

THE AMERICAN ACADEMY OF HIV MEDICINE ■ SPRING 2023

HIV

SPECIALIST

Getting to Status Neutral



The Status Neutral Revolution

Status Neutral Care in Primary Care

Rapid Start Programs

Need PrEP? Don't Forget the Pharmacists

HIV Criminalization Laws and the Status
Neutral Approach

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Executive Director, AAHIVM

The Many Facets of Status Neutral Care

THERE'S A LOT OF EXCITING AND OPTIMISTIC TALK in public health circles and within federal government agencies around "HIV status neutral care," a whole-person approach centered on comprehensive sexual health, and it's a concept and approach that closely aligns with the national Ending the HIV Epidemic goals, as reported here by Dr. Demetre Daskalakis, Director of the Division of HIV Prevention at the Centers for Disease Control and Prevention.

In his article, Dr. Daskalakis shows how, with a status neutral approach, a person goes to see their medical provider and they are tested for HIV and discuss risk factors and other sexual health considerations, but the HIV test result is no longer an all-or-nothing proposition. If the test comes back positive, they discuss with their provider the appropriate treatment regimen for them and start as soon as possible. As we know from U=U science, once viral suppression has occurred after

taking treatments, that HIV infection stops with them. Partners are protected and the individual health of that patient soars to a basically normal prognosis.

And if the test is negative, the patient or client talks with their provider about prevention options that may be right for them. It's possible that they start taking PrEP, at which point they would be totally protected from HIV. (It's fitting here that existing PrEP formulations are also used in HIV treatment regimens as well.) The point is to facilitate rapid treatment start and PrEP uptake where appropriate (in addition to other prevention and sexual wellness measures), normalize and de-stigmatize HIV care, testing and prevention, and effectively scale up this approach in the clinic and in public health systems with an eye towards ending new transmissions.

It's important to underscore potential pitfalls too, and there's understandable concern in the community about status neutral as an approach in parts of the country that continue to effectively criminalize HIV, as discussed here in the article by Deirdre Johnson and Kamaria Laffrey. The takeaway isn't that a status neutral framework won't work in these places, necessarily, but rather that more anachronistic advocacy work needs to be done in those states to remove any criminal stigma from one's HIV status before such an approach can be fully embraced by clients fearing prosecution as potential fallout from something as simple as a medical test.

In this issue, we're also thinking about status neutral care within the context of a full care-team approach, and we have articles by Jessi Truelove, PharmD, and Elizabeth Camper, PharmD, and a CE-accredited article by Kendrick Ware, PharmD, underscoring the important role of the pharmacists in reaching underserved communities with PrEP services and access, as well as a look at state-based legislation around pharmacists' scope of practice and their ability to prescribe for PrEP and PEP, and what the whole care team needs to know in those places. Also, in the 'At the Forefront' column this month, we will feature our first of four articles on the Academy's PA Preceptorship Program, with the first discussing the ways that PAs can help mitigate physician workforce shortages in HIV and specifically how the PA Preceptorship Program is working to train the next generation of PAs in HIV medicine.

It's important to remember here that the Academy is broadly representative of the full HIV care team, and all the medical professions that comprise this critical model of interdisciplinary care, and that each component of this care team will have a key role to play in the hopeful scale-up of HIV status neutral care. Effectively ending the HIV epidemic in the United States will require engagement from all the pieces of the care system to make sure that we can support and ally with the federal government in our work, and our members are, as always, at the forefront of this movement.

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

Researcher Workbench

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.

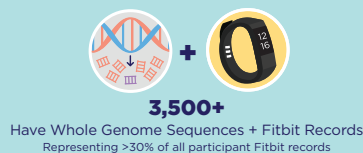
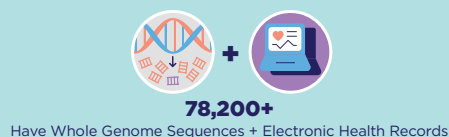
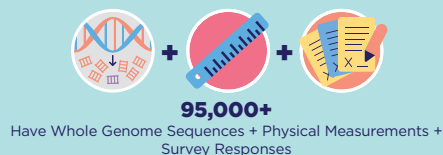
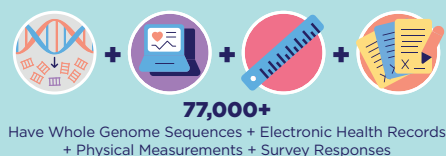


Data From

329,000+ Participants



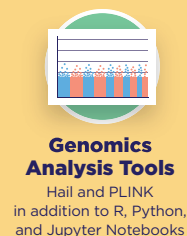
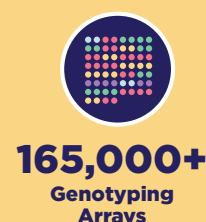
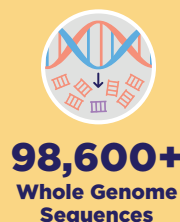
Genomic Data is Paired with Rich Phenotypic Data



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.



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



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.



IN THE NEWS

Janssen and Global Partners to Discontinue Phase 3 Mosaico HIV Vaccine Clinical Trial

Independent, scheduled review of Phase 3 Mosaico study finds investigational vaccine regimen lacks efficacy in preventing HIV
No vaccine-related safety issues identified

THE JANSSEN PHARMACEUTICAL COMPANIES of Johnson & Johnson, together with a consortium of global partners, [on January 18, 2023] announced the results of an independent, scheduled data review of the Phase 3 Mosaico study (also known as HPX3002/HVTN706) of Janssen's investigational HIV vaccine regimen. The study's independent Data and Safety Monitoring Board (DSMB) determined that the regimen was not effective in preventing HIV infection compared to placebo among study participants. No safety issues with the vaccine regimen were identified.

In light of the DSMB's determination, the Mosaico clinical trial will be discontinued. Participant notifications and further analyses of the data are underway. Throughout the trial, study investigators have ensured that any individuals who contracted HIV received prompt HIV treatment and care.

"We are disappointed with this outcome and stand in solidarity with the people and communities vulnerable to and affected by HIV," said Penny Heaton, MD, Global Therapeutic Area Head, Vaccines, Janssen Research & Development, LLC. "Though there have been significant advances in prevention since the beginning of the global epidemic, 1.5 million people acquired HIV in 2021 alone, underscoring the high unmet need for new options and why we have long worked to tackle this global health challenge. We remain steadfast in our commitment to advancing innovation in HIV, and we hope the data from Mosaico will provide insights for future efforts to develop a safe and effective vaccine. We are grateful to our Mosaico partners and the study investigators, staff, and participants."

About the Phase 3 Mosaico Study

Mosaico, a Phase 3 study of Janssen's investigational HIV vaccine regimen, began in 2019, and completed vaccinations in October 2022. The study included approximately 3,900 cisgender men and transgender people

who have sex with cisgender men and/or transgender people, who represent groups and populations vulnerable to HIV, at over 50 trial sites in Argentina, Brazil, Italy, Mexico, Peru, Poland, Puerto Rico, Spain, and the United States.

The study evaluated an investigational vaccine regimen containing a mosaic-based adenovirus serotype 26 vector (Ad26.Mos4.HIV) administered during four vaccination visits over one year. A mix of

soluble proteins (Clade C/ Mosaic gp140, adjuvanted with aluminum phosphate) was also administered at visits three and four.

The Mosaico DSMB analysis, based on the data available to date, indicated that the regimen does not protect against HIV and the study is not expected to meet its primary endpoint. No safety issues with the vaccine regimen were identified. In light of this, the study will be discontinued, and further analyses are underway.

The DSMB's determination follows the primary analysis of the Phase 2b Imbokodo study, which was announced in August 2021 and found that a similar investigational HIV vaccine regimen did not provide sufficient protection against HIV in a population of young women in sub-Saharan Africa. The investigational vaccine regimen used in the Imbokodo study was found to have a favorable safety profile.

The Mosaico study was led by a global public-private partnership including the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), the HIV Vaccine Trials Network (HVTN), the U.S. Army Medical Research and Development Command (USAMRDC), and Janssen Vaccines & Prevention B.V. Since 2005, Janssen Vaccines & Prevention B.V. has been participating as a sub-grantee in the NIH-supported Integrated Preclinical/Clinical AIDS Vaccine Development (IPCAVD) program under grants AI066305, AI078526, AI096040, and AI128751 (Principal Investigator, Prof. Dan Barouch).



Report Challenges Court Decision on PrEP and Public Health

A NEW REPORT from a team of medical, public health, and legal experts challenges a federal court decision ruling it unconstitutional to mandate employer-sponsored insurance coverage of pre-exposure prophylaxis (PrEP), a highly effective biomedical measure for preventing HIV. The decision, the authors show, fails to address the scientific evidence, slights the compelling public interest in HIV prevention, engages in invidious stereotyping of LGBTQ people, and creates a loophole by which employers could deny insurance coverage for nearly any medical condition for any group whose conduct is disfavored by a religious belief.

The report, “*Braidwood Misreads the Science: the PrEP Mandate Promotes Public Health for the Entire Community*,” was issued on Feb. 13, 2023, by co-authors Meredith McNamara, MD, MSc (Yale School of Medicine); Dini Harsono, MSc (Yale School of Public Health); E. Jennifer Edelman, MD, MHS (Yale School of Medicine); Aliza Norwood, MD (University of Texas at Austin Dell Medical School); Samantha V. Hill, MD, MPH (University of Alabama at Birmingham); A. David Paltiel, PhD, (Yale School of Public Health, Yale School of Management), Gregg Gonsalves, PhD (Yale School of Public Health); and Anne Alstott, JD (Yale Law School).

“Our goal with this report is to inform litigation and policy with scientific evidence that demonstrates the compelling public interest in unfettered access to PrEP,” said McNamara. “PrEP is an extremely valuable preventative currently benefiting many individuals who are at risk for HIV.”

In September 2022, a federal district judge in Texas ruled in favor of plaintiffs challenging the federal mandates that require private insurance policies to cover PrEP, a class of medications that is highly effective in preventing HIV infection. PrEP has been celebrated as a major success

in the global fight to end HIV, and the United States Preventive Services Task Force (USPSTF) recommends PrEP as evidence-based care to promote HIV prevention. Federal law requires most private insurers to cover preventive care that are strongly recommended by the USPSTF.

The Texas lawsuit, *Braidwood Management v. Bexerra*, granted two separate legal challenges to the PrEP mandate. First, the court held that the process for appointing the USPSTF violated the Appointments Clause of the U.S. Constitution. Plaintiffs have requested a nationwide injunction, which could invalidate all preventive care mandates issued by the USPSTF, including cancer screenings, immunizations, and medications that treat diabetes and help control cholesterol.

Second, the judge ruled that the PrEP mandate violates the plaintiff’s rights under the Religious Freedom Restoration Act (RFRA). The owner of Braidwood had alleged that “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 [that] providing coverage of PrEP drugs in Braidwood’s self-insured plan would make him complicit in those behaviors.”

Several medical societies, including the American Medical Association and the American Cancer Society, have emphasized

the importance of USPSTF mandates for public health. The new report adds a focus on PrEP and argues that the *Braidwood* decision disregards the compelling state interest in HIV prevention via private insurance and fails to consider the state’s compelling interest in LGBTQ equality.

The co-authors produce new empirical evidence to show that the public health consequences of a nationwide injunction

against the PrEP mandate would be serious and adverse. They found that if PrEP coverage among men who have sex with men is reduced from its current base value of 28 percent to 10 percent, the result would be an expected additional 2,083 new HIV infections (up from a base of 28,200 infections) in the coming year. This is a conservative estimate, the authors explain, and does not take into account the detrimental effect to other communities.

Additionally, the report shows that the decision constructs a religious exemption that rests on unfounded empirical assertions. As framed, the exemption could open a legal loophole for nearly any business to deny insurance coverage on religious grounds, since courts cannot reliably distinguish between sincere and insincere religious beliefs.

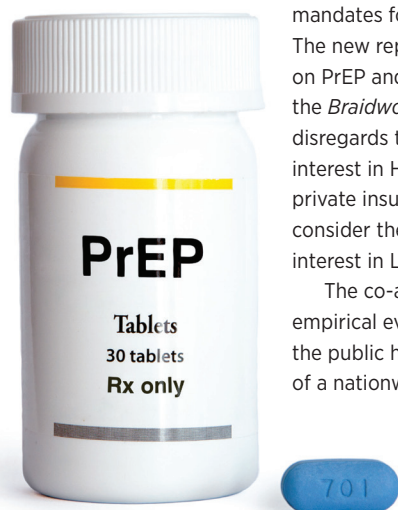
“The *Braidwood* exemption is dangerously permissive and discriminatory. As framed, it could permit nearly any business to claim a religious exemption and opt out of virtually any type of preventative measure or health care,” said Alstott.

According to the report, scientific evidence shows that the state has a compelling public interest in enforcing the PrEP mandate, which benefits everyone as a public health measure, much like a vaccine. But the decision frames PrEP as a niche treatment that only benefits some individuals.

“Behaviorally vulnerable populations including youth and LGBTQIA+ people, as well as heterosexual people living in the Southern U.S., will be particularly harmed by the *Braidwood* ruling, which has the potential to further worsen disparities in HIV in this region of the country,” said Hill.

The impact of the decision in the Texas case is not limited to individuals who take PrEP, the authors warn. “If the *Braidwood* court decides to adopt an injunction against the PrEP Mandate and to grant a religious exemption to PrEP insurance coverage, the *Braidwood* decision will undermine public health for all,” they write.

To read the report, visit: https://law.yale.edu/sites/default/files/documents/pdf/prep_report_final_feb_13_2023_rev.pdf



IN THE NEWS

Update to Clinical Guidelines for Infant Feeding Supports Shared Decision Making

Clarifying Breastfeeding Guidance for People with HIV

HHS HIV CLINICAL PRACTICE GUIDELINES now incorporate breastfeeding options for people with HIV on antiretroviral therapy with sustained undetectable viral load (levels of virus in the blood).

People with HIV (PWH) who are considering conception, are pregnant, or in the postpartum period should receive evidence-based counseling to support decision making about infant feeding. The updated guidelines note that:

- The risk of postnatal HIV transmission to an infant is zero with the use of safe replacement feeding. Properly prepared formula or pasteurized human donor milk from a milk bank eliminates risk of HIV transmission to the infant.
- The risk of HIV transmission while breastfeeding is less than one percent (but not zero) for PWH on antiretroviral therapy (ART) with sustained undetectable viral load through pregnancy and postpartum.
- Clinicians should support the choices of people with HIV to breastfeed (if they are virally suppressed) or to formula/replacement feed.
- It is inappropriate to engage Child Protective Services (CPS) or similar services in response to infant feeding choices of PWH.

Due to the potential of HIV transmission in human milk, previous clinical guidelines in the United States did not recommend breastfeeding for individuals with HIV in the United States.

The 2023 guidelines update integrates community input and recent evidence-based data. Together, this information demonstrates increasing interest in breastfeeding among PWH and their providers, quantifies the risk

of HIV transmission for PWH who are virally suppressed (<1%), and recognizes that restricting breastfeeding may increase the inequities that already exist for many women with HIV. These inequities include health risks (e.g., obesity, diabetes, reproductive cancers) and/or access to safe water and formula. Research demonstrates maternal and infant health benefits from breastfeeding include bonding, nutritional gains, and immunologic support; breastfeeding is congruent with many community norms and



cultural traditions.

Additional updates to the guidelines include revised and reorganized content and some revised section titles. See all updates on the [ClinicalInfo.HIV.gov](https://clinicalinfo.hiv.gov) website.

The NIH Office of AIDS Research Advisory Council (OARAC) advises the OAR Director, NIH Director, HHS Secretary and Assistant Secretary for Health. OARAC responsibilities include coordinating five working groups, also known as panels, to develop HIV clinical practice guidelines that are disseminated publicly at [CLINICALinfo.hiv.gov](https://clinicalinfo.hiv.gov).

The HHS Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal

Transmission in the U.S. ("Perinatal Panel"), led by academic and NIH experts, includes approximately 40 voting members with lived experience and expertise in managing the care of pregnant persons with HIV, with specialties in obstetrics, gynecology, infectious diseases, women's health, community perspectives, maternal pharmacology, and perinatal HIV transmission prevention.

The panel included community input in the development and revision process of the infant feeding guidelines, and specifically reached out to community partners to gather feedback. In collaboration with the HHS Pediatric Antiretroviral Panel, the HHS Perinatal Panel aimed to balance the low risk of transmission with strong community desire to breastfeed, acknowledging community concerns and the desire for bodily autonomy, while promoting a greater focus on shared decision making. The guidelines are structured to address the care of all pregnant individuals with HIV, their infants, and people who are trying to conceive.

Note: The term "breastfeeding" is used to describe feeding a child one's own milk (either direct feeding or with expressed milk). When counseling individuals with HIV about infant feeding, it is important to assess and use their preferred terminology; some transgender men and gender-diverse individuals may prefer using the term "chestfeeding" rather than "breastfeeding." We urge providers to consult community-based resources for more information about inclusive, affirming language around gender in health care settings.

The U.S. Preventive Services Task Force Issues Draft Recommendations on HIV Pre-Exposure Prophylaxis

THE U.S. PREVENTATIVE SERVICES TASK

FORCE (USPSTF) issued an updated draft recommendation on pre-exposure prophylaxis (PrEP). In a highly consequential action for the HIV community, the USPSTF is recommending with an “A” rating that clinicians offer PrEP “with effective antiretroviral therapy to persons who are at high risk of HIV acquisition,” that in this draft newly extends to long-acting PrEP in addition to oral PrEP. The A rating means that plans and issuers must cover PrEP without cost sharing.

“The Academy has been advocating for this outcome, and we are quite pleased with the draft recommendations. The use of PrEP is critical to ending the HIV epidemic and for ensuring that the federal Ending the HIV Epidemic initiative can meet its goals,” says Bruce J. Packett, the Executive Director of the American Academy of HIV Medicine. “And on a client services level, ensuring that the cost of all modalities of PrEP is covered will positively impact people at risk for HIV who are lower income or have socioeconomic barriers to care.”

PrEP is both an incredibly effective and significantly underutilized prevention intervention in the United States. As well, the use of PrEP varies widely by demographics, due to a number of identifiable barriers, with uptake in the Black and Latinx communities disproportionately much lower. Ensuring providers are up-to-date on the latest clinical recommendations for PrEP is particularly important given these persistent gaps in usage. The USPSTF’s rating is an opportunity to increase access to this effective HIV prevention tool, which can include either daily pill-based regimens or long-acting injectables that can be administered monthly or every other month.

The USPSTF is an independent, volunteer panel of national experts in prevention and evidence-based medicine. The Task Force makes evidence-based recommendations about clinical preventive services.

The Task Force’s draft recommendation statement and draft evidence review have been posted on the Task Force website at www.uspreventiveservicestaskforce.org.

The American Academy of HIV Medicine Applauds Proposed Blood Donation Guidelines Focused on Individual, Science-Based Assessments

ON JANUARY 27, 2023, the Food and Drug Administration (FDA) announced a proposal to update the guidelines on donating blood for men who are gay, bisexual, or who have sex with men. The Academy applauds this step forward in equity for blood donations and calls on the FDA to expedite research on technology that will also extend the ability to donate to groups who are still left out of this proposed change.

Under current FDA guidelines implemented in 2020, men who have had sex with men or are gay or bisexual and have been sexually active within three months prior to donating blood are barred from donating. The deferral period does not take into account other factors, including whether men are in monogamous relationships. The new proposed guidelines will remove the time-based deferral for gay, bisexual, and men who have sex with men and will instead use a donor history questionnaire that can more reliably assess HIV risk factors for all donors, regardless of gender or sexual orientation.

“For years, the Academy has strongly advocated for changes to the blood donation policy,” said Bruce J. Packett, executive director of the American Academy of HIV Medicine. “We are pleased that the FDA is finally turning to a science-based assessment system for each individual instead of a blanket ban that has unfairly stigmatized and discriminated against gay and bisexual men or men who have sex with men.”

The new proposed guidelines are a significant step in the right direction, though they still fall short in a couple of areas. First, blood donation deferrals will continue to be in use for people who are using HIV

pre-exposure prophylaxis (PrEP). Research has shown that in some cases the use of PrEP may interfere with HIV tests, producing false negative results. However, new technologies are in development to prevent transmission of pathogens, such as HIV, in plasma and platelets. The FDA should make every effort to expedite the development of this technology, which is currently in phase III of clinical trials. As well, the new guidelines focus on the number of partners a potential donor has had in the past three months rather than simply focusing on whether donors have had a new partner.

“This move by the FDA puts public health first and ensures crucial health care needs are met, especially in light of the recent critical shortages in our country’s blood supply,” said Packett. A year ago, the American Red Cross announced a blood shortage crisis in the United States, and the country experienced a similar shortage in 2012. Allowing a wider eligibility of blood donors using science-based criteria grounded in updated HIV research will make sure that more people can donate much needed blood to secure the U.S. blood supply.

The FDA had a 60-day comment period open for the proposed guidelines. After the close of the comment period, the FDA will finalize the guidelines. Afterward, blood collection centers in the U.S. will then implement the new individual assessment criteria. To read the FDA’s announcement, visit: <https://www.fda.gov/news-events/press-announcements/fda-proposes-individual-risk-assessment-blood-donations-while-continuing-safeguard-us-blood-supply>. To review the full draft guidelines, visit: <https://www.fda.gov/media/164829/download>.

Getting to Status Neutral

By DEMETRE C. DASKALAKIS, MD, MPH, CENTERS FOR DISEASE CONTROL AND PREVENTION, DIVISION OF HIV PREVENTION



Introduction

SIGNIFICANT ADVANCES IN HIV PREVENTION TECHNOLOGY have resulted in an opportunity to control the HIV epidemic despite the lack of an effective vaccine or a cure. HIV medications we use to treat people with HIV maintain people's health and increase their quality of life by suppressing their HIV viral load. Beyond the personal health benefits of treatment, people with a suppressed HIV viral load do not transmit the virus sexually: Undetectable = Untransmittable (U=U).



For people with an HIV negative test who, because of their behavior or social circumstance, might acquire HIV infection, we have pre-exposure prophylaxis (PrEP), which is HIV medications that can be used to prevent HIV acquisition. Neither PrEP nor HIV treatment are just about pills or shots. They represent a critical package of services that address not only HIV, but also the other health and social factors that need to be addressed so that people can attain their optimal health.¹

HIV and HIV risk factors do not exist in isolation. They are intertwined with other infectious and non-infectious disease epidemics and are potentiated by social determinants of health that serve to galvanize them into a more onerous threat to individual and population health—often referred to as a “syndemic.” These syndemics do not discriminate by HIV status—they affect individuals and populations challenged by HIV, sexually transmitted infections, viral hepatitis, substance use, and mental health concerns. These interacting epidemics are further potentiated by stigma, systemic racism, economic disadvantage, unstable housing, and a host of other negative social determinants of health.²

The people affected by these syndemics experience many of the same social forces and service barriers that impact their health, whether they have HIV or not. It is critical to remember that the person with HIV was once a person with risk factors for HIV. Many, if not all, of the services that are required to allow them to achieve their optimal health are agnostic to the result of their HIV test, but in many circumstances, our systems, that are built to serve them, are not. Structures that were necessary early in the domestic response to HIV may no longer serve the common goals we have for those who have or are at-risk of HIV. How can we evolve the institutional structures that maintain a “serodivide” in service delivery and that may maintain that same “serodivide” and resulting stigma in the lives of people affected by HIV?

People do not care who funds their services. They are concerned with getting the services they need to support their health and well-being. “Statusing” a place or a service may be aversive to people who could benefit from that place or service. Can we transcend the administrative and funding silos that maintain a “statused” system? How can we focus on serving the multi-dimensional needs and wants of the whole individual, so that we can offer them HIV treatment and preventative services in a more efficient way, tied to other syndemic and support services, and with cultural humility?³

“Status Neutral” Service Delivery

The status neutral framework provides care for the whole person by offering a “one door for all and no wrong door for anyone” approach: People with HIV and people seeking HIV prevention services can access treatment, prevention, and other critical services in the same place.^{1,3} Normalizing HIV treatment and prevention helps to destigmatize both. In a status neutral approach to service, a provider continually assesses and reassesses a person’s clinical and social needs. It focuses on a cycle of prevention and care rather than a linear continuum. Becoming virally suppressed or starting PrEP is not an end state, but rather a continuous process of shared decision making and supportive service delivery. The goal of such service and care delivery is to engage people in systems

Normalizing HIV treatment and prevention helps to destigmatize both. In a status neutral approach to service, a provider continually assesses and reassesses a person’s clinical and social needs. It focuses on a cycle of prevention and care rather than a linear continuum.

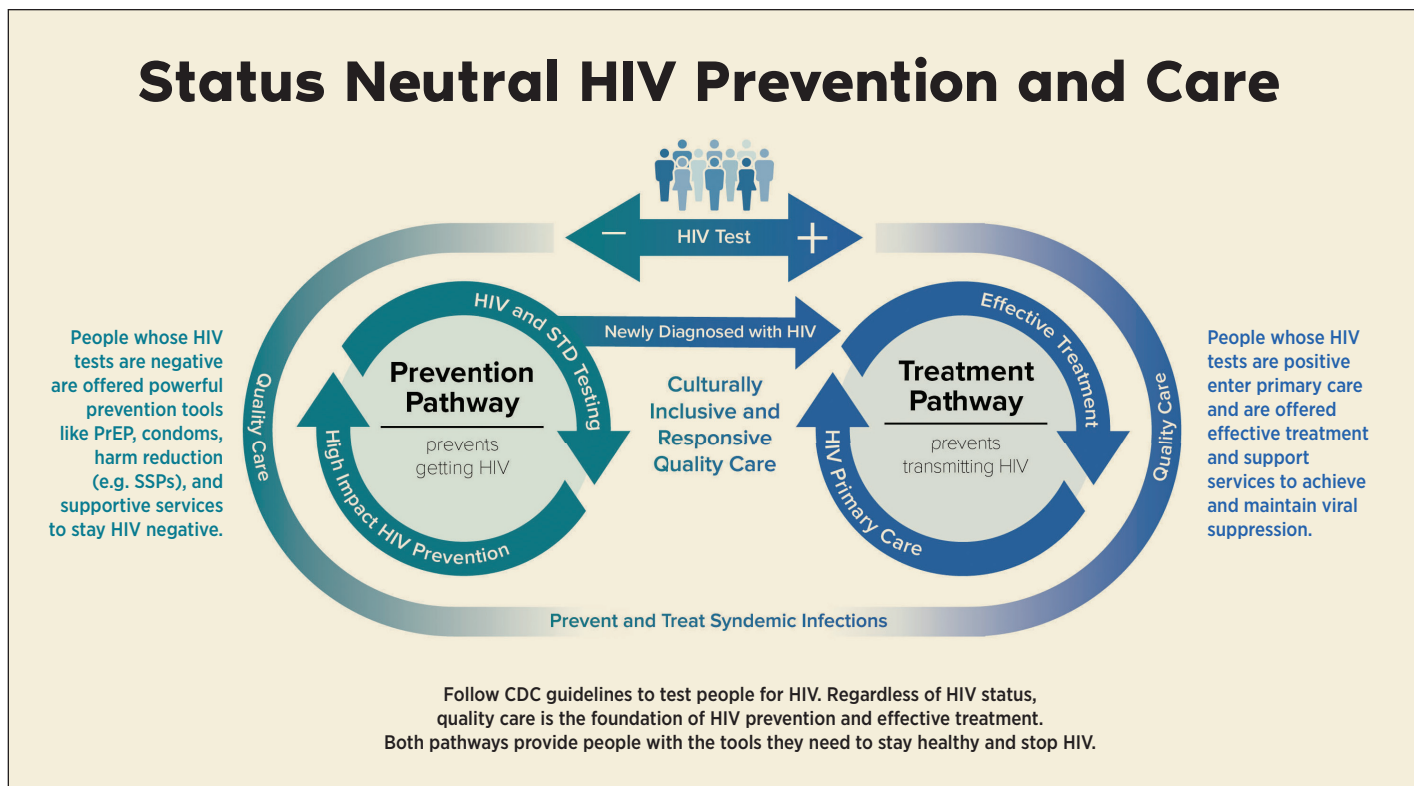
of treatment and prevention to help support better health outcomes and to do so without creating or deepening “serodivide.”⁴

Status neutral service provision may begin at any point of entry where medical or social services are provided and is unlocked by an HIV test—the first step to navigating HIV prevention and treatment. In a status neutral approach, an HIV test spurs action regardless of the result by recognizing the opportunity created by a negative or positive result for an individual to achieve better health.

If a person’s HIV test is negative, there is a great opportunity to engage the person in HIV prevention and offer powerful tools that prevent HIV, like PrEP. The prevention pathway emphasizes a consistent re-evaluation of the engaged person to match prevention and social support strategies to the individual’s circumstance and desires. Being engaged in status neutral preventive services also means expedited connection to HIV care if their HIV status changes. Other prevention strategies, such as condoms and drug user harm reduction services, are also an important part of this prevention pathway, especially for people who are not ready or eligible for PrEP. It is not about getting a pill into someone’s mouth; it is about engaging them with services that support them so that they can consider HIV prevention tools that may be right for them, including PrEP, condoms, good sexual health follow up, or harm reduction services.

If a person receives a positive HIV test result, the provider offers a prescription for effective treatment to help them become virally suppressed and maintain an undetectable viral load, as well as other clinical and wrap-around services to support general health and achieve and maintain a high quality of life. The proximal goal of the treatment pathway is also not about having someone take a pill or getting someone’s viral load suppressed; it is about engaging them with services that

Figure 1. The Status Neutral Framework¹



support them so that they can engage in HIV primary care and reap the personal benefits of treatment, including prevention of HIV complications and the anti-stigma and self-image benefits of U=U.

These interlinked HIV treatment and prevention pathways are embedded in other syndemic services that serve the individual regardless of their HIV status. These services' delivery systems include: sexual health, transgender, and other LGBTQ-focused care; viral hepatitis treatment and prevention; health care for people who use drugs; mental health care; and general primary care.

Beyond medical services, this model must include broader services that address social determinants of health and facilitate a path to optimal HIV and other health outcomes. These services include housing, food, transportation, employment assistance, harm reduction services, overdose prevention, mental health, and substance use disorder services. Most of the core social services people require are not specific to the result of their HIV test, a feature that

should be reflected in service delivery, where possible.^{3,5,6}

Importantly, this package of services must then be delivered in a culturally affirming way by supportive and accepting providers who have been trained to recognize and address implicit biases. Status neutral delivery sites should be optimized to ensure a positive experience for the person seeking services regardless of HIV status or demographic background.^{1,5,6}

Why a Status Neutral Service Model Should be Considered

Status neutral services are needed for reasons that span addressing HIV-related stigma to increasing efficiency of service delivery.¹

Decreasing new HIV infections

A status neutral approach means that regardless of HIV status, people can access services and support, so they have what they need to prioritize their HIV-related health by accessing interventions like PrEP and HIV treatment. When people are supported to

fully use these interventions, the outcome is the same—HIV infections and other infections are identified, prevented, and treated. The “one door for all and no wrong door for anyone” approach could create a less onerous point of entry into the prevention and care system for many who might not feel comfortable with HIV-status specific environments. For example, New York City's status neutral approach to HIV prevention and care, first introduced in 2016, contributed to annual declines in new HIV diagnoses thereafter. New York City saw a 22 percent decrease in new HIV diagnoses from 2016 to 2019.

Supporting and enabling optimal health through continual engagement in comprehensive, “whole person” care

By offering HIV services alongside other health care and social support services used by the community, HIV prevention and treatment can become part of the fabric of holistic care. As their needs evolve, a person can be seamlessly connected to new services. Potential outcomes include improved HIV

GETTING TO STATUS NEUTRAL

care, as well as better overall health and social stability for every individual. Embedding status neutral services into transgender health, other LGBTQ health, women's health, health services for people with unstable housing, health services for older people, and/or drug-user health creates an opportunity that supports critical health goals, including HIV treatment and prevention. For example, Chicago has created comprehensive status neutral health homes that offer the same services to people with HIV and people who could benefit from prevention services. Services include primary care, medications, care coordination, and behavioral health.

Opportunities for more efficient service delivery

Parallel services and structures historically created for people with HIV or people who could benefit from prevention services can impede the most efficient use of resources. This separation of services can also inadvertently hinder connection to care by maintaining stigmatizing structures in health care that are aversive to many people. Identifying opportunities to resolve these divisions allows for more streamlined and integrated care. Washington, DC, has seen increased capacity and improved outcomes and engagement at organizations using a status neutral approach. Using this approach has increased viral suppression rates three percent across all funded jurisdictions and increased linkage to preventive services like PrEP and harm reduction for people who tested negative for HIV.

Improving health equity

The status neutral framework integrates HIV and prevention services to better address social determinants of health regardless of HIV status. The framework also encourages the delivery of culturally affirming care by ensuring providers recognize and address their implicit biases on issues like race, ethnicity, sexual orientation, or gender identity. These biases sometimes prevent people from returning for care and other services that support that care. Likewise, countering stigma is essential to ensure that people with HIV are not defined by their status, and that people seeking HIV prevention and care services are empowered to access these tools without facing judgment or being reduced to the result of a laboratory test. Addressing racial bias and stigma results in better care experiences for patients and increases the likelihood that they remain in care and stay healthy.^{1,3,7,8}

Where It Can Work

Status neutral service delivery can be adapted for different jurisdictions, individual clinics, or discrete social service programs. Not every venue is appropriate for a full transformation to status neutral service delivery, but it should be considered as an option given the potential benefit. Importantly, status neutral services should be designed to enhance service delivery to all people who could benefit, but it is critical that this framework supports and enhances core services for people with HIV. Resources must not be pulled away from HIV treatment services that maintain the health and quality of life of the people that the HIV prevention and care system exists to serve.

On January 17, 2023, the Centers for Disease Control and Prevention's (CDC) Division of HIV Prevention and the Health



Resource Service Administration (HRSA) HIV/AIDS Bureau disseminated a letter to their grantees encouraging them to consider braiding their prevention and treatment funding to facilitate implementation of status neutral services. The letter encouraged service providers to look across public and private funding streams to identify ways to braid funds to achieve a more robust status neutral suite of services. This includes braiding mental health, housing, and harm reduction resources to build a status neutral health home that serves people regardless of their HIV test result.⁹

What This Means for Providers

There is a great opportunity to critically assess the HIV prevention and care system to identify ways that it can evolve to better serve people regardless of their HIV test result. Many clinical and social service providers have already shifted their work in this direction with blended panels of people with HIV and people seeking HIV prevention services. To resolve the institutional “serodivide,” practices and programs should look at how they can create packages of services that address the social determinants of health that affect their key populations regardless of HIV status. This critical review may identify gaps in services and provide an opportunity for service providers to advocate locally and nationally to further expand support for services critical to achieving optimal health.



Some people may be comfortable seeking care or services in an HIV-specific space while others might not. What is the right balance in branding for our environments to optimize the openness of our programs for all people who could benefit, regardless of HIV status?

openness of our programs for all people who could benefit, regardless of HIV status?

A Path Forward

Working together creatively and prioritizing the outward face of care delivery over the historical administrative and funding silos will help lead to status neutral health homes with “one door for all and no wrong door for anyone.” Collaboration between federal, state, and local public health staff and with medical and social services providers is necessary to make progress toward this vision. The CDC and HRSA have provided flexibilities in their funding, where possible, to facilitate the creation of status neutral services, while offering training, support, and technical assistance to state and local health departments and health care and service providers to help implement this model. More cross-agency collaboration will be needed to integrate status neutral services with other primary care, behavioral health, and social services. We need to continue to share what we learn as we work to implement this model and work closely with the community to calibrate service delivery to maximize its effectiveness in supporting their health and well-being. **HIV**

From the administrative perspective, how should practices and programs be structured to braid funding? Are there opportunities to braid HIV-specific and other funding between programs to create flexibility in who a program or staff member can serve, regardless of HIV status? How can these resources be used to generate a true health home with “one door for all and no wrong door for anyone” for people who could benefit from status neutral services? Are there program or practice environments that serve populations that could benefit from status neutral services, such as in sexual health, transgender health, women’s health, and/or drug-user health? Are there environments that serve people with or at-risk for HIV that could be further enhanced by expertise or programming for these same populations? Is the payer mix and funding portfolio able to support status neutral service provision? If not, can payer types be diversified or new funding opportunities be pursued to help achieve that vision?

In summary, consider how our practices or programs communicate to the people served by our mission. Are there ways to communicate with them that focus on their health and quality of life rather than HIV status? Some people may be comfortable seeking care or services in an HIV-specific space while others might not. What is the right balance in branding for our environments to optimize the



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The Status Neutral REVOLUTION

How HIV Prevention research and a novel approach to HIV care changed my perspective on ending the HIV epidemic.

By JONATAN GIOIA, MD

Lessons Learned from Empowering Research

I had recently obtained my medical degree at the University of Buenos Aires, Argentina, when the Houston HIV/AIDS Research Team (HART) offered me a unique opportunity to contribute to the science of HIV prevention. Driven by my passion for public health and research, I did not hesitate to embark on an adventure to become part of the University of Texas Health Houston.

For six years, during my tenure as HIV Clinical Trials Project Manager, I had the privilege to work on the planning and implementation of HPTN 083. This study was the first clinical trial to compare the efficacy of long-acting cabotegravir to daily oral Truvada (FTC/TDF) for HIV pre-exposure prophylaxis (PrEP).¹ It was exciting to see an excellent opportunity to expand our prevention toolkit. Even though we had developed successful strategies to prevent HIV acquisitions, the incidence of HIV in Houston remained stable over a decade, with more than a thousand new diagnoses yearly.² We knew that even though condoms were a successful barrier to HIV and other sexually transmitted infections (STIs), there had been a rise in people not living with HIV reporting condomless sex. The emergence of oral PrEP was not the root cause of these behavioral changes.³ In fact, when the trial started in early 2017, access to PrEP was still cumbersome for many people. In addition, we know that taking a pill daily can be a challenge. Therefore, a new long-acting injectable could be a game changer for vulnerable communities.

HPTN 083's commitment to recruiting communities that HIV has significantly impacted was a giant step towards meaningful representation in clinical trials. The protocol team tasked us to enroll at least 10 percent of study participants among transgender women and 50 percent from the Black community. Though challenging, I was motivated by the idea that sharing resources and participating in clinical research could empower communities that health care systems have historically neglected. Planning the logistics and recruitment

strategies to achieve success taught me two critical lessons regarding approaching and implementing HIV services.

First, it became clear that it was fundamental to understand the role of social determinants of health to end the HIV epidemic. For instance, access to transportation in a huge city like Houston is essential for people attending their appointments. When people are unhoused or affected by food insecurity, PrEP or HIV treatment will not likely be their priority. In addition, it is essential to mention that HIV services are not exempt from systemic oppression, racism, and discrimination. These factors have to be considered when approaching health care needs.

The second lesson that I have learned is that we need to dismantle the idea that we fight against HIV. We respond to HIV and must create strategies to engage people in health care beyond their status. In doing so, we can tackle one of the most challenging barriers behind the HIV epidemic: stigma. The way we talk about HIV and people with HIV matters. HIV stigma has forced us into a binary narrative (i.e., "positive" or "negative") that seems unavoidable.

I was elated to find there was ongoing research around the lessons I was learning while engaging the community in HIV prevention research. I had a scientific epiphany when I discovered the "status neutral" approach to HIV health care.

The Status Neutral Approach to HIV Health Care

We are the generation that can end the HIV epidemic. As we continue optimizing HIV prevention, treatment, and research for a cure, we must continue establishing health care frameworks that will empower those seeking HIV health care services. Imagine a world where people are not literally separated by their HIV status when engaging in health care, where people in dating apps do not focus on people's HIV status but on their attitudes toward health care. Normalizing testing and doing something about it (getting on PrEP or accessing treatment to become undetectable) would be enough to vanish the stigma. Could you imagine television and social media advertising combining prevention strategies and including people with and without HIV? How would service retention be improved if providers did not unconsciously discriminate between those who live with HIV and those who do not? How much better could resources be leveraged if they were offered under the same roof regardless of HIV status?

The status neutral approach emerged to address these questions and stomp out our binary framework. Its origin can be traced to when researchers designed the care continuum for PrEP.⁴ For instance, under the premise that “every new HIV acquisition is preventable and every HIV-related death is avoidable,” the Treatment Action Group proposed a cyclical approach to HIV prevention based on the idea of periodic retesting.⁵ Under this model, health care facilities should integrate HIV treatment into HIV prevention services, and HIV testing would be the fundamental tool for entry into the continuum. After getting tested, people will either be engaged in HIV prevention or HIV treatment services. Effective linkage to services will prevent the acquisition and transmission of HIV. Both groups receive primary care support to remain virally suppressed or stay HIV-negative.

A great example of this paradigm change was implemented in 2016 in New York City among men who have sex with men.⁶ Under this framework, HIV testing sparked a pathway for action—PrEP, post-exposure prophylaxis (PEP), or treatment. Establishing clinics that could provide any of these services under the same roof proved to be highly beneficial in connecting people to services.⁷

We have a unique opportunity to apply these approaches to our daily practice and institutions. The Centers for Disease Control and Prevention (CDC) has endorsed and guided this approach to be adopted nationwide.⁸ Results have been impressive. For instance, New York saw a 22 percent decrease in new HIV diagnoses from 2016 to 2019. You can see the “status neutral” approach illustrated on page 15.

Creating Safer, Braver Spaces

Adopting a status neutral approach for recruiting people for HIV prevention research studies was crucial for our success. We engaged all sorts of community stakeholders, assuming that HIV testing was the gateway to be linked to services. We spread the word in LGBTQ+ bars and other venues like bathhouses. We found great partnerships with mobile testing units from community-based organizations and state agencies. At the same time, we were also enrolling for studies focused on people with HIV. Thus, we were able to provide a unique synergistic research approach. Our research recruitment approach became “status neutral.”

A status neutral approach to health care should be applied to promote conversations around HIV that do not put the focus on someone's status but rather empower people to live healthier lifestyles.

One of our greatest successes was changing our participants' perceptions of our offices. Our facilities were located in one of the country's first freestanding clinics to serve people with HIV exclusively. Due to the stigma surrounding the building, I found many people who, even though they were interested in the trial, would not likely go to this clinic. At first, some participants mentioned they used the back entrance to avoid being seen. If they ran into someone they knew, they would sometimes share feelings of surprise—and stigma—because they felt they were disclosing their status just by receiving services there. My response to these worries always included a status neutral educational approach.

First of all, I stressed that the facility was no longer only providing HIV treatment services but also prevention services, so there was no way to determine someone's status by being there (even though the clinic offered services on different floors). Second, a conversation around stigma needed to happen. What were the beliefs each participant had about people receiving HIV treatment at the same place as them? Would that discourage them from continuing to receive services? On that note, introducing “Undetectable = Untransmittable” (U=U) and treatment as prevention was very important to counteract stigma and bias. We pointed out that everyone who came to the clinic was there for the same reason, regardless of their status: They wanted to take care of their health. That message resonated with many of the participants, who eventually stopped coming to the appointments in disguise.

While implementing the study, we transformed a historically stigmatized space and turned it into a place where people could receive more than HIV prevention services. Knowing that HIV is just the tip of the iceberg regarding health, we should consider our patient interactions as opportunities to treat them holistically. A status neutral approach to health care should be applied to promote conversations around HIV that do not put the focus on someone's status but rather empower people





to live healthier lifestyles. Safe spaces refer to establishing non-judgmental zones where people can express themselves. Brave spaces refer to the idea of establishments where people are encouraged and empowered to use their voices. As safety looks different for everyone, interactions need to be tailored individually.

The key components of these spaces include culturally sensitive care. The framework encompassed sex-positivity, gender affirmation, and holistic support. On this note, we understood that initial conversations with participants around PrEP were crucial. Many of them mentioned previous experiences with providers who misjudged them for trying to use PrEP, weaponizing the concept of “risk compensation” against them. There were also instances where community members would negatively judge PrEP users. Informed, judgment-free providers can help fight stigma, build healthy partnerships with their patients, and improve service retention.

Last but not least, it is essential to mention the contributions and feedback from the community: “Nothing about us without us.” Establishing community advisory boards and fairly compensating community members for their expertise and lived experience can tremendously help strategize and tailor a status neutral approach. Even though we

classically understand HIV testing as the gateway to engagement in HIV services, we can also consider that any social determinant of health can act as an opportunity to engage people in health care. The community can help develop a needs assessment initiative to meet people where they are and take them where they want or need to be.

A Status Neutral Future

This story ends happily as the FDA approved cabotegravir for PrEP in December 2021.^{9,10} At our site level, we met our recruitment metrics and the community celebrated our long-time efforts to empower the Houston community through HIV prevention research.¹¹ Aside from this significant milestone to which I had the privilege to contribute, I am proud to have shared conversations with stakeholders and the community about the importance of working towards a status neutral world. Changes in paradigms can provide our patients with a unique opportunity for liberation. Whether it starts at an HIV testing site or a conversation sparked at a food bank or community health fair, status neutral is an opportunity to eradicate stigma. An effective response to finally end HIV embraces and celebrates the freedom to be ourselves beyond our status. **HIV**



Originally from Buenos Aires, Argentina, **JONATAN GIOIA, MD, ACRP-CP**, moved to Houston, Texas, motivated by his passion for research and interest in the HIV field. He is interested in

addressing health disparities and developing novel interventions for community engagement. Aside from his research work, Jonatan is a local activist. He currently serves as Somos LOUD National Advocacy Director and Houston’s chapter president, where he is committed to engaging, empowering, and educating Houston’s LGBTQ+ and Latinx communities.

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IN GEAR

Implementing Status Neutral Care in Primary Care Settings

By MYRA RUTLAND, DNP, FNP-BC

NO MATTER HOW WE SAY IT, attach timelines, plug in “catchy” acronyms, there will be no Ending the HIV Epidemic (EHE) until status neutral care becomes woven into the fabric of primary care. According to the Centers for Disease Control and Prevention (CDC), the definition of status neutral HIV care means to be intentional about caring for the “whole person” regardless of HIV status. All tools afforded providers in health care settings that address social determinants of health should be mobilized to provide a systematic approach to optimal health for at-risk populations.¹

Status neutral care aims to meet people where they are, remove barriers, and eliminate stigma around seeking prevention for HIV or HIV treatment. The approach to care for people with HIV (PWH) or those without HIV should be indistinguishable. How health care finds itself where there is need for neutral status is a complex, lengthy conversation, but most would agree the heart of the matter is stigma.

Merriam-Webster’s dictionary defines stigma as “a mark of disgrace associated with a particular circumstance, quality, or person.” It signifies shame, being undesirable, worthless, and filthy. Stigma and discrimination partner together to create a gulf between the person being stigmatized and the audience/persons they seek to engage with. One patient summed up her lived experience as a PWH saying, “It’s not my fault. I am not dirty!”

Where Care Happens and Why It’s Important

More than 50 percent of PWH get care at Ryan White clinics across the country.² However, it should not be presumed that these same sites also provide HIV prevention in the form of pre-exposure prophylaxis (PrEP) or post exposure prophylaxis (PEP). While these two populations may have similar needs, provisions for care do not always intersect.

The former scenario creates a conundrum. If a PWH is seen or succumbs to their internal dialogue that “others” see them going to an HIV dedicated clinic, it can create a sense of anxiety because the act itself involuntarily “outs” them. Likewise, if a person visits a sexually transmitted infection (STI) clinic this could perpetuate any stigma of being labeled as “promiscuous,” regardless of the reason for the visit.

Some providers and health professionals may think that HIV testing is the point of entry for status neutral care. However, a whole person approach lends itself to helping any and all patients identify risks which could predispose them to HIV. In order to capture a greater population of people to be tested, having an HIV test must be normalized and the sting of stigma removed. Therefore, the status neutral care entry point should begin with a comprehensive needs assessment during the patient provider encounter.

Moreover, progression of this approach disassembles silos that perpetuate either “providers of HIV” or “providers of PrEP/PEP.” If the ultimate goal is to ensure that risk factors such as needs for housing, insurance, transportation, food, treatment for substance use disorder, contraception, and more are met, then not only should the net be cast wider, but also we are going to need more fishermen. This model is intuitively more inclusive because it assumes that any person



in the presence of almost any provider should be assessed for HIV treatment or prevention.

Primary Care and Its Role in HIV Care

Primary care providers (PCPs), as well as pediatricians, dentists, obstetricians/gynecologists and more, are all uniquely poised to significantly impact EHE. They see the most patients for almost any complaint, from a sore throat, fatigue, thrush or an unusual rash, that could be signs of acute HIV. According to the CDC National Center for Health Statistics 2021 data, approximately 82 percent of adults had a visit with a doctor or other health care professional in the preceding year.³ Sexual health is a part of assessing the overall health of human beings.

However, to the dissatisfaction of many, these discussions are often overlooked or abbreviated. Providers have the greatest discomfort talking about “the deed” with those over 65 and those under 18 years age. In fact, discussion with teenagers regarding sex lasts about 36 seconds in a 22-minute appointment.⁴

PCPs must shift to ensuring that the sexual health needs of their patients are addressed despite personal discomfort. The visit is about the best interest of the patient and a practical application of the Hippocratic Oath or Nightingale Pledge. Sexual health is just another system. If a provider failed to assess the risk of an obese patient for diabetes type two, they would be grossly negligent. Omission of a reasonable sexual history could be a missed opportunity to identify preventive measures to avoid transmission of or provide treatment for HIV.

The use of the “Five Ps” provides a framework to assess risk in patients during the history and physical exam: partners, practices, protection from STIs, past history of STIs, and pregnancy intention.⁵ The excuse that there is not enough time is not acceptable. Such an excuse presumes PCPs do not know how to abbreviate questions and cut to the chase. If medical education can teach providers to be direct and flat-footed in delivering devastating news, then surely it can teach providers to simply ask, “Are you sexually attracted to men, women, or both?”

Status neutral care aims to meet people where they are, remove barriers, and eliminate stigma around seeking prevention for HIV or HIV treatment.

with a straight face and without judgment.

Incorporating even a brief sexual history can open the door to educating about PrEP/PEP and then close the deal by offering a prescription. PCPs must assure patients that having HIV itself is not a death sentence, but having undiagnosed/untreated HIV can be a real threat to mortality.

Using the “MEET” model of mobilize, engage, educate, and train can aid in status neutral care. It could be the foundation of utilizing PCPs and other nontraditional HIV/PrEP/PEP providers to EHE.

1. Mobilize each clinical and non-clinical member in the organization to recognize that they play a significant part in EHE. Start and continue conversations on providing a safe, confidential place to get health care for all persons regardless of their status. Providing care in a nonjudgmental way will reduce the stigma that so many people encounter during medical visits.

2. Have trusted members engage patients in identifying preferred pronouns, names, and gender identity. Have staff assist in completing questionnaires that query the Five Ps. This can guide dialogue with patients.

3. Educate patients. Provide unbranded literature regarding testing and PrEP/PEP in patient registration areas and bathrooms. Ensure that information on your organizational website provides basic information on HIV, the correlation with HIV and STIs, and the various ways PrEP/PEP are prescribed. Provide links for patients to examine reliable sources.

4. Spare no expense in training staff. Begin with diversity, equity, and inclusion training. Acceptance and respect for others, even if it is not what you personally would subscribe to, must be paramount and expressed in the organizational mission statement. There is no room for judgment, discrimination, division, or hate.

Health care curricula must educate PCPs in the basics of identifying risks and

taking appropriate action to provide preventive, secondary, or tertiary HIV care. This is especially critical now when providers who have been on the front lines of HIV care since the 1980s are looking to hang up their stethoscopes.

Organizations like the Mid-Atlantic Aids Education Training Center and American Association of HIV Medicine provide education resources to interested health care professionals. An infectious disease provider on staff or one versed in HIV care can alternatively provide staff education and be a resource champion. This would be a successful way of incorporating prevention and treatment in a nontraditional status neutral setting.

Despite puritanical behaviors of some PCPs, others readily embrace a whole person approach to sexual health care. They educate on HIV prevention, test, or refer for treatment. Spectrum Health Services Inc., a federally qualified health care center headquartered in West Philadelphia, is a prime example of this. From January 2020 to December 2022, they more than quadrupled the number of patients on PrEP. Almost all the staff participate in some way to ensure a positive sexual health experience. There are condom “candy jars” kept in the foyer of each clinic entrance and in the pods of each exam area. The condoms are in little brown paper bags with a small strip of paper with information on PrEP and PEP, the Spectrum logo, and a hotline number on it. Patients or non-patients are welcome to get free condoms anytime the doors are open.

Spectrum gives out approximately 2,000 or more condoms a month at each of their clinics in West, North, and South Philadelphia. With the opening of a new clinic in Northeast Philadelphia in January of this year, they are poised to hand out over 96,000 free condoms a year. This is significant because according to the Philadelphia Tribune, Philadelphia is typically third or fourth in the country for the highest number of cases of STIs.⁶

The medical assistants and nursing staff are trained to offer a rapid HIV test to patients

Spectrum Health Services PrEP Progress January 2020 to December 2022

Date range	Pts on PrEP
1/1/2020-6/30/2020	38
1/1/2020-12/31/2020	60
1/1/2020-3/9/2021	70
1/1/2020-6/11/2021	91
1/1/2020-7/9/2021	93
1/1/2020-9/15/2021	107
1/1/2020-10/31/2021	111
1/1/2020-12/31/2021	117
1/1/2020-2/28/2022	127
1/1/2020-3/31/2022	137
1/1/2020-6/30/2022	157
1/1/2020-12/31/2022	171

for all physical exams, and other encounters that the provider or patient requests. Rapid HIV testing is offered to every patient 13 years and older. Spectrum PCPs offer testing at least annually during physical exam visits, whenever patients ask for them, when symptoms present, when there are recent STIs, or when there is known exposure to HIV.

Spectrum offers a walk-in clinic that provides birth control, pregnancy testing, and STI screening and treatment services. This is offered to anyone interested, and they do not have to be Spectrum patients. The clinic is generically called a “walk-in clinic” where services are spelled out; this helps to remove the stigma associated with it being solely an STI/HIV clinic.

Continuing education unit (CEU) requirements ensure that professionals become educated in risk assessment, preventative care, and treatment for HIV. Similar to the requirement of obtaining pharmaceutical CEUs, there needs to be a minimum number of hours of HIV education towards license renewal. Offering financial aid and or tuition repayment for becoming certified in HIV should be incentivized.

With syphilis and gonorrhea at their highest rates in 30 years, HIV testing must be emphasized. Messaging for this and all sexually transmitted infections should provide education on why frequent assessment of risk is warranted. One way to frame it to an individual is to state realistically and matter-of-factly that HIV testing is for every sexually active being, not just a special population.

In my personal experience, I have found

framing testing around education to be very successful. Most of my patients have embraced HIV testing freely with very few instances of push-back. Notably, my Black female patients are very receptive to discussing HIV tests and prescriptions for PrEP/PEP. Unfortunately, many either had not heard of it or thought it was just for men who have sex with men. All patients were pleasantly surprised at opportunities to have an open discussion surrounding sex.

Work Still Remains

Two stigmatizing barriers that continue to oppress persons at risk of HIV or PWH are inability of or difficulty with obtaining life insurance if on PrEP or diagnosed with HIV, and the criminalization of HIV. While laws regarding insurance vary from state to state, it is clear that insurance companies are not in a posture of altruism. In one case, the patient never had an STI, no underlying health conditions, and on no medications except Truvada for PrEP. Two life insurance companies denied her coverage.

Finally, HIV criminalization is a lack of education regarding what HIV is and is not. In order for laws regarding criminalization to change, stigma must be dispelled. Respect for the legitimacy of science must be embraced and be the driving force behind legislation. Ignorance breeds fear. It drives a wedge between those with HIV and at risk for HIV and those who believe they are beyond the reach of HIV. Fat shaming an obese person for putting themselves at risk for cardiovascular disease—the number one cause of death in the U.S.—would never be acceptable. Why is it okay to continue to blame PWH? It is time for medical professionals and society to grow up, join up, and gang up on HIV, not PWH. Let us end the HIV epidemic together. **HIV**



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member of the Pennsylvania Steering Committee for the American Academy of HIV Medicine, is very active in her community, and loves music.

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Rapid Start Programs

**Exploring the Principles of
Status Neutral Care
in Practice**



By SAFERE DIAWARA, MD, MPH



THE MISSION OF THE VIRGINIA DEPARTMENT OF HEALTH (VDH) is to protect the health and promote the wellbeing of all people in Virginia. Status neutral service provision is an example of a syndemic approach to public health to deliver comprehensive health care, regardless of a person's HIV status. To fully realize its service mission, the VDH relies on community health partners to deliver HIV prevention and ancillary services to persons with risk factors for acquiring HIV. In addition, these partners administer a continuum of prevention and care services to people with HIV (PWH). The VDH Division of Disease Prevention (DDP) recognizes the need for qualified, experienced community-based organizations, including faith-based institutions, to spearhead health promotion and disease prevention efforts.

Rapid Start Programs in Virginia

An essential part of status neutral delivery is moving someone who acquires HIV along the treatment pathway to quickly achieve and maintain viral suppression. To that end, the VDH DDP used the Ryan White HIV/AIDS Program (RWHAP) rebate funds in 2022 to support an HIV rapid antiretroviral therapy (ART) program, the Virginia Rapid Start Collaborative Initiative. The Initiative, referred to as Rapid Start, was implemented in 13 Virginia RWHAP clinics, community-based organizations, and federally qualified health centers throughout Virginia's five health planning regions. Rapid Start is defined by immediate linkage to HIV care and initiation of ART at the time of HIV diagnosis. The potential benefits of Rapid Start include: 1) improving individual patient health by decreasing the time to viral suppression, while reducing transmission potential within the community and 2) improving rates of early engagement and potential long-term retention in care.¹ Early engagement and retention of PWH in HIV care is critical in achieving viral suppression, which is an effective measure to reduce the spread of HIV (e.g., treatment as prevention). This strategy will likely decrease the risk of subsequent HIV transmission events.²

Although Virginia did not receive funding for the federal Ending the HIV Epidemic (EHE) Initiative, the first two years of Virginia's Rapid Start program show key improvements focused on EHE's second key strategy: Treat people with HIV rapidly and effectively to reach sustained viral suppression.³ Results for people receiving ART in Virginia's Rapid Start are as follows: In the first 24 months 262 patients were served, including 83 percent newly diagnosed and 17 percent reengaging in care. Of those served, 88 percent of patients began ART within seven days, 34 percent were virally suppressed at 30 days, and 59 percent virally suppressed at over 60 days. Overall, Rapid Start clients had an 84 percent viral suppression rate. To continue this success, VDH now encourages all HIV service providers to engage in a community-wide Rapid Start protocol.

Initiating ART medications sooner, ideally the same day as diagnosis, is critical to achieve viral load suppression in less time, as well as to provide quality care for newly diagnosed clients. Better patient outcomes produce more empowered patients and staff. Furthermore, this strategy meets the EHE's second key strategy of promptly linking individuals newly diagnosed with HIV to care and treatment and proactively addresses health disparities. Providing immediate linkage

to care produces shorter time to virologic suppression and higher retention rates with adherence. As well, data show that newly diagnosed PWH started on ART have enhanced linkage to and improved retention in care.

Efforts to reach PWH that were out of care saw improved retention in care rates through expanded reengagement in care activities, which VDH DDP codifies with Data-to-Care activities. The Virginia Rapid Start teams use the collaborative learning improvement model as an effective way of testing small changes. Strong relationships between HIV testing sites, disease intervention specialists for active referrals, and care facilities are needed for quick referrals and successful rapid start programs.

What We Learned

Some challenges discovered while implementing the Rapid Start Program involved funding, access, training, and buy-in. These challenges include:

- funding for and access to medications for uninsured and underinsured persons (e.g., no pharmacy on site, wait time on program's client eligibility approval, and prohibitions on pharmaceutical assistance program)
- funding for staff and operational expenses
- high staff turnover necessitating repeated program training
- providers' buy-in (rapid ART may require providers to add time to their schedules)

When beginning a rapid start ART program, inquire about expedited RWHAP AIDS Drug Assistance Programs eligibility, other medication and insurance assistance programs, and in-house pharmacy availability. Set expectations for patients not in care or falling out of care, as

RAPID START PROGRAMS

they are likely to require significant support. Set up resources, develop a referral system and network, and ideally use warm handoffs. In addition to rapid ART-required protocols, allow for tailoring the protocols to an agency's specific programmatic circumstances.

Buy-in from agency leadership is essential and all staff should know the program. Educate all staff, as well as supervisors, who interact with rapid start patients. Other important points to consider are building time for emergent appointments into provider schedules, having flexibility in appointments, and flexibility in provider availability (for initial and ongoing visits). Develop flow charts, operating procedures, processes to refer newly diagnosed patients to HIV care, processes to accelerate insurance and RWHAP eligibility determinations and approval processes, and adjust processes as needed (e.g., quality improvement reviews). Ensure quick access to HIV providers, as well as needed labs and ART. Additionally, use of the "Plan, Do, Study, and Act" small steps improvement model and collaborative learning model helps to determine the impact of changes.

Some advice is self-evident for any health care system or provider considering a rapid start ART program. You will need to secure leadership support as well as establish goals and metrics for the program. You should also track data related to demographics, days from diagnosis to first visit, ART start date, viral suppression numbers and rates, and retention rates. Analyze your data for trends, variations, disparities, and loss to follow-up. Finally, continuously communicate program results to ensure program success.

Other Collaborations to Support Status Neutral Care

The VDH collaborates with several community partners, including community health centers, to ensure that PWH are linked to HIV treatment services as soon as possible. Collaborations include work with RWHAP and non-RWHAP providers to determine what services are needed in their communities, increasing access to those services in the field, and ultimately improving HIV health outcomes. The Virginia Rapid Start efforts from the VDH and community partners is an instance of such collaboration. The VDH

Rapid Start is defined by immediate linkage to HIV care and initiation of ART at the time of HIV diagnosis.



allows all the community-based providers to lead the collaborative and identify needs for the state, ensuring the success of the Rapid Start Program and growth with more partnerships.

The Virginia RWHAP Quality in Care Cross-Part Collaborative is a great example of that partnership growth. Collaborative membership comprises over 35 community-based providers, clinics, and federally qualified health centers across Virginia's five health planning regions, all funded through prevention and/or care funds. The goals of the Collaborative are to build sustainable partnerships and support HIV service delivery expansion in communities highly affected by HIV, especially among racial and ethnic minorities. By working with these Partners, the VDH can increase the timely identification of undiagnosed HIV infection, establish new access points for HIV care and treatment, and improve outcomes along both the HIV prevention and treatment continuums of care. To support this, the VDH procured and uses a new client-level data system to capture service utilization for prevention and care services, which helps improve the collection, review, and report of health outcome performance measures across Cross-Part funded agencies.

The VDH and community health centers serve the same populations, working together and better serving communities by improving care coordination, quality of services, and effective use of all resources. The Cross-Part Collaborative also increases access to critical services for underserved populations. The Collaborative's success and sustainability are based on:

1. Developing SMART objectives (i.e., specific, measurable, achievable, relevant, and time-bound) aligned with Virginia's Care and Prevention Integrated Plan
2. Communicating openly among partners
3. Assessing joint improvements to community health care delivery
4. Reviewing funding opportunities

5. Identifying priorities and opportunities
6. Sharing resources
7. Creating a plan for activities that focus on partnership development
8. Learning about the programs covered by each partner

Linkage to care and retention in HIV care and education about HIV are essential components in stopping the transmission of the disease. To ensure every person who can benefit from these resources can access them, VDH currently uses a braided approach from prevention and care funding streams to remove barriers to services. Additionally, VDH encourages all Community Health Partners to use available program funding to expand access to medication, connect people to care, and ensure services are well coordinated along the status-neutral continuum. Implementing HIV prevention and treatment activities in places where people seek other health services, such as sexual health services, mental health and recovery services, and transgender care services can help reduce HIV stigma, prioritize health equity, and ensure the success of status neutral care. **HIV**



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Virginia Ryan White Peer Review process for quality assurance, rapid initiation of HIV antiretroviral therapy or "Rapid Start" Program, and Eastern regional HRSA's Patient Safety Clinical Pharmacy Services Collaborative. He also leads the Ryan White Cross-Part Collaborative, Virginia Quality in Care Consumers Advisory Committee, Virginia Ryan White Quality Management Advisory Committee, and Virginia Anti-Retroviral Treatment and Access to Services (ARTAS) Pilot Project.

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NEED PrEP?

Don't Forget the Pharmacists



By JESSI TRUELOVE, PharmD, AAHIVP, and
ELIZABETH CAMPER, PharmD, BCMTMS, AAHIVP

IN PHARMACY SCHOOL, you are constantly told that pharmacists are the most accessible and trusted health care providers. But once in practice, you realize that despite being told this, pharmacists are not always treated as part of the health care team. Pharmacists played an integral role in providing the COVID-19 vaccine rollout, yet in most states, pharmacists cannot provide immunizations without a written agreement with a physician. Inconsistencies like this can cause pharmacists to feel disconnected from the broader patient care goals. But we are accessible. We know our patients. We are here to help.

NEED PrEP?

In order to reach the current goal of status-neutral HIV care, HIV prevention services must become more readily accessible in a stigma-free, efficient, and easily accessible manner.¹ Within the past five years, several states have passed legislation that allows pharmacists to help fill this role, such as California, Colorado, Idaho, Illinois, Maine, Nevada, Oregon, Utah, and Virginia.² However, outside of these areas, pharmacists must rely on the state having laws with broad enough collaborative drug therapy agreements (CDTA), or collaborative practice agreements, to prescribe HIV pre-exposure prophylaxis (PrEP).² Pharmacies with the time and resources to perform clinical consultations are ideally suited for patient care services such as PrEP. The updated 2021 Centers for Disease Control and Prevention (CDC) PrEP guidelines are direct when saying all sexually active adolescents and adults should be informed about PrEP and provide easy-to-follow monitoring parameters for continuing treatment.³ Pharmacist-led PrEP is not a way to replace HIV prevention in primary care, but rather a way to supplement it and provide a mode of access for those not currently engaged in the health care system.

Pharmacies can expand PrEP access and improve retention due to increasing access in areas with low PrEP coverage, having flexible hours that include evenings and weekends, as well as varied entry points to care due to being decoupled from other forms of health care.⁴ This endeavor is not something pharmacies can or should enter into alone, though. To create a successful program, it is vital to network with local health jurisdictions, PrEP navigators, and local agencies that perform HIV and sexually transmitted infection (STI) screenings.⁴ For pharmacies that are not already specializing in HIV care, specific HIV prevention and STI training are necessary as well.

Fortunately, both of us work at a nonprofit pharmacy specializing in HIV treatment in Seattle, Wash., so we are knowledgeable about HIV prevention options. While Washington is not one of the states with established HIV prevention legislation, it does have broad collaborative drug therapy laws. In Washington, CDTAs can allow pharmacists to vaccinate, order labs, prescribe medications, and administer medications if they can find a protocol prescriber. The protocol provider enters into an agreement with the pharmacist, and this agreement grants individual prescriptive authority to the pharmacist as specified in the CDTA.

Finding a protocol prescriber was one of our biggest challenges to overcome. We approached members of our state pharmacy association, Washington State Pharmacy Association, for assistance in this endeavor. Through that organization, we connected with a Public Health Seattle & King County member utilizing a grant from the CDC to create a demonstration project: the Pharmacy Integration into PrEP and ART Provision and Retention (PIPAR) program.

The PIPAR program created a template to provide pharmacies with the tools and training to create new HIV prevention programs.⁴ It created a same-day PrEP model, wrote a template CDTA document, introduced us to community partners, and connected us with a Seattle & King County Public Health physician who believed in our ability to reach and care for patients. We were one of four pharmacies involved with the PIPAR project to launch and were the first to have a patient in March 2022. During the first several months of our program's launch, Seattle & King County Public Health advertised our services on various social



Pharmacies can expand PrEP access and improve retention due to increasing access in areas with low PrEP coverage, having flexible hours that include evenings and weekends, as well as varied entry points to care due to being decoupled from other forms of health care.⁴

media platforms. This partnership has been valuable for our program as we are still listed on the Public Health Seattle & King County website as a PrEP provider and receive many referrals from local health department HIV and STI test sites.

The model we use at our clinic to provide efficient, same-day care requires flexibility in scheduling and workload outside the typical pharmacy scope of practice. We utilize CDTAs to prescribe and administer routine vaccinations (such as hepatitis B), prescribe and administer treatment for chlamydia and gonorrhea, order laboratory testing, and prescribe PrEP therapy. We utilize a Clinical Laboratory Improvement Amendments' waiver to perform rapid point-of-care HIV tests as part of our routine screening and workflow. We obtained phlebotomy licenses to perform venous blood draws for hepatitis B immunity, HIV status, syphilis exposure, and serum creatinine. We

then use our clinical pharmacist knowledge to screen for drug interactions, counsel on the medications, and prescribe PrEP.

We have been working on getting credentialed with insurance companies and learning how to bill medically to collect revenue from our services. We are lucky that in 2015 Washington passed the Engrossed Substitute Senate Bill (ESSB) 5557, the first piece of legislation requiring health insurance companies to credential and pay for services from pharmacists.⁴ However, because this legislation is not yet widespread, the credentialing process is time-consuming, repetitive, and met with much resistance.

As part of our protocol, we assess if our patients have access to primary care and, if not, assist them in finding a provider. If we are successful in helping them establish care, we encourage them to initiate care with their new provider if that is what they choose. In our first year of operation, 56 percent of our patients did not have a primary care provider, and only five percent were interested in being referred to primary care. Out of our patients who were already connected with providers,

there are three main reasons they sought PrEP elsewhere: the health system was too complicated, they were concerned about privacy, and no one ever asked them about HIV prevention. We also attempt to refer our patients to PrEP navigators but, typically, the patients choosing to use our services have chosen us to avoid referrals, making multiple stops, and traditional medical care.

We utilize several types of technology in our clinic. Scheduling can be done online by scanning a QR code. The initial intake form can be completed online so the patient can avoid answering some of the more sensitive questions out loud or in front of a staff member. Preparing for the appointment ahead of time allows us to arrange translators for patients who are not fluent in English. Our established patients can use secure text messaging to chat with the pharmacy staff, get lab results, and schedule future appointments. For some patients, the ease of scheduling and ability to do things virtually convinced them to finally initiate HIV prevention medication.

Through our work with Public Health Seattle & King County, we have learned

that creating new health care programs is a slow process. It takes a long time for people to learn about the services being offered. It takes time to build relationships with others in the community. It takes time to become credentialed, learn new skills, and advocate the value of your time and services. But every time a patient provides positive feedback, every time we vaccinate someone against hepatitis B, every time we get to feel like we are making a difference, it makes all of the time and effort spent worth it. Patient care programs such as pharmacist-initiated PrEP directly incorporate pharmacists back into the health care team. These programs allow us to utilize our training and knowledge and improve patient outcomes. **HIV**



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Fix the Law First

HIV Criminalization Laws Work Against a Status Neutral Approach

By DEIRDRE JOHNSON and KAMARIA LAFFREY

AS NATURAL-BORN OPTIMISTS, we take seriously the hope our optimism aligns with the inclusive strategies and knowledge that we can't end HIV unless we address all the communities impacted most by HIV. As Black women, our understanding of status neutral and the overall response to HIV/AIDS leads us to grapple with these questions:

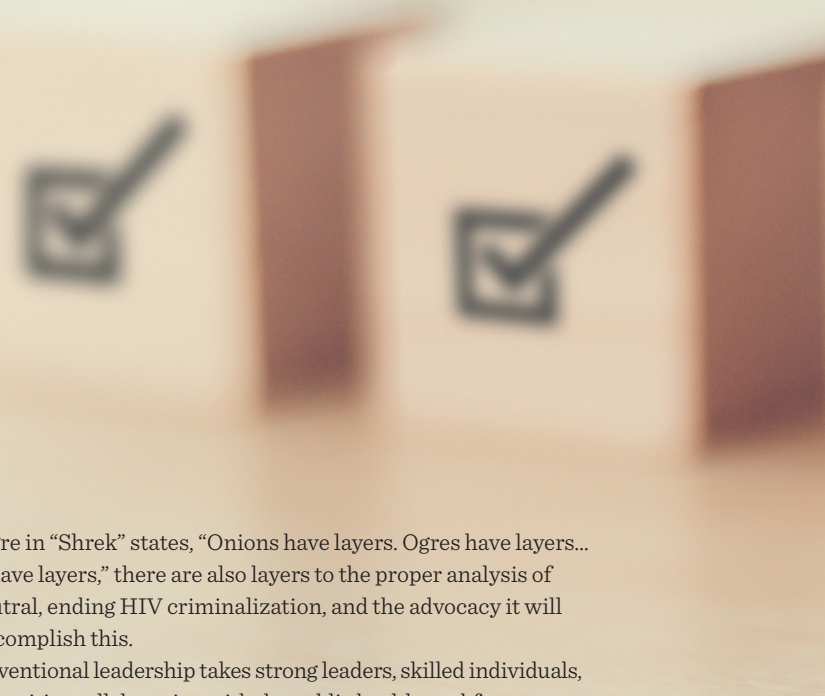
- What is neutral in the Meaningful Involvement of People with HIV/AIDS (MIPA)?
- Does status neutral create a human rights environment for people with HIV (PWH)?
- Are racial and gender disparities prioritized and addressed in a neutral clinical approach?
- Will this reduce the utilization of identifying priority populations—like sex workers and immigrant/migrant communities—by including more communities in the overall strategy?
- Also, where does this lead to the actual quality of life for people with HIV when looking at the HIV epidemic systemically and historically?

Being optimistic in a world of developing possibilities to end HIV can feel like a fairy-tale movie with a non-stereotyped hero, like an ogre from a swamp. Unconventional leadership and letting key players meaningfully support us to a happy ending need to be a part of the blueprint design for ending HIV. And

like the ogre in “Shrek” states, “Onions have layers. Ogres have layers... We both have layers,” there are also layers to the proper analysis of status neutral, ending HIV criminalization, and the advocacy it will take to accomplish this.

Unconventional leadership takes strong leaders, skilled individuals, and communities collaborating with the public health workforce, agency partners, funders, researchers, lawmakers, and other stakeholders to put their whole bodies into their work. This type of leadership needs to have the ability to repeatedly step back to analyze what they need to learn to go forward, to continue to fight for change, and to know what they need to let go of that doesn't work anymore, even if that means stepping out of the way. In that same vein, the terminology of “status neutral” in the context of HIV criminalization reform gives us pause.

The cycle of emotions that coincide with an HIV diagnosis can be shock, confusion, understanding, denial, bargaining, depression,





For status neutral to be impactful in all aspects of HIV reduction of stigma and new transmissions, we must consider and understand HIV criminalization laws, and how the implementation of status neutral will add to the historical pattern of making new advances while keeping old legislation.

FIX THE LAW FIRST

acceptance, and action. An HIV diagnosis can hold significant impact on how one moves through the last step of action and how it impacts healing. Beyond the clinical experience, those of us living with HIV have to fight to be validated against society's moral judgment and biases. We also feel that we have to carry the burden of being responsible for every HIV-negative person living without any solid protections for our lives against stigma, discrimination, and criminalization.

In the early days of the HIV epidemic, people were blamed, ostracized, stigmatized, and categorized by their sexual orientation/preference, identification, race, and geographical location. On top of that, in the early 1990s, states were mandated to enact the legislation that we have today, utilized against people because of their HIV-positive status to receive funds that would "benefit" PWH. The catch was that there had to be a provision to criminalize PWH who may transmit HIV to others with intent, even though in most cases HIV is not intentionally transmitted. These provisions came about due to a lack of leadership in the climate of fear, judgment, and moral disapprobation that determined whether or not we deserved our diagnosis.

For status neutral to be impactful in all aspects of HIV reduction of stigma and new transmissions, we must consider and understand HIV criminalization laws, and how the implementation of status neutral will add to the historical pattern of making new advances while keeping old legislation. These laws were egregiously created at the beginning of the epidemic when treatment and prevention services were in desperate need; however, the laws were built into state codes and utilized to prosecute based solely on a person's HIV status for states to receive federal government support in funding, research, and resources.¹ One of the many disconnects for us is in all the language we have seen about the status neutral model is that HIV criminalization never intersects with the approach, which is a problem. These criminalization laws work against public health, do not contribute to the reduction of HIV transmission rates, and do not align with current scientific advancements on how HIV transmission occurs. Where is the status neutral in identifying a meaningful approach in ending the laws based on an HIV-positive status if this method is to be widely effective in ending HIV stigma and the epidemic?

Recently many events have happened that have had an impact on advocates in all spaces. The introduction of status neutral has shed light on the lack of transparency from federal agencies. It highlights hindsight of what potentially could have worked at the beginning of the epidemic as a more appropriate public health response. Currently, many federal grant opportunities offer grants for status neutral approaches, strategies, programs, views, and visions for organizations to be considered for certain funds. Funding is essential for individuals to access testing, pre-exposure prophylaxis (PrEP), and other prevention strategies, but at what cost to the removal of stigma for communities of PWH is it worth it if this approach is not fully inclusive? Most of the programs proposed are reminiscent of the beginning stages of states receiving Ryan White funds. The question is how is that funding strategy impacted if it's "neutralized," and how can this approach align



with the decriminalization of HIV if the laws don't reexamine modes of HIV transmission, actual transmission in criminal cases, proof of disclosure, or malicious intent?

While there is an understanding that status neutral is believed to be a practical clinical approach to providing care for those living with HIV or vulnerable to acquiring HIV, it is not a one-size-fits-all approach. The deeper understanding and analysis of populations most impacted by HIV having access to support services regardless of status (sex workers, immigrant and migrant populations, transgender people, young black men who have sex with men) and the status neutral language highlights the key that everyone should have access to health care, housing, and support. However, as communities of PWH have named, the framework for creating a human rights environment requires having people with lived experience at the table. This framework was not necessarily done when the status neutral approach was developed, piloted, resourced, and studied.

If the approach to status neutral is to work as intended, where will the voices of community members impacted by the method be recognized? Does status neutral include sex workers and immigrant/migrant populations? It's hard to realize if this seemingly unbiased approach is inclusive when the federal response to HIV doesn't acknowledge these populations in their national implementation plan.

To even consider new strategies for ending HIV, we have to remove policies that criminalize individuals for manageable chronic illnesses...

To be inclusive in this model, we must look at people beyond the clinical and biomedical approach. A person's identity and how they feel about being authentic and whole plays a role in how they embrace an HIV diagnosis and, before that, how the community they are now a part of has been a part of forming decisions that impact their lives. That balance of a power dynamic in informed leadership and living with HIV also can contribute to how people with HIV identify themselves, through race, sexual orientation or preference, and even socioeconomic status. As well, it drives how they can access and adhere to a treatment regimen and their medical care. Depending on their geographic location, other systemic social service assessments have to be considered around transportation, childcare, employment status, housing, access to food and nutrition and, in cases of HIV criminalization, the penalty of being added to a sex offender registry. All these things impact needs and the quality of life.

These issues are creating harm and not being considered beyond the model's clinical scope, so having PWH formally engaged in developing policies that affect their quality of life is critical. Taking a close and authentic look at the methods and strategies implemented historically can highlight various lanes within the pathway to ending new HIV transmissions, increasing prevention strategies, and ending the laws that criminalize PWH.

What is essential in that critical analysis is also an individual assessment of recognizing that being in a workforce for an extended amount of time, dedicated to something controversial and nuanced, is also a space for neutrality. How clinicians provide care, the language they use when they produce a study, and the care focus for medical case managers expected to identify vast yet limited resources should also be under the scope of implementing status neutral as we examine the journey of providing reasons to prevent HIV and be receptive for HIV care in the same way. They are equally crucial for individual and collective reckoning.

When it comes to a status neutral approach, what it has meant for communities of

PWH is that there is an implicit implication to erase PWH, especially in the way of funding, which will create an undue burden and derail the HIV criminalization reform efforts across the country. Many of the services impacted by adopting the neutral approach will mean that essential services for PWH will be at risk of being heavily reduced, which seems to work against public health efforts and funding sources already limited in response to HIV, including treatment and care.

We are unclear where this leaves individuals with a new diagnosis who need treatment and support services in light of criminalization. Seemingly, there is no transparent and inclusive strategy for an evidenced and fully informed rollout of status neutral in the decriminalization of HIV framework. In that case, we will never be able to end HIV criminalization laws, let alone end HIV. If a strategy exists that meaningfully addresses this concern, it has not been discussed or addressed with communities of PWH, and this continues to whitewash, erase, and invalidate marginalized communities that have been named as priority populations, which then creates less room for communities not even recognized. This eliminates opportunities for innovation for an HIV response in those communities. That does not translate to status neutral but to negligence.

When it comes to the need for HIV criminalization reform, there are no blurred lines. We must eliminate the antiquated laws perpetuating stigma, fear, and discrimination—especially for marginalized communities—before considering tapping into status neutral approaches. To even consider new strategies for ending HIV, we have to remove policies that criminalize individuals for manageable chronic illnesses and focus on neutralizing misinformed, stigmatizing language and practices that create harm before we can begin to consider looking through a lens of status neutrality thoroughly.

As two Black women, in the south, living with HIV, and leading unapologetically, we have to take a position and stand firm on recognizing that taking a status neutral approach is a start, but not until we can set and secure a

fully inclusive foundation, funding, and focus so that PWH will not end up on the chopping block, put on a back burner, erased, white-washed, or even forgotten. It will not be until we have been able to recognize that all layers of advocacy and impacted voices are essential to obtain the reality of normalization, not neutralization, of HIV prevention and care as a part of our daily quality of life. **HIV**



DEIRDRE JOHNSON has lived with HIV for over 20 years, but is most passionate about her activism on eradicating stigma and ending criminalization of people living with HIV.

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Living with Black Girl Magic, HIV, and chronic optimism, **KAMARIA LAFFREY** serves nationally as co-managing director for HIV policy reform with The SERO Project, leading

her state coalition in these efforts, and in both roles offers strategic planning and community mobilization training to state leaders living with HIV to change their HIV criminalization laws.

Deirdre and Kamaria are both members of organizations supported and anchored by the United States People Living with HIV Caucus (also known as the HIV Caucus) through the Sero Project. The HIV Caucus was formed in 2010 as a national voice for people with HIV (PWH). Members are PWH-led groups, organizations, networks, and individual advocates living with HIV. The Caucus represents communities most impacted by HIV in the U.S. and advocates for human rights and dignity for PWH.

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Legislation and HIV PrEP/PEP Prescribing for Pharmacists: Considerations for the Care Team

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This accredited continuing education activity is jointly provided by



FACULTY: Kenric B. Ware, PharmD, MBA, AAHIVP, Associate Professor of Pharmacy Practice at South University School of Pharmacy

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:

- Examine key aspects of state legislation authorizing pharmacist-prescribed HIV prevention modalities
- Discuss rationales for parameters placed on pharmacist-prescribed HIV prevention regimens
- Evaluate perceptions among patients and other healthcare team members about pharmacist-readiness to prescribe HIV prevention therapies
- Explore interprofessional challenges and opportunities associated with pharmacist-prescribed HIV prevention implementations.



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Legislation & HIV PrEP/PEP Prescribing for Pharmacists

What the Care Team Needs to Know

By KENRIC B. WARE, PharmD, MBA, AAHIVP

THE ROLE OF PHARMACISTS within interprofessional teams is steadily evolving to reflect their presence as facilitators of disease prevention and management strategies. While pharmacists customarily retain medication-dispensing functions, the health care community is trusting pharmacists to contribute in nontraditional capacities.¹ An example of such trust is some states' approval of pharmacists as prescribers of human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) and HIV post-exposure prophylaxis (PEP).²⁻⁴

HIV PrEP's indication includes people not living with HIV, in conjunction with safer sex practices, to reduce the likelihood of HIV seroconversion.⁵ Likewise, HIV PEP is another option for people not living with HIV to use after a known or suspected HIV encounter, taken within 72 hours of the occurrence and for 28 days.⁵ Both prevention modalities, HIV PrEP and PEP, are associated with laboratory and sexually transmitted infection (STI) monitoring, along with recurring HIV testing, to ensure that people will continue to benefit from HIV prevention.⁵ Pharmacists' abilities to conduct disease state assessments, accompanied by their drug therapy knowledge, positions them to initiate and maintain HIV PrEP/PEP care, and to play a greater role as part of HIV prevention teams.⁶⁻⁸

National Landscape of Pharmacists Prescribing PrEP/PEP

Pharmacists' ability to prescribe HIV PrEP/PEP is limited to selected states within the United States (U.S.).⁹ Presently, these states are California, Colorado, Maine, Nevada, New Mexico, New York, Oregon, Virginia, and Washington.⁹⁻¹⁰

While each state's statutes may vary, there are commonalities that govern pharmacists' core responsibilities. When comparing the states' individual pharmacist-prescribed PrEP/PEP regulations, California's guidance is largely representative, serving as a prototype to expound upon. In California, legislation specifies a PrEP regimen as a fixed-dose combination of tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC) or an *equivalent product*.³ Inclusion of the verbiage *equivalent product* accounts for other HIV PrEP regimens available for use aside from TDF/FTC. Pharmacists in California must also undergo a training

program approved by California's board of pharmacy, in collaboration with its medical board.³ California's regulations permit pharmacists to prescribe at least a 30-day supply, not to exceed a 60-day supply of PrEP, subjected to different stipulations.³ Moreover, California's pharmacist prescribing stipulations that mirror other states include patients not living with HIV, no signs or symptoms of acute HIV, an absence of contraindicated therapies to PrEP use, and continual pharmacist counseling on sustained PrEP administration. The guidance dictates that HIV testing occurs within seven days by an available FDA-approved testing apparatus. In the absence of an ability to confirm an HIV negative result, pharmacists must order an HIV test. If it is determined that an individual is HIV positive, the pharmacist or a designated testing organization must refer the individual to a primary care provider (PCP) in the area.³

As it relates to PEP, California pharmacists have the latitude to assess a prospective client and gauge whether an HIV exposure occurred within 72 hours. Pharmacists can conduct the associated HIV testing or refer HIV testing elsewhere. Training opportunities exist for pharmacists to learn how to deliver HIV testing results in a confident and patient-centered manner.⁵ Pharmacists are in turn also responsible for discussing pertinent points related to PEP; a notable consideration is PEP's use should be for 28 days without any interruptions.

Additionally, legislation requires pharmacists to correspond with individuals' PCPs or endeavor to coordinate access to PCPs in their absence. No explicit provision deters pharmacists from delegating these linkage-to-care duties to other pharmacy personnel. However,

accountability for ensuring that a PCP relationship materializes or documenting barriers to establishing the relationship, along with any progress made in this direction, would presumably rest entirely with pharmacists.¹¹⁻¹²

Perceptions of Pharmacists as HIV PrEP/PEP Prescribers

Although pharmacists have the professional training to prescribe HIV PrEP/PEP therapies, it can be valuable to understand the perceptions of their capabilities to perform these functions. Since prescribing authority is not commonly ascribed to pharmacists, observers of this trend may have varying viewpoints about its utility.

Researchers, for example, recently explored perspectives of pharmacists prescribing HIV PrEP among specialty pharmacy clients in Arizona.¹³ Of the nearly 50 survey respondents (n=49), over 95 percent of the study population identified as male. The majority of survey respondents reported an age range between 20 to 29 years old. The participants' race/ethnicity distributions comprised approximately 70 percent White/non-Hispanic, 25 percent Hispanic, and five percent Asian American. When queried, over 90 percent of participants stated they would be willing to consult a pharmacist for HIV PrEP information or testing. However, almost 20 percent of these individuals expressed discomfort with having a pharmacist prescribe their first HIV PrEP prescription. Furthermore, roughly 20 percent of the sample remarked that increasing accessibility to HIV PrEP would result in decreased use of barrier protections.

Several factors may affect the ability of these findings to be widely extrapolated to the general population. Representation from less than five percent of people who identify as female or gender non-binary could have limited insights that were likely to emerge from a more gender diverse sample. In addition, hearing from teenagers and older populations about whether they feel pharmacists are equipped to prescribe HIV PrEP would have been helpful, particularly because these subsets could be viable HIV PrEP candidates in different scenarios. Epidemiological data within the U.S., particularly in the Southeast, reveals that people identifying as Black/African American would stand to benefit from HIV PrEP given the disproportionate

HIV incidence and prevalence rates observed among this population.⁵ Their lack of inclusion within these results indicates a future opportunity to investigate their beliefs about pharmacists as HIV PrEP prescribers.

Survey participants expressed support for pharmacists contributing in an HIV PrEP educational or resource capacity. However, there was hesitation within the sample about pharmacists prescribing an initial HIV PrEP regimen. The main reason articulated was the belief that pharmacists do not receive the necessary training to handle this level of responsibility. A subset of the sample also held stigmatizing beliefs towards PrEP itself, convinced that improving its availability would equate to individuals taking less precautionary measures. Participants favored pharmacist-prescribed PrEP overall, with more of a preference for pharmacists discussing rather than initiating PrEP.

As a complement to learning about client perceptions, a California-based survey queried pharmacists, pharmacy administrators, and medical providers about the perceived benefits and uncertainties surrounding pharmacist-prescribed PrEP.³ The participants interviewed spanned different health care practices, with pharmacists employed in clinic and community-based arenas, pharmacy administrators in community pharmacy settings, and medical providers with oversight responsibilities in community clinics. This investigation took place while authorities were evaluating California's pharmacist-prescribed PrEP/PEP legislation. California would eventually become the first state with pharmacist-prescribed PrEP/PEP legislation. Therefore, the authors projected that their findings would help to guide other states in a quest for their pharmacists to achieve similar professional latitude.

Advantages of pharmacists prescribing PrEP that were agreed upon by the interviewees included their ease of accessibility, experience facilitating medication adherence, and the help this could offer understaffed PCPs. Conversely, respondents cited infrastructure challenges to pharmacist-prescribed PrEP, having reservations about how conducive pharmacy settings would be to performing sexual risk assessments. Medical providers within the study sample specifically pointed

to limitations in pharmacists' training to navigate concomitant concerns that clients could likely present with in a pharmacy (e.g., syphilis manifestations) that a primary care setting would be equipped to readily address. This group of medical providers also suggested that clients receiving pharmacist-prescribed PrEP would regard these encounters as substitutes for comprehensive medical assessments. Pharmacists within the study sample acknowledged another foreseeable barrier: whether insurers would cover the costs of associated labs and their consultation time. The blend of opportunities and obstacles to pharmacist-prescribed PrEP are prone to be largely location-specific, compelling each state to work internally to generate solutions that work best for their individual contexts.

Pharmacy Workflow Dynamics in Relation to Pharmacist-prescribed PrEP/PEP

Pharmacies' capacity to scale up pharmacist-prescribed PrEP/PEP or to introduce this approach is likely indicative of their existing workload demands. Varying prescription volumes and other pharmacy operations are inclined to affect uptake of pharmacist-prescribed PrEP/PEP. As an example, consultation rooms or isolated areas in pharmacy locales traditionally accommodate vaccine administrations. Pharmacist-driven dialogue with clients around PrEP/PEP, including therapy discussions and delivery of HIV testing results, if conducted at the pharmacy or elsewhere, would necessitate use of a secluded area. Without reimbursement strategies solidified to compensate pharmacists for this time, other revenue generating interventions, such as administering vaccinations, would likely receive priority usage of the private space.

Overall, community pharmacy layouts do not typically account for private counseling areas for pharmacist and client interactions. Prior to attempts at internal redesigns, community pharmacy administrative personnel would presumably want to brainstorm any anticipated effects on clients accessing the pharmacy and on staff workflow considerations. If pharmacy settings undergo physical restructuring, financing these renovations would foreseeably be costly, likely compelling requests for funding support from external entities.

As a component of verification processes within drug-dispensing functionalities, prescriptions written for STIs, detected by names of drugs, frequencies, and durations, may serve as “PrEP prompts.” These therapeutic indicators could alert pharmacists to initiate conversations with recipients about PrEP and to assess whether they could benefit from it. This approach may also find favor with items that do not require a prescription prior to dispensing, such as emergency contraceptive products. If desirable, pharmacy locales would have to assess their daily procedures to devise operating standards that actualize “PrEP prompts” in a manner where pharmacists are equipped to invite these exchanges and that promotes client confidentiality.¹⁴ In addition, leveraging expertise of pharmacy technicians as liaisons to pharmacist-prescribed PrEP/PEP has implications that warrant further exploration.

Pharmacy Partnerships with Community-based Organizations as Promising Paths Forward

In anticipation of generating or sustaining pharmacist-prescribed PrEP/PEP responsibilities, collaborations with community-based organizations (CBOs) within the vicinity of interested pharmacies has enduring potential. Ensuring favorable proximities between pharmacies and CBOs is likely a key factor in client willingness to receive services from both locales. Opportunities for shared responsibilities between pharmacies and CBOs could present as HIV testing and sexual health assessments orchestrated by CBOs, whereas pharmacists/pharmacies undertake counseling services on PrEP/PEP regimens or antiretroviral therapy (ART) indicated for HIV treatment, in the event that HIV seroconversion has occurred. In an effort to establish holistic care considerations, the pharmacy-CBO relationships could transcend PrEP/PEP interactions, where pharmacists/pharmacies perform comprehensive medication reviews for CBO clients and interested staff. In turn, CBOs would have a vested partnership with pharmacies where their clients and staff can receive routine vaccinations and other pertinent preventative or maintenance health interventions.

Legislation & HIV PrEP/PEP Prescribing for Pharmacists: What the Care Team Needs to Know

ASSESSMENT QUESTIONS

- Each of the following states currently authorize pharmacists to prescribe HIV PrEP/PEP EXCEPT:
 - California
 - Colorado
 - Georgia
 - Nevada
- Which statement is CORRECT regarding stipulations placed on pharmacists' HIV PrEP/PEP prescriptive authorities?
 - Pharmacists can provide HIV PrEP or PEP to individuals if their viral loads are undetectable
 - Pharmacists can prescribe HIV PrEP/PEP in a limited capacity
 - Pharmacists can prescribe one formulation of HIV PrEP, but not others
 - Pharmacists can prescribe HIV PrEP/PEP if they are employed in a hospital setting
- Which of the following represents a concern some medical providers have with pharmacist-prescribed HIV PrEP/PEP?
 - Clients may not be able to access pharmacists due to their limited availability
 - Clients may not feel comfortable going to a pharmacy for HIV PrEP/PEP care due to feeling stigmatized
 - Clients may not believe that pharmacists are knowledgeable enough about HIV PrEP/PEP
 - Clients may not distinguish an HIV PrEP/PEP pharmacy visit from a comprehensive medical care appointment

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Impact of Pharmacist-prescribed PrEP on Team-based Approaches to Client Services

Pharmacist-prescribed PrEP implementations further position pharmacists to have more accountability for therapy optimization, including medication acquisition logistics, preferred drug formulations, optimal administration parameters, along with

assessment and monitoring of concomitant conditions. Through instituting pharmacist-prescribed PrEP, other health care team members who presently assume drug procurement responsibilities can relinquish these roles to pharmacy personnel, allowing for redirection of their expertise to other client-focused areas. Pharmacists are equipped to educate team members about therapeutic

benefits of available PrEP preparations and facilitate product interchanges among different PrEP options due to client preferences or clinical indicators. Furthermore, pharmacists and pharmacy personnel managing the totality of PrEP-specific prior authorization (PA) processes will save other health care team members time from contacting insurance plans and subsequently pharmacy locations to resolve PA scenarios.

Pharmacists performing point-of-care HIV testing in private locations could mitigate the need for clients to make separate clinic appointments and likely save them money on office visit costs, such as co-pay fees. Moreover, clinic personnel can re-purpose testing appointment timeslots to create more availability for clients to receive generalized medical care. Pharmacists will also presumably coordinate STI testing, such as chlamydia, gonorrhea, and syphilis, with internal or external facilities, working alongside laboratory personnel. While pharmacists will begin to proceed with greater autonomy as it relates to assessing PrEP suitability for candidates and prescribing PrEP, practitioners outside of the pharmacy setting will need to remain abreast of pharmacist interactions with shared clientele.

Presently, in some community pharmacy settings when clients receive vaccinations, pharmacy personnel fax associated paperwork to designated primary health care providers. A similar arrangement figures to work to notify providers of pharmacist-initiated PrEP regimens. When clients disclose that they do not have a PCP, pharmacists can reach out to providers preferably in the pharmacy's area to create and sustain relationships that link clients to comprehensive health services. Venturing outside of the pharmacy-specific locale, in an effort to bring pharmacists and non-pharmacists together to promote HIV prevention, having a joint presence at recurring HIV advocacy events, such as World AIDS Day, provides an opportunity for community members to become more acquainted with pharmacists' skill sets and for pharmacists to learn more about community needs.

While it is not apparent if any non-pharmacist associations have publicized their positions on pharmacist-prescribed PrEP/

PEP, these pharmacist responsibilities are not without their challenges. An interest of various health care institutions will likely be to establish checks and balances among medication distribution systems that prioritize a different pharmacist prescribing PrEP from the one dispensing it. An expected rebuttal to this preference would be pharmacies with low prescription volumes might not be able to afford having more than one pharmacist per work shift. An additional obstacle that figures to surface is minimal or no reimbursements on pharmacist-prescribed PrEP/PEP encounters due to insurance companies not classifying pharmacists as providers/prescribers. Learning which insurance companies exclude pharmacists from their prescriber/provider designations will likely be a cumbersome and time-consuming process.

The dawn of pharmacist-prescribed HIV PrEP/PEP is poised to expand access to proven HIV prevention modalities to populations where utilization remains suboptimal. While this strategy is not currently available everywhere in the nation, states that have adopted this approach have put forth regulations geared towards capitalizing on pharmacists' skill sets and retaining medical professional involvement in the process. Invariably, it may take some time for public perception to grasp the paradigm shift from pharmacists depicted solely as medication dispensers to medication dispensers and prescribers.¹⁵ However, pharmacists remain conveniently stationed throughout diverse practice settings, prepared with sufficient training, to initiate and maintain PrEP/PEP therapeutic regimens for allotted periods. Nevertheless, barriers to implementation and longevity exist, which call upon stakeholders from various aspects of health care to work collectively towards solutions that are germane to their respective demographics. **HIV**



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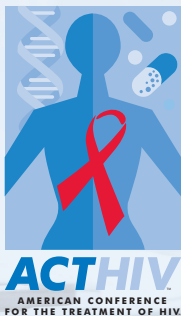
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PA Preceptorship Program is Training the Future

BY ANGELA KAPALKO, PA-C, AAHIVS

A **RECENT REPORT** by the Association of American Medical Colleges projects a physician shortage of up to 124,000 doctors by 2034.¹ Primary care specialties, such as family medicine and pediatrics, are projected to lose between 17,800 and 48,000 physicians.² The data from the report was collected before the COVID-19 pandemic, so it's likely these numbers will shift significantly higher due to physician burnout and physicians leaving the workforce early. A report from last year supports this assumption. According to the findings, 117,000 physicians left the workforce in the fourth quarter of 2021, and the specialties that had the greatest exodus were internal medicine and family practice.³

This shortfall can have serious implications across the spectrum of health care. Nowhere will it be felt more than in underserved communities, especially within those populations who are at highest risk of acquiring HIV or those with HIV who are unable to access care or receive continuous care. The most vulnerable among us will be hit hardest without adequate health care. And to get adequate care, the United States health care system will need to have enough people to provide that care. Not only do we need to treat our patients who have HIV, but we must also work to end the HIV epidemic with a range of preventive interventions across all populations. This, too, requires the needed numbers of health care workers who can provide those interventions.

How PAs Can Help

This is where PAs (physician assistants/physician associates) come in. PAs are licensed clinicians who can practice medicine in every specialty and setting. PAs work as a team with physicians and other health care providers to extend care. PAs are educated in general medicine and are trained to practice medicine using a curriculum modeled on medical school education. PAs are educated at the master's degree level and PA programs generally take 27 months to complete, including both classroom instruction and more than 2,000 hours of clinical rotations.⁴

Because of PAs' medical training and experience, they are well suited to expanding the clinical team and can be a great answer to the projected physician shortages. PAs have the clinical expertise to handle their own patient loads. They diagnose illnesses, provide treatment, and prescribe medication. As well, since PAs have a generalist medical background, they can specialize in any area of care, including primary care, pediatrics, infectious disease, and HIV medicine. According to the most recent numbers from the National Commission on Certification of PAs, in 2020 there were approximately 19,312 PAs in family medicine/general practice, 14,792 PAs in internal medicine, and 2,000 PAs in pediatrics.⁵

PA Preceptorship Program

To bring more PAs into HIV medicine, the Academy has begun 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.

The program, which officially kicked off last year, currently has three students who are matched with clinicians. 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 treatment and prevention. 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. **HIV**

How to Participate

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 **HIV**



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

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CAROLYN CHU, MD, MSC, AAHIVS

AAHIVM Chief Medical Officer

FEATURED LITERATURE:

Melvin AJ, Yee KL, Gray KP, et al. Pharmacokinetics, tolerability, and safety of doravirine and doravirine/lamivudine/tenofovir disoproxil fumarate fixed-dosed combination tablets in adolescents living with HIV: Week 24 results from IMPAACT 2014. *J Acquir Immune Defic Syndr*. 2023 Feb 1; 92(2): 153-161. PMID: 36215957.

IMPAACT 2014 is a phase I/II open-label, nonrandomized multicenter study investigating the safety, tolerability, and pharmacokinetics of the adult doravirine tablet and adult doravirine/lamivudine/tenofovir disoproxil fumarate (DOR/3TC/TDF) FDC tablet in youth with HIV-1 infection. This study presents single-dose pharmacokinetics analyses (Cohort 1, with nine participants having complete data) and 24-week treatment outcomes for DOR/3TC/TDF in adolescents aged 12 to <18 years (Cohort 2, with 45 participants all weighing ≥ 45 kg). Two Cohort 2 participants were ARV-naïve and 43 were virologically suppressed, with over half switching from efavirenz-based regimens (median ART duration prior to enrollment: 2.8 years). Overall, doravirine was well-tolerated by all participants. Three Cohort 2 participants had grade 3 decreased eGFR, two with concomitant grade 3 increased creatinine. Actual creatinine and eGFR values remained normal for age despite these changes, and no participant met the safety end point (i.e., eGFR < 60 mL/min/1.73m²). There were no medication discontinuations related to adverse events. Forty-two out of 45 (93.3%) of Cohort 2 participants achieved or maintained HIV-1 RNA < 50 copies/mL. There were no significant changes in liver or kidney function measurements, and BMI remained stable. For Cohort 2 participants transitioning from efavirenz-containing regimens, the effects of CYP3A induction waned by week four and did not affect virologic efficacy.

AUTHOR'S COMMENTARY:

Results of this study were initially presented at CROI 2021, and 24-week virologic efficacy results show favorable effects comparable to data reported from adult trials. DOR plus a two-NRTI backbone is currently recommended as an alternative NNRTI-based regimen for initial treatment of HIV infection in children and adolescents weighing at least 35 kg, and DOR is also listed as a potential switch option for children and adolescents weighing at least 35 kg who are virologically suppressed on an efavirenz- or nevirapine-based combination. DOR may present an attractive option for scenarios where providers or caregivers/patients wish to avoid INSTI-associated weight gain or increases in lipid levels, however this should be balanced with potential concerns regarding TDF, since the only currently available FDC containing DOR utilizes TDF. Nevertheless, PK analyses suggest that DOR concentrations for the 100-mg tablet in adolescents are comparable with adult levels and is generally safe and well-tolerated.

FEATURED LITERATURE:

Harris TN and Buscemi LR. Evaluation of treatment simplification strategies in patients living with HIV with multi-drug resistance. *Ther Adv Infect Dis*. 2023 Jan 19; 10:20499361221149869. doi:10.1177/20499361221149869. PMID 36699503.

This observational, retrospective cohort study described virologic outcomes of a single-center initiative evaluating ART simplification among PWH with a history of multi-drug resistance and treatment failure. Patients received medical services at a non-urban, Ryan White funded clinic and were on “salvage” therapy (defined as ≥ 3 agents from at least three classes) between July 2016 and July 2021. Clinical information for 50 adults was extracted from health records, including data on prior and current regimens and genotypes. Cumulative resistance profiles were constructed and genotypic sensitivity scores were calculated for current regimens and also for new simplified regimens, if applicable. Twenty-eight out of 50 patients underwent simplification (defined as a pill burden reduction by at least one pill/day); five of these 28 patients were viremic prior to the change. Baseline characteristics were generally similar between patients who underwent simplification (median baseline GSS 3) and those who did not (median baseline GSS 2.5), although there were more patients with darunavir-specific mutations in the non-simplified group. Patients in the simplified group had their regimen reduced by a median of six pills/day to a median of two pills/day: most were simplified to a single-tablet or two-tablet regimen. Twenty-four out of 28 (85.7%) in the simplified group achieved or maintained virologic suppression at their most recent clinic visit, versus sixteen out of 22 (72.7%) in the non-simplified group. Twenty-three out of 28 (82.1%) in the simplified group were suppressed $\geq 80\%$ of the time over the past two years, versus sixteen out of 22 (72.7%) in the non-simplified group. Three patients in the simplified group and five in the non-simplified group experienced virologic failure, however no emergence of new resistance mutations was observed.

AUTHOR'S COMMENTARY:

Although this small, “real world” study did not observe significantly different virologic outcomes among comparison groups, median ARV pill burden decreased from six to two pills/day for patients undergoing simplification and > 85 percent who underwent simplification achieved or maintained virologic suppression at study endpoint. In the simplification group, 75 percent had anticipated high-level NRTI resistance, 78.6 percent had anticipated high-level NNRTI resistance, 7.1 percent had anticipated DRV-specific mutations, and zero had anticipated high-level INSTI resistance. The three most common simplification regimens utilized were BIC/FTC/TAF plus DRV/cobi, BIC/FTC/TAF, and DTG/RPV plus DRV/cobi. These findings

may be of interest not only for general ART switch decision-making, but could also potentially help inform construction of streamlined “optimized background regimens” for patients who are being considered for newer ARV agents such as fostemsavir and lenacapavir. The multidisciplinary approach utilized in this effort also highlights the important role pharmacists hold in helping to construct effective and well-tolerated regimens, drug interaction assessments, and adherence support through interventions such as regular medication reviews and pill box fills.

FEATURED LITERATURE:

Aebi-Popp K, Kahlert CR, Crisinel PE, et al. Transfer of antiretroviral drugs into breastmilk: a prospective study from the Swiss Mother and Child HIV Cohort Study. *J Antimicrob Chemother*. 2022 Nov 28; 77(12): 3436-3442. doi:10.1093/jac/dkac337. PMID 36177836.

This study describes ARV concentrations in the breastmilk and maternal plasma of 21 Swiss mothers on HIV treatment (2019-2021), to estimate daily infant ARV dose from breastfeeding. Infant plasma ARV concentrations were also measured. All mothers had viral load < 50 copies/mL (ideally throughout pregnancy) and routine clinical evaluation occurred via monthly visits per Swiss care guidelines. No infants received post-exposure prophylaxis, as per Swiss recommendations. Maternal breastmilk and plasma samples were obtained at one-, three-, and six-month follow-up visits after delivery. Infants were tested at one and six months of age by PCR and again three months after weaning; serologic testing was performed at 18-24 months of age. Most mothers were receiving INSTI-based treatment (1 bictegravir, 3 dolutegravir, 10 raltegravir), two were on rilpivirine-based combinations, and two were on ritonavir-boosted darunavir. Three were receiving tenofovir alafenamide (TAF). No HIV transmissions were identified. Sample analyses demonstrated rilpivirine and tenofovir [derived from TAF] transfer well in breastmilk (similar to other NNRTIs and most NRTIs). By contrast, darunavir/ritonavir (like other PIs) has low transfer. INSTI transfer was variable: bictegravir and dolutegravir have low transfer, and raltegravir has moderate-high transfer. Very low or undetectable levels for rilpivirine, raltegravir, darunavir/ritonavir, and tenofovir [derived from TAF] were observed in infants. Efavirenz, nevirapine, and dolutegravir were detectable in infants. Overall, the estimated daily infant ARV dose from breastfeeding was low for all evaluated ARVs and fell within the safety threshold (exposure index < 10%).



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AUTHOR'S COMMENTARY:

Information from this investigation may help address questions regarding the breastfeeding-associated safety of various ARVs when taken as part of maternal HIV treatment. Unsurprisingly, study data demonstrate that ARVs transfer into breastmilk and in breastfed infants to different extents: results for DRV/RTV and RPV generally followed historical observations in the PI and NNRTI classes, respectively. By contrast, transfer differed between specific INSTIs. Not all studied ARVs achieved effective inhibitory concentrations in the breastfed infant, and therefore one caution noted by authors is that the clinical relevance of subtherapeutic ARV concentrations in breastmilk (as well as differential drug exposure in infants) is unknown. Both may lead to concerns related to “potential development of resistance in the rare event of vertical transmission” as well as “monotherapy exposure and related risk of acquiring resistant HIV strains.” It is also noteworthy, however, that no postnatal transmissions were identified among breastfed infants, none of whom received any post-exposure prophylaxis. **HIV**

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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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