

THE AMERICAN ACADEMY OF HIV MEDICINE ■ SUMMER 2023

HIV

SPECIALIST



HIV Health Care and Policy

Current Issues

Prevention & PrEP Access

What *Braidwood v Becerra*
Means for Public Health

Navigating Medicaid Unwinding

340B Drug Pricing Program

A State Law's Unintended Consequences

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HIV and Syphilis Co-Infection

- Approximately 1.2 million people in the U.S. have HIV. About 13 percent of them don't know it and need testing
- HIV continues to have a disproportionate impact on certain populations, particularly racial and ethnic minorities and gay, bisexual, and other men who have sex with men
- In 2019, an estimated 34,800 new HIV infections occurred in the U.S.
- The incidence of syphilis is rising all over the world, partly due to the increased transmission in HIV patients and other high risk groups such as men who have sex with men
- Having an HIV infection raises the risk of syphilis infection up to 7 times.
- In 2020, 133,945 cases of all stages of syphilis were reported, including 41,655 cases of primary and secondary (P&S) syphilis, the most infectious stages of the disease
- All patients presenting with syphilis should be offered HIV testing and vice versa. In geographic areas in which HIV prevalence is high, patients who have primary syphilis should be retested for HIV after 3 months if the first HIV test result was negative



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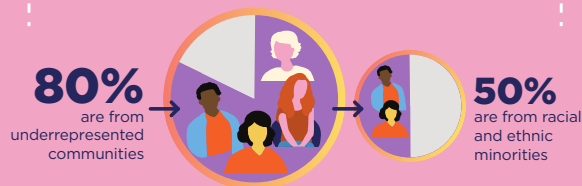
Controlled Tier and Genomic Data

The *All of Us* Research Program is building one of the most robust databases to transform the future of health research with extensive health data generously contributed by our diverse cohort. Data is accessible with tiered access, including Public, Registered, and Controlled tiers.

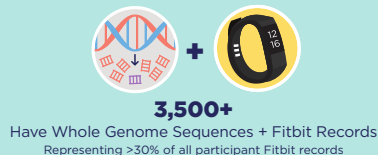
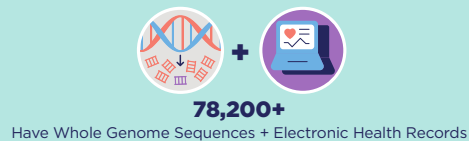
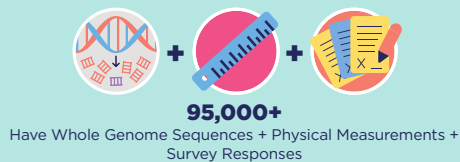
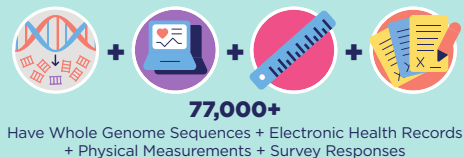


Data From

329,000+ Participants



Genomic Data is Paired with Rich Phenotypic Data



Within the Controlled Tier

Genomic Data and Tools

Includes all of the data available in the Registered Tier as well as genomic data, additional clinical fields in EHRs, and more granular demographic data both from surveys and EHRs.



98,600+
Whole Genome Sequences



165,000+
Genotyping Arrays



593,500,000+
Unique Variants
Represented and searchable through the public data browser



Genomics Analysis Tools
Hail and PLINK in addition to R, Python, and Jupyter Notebooks

More Individual-Level Information

- COVID-19 testing and diagnosis data
- Real dates of health events
- Residential location (first 3 digits of ZIP code)
- ICD codes



More Granular-Level Information

Non-generalized, demographic data provided by participants

- Race and ethnicity
- Sex at birth
- Gender identity
- Sexual orientation
- Education
- Employment status

Data Available in the Researcher Workbench



267,600+
Physical Measurements



214,200+
Electronic Health Records (EHR)



11,600+
Fitbit Records



329,000+
Survey Responses

For more information about our data, go to:

ResearchAllofUs.org

Data as of March, 2022

All of Us and the All of Us logo are registered service marks of the U.S. Department of Health and Human Services.

The *All of Us* Research Program's expansive dataset is housed on a broadly-available, secure platform. The Controlled Tier is available to registered researchers who have taken additional steps and training.



**AMERICAN ACADEMY OF
HIV MEDICINE**



By BRUCE J. PACKETT II

Executive Director, AAHIVM

From the Director

IN THE EVER-EVOLVING LANDSCAPE OF HEALTH CARE AND PUBLIC POLICY, it is essential that we stay informed and engaged to protect the well-being of our patients, providers, and communities. I am proud to present our summer issue, which delves into the critical matters coalescing right now around this crucial intersection of health care and public policy.

Our Director of Public Policy, Leslie McGorman, sets the stage with an overview of the state of HIV health care and policy through the lens of prevention and pre-exposure prophylaxis (PrEP) access. She highlights how health care has become a divisive political topic and explains how gains in funding for HIV prevention and treatment are insecure in our current climate. She delves into specific instances where these gains are threatened and underscores the importance of advocacy to not lose hard-won successes.

Another facet of access is insurance coverage for those who need HIV preventive care or treatment. The conclusion of

the Medicaid continuous enrollment condition from the COVID-19 Public Health Emergency, though, poses a significant threat of insurance loss to millions of people. In her article, Molly Tasso offers practical tips for providers in assisting individuals with HIV to navigate the complexities of losing Medicaid coverage in their respective states. Her insights provide invaluable guidance during this unwinding phase.

Dr. Meredith McNamara brings us a thought-provoking analysis of the recent *Braidwood Management Inc. v Becerra* case, highlighting the perils of judicial overreach in health care. She candidly shares her journey of assembling a multidisciplinary team to challenge the anti-science underpinnings of the ruling, inspiring providers to take action and stand up for evidence-based care.

Joe Dunn and Vacheria Keys discuss the federal 340B Drug Pricing Program, a crucial resource for Ryan White Clinics, health centers, and safety-net providers. They write about the program's vulnerability to attacks and share their perspectives on safeguarding it to ensure that federal resources are stretched to their fullest potential.

Dr. Orlando Harris and Dr. Tommi Gaines take us through a fascinating exploration of the unintended consequences of legislation on health care. Drawing from California's experience with a new law

covering STI home test kits, they shed light on how the law can cause an unforeseen exacerbation of the STI epidemic. Their analysis serves as a reminder of the complexities involved in crafting effective legislation.

In an engaging interview, Angela Kapalko discusses the PA Preceptorship Program with the first PA student and preceptor who successfully matched for the program. They provide insights into their collaborative experience, share valuable lessons learned, and offer guidance for PAs and PA students interested in participating in this program.

Lastly, we bring you a CE-certified article on the updated guidelines for breast- and chest-feeding issued by the U.S. Department of Health and Human Services Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission. Dr. William Short and Dr. Liz Lowenthal distill these essential guidelines, providing clinicians with the knowledge to deliver optimal care to pregnant individuals with HIV.

This summer issue represents our commitment to informing and empowering health care professionals like you as we navigate the intricate web of health care and public policy. Stay engaged, stay informed, and let us stand united in our dedication to providing evidence-based, compassionate care to those affected by HIV.

Wishing you a summer of continued learning and growth.

A stylized, handwritten signature in black ink, appearing to read 'B. Packett'.

IN THE NEWS

For the First Time Ever, Human Rights Campaign Officially Declares ‘State of Emergency’ for LGBTQ+ Americans

Issues National Warning and Guidebook to Ensure Safety for LGBTQ+ Residents and Travelers

HRC's First-Ever Emergency Declaration Comes After More Than 75 Anti-LGBTQ+ Bills Signed Into Law This Year (More Than Double The Number From Last Year), Creating an Imminent Threat to the Health and Safety of LGBTQ+ People and Families Nationwide

ON JUNE 6, the Human Rights Campaign (HRC)—the nation's largest lesbian, gay, bisexual, transgender and queer (LGBTQ+) civil rights organization—officially declared a state of emergency for LGBTQ+ people in the United States for the first time in its more than 40-year history, following an unprecedented and dangerous spike in anti-LGBTQ+ legislative assaults sweeping state houses this year. A new report released by HRC today—*LGBTQ+ Americans Under Attack*—details more than 75 anti-LGBTQ+ bills that have been signed into law this year alone, more than doubling last year's number, which was previously the worst year on record.

The sharp rise in anti-LGBTQ+ measures has spawned a dizzying patchwork of discriminatory state laws that have created increasingly hostile and dangerous environments for LGBTQ+ people, prompting HRC to also issue a national warning and downloadable guidebook for the LGBTQ+ community—including health and safety resources, a summary of state-by-state laws, “know your rights” information, and resources designed to support LGBTQ+ travelers as well as those already living in hostile states. This guidebook will arm LGBTQ+ people with resources and information to help ensure safety in all 50 states.

Kelley Robinson, the President of the Human Rights Campaign, issued the following statement:

“LGBTQ+ Americans are living in a state of emergency. The multiplying threats facing millions in our community are not just perceived—they are real, tangible, and dangerous. In many cases they are resulting

in violence against LGBTQ+ people, forcing families to uproot their lives and flee their homes in search of safer states, and triggering a tidal wave of increased homophobia and transphobia that puts the safety of each and every one of us at risk. As we kick off LGBTQ+ Pride Month, HRC will be working tirelessly to educate and arm the LGBTQ+ community with information and resources to ensure their safety—whether they're planning summer travel through regions that are becoming increasingly hostile to LGBTQ+ people, or whether they already live in a state where legislative assaults and political extremism are continuing to put a target on our backs.”

“There is an imminent threat to the health and safety of millions of LGBTQ+ people and families, who are living every day in uncertainty and fear. Our number one priority will always be ensuring that LGBTQ+ people are safe and have the tools they need to defend and protect themselves against acts of hostility, discrimination and—in the most extreme cases—violence. It's also incumbent on our allies across the country to stand with us and make it clear that they won't sit idly by while extremists attack and malign LGBTQ+ people and our families. We'll fight tooth and nail to ensure the safety and dignity of every LGBTQ+ person is respected and protected—without exception.”

Nadine Smith, the CEO of Equality Florida, stood alongside HRC issuing the following statement:

“Florida stands at the forefront of the fight against these oppressive laws now proliferating throughout the nation. It is heartbreaking to witness families uproot themselves in search of access to health care and inclusive classrooms, free from book bans and censorship. Our universities, once renowned for their talent and innovation, are witnessing a drain of exceptional educators and students who now seek refuge in places where academic freedom and excellence

prevail over political indoctrination. Our state's economy has lost over \$1 billion as businesses and conferences withdraw their investment in our state. The assault on freedom is not limited to one state but permeates across America. The erosion of civil liberties by extremists to further their own political ambitions poses a direct threat to the health and safety of LGBTQ individuals. It is imperative for all of us to recognize the gravity of this moment and commit ourselves to being on the frontlines, unwavering in our fight for freedom.”

An Escalating Crisis for LGBTQ+ People Across the Country

Extremist politicians and their allies have ushered in an unprecedented climate of fear, hostility, and discrimination that's already rippling consequences across the LGBTQ+ community. As detailed in HRC's legislative impact report, there has been a steady increase in anti-LGBTQ+ bills introduced in state legislatures over the last several years—from 115 bills introduced in 2015 to more than 500 in 2023. This year, more than 75 bills have been signed into law—more than doubling last year's number.

The 2023 state legislative session was the worst year on record for anti-LGBTQ+ legislation:

- More than 525 bills were introduced in 41 states.
- Over 220 of these bills explicitly targeted transgender people.
- Over 76 bills have been signed into law as of June 5, 2023—more than any year on record, and more than double over last year.

Transgender, nonbinary, and gender non-conforming youth in particular have been directly impacted by anti-LGBTQ+ legislation, losing access to life saving medical care, comprehensive and inclusive education, and activities, spaces, and facilities.



- Transgender sports bans (21 states): 30 percent of high school aged transgender youth—approximately 90,100 of the estimated 300,100 transgender youth aged 13–17 in the U.S.—are living in states where they are unable to simply play alongside their friends. As these bills extend all the way down into kindergarten and, in some states, through college, many more transgender youth and young adults are impacted as well.
- Gender-affirming care bans (20 states): 30.9 percent of all transgender youth age 13–17 are living in states where they can no longer access life-saving, best practices medical care. In some states, care has been banned not only for youth, but adults as well, especially through bans on public funds going to provide this best practice health care. More than 30 states introduced gender affirming care bans during the 2023 legislative session, meaning that at its height, half of all transgender youth in the U.S. were at risk of losing access to gender-affirming care.
- Bathroom bans (9 states): 14.8 percent of transgender people (age 13+)—over 243,000 of the 1.6 million transgender people in the U.S.—live in states where they are unable to use bathrooms, locker rooms, and/or other facilities in accordance with their gender identity while in K–12 (public) school buildings, if not elsewhere. This includes 32,700 transgender youth nationwide, or 10.9 percent of all transgender youth age 13–17. Over 110,000 transgender people (age 13+) live in states where they are also banned from using bathrooms and facilities in some public settings and buildings outside of K–12 schools.

Families in the States Speak Out

The targeting of transgender and nonbinary youth by extremist politicians is creating a crisis for families—millions of whom live in regions that present threats of danger to them and their children. Families from some of the most hostile states across the country stood alongside HRC... to give platform to the voices of millions being shamelessly attacked and targeted by their governing leaders.

Texas Parent Wendy: “Being forced to leave our family and friends, with Texas roots over a hundred years, is going to be the hardest thing we’ll ever do,” said Wendy, a mother of four in Texas who is relocating to Minnesota this summer. “Our close knit family, especially my mom, is devastated. Going from seeing each other every week to every other month is going to be emotionally challenging.”

Montana Parent Megan: “It’s difficult to articulate what it’s like to be forced out like this,” said Megan, a parent of a transgender child living in Montana who is looking for jobs in other states. “It sort of makes you feel like a refugee, as we’ll obviously do whatever we need to do to keep our child safe. But we have great jobs in Montana, a tight friend circle that includes people who really care for and love us, and so leaving all of that behind for our whole family and starting new is difficult for us, as well as our children, who will also be fully uprooted, obviously.”

Texas Parent Rachel: “My family has been fighting for many years to be able to safely stay in our home state of Texas while supporting our transgender daughter,” said Rachel

Gonzales in Texas, a member of HRC’s Parents for Transgender Equality Council. “Despite the exponentially heightened threats we face today from hate-filled legislators, we are still surrounded by Texans who know, love, and support us. It is horrifying that so many families are being used as pawns in this manufactured debate from political extremists. We want every trans kid and adult here to know that they are not alone, we are staying put, and we’ll be fighting right here alongside you.”

Florida Parent Daniel: “When a child’s basic needs are not being met, or when a child is neglected or endangered in the home, Child Protective Services is called. But what happens when it’s the State that’s endangering a child? When the State is not allowing basic needs to be met?,” said Daniel, the dad of a transgender young person in Florida who recently moved to Minnesota. “We have become our own version of Child Protective Service and removed our child from the danger and neglect from the State.”

Empowering LGBTQ+ People to Protect Themselves, Fight Back

To ensure that LGBTQ+ people have the information and resources they need to not only ensure their safety while residing in or traveling through some of the most hostile regions of the country, HRC today released an LGBTQ+ guidebook for action, for navigating the current climate. The guidebook is part of a larger effort by which HRC will spend the coming months working to furnish the LGBTQ+ community with information and resources it needs to navigate the increasingly hostile climate, and it includes:

- State-by-state run down of anti-LGBTQ+ policies as well as LGBTQ+ protections
- How to determine access to LGBTQ+ health care
- Resources for financing a move to safer states and finding employment
- Navigating school boards
- Information for filing complaints for violation of civil rights laws
- Identifying the source of harmful rhetoric and legislative attacks
- How to engage in local advocacy opposing anti-LGBTQ+ efforts
- How to navigate tough conversations about anti-LGBTQ+ hate with friends and family

More information on today’s announcement can be found on HRC’s website [hrc.org]:

- New Report: LGBTQ+ Americans Under Attack
- LGBTQ+ Guidebook for Action
- HRC National Warning: Resources Page

IN THE NEWS

Potential Risk for New Mpox Cases

Distributed via the Centers for Disease Control and Prevention's Health Alert Network on May 15, 2023

Summary

In the United States, cases of mpox (formerly monkeypox) have declined since peaking in August 2022, but the outbreak is not over. The Centers for Disease Control and Prevention (CDC) continues to receive reports of cases that reflect ongoing community transmission in the United States and internationally. This week, the CDC and local partners are investigating a cluster of mpox cases in the Chicago area. From April 17 to May 5, 2023, a total of 12 confirmed and one probable case of mpox were reported to the Chicago Department of Public Health. All cases were among symptomatic men. **None of the patients have been hospitalized.** Nine (69%) of 13 cases were among men who had received two JYNNEOS vaccine doses. Confirmed cases were in nine (69%) non-Hispanic White men, two (15%) non-Hispanic Black men, and two (15%) Asian men. The median age was 34 years (range 24–46 years). Travel history was available for nine cases; four recently traveled (New York City, New Orleans, and Mexico).

Although vaccine-induced immunity is not complete, vaccination continues to be one of the most important prevention measures. The CDC expects new cases among previously vaccinated people to occur, but people who have completed their two-dose JYNNEOS vaccine series may experience less severe symptoms than those who have not.

Spring and summer season in 2023 could lead to a resurgence of mpox as people gather for festivals and other events. The purpose of this Health Alert Network (HAN) Health Update is to inform clinicians and public health agencies about the potential for new clusters or outbreaks of mpox cases and to provide resources on clinical evaluation, treatment, vaccination, and testing.

Background

A global outbreak of mpox began in May 2022. Previous outbreaks in places where mpox is not endemic were mostly related to international travel; however, this outbreak spread rapidly across much of the world through person-to-person contact, disproportionately affecting gay and bisexual men, other men who have sex with men (MSM), and transgender people. Most patients with mpox have mild disease, although some, particularly those with advanced or untreated HIV infection, may experience more severe outcomes.

As of May 10, a total of 30,395 cases have been reported in the United States. This outbreak had a peak of about 460 cases per day in August 2022, and gradually declined, likely because of a combination of temporary changes in sexual behavior, vaccination, and infection-induced immunity.^{1,2} However, the CDC continues to receive reports of new cases and clusters in the United States and internationally.

Although approximately 1.2 million JYNNEOS mpox vaccine doses have been administered in the United States since the beginning of the outbreak, only 23 percent of the estimated population at risk for mpox has been fully vaccinated. Vaccine coverage varies widely among jurisdictions. The projected risk of a resurgent mpox outbreak is greater than 35 percent in most jurisdictions in the United States without additional vaccination or adapting sexual behavior to prevent the spread of mpox.³ Resurgent outbreaks in these communities could be as large or larger than in 2022.

To help prevent a renewed outbreak during the spring and summer months, CDC is urging clinicians to be on alert for new cases of mpox and to encourage vaccination for people at risk. If mpox is suspected, test even if the patient was previously vaccinated or had mpox. Clinicians should also refamiliarize themselves with mpox symptoms, specimen collection, laboratory testing procedures, and treatment options.

Recommendations for Clinicians Evaluating and Treating Patients

Conduct a thorough patient history to assess possible mpox exposures or epidemiologic risk factors. Mpox is usually transmitted through close, sustained physical contact and has been almost exclusively associated with sexual contact in the current global outbreak. It is important to take a detailed sexual history for any patient with suspected mpox.

Perform a complete physical examination, including a thorough skin and mucosal (e.g., oral, genital, anal) examination. Doing so can detect lesions of which the patient may be unaware.

Consider mpox when determining the cause of a diffuse or localized rash, including in patients who were previously infected with mpox or vaccinated against mpox. Differential diagnoses include herpes simplex virus (HSV) infection, syphilis, herpes zoster (shingles),



disseminated varicella-zoster virus infection (chickenpox), molluscum contagiosum, scabies, lymphogranuloma venereum, allergic skin rashes, and drug eruptions. Specimens should be obtained from lesions (including those inside the mouth, anus, or vagina), if accessible, and tested for mpox and other sexually transmitted infections (STI), including HIV, as indicated. The diagnosis of an STI does not exclude mpox, as a concurrent infection may be present.

Patients with mpox benefit from supportive care and pain control. Mpox can commonly cause severe pain and can affect anatomic sites, including the anus, genitals, and oropharynx, which can lead to other complications. Assess pain in all patients with mpox virus infection and recognize that substantial pain may exist from mucosal lesions not evident on physical exam. Topical and systemic strategies should be used to manage pain. Pain management strategies should be tailored to the needs and context of an individual patient.

Tecovirimat is considered first-line among options that have not been approved by the U.S. Food and Drug Administration to treat eligible patients with mpox. If a clinician intends to prescribe oral tecovirimat, consider seeking access through enrollment in the AIDS Clinical Trials Group (ACTG) Study of Tecovirimat for Human Monkeypox Virus (STOMP) so that the trial can determine efficacy of this drug. This trial includes a placebo-controlled, randomized arm, and an open-label option for individuals with severe disease or those who decline randomization. Remote enrollment is available. For patients not eligible for the STOMP trial or who decline to participate, stockpiled oral tecovirimat is available upon request for mpox patients who meet treatment eligibility (e.g., have severe disease or are at increased risk for severe disease) under the CDC's Expanded Access Investigational New Drug

(IND) protocol. More information about evaluating and treating patients can be found on the CDC mpox Clinical Guidance web pages.

Clinicians should notify their state or local health departments of any suspected or confirmed mpox cases.

Recommendations for Vaccinating Patients

JYNNEOS vaccine can be given as post-exposure prophylaxis (PEP) both to people with known or presumed exposure to the mpox virus. Vaccine can also be given to people with certain risk factors and recent experiences that may make them more likely to have been exposed to mpox. As PEP, vaccine should be given as soon as possible, ideally within four days of exposure; however, administration four to 14 days after exposure may still provide some protection against mpox. People who are vaccinated should continue to avoid close, skin-to-skin contact with someone who has mpox. JYNNEOS involves two vaccine doses given 28 days apart; peak immunity is expected 14 days after the second dose.⁴

Previous studies have suggested that JYNNEOS vaccination is protective against mpox. When combined with other prevention measures, vaccination prior to exposure and PEP vaccination strategies might help control outbreaks by reducing transmission of the mpox virus, preventing disease, or reducing disease severity and hospitalization. Duration of immunity after one or two doses of JYNNEOS is unknown.

Currently, the CDC does not recommend routine immunization against mpox for the general public. Mpox vaccination should be offered to people with high potential for exposure to mpox:

- People who had known or suspected exposure to someone with mpox.
- People who had a sex partner in the past two

weeks who was diagnosed with mpox.

- Gay, bisexual, and other MSM, and transgender or nonbinary people (including adolescents who fall into any of these categories) who, in the past six months, have had
 - A new diagnosis of one or more sexually transmitted diseases (e.g., chlamydia, gonorrhea, syphilis).
 - More than one sex partner.
- People who have had any of the following in the past six months
 - Sex at a commercial sex venue.
 - Sex in association with a large public event in a geographic area where mpox transmission is occurring.
 - Sex in exchange for money or other items.
- People who are sex partners of people with the above risks.
- People who anticipate experiencing any of the above scenarios.
- People with HIV infection or other causes of immunosuppression who have had recent or anticipate potential mpox exposure.
- People who work in settings where they may be exposed to mpox.
 - People who work with orthopoxviruses in a laboratory.

Extensive risk assessment should not be conducted in people who request vaccination to avoid the barriers created by the stigma experienced by many who could benefit from vaccination. People in the community at risk (e.g., gay, bisexual, or other MSM; transgender or nonbinary people) asking for vaccination is adequate attestation to individual risk of mpox exposure. People who previously received only one JYNNEOS vaccine dose should receive a second dose as soon as possible.

REFERENCES

1. Endo, A., et al. Heavy-tailed sexual contact networks and monkeypox epidemiology in the global outbreak. *Science*. 2022; 378 (6615):90–94. <https://doi.org/10.1126/science.add4507>
2. Clay, P.A., et al. Modelling the impact of vaccination and behavior change on mpox transmission in Washington D.C. *medRxiv* (Preprint), 2023. <https://doi.org/10.1101/2023.02.10.23285772>
3. Centers for Disease Control and Prevention. Risk assessment of mpox resurgence and vaccination considerations. April 4, 2023. <https://www.cdc.gov/poxvirus/mpox/response/2022/risk-assessment-of-resurgence.html>
4. Rao, A., et al. Use of JYNNEOS (smallpox and monkeypox vaccine, live, nonreplicating) for preexposure vaccination of persons at risk for occupational exposure to orthopoxviruses: recommendations of the Advisory Committee on Immunization Practices — United States, 2022. *MMWR Morb Mortal Wkly Rep*. 2022; 71:734–742. <https://dx.doi.org/10.15585/mmwr.mm7122e1>

IN THE NEWS

The American Academy of HIV Medicine Unequivocally Supports an Evidence-Based, Patient-Centered Approach to Infant Feeding

AS A PROFESSIONAL ASSOCIATION representing frontline HIV care providers, the **American Academy of HIV Medicine strongly supports shared decision making and evidence-based, patient-centered choice on infant feeding options for people with HIV (PWH).** This position is in alignment with the latest clinical guidelines issued in January by the U.S. Department of Health and Human Services (HHS) Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission in the U.S.

These guidelines represent an important step forward in supporting pregnant persons with HIV and their options for breast- and chest-feeding, including the use of appropriate and inclusive language for trans and nonbinary pregnant persons. Some key updates from the guidelines underscore the importance of shared decision making and support of patient choice, including:

- Individuals should be counseled on the risk of HIV transmission. For PWH on antiretroviral therapy with sustained undetectable viral load through pregnancy and postpartum, breast-feeding has a less than one percent (but not zero) risk of HIV transmission to a breastfeeding infant.
- Individuals with HIV who are on antiretroviral therapy with a sustained undetectable viral load and who choose to breastfeed should be supported in this decision.
- Individuals with HIV who choose to formula feed should be supported in this decision. Providers should ask about potential barriers to formula feeding and explore ways to address them.
- It is inappropriate to engage Child Protective Services or similar authorities in response to infant feeding choices of PWH.

Based on these latest guidelines, the **Academy firmly believes that a more patient-centered approach to infant feeding can and should be reached.** Providers should prioritize their own knowledge and understanding of these guidelines, as well as that of their team. We believe that any stigmatization of a virally suppressed PWH choosing the option of feeding that works best for themselves and their



baby must immediately halt, particularly in its most egregious form of engaging Child Protective Services or another entity that can irreparably harm a family. HIV criminalization laws still exist in many states and interactions with protective authorities could have very different consequences for a PWH than they would for a person who does not have HIV.

We believe that providers should counsel their patients on infant feeding options with accurate, relevant, and evidence-based information and data. As with all medical decisions made between the provider and the patient, the Academy believes in the sanctity of that relationship and in protecting those shared decisions from unreasonable interference by politically motivated policymakers or because of stigma or misinformation.

To access the full guidelines, “Infant Feeding for Individuals with HIV in the United States,” visit: <https://clinicalinfo.hiv.gov/en/guidelines/perinatal/infant-feeding-individuals-hiv-united-states>

FDA Finalizes Move to Recommend Individual Risk Assessment to Determine Eligibility for Blood Donations

ON MAY 11, the U.S. Food and Drug Administration (FDA) finalized recommendations for assessing blood donor eligibility using a set of individual risk-based questions to reduce the risk of transfusion-transmitted HIV. These questions will be the same for every donor, regardless of sexual orientation, sex, or gender. Blood establishments may now implement these recommendations by revising their donor history questionnaires and procedures.

This updated policy is based on the best available scientific evidence and is in line with policies in place in countries like the United Kingdom and Canada. It will potentially expand the number of people eligible to donate blood, while also maintaining the appropriate safeguards to protect the safety of the blood supply.

These final recommendations are consistent with the policy initially proposed in January. The FDA worked diligently to review and consider all comments submitted to the agency to finalize these recommendations as quickly as possible.

"The FDA has worked diligently to evaluate our policies and ensure we had the scientific evidence to support individual risk assessment for donor eligibility while maintaining appropriate safeguards to protect recipients of blood products. The implementation of these recommendations will represent a significant milestone for the agency and the LGBTIQ+ community," said Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research. "The FDA is committed to working closely with the blood collection industry to help ensure timely implementation of the new recommendations and we will continue to monitor the safety of the blood supply once this individual risk-based approach is in place."

This policy eliminates time-based deferrals and screening questions specific to men who have sex with men (MSM) and women who have sex with MSM. Under the final guidance issued today, all prospective blood donors will answer a series of individual, risk-based questions to determine eligibility. All prospective donors who report having a new sexual partner, or more than one sexual partner in the past three

months, and anal sex in the past three months, would be deferred to reduce the likelihood of donations by individuals with new or recent HIV infection who may be in the window period for detection of HIV by nucleic acid testing.

Additionally, under these final recommendations, those taking medications to treat or prevent HIV infection (e.g., antiretroviral therapy (ART), pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP)), will also be deferred. Though these antiretroviral drugs are safe, effective, and an important public health tool, the available data demonstrate that their use may delay detection of HIV by currently licensed screening tests for blood donations, which may potentially give false negative results. Although HIV is not transmitted sexually by individuals with undetectable viral levels, this does not apply to transfusion transmission of HIV because a blood transfusion is administered intravenously, and a transfusion involves a large volume of blood compared to exposure with sexual contact. As stated in the guidance, individuals should not stop taking their prescribed medications, including PrEP, or PEP, in order to donate blood. The FDA remains committed to evaluating additional data and new technological developments as they

become available to inform our donor eligibility recommendations.

The FDA has been evaluating alternatives to time-based deferrals for MSM and helping to facilitate the generation of scientific evidence that would support an individual risk based-assessment blood donor questionnaire. This scientific information has given the agency a solid foundation to support this new policy. The FDA strongly believes the implementation of an individual risk-based approach will not adversely affect the safety or availability of the U.S. blood supply.

The FDA carefully reviewed numerous data sources, including data from countries with similar HIV epidemiology that have implemented an individual risk-based approach for assessing donor eligibility, surveillance information obtained from the Transfusion Transmissible Infections Monitoring System, performance characteristics of nucleic acid testing for HIV and the FDA-funded Assessing Donor Variability And New Concepts in Eligibility (ADVANCE). The ADVANCE study examined the rates of HIV risk factors, such as anal sex and rates of HIV infection, as well as the usage of medications to treat or prevent HIV infection, among MSM study participants. **HIV**



HIV Health Care Policy in 2023

Prevention & PrEP Access

By LESLIE McGORMAN, MPPA



AS WE HEAD INTO THE SUMMER MONTHS, it's a good time to reflect on all that has happened in domestic HIV health care policy during the first half of the year. Health care continues to be a prism through which to see every other contemporary political and policy issue. It also continues to be used as a wedge issue by federal and state policymakers. Gains in funding for prevention and treatment continue to be precarious, and the HIV workforce is still reeling from the COVID-19 pandemic and the squeeze on local and state public health infrastructure. But with each setback, there are new opportunities for scientific and policy advancements in the field of HIV prevention, research, and care. This particular reflection will focus on HIV prevention and access to pre-exposure prophylaxis (PrEP).

U.S. Preventive Services Task Force

Access to PrEP, including insurance coverage of the medication, continues to be an immensely important tool for ending the HIV epidemic, but barriers persist. Uptake (prescriptions filled) is not equitable across racial and ethnic groups or across gender identities. There are many policy levers that would need to be pulled to achieve coverage for all, regardless of whether a person is insured, uninsured, or underinsured. But during 2022 and 2023, a primary mechanism was available

for us that would continue to mandate PrEP coverage in the private insurance market: the U.S. Preventive Services Task Force's (USPSTF) updated review of PrEP.

As background, the USPSTF is an independent, volunteer panel of national experts in disease prevention and evidence-based medicine.¹ USPSTF issues recommendations based on rigorous review of existing peer-reviewed evidence. These recommendations are intended to help primary care clinicians and patients decide together whether a preventive service is right for a patient's needs. Those recommendations are conveyed via a letter grade system based on the strength of the evidence and the balance of benefits and harms of a preventive service.

Preventive services with an A or B grade must be covered by most private insurance plans because there is high certainty that the net benefit is substantial and should be offered or provided (Grade A) or there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate-to-substantial and should be offered or provided (Grade B). USPSTF



recommendations cover a broad range of preventive services, including tobacco cessation, various cancer screenings, screening for depression, contraceptives, prenatal care, etc. The number of people with private insurance who would have access to these preventive services without cost sharing is estimated to be at least 151 million.²

Since 2019, HIV PrEP has had an A grade from the USPSTF, but the American Academy of HIV Medicine joined partner organizations in requesting the Task Force also conduct a review and issue a rating that includes oral *and* long-acting injectable PrEP. In December of 2022, the USPSTF released its draft recommendation on PrEP, recommending an “A” grade for both oral and long-acting injectable PrEP. In 2023, the Academy submitted comments in support of preserving the A grade in the final recommendation, while also requesting that the USPSTF streamline future review by extending this grade to any modality that effectively prevents HIV. Precious time is lost while the USPSTF does its review, making it harder for those in need to access the medication without cost-sharing.

While there are still coverage barriers resulting from insurer and laboratory non-compliance, final recommendations of an A grade would be truly consequential for all those vulnerable to HIV or those who simply wish to utilize PrEP for extra protection but do not want to take a daily pill. The USPSTF has rightfully recognized the importance of PrEP, particularly as there is not yet a cure for HIV.

Unfortunately, final recommendations may be on hold until a ruling in the *Braidwood Management Inc. v. Becerra* case that challenged the USPSTF’s authority as a regulatory body as well as PrEP coverage by certain employer-based insurance plans. [Read more on the *Braidwood* case on page 18.]

National Coverage Determination

The Academy also submitted comments in support of a simultaneous process being conducted by the Centers for Medicare and Medicaid Services (CMS) called a national coverage determination (NCD). Through an NCD process, CMS assesses whether a certain medication or service should be covered in Medicare Part B. As a reminder, Medicare

Part B is medical insurance that covers preventive services like vaccines and wellness visits, outpatient care, etc., and Medicare Part D is drug coverage that helps cover the cost of prescription drugs.³ Currently, Medicare Part D only covers oral PrEP medication and sometimes with cost-sharing. Beneficiaries who would have greater success with long-acting provider-administered PrEP are left behind. A national coverage determination is the only pathway to coverage under Medicare Part B for a provider-administered drug; without a remedy, inequities will remain.

PrEP uptake is central to the prevention pillar of the federal Ending the HIV Epidemic initiative and new modalities have the potential to increase access.⁴ It’s important to ensure that Medicare beneficiaries can access PrEP, both for individuals over 65 who age into Medicare, as well as disabled individuals under 65. Also critical is access for “dual-eligibles,” many of whom face adherence challenges with a daily pill regimen and would benefit from long-acting PrEP agents administered by a health care provider. Essentially, by improving Medicare beneficiaries’ access to PrEP, CMS will help reduce new HIV infections *and* reduce future costs in other parts of the Medicare system, including Part D.

CDC’s New HIV Surveillance Data

While the aforementioned strategies for increasing PrEP coverage are underway, there are new data about PrEP uptake that paint a more complete picture of how complicated “access” truly is. In May, the Centers for Disease Control and Prevention (CDC) published new HIV surveillance reports that include data from 2021. While primarily focused on HIV incidence and prevalence, data showed greater PrEP uptake among certain groups, but also confirmed persistent inequities between groups.⁵ Data show that of the 1.2 million people who would benefit from PrEP in the U.S., only 30 percent were prescribed it (compared to 13 percent in 2017).

And of those prescriptions, a whopping 78 percent were procured by White people, 21 percent by Hispanic/Latino people, and only 11 percent by Black/African American people. For context, to reach our country’s HIV elimination 2025 benchmark, each racial and ethnic group would have to reach 50 percent coverage. The CDC describes the situation as such: “Deeply entrenched social determinants of health continue to drive these disparities and their outcomes. Most new HIV infections in 2021 were among gay and bisexual men, the majority of whom were Black or Hispanic/Latino. About one-fifth of new HIV infections in 2021 were among women, and over half of those were among Black women.” Efforts to improve PrEP access must be rightsized to match community need.

Tennessee HIV Prevention Funding Crisis

Despite widespread agreement that HIV prevention is critical to ending the HIV epidemic, unusual state-level restrictions arose in 2023. In March, news began to circulate that Tennessee Gov. Bill Lee (R)



announced the state would reject more than \$8 million in CDC HIV prevention funds (surveillance, testing, and prevention) and fund existing programs using only state dollars. The Governor stated the decision to forego funding after May 31, 2023, was to help the state “decrease its reliance on federal funding and assume increased independence.” Moreover, the Governor’s office said that it will redirect grant funds to serve different populations, including “victims of human trafficking, mothers and children, and first responders” rather than those most at risk for HIV. This statement came as a surprise to many, particularly since it was unclear how the state would replace the funding. The Governor’s true intentions were further complicated by the fact that predominantly Black/African American communities in Shelby County would bear the greatest burden of these cuts.

As the community of Tennessee HIV providers and advocates worked diligently to mitigate the catastrophic harm that could come from this policy shift, the Academy joined nearly 50 organizations in urging the CDC to: 1) Find alternative funding mechanisms for Tennessee grantees receiving 18-1802 and/or 20-2010 from the Tennessee Department of Health, through May 31, 2023; 2) Establish a protocol in the event a similar situation occurs in other jurisdictions. The protocol should be applicable to funding mechanisms across the National Center for HIV, Viral Hepatitis, STD, and TB Prevention; and 3) Work directly with impacted community-based organizations, local health departments, and other HIV prevention service providers, including convening listening sessions to understand and better respond to immediate and future needs.

In response to this urgent crisis, the CDC was able to identify a workaround that would allow direct funding to some of the grantees, though it is a temporary, one-off fix to be sure. Specifically, the CDC announced a Notice of Award of a Single-Source Cooperative Agreement to fund United Way of Greater Nashville (UWGN). Under PS23-0073, approximately \$4M will be awarded to UWGN for a one-year funding period starting June 1, 2023. The CDC funding awarded to UWGN will ensure critical HIV prevention and care services are available to all who could benefit from them in Tennessee. However, it’s

unclear whether the CDC has the capacity to deploy such mechanisms should other states replicate what Tennessee has done.

Ultimately, a single state governor could upend a stable HIV prevention funding stream, which could greatly diminish the work being done by the federal government to ensure PrEP coverage. Getting the medication paid for is only one element of PrEP access and it must not be where the work ends.

National PrEP Program and the President’s Budget

As we’ve explored, there are many elements to achieving comprehensive coverage and access to PrEP. One final strategy that has been prominent thus far in 2023 is the creation of a national PrEP program. In the President’s Fiscal Year 2024 budget proposal, the administration again proposed the creation of a national PrEP program (the proposal was first included in the FY’23 budget). The budget proposal calls for an investment of \$237 million in FY’24 and \$9.8 billion in mandatory spending over 10 years in the national “PrEP Delivery Program.” The program would provide PrEP without cost-sharing to those who are uninsured and underinsured. In response to feedback from organizations such as the Academy, the Administration also included essential wrap-around services through states, the Indian Health Service, tribal entities, and localities, as well as establishing a network of community providers to reach underserved areas and populations.

The proposal also includes important language about removing barriers via Medicaid, including requiring states to cover PrEP and associated laboratory services with no cost sharing for Medicaid and CHIP beneficiaries, and places guardrails on utilization management practices, like prior authorization and step therapy. Given that there is unlikely to be agreement across party lines on budgetary spending, it’s important to remember that the

President’s budget only reflects the White House’s spending priorities and does not really influence investments that Congressional appropriators will make.

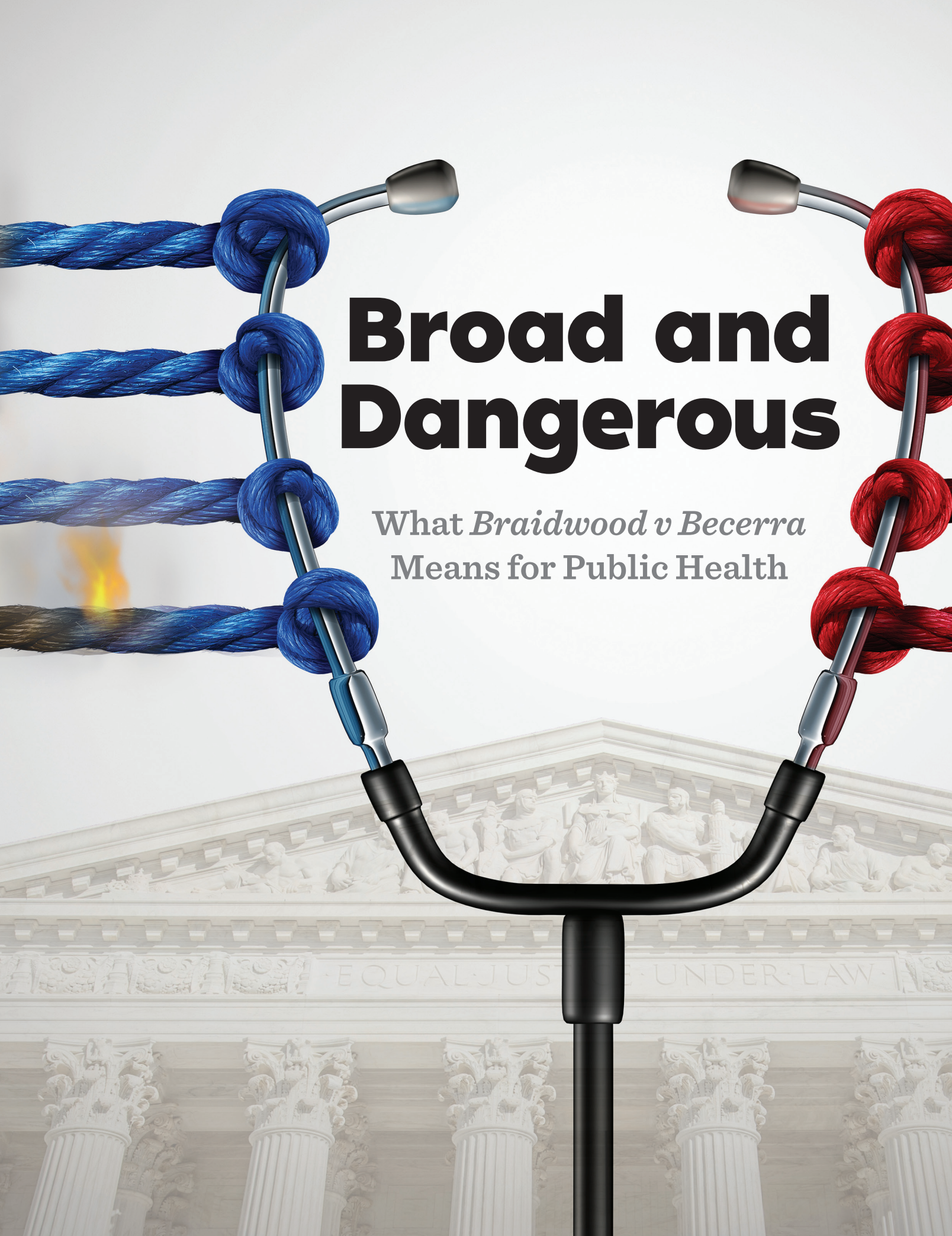
Ultimately, funding for HIV prevention remains vulnerable to political infighting that could prevent Congress from reaching a budget deal. The fight over raising the “debt ceiling” offered a preview of where some members of Congress would like to see cuts—by and large within the non-defense discretionary funding bucket that funds much of our health care system, among many non-health-related government functions. It will require sustained advocacy to preserve the funding necessary to prevent HIV and reach an end to the HIV epidemic. **HIV**



LESLIE MCGORMAN, MPPA, joined AAHIVM in April 2021, where she serves as the Director of Public Policy. In that role, she leads the organization’s policy and advocacy strategy to ensure representation of the HIV clinical care team and the Academy’s 4,000+ members and credentialed providers. Prior to the Academy, Leslie worked as a consultant for nonprofit organizations and political campaigns and served as a long-time federal lobbyist. She also spent several years at a leading political and advocacy organization focused on preserving and expanding reproductive rights, where she led a team of health care lobbyists focused both on state and federal policy issues.

REFERENCES

1. U.S. Preventive Services Task Force. About the USPSTF. Accessed June 9, 2023. <https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf>
2. Assistant Secretary for Planning and Evaluation. *Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act (Issue Brief)*. January 11, 2022. Accessed June 9, 2023. <https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d70dd2/preventive-services-ib-2022.pdf>
3. Medicare.gov. Parts of Medicare. Accessed June 9, 2023. [https://www.medicare.gov/basics/get-started-with-medicare/medicare-basics/parts-of-medicare#:~:text=Part%20B%20\(Medical%20Insurance\)%3A,hospital%20beds%2C%20and%20other%20equipment](https://www.medicare.gov/basics/get-started-with-medicare/medicare-basics/parts-of-medicare#:~:text=Part%20B%20(Medical%20Insurance)%3A,hospital%20beds%2C%20and%20other%20equipment)
4. HIV.gov. What Is Ending the HIV Epidemic in the U.S.? Updated: July 1, 2022. Accessed June 9, 2023. <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview/>
5. Centers for Disease Control and Prevention. Monitoring Selected National HIV Prevention and Care Objectives by Using HIV Surveillance Data—United States and 6 Dependent Areas, 2021. Updated May 23, 2023. Accessed June 9, 2023. https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-28-no-4/index.html?ACSTrackingID=USCDC_1046-DM106103&ACSTrackingLabel=CDC%20Releases%20New%20HIV%20Surveillance%20Reports&deliveryName=USCDC_1046-DM106103



Broad and Dangerous

What *Braidwood v Becerra*
Means for Public Health



By MEREDITH McNAMARA, MD, MSc

WHEN PEOPLE THINK OF PUBLIC HEALTH, they often think of legislation or policies created by governing bodies who obtain input and research from scientists, stakeholders, and affected groups. What often gets overlooked, though, is how court cases can shape public policy. The recent *Braidwood Management Services Inc. v Becerra* case highlights what's at stake when outsized power over public health is placed in the hands of just a few unelected individuals.

Braidwood is one of nearly 2,000 legal challenges to the Affordable Care Act (ACA), but it is the first to involve religious objection to HIV prevention. Since the initial ruling in September 2022, awareness of this case and its implications has been a slow burn that has since culminated in a national outcry about threats to preventive health care. A less recognized aspect of this case is the harm caused by religious exemptions that stereotype LGBTQ+ people and target HIV prevention. According to the plaintiffs and the judge who ruled in their favor, (PrEP) is spelled with four scarlet letters that denote objectionable sexual behavior. Advocates for health justice can bring their expertise to bear in this case and in other legal actions that unscientifically interfere with health care.

What happened in this case

For those without a legal background, *Braidwood* is confusing. The basis of the lawsuit is that the plaintiffs, who are individuals and self-identified Christian small businesses, feel that preventive care mandates issued by the ACA are both unconstitutional and violate their religious freedom. In September 2022, Judge Reed O'Connor, a federal judge in Texas, ruled in favor of the plaintiffs, who challenged federal mandates that require private insurers to cover PrEP for HIV. Judge O'Connor specifically ruled that the preventive service requirement of the ACA was a violation of the Appointments Clause because members of the independent United States Preventive Services Task Force (USPSTF) were not accountable to the federal government.

This aspect of the ruling struck legal scholars as odd, with some describing reliance on the Appointments Clause as a convenient loophole for attacking preventive care. Further, Judge O'Connor also found that the requirement to cover PrEP violated the plaintiffs' rights under the Religious Freedom Restoration Act. In March 2023, Judge O'Connor's subsequent ruling issued "remedies" for the ruling. In this phase of the case, he struck down all USPSTF mandates and allowed the plaintiffs to deny employees PrEP coverage based on their religious beliefs. The ruling took effect immediately.

Several states issued statements affirming the importance of preventive care mandates and protection for PrEP access. The Department of Justice (DOJ) immediately filed an appeal in the Fifth Circuit Court of Appeals. The DOJ also requested that Judge O'Connor issue a partial stay in his own ruling while it was being heard on appeal. Judge O'Connor essentially stated that he did not have time to rule on the stay. So, the DOJ filed another motion for a partial stay, this time requesting the Fifth Circuit to temporarily block the lower court ruling from going into effect. On May 15, the Fifth Circuit Court of Appeals granted that stay, temporarily blocking the preventive services ruling from going into effect while it is being briefed at the higher court. It is unknown how quickly the Fifth Circuit will rule on the *Braidwood* case overall. Whatever the Fifth Circuit Court ruling ends up being, it is very likely that it will be appealed to the Supreme Court.

Sociopolitical climate surrounding bodily autonomy and standard health care

Braidwood is one of many instances of legal interference into standard health care that seem to be a new norm in American life. Two years before *Braidwood* was filed, *Dobbs v Jackson Women's Health Organization* hit the judicial circuit and ultimately led to the Supreme Court overturning abortion protections codified by *Roe v Wade*. Earlier this year, a suit called *Alliance for Hippocratic Medicine v Food and Drug Administration* was ruled on and led to the injunction of approval of mifepristone, which is commonly used in medication abortions. Parallel to these judicial actions, bans on abortion and gender-affirming care have rippled throughout state legislatures. Criminal punishments often accompany such bans for those who receive and provide care, as well as those who refer, transport, and support patients in need.

Invasive governmental actions cannot be advanced out of spite towards disfavored groups of people or for plainly ideological reasons. To land somewhat softly in public opinion, these actions must be justified. They are often done so with anti-science rhetoric and intentional misinformation.

Disinformation and bad science in *Braidwood*

The Department of Justice had barely mentioned the benefits of HIV prevention in early phases of *Braidwood* litigation. The initial *Braidwood* ruling sent shockwaves through LGBTQ+ news and health circuits but received little media attention elsewhere. Now that the remedies could strike down all preventive care mandates, our national consciousness seems dialed into the profound implications of this case. But we must not forget the disdain that this ruling espouses for the LGBTQ+ community and those at risk of HIV. As an adolescent medicine physician with clinical experience in preventing and treating HIV, a particular passage of Judge O'Connor's writing stung me deeply:

[The plaintiff] objects to providing coverage for PrEP drugs because he believes that (1) the Bible is "the authoritative and inerrant word of God," (2) the "Bible condemns sexual activity outside marriage between one man and one woman, including homosexual conduct," (3) providing coverage of PrEP drugs "facilitates and encourages homosexual behavior, intravenous drug use, and sexual activity outside of marriage between one man and one woman," and (4) providing coverage of PrEP drugs in Braidwood's self-insured plan would make him complicit in those behaviors.'

Judge O'Connor had done more than just chip away at the ACA. He endorsed LGBTQ+ stereotypes and stigma. He prioritized religious belief over fact. And, he neglected the compelling public health interests at stake. While opposition to same-sex intimacy may be one way to interpret Biblical text, it's not clear to me how PrEP access is related. There are data-driven arguments to debunk the *Braidwood* plaintiffs' implied assertion that access to PrEP leads to sex and drug use. And there are glaring instances of public health truths that were omitted from federal litigation about HIV prevention. To support further challenges to this ruling, these arguments and facts need to be resoundingly clear.

In reading deeply into this decision, precedents established by *Braidwood* could permit any employer to deny any type of coverage for religious reasons. Florida recently legalized anti-LGBTQ+ medical discrimination with the "Protections of Medical Conscience Act," which allows health care providers and payers to deny service based on ethical, moral, or religious beliefs. This law is the legislative realization of *Braidwood* and similar laws in other states may follow.

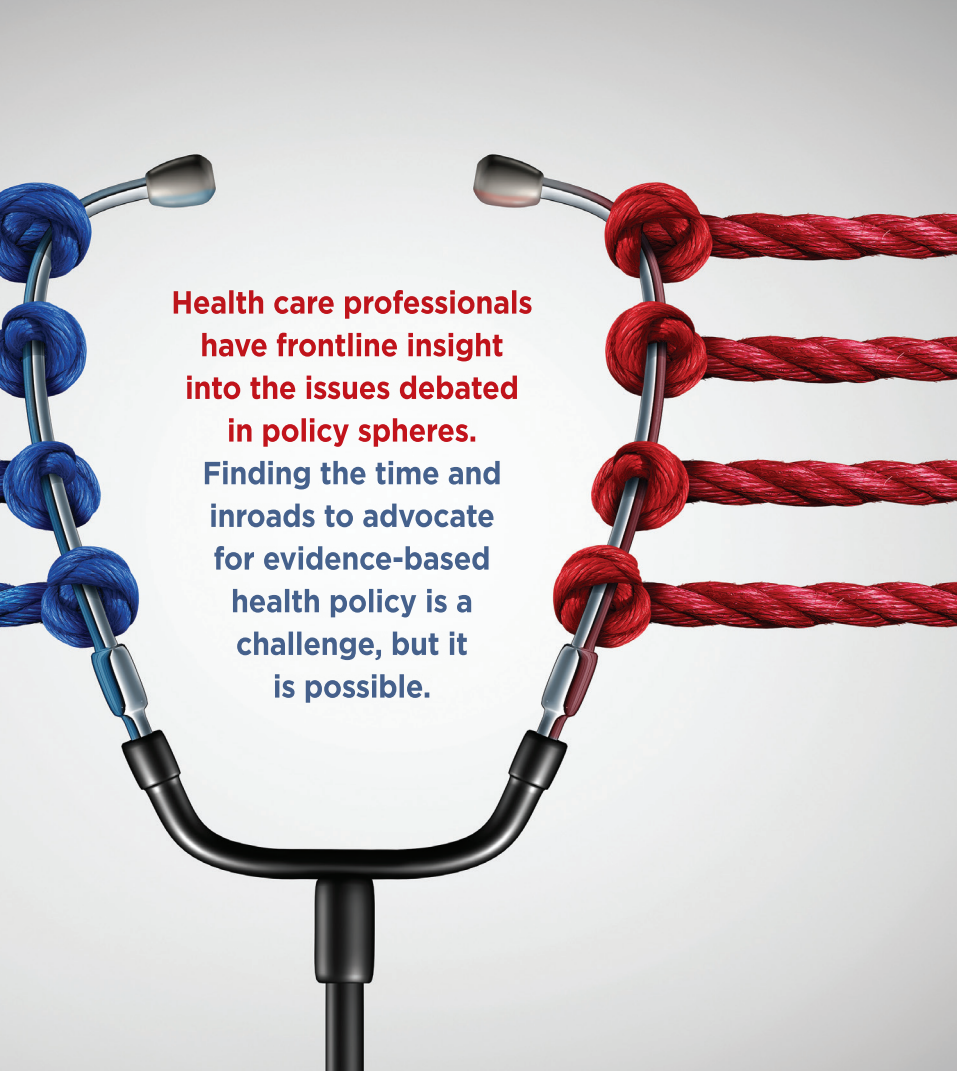
How to take action

Health care professionals have frontline insight into the issues debated in policy spheres. Finding the time and inroads to advocate for evidence-based health policy is a challenge, but it is possible. I helped assemble an interdisciplinary group of colleagues who took action to infuse discussion about *Braidwood* with scientific evidence and skepticism for the plaintiffs' positions.

Our work with *Braidwood* was a two-pronged approach: (1) a comprehensive and exhaustive report on the medical disinformation and legal problems with the ruling and (2) a modeled prediction of new HIV infections if cost-sharing of PrEP were to decrease.^{1,2} I have produced such reports before to compliment and support advocacy that protects access to gender-affirming care for transgender youth.^{3,4} These reports have been cited in litigation challenging bans on care, informed the media, and supported families. The primary goal of the report is to describe and dispel disinformation with extensive citations to the literature. The modeled prediction provided a conservative estimate of the number of infections which may result from a 10 percent reduction in cost-sharing from PrEP—over 2,000 new infections.

Our group included health care providers in adolescent medicine and internal medicine—two of whom are in the South—with specific experience in preventing and treating HIV. A legal scholar helped interpret the judicial decision and craft legally relevant arguments against the ruling. Experts in public health and health policy with career experience in HIV spoke to the population-level harms and grounded our analysis in a historical context.





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How health care providers can advocate and activate

Legal interference into the clinician-patient relationship and private decision-making will likely escalate in the coming years. Health care providers may not consider themselves activists, but many will not be able to tolerate the harms without acting. Those wishing to confront disinformation in health policy may draw some guidance from our group's work. First, everyone possesses a unique skillset—a series of strengths that lend themselves to advocacy in policy. Perhaps it's the ability to perform a thorough literature review, to write persuasively, to form interdisciplinary connections, to lead effectively, to speak authoritatively with non-expert audiences, to harness social media, or to describe lived experience. Before diving headfirst into the current climate, take a personal inventory of your strengths and feel empowered to showcase them.

Second, change happens through collaboration. Identify colleagues who have different strengths and skills, but similar values. Consider the various forces and fields that contribute to the well-being of your patients, whether it's public health, mental health, clinical medicine, policy, social work, business and industry acumen, or others. Keep your working group small enough to ensure accountability and ease of coordination but strike a balance with the need for diversity of expertise.

Third, establish values in your advocacy work to guide and inspire you. For our group, those values included education, intersectionality,

and community. We involve trainees in our work because they must be prepared to inherit the current sociopolitical landscape. We prioritize the experiences of those most harmed by disinforming health policy, including Black, Hispanic/Latino, and LGBTQ+ people. Our report contains extensive analysis regarding the harms of HIV and benefits of prevention in these vulnerable populations. Also, consider the needs and feedback of organizers and community advocates. Your work is a valuable opportunity to amplify their complimentary expertise. This level of insight and collaboration may be accomplished through shared authorship, solicited feedback on written products, and shared media platforms, to name a few.

Fourth, establish fluid and achievable goals. Consider your work a success if it is simply accomplished and if you maintain fidelity to your values. The well-being of activists and those in healing professions is strained in this climate. We wear ourselves down by establishing unattainable policy goals.

By providing our expertise in legal proceedings or during the development of state and/or federal legislation, providers can ensure clinical voices are heard. During this time of anti-science rhetoric and disinformation, it will take our collective voices to protect vulnerable populations, patient-provider autonomy, and public health overall. **HIV**

REFERENCES

1. Paltiel AD, Ahmed AR, Jin EY, et al. Increased HIV transmissions with reduced insurance coverage for HIV preexposure prophylaxis: potential consequences of *Braidwood Management v. Becerra*. *Open Forum Infect Dis*. 2023;10(3):ofad139. doi:10.1093/ofid/ofad139
2. McNamara M, Harsono D, Edelman EJ, Norwood A, et al. *Braidwood Misreads the Science: the PrEP Mandate Promotes Public Health for the Entire Community*. 2023. https://law.yale.edu/sites/default/files/documents/pdf/prep_report_final_feb_13_2023_rev.pdf
3. Boulware S, Kamody R, Kuper L, McNamara M, Oleszski C, Szilagyi N, Alstott A. *Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims*. 2022. Yale University. Accessed May 14, 2023. https://medicine.yale.edu/lgbtqi/research/gender-affirming-care/report%20on%20the%20science%20of%20gender-affirming%20care%20final%20april%2028%202022_442952_55174_v1.pdf
4. McNamara M, Abdul-Latif H, Boulware S, Kamody R, et al. *A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria*. 2022. Yale University. Accessed July 13, 2022. https://medicine.yale.edu/lgbtqi/research/gender-affirming-care/florida%20report%20final%20july%208%202022%20accessible_443048_284_55174_v3.pdf

MEANS AND METHODS

Four Ways to Help People with HIV Navigate the Unwinding of Medicaid Continuous Coverage

By MOLLY TASSO



IN EARLY 2020, Congress put protections into place for people enrolled in Medicaid to ensure that they were able to stay covered during the COVID-19 pandemic. Under this “continuous coverage requirement,” states were not allowed to disenroll Medicaid enrollees from the program. This meant that regular Medicaid eligibility renewals stopped and Medicaid rolls swelled to unprecedented numbers. States also received a bump in Medicaid funding as a way to offset additional costs.¹ As of April 1, 2023, and in recognition that the emergency phase of the COVID-19 pandemic has ended, this continuous coverage requirement is no longer in place. All states have begun “unwinding” the continuous coverage protection, a process that will take about 14 months to complete. In practice, this involves redetermining the eligibility of almost 93 million Americans enrolled into Medicaid, a herculean undertaking for state Medicaid offices.²

During the unwinding process, approximately 15 million people, including people with HIV (PWH), could lose coverage. While many individuals may lose coverage because they are no longer eligible for the program, an estimated 6.8 million will lose coverage because of out-of-date paperwork or for waiting too long to respond to requests for information from Medicaid, even though they are actually eligible. What’s more, an August 2022 report from the U.S. Department of Health and Human Services’ Assistant Secretary for Planning and Evaluation Office of Health Policy suggests Black and Latino individuals

During the unwinding process, approximately 15 million people, including people with HIV (PWH), could lose coverage.

will be disproportionately impacted by administrative churn, a worrying statistic that could further exacerbate existing health inequities.³

Access to health insurance goes hand in hand with improved health outcomes, including viral suppression, for PWH. Throughout the unwinding period, HIV providers will play an important role in supporting PWH to either successfully redetermine their Medicaid eligibility or enroll into alternate health coverage options.⁴

The following are four ways HIV providers can help patients remain enrolled in coverage and avoid experiencing gaps in care:

1 Understand state processes for Medicaid renewals

All states were required by the Centers for Medicare and Medicaid Services (CMS) to develop and make public a Medicaid renewal plan. In these plans, states outline their approach to a staggered unwinding and if they are prioritizing certain populations to redetermine earlier in the process.⁵ It will be important for providers and other people working directly with PWH to review publicly available state plans, and understand the process for conducting Medicaid renewals.

For Ryan White HIV/AIDS Program (RWHAP) funded providers, it will be helpful to know if and how a state's AIDS Drug Assistance Program (ADAP) is working with the state's Medicaid program to identify individuals who may be losing Medicaid eligibility and who are eligible for ADAP. In some states, PWH who are enrolled into Medicaid may not have a connection to the RWHAP.

Patients and providers should remain vigilant throughout the unwinding process and be sure to report problems to the Medicaid office. If questions or concerns arise—or something simply doesn't make sense—don't hesitate to reach out to the state Medicaid office.

2 Conduct outreach to patients and support enrollment into other coverage options

Inform patients enrolled in Medicaid about the ending of the Medicaid continuous coverage requirement and encourage them to confirm or update their contact information with their state Medicaid agency.

Remind patients to check their mail frequently for letters from their state Medicaid agency and respond promptly to requests for information. For patients who need to submit documentation as part of their Medicaid renewal, providers and other individuals who interact directly with PWH should help them in this process or link them to a case manager or benefit specialist who may be able to help.

3 Help eligible patients to identify other coverage options if they are no longer eligible for Medicaid

Patients who are no longer eligible for Medicaid should explore all available health coverage options, including Marketplace, employer-sponsored insurance, and Medicare coverage. People losing Medicaid coverage will be eligible for "Special Enrollment Periods," allowing them to enroll in other coverage outside of regular open enrollment windows. In addition, because of enhanced subsidies for Marketplace coverage, Marketplace plans could be available for very low cost based on income, making them an affordable option for individuals who are now over income for Medicaid.

Patients may need help making sense of their options and successfully completing enrollment, so be sure to provide referrals to enrollment assisters in your area. The goal is to avoid gaps in coverage and care and to ensure continuity of medication access for all RWHAP clients.

4 Educate enrollment networks about the RWHAP and the health coverage needs of PWH

Many patients transitioning off of Medicaid may not be connected to the RWHAP and may receive enrollment assistance from Navigator entities, Certified Application Counselors organizations, or State Health Insurance Program counselors, who specialize in Medicare enrollment. These enrollment assisters may or may not be familiar with the RWHAP and health coverage needs of PWH. To the extent possible, providers and other front line staff should engage with external enrollment entities in their area and make sure they are aware of the RWHAP, including the role of ADAP in supporting access to health coverage. **HIV**



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Health Resources and Services Administration HIV/AIDS Bureau-funded project that supports RWHAP recipients, subrecipients, and providers to help PWH enroll into and maintain health coverage, and ultimately improve health outcomes.

REFERENCES

1. Medicaid.gov. Unwinding and Returning to Regular Operations after COVID-19. Accessed May 10, 2023. <https://www.medicaid.gov/resources-for-states/coronavirus-disease-2019-covid-19/unwinding-and-returning-regular-operations-after-covid-19/index.html>
2. Medicaid.gov. January 2023 Medicaid & CHIP Enrollment Data Highlights. Accessed May 10, 2023. <https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html>
3. Office of the Assistant Secretary for Planning and Evaluation. *Unwinding the Medicaid Continuous Enrollment Provision: Projected Enrollment Effects and Policy Approaches*. U.S. Department of Health and Human Services. August 19, 2022. Accessed May 10, 2023. https://aspe.hhs.gov/sites/default/files/documents/404a7572048090ec1259d216f3fd617e/aspe-end-mcaid-continuous-coverage_IB.pdf
4. TargetHIV. Help Medicaid Clients Stay Covered and Avoid Gaps in Care. Updated April 24, 2023. Accessed May 15, 2023. <https://targethiv.org/blog/help-medicaid-clients-stay-covered-and-avoid-gaps-care>
5. Georgetown University Health Policy Institute Center for Children and Families. 50-State Unwinding Tracker. Published April 1, 2023. Updated May 9, 2023. Accessed May 15, 2023. <https://ccf.georgetown.edu/2023/04/01/state-unwinding-tracker/>

Protecting the 340B PROGRAM for Every Community

By Joe Dunn
and Vacheria Keys, JD

OVER 50 YEARS AGO, the federal government, as part of President Lyndon Johnson's war on poverty, started a new program with a simple question: Can locally governed health care organizations improve care for the underserved while lowering costs? Fast forward to today—the community health center movement has grown to over 1,400 mission-driven centers serving over 30 million patients, or one in 11 Americans.¹ They provide high-quality, affordable primary and preventative medical and dental care, behavioral health, and pharmacy services to individuals and families in medically underserved areas, regardless of insurance status or ability to pay. Health centers are the primary medical homes for some of the most vulnerable patients in the nation and U.S. territories, including over 200,000 individuals with HIV.² Needless to say, we believe the answer to that simple question from five decades ago is a resounding yes.

A major catalyst to the growth and success of health centers, along with federal grant funding, has been the 340B Drug Pricing Program (340B Program), which enables health centers, Ryan White Clinics, and other safety-net providers to stretch federal resources as far as possible. The 340B Program permits health centers to purchase outpatient medications at lower prices, which generates savings that health centers are then required to reinvest in activities that further the mission of improving patients' lives. Thanks to these resources, health centers can meet the unique needs of their communities and invest in services and programs not covered by reimbursement or other grant funding. The program is an essential tool for ending the HIV epidemic because it provides flexible funding for services and medications when grant funding falls short.

Today, we are left to ask another seemingly simple question: Can safety-net providers count on the 340B Program being around for the next 30 years to help serve their patients? The answer is “no” unless Congress steps in. Over the last three years, the shoestring budgets that health centers typically operate with are going into the red because of repeated assaults on the 340B program coming from every direction.



Health centers use contract pharmacies to ensure patients can more easily access drugs at nearby pharmacies. These arrangements are crucial given the difficulty health center patients may experience getting to specific pharmacies as well as the fact that just over half of all health centers can afford in-house pharmacies. Comparatively, nearly nine in 10 health centers rely on contract pharmacies, according to a survey from the National Association of Community Health Centers (NACHC).³ But these contract pharmacies are increasingly in the crosshairs.

Health centers have been caught in an ongoing tug-of-war with drug manufacturers (who want significant changes to the 340B Program) and large, well-resourced hospitals (who have little incentive to push for any changes). With nearly 10 drug manufacturers restricting access to 340B Program priced drugs at contract pharmacies, 24 percent of health centers estimate that HIV/AIDS treatments will be affected and patients who depend on these treatments will be harmed.⁴ If the contract pharmacy restrictions persist, health centers will be forced to cut wrap-around services as well as essential staff, such as community health workers, pharmacists, social workers, and navigators.⁵ A stable 340B Program is a critical component of public health; without it, medications and services are out of reach for the most vulnerable Americans.

Adding to the challenge are Pharmacy Benefit Managers (PBMs) who have taken advantage of the lack of federal oversight to siphon away savings from the health centers. Ostensibly, PBMs determine which pharmacies will be included in a prescription drug plan's network and how much said pharmacies will be paid for their services. The 340B Program does not protect health centers from this practice. Instead, health centers experience unpredictable fees, restrictive contracting terms, and aggressive auditing tactics to lower reimbursement. At the same time, PBMs take rebates from drug manufacturers on the same drugs they are taking from health centers' savings.

Countless lawsuits and administrative actions have had little effect on these practices, which is why NACHC's leadership decided

to act before it was too late. Operating on razor-thin margins, health centers cannot afford to wait another day for legislative solutions to protect their 340B Program savings permanently. This is why NACHC partnered with Pharmaceutical Research and Manufacturers of America (PhRMA) to form the Alliance to Save America's 340B Program (ASAP 340B). ASAP 340B is indeed an unlikely alliance that came about after safety-net providers and drug manufacturers saw a need to develop practical solutions to instill accountability and transparency in the program and ensure its long-term survival.

ASAP 340B has initially rallied behind ten core principles that address long-standing challenging issues. These principles represent policies that will improve the 340B Program for all participants. For example, the first principle is to ensure the program's intent is clear in the statute. The well-worn quote that the program is to enable covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" is from a Congressional report that is often cited but does not have the force of law. It also includes bedrock protections for contract pharmacy arrangements to ensure that the most vulnerable patients can access their medications without any hassle.

Moreover, another principle would migrate a key feature of the health center program—the sliding fee scale—to all 340B Program providers. ASAP 340B partners believe this is a vital element that will ensure sound use of resources and remove the unnecessary stress patients may feel about how they will afford their medication.

ASAP 340B represents a bold new approach designed to spur more conversations with 340B Program-covered entities, policymakers, and other stakeholders. We hope this effort generates ideas and is a way to build consensus around pragmatic solutions to protect the 340B Program as an essential public health tool. If successful, it would provide a decisive answer to the question above by providing stability and predictability for safety-net providers and their patients for the next 30 years. Anything less would leave health centers and others asking much more

difficult questions in the future, like how to serve their patients and keep their doors open. Let's not hope it comes to that. **HIV**



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REFERENCES

- 1 National Association of Community Health Centers. America's Community Health Centers. Published 2022. Accessed May 20, 2023. <https://www.nachc.org/research-and-data/americas-health-centers-2022-snapshot/>
- 2 Health Resources and Services Administration. Health Center Program Uniform Data System. 2022
- 3 National Association of Community Health Centers. 340B: A Critical Program for Health Centers. Published 2022. Accessed May 20, 2023. <https://www.nachc.org/wp-content/uploads/2022/06/NACHC-340B-Health-Center-Report--June-2022-.pdf>
- 4 Ibid.
- 5 Ibid.

Unintended Consequences

**California's New Law to Cover
STI Home Testing Kits will Leave
the Most Vulnerable Behind**

By Orlando Harris, PhD, RN, FNP, MPH, FAAN
and Tommi Gaines, DrPH, MS



PRIOR TO THE COVID-19 PANDEMIC, sexually transmitted infections (STIs) had been on the rise in the United States (U.S.). Further exacerbating the STI crisis, the pandemic upended public health efforts, such as STI contact tracing, case investigators, partner notifications, and treatment outreach, due to the redirection of financial resources and redeployment of the public health workforce. To combat rising infection rates, California enacted legislation on January 1, 2022: Senate Bill 306 (SB 306), also known as the STI Coverage and Care Act. This legislation made California the first state in the nation to require health care plans and insurers to cover the costs of home test kits for HIV and other STIs. SB 306 aims to reduce barriers to STI services, including HIV and STI testing, and expand access to services at home and in the community for patients and their partners.¹

SB 306 was enacted in response to the alarming and persistent rise in STI rates across the state of California over several years. Notably, from 2013 to 2019, national rates of chlamydia, gonorrhea, and syphilis rose more than 40 percent, with California bearing the highest number of infections.^{2,3} The Centers for Disease Control and Prevention (CDC) estimates that one in five people in the U.S. have an STI, with an estimated cost of \$16 billion for treatment. At the state level, STI treatment costs the California health care system an estimated \$1 billion annually.^{4,5} Young people (ages 15 to 24), sexual minorities, and certain racial and ethnic groups are particularly impacted by a significant burden of HIV and STIs. According to the CDC, in 2020, over half (53%) of the reported cases of chlamydia, gonorrhea,

and primary and secondary syphilis were among young people.^{4,6,8} Similarly, racial minority groups, such as African Americans and Hispanic/Latinx, accounted for a significant proportion of reported STI cases. Sexual minority men also experienced disproportionate rates of STIs, with gay and bisexual men accounting for 43 percent of primary and secondary syphilis cases.⁷

Prior to the passing of SB 306, efforts were already underway at the federal level to curb the HIV epidemic across specific regions in the U.S. In 2019, the U.S. Department of Health and Human Services launched a 10-year initiative, Ending the HIV Epidemic (EHE), with a goal of achieving 75 percent reduction in new HIV infections by 2025 and at least 90 percent by 2030.⁸ The EHE initiative leverages critical scientific biomedical advances to scale up key HIV prevention strategies, including HIV testing.⁸ The initiative focuses on 48 counties, eight of which are in California, with a high burden of HIV (defined as EHE jurisdictions) for targeted scale-up of HIV prevention and treatment interventions. The EHE Initiative focuses on four key strategies that include early *diagnosis* of all people with HIV, *treat* the infection rapidly to achieve viral suppression, *prevent* new HIV infections, and *respond* quickly to potential HIV outbreaks to get prevention and treatment services to people who need them.⁸ Adequate implementation of SB 306 would aid the state of California in achieving three of the four key strategies: diagnose, prevent, and respond.



Centering Communities: Intersection of Research, Health, and Public Policy

As researchers, community experts, and clinicians of color, we undertook the review and analysis of SB 306 to identify deficiencies in the written text and implementation of the law. This work was conducted as part of our larger policy research consortium, We the People: An HIV Policy Research Center that Works for All of California, funded by the California HIV/AIDS Research Program (H21PC3601). The consortium is comprised of community policy experts, academics, and clinicians. Our goal is to respond in real time to California's evolving HIV policy landscape by conducting rapid policy research and analysis. The work we conduct at the consortium centers communities by involving them in all aspects of our research. Often laws and policies are written and implemented without a thorough review and analysis of their impact on communities—more specifically, communities of color. Our research, often led by Black researchers, specifically focuses on the impact of HIV and tobacco policy on California's communities of color. As such, our policy research consortium was the ideal center to conduct the review of SB 306, which is buttressed by our collective expertise and lived experiences.

As researchers, clinicians, and community experts, we are intimately aware of the impact that rising HIV and other STIs have on Black and Latinx communities. Many of us are not divorced or far removed from the devastating impact of HIV on Black gay and bisexual men, Black transgender women, or Black heterosexual women. Some of our members also have intersecting identities (i.e., same gender loving, queer, Black or Latino) and have experienced these disparities directly. Therefore, our research on health disparities and inequality can help transform public health and policy to ensure that they are more equitable for all Californians. Our analysis of SB 306 is one example of our consortium's work.

SB 306 Implementation Challenges

When SB 306 was signed into law, excitement among advocates, community-based organizations and the general public was high since its intent was to make HIV and STI testing affordable and accessible for all Californians.⁹ For example, a comprehensive home STI test kit that is commercially available costs on average \$289 out of pocket, which is cost prohibitive, especially for young people, sexual minorities, and racial and ethnic minority groups. By requiring insurers to cover the costs of home test kits, financial

home test kits are defined as a product that allows individuals to self-collect specimens for HIV and other STIs in a remote location outside of a clinical setting. For test kits to be covered they must be approved or cleared by the U.S. Food and Drug Administration for home use and approved for waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). CLIA-waived tests are required to be simple to use and have a low risk of producing incorrect results. Other provisions that must be met before home test kits are covered by a health insurance plan include the requirement that home test kits be deemed medically

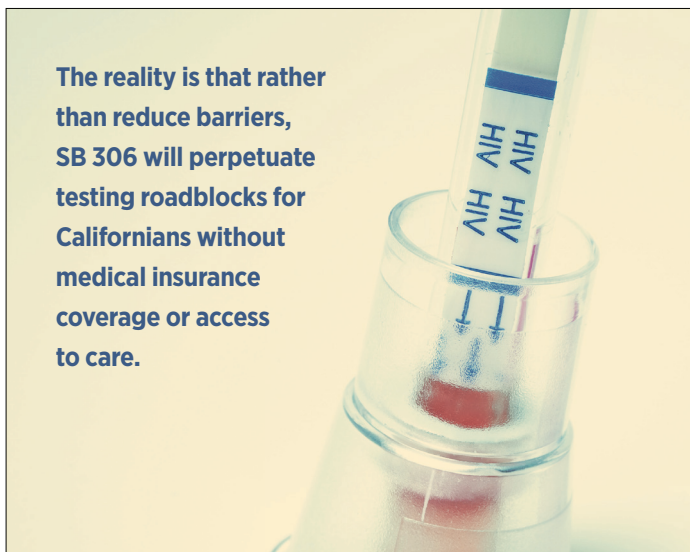
necessary or appropriate. The law also requires an in-network clinician's prescription or standing order for home test kits to be covered by a health insurance plan.

These two requirements are problematic since nearly one in 10 Californians are uninsured, and approximately five million Californians live in a health care desert or do not have a usual source of health care. The reality is that rather than reduce barriers, SB 306 will perpetuate testing roadblocks for Californians without medical insurance coverage or access to care. This means that the very groups

who are at highest risk of HIV and STIs will be the ones least able to access home testing under the new law. Our research demonstrates that many California counties exhibiting a high proportion of uninsured residents are also places with high HIV and STI rates. Several of these counties are health care deserts with limited clinicians to issue a standing order or prescribe at-home STI testing kits.

Indeed, the STI burden is not evenly distributed across the state of California.¹⁷ Infection rates disproportionately affect racial and ethnic minorities, youth, and gay and bisexual men, who often face barriers to accessing health care. Regrettably, these marginalized groups, along with other disadvantaged Californians, are at risk of being further marginalized by SB 306, which will widen existing health disparities.

The reality is that rather than reduce barriers, SB 306 will perpetuate testing roadblocks for Californians without medical insurance coverage or access to care.



barriers would be removed. Moreover, a key advantage of home STI testing is the ability to conduct screening in the privacy of one's own space. Multiple studies have found that higher screening uptake occurs when individuals are empowered to conduct at-home HIV and STI self-testing compared to clinic or lab-based testing.^{10,11} For many communities, especially those who experience higher rates of stigma and discrimination or have higher levels of medical distrust due to historical and contemporary mistreatment from the medical community, at-home testing might be a preferred option due to its convenience, ease of use, and privacy.¹²⁻¹⁵

However, after one year of implementation, we found parts of the legislation may unintentionally fuel California's STI epidemic, thereby widening disparities. Under the legislation,

Recommendations to Improve SB 306

For the implementation of SB 306 to reach the communities that are disproportionately impacted by HIV and other STIs, the California legislature will need to make several improvements. First, the legislature will need to remove the requirement that home test kits must be deemed medically necessary by an in-network clinician or furnished through a standing order for patient use. Second, there should be a scale-up of existing programs offering free STI home testing kits, which do not require a clinician's prescription and allow an individual to determine their medical necessity.

Other community organizations have successfully implemented STI home testing kits and do not require a prescription. Those programs also allow the individual to determine its medical necessity.^{16,17} For example, TakeMeHome is one such program that enables health departments to offer free in-home sexual health tests to individuals requesting a home-based kit.¹⁸ However, the service is limited to eligible zip codes. Expanding programs that offer home-based testing without the requirement for a prescription or a standing order to all Californians would address the key limitations of SB 306 and ensure that access

to home testing is equitable and effective in ending the HIV and STI epidemic in the state. Last, creating the necessary medical billing codes to enable California's public health insurance program, Medi-Cal, to initiate payment for home testing kits must be a priority. As of now, nearly six million Californians aged 12 to 64 years who are enrolled in Medi-Cal lack access to free home testing under SB 306.

Cutting-edge solutions are needed to stem the rising tide of new HIV and STI infections in California. SB 306 is one such solution, but its limitations will only make it a hindrance to change. Without any modifications, the law only ensures that Californians with a medical insurance plan living in areas with more health care providers will have access to home test kits, thereby disenfranchising uninsured people and Californians who reside in other parts of the state facing an acute shortage of health care. While the state legislatures' intentions with SB 306 were novel and innovative, it still leaves many behind.

As scientists and clinicians of color on the frontline of fighting the HIV epidemic, we were hopeful that getting an HIV and STI home test kit would be as easy as getting a free COVID-19 home test kit. But sadly, the good intentions behind SB 306 will only make things worse. It is not too late to amend the law. **HIV**



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As a trained biostatistician, her research utilizes statistical and spatial methodologies to address the physical, social, and structural context of health among overlooked and medically underserved populations. She is engaged in multiple projects that investigate prevention and treatment resources for substance use and infectious diseases, with a particular emphasis on Native American communities in the Southwest U.S.

REFERENCES

- California Legislative Information. SB-306 Sexually Transmitted Disease: Testing. October 5, 2021. Accessed May 30, 2023. https://leginfo.ca.gov/faces/billNavClient.xhtml?bill_id=20210220SB306
- California Department of Public Health. Sexually Transmitted Diseases Control Branch, State Summary Graphs and Tables. Accessed December 3, 2022. <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/STD-Data.aspx>
- Centers for Disease Control and Prevention. Sexually Transmitted Disease Surveillance 2020. Atlanta: U.S. Department of Health and Human Services; 2022.
- Weinstock HS, Kreisel KM, Spicknall IH, Chesson HW, Miller WC. STI prevalence, incidence, and costs in the United States: new estimates, new approach. *Sex Transm Dis*. 2021;48(4):207. doi: 10.1097/OLQ.0000000000001368
- Centers for Disease Control and Prevention. Incidence, Prevalence, and Cost of Sexually Transmitted Infections in the United States. Updated March 16, 2022. Accessed May 30, 2023. <https://www.cdc.gov/nchhstp/newsroom/fact-sheets/std/sti-incidence-prevalence-cost-factsheet.html#:~:text=CDC%E2%80%99s%20latest%20 estimates%20indicate%20that%2020%25%20of%20 the,nearly%202416%20billion%20in%20direct%20 medical%20costs%20alone>
- Centers for Disease Control and Prevention. HIV in the United States by Race/Ethnicity: HIV Incidence. Updated April 12, 2022. Accessed May 30, 2023. <https://www.cdc.gov/hiv/group/racialethnic/other-races/incidence.html>
- Center for Disease Control and Prevention. HIV by Age: HIV Incidence. Updated April 7, 2022. Accessed May 30, 2023. <https://www.cdc.gov/hiv/group/age/incidence.html>
- Centers for Disease Control and Prevention. About Ending the HIV Epidemic in the U.S. Initiative. Updated September 7, 2022. Accessed May 30, 2023. <https://www.cdc.gov/endhiv/about.html>
- Holmes JJ. California becomes first state to require insurance to cover the costs of at-home STD tests. *LGBTQ Nation*. January 15, 2022. Accessed May 20, 2023. <https://www.lgbtqnation.com/2022/01/california-becomes-first-state-require-insurance-cover-cost-home-std-tests/>
- Bluth R. With sexually transmitted infections soaring in California, new law pushes at-home tests. *Los Angeles Times* (Kaiser Health News). January 2, 2022.
- Fajardo-Bernal L, Aponte-Gonzalez J, Vigil P, et al. Home-based versus clinic-based specimen collection in the management of Chlamydia trachomatis and Neisseria gonorrhoeae infections. *Cochrane Database Syst Rev*. 2015;2015(9):CD011317. doi: 10.1002/14651858.CD011317.pub2
- Chernesky MA, Hook EW 3rd, et al. Women find it easy and prefer to collect their own vaginal swabs to diagnose Chlamydia trachomatis or Neisseria gonorrhoeae infections. *Sex Transm Dis*. 2005;32(12):729–33. doi: 10.1097/01.qlq.0000190057.61633.8d
- Gaydos CA, Dwyer K, Barnes M, et al. Internet-based screening for Chlamydia trachomatis to reach non-clinic populations with mailed self-administered vaginal swabs. *Sex Transm Dis*. 2006;33(7):451–7. doi: 10.1097/01.qlq.0000200497.14326.fb
- Cushman TA, Graves SK, Little SJ. Attitudes and preferences regarding the use of rapid self-testing for sexually transmitted infections and HIV in San Diego area men who have sex with men. *Open Forum Infect Dis*. 2019;6(3):ofz043. doi: 10.1093/ofid/ofz043
- Wood BR, Ballenger C, Stekler JD. Arguments for and against HIV self-testing. *HIV AIDS* (Auckl). 2014;6:117–26. doi: 10.2147/HIV.S49083
- California Department of Public Health, Center for Infectious Diseases. Sexually Transmitted Diseases, 2001–2018. STDs-by-Disease-County-Year-Sex.csv. Accessed May 30, 2023. <https://data.cdphs.ca.gov/dataset/stds-in-california-by-disease-county-year-and-sex>
- Melendez JH, Gilliams EA, Yu T, et al. Rapid uptake of testing for chlamydia, gonorrhea, and HIV from an online platform, April–October 2020. *Am J Public Health*. 2022;112(7):985–989. doi: 10.2105/AJPH.2022.306835
- Johnson MC, Chung R, Leung SJ, Edelstein Z, Yuan Y, Flavin SM. Combating stigma through HIV self-testing: New York state's HIV home test giveaway program for sexual minorities. *J Public Health Manag Pract*. 2022;28(2):174–183. doi: 10.1097/PHH.0000000000001138.

Fieldnotes from the PA Preceptorship Program

An interview with the first matched preceptor and mentee

INTERVIEWER: PA Preceptorship Program Director Angela Kapalko, PA-C, AAHIVS

INTERVIEWEES: Waverly Datner, PA student, and Gina Sabbatini, PA-C, AAHIVS

ANGELA KAPALKO, PA-C, AAHIVS, who heads the new PA Preceptorship Program for the Academy, recently sat down with PA student Waverly Datner, who was the first student matched with the program, and her preceptor, Gina Sabbatini, PA-C, AAHIVS. They discussed their experiences with the program and shared some insights for future matches. Below is an edited transcript of their conversation.

ANGELA: Welcome Waverly and Gina. Thanks for sharing your experiences. Let's jump into talking about the PA Preceptorship Program. How did you hear about it?

WAVERLY: I actually learned about it from you because you had given a couple of lectures in my class and you talked a little bit about your job. And I was like, "Oh, that sounds really cool, something I'd be interested in." And so I reached out because I started thinking about where I would want to do clinical rotations. At the time you said that you couldn't take a student, but you said there is a preceptorship in Memphis, Tennessee, if I'd be willing to do it there. Initially, I was like, "Oh, I'm definitely not going to Memphis, Tennessee." But then I thought about it some more and I thought it was something I would be really interested in. I felt like it'd be a good opportunity and thought that one month isn't that long. So, you put me in touch with Gina.

ANGELA: Gina, how did you hear about the program?

GINA: I first heard about it through the Academy's weekly email, I think, and I just clicked on the link and submitted my application.

ANGELA: What drew each of you to HIV? Was there any one particular thing that made you think, "Oh, that's interesting."?

WAVERLY: I feel like part of it has to do with the fact that it's not talked about much in my undergrad and graduate classes. The only time I ever heard about HIV was through an elective course that I took in undergrad about health disparities in medicine, which made me kind of frustrated and interested at the same time. I kept thinking that everyone should have to take this class; it shouldn't just be an elective. And then infectious diseases just in general are interesting to me. The main

reason why I'm interested in HIV medicine is because I feel like it's an area of medicine where I can do more than just treat patients. I can help make a difference for someone or for future patients. And I feel like that's always been my ultimate goal with going into medicine—to make health care better in general.

I feel like it's a space where patients tend to be put in more vulnerable positions because of stigma, and my goal has always been to make patients feel super comfortable and like they're in a non-judgmental zone and that they can come to me with anything.

GINA: So out of undergrad I went into clinical research, and I did clinical research like drug trials and drug studies for about six years. I then decided I wanted to do more for treating patients and following my own patient panel. So then I went to PA school. So being a PA was not my first career.

In PA school, during my clinical rotations, I did three months in family medicine, pediatrics, and OB-GYN care with a Federally Qualified Health Center (FQHC). During that time, I was precepted by clinicians who were practicing HIV medicine there. So that's how I got into it.

Then, after PA school, I got hired on with that FQHC. I worked there for five years, but within the first few months of me being there, they needed a specialty provider in HIV medicine. So I volunteered, and the rest is history. August will be seven years as a practicing PA, and almost the whole time doing HIV medicine. And now at St. Jude it's mainly HIV medicine, and then some clinical research and other infectious diseases stuff and PrEP. But primarily HIV.

ANGELA: So the two of you...tell me how this setup works. Gina, what was the process like



Gina Sabbatini, PA-C, AAHIVS



Waverly Datner, PA student

before Waverly showed up? And what was the process for getting Waverly as a mentee?

GINA: The biggest thing for our particular situation is that St. Jude is such a huge institution, and with any rotation or preceptorship there has to be a contract agreement between the school and the program. So that took months, and I think a big part of it getting finalized was because Waverly and I were really pushing for it and Waverly's professor was pushing for it. A whole team at St. Jude was instrumental in getting the contract expeditiously finalized in the days leading up to Waverly's start date.

WAVERLY: The challenging part was that getting the agreements signed was out of our control. It was kind of just a waiting game. But once you put me in touch with Gina and my professor told me it was fine for me to do it, it was super easy on our parts just to talk about the various details, like starting hours and things like that. But it was just a waiting game until the legal teams told us we had the go ahead. Some of the difficulties were because St. Jude is such a big hospital, and my program did not have an affiliation already in place. I'm the first student from my PA program to ever go there for a rotation.

GINA: Yeah, which is super exciting. Now that we have the affiliation agreement, it's

good for one year, so we should be able to more readily accept additional students from that PA Program.

ANGELA: Yeah, it's kind of like these are some of the things that we're still learning and moving our way through so we can really continue to build this preceptorship program. How long were you guys emailing back and forth before your rotation?

WAVERLY: I reached out at various points from the time that I said I wanted to do it to leading up to the day before I started.

GINA: So that was probably like weeks to months. But then, as it got closer, I gave Waverly my cell phone number so she could text with questions or whatever came up.

ANGELA: Let's talk about the rotation. How did it go?

WAVERLY: I thought everything went really well. Everyone was super nice and friendly, which is what I was expecting for being a pediatric hospital. I mainly worked with Gina, but I also got to work with the NPs, the other PAs, nurses, social workers, and psychologists, which was super cool because they do a multi-disciplinary approach to things. That was honestly one of my most favorite parts, getting to see that collaboration for the

patients. I got to sit in with the social worker at one point and see that relationship. I got to present some patients in their clinical rounds, which includes the doctors as well. But yeah, once I felt comfortable, I could see patients on my own and do the chart on my own, which was awesome. I feel like I had a little bit more autonomy in that sense than I've had in previous rotations.

GINA: Yeah, I thought it went pretty well, coming from an FQHC and practicing primary care. Here at St. Jude our patient volume is less, which I think is good because I have more time to spend with each patient and to discuss differentials, treatment plans, and such with students or trainees.

Patients in our HIV clinic are currently managed by four practitioners – two PAs and two NPs. Our supervising physicians are always available for consult and present for clinical rounds. So Waverly really was able to go in with the other practitioners and among the four of us I think she got enough exposure.

Our clinic is not a traditional pediatric rotation. We have a few babies and a few younger kids, but most of our patients are teens, adolescents, and young adults.

ANGELA: Gina, was the preceptorship manageable for you?

GINA: Yeah, I think it was totally manageable. And we do have a multi-disciplinary team. They were all very open and willing to have her come in and chat.

ANGELA: What can this program do better? What can we help with before the rotation begins? Would it be helpful to have didactics or webinars to watch or listen to before you get to the rotation? Gina, is there anything that you can foresee?

WAVERLY: So I had a 15-hour drive and I listened to podcasts about HIV just to kind of get my mind thinking about it, because, like I said, I feel like I haven't had a ton of exposure to it. And something else, just to sidetrack to what you were saying previously is I've never seen a provider talk about PrEP in any of my rotations. And now in hindsight, I'm like, "How is that possible?" Because I realize how easy it is to do and it makes me want to do it no matter where I end up.

Anyway, I listened to some podcasts, which were kind of helpful. But I don't know how much I would have done to prepare if I didn't have that 15-hour drive, because I was coming right out of my ER rotation and then transitioning into this pediatric rotation.

Maybe one thing that would have been helpful would be a list of common diagnoses seen in people with HIV, because I was surprised to see the amount of syphilis that we saw. And STIs in general. I wasn't expecting that, and I feel like maybe if I had brushed up on those things that would have prepared me a little bit better.

GINA: Before Waverly's rotation started, I think I shared with her just some common resources that are out there. Like the Department of Health and Human Services clinical guidelines, the National HIV Curriculum, etc. But those are so detailed and so in depth. I think something like the Academy's online courses for Women and HIV that are pretty brief would be helpful for students. Knowing the diagnostic testing for HIV, first line treatment options—because we rarely have anybody that's not on a first line treatment option—STIs and the Centers for Disease Control and Prevention's guidelines for those treatments.

ANGELA: Any last comments? Anything that was really interesting that you'd like to share?

About the PA Preceptorship Program

To bring more PAs into HIV medicine, the Academy began the PA Preceptorship Program, which connects PAs in their clinical year with PA specialists for rotations in underserved care, sexual health, and HIV prevention and treatment. The goals of the program are to increase the number of PAs in HIV prevention and treatment, to give PA students the opportunity for rotations that their programs may not offer, and to help new PA graduates in networking.

We are looking to connect even more PA students with practicing PAs. For students to qualify, they should be in their didactic year of their PA program (ideally). They also should have an interest in public health, sexual health, underserved care, or HIV prevention and treatment. Students will receive direct mentorship and training

from an HIV Specialist, a free copy of the Fundamentals of HIV Medicine, and free membership to AAHIVM for a year after graduation.

Preceptors can be any PA HIV Specialist in the country. Preceptors will receive a \$500 stipend, a free membership to AAHIVM for a year, and an unsurpassed opportunity to train the next generation of HIV specialists. Together we can ensure the health care workforce shortage doesn't happen and that current and future patients can be well served for their sexual health and HIV care needs, from prevention to treatment.

If you are interested in precepting or you are a student interested in connecting with a preceptor, please contact Angela Kapalko at PAPreceptorship@aahivm.org.

WAVERLY: What I would want people to know about doing a rotation like this is that we saw all types of patients: infants, children, adolescents, some adults, and some pregnant people. Some were male, female, transgender, gender fluid. We saw everything. And I think that if a stranger were in the room with us, they wouldn't even necessarily know sometimes that the patient had HIV, which was super cool for me to experience and something that I would want other people to realize.

ANGELA: And what about a career like this in the future?

WAVERLY: Yeah, definitely. That's part of the reason why I wanted to do it, to see if I could do it in the future. It definitely confirmed that I would want to. I really, really liked it, and it just felt rewarding. The one thing that I loved is that the patients were so comfortable telling Gina anything.

GINA: Sometimes they got pretty comfortable talking with Waverly, too.

WAVERLY: But to me, it was so awesome because, like I was saying earlier, I just would never want someone to feel scared or embarrassed about anything. So it was super special, and I really liked it.

ANGELA: That's excellent. Thank you guys so much for participating in the PA Preceptorship Program and for being our first match. **HIV**



ANGELA KAPALKO, PA-C, AAHIVS, practices at Philadelphia FIGHT Community Health Centers, an FQHC in the heart of downtown Philadelphia, Pennsylvania. Angela

worked to formalize the education program at FIGHT for Advanced Practice Clinician (APC) students, specifically NP and PA students. As the main preceptor for all APC students, she organizes student schedules with other clinicians, coordinates didactic programs for the students, and coordinates rotations at the other health centers at FIGHT.

GINA SABBATINI, PA-C, AAHIVS, currently practices HIV Medicine in the Hughes Infectious Diseases Clinic at St. Jude Children's Research Hospital in Memphis, Tennessee. Gina previously served as HIV Lead Clinician at West Tennessee's largest Federally Qualified Health Center. Ms. Sabbatini has regularly precepted and served as mentor to PA, NP, and medical students throughout her career and is passionate about decreasing stigma and ending the HIV epidemic through clinician education. She currently serves as Preceptor and Mentor for the Academy's PA Preceptorship and Mentoring Programs, respectively.

WAVERLY DATNER is a second-year PA student at Saint Joseph's University in Philadelphia, Pennsylvania. She grew up in Havertown, Pennsylvania, and received her undergraduate degree from Ithaca College in Ithaca, New York. She will be graduating this August and is eager to see what the future holds as she begins her PA career.

Dr. Wilbert Jordan

IN APRIL, THE HIV COMMUNITY LOST A PIONEER AND ICON IN HIV/AIDS CARE, Wilbert C. Jordan, MD, MPH. Dr. Jordan spent his extensive career working on behalf of those with HIV/AIDS as well as those who are underserved in health care and society. He made significant contributions, both nationally and internationally, and leaves behind a legacy of service, mentoring, and providing the highest levels of care for all people.

Dr. Jordan was Professor Emeritus at Charles R. Drew University of Medicine and Science and the founder of the OASIS Clinic in Los Angeles, Calif. He was also a longtime advisor of the Academy through the Public Policy Committee and through various ad hoc advisory councils on topics important to HIV care access, especially among Black and other minoritized communities who are disproportionately affected by HIV. Previously, he served as the past Associate Dean and Director, Office of Post-Graduate Medical Education, Charles R. Drew University of Medicine and Science. Prior to that, he was an Instructor in Human Sexuality and Preventive Medicine at Howard University, School of Medicine, in Washington, D.C.

In 1966, Dr. Jordan graduated from Harvard College and went on to receive his MD in 1971 from Case Western Reserve University School of Medicine. He then completed an internship and junior residency in internal medicine at Beth Israel Hospital. He was a Robert Wood Johnson Clinical Scholar and in 1976 earned a master's in public health at the University of California, Los Angeles. Afterward, he completed rotations in internal medicine and infectious diseases. From there, his work in HIV/AIDS began, essentially at the very beginning of the epidemic.

According to an excerpt from the Encyclopedia of Arkansas, Dr. Jordan stated: "I treated my first patient [with AIDS] in 1979, but I didn't know what he had. And



when the CDC report came out in 1981, I called him back and I told him, 'I think I know what you have now.'" From that first encounter through the time of his death, Dr. Jordan worked tirelessly on behalf of those with HIV/AIDS. He quickly realized that stigma against the communities most at risk for HIV kept them from accessing needed health care.

That was the impetus for his establishing the AIDS Clinic at King-Drew Medical Center in 1984 (later called the OASIS Clinic). The care he provided there was revolutionary.

He not only wanted to provide treatment and medications, but he also sought to address the socioeconomic impacts on health, such as food insecurity, insufficient housing, and bias against the LGBTQ community and other minority groups.

He also was committed to serving the Black community, which is still disproportionately impacted by HIV. In 1985, he contributed to the Report of the Secretary's Task Force on Black and Minority Health. As well, he served as the director of the Minority AIDS Project and chaired the Black Los Angeles AIDS Consortium.

Throughout his career, he received numerous awards and recognitions, including the Surgeon General's Award in 2000, the Black AIDS Institute Hero in the Struggle award in 2001, and the B.E.T. Community Service Pioneers Award in 2002. He also was honored with the Bishop Leontine T.C. Kelly Award for Courage in 2013, the Better Brothers Los Angeles Advocate Award in 2015, and the Legacy Award by Charles R. Drew University in 2017. **HIV**

New Recommendations for Infant Feeding for Parents with HIV in the U.S.

What the Care Team Needs to Know

Release Date: July 3, 2023 | Expiration Date: October 3, 2023

This accredited continuing education activity is jointly provided by



and



FACULTY: William R. Short, MD, MPH, AAHIVS, and Elizabeth D. Lowenthal, MD, MSCE

TARGET AUDIENCE: This activity is intended for frontline providers of care to persons at risk for or who are living with 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 goal of this article is to help members of the frontline HIV care team to be better able to:

- Describe changes in the Perinatal HIV Guidelines released January 31, 2023.
- Explain the science and the social context that supports those changes.
- Work with your team to implement the new guidelines in the care of your patients.



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New Recommendations for Infant Feeding for Parents with HIV in the U.S.

What the Care Team Needs to Know

BY WILLIAM R. SHORT, MD, MPH, AND ELIZABETH D. LOWENTHAL, MD, MSCE

Case

A 27-year-old cisgender female with HIV presents for a routine follow-up visit. She is currently taking emtricitabine/tenofovir alafenamide and dolutegravir and has been on her current regimen since her diagnosis three years ago. Her HIV-1 viral load is suppressed and has been for the last two and a half years. She brings her husband in and they would like to discuss plans to have a child within the next year, and she is interested in breastfeeding. How do you best counsel her on infant feeding?

Introduction

Choosing what to feed their infant is one of the most important decisions new parents have to make. The decision can be complicated by mixed messages from care team members who are uncomfortable talking about infant feeding for people with HIV (PWH). In general, pregnant people are often told that “breast is best” since breastfeeding offers numerous benefits to both the infant and the mother. Breast milk is designed to meet the nutritional needs of a growing baby,

containing a perfect balance of proteins, carbohydrates, fats, and antibodies that support the baby’s optimal development and immune function. Breastfed infants are less likely to suffer from respiratory and ear infections and sudden infant death syndrome (SIDS); later in life they are at lower risk of asthma, allergies, and obesity than formula-fed infants.¹⁻⁶ Breastfeeding also has benefits to the mother (See Table 1) and promotes bonding between mother and child.⁷ Strong early bonding can have long-lasting positive effects on the child’s emotional and social development.

HIV Transmission through Breastmilk in the Pre-ART Era

Early guidelines released by organizations in the United States (U.S.) discouraged breastfeeding for PWH for good reason. Prior to the availability of antiretroviral therapy (ART), the risk of HIV transmission via breastmilk was high. For those with established infection, an average of 14 percent (95% CI, 7%–22%) transmitted HIV to the infant via breastfeeding.⁸ Risk can be even higher under specific circumstances. For example, based on a meta-analysis, the frequency of HIV transmission during acute seroconversion was estimated to be 29 percent (95% CI, 16%–43%).⁹

In 1992, a randomized clinical trial conducted in Nairobi compared HIV acquisition in breastfed versus formula fed infants born to women with established HIV. The primary outcome was HIV-1 transmission in each arm during the first two years of life. For the primary analysis, 401 mother-infant pairs were included in the analysis. The median duration of breastfeeding was 17 months. The cumulative probability of acquiring HIV at 24 months was 36.7 percent (95% CI, 29.4%–44.0%) in

Table 1.
Breast Milk Feeding Considerations for People with HIV

Health Benefits	Infant: Lower risk of infants developing asthma, obesity, Type 1 diabetes, severe lower respiratory disease, otitis media, sudden infant death syndrome, gastrointestinal infections, and necrotizing enterocolitis. Breastfeeding parent: Decreased risk of hypertension, Type 2 diabetes, and breast and ovarian cancers.
Equity Considerations	Black women are disproportionately affected by HIV. People of color experience a greater burden of many health conditions that may be mitigated by breastfeeding.
Cultural Considerations	Environmental, social, familial, and personal pressures to breastfeed. Fear that not breastfeeding would lead to disclosure of their HIV status.

the breastfeeding arm and 20.5 percent (95% CI, 14.0%-27.0%) in the formula feeding arm ($p=0.001$; prevalence of breast milk transmission 16.2% (95% CI, 6.5%-25.9%)).¹⁰

Does U=U Apply to Breastfeeding?

The concept of undetectable equals untransmittable (U=U) is well established for sexual transmission of HIV when a person with HIV has an undetectable HIV viral load for more than six months.¹¹ If a person conceives on ART with an undetectable HIV viral load and maintains that undetectable viral load through pregnancy and delivery and the infant receives postnatal prophylaxis, perinatal HIV transmission is virtually zero.¹² While many small studies of breastfeeding women on suppressive ART have shown no HIV transmissions, others have shown that a few transmissions still do occur with an average rate of HIV transmission of 0.3 percent at six months and 0.6 percent at 12 months.¹³ With an average of three infants of every thousand acquiring HIV with six months of breastfeeding, it cannot be said that U=U in this context.

In women who are not on ART, infant prophylaxis during breastfeeding can protect against transmission, but it is also not 100 percent effective. A 14-site randomized open-label clinical trial with 2,431 mother-infant pairs, Promoting Maternal Infant Survival Everywhere (PROMISE), was conducted in women with HIV with CD4 counts > 350 cells/mm³ and their breastfed newborns who were born without HIV. They were randomized six to 14 days postpartum to receive either ongoing maternal ART (mART) or a daily dose of infant nevirapine prophylaxis (iNVP), and that continued until breastfeeding cessation, infant HIV transmission, toxicity, or 18 months' postpartum. Not all mothers maintained full viral suppression. In the mART arm, seven of 1,219 (0.57%) analyzed infants acquired HIV and seven of 1,211 (0.58%) analyzed infants in the iNVP arm acquired HIV (hazard ratio 1.0, 96% repeated confidence interval 0.3-3.1).¹³ Either mART or iNVP resulted in rates of transmission of approximately six per 1000, with a median period of breastfeeding of 16 months. To date, no study has been powered to determine whether combining maternal ART and infant ART can lower the risk further.

Current U.S. Guidelines

Acknowledging that the risk of transmission of HIV through breastmilk can be made very low with modern ART and that there are compelling benefits, in January 2023, the U.S. Department of Health and Human Services (HHS) perinatal HIV guideline panel released their annual update. For the first time, they do not recommend a specific feeding choice for people with well-controlled HIV.¹⁴ With an emphasis on education about risks and benefits of feeding options, there is now a focus on patient-centered, shared decision-making around infant feeding choices.



Many gaps persist in our knowledge regarding how to best support PWH who choose to breastfeed their infants in order to mitigate risks and maximize benefits. For the breastfed infants, key areas to stress during decision-making include:

- Maintaining viral suppression postpartum is more challenging for some parents; studies have shown high rates of maternal viremia in the postpartum year.¹⁵
- "Mixed feeding" with breastmilk and formula (or other foods) may increase the risk of HIV transmission over exclusive breastfeeding.
- We do not know the extent to which adding infant prophylaxis may further decrease risk of transmission in the context of continuous maternal suppressive ART.

With regards to mixed feeding, in the pre-ART era, the risk of transmission of HIV through breastfeeding was up to 11 times higher in infants exposed to both breastmilk and infant formula or solid foods compared to those who were exclusively breastfed.⁷ However, the extent to which mixed feeding may increase the risk of HIV transmission compared with exclusive breastfeeding when the breastfeeding parent is on suppressive ART is uncertain. Exclusive breastfeeding beyond six months of age is rare since older infants require complementary foods. Thus, results of the meta-analysis of breastfed infants with mothers on ART showing rates of transmission of 0.3 percent at six months and 0.6 percent at 12 months suggest that for older infants adding complementary foods does not multiply risk as it did in the pre-ART era. These results cannot be extrapolated to the newborn period when gut permeability is higher and establishment of the intestinal microbiome is strongly influenced by inclusion of formula in the diet.¹⁶

Antiretroviral Prophylaxis for Newborns

There is no consensus on antiretroviral (ARV) prophylaxis for breastfeeding infants of PWH with sustained viral suppression. Even in the absence of breastfeeding, the duration of postpartum prophylaxis has become controversial due to the lack of data comparing shorter versus historically accepted rates of infant prophylaxis. Most HHS perinatal HIV guideline panel members agreed on adopting the British HIV Association recommendation of only two weeks of infant zidovudine (ZDV).¹⁷ However, several Panel members prefer to maintain a duration of ZDV prophylaxis of four to six weeks. For longer durations of prophylaxis during breastfeeding, nevirapine (NVP) has a better side effect profile than ZDV and is similarly effective.¹⁸ Infant prophylaxis approaches range from no prophylaxis as long as maternal suppression is maintained, to daily prophylactic NVP dosing, or three-drug prophylaxis throughout breastfeeding. Prophylaxis decisions may change throughout the time of breastfeeding, depending on maternal circumstances (e.g., the presence of cracked nipples, mastitis, or maternal missed

medication doses may prompt consideration of adding or increasing infant prophylaxis). Thus, ongoing discussions between the care team and parents are key to ongoing collaborative decision-making.

Child Protective Services

The new HHS guidelines specifically state that “parents’ feeding choice alone is not a reasonable justification for involving child protective services (CPS) for persons with HIV who want to breastfeed.” While HIV can be a serious health concern, it is not the only important consideration driving feeding choices. When a breastfeeding parent is effectively managing her HIV through medication and regular medical care, and has received appropriate counseling on breastfeeding precautions, it is **not necessary** to involve CPS. Instead, supporting the mother’s informed decision to breastfeed and providing ongoing health care support with collaboration between maternal providers, infant providers, and a lactation consultant, can ensure that both receive the benefits of breastfeeding while effectively mitigating the risk of HIV transmission. It is essential to recognize that CPS involvement has disproportionately impacted marginalized populations, including people of color and PWH, and can result in punitive rather than supportive actions.¹⁷ While CPS exists to protect children at true risk of abuse and neglect, it is not a natural partner in the promotion of the well-being of the breastfeeding child with well-informed and engaged parents with HIV.

Counseling and Management

An interprofessional team consisting of HIV providers, pharmacists, lactation consultants, pediatricians, obstetricians, nurses, and counselors provides comprehensive information and guidance to PWH regarding the benefits and risks of breastfeeding as well as data on risk-mitigation. Table 2 highlights key recommendations that need to be included in the counseling. The team collaborates to ensure that parents have accurate and up-to-date information about the transmission risks associated with breastfeeding, the role of ART, and strategies to minimize transmission risk while promoting infant health. Table 1 highlights infant feeding considerations.

New Recommendations for Infant Feeding for Parents with HIV in the U.S.

ASSESSMENT QUESTIONS

1. JL is a cisgender female with well controlled HIV (on a stable ART regimen with a suppressed HIV-1 viral load for the past three years) who is currently 16 weeks pregnant and would like to exclusively breastfeed for six months. You discuss that the risk of transmission from breastfeeding would be?
 - A. 0%
 - B. <0.1%
 - C. <1%
 - D. 5%
2. All of the following are essential components that should be included when counseling a person with HIV who has decided to breastfeed EXCEPT?
 - A. Maintenance of HIV-viral suppression is essential.
 - B. Child protective services are often helpful when a parent decides to breastfeed their newborn.
 - C. It is unknown to what extent infant prophylaxis further decreases HIV transmission risk in the context of maternal ART.
 - D. It is essential to have a team approach with maternal and infant providers working with parents to provide guidance and support for breastfeeding people living with HIV.
3. Which of the following statements regarding the Promoting Maternal Infant Survival Everywhere (PROMISE) study is CORRECT?
 - A. There was no difference in HIV transmission risk between those who received maternal ART or infant prophylaxis.
 - B. There were no HIV transmissions in the group that received both maternal ART and infant prophylaxis.
 - C. All mothers maintained viral suppression throughout the study.
 - D. The study was powered to determine whether combining maternal ART and infant ART could lower the risk of HIV transmission

Table 2. Key Recommendations on Infant Feeding for Individuals with HIV

Key Recommendations

- People should receive evidence-based, patient-centered counseling to support shared decision-making about infant feeding. This counseling should ideally occur prior to conception.
- Replacement feeding with formula or banked pasteurized donor human milk is recommended to eliminate the risk of HIV transmission through breastfeeding when people with HIV are not on ART and/or do not have a suppressed viral load during pregnancy (at a minimum throughout the third trimester), as well as at delivery.
- Individuals with HIV who are on ART with a sustained undetectable viral load and who choose to breastfeed should be supported in this decision.
- Individuals with HIV who choose to formula feed should be supported in this decision. Providers should ask about potential barriers to formula feeding and explore ways to address them.
- Engaging child protective services or similar agencies is not an appropriate response to the infant feeding choices of an individual with HIV.

Case Resolution

The patient and her husband were counseled by her HIV provider during her routine medical visit and their desires and intentions for breastfeeding were discussed. Additionally, they received counseling about the risks and benefits of breastfeeding. She was referred to the perinatal nurse manager for a discussion about the management of her infant after delivery. The pharmacist reviewed her ART regimen and took a detailed medication history, including any use of over-the-counter medications and recommended that she begin a prenatal vitamin with folic acid. The pediatric HIV provider and the hospital team were informed of the feeding plan and the pediatrician further reinforced benefits, risks, and risk-mitigation strategies. She had an uncomplicated pregnancy and delivered a healthy baby boy. After engaging in shared decision-making with her care team, she received early support to promote exclusive breastfeeding at the birth hospital and breastfed exclusively for six months with the support of her team, which included her pediatrician, case manager, and a lactation consultant.

Conclusions

In conclusion, the approach to breastfeeding in the context of HIV has evolved over time, reflecting a more nuanced understanding of the risks and benefits involved. While breastfeeding carries a potential low risk of HIV transmission, exclusive formula feeding carries a different set of risks. A comprehensive approach aims to balance the nutritional and immunological benefits of breastfeeding with the need to minimize the risk of HIV transmission. By providing ongoing support and monitoring, the care team can help PWH make informed decisions about breastfeeding that consider their individual circumstances and prioritize the health and well-being of both individuals. **HIV**



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REFERENCES

1. Kuznetsova A, Sood N, Spinazzola R, et al. Breast is best? The influence of breast feeding campaigns on NICU mothers who exclusively breastfeed compared to mothers who are unable. *Pediatrics*. 2020;146 (1_MeetingAbstract):137–139.
2. Brines J, Billeaud C. Breast-feeding from an evolutionary perspective. *Healthcare*. 2021;9(11):1458.
3. Horta BL. Breastfeeding: investing in the future. *Breastfeeding Med*. 2019;14(S1):S–11.
4. Yasmeen T. Benefits of breastfeeding for early growth and long term obesity: a summarized review. *Int J Med Sci Diagnosis Res*. 2019;3(1):44.
5. Thompson J, Tanabe K, Moon RY, et al. Duration of breastfeeding and risk of SIDS: an individual participant data meta-analysis. *Pediatrics*. 2017;140(5):e20171324.
6. Li R, Dee D, Li CM, et al. Breastfeeding and risk of infections at 6 years. *Pediatrics*. 2014;134 (Suppl 1):S13–20.
7. Weaver JM, Schofield TJ, Papp LM. Breastfeeding duration predicts greater maternal sensitivity over the next decade. *Dev Psychol*. 2018;54(2):220–227.
8. Van de Perre P, Simonon A, Msellati P, et al. Postnatal transmission of human immunodeficiency virus type 1 from mother to infant—a prospective cohort study in Kigali, Rwanda. *N Engl J Med*. 1991;325:593–598.
9. Dunn DT, Newell ML, Ades AE, et al. Risk of human immunodeficiency virus type 1 transmission through breastfeeding. *Lancet*. 1992;340(8819):585–588.
10. Nduati R, John G, Mbori-Ngacha D, et al. Effect of breastfeeding and formula feeding on transmission of HIV-1: a randomized clinical trial. *JAMA*. 2000;283(9):1167–1174.
11. Okoli C, Van de Velde N, Richman B, et al. Undetectable equals untransmittable (U = U): awareness and associations with health outcomes among people living with HIV in 25 countries. *Sexually Transmitted Infections* 2021;97:18–26.
12. Mandelbrot L, Tubiana R, Le Chenadec J, et al. No perinatal HIV-1 transmission from women with effective antiretroviral therapy starting before conception. *Clin Infect Dis*. 2015;61(11):1715–1725.
13. Flynn PM, Taha TE, Cababasy M, et al. Prevention of HIV-1 transmission through breastfeeding: efficacy and safety of maternal antiretroviral therapy versus infant nevirapine prophylaxis for duration of breastfeeding in HIV-1-infected women with high CD4 cell count (IMPACT PROMISE): a randomized, open-label, clinical trial. *J Acquir Immune Defic Syndr*. 2018;77(4):383–392.
14. 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*. HIV.gov. Updated January 31, 2023. Accessed June 15, 2023.
15. Adams JW, Brady KA, Michael YL, et al. Postpartum engagement in HIV care: an important predictor of long-term retention in care and viral suppression. *Clin Infect Dis*. 2015;61(12):1880–7.
16. O'Sullivan A, Farver M, Smilowitz JT. The influence of early infant-feeding practices on the intestinal microbiome and body composition in infants. *Nutr Metab Insights*. 2015;8(Suppl 1):1–9.
17. Department of Health and Human Services. *Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection*. HIV.gov. Updated April 11, 2023. Accessed June 21, 2023.
18. Font SA, Berger LM, Slack KS. Examining racial disproportionality in child protective services case decisions. *Child Youth Serv Rev*. 2012;34(11):2188–2200.

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CAROLYN CHU, MD, MSC, AAHIVS

AAHIVM Chief Medical Officer

FEATURED LITERATURE:

Griesel R, Zhao Y, Simmons B, et al. Standard-dose versus double-dose dolutegravir in HIV-associated tuberculosis in South Africa (RADIANT-TB): a phase 2, non-comparative, randomised controlled trial. *Lancet HIV*. 2023 May 22;S2352-3018(23)00081-4. PMID: 37230101.

This single-site study examined week 24 virologic outcomes among 108 adults receiving standard-dose dolutegravir-based ART and rifampicin-based antituberculosis therapy. Participants were either ART-naïve (81%) or first-line ART interrupted (19%), and on rifampicin-based therapy for less than three months. Participants received either supplemental dolutegravir 50mg or placebo (taken 12 hours after 300mg TDF plus 300mg 3TC plus 50mg DTG). Standard tuberculosis therapy with rifampicin, isoniazid, pyrazinamide, and ethambutol was administered for the first two months, followed by isoniazid plus rifampicin for four months; supplemental dolutegravir or placebo was continued for two weeks after antituberculosis therapy was stopped. Plasma samples were also collected for dolutegravir trough concentrations and dried blood spots for tenofovir diphosphate. Overall, 43/52 (83%) receiving supplemental dolutegravir vs. 44/53 (83%) receiving placebo had viral load < 50 copies/mL at week 24. Among ART-naïve participants, 36/43 (84%) in the supplemental dolutegravir arm vs. 36/42 (86%) in the placebo arm had VL < 50 copies/mL. In participants with prior first-line interrupted ART, 7/9 (78%) in the supplemental dolutegravir arm vs. 8/11 (73%) in the placebo arm had VL < 50 copies/mL. Overall, 6/9 (67%) and 5/9 (56%) of participants in the supplemental dolutegravir arm and placebo arm, respectively, had VL 50-999 copies/mL. In the 19 participants with protocol-defined virological failure, no treatment-emergent INSTI resistance mutations were detected up to week 48. No significant differences were observed with regard to Grade 3 and 4 adverse events.

AUTHOR'S COMMENTARY

Findings from this randomized trial add to prior retrospective cohort, dose-ranging, and pharmacokinetic studies which suggest that twice-daily dolutegravir dosing with rifampicin-based antituberculosis therapy may not be necessary. These observations may be particularly valuable for resource-limited settings with high prevalence of HIV and tuberculosis. However, because this study was not powered for formal between-arm efficacy comparison, further trials (e.g. phase three) and/or large cohort analyses may be needed to prompt changes in established guidelines and clinical practice. Future studies should also include people with prior ART treatment (who may or may not have NRTI and/or INSTI resistance associated mutations) to help generalize these findings even further.

FEATURED LITERATURE:

Marks KM, Kang M, Umbleja R, et al. Immunogenicity and safety of Hepatitis B vaccine with a Toll-like Receptor 9 Agonist Adjuvant (HEPLISAV-B) in HBV Vaccine-naïve People with HIV. *Clin Infect Dis*. 2023 Apr 5; ciad201. PMID: 37017075.

ACTG A5379 (BEe-HIVe) is an international, multicenter open-label study examining use of a recombinant HBsAg vaccine adjuvanted with CpG 1018 (HepB-CpG) in people with HIV who were non-responders to prior HBV vaccination (Group A) and people with HIV who have no known prior HBV vaccination (Group B). This study describes Group B seroprotective humoral responses and safety outcomes. The study enrolled adults with negative HBsAg, anti-HBc, and anti-HBs; on ART with CD4 ≥ 100 cells/mm³ and HIV-1 RNA < 1000 copies/mL; and no co-occurring chronic kidney disease stage G4/G5, cancer diagnosis within the previous five years (except resolved Kaposi Sarcoma and designated skin cancers), use of immunosuppressive agents, and pregnancy or breastfeeding. Three doses of HepB-CpG were administered at weeks zero, four, and 24; serum anti-HBs measurements were taken at each study visit. Out of 75 participants, 68 had complete data for analysis: all 68 (100%) achieved seroprotection at four weeks after the three-dose vaccine series, and of these 88% had anti-HBs > 1000 mIU/mL. The seroprotection rate was 98.5 percent at week 24, prior to the third dose. One or more related adverse events were experienced by 61 percent—the highest was Grade 1 in 39 percent, Grade 2 in 20 percent, and Grade 3 malaise in one participant. Vaccination site pain (40%), malaise (26%), fatigue (23%), myalgia (22%) and headache (22%) were the most common. Post-vaccine fever occurred in three percent. All participants who experienced an adverse event subsequently reported recovery/resolution.

AUTHOR'S COMMENTARY

The Hepatitis B Virus Infection section of the Department of Health and Human Services Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV indicates that if a two-dose HBV vaccine is preferred, HepB-CpG is an option (CIII). For this investigation, a three-dose schedule was selected due to “known challenges with HBV vaccination response in PWH.” Although 100 percent seroprotection was achieved four weeks after three doses of HepB-CpG, 98.5 percent had seroprotective titers after two doses, a response similar to that observed in registrational trials which utilized a two-dose schedule in immunocompetent adults. Authors note that certain populations, such as people with chronic kidney disease, may benefit from additional doses of HepB-CpG. Further, while anti-HBs ≥ 10 mIU/mL is the generally recognized correlate for seroprotection, the antibody level achieved is associated with duration of maintenance of antibody titers above the seroprotective threshold (and therefore higher peak antibody levels may be desired). Group B participants are being followed to determine the durability of response after three doses.

FEATURED LITERATURE:

Moodley D, Lombard C, Govender V, et al. Pregnancy and neonatal safety outcomes of timing of initiation of daily oral tenofovir disoproxil fumarate and emtricitabine pre-exposure prophylaxis for HIV prevention (CAP016): an open-label, randomised, non-inferiority trial. *Lancet HIV*. 2023 Mar;10(3): e154-e163. PMID: 36746169.

CAP016 was an open-label trial conducted at a single hospital-based research site in Durban. Eligible pregnant adults at 14–28 weeks' gestation at time of enrollment were assigned to either immediate PrEP initiation during pregnancy or deferred PrEP initiation at breastfeeding cessation. Enrollment started in September 2017 but was stopped in December 2019 when South Africa's PrEP guidelines expanded to include pregnant people in the national roll-out. Five hundred and forty women were ultimately enrolled (271 randomized to immediate PrEP and 269 to deferred PrEP). Median timing for PrEP start in the 'immediate initiation' group was 19 weeks' gestation, with median time on study from randomization to delivery of 19.7 weeks. Mean calculated adherence was 87 percent at four weeks, 93 percent at eight weeks, 94 percent at 12 weeks, and 95 percent at 16 weeks after PrEP initiation—nausea and vomiting in the first month (11%) as well as headache (14%) were reported as reasons for missed doses. Immediate PrEP initiation was not associated with preterm birth or small for gestational age birth. Investigators were unable to determine non-inferiority for less frequent outcomes (e.g., very preterm birth, low birthweight, very low birthweight, and stillbirth). No renal function abnormalities were observed. Four maternal HIV seroconversions were observed: three in the immediate PrEP group between 27 weeks and 35 weeks gestation, and one in the deferred PrEP group at 32 weeks gestation. All four neonates tested negative for HIV within 14 days of birth.

AUTHOR'S COMMENTARY

These study findings add to existing evidence suggesting that tenofovir disoproxil fumarate and emtricitabine can be safely used in pregnancy, specifically that PrEP initiation does not increase occurrence of preterm birth, small for gestational age, or any adverse pregnancy outcome. Participants did not experience renal toxicity (changes in maternal and infant bone mineral density, and infant growth parameters will be reported separately). Of note, nausea/vomiting and headache were relatively common after PrEP initiation—these may be important considerations when offering PrEP to pregnant people and also during early follow-up assessments of medication tolerability and adherence. As providers gain experience with PrEP and pregnancy, best and promising practices regarding HIV testing, timely communication with labor and delivery units, and postpartum/postnatal follow-up (including breastfeeding considerations) should be identified and disseminated.

FEATURED LITERATURE:

Hill LA, Abulhosn KK, Yin JF, Bamford LP. Single-center experience evaluating and initiating people with HIV on long-acting cabotegravir/rilpivirine. *AIDS*. 2023 March 15; 37(4): 605-609. PMID: 36730069.

This retrospective analysis describes a single-center's experience evaluating individuals who expressed interest in cabotegravir/rilpivirine (CAB/RPV). Patients received care at a Ryan White-funded, HIV primary care clinic affiliated with an academic institution. The center's protocol involved referral to the pharmacy team for clinical assessment to determine appropriateness of CAB/RPV consideration, additional work-up as indicated, insurance coverage assessment, patient education (this included discussion of the oral lead-in option), and CAB/RPV initiation. If a baseline or prior resistance test was available and the patient had maintained viral suppression, no resistance testing was conducted. By contrast, if no prior resistance testing was available, a proviral DNA resistance test was pursued regardless of prior ART and viral suppression history. Three hundred and eighty-three individuals were referred for evaluation and had a definitive decision about whether to transition to CAB/RPV between April 2021 to June 2022; 201/383 (52.5%) ultimately initiated CAB/RPV. Univariate analyses indicated that patients initiating CAB/RPV were younger, more likely to be on a two-drug regimen, and less likely to be on a multi-class or PI-based regimen. Reasons for not initiating CAB/RPV included inconsistent clinic attendance or difficulty contacting the patient (19.8%), patient decision (18.7%), previously known (15.4%) or newly identified (12.1%) NNRTI resistance, detectable viral load (8.2%), incomplete resistance work-up (8.2%), insurance coverage challenges or out-of-pocket cost concerns (7.1%), previously known (2.7%) or newly identified (1.6%) INSTI resistance, active hepatitis B (2.2%), or other reasons (3.8%).

AUTHOR'S COMMENTARY

These results describe the largest cohort to date of people referred for CAB/RPV evaluation and initiation in a real-world clinical setting. Just over half of those referred ultimately transitioned to the new combination; among people who did not initiate CAB/RPV, reasons varied across both clinical and logistical considerations. Patient choice was the second most common reason for not initiating CAB/RPV among this center's population, an observation that warrants further exploration as noted by authors. Authors also indicate their experience suggests that "use of proviral DNA resistance testing may be an important tool to avoid potential virologic failures when switching [patients] to CAB/RPV." **HIV**



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