injectable antiretrovirals outside of the clinical trials is going to be probably within the next year or so, by the end of 2019 I would say."

But is it for everyone? Will patients really choose an injection over pills?

"I think it depends on the patient," said Thanes Vanig, MD, a longtime HIV provider based in Phoenix.

"A few years ago when I talked to patients, they were excited. But now when I talk to them again—I think you have to differentiate between people who have been on HIV medications for like 20–25 years—they are actually excited. I think they have pill fatigue. They don't want to take pills anymore. I think for younger generations, one pill is just so easy to take. Most of my patients are MSM [men who have sex with men] [and working professionals]. If they travel a lot, it might be a hassle for them to come in for an injection."

"It probably is not going to be an option for everyone," said **Daniel Lee, MD**, Clinical Professor of Medicine at U.C. San Diego's Owen Clinic. "I think there are certain challenges certainly with the injectable. First of all, the downsides with injectable medications may include possible side effects—if it's a longer-acting medication, then theoretically the side effects last the length of however long the injection is."

There's also a lead-in phase before patients can start the injectable regimen. "In terms of even getting people on the long-acting," said Lee, "my understanding is that the plan is to first put people on the same medication, but in oral form to make sure that they tolerate it. This lead-in period will probably last a month or several weeks before they get switched over to the long-acting injection, just to document that there's tolerability and that there are no side effects. These can be barriers to people who aren't even adherent during the initial oral phase."

While the idea of receiving injectable treatment once every one or two months sounds like it would be easy, there could be issues for some. The cabotegravir/rilpivirine long-acting injectable would actually be two large injections, and there might be issues with storage since the medications come in big boxes which may need to be refrigerated, according to Vanig.

"Actually, when I tell patients it's not one shot—that it's actually two large injections—they're like, 'Oh my god.' It reminds them of Bicillin for syphilis," said Vanig.

And what about long-acting injectable PrEP for prevention?

"The analogy I make is to contraceptives," said Baeten. "A woman seeking contraception can walk into her doctor's office and would be presented with a number of options—there's a pill she can take every day, or a shot she can take every few months, or maybe an implant that will last for a long time. Each option has its pluses and minuses, and side effects. Some people don't want something that's inside them for a long time, while other people won't mind. Each person has to decide for themselves which pluses and minuses will make the most sense for them," he explained.

Will injectables solve adherence issues?

"The other side of the coin is that even if a person is on a longer-acting medication, how adherent are they going to be?" Lee asked. "All of a sudden they're just getting an injection every now and then—will that lead to more non-adherence? I think these are questions that we don't know the answers to. The nice thing about seeing people so regularly, whether it's every several months or so, is that we can infer that things are okay. I wonder if the longer-acting medications will affect people's adherence. Will they forget that they have HIV? That may lead to other issues down the line."

"But ultimately I think it's a great option for a lot of people who have pill fatigue. I think that's kind of huge for people who have been HIV positive a long time," he added.

"Just because it's a shot doesn't mean that adherence problems are solved. That's really important," said Baeten. "To be effective long-term, either as treatment or prevention, means getting that shot, and getting it again and again. That means either the shot has to be patient-friendly, or the location where they get the shot—the clinic, the pharmacy—has to be patient-friendly, too. Otherwise, you're not going to solve some of the really big adherence challenges, which are getting back to a clinic, *wanting* to go back and getting a refill."

Making injectable therapy patient-friendly is exactly what Hardy has in mind. "What could be set up—as national pharmacy chains have done in the U.S., like CVS or Walgreens—is that as long as someone has a prescription in the pharmacy, they could actually go to whatever pharmacy around the country to get their injection," said Hardy. Being able to get an injection at any pharmacy in the country may not immediately solve adherence issues, but could make adherence much easier.

"I think one of the lessons we've learned in HIV therapy since 1996 is that adherence is everything. If you don't take the meds, you don't become undetectable," said Hardy. "Having worked in a center here in D.C. where most of

it would be easy, **there could be issues for some**.

our patients are undetectable, but about 20 percent are not, that 20 percent is a real challenge. If the responsibility for prescribing, obtaining, and injecting the medication is put on the health care practitioner and taken away from the patient, that would probably work a hell of a lot better."

Hardy further explained, "Because [for] health care practitioners, that's their business, that's what they're trained to do. Patients in many situations are not trained to take pills. Many people don't like taking pills. People don't like remembering taking pills every day. If all you had to do was show up at a clinic, or even a pharmacy, once every two months, walk into a private room, drop your pants, get two shots, walk out, that would make being HIV positive a whole different story. I think that that could really revolutionize the way therapy is given."

Are injectables something that patients could eventually administer themselves at home?

"Well that's certainly the hope," said Lee. "I trust that our pharmaceutical companies will be working on a formulation that can be administered by patients on their own. I think that's the next Holy Grail, developing an injectable medication that can be of lower volume to inject and can be something that may be self-administered. It takes time to develop that type of formulation, but I think it's certainly feasible. We seem to continue to move forward, so I have good hope".

"The [current] volume of the injections are either 2 mLs or 3 mLs. One mL is about a teaspoon, so the 2 mL is quite a bit of substance, so trying to inject that much into one's own buttock can be problematic," explained Hardy. "Although people have done intramuscular injections on an ongoing basis before, for example, back in the bad old days when we had to use a lot of testosterone to keep people from wasting, a lot of men injected their own testosterone at home, or had a friend do it. This could be done at home, but I think it's going to have to be something that's going to have to be very carefully managed."

What about the forgiveness window in between when one shot runs out and you need the next one?

"It's not known yet—neither for treatment nor prevention, because the drugs are still in research studies to figure it out," said Baeten. "Defining that is going to be critical. You need to know what your forgiveness window is going to be. That takes time to figure out, and will be figured out."

This may include going back to daily pills if a patient can't get to the clinic for their next shot.

Long-acting injectables do appear very promising for HIV treatment and prevention. As Baeten points out, just having additional options would be welcome.

Not only would long-acting injectables be a new option that could address pill fatigue, they could also help reduce stigma because people living with HIV would not have to carry around pill bottles and could discreetly get their shots once every two months.

IMPLANTABLES

Implantables with long-acting HIV medications are another emerging option for treatment and prevention. Although the research is not nearly as far along as long-acting injectables, implantables could offer another long-acting option for people who don't want to take pills every day.

"There's some really cool research being done on implants of various types using different medications and slightly different ways of making the implants," said Baeten. "There are implants that are put in and removed. There are implants that people are working on that might be dissolvable. These are all very, very early studies right now—most are before human studies—but they all suggest that this could be workable. So, that makes me really excited. There's a segment of people out there for whom an implant would be just the ticket."

However, with implantables, especially if they cannot be removed or are difficult to remove, side effects could be a worry.

"We have implantables for things like testosterone. For HIV, it does become a challenge in terms of possible side effects. I think with any kind of implant, it probably would be similar to the injectable in the sense that there may need to be a trial period with the medications involved before you implant it, to make sure that there are no tolerability issues," said Lee.

What would an implantable look like in practice?

Lee points to current testosterone implants as an example. The implant would go right under the skin, maybe in the buttocks. The implant looks like a little matchstick and is designed for slow release.

"But the issue with an implant is that you have to remove it, to be replaced by the next implant," said Lee. "What I don't know with implantable agents is how many would need to be inserted, and if you take the implant out, my guess is that

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Thanes Vanig, MD
HIV PROVIDER, PHOENIX

Like long-acting injectables,

Daniel Lee, MD
CLINICAL PROFESSOR OF MEDICINE, UNIVERSITY OF CALIFORNIA SAN DIEGO, OWEN CLINIC

Mitchell Warren
EXECUTIVE DIRECTOR, AVAC

you can't just put the new one in the same location. You probably need that area to heal, so you would need to put it in, let's say, the other buttock. The chance of scarring or infection might be a little higher. But implants can also be removed if there are side effects, so I think that makes implants perhaps a little better than injectable agents."

Another wrinkle for implantables is who would do the implanting. It's not exactly something patients could do at home themselves. Lee notes that either a surgeon or specialist could place the implant, or HIV providers would need training to do so.

Like long-acting injectables, long-acting implantables could greatly reduce stigma and further normalize living with HIV.

■ DAPIVIRINE RING

Next we have a vaginal ring for HIV prevention. Results from the HOPE study showed that when a ring was used most of or all the time, HIV risk reduction was at least 56%. "The dapivirine ring is a PrEP agent, so it's PrEP that happens to be delivered in a topical way," explains Baeten. "It's delivered in the mucosa rather than being delivered in a shot. It's not an implant because it's easily taken in and out, so it doesn't live permanently inside the body. It acts as a microbicide because its major action is right at the site, that mucosal site. It prevents HIV in the same way these other things prevent HIV, by blocking the virus right at the beginning where it would infect somebody."

"The only PrEP products that have shown that they can reduce HIV so far are the Truvada [emtricitabine/tenofovir disoproxil fumarate] pill and the dapivirine ring. Everything else is in the testing phase. The first out of the barn was the pill, then the dapivirine ring. The dapivirine ring has shown that it does work; it reduces HIV. Right now, it's in the process of being evaluated by regulatory authorities, to validate that the data are right and that the product is effective so it can become part of the armamentarium," said Baeten.

Why is the dapivirine ring exciting?

"I'm super excited about all of these options for PrEP and I am particularly excited about the ring because I think it fills a prevention need that hasn't been filled yet. It is private, it's easy to use; it's also easy to stop. It's incredibly, incredibly safe. And incredibly safe is really important, particularly for women. The ring releases a lot of drug in the vagina where the HIV would come into contact—but it releases only a very small amount of drug into the body. Because of that, it is incredibly safe," said Baeten.

The ring could also be safe if a woman were to become pregnant. "Many women think about drug exposure to an infant. The dapivirine ring could be a great option for a woman who wants something private that she can control," said Baeten.

■ VACCINES

"Vaccines are the great hope of HIV, of course," said Baeten. "There are some really interesting vaccines being tested right now that everyone has their fingers crossed for, because they will point the way to what might become an effective HIV vaccine. The science going into vaccines is top notch; if there's potential to develop an HIV vaccine, the things being developed right now have done all the right things to where we hope to find something that reduces HIV."

What would an effective vaccine look like?

"A lot of people who work on vaccines have come to realize that developing a vaccine is going to be really hard, and if a vaccine is found, it's not going to be a perfect 100% protective vaccine. I think everybody would be thrilled if they found a vaccine that reduced HIV risk by 50%. That is going to require really reframing and rethinking how we see a vaccine. Because when most people think of a vaccine, they imagine it working 99–100%. Something that works 50% is different—especially something that works 50% that might also require three, four, five shots to get up to fully working—which is what all the HIV vaccines being tested now require," said Baeten.

One candidate that is in Phase 2b research is the Ad26 vaccine. The study, called APPROACH, shows a lot of promise in human participants. Another vaccine candidate currently in an efficacy study is a modification of the ALVAC vaccine. This was the first vaccine candidate to show moderate efficacy back in the landmark RV144 study in 2009.

"Results are still three to four years away for both, and the path to licensure is not entirely clear, but it is quite promising to have these two approaches in simultaneous late-stage trials," said **Mitchell Warren**, executive director of AVAC, a global HIV prevention advocacy and policy network. "In addition, there are a number of next-generation candidates in earlier stages of development."

Could a vaccine lead to a cure?

"I do think the cure will be in the form of a vaccine, in terms of getting the immune system involved in taking care of the virus itself," said Lee. "I

long-acting implantables could greatly **reduce stigma and further normalize living with HIV.**

don't think that it's going to be a medication because obviously with pills and with medications, you can't get the medication to reach everywhere. We always end up with toxicity as a result. The immune system is the only thing that can get everywhere. So, I think that the cure is going to have to come from a vaccine of some sort."

■ ANTIBODIES

Perhaps the area of prevention science that has evolved the quickest is in broadly neutralizing antibodies (bNabs). "While we have a few vaccine candidates and a few antiretrovirals for prevention, we have dozens of newly discovered antibodies," said Warren.

"The VRC01 antibody is currently in large efficacy trials—using an infusion every two months. While infusion is not a viable public health strategy, the trials are proof of concept to see if the antibody can reduce the risk of transmission. If it can, the field is primed to focus on three priority next steps—how to manufacture antibodies so they can be injected, not infused; how to increase durability so the injections could move to every six or 12 months, as opposed to every two months; and which antibodies to combine, as it is now increasingly clear that we would need two to three antibodies, just as antiretroviral therapy requires a combination," Warren explained.

What about antibodies for treatment?

We do have one monoclonal antibody already approved for HIV treatment. Trogarzo (ibalizumab) is a new medication for people who are highly resistant to current antiretroviral therapy.

It's a great new option for patients who need salvage therapy," said Lee. "However, Trogarzo needs to be administered every two weeks via intravenous infusion. At the same time, patients would still need to take pills every day.

"I just wrote my first prescription a few days ago. It's relatively new in terms of I haven't had that experience yet. Some of the challenges are that it requires an infusion and space to do the infusion, so we are in the process of trying to figure out if a nurse can go out to the patient, but then there are also issues of [insurance] coverage."

Infusion requires a registered nurse to administer, which means having enough training to do the procedure. Infusion also requires dedicated space for an IV to be inserted and run for at least 30 minutes. This can be an issue, especially in smaller clinics or clinics with a lack of space.

"However, the studies do suggest that Trogarzo is quite good for people who need it, and we have a few people in our clinic that do require it—for whom many if not all of the currently available HIV medications have failed," said Lee. "And while it's not meant for monotherapy [it's used in combination with other active or partially active agents], the results look very good. So, I think we feel that it will actually get people to be better controlled and for some people it can certainly get them to be undetectable. But I'm looking forward to having a bit more experience with it."

Could future antibodies be a first-line option? Would people want to do infusions instead of taking pills?

"That's an interesting question," said Lee. "I think that for first-line treatment, it may be a bit early just because it requires an infusion. I'm not sure we're quite there yet. There are additional costs that come with infusions that make it more complicated in terms of getting the guidelines to recommend an infusion up front. I think the only way that that changes is if these monoclonal antibodies somehow can change the course of HIV infection by doing it early up front."

■ RECTAL DOUCHE

Another option that may be useful is a rectal PrEP douche, which could be used as an on-demand product. For those who may already use an anal douche for cleansing before sex, one that also contains a PrEP agent could also help protect against HIV.

"Right ahead of sex, either a few hours or a few moments before, because sex isn't always planned and some people don't want to think about a prevention option otherwise. They don't want to think about it every day or they don't want to make clinic appointments, but they want something that's right there when they need it," said Baeten.

Research for this is still at a very early stage, but could offer yet another option.

Similarly, another option could be a PrEP that's inserted anally or vaginally to immediately release HIV meds.

"That is the next frontier as well. And there's some really good science that's just moving into people that's testing those options as well. And I think that also fills a big need," said Baeten.

■ TWO-DRUG REGIMENS

Perhaps a hidden-in-plain-sight option of the future that's already here are two-drug regimens. Three-drug regimens have been the gold standard of HIV treatment for decades now. And for the past decade, a single-tablet regimen containing three drugs has been the norm. But could two drugs be better than three?

Juluca (dolutegravir/rilpivirine) is a two-drug HIV regimen approved for maintenance therapy. That means that once a person has achieved an undetectable viral load using a three-drug regimen, they can switch to Juluca. The idea is that if you can maintain an undetectable viral load with a two-drug regimen, you could theoretically reduce the cost of drugs and maybe reduce potential toxicities.

Dolutegravir/lamivudine (DTG/3TC) is another two-drug regimen that's being studied for HIV treatment. In two Phase 3 studies, DTG/3TC was found to be non-inferior to a standard three-drug regimen. The single-tablet, two-drug regimen was submitted to the FDA for approval in October 2018.

The aforementioned cabotegravir/rilpivirine injectable regimen will also be a two-drug regimen, so perhaps two-drug regimens will be the new norm in the future.

■ CONCLUSION

As you can see, there are many new emerging options for HIV treatment and prevention. Some are a lot closer to being approved than others, but all have potential to provide more options for everybody. For many, long-acting injectable therapy may be the welcome change they've been waiting for. For others, a long-acting implantable may be more appealing. And for others still, taking pills may continue to be what works best for them. Until there's a cure or vaccine, we continue to fight HIV in as many ways as possible. PA

WARREN TONG is a freelance health and science journalist, with an extensive background writing about HIV and hepatitis C.

THE CUTTING EDGE

Innovations in prevention and care can be found anywhere—
Michelle Simek highlights three examples

When you think of edgy HIV/AIDS programs that are tapped into current culture and trends, you may tend to think first of programs in large, coastal cities such as Los Angeles, New York, San Francisco, or Washington, D.C.—perhaps even Seattle; Portland, Maine; or Boston. But innovative work in HIV prevention and treatment interventions is happening in the Midwest and the South, too.

HOTTER IN CHICAGO

'It was magical to see them bond with each other.'


Ashley Martel
TPAN

TEST POSITIVE AWARE NETWORK (TPAN) is a Chicago-based AIDS service organization (ASO) that has been around since 1987 (and is the publisher of POSITIVELY AWARE). TPAN used to be known as an agency that served mostly gay, white men, but as the epidemic has changed, so has the agency's clientele. Always trying to stay one step ahead, TPAN applied for and received a sizable five-year grant from the Substance Abuse and Mental Health Services Administration (SAMHSA) for a program tailored to young, African American men who have sex with men (MSM). The program, called Healthy Outcomes Through Treatment Empowerment and Recovery (HOTTER), was so successful that the funding was extended for an additional year, and HOTTER was asked to share their best practices and lessons learned at the national SAMHSA conference.

Instead of using the typical approach to HIV prevention, TPAN chose to be strategic. They spoke with community members, listened to their suggestions and incorporated their ideas into the proposal. "We put a lot of thought into this grant proposal," says Julie Supple, TPAN's Director of Client Services. "We looked at what worked and what didn't. We had to be different." The staff also thought very carefully about exactly when to introduce HIV/AIDS into the curriculum, because "we didn't want to make it all about HIV, especially when we work at an ASO." They decided on a holistic approach to HIV prevention, an idea which resonated with the community. The young people said they wanted to hear about much more than just HIV.

TPAN hired culturally appropriate staff to recruit for the program and were very successful in using social media apps to reach the community, as "app outreach is kind of an art." They created a "special, safe place for clients" at TPAN and brought together 15–20 young MSM of color for two to three weeks. These groups were a mixture of HIV-positive and HIV-negative men between the ages of 18 and 29. They received counseling that addressed HIV, hep C, substance abuse, and behavioral health issues.

These intimate discussions brought clients together. They became very close; participants stayed committed and engaged—a testament to the program as TPAN is located on the North Side of Chicago and most of the clients (approximately 80%) came from the South or West sides. And many participants were unstably housed, meaning couch crashing, living on the street, or anywhere in between. To meet client needs, HOTTER staff worked in a consciously "flexible, client-centered team environment." Since some of the clients traveled more than two hours to get to TPAN, this flexibility was crucial. Even mental health therapists would accommodate a late client and make sure that they received a full session.

Once the groups ended, participants were treated to a weekend retreat at a hotel in Chicago—a unique experience that culminated with a special dinner and graduation ceremony. It was during these retreats that HIV diagnoses were discussed.

According to Ashley Martell, HOTTER Program Manager, the clients would "share their status openly when we got to the retreat." And all would leave the retreats forever changed for the better. "It was magical to see them bond with each other."

Most graduates would access the supportive drop-in space TPAN created just for them, The Tea Room, and attend post-graduation events. And while "every retreat was structured in the same way, each one was unique. We brought topics to the table but it was the clients who

molded the experience for themselves." Every session would have topics such as "stigma, race, LGBTQ issues, PTSD, substance use, barriers, and HIV, but it was different every time."

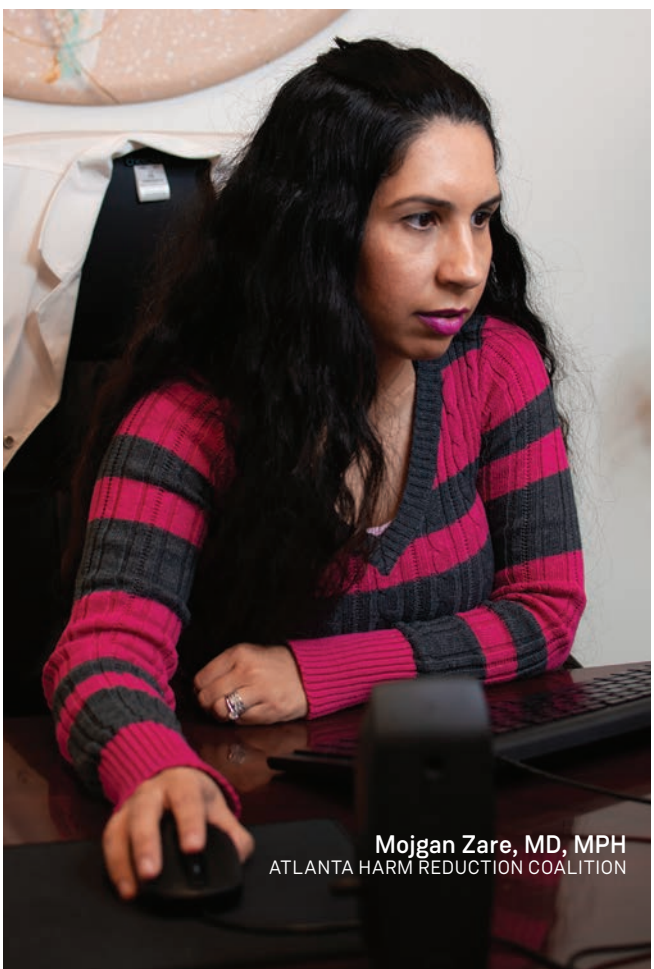
While HOTTER ended in September of last year, its impact continues. In six years, the program worked with 35 groups, each containing 15–20 young men. Program evaluators found that after graduation, participants reported less substance use and less sexual risk-taking. Fortunately, TPAN received another SAMHSA grant that started in October 2018, which will have a similar scope and reach out to similar populations. And through The Tea Room, TPAN is now serving even more youth, with laundry facilities, food, and a computer center.

One former HOTTER client, Pierre James Little, graduated from the program in 2013, but stays connected to TPAN through case management services and a support group. "HOTTER did a lot for me," Pierre said. "I just love the staff at TPAN—ya'll support me through it all, keep me uplifted, make sure I am always on my feet, and have always helped me make sure I am on my meds and have the right doc. I met others in the program and now have actual meaningful support and friendships—like true friendships that have lasted through and through. When the support group started it really helped me stay linked with other graduates and friends in a way that was easier. The group was a fun place to hang out and talk—the most meaningful thing I got out of it was learning how to disclose my HIV status and feel comfortable and confident in that. Overall, HOTTER helped motivate me to become a better Pierre."

SYRINGE EXCHANGE IN THE DEEP SOUTH

'This is true public health—a bunch of folks coming together to hold hands and help the community.'

ATLANTA IS HOME to the Centers for Disease Control and Prevention (CDC), has hosted the Olympics, and is the title and subject of a top-rated TV show. It is also firmly in the Bible Belt and contains over 1,000 places of worship. Atlanta has the dubious honor of having the fifth-highest rate of new HIV infections of any city in the country, and Georgia has the highest rate of any U.S. state. The city is also home to the Atlanta Harm Reduction Coalition (AHRC), a grassroots harm reduction agency that passes out clean syringes, bread, coffee, condoms, hygiene kits, knowledge, and support to people who inject drugs (PWIDs). It is currently the only syringe exchange program in the entire state of Georgia. Since syringe exchange is illegal in Georgia, AHRC is truly intriguing.



Mojgan Zare, MD, MPH
ATLANTA HARM REDUCTION COALITION

MARTEL: JOHN GRESS; ZARE: JOHNNIE RAY KORNEGAY III

The coalition was founded in 1994 by a group of concerned citizens (professors at Emory University, public health workers, and students) who were seeing PWIDs from Atlanta die from HIV/AIDS at alarming rates. This was happening most particularly in The Bluff (also known as English Avenue) in Central Atlanta, which was (and still is) a hub for street drug activity and crime. Those concerned citizens banded together to start AHRC and distributed clean needles. In 1994, Georgia law stated that only medical doctors and pharmacists could dispense syringes (this same law is still in effect today). If you distributed clean needles and were not licensed, you could be charged with a crime.

The original AHRC activists said "forget the law, let's save lives" as they went ahead and did something radical. Instead of expecting the injection community to come to them, they went to The Bluff. And very slowly, little by little, person by person, they built trust in a marginalized community that has very little trust to give.

Public health wonks agree: syringe exchange helps prevent HIV, hep C, and bacterial infections. Executive Director Mojgan Zare, MD, MPH, says that AHRC helps substance users get plugged in. "They get treatment if they want to as well as access to prevention intervention tools to protect themselves from acquiring HIV and hep C." The program has two vans and is out in the community every Monday, Wednesday, and Sunday, no matter the weather. AHRC passes out clean syringes, coffee, water, and snacks. For those who are interested, the agency also distributes Narcan (a medication that acts against opioids and is used to reverse potentially lethal overdoses), and teaches the community how to administer it safely and correctly.

Dr. Zare says that AHRC started as a collaborative effort and remains so to this day. "It's not just the agency's work that makes my heart smile," she says. "People from Washington State and Illinois are involved. Panera Bread donates. Regular folk from other parts of Georgia bring in coats and hygiene kits" for clients. "This is true public health—a bunch of folks coming together to hold hands and help the community. Not just one person, but the entire community."

Even the local police department is supportive of AHRC. "The cops come and

protect the needle exchange, even though it is against the law," she said. An Atlanta police officer was quoted by a local reporter on camera as saying, "They are here to help the community so I'm here to help, too." In addition to police, clients volunteer to help keep the other clients in line. Fighting or other disruptions rarely happen during needle exchange hours.

Dr. Zare sums it up: "We are not there to collect data. We are not there to push them into services. We are there to have a human connection with them."

PEER EDUCATION FOR TEXAS INMATES

'Each person educated is one more person better equipped to live a healthier life.'

Nike Blue
AIDS FOUNDATION HOUSTON

AIDS FOUNDATION HOUSTON, Inc. (AFH) was founded in 1982, and was the first ASO in Texas. In 2018, the city of Houston ranked 11th in the U.S. for new HIV infections. And approximately 26% receive an AIDS diagnosis at the same time they test positive for HIV. This means they received a late diagnosis and their immune systems may have already been damaged before the virus was detected. According to Nike Blue, the Chief Program Officer of AFH, this is due to the lack of access to medical care that plagues the state and region. And linkage to medical care is one of many programs that AFH offers, in addition to a food bank, a camp for children who are HIV-positive, and education on PrEP (a medication that prevents HIV infection).

AFH takes Houston's high HIV infection rate very seriously and knows that HIV is very present in incarcerated communities. In 1999, AFH started an innovative prevention program in the Texas prison system called The Wall Talk Peer Education Program. "We started the program within four prison units and have since expanded to 100 of the 114 Texas Department of Criminal Justice (TDCJ) units," says Blue. "We have also added additional curricula to support other needs within the prison system," thanks to feedback from inmates.

The goal of The Wall Talk is to "teach peer-based educational classes, thus increasing knowledge, prevention, and treatment for HIV and other chronic illnesses within the prison population." The program begins with training inmates to become peer educators. Once trained, the peer educators use The Wall Talk curriculum to educate other inmates. The program consists of six sections that include (but are not limited to) HIV prevention, treatment adherence, life skills, discharge planning, STI education, prison rape elimination, and information specifically for female inmates, including health and pregnancy.

The training uses traditional teaching, extensive role-play exercises, and other methods to help peer educators refine their skills and gain confidence in delivering critical HIV prevention messages. The groups are kept small so that each peer educator has an opportunity to practice their communication skills with each other and also learn current and relevant information about HIV/AIDS.

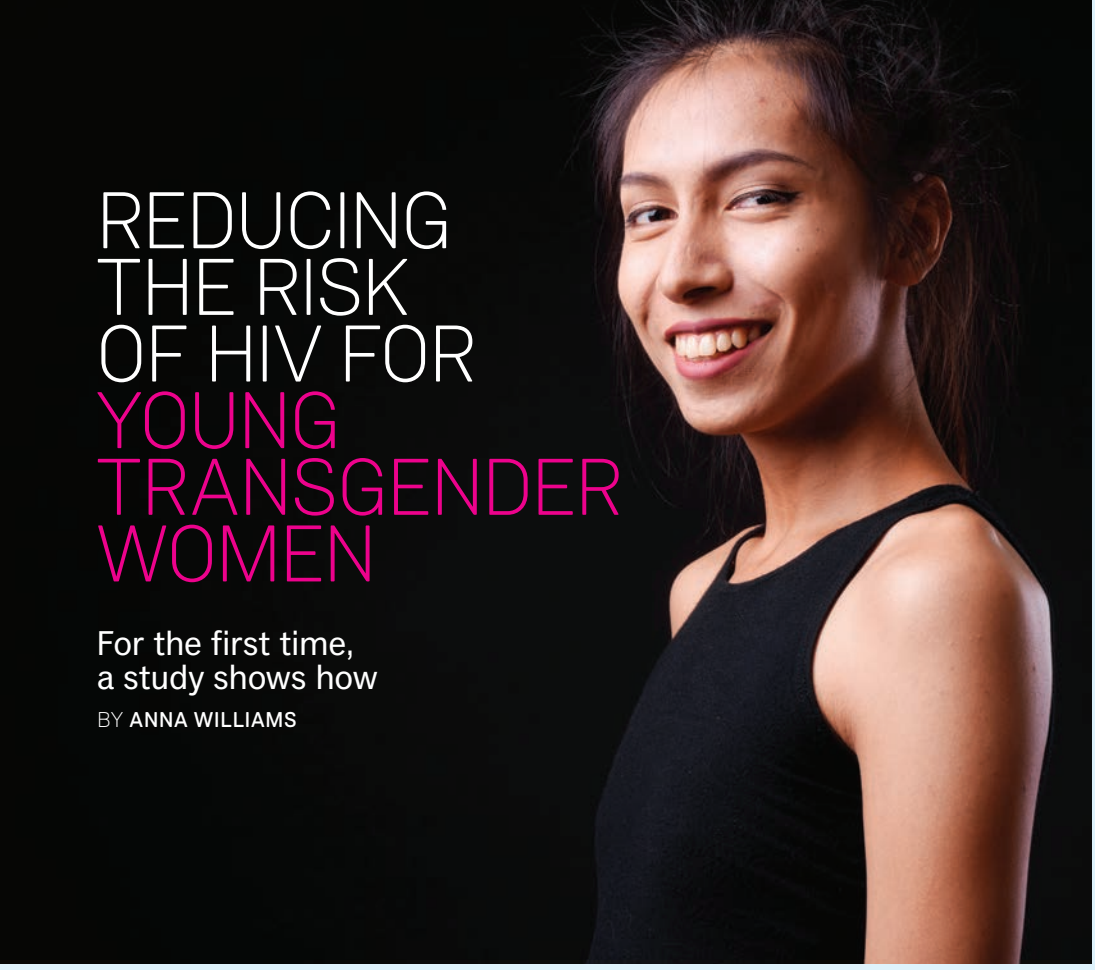
Nike defines programmatic success by the number of new peer educators and students taught annually. "For every peer educator trained, that represents an incarcerated person, though serving a prison sentence, has made the conscious decision to be a positive role model for others and correct misinformation about HIV and STIs across the prison system. Each person educated is one more person better equipped to live a healthier life." One peer educator (who chose to remain anonymous) said, "I'm serving a life sentence, so I'm never gonna get out of here. This gave me a chance to give back—help some of these young cats make better decisions for themselves and their families."

To date, The Wall Talk curriculum has reached 80,000 prisoners within TDCJ. "80,000 sounds like a large number, but we have much more work to do," says Nike. "Every year TDCJ houses about 146,000 inmates. Of those, 70,000 are released, and 70,000 more are incarcerated. And 95% of all of them will be released and return to the community at some point...so education, rehabilitation, and prevention are extremely important if we are going to make a difference when it comes to ending new HIV transmissions, increasing HIV viral suppression, and ending the stigma and discrimination that oftentimes exacerbates HIV within communities."

New York and Los Angeles may get a lot of attention when it comes to HIV/AIDS. But Chicago, Atlanta, and Houston have proven that innovation does not only come from the right or left coasts. Innovation can come from anywhere. And each of these special programs has one thing in common—they all began by connecting with community. PA

MICHELLE SIMEK works at an HIV/AIDS clinic in Los Angeles, California. In 2006, she was honored with the annual Social Service Provider of the Year Award by the Los Angeles Women's HIV/AIDS Task Force, and currently serves on its executive board. She is also an actor and writer. In her spare time, she goes to see live music, reads voraciously, and pets her cat, Baxter.

PHOTO COURTESY OF NIKE BLUE



REDUCING THE RISK OF HIV FOR YOUNG TRANSGENDER WOMEN

For the first time, a study shows how

BY **ANNA WILLIAMS**

A behavioral intervention program significantly reduced the sexual risk for HIV infection among young transgender women, according to the results of a Northwestern Medicine clinical trial.

The study, published in *JAMA Pediatrics*, is the first to demonstrate the efficacy of an intervention to reduce sexual risk among young transgender women—a population with extremely high HIV infection rates.

"More than 30 years into this epidemic, it is somewhat appalling that to date there has not been an intervention that has been shown to be effective with transwomen, a group at very high risk for acquiring HIV, based largely upon sexual behavior. This study changes that," said first author Robert Garofalo, MD, MPH, chief of Adolescent Medicine in the Department of Pediatrics.

Transgender women's odds of contracting HIV are estimated to be 34 times greater than that of all adults of reproductive age, with research suggesting a particularly high infection rate among younger transgender women.

Still, there has been a lack of evidence-based interventions that focus on reducing sexual risk among this population.

In the current study, investigators evaluated Project LifeSkills, a novel HIV prevention program specifically targeted to young transgender women and led by peers. The group-delivered, empowerment-based curriculum included basic information on HIV but also addressed environmental factors—such as housing, medical care and employment—and promoted behavioral skills, including condom use and communication with sexual partners.

The intervention is grounded in the social realities of the population, Garofalo explained. "It was never an esoteric research project but was driven and directed by the community. Young transwomen were part of every aspect of the study—from study design, to intervention development, to recruitment and study implementation," he said.

The randomized clinical trial of the intervention included 190 sexually active transgender women between the ages of 16 and 29 at community-based sites in Chicago and Boston. Project LifeSkills was delivered in six two-hour sessions over the course of three weeks.

At one-year follow-up, the investigators found that the LifeSkills intervention resulted in a nearly 40 percent reduction in condomless sex among participants, compared to those who received standard care.

"We are so proud that it is the first evidence-based intervention for sexual risk reduction and HIV prevention for transwomen," said Garofalo, also a professor of Pediatrics in the Division of Adolescent Medicine and of Preventive Medicine. "Our hope is that LifeSkills can now be used by agencies all across the country that serve transwomen, and that it can be used in coordination with other prevention strategies like PrEP as part of a more holistic approach to curb the epidemic."

Garofalo notes that the project is the result of more than 15 years of work.

"As investigators, you hope that one day your work can be used practically to help the communities you care about," he said. "For us and for this community this is a landmark moment in that this intervention is practical and one that can now be implemented in places across the U.S. and abroad that are doing HIV prevention work with young transwomen."

Garofalo is also a pediatrician at the Ann & Robert H. Lurie Children's Hospital of Chicago; director of the Gender, Sexuality and HIV Prevention Center; and a member of the Stanley Manne Children's Research Institute.

The study was co-authored by Lisa Kuhns, PhD, MPH, research associate professor of Pediatrics in the Division of Adolescent Medicine, along with investigators from Harvard University and Brown University.

The research was supported by the National Institute of Mental Health of the National Institutes of Health, and in part by the Northwestern University Clinical and Translational Science Institute and the National Center for Advancing Translational Sciences.

ANNA WILLIAMS is a content specialist in the medical school's Office of Communications. She writes news stories about basic science and clinical research, as well as events, education, and faculty news. She holds a bachelor's degree in journalism from New York University. anna.williams@northwestern.edu.

BUILT TO LAST

A leading researcher talks about long-acting medications in development

Instead of having to take HIV medication every day, what if antiretroviral treatment lasted weeks—or even months? David A. Margolis, MD, MPH, is an infectious disease specialist who has spent the last eight years as medical director of HIV drug development at GlaxoSmithKline and ViiV Healthcare, helping to oversee clinical programs from initial human tests through final testing before FDA approval. He is leading ViiV's effort to develop cabotegravir as a long-acting HIV drug. Margolis discusses cabotegravir and other long-term options being considered.

What can you tell us about long-acting antiretrovirals?

There is only one long-acting antiretroviral currently approved for the treatment of HIV, **ibalizumab**, which is indicated for heavily treatment experienced patients with resistant virus. Ibalizumab is an antibody that blocks the attachment of HIV to CD4 cells, and is administered by intravenous infusion every two weeks, in combination with daily oral therapies.

There are currently no completely long-acting regimens approved for HIV treatment.

The two long-acting (LA) drugs that are the most advanced in clinical development are **cabotegravir** (CAB) and **rilpivirine** (RPV) LA. CAB is an HIV integrase inhibitor and RPV is a non-nucleoside reverse transcriptase inhibitor (NNRTI), and both drugs are in development as gluteal intramuscular injections, which can be administered every month or every other month as a two-drug regimen. There are currently three ongoing Phase 3 clinical trials evaluating the safety and efficacy of this injectable regimen. Two compare the long acting regimen to standard oral therapy and the other directly compares monthly to every other month dosing. Neither CAB LA or RPV LA is approved for use at this time.

Other long-acting drugs with novel mechanisms of action in targeting HIV are in very early clinical development and will not be available for several years, if proven successful.

Why do we need LA ART?

The current treatment of HIV requires life-long adherence to a combination of oral medications. While the available treatments for HIV are very effective at controlling viral replication, several challenges remain for patients living with HIV. Three areas where patients may benefit from an LA ART (antiretroviral therapy) option are with medication adherence, freedom from pill taking and a more discreet dosing option.

Effective HIV treatment requires continual drug levels to prevent HIV replication, necessitating strict adherence to medicines. Some patients have difficulty taking daily medications and a less frequent dosing option may improve overall adherence, and treatment outcomes. In patients who already maintain good overall compliance with pills, there may be a desire to reduce the number of pills taken on a daily basis.

Additionally, having a pill bottle or bottles with HIV medication may make it harder to maintain privacy around an HIV diagnosis. By shifting dosing of HIV medicines from the patient's home to the health care provider's office, some patients may feel that they have greater control over their diagnosis, and from unwanted disclosures. The

more frequent interactions with the health care team to receive LA ART does come with a greater time commitment from the patient, but could also have advantages in re-enforcing linkage and retention in care.

Ultimately, the goal for HIV treatment is to provide patients with as many safe and effective options as possible, allowing for people living with HIV to choose the option that will work best for their lives, while protecting their health over time.

What have we learned about how people feel about using LA ART? Are long-acting agents used for treating other conditions?

Until now, LA ART has been a theoretical concept for patients living with HIV. There have been a number of surveys looking at the preferences of patients for various treatment options. One recent survey by Weld and colleagues evaluated interest in long-acting antiretrovirals in 303 young people (13–24 years old) living with HIV in the U.S. This survey showed that 88% of these patients reported a probable or definite willingness to use LA ART. Other studies have shown a similar level of interest in injectable dosing options for HIV, including once-monthly dosing.

The largest experience we have to date in patients actually taking LA ART comes from the Phase 2b LATTE-2 study, which evaluated every 4 week or every 8 week dosing with CAB + RPV LA, compared to once daily oral dosing in 286 individuals with suppressed HIV virus (HIV-1 RNA VL <50 c/ml). Preference data from this trial through both 48 and 96 weeks showed a high level of satisfaction with LA therapy and a high percentage of the study participants stated a desire to continue with LA dosing beyond week 96. LATTE-2 was the precursor study to the ongoing Phase 3 trials with CAB + RPV LA.

Long-acting therapies have been used successfully in other therapeutic areas. One notable area is hormonal contraception, where various forms of long-acting contraceptive agents (injectables, implants, IUDs) provide a wide array of options for women seeking to prevent or delay pregnancy. Additionally, there are a number of long-acting antipsychotic medications which have proven beneficial for the treatment of mental health disorders.

How will injections be administered if CAB/RPV-LA is approved?

Cabotegravir and rilpivirine are administered as gluteal intramuscular injections, at separate injection sites. The ATLAS and FLAIR Phase 3 studies are evaluating once-monthly CAB + RPV LA dosing. A third Phase 3 study, ATLAS-2M, is being conducted to evaluate an every two month dosing option, when compared to monthly dosing.

Do you believe there is a sweet spot for frequency of dose?

There will likely be several factors a patient will need to consider when deciding to initiate LA ART therapy. The largest difference for them will be trading away pharmacy prescriptions for more frequent visits to their health care provider to receive injections. For patients who are interested in moving off of daily oral therapy, the frequency of these visits, and their ability and flexibility to set a routine around monthly or every other month clinic visits, may define their level of interest. Most of the patient survey data on LA ART to date suggests that injections administered at least monthly would reach that threshold where patients would consider initiating an LA ART regimen.

What has surprised or excited you the most when doing your research on LA ART?

The most meaningful area of this research for me has been learning about the persistent struggles and challenges that people living with HIV bear, even in the age of highly effective oral treatment options. One area where LA ART has the potential to impact patient lives is in providing them a sense of freedom from their daily reminder of HIV that can come with pill taking. LA ART could also increase options for maintaining greater discretion over their diagnosis and may allow patients to travel more freely, without having to carry or refill prescriptions. Providers will be able to consider some of these additional challenges that patients bear in their daily lives, when these may become more evident as different treatment modalities become available.

What other forms of long-acting agents are being looked at other than injectables?

In addition to injectable therapies, there are very early research efforts looking at either dissolvable or non-dissolvable medication implants, similar to those currently being used for hormonal contraception.

What can you tell us about long-acting PrEP?

There is considerable interest in looking for medications to complement daily oral Truvada for use as PrEP (pre-exposure prophylaxis). There is a large body of data supporting the efficacy of Truvada for preventing the acquisition of HIV in men and women who are at risk of acquiring HIV. One of the biggest challenges identified in these trials is the variable adherence to oral medications that was observed, limiting the overall effectiveness of this approach. Long-acting PrEP may overcome some of these hurdles. Intravaginal cervical rings containing dapivirine, an NNRTI, have been evaluated in large Phase 3 trials and continue to be researched in open label extension studies. CAB LA is currently being evaluated as a once every 2 month injection in two large, global Phase 3 trials in men and women to determine the safety and efficacy of this approach, relative to daily oral Truvada, for preventing the acquisition of HIV. Neither dapivirine rings or CAB LA are approved for use as PrEP at this time. PA

DAVID A. MARGOLIS, MD, MPH, is an Infectious Diseases trained physician. He is lead physician for the cabotegravir long-acting clinical development program at ViiV Healthcare. Raised in southern California, he attended Duke University medical school and completed a combined Master's in Public Health at the University of North Carolina, Chapel Hill and an ID fellowship at the University of California, San Diego. He is also medical director of HIV drug development at GSK and ViiV Healthcare, and continues to see patients on a weekly basis as an assistant consulting professor in infectious diseases at Duke University.

ARTEM EGOROV-ISTOCK MARGOLIS: COURTESY OF DAVID MARGOLIS

THE NEXT GENERATION OF LONG-TERM SURVIVORS

A decade after testing positive, **David Durán** reflects on his life with HIV

I awoke that day in 2008 feeling pretty great, knowing that I was going to help my friend out that same morning. The night before he had come to me in a panic about having condomless sex, and worried about possibly being exposed to HIV. During this time in my life, I was volunteering with a local organization that put on the AIDS Walk in the city we were residing in, and I was somewhat well-versed within the HIV world when it came to getting tested regularly and where to go for a test. So, I felt like he had come to the right friend. I remember reassuring him that night, and telling him that no matter what the outcome, everything was going to be okay. I even offered to take the test as well, for moral support, and because I was overdue for a checkup. I was approaching a year of the aftermath of a failed marriage, a year in which I had chosen to stay mostly celibate; therefore, in my mind, my test was more for moral support than an actual necessity.

Driving him to the clinic that morning, I could see the fear in his eyes; he was truly concerned about his potential results. All I could do was continue to reassure him that everything would be all right. After we checked in, they called him in for his test. Thinking back, I can't recall why or how he ended up going first because the point of me being there was to support him, and in hindsight, I should have been the one to head back first. It wasn't long before he emerged from behind a door, with a smile on his face. He was negative, and all his worries had magically disappeared. We then traded places and I walked back to a room with the HIV test counselor. Feeling rather confident, I engaged in small talk while she pricked my finger and proceeded with the rapid test. I was mid-sentence when I looked over at the counselor and heard her clearly say, "Baby, you positive." I don't know if I will ever be able to forget that moment, the sound of her voice or the feeling of having all the air knocked out of me at once. I sat there, silent. She asked if she could bring my friend in, and I nodded yes.

When the door reopened he was standing there, immediately taking over the role of supportive friend, the part I was supposed to play that day. He walked me to my car while consoling me, and then drove me home. The day had not gone exactly how I had imagined it would. I was thankful for my friend's results but completely devastated by mine. Each year on the anniversary of finding out I was HIV-positive I like to look back on that day, and spend time thinking about how

‘Those of us who are newly diagnosed or long-term survivors need to **show the world and ourselves that life goes on**.’

PHOTO: CLARK HARDING

far I’ve come since that moment when I thought my life was over. It’s now been 10 years, and I can hardly recognize the person I was back then.

TWO YEARS WASTED

Looking back, I wasted two years of my life feeling sorry for myself. The internal shame, guilt, and embarrassment were something I held onto. I thankfully formed a small support circle but then closed the doors to the rest of the world. I drank—a lot—and became depressed. I was fired from my job for not working and then I drank some more. This vicious downward spiral continued for months and months, until the day that the fog finally lifted and I was able to come to terms with my diagnosis. When I realized that my life was going to be just fine, as I had reassured my friend about his life that day in the HIV clinic, things finally started to come together. If I could rewrite history from that day, I would take the knowledge and confidence I have now and somehow give it all to my younger self, so that I could have avoided those two years of sadness and loneliness that I had created.

ADVANCES IN TREATMENT

I was fortunate to have been diagnosed in 2009, when the development of highly active anti-retroviral therapy (HAART) had just reached its peak. I was quickly placed on a regimen and within months I was healthy and undetectable. That was it. Life was pretty easy living with HIV. I had some minor issues with finding the right drugs to take at first, but I experienced nothing that was life threatening. I’ve now been taking the same medication for almost seven years, never once having any issues or complications due to my HIV or HIV medication. One pill a day and life goes on. This certainly wasn’t the case in the mid-’80s or ’90s though, as things were very different then, and those who were diagnosed during the first waves of the epidemic and were lucky enough to survive live very different lives from the one that I live. During those times, the advancements in treatment were major breakthroughs, lifesaving to say the least. During my decade of being positive, we’ve gone from a three-in-one single-tablet regimen (STR) to a two-in one STR that does essentially the same thing. Obviously I’m simplifying the significance of drug research and advancement but the reality is, the changes we’ve seen more recently are subtler when it comes to HIV treatment. When it comes to prevention though, we saw the approval of PrEP (pre-exposure prophylaxis), so there’s been a lot we can all be thankful for.

NEXT GENERATION

When is someone considered a long-term survivor? I’d say a decade is a good starting point, so I’m officially categorizing myself a long-term survivor of HIV. Although I can confidently say that I’m in a new generation of long-term survivors, we are the second, third, and fourth wave of survivors living with HIV that came after the initial days of not even knowing what HIV was. We already had all the information out there. We knew the risks, and we were slightly conditioned to feel confident that everything would end up being okay in the end, if that day ever came where we were sitting in a room with an HIV test counselor holding a test strip that just determined we were HIV-positive. For us, things weren’t nearly as scary as for the original survivors, who in my opinion deserve our utmost respect because truly, they survived something most of us can’t even begin to fathom. But as time passes, and years are added to our lives with HIV, fresh groups of newly-diagnosed individuals begin their own personal journeys with HIV. Those new generations of long-term survivors, which include people like me who have primarily been on the same regimen for a decade or more, is expectantly waiting to see what effects these drugs will have on our bodies, but the truth is they are much safer, more tolerable, and easier to take than those earlier regimens.

TO THE FUTURE GENERATION

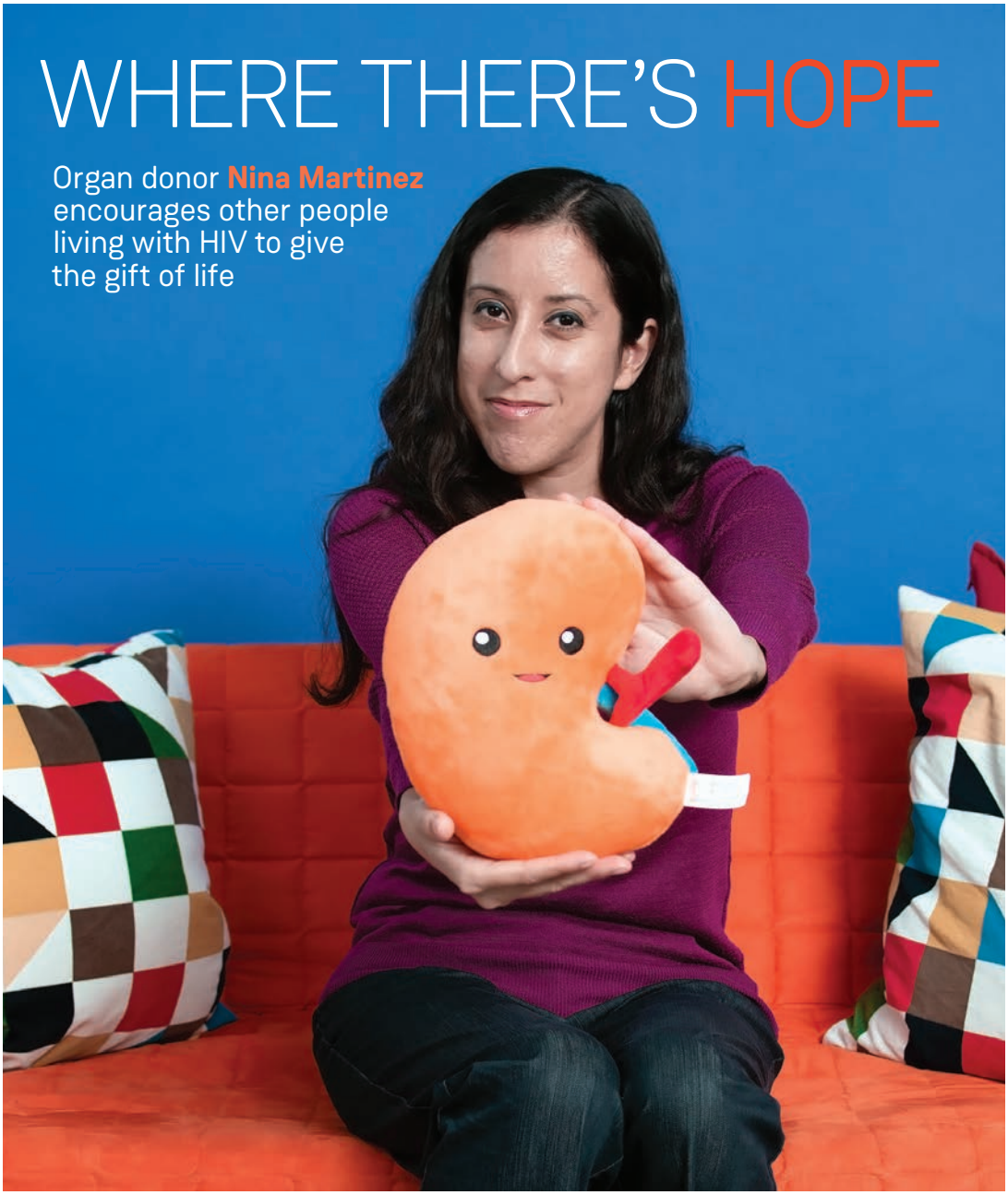
For someone who is newly diagnosed, the good news is, life is most likely going to be just fine. In the 10 years since my diagnosis, nothing has happened to prove otherwise. We’ve come so far from where we once were, that now living with HIV is just like living life, with some slight modifications to your routine. I’ve personally reached a point where my healthcare provider asks to see me only twice a year; he would prefer it be once a year, but my insurance requires at least semi-annual visits. This is how far we’ve come in terms of life with HIV. I always tell people, “your HIV doesn’t define you, it’s just one small piece of what makes you, *you*.”

I would hope that one day, new HIV transmission rates will drastically drop, helping to finally put an end to the virus, but this isn’t possible until everyone is informed and aware about HIV. Those of us who are newly diagnosed or long-term survivors need to show the world and ourselves that life goes on. We need to be that person our friends can come to with questions. We need to be that friend who offers someone a ride to the clinic. We need to continue to spread the news about preventative options like PrEP and U=U. And finally, we need to stop hating ourselves for having something that we can’t fix or make go away. For me, it’s been 10 years, and I look forward to continuing to look back on my journey...in another decade and beyond. PA

DAVID DURÁN is an HIV advocate and writer who contributes to a number of publications, and is a speaker and presenter at conferences around the world.

WHERE THERE'S HOPE

Organ donor **Nina Martinez** encourages other people living with HIV to give the gift of life



I was not all that enthusiastic in the fall of 2013 when the HIV Organ Policy Equity (HOPE) Act was passed, allowing people living with HIV to donate their organs to other people living with HIV. As a child, I had always been told how lucky I was to be alive—and that was before my HIV diagnosis at age eight. My adolescence after my diagnosis was full of uneasy and uncertain expectations for long-term survival. I had finally made my peace with HIV by the time the HOPE Act became law. But knowing I could make new decisions about what I wanted to happen with my organs when I died threw me back to the existential crisis of my youth.

Six months after the HOPE Act was enacted, fans of the ABC-TV series *Grey's Anatomy* heard Dr. Richard Webber announce, "Dr. Grey is about to do the first HIV-positive to [HIV-] positive kidney transplant in the state since the new law went into effect." Keith, the transplant candidate in this episode, remarks, "You know, it's ironic. I spent years fighting HIV. I get myself to the point where the virus is virtually nonexistent in my body. I survive. And now I die of kidney disease." The season 10 episode ("I'm Winning") follows Keith's very-much alive friend Marty and Marty's donation decision to help Keith; Keith, after all, had been present at the time of Marty's HIV diagnosis. Finally, I saw something in the HOPE Act that gave me, well, *hope*.

There is a lot of truth to what Keith said. People living with HIV have higher rates of kidney failure. This is partly due to the virus—there are several HIV-related kidney diseases—and partly the result of some medications. Older antiretrovirals were more culpable, but newer medications can also cause kidney dysfunction. As people are living longer with HIV thanks to highly active antiretroviral therapy, they are also experiencing more kidney failure related to hypertension, diabetes, and cardiovascular disease—all of which can come with older age. About one year after that *Grey's* episode aired, I learned that my former neighbor, Beth, who is not living with HIV, wanted to (and did) become a living donor. The problem at hand was stark: 20 people, on average, die each day waiting on a life-saving organ transplant.

A person's wait can depend on location, their compatibility with an available organ, whether the organ is properly sized, and many other factors. Of particular note, the mortality rate among kidney transplant candidates living with HIV is nearly twice that reported for candidates not living with HIV. There are many ethical issues surrounding the ranking of waitlist candidates, and the length of the waitlist disproportionately affects many vulnerable populations. While HIV status does not give a transplant candidate priority status, the HOPE Act increases equity on the waitlist by providing a donor pool specifically for people living with HIV.

Knowing the importance of living donation, I was hooked on the

PHOTO: JOHNNIE RAY KORNEGAY III

idea that I could become a living kidney donor. I had conversations in late 2015 with several Atlanta physicians about the feasibility of people living with HIV becoming living donors. These conversations largely went nowhere since it had taken two years following passage of the HOPE Act to develop the research guidance that would carefully oversee HIV-to-HIV transplantation. Meanwhile, I registered as an organ donor (also called “deceased organ donor”) in January 2016.

Two months later, researchers at Johns Hopkins performed the first liver and kidney HIV-to-HIV transplants. An HIV-positive donor, who made her end-of-life donation decision known to her family, saved two lives that day. As of October 2018, more than 80 donor transplants have been performed under HOPE protocols at 15 transplant centers. The next milestone in HIV-to-HIV transplantation is to demonstrate the safety of living donation now that we know deceased donor HIV-positive kidneys are safe for people living with HIV.

“Until recently, I thought organ donation was a crime because of my HIV-positive status,” says Carrie Foote, Associate Professor of Sociology and Director of Graduate Studies at Indiana University-Purdue University, and Chair of the HIV Modernization Movement-Indiana (HMM). “Learning it was not, I registered. While more organ donations are possible because of the HOPE Act, at least eight states have antiquated laws that prohibit people living with HIV from both deceased and living donation. Regardless, most people living with HIV are unaware they can be organ donors, especially that they can be living donors. It’s time to end such laws and remove related barriers to organ donation, so that people living with HIV can give the ‘gift of life.’”

A person’s risk of kidney failure varies based on age, sex, race, history of high blood pressure, diabetes, and heart disease. The risk of kidney failure attributable to HIV is a reasonable one for someone living with well-controlled HIV. HIV is thus similar in this regard to other risk factors considered acceptable for living donors, such as smoking.

All living donors, regardless of HIV status, will experience a decline in kidney reserve after donating, which increases the risk for developing kidney disease later. It is the transplant team’s job to very carefully evaluate a potential donor’s risk of kidney disease and advise a potential donor not to donate if they determine the future risk of kidney failure is too high. In the event that a living donor’s remaining kidney fails after donation, they are entitled to receive priority status when it comes to being listed for and receiving a transplant from a deceased donor.

I learned this past summer that a friend was undergoing tests to become a kidney transplant recipient. It had been nearly three years since the initial conversations with my physician about becoming a living donor. Searching online to discover if there were any new protocols that would provide me the opportunity, I found that, in January 2018, Johns Hopkins had become the first transplant center approved to evaluate potential living kidney donors with HIV. I decided to undergo donor screening without a doubt in my mind that I wanted to do this. If approved to do so, I will be donating a kidney to someone on the HOPE transplant waitlist if I cannot donate to my intended recipient.

“Becoming a living donor is the best decision I have ever made,” says Heather Winfree, who donated a kidney to her husband in September 2017. Although neither of them are living with HIV, she was thrilled that the donor list would be expanded. “When I heard that people living with HIV could be potential donors, to say it gave me hope—for those still waiting on their miracle—would be an understatement. By expanding the donor pool to include people living with HIV, wait times will decrease for everyone, which means more lives saved.”

So, what can you do if you are living with HIV and want to become an organ donor? Share your decision with others and let them know you want to save lives! You can document your decision by:

- **selecting “Yes”** to organ donation when you obtain or renew your driver’s license;
- **registering online** through Donate Life America at registerme.org; and/or
- **registering through** the iPhone’s Health app (currently the only app that allows you to register as a donor).

A health care directive or living will, such as Five Wishes or Voicing My Choices (for adolescents and young adults), can jumpstart conversations with others regarding your preferences and wishes for organ donation. For clinical research opportunities, you can search the clinicaltrials.gov website for studies by their registry number; this number is “NCT” followed by an eight-digit number, and ongoing studies are provided in the “Resources” section on this page.

To learn more, you can also send an e-mail message to hopeinaction@jhmi.edu.

“After being denied an organ transplant because I was HIV-positive, I now work to educate others,” says transplant recipient Gary Garcia of Dallas, Texas. “I believe everyone deserves care, compassion, and the best chance at life. I am living a full, healthy life after a liver transplant, and with my HIV still undetectable.” PA

NINA MARTINEZ has been living with HIV since 1983 when she was diagnosed at six weeks old. After pursuing graduate studies in epidemiology at Emory University, she served as a public health analyst at the Centers for Disease Control and Prevention. Nina is an active clinical research volunteer at the National Institutes of Health, currently participating in a 10-year study of clinical outcomes in people who acquired HIV within the first decade of life. Nina is more recently known for her efforts to push HIV criminalization reform in Georgia as a steering member of the Georgia HIV Justice Coalition.

RESOURCES

Johns Hopkins Comprehensive Transplant Center
hopkinsmedicine.org/transplant/living_donors

How to sign up as an organ donor from your iPhone’s Health app
idownloadblog.com/2016/10/07/sign-up-organ-donor-health-app-iphone

Donate Life America
registerme.org

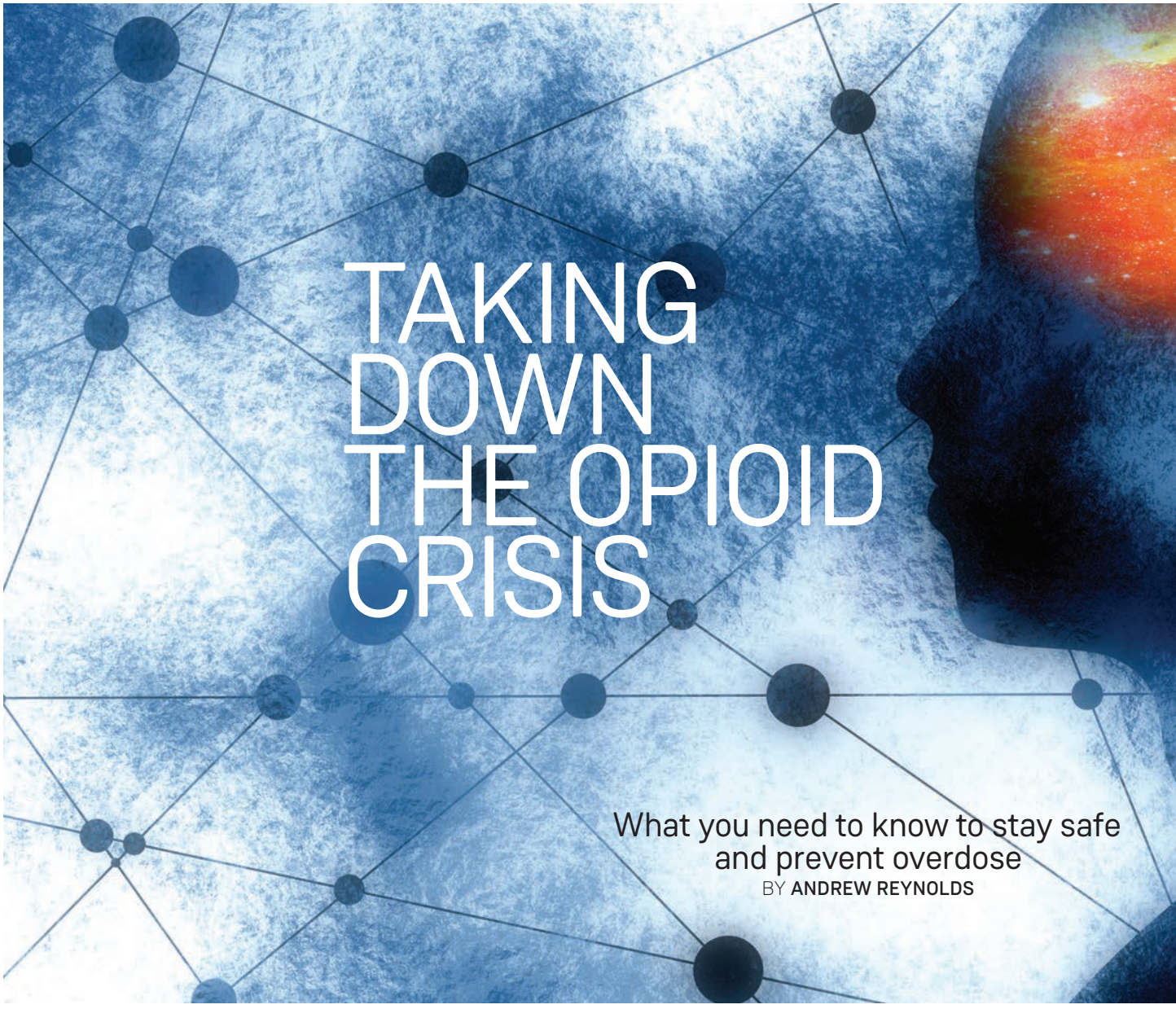
Five Wishes / Voicing My Choices
fivewishes.org

ClinicalTrials.gov
clinicaltrials.gov
Enter registry number: “NCT” followed by eight-digit number.

HOPE in action: A clinical trial of HIV-to-HIV deceased donor kidney transplantation
NCT03500315

HOPE in action: A clinical trial of HIV-to-HIV liver transplantation
NCT03734393

Prospective clinical trial of HIV+ living donor kidney donation for HIV+ recipients
NCT03408106



TAKING DOWN THE OPIOID CRISIS

What you need to know to stay safe and prevent overdose

BY **ANDREW REYNOLDS**

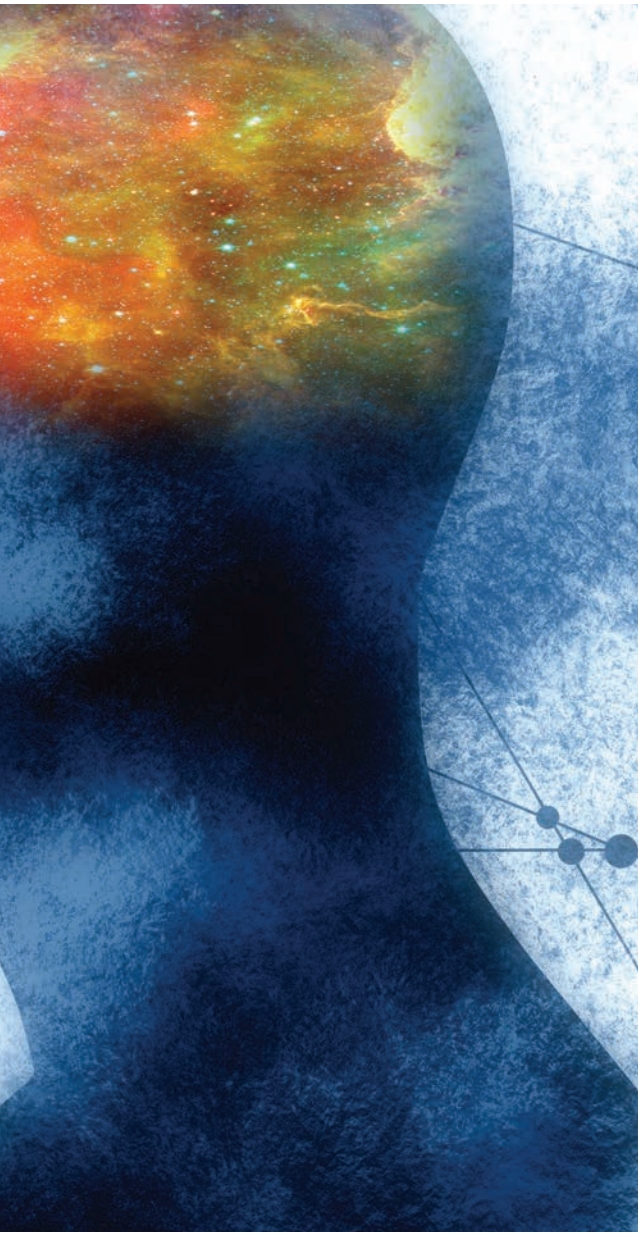
To say that media coverage of the opioid crisis is a hot topic would be an understatement: A quick Google keyword search of "opioid crisis" will get you over 84 million hits! This attention is certainly warranted, as opioid use has increased dramatically and has led to significant death, disease, and suffering in the United States.

This article will provide you with a broad overview of the scope of the problem, basic information to understand what opioids are and how they lead to overdoses, and some harm reduction tips and resources so that you, or someone you know who uses drugs, can be safe.

The scope of the problem: Opioid use and its medical consequences

When you look at the numbers, the scope of drug use in the U.S., including opioids, is quite astounding. According to the Centers for Disease Control and Prevention (CDC), there are over 48.5 million Americans who have used illegal drugs or misused prescription drugs. Among this group, 11.5 million people have misused prescription opioids. To put opioid use in context, the U.S. makes up 5% of the world's population, yet we account for 80% of opioid use.

For many in the U.S., the transition to injecting heroin starts with taking prescription opioids, becoming physically dependent upon them, and then moving to injection. There are several reasons why this leap is made, including but not limited to job loss and a resulting loss of health insurance to cover the cost of the medications, or changes in prescribing after a person has become addicted to them without the medical and social support to withdraw safely. In the face of terrible opioid withdrawal symptoms, people often turn to heroin. Heroin use has increased by 60% from 2002 to 2013. In 2016, the last year data were available, approximately



950,000 Americans reported using heroin in the past year, with younger individuals aged 18 to 25 having the greatest increases.

The consequences of this opioid use have been devastating.

Overdose death rates now exceed death rates due to AIDS during the 1990s. There were over 72,000 overdose deaths in 2017, and this number has been on the rise year after year and shows no sign of stopping. The death rate is so bad, and hitting such a young portion of the U.S. population, that the average life expectancy in this country has actually dropped for two years running.

In addition to the dramatic increase in overdose deaths, we're also seeing an increase in infectious diseases associated with injection drug use.

Rates of hepatitis C (HCV) are also on the rise, with over 41,000 newly infected persons in 2016, a number that is more than three times what it was in 2010. Mirroring the increase in injection heroin use among young people, we are seeing dramatic increases of HCV infections among youth, with

How to prevent an opioid overdose

An overdose does not have to result in death. In fact, it's remarkably easy to prevent and reverse one! When someone is overdosing, there are things you can do to help them survive it. There's a medication that can bring someone out of an overdose: naloxone. It may be available where you live, but even if it is not, there are some things you can do to keep a person alive and get them the help they need to stay alive.

1 Recognizing an opioid overdose

As mentioned earlier, an opioid overdose causes a person to stop breathing. There are signs to look for when this happens, including the following:

- **The lips turn bluish or gray**
- **Clammy, sweaty skin**
- **Shallow breaths, heavy snoring, or making gurgling sounds**
- **Unresponsive to loud noises, and won't wake up**

A person is not overdosing if they are still breathing, but just in a heavy nod. That said, stay with them and watch them to make sure they don't fall unconscious and stop breathing.

2 Check for responsiveness

Do they respond to you when you yell or give them a light shake? If that doesn't work, try a sternum rub where you rub your knuckles across their chest bone for about 10 seconds.

If they are breathing, but non-responsive, stay close and keep an eye on them.

3 Call 911

This can feel scary, as you don't want to risk getting arrested. You can call, though, and not mention drugs. Just say that your "friend is unconscious and I can't wake them" or "my friend isn't breathing." Give the 911 operator the address and location.

4 Give the person Narcan

Narcan is a medication that will reverse an overdose. It comes in a nasal or injectable form. It is safe for everyone to take with no fear of an allergic or other negative reaction—well, other than the fact that the person receiving it will feel some pretty heavy withdrawal symptoms, but that's a better option than death!

- **If you have the nasal spray Narcan, you spray one half in one nostril and the other half in the other nostril.**
- **If you have the injectable Narcan, find a meaty part of the body—the shoulder, the thigh, or even the outer part of the butt—and inject 1 cc into the muscle. You do not need to find a vein to inject.**
- **If the person does not respond, give a second dose of Narcan. If they still aren't responding, call 911 and do rescue breathing until paramedics arrive.**

5 Rescue breathing

This isn't CPR—you don't have to worry about pushing the chest to keep the heart beating, because in an overdose, the heart doesn't stop—the breathing does, so all you have to do is rescue breathing.

- **Make sure there is nothing in their mouth and that their throat is clear.**
- **Tilt the head back, lift the chin and pinch the nose.**
- **Give the person one breath every five seconds.**

6 After Narcan

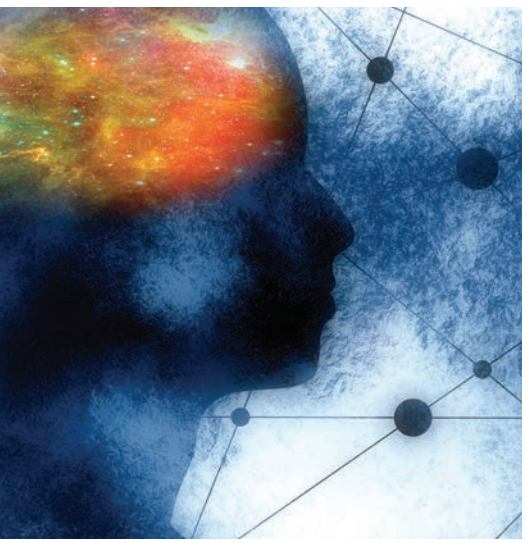
Narcan will wear off anywhere between 20–90 minutes after a person has taken it. If it wears off and there is still enough opioid in the person's system, they can fall back into the overdose.

Stay with the person in case they go back into an overdose. You can administer Narcan again if needed, and stay with them for help and support.

SOURCE: The DOPE Project, "Be a Lifesaver: Overdose Prevention and Survival" brochure.

people aged 18 to 29 experiencing the highest rates of new infections.

While we have seen dramatic increases in overdose deaths and HCV infections related to the opioid crisis, we've had a remarkable success in preventing HIV from injection drug use. In 1990, injection drug use accounted for 40% of new HIV infections,



but it was just 6% as recently as 2015. The success is due to the expansion of harm reduction services such as needle exchange (aka syringe access services) and other interventions aimed at reducing HIV in people who inject drugs (PWID).

That said, there have been warning signs that this progress is in danger. For the first time in 20 years, HIV infections among PWID increased in 2015. This was in large part due to an HIV outbreak in Scott County, Indiana, where over 200 PWID were infected with HIV. Since then, we have seen an HIV outbreak in Massachusetts, and the CDC has identified 220 other counties that are vulnerable to an HIV (and HCV) outbreak as a result of injection drug use and a lack of harm reduction services.

What are opioids?

Opioids are a class of drugs that create a morphine-like effect for pain relief and have other medical uses. They are naturally occurring substances, such as heroin (derived from some varieties of the poppy plant), or synthetic, like oxycodone (brand name Oxycontin) or hydrocodone (brand name Vicodin). They are also very addictive. Modes of administration can vary, but opioids are often injected, smoked or snorted.

The introduction of fentanyl into the drug supply has had a devastating impact. Fentanyl is a synthetic opioid that can be 50–100 times stronger than morphine. It is a legitimate medication with some positive therapeutic benefits when administered properly, but unfortunately it has entered the illegal drug market and has dramatically increased the risk of overdose. When it's included in a person's drug, say heroin, it can lead to an overdose because the person doesn't know it has been added and the drug's effect is too strong to handle.

What is an overdose?

An overdose happens when too much of a drug is in one's body and leads to a toxic health problem. You can overdose on any number of drugs, both legal and illegal: Binge drinking alcohol can lead to acute liver failure. Too much cocaine can lead to heart attack, seizures, or a stroke. With opioids, when someone gets too much of it, the person's breathing will slow and eventually stop. Everything else is working in the short-term—the heart is pumping, the kidneys are functioning and the brain is firing—but without breathing a person will die. Fortunately, overdose deaths can be prevented by administering rescue breathing and/or Narcan (naloxone)—see below for more information about this.

Harm reduction and opioid use: What you need to know

There are many things that you can do to reduce your risk of overdose, and acquiring HIV or HCV. This top 10 list can serve as a guide to keep you safer if you are using opioids. It may be difficult to do some or all of these, as you may not have a syringe access program in your area or an ability to get naloxone.

1. Never use alone

This tip by itself can help prevent overdose deaths. Most overdose deaths happen when a person uses opioids alone and then overdoses with no one around to step in and help with rescue breathing, naloxone administration, or calling 911. Use with someone you trust, make an overdose plan, and watch out for each other. Make sure you have naloxone on hand, know how to do rescue breathing, and have a phone (or be able to get to a phone) if needed.

2. Don't mix your drugs

Mixing some drugs can lead to an overdose, especially ones that might interact with each other and make the overdose risk worse. Never mix alcohol with opioids or benzodiazepines (like Xanax, Valium, or Ativan) as they can greatly increase your risk of overdose.

Be careful even if you aren't using opioids. Fentanyl is being found in other drugs such as cocaine, crystal meth, and ketamine. So, you might not think you're taking opioids, but if your drug is laced with fentanyl, drinking alcohol on top of it could increase your risk of overdose.

3. Test your drugs

There are a couple of different ways to do this. If you have access to something called "fentanyl test strips," you can use them to test for fentanyl in your drugs. If there's fentanyl in it, you can make plans to be safer when using and be on heightened awareness for an overdose.

If you don't have these test strips, try a tester shot, where you use less than you normally would and watch for its effect. This is especially important if your tolerance has changed (perhaps you haven't used in a while or you've been sick lately and feeling a little weaker than usual) or if you have a new source for your drugs. If you hear stories of people in your area overdosing, be careful with your drugs and watch out for each other.

4. Carry naloxone (Narcan) with you

Related to never using alone, carry naloxone with you so you can reduce an overdose should one happen. Check out "How to prevent an opioid overdose" on page 31 for how to use Narcan. It is available for free at various community places, such as needle exchanges.

In addition to lowering your risk for overdose, there are steps to take to help prevent disease transmission.

5. Don't share syringes

This helps prevent HIV, HCV, and HBV. It's is an obvious disease prevention tip, but because of politics and stigma, it may be hard for you to get unused syringes and enough injection equipment. It is well established that both HIV and HCV can be transmitted from sharing syringes and injection equipment, and that needle exchange reduces the risk of these infections. The science is unimpeachable, but the resistance to allowing them remains strong. Check out the North American Syringe Exchange Network's directory to see syringe access services in your area: nasen.org/directory/search.

6. Take a break from injecting
If you can take a break from injecting or switch to smoking or snorting drugs, it could reduce your risk of HIV and HCV as it reduces your risk for blood-to-blood transmission. Don't share straws or pipes, as blood can be on them and potentially transmit HCV—the risk is low, but not zero.

7. Test for HIV and HCV routinely
Testing for HIV and HCV in and of itself won't prevent these diseases, but knowing your status as soon as possible is good for both your health and the health of your injection or sexual partners so that you can take action to prevent new infections. If you test positive for HIV, you can start medications ASAP, get your viral load to undetectable, and minimize both the damage to your immune system and risk of transmitting HIV to others.

8. Get treated for hepatitis C
If you test positive for HCV, you can get cured. The older treatments were tough: You had to have an injection and pills; they had very difficult side effects and not everyone was cured. Thankfully, the new HCV treatments, called direct-acting antivirals or DAAs, are easier to take than ever before: They are all pills, usually taken once per day for 8–12 weeks, and have very high cure rates with very few side effects, even for people living with HIV. For more information, call HELP-4-HEP, a non-profit HCV education, support, and referral phone line at 877-HELP-4-HEP (877-435-7443).

9. Get vaccinated against hepatitis A (HAV) and hepatitis B (HBV)
Make sure you've been vaccinated against HAV and HBV. Hepatitis A and B are both viral infections that can affect the liver. The vaccine is safe and effective for everyone, including those living with HIV or HCV.

10. Get on Medication Assisted Therapy (MAT)
This is another strong, evidence-based intervention that has been shown to reduce overdoses, and HIV and HCV infections. It makes sense: If someone is on methadone or buprenorphine, then they are not injecting opioids and thus not at risk. That said, access to MAT can be challenging and may not be available in your area. Call the SAMHSA National Helpline at 800-662-HELP (4357) for a free and confidential referral and for information about drug treatment.

ANDREW REYNOLDS is the Hepatitis C Education Manager at Project Inform, and facilitates several HCV support groups in the San Francisco Bay Area. He's also a counselor on the HELP-4-HEP HCV phoneline (877-435-7443). Call him if you have any questions about HCV care and treatment.

INSITE: LAURA THOMAS

LOCATED IN VANCOUVER, CANADA, INSITE IS THE FIRST LEGAL SUPERVISED DRUG INJECTION SITE IN NORTH AMERICA.

Making the case for safer consumption spaces

A report released by AIDS United and Project Inform makes the case for establishing protected places where people can safely inject drugs. Citing government and public research conducted in the U.S., Canada, Australia, and Europe, the report states a number of public health benefits, starting with a reduction in the number of drug overdose deaths and new HIV and hepatitis C infections.

There were an estimated 72,000 overdose deaths of both prescription and illicit drugs in the U.S. in 2017. The Centers for Disease Control and Prevention (CDC) determined that people who inject drugs (PWID) accounted for 9% of new HIV diagnoses in the U.S. and about 68% of new hepatitis C (HCV) cases in 2016.

While syringe services programs, such as needle exchange, have been shown to greatly reduce transmission of HIV and HCV, they have been unable to counter the steady rise in drug-related deaths. The widespread non-prescription use of opioids has fueled the sharp increase in drug use—and overdoses.

Titled *Bringing Safer Consumption Spaces to the United States*, the report determines that a comprehensive and holistic approach to the explosion of drug use should include harm reduction in the form of safe, controlled spaces for PWID.

There are no officially designated safer consumption spaces (SCS) in the U.S., although some operate below the public's radar in certain communities. There are more than 100 SCS operating in over 66 cities in Canada, Australia, and Europe.

"A holistic, comprehensive approach to drug user health and prevention, which includes a spectrum of evidence-based prevention, treatment, and social services to maximize quality of life and health outcomes, is necessary to combat the opioid, HIV, and viral hepatitis crises," said Jesse Milan, Jr., president and CEO of AIDS United. "Yet our government response to date has lacked any significant investment in harm reduction. We are calling on private philanthropy to step in and support organizations working to implement and legalize these life-saving services."

In addition to reducing the number of overdoses, SCS lower the risk of exposure to infectious disease. The report also details other public health benefits of safer consumption spaces, specifically the opportunity to link PWID to assistance with substance use treatment, mental health care, housing, and other social services.

AIDS United and Project Inform interviewed staff members and clients at 12 nonprofit community-based organizations throughout the U.S. One interviewee described how the displacement of people living in a homeless encampment led to an increase in fatal overdoses. As people scattered to different parts of the city, they no longer had access to the services they used, resulting in increased deaths.

An article in POSITIVELY AWARE's September + October 2017 issue by Project Inform's Andrew Reynolds outlined the benefits—and controversy—surrounding SCS.

The federal government is opposed to SCS, and public opinion disapproves of such facilities, taking a "not in my backyard" attitude. AIDS United and Project inform produced the report to develop practical strategies for funding and advocating for SCS and the public health needs of PWID. —**RICK GUASCO**

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