THE AMERICAN ACADEMY OF HIV MEDICINE ■ SPRING 2022

HIV SPECIALIST

BARRIERS TO ACCESS

PEP Support Program

Access to HCV Treatment

Shame as a Barrier

STI Update

16TH ANNUAL

ACTHIV

THE AMERICAN CONFERENCE FOR THE TREATMENT OF HIV

REGISTRATION NOW OPEN!

MAY 5-7, 2022

HYATT REGENCY DENVER

650 15th Street • Denver, Colorado 80202

ACTHIV™ IN-PERSON AND VIRTUAL

The planning committee of the American Conference for the Treatment of HIV™ (ACTHIV™) believes an in-person conference provides the best learning experience as in-person attendees are able to learn from one another as well as from expert clinical faculty educators.

At ACTHIV™ 2022, those who attend in Denver will be able to interact and ask questions not only of our faculty, but also of each other and our exhibitors. They can also take advantage of learning opportunities beyond the main conference sessions including the poster session, exhibit hall, satellite symposia, and the New Providers track for clinicians who are newer to caring for people with HIV. And of course there will be plenty of networking opportunities during breakfasts, breaks and lunches daily as well as during the Welcome Reception on Thursday evening for attendees to build their professional networks and interact with HIV team members from across the US.

Recognizing, however, that everyone who would like to attend ACTHIV™ 2022 in person may not be able to do so due to COVID-19, we are pleased to announce that the main conference sessions will be offered online to virtual attendees in real time.

As an added bonus, whether you attend in-person or virtually, you will be able to access all the main conference sessions online for three weeks after the learning event – providing you with an opportunity to re-engage with the sessions.

ABOUT ACTHIV™

The American Conference for the Treatment of HIVTM (ACTHIV™) is the premier conference in the US dedicated exclusively to the frontline care team and its members who are caring for persons living with or at risk of acquiring HIV. The conference delivers information on new developments and research findings that can be rapidly translated and directly applied to the clinical setting.

REGISTRATION FEES FOR BOTH IN-PERSON AND VIRTUAL ATTENDANCE:

Whether you attend in-person or virtually, your registration fee includes the opportunity t o apply for **CME/CE credits** for your participation in the main conference sessions.

- **Attendee Registration** (After March 15, 2022) **$500**
- **Students/Residents/Fellows in Training** (After March 15, 2022) **$275**

Visit ***ACTHIV.org*** for more information and to register.

THE AMERICAN ACADEMY OF HIV MEDICINE

HIV SPECIALIST

WWW.AAHIVM.ORG ■ SPRING 2022 ■ VOLUME 14, NO.1

CONTENTS

FEATURES

DEPARTMENTS

LETTER FROM THE

DIRECTOR

By BRUCE J. PACKETT II
Executive Director, AAHIVM

Breaking Barriers

DR. SUSANA WILLIAMS KEESHIN of the Academy board of directors penned the lead article for this issue of *HIV Specialist* which focuses on barriers to access (to comprehensive HIV care, treatment and prevention), and explicitly underscores where barriers begin, chronologically: it starts in our educational institutions. Focusing on her state of Utah, but really mirroring attitudes and policies around sex education across the country, she points out that public educators are explicitly forbidden from talking about sex in a de-stigmatizing, inclusive and objective way with policies crystallizing instead around that old, empirically-disproven chestnut of "abstinence."

The Academy is focusing its advocacy and programmatic efforts around all issues and policies that create barriers to access in HIV. However, the growing focus of the organization into sexual health has been well-noted, and, in anticipation of the forthcoming launch of the first course in our comprehensive sexual health curriculum for all providers of medical care, we are expanding our efforts to address this broader space of concern under the rubric of tackling and defeating syndemics. Specifically, this issue of the magazine features the first of what will be an ongoing, regular column on sexual health in *HIV Specialist*, written here by Dr. Ross Hewitt and focusing on STIs in the HIV clinic, and what's new in that clinical area.

Dr. Williams Keeshin's article goes on to paint a masterpiece on how various socio-economic policies and public and private payer coverage policies exacerbate the strongly disproportionate effect of HIV on communities of color in her state, specifically in terms of access to care and prevention services. As we saw in the last issue on HIV and justice, it's never been appropriate and is now completely indefensible for HIV advocates and providers to "stay in their [clinical] lane." Systemic issues of racial equity and inequality, stigma, criminalization/incarceration and spiraling health access problems means that HIV clinicians aren't just focused on the medicine, but rather on the larger reasons why we can't end HIV, and why so many at-risk and people with HIV (PWH) can't get care in the U.S. without major policy, political, economic, educative and cultural change.

The Academy's Council for Racial Equity (ACRE) was founded by a group of our African American medical providers within the organization to help guide and advise the organization on its activities and programs to help keep the full range of systemic problems in sharp relief. Starting with this issue, the Academy will feature an article in every quarterly issue conceived and written by a member (or members) of the ACRE to help us keep the focus on what's preventing access for so many people of color in the U.S. Inside this issue, Charmaine Miller-Spencer, MS, APRN, NP-C, AAHIVS discusses the issue of shame and how it impacts access and retention, functioning as it does as a kind of obverse or individually-internalized underside of the structural, external and social issue of stigma. We spend a lot of time talking about stigma from a policy lens, but it's important too to look at what's happening with each person individually and psychologically in that context.

I'm excited by the breadth of topics addressed in this issue, and think there's something compelling here for every reader, whether it's looking at the choppy access to the important new long-acting injectable treatment modalities, news about a new HIV cure case, telehealth as a compelling possible solution to many access barriers, the unique difficulties in access to care and testing experienced by adolescents, or the strong reminder that we still need to do more in the space of access to curative treatment and care for Hepatitis-C, plus more.

Learn more, too, about how the Academy is growing and diversifying its staff to better provide programs and deliverables to its members and other clinicians working on HIV, creating a comprehensive resource page for long acting injectable agents, and highlighting the individual stories of its unique members working in HIV.

IN THE NEWS

American Academy of HIV Medicine Names Angela C. Riley as Education and Web Programs Manager

THE ACADEMY recently announced the appointment of Angela C. Riley, PharmD, as their new Manager of Education and Web Programs. A licensed pharmacist, Angela's clinical background will be instrumental in creating the Academy's educational content, which extends to all members of the HIV care team.

Angela received her Doctorate in Pharmacy from Midwestern University and her Bachelor of Science in Pharmacy degree from Texas Southern University. She is currently licensed as a pharmacist in Texas, New York and Illinois. Although she will continue to serve the community as a Consultant Pharmacist, she has most recently been in academia as Associate Clinical Professor at Binghamton University School of Pharmacy and Pharmaceutical Sciences.

"Providing quality HIV medical education offerings is a top priority for the Academy," said Executive Director Bruce J. Packett. "The combination of Angela's clinical expertise and her background in education will be invaluable in shaping the future programs and content created by our education department."

One of Angela's first priorities is the development of a comprehensive website on the use of long-acting agents (LAA) for treatment and prevention of HIV including the drug mechanisms and methods of use; a centralized hub of best practices and procedures for procuring and dispensing long-acting agents; information on LAA availability and coverage; information for patients; and information about the pipeline of agents under development.

In addition to the LAA website, Angela will be working with top HIV faculty around the country on the ongoing development of the Academy's educational workshops, webinars, digital learning courses and the Academy's *Fundamentals of HIV Medicine* textbook. She will also be instrumental in managing the content creation of the organization's forthcoming sexual health curriculum.

Angela is a member of several professional pharmacy organizations and is also active in her community, currently serving as a councilmember for the city of Binghamton, New York. She is also a member of the Broome County Office for Aging Advisory Board, the Community Foundation for South Center New York and Delta Sigma Theta Sorority, Inc.

Study shows mRNA vaccine technology can be used for HIV vaccines

BY SARAH AVERY, DUKE UNIVERSITY

USING MRNA TECHNOLOGY like that in the COVID-19 vaccines, researchers have demonstrated a successful way to deliver a potential HIV vaccine, researchers at Duke Human Vaccine Institute report.

Publishing online March 15 in the journal *Cell Reports*, the research team describes an important advancement in what is a complex vaccine development process. The approach uses mRNAs within lipid nanoparticles that are capable of stimulating HIV antibodies.

"This work demonstrates that we now have a practical platform for producing a complex HIV vaccine," said co-senior author Barton Haynes, M.D., director of the Duke Human Vaccine Institute. "The mRNA technology has been highly successful for COVID-19, and we previously found that it was also effective for a Zika vaccine. But HIV is so much more complicated. This is a major step forward."

Haynes and colleagues—including co-senior author Drew Weissman, M.D., Ph.D., the Roberts Family Professor in Vaccine Research at the Perelman School of Medicine at the University of Pennsylvania—found that mRNAs, which use genetic material to teach immune cells to recognize the targeted pathogen, are able to encode complex antigens that are key to HIV vaccine development.

Because the virus that causes AIDS mutates rapidly, only certain sites on its outer envelope remain intact through the ongoing changes. A successful vaccine requires perfectly structured proteins aimed at these sites to trigger the immune response—a technical hurdle that proved challenging with older vaccine technologies.

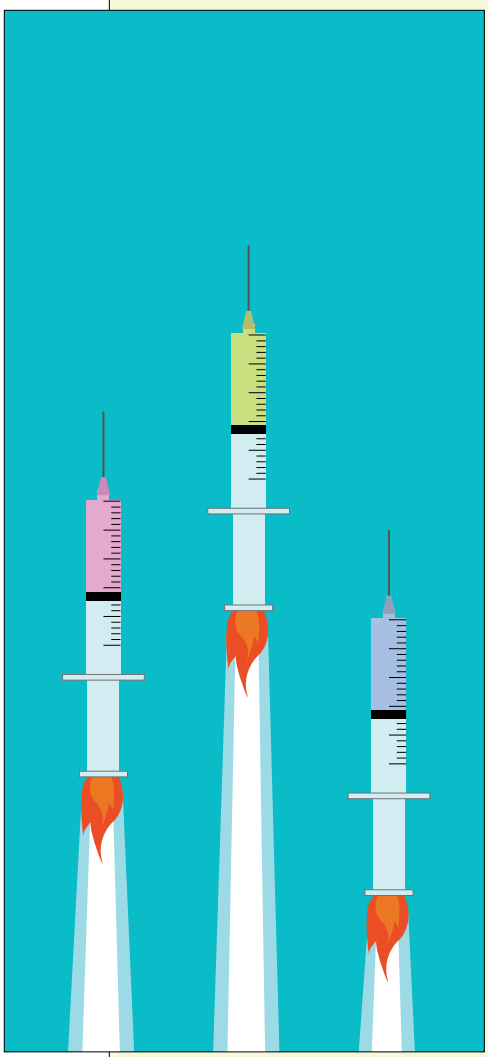
The research team was able to build an mRNA vaccine that could encode for the acquisition of the critical mutations, and monoclonal antibodies that neutralize diverse HIV.

"I began studying HIV and AIDS at the National Institutes of Health, and those that face the diseases have continued to be a group of people I really care about," said Weissman, whose decades-long mRNA research led to the effective SARS-CoV-2 mRNA vaccines. "I am excited that the mRNA-vaccine platform, which has helped to slow the spread of COVID-19 and decrease death from it, may be able to be put to work to protect people from HIV. These remarkable results may mark the next era of mRNA research and healthier futures for more people."

"Manufacturing complex nanoparticle protein immunogens on a large scale presents significant challenges, so we are encouraged that the use of mRNA raises the possibility of making such a complex immunization regimen both logistically achievable and potentially cost-effective," Haynes said.

IN THE NEWS

AAHIVM to Launch New Web Resource on Long-Acting Agents



IN RESPONSE to the Food and Drug Administration's recent approval of Apretude (cabotegravir extended-release injectable suspension) for prevention of HIV and the robust pipeline of additional long-acting antiretroviral agents currently under development, the American Academy of HIV Medicine is pleased to announce it has received funding to develop a comprehensive digital resource on the use of long-acting agents for clinicians, pharmacists and patients interested in using these new products. The Academy represents the vast majority of healthcare professionals providing care and prevention services for those with and at-risk for HIV.

Launching in the first half of 2022, the website will contain detailed information about the use of long-acting agents (LAA) for treatment and prevention of HIV including the drug mechanisms and methods of use; a centralized hub of best practices and procedures for procuring and dispensing long-acting agents; information on LAA availability and coverage; information for patients; and information about the pipeline of agents under development.

"Long-acting agents represent the culmination of years of research and offer the ability to simplify HIV treatment and prevention, bring more people into care and reduce stigma," stated Bruce J. Packett, executive director of the Academy. "However, our members have expressed significant concerns regarding cost, availability, coverage and dispensing. In response, the Academy is pleased to be able to offer this important centralized resource hub designed for the HIV care team and their patients."

The United States is in a place to end the HIV epidemic thanks to unprecedented advances in HIV treatment and prevention medications. Long-acting agents are going to help get us even closer to that goal by offering excellent clinical results, while also combatting many of the systemic and societal barriers facing people with HIV. Therefore, expediting the emergence of LAAs into the clinical care space is essential.

By developing this website resource, the Academy is helping ensure that doctors, pharmacists, advanced practice providers and the entire HIV care team—along with patients—can take advantage of these new tools with confidence and without any time lost.

STOCK.ADOBE.COM/ GENETTICA

UCLA HEALTH AT CROI

Presenting the case of a woman with HIV-1 in remission following specialized stem cell transplantation for leukemia

UCLA RESEARCHERS presented the first case of a U.S. woman living with HIV-1 that is in remission after she received a new combination of specialized stem cell transplants for treatment of acute myeloid leukemia (AML). The oral abstract was presented at CROI 2022, the Conference on Retroviruses and Opportunistic Infections.

"This woman has been in remission of AML for 4½ years and has had no HIV rebound in the 14 months since antiretroviral therapy was stopped," said Dr. Yvonne Bryson, a distinguished professor and specialist in pediatric infectious diseases and HIV pathogenesis at the David Geffen School of Medicine at UCLA and the UCLA Mattel Children's Hospital, who led the National Institutes of Health-supported, multicenter, observational study (IMPAACT P1107).

If HIV remission continues and she is determined to be cured, she would be only the third person to achieve cure and the first HIV remission to have been successfully engrafted with umbilical cord blood cells with a mutation that is protective against HIV-1 (CCR5-delta32/32 homozygous) combined with stem cells from an adult, haploidentical ("half-matched") related donor. The two previous patients with HIV cure received adult donor cells—one from bone marrow and one from blood stem cells—that had the protective mutation, but no umbilical cord blood cells.

The woman is of mixed race who was diagnosed with acute HIV in 2013 and high-risk AML in 2017. She was successfully transplanted with cord blood cells having the HIV-protective CCR5-delta32/32 mutation and with adult stem cells from a related donor. She had rapid engraftment with 100 percent cord cells by day 100 post-transplant and did not experience graft-versus-host disease, as the two earlier patients did, and she remains clinically well, with no detectable evidence of HIV infection, the researchers said.

Although stem cell transplantation is not a therapy for HIV, its effects in patients living with HIV and undergoing therapy for blood or lymph cancers provide researchers with insights and potential targets in HIV treatment.

"This study provides hope for the use of cord blood cells or a combination of cord blood cells and haploidentical (half-matched) grafts to achieve HIV-1 remission for individuals requiring transplantation for other diseases. It also provides proof that HIV-1 viral 'reservoirs' can be cleared sufficiently to afford remission and possibly cure in the setting of resistant target cells," said Bryson, the protocol chair for the International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT), the organization conducting the observational IMPAACT P1107 study.

The CCR5-delta32 mutation is rare, but cord blood banks may provide a previously untapped resource, according to the researchers, and the combination therapy would enable clinicians to take advantage of the unique benefits offered by each type of graft for more diverse populations.

"Adult donor grafts provide many cells initially and rapid engraftment, but histocompatibility can be an issue leading to risk of graft-versus-host disease. Umbilical cord blood grafts have a lower cell dose and take longer to engraft, but they can be banked for ready availability, and they pose less risk for GVHD," Bryson said. "With the combination, the adult graft provides accelerated engraftment until the cord graft takes over."

Bryson leads the IMPAACT P1107 study with protocol virologist and scientific committee chair Deborah Persaud, a pediatric infectious disease specialist at Johns Hopkins Medicine. The protocol team includes Anne Coletti, Koen Van Besien, Savita Pahwa, Renee Browning, Lawrence Petz, Marshall Glesby, Theodore Moore, Fredrick Bone, Amanda Golner, Rohan Hazra, Nicole Tobin, Meredith Warshaw, Patricia Anthony, Dwight Yin and Elizabeth Smith.

Clinical research site investigators at Weill Cornell Medical College include JingMei Hsu, Koen Van Besien from the transplant team, and Marshall Glesby, infectious disease, and collaborators include Lawrence Petz, StemCyte; Marcie Riches, Center for International Blood and Marrow Transplant Research (CIBMTR); and John Mellors, AIDS Clinical Trials Group (ACTG).

Additional contributors include Ruth Cortado, Bryson Laboratory at UCLA; Dianna Hoeth, Mellors Laboratory at the University of Pittsburgh; Suresh Pallikkuth and Margaret Roach, Pahwa Laboratory at the University of Miami; and Ya Hui Chen, Adit Dhummakupt, and Joseph Szewczy, Persaud Laboratory at Johns Hopkins University.

IMPAACT P1107 is funded by the U.S. National Institutes of Health. Overall support for the International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT) is provided by the National Institute of Allergy and Infectious Diseases (NIAID) with co-funding from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the National Institute of Mental Health (NIMH), all components of the National Institutes of Health (NIH), under Award Numbers UM1AI068632-15 (IMPAACT LOC), UM1AI068616-15 (IMPAACT SDMC) and UM1AI106716-09 (IMPAACT LC), and by NICHD contract number HHSN275201800001I. NIAID funding for the ACTG Weill Cornell Medicine – Rutgers New Jersey Medical School Clinical Trials Unit was provided under 5UM1AI069419.

The authors report no additional disclosures or potential conflicts of interest.

STOCK.ADOBE.COM/ IUSHAKOVSKY

IN THE NEWS

New Clinical Data Support the Sustained Efficacy of Long-acting Lenacapavir, Gilead's Investigational HIV-1 Capsid Inhibitor

One-Year Data From the CAPELLA and CALIBRATE Trials Show Lenacapavir Leads to High Rates of Virologic Suppression in Heavily Treatment-Experienced People Living with Multi-Drug Resistant HIV and Treatment-Naïve People Living with HIV

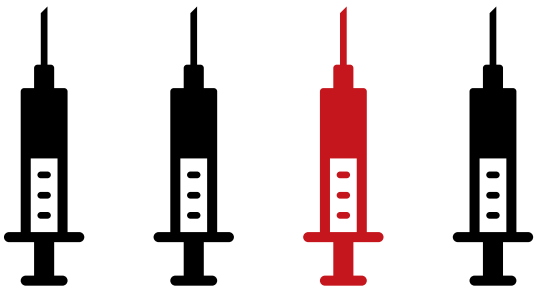
GILEAD SCIENCES, Inc. announced new one-year results from the ongoing Phase 2/3 CAPELLA trial evaluating lenacapavir, the company's investigational, long-acting HIV-1 capsid inhibitor, in heavily treatment-experienced people living with multi-drug resistant HIV. The findings demonstrated that lenacapavir, administered subcutaneously every six months in combination with other antiretrovirals, achieved high rates of virologic suppression and clinically meaningful increases in CD4 counts in people living with HIV whose virus was no longer effectively responding to their current therapy. In this patient population with high unmet medical need, 83 percent (n=30/36) of participants receiving lenacapavir in combination with an optimized background regimen achieved an undetectable viral load (<50 copies/mL) at Week 52. The data were presented at the 29th Conference on Retroviruses and Opportunistic Infections (virtual CROI 2022).

"I am really encouraged by the results presented today showing that the positive outcomes achieved with lenacapavir can be sustained at one year of treatment, which is a remarkable achievement for this group of people living with HIV who have limited treatment options and are at a greater risk of progressing to AIDS," said Onyema Ogbuagu, MD, FACP, Director of HIV Clinical Trials program at Yale School of Medicine. "The potential of a long-acting antiretroviral treatment option that may achieve and maintain an undetectable viral load and that is administered only twice a year would be a true advancement that could potentially transform how providers care for certain patients with the virus."

Lenacapavir is Gilead's potential first-in-class, investigational long-acting HIV-1 capsid inhibitor in development for the treatment and prevention of HIV-1 infection. Lenacapavir's multi-stage mechanism of action is distinguishable from currently approved classes of antiviral agents and could provide a new avenue for the development of long-acting therapy options for people living with or at risk for HIV-1. While most antiretroviral agents act on just one stage of viral replication, lenacapavir inhibits HIV-1 at multiple stages of its lifecycle and has no known cross resistance to other existing drug classes. If approved, lenacapavir would be the only HIV-1 treatment option administered twice yearly.

"Continued scientific innovation is essential to helping end the global HIV epidemic. Gilead is committed to driving advances in HIV treatment with the goal of offering long-acting options that address the differentiated needs and preferences of a diverse range of individuals and communities impacted by this disease," said Jared Baeten, MD, PhD, Vice President, HIV Clinical Development, Gilead Sciences. "These latest results provide further evidence of the potential for lenacapavir, as a breakthrough innovation, to fulfill the needs of heavily treatment-experienced people living with multi-drug resistant HIV, irrespective of their prior treatment history."

In addition to high rates of viral suppression, participants in CAPELLA achieved a mean increase in CD4 count of 83 cells/μL. Data previously presented at *virtual* CROI 2021, showed that the CAPELLA trial achieved its primary endpoint by demonstrating that a significantly higher proportion of participants randomly allocated to receive lenacapavir (n=24) achieved a clinically meaningful viral load reduction of at least 0.5 log10 copies/mL from baseline compared with those randomly allocated to receive placebo (n=12) during the 14-day functional monotherapy period (88% vs. 17%, p<0.0001). Those who received lenacapavir achieved a statistically significant greater mean decrease in viral load than those who received placebo during the functional monotherapy period (-1.93 $\log_{10}$ copies/mL vs. -0.29 $\log_{10}$ copies/mL, p<0.0001).



Lenacapavir was generally well tolerated in CAPELLA, with one adverse event (AE) leading to study drug discontinuation at Week 52 and no serious adverse events related to lenacapavir. The most common adverse events observed to date in the CAPELLA study were injection site reactions (63%), which were mostly mild or moderate in severity. The most common adverse events, excluding injection site reactions, were nausea and diarrhea (13% each) and COVID-19 (11%).

Gilead presented additional lenacapavir clinical data from the Phase 2 CALIBRATE trial, an ongoing, open-label, active-controlled trial in treatment-naïve people with HIV-1 infection. The trial showed lenacapavir, given subcutaneously in combination with oral daily emtricitabine/tenofovir alafenamide (F/TAF) in the first 6 months, followed by combination with either oral daily tenofovir alafenamide (TAF) or bictegravir (BIC), or given orally in combination with emtricitabine/tenofovir alafenamide (F/TAF), achieved high rates of viral suppression by Week 54. Specifically, in the subcutaneous lenacapavir + TAF arm, 90 percent achieved an undetectable viral load (<50 copies/mL). In the subcutaneous lenacapavir + BIC arm, 85 percent achieved an undetectable viral load. In the oral lenacapavir + F/TAF arm, 85 percent achieved an undetectable viral load. Lenacapavir was generally well tolerated, with no study drug-related serious AEs. The most common AEs observed were injection site reactions (ISRs), which were generally mild or moderate in severity. The most frequent non-ISR AEs were headache and nausea (13% each) and COVID-19 (10%).

These results support the ongoing evaluation and further development of lenacapavir in combination with other long-acting partner agents for the treatment of HIV-1 infection and support Gilead's long-acting oral and injectable development program.

About CAPELLA (NCT04150068)

CAPELLA is a Phase 2/3, double-blinded, placebo-controlled global multicenter study designed to evaluate the antiviral activity of Gilead's investigational, long-acting HIV-1 capsid inhibitor lenacapavir administered every six months as a subcutaneous injection in heavily treatment-experienced people with multi-drug resistant HIV-1 infection. CAPELLA includes men and women living with HIV-1 and is being conducted at research centers in North America, Europe and Asia.

In CAPELLA, 36 participants with multi-class HIV-1 drug resistance and a detectable viral load while on a failing regimen were randomly allocated to receive oral lenacapavir or placebo in a 2:1 ratio for 14 days, in addition to continuing their failing regimen (functional monotherapy). An additional 36 participants were enrolled in a separate treatment cohort. Both cohorts are part of the ongoing maintenance period of the study evaluating the safety and efficacy of subcutaneous lenacapavir administered every six months in combination with an optimized background regimen. The primary endpoint was the proportion of participants randomly allocated to receive lenacapavir or placebo for 14 days, in addition to continuing their failing regimen, achieving ≥0.5 log10 copies/mL reduction from baseline in HIV-1 RNA at the end of the functional monotherapy period.

Following the 14-day functional monotherapy period, participants randomly allocated to receive lenacapavir or placebo, in addition to continuing their failing regimen, started open-label lenacapavir and an optimized background regimen, while those enrolled in a separate treatment cohort received open-label lenacapavir and an optimized background regimen on Day 1. This ongoing maintenance period of the study is evaluating the additional trial endpoints of safety and efficacy of subcutaneous lenacapavir administered every six months in combination with an optimized background regimen.

For further information, please see https://clinicaltrials.gov/ct2/show/NCT04150068. **HIV**

BARRIERS TO ACCES

S IN HIV CARE

By Susana Williams Keeshin, MD, AAHIVS

WITH ALL THE CLINICAL ADVANCES THAT HAVE BEEN MADE in the area of HIV treatment and prevention over the last 40 years, we have never been closer to ending the HIV epidemic. From pre-exposure prophylaxis (PrEP) to the latest long-acting agents, the HIV clinical arsenal is robust. However, the epidemic is far from over without access to these new clinical options.

I am often asked, "What are the barriers to access to HIV care and prevention?" Racism, stigma, stable and affordable housing, healthcare delivery, mental health conditions, and substance use disorders are among the litany of challenges people with HIV (PWH) face in this country. However, being able to identify these barriers is just the first step. We must examine each area of the U.S. and individual states carefully, as barriers may be similar but differ in impact and have different solutions.

As an HIV specialist in Salt Lake City, Utah, the greatest barriers I see are access to affordable HIV care and medication, racism, and anti-immigration, all intermixed with stigma. To understand some of these barriers, we need to understand some basic Utah HIV statistics.

Like the U.S. as a whole, the rate of new diagnoses of HIV has remained stable in Utah for the past ten years. Utah is considered a low incidence state with a rate of 5.3 per 100,000, lower than the U.S. rate of 13.2 per 100,000.[1] However, Utah has the lowest percentage of adults reporting ever being tested for HIV (25%) out of all states with the national average at 37.1 percent.[2] Common barriers to HIV testing are perceived low risk of HIV both from the patient and provider perspective.

Let's Talk About Sex

Perceived risk has its roots based in sex education. Utah is one of three states which require a parent's written opt-in consent for their child to participate in sex education. When parents do opt-in, the education is far from comprehensive. The curriculum (Utah Code § 53G-10-402) must stress "the importance of abstinence from all sexual activity before marriage and fidelity after marriage as methods for preventing certain communicable diseases, and [the importance of] personal skills that encourage individual choice of abstinence and fidelity."[3] Additionally, the curriculum is not required to include sexual orientation or gender identity instruction. Teachers are explicitly prohibited in using material on:

1. The intricacies of intercourse, sexual stimulation, or erotic behavior;
2. The advocacy of premarital or extramarital sexual activity; or
3. The advocacy or encouragement of the use of contraceptive methods or devices.[3]

The Society for Adolescent Health and Medicine revised their position against policies and programs promoting abstinence as a sole option for youth in 2006 with an update in 2017.[4] Evidence suggests that abstinence-only policies and programs are ineffective in preventing HIV, sexually transmitted infections (STI), or pregnancy.[5,6] Moreover, these programs are often harmful and stigmatizing to sexual minority youth.[7,8] It is unethical for me to withhold information concerning HIV/STI prevention and pregnancy as a medical provider. However, in our public schools, this is the norm. Comprehensive sex education is a public health concern, not simply a familial issue.

Provider perceived HIV risk in youth is low in Utah. A survey of Utah primary care providers who care for patients aged 15 to 24 found the two main reasons providers are not testing for HIV are misconception that their patients are not sexually active and low prevalence of HIV in their practice.[9] Only 16 percent of youth providers reported always or often testing for HIV. However, based on the most recent STI statistics from the Utah Health Department, people aged 15 to 24 represent 16 percent of Utah's population, but this group accounts for 59 percent of all reported cases of chlamydia and 33 percent of gonorrhea.[10] Our youth providers are clearly underestimating the sexual activity of their patients.

As parents, grandparents, aunts, uncles, and cousins, we can advocate for the youth in our lives at their schools, the school district, and the state level. We need to ensure their sexual education embraces

a holistic approach validated by science that can normalize a space that includes sexually active minority youth. Important themes of a comprehensive sexual education include communication skills, consent, contraception, accurate information about human development, anatomy and reproductive health, HIV/STI prevention, and emphasizes human rights, gender equality, and sexual diversity. As healthcare providers, we also need to talk to our adolescent patients in a non-judgmental, comfortable and accurate approach about sexual and reproductive health.

Utah by the Numbers

Turning to HIV demographics, the most recent 2020 census data of race and ethnicity in Utah reports 75.4 percent White, 15.1 percent Latinx , and 1.1 percent Black Utahns.[11] However, when looking at the racial/ethnic demographics of new HIV diagnoses, we see 50 percent are White, 34 percent are Latinx, and 8 percent are Black.[12] Latinx patients are more likely to be diagnosed with advanced AIDS more than any other ethnic group and foreign-born Utah residents are more likely to be diagnosed with AIDS at the time of diagnosis.[12]

Medicaid expansion occurred in Utah in 2020 and has helped many of our patients, but disproportionally left unauthorized immigrants completely dependent on Ryan White funding. Eligibility for the Utah Department of Health (UDOH) Ryan White B program—which funds HIV medical services, the AIDS Drug Assistance Program (ADAP), health insurance premiums and cost-sharing assistance—is set at 250 percent of the Federal Poverty Level (FPL) or $16.35/hour.[13] The most recent data, prior to Medicaid expansion in 2019, estimated that one-third of all PWH in Utah were enrolled in Ryan White B/ADAP.[12] Nationally, two states have a lower FPL: Texas and Idaho are both at 200 percent. Nine other states use 300 percent and the other thirty-eight states use 400-500 percent of FPL as eligibility for ADAP. In the U.S., 70 percent of Ryan White clients are either Black (71.6%) or Latinx (23.3%) PWH, dramatically highlighting racial and ethnic disparities.[13]

The greatest barriers I see are access to affordable HIV care and medication, racism, and anti-immigration, all intermixed with stigma.

A Case Study

To better understand how this disproportionately affects the Latinx population, consider my patient Mr. Hernandez (name and key specifics changed). Mr. Hernandez is a 54-year-old man diagnosed with HIV five years ago. He has worked for the same construction company doing installation for the past eight years making $25/hour for eight to nine months of the year ($35,000/year). His rent for a three-bedroom apartment is $2,000/month (69% of income). The average rent in Salt Lake City for a one-bedroom apartment is $1,470/month. Mr. Hernandez does not qualify for Medicaid or employer-based health insurance because he is an unauthorized immigrant. He also does not qualify for Ryan White B as his FPL is 270 percent. However, he doesn't count his wife and her three children on his Ryan White application. Adjusting his FPL for five people (112%) would allow his medication to be covered by Ryan White. However, they are worried that their information and address will be seen by the state government and they will subsequently be deported. Mr. Hernandez's HIV is well controlled as he applies yearly for patient assistance through a pharmaceutical company to receive his antiretroviral therapy (ART). However, we struggle to keep his diabetes in control due to out-of-pocket costs for insulin.

The low FPL eligibility percent keeps many in low-paying jobs, having to make difficult decisions about whether to work over-time, accept advancement/raises or qualify for Ryan White/ADAP services. The FPL does not take into account affordable housing. The National Low Income Housing Coalition found the average minimum-wage employee in the U.S. would need to work 97 hours per week to cover an affordable two-bedroom home at Fair Market Rent, as defined by the U.S. Department of Housing and Urban Development.[14] Affordable was defined as costing no more than 30 percent of a household's gross income for rent and utilities. They estimate in Utah for a one-bedroom apartment the hourly wage should be at least $16.71 an hour and in Salt Lake City $19.25 an hour.[14]

The Health Resources & Service Administration (HRSA) and state health departments need to re-evaluate how FPL can affect medication access and adherence between states and urban centers. Most states have

STOCK.ADOBE.COM/ JOZEFMICIC

already adopted an FPL eligibility at 400-500 percent and this should be standardized to better account for affordable housing. Careful consideration should look at racial/ethnic minorities and foreign-born PWH.

Covering the Cost

In the past two years, we have seen new barriers in accessing medication in our insured patients. In 2022, at least three employer-based health insurance plans and in 2021 four plans did not cover ART. For these patients, we rely on pharmaceutical patient assistance programs to access HIV medications. These pharmaceutical programs were originally created as a short-term solution not as the sole source for HIV medication.

However, more and more insurance plans are restricting the use of patient assistance plans or co-pay cards. Insurance plans with co-pay accumulators or copay adjustment programs focus on specialty drugs, including ART, for which the drug manufacturer provides copayment assistance. These insurance plans exclude manufacturers payments toward a patient's deductible or out-of-pocket maximum. This places more cost on PWH and make it difficult to afford ART.

A 2019 KFF Health Tracking poll found that 29 percent of the general adult population report not taking their medicines as prescribed in the past year due to cost.[15] Furthermore, 12 percent cut pills in half or skipped doses to extend their supply.

I emphasize to every one of my patients the importance of viral load suppression. I echo the undetectable = untransmittable (U=U) message. However, these prohibitive insurance plans make it difficult to achieve viral load suppression. This leads to not only being detectable, but also to worsening of disease, increase hospitalization and antiretroviral resistance.

One of the goals of the Affordable Care Act was to improve the affordability of prescription drugs. However, under current law, insurers are allowed to provide coverage for some HIV medications and not others. On the federal level, the U.S. Department of Labor employer-based health insurance plans are regulated under the Employee Retirement Income Security Act (ERISA) of 1974. ERISA imposes minimum standards for employer-sponsored health insurance, including documentation, reporting and fiduciary requirements. The ACA had little impact on ERISA. However, an amendment under pre-existing conditions could specify ART and other costly medications be covered.

As healthcare professionals, we want to provide the most potent and tolerable medication for our patients. This is not always the cheapest strategy. To keep our patients undetectable, insurers should respect our ability to choose medications in partnership with our patients. States have taken action to protect patients from copay accumulator adjustment policies by enacting legislation that requires insurers to count third party payments, including copay assistance, toward patient cost-sharing limits. A coalition of dozens of groups representing patients across our state, Utah All Copays Count Coalition, have backed a bill this 2022 legislative session to ban copay accumulators in our state.

Current policies in Utah, with their roots in stigma, racism and anti-immigration, create barriers, but are not insurmountable. We must listen to our patients to understand their specific needs. As HIV care providers, along with our partners in epidemiology, public health and policymakers, we play a critical role in evidence-based advocacy that can change and overcome the current barriers to access to HIV treatment and prevention. **HIV**

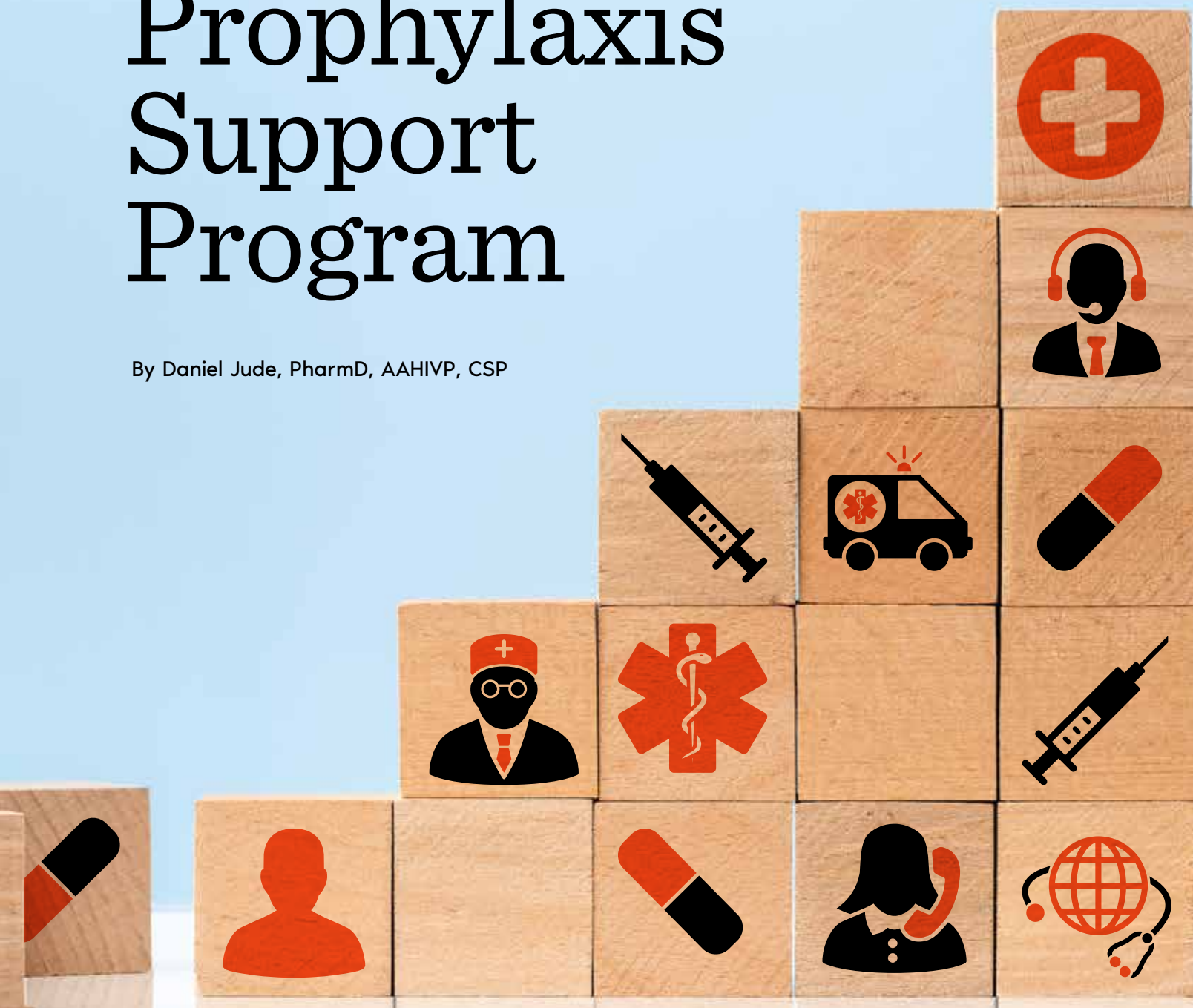
DR. SUSANA WILLIAMS KEESHIN is an adult and pediatric Infectious Disease/HIV specialist at the University of Utah School of Medicine in Salt Lake City, Utah. She co-founded a free PrEP clinic for people without insurance in Salt Lake City. She currently serves on the Board of Directors for the American Academy of HIV Medicine.

REFERENCES

1. Centers for Disease Control and Prevention (CDC). Estimated HIV incidence and prevalence in the United States, 2015–2019. *HIV Surveillance Supplemental Report* 2021;26(No. 1). http://www.cdc.gov/ hiv/library/reports/hiv-surveillance.html. Published May 2021. Accessed 2/10/2022
2. Centers for Disease Control and Prevention (CDC). Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2020.
3. Public Education System—Local Administration, Utah Code § 53G-10-402 (2020)
4. Society for Adolescent Health and Medicine. Abstinence-Only-Until-Marriage Policies and Programs: An Updated Position Paper of the Society for Adolescent Health and Medicine. J Adolesc Health. 2017;61(3):400-403. doi:10.1016/j.jadohealth.2017.06.001.
5. Underhill K, Operario D, Montgomery P. Abstinence-only programs for HIV infection prevention in high-income countries. Cochrane Database Syst Rev. 2007 Oct 17;(4):CD005421. doi: 10.1002/14651858.CD005421.pub2. PMID: 17943855.
6. Chin HB, Sipe TA, Elder R, et al. The effectiveness of group-based comprehensive risk-reduction and abstinence education interventions to prevent or reduce the risk of adolescent pregnancy, human immunodeficiency virus, and sexually transmitted infections: two systematic reviews for the Guide to Community Preventive Services. Am J Prev Med. 2012;42(3):272-294. doi:10.1016/j.amepre.2011.11.006
7. Russell ST, Ryan C, Toomey RB, Diaz RM, Sanchez J. Lesbian, gay, bisexual, and transgender adolescent school victimization: implications for young adult health and adjustment. J Sch Health. 2011;81(5):223-230. doi:10.1111/j.1746-1561.2011.00583.x
8. Elia JP Eliason MJ (2010) Dangerous Omissions: Abstinence-Only-Until-Marriage School-Based Sexuality Education and the Betrayal of LGBTQ Youth, American Journal of Sexuality Education.2010;5:1, 17-35, DOI: 10.1080/15546121003748848
9. Schwarz Josten M, Keeshin S, Knowledge, Practices, and Attitudes of Youth Providers About STI, HIV Testing, and PrEP, Open Forum Infectious Diseases, Volume 5, Issue suppl_1, November 2018, Page S697, https://doi.org/10.1093/ofid/ofy210.1998
10. Utah Department of Health Bureau of Epidemiology. Sexually Transmitted Disease Surveillance 2010-2019, 2020. https://ptc.health.utah.gov/wp-content/uploads/2021/10/2010-2019-Utah-STD-Surveillance-Report-1.pdf. Accessed 2/10/22
11. U.S. Census Bureau. State Profiles:2020. https://www.census.gov/library/stories/state-by-state/utah-population-change-between-census-decade.html. Published August 2021. Accessed 2/10/2022.
12. Utah Department of Health Bureau of Epidemiology. 2019:Annual HIV surveillance Report. 2020
13. https://ptc.health.utah.gov/wp-content/uploads/2021/10/2019-HIV-Surveillance-Report_Final-1.pdf. Accessed 2/10/22
14. ADAP Financial Eligibility as a Percent of the Federal Poverty Level. Kaiser Family Foundation. 2018. https://www.kff.org/hivaids/state-indicator/adap-financial-eligibility-as-a-percent-of-the-federal-poverty-level/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D. Accessed 2/10/22
15. National Low Income Housing Coalition. Out of Reach 2021: The High Cost of Housing report. https://reports.nlihc.org/oor. Accessed 2/10/22
16. Kirzinger A, Lopes L, Wu B, Brodie M. KFF Health Tracking Poll -February 2019 Prescription Drugs. Kaiser Family Foundation, 2019. https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/. Accessed 2/10/22

Building a Post-Exposure Prophylaxis Support Program

By Daniel Jude, PharmD, AAHIVP, CSP



Access to prevention modalities is key to reaching our collective goal to end the HIV epidemic.[1] For post-exposure prophylaxis (PEP) patients, antiretroviral medications should be initiated as soon as possible within 72 hours after exposure to maximize risk reduction. PEP scenarios are considered emergencies due to timing and include both occupational scenarios (e.g., needle stick, fluid splashing, altercation during arrests, exposure while providing emergency response services, etc.) and non-occupational scenarios (e.g., sexual assault, broken condom, black-out events, "Good Samaritan" events where bystanders respond to an emergency, etc.).[2,3] In many of these situations, patients present to emergency departments (ED) and urgent care facilities for care. Providers will send prescriptions to an outpatient pharmacy, educate patients about self-care, and instruct patients to schedule an appointment with a non-urgent provider if warranted. However, care coordination is essential due to emergency care providers not being equipped to ensure patients begin therapy and receive additional care if required.[4]

Access Barriers

Because of the very high cost of PEP medications, insurance coverage can prevent patients from continuing therapy after discharge.[5] Provision of the recommended 28-days of PEP medications in the ED before discharge would be ideal, but this is cost-prohibitive for ED operations without a path for reimbursement. When patients go to the pharmacy to pick up their medications, they may be unable to afford their therapy due to a high copay or lack of insurance coverage. Drug manufacturer copay card programs exist but are often missed as an opportunity to drive access. Income-based free drug programs sponsored by the drug manufacturers also exist but require paperwork coordination and provider signatures, which can be difficult to accomplish in a timely manner in busy EDs or once providers end their shifts. Ideally, access support programs would provide these resources proactively to optimize patient access and outcomes.

Pharmacy-Based PEP Support Program

A specialty pharmacy refers to a pharmacy that provides medication access and clinical support to patients who have complex conditions and/or require complex, high-cost medications. Specialty pharmacy clinical support services include medication administration and side-effect teaching, thorough drug safety assessment including interactions, treatment appropriateness, and follow up contact to assess medication adherence and tolerability. Specialty pharmacy access support services include benefits investigation, prior authorization support, copay card set up, and navigation of grants and other funding sources for medications.[6]

HIV medications often qualify as specialty therapies due to their high cost and clinical complexity. Using existing specialty pharmacy services within a health system, I created a program in 2019 supporting PEP medication access through North Memorial Health's two separate EDs in the Twin Cities Metro area in Minnesota. I partnered with our IT department to leverage our electronic health records (EHR) to create an urgent alert when any antiretroviral was ordered by an ED provider. I downloaded the secure mobile app version of the EHR to my smartphone to allow for mobile notifications. Once alerted, I would either physically visit the patient in the ED or call into the ED to provide services and coordinate pharmacy access and care telephonically. To better support continuity of care beyond medications, I added three components to our standard patient assessment: 1) insurance access, 2) primary care/follow up care access, and 3) mental health services access.

ISTOCK/ TURK STOCK PHOTOGRAPHER; STOCK.ADOBE.COM/AHA-SOFT/ MARTIALRED

Current State

In two years, we have supported over 100 patients through this pharmacy-based PEP support program. Just over half of these patients were non-occupational exposures, which consisted mostly of sexual assault victims with complex and varied needs. To address these needs, we referred patients to mental health services, coordinated access to medications when medication orders were sent to external pharmacies, and discontinued medication orders when patients failed to follow-up to prevent inappropriate use of PEP medications. We also referred multiple patients to benefits specialists at a local HIV service organization, which resulted in patients being enrolled in insurance, receiving help to access medications and other follow-up care for sexual assault victims.

Occupational exposures were mostly complicated by prior authorizations through Worker's Compensation plans and tracking down source patient blood-borne pathogen status when available.

Best Practices and Lessons Learned

Pharmacy Relationship

Specialty pharmacy care delivery models are an ideal fit for supporting PEP medication access. However, many health systems and EDs do not have specialty pharmacy services at the local level. An outpatient pharmacy can provide support by performing the same duties and functions without a full 'specialty pharmacy' designation, though the quality of services requires full engagement of both staff and leadership in the pharmacy.

All health system EDs can benefit from establishing a partnership with a specialty pharmacy or supportive outpatient pharmacy, ideally one managed by the same health system with shared access to the EHR. EDs should, as standard practice, have protocols for handling potential HIV exposures which should include evidence-based formulary selection of PEP medications as well as pharmacy care coordination. Once a specialty pharmacy or supportive outpatient pharmacy partner is found, it is important to work through inventory expectations and timing. Ideally, the selected pharmacy should be open seven days a week, and the ED should be prepared to provide patients with an extra supply of PEP meds if the pharmacy is closed on the weekends.

PEP Rx Alert

The goal of the PEP Rx alert is to proactively engage the pharmacy when a PEP prescription is ordered so access support and clinical services can be provided to the patient. Training ED staff to add another manual step to a complex process is burdensome, so leveraging the EHR to automate this alert is advantageous. Every EHR is different, so be prepared to be creative in working with your IT department to determine the best mechanism to send and receive alerts. Whatever the mechanism, make sure someone is monitoring the 'in-basket' during normal business hours. While the ED must be open 24 hours and be able to provide access to the first dose of PEP medications, the specialty pharmacy does not need to be so long as the ED reviews program expectations with the patient and the specialty pharmacy team engages patients immediately upon opening the next day.

Specialty pharmacy clinical support services include medication administration and side-effect teaching, thorough drug safety assessment including interactions, treatment appropriateness, and follow up contact to assess medication adherence and tolerability.

Access Programs

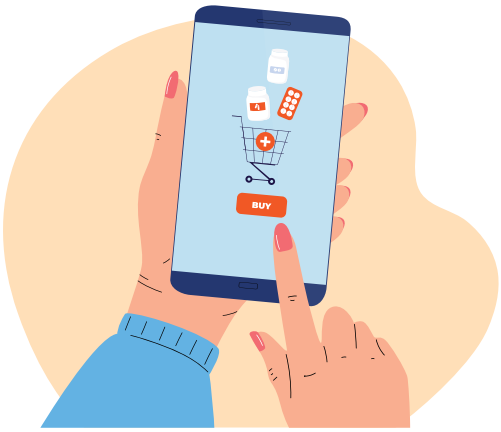
The pharmacy program should be intimately familiar with all copay cards and financial assistance programs available through the manufacturers of PEP medications, public health programs, or the ED's health system. Policies and procedures should be established to promote standardized approaches to addressing access barriers, specifically for employees that are not familiar with how to navigate often complex applications for copay cards and financial assistance programs. Questions to address include: Do you need the patient's income? Do you need the ordering provider's signature? Will the medications need a prior authorization completed due to an insurance barrier?

Other Medications

When patients present with potential sexual exposure to HIV, other medications are often prescribed to prevent transmission of bacterial sexually transmitted infections (STI). Be prepared to collaborate with providers and to counsel patients regarding CDC-recommended interventions. Anti-nausea meds are also often prescribed to help manage side effects of both PEP medications and those to treat bacterial STIs.

Follow-Up Referrals

Be prepared to counsel patients on Pre-Exposure Prophylaxis (PrEP) if they are sexually active. Familiarize yourself with local services for mental health, sexual health, benefits navigators, and primary care. Leverage educational materials to promote access to referrals, including contact information, hours of operation, etc. Utilize a follow-up call to address referral access as well as medication adherence and tolerability.



Emotional Support

Most patients taking PEP are experiencing some level of stress or trauma. For occupational exposures, patients are often processing emotions such as frustration with themselves that they made a mistake at work or guilt that they are burdening their employer and coworkers with time away and extra costs. I suggest becoming familiar with CDC guidelines and recommendations on risk assessment. It is important to be prepared to speak to general risks but defer to providers for the ultimate decision on whether to start and continue PEP medications.

For sexual assault victims, be mindful of tone, body language, and even gender-presentation. This is the ideal time to utilize trauma-informed care principles such as empowering the patient and practicing humility in all communications. These patients might not be in a mental state to communicate complex concepts like medication administration and side effects. Reconnecting with the patient the next day to provide follow-up educational opportunities is essential in this situation. If working with a parent or guardian, acknowledge the mental health needs of the caretaker as well since trauma can impact the entire family unit.

Sexual Assault Nurse Examiners

All EDs will have protocols in place for sexual assault examinations due to the legal component. The protocols will be based on local resources, laws, and regulations. Make sure to understand the local protocols for your community, and proactively collaborate with any internal or external service line that supports this step in the process.

Measuring Outcomes

Though the goal of HIV prevention is obtaining a negative HIV test three months after exposure, that specific data point might be unavailable to the program. Consider monitoring the number of referrals and interventions consistently to demonstrate value.

Justification of Payroll

All programs require a justification of time and payroll to keep the program alive and active. For the health system, money can be saved by filling worker's compensation prescriptions internally, while revenue associated with the PEP medications can help fund specialty pharmacies and other critical services to support patients in need.

Summary

PEP support programs should involve a specialty pharmacy service or supportive outpatient pharmacy service component, and pharmacists can play an important role in driving the program and supporting care coordination tasks to ensure patients can access therapy and other needed care. The medications used to prevent HIV will continue to be prohibitively expensive for uninsured individuals, therefore the benefits of creating a program where either the pharmacy or the ED can bill for medication costs are essential. Collaboration is key to building trust across many service lines, including pharmacy, nursing, providers, social work, and mental health services. As programs supporting PEP access are built, health systems and other institutions will optimize HIV prevention, and patients will receive a higher quality of care. **HIV**

DANIEL JUDE, PharmD, serves as a clinical pharmacy specialist at Trellis Rx, a leading specialty pharmacy services partner for health systems. He currently practices in the Infectious Disease Clinic at North Memorial Health in Robbinsdale, Minn. With over a decade of experience in specialty pharmacy, Daniel brings extensive background in clinical program building and management to Trellis Rx. He is passionate about improving access to care and outcomes for patients with HIV and participates with multiple Minnesota public health work groups.

REFERENCES

1. United States Department of Health & Human Services. Key Strategies in the Plan. https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/key-strategies (accessed 2022 Feb 17).
2. Dominguez, Kenneth L.;Smith, Dawn K.;Vasavi Thomas, et al. Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016. https://stacks.cdc.gov/view/cdc/38856 (accessed 2022 Feb 17).
3. Kuhar, David T.;Henderson, David K.;Struble, Kimberly A et al. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis. https://stacks.cdc.gov/view/cdc/20711 (accessed 2022 Feb 17)
4. Johns Hopkins University, Armstrong Institute for Patient Safety and Quality. Improving the emergency department discharge process: environmental scan report. (Prepared by Johns Hopkins University, Baltimore, MD, under Contract No. HHSA 2902010000271.) Rockville, MD: Agency for Healthcare Research and Quality; December 2014. AHRQ Publication No. 14(15)-0067-EF.
5. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Cost Considerations and Antiretroviral Therapy https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv (accessed 2022 Feb 17)
6. National Association of Specialty Pharmacy. NASP Definitions of Specialty Pharmacy and Specialty Medications. https://naspnet.org/wp-content/uploads/2017/02/NASP-Defintions-final-2.16.pdf (accessed 2022 Feb 17)

SHUTTERSTOCK/ LULU877

Expanding Access to Hepatitis C Treatment to the Margins

By Tim Nolan, ANP, AAHIVS

THE INITIAL CHALLENGE TO ACCESS hepatitis C (HCV) care in rural North Carolina became clear through an honest exchange with a patient. Many of our most apparent challenges to care are often revealed by the patient consumer. In the middle of successful treatment for HCV, a young person who injects drugs (PWID) commented, "None of my friends come to clinics like this. They all stay out in the woods." By naming the fact that most of those at risk for HCV would rarely approach a standing brick-and-mortar clinic, it became clear at that moment that direct-acting antiviral (DAA) treatments needed to be delivered within the service that PWID do access: syringe exchange and harm reduction services.

A new care model needed to be developed to radically simplify access to the new life-saving HCV treatments that had become available, bringing them to those who would not access traditional care and yet would continue to inject drugs, leading to potential transmission.

A Cure Comes to Market

In 2014, with the introduction of ledipasvir/sofosbuvir, a one tablet DAA formulation, the world of hepatitis C treatment and the prospects for cure changed dramatically. Since that time, further DAA agents have been introduced, and we now see 98 to 99 percent HCV cure rates through the use of pan-genotypic drugs. Unfortunately, the HCV epidemic moved well past primarily affecting baby boomers during this same time. With the development of the opioid and

ISTOCK/ GEARSTD

methamphetamine drug crises in the United States, a large swath of those now needing treatment lies in a younger age group ranging from ages 15 to 50.

Initially, the seemingly greatest obstacle to getting an individual treated was getting medical providers to screen baby boomers and then getting the insurance providers to approve payment. However, with the new face of the epidemic, the obstacles to HCV care have become much grander. Active injection drug use, mental illness, homelessness, social chaos, lack of transportation, and a broader lack of general trust in the existing medical system are several of the key obstacles that keep the U.S. sustained viral response (SVR) rate or cure at less than 10 percent overall. To address the current HCV epidemic, the approach to treatment must radically change to take these curative medications to those needing treatment in their marginalized, often chaotic settings.

Meeting People Where They Are

In February 2020, a unique collaborative effort was established in the Piedmont region of the southern Appalachian Mountains of North Carolina. Working to address the lack of access to care and treatment for this hard-to-reach population, High Country Community Health, the regional Federally Qualified Health Center (FQHC), and its HCV provider, joined with the well-established local harm reduction/syringe service provider (SSP), Olive Branch Ministry, in development of an effort to bring DAA treatment to the individuals utilizing the SSP services.

Syringe service participants were invited to host a "hepatitis C testing gathering" in their existing exchange "space," be it a home, garage, tent, car, or "trap house." Through the host's invitation, participants would receive a rapid HCV antibody test. If they tested positive, their treatment labs were immediately performed on-site (HCV RNA, HIV screening, HBsAg, CMP, CBC). These labs were run through the indigent program of the FQHC, interpreted by the provider, and the individual was notified if DAA treatment was indicated. Treatment was accessed through existing drug assistance programs and was delivered to the individual with education regarding possible side effects, need for full adherence, and follow-up labs. With the delivery of their second month supply of medication, four-week SVR labs were be performed to assess response to treatment.

Through the entirety of this care process, no clinic visit was required by the individual patient. The need to come to an established brick-and-mortar clinic was understood to be a profound barrier to care for this community. Care, including labs and medication, was brought to the individual. All care remained in the context of continued harm reduction practice/syringe exchange services to reduce transmission and the possibility of reinfection.

Program Results

Over nearly two years, the agencies together observed the following through this novel effort:

- 95 individuals, either diagnosed through rapid on-site testing or self-identified, engaged in low threshold to access HCV care. All of these individuals were seen in a non-clinic setting and would most likely not have engaged in care otherwise.
- 21 individuals were determined to have self-cleared HCV
- 51 individuals received DAA medication through established drug access programs. 41 of these individuals completed treatment, and eight remain currently in treatment.
- 24 individuals initiated treatment but ultimately were lost to care before completing.
- Two individuals completed initial treatment and then with future interaction were determined to have been reinfected.

As the program developed, another need of a small subset of those participating emerged: low threshold medication for opioid use disorder (MOUD). In the setting of harm reduction/SSP outreach services and the thriving low threshold HCV treatment program, participants were encountered who requested access to MOUD without attending typically required clinic visits. These were individuals who, as with their HCV, would find it nearly impossible to access care as traditionally defined due to lack of transportation, employer issues, or simple social/structural chaos. The agencies responded by developing a low threshold MOUD program for select participants, and the program continues as of this writing.

The implications of these low threshold efforts to the future of HCV treatment, MOUD care, and HIV care are profound and revealing. All HIV care providers are deeply aware that there exists a growing populace whose HIV care needs are not met by our existing stationary systems. These patients will simply not receive care if care is not delivered to where they are.

The successes of HCV outreach care can and should be replicated for those needing HIV care and who for many of the reasons described above fail to present for such care. The goals of reducing HCV and HIV in these affected communities and an adequate response to the monstrous opioid and methamphetamine epidemics can only be addressed if care to those affected occurs where they find themselves in this moment of their lives. **HIV**

TIM NOLAN is an Adult Nurse Practitioner who has provided HIV care for over thirty years. Initially providing care in New York City, he now provides HIV care, hepatitis C treatment and medication for opioid use disorder in the foothills of North Carolina. He also volunteers with the regions Harm Reduction/Syringe Service organization, Olive Branch Ministry.

Growing Pains

Access to HIV Testing and Care for Young People

By Peter Thomas Leistikow and Joseph Steven Cervia, MD, AAHIVS

IT WAS THE END OF MY THIRD YEAR OF MEDICAL SCHOOL when I saw a 16-year-old boy in the emergency department for persistent abdominal pain. Gaining his trust by sending mom out of the room during our interview, I learned that he had recently engaged in sexual activity with both boys and girls. At the time, my co-author, Dr. Joseph Cervia, and I were collaborating on a new manuscript on the importance of HIV testing and linkages to care for adolescents and young adults ages 13 to 24. I would be remiss if I ignored the lessons learned. It had to be done. I asked him if he wanted to get tested. He agreed, but he had some questions. Namely, he wanted to know if his mom would find out. He wanted to know if it were possible that he had AIDS. These anxieties reflect the broader barriers to HIV testing, such as fear of results or stigma, lack of knowledge about testing, low perception of individual risk, and lack of experience with testing by providers.[1]

In addition, young people also encounter several age-specific barriers such as result confidentiality, inconsistent local laws and guidelines on parental consent requirements, and lack of same-day test results. With these additional challenges, we need to consider how we reach this important population. Although adolescents and young adults account for one in five new HIV transmissions, it is estimated that 44 percent of young people with HIV do not even know their diagnosis.[2] Despite Centers for Disease Control and Prevention (CDC) guidelines recommending routine HIV screening for patients aged 13 to 64, studies of adolescents and young adults report low rates of HIV test utilization, even among those who state that they are sexually active.[3,4] It is clear that when it comes to delivering HIV testing to adolescents and young adults, our medical system is experiencing growing pains.

Together with Vidhi Patel and Christian Nouryan of the Institute of Health Innovations and Outcomes Research and the Zucker School of Medicine at Hofstra/Northwell, we published the manuscript, "Acceptability of HIV testing for adolescents and young adults by delivery model: a systematic review" online ahead of print in December 2021.[5] This paper was an endeavor to address one question: How do adolescents and young adults access HIV testing and care? Namely, we wanted to know which care delivery models consistently and effectively offer HIV testing and establish linkages to effective HIV treatment and ongoing care for these young people if the results come back positive.

ISTOCK/ DRAZEN ZIGIC

We performed a systematic review of the literature to answer these questions. Broadly, the models of HIV care delivery can be categorized as emergency departments (ED), primary care offices or hospitals, community-based programs (such as after-school screenings or mobile screening vehicles), or sexually transmitted infection (STI) clinics. After reviewing the 59 studies that met the criteria for inclusion in the review, we found that in North America, EDs have the highest rates of adolescent and young adult acceptance of HIV testing. Not only do approximately 75 percent of adolescents and young adults who are offered an HIV test in the ED accept it, but they are also more likely to subsequently be linked to HIV care than in any other setting. Test acceptance levels remain high for EDs whether they use a strategy of testing all adolescent and young adult patients unless they refuse (opt-out) or ask each patient whether they would like testing as I did for my patient with abdominal pain (opt-in). These findings indicate that EDs have an important role in ensuring the proper detection and treatment of HIV. Reconsidering how we use EDs in the fight against HIV may be an important element in addressing the growing pains of a medical system besieged by old and new pandemics.

Future Directions

Partnership

If knowing is half the battle, our finding that EDs are important sites for HIV testing and linkage to treatment should be an impetus for those who provide care for people with HIV to deepen their relationships with ED staff. In comparison with staff on the inpatient wards who may regularly work with dedicated practitioners of infectious disease and HIV medicine, those who work in the ED may be less familiar with providers of HIV care, impairing continuity of care.

HIV specialists may consider volunteering to offer continuing education at ED conferences and grand rounds focused on HIV testing and linkages to care for young people to establish and strengthen collaboration. Many advances in HIV testing and antiretroviral therapy have occurred since days of old, and education tailored to addressing the latest treatments for HIV may spread awareness that HIV is ultimately a treatable chronic condition in the setting of proper resources and education. HIV specialists can also draw from their experiences in testing and treatment discussions to advocate for culturally competent HIV counseling that effectively alleviates the fears of historically marginalized groups.

HIV care providers can consult with ED staff to facilitate testing for at-risk patients and make themselves available to newly identified people with HIV to promote linkage to care even before discharge. Collaborative relationships between HIV specialists and ED providers can create and bolster relationships between patients and providers, especially after a new HIV diagnosis.

Developing Robust Screening

Recognizing that EDs are particularly effective at delivering HIV testing for young people, it is natural to try to determine their "secret ingredient" for success. One answer lies in accessibility: Adolescents and young adults generally make up a relatively healthy population that may not interact with the medical system beyond acute issues that bring them to the ED. Another lies in robust screening protocols. While in our systematic review we found that opt-in studies had a significantly higher HIV test acceptance rate than those that utilized the opt-out model, EDs that use an opt-out model may have higher absolute numbers of patients screened for HIV despite a greater percentage of refusals. Additionally, opt-in programs may be bolstered by policies that encourage HIV tests to be offered, such as the mandatory HIV screening requirement for all patients older than 13 arriving at EDs in New York.

ED-based screening initiatives such as the Screening, Brief Intervention, and Referral to Treatment (SBIRT) already espouse

ISTOCK/ DRAZEN ZIGIC

"You're on your own, kid
You are
Make my way through the motions, I try to ignore it
But home's looking farther the closer I get
Don't know why I can't see the end
Is it over yet? Hmm
A short leash and a short fuse don't match
They tell me it ain't that bad, now don't you overreact
So I just hold my breath, don't know why
I can't see the sun when young should be fun (Fun)
And I guess the bad can get better
Gotta be wrong before it's right
Every happy phrase engraved in my mind
And I've always been a go-getter
There's truth in every word I write
But still the growing pains, growing pains
They're keeping me up at night"

–Alissia Cara, Growing Pains

a "we ask everyone" ideology that applies to HIV screening as well. These initiatives can work in tandem with existing screening measures that prioritize groups vulnerable to HIV to expand HIV testing to all patients entering the ED. Providers of HIV care can work with EDs to incorporate HIV testing into the existing panel of ED screening questions and provide training on approaching these topics with sensitivity and effective patient education.

Patient Education

The handout is a staple of public health. Whether a pamphlet detailing vaccine benefits and side effects or a pharmacy medication summary, we depend on easily understood and visually engaging materials to involve patients in their care and provide a receipt for medical interventions rendered. Although it is possible to make these materials freely available online, EDs have the unique opportunity to put these sorts of patient education materials directly into the hands of a largely healthy population encountering an acute illness—adolescents and young adults. Bedside patient screening and education do not preclude the use of effective patient education materials developed by HIV specialists. Rather, such educational materials can reinforce these initiatives while expanding awareness of outpatient resources for HIV after the ED visit has concluded. HIV care specialists can use these materials to be distributed in the ED to make adolescents and young adults more aware of the symptoms, risk likelihood, and prevention strategies for HIV, including PrEP for select groups. Adolescents and young adults may have a low perceived risk for contracting HIV, so effective patient education is instrumental in preventing HIV in this population.

Areas for Further Study

In many ways, the effectiveness of EDs in HIV screening is a testament to the idiosyncrasies and disparities inherent in the U.S. healthcare system. Further research is needed to determine the cost feasibility of ED screening for HIV relative to other screening sites. Future studies should also evaluate the effectiveness of linkage to HIV care from EDs and establish that HIV care is reaching the gold standard of undetectable equals untransmittable (U = U), slowing the spread of disease to others in the adolescent and young adult peer group. Lastly, the current literature on HIV testing for young people suffers from a lack of data on the intersection of race and gender in test acceptance and linkage to care. If we are to address the needs of underserved populations, we need to know more about the effectiveness of our current approach, especially as we expand testing from the traditionally overlooked HIV testing site, the ED.

Conclusion

While there is still much to be discovered regarding adolescents' and young adults' ever-changing attitudes and preferences toward HIV testing, the knowledge that EDs are an effective venue for HIV testing for this key population should be cause enough to establish and strengthen ties between HIV providers and ED staff. Seen in a new light, these growing pains are simply proof that we are moving onto something greater, a system ready to address the needs of all patients along the continuum of HIV care. **HIV**

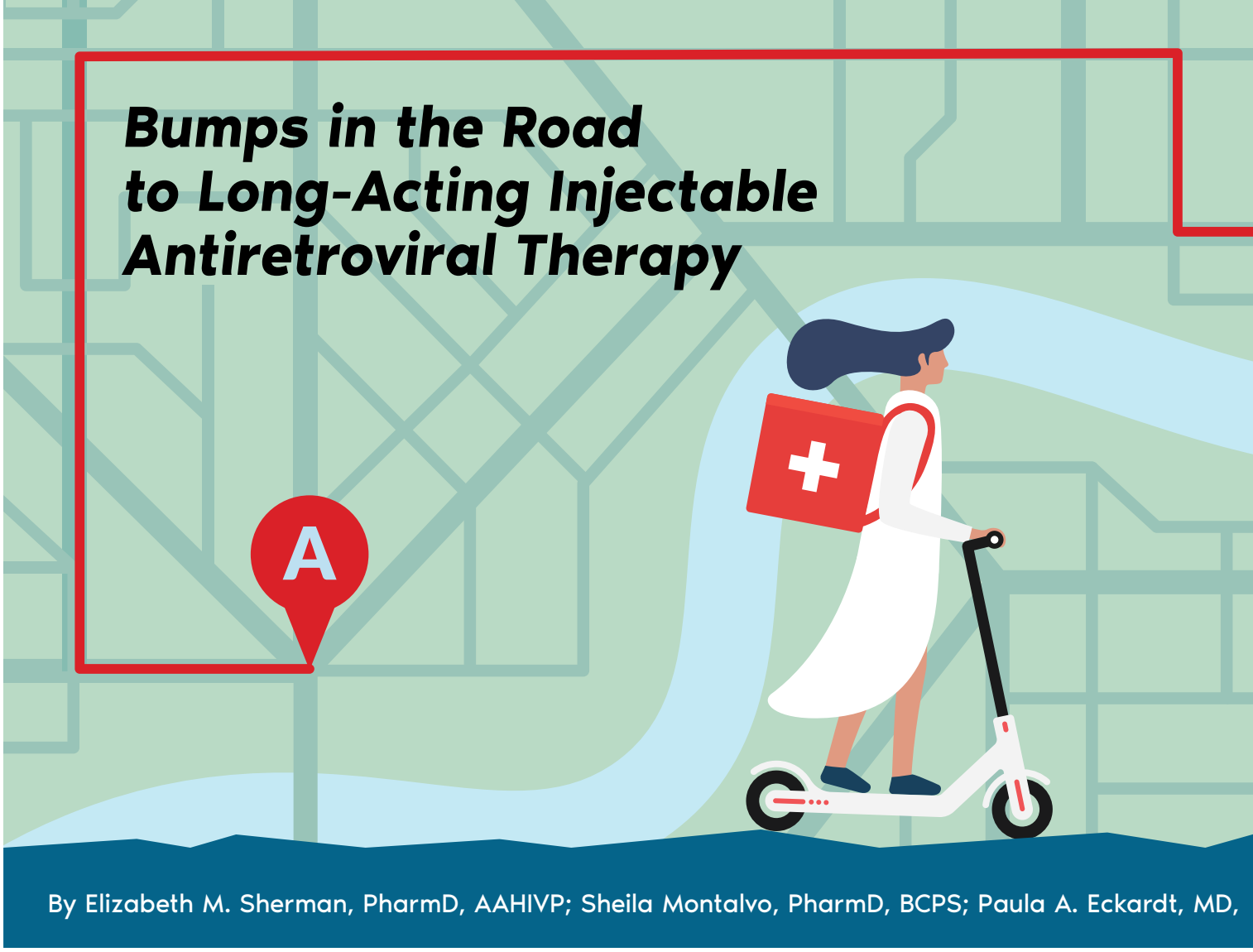
PETER LEISTIKOW is a fourth-year medical student at the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell in Hempstead, N.Y.

DR. JOSEPH S. CERVIA is a clinical professor of Medicine and Pediatrics at the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell in Hempstead, N.Y. He is also senior medical director at HealthCare Partners, IPA & MSO in Garden City, N.Y.

REFERENCES

1. Leblanc NM, Flores DD, Barroso J. Facilitators and barriers to HIV screening: a qualitative Meta-Synthesis. Qual Health Res 2016;26:294–306.
2. amfAR. Statistics: United States, 2020. Available: https://www.amfar.org/about- hiv-and-aids/facts-and-stats/statistics-united-states/
3. Branson BM, Hands eld HH, Lampe MA, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. MMWR Recomm Rep 2006;55:1–17.
4. Van Handel M, Kann L, Olsen Emily O'Malley, et al. HIV testing among US high school students and young adults. Pediatrics 2016;137:e20152700.
5. Leistikow P, Patel V, Nouryan C, Cervia J. Acceptability of HIV testing for adolescents and young adults by delivery model: a systematic review. J Investig Med 2021. Epub ahead of print: December 2021. doi:10.1136/jim-2021- 002056.

Bumps in the Road to Long-Acting Injectable Antiretroviral Therapy



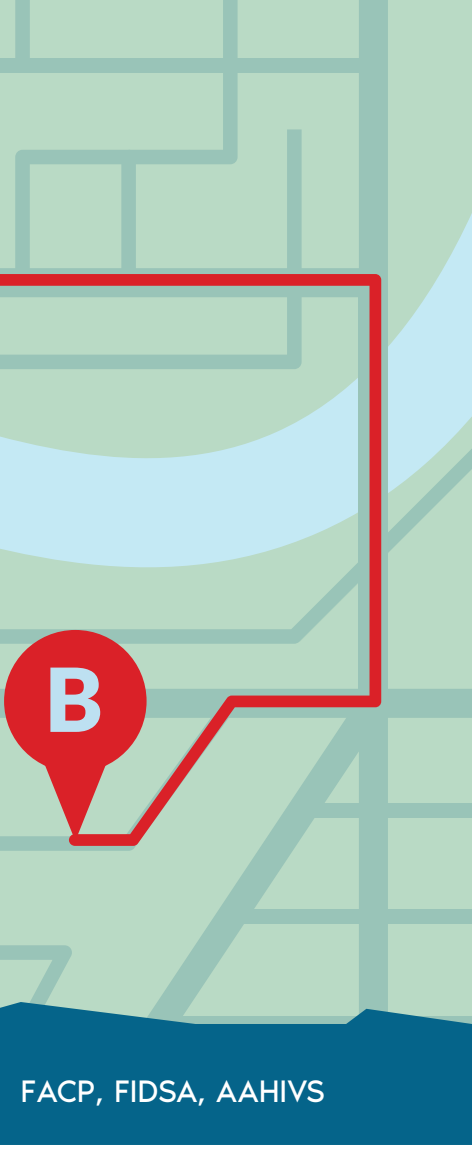
By Elizabeth M. Sherman, PharmD, AAHIVP; Sheila Montalvo, PharmD, BCPS; Paula A. Eckardt, MD,

WE WERE ELATED when the first long-acting (LA) injectable antiretroviral therapy (ART), cabotegravir/rilpivirine, was approved in January 2021. This was the first of many new and emerging LA ART regimens for the treatment of HIV. These monthly, and now bi-monthly, injections were a dream come true because they removed the requirement of taking daily oral medication for treating HIV, representing a significant advancement in HIV medicine. Many of our patients established an early interest in switching their ART regimen to the LA medications, as they saw an opportunity to rid themselves of a daily reminder of their HIV status and the potential to improve their adherence. With two clinical pharmacists in our Ryan White-funded HIV clinic serving over 1,500 people with HIV in South Florida, we soon began building a list of potential patients who were clinically eligible and interested in switching their current ART to these new agents.

However, our enthusiasm and the patients' optimism were soon tempered when faced with the reality of accessing these medications in our clinical setting. The rollout of LA ART leaves room for improvement as access to LA ART has proven impractical for many who would benefit from it. Our experience within our health system has been challenged by difficulties navigating insurance benefits and acquiring these medications.

We should start by noting that we have had no issues obtaining the cabotegravir and rilpivirine oral lead-in medications. The company is quick, efficient, and able to accommodate these requests seamlessly. The oral lead-in is often received within two days of making the request. However, we warn prescribers that while the oral lead-in is easy to obtain, the ensuing process to obtain the intramuscular injections can be problematically tedious and time-consuming. Providers should be forewarned to avoid ordering the oral lead-in therapy before the injection is fully approved by a patient's insurance.

In one instance, a provider ordered the oral lead-in before ordering the injection, and the patient finished the oral lead-in without having the injection available to administer. In this case, the issue resolved when the patient received the initiation injection seven days later. Ideally, this patient should have received their initiation injection on the last day of oral lead-in. If the two distinct processes for ordering the oral lead-in and ordering the injections communicated better



FACP, FIDSA, AAHIVS

with each other, we believe sub-optimal circumstances such as the one described could have been better prevented.

Improving Access for Injectables

We continue to struggle with the acquisition of the injectable agents themselves. We have found that benefits investigations may be inaccurate, particularly if the patient has more than one form of insurance or coverage. In the case of more than one payor source, benefits investigations are performed independently and fail to consider how the two payors work simultaneously for coverage. Often the investigation reveals that a medical or pharmacy prior authorization is necessary, which results in additional delays in obtaining the medication.

We have found it necessary to take additional steps in acquiring this medication, specifically contacting the designated specialty pharmacy to ensure the LA injectable is processed correctly. Some insurance plans consider LA ART as non-formulary and will exclude it entirely—an obstacle we are unable to overcome. In cases where the medication is covered, various insurance plans cover it differently. Florida Medicaid and Medicare cover it under pharmacy benefits and allow for quick processing of the medication. However, we have found that most commercial insurances cover it under medical benefits, an obstacle for pharmacies to process efficiently. If an insurance will only cover the medication under medical benefits and the pharmacy processes the prescription under pharmacy benefits, the claim will be rejected and oftentimes does not move forward in the process at the pharmacy.

This distinction between medical and pharmacy benefits is important and presents an additional recurring problem. Pharmacies need to process prescriptions differently depending on how they are covered. For example, although our clinic provides medical care to our patients, pharmacies cannot process these prescriptions unless our clinic is known to the insurance companies as a medical benefits provider. Up until now, this has not been a common challenge in our practice and the remedy has proven time- and labor-intensive.

And then there are seemingly arcane issues that we face resulting in delays, such as inconsistencies between the online and paper enrollment forms and challenges with obtaining a copay card online. These smaller issues are not insurmountable, but they further indicate that the process must be improved.

Lessons Learned

Throughout this process we have learned some important lessons. Specifically, it is necessary to have a highly organized system or dedicated person, to oversee the medication acquisition process. It is necessary to meticulously plan and track each patient to ensure the medication is ordered and available on time. As always, efficiency improves with experience as the key features of typical situations and insurance companies are learned. Accordingly, we have streamlined a process for obtaining medication through buy-and-bill. Our healthcare system's specialty and home infusion pharmacies were able to navigate this process flawlessly for us and we are grateful for their collaboration in medication procurement for our patients.

HIV has an unfortunate history of disparities in access to care and treatment, particularly for underserved communities. With the goal of ending the HIV epidemic, we need to make modern advances in HIV medicine easily accessible to all patients, not just those with exceptional insurance or those who can afford to pay out of pocket. While we cannot speak for the rest of the country, we can attest to our experience in South Florida which carries the highest HIV burden of any metropolitan area in the country. Our ability to easily acquire LA ART for our patients is significantly limited. The willingness of providers and patients to adapt to new medication delivery systems depends on their implementation and the global perceptions of their advantages.

LA ART is a huge part of the future of HIV medicine, and we know several additional LA ART agents are likely to receive approval in the near future. The challenges we describe can be overcome by competent providers, especially those with abundant resources, but they represent an undue challenge to those serving vulnerable patient populations. It is imperative that we work together now to streamline acquisition and ensure equitable patient access to these medications. **HIV**

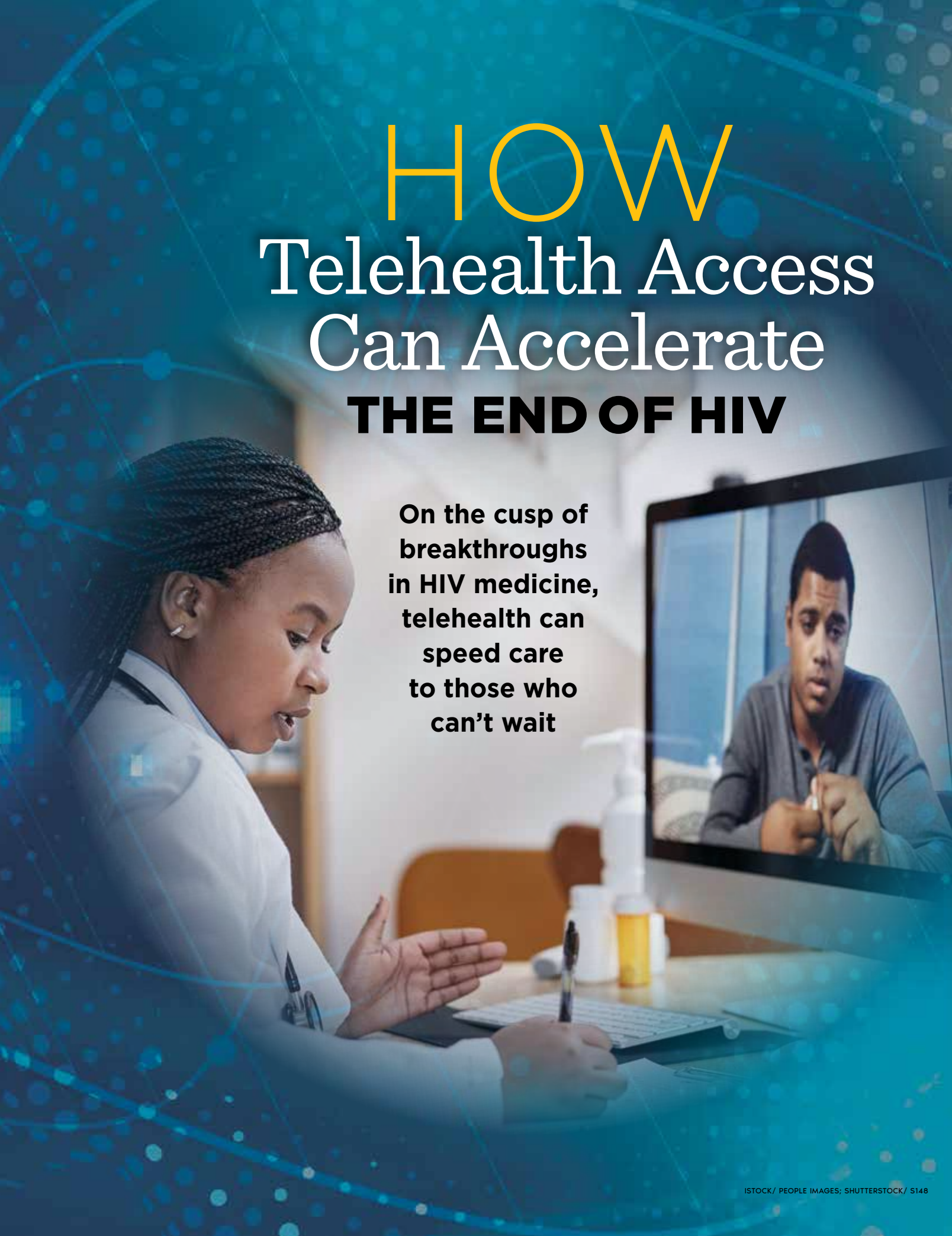
ELIZABETH SHERMAN, PharmD, is an associate professor of Pharmacy Practice at the Nova Southeastern University College of Pharmacy in Fort Lauderdale, Fla. She holds a clinical appointment with the Memorial Healthcare System Division of Infectious Disease in Hollywood, Fla. as a clinical pharmacist with expertise in HIV/AIDS.

SHEILA MONTALVO, PharmD, is HIV/Infectious Disease clinical pharmacist for the Memorial Healthcare System. She currently practices at both Memorial Physician Group's Division of Infectious Disease in Hollywood, Fla. and Memorial Specialty Pharmacy in Miramar, Fla. providing comprehensive pharmaceutical support to patients within their Ryan White HIV/AIDS Program-funded clinic and pharmacy.

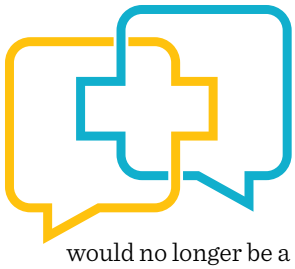
DR. PAULA ECKARDT is the chief of Memorial Division of Infectious Disease, medical director of Antimicrobial Stewardship and Infection Control, and medical director of Memorial Health Care System's Ryan White Clinic in Hollywood, Fla. She is also a clinical assistant professor of medicine at FIU Herbert Wertheim College of Medicine in Miami, Fla. and an affiliate assistant professor of Clinical Biomedical Science at FAU College of Medicine in Boca Raton, Fla.

HOW Telehealth Access Can Accelerate THE END OF HIV

On the cusp of breakthroughs in HIV medicine, telehealth can speed care to those who can't wait



ISTOCK/ PEOPLE IMAGES; SHUTTERSTOCK/ S148



By Emily Rymland, DNP, FNP-C, AAHIVS

IT IS SIMULTANEOUSLY AN EXHILARATING AND DEEPLY FRUSTRATING TIME to provide HIV care. When I entered HIV medicine in the 80s, starting as a hospice nurse in San Francisco caring for dying patients, I dreamed of a future when HIV would no longer be a death sentence. Now with HIV treatments, pre-exposure prophylaxis (PrEP), and the knowledge that undetectable equals untransmittable (U=U), we've reached that future. HIV is an easily treatable chronic condition, easier to manage medically than diabetes.

And yet, the virus is still spreading, people are still unable to access care and, tragically, are still dying globally and in the United States. Certain groups are disproportionately bearing the brunt of the epidemic because education, prevention, and care are not equitably distributed. People of color, transgender individuals, women, and cisgender men are often left out of the conversation. Too many medical providers don't want to talk about sex and therefore don't address the need for testing or PrEP. Stigma prevails, and stigma is a killer.

To reach these populations and accelerate the end of HIV, we must put the full force of our efforts behind strategies we know to work, and one of the most important and effective tools is telehealth.

The Potential and Promise of Telehealth for HIV Prevention

For the past three years at the telehealth provider Nurx, I've helped pioneer the delivery of PrEP, post-exposure prophylaxis (PEP), sexually-transmitted infections' (STI) testing, and HIV care through telehealth. At Nurx, we provide primarily asynchronous care, meaning that patients and providers interact through online health assessments and secure messaging. There are no appointments required and, in most cases, no phone calls either. This type of care certainly looks and feels different from how most medical providers were trained, but I've learned that it is superior to the traditional brick-and-mortar clinic for many types of care.

The most obvious advantage of telehealth is that faster is better. The more rapidly patients can access care, the better the outcomes. This is true in many specialties, but it is very true for PrEP, PEP, and HIV care. Reducing the wait between when a person thinks they might need PrEP or HIV testing to when they can request it is vital to ending the HIV epidemic. Many people cannot easily access a brick-and-mortar clinic. They may not be able to get away from work or family responsibilities to get to an appointment, or they may live far away from a PrEP-educated provider and cannot afford gas or transportation.

Privacy and Safety Result in Better Care

Speed and convenience are vital, but the truly valuable and unique benefit of telehealth for HIV prevention is the direct access to private and stigma-free care. Now, anyone can connect with AAHIVS-certified and primary care providers who have been trained to deliver PrEP and HIV testing and care via telehealth. With this model, patients can reach out any time, day or night, from their phones or computers, in whatever setting they prefer. Virtual care empowers patients to be honest because people are more forthcoming when they feel safe.

We've done a good job of reducing the stigma around HIV in some areas of the country. Therefore, it may be easy to forget that in the majority of the U.S., there remains immense fear of HIV and shame surrounding the ways people contract it, even on the part of providers. We had a patient taking PrEP in his 40s who had been going to the same family doctor in his small town since childhood, but the doctor didn't know the patient was gay. Too many medical providers don't ask about patients' sexual practices. In some cases, even when a patient asks for information on PrEP or testing, the medical provider will say that they don't "do" sexual healthcare and that it's not part of primary care. That needs to change. Sexual health is health.

Even people with non-judgmental, sex-positive medical providers may be too ashamed to be honest about their sexual practices in a brick-and-mortar setting, and this is especially true in rural areas and more religious or socially conservative communities. I've had many Nurx patients taking PrEP say things like, "I could never get PrEP in person. In my town, my uncle is the pharmacist, and my cousin is the phlebotomist." There is nowhere for them to go without exposure. For people in small towns and many southern states, sending them home lab test kits and prescriptions in unmarked boxes is critical to getting them and keeping them on PrEP.

When we allow people to open up and ask questions, from the privacy of home, on their phones or computers, we break through the lingering stigma of HIV and silence around sex. And while most patient-provider interaction at Nurx happens through online

ISTOCK/ KARNO MUJI SAPUTRA

messaging, our patients are anything but silent about their sexual practices. In the decades when I delivered sexual and reproductive healthcare in brick-and-mortar settings, I never heard the level of openness and honesty from patients that I have during the past few years of caring for people through telehealth! The safety provided by the relative anonymity of a phone or computer screen empowers them to share very personal details. They're more likely to disclose their sexual history, practices, and plans. I recently had a female patient tell me that she's planning to have sex with multiple partners she doesn't know, and she wants to be safe. There are very few brick-and-mortar settings, even in liberal cities, where a patient could say that without being shamed or warned about safety. But at Nurx, we say, "Great, good for you. Let's get you started on PrEP, and this is what your STI testing schedule should be."

Telehealth puts the PrEP Decision in Patients' Hands

Empowering patients to be honest about their sexual practices means allowing them to decide if PrEP is right for them without pushing it or gatekeeping access. In a traditional care setting where a provider only sees a patient once a year, often less, conversations around PrEP may feel more loaded and limited by whatever is going on in the patient's life at that time. With telehealth, we can let patients start on PrEP any time and make that decision themselves. We encourage openness, but if a patient has determined they need PrEP and do not want to share why, that's completely respected. Typically, we've found that people on PrEP due to injection drug use often don't disclose. And that's OK.

Additionally, sometimes PrEP is for someone's mental health instead of their physical health. For example, we've had patients whose partners have HIV and are on treatment and undetected but they still want PrEP because they have anxiety around HIV transmission. In that case, we will prescribe it and say, "We're glad your partner's undetectable, and you're not at risk, but you can have PrEP as an additional protection so you can enjoy your sex life." Sex is more than just physical acts. If PrEP promotes intimacy and self-empowerment, I am always in favor of it.

Patients can decide if they should be on PrEP. We don't care why they need it. If patients feel they need it, we're going to give it to them as long as they don't have a medical condition that requires more complex in-person care. Otherwise, they are in control of their own health, and the Nurx team is here to serve them.

Finding Opportunities to get the PrEP Message to Women

I hope that soon AAHIVS-certified providers like myself will not be the main prescribers of PrEP. OB-GYNs, primary care providers, and pediatricians should be the ones prescribing it and having conversations about it at every routine check-up. The goal of PrEP is to keep patients out of the care of HIV care providers. Convincing OB-GYNs and women's health providers to normalize and routinely talk about PrEP would get the message to women that PrEP is for them too—a message that collectively we are failing to communicate.

At Nurx, between five and eight percent of our patients taking PrEP are women. I'm proud we're reaching them, but we need to reach more. Everyone in the HIV community and in healthcare needs to understand that HIV affects women and transgender people. In the U.S, one in five new HIV diagnoses are in women, and of women in the U.S. who would benefit from PrEP, only seven percent are taking it. [1,2]

One way that we do this outreach at Nurx is through our STI testing services. We send people test kits that allow them to collect samples at home and mail them in to our partner lab. When the results are in, a member of the Nurx medical team gets in touch with them, and if they're positive for anything we either prescribe medication directly or connect them to care.

Other companies selling at-home tests offer a menu of stand-alones, so that a patient can choose to test only for chlamydia, for example. But we decided that all three of our test kits should include HIV tests, because if people are at risk for any STI, they are at risk for HIV as well. Whenever someone requests STI tests, we include a message to them about PrEP: "Do you know about PrEP? It's a pill you take once a day to prevent HIV." We then give them a discount on their medical consult if they want to pursue it.

We also reach women and others who may need PrEP because we prescribe PEP. Often these are current patients from the Nurx birth control or acne services who request STI testing. When patients start the online assessment to request PrEP or STI testing, they're first asked if they know or suspect they were exposed to HIV in the last 72 hours. If they answer "yes" to this, then it creates an urgent ticket in our system and a member of our team reaches out to them within one to eight hours to prescribe them PEP if indicated, and offer emergency contraception. We always use these interactions as an opportunity to tell them about PrEP. In the case of women, most have not heard of PrEP. We explain what it is and help them decide if it's something that they need.

We are very focused on educating women about PrEP, and use emails, blog posts and social media to get the word out to Nurx's 400,000+ birth control patients. We would never say that PrEP is for everyone. Our medical providers or RN team will work with the patient to help them decide if this works in their lives. We say that anybody who wants it should be on it, but it's not for us to say if PrEP is right for them. It's for the patient to decide.

STOCK.ADOBE.COM/ JPC-PROD

To accelerate the end of HIV, we must put the full force of our efforts behind strategies we know to work, and one of the most important and effective tools is telehealth.

Increasing Testing Through Technology

With injectable PrEP, HIV vaccines, and potential cures for HIV on the horizon, it feels like the end is almost in sight. But unless we do a better job of reaching people most in need of testing, prevention and treatment, the epidemic will drag on much longer than it needs to. We must normalize and destigmatize testing, and, most importantly, educate medical providers about the need. Primary care providers should propose HIV testing at every annual appointment and more frequently if warranted.

Just this year, I have told 12 people who took HIV home tests through Nurx that they have HIV. Even though over the years I have delivered positive HIV results to hundreds of people, these are never easy phone calls to make, especially now with PrEP and U=U, there is no reason I should have to make these calls at all.

Recently I had to tell two different young women in Atlanta, one Black and one Latina, that they have HIV. Both had been sick for over a year, with rashes, weight loss and general malaise. They had been to their doctors but no one had thought to test them for HIV. Neither had a history of drug use. Both had contracted HIV from heterosexual sex. Each had reached out to us thinking they had an STI that the providers weren't testing for, maybe undiagnosed chlamydia. Both women had a CD4 count under 200! This is unacceptable. These two women sought help over and over again and no one addressed the possibility of HIV.

Healthcare providers need to stop making assumptions about people's risk factors based on gender, sexuality or class. Had these two women not found us, it is possible they would have ended up getting diagnosed in the ICU. It's hard to believe this could happen in 2022 in the United States. These two calls were the hardest I have done in my 30-year career.

Whether because brick-and-mortar clinic provides aren't testing or people don't have access to a doctor or clinic, home tests through telehealth are critical. One of the ways we encourage home testing is by making it abundantly clear in all of our marketing and messaging to patients that our medical team is here for them no matter what the results of their tests. We will prescribe treatment or connect them with care and be available to them every step of the way. We directly treat any STI that can be treated orally, and for all others we have our RN team do a warm hand-off to a local provider for care.

I'm currently running a pilot program providing HIV care through telehealth to about 30 patients. When somebody is diagnosed with HIV through one of our PrEP or STI test home kits, they don't always have any local options for treatment. They may be in a small town or might not be willing to disclose their sexuality to a local provider. In other cases, patients do have access to HIV care near them, but prefer the convenience of getting care through Nurx. We don't deliver HIV treatment from our pharmacy currently, but we order medication to their local pharmacies and order tests to their local labs.

In addition, a member of our team, Manny Rios, conducts a bi-weekly online support group for men newly diagnosed with HIV and works as our case manager with all our newly diagnosed people with HIV even if they choose to go to local care. There are currently about 10 men in the group, and they come from all over the country and all walks of life, and it's been a lifeline for some of them who don't have anybody else they're willing or able to talk to about their diagnosis. Providing psycho-social support is an important piece of keeping people adherent and healthy, and technology makes it easier to deliver.

Although I do occasionally miss providing care to patients face-to-face, I can reach so many more patients through telehealth. They are patients I never would have seen in my former San Francisco Bay Area clinic. Recently I received a text from a person with HIV who wrote to tell me, "I'm undetectable!" I could sense the excitement in the message and I was grateful that this news was shared with me. The impact that Nurx is having on helping to end the HIV epidemic fills my heart every day. The AIDS crisis is what caused me to enter medicine and I said then that I would keep working until the HIV epidemic is over. I hope the end is finally in sight, and I believe telehealth is the bridge that will help us get there.

I feel honored by every interaction with each patient. I love teaching our providers about PrEP, PEP and sexual health. Our entire team takes great pride in the care we offer and the access we provide. I am hopeful that our program grows and that more people feel safe reaching out to us so they all can get the care they need and deserve. **HIV**

EMILY RYMLAND, DNP, FNP-C, AAHIVS is the director of nursing and clinical services and sexual/trans/HIV medical advisor at the telehealth company Nurx. She also runs the Buseesa Community Development Center, a small bush clinic in western Uganda. Prior to Nurx, Emily worked at the East Bay AIDS Center, and she has practiced at clinics throughout Northern California. She was motivated to enter medicine in the 1980s when many of her friends got sick with AIDS, and she began as a hospice nurse providing palliative care to AIDS patients in San Francisco, Calif. She has made it her life's mission to help end HIV.

REFERENCES:

1. Centers for Disease Control, Diagnoses of HIV Infection in the United States and Dependent Areas, 2018
2. National Center for HIV/AIDS, Viral Hepatitis, STI and TB Prevention, Selected National HIV Prevention and Care Outcomes

BY CHARMAINE MILLER-SPENCER, MS, APRN, NP-C, AAHIVS

Shame as a Barrier to Optimal Healthcare in People with HIV

FOR APPROXIMATELY FORTY YEARS people have been diagnosed with HIV. While great strides have been made in disease treatment and management, HIV remains a stigmatized disease. According to the Centers for Disease Control (CDC), there are approximately 1.2 million people in the United States with HIV.[1] People with HIV live with the burden of stigma, discrimination, fear of status disclosure and shame. However, it is the latter—shame—that negatively impacts both the individual and the community.

In a 2017 article on health-related shame, the author defines shame as a negative emotion that arises when judged by others to be flawed, inadequate, inappropriate or immoral. It further states that shame is an alienating and isolating experience that is far from trivial, often deeply disturbing and a cause of significant distress.[2] When a person feels shame, they live with feelings of embarrassment, inadequacy, humiliation, unworthiness and self-reproach.

Shame, Guilt, Stigma

In order to fully understand the impact shame has on people with HIV it is necessary to distinguish shame from guilt and stigma, which are closely associated but distinctly different. Most simplistically, shame is a failure to meet your own standards of behavior while guilt is a failure to meet others' standards of behavior. Shame is private while guilt is public. Shame results in internal punishment while guilt results in external punishment.

Like guilt, stigma comes from an external source. The American Psychological Association Dictionary of Psychology defines stigma as, "the negative social attitude attached to a characteristic of an individual that may be regarded as a mental, physical, or social deficiency. A stigma implies social disapproval and can lead unfairly to discrimination against and exclusion of the individual."[3]

HIV-stigma can draw upon prejudicial and other negative attitudes to sex and sexuality, where attitudes prevail that identify certain sexual acts as abnormal, perverse, or related to attitudes about the appropriate amount of sex or number of sexual partners an individual should have.[4]

Shame and the Individual

I recall a line from a movie where one of the characters said, "I have shamed myself past all forgiveness." It is this belief about one's self that gives rise to feelings of unworthiness, humiliation, embarrassment and mortification. These feelings can cause an individual to isolate themselves and attempt to hide the condition that causes them shame. People with HIV who attempt to hide their status may experience periods of medication non-adherence and treatment interruption. Additionally, individuals attempting to hide their HIV status, especially at the start of a new relationship, may drop out of care. Interruption in antiretroviral therapy can lead to drug resistance and disease progression.

Phil Hutchinson, et al. identified ways in which shame negatively impacts attempts to combat and treat HIV. They state that shame can serve as a barrier to engaging with or being retained in care, and shame can prevent an individual from disclosing all the relevant facts about their sexual history to the clinician.[5] I have spoken to patients with HIV who failed to disclose their HIV status when seeking emergency care because of embarrassment. This failure to disclose could have adverse outcomes for the individual in that it may change the medical evaluation and management done by the clinician. I also have patients in my practice who delayed engaging in care after their initial HIV diagnosis because of shame. These delays put patients at risk for disease progression, advanced disease and opportunistic infections.

To feel unworthy is to also feel undeserving of wellness. Dolezal, et al. state chronic shame can become debilitating or even pathological, affecting one's life chances, one's relationships and as recent research has demonstrated, one's health outcomes.[6]

Shame and the Community

While shame is an internal emotion experienced by an individual, it can also have external consequences for the community. When people with HIV, either because of shame or other reasons, stop taking their antiretroviral medications, the potential for HIV transmission through sex is increased. Increased HIV viral load increases the risk of HIV transmission. It is imperative to keep viral load suppressed to an undetectable level in order to dramatically decrease the risk of transmission to an HIV-negative partner.[7]

Fortenberry, et al. state stigma and shame associated with sexually transmitted diseases and HIV are important barriers to appropriate diagnostic and treatment services.[8] These barriers cause delays in diagnosis and treatment, thus increasing viral burden and the rate of HIV transmission within the community.

Overcoming the Barrier of Shame

Overcoming the barrier of shame is not the sole responsibility of the individual experiencing shame. Removing the stigma-related shame of HIV requires changing attitudes and beliefs of the community. It involves combating ignorance with education. It includes changing and repealing laws that discriminate against and criminalize people with HIV. It also requires creating a culture where people with HIV don't fear rejection for disclosure of their status and would get the same support from the community as a person diagnosed with any other chronic disease.

Shame can serve as a barrier to engaging with or being retained in care, and shame can prevent an individual from disclosing all the relevant facts about their sexual history to the clinician.[5]

HIV care providers need to recognize that shame may be the cause of treatment interruptions and non-compliance. When this is the case, we should be proactive in referring patients for counseling. Our HIV care settings need to have a culture where people with HIV feel valued, respected and nurtured; not just because they have HIV, but because they are people deserving of the best care we have to give. **HIV**

CHARMAINE MILLER-SPENCER is a nurse practitioner working in the field of HIV/AIDS care since 2006. She is currently employed by Parkland Health providing care to an underserved population in Southeast Dallas, Texas. Charmaine has been a credentialed HIV Specialist™ with the American Academy of HIV Medicine since 2011. Charmaine serves on the Academy's Texas Steering Committee and is a member of the Academy Committee on Racial Equity (ACRE).

REFERENCES

1. U.S. Statistics. HIV.gov. Updated June 2, 2021. Accessed February 20, 2022. https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics
2. Dolezal L, Lyons B. Health-related shame: an affective determinant of health? Med Humanit 2017; 43:257-263.
3. Vanden Bos G R (Ed.). APA college dictionary of psychology. American Psychological Association; 2016.
4. Hutchinson P, Dhairyawan R. Shame, stigma, HIV: philosophical reflections. Med Humanit 2017;43(4):225-230.
5. Hutchinson P, Dhairyawan R. Shame, stigma, HIV: philosophical reflections. Med Humanit 2017;43(4):225-230.
6. Dolezal L, Lyons B. Health-related shame: an affective determinant of health? Med Humanit 2017; 43:257-263.
7. Nambiar P, Short W. Mechanisms of HIV transmission. Fundamentals of HIV medicine: 2019 edition: for the HIV specialist. Oxford University Press; 2019:21-24.
8. Fortenberry J D, McFarlane M, Bleakley A, et al. Relationships of stigma and shame to gonorrhea and HIV screening. Am. J. Public Health. 2002;92(3):378-381.

ISTOCK/ NADIA_BORMOTOVA

SPOTLIGHT

BY AARON AUSTIN, MEMBERSHIP DIRECTOR

Angela Kapalko, PA-C, MS, AAHIVS
Philadelphia, Pennsylvania

ANGELA KAPALKO completed her undergraduate work at the University of the Sciences in Philadelphia. She was in the Physician Assistant Studies program, which at the time was a sister program of the Philadelphia College of Osteopathic Medicine. Kapalko completed her studies at PCOM in 2007 with a Masters in Science in Physician Assistant Studies. Recalls Kapalko, "One of my rotations was with a local private practice provider who, although he was Internal Medicine trained and not Infectious Diseases trained, had a fair amount of HIV patients. His name was Dr. Mark Watkins and he was my mentor in HIV care. He started during the beginning of the epidemic and was one of the first HIV-treaters in the city of Philadelphia. He taught me an immense amount on how to care for HIV patients. He was the reason I got into this field."

Today, Kapalko is in practice at Philadelphia FIGHT Community Health Centers, an FQHC in the heart of downtown Philadelphia. Originally started as a stand-alone AIDS Service organization and clinical research for HIV therapy, FIGHT was able to expand in 2012 to not only care for HIV+ patients, but also to serve HIV- patients, specifically targeting people who are in high risk groups for HIV. One health center of FIGHT, the Jonathan Lax Treatment Center, is a specialty clinic serving roughly 1700 HIV+ patients each year. They provide primary care for adults living with HIV/AIDS. The clinic is made up of three physicians, three physician assistants, and two nurse practitioners. Additional staff include pharmacists, clinical Mas, on site phlebotomists, a behavioral health consultant and many medical case managers.

For the first 10 years of Ms. Kapalko's career at FIGHT, she served as the Senior Research Coordinator. Says Kapalko, "Half of my job was running all of our clinical trials. The other half of my job was being in the clinic seeing patients, mainly as the clinician who sees walk-in patients and sick visits when they can't get in to see their regular provider." In May of 2017, Ms. Kapalko decided she needed a change and more of a challenge. "I realized that when I was in the clinic seeing patients, I was at my most happiest. I felt I was able to do more for patients who were in crisis, out of care, acutely ill, than seeing research patients. Not that I didn't love research, it just wasn't challenging enough for me!" Kapalko now has a growing practice, treating everything from chronic health issues like diabetes, obesity, and hypertension, HCV treatment for HIV/HCV co-infected patients, and substance abuse treatment with medication assisted treatment (MAT), all while working HIV treatment into their care. "My normal clinic day is anything but normal. My schedule is filled with new patients, follow up routine visits, acute care visits, HCV treatment, suboxone visits, surgical clearance, and throw in some diabetes medication management for good measure!"

With the change to full time clinician at the Lax Center, she also decided to formalize the education program at FIGHT for Advanced Practice Clinician students, specifically NP and PA students. Kapalko is the main preceptor for all APC students who rotate through the Lax Center, as well as organizing student schedules with other clinicians, coordinating didactic programs for the students, and coordinating rotations at the other health centers at FIGHT. "I love education, not just student education but patient education, staff education, and self-education. I was fortunate as a student to have amazing preceptors and mentors, and I want my students to feel that same way. I want to give them the best educational experience possible, and help train the clinicians whom we desperately need in this area of healthcare."

Kapalko has been with Philadelphia FIGHT's Jonathan Lax Treatment Center since graduating in 2007. Says Kapalko, "I found my perfect job! I got into medicine to be in public health and to take care of people who no one wants to take care of. I always knew my mission was to serve the underserved. I now know I need to pass on my passion to the next generation of clinicians so we can continue to do the great work we do."

There are two primary elements about Kapalko's work that she finds extremely rewarding. The first is her new found love for diabetes treatment in her practice and getting to help patients manage another chronic illness other than HIV.

"A few years ago while looking at our data, I realized that our HIV data was some of the best in the country! I was shocked to see that we had a fair number of patients with poorly controlled diabetes and knew this needed to change. I made it my new mission to re-educate myself on all things diabetes, including

all of the newer agents, how they interact with HIV medication, and how I could incorporate our current HIV services with my diabetic patients."

Kapalko assists other providers in the practice with complicated diabetic patients, not just in medication management but coordination with other healthcare team members at the clinic to improve patient care.

Angela Kapalko, PA-C, MS, AAHIVS
Education Coordinator for APC Students
The Jonathan Lax Treatment Center
Philadelphia FIGHT Community Health Centers
Philadelphia, Pennsylvania

"I really do believe diabetes is far more complex than HIV, but as HIV providers, we are the perfect providers to troubleshoot barriers to care because that is what we do all of the time. Although it is a challenge, it is a great reward when a patient is more confident with their health and feels like they have a better understanding and ability to make meaningful changes themselves."

The second thing about her work that Kapalko finds most rewarding is educating. She has a passion for not just teaching her patients about health and health advocacy, but students and other healthcare providers as well. "Training the next generation of healthcare providers, including PAs, NPs and young MDs really drives me. I always tell my students 'my job is to not only teach you medicine, but really how to just be a good provider for the patient in front of you in that moment". On top of her precepting in the clinic, Kapalko also does lecturing for multiple PA, NP and RN programs, trains other clinicians through AETC, and is a mentor for the American Academy of HIV Medicine's mentorship program. Says Kapalko "Networking in medicine is key. When I heard about the mentorship program, I knew this was the next way I could meet other clinicians across the country in a real win/win situation! The mentee will have some goals and learning gaps that I can assist with, but I will also learn from them and make connections that I normally wouldn't have made."

When it comes to motivating her patients to adhere to treatment regimens, Kapalko first finds out what their lives are like. She likes to know their routines. Additionally, knowing how they feel about their HIV and who in their lives knows about their HIV is critical. Kapalko tailors her discussions with each patient. Instead of asking a patient "why don't you take your medication," Kapalko will ask "tell me about your week and which days you were able to take your medication." She finds that this approach works better as it is less threatening and also more informative. Kapalko likes to learn how her patients see their future. "Trying to tie their medication and adherence to their future is key. I always want them looking forward."

One incredible success at Kapalko's FQHC was being recognized by Million Hearts® as a Hypertension Control Exemplar with their Innovation Competition proposal and implementation during the COVID-19 pandemic. Says Kapalko, "Once stay-at-home orders began and we were no longer able to see patients in the office, we could do a lot of care from ones own home". Blood pressure cuffs that could be linked to an app and monitored by staff were sent to patient's homes and a protocol was developed for medication monitoring and adjustments run fully by FIGHT Pharmacists. "Our pharmacists are integral to our clinic, and as a provider, they were able to take something off our plates so we could focus on other major medical issues", says Kapalko,

Throughout her career, Kapalko has been able to speak at national conferences on topics she is extremely passionate about. In 2014, she. had the unique opportunity of speaking at the American Association of the Study of Liver Diseases (AASLD)'s Associates Course on the topic of HIV/HCV co-infection. Says Kapalko, "Education is extremely important to me, and has become more important as my career progresses. Being able to speak at a national conference as an expert in HIV/HCV Coinfection was incredible". Since then, Kapalko was able to present at the Pennsylvania Society for PAs (PSPA) Annual Conference in 2016, providing an HIV Update, including PrEP for the primary care providers, and had the honor of speaking at ACTHIV 2019 Conference on Primary care Basics and HIV. Looking to the future of HIV care, Kapalko holds out hope for advancements towards cure and envisions a more complete and inclusive health system that breaks down barriers to care for all people.

When asked why she is an AAHIVM Member, Kapalko says, "As a physician assistant, I did not have a residency or fellowship as physicians did. PAs are trained in all areas. Because of this, I felt the need to be credentialed as an HIV Specialist™ by AAHIVM, which holds the standard in HIV care in the USA. Once I was credentialed, becoming a Member was a no-brainer. I am able to connect with other like-minded colleagues who have the same drive and passion as myself. AAHIVM is great for fostering this kind of connection."

Kapalko has served on both the Pennsylvania Steering Committee and the Physician Assistant Steering committee for a number of years. She took over the role of Physician Assistant Committee Chair in 2019 and has made it her mission to increase the PA members and specialists apart of the academy.

"PAs are incredible team players in the healthcare landscape. I want to make sure PAs continue to be brought into and trained in HIV medicine so we can continue the excellent healthcare we have always provided to our patients" **HIV**

Kapalko, third from left, with the The Jonathan Lax Treatment Center crew

ABOUT THE AUTHOR: AAHIVM Membership Director **AARON AUSTIN** organizes, engages and leads the Academy's global membership of frontline HIV care providers around initiatives of advocacy, education and professional development. He is currently completing coursework for his MPH at The George Washington University Milken Institute School of Public Health.

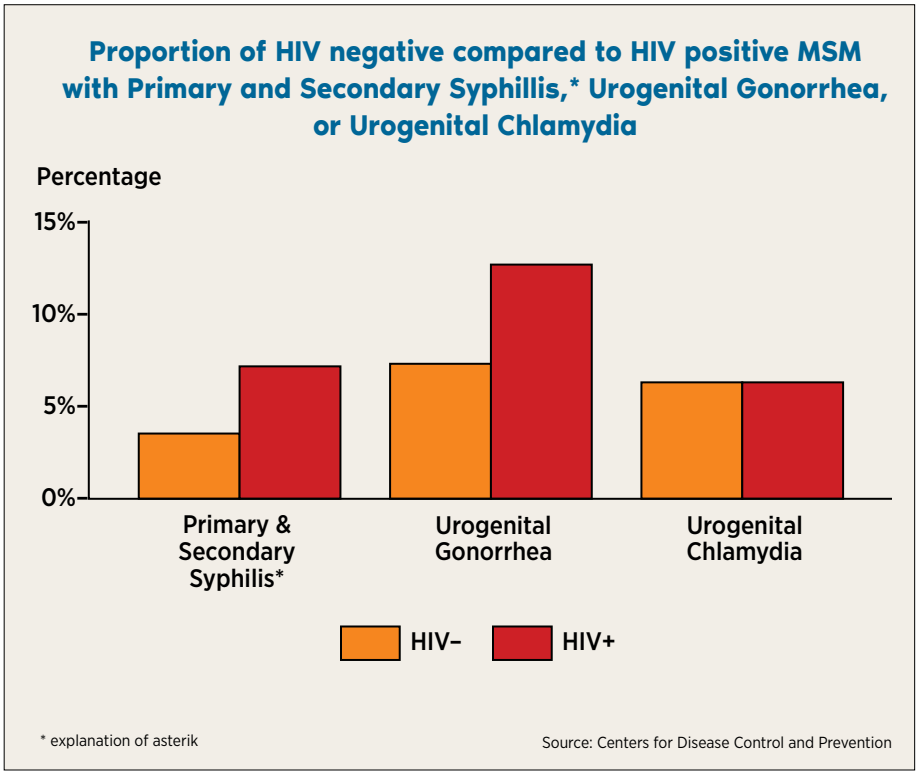
BY ROSS G. HEWITT, MD, FIDSA, FACP, AAHIVS

STIs in HIV Care

A Clinical Update

THE INCIDENCE of sexually transmitted infections (STI) has been gradually rising over the last decade in the general population and in people with HIV (PWH; Figure 1).[1] The advent of antiretroviral (ARV) therapy that results in maintained levels of undetectable virus in the plasma is clearly correlated with the virtual lack of transmissibility of HIV through sex.[2] While some stigma remains, PWH are experiencing sexual freedom that is important to living a full and complete life. Concurrently, the decrease in condom use by sexually active people, including PWH, has contributed to the increase of STIs.[3]

Figure 1



STI Incidence in People with HIV

According to the Centers for Disease Control (CDC), the incidence of chlamydia and gonorrhea infections has doubled over the past decade.[1] However, the rise in syphilis, which has been called a modern epidemic, is the most concerning because of its potentially severe clinical manifestations.[4]

The incidence of syphilis rose in the United States from 2014 to 2018 by 81 percent. Men accounted for 86 percent of all infections, and 42 percent of those were in men with HIV.[1]

At four different HIV clinical care sites, from January 2014 to November 2018, syphilis incidence steadily increased.[5] The highest rates were observed in younger cisgender men who have sex with men (MSMs), transgender women, Hispanic persons, people who inject drugs, those with detectable HIV RNA, rectal infections, and hepatitis C.

Public health investigators in North Carolina found significant overlap in population networks of new cases of syphilis and HIV in predominantly Black MSMs from May 2018 to February 2020.[6] Sometimes, the overlap of HIV and syphilis can result in more advanced disease of both infections, as was observed in a cluster of neurosyphilis cases in PWH in Vermont in 2017-2018.[7] In addition, ocular syphilis, which can result in diminished or loss of vision, was twice as common in PWH than in those without HIV from 2010 to 2018, and its incidence rose as syphilis cases rose in British Columbia, Canada.[8]

Included in the overall rise of syphilis is also the rise of congenital syphilis cases, as

a result of heterosexual transmission, which can have very severe clinical sequelae.[1] Most health departments prioritize the navigation of pregnant people diagnosed with syphilis into appropriate care along with contact tracing of recent sexual partners. Thus far, maternal HIV and syphilis do not appear to be syndemic, but epidemiological monitoring continues around the world.[9]

The Impact of Asymptomatic STIs

An important characteristic of the natural history of STIs is that all STIs can result in asymptomatic infection at genital (penile and cervicovaginal), oropharyngeal, and rectal sites.[10]

Sexually active PWH, just as in the general population, can unknowingly harbor and transmit STIs. This has given rise to routine recommendations for three site screening for chlamydia and gonorrhea for anyone engaging in receptive anal intercourse, as well as serologic screening for syphilis.[11] Increased serologic screening for syphilis contributed to an increase in diagnoses overall and at earlier stages of syphilis in MSMs in Australia.[12]

Men who practice receptive anal intercourse with other men were also shown to be more likely to be diagnosed with secondary syphilis when compared to MSMs that did not practice receptive anal intercourse.[13] This means that the primary stage anal chancres in men who "bottom" go undiagnosed, and only weeks later, when the symptomatic manifestations of secondary syphilis emerge, is the infection diagnosed. The result is a lost opportunity to interrupt transmission earlier and treat at the primary stage. New strategies are needed to address this clinical dilemma.[13]

Asymptomatic pharyngeal and rectal gonorrhea and/or chlamydia can be diagnosed in the absence of a positive penile or urine sample, especially in MSMs.[14,15] This supports the recommendation of three site screening in this population. The duration of pharyngeal infection by chlamydia ranged from two to nine weeks, with a short duration in those with a history of previous chlamydia infection.[16]

Mycoplasma genitalium has increasingly become a diagnosed STI, particularly in MSMs.[17] Current recommendations are not to treat this infection when asymptomatic and avoid asymptomatic screening.[18] Antibiotic resistance is common, and combination treatment is often needed in symptomatic cases.[19]

Advances in Detection of STIs

Nucleic acid amplification assays for chlamydia and gonorrhea have been the standard of care for several years.[20] They have increased sensitivity and specificity, and samples can be self-collected by patients in the privacy of a restroom.[21]

Laboratories in the United States and Europe now utilize a "reverse testing algorithm" to screen for syphilis. A treponemal-specific antibody test is used first, then confirmed with a nonspecific test, such as the RPR. This is a change from the old algorithm, which used the RPR first. The reverse algorithm is more sensitive, specific, and cost-effective. While the European reverse algorithm is slightly different, it was as accurate at detecting syphilis infections as its American counterpart.[22] The RPR should only be used now to follow the response to treatment.

The use of *Treponema pallidum* DNA (TP-DNA) is under active investigation as a new method to detect syphilis.[23] TP-DNA was detected in peripheral blood, oropharynx, anorectal, and urine in MSMs as seen at a sexual health center in Amsterdam in earlier stages of infection. It was not detected in patients with late latent syphilis, treated syphilis, or those without syphilis.[24] *Treponema pallidum* ribosomal RNA can also be detected in cerebrospinal fluid.[23]

STOCK.ADOBE.COM/ ICEDMOCHA

Figure 2

CDC recommended regimens for uncomplicated gonococcal infections, 2020

Regimens for uncomplicated gonococcal infections of the cervix, urethra, or rectum:

Ceftriaxone 500 mg IM as a single dose for persons weighing <150 kg (300 lb).

- For persons weighing ≥150 kg (300 lb), 1 g of IM ceftriaxone should be administered.
- If chlamydial infection has not been excluded, providers should treat for chlamydia with doxycycline 100 mg orally twice daily for 7 days. During pregnancy, azithromycin 1 g as a single does is recommended to treat chlamydia.

Alternative regimens for uncomplicated gonococcal infections of the cervix, urethra, or rectum if ceftriaxone is not available:

Gentamicin 240 mg IM as a single dose plus azithromycin 2 g orally as a single dose OR
Cefixime 800 mg orally as a single dose. If treating with cefixime, and chlamydial infection has not be excluded, providers should treat for chlamydia with doxycycline 100 mg orally twice daily for 7 days. During pregnancy, azithromycin 1 g as a single does is recommended to treat chlamydia.

Recommended regimen for uncomplicated gonococcal infections of the pharynx:

Ceftriaxone 500 mg IM as a single dose for persons weighing <150 kg (300 lb).

- For persons weighing ≥150 kg (300 lb), 1 g of IM ceftriaxone should be administered.
- If chlamydia coinfection is identified with pharyngeal gonorrhea testing is performed, providers should treat for chlamydia with doxycycline 100 mg orally twice a day for 7 days. During pregnancy azithromycin 1 g as a single dose is recommended to treat chlamydia.
- No reliable alternative treatments are available for pharyngeal gonorrhea. For persons with a history of a beta-lactam allergy, a thorough assessment of the reaction is recommended.*

For persons with an anaphylactic or other severe reaction (e.g., Stevens Johnson syndrome) to ceftriaxone, consult an infectious disease specialist for an alternative treatment recommendation.

Abbreviation: IM = intramuscular.

*CDC. Sexually transmitted diseases treatment guidelines. MMWR Recomm Rep 2015;64(No. RR-3). https://www.cdc.gov/mmwr/preview/mmwrhtma/rr6403a1.htm.

Updated Treatment Strategies

The CDC published revised treatment guidelines for gonorrhea in late 2020 (Figure 2, box insert).[25] The CDC recommends a single 500 milligram (mg) intramuscular (IM) dose of ceftriaxone to treat uncomplicated urogenital, anorectal, and pharyngeal gonorrhea. Concurrent treatment with doxycycline (100 mg orally twice a day for seven days) is recommended if concurrent chlamydia infection has not been excluded. This change from the previous recommendation of a 250 mg IM dose with a 1 gram (g) single oral dose of azithromycin is expected to lower the use of presumptive azithromycin or doxycycline while providing high cure rates and low levels of ceftriaxone resistance. There was also concern about the pharmacokinetics of ceftriaxone in the oropharynx since most treatment failures were observed in pharyngeal gonorrhea. A test of cure is therefore recommended for pharyngeal gonorrhea.[25]

For treatment of rectal *Chlamydia trachomatis* infection, doxycycline 100 mg twice daily for seven days was found to be superior to a 1 g single oral dose of azithromycin with intent-to-treat cure rates of 91 percent vs. 71 percent (P <.001) respectively, in a clinical trial conducted in 2016 - 2019 and published last year.[26] Similar data from other investigators has prompted some providers to now consider doxycycline as the preferred treatment option for rectal chlamydia in MSMs.[27]

Treatment guidelines for syphilis have not changed since the CDC published its STI treatment guidelines in 2015.[11] Intramuscular benzathine penicillin remains the primary treatment consideration (the schedule varies with disease stage). Oral doxycycline for four weeks remains the alternative for penicillin-allergic patients but should be avoided in pregnancy and sexually active people of childbearing potential with inadequate contraception.

Doxycycline as Prevention for Bacterial STIs?

Due to its efficacy against both chlamydia and syphilis, doxycycline is under active investigation as a preventative agent for bacterial STIs. Many trials are being conducted in concert with pre-exposure prophylaxis (PrEP) trials to prevent HIV. Early, smaller trials published in 2018–2019 showed an approximate 70 percent reduction in syphilis and chlamydia in MSMs.[29] Gastrointestinal side effects may limit this strategy for certain individuals.

These results are promising, but definitive clinical trials are ongoing to determine the appropriate dose and schedule of administration of doxycycline in the appropriate populations. Thus far, the CDC has not yet endorsed this prevention method.

In the Exam Room

During routine HIV care, a brief sexual history since the last visit is recommended.[30] Three site screening (urine/genital, pharyngeal, and rectal) along with serologic syphilis screening that accompanies HIV RNA testing is also recommended. If diagnosed, prompt and accurate treatment accompanied by a discussion about sexual partner notification is important. Patients greatly appreciate being diagnosed and treated accurately in a non-judgemental manner for STIs. Such interactions can bring great professional and personal satisfaction

while helping to strengthen the patient-provider relationship.

The diagnosis and treatment of STIs in PWH occurs via various providers, the use of which is influenced by the ability to access care at the local level. Primary care clinics, community clinics, urgent care centers, emergency rooms, and health department providers all frequently diagnose and treat STIs in PWH. STI and HIV speciality providers may need to be called upon to help provide STI training across this range of care providers.[31]

Summary

As the incidence of STIs continues to rise, their detection, diagnosis, and treatment remains a key component of HIV care. The recommended treatment dose for gonorrhea has increased. Nucleic acid detection of syphilis and doxycycline as STI prophylaxis are both under investigation. Frank, regular discussions about sexual activity, the benefits of condom use, and increased screening for STIs are needed by all types of HIV care providers. **HIV**

DR. ROSS G. HEWITT is a retired HIV and STI specialist who practiced in Buffalo and New York City over a 38-year span. He has been an active HIV community advocate and an ACTG Investigator. He currently serves on the Academy Committee for Racial Equity (ACRE).

REFERENCES

1. Centers for Disease Control and Prevention. (2021). Sexually transmitted disease surveillance 2019. Atlanta, GA: US Department of Health and Human Services.
2. Rodger AJ, Cambiano V, Bruun T, Vernazza, P., Collins, S., ... and Lundgren, J., for the PARTNER Study Group. (2019). Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. Lancet 393(10189), 2428–2438, DOI: 10.1016/S0140-6736(19)30418-0.
3. Khosropour C, Dombrowski, J. C., Barbee, L. A., Kerani, R. P., Berzkalns, A. Golden, M. R. (2021). Changing patterns of sexual behavior and HIV/STI among men who have sex with men in Seattle, 2002 to 2018. *Journal of acquired immune deficiency syndromes,* 87(4), 1032-1039. DOI: 10.1097/QAI.0000000000002686.
4. Ghanem, K. G., Ram, S., Rice, P. A. (2020). The modern epidemic of syphilis. *New England journal of medicine,* 382(9), 845-854, DOI: 10.1056/NEJMra1901593.
5. Menza, T. W., Berry, S. A., Dombrowski, J., Cachay, E., Dionne-Odom, J. (2021). Syphilis testing and diagnosis among people with HIV engaged in care at four United States clinical sites, 2014-2018. *Clinical infectious diseases,* https://doi.org/10.1093/cid/ciab944.
6. Dennis, A. M., Cressman, A., Pasquale, D., Frost, S. D. W., Kelly, E. (2021). Intersection of syphilis and human immunodeficiency virus (HIV) networks to identify opportunities to enhance HIV prevention. *Clinical infectious diseases,* https://doi.org/10.1093/cid/ciab431.
7. Singh, D., Switzer, W. M., Belcher, R., Daltry, D., Read, J. S. (2021). Identification of a human immunodeficiency virus type 1 and neurosyphilis cluster in Vermont. *Clinical infectious diseases,* 73(9), e3244–e3249, https://doi.org/10.1093/cid/ciaa1834.
8. Hamze, H., Ryan, V., Cumming, E., Lukac, C., Wong, J. ...and Grennan, T. (2020). Human immunodeficiency virus seropositivity and early syphilis stage associated with ocular syphilis diagnosis: a case-control study in British Columbia, Canada, 2010–2018. *Clinical infectious diseases,* 71(2):259–266, DOI: 10.1093/cid/ciz794.
9. Cambou, M.C., Saad, E., McBride, K., Fuller, T., Swayze, E., and Nielsen-Saines, K. (2021). Maternal HIV and syphilis are not syndemic in Brazil: Hot spot analysis of the two epidemics. *PLoS ONE* 16(8): e0255590, https://doi.org/10.1371/journal.pone.0255590.
10. Rieg, G., Lewis, R. J., Miller, L. G., Witt, M. D., Guerrero, M. and Daar, E. S. (2008). Asymptomatic sexually transmitted infections in HIV-infected men who have sex with men: prevalence, incidence, predictors, and screening strategies. *AIDS Patient Care STDs.* 22(12), 947–954, doi: 10.1089/apc.2007.0240.
11. Workowski, K.A., Bolan, G.A. (2015). Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2015. *Morbidity and mortality weekly report recomendations and reports* 64(3), 1–137.
12. Chow, E. P. F., Callander, D., Fairley, C. K., Zhang, L. (2017). Increased syphilis testing of men who have sex with men: greater detection of asymptomatic early syphilis and relative reduction in secondary syphilis. *Clinical infectious diseases,* 65(3), 389–395, https://doi.org/10.1093/cid/cix326.
13. Cornelisse, V. J., Chow, E. P. F., Latimer R. L., Towns, J., Chen, M. (2020). Getting to the bottom of it: sexual positioning and stage of syphilis at diagnosis, and implications for syphilis screening. *Clinical infectious diseases,* 71(2), 318–322, https://doi.org/10.1093/cid/ciz802.
14. Barbee, L. A., Khosropour, C. M., Soge, O. O., Hughes, J. P., Haglund, M. (2021). The natural history of rectal gonococcal and chlamydial infections: the ExGen study. *Clinical infectious diseases,* https://doi.org/10.1093/cid/ciab680.
15. Evers, Y. J., Dukers-Muijrers, N. H. T. M., van Liere, G. A. F. S., van Bergen, J., Kuizenga-Wessel, S. (2021). Pharyngeal *Chlamydia trachomatis* in men who have sex with men (MSM) in The Netherlands: a large retrospective cohort study. *Clinical infectious diseases,* https://doi.org/10.1093/cid/ciab685.
16. Khosropour, C. M., Soge, O. O., Golden, M. R., Hughes, J. P., Barbee, L. A. (2021). Incidence and duration of pharyngeal chlamydia among a cohort of men who have sex with men. *Clinical infectious diseases,* https://doi.org/10.1093/cid/ciab1022.
17. Williamson, D. A., Chen, M. Y. (2020). Emerging and reemerging sexually transmitted infections. *New England journal of medicine,* 382(21), 2023-2032, DOI: 10.1056/NEJMra1907194.
18. Golden MR, Workowski KA, Bolan G. (2017). Developing a public health response to *Mycoplasma genitalium. Journal of infectious diseases,* 216(suppl2), S420-S426.
19. Berçot, B., Charreau, I., Rousseau, C., Delaugerre, C., Chidiac, C. (2021). High prevalence and high rate of antibiotic resistance of *Mycoplasma genitalium* infections in men who have sex with men: a substudy of the ANRS IPERGAY pre-exposure prophylaxis trial. *Clinical infectious diseases,* 73(7) e2127–e2133, DOI: doi.org/10.1093/cid/ciaa1832.
20. Schachter, J., Moncada, J., Liska, S., Shayevich, C. Klausner, J. D. (2008). Nucleic acid amplification tests in the diagnosis of chlamydial and gonococcal infections of the oropharynx and rectum in men who have sex with men. *Sexually transmitted diseases.* 35(7), 637-642, doi: 10.1097/OLQ.0b013e31817bdd7e.
21. Ogale, Y., Yeh, P. T., Kennedy, C. E. Toskin, I., Narasimhan, M. (2019). Self-collection of samples as an additional approach to deliver testing services for sexually transmitted infections: a systematic review and meta-analysis. *British medical journal of global health,* 4(2), e001349. doi: 10.1136/bmjgh-2018-001349.
22. Peng, J., Lu, Y., Yu, H., Wu, S., Li, T., ... and Sun, Z. (2018). Analysis of 2 reverse syphilis testing algorithms in diagnosis of syphilis: a large-cohort prospective study. *Clinical infectious diseases,* 67(6):947–953, DOI: 10.1093/cid/ciy198.
23. Marra, C. M., Maxwell, C. L., Sahi, S. K., Tantalo, L. C., Dunaway, S. B. (2021). Previous Syphilis Alters the Course of Subsequent Episodes of Syphilis. *Clinical infectious diseases,* DOI: doi.org/10.1093/cid/ciab287
24. Nieuwenburg, S. A., Zondag, H. C. A., Bruisten, S. M., Jongen, V. W., Schim van der Loeff, M. F. (2022). Detection of *Treponema pallidum* DNA during early syphilis stages in peripheral blood, oropharynx, ano-rectum and urine as a proxy for transmissibility. *Clinical infectious diseases,* DOI: doi.org/10.1093/cid/ciac056.
25. St. Cyr, S., Barbee, L., Workowski, K. A., Bachmann, L. H., Pham, C., Schlanger, K., ...and Thorpe, P. (2020). Update to CDC's treatment guidelines for gonococcal infection, 2020. *Morbidity and mortality weekly report* 69(50), 1911–1916, DOI: dx.doi.org/10.15585/mmwr.mm6950a6.
26. Dombrowski, J. C., Wierzbicki, M. R., Newman, L. M., Powell, J. A., Miller, A. (2021). Doxycycline versus azithromycin for the treatment of rectal chlamydia in men who have sex with men: a randomized controlled trial. *Clinical infectious diseases,* 73(5), 824–831, DOI: doi.org/10.1093/cid/ciab153.
27. Lau, A. S., Kong, F. Y. S., Fairley, C. K., Templeton, D. J., Amin, J., ... and Hocking, J. S. (2021). Azithromycin or doxycycline for asymptomatic rectal *Chlamydia trachomatis. New England journal of medicine,* 384(25), 2418-27, DOI: 10.1056/NEJMoa2031631.
28. Rolfs, R. T., Joesoef, M. R., Hendershot, E. F., Rompalo, A. M., Augenbraun, M. H., ... and Sandra Larsen, S., for The Syphilis And HIV Study Group (1997). A randomized trial of enhanced therapy for early syphilis in patients with and without human immunodeficiency virus infection. *New England journal of medicine,* 337(5), 307-314.
29. Grant, J. S., Stafylis, C., Celum, C., Grennan, T., Haire, B., ... and Klausner, J. D. (2020). Doxycycline prophylaxis for bacterial sexually transmitted infections. *Clinical infectious diseases* 70(6), 1247–53. DOI: 10.1093/cid/ciz866.
30. Thompson, M. A., Horberg, M. A., Agwu, A. L., Colasanti, J. A., Jain, M. K. (2021). Primary care guidance for persons with human immunodeficiency virus: 2020 update by the HIV Medicine Association of the Infectious Diseases Society of America. *Clinical infectious diseases,* 73(11), e3572–e3605, DOI: doi.org/10.1093/cid/ciaa1391.
31. Guilamo-Ramos, V., Thimm-Kaiser, M., Benzekri, A., Mead, A., Hook, III, E. W. (2021).The National Academies report on sexually transmitted infections: implications for clinical training, licensing, and practice guidelines. *Clinical infectious diseases,* 73(9), 1711–1716, DOI: doi.org/10.1093/cid/ciab609.

UPDATE

CAROLYN CHU, MD, MSC, AAHIVS
AAHIVM Chief Medical Officer

FEATURED LITERATURE:

Solomon SS, Wagner-Cardoso S, Smeaton L, et. al. A minimal monitoring approach for the treatment of hepatitis C virus infection (ACTG A5360 [MINMON]): a phase 4, open-label, single-arm trial. Lancet Gastroenterol Hepatol. 2022 Jan 10: S2468-1253(21)00397-6. doi: 10.1016/S2468-1253(21)00397-6. Online ahead of print. PMID: 35026142

The MINMON trial examined efficacy and safety of a minimal monitoring strategy for delivering HCV treatment to a diverse, global population of treatment-naïve participants. 400 HBsAg-negative adults seen at infectious disease clinics—most affiliated with universities—in Brazil, South Africa, Thailand, Uganda, and the U.S. were staged based on FIB-4 index (no pre-treatment HCV genotype assessment was performed): compensated cirrhosis was defined as FIB-4 ≥ 3.25 and Child-Pugh score ≤ 6. Enrollment occurred between October 2018 and July 2019: over 40 percent of participants were living with HIV (99% were receiving suppressive non-efavirenz based ART). 12 weeks of sofosbuvir/velpatasvir was dispensed at study entry, and no scheduled clinic or laboratory monitoring visits were conducted before the 24-week efficacy outcome assessment. Remote contact occurred at: (a) week 4 to assess adherence, and (b) week 22 to schedule outcome assessment visit (participant contact information was updated at both points). 91 percent of participants self-reported completing all study medications at the expected 84-day timepoint (+/- 1 week). 89 percent reported taking 100 percent of medications within the treatment period and eight percent reported taking 90 to 99 percent. Overall, 95 percent experienced SVR: subgroup analyses indicated lower SVR rates among participants with cirrhosis (88.2% vs. 95.6%), participants < 30 years of age (84.8% vs. 95.9%), and participants with genotype 3. SVR was greater than 94 percent for participants with current or previous history of substance use. Four percent experienced at least one serious adverse event, and six percent experienced non-serious events: five cases of non-serious events were attributed to study medication.

AUTHOR'S COMMENTARY:

Findings of this trial, shared at the 2020 AASLD Liver Meeting, are highly encouraging and especially relevant given the clinical evaluation and follow-up modifications that some practices have explored or adopted to maintain delivery of HCV services during the COVID-19 pandemic. High rates of participant follow-up and SVR were observed using the MINMON intervention model that included baseline dispensation of the full 12-week treatment course and elimination of all scheduled on-treatment in-person clinical and laboratory monitoring visits. As authors note, changes in such medication dispensing and monitoring workflows "reduce patient, provider, and health system costs." Additional studies exploring other HCV treatment regimens and also outcomes for specific subgroups (i.e. younger individuals as well as people with genotype 3, cirrhosis, and/or prior HCV treatment experience) will shed further light on new approaches to HCV care delivery that balance safety, efficacy, patient/provider experience, and health system resources.

FEATURED LITERATURE:

Leistikow PT, Patel V, Nouryan C, Cervia JS. Acceptability of HIV testing for adolescents and young adults by delivery model: a systematic review. J Investig Med. 2022 Dec 8; jim-2021-002056. doi: 10.1136/jim-2021-002056. Online ahead of print.

This systematic review and qualitative analysis, undertaken July 2019, aimed to compare rates of HIV testing acceptance and linkage to care for adolescents and young adults across various delivery models: emergency department (ED), primary care/inpatient setting, community-based program, or STI/family planning clinics. 59 studies from North America, Africa, Asia, Australia, and Europe were identified for data review and analysis. In the North American context, the greatest acceptance of testing occurred in ED settings (77.7%), while in other regions acceptance was highest in primary care/hospital settings (93.3%). Review of ED-based studies found a significant association by testing strategy, with opt-in approaches resulting in a higher acceptance rate compared to opt-out (82% vs. 75%). Overall, highest linkage to care rates were reported for ED-based testing, followed by primary care/hospital settings. However, when only North American studies were examined, primary care/hospital settings had the lowest linkage to care rates (38.8%) compared to ED-based testing (93.5%), STI/family planning clinics (81.4%), and community-based programs (69.9%).

AUTHOR'S COMMENTARY:

This review is a timely one, given the recent release of the updated National HIV/AIDS Strategy for the United States (2022-2025). Youth compose 21 percent of new HIV diagnoses in the U.S., however are the least likely of any age group to remain in care and have a suppressed viral load. Trends over the last decade indicate decreases in the percentage of sexually active high school students who used condoms during last intercourse, and less than ten percent reported STI screening within the past year. Findings from this analysis may help inform how to design and implement youth-centered and culturally informed HIV screening/testing and linkage services which are likely to result in high rates of testing acceptance and engagement in care.

FEATURED LITERATURE:

Guajardo E, Giordano TP, Westbrook RA, et. al. The Effect of Initial Patient Experiences and Life Stressors on Predicting Lost to Follow-Up in Patients New to an HIV Clinic. AIDS and Behavior. 2022 Jan 5; doi: 10.1007/s10461-021-03539-8. Online ahead of print.

This study aimed to describe and explain the effects of initial patient experiences and life stressors on being lost to follow-up (LTFU) in the first year after establishing HIV care. Authors conducted a prospective cohort study involving 450 adults newly receiving services at a large HIV clinic in the south-central region of the U.S. Enrollment occurred between February 2016 and June 2017. Time since HIV diagnosis was ≤ 3 months for 34.4 percent of participants, and 19.3 percent had been living with HIV for more than ten years but were new to the study clinic. Participants completed a five-item survey regarding experience with their new HIV provider and were also asked if they had experienced certain stressful life events in the preceding 6 months. Investigators also assessed drug/alcohol use, anxiety, depression, social support, and self-efficacy using brief validated measures. Multivariate analyses indicated that patients with better HIV provider experiences at the first visit were significantly less likely to be LTFU (6-mo adjusted OR 0.866 and 12-mo adjusted OR 0.825); additionally, patients with a higher burden of life stressors were significantly more likely to be LTFU (6-month adjusted OR 1.232 and 12-mo adjusted OR 1.263). Exploratory secondary analyses indicated that for patients with CD4 < 200 cells/mm3, patient experience with their provider became more important.

AUTHOR'S COMMENTARY:

Findings of this study likely reinforce what many would view as a "common sense" connection between patience experience and HIV outcomes: major life events (e.g. death of loved one, disrupted partnerships, economic destabilization) and poor experiences with providers and/or health care systems can have significant negative impacts on engagement in care. In this cohort, striking rates of recent life changes were observed: over 30 percent of participants reported death of a close family member or friend, almost 30% reported a change in health insurance, and over 40 percent reported a loss of income or financial benefits. Although mean overall patient experience score was 8.86 (on a 0-10 scale), significant differences were observed in LTFU based on initial score. Further, authors suggest "it may be that positive experiences [with providers] are particularly important in patients with poorer health status". As we continue efforts to expedite linkages to care and rapid ART initiation/re-initiation, and in a pandemic environment which has exacerbated hardship for the vast majority of our patients, findings such as these may help shed light on promising practices to establish trust and build relationships with new patients. It also highlights the importance of identifying recent major life stressors, possibly through a standardized approach, to facilitate timely response and support.

FEATURED LITERATURE

Siddiqui J, Samuel SK, Hayward B, et. al. HIV-associated wasting prevalence in the era of modern antiretroviral therapy. AIDS. 2022 Jan 1; 36(1): 127-135. doi: 10.1097/QAD. 0000000000003096. PMID: 34628440.

Authors analyzed medical and pharmacy claims to assess prevalence and comorbidity burden of HIV-associated wasting (HIVAW), utilizing information from the IBM MarketScan Commercial, Medicare Supplemental and Multi-State Medicaid Research Databases. PWH with evidence of HIVAW were identified by proxy based on a previously developed algorithm specific to claims data; patients were excluded if they had any malignancy diagnosis claim. Estimated HIVAW cumulative prevalence (July 2012 to March 2019) was 18.3 percent. The proportions of PWH with ART claims were similar in the HIVAW and non-HIVAW cohorts, however the proportion with one or more diagnosis claims of an opportunistic infection or HIV/AIDS-related condition was 64.2 percent in the HIVAW cohort versus 38.6 percent in the non-HIVAW cohort. A significantly higher percentage of the HIVAW cohort were on Medicaid (86.7% vs 63.8%). The most prevalent co-occurring conditions in the HIVAW cohort were dyslipidemia (48.5%), depressive disorders (46.1%), and chronic pulmonary disease (45.1%); mean Charlson Comorbidity Index score was 3.6 vs. 2.0.

AUTHOR'S COMMENTARY:

Few, if any, studies have described prevalence estimates of HIVAW in the contemporary treatment era—this analysis of over 42,500 PWH found that over six years, 18.5 percent of insured PWH receiving medical care met the definition of HIVAW (~3% annual prevalence). Investigators observed that HIVAW was most strongly associated with Medicaid coverage and hospitalizations, but not ART use, affirming that HIVAW continues to occur even among people on HIV treatment. Because of its multi-factorial nature and overlap with prevalent conditions in an aging population of PWH, HIVAW may not necessarily be the leading consideration when evaluating patients experiencing weight loss/body mass changes, decreased physical endurance and overall level of function. Nevertheless, authors highlight these data suggest the need to monitor for unintentional weight loss in PWH … [and further] evaluate the risk of HIVAW by comorbidities and payer type. **HIV**

NEW FROM CDC

HIV NEXUS

CDC RESOURCES FOR CLINICIANS

HIV Nexus Is Your Resource for Information Across the HIV Prevention and Care Continuum.

You can now easily download and order the latest educational materials from the Centers for Disease Control and Prevention (CDC) on:

- Integrating routine HIV screening into your practice to reduce new HIV infections and link newly diagnosed patients to HIV treatment and care.
- Prescribing pre-exposure prophylaxis (PrEP) to your patients as part of a comprehensive HIV prevention plan.
- Promoting treatment as prevention as an HIV intervention strategy to help your patients achieve and maintain an undetectable viral load and prevent HIV transmission.

Access free CDC resources for your practice and patients at: cdc.gov/hiv/clinicians/materials.

CDC

LET'S STOP HIV TOGETHER™

Ending the HIV Epidemic