

THE AMERICAN ACADEMY OF HIV MEDICINE ■ SPRING 2024

HIV

SPECIALIST



Women
and HIV

THE DR. DAWN K. SMITH HIV PREVENTION CLINICAL FELLOWSHIP

A 12-month Clinical Program to Increase PrEP Awareness and Access

The Dr. Dawn K. Smith HIV Prevention Clinical Fellowship is designed for non-infectious disease clinicians – physicians, PAs, nurse practitioners, and pharmacists – in primary care, family medicine, emergency medicine, pharmacy, and more.

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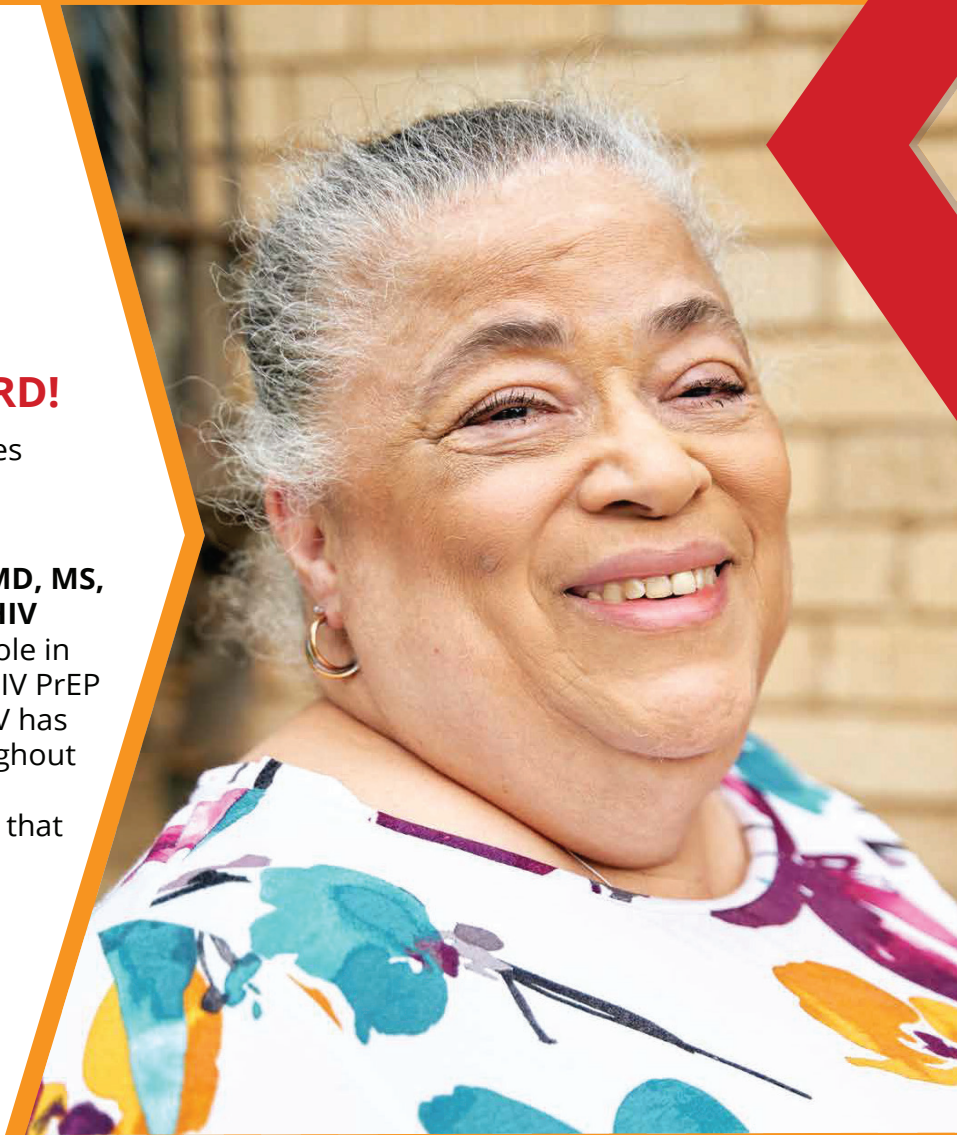


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Honoring the legacy of Dawn K. Smith, MD, MS, MPH, a champion of health equity and HIV prevention. Dr. Smith played an integral role in the development and implementation of HIV PrEP and studied the disproportionate affect HIV has on underrepresented communities. Throughout her career, she worked to eliminate health disparities and was committed to ensuring that all people had PrEP access. The AAHIVM Dr. Dawn K. Smith HIV Prevention Clinical Fellowship pays tribute to Dr. Smith's extraordinary contributions to HIV prevention by training a new generation of clinicians in PrEP and HIV prevention.

The Dr. Dawn K. Smith HIV Prevention Clinical Fellowship is funded by a grant through Viiv Healthcare.



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Half the Population Shouldn't Be Overlooked

THIS SPRING 2024 ISSUE OF HIV SPECIALIST directs its focus on what most of us in the field well understand as an oft-overlooked aspect of the ongoing HIV epidemic in the U.S., and what will be repeatedly underscored in the articles in this issue: women, particularly and especially Black and African American women and other women of color, who are disproportionately affected by HIV. The Centers for Disease Control and Prevention (CDC) tells us that the approximately 3,100 new annual HIV cases among Black and African American women is, among women, the highest of any race or ethnicity, and over 90 percent of these new infections are a result of heterosexual contact.

Many HIV advocates know well the passion and impact of the late, great Dr. Dawn Smith, who dedicated much of her life's work in research and public health at the CDC to shining a bright light on this group, and the outstanding need for the spectrum of HIV prevention tools and resources to reach everyone, especially those in historically underserved communities and populations. The Academy is honoring the legacy of Dr. Smith with our recently announced (CROI 2024) Dr. Dawn K. Smith HIV Prevention Clinical Fellowship for health care clinicians in non-traditional/non-ID settings. These clinicians will embark on an intensive one-year PrEP training with expert HIV prevention preceptors and trainers in the field and in the Academy's constituencies, with a capstone presentation and an expectation of setting up comprehensive PrEP services that prioritize underserved communities. Additionally, forthcoming updates to the Women and HIV course (including new guidelines on breast- and chest-feeding in people with HIV) on the Academy's Clinical Education Center will be available and re-accredited shortly following this issue's publication.

Here in this issue, as well, are some immediately employable perspectives in clinical care, research, prevention, and public health as it relates to women and the HIV epidemic. Our lead article, "Medical Providers Can Bridge Disparities" by Jaymee Leak Matthews, DNP, APRN, FNP-C, details the persistent disparities in HIV care affecting Black women, despite significant improvements in HIV care, prevention, and treatment generally. Dr. Matthews wants us all to recognize that medical providers could have a significantly positive impact in addressing these disparities and improving Black women's health outcomes, and sheds some light on how we can get there.

In "HIV Pre-Exposure Prophylaxis and Cisgender Women," Britt Gayle, MD, MPH, AAHIVS, David Ahamba, MD, MPH, CTropMed, AAHIVS, and Hadrian Holder, MD, MPH, AAHIVS,



By Bruce J. Packett II
Executive Director, AAHIVM

discuss the importance of PrEP for cisgender women and clinical considerations for prescribing. This article dovetails with Dr. Matthews' piece and others herein, advocating for increased PrEP awareness and access among at-risk populations.

Brooke Davidoff's "PrEP Navigators and Women's Health" delves into the crucial role of PrEP navigators in supporting women, including Black women, in navigating PrEP uptake and adherence.

Dr. Kara S. McGee's article, "Antiretroviral Therapy Guidelines for Pregnant People with HIV," outlines the specialized care required for pregnant individuals with HIV to prevent mother-to-child transmission, detailing the significance of tailored approaches in maternal HIV care.

Avani Dalal, MD, shares heartfelt insights in "SOUL Stories," recounting her experiences at the SOUL Clinic, exemplifying the value of women-led spaces in HIV care and support.

Lastly, our CE Article, "Assessing the Drivers of Chronic Pain in People with HIV" by R. Douglas Bruce, MD, MBA, MA, MS, and Vasudev C. Mandyam, MD, explores the multifaceted nature of chronic pain in HIV patients and strategies for effective pain management; and Academy Program Manager Deja Robinson recounts insights learned from the Academy's HIV Care Retention Workshop Series, which provided a platform for sharing local innovations, real-life impact stories, and priorities for the future in our "At the Forefront" column this quarter.

We hope this issue enlightens and inspires work toward equitable, effective HIV care and prevention for women everywhere, and especially in traditionally underserved communities and communities of color.

IN THE NEWS

The American Academy of HIV Medicine Announces Fellowship to Improve HIV Prevention and PrEP Access

ON MARCH 5, THE AMERICAN ACADEMY OF HIV MEDICINE (AAHIVM) announced the Dr. Dawn K. Smith HIV Prevention Clinical Fellowship, funded by a grant through ViiV Healthcare. The fellowship will provide comprehensive HIV prevention training for non-infectious disease clinicians and will focus efforts in communities disproportionately affected by HIV.

"The Academy is committed to working toward ending the HIV epidemic, and broadly employing the full scale of our prevention options plays a critical part in that," says Bruce J. Packett, II, Executive Director of AAHIVM. "Unfortunately, communities of color and other populations in certain parts of the country who have faced systemic barriers to care often lack access to providers who are trained in HIV prevention. The Dr. Dawn K. Smith HIV Prevention Clinical Fellowship aims to overcome some of those barriers to care by training health care providers who may be new to infectious disease or HIV and who practice medicine in underserved communities."

The Academy will leverage its member base of highly experienced HIV clinicians, researchers, and educators to train fellows in the latest science and practice of HIV prevention, focusing on HIV pre-exposure prophylaxis (PrEP). PrEP—a medication to prevent HIV—is exceedingly effective when taken as prescribed. According to the Centers for Disease Control and Prevention, PrEP can reduce the risk of HIV from sex by approximately 99 percent and from injection drug use by about 74 percent.¹

Although PrEP is a key tool in HIV prevention, recent data shows that there are significant disparities in its use, especially in the Southern region of the United States. Research indicates that, in the South, Black people comprised 48 percent of those who were newly diagnosed with HIV in 2021, but only about 21 percent of Black people were prescribed PrEP at that time.²

"This fellowship will help focus training and resources in the areas that stand to make the biggest impact in changing the trajectory of the HIV epidemic," says Kimberly Smith, MD, MPH, Head of Research and Development at ViiV Healthcare. "Dr. Dawn K Smith was a mentor to me and many researchers, providers and advocates who seek to address disparities in HIV incidence and address HIV prevention in communities of color particularly for women. A fellowship that focuses on training future leaders in this field is a fitting tribute to recognize her many contributions. The American Academy of HIV Medicine is the perfect organization to help equitably connect the community to preventative care, and ViiV Healthcare is pleased to support such an important program that will bring us closer to ending the HIV epidemic."

The fellowship is a 12-month clinical program designed for clinicians in primary care, family medicine, emergency medicine, pharmacy, obstetrics and gynecology, and more. Clinicians who qualify include physicians, physician assistants/physician associates, nurse practitioners, and pharmacists. The Academy will prioritize applicants who will serve in



under-resourced areas, especially in the federal Ending the HIV Epidemic jurisdictions in the South. Fellows will perform a mix of clinical work, self and collaborative study, didactics, teaching, and quality improvement activities as well as will access online tools and attend conferences. The fellows will also receive a stipend to support the development of a PrEP clinic in their own practices.

The program honors the legacy of Dawn K. Smith, MD, MS, MPH, a champion of health equity and HIV prevention. Dr. Smith played an integral role in the development and implementation of HIV PrEP and studied the disproportionate affect HIV has on underrepresented communities. Throughout her career, she worked to eliminate health disparities and was committed to ensuring that all people had PrEP access. The Dr. Dawn K. Smith HIV Prevention Clinical Fellowship pays tribute to Dr. Smith's extraordinary contributions to HIV prevention by training a new generation of clinicians in PrEP and HIV prevention.

Applications for the Dr. Dawn K. Smith HIV Prevention Clinical Fellowship are open to clinicians licensed to practice in the United States and can be submitted at: <https://aahivm.org/dawn-k-smith-hiv-clinical-fellowship/>. The deadline for application is May 15, 2024, and the program will begin in July of 2024.

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IN THE NEWS

Children Surpass a Year of HIV Remission After Treatment Pause

NIH-funded trial shows promising outcomes with treatment started promptly after birth.

FOUR CHILDREN have remained free of detectable HIV for more than one year after their antiretroviral therapy (ART) was paused to see if they could achieve HIV remission, according to a presentation [on March 6] at the 2024 Conference on Retroviruses and Opportunistic Infections (CROI) in Denver. The children, who acquired HIV before birth, were enrolled in a clinical trial funded by the National Institutes of Health in which an ART regimen was started within 48 hours of birth and then closely monitored for drug safety and HIV viral suppression. The outcomes reported follow planned ART interruptions once the children met predefined virological and immunological criteria.

“These findings are clear evidence that very early treatment enables unique features of the neonatal immune system to limit HIV reservoir development, which increases the prospect of HIV remission,” said NIAID Director Jeanne Marrazzo, MD, MPH. “The promising signals from this study are a beacon for future HIV remission science and underscore the indispensable roles of the global network of clinicians and study staff who implement pediatric HIV research with the utmost care.”

Advances in ART have significantly reduced perinatal HIV transmission, when a child acquires HIV while in the uterus, during birth, or through consumption of milk from a lactating person. If transmission does occur, children must take lifelong ART to control replication of the virus and protect their immune systems from life-threatening complications. Typically, interruption in treatment will lead to rapid resumption of HIV replication and detectable virus in the blood within weeks. However, in 2013, a case report described an infant born with HIV in Mississippi who initiated treatment at 30 hours of life, was taken off their ART at 18 months of age and remained in remission with no evidence of detectable HIV for 27 months.

Building on the observation that very early ART initiation may limit HIV’s ability to establish reservoirs of dormant virus in infants, researchers began an early-stage proof-of-concept study of very early ART in infants conducted in Brazil, Haiti, Kenya, Malawi, South Africa, Tanzania, Thailand, Uganda, the United States, Zambia, and Zimbabwe. Previous publications from the clinical study showed that ART initiated within hours of birth was safe and effective at achieving and maintaining HIV suppression. A small subset of children achieved sustained HIV suppression and met other predefined study criteria for interrupting ART. These criteria include a durable absence of HIV replication from 48 weeks of ART initiation onward, no detectable antibodies near the time of ART interruption, and having a CD4+ T-cell count (the main immune cell target of HIV) similar to those of a child without HIV. Children who met these criteria, were older than two years, and had stopped consuming human milk were eligible to interrupt ART.



Data presented at CROI summarized the experience of six children, all aged five years, who were eligible for ART interruption with close health and safety monitoring. Four of the six children experienced HIV remission, defined as the absence of replicating virus for at least 48 weeks off ART. One of them experienced remission for 80 weeks, but then their HIV rebounded to detectable levels. Three others have been and remain in remission for 48, 52, and 64 weeks, respectively. However, two children did not experience remission, and their HIV became detectable within three and eight weeks after ART interruption, respectively. The two children whose HIV returned at eight and 80 weeks experienced mild acute retroviral syndrome (ARS) with symptoms including headache, fever, rash, swollen lymph nodes, tonsillitis, diarrhea, nausea, and vomiting. One child had

markedly low white blood cells, which are a type of immune cell. Both the ARS and white blood deficiency resolved either prior to or soon after restarting ART. The three children who experienced viral rebound resumed HIV suppression within six, eight, and 20 weeks of restarting ART.

“This is the first study to rigorously replicate and expand upon the outcomes observed in the Mississippi case report,” said lead study virologist Deborah Persaud, MD, professor of pediatrics at the Johns Hopkins University School of Medicine, and director of the Division of Pediatric Infectious Diseases at Johns Hopkins Children’s Center, Baltimore. “These results are groundbreaking for HIV remission and cure research, and they also point to the necessity of immediate neonatal testing and treatment initiation in health care settings for all infants potentially exposed to HIV in utero.”

The latest findings show that very early ART initiation has varying but favorable outcomes on control of HIV. While ARS was generally mild and resolved in both cases, the authors cautioned that close monitoring for this potential event is needed in ongoing and future HIV remission research involving ART interruption. The children participating in this study took ART regimens with medicines that have been part of standard first-line therapy for decades. Further research is planned or underway to understand how these observations could differ in children receiving newer, more potent generations of antiretroviral drugs, and to identify biomarkers to predict the likelihood of HIV remission or rebound following ART interruption. Additional studies are also needed to understand the mechanisms by which neonatal immunity and very early ART initiation limited the formation of HIV reservoirs and contributed to the remission observed in this study.

“ART shifted the HIV care paradigm, but treatment is a long road, especially for children as lifetime HIV survivors” said Adeodata Kekitiinwa, MBChB, MMed, emeritus clinical associate professor in the Department of Pediatrics at Baylor College of Medicine, study investigator of record and clinical research site leader in Kampala, Uganda. “This trial takes us a step closer to realizing another paradigm shift in which our approach to ART

could be so effective that it might be used for a season of life, rather than its entirety.”

This ongoing research is being conducted by the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network, which is funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, 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).

The research was led by study co-chairs Ellen Chadwick, MD, professor of pediatrics at Northwestern University Feinberg School of Medicine, Chicago, and Yvonne Bryson, MD, professor of pediatrics at the David Geffen School of Medicine and Mattel Children's Hospital at UCLA, and director of the Los Angeles Brazil AIDS Consortium. Dr. Kekitiinwa, Boniface Njau, MS, study coordinator at Kilimanjaro Christian Medical Centre in Tanzania and Teacler Nematadzira, MBChB, site investigator at the University of Zimbabwe-University of California San Francisco Collaborative Research Program continue to lead the study teams overseeing care of children who experienced HIV remission. Jennifer Jao, MD, MPH, professor of pediatrics at Northwestern University Feinberg School of Medicine has since assumed a study co-chair role with Dr. Chadwick. The full IMPAACT P1115 study team consists of hundreds of staff across 30 NIAID- and NICHD-supported sites in the 11 study countries.

NIH is grateful to the research sites and study participants, and to the families, caregivers, and communities that continue to support their involvement in HIV science.

For more information about the trial, known as IMPAACT P1115, please see ClinicalTrials.gov using the identifier NCT02140255.

NIAID conducts and supports research—at NIH, throughout the United States, and worldwide—to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing, and treating these illnesses. News releases, fact sheets, and other NIAID-related materials are available on the NIAID website: <https://www.niaid.nih.gov/>.

Justice Department Sues Tennessee for Enforcing State Law that Discriminates Against People with HIV

ON FEBRUARY 15, The Justice Department filed a lawsuit against the State of Tennessee and the Tennessee Bureau of Investigation (TBI) for violating the Americans with Disabilities Act (ADA). The department previously notified Tennessee and the TBI that they violated the ADA by enforcing the state's aggravated prostitution statute against people living with human immunodeficiency virus (HIV). That letter of findings detailed the minimum remedial measures necessary to address the discrimination.

“The enforcement of state criminal laws that treat people differently based on HIV status alone and that are not based on actual risks of harm, discriminate against people living with HIV,” said Assistant Attorney General Kristen Clarke of the Justice Department's Civil Rights Division. “People living with HIV should not be subjected to a different system of justice based on outdated science and misguided assumptions. This lawsuit reflects the Justice Department's commitment to ensuring that people living with HIV are not targeted because of their disability.”

The department's investigation found that the state and TBI subject people living with HIV to harsher criminal penalties solely because of their HIV status, violating Title II of the ADA. Tennessee's aggravated prostitution statute elevates what would otherwise be misdemeanor conduct to a felony because the individual has HIV, regardless of any actual risk of harm. A person convicted of aggravated prostitution faces three to 15 years in prison and a fine up to \$10,000, while a person convicted of a misdemeanor charge based on the same conduct is subject to a penalty of no more than six months in prison and up to a \$500 fine.

Aggravated prostitution is also categorized as a “violent sexual offense” mandating registration by those convicted on the Tennessee Sex Offender Registry, in most cases for life. The state maintains the registry through the TBI. Individuals placed on the registry due to convictions for



aggravated prostitution are restricted in where they may live, work, and go in public, and have experienced increased homelessness and unemployment. These individuals also face public disclosure of information about their HIV status, which can lead to harassment and discrimination. For example, the complaint identifies one person who has struggled to find safe housing that complies with the registry's requirements and has experienced periods of homelessness, has been denied employment because she is on the registry, and is prevented from spending time alone with her nephew because of her conviction.

The Justice Department plays a central role in advancing the ADA's goals of equal opportunity, full participation, independent living, and economic self-sufficiency for people with disabilities. For more information on the Civil Rights Division, please visit www.justice.gov/crt. For more information on the ADA, please call the department's toll-free ADA Information Line at 1-800-514-0301 (TTY 1-833-610-1264) or visit www.ada.gov.

IN THE NEWS

The Proliferation of State Actions Limiting Youth Access to Gender-Affirming Care

BY LINDSEY DAWSON AND JENNIFER KATES

Just as LGBTQ identity is increasing in the U.S. and national support for same-sex marriage is holding at an all-time high, states are enacting a range of new laws and policies aimed at limiting LGBTQ people's access to social institutions in domains such as school and health care. Transgender people's rights, in particular, have become a divisive partisan issue that is already playing a role in discourse and debate in the 2024 election.

One area that has received considerable attention is young people's access to gender-affirming care. Gender-affirming care services are widely considered medically necessary best practices for those that need them, including for youth. Virtually all major U.S. medical associations support youth access to gender-affirming care, including the American Medical Association, American Academy of Pediatrics, and the American Psychological Association, among others. In particular, these groups point to the evidence demonstrating that medically necessary gender-affirming care enhances mental health outcomes for transgender youth, including by reducing suicidal ideation.

Professional guidance for gender-affirming care, including for young people, is provided by the Endocrine Society and the World Professional Association for Transgender Health, bodies that also support access to this treatment model. Despite the evidence around the role gender-affirming care can play in promoting well-being and support from the medical community, those seeking to enact state restrictions to this care contend that such policies are necessary to "protect children" and that the potential medical risks linked to gender-affirming care outweigh any benefits. Notably, not all trans people choose to incorporate the medical services these policies prohibit as part of their transition and instead focus on social transition. Further, while the number of young trans people using puberty blockers or hormone therapy has increased modestly in recent years, overall number of those using these prescriptions remains fairly low and multiple studies have shown gender-affirming surgery is rare among youth.

Gender-Affirming Care

Gender-affirming care is a model of care that includes a spectrum of "medical, surgical, mental health, and non-medical services for transgender and nonbinary people" aimed at affirming and supporting an individual's gender identity.¹ Gender affirmation is highly individualized. Not all trans people seek the same types of gender-affirming care or services and some people choose not to use medical services as a part of their transition.

Over the past 18 months, there has been a rapid increase in the number of states that have enacted laws and other policies that prohibit or restrict minor access to gender-affirming care. Our new tracker provides a regularly updated overview of state policy developments aimed at restricting minor access to gender-affirming care as well as the litigation challenging it.² This policy watch summarizes findings as of January 30, 2024.

Current Status

- In less than two years, the number of states with laws or policies limiting minor access to gender-affirming care has increased more than five-fold, climbing from just four states in June 2022 (AL, AR, TX, AZ) to 23 states by January 2024 (AL, AR, AZ, FL, GA, IA, ID, IN, KY, LA, MO, MS, MT, NC, ND, NE, OH, OK, SD, TN, TX, UT, WV). *(See Figure 1)*
- As the number of states enacting such policies increases so do the number of trans youth potentially impacted. The 23 states with laws and/or policies limiting youth access to gender-affirming care are home to an estimated 38 percent of young trans people between the ages of 13-17.3. *(See Figure 2)*
- Of the 23 states with laws/policies restricting youth access to gender-affirming care: 17 are currently in effect in full. Four are temporarily blocked in full or in part and one is permanently blocked in court, though an appeal is pending. The law in Ohio does not go into effect until April 2024. (See Litigation section for additional discussion of legal activity in this area.)
- While all of the laws/policies examined seek to limit or prohibit access to key gender-affirming care services for young people, they range in their complexity. Some are comparatively limited (e.g. banning only surgical care, which is rare among youth), while others are more far reaching in terms of their scope of prohibitions, penalties, and individuals impacted. *(See Figure 3)*

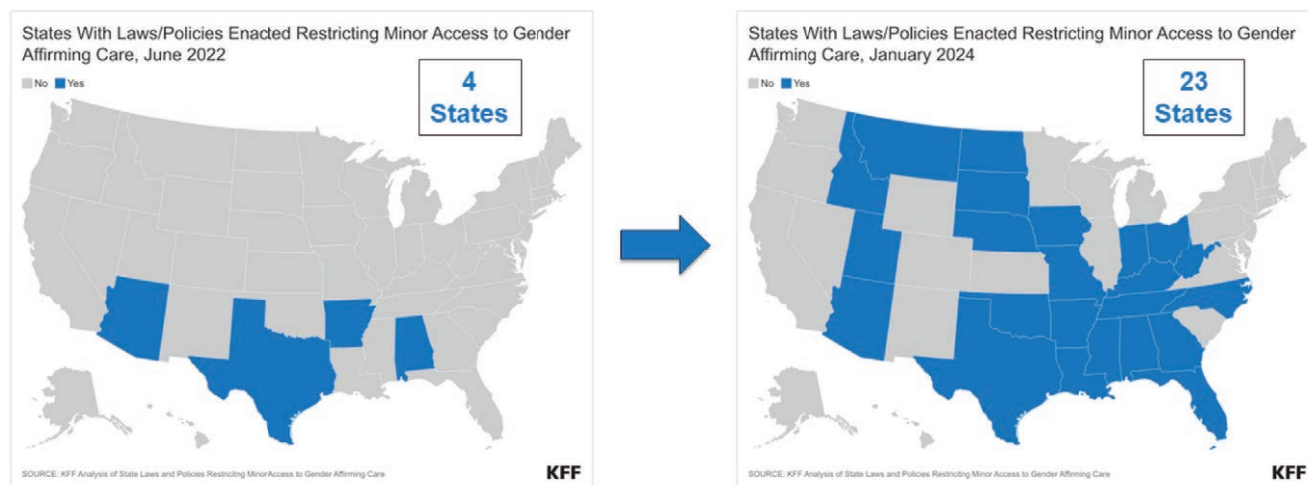
Other Groups Impacted By State Laws/Policies

Although these laws/policies primarily center on restricting minor access to gender-affirming care, many also include provisions impacting other groups that are found to provide or otherwise support such youth access, as follows:

Medical Providers

- Nearly all states (21 of the 23) include specific provisions with penalties for providers (exceptions are AZ and WV).
 - Twenty states include either professional or civil penalties (AR, FL, GA, IA, ID, IN, KY, LA, MO, MS, MT, NC, ND, NE, OH, OK, SD, TN, TX, UT). Professional penalties may include a loss of a medical license or referral to medical licensing boards for further action.
 - Five states (AL, FL, ID, ND, OK) include felony penalties for providers.
 - Eight states (AR, FL, IA, IN, MS, MT, OH, UT) include provisions prohibiting providers from offering minors referrals for or otherwise "aiding and abetting" access to gender-affirming care.

FIGURE 1. A Growing Number of States Have Moved to Ban or Restrict Minor Access to Gender Affirming Care



SOURCE: KFF Analysis of State Laws and Policies Restricting Minor Access to Gender Affirming Care.

NOTE: Last updated 1/24/24

KFF

Parents

- Four states (FL, MS, OH, TX) include provisions directed at parents or guardians. For example, Florida's law, which affects parents most directly, modifies state custody laws to permit the state to take physical custody (or modify another state's custody determination) of the child, if a child present in the state is "at risk of or is being subject to" gender-affirming care. A Texas directive defines certain gender-affirming services as child abuse calling for investigation of and penalties for parents supporting access to care, which could include the removal of their children.

Teachers, counselors, and other officials

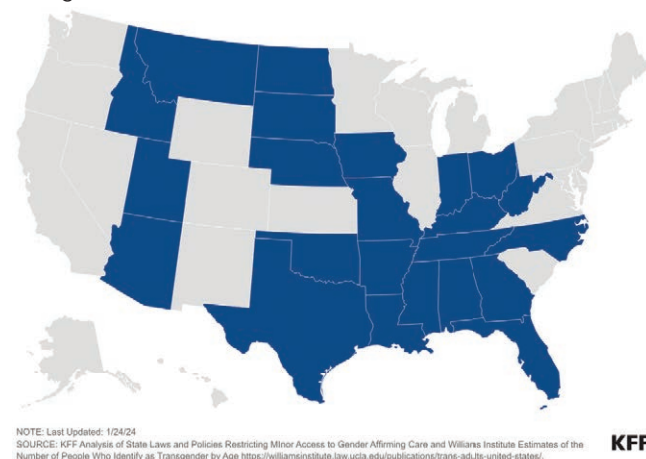
- Four States (AL, MS, MT, TX) include laws/policies that impact school officials such as teachers and counselors, among others. The Alabama law prohibits nurses, counselors, teachers, principals, and other administrative school officials from "encouraging" or "coercing" minors from withholding that their gender identity is different from their sex assigned at birth from their parent/guardian. Because the Mississippi law prohibits "aiding and abetting" youth access to gender-affirming care by any person, teachers and other school officials could be implicated. Montana prohibits any state official, such as a school counselor, from providing or "promoting" gender-affirming care. As mentioned above, Texas's definition of certain gender-affirming services as child abuse implicates a range of professionals such as teachers who are mandated reporters.

Transgender Adults

- In addition to prohibiting minor access to gender-affirming care, seven states (AL, AR, FL, MO, MS, NC, NE) limit adult access in some way. These include provisions that would, for example, allow private health plans, Medicaid, and/or correctional facilities to exclude all gender-affirming

FIGURE 2. 38% of Trans Youth (Ages 13–17 Live in a State with a Law/Policy Limiting Their Access to Gender Affirming Care

Share of U.S. trans youth ages 13–17 living in a state with law limiting access to GAC

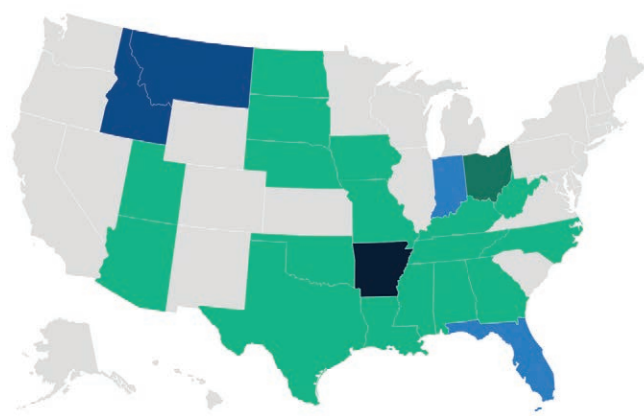


care coverage and/or prohibit them from providing such services; prohibit the use of federal funds for gender-affirming care; require informed consent practices beyond those typically required in medical practice; and render gender-affirming services non-tax deductible under state income tax law or due to some states definition of minors, those who are 18 years old.

IN THE NEWS

FIGURE 3. Current Status of State Laws Restricting Minor Access to Gender Affirming Care

■ In effect ■ Passed, not yet in effect ■ Permanently blocked
■ Temporarily blocked ■ Temporarily blocked in part

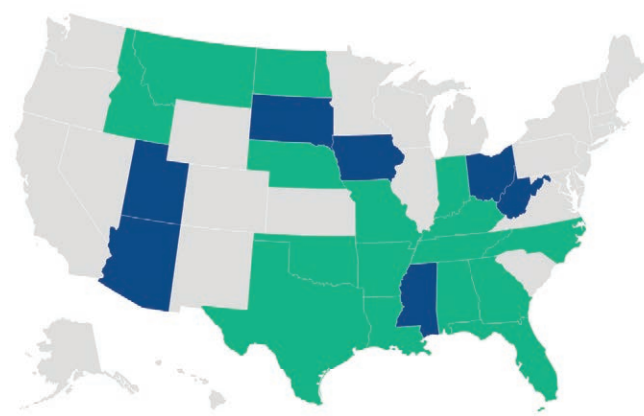


NOTE: Last Updated: 1/24/24
SOURCE: KFF Analysis of State Laws and Policies Restricting Minor Access to Gender Affirming Care and Related Legislation.

KFF

FIGURE 4. Among 23 States That Have Enacted Laws Limiting Youth Access to Gender Affirming Care, 16 Are Being Challenged in Court

■ No ■ Yes



NOTE: Last Updated: 1/24/24
SOURCE: KFF analysis of Laws and Policies Restricting Minor Access to Gender Affirming Care.

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Exceptions

- Six states provide exceptions, allowing access to this care in certain circumstances (GA, FL, OH, NC, NE, ND), including some limiting access to minors who were receiving these services prior to the law's enactment (e.g. NC, ND, OH). Nebraska has a broader process available but it includes strict requirements to qualify for exceptions for individuals, families, and providers. Another six states (LA, IN, KY, OK, SD, and TX) that allow for these exceptions do so with a requirement or expectation that the minor will taper their use and be "weaned" from treatment within a certain time frame.
- Notably, despite the prohibitions around gender-affirming care for trans youth, all 23 states allow the same services prohibited under the law/policy to be used in other medical circumstances (e.g. when they are prescribed to address "precocious puberty" or chromosomal sex differences, among other "conditions").

Litigation

- Just as the number of states enacting such policies has increased, so has the number of lawsuits challenging them. The majority of states with laws/policies in place (16 or 23) are facing legal challenges.
 - Several (six) have reached appeals courts, and the plaintiffs in the Tennessee and Kentucky cases have petitioned the U.S. Supreme Court to review their claims, with the U.S. Department of Justice filing a similar petition. (See Figure 4)

Looking Ahead

State policy making that limits youth access to gender-affirming care can be viewed in a broader context of other actions states have taken to restrict young trans people's access to social institutions. For example, states have enacted so called "bathroom bills," "don't say gay bills," requirements that schools notify parents if minors use gender pronouns

not reflective with their sex assigned at birth, and laws that limit transgender students' access to sport. (The Movement Advancement Project tracks a range of these policy areas, including youth access to gender-affirming care.) Conversely, other states have made efforts to secure trans people's access to health care (including adults) by creating coverage requirements for private insurance and Medicaid and enacting shield laws to protect patients/providers seeking care when it is prohibited in their home state.

LGBTQ rights, especially those impacting young people, are shaping up to be a major issue in the 2024 election and are being debated heavily at the state and local level, as evidenced by the proliferation of laws and policies seeking to limit youth access to gender-affirming care.

Looking ahead, it will be important to monitor whether states continue to enact these policies, how litigation takes shape, and whether the Supreme Court elects to take the cases that it has been petitioned to hear. These laws and policies have political implications, but importantly also have the potential to affect the wellbeing of young trans people and LGBTQ people more broadly, with implications as well for health care providers, parents, and teachers.

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Biden-Harris Administration Awards \$5.1M in Support of LGBTQI+ Youth and Families

ON FEBRUARY 16, the U.S. Department of Health and Human Services (HHS), through the Substance Abuse and Mental Health Services Administration (SAMHSA), announced four awards totaling \$5.1 million for Family Counseling and Support for Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, Intersex+ Youth, and their Families.

These grants are in addition to \$1.7M in grant funding previously awarded in 2023 to four other recipients. All eight awardees will be engaging LGBTQI+ youth and their families to prevent risk of health conditions, including behavioral health conditions (e.g., suicidality, depression, homelessness, drug use, HIV) and promote well-being for LGBTQI+ youth by establishing family counseling and support programs and training providers on family counseling and support interventions tailored for LGBTQI+ families.

"The health of our nation begins with the wellness of our youth, and every young American must receive adequate behavioral health supports regardless of their gender identity or sexual orientation," said HHS

Secretary Xavier Becerra. "Facilitating behavioral health services for communities in need are a vital part of our obligation to ensure overall health and human dignity."

"The pursuit of equity in behavioral health care remains a key component of SAMHSA's mission," said Miriam E. Delphin-Rittmon, PhD, HHS Assistant Secretary for Mental Health and Substance Use and the leader of SAMHSA. "We remain steadfast in our commitment to ensure behavioral health services for all, with distinct attention to young people in particular need."

Various SAMHSA publications and other agency-facilitated supports for the LGBTQI+ population have been made available in recent years:

- In June 2023, SAMHSA published the data report Lesbian, Gay, and Bisexual Behavioral Health: Results from the 2021 and 2022 National Surveys on Drug Use and Health. The report indicates that lesbian, gay, and bisexual adults are more likely than straight adults to use substances, experience mental health conditions including major depressive episodes, and experience serious thoughts of suicide.

- FindSupport.gov in June 2023 began specifically identifying relevant available resources for LGBTQI+ individuals seeking access to inclusive and affirming mental health care and supports. These resources include how to avoid and deal with harmful approaches like 'conversion therapy.' FindSupport.gov was launched in May 2023 as a user-friendly website, designed for the general public, to help people identify available resources, explore unbiased information about various treatment options, and learn how to reach out to get the support they need for issues related to mental health, drugs, or alcohol.

- SAMHSA published Moving Beyond Change Efforts: Evidence and Action to Support and Affirm LGBTQI+ Youth in March 2023, a report that provides behavioral health professionals, researchers, policymakers, and other audiences with a comprehensive research overview and accurate information about effective and ineffective therapeutic practices related to youth of diverse sexual orientation and gender identity.

- In July 2023, the 988 Suicide & Crisis Lifeline expanded specialized services for LGBTQI+ youth and young adults with 24/7 call, text, and chat for individuals who want to connect with a counselor specifically focused on meeting their needs. A pilot program, which ran September 2022 through June 2023, demonstrated a significant demand for the service, which accounted for about six percent of calls, 11 percent of chats, and 15 percent of texts routed to the 988 Lifeline network during the pilot phase.

- Since 2020, SAMHSA has funded a Center of Excellence for LGBTQ+ Behavioral Health Equity, which is designed to support the implementation of change strategies within mental health and substance use disorder treatment systems to address disparities impacting the LGBTQ+ community.

Learn more about SAMHSA's equity efforts to support the needs of LGBTQI+ individuals at <https://www.samhsa.gov/behavioral-health-equity/lgbtqi>.



Medical Providers Can Bridge

Supporting Black
women in HIV
prevention and
treatment



Disparities

By Jaymee Leak Matthews, DNP, APRN, FNP-C

THE UNITED STATES' medical advancements in the prevention and treatment of HIV in the last 20 years have led to evidence-based methods that reduce transmission of the virus as well as decrease HIV related morbidity and mortality. However, the coordinated efforts throughout the country to deliver HIV services (testing, counseling, pre-exposure prophylaxis (PrEP), antiretroviral treatment (ART), and syringe service programs) have shown dismal impacts, particularly in the southern U.S. HIV disparities are worse along ethnic and racial lines. In 2021, Black Americans aged 13 and older represented approximately 12 percent of the U.S. population. This 12 percent of the more than 330 million Americans accounted for 40 percent of people with HIV (PWH).¹ HIV incidence rates are the estimated number of HIV infections during a specific time period.³ New HIV infections in the U.S. remained about 38,000 infections per year (HIV incidence).¹⁴

Surprisingly, overall new HIV incidence rates decreased from 2017 to 2021; however, the rate of HIV incidences for Black persons was still more than seven times the rate of White persons. At the end of 2021, Black men assigned male at birth, accounted for 75 percent of new HIV infections through male-to-male sexual contact and men who have sex with men (MSM) were affected the most when compared to all other groups by ethnicity and race.² Comparatively, yet conversely, Black women who engaged in male to female receptive sexual contact were the most affected group among women assigned female at birth. Black women accounted for 18 percent (6,666) of the 36,136 new HIV diagnoses in 2021.³ New HIV diagnoses of Black women were estimated to be more than 50 percent of all new HIV cases in the U.S. among all women assigned female at birth.¹⁵ New HIV infection rates for Black women in 2021 were 10 times the number of White women and four times the number of Hispanic women.⁵

Interpreting Data

Using data from the Centers for Disease Control and Prevention (CDC), among people assigned male at birth, HIV infections decreased but remained stable among people assigned female at birth.² Stability here is relative and should be dissected to achieve clarity. "Stable" new HIV infection rates for Black women would translate to not increasing rates but also not decreasing either. Decreased rates (considering for disparities in infection rates) from 2017-2021 for HIV infections for Black males can be interpreted in other ways, too. One is antiretroviral medications and other methods to mitigate the spread of HIV are being effectively and more consistently employed by the male population. Conversely, in the case of Black women, another perspective could posit Black women were not using the same evidence-based tools as effectively or consistently, likely due to lack of awareness or lack of access to prevention medications when in contrast to their Black male or White female counterparts.

The argument posed here is interpreted from HIV transmission data, which suggests a pattern of continued failure to prevent HIV transmission and lower HIV incidence rates in Black women who acquire HIV through receptive vaginal sex from 2017-2021. According to the CDC, among men most HIV infections were attributed to male-to-male sexual contact.¹¹ Among women, most HIV infections were attributed to heterosexual contact, which is the group most affected in that transmission category.^{4,11} Additionally, Black women have been shown to be less likely to have attained viral suppression and more likely to die sooner for HIV complications than White and Latina women.¹⁴

Transmission of HIV is preventable, but prevention methods are not accessible to all equally. HIV is mainly spread through sexual contact or injection of drugs with other persons who have HIV. Correct and effective use of barrier methods (condoms), PrEP, viral suppression, abstinence, and status awareness help reduce the risk of HIV transmission. Black women, especially poor Black women, are challenged to access high-quality HIV preventative care or HIV treatment due to stigma, racism, non-social support, poor medical professional engagement, medical mistrust and unmet social needs.¹⁴ An ecological analysis by Watson et al. analyzed the role social determinants of health (SDOH) has on the risk of mortality among Black women with HIV acquired through heterosexual contact.¹⁷ Their study suggested lack of health insurance (access) and poverty as predictors of mortality and the need for increased prevention, HIV care, and changes in policy for Black women with HIV.¹⁷

History of Mistreatment in Health Care

Some background information should be mentioned here to speak to the federal benchmark for successful linkage to care to help women with HIV obtain viral suppression, which leads to prevention through treatment. Linkage to care within 30 days of a positive HIV diagnosis is the metric used by the CDC to determine failed linkage or delayed entry into care.¹² However, the origins of HIV disparities for Black women, in most cases, must be viewed through the lens of general health disparities experienced by Black women in health care universally. Natalia Kanem, executive director of the UN Population Fund stated in a 2023 news release that, “The scourge of racism continues for Black women and girls in the Americas, many of whom are descendants of the victims of enslavement.” She continued to say, “Too often, Afro descendent women and girls are abused and mistreated, their needs are not taken seriously, and their families are shattered by the preventable death of a loved one during childbirth. Justice and equality will only be possible when our health care systems see these women and provide them with respectful, compassionate care.”⁶

Ms. Kanem’s statement, while focused on childbirth issues (also an issue for Black women), focuses on historical and systemic issues that continue to create and maintain barriers to health education and health interventions needed to bridge the disparities experienced by Black women, especially and including HIV. Health care interventions for women of African descent have been documented to have been withheld during critical times in patient care. Black women face increased complications in health care due to verbal and physical abuse, denial of care, and alleviation of pain relief resulting in some deaths.⁷

Interventions to Reduce HIV

The disproportionate impact of HIV on Black women who are at high risk for HIV transmission means that they need more access to evidence-based interventions that can reduce the risk of HIV and of other sexually transmitted infections (STI).⁸ Gilbert et al. conducted a randomized clinical trial called Empowering African American



High-quality health care, including HIV testing, treatment, and other prevention services, addresses social and structural barriers and can improve health outcomes for Black women.

Women on the Road to Health (E-WORTH).⁹ E-WORTH employed a hybrid individual- and group-level, multi-session, culturally tailored intervention versus a streamlined HIV testing control condition to decrease HIV and STI risk among Black women in community corrections over a 12-month period. The findings from their trial indicated a significant decrease (54%) in likely STI infections (chlamydia, gonorrhea, or trichomoniasis) and 38 percent fewer condomless sex acts in a prior 90-day period.⁹

Innovations in prevention and treatment of HIV continue to fail to reach minority communities already marginalized through socioeconomic and cultural factors. There are limited studies that support relevant interventions for Black women in HIV prevention and HIV care. Despite dissemination of implemented behavioral interventions, the advent of PrEP, and innovations of ART, Black people still bear the greatest burden of the HIV epidemic.¹³

Provider Impact

The CDC has promoted a “high-impact prevention” approach to HIV, which supports the implementation of interventions that

are not only evidence-based, but are also deemed scalable, cost-effective, and have a high likelihood of population-level impact.¹⁰ High-quality health care, including HIV testing, treatment, and other prevention services, addresses social and structural barriers and can improve health outcomes for Black women. There is a plethora of clinical tools available to providers in addressing how Black women can be provided high-quality health care in the prevention and treatment of HIV. Further research is needed to assess and identify strategies to reduce the barriers to HIV prevention access and engagement into the HIV care continuum.

However, studies in the last few years have suggested how the employment of resilience-based strategies provide Black women with coping mechanisms to face documented health care-experienced stigma and discrimination.^{14,15} According to the National HIV/AIDS Strategy (2022–2025), which aims to reduce disparities and improve health outcomes for Black women in HIV health care, medical providers should employ creative health care deliveries to address knowledge deficits of patients. Medical providers can further address social

and structural barriers to HIV care engagement by using complementary emerging strategies, such as motivational interviewing, that support linkage and retainment in HIV care and empowerment in adoption of HIV prevention methods^{14,15} The CDC provides guidance to clinicians and clinics to retain patients in HIV care. This guidance aims to reduce barriers to care, to build positive relationships, and to encourage providers to engage in mini-conversations with patients at every visit.¹⁸

Clinicians should use this guidance in building trust with patients by being direct, supportive, and non-judgmental. Clinicians must acknowledge the documented history of the mistreatment of marginalized communities by health care practitioners and adjust their practices to ensure they are providing culturally competent, holistic care. They should use open-ended questions that allow for shared decision-making, which empowers women to share experiences while creating trust between patients and providers. Clinicians should encourage discussions and educate patients on substance use, sexual behavior, and mental health.¹⁸ Lastly, socioeconomic and structural barriers can also be addressed by directing patients to resources that could meet lifestyle needs (childcare, transportation, food, housing), offering extended office hours with walk-in clinics, referring patients to substance use and mental health services and helping patients identify friends and family who can support them in their HIV care.¹⁸

Conclusion

While HIV remains a global health issue, in the U.S. new HIV infections are more prevalent in certain populations—Black men and women—who bear a far greater burden than their White and Latino peers. However, the disproportionate impact of HIV on Black American women has seen neither an increase nor decrease for Black women who were assigned female at birth. Since Black women acquire HIV through heterosexual contact at almost seven to 13 times more often than White women and four to six times more often than Latina women, it can be suggested that prevention and treatment methods are not being utilized effectively in this population. Additional studies are needed to evaluate the reason why Black women who engage in male to female receptive sexual contact are more at risk for acquiring HIV or are not seeking means for viral suppression. There needs to be more support for relevant interventions for Black women in HIV prevention and HIV care.

In the meantime, clinicians must employ creative health care practices (motivational interviewing, simple explaining, building trust) that address barriers that will help with prevention uptake and retainment in HIV care to ultimately avoid HIV transmission in HIV-negative Black women and to achieve viral suppression in Black women with HIV. Clinics and health systems should allow for the uptake of resilience-based strategies that can help Black women to reduce or remove the residual effects of years of stigmas, mistreatments, and racism they have experienced. Optimal outcomes can result in decreasing new HIV infections for Black women, which will achieve better health outcomes for all populations. **HIV**



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HIV

Pre-Exposure Prophylaxis



and CISGENDER WOMEN

By Britt Gayle, MD, MPH, AAHIVS;
David Ahamba, MD, MPH, CTropMed, AAHIVS;
and Hadrian Holder, MD, MPH, AAHIVS

PRE-EXPOSURE PROPHYLAXIS (PrEP) is the term used to describe the use of antiretrovirals (ARVs), to prevent the acquisition of HIV. These medications are currently the most effective biomedical means to protect people, including women, against HIV acquisition. PrEP's benefits prompted the United States Preventive Services Task Force to assign a grade "A" recommendation for the prescription of PrEP to adolescents and adults at increased risk of HIV.¹

Despite expanding access to PrEP globally, women are disproportionately impacted by barriers to PrEP. A significant disparity in PrEP uptake exists between cisgender men and cisgender women, with data from the Centers for Disease Control and Prevention (CDC) revealing that 41 percent of eligible cis-men have received PrEP prescriptions compared to 15 percent of eligible women.² PrEP awareness and uptake must increase among those who are most vulnerable, including women, in order to reduce HIV incidence.

Currently FDA Approved Forms of PrEP

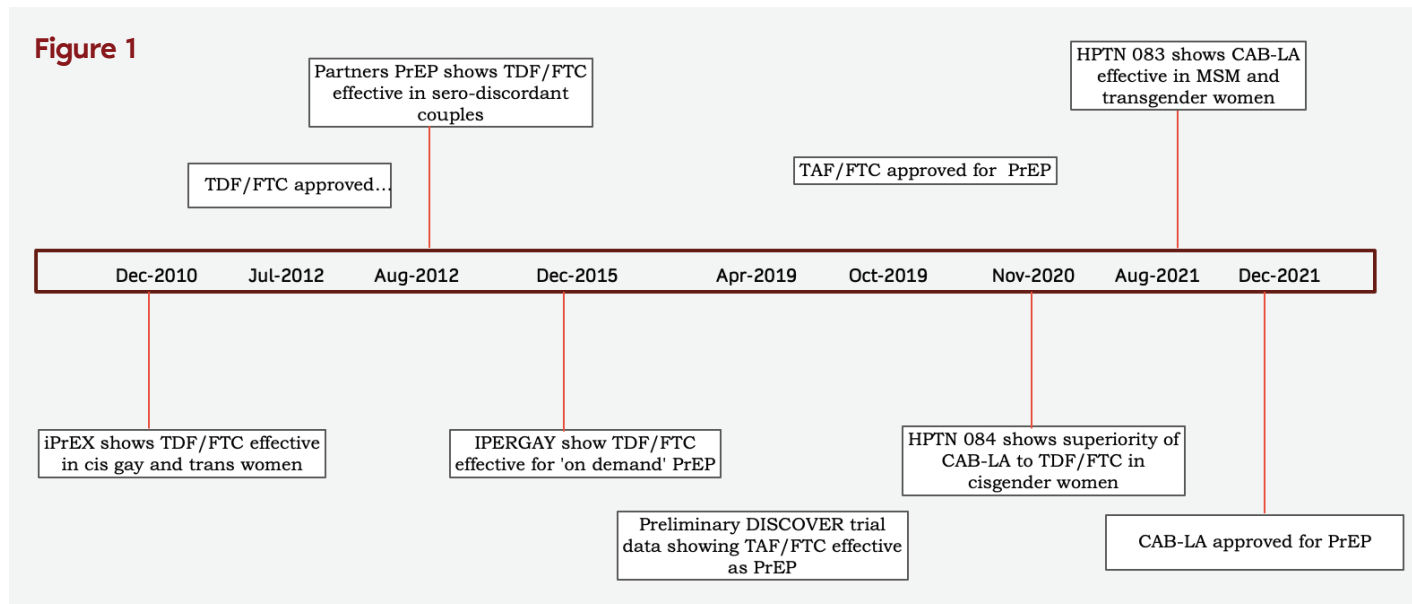
Oral PrEP

The first form of PrEP approved in the U.S. was tenofovir disoproxil fumarate/emtricitabine (TDF/FTC), receiving its FDA approval for HIV prevention in 2012. The CDC published its first version of guidelines describing those who may benefit from PrEP and how to prescribe and monitor patients receiving PrEP in 2014.

While additional research has resulted in a near consensus regarding the persistent efficacy of oral PrEP among men who have sex with men (MSM) and transgender women engaging in anal intercourse who take PrEP daily (as few as four doses a week or engage in on-demand PrEP regimens), pharmacokinetic studies have demonstrated lower tenofovir diphosphate concentrations in vaginal tissues versus rectal tissues. This results in more rigorous adherence standards being imposed upon women.

For example, cis-women are typically counseled that three weeks of adherence to TDF/FTC is required before relying upon it to provide protection from HIV and that near perfect adherence (i.e. a maximum of one missed dose a week) is necessary to maintain protective concentrations; a requirement that likely impairs PrEP interest, uptake, and persistence.³ Cis-women, like other demographic groups, experience "seasons" of risk, but are limited to only one form of PrEP that is relatively compatible with fluctuating levels of risk. Women taking oral PrEP may therefore benefit from greater efforts at maintaining engagement to facilitate continued adherence or decrease barriers to resuming oral PrEP in response to an increase in risk. Greater adoption of same-day PrEP protocols may also be beneficial.⁴

A modeling study simulating emtricitabine and tenofovir pharmacokinetics questioned whether the impact of significantly lower adherence among cis-women in clinical trial was sufficiently considered when formulating adherence requirement guidance for them, in light of the large proportion of cis-women in the studies with undetectable plasma tenofovir levels (HPTN 084: 44 percent; FEM-PrEP: 64 percent; VOICE: 71 percent; Partners PrEP: 19 percent; TDF2: 44 percent). After reassessing the adherence data from the five clinical trials and performing simulations that placed those with undetectable levels into a separate sub-cohort, the authors concluded that three of the studies were underpowered to estimate efficacy among cis-women and that the studies with sufficient power suggested an average

Figure 1

efficacy among cis-women of at least 90 percent. The authors also observed a higher estimated PrEP efficacy in cis-women when peripheral blood mononuclear cell (PBMC) concentrations were used as an indicator of protection compared to local tissue concentrations, with high levels of protection anticipated with adherence to at least three doses a week.

Furthermore, the authors' simulations demonstrated that models using local tissue concentrations underestimated the new PrEP efficacy results generated following the establishment of a separate "drug undetected" sub-cohort and therefore lacked predictive power. While additional clinical research data is needed to better understand exposure-site pharmacokinetics and more definitively establish adherence requirements for cis-women, this study suggests that the current rigid adherence requirements for cis-women may not be statistically supported.⁵

The first U.S. observational open-label demonstration project of PrEP among at-risk cis-women followed cis-women prescribed daily oral TDF/FTC for 48 weeks; 46 percent remained on PrEP at the conclusion

of follow up and 18 percent had tenofovir diphosphate concentrations consistent with adherence to six to seven doses a week. More than a third (12/31) of those who remained on study but off PrEP reported discontinuing PrEP due to adverse effects, and one out of 15 participants who requested to withdraw from the study cited adverse effects.

Injectable Cabotegravir

Intramuscular injections of cabotegravir was approved for use as PrEP among cis-women engaging in receptive vaginal intercourse, following release of the results from the HPTN 084 trial, a phase 3, randomized, double-blind, double-dummy, active-controlled superiority trial in 20 clinical research sites in seven countries in sub-Saharan Africa.³ Eligible patients were those who reported being assigned female sex at birth, aged 18- to 45-years-old, reported a minimum of two episodes of vaginal intercourse in the previous 30 days, had an undetectable HIV RNA up to 14 days from enrollment, agreed to use a long-acting reversible contraception method and were at increased risk of HIV infection per an HIV risk score. Pregnant and breastfeeding women were excluded. Patients were assigned 1:1 to either active cabotegravir with TDF/FTC placebo or active TDF/FTC with

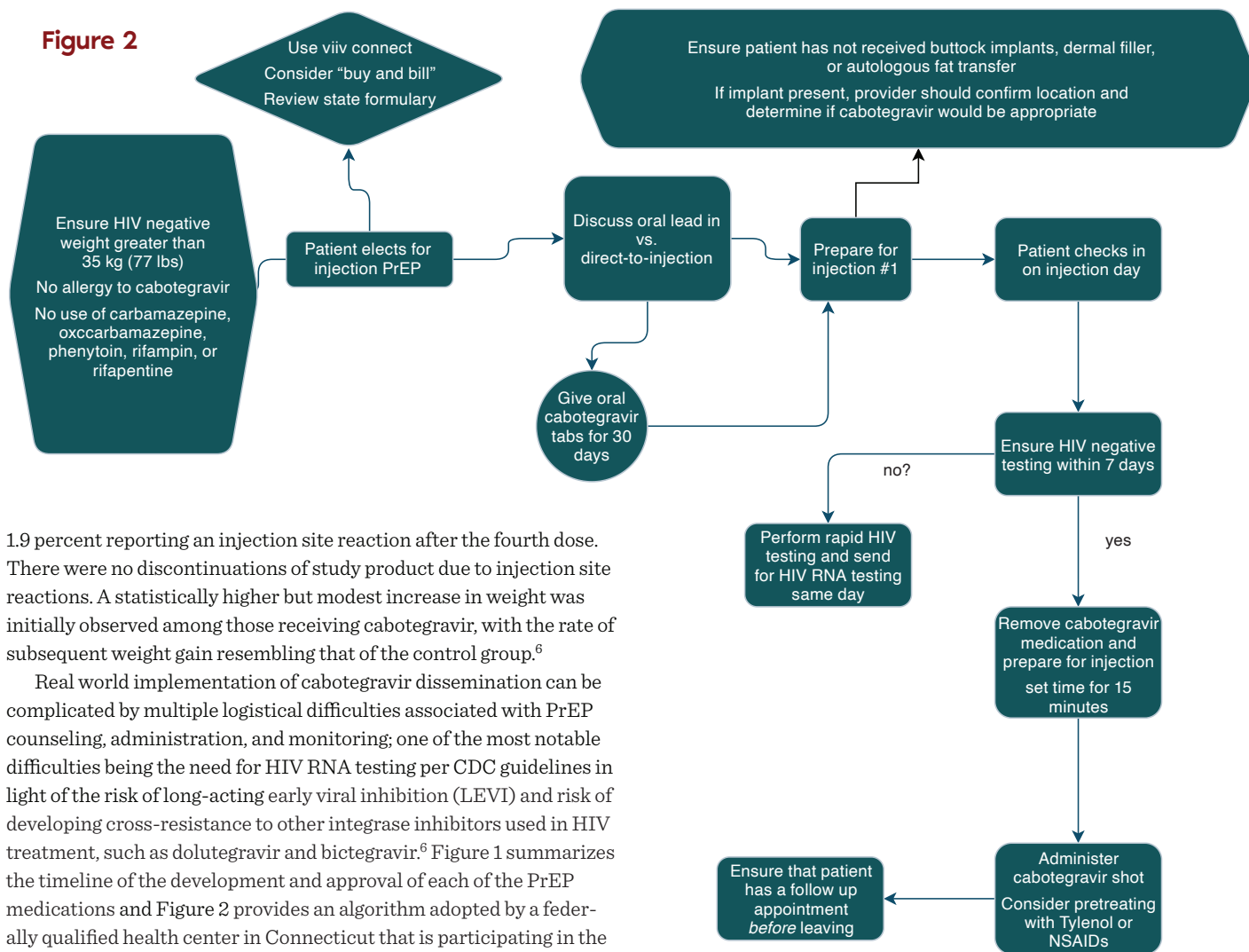
cabotegravir placebo. All study staff and participants were masked to study arm assignment with the exception of the pharmacist responsible for study product preparation.

A total of 3,224 participants were enrolled and 40 incident HIV infections occurred, four in the cabotegravir group and 36 in the TDF/FTC group, indicating that members in the cabotegravir arm had an 88 percent lower risk of HIV infection compared to those in the TDF/FTC arm (hazard ratio of 0.12 (0.05–0.31, $P < 0.0001$)) and absolute risk difference of –1.6 percent (–1.0 percent to –2.3 percent). The primary source of the superior performance among the cabotegravir group was the significant difference in adherence; 93 percent of those in the cabotegravir arm received their injections on-time while only 18 percent of the 1,197 dried blood spot samples had tenofovir diphosphate concentrations corresponding with adherence to at least four doses a week over the past month. None of the 36 participants with incident infections in the TDF/FTC arm had tenofovir diphosphate concentrations corresponding with adherence to six to seven doses a week.

While 38 percent of cis-women reported experiencing injection site reactions, the reactions were mostly limited to pain and diminished over time, with 28.8 percent reporting a reaction after the first dose and



Figure 2



1.9 percent reporting an injection site reaction after the fourth dose. There were no discontinuations of study product due to injection site reactions. A statistically higher but modest increase in weight was initially observed among those receiving cabotegravir, with the rate of subsequent weight gain resembling that of the control group.⁶

Real world implementation of cabotegravir dissemination can be complicated by multiple logistical difficulties associated with PrEP counseling, administration, and monitoring; one of the most notable difficulties being the need for HIV RNA testing per CDC guidelines in light of the risk of long-acting early viral inhibition (LEVI) and risk of developing cross-resistance to other integrase inhibitors used in HIV treatment, such as dolutegravir and bictegravir.⁶ Figure 1 summarizes the timeline of the development and approval of each of the PrEP medications and Figure 2 provides an algorithm adopted by a federally qualified health center in Connecticut that is participating in the PILLAR and EBONI trials.

Disparities Related to PrEP

Disparities in Risk Perception

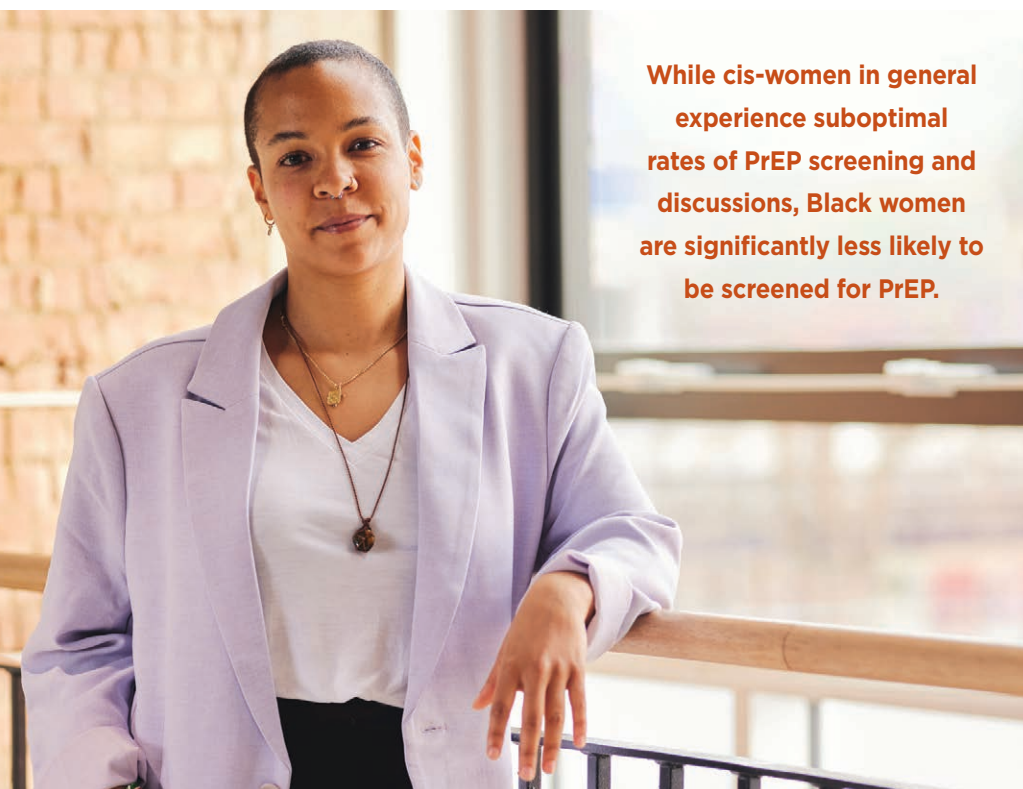
There is a consistent trend across the literature of an underestimation of self-perceived HIV risk that can be attributed to multiple factors. A major factor driving the disparity between perceived and actual HIV risk is the underestimation of the prevalence of HIV within one's geographic and/or social networks. Brookmeyer, et al observed that "providers may discuss sexual history differentially based on patients' demographic characteristics."⁷ Such practices are frequently based on providers' assumptions influenced by implicit biases and render providers more susceptible to differentially avoiding standardized detailed sexual history taking approaches, such as the CDC's five Ps.

Providers who consistently and equitably collect detailed sexual histories may be more likely to offer sexual health preventative care, such as PrEP, thus demonstrating the importance of ensuring that providers receive adequate training in consistently and comfortably taking sexual histories. Though the CDC broadened the eligibility criteria for PrEP to include any patient requesting PrEP in its 2021 version of the guidelines, use of such criteria is dependent upon the patient being aware of her risk factors, despite many women being unaware of their partner's behavior.

Disparities in PrEP Awareness

Cis-women are less likely to be aware of PrEP and their eligibility for PrEP compared to men, and some research has demonstrated that cis-women with CDC indications for PrEP are not more likely to be aware of PrEP.⁸ Awareness of eligibility is highly dependent upon public messaging. An analysis of X/Twitter content between 2009 and 2022 observed that 43.2 percent of the 1,256 initial tweets about PrEP focused on women and were produced by 396 unique users, with most of the users being organizations. Of the individual users, 64.6 percent were American. Almost a quarter of the tweets (24.2 percent) had messaging targeted to Black women, 31.4 percent contained messages focusing on the benefits of PrEP, and 22.4 percent focused on the self-efficacy associated with taking PrEP.

However, the researchers observed that the number of tweets significantly decreased after 2018, prior to the approval of injectable cabotegravir as PrEP.⁴ It's important to acknowledge, however, that increased awareness alone is not independently associated with increased intention to initiate PrEP; instead, community level interventions that address community and structural factors must also be established.⁹



While cis-women in general experience suboptimal rates of PrEP screening and discussions, Black women are significantly less likely to be screened for PrEP.

Disparities in PrEP Engagement and Retention

Individual, interpersonal, community, and structural factors can serve as significant barriers to PrEP initiation and persistence.⁹ For example, cis-women have cited family practice clinics and providers as trusted parties and 40 percent of women in the U.S. exclusively access reproductive health care. However, most sexual and reproductive health clinics do not routinely discuss nor offer PrEP, decreasing cis-women's access to PrEP.¹⁰ There is mixed evidence regarding the impact of provider recommendations for PrEP, with basic statements not associated with an increase in intent to start PrEP, but more extensive discussions being beneficial.⁹ Unsurprisingly, the fear of being shamed for PrEP use was associated with a decreased probability of expressing the intention to initiate PrEP.¹¹

Populations of Specific Interest *Black Cisgender Women*

Black cis-women have a disproportionately high incidence of HIV but also are under-represented among those receiving PrEP.² Research examining PrEP perception, uptake, and barriers among Black cis-women has revealed that they are frequently not

informed of their potential eligibility for PrEP by medical providers, with thorough discussions addressing common questions and concerns regarding PrEP being even rarer.

The stigmatization of HIV unfortunately extends to PrEP, especially in light of the fact that the ARVs currently used for PrEP are also part of ARV regimens used to treat HIV. Furthermore, use of PrEP is frequently interpreted as an insinuation of partner infidelity, lack of disclosure regarding sexual orientation (i.e. being on the “down low”), or as an indicator of the woman’s “promiscuity,” exposing Black cis-women to increased pressure to avoid PrEP in order to maintain the stability of the romantic relationship and their perception within the community. Other research has asserted that the traditional risk factors included in the CDC guidelines omit risk factors of greater relevance to Black cis-women, such as having a sexual partner with a history of incarceration.

Multiple studies have identified a significantly lower prevalence of PrEP awareness among non-Hispanic Black cis-women in a variety of regions within the U.S., including Rhode Island.⁸ While cis-women in

general experience suboptimal rates of PrEP screening and discussions, Black women are significantly less likely to be screened for PrEP. Some studies concluded that Black women were significantly more likely to report an intent to use PrEP in response to a discussion with a provider compared to White women, despite Black cis-women expressing higher levels of distrust of the health system.⁴ However, providers’ implicit biases may result in the providers being less likely to inform Black cis-women of their eligibility for PrEP, which was highlighted in a study comparing providers’ probability of prescribing PrEP based on clinical vignettes.⁹

A significant gap between expressed intention and PrEP initiation and adherence in Black women has also been observed in multiple studies, with a longitudinal study performed in 2016 finding that only seven out of 30 participants who expressed interest in starting PrEP presented to the PrEP clinic. A different study examining PrEP adherence found that 18 percent of those who started PrEP continued to adhere to the regimen six months later.¹³

Pregnant and Breastfeeding Patients

The Perinatal HIV Clinical Guidelines advises health care providers to discuss PrEP with all sexually active people without HIV, including individuals who are pregnant, postpartum, or breastfeeding. The only FDA approved PrEP option currently recommended for pregnant and breastfeeding women is TDF/FTC, as the other ARVs lack sufficient safety and efficacy data during pregnancy and breastfeeding. The Perinatal HIV Clinical Guidelines also emphasize that people who become pregnant while taking TDF/FTC can safely continue PrEP throughout pregnancy and breastfeeding.

A 2019 survey of 250 family medicine residency program directors included questions regarding the initiation and management of PrEP in the obstetric setting. Almost a fifth (18.8 percent) of program directors stated that their obstetrics team had prescribed or continued a prescription for TDF/FTC for a pregnant patient receiving prenatal care and 3.2 percent reported discontinuing a pregnant patient’s PrEP prescription.¹⁴

Adolescents and Young Women

An increased risk of HIV among adolescents and young adults (AYA) is observed within the U.S. and globally. However, PrEP remains an effective tool to protect against risk when used consistently and correctly, but its uptake and consistent use can be limited by multiple barriers, including limited privacy and autonomy, lack of financial resources and lack of family/social support.¹⁵ Cis-women AYA also encounter the adherence requirement burdens that older cis-women face, but at an age when experience with daily medication adherence is even less likely and the challenge of reconciling adherence requirements with “seasons” of HIV exposure may be even greater. While literature examining PrEP uptake and maintenance among this group remains limited, multiple projects have incorporated interventions, such as provider education, creation of youth focused spaces providing PrEP, and novel targeted engagement strategies (e.g. social media, frequent telehealth interactions, and other virtual connection strategies) to promote uptake and assist with adherence barriers.

Conclusion and Next Steps

While cis-women are currently forced to navigate a variety of barriers in the individual, interpersonal, community, institutional, and structural domains, opportunities

to improve uptake and utilization of PrEP also exist. For example, current oral PrEP adherence requirements may be reduced with research more focused on accurately assessing PrEP effectiveness among cis-women with moderate or greater adherence. Techniques for assessing the effectiveness of changes in adherence in response to changes in HIV risk should also be developed and applied to pharmacologic research in order to identify more accurate areas of protection and guide the creation of new medications that provide greater flexibility and confidentiality.

Culturally sensitive messaging that provides insight into the relationship between individual and community-level risk can be coupled with holistic, community-based approaches to normalizing PrEP, with social media and mobile technology’s reach, accessibility and potential confidentiality being instrumental. The expansion of medical provider training in sexual history taking, PrEP screening, discussing PrEP, and prescribing PrEP will contribute to increased uptake and reduced losses across the continuum of care, and health care settings must adapt the policies to improve access to PrEP services. Most fundamentally and importantly, women must play an active role in leading and implementing these efforts, especially members of the communities of interest. **HIV**



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PrEP Navigators and Women's Health

Why we need to ensure
all women have access to
PrEP navigators

By Brooke Davidoff

HIV PRE-EXPOSURE prophylaxis (PrEP) marked an incredible change in how people can protect themselves—and their loved ones—from HIV. PrEP is a medication that, if taken as prescribed, prevents people from acquiring HIV through sex by up to 99 percent.¹ Unfortunately, though, PrEP isn't being used as widely as it should. According to the Centers for Disease Control and Prevention, in 2021 only about 30 percent of people who should be using PrEP were prescribed it.²



As well, that usage is not equal based on one's sex. According to TheBodyPro: "One in five new HIV infections were among women, yet women make up less than 10 percent of...[PrEP] prescriptions nationwide."³ If I'd have known I was at risk and PrEP was available when I was negative, I would have looked into getting on it.

There are many reasons for the lack of PrEP prescribing and use—from economic barriers, to inadequate patient education, to limited provider knowledge, etc.—and there are many proposed solutions to overcome these barriers. One solution that aims to improve patient outreach and education is the use of PrEP navigators.

What is a PrEP Navigator?

PrEP navigators serve a critical role in ensuring people have information on and access to PrEP. They work in various settings, including in family practices, dedicated HIV and/or sexual health clinics, and even in university health centers. They screen and test people for HIV as well as their risk of acquiring HIV. They educate on PrEP, initiate access to it, and can assist existing PrEP patients.

PrEP navigators not only support those without HIV, but they also can assist people with HIV in unique ways. Ryan Wilks, a PrEP navigator who works at University Health in Kansas City, says, "I think PrEP is paramount to people with HIV because while they already have HIV, they can arm those in their life with knowledge of PrEP, especially their sexual partners." Wilks continued, "So, PrEP opens up a lot sexually for a lot of people, both with and without HIV."

"When people with HIV enter a sexual or romantic relationship with someone who does not have HIV, there is a level of anxiety surrounding disclosing their HIV status. There is fear that it will scare off potential matches because the stigma surrounding HIV is so thick. Being able to disclose your status with the add on of 'and there is a safe medication you can take to prevent you from acquiring HIV' gives people agency over their health in a really important way," Wilks said.

How PrEP Navigators Support Women's Health

PrEP navigators are an important resource for women's health. They can explain to women who want to have casual sex and who don't want to risk HIV that PrEP can give them piece of mind. Also, some women don't want to have an awkward conversation about condom use with their partners. In these cases, PrEP is the best way to protect themselves from HIV.

A PrEP navigator can serve as a sex educator—someone who can step in and fill in the gaps from our abysmal sex education that most of us received in school. It seems that most of the sex education that girls receive focuses on how not to get pregnant and then what girls or women should do once they're pregnant. Girls and women aren't taught to bring up sexual health topics to their providers on their own. A recent study shows that women are not inclined to ask for HIV testing unless someone on their health care team brings it up.⁴ That

same study shows that often providers don't initiate this conversation with women or girls.

Without sexual health education, cisgender women will continue to expose themselves and be diagnosed with HIV when they don't have to be simply because the education is lacking that they are in need, at risk, and can prevent this from happening to themselves. Because PrEP navigators can function as part of the health care team, they are able to take the time to start these conversations with girls and women. Then, navigators can walk girls and women through the steps they need to take for HIV testing and to access and use PrEP.

There can be a lot of fear when people get tested for HIV, and PrEP navigators can help women work through their fear, too. "Fear is only counterproductive if it stops you from doing something. I think it's perfectly normal to be afraid while getting an HIV test," says Wilks. "I do what I can to console the fear that people express while getting tested, and that usually comes in the form of education about HIV. The more a person knows about HIV the more power they have over fear." Equipping women with the power to protect themselves and to have a sense of control over their health is one of the most important things we can do.

What We Can Do

Websites like pleaseprepme.org has a page just for women about the positives of getting on PrEP to protect oneself. Ready, Set, PrEP is another program looking to help get HIV transmissions to zero. Unless people without HIV realize that the power to stay negative is in their hands and it's never been easier to protect oneself from HIV, then we'll truly never get to zero. PrEP navigators have a big role to play in supporting PrEP awareness and uptake.

I fear that until more positive women speak up and loud enough our negative sisters will continue to acquire new HIV infections because they do not realize how they are playing Russian roulette by having sex without PrEP. **HIV**



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By Kara S. McGee, DMS, MSPH, PA-C

PREVENTION OF MATERNAL TO CHILD TRANSMISSION OF HIV is one of the great scientific advances of modern times. Since the early 1990s, the estimated annual number of infants born with perinatally acquired HIV has decreased significantly. In 1991, there were an estimated 1,760 infants born with perinatal HIV and among children born in 2019 in the United States, 32 had HIV attributed to perinatal transmission.^{1,2} In the U.S., from 2016 to 2019, there were 11,757 children born who were exposed to HIV but did not acquire HIV perinatally.¹ From 2010 to 2019, perinatal HIV transmission rates in the U.S. declined from 1.6 percent to 0.9 percent.³

Antiretroviral Therapy Guidelines

It is estimated that among infants who acquire HIV perinatally, approximately 20 percent of transmission events occur before 36 weeks gestation, 50 percent between 36 weeks and delivery and 30 percent during labor and delivery.⁴ Cases of perinatal transmission of HIV in the U.S. are associated with multiple factors, including incomplete implementation of routine antenatal and third trimester HIV testing.^{2,5} A study of 179 infants diagnosed with perinatally acquired HIV infection found that women with HIV who received late HIV testing, no antiretroviral therapy (ART) during pregnancy, had low CD4 cell counts, or had substance use disorder were significantly more likely to have infants with perinatally acquired HIV.⁶ Other barriers to preventing maternal to child transmission of HIV include HIV risk for women being underestimated, lack of HIV testing among partners of pregnant people, and the underutilization of HIV pre-exposure prophylaxis (PrEP) among women, especially during pregnancy and breastfeeding.⁷

Prevention of Maternal to Child HIV Transmission

Improvements in the rates of maternal to child transmission of HIV are a result of the implementation of HIV screening during pregnancy and increased access to ART during the prenatal and antenatal periods of pregnancy. In the absence of these interventions, the estimated rate of perinatal transmission of HIV is approximately 25 percent.⁴ Maternal ART-based prevention approaches are a cornerstone of prevention of maternal to child transmission of HIV. One of the first clinical trials carried out by the Pediatric AIDS Clinical Trials group showed that administering zidovudine to pregnant women and their infants reduced the risk of perinatal HIV transmission by 70 percent.⁸ Another study of the prevention of maternal to child transmission of HIV is the Promoting Maternal and Infant Survival Everywhere (PROMISE) trial conducted in seven countries. The PROMISE trial found a transmission rate of less than two percent among pregnant women receiving triple drug ART during



HIV

for Pregnant People with

pregnancy.⁹ An analysis of cohort data from the multicenter French Perinatal Cohort found zero cases of perinatal HIV transmission among 2,651 infants born to individuals who were receiving ART before pregnancy, continued ART during pregnancy and had a plasma viral load <50 copies/mL at the time of delivery.¹⁰

ART to Prevent Perinatal HIV Transmission

The U.S. Department of Health and Human Services Perinatal HIV Clinical Guidelines provide guidance on the use of antiretroviral (ARV) drugs during pregnancy to reduce perinatal HIV transmission.¹¹ The guidelines recommend combination ART for all pregnant people with HIV (PWH) in addition to all of the standard antepartum care and assessments for all pregnant people. Antepartum medical care should be coordinated among obstetric and HIV specialty care providers to ensure all medical-related care needs are being met.

To maximize their health and prevent perinatal transmission of HIV, pregnant people should start ART as early in pregnancy as possible. The goal of ART during pregnancy is HIV viral suppression to undetectable levels throughout pregnancy, labor and delivery and into the postpartum period. The ARV drugs recommended for use during pregnancy are similar to but not entirely the same as the ARV drugs recommended for nonpregnant PWH. Pregnant people are often excluded from clinical trials that test ARV medications and, therefore, much of the data about ARV drug safety and efficacy is inferred from data about the use of these agents in nonpregnant people.¹²

When considering what ARV drugs to recommend for pregnant PWH, the Perinatal HIV Clinical Guidelines consider birth defect risks, preterm birth, and other adverse pregnancy outcomes as well as maternal health outcomes and how pregnancy affects ARV drug pharmacokinetics. The Perinatal HIV Clinical Guidelines expert panel uses a variety of data sources to determine the recommended ARV medications for use during pregnancy. The data sources include:

• To maximize their health and prevent perinatal transmission of HIV, pregnant people should start ART as early in pregnancy as possible.



data from clinical trials and prospective cohort studies conducted among pregnant people; evidence from clinical studies on the risk of maternal and infant drug toxicity and adverse pregnancy outcomes; pharmacokinetic and drug exposure data during pregnancy; data from animal teratogenicity studies; and data from the Antiretroviral Pregnancy Registry.¹¹ The Antiretroviral Pregnancy Registry is an international registry that provides data on birth defects associated with prenatal exposure to ARV drugs used to treat HIV. The registry is voluntary, so data is limited to those clinicians who report outcomes to the registry.¹³

Pre-conception Approaches to ART

The Perinatal HIV Clinical Guidelines recommend that reproductive plans be reviewed regularly with PWH. This allows for ARV medications to be started and viral suppression achieved prior to pregnancy. In addition, this allows for a discussion about the most appropriate ARV drug regimens based on pregnancy intention. These early discussions are even more important since the introduction of long-acting injectable ARV drugs to treat HIV. Current guidelines recommend that long-acting injectable ARV drugs be stopped at least one year

before conceiving to ensure that long-acting drugs are fully eliminated so that the developing fetus is not exposed to these agents.¹¹

Pregnant People and ART

Table 1 provides an overview of the preferred ARV drug regimens for the treatment of pregnant PWH according to whether the individual is ARV medication naïve or is currently taking ARV drugs.

For pregnant people who have never received ART, the panel recommends the use of integrase strand transfer inhibitor (INSTI) dolutegravir plus two nucleoside reverse transcriptase inhibitors (NRTIs). Dolutegravir is a preferred option in pregnancy due to potency, tolerability, and high barrier to resistance.¹⁴ Multiple studies have demonstrated safety and efficacy of dolutegravir during pregnancy.^{15,16} Additionally, for ARV medication-naïve PWH who present to care later in pregnancy or who are diagnosed with acute HIV infection during pregnancy, dolutegravir can suppress viral loads rapidly, allowing for viral suppression to occur prior to labor and delivery.¹⁷

PWH who are on ART who present for pregnancy care should continue their current ARV medications during their pregnancy as

long as the regimen is safe and maintains a suppressed viral load. ARV drugs that are associated with high risk of toxicity or low virologic efficacy should be stopped and patients switched to other ARV drugs that are preferred during pregnancy. This scenario is less likely because most of the ARV drugs associated with toxicities and inferior viral suppression are no longer used in the management of HIV.¹¹

However, pregnant PWH may be fully virally suppressed on an ARV drug regimen that has pregnancy-associated pharmacokinetic concerns. Pregnant PWH who are on atazanavir/cobicistat, darunavir/cobicistat, or elvitegravir/cobicistat are at higher risk of virologic failure later in pregnancy due to these drugs having lower plasma drug levels in the second and third trimesters.^{18,19} In this scenario, clinicians should consider more frequent viral load monitoring or changing to a recommended ARV drug regimen. Pregnant PWH may also present for care using a two-drug ARV drug regimen, most commonly dolutegravir/lamivudine or dolutegravir/rilpivirine. While no data exists on the use of these two-drug regimens in pregnancy, the individual components are preferred or alternative ARV drugs in the Perinatal HIV Clinical Guidelines. There is also limited data on the

Table 1: Recommended ARV Regimens for Pregnant People with HIV¹¹

Pregnant PWH who are ARV drug naïve:

- Dolutegravir (DTG) plus tenofovir disoproxil fumarate (TDF) or tenofovir alafenamide (TAF) plus emtricitabine (FTC) or lamivudine (3TC) or
- Dolutegravir/abacavir/lamivudine (only for individuals who are HLA-B*5701 negative and without chronic HBV coinfection)

For pregnant PWH with any prior use of long-acting injectable cabotegravir as PrEP:

- Darunavir/ritonavir plus (TDF or TAF) plus (FTC or 3TC) or
- Darunavir/ritonavir plus abacavir plus 3TC (only for individuals who are HLA-B*5701 negative and without chronic HBV coinfection)

Pregnant PWH who are taking ARV drug therapy when they become pregnant:

- Continue current ARV drug regimen as long as viral load is suppressed
- Cobicistat-boosted regimens: Consider more frequent viral load monitoring in second and third trimesters or change to preferred ARV drug regimen
- Long-acting injectable cabotegravir and rilpivirine: Consider more frequent viral load monitoring during pregnancy or change to preferred ARV drug regimen

Pregnant PWH who are treatment-experienced but not currently on ARV drug therapy:

- Gather full history and records of ARV medications used in the past



- Assess barriers to medication adherence
- Perform resistance testing but initiate ART without waiting for results
- Use previous ART if it was fully virally suppressive
- For people who have advanced HIV disease, a history of extensive prior ART, or previous significant toxicity or nonadherence: Consult an HIV treatment specialist

long-acting injectable cabotegravir/rilpivirine in pregnancy. Because data is so limited, if a person with HIV presents for pregnancy care on long-acting injectable cabotegravir/rilpivirine, recommendations are to continue the suppressive long-acting injectable regimen with more frequent viral load monitoring or switch to a preferred three-drug ARV drug regimen.¹¹

Pregnant PWH who have used ART in the past but who are not currently using ART medications should have HIV treatment re-started as soon as possible. In order to determine the best ARV drug regimen to use in this scenario, the clinician should gather a history of all ARV medications used previously (including if those medications led to viral suppression and whether they were tolerated), review results of prior resistance testing, and assess for barriers to medication adherence. In this scenario, resistance testing should be performed but ART should be started before receiving the drug resistance testing results in order to reduce perinatal transmission risk.

In the absence of a history of virologic failure or HIV drug resistance, reinitiating a previous ARV drug regimen that suppressed viral load is appropriate. Ideally, the regimen should be a preferred ARV drug regimen from the Perinatal HIV Clinical Guidelines. For pregnant PWH who are off ARV drug therapy when they present for pregnancy care and have a history of HIV drug resistance and/or are highly ARV drug treatment experienced, it is important to promptly consult an HIV treatment specialist about the options for appropriate ART.¹¹

Resources for Clinicians

There are multiple resources for clinicians with questions about ARV medications for pregnant PWH. These include:

- U.S. Department of Health and Human Services
“Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States” available at: <https://clinicalinfo.hiv.gov/en/guidelines/perinatal/recommendations-arv-drugs-pregnancy-overview?view=full>
- The National Clinician Consultation Center Perinatal HIV Hotline, which provides rapid perinatal HIV consultation from practicing HIV specialists: 1-888-448-8765.
- The National HIV Curriculum section on Preventing Perinatal HIV Transmission available at: <https://www.hiv.uw.edu/go/prevention/preventing-perinatal-transmission/core-concept/all>

Summary

Using an evidence-based, comprehensive approach, perinatal transmission of HIV is preventable. In addition to all pregnant people being screened for HIV, a cornerstone of the prevention of perinatal HIV transmission is suppressive combination ART during pregnancy. All persons diagnosed with HIV should promptly start ART and continue therapy throughout their pregnancy. Consulting up-to-date guidelines and recommendations for ARV medications for use in pregnancy is key to ensuring that perinatal HIV transmission rates continue to decline in the U.S. **HIV**



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AMERICAN ACADEMY OF
HIV MEDICINE



Stories from Kaiser
Permanente Oakland
Medical Center's
Sharing Our United
Lives (SOUL) Clinic,
run by women for
women with HIV

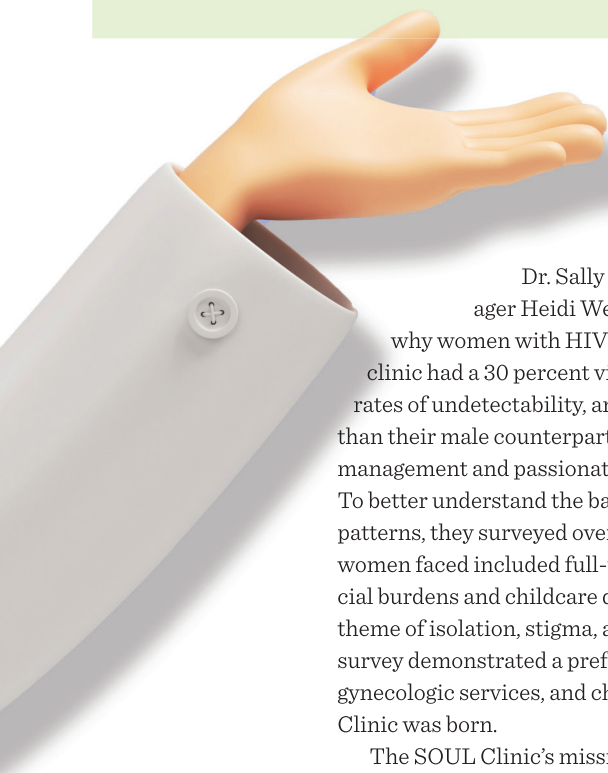
By Avani Dalal, MD

SOUL Stories

Sharing Our United Lives

“We have managed to close the gap in care that existed previously. While the women continue to deal with many of the same psychosocial stressors and still carry the trauma they have experienced in their lives, they know they can show up for their women’s clinic appointment to a group of familiar faces and feel safe, eat dinner, reconnect with old friends, and leave here feeling loved and empowered.”

—Heidi Werbel, on the impact of the SOUL Clinic



Dr. Sally Slome and nurse case manager Heidi Werbel struggled to understand why women with HIV in their multidisciplinary clinic had a 30 percent visit adherence rate, lower rates of undetectability, and higher loss to follow up than their male counterparts, despite intensive case management and passionate, experienced providers. To better understand the barriers contributing to these patterns, they surveyed over 50 women. The obstacles women faced included full-time or multiple jobs, financial burdens and childcare difficulties, and a universal theme of isolation, stigma, and shame emerged. The survey demonstrated a preference for an evening clinic, gynecologic services, and childcare. In 1999, the SOUL Clinic was born.

The SOUL Clinic’s mission is to provide comprehensive women’s health services to women with HIV in a safe environment that promotes wellness and social interaction. At SOUL Clinic, women with HIV receive multidisciplinary services provided by female health care professionals, including social workers, case managers, HIV primary care providers, and gynecologists. Each member of the team assists the patient in unique aspects of their life, including HIV related health care, primary prevention and care, gynecologic services, and mental health. Experienced providers and consultants help women navigate insurance related issues, legal issues, and access community resources.

A catered dinner and childcare are provided during each evening clinic, and a women’s support group takes place simultaneous to provider visits. The ability for

these women to find a community of people with shared experiences quickly became an essential aspect of the SOUL Clinic; women without medical appointments often attended for food and friendship. Over the years what started as one clinic session per month grew to three sessions each month. The leadership of the clinic has kept the women involved in shaping the SOUL Clinic and has been able to offer many unique services, including acupuncture, massage, and quilt making.

When I started my HIV fellowship in the summer of 2022, the SOUL Clinic entered its twenty-third year and I was able to experience its magic. At that time, the evening clinic ran once a month, and I dove in headfirst to provide HIV primary care and gynecologic services for these women. I had the opportunity to counsel new diagnoses, assist women in disclosing to partners and family, provide pregnancy related HIV care, offer gender-affirming care, and navigate social issues, such as intimate partner violence and substance use. I cannot put into words the impact it had on not only my career trajectory and professional interests but also on me as a person. It is my honor and privilege to share stories from the SOUL Clinic.

A Tale of Two Disclosures

“What am I going to tell my mom?”

“What am I going to tell my partner?”

—Two different women, two new diagnoses, and a similar concern: fear surrounding disclosure.

The first young woman requested her mother be brought in for the appointment. Unable to get the words out herself no matter how hard she tried, she wanted me to be the one to tell her mom, and they both sat in front of me. The daughter, my patient, was clearly on edge, head bowed down and anxiously wringing her palms, which were lined with the telltale signs of syphilis. Her mother was calm and still, hovering on the edge of a precipice, staring straight into my eyes as I gave the news.

I could read the devastation on her face for her young daughter who was already suffering from a chronic medical condition that required daily medication injections. I counseled them both, re-emphasizing the words to my patient for the second time, while her mother processed them for the first: One pill once a day. Undetectable equals untransmittable. The mother held her daughter’s hand and offered words of comfort, telling her it would be alright. I found out later as my patient and I debriefed—the relief palpable on my patient’s face—that her mother was in another room falling apart in Heidi’s arms.

My second patient and I practiced the disclosure in advance. We role-played so she could find the right words to tell her partner. They had been together for over 20 years, bouncing from hotel to hotel wherever they could find work. They had experienced it all—substance use, homelessness, financial insecurity, and indiscretions along the way that led her to our clinic. As we practiced, I felt the pauses and tremble in her voice as she pushed the words out, words that even for me, after numerous disclosures, still get stuck in my throat.

She said the words until they felt less foreign to her, less like they belonged to someone else, and we sent her off with words of encouragement. She came back twice without disclosing, but the third time was the charm. She told us that it was the hardest thing she ever had to do, but now that it was done she was relieved. They would work on it together. She hadn't lost him completely, and that's all that mattered to her. Now she could focus on other things. Taking care of her own health, getting her partner tested, and proposing. And she went on to accomplish all of this. She achieved viral suppression, her partner got tested, and she showed us a video a few months later of her getting down on one knee and him saying yes.

It's Not Just the Journey

"I circled the building over five times before I worked up the courage to come inside."

She was petrified to walk into the office, for people to look at her and read the word HIV stamped across her forehead. No one besides her son knew about the diagnosis. He offered to accompany her, but she refused. She wanted to be able to do it on her own. She sat there in front of me, tearful, fingers trembling, voice shaky. But her bravery was obvious, in the way she met my eyes with her own and in the strength of her voice.

We validated her fears and allowed space for the stigma that existed. Then we reassured her that our office space was for primary care, not all that receive care here have HIV, and that we would always do our best to provide her with safety and anonymity. She cried in relief at the kindness we showed her as she established care with our practice for the first time.

"It takes me about two hours—without traffic—to get here."

A different woman moved to a different part of the state a few years ago but refused to transition her care there. When I asked her why, she told me it's because this was her home, her community, her people. The providers here are the ones that embraced her when she was first diagnosed, the women with HIV at this clinic are those that have traversed many years of her life with her, and she cannot imagine getting care anywhere else.

She recounted all the challenges she faced in her life: a job she recently lost, pain from a work-related injury, the concern of how to

make ends meet for her and her children, to be able to continue providing a roof over their heads and food in their bellies. She showed me the ink that paints her skin, showcasing the numerous people she has lost along the way and told me their stories.

Finally at the end of our appointment, I asked her about her HIV, inquiring about her ability to take her medications amid the many challenges she faces on a daily basis. "That part is easy," she said. To me, it was wondrous. So many times, I tell patients that one pill a day will keep the virus at bay, my own twist on the old apple adage. I make it sound simple in hopes that they will believe it is that easy, but it's in these moments I realize how much we ask of our patients and am impressed by their ability to maintain their viral suppression while battling all the other complexities of life.

My Body and My Choices

"Can I still have kids?"

My 20-something-year-old newly diagnosed patient asked me that. "Of course," I replied. I gave her the facts. I shared with her the advances in antiretroviral therapy (ART). I told her about the latest infant feeding guidelines that allow for breast and chest feeding, that achieving viral suppression means she can have a vaginal delivery. My words registered, but she had trouble processing them.

The data I shared didn't alleviate her concerns about her reproductive future. She asked me this same question at each subsequent visit before I had an idea that would allay her fears. My next patient of the night had already been checked in. She was waiting for me with her three-month-old infant in tow. This was her second child since her diagnosis, both of her children born healthy, without carrying their own HIV diagnoses.

I connected my patients to each other, explaining to my more veteran patient how she may be inspirational to the woman struggling with her new diagnosis and implications on her reproductive health. As I closed the door behind them and heard the conversation begin, I realized what matters most to my patients. While the numbers and figures of the data reassure me and allow me to provide optimal, safe, evidence-based care, what matters to these women are the words, the stories born of their lived and shared experiences.

I saw it on the faces of the two women that day. The relief in one, whose fears about her reproductive health had been assuaged, and the strength in the other, who spent her appointment reminiscing with me about her own journey since her diagnosis and reassuring me that the younger woman was going to be okay.

"I can't do this right now. I can't have this baby."

Another patient was diagnosed with HIV during a primary care visit, both the pregnancy and HIV a shock to her already fragile system. She was struggling with the loss of a loved one, being a single mother to a

toddler, trying to make ends meet, a new life in a foreign country with a language that is not her own, and now a new HIV diagnosis and the possibility of bringing a new life into her already overwhelmed world.

I held her hand as she cried; the tears welling up in my eyes too. We discussed her options, and she made the choice that was best for her: termination. The relief in her voice was palpable at having authority in a situation that felt so out of her control. She came back a month later. Her labs showed significant improvement in her viral load. But more than that, she seemed lighter and less burdened by what was once a heavy darkness.

Home is Where the Health is

“Thank you for making the trip all the way out here.”

The next woman whose story I’d like to tell had been a patient of the clinic for many years. Well-known to many providers, she had a long history of substance use that weakened her heart, causing her to struggle to breathe and keep fluid off her body. Her desire to start gender-affirming hormone therapy was put on hold due to her inability to remain in the outpatient setting long enough to initiate the medications. Instead, for every few days she spent at home, she spent weeks in the hospital getting her fluid balance optimized, until the changes to her medications and fluid and salt restrictions were so confusing that she left only to come back.

During my time with her, she transitioned to hospice, desiring quality over quantity of life, wanting the comforts of her own home over days spent in hospital rooms. The decision was a difficult one for her to make, but she did it with grace. I was fortunate to be able to visit her at home in her final days.

During that visit, I talked with her, held her wrinkled hands as she spoke. Her happiness at our visit was evident. Though she became out of breath quickly and couldn’t walk far, it was obvious that she wanted us to be comfortable in her space, offering us the best furniture to sit on and any refreshments she had to offer. Our patients always meet us in our spaces, in our offices, on our terms, at scheduled times.

The privilege to get to see into the lives of our patients within their own spaces is one I will never take for granted. In doing so, we are able to dig a little more deeply into the impact of their environment on their health and through this unique lens we gain otherwise unidentified insights into our patients’ lives. I’m glad the last memory of her I hold in my mind isn’t of her in the office struggling to breathe or seeming so small in a sterile hospital room. Instead, I remember her resting on the couch, a wide smile painted on her face, as she tells us stories about her life, surrounded by all the stuff she gathered over her many years.

Reflections

These are just a handful of the many SOUL stories that I carry with me. There are others: the devastation of uncovered rilpivirine resistance to injectable long-acting ART for a young woman who had never achieved viral suppression. The terror of calling the police to do a safety check on a young woman who recently experienced intimate partner violence, missed her appointment, and couldn’t be reached by phone. The heart-wrenching diagnosis of delusional parasitosis in a middle-aged woman whose real battle is with methamphetamines. The fervent hope that my words aren’t being lost in translation as the interpreter speaks them for me.

The joy of prescribing gender-affirming hormone therapy to a young woman who has been dreaming about it her whole life, combined with the despair of also prescribing her ART. The elation of meeting children who don’t carry the same diagnosis as their mothers. The excitement of less pills as CD4 counts rise above 200 to no more pills as we transition a woman from oral to injectable ART. The pride at not just achieving viral suppression but also in graduating college, finding dream jobs, and getting married. I’ve cried tears of joy with these women, given and received the warmest embraces, and journeyed the many moments of their lives with them.

The SOUL Clinic is an embodiment of all these stories that make up the tapestry of women with HIV. It is a place that allows women to seek shelter and community from a world where they often face stigma, shame, and isolation. At SOUL, women know they not only get the medical care they need, but also warm meals and even warmer embraces. The SOUL Clinic’s unique design allows women to seek care while being mindful of their other obligations, such as careers and childcare, and provides them with a safe space to bring their medical and nonmedical concerns.

There are simultaneously too many and not enough words to describe the impact my time with the SOUL Clinic has had on my journey. Many of my stories overlap, containing themes that appear time and time again, stark reminders of the complexities women with HIV face that extend far beyond their diagnosis. I carry these women and their words with me. They provide me comfort on the days my job feels overwhelming; when there are too many charts to close, too few resources to support my patients, and endless battles against insurance companies. They remind me of my purpose and my vision for a better future.

These women—with their resilience, bravery, and fortitude—drive my passion for the work I do. These SOUL stories I keep securely in my heart as some of my most precious possessions. Today, I share them with you in hopes that you think of them as you care for your own patients, remembering the humanity, the unique challenges, and ultimately the honor and privilege in caring for women with HIV. **HIV**



AVANI DALAL, MD. is a lifelong Pennsylvania native. She completed medical school at Temple University followed by her residency in family practice at Chestnut Hill Hospital, both in Philadelphia, Penn. After residency, she left for the West Coast and pursued a fellowship in HIV medicine at Kaiser Permanente Northern California in Oakland, Calif. After graduating, she returned to Philadelphia where she joined Einstein Healthcare Network and currently serves as a primary care physician for the Immunodeficiency Clinic and Pride Program. In her free time, she can be found playing video games, adventuring across the globe, and going on long walks with her corgi.

Insights from the Academy's HIV Care Retention Workshop Series

BY DEJA ROBINSON, AAHIVM EDUCATION PROGRAM MANAGER

THE RECENT HIV CARE Retention Workshop Series, held across five cities—Detroit, Cleveland, Memphis, Fort Lauderdale, and Houston—fostered collaboration and knowledge exchange within the HIV care community, and we'd like to share what we've learned. Organized by the American Academy of HIV Medicine, the workshops brought together providers, nurses, social workers, pharmacists, case managers, and advocates dedicated to enhancing the quality and retention of care for people with HIV (PWH).

Workshop Overview

The workshops served as dynamic forums for participants to discuss the latest advancements, challenges, and collaborative opportunities in HIV care. Led by Gina Lamar Evans, MPH, of NEFUSE Case Management and Training Services, the interactive workshops featured a keynote presentation, case-based discussions, and panel sessions, engaging an interprofessional team to create hypothetical action plans via case studies. The case studies reflected local demographics and covered patients on PrEP, those previously in HIV care, and those never engaged in care. Offering a thorough review of the current landscape in HIV care, the diverse range of topics included barriers to care, points of care entry and exit, and local/regional referral needs for clinical services.

Participant Insights

In our recent interviews with participants, we gained valuable insights into the state of



HIV care and prevention, as well as information on innovative strategies and success stories within each community.

LonDyn Hudson, PrEP Navigator at Matrix Human Services, said, "Every state has similar challenges, and that's distrust in the system and medical health care professionals." However, she emphasized the success of visible organizations and community-led state councils in building trust in Detroit. Her top priority is advocating for Black and Brown women in Detroit, aiming to be their voice in ending the HIV epidemic. LonDyn emphasized the importance of innovation, strategic planning, and continued focus on the mission, stating, "Getting people into care will be a walk in the park." LonDyn highlighted collaborations with local drag entertainers, house and ballroom communities, and the leather scene as important gateways to promote prevention and care within those communities.

In Florida, Jose Ramon Aguilar, Founder and Executive Director of Aguilar Salud, stated "Our test and treat model has shown great effectiveness, especially in the wake of the Pulse tragedy," highlighting the strength of unity and love in response to challenges. According to Jose, many people in Orlando face health care challenges, such as limited health care access, cultural stigmas, and misinformation. However, initiatives like Aguilar Salud's "La Cena" program, which provides culturally appropriate testing and health services, showcase how innovation can overcome challenges.

In Houston, Dr. Tisha Rowe, Founder of the Honeycomb Clinic, shared her thoughts: “I think it’s alarming and disturbing that the majority of the HIV cases in Houston are in minorities and rates are higher than the national average.” Houston Latinos account for 29 percent of all HIV/AIDS cases, exceeding the U.S. Latino rate of 24.7 percent. Similarly, Black and African-American individuals in Houston account for 50 percent, compared to the national rate of 40.3 percent.¹ She emphasized the need for increased testing and noted the effectiveness of an opt-out testing strategy at Honeycomb Clinic. Routine inclusion of HIV testing for all patients, unless they choose to opt out, has proven successful in normalizing testing as a routine part of health care.

Caleb Brown, Research Associate at Yale University, emphasizes the importance of a smooth patient experience during clinic transitions. He states, “When people move from one clinic to another, it’s imperative that their experience be as seamless as possible.” He highlights the funding challenges in Houston, where reliance on federal funds poses limitations. Caleb hopes for a dedicated city budget line to address gaps caused by these restrictions. Looking ahead, Caleb envisions “further expansion of prevention and testing services into unconventional settings,” and emphasizes the need for “community involvement to end the HIV epidemic.”

Key Takeaways

1. Promoting Community Engagement

A recurring theme across all workshops was the emphasis on community engagement. Speakers and participants alike highlighted the integral role of communities in supporting PWH and the need for tailored interventions that address the unique needs of each city.

2. Innovations in Care Retention

Incorporating the latest research findings and practical applications, presentations highlighted innovative strategies to enhance care retention. The workshops provided a platform for sharing evidence-based approaches, from opt-out testing strategies and test and treat models to collaborating with house and ballroom communities.

3. Addressing Disparities

Acknowledging and addressing disparities in HIV care was a focal point. Speakers emphasized the importance of targeted efforts to reduce disparities among different populations so that there is equitable access to quality care across all demographics.

Participant Feedback

Feedback from participants underscored the success of the workshops in fostering collaboration and knowledge exchange. Many expressed appreciation for the diverse perspectives shared and the practical insights gained from common experiences. Health care providers and case managers gained broader perspective on regional barriers to retention in PrEP care and HIV treatment. They also learned how to better identify common barriers like time constraints, costs, mental health/substance use, and stigma. The workshops not only provided valuable education but also inspired attendees to implement positive changes within their respective communities.

Conclusion

The HIV Care Retention Workshop Series served as a beacon of collaboration, knowledge-sharing, and inspiration across five cities. Insights gained from participants underscored the urgency of addressing disparities, increasing testing efforts, and implementing innovative strategies. These workshops provided a platform for sharing local innovations, real-life impact stories, and priorities for the future and contributed to a collective vision for enhanced HIV care outcomes nationwide. **HIV**



As the Education Program Manager at AAHIVM, **DEJA ROBINSON** brings a wealth of expertise in health care and education. With a Bachelor’s degree in Biology and Chemistry from Howard University, Deja has a solid foundation in the sciences. Currently pursuing a Master’s in Public Health at UNC Chapel Hill, Deja is dedicated to advancing health care and education initiatives for improved community outcomes.

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As part of our diversity, equity, inclusion, and justice (DEIJ) efforts, we aim to select venues that align with our values of community development. For instance, in Cleveland, we hosted the event at Edwin’s Too, a restaurant that hires former inmates to support their rehabilitation and empowerment. We invite readers to consider hosting a workshop and to let us know if they are aware of similar venues focused on community development for underserved communities. Your support would be greatly appreciated.

Assessing the Drivers of Chronic Pain in People with HIV

Principles for Practice for the Care Team

Presentation date: May 5, 2023 | Release Date: April 1, 2024 | Expiration Date: July 1, 2024

This accredited continuing education activity is provided by American Academy of CME, Inc.



This article is based on a presentation from the 17th Annual American Conference for the Treatment of HIV® (ACTHIV® 2023), which held May 4-6, 2023. The conference was supported by educational grants from Gilead Sciences; Janssen Therapeutics, Division of Janssen Products, LP; Merck, Theratechnologies, and ViiV Healthcare.

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Estimated time to complete: 30 minutes

TARGET AUDIENCE

This activity is intended for frontline providers of care to persons at risk for or who have HIV, including specialist and primary care physicians, NPs, PAs, nurses, and pharmacists. Other HIV care team members are also encouraged to participate.

DESCRIPTION/LEARNING OBJECTIVES

The presentation on which this article is based was selected by ACTHIV® 2023 conference attendees and the conference planning committee as being among the best sessions of the conference. The goal of this article is to help members of the frontline HIV care team to be better able to:

- Describe the basic principles that the care team should follow when assessing chronic pain in people with HIV.

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Assessing the Drivers of Chronic Pain in People with HIV

Principles for Practice for the Care Team

BY R. DOUGLAS BRUCE, MD, MBA, MA, MS, AND VASUDEV C. MANDYAM, MD

AS PEOPLE AGE, the aches and pains of younger years only get louder. People with HIV (PWH), who experience significant pain, may struggle with increasing pain as they age. Between 39 to 85 percent of PWH experience chronic pain.¹ Unsurprisingly, some groups may struggle to access treatment for these pains, such as women, people with lower education levels, and people with a history of substance use.² Thus it is important for the members of the care team to be able to work together to improve pain assessment for PWH for whom they may be caring.

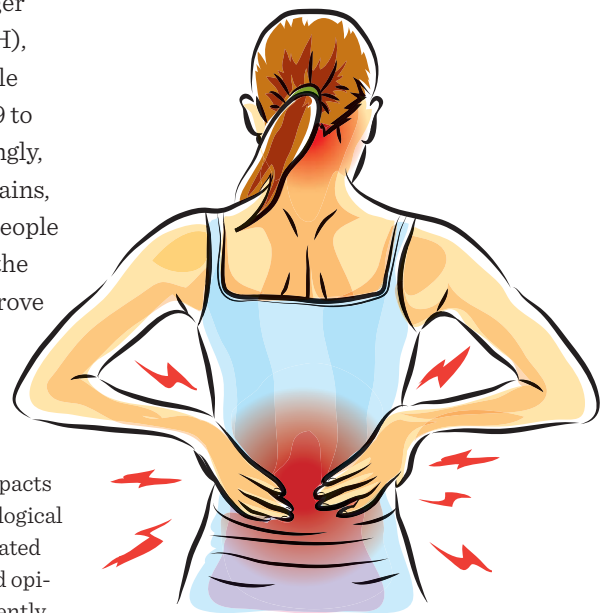
Pain is Complicated

For over a decade there has been evidence that the HIV envelope protein, gp120, impacts the mu opioid receptor and impacts analgesia.³ Adding to this, chronic opioid use impacts the neurological complications of HIV, including the development of HIV-associated neuropathic pain.⁴ Given this complex overlap between HIV and opioid pathways, the treatment of chronic pain in PWH is consequently complex and effective treatments have been frustratingly sparse.

The development of chronic pain is not straightforward. There is, of course, the organic or biological aspect of pain. This is often the focus of medical diagnostics. It seeks to answer the question, “What is causing the pain?” In addition to the biological component of pain, there are pathologic downstream effects in pain signaling, which can lead to maladaptive responses, such as hyperalgesia (heightened pain perception), allodynia (pain from benign stimuli), and anticipatory pain.⁵ These all inform the subjective experience of pain.

Subjective does not mean the pain is less important, it simply means that the same amount of pain is experienced differently among different people. Environmental factors, such as a lack of sleep, can make the experience of pain worse. Intrinsic factors within the individual, such as depression, anxiety, and post-traumatic stress disorder, can make the “noise” of pain sound much louder. The louder the pain sounds, the more debilitating it may feel.

It is important for the care team to remember that there are internal and external or environmental factors that impact pain and require different interventions. Internal factors, for example, are those things inside the person such as their neurobiology (how the



nerves work), other diseases which can cause pain (e.g., diabetes), and psychological factors (e.g., depression) which are known to worsen pain. External or environmental factors are those things in the world around the person that impact their pain such as medications, toxins in the environment, work-related exposures, etc. For example, someone with HIV may have internal drivers of pain such as HIV impacting the nerves directly and may have external drivers of pain such as homelessness causing psychological distress and sleep deprivation which are strong amplifiers for their pain. Because medications are insufficient to address complex social determinants of health which contribute to the experience of chronic pain, it is important for treatment plans addressing chronic pain to be inclusive of all the drivers of pain.

Principles for Evaluating Pain

When evaluating a person presenting with chronic pain, the provider should begin with a validation of the complaint of pain. The individual has expressed that they are suffering and in need of assistance, and the appropriate initial response is to validate that complaint through reflective listening and empathy. Failing to validate the complaint of pain can lead to mistrust and a breakdown in communication, complicating the ability to obtain further history. Contrary to the fears of some providers, validating the complaint does not commit the care team to initiating any specific treatment or medication.

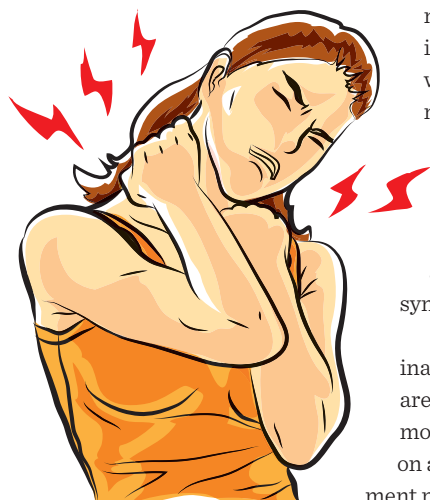
In addressing a new complaint of pain, the care team should undertake a detailed history and physical examination to ascertain the etiology of the pain. Often patients with chronic pain have extensive records in the chart and the temptation is to rely heavily upon what

was previously documented instead of collecting a new history and performing a physical examination. Because chronic pain is complicated, when a patient with chronic pain is seen by a new provider, that provider should take the time to confirm the diagnosis and the treatment plan. This should include the onset of the pain, duration, character of the pain, aggravating and alleviating factors, impact on activities of daily living, and any constitutional symptoms that may help point to an etiology.

With the history in mind, the physical examination should include direct observation of the area and critical ancillary measures (e.g., range of motion). It is important to document limitations on activities of daily living because goals of treatment must include functional outcomes in addition to pain control. The history and physical should direct any imaging or laboratory studies necessary to ascertain

the etiology and plan for therapy. While the patient may question the necessity of repeating a history and physical examination, it is important for the patient to understand that the complicated nature of pain requires the examination to make sure nothing is missed and the appropriate care is being provided.

If a patient has left a previous practice that was treating their pain, it is important to understand why. Is the change due to the care team at the previous practice failing to be empathetic, for example, or is the change motivated by the patient wanting a particular medication that the previous provider was unwilling to provide? Regardless of the specifics, it is reasonable to obtain a release of information to understand the patient's history. Optimally, this information is provided after the care team has independently obtained a history and physical examination. To read the transferring information first (just like reading the chart history first) will anchor the new provider on old information which may or may not be optimal.



Pain and Comorbidities

A patient presenting with chronic pain may benefit from a psychiatric evaluation to evaluate for co-morbidities that may be causing and/or complicating the patient's chronic pain. Sometimes patients can be offended at the need for a psychiatric evaluation because they assume that the provider is suggesting that the pain is not real but imaginary. This is an important reason for the initial validation of pain. The provider can reference back to that initial validation and remind the patient that the reality of the pain is not in question. Rather, the question is whether there are additional drivers for the pain. It is helpful to educate patients that chronic pain does not just originate from the physical tissue where the initial injury may have occurred, but also in the brain where nerves and pain signaling can be influenced by psychological health.

One technique is to empathize that being in pain daily can certainly lead to feeling down and depressed. And anyone with back pain can testify to the anxiety that a certain movement might trigger a back spasm and paralyzing pain. In reminding a patient that chronic pain can logically cause depression and anxiety, the door is open to suggest that the opposite is also true, as depression and anxiety can make pain worse. The patient can be informed that behavioral health interventions provide tools to help cope with the depression and anxiety related to chronic pain.

Additionally, all patients should undergo a substance use history, including past personal and family use of substances. This should include alcohol and marijuana. All patients with chronic pain should be screened to avoid any bias and profiling in patients who are or are not screened for substance use. The use of validated instruments such as the ASSIST, AUDIT, DAST, or CAGE-AID can be built into the operational flow of the clinic and provide meaningful assessments.⁶

While the use of substances may not meet thresholds for hazardous use or dependence, if a patient has a habit of using a substance as a coping mechanism, this could be a warning sign of future risk. Additional risk factors for misuse of prescriptions for pain treatments

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include younger age, history of substance use, family history of substance use, psychiatric history, and possibly a prior history of motor vehicle collisions.⁷ Similar to the explanation that psychiatric questions are not intended to stigmatize a patient, it is important to frame substance use questions as part of the standard evaluation, and explain that these questions help to understand the drivers of pain, and to inform which treatments are both helpful and safe.

A Comprehensive Treatment Plan is the Goal

Ultimately the goal for the patient and the provider should be a comprehensive treatment plan with input from a multi-disciplinary team. A patient may, for example, require physical therapy to help with low back pain, nutritional counseling to support weight loss (which impacts low back pain), and counseling to help replace substances, such as alcohol, used for self-management of the pain. The key goal throughout the treatment process is to align the patient's treatment goals with the varied services that may be required to meet those goals. Essentially, effective pain management requires a team approach.

It is important to determine the functional goals for the patient. Full cessation of pain is likely unachievable in most patients with chronic pain. It is important for the patient to define a goal that provides meaningful value and is achievable. A patient, for example, may

have knee pain after walking one block and this prevents the patient from walking to the store or visiting a friend. Their goal might be to have pain relief to be able to walk four blocks. That becomes an objective goal that can be measured, and treatments titrated to achieve that meaningful goal. Another example might be a patient who wishes to have sufficient control of back pain to pick up a grandchild.

The pharmacological treatment of chronic pain in PWH has been reviewed elsewhere and is an area of ongoing investigation.⁸ The key themes in this discussion have been on the importance of empathy with the person in pain, extensive investigation into the complicating drivers of chronic pain, and the multi-disciplinary manner in which a treatment plan may need to be constructed to help the person in pain. The treatment of chronic pain is a journey that will require frequent re-assessments and ongoing support from the care team.

From academics to community health, **R. DOUGLAS BRUCE, MD**, has worked to develop and implement research and public health interventions both locally and internationally. Dr. Bruce is a global expert in substance use disorders among people with HIV/hepatitis C. He has translated research into clinical environments to improve clinical outcomes and to reduce health disparities. Dr. Bruce has provided technical assistance to the CDC, the United Nations, USAID, and non-governmental organizations to

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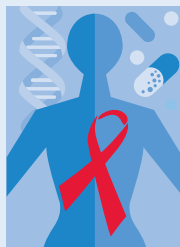
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FEATURED LITERATURE

Kaperak C, Eller D, Devlin SA, et al. Reflex HIV-1 RNA testing enables timely differentiation of false positive results from acute HIV infection. *Open Forum Inf Dis*. 2023 Dec 12. <https://doi.org/10.1093/ofid/ofad629>

Investigators from the University of Chicago evaluated routine HIV screening and testing data from 2014 to 2021 to determine how implementation of a new process involving reflex HIV-1 RNA testing affected resolution of discordant screening results, identification of acute HIV infection, and time to linkage to care. From 5/14/2014 to 9/27/2016 (prior to reflex RNA implementation), 190 unique patients had reactive fourth generation screening results with 79 (41.6%) confirmed new diagnoses and 89 (46.8%) confirmed existing diagnoses. Of 29 discordant results, seven cases involved acute HIV, nine false positives, and 13 patients could not be located or did not return for further testing.

From 9/28/2016 to 6/30/2021 (after reflex RNA testing was incorporated), 1371 unique patients had reactive screening results with 208 (15.2%) confirmed new diagnoses and 645 (47.0%) confirmed existing diagnoses. Of 553 discordant results, 35 cases involved acute HIV, 515 false positives, and three cases could not be confirmed due to lack of additional testing data. With reflex testing, reactive HIV screening assays were significantly more likely to be confirmed (either as true or false positives), people with newly diagnosed infection were linked to care more quickly, and fewer patients needed to be contacted regarding discordant results or to initiate linkage/re-linkage to care.

AUTHOR'S COMMENTARY

As we continue moving into an era of “test-and-treat” for infectious diseases of public health importance, the role of expedient HIV viral load testing after reactive screening (possibly as the second step after initial Ag/Ab screening, rather than the currently recommended approach utilizing a supplemental differentiation immunoassay) continues to be considered. Although both reflex testing (such as described here) and a new diagnostic algorithm involving broader NAT testing may introduce additional costs, this study helps provide detail on the potential clinical and population-level benefits of such an approach—particularly in highly impacted communities. Authors of this study note that reflex testing “significantly decreased the number of discordant results and improved identification of acute HIV infection in a timely manner, while freeing resources to provide linkage to care.” It also obviated the need to recall patients for an additional blood draw, which may be challenging to operationalize in certain settings.

FEATURED LITERATURE

Stewart J, Oware K, Donnell D, et al. Doxycycline prophylaxis to prevent sexually transmitted infections in women; dPEP Kenya Study Team. *N Engl J Med*. 2023 Dec 21;389(25):2331-2340. doi: 10.1056/NEJMoa2304007. PMID: 38118022

In this randomized open-label trial, 449 non-pregnant cisgender women (18 to 30 years old) taking TDF/FTC daily as PrEP were enrolled to receive doxycycline PEP and quarterly STI testing and treatment. Over 12 months of follow-up, participants completed quarterly questionnaires and received weekly short message surveys eliciting information on sexual exposures and doxycycline use. The median number of doses/month was four (IQR 0-8), number of sex acts/month was four (IQR 2-8), and number of partners/past quarter was one (IQR 0-2). Over 90 percent of quarterly timeline follow-back calendars indicated at least 80 percent doxycycline coverage after condomless sex in the previous two weeks, with most doses taken within 24 hours.

In over 90 percent of weekly SMS surveys, 55 percent of participants in the doxycycline group reported taking it at least as many days as they had sex. Among 50 participants randomly selected for hair analyses, medication was detected in at least one visit in 28 (56%); across quarterly visits medication was detected in 58/200 (29%) of visits. After excluding visits in which doxycycline was on hold, medication was detected in 58/178 (32.6%). There were 25.1 incident STIs per 100 person-years in the doxycycline-PEP group versus 29.0 in the standard-of-care group. Of the total 109 incident STIs, 85 (78.0%) were *C. trachomatis*, 31 (28.4%) *N. gonorrhoeae*, and one (0.9%) *T. pallidum*.

Overall, quarterly STI incidence was not significantly lower with doxycycline PEP: relative risk 0.88 (95% CI, 0.60 to 1.29). Subgroup analyses incorporating age, contraception use, history of transactional sex, and STI detection at baseline yielded similar results. No serious adverse events occurred, and nausea was the most common (7.2%) side effect. Social harms were reported four times among three participants because of unintentional disclosure of doxycycline PEP use.

AUTHOR'S COMMENTARY

In contrast to studies enrolling cisgender men and transgender women in France and the U.S., the incidence of bacterial STIs among cisgender women participants receiving HIV PrEP in Kenya was not significantly reduced with doxycycline PEP. Low detection of doxycycline use (based on hair analyses) may have been the primary reason for these results, along with differences in sexual networks and relationship dynamics as well as other factors such as the high background prevalence of high-level tetracycline-resistant *N. gonorrhoeae*. PrEP care offers a valuable opportunity to integrate comprehensive sexual health services and prevention interventions for many populations. Identification of acceptable and effective options for cisgender women should remain a priority for research and implementation efforts going forward.

FEATURED LITERATURE

Heo M, Norton BL, Pericot-Valverde I, et al. the HERO Study Group, National Stakeholder Advisory Board, Optimal Hepatitis C Treatment Adherence Patterns and Sustained Virologic Response among People Who Inject Drugs: THE HERO Study. *J Hepatol.* 2024 Jan 17: S0168-8278(23)05374-6. doi: 10.1016/j.jhep.2023.12.020. PMID: 38242324.

This study describes various medication adherence patterns and SVR outcomes among treatment naïve, non-pregnant adult PWID enrolled in the HERO Study (a U.S. trial comparing modified DOT and patient navigation across eight opioid treatment programs and fifteen community health centers) who initiated sofosbuvir/velpatasvir (x12 weeks). Electronic blister pack and SVR data were available for 496 participants, which comprised the per-protocol sample. Adherence was summarized according to various patterns, such as total adherent days, consecutive missed/non-adherent days, and early discontinuations. Multivariate models accounted for several factors including study site/setting, age, employment, injection frequency and recency, and urine drug screen results.

The median total adherent days was 63 (75%) per 84-day treatment course, and observed SVR rate was 460/496 (92.7%). Participants with early or premature medication discontinuation (i.e., first- and second-month discontinuation) were less likely to achieve SVR. Participants who missed more than 14 consecutive adherent days had a significantly smaller chance of achieving SVR compared to people who missed ≤ 7 consecutive days (regardless of when it occurred). Greater total adherent days were significantly associated with SVR only among the subgroup with < 50 percent adherence rate. Overall, greater total adherent days, longer consecutive adherent days, and shorter consecutive missed days were all associated with 90 percent or higher SVR rate.

AUTHOR'S COMMENTARY

Recommendations on managing incomplete HCV treatment adherence were a welcome addition to clinical guidelines, however they were based on limited data and ultimately reflected expert opinion of AASLD-IDSA HCV Treatment Guidance Panel members. These results from the HERO Study, which include an extensive and detailed characterization of adherence patterns across a large group of participants, offer much needed information to refine our understanding of how different patterns of DAA adherence (including number of missed days as well as timing of discontinuations) affect treatment outcomes. Although these findings involve only a single 12-week DAA regimen, and some cases classified as treatment failures might have actually represented reinfections, these results can help potentially identify which adherence interventions might be most useful to offer, and when to implement them, to ensure optimal patient and community level HCV treatment outcomes.

FEATURED LITERATURE

Erly S, Dombrowski JC, Khosropour C, Reuer JR, Boersema K, Sharma M. Cost analysis of implementing a 12-month recertification criterion for Ryan White HIV/AIDS Program's AIDS Drug Assistance Program in Washington state. *Public Health Rep.* 2024 Feb 8:333549241227118. doi: 10.1177/00333549241227118. PMID: 38327231

Washington state investigators modeled five-year costs and virologic suppression outcomes of changing from a six- to a 12-month ADAP recertification schedule, to help inform policy decisions on the feasibility and effect of implementing new recertification timings. Key outcomes included: (a) projected cost of the Washington State ADAP, (b) number of people virologically suppressed, and (c) number of people who received services while ineligible for ADAP. The model was stratified by health insurance type (public, private, or none) and receipt of case management services; 2017-2019 enrollment data informed transition probabilities. Data on the monthly cost of ADAP services by health insurance type and case management status were obtained from the state Department of Health administrative database.

Under a continued six-month recertification criteria, the model estimated ADAP would enroll 4,727 clients/month at a per-client cost of \$7,966 (at the end of the five-year period, 6,834 clients would be virologically suppressed and total program cost was estimated at \$37,663,000). With a 12-month recertification, ADAP would enroll 5,331 clients/month at a per-client cost of \$7,543 (at the end of the five-year period, 7,079 clients would be virologically suppressed and total cost was estimated at \$40,217,000). Under the 12-month scenario, 245 more people would be virologically suppressed by the end of 2025. The \$423 reduction in cost/client corresponded to approximately five percent lower administrative cost.

AUTHOR'S COMMENTARY

Studies such as these are vital to identifying administrative and policy opportunities which might lead to improved health outcomes and address long-standing structural inequities within a constrained funding environment. Findings of this analysis, which are specific to the ADAP Program, mirror results from similar evaluations of Medicaid eligibility policies which support less frequent recertification processes. Authors note their model did not take into account additional, indirect outcomes, such as improvement in co-occurring health conditions and reductions in HIV transmission, therefore the benefits described above may be underestimating the broader impact of continuous coverage and program support. **HIV**

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