

THE AMERICAN ACADEMY OF HIV MEDICINE ■ SEPTEMBER 2021

# HIV SPECIALIST

## HIV Information Modalities

Management  
of Cirrhosis

HIV Primary Care

The Art of HIV  
Advocacy

Mandated  
Coverage  
of PrEP

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# ANAC2021

## WASHINGTON D.C.

### Nov. 11-13, 2021

Renaissance Washington, D.C.  
Downtown Hotel



#### Conference Objectives:

1. Discuss innovative biomedical, psychosocial and behavioral research in HIV, with an emphasis on:
  - Aging
  - Co-occurring conditions
  - Inequities in HIV incidence and health outcomes
  - End of life and palliative care
  - Prevention and wellness
  - Self-care for nurses
  - Social determinants
  - Symptom management
2. Describe innovations in HIV prevention and treatment that support the National HIV/AIDS Strategy and the Ending the Epidemic plan.
3. Illustrate the impact of nurses and other healthcare professionals by addressing HIV in global settings.
4. Increase capacity of nurses and other healthcare professionals to effectively engage in advocacy and health policy for people affected by HIV.
5. Describe the impact of COVID-19 on nurses, healthcare, communities and people affected by HIV.
6. Examine inequities in HIV incidence and outcomes, healthcare or social determinants of health.
7. Identify the important roles of nurses and nurse leadership in the context of 2021 as the Year of the Nurse.
8. Enhance the capacity of nurses and other healthcare professionals to identify, treat, and care for people with and at risk for HIV.

**For more information, visit [nursesinaidscare.org](https://nursesinaidscare.org).**

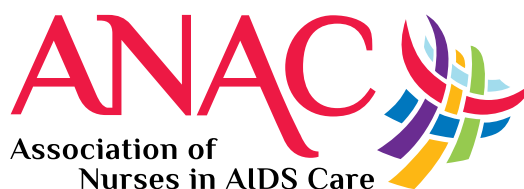
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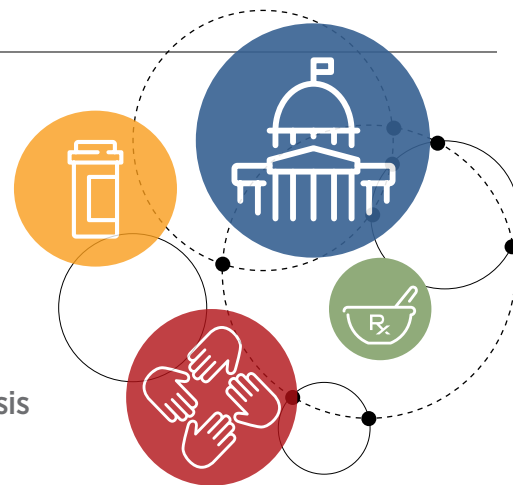
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## Keeping Connected to our Members

**THE ACADEMY** is always looking for novel modalities, strong partnerships and top faculty to deliver trustworthy and up-to-date medical information to its members, credentialed providers, and others caring for and preventing HIV. We certainly recognize that we live in an age where a specific kind of weariness sets in with the sheer volume and incessant streams of information available and bombarding us, and we continue to ask the important question of: where can the HIV care providers go to gather the clinical knowledge they need to provide optimal care to their patients, and how can the Academy best serve its members and other providers in the arena of CME and medical education more generally?

Obviously the sources and modalities of clinical education are multifold, encompassing clinical conferences, for-profit med-ed companies, federal agencies and professional medical organizations like the Academy. We strive to balance providing our own content from our network of HIV Specialists and other HIV thought leaders within the organization along with dynamic partnerships with some of the other sources of med-ed and clinical guidelines described above. The full mosaic of these offerings, partnerships, resources and cross-promotions from the Academy, we hope, provides our members with a comprehensive breadth of HIV clinical care and guidance, from primary care, aging and HIV, prevention and the latest treatment advances.

Undeniably, the resilient COVID-19 pandemic has presented challenges in our ability to reach members and others with this critical medical information. We've been forced into a kind of creative pivot in our communications and promotions, and we're certainly endeavoring to create a more dynamic digital education experience to reach more providers in key parts of the country, given the lack of in-person opportunities at this point in time due to public health concerns. To this point, the Academy has always heralded new and innovative technologies in its delivery of information—reference, for instance, our annual Technology in HIV Award for leveraging these emerging innovations. Even still, we've heard from our surveys and from member voices that in-person med-ed events continue to be a valued source of medical information dissemination, providing an opportunity for networking, collaboration, peer-to-peer exchange of information, innovation, case studies and best practices, and other nooks of the patient experience and clinical world that we can't always cover with a universal digital program. We certainly hope, as an organization that really seeks to leverage these horizontal, grassroots networking opportunities, to return to the cities, states and clinics where our providers work to provide that unique, peer-to-peer experience with our medical education programming.

I'm sure many feel the same way about the ability to attend conferences in person. In this issue of *HIV Specialist*, the Academy would like to highlight its longstanding and productive partnership with the American Conference for the Treatment of HIV (ACTHIV), where clinicians treating and preventing HIV can attend and have access to the latest clinical science and research around HIV care and prevention. Thanks again to John Juckniewicz, president of the American Academy of CME, which accredits all the programming for ACTHIV and other clinical conferences, as well as to all the authors of the articles in this issue, which encompass major clinical highlights from ACTHIV 2021 in the areas of hepatic function, primary care updates, transgender care, and much more.

We can only strive to continue to remain and to continue to improve upon being a trusted source for clinical information in HIV in the years to come, as we find and add novel and innovative tools in our prevention, care and treatment toolbox with an eye ever on the prize of functionally ending new transmissions of HIV in the US.

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

# IN THE NEWS

## Experimental Phase 2b HIV Vaccine Regimen Provides Insufficient Protection in Preventing HIV

No safety signals of concern for study participants

**A** **PRIMARY ANALYSIS** of an experimental HIV vaccine regimen being studied in a high-incidence population of young women in sub-Saharan Africa found the experimental vaccine did not provide sufficient protection against HIV infection. No significant safety concerns were identified, but because the vaccine regimen failed to meet the study's primary endpoint, with results falling short of statistical significance, the Imbokodo study, also called HVTN 705/HPX2008, will be discontinued. Further analysis of the Imbokodo study is ongoing, and the study has provided enough data to progress with key immunological correlates research. Participants in this Phase 2b proof-of-concept study will be unblinded and will continue to be referred to high-quality treatment and care.

The analysis of the study was reviewed by an independent data and safety monitoring board (DSMB).

"The high rates of HIV acquisition seen in the Imbokodo study of young women in sub-Saharan Africa remind us that, despite great progress made in treatment and prevention, HIV remains a huge health challenge for the region," said Glenda Gray, MBBCH, FCPaed (SA), Protocol Chair and Co-Principal Investigator and Director of HVTN Africa Programs and President & CEO of the South African Medical Research Council. "This underpins the need to apply the knowledge gained from this trial to continue to advance the pursuit of a global HIV vaccine."

The development of a safe and effective HIV vaccine is critical for global health. In the 40 years since the virus was discovered, a vaccine has proved elusive because of the virus' unique ability to attack and evade the immune system.

This study began in 2017, reached full enrollment in 2019, and completed vaccinations in June 2020. The study was evaluating the experimental regimen in approximately 2,600 women between ages 18 and 35 across five countries: Malawi, Mozambique, South Africa, Zambia and Zimbabwe. According to UNAIDS, women and girls accounted for 63 percent of all new HIV infections in this region in 2020.

The experimental vaccine consisted of an adenovirus containing four "mosaic" immunogens—called mosaic because they are designed to induce immune responses against multiple global HIV strains. The regimen included four doses of the mosaic Ad26 vaccine; the final two doses were given together with doses of an HIV protein called clade C gp140 mixed with an aluminum phosphate adjuvant to boost immune response. Different HIV subtypes, or clades, predominate in various geographic regions around the world. Clade C HIV is common in southern Africa, where the Imbokodo study was conducted.

In preclinical studies, regimens with mosaic-based vaccines elicited a strong immune response associated with protection against HIV in monkeys. Findings from two early-stage human clinical trials, called TRAVERSE and APPROACH, also suggested that these vaccines were well-tolerated and could generate anti-HIV responses in healthy adult volunteers, increasing hope for good results in the Imbokodo trial. The vaccine was initially developed by the laboratory of Dan H. Barouch, M.D., Ph.D., at Beth Israel Deaconess Medical Center and Co-Principal Investigator of the HVTN, together with Janssen and other partners.

"Despite the use of the Ad26 technology, which is effective for COVID-19, the Imbokodo

study illustrates that HIV is a virus that requires a higher degree of immune response to achieve effective protection," said Larry Corey, MD, Principal Investigator, HVTN Leadership Operations Center, which is based at Fred Hutchinson Cancer Research Center in Seattle, Wash. "We hope the details from the trial will provide evidence for what level of immune responses are required to achieve an effective vaccine. The study team and entire HVTN operations program thanks everyone who participated in this study, which will continue to provide important data to help drive forward the search for an HIV vaccine."

The Imbokodo study was supported by a public-private partnership led by Janssen Vaccines & Prevention B.V.; the Bill & Melinda Gates Foundation; the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH); and the HIV Vaccine Trials Network (HVTN), headquartered at the Fred Hutchinson Cancer Research Center. Additional partners providing support included the U.S. Army Medical Research and Development Command (USAMRDC), the Ragon Institute of Massachusetts General Hospital and Massachusetts Institute of Technology and Harvard University. The study was conducted at clinical sites coordinated by HVTN, and the South African Medical Research Council (SAMRC) helped to implement Imbokodo in South Africa.

The Imbokodo primary analysis occurred 24 months after the last participant had their first vaccination. The study's primary endpoint was based on the difference in number of new HIV infections between the placebo and vaccine groups from month seven (one month after the third vaccination timepoint) through month 24. This data found that through 24 months of



# IN THE NEWS

follow up, 63 participants who received placebo (4.32% incidence) compared to 51 participants who received active vaccine acquired HIV (3.61% incidence). This analysis demonstrated a vaccine efficacy of 25.2 percent (95% confidence interval of vaccine efficacy -10.5% to 49.3%). Further analysis of the results from the Imbokodo study is ongoing.

Although the Imbokodo study will not continue, another HIV vaccine trial is ongoing in a different population and in different areas of the world. The Phase 3 Mosaico study, or HVTN 706/HPX3002, is testing the safety and efficacy of an “optimized” experimental vaccine regimen that includes the same mosaic Ad26 priming immunogen but has an optimized booster regimen that includes a mosaic envelope plus a Clade C booster. This optimized booster gives higher and broader immune responses than the booster used in Imbokodo. Study participants are men who have sex with men (MSM) and transgender populations in North America, Latin America and Europe.

Drs. Gray and Corey said the Imbokodo research team will continue to analyze data from the study and publish complete findings to guide future investigations and vaccine development.

“The Imbokodo study provides valuable safety data on the mosaic Ad26 regimen as we move forward, but the disappointing efficacy results and the unabated HIV acquisition rates in women in sub-Saharan Africa—even during times of countrywide lockdowns—highlight the continuing importance of developing an effective HIV vaccine. With the Mosaico study in progress and other efforts underway, we remain committed to the fight against HIV and the enduring medical and social consequences of the 40-year pandemic of HIV.” Drs. Gray, Corey, and Barouch said.

## Mortality Risk in Transgender People Twice as High as Cisgender People, Data Spanning Five Decades Suggests

**T**RANSGENDER PEOPLE are twice as likely to die compared to cis men and cis women, according to an analysis of national data from the Netherlands spanning five decades. The findings, published in *The Lancet Diabetes & Endocrinology* journal, indicate that the heightened mortality risk among transgender people did not decrease between 1972 and 2018, highlighting a pressing need for action to address these long-standing and significant health disparities.

Previous studies have reported increased mortality rates among transgender people, however, it was not known whether this trend has changed over the past few decades.

Lead author Professor Martin den Heijer, of Amsterdam UMC, the Netherlands, said: “The findings of our large, nationwide study highlight a substantially increased mortality risk among transgender people that has persisted for decades. Increasing social acceptance, and monitoring and treatment for cardiovascular disease, tobacco use, and HIV, will continue to be important factors that may contribute to decreasing mortality risk in transgender people.

“Gender-affirming hormone treatment is thought to be safe, and most causes of death in the cohort were not related to this. However, as there is insufficient evidence at present to determine their long-term safety, more research is needed to fully establish whether they in any way affect mortality risk for transgender people.”

Transgender people can undergo medical therapies that bring about physical changes that more closely match their gender identity. These typically include gender-affirming

hormone therapy and surgery. Transgender men receiving gender-affirming hormone therapy are usually treated with testosterone to promote the development of masculine features, while transgender women typically receive antiandrogens and oestrogens, which induce feminine physical characteristics.

The study cohort consisted of 4,568 adult transgender people (2,927 transgender women and 1,641 transgender men) who had attended the gender identity clinic at Amsterdam UMC between 1972 and 2018, and were receiving gender-affirming hormone treatment. Data was gathered from medical files on participants’ age at the start of hormone treatment, the type of treatment, smoking habits, medical history, and the last date of follow-up. The average age at the start of hormone treatment was 30 years in transgender women and 23 years in transgender men. The average follow-up time in transgender women was 11 years and five years in transgender men.

The ratio of deaths among transgender men and transgender women compared to rates for the adult Dutch population were calculated using data held by Statistics Netherlands (CBS), which holds a record of all death of residents of the Netherlands. Where possible, mortality risk was divided into categories including cardiovascular disease, infection, cancer, and non-natural causes including suicides. Data on cause of death (if known) was available from 1996 onwards.

During follow-up, 317 (10.8%) transgender women and 44 (2.7%) transgender men died, resulting in an overall mortality of 628 deaths per 100,000 people per year.

Mortality risk was almost double among transgender women compared to men in the



general Dutch population, and nearly three times greater compared to cis women (ratios of 1.8 and 2.8, respectively). Mortality risk did not decrease over the five decades included in the analysis.

Compared with cis men, transgender women had 1.4 times greater risk of death because of cardiovascular disease (1.4 mortality ratio). Mortality risk was almost double for lung cancer (2.0 ratio), more than five times greater for infection (5.4 ratio), and nearly three times as high for non-natural causes of death (2.7 ratio). The greatest mortality risk from infection was associated with HIV-related disease, at nearly 15 times higher than for cis men (14.7 ratio). For non-natural causes of death, the greatest risk was suicide, at three times greater than for cis men (3.1 ratio).

Compared with cis women, transgender women were more than two times as likely to die of cardiovascular disease (2.6 ratio). They were three times more likely to die from lung cancer (3.1 ratio), almost nine times more likely to die from infection (8.7 ratio), and six times more likely to die from non-natural causes (6.1 ratio). Heart attacks accounted for the greatest risk of death from cardiovascular disease, at three times higher than for cis

women (3.0 ratio). Mortality risk from HIV-related disease was close to 50 times higher than for cis women (47.6 ratio), while the risk of suicide was almost 7 times greater (6.8 ratio).

Mortality risk in transgender men was similar to cis men (1.1 ratio) but almost double compared to cis women (1.6 ratio). Mortality risk for transgender men did not decrease over the five decades studied. Mortality risk in transgender men who started hormone treatment between 1990 and 2000 was two and half times as high as cis women (2.6 ratio). Compared to cis women, mortality risk for transgender men was more than double from 2000 to 2010 and 2010 to 2018 (2.1 and 2.4 ratios, respectively). Transgender men were at more than three times greater risk of death from non-natural causes (3.3 ratio) than cis women. No increased mortality risk was observed compared with cis men.

First author Christel de Blok, of Amsterdam UMC, the Netherlands, said: "We found that most suicides and deaths related to HIV occurred in the first decades we studied, suggesting that greater social acceptance and access to support, and improved treatments for HIV, may have played an important role in reducing deaths related to these causes among transgender people in recent years. It was surprising that mortality risk was higher in transgender people who started gender-affirming hormone treatment in the past two decades, but this may be due to changes in clinical practice. In the past, health care providers were reluctant to provide hormone treatment to people with a history of comorbidities such as cardiovascular disease. However, because of the many benefits of enabling people to access hormone therapy, nowadays this rarely results in treatment being denied."

The authors acknowledge some limitations. The occurrence and causes of death were well documented, however, it cannot be ruled out that other factors not recorded in medical files may contribute

to increased mortality risk. As there were relatively few deaths among transgender men in the cohort, analysis on cause of death was limited. Although the cohort included people with a wide age range, the population was relatively young. Analysis of data on transgender youth was also not possible as the young people in the cohort were very diverse, starting hormone therapy at different ages and stages of puberty. As this study focused only on transgender people who received treatment in the Netherlands, more than 90 percent of which were white, the authors say the data should be interpreted with caution in other regions.

Writing in a linked comment, Dr. Vin Tangpricha of Emory University, who was not involved in the study, addresses the subject of gender-affirming hormone therapy, saying: "Increased publication of data on the safety of gender-affirming hormone therapy in the transgender population, which is lifesaving for many people, is encouraging. Continued refinement of delivery of care for transgender people will help to improve the lives of a clinically vulnerable growing population."

On observed disparities between transgender women and transgender men, Dr. Tangpricha says: "Transgender men do not appear to have as significantly increased comorbidity following receipt of gender-affirming hormone therapy when compared with transgender women. These results could reflect the use of an established regimen of testosterone administration extrapolated from hypogonadal men. The differences could also reflect disparities in the access of health care, differences in the effect of sex hormones on cardiometabolic risk profile, differences in body composition, or societal factors. Future studies should examine which factors—hormone regimen, hormone concentrations, access to health care, or other biological factors—explain the increased risk of morbidity and mortality observed in transgender women as opposed to transgender men."

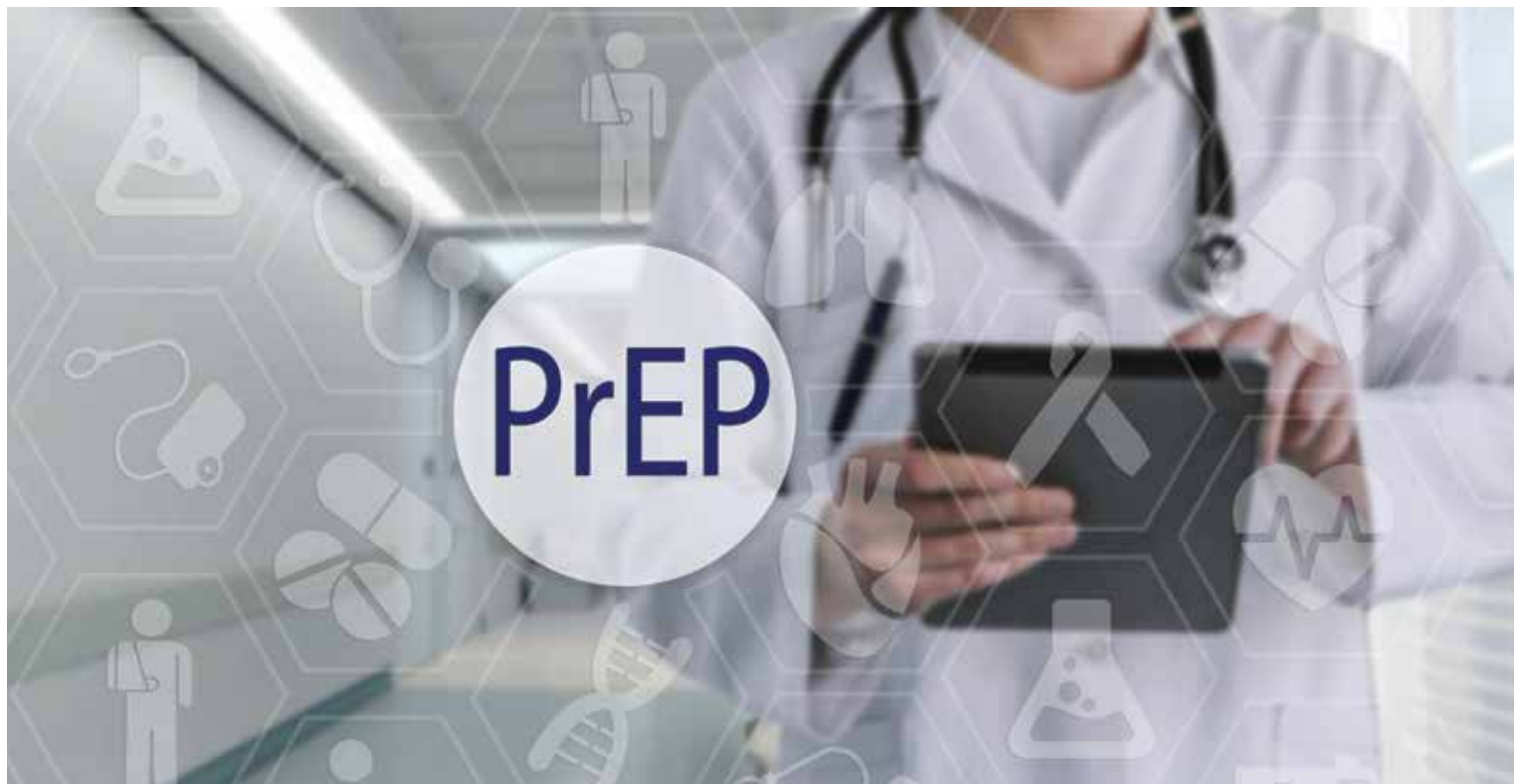
# IN THE NEWS

## New Report on COVID-19's Impact on PrEP, PEP and Sexual Healthcare

**T**HE NATIONAL COALITION OF STD DIRECTORS (NCSD) in collaboration with NASTAD, released a report on the impact of COVID-19 on PrEP, PEP, and broader sexual healthcare. The report finds that throughout the COVID-19 pandemic, much of the sexual health workforce was pulled into COVID-19 detail, causing significant service disruptions. Here are a few of the report's highlights:

- Sexual health programs implemented harm reduction practices to mitigate COVID-19 risks when serving clients. Sexual health clinics have played a crucial role in mitigating the COVID-19 pandemic by using their specialized resources and infrastructure, including Disease Intervention Specialists and contact tracers. However, there are concerns that COVID-19 will lead to the closing of sexual health clinics and interruption of services due to staff and resources diversion.
- PrEP and PEP programs were impacted across the care continuum, from awareness to adherence. As sexual health clinics reported clinic closures, reduced clinic hours and services, STD testing kit shortages, and diminished laboratory capacity, the initiation and retention of PrEP patients, as well as access to PEP, was disrupted throughout this past year. Another challenge impacting PrEP/PEP is the pandemic's impact on unemployment, triggering a loss in health insurance and an added barrier for paying for PrEP/PEP services and prescriptions.
- Jurisdictions are tasked with ending an epidemic during a pandemic. Ending the HIV Epidemic initiative goals may be affected due to the challenges COVID-19 has had on the health care system.
- TelePrEP programs can significantly increase PrEP access during COVID-19 and beyond. HIV/STD self-testing programs can help individuals complete their routine PrEP screenings, reducing barriers for clients.

Readers can view the full report at [https://www.ncsddc.org/wp-content/uploads/2021/04/COVID\\_1YearLater.pdf](https://www.ncsddc.org/wp-content/uploads/2021/04/COVID_1YearLater.pdf).





# Impaired T cell Function Precedes Loss of Natural HIV Control

BY MASSACHUSETTS GENERAL HOSPITAL

**HIV IS A MASTER** of evading the immune system, using a variety of methods to prevent the body from being able to find and kill it. The vast majority of people living with HIV require daily medication to suppress the virus and therefore prevent the development of AIDS.

But for a small subset of people, this battle between the immune system and the virus looks quite different. Known as controllers, they have immune systems that can suppress the virus without any need for medication. While most controllers can suppress the virus indefinitely, some eventually lose control over the virus and require medication to achieve viral suppression. In a paper recently published in *Immunity*, researchers at the Ragon Institute of MGH, MIT and Harvard reported that, in these cases, control is lost after a type of immune cell, called a cytotoxic T cell, loses the ability to proliferate and kill HIV-infected cells.

In order to find these differences, the researchers, led by Ragon Research Fellow David Collins, Ph.D., compared samples collected over several years from cohorts of HIV controllers at Ragon and the University of California at San Francisco. The study included 17 subjects with aborted control and 17 with durable control, whose immune systems continued to suppress HIV over years of observation.

In a successful immune response, cytotoxic T cells recognize small pieces of HIV, called antigens, which are found on the surface of infected cells. The T cells then kill the infected cells, destroying the virus inside. If mutations in HIV were changing the antigens, the T cells may no longer be able to recognize them. Therefore, the most likely difference, the team thought, may be in the antigens themselves.

First, the team compared what type of antigens were presented by infected cells. Ragon Member and co-author Gaurav Gaiha, MD, DPhil had previously shown that in controllers, cytotoxic T cells often recognize

HIV antigens that are unlikely to mutate.

When the team compared the two groups, they found that both sets of T cells responded to the same types of unlikely-to-mutate antigens, meaning they were starting from similar immune responses.

Working with Ragon Core Member and co-author Todd Allen, Ph.D., and his team, the researchers next sequenced HIV from before and after loss of control, looking for mutations that could cause changes in the antigens the T cells recognized. Even though HIV constantly mutates, within their cohort of 17 patients, they found only one mutation that allowed the antigen to escape T cell recognition. Mutational escape wasn't the answer, either. There was also no evidence of superinfection, the term for contracting a second, separate HIV infection, another theory that had been suggested in case studies. The difference, therefore, was likely in the immune response itself, instead of being driven by the virus.

The team looked more closely at the HIV-specific T cells in both groups, focusing on how well the T cells could perform their various functions. Cytotoxic T cells have two important functions when they encounter a cell presenting an HIV antigen. The first is their ability to kill infected cells by systematically rupturing them (called cytolysis). The second function is their proliferative function: creating more HIV-specific T cells that can then hunt down and kill other infected cells.

In progressors—people with HIV who cannot control the virus naturally and who require medication to suppress it—T cells quickly become desensitized to the HIV antigens and stop responding to them, a state known as T cell exhaustion. Researchers thought perhaps a similar process was happening to T cells when control was lost, but they found no such evidence. With the loss of control came a clear dysfunction of the T cells—the inability to kill cells infected by HIV—but it was a different type of dysfunction

than was observed in most infections.

In the group of people who lost control of HIV, there was a measurable decrease in the proliferative and cytolytic ability of the T cells seen in samples taken before the loss of control, sometimes even years before. In addition, this dysfunction was only seen in response to HIV; the T cells were able to respond properly to other viral antigens. The researchers had thought that T cell dysfunction would come after or during loss of control, but here, the evidence shows that T cell dysfunction actually precedes it.

“Loss of proliferation was the most consistent predictor of aborted control in our study,” says Collins. “In these cases, HIV-specific T cells gradually lost their ability to proliferate and become cytolytic, sometimes years before control was lost.”

In analyses led by Ragon computational biologist and second author Jonathan Urbach, Ph.D., the team next compared the genes expressed by the T cells in the two groups and found another important difference, one linked to their earlier observations. The T cells in the loss of control group had increased expression of *KLF2*, a gene that, when expressed at high levels, impairs the ability of T cells to proliferate.

“This study shows that loss of control is notably different from the inability to control the virus found in the canonical immune response to HIV,” says Ragon Director Bruce Walker, MD, the paper's senior author. “It further underlines the importance of a functional, effective T cell response to HIV in natural immune control of the virus. And with each secret HIV reveals comes an opportunity for us to use that knowledge to our advantage.”

That knowledge might ultimately help researchers work towards treatments and vaccines that could train progressors' immune systems. Further work remains to understanding why T cells become dysfunctional in some people and not in others.



# Staying Connected

## Maximizing Modalities of Information Delivery

**S**TAYING UP-TO-DATE on the latest advances in HIV treatment and prevention can be a daunting task in seemingly normal times. However, that task became especially cumbersome over the past year and a half. The intersection of the HIV epidemic and the COVID-19 pandemic can often feel like a never-ending juggernaut of data. Streams of research, guidelines and breaking news fly past daily at record speed. The information is vital to the medical community tasked with piecing together a clinical puzzle in record time in order to save lives. For many in HIV care, that notion seems quite familiar, harkening to the early days of the HIV/AIDS epidemic.

While there are certainly similarities to the health crisis of the 1980s, the healthcare heroes of that time did not have to fight an entirely new enemy while the whole world was in quarantine. COVID-19 forced the medical community to get creative in staying current with the latest on battling the novel virus, all while remaining connected physically and emotionally to their patients.

In the pages that follow, we showcase some of the modalities currently delivering important medical information to providers and directly to people with HIV. While the coronavirus shut down much of the world, many lines of communications remain open. Thanks to shifting models of clinical delivery, such as virtual medical conferences and newly-developed telehealth offerings, to tried and true outreach models including grassroots advertising and community outreach, vital information continues to flow. Most importantly, the HIV care team continues to provide optimal care to people with HIV in a very challenging environment.



# ACTHIV

## Meeting the Expanding Educational Needs of HIV Care Providers

By JOHN JD JUCHNIEWICZ, MCIS, CHCP, FACEHP

**T**HOSE ON THE FRONTLINES of caring for people with HIV (PWH) have faced a challenging year and a half. Yet, during the Covid-19 pandemic, they continued to work together as HIV care teams to meet the needs of PWH.

Whether new to HIV care or experienced, HIV providers making time in their busy work and personal schedules to continue to enhance their expertise in HIV medicine. In May 2021, more than 500 HIV clinicians stepped into the virtual world to do just that by attending the 15th annual American Conference for the Treatment of HIV (ACTHIV 2021). Promoting a team approach to HIV care, this conference is designed to meet the needs of those on the frontlines of caring for PWH. Over three days, learners attended sessions led by an interprofessional group of faculty educators who possess content expertise and regularly engage in patient care. Sessions provided in-depth education on new developments, research findings, and, perhaps most importantly, how they can be translated into the clinical setting for a wide variety of health care professionals involved in HIV care.

In the pages that follow, members of the ACTHIV Conference Planning Committee, who also served as faculty educators during the conference, provide highlights of two sessions that were selected by attendees and planners alike as among the Best of ACTHIV 2021: “Management of Cirrhosis in the HIV/HCV Patient Post-Sustained Virologic Response,” which was part of the hepatitis session at the conference, and “HIV Primary Care,” a session which explored



the recently released *Primary Care Guidance for Persons With Human Immunodeficiency Virus: 2020 Update* by the HIV Medicine Association of the Infectious Diseases Society of America.

While the ACTHIV Institute, a division of the American Academy of CME, Inc., is extremely proud of our flagship ACTHIV annual conference, ACTHIV Institute offers much more. Our organization, which is guided by some of the leading experts in the field of HIV, is committed to bringing HIV clinical education to providers throughout the year. In the coming months, we will be offering a robust lineup of CME/CE-accredited webinars on clinically-relevant topics and plan to partner more in the future with

HIV Specialist and others to create educational content that is applicable and translatable into providing optimal care for PWH.

We hope that the information in the pages that follow, along with the additional content we will be creating during the year, will not only enhance your knowledge but will assist you as you care for your patients as a member of your HIV care team. **HIV**



**JOHN JUCHNIEWICZ** is president of the American Academy of CME, Inc., a non-profit education foundation. John also leads the efforts of the ACTHIV Institute within the Academy to collaborate with expert clinicians in developing and implementing HIV education for healthcare professionals—including the annual ACTHIV conference.



CONFERENCE

# Management of Cirrhosis

IN THE HIV/HCV PATIENT POST-SVR

By Jennifer Price, MD, PhD



**OVER TIME**, chronic liver disease from hepatitis C virus (HCV) or any other cause can lead to increased fibrosis and eventually cirrhosis. Cirrhosis is considered “compensated” when patients do not have any clinical symptoms of cirrhosis or significant liver synthetic dysfunction. Once clinical symptoms develop, such as ascites, variceal bleed, hepatic encephalopathy (HE), or jaundice, the patient has now moved into the “decompensated” phase of cirrhosis (Figure 1). This is very important because it is a more advanced stage of cirrhosis, and the risk of mortality is significantly higher and survival lower in patients with decompensated cirrhosis. Additionally, patients with either compensated or decompensated cirrhosis are at

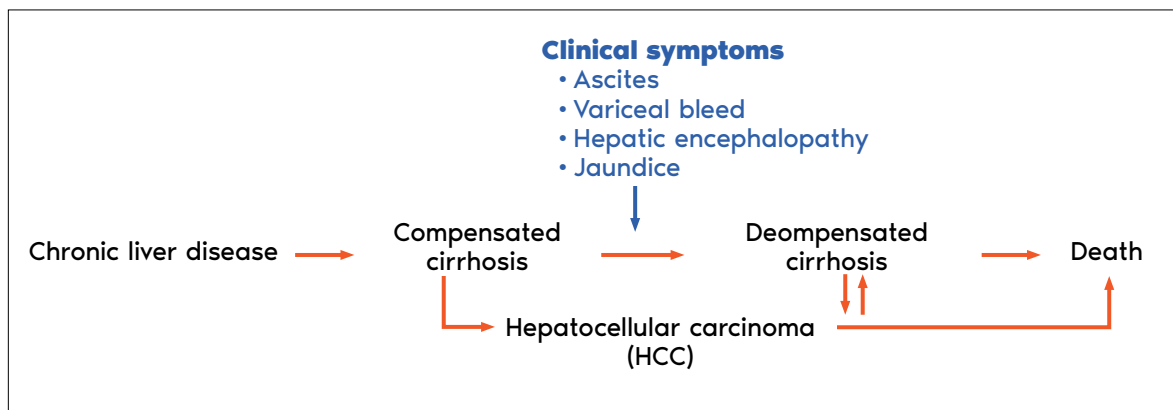
an increased risk of developing hepatocellular carcinoma (HCC). The Child-Turcotte-Pugh (CPT) score estimates cirrhosis severity (Figure 2). CPT A (5-6 points) refers to compensated cirrhosis, CPT B (7-9 points) is decompensated cirrhosis, and CPT C (10-15 points) is further decompensation.

## Management of Compensated Cirrhosis

### Step 1. Treat etiology of liver disease

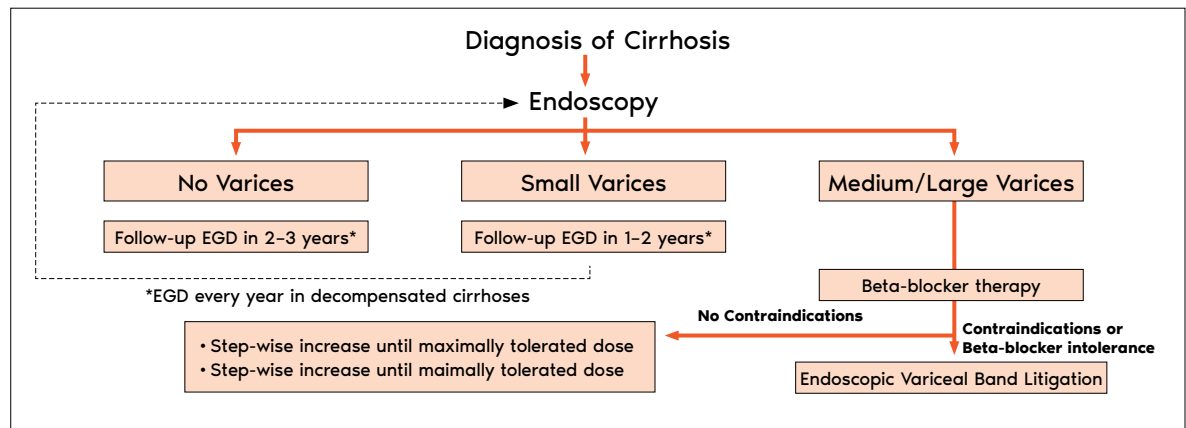
The first step in managing compensated cirrhosis is to treat the etiology of the underlying liver disease. For HCV-related cirrhosis, that means eradicating the virus. Sustained virologic response (SVR) after HCV treatment, also known as HCV cure, significantly lowers the risk of all-cause mortality, liver-related mortality or need for a liver transplant, HCC, and liver failure.<sup>1</sup>

**Figure 1. Natural history of cirrhosis**



**Figure 2. Child-Turcotte-Pugh (CPT) score to estimate cirrhosis severity**

	Points		
	1	2	3
Encephaloathy	None	Mild-Moderate (grade1 or 2)	Severe (grade 3 or 4)
Ascites	None	Mild-Moderate (diuretic responsive)	Severe (diuretic refractory)
Bilirubin (mg/dL)	<2	2-3	>3
Albumin (g/dL)	>3.5	2.8-3.5	<2.8
INR	<1.7	1.7-2.3	>2.3
<div>Child A: 5-6 Points Compensated</div> <div>Child B: 7-9 Points Decompensated</div> <div>Child C: 10-15 Pints Further Decompensated</div>			

**Figure 3. Algorithm for esophageal varices screening in patients with compensated cirrhosis**

### Step 2. Screen/prevent complications of cirrhosis

Once a patient has achieved SVR, the next step in managing cirrhosis is screening for cirrhosis complications. Achieving SVR after direct acting antiviral (DAA) therapy for HCV decreases the risk of developing HCC. In a large Veterans Affairs study of approximately 22,500 patients, 39 percent with cirrhosis, SVR with DAA treatment was associated with a 76 percent reduction in HCC risk.<sup>2</sup> Importantly, however, the absolute risk of HCC remained elevated despite SVR and was highest in patients with cirrhosis before treatment at 1.0-2.2 percent per year, which is above the threshold warranted for ongoing HCC surveillance. Thus, post-SVR HCC surveillance for patients with cirrhosis should continue with abdominal ultrasound with or without alpha-fetoprotein (AFP) every six months.<sup>3</sup> In some patients, particularly those with increased subcutaneous tissue in whom ultrasound visualization may be poor, we often alternate the ultrasound with another imaging modality such as quad phase CT or contrast MRI.

Importantly, HCC surveillance should be based on *pre-treatment* fibrosis staging because the accuracy of non-invasive estimates of fibrosis such as vibration-controlled transient elastography (VCTE) or FIB-4 after SVR remains unclear. Moreover, pre-treatment FIB-4 identifies patients at elevated HCC risk post-SVR. Patients with cirrhosis and a pre-treatment FIB-4  $\geq 3.25$  have the highest risk of developing HCC despite HCV cure, and the risk persists up to 10 years after SVR.<sup>4</sup> Among patients without a known diagnosis of

cirrhosis, pre-treatment FIB-4  $\geq 3.25$  is also associated with an elevated risk of HCC post-SVR. This risk is similar to that of patients with cirrhosis but FIB-4  $< 3.25$  pre-treatment.<sup>2,4</sup> Given that pre-treatment FIB-4 is an excellent predictor of HCC risk after SVR and involves readily available labs or clinical data (age, ALT, AST, and platelet count)<sup>5</sup>, check FIB-4 in patients before starting HCV treatment and use it to develop a post-SVR management plan. Longitudinal (pre- and post-treatment) FIB-4 may still be informative. HCC risk after HCV cure is highest in patients with cirrhosis who have both pre- and post-treatment FIB-4  $\geq 3.25$ . Although a decline in FIB-4 from  $\geq 3.25$  pre-treatment to  $< 3.25$  post-treatment is associated with a reduced HCC risk, the absolute risk is still high enough to warrant surveillance.<sup>4</sup>

The other major complication of cirrhosis that we can screen for is esophageal varices. These are seen in 45–50 percent of patients with cirrhosis, and the prevalence increases with each CPT class. Active bleeding is associated with 20–30 percent mortality. We can reduce the risk of variceal bleeding using non-selective beta-blockers or band ligation. Thus, upon diagnosis of cirrhosis, patients should get an index esophagogastroduodenoscopy (EGD; Figure 3). If no varices are present and the patient has compensated cirrhosis, they should get a repeat EGD in two to three years. If small varices are seen, EGD is typically repeated in one to two years. If medium or large varices are present, then a non-selective beta-blocker should be started, increased to the maximally tolerated dose, and continued. If the patient has contraindications to beta-blockers or is intolerant, then banding should be performed.

In low-risk patients with cirrhosis but without clinically significant portal hypertension, EGD can be safely avoided. While direct portal pressure measurements are not routinely performed, a liver stiffness measurement (LSM)  $\geq 20$  kPa on VCTE is quite good at detecting clinically significant portal hypertension. Studies have demonstrated that in patients with compensated cirrhosis who have LSM  $< 20$  kPa and platelet count  $> 150,000$  mm<sup>3</sup>, also known as the Baveno VI criteria, EGD can be safely avoided as patients meeting these criteria have a very low probability ( $< 5\%$ ) of having high-risk varices.<sup>6</sup> Notably, the Baveno VI criteria have been validated in patients who have achieved SVR and in persons with HIV.<sup>7,8</sup>

### Step 3. Minimize risk of further liver disease progression

The third and final step to managing compensated cirrhosis is minimizing the risk of further liver disease progression. The most common modifiable risk factors for liver disease progression post-SVR are viral, metabolic, and toxin-related. To prevent HCV reinfection, we need to counsel our patients about transmission risk and harm reduction.<sup>9</sup> In addition, hepatitis A and B vaccination is recommended for all patients with cirrhosis. Metabolic factors, including diabetes/insulin resistance and obesity, are important risk factors for developing hepatic steatosis (or fatty liver), liver disease progression, and HCC. Therefore, we counsel our patients to aim for normal weight and optimize metabolic syndrome components.

Regarding toxins, no amount of alcohol is “safe” in patients with cirrhosis, and therefore patients should be counseled to abstain completely. Patients should also be screened for hazardous alcohol use before treatment, and this should continue to be assessed after cure. Finally, we aim to avoid drug-induced liver injury and focus on drugs that may worsen volume or renal status. For example, nonsteroidal anti-inflammatory drugs (NSAIDs) are commonly used in patients with cirrhosis but should be avoided due to the risk of renal vasoconstriction and renal failure. By contrast, acetaminophen is often avoided due to dose-dependent hepatotoxicity but is safe in patients with cirrhosis in low doses and can be used if <2000 mg/day. Finally, many clinicians avoid statins in patients with liver disease, but statins are safe and may have beneficial effects on the liver.<sup>10</sup> Thus, they

should not be withheld in patients with clinical indications, even if they have cirrhosis.

### Patients with Decompensated Cirrhosis who Achieve SVR

While we hope to treat our patients’ HCV before they reach the decompensated stage, many patients present with decompensated cirrhosis. In these cases, we often want to know the likelihood that their liver decompensation will improve after SVR. Our experience with alcohol-related and hepatitis B-related decompensated liver disease has demonstrated that patients can transition from decompensated cirrhosis to compensated cirrhosis (i.e., “re-compensate”) after sustained alcohol abstinence or hepatitis B antiviral therapy, respectively. What about patients with HCV-related decompensated liver disease? This was evaluated in a retrospective analysis from four trials of sofosbuvir-based treatment in patients with decompensated cirrhosis.<sup>11</sup>

The authors looked at the proportion of treated patients who achieved a clinically meaningful benefit of HCV treatment, defined as sustained down-staging from CPT B or C to CPT A. By 36 weeks after starting HCV treatment, approximately 20 percent had improved to CPT A. Not surprisingly, the likelihood of improving to CPT A was significantly higher in patients who achieved SVR than those who did not. Additionally, the patients who were less decompensated at baseline were more likely to improve than those who were the most decompensated. This tells us that “re-compensation” can occur in patients with CPT B or C cirrhosis who achieve SVR, but this is not universal and is less likely to happen

the more advanced the stage of cirrhosis. This is very important to think about when counseling patients and managing expectations surrounding HCV treatment.

### Key Takeaways for the Care Team

Pre-HCV treatment cirrhosis estimation is essential to determine the post-SVR management plan. Providers should send the work-up for cirrhosis determination before starting treatment. Patients with cirrhosis require HCC surveillance every six months and screening for esophageal varices unless they meet all of the following criteria: compensated cirrhosis, no history of varices, liver stiffness <20 kPa, and platelet count >150,000/mm<sup>3</sup>. After SVR is achieved, the care team should focus on modifiable risk factors for liver disease progression. This includes counseling and harm reduction for HCV reinfection, ensuring patients receive hepatitis A and B vaccinations if they are non-immune, managing metabolic comorbidities, and counseling regarding alcohol abstinence. With more advanced cirrhosis, the likelihood of achieving a clinically meaningful benefit from SVR decreases. This is important for pre-treatment counseling and expectation setting for patients with advanced cirrhosis and underscores the importance of diagnosing and treating HCV earlier in the disease stage. **HIV**



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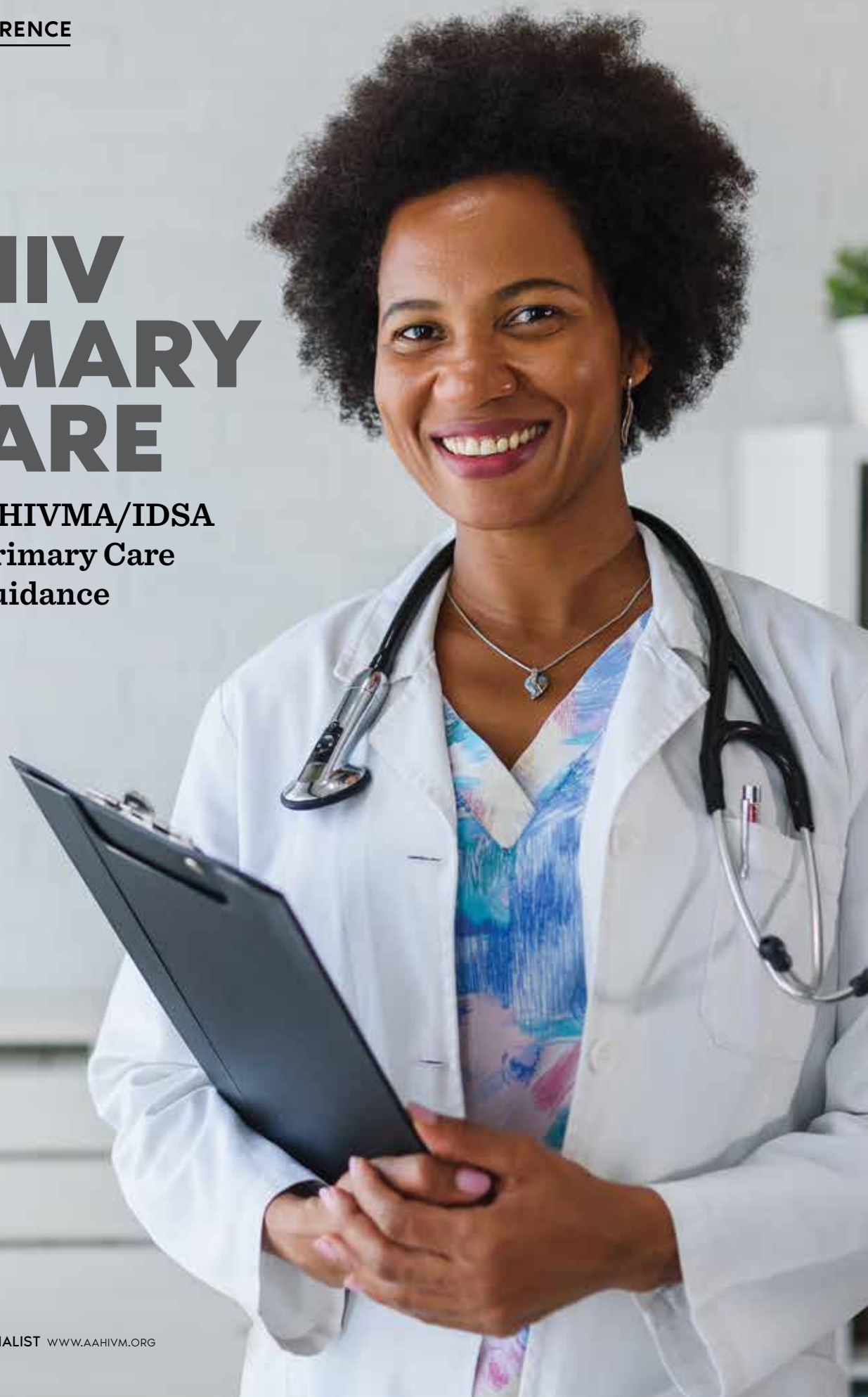
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CONFERENCE

# HIV PRIMARY CARE

Updated HIVMA/IDSA  
HIV Primary Care  
Guidance





By Melanie Thompson, MD  
Co-chair, HIVMA/IDSA HIV Primary Care Guidance Panel

**S**CIENTIFIC BREAKTHROUGHS in antiretroviral therapy (ART) allow people with HIV to enjoy a near-normal life expectancy without progression to AIDS. With increased longevity in addition to ongoing new transmissions, the number of people living with HIV continues to increase, making access to high-quality HIV primary care more important than ever. More care providers with HIV expertise are needed, and updated guidance is essential for new care providers entering the field and for those already on the front lines of HIV primary care. The HIV Medicine Association (HIVMA) of the Infectious Disease Society of America (IDSA) recently updated its HIV Primary Care Guidance to address the evolving needs of people with HIV and the providers who care for them.<sup>1</sup> Key points from the Guidance were presented at a workshop during ACTHIV 2021 and are summarized here. Unless otherwise noted, the Guidance document is the primary reference for all presentations from the workshop.

### Guidance Methodology

The Guidance panel consists of HIVMA members who are experts in front-line HIV management, including two Co-chairs with experience in HIV guideline development. Potential or apparent conflicts of interest were declared according to IDSA standards, and no limiting conflicts were identified. The panel reviewed peer-reviewed literature published or presented between 2013 and December 2019, guidelines and ACIP updates through January 2020, and data on the SARS CoV-2 pandemic through August 2020. The online guidance was published in *Clinical Infectious Diseases* in November 2020, and an updated print version is pending. The complete Guidance can be accessed online at [HIVMA.org](http://HIVMA.org) and [IDSociety.org](http://IDSociety.org).

### The Initial Evaluation

Dr. Tulika Singh discussed key elements of the initial evaluation and maintenance visits. The most critical element in the initial evaluation is to build rapport with the patient, as a strong patient-clinician relationship will be the foundation of successful care engagement going forward. In addition, the care team should use this visit to understand any needs for supportive services, including housing, food, or transportation, and whether case management would be beneficial. The first visit also is an ideal opportunity to assess the patient's knowledge about HIV and willingness to begin ART, including on the day of the visit, if possible.

### History

The medical history includes HIV-specific information, such as the approximate date of diagnosis, whether care was previously received, and whether any opportunistic illnesses have occurred. Old medical records should be requested. The patient should be asked about historical CD4 counts and HIV-1 RNA levels, as well as any previous viral resistance, recognizing that this information will often need to be ascertained through medical records. A complete history of exposure to ART or

#### Several key changes appear in the updated Guidance, compared to the 2013 version.

- "People First" and gender-neutral language are used to acknowledge the importance that a sensitive and welcoming environment plays in providing optimal care for people with HIV.
- Optimizing care engagement, medication adherence, and viral suppression were discussed in the context of delivering patient-centered care.
- Recommendations for conducting initial and maintenance evaluations were updated.
- The section on metabolic and non-communicable comorbidities associated with HIV, ART, and aging was expanded, and the statin drug interaction table was updated.
- Considerations for preventing perinatal HIV transmission with cisgender women/transgender men of childbearing potential and considerations for children and adolescents were updated.
- A new section was added to address transgender and gender-diverse populations 18 years of age and older.
- Finally, because the Guidance was being prepared during the SARS CoV 2 pandemic, a section on novel coronavirus disease 2019 (COVID-19) in people with HIV was added.

pre- or postexposure prophylaxis (PrEP or PEP) should also be elicited. Additional details are available in Table 1 of the Guidance.

The general medical history should focus on past or present medical conditions, such as gastrointestinal or liver disease (including viral hepatitis), cardiovascular disease or risk factors (smoking, hypertension, hyperlipidemia, diabetes mellitus), or renal disease. A detailed outline of areas for exploration in the medical history is found in Table 2 of the Guidance. Past sexually transmitted infections and treatment should be discussed as well as any prior anal diseases, including abnormal anal cytology. Discussion of other past infectious diseases should include sexually transmitted infections (STIs), chickenpox and shingles, measles, and tuberculosis. Immunization records should be requested. Gynecologic, cervical Pap test, and pregnancy history should be discussed along with intentions about conceiving in the future and the need for contraception. Mental health and psychoactive substance use history is essential and often under-addressed in people with HIV. A detailed history should be taken, including discussion of trauma and intimate partner violence. Hospitalizations and surgeries should be documented along with transfusion history.

The family history should focus on common comorbidities, including early cardiovascular disease, hypertension, hyperlipidemia, diabetes, or cancer. The social history should explicitly address sexual orientation and gender identity, including correct pronouns and names, especially if different from those listed on official documents. The clinician or the care team should elicit information about current housing, employment, transportation, educational attainment, and social support. The sexual history includes past STIs and discussion of sexual partners, HIV status disclosure, sexual exposure sites, condom use, and use of PrEP or PEP. All current prescription medications, over-the-counter medications, supplements, and herbal agents should be recorded, along with any history of allergies or intolerance. The review of systems and physical examination should focus on conditions commonly associated with HIV and comorbidities, as outlined in Table 3 of the Guidance.



### Initial Laboratory Workup

If not available, confirmation of HIV status should be obtained using current CDC HIV testing algorithms. HIV-1 RNA and CD4+ cell count and percentage should be obtained for all patients at the time of presentation. Measurement of CD8 cell count or CD4:CD8 ratio is unnecessary and does not contribute to clinical decision-making. Antiretroviral resistance testing should be obtained in patients whose virus is not suppressed. For those who have never been on ART or who have been on nucleoside reverse transcriptase inhibitor (NRTI)-based PrEP, genotypic resistance testing for NRTIs, non-nucleoside reverse transcriptase inhibitors (NNRTIs), and protease inhibitors (PIs) should be obtained.

Due to the low rate of transmission of integrase strand transfer inhibitor (INSTI) resistance-associated mutations, testing for INSTI resistance is not routinely recommended unless there is suspicion for INSTI mutation transmission. If treatment with abacavir is anticipated, an assay for human leukocyte antigen subtype B\*5701 (HLA B\*5701) should be obtained to assess the risk of hypersensitivity reaction to abacavir. If treatment with the CCR5 receptor antagonist maraviroc is anticipated, a coreceptor tropism assay should be obtained. Where rapid initiation of antiretrovirals is possible, baseline laboratory tests should be obtained before treatment initiation, but it is not necessary to delay treatment until results are obtained. Abacavir should not be initiated before HLA B\*5701 results are available, and regimens that do not treat hepatitis B should generally not be initiated unless hepatitis B surface antigen (HBsAg) is negative. Test results should be reviewed as soon as available to determine whether ART should be changed because of renal status or the presence of genotypic resistance.

Other routine labs include complete blood count (CBC) with differential, electrolytes, creatinine, blood urea nitrogen, alanine aminotransferase, aspartate aminotransferase, total bilirubin, alkaline phosphatase, and urinalysis. In patients at risk for diabetes, hemoglobin A1c (A1C) should be drawn before ART initiation. The initial

evaluation of lipids and blood glucose does not need to be fasting, but abnormal values should be repeated in the fasting state. All persons of childbearing potential should have a pregnancy test.

Screening for coinfections includes obtaining an RPR or treponemal-specific antibody for syphilis; pharyngeal, anogenital, and urine NAAT testing for gonorrhea and chlamydia; and trichomonas NAAT in individuals who have vaginal sex. A tuberculin skin test or IGRA should be used to screen for latent *Mycobacterium tuberculosis*, and chest radiography should be performed in persons with evidence of latent infection. Viral hepatitis A, B, and C screening includes hepatitis A total or IgG antibody, HBsAg, hepatitis B surface and core antibodies (HBsAb, HBcAb), and hepatitis C antibody. Anti-varicella IgG may be obtained if there is no history of chickenpox or shingles. Due to recent measles outbreaks, a measles IgG antibody titer may be obtained if evidence of adequate vaccination with an MMR vaccine is not available. Persons born in the US before 1957 are presumed to have immunity. Routine screening of all persons for herpes simplex virus IgG, cytomegalovirus (CMV) IgG, and toxoplasma IgG is not recommended. Cryptococcal antigen screening may be considered in those with CD4+ count < 100 cells/ $\mu$ L but is not routinely recommended for those with higher CD4 counts. In a person with a low risk of CMV infection, CMV IgG screening may be considered if blood transfusion is contemplated to support the use of CMV-free blood products.

Cervical and/or anal Pap tests should be obtained if indicated. Abnormal results will require referral for colposcopy or high-resolution anoscopy. Screening for deficiency of glucose-6-phosphate dehydrogenase should be conducted in appropriate racial and ethnic groups so that oxidant drugs such as dapsone, primaquine, and sulfonamides can be avoided if a deficiency exists. Serum testosterone level should be considered in cisgender males with fatigue, weight loss, loss of libido, erectile dysfunction, depression, or who have evidence of reduced bone mineral density. Additional information on laboratory assessments is available in Table 4 of the Guidance.

## Routine Monitoring and Screening

HIV-1 RNA and CD4 cell count should be monitored according to the Department of Health and Human Services (DHHS) adult and adolescent and pediatric antiretroviral therapy guidelines.<sup>2,3</sup> Screening for syphilis and three-site screening for chlamydia and gonorrhea should be performed every three to six months if the risk of acquisition is high, and annual screening for trichomonas should be performed for persons having vaginal sex. Sexually active men who have sex with men, transgender women, and people who inject drugs should have annual screening for hepatitis C. Those at risk for tuberculosis should be screened annually with a tuberculin skin test or IGRA. CBC and chemistry panels should be monitored as needed to assess medication toxicity or to monitor comorbid conditions. For those at risk for kidney disease, a urinalysis should be monitored annually. Persons of childbearing potential should be asked about their plans and desires regarding pregnancy, and contraceptive advice should be provided. All persons with HIV should have semiannual oral health examinations.

Screening for cancer is vital in people with HIV. Along with smoking cessation interventions, a low dose CT scan should be ordered in persons 55–77 years of age who currently smoke or have quit within 15

years. An anal exam should be performed annually, and an anal Pap smear should be performed for persons having anal receptive sex if high-resolution anoscopy is available. Persons with cirrhosis or hepatitis B or C should have a liver ultrasound every six months. Screening for breast, colon, prostate, and lung cancer is the same as the general population. See below for Dr. Bill Short's discussion of cervical cancer screening recommendations for persons with HIV.

## Vaccines

Dr. Mamta Jain discussed vaccination schedules for people with HIV. According to CDC opportunistic infection guidelines and recommendations from the CDC Advisory Committee for Immunization Practices (ACIP), the need for vaccines should be reviewed yearly and updated as needed.<sup>4,5</sup> Persons with HIV should be vaccinated against SARS CoV-2. Data regarding the immune response of persons with CD4 counts below 200/ $\mu$ L is lacking, and they may have a less robust response, as is seen with other vaccines. According to a recent ACIP recommendation, persons with advanced HIV or untreated HIV who received two doses of an mRNA vaccine should receive a third dose of an mRNA vaccine.<sup>6</sup> Influenza vaccines should be given annually to persons six months and older, but live vaccines should





be avoided if the CD4 count is below 200/ $\mu$ L. Tetanus-diphtheria-pertussis (TdAP) vaccine should be given to any adult who has never received this vaccine, pregnant persons at 27–36 weeks of pregnancy (during each pregnancy), and pre-teens 11–12 years of age. DTaP should be given to younger children. After one dose of TdAP, tetanus-diphtheria (Td) or TdAP should be given every 10 years, or if needed for wound management. Measles, mumps, and rubella (MMR) vaccine should be given to all persons born in 1957 or later if they do not have immunity.

Pneumococcal conjugate vaccine (PCV13) should be given to persons with HIV who have not received any pneumococcal vaccine, with a dose of 23-valent pneumococcal polysaccharide vaccine (PPV23) at least eight weeks later (for people with a CD4 count above 200/ $\mu$ L). If PPV23 is given as the first pneumococcal vaccine, a single dose of PCV13 should be given at least a year later for adult patients and at least eight weeks later for adolescents less than 19 years of age. One additional dose of PPV23 is recommended if at least five years have elapsed since the first dose of PPV23 was given. A final dose of PPV23 is recommended after age 65 and should be given at least five years after any doses given before age 65.

If initial screening indicates inadequate immunity to hepatitis A and B, immunization should be given. If CD4 count is below 200 cells/ $\mu$ L, the response may not be optimal, and delaying vaccination until immunologic and virologic response to ART has occurred may be considered, depending on the level of hepatitis risk present. Priority for hepatitis A vaccination should be given to populations in which outbreaks are likely to occur, including undomiciled individuals, people who inject drugs, gay and bisexual men, those with prior incarceration, and those with chronic liver disease. In a community outbreak of hepatitis A, the vaccine may be given without checking immune status. Periodically, immune status should be checked and a booster provided as needed. Immunosuppressed individuals should receive a higher dose of hepatitis B vaccines. HBsAb should be checked one to two months after completing the series or at the next visit to assess response. The series should be repeated if immunity is inadequate,



perhaps with an additional booster if standard doses were used. Those with a positive HBcAb but negative HBsAb should be vaccinated. Hepatitis B immune status should be checked periodically to determine if a booster is needed.

Serogroup A, C, W, and Y meningococcal vaccine should be given to adults with HIV, with revaccination every five years. Vaccines for travel, including live virus vaccines, should be given to people with HIV who have a CD4 cell count of at least 200/ $\mu$ L. Live virus vaccines should generally be avoided below this CD4 level or if an AIDS-defining illness exists. The nine-valent human papillomavirus (HPV) vaccine is recommended in a three-dose schedule for those nine–26 years of age, but vaccination may also be offered to those 27–45 years. Two doses of single-antigen varicella vaccine may be given to individuals without immunity to varicella zoster virus (VZV), including children above age eight who have a CD4 count above 200/ $\mu$ L and those aged one to eight years with a CD4 percentage of at least fifteen percent. Persons without immunity to VZV who have direct exposure to a person with varicella or shingles should receive varicella immune globulin (VariZIG) as soon as possible but within ten days. Recombinant zoster vaccine should be given to adults above age 50 using the standard regimen. Table five of the Guidance provides additional detail on maintenance screening and monitoring and schedules for routine vaccinations.

## Cervical Cancer Screening and Perinatal HIV Transmission

Dr. Short discussed cervical cancer screening and prevention of vertical HIV transmission. Persons with HIV have greater persistence of cervical HPV infection (especially for high-risk subtypes), lower rates of spontaneous regression, and high recurrence rates. Pap testing should begin within one year of the onset of sexual activity. Screening for cervical cancer should be done annually for persons with HIV between 21 and 29 years of age, although some recommend a Pap test six months after the baseline test. If three consecutive tests are normal, follow-up screening should be in three years. Pap and HPV co-testing is not recommended for women younger than 30. For individuals aged





30 and older, Pap tests also can be performed every three years following three consecutive normal tests, or if HPV testing is done with a Pap test and both are negative, the next Pap test can be done in three years. A positive HPV test but normal cytology should be followed up with co-testing in one year. If the follow-up Pap is abnormal or HPV testing is positive, referral for colposcopy is recommended. For people with HIV, there is no cut-off age for Pap screening.

ART for the mother and prophylaxis for the infant can prevent new pediatric infections and preserve maternal health, as maternal HIV viral load is the key determinant of transmission risk. Perinatal HIV transmissions have declined dramatically, including among African Americans whose rates are disproportionately high. A cohort study in France found no transmissions among women on ART before pregnancy with a viral load below 50 copies/mL.<sup>7</sup> Perinatal HIV elimination goals in the U.S. are to have below 1 transmission per 100,000 live births and below one percent vertical transmission among exposed infants.<sup>8</sup> Because unintended pregnancy is common, discussion with persons of childbearing potential about plans and desires for pregnancy is essential to support informed decisions about contraception. Because the greatest risk to the fetus is very early in pregnancy, all medications should be reviewed for teratogenic potential, including over-the-counter medicines. Transmission has been observed through breast milk, and chest/breastfeeding should be avoided in the U.S.

### Special Considerations for Adolescents

Dr. Allison Agwu discussed the epidemiology of HIV in adolescents and issues related to the care of adolescents with HIV, including vaccinations and transition from pediatric to adult care. Male adolescents and young adults aged 13–24 with HIV are most likely to have acquired HIV through male-to-male sexual context, with only 10 percent due to perinatal transmission. For females, 41 percent have acquired HIV through perinatal transmission and 48 percent through heterosexual contact. Injection drugs are a less frequent but important route of HIV transmission for this age group.<sup>9</sup> Because of decreasing rates of perinatal transmission, 47 percent and 38 percent of persons with perinatal acquisition are now aged 13–24 and 25–34 years, respectively. The HIV continuum of care for youth lags considerably behind that of the total U.S. population.<sup>10</sup>

Cognitive, biological, and behavioral/social factors contribute to HIV acquisition risk for youth.<sup>11,12,13</sup> Cognitively, they lack maximal maturation of “executive suite” brain development and tend to think concretely, with limited ability to perceive consequences of behaviors, thus supporting the perception of invulnerability. They also may lack education about STIs, including HIV, and fear disclosing sexual activity to adults, especially parents. Early puberty in females and cervical ectopy in adolescent girls may enhance acquisition, as may the presence of bacterial vaginosis or other STIs. Behavioral and social issues include the likelihood of having multiple partners, some of whom may be older and/or bisexual. Inconsistent use of barrier methods is common, as are STIs. Youth with HIV experience multiple intersectional barriers, including HIV stigma and discrimination; limited support systems due to loss, non-disclosure, or dysfunction; limited health literacy; psychological issues with adjusting to the HIV diagnosis or illness; and logistic barriers to obtaining care. Comprehensive care for youth must be culturally sensitive and youth-friendly, non-stigmatizing, flexible, and multidisciplinary.

Vaccinations for youth with HIV should follow ACIP schedules for children and adolescents with HIV. These include vaccinations for hepatitis A and B, Tdap, influenza,

meningococcus, and HPV. However, it should be noted that fewer than half of eligible adolescents have received HPV vaccination in the U.S. In addition, adolescents should be vaccinated against SARS CoV-2 as soon as possible. Currently, eligibility begins at age 12, but this may expand soon to include younger children.

Transition to adult care is treacherous for adolescents with HIV. Youth may be resistant to the change or feel abandoned, fear risk of HIV disclosure if transitioning to an adult HIV clinic, or simply be averse to being thrown into unfamiliar and intimidating adult clinics. System-level barriers include lack of communication among providers on both sides of the transition, lack of provider experience or interest in treating adolescents with HIV, lack of co-located care for issues other than HIV care, and differences between the cultures of the transitioning clinics. These barriers can be lessened by good and frequent communications between pediatric and adult care providers; involvement of family, if possible; interactions with a multidisciplinary care team; orientation before transition; and a “soft handoff” to a specific point person on the adult side. All of these actions can assist with care engagement and improved health outcomes.

### Metabolic and Other Noncommunicable Comorbidities

Dr. Waridibo Allison presented the session on metabolic and non-communicable comorbidities. As people age with HIV, they develop comorbidities earlier than those without HIV. To avoid long-term consequences from comorbidities, they should be diagnosed early and managed aggressively. Lipids should be measured before and within one to three months after beginning ART. After that, the frequency of testing depends on interventions and responses. HIV should be considered a risk factor for the development of atherosclerotic cardiovascular disease. Lipid management should follow the 2018 American College of Cardiology, American Heart Association Guidelines.<sup>14</sup> It is crucial to manage statin interactions with protease inhibitors, cobicistat, and non-nucleoside reverse transcriptase inhibitors. Lovastatin and simvastatin are contraindicated with protease inhibitors and cobicistat. Table 6 of the Guidance contains more detail about these interactions.

Persons should be screened for diabetes upon entry to care. Because of interactions with ART, hemoglobin A1c (A1c) is not used to diagnose diabetes in persons with HIV on ART. Diagnosis is based on plasma glucose in these individuals, whether fasting glucose or 2-hour glucose tolerance test. A1C can be followed for monitoring of treatment after diagnosis. Some medications used to lower glucose may have drug interactions with some HIV therapies. This should be assessed and monitored.

Bone density assessment by dual-energy x-ray absorptiometry (DEXA) scan should be performed in post-menopausal persons and men 50 years or older. Medical therapy should be instituted as needed for osteopenia or a history of fragility fracture. Osteomalacia can be caused by tenofovir disoproxil fumarate or vitamin D deficiency and should be distinguished from osteopenia/osteoporosis. Routine screening of vitamin D levels is not currently recommended. For transgender individuals, DEXA screening should begin at 65 years or as early as 50 years if there are risk factors for osteoporosis. Gonadectomy and 5 or more years without hormone replacement therapy should prompt screening regardless of age.

Neurocognitive impairment is more common in persons with HIV than those without HIV. Impairment from HIV-associated neurocognitive disorder (HAND) can range from asymptomatic to dementia. Therefore, neurocognitive decline should be thoroughly evaluated, and any reversible conditions such as thyroid disease should be excluded. Although there are no specific treatments for HAND, accurate diagnosis and assessment are important. In addition, diagnosis allows evaluation of the need for assistance with activities of daily living and other interventions that can enhance the quality of life.

### Healthcare for Transgender and Nonbinary Adults

Dr. Jonathan Colasanti reviewed principles of HIV care for transgender or gender-diverse adults. Transgender individuals experience high levels of stigma and discrimination, as seen in the increasing numbers of laws and policies that discriminate against them and the increasing levels of death by violence seen in this population. These issues, along

with a high risk of HIV acquisition among transgender persons, have led to the inclusion of a new section of the Guidance focusing on issues unique to transgender individuals and those who are nonbinary or gender diverse.

Transgender persons with HIV have lower levels of viral suppression, and their experience of stigma and discrimination is negatively correlated with gender affirmation, healthcare empowerment, and viral suppression.<sup>15,16</sup> Therefore, the Guidance recommends that all transgender and gender diverse individuals with HIV have access to gender-affirming, nondiscriminatory, non-stigmatizing, and culturally sensitive care. This should include incorporating gender-neutral language into all forms and documentation and including gender identity options beyond sex at birth. Correct identification of sexual orientation and gender identity allows for appropriate screenings and care, and enhances trust in care providers. Healthcare providers should become familiar with preferred terminology for gender, gender identity, gender expression, and gender-affirming care. A helpful glossary (adapted from Safer, 2019<sup>17</sup>) appears in the Guidance as Table 7.

Gender-affirming medical and/or surgical therapy should be offered to transgender individuals, following the World Professional Association for Transgender Health (WPATH) standards of care.<sup>18</sup> Initiation of gender-affirming medical therapy involves an intensive discussion of risks and benefits, an assessment for gender dysphoria and discussion of appropriate interventions (including hormone therapy, surgical interventions, and/or psychotherapy), and assessment of wishes for childbearing and future fertility. To set appropriate expectations, patients should understand the medical effects and time course for feminizing and masculinizing effects following initiation of hormone therapies.

When the decision to initiate gender-affirming hormone therapy is made, the initial workup should include assessing risk for breast cancer, cardiovascular disease, and venous thromboembolism (VTE). Smoking



cessation should be discussed if the individual is a smoker. Masculinizing therapy with testosterone may cause erythrocytosis or acne, and testosterone levels and CBC should be monitored at baseline and every three months for the first year, then every six to 12 months after stability. Feminizing therapies are aimed at suppressing testosterone levels and raising estrogen levels. Therapies may include antiandrogens such as spironolactone, cyproterone acetate, or leuprolide, with appropriate monitoring. Orchiectomy is the most effective antiandrogen therapy. Estrogen therapies with estradiol and other estrogens carry VTE risk, so injectable or patch formulations are preferred over oral estrogens. Oral conjugated estrogens should be avoided because of their high risk of VTE. Laboratory monitoring includes baseline measurement of estradiol, testosterone, potassium, prolactin and triglycerides. These should be assessed every three months for the first year, then every six to 12 months once stable.

Protease inhibitors, cobicistat, and NNRTIs may cause interactions with hormone therapies. These should be discussed in advance and monitored as needed. It is essential to discuss that the use of ART will not adversely impact or preclude the use of hormone therapy, as the efficacy of hormone therapy often is the higher priority for these individuals, and reassurance on this issue is a critical element to support adherence to ART. Drug interactions with other medications also should be reviewed.

Dr. Michael Horberg, co-chair of the Guidance panel, wrapped up the day's presentations. He summarized the components of the initial visits to establish care, emphasizing that more than one visit will likely be needed, especially with the reality of telemedicine in the time of COVID-19. A face-to-face visit including a full physical examination and labs will be needed early in care engagement, at the least. While taking a medical history, the focus should be on establishing rapport and putting the patient at ease. Remember to address why the patient is presenting to care, if not just to establish HIV care. Readiness to begin or reinstate ART should be assessed, as well as the need for social services, particularly as many have lost jobs or income during the pandemic.

To optimize care engagement, medication adherence, and viral suppression, timely access to routine and urgent primary care are essential, including evenings and weekends where feasible. It is crucial to provide linguistically and culturally appropriate care and incorporate evidence-based and evidence-informed interventions. In a multidisciplinary care model, the identification of a primary care clinician, who could be the HIV specialist, is essential. Discussion of "U = U" or "Undetectable equals Untransmissible" is vital

to encourage adherence to ART and visits and reduce stigma. During routine health maintenance, it is important to encourage smoking cessation and provide recommendations for safer sex and safer substance use. Oral health and cancer screening are especially important for people with HIV, as is screening for and management of metabolic disorders.

There are special considerations for different populations. It is important to understand desires for childbearing and contraception. All pregnant persons should be treated with ART as recommended by DHHS perinatal guidelines. Chest/breastfeeding should be avoided in the US. An individual and developmental approach to treatment and care is important for adolescents, ideally with a specialist in adolescent HIV care. Transition to adult care must be coordinated and deliberate. Vaccinations should be administered according to the ACIP schedules for children with HIV. Finally, transgender and gender-diverse populations deserve access to care that is gender-affirming, nondiscriminatory, non-stigmatizing, and culturally sensitive. Gender-neutral language should be used, and gender identity options on forms should be expanded beyond natal sex. WPATH guidelines, which are likely to be updated by the end of 2021, should be followed for gender-affirming

treatment, including monitoring of laboratories. Cancer screening should be based on guidelines for the organs and tissues present in the patient. Most importantly, staff should be educated about gender identity and sexual orientation and appropriate case management or behavioral health referrals. Patients should be addressed using proper pronouns and—always—their preferred name.

Clinicians are encouraged to incorporate HIV primary care into daily practice and make use of the HIVMA/IDSA HIV Primary Care Guidance for patient care. In the future, the Guidance will be periodically updated online at [HIVMA.org](http://HIVMA.org). **HIV**



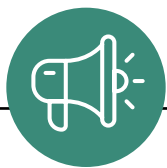
**DR. MELANIE THOMPSON** was a founding Board member of ACTHIV and is currently Co-Chair of the HIV Medicine Association (HIVMA)/IDSA HIV Primary Care Guidance Panel, along with Michael

Horberg. She is also a past chair of the HIVMA Board of Directors.

Dr. Thompson has conducted over 400 studies in the areas of HIV treatment, prevention and diagnostics; viral hepatitis treatment and diagnostics; sexually transmitted infection diagnostics; and epidemiology as Principal Investigator of the AIDS Research Consortium of Atlanta (ARCA). As an HIV clinician, she has cared for thousands of people with HIV in Atlanta since seeing her first patient in with HIV in 1982.

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# The ART of HIV Advocacy

## SMASHING STIGMA THROUGH SOCIAL MEDIA OUTREACH

By Michael Hoeben

**I**N THE EFFORT TO END THE HIV EPIDEMIC, geography matters. According to the Centers for Disease Control and Prevention (CDC), the South is home to the highest number of people living with HIV (PWH),<sup>1</sup> accounting for 51 percent of all new HIV diagnoses in the U.S. in 2018.<sup>2</sup> Across the U.S., most new HIV diagnoses occur in urban areas; however, in the South, suburban and rural areas make up a higher proportion (24%) of new diagnoses compared to other U.S. regions.<sup>3</sup> Simply stated, the South's PWH population is both large and geographically dispersed, creating unique, multifactorial challenges for HIV prevention and care, as well as unique barriers to care access for PWH.<sup>4</sup> This geographic complexity is only the beginning of the problem, as social, cultural, and economic factors further complicate the issue, along with race/ethnicity, insurance coverage, and so forth.<sup>5,6</sup> For example,

recent research estimates 32 percent (3.6 million) of U.S. LGBTQ+ adults, including 525,000 transgender adults, reside in the South, with over 40 percent of this community identifying as people of color (POC).<sup>7</sup> Southern Blacks represented 53 percent of new HIV diagnoses in the region, with gay, bisexual, and other men who have sex with men comprising 60

percent of new HIV diagnoses amongst African Americans in the South.<sup>8</sup> Despite this diversity, HIV stigma continues to be pervasive and is directly fueled by stigma, prejudices, and biases around sexual orientation, gender identity, substance use, poverty, and sex work, thus eroding people's willingness to disclose their HIV status or to seek HIV testing/services, which translates to lower or delayed access to HIV prevention and care.<sup>9</sup>

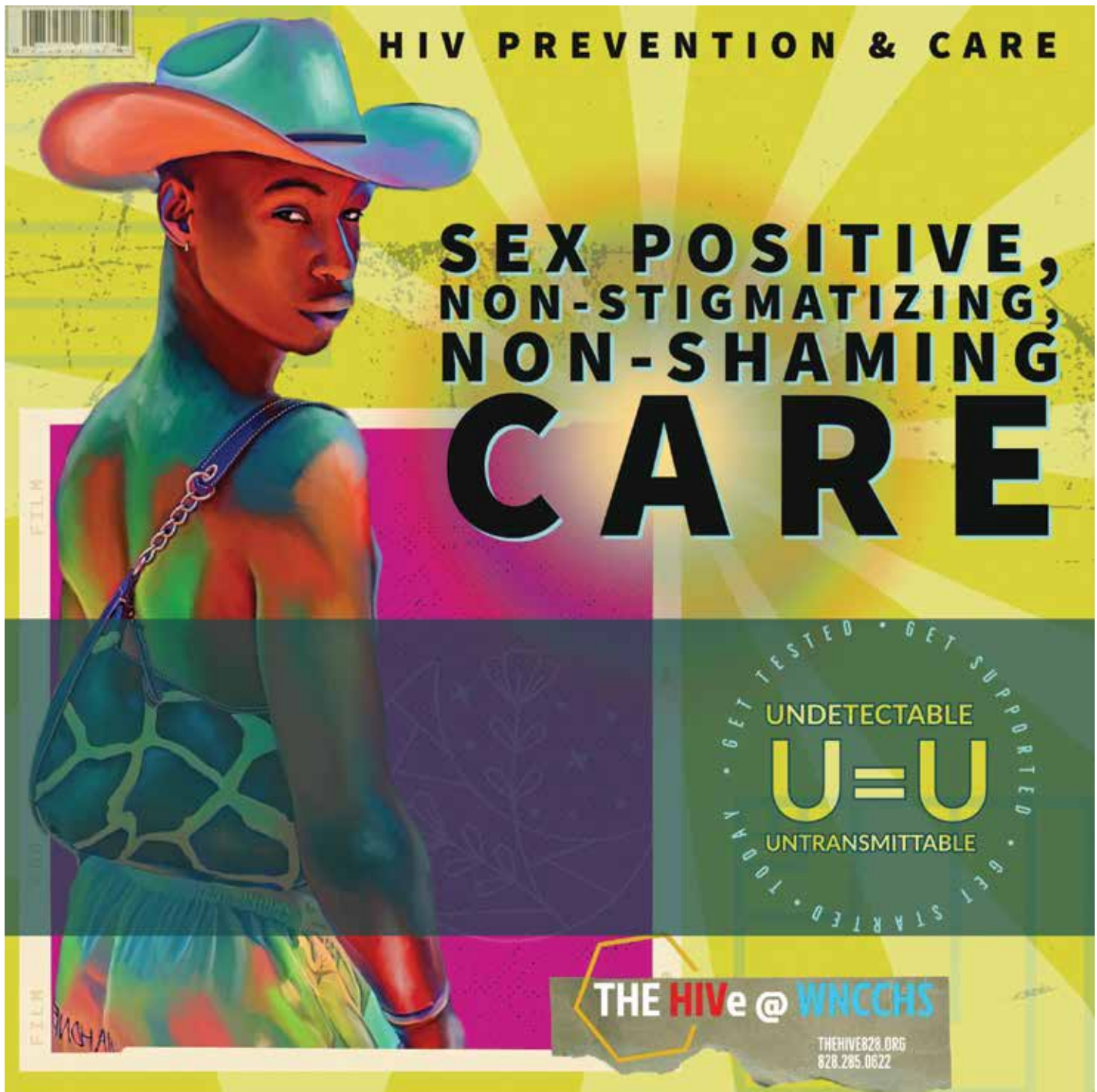
The key takeaway is this: The intersection of marginalized identities occurring in the South results in layers of disparities and inequities that perpetuate the region's disproportionate HIV risks and vulnerabilities. This is the context in which Western North Carolina Community Health Services (WNCCHS) lives, works, and serves. Therefore, innovation is vital to reaching, engaging, and supporting PWH in the South.

### Who are We?

WNCCHS is a federally qualified community health center (FQHC) located in Asheville, North Carolina. WNCCHS also serves as the NC Region 1 Ryan White Administrator overseeing Ryan White Part B, C, and D programs in Asheville/Buncombe County and the 18-county service of Western North







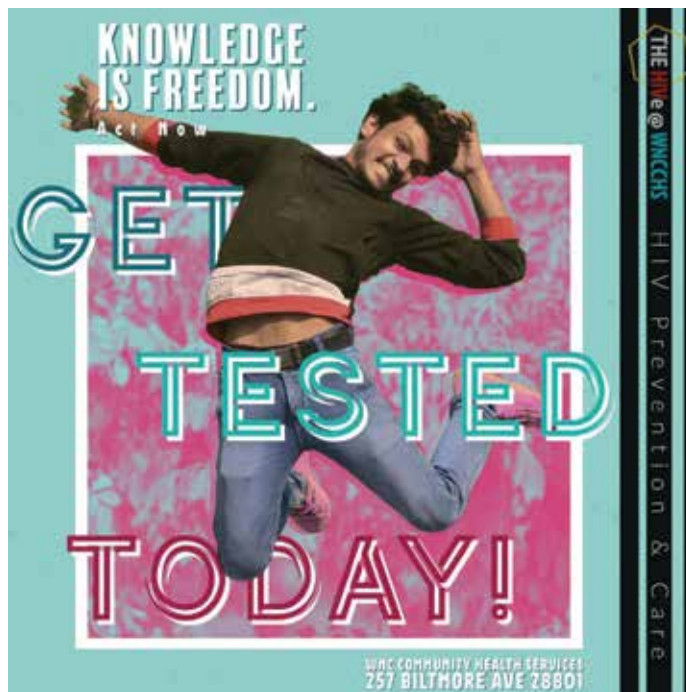
Carolina. As reported by Health Resources and Services Administration (HRSA), WNCCHS served a total of 11,715 patients in 2020, 91.52 percent of whom were at or below 200 percent of the Federal Poverty Limit (FPL), 61.8 percent of whom were uninsured, and 19.52 percent of whom were homeless.<sup>10</sup> A slight majority (52.67%) of these patients identified as racial and/or ethnic minorities.<sup>11</sup> Additionally, 6.27 percent (n=699) of our patient base were PWH.<sup>12</sup> Essentially, as an

FQHC, WNCCHS primarily serves historically politically, economically, and socioculturally marginalized groups.

### So What?

While WNCCHS exists in what is commonly considered the rural, white, conservative South, the actual community we serve is far more diverse and complex. Therefore, meaningful progress in ending the HIV epidemic in the South demanded a significant shift in

our outreach and marketing efforts. As an organization whose very existence was born out of the emerging need for competent, affordable, accessible HIV care, we intimately understand how stigma drives dehumanization inside and outside of the healthcare context. Researchers Beer et al. (2021) concluded that, "Stigma was higher among younger age groups, women and transgender people, Black and Hispanic/Latino men and women, and Black and Hispanic/Latino men



who have sex with men,” finding that HIV stigma was “associated with lower antiretroviral therapy use and adherence, missed HIV care visits, and symptoms of depression or anxiety.”<sup>13</sup> In addition, the team cited “the need for enhanced stigma-reduction efforts among specific groups and the importance of addressing the stigma around disclosure and community attitude.”<sup>14</sup> These findings give weight to the thinking that led to our development of THE HIVE 828, a standalone website (thehive828.org) and social media presence (@THEHIVE828) for WNCCHS’s HIV prevention and care program, the purpose of which was to prioritize and center those most vulnerable to and impacted by HIV by using a sex-positive, non-stigmatizing, non-shaming framework.

### Welcome to THE HIVE

The overarching goal of THE HIVE is to foster a stigma-smashing cultural shift by taking a more positive, upbeat, and often humorous approach to the HIV prevention and care conversation, as a large majority of the images and messaging typically associated with HIV tend to take on a more serious—and often sad—tone. Additionally, WNCCHS partnered with OUTthINK Studio, a virtual, digital arts studio committed to leveraging art to prioritize social justice and human rights advocacy work in organizational communications to ensure that THE HIVE outreach embodied diversity, inclusivity, and values needed to effectively reach and represent marginalized groups of interest.

THE HIVE 828 was formally launched on September 4th, 2020. Early on, analysis showed that Site Visits were the most useful performance metric; evidence suggested that PWH were less likely to Like/Follow us on social media but still clicked through to access the website. Since program launch, this creative, multimedia, digital outreach campaign has resulted in 6,351 total site sessions and 5,333 unique site

visitors as of August 10, 2021, with 89 percent of this traffic driven by social media outreach. Only 8 percent of HIVE website visits come through the WNCCHS main website. THE HIVE’s social media advertising boasts a total reach of over 440,000 amongst Region 1 network users; paid reach and impressions are 220,000+ and 533,100+, respectively. In total, while these outcomes demonstrate the value-adding benefits of this strategic outreach, the initiative is rooted in a deeper understanding of the power of media representation as a vehicle for changing how individuals perceive themselves and others, which, of course, is the foundation for constructing a more diverse, inclusive community where all people, irrespective of their identity or status, feel welcomed, appreciated, and embraced as respected, worthwhile members of society.

### Conclusion: Humanizing HIV

I seized the opportunity to join WNCCHS as the Transgender Health Coordinator in September of 2019. As a queer, transgender man and uninsured patient of WNCCHS, I intimately understand the vital role that FQHCs play in promoting greater healthcare equality and equity; for me, WNCCHS was my only option for healthcare. As my role at WNCCHS evolved and expanded to HIV services, the magnitude of marginality in HIV and the impact thereof ignited a desire to







help humanize HIV, which led to the creation and ongoing messaging of THE HIVE, as well as my co-founding OUTthINK in partnership with my queer, Anishinaabe/Ojibwe wife and artist, Myela Slattery. The unflinching commitment of WNCCHS's leadership and board, along with the ongoing advocacy of our Director of Development and Collaboration/Ryan White Coordinator, W. Scott Parker, is core to THE HIVE's success. Without total top-down buy-in, this bottom-up outreach would have stalled from the start.

The truth is that we cannot end the epidemic without effective HIV prevention and care. Yet, at the same time, these efforts are destined to fall short if we are (1) unable to reach those most vulnerable to the impacts of HIV and (2) fail to mend the eroded patient-provider relationship that has been and continues to reflect deep-seated fears, insecurities, and mistrust. Put differently, who we focus on and how we share these stories profoundly influences our success at local, state, regional, national, and, ultimately, global levels.

Diversity is the reality of HIV care, and inclusion is the future of HIV care optimization. As a transgender man, I know what it means to see yourself, your community, and your lived experience shared in this way. When the world sees your very existence as cause for concern, silence, and erasure, the seemingly simple yet powerful acts of being seen, included, and celebrated are transformative. At the very least, the "We care" message is received through meaningful representation and outreach. Over time, art empowers healthcare advocacy by normalizing and uplifting diversity. In sum, THE HIVE addresses both internalized and external stigma ultimately by showing and telling stories of and from the margins, championing the belief in "the power of seeing and celebrating the "other" as critical in breaking down the biases and barriers that continue to divide the human family."<sup>15</sup>

HIV care is part of WNCCHS's organizational DNA—it is our origin story. However, as society evolves, our role must also evolve to keep pushing progress forward. WNCCHS began as a refuge for those forced to the margins. We continue to serve in this capacity but with an amplified voice and vision as we work to generate greater

healthcare equality and equity for *all*. Yes, the HIV epidemic has devastated lives and communities. Still, today, we are invigorated by the truth of HIV science, which is that HIV is preventable and treatable. We have seen the beauty, resilience, and dignity of the human beings affected by HIV through this shared journey. The blending of art and advocacy stands strong as a viable, effective means for uplifting our patients while also helping to better inform, educate, and serve our community. **HIV**



**MICHAEL HOEBEN** (he/him) is the Transgender/HIV Bridge & Retention Coordinator at WNCCHS, an Asheville-based FQHC serving 800+ PWH and 500+ trans/gender non-conforming

patients. He is also the co-founder of OUTthINK Studio and creator of THE HIVE, believing in the power of blending art and advocacy to ignite societal change.

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# INNOVATIVE STRATEGIES

## to Reach Rural HIV Populations







By Madhuri J. Lad, DO, FACOI, AAHIVS

**HAVE A PATIENT** who lives in Poteau, Okla., two and a half hours from my office in Tulsa, with her husband, who also has HIV. Last year, after a brutal ice storm in February 2020, a water pipe was damaged in their home. With no running water and no repair person available, she didn't want to come to her appointment because she could not shower. Luckily, my colleagues, Damon Baker, DO, and Johnny Stephens, PharmD, began our telemedicine program in 2014 to accommodate our patients in the more rural areas of the state. So instead of maneuvering the multiple challenges of getting to me, my patient and her husband utilized our mobile unit, saw me via a virtual appointment, obtained refills at their local pharmacy, and had labs drawn at the local rural hospital.

This is only one example of how telehealth can help support the HIV care continuum, which can be unreliable in rural and underserved areas of the U.S.<sup>1</sup> Geographic isolation and poverty increase the need for basic human services. Since linkages to care are positively correlated with prognosis and negatively correlated with disease transmission, there remains a critical public health need to address vulnerable populations in rural, underserved areas for each step of the HIV care continuum.<sup>1</sup>

In 2019, the federal government introduced *Ending the HIV Epidemic in the U.S.* (EHE), which focuses its Phase I efforts on seven states with a substantial number of HIV diagnoses (over 10%) in rural areas. Oklahoma has been classified as one of these seven states.<sup>1</sup> In 2018, there were 6,244 people with HIV in Oklahoma.<sup>2</sup> Although many are located in the two largest cities of Tulsa and Oklahoma City, these are also the locations with the most resources for testing and HIV care. We are missing opportunities to intervene in rural areas if resources are not available to diagnose and treat. If testing can be expanded across the state, telehealth services could link patients into care to help end the HIV epidemic in Oklahoma. Telehealth is an excellent modality for outreach and direct patient care that can link and retain patients in care, leading to viral load suppression in rural Oklahoma. This is the approach at my university-based Ryan White HIV clinic at Oklahoma State University Center for Health Sciences Internal Medicine Specialty Services.

## Expansion of OSU-CHS Telemedicine

Transportation is a common barrier to care in rural Oklahoma. The use of telemedicine technology can mitigate this barrier and assist with linkage, retention, and viral load suppression in patients with HIV in rural eastern Oklahoma. Using a mobile unit or telemedicine bus in connection with telemedicine equipment at Oklahoma State University Center for Health Sciences (OSU-CHS) has helped reach patients in McAlester and Poteau, which are two and two and a half hours away from the clinic, respectively. Telemedicine has been conducted since 2014 from our location in Tulsa. Still, over the last few years, we have made improvements to overcome the challenges of this technology, primarily the connectivity challenges in a rural setting. By upgrading our equipment, changing platforms, obtaining hotspots, and contracting with local hospitals and federally qualified healthcare centers (FQHC) for building space, we have successfully improved our telemedicine program to efficiently reach more patients. In addition, we just recently expanded to a third location in Tahlequah in eastern Oklahoma. These innovative strategies have helped us achieve an 88 percent viral load suppression at our clinic, aiming to end the HIV Epidemic in Oklahoma.

## Rapid Start Through Telemedicine

This year, we have also expanded our rapid start program to incorporate telemedicine for newly diagnosed patients. Diagnosing HIV early and rapidly initiating therapy is essential for health, as well as for reducing transmission. Our original rapid start program in Tulsa implemented three years ago has shown that reduced time to a physician appointment led to earlier viral suppression and improved retention in care. Rapid start through telemedicine has now been implemented to assist earlier treatment in rural areas. Through agreements with FQHC's or local hospitals for telemedicine, these rural areas are testing and able to link their patients immediately. Newly diagnosed patients can be seen on a telemedicine visit and started on antiretroviral therapy (ART) with samples available at the telemedicine site. They can also be seen initially at our

Tulsa clinic for ART initiation and then transitioned to telemedicine for subsequent visits. The Oklahoma State Department of Health also received HRSA funding to hire two nurse practitioners who travel around the state for rapid start of ART by providing 30 days of ART and linkage to HIV care to one of the two Ryan White clinics in Oklahoma. Some of the referrals that are linked from rural areas are easily transitioned into our telemedicine program. This has linked patients from Tulsa to as far as Hugo, which is three and a half to four hours away from Tulsa.

## Multidisciplinary Services

As people with HIV age, we find other chronic illnesses that need to be addressed and treated. Offering primary care and preventative services for these patients is the key to keeping them healthy. Using technology with equipment such as otoscopes and dermascopes with cameras and digital stethoscopes makes it possible to conduct a medical telemedicine visit and offer primary care services with a more detailed physical exam. Detecting and treating chronic illnesses earlier helps longevity and health as well as the quality of life.

I recently diagnosed one of my routine telemedicine patients with diabetes, started him on treatment, and got his diabetes under control through telemedicine follow-up visits. However, sometimes the services a patient needs are more than can be offered with our telemedicine program. Therefore, specialists closest to these rural areas can be utilized to decrease transportation issues for patients.

Addressing the other barriers to care, such

as mental health and substance use, are an integral part of any HIV practice, particularly in rural areas. Being able to offer mental health screenings (even during a telemedicine visit) is vital, but even more important is addressing mental health when it is a barrier to care and adherence. The use of telemedicine for a medical visit can incorporate a depression screening, such as a PHQ-9, and can even include a therapy session or linkage to local mental health services. Telemedicine therapy sessions are a service we are just starting to offer patients and are the future of HIV care to address this barrier that impacts the HIV care continuum, ultimately leading to viral suppression.

## Technology and Cost

Our tools have become so advanced through the years. With the help of technology, even acute complaints, such as ear pain, rash, or cough, can be addressed by using our specialized camera otoscope, dermascope, and stethoscope program to examine the patient who is miles away. Images are projected on the computer screen for the provider when the nurse examines the patient. Heart and lung sounds are live but can also be recorded and sent as a file. This is all a part of the future of medicine, so embracing it can have an unimaginable impact on outcomes.

A few years ago, we used a Polycom camera, which provided great images but was very expensive. The platform utilized now is Zoom and is only \$15.00 annually per provider with a room connector charge of \$400 annually. The Avizia Horus scopes bundle (three scopes) is \$6000 with a service fee of





\$600. The ThinkLabs One digital stethoscope is \$500. A laptop or desktop is required. We have recently purchased the Eko Digital Stethoscope that also has ECG capability. It is \$400 but has an annual fee of \$1200 per year. We previously had this equipment on the bus but have created a cart with the equipment and laptop for each telemedicine location.

## Challenges of Telemedicine

The mobile unit was the largest expense along with gas and maintenance. When accounting for mechanical issues as well as weather issues, the bus became our biggest challenge. Storage of the bus and finding a secure location to conduct these telemedicine clinics proved challenging as well. Efficiency was often a concern when utilizing staff to drive to and from a locations hours away. Connectivity on the bus often had difficulty in rural areas as well. We tried hot spots and always had a cell phone back up from different cell phone providers. Due to these challenges, we decided to transition from the mobile unit to an office space.

Since ongoing software updates and staff inexperienced with telemedicine equipment can be challenging, Information Technology (IT) specialists and nurses are trained appropriately while having knowledgeable backup staff in case the primary staff is not available. In addition, being familiar with the closest centers in these rural areas for referrals for specialists is of value. Finally, as with most clinics, canceled appointments can be difficult to prevent but can be even more challenging when staff is sent to conduct a telemedicine clinic for the day, and only a few patients attend appointments. Our telemedicine program's inefficiencies changed as we trained

staff locally and moved to a building space in these rural areas. The mobile unit was unique, but we decided there could be a more efficient way to conduct our telemedicine clinic.

## Transitioning from a Mobile Unit to Building Space

Previously our licensed bus driver, who is also our IT specialist, drove with our nurse to the rural location to conduct the appointment using the Horus scopes and Eko or ThinkLabs stethoscope programs. The physician corresponded from the Tulsa site using Zoom. However, this previous method was neither cost-effective nor time-efficient. We found that training staff at the corresponding sites required less time than driving the bus to each site. Therefore, we contracted with local hospitals or FQHC's to utilize building space to conduct the appointments instead of conducting the appointments on the bus.

Switching to contracting with hospitals or FQHC's for building space has helped cost and improved connectivity. Some rural areas did not charge for the space as it is a much needed service for them. We pay salaries for hours needed for the nurses at their location and provide training. IT staff at the site also receive training. This proves to be much more cost-effective and time-efficient than paying our staff extra time to drive to and from the rural locations. It does require equipment and a laptop to be at each location when not using a mobile unit, but this is still cost-effective than the mobile unit's maintenance costs.

Once the front desk schedules the appointment, our nurse sends lab orders to the outlying lab. She obtains the results and interfaces the data into our EMR for review by the physician before the appointment. If the

labs are not completed, then the appointment is canceled and rescheduled. We conduct a telemedicine clinic at each location once every two weeks.

## The Goal of Viral Suppression

We continue to strive for our goal to end the HIV Epidemic in Oklahoma. Thanks to innovative ideas in telemedicine, we have achieved an 88 percent viral load suppression at our clinic. While nothing is as good as an in-person visit and exam, a telemedicine visit may make the difference for some patients in rural areas to stay in care. The use of telemedicine has assisted with retention in care by mitigating the barrier of transportation and ultimately leading to viral suppression for people with HIV in Oklahoma.

I have a patient who resides 30 minutes outside of Poteau. His truck often breaks down, and he has trouble even making it to the Poteau telemedicine clinic. A few months ago, his truck was working, and he had the money for gas, so he decided to drive all the way to Tulsa to see me in person for the first time. These are the relationships that I cherish in rural Oklahoma, knowing that I am making a difference. **HIV**



As Assistant Medical Director of the Internal Medicine Specialty Services Ryan White Clinic, **DR. MADHURI J. LAD** is part of a multidisciplinary team

for treatment of patients living with HIV in eastern Oklahoma. Oklahoma has been designated as one of the seven states with a high rural burden for ending the HIV epidemic. Her experience includes telemedicine and providing care to these rural areas in eastern Oklahoma. She presented the telemedicine program and her program with rapid start of antiretrovirals for patients living in Oklahoma at the 2020 National Ryan White Conference and qualified for the HRSA Best Practices Target HIV website for both these rapid start and telemedicine programs. Dr. Lad is the facilitator for the OSU HIV and Viral Disorders ECHO (Extension for Community Healthcare Outcomes). She is an internist and received her certification for the treatment of HIV from the American Academy of HIV Medicine six years ago.

## RESOURCES

1. <https://www.cdc.gov/endhiv/about.html> and <https://ahead.hiv.gov>
2. <https://aidsvu.org/local-data/united-states/south/oklahoma/>





# Tablets for

By Alan Witchey, President and CEO of Damien Center and Damien Cares

**D**AMNIEN CENTER is an AIDS Service Organization (ASO) serving nearly 4,000 people annually, located in a hotspot of new HIV transmissions on the near east side of Indianapolis. It is Indiana's oldest and largest ASO, yet it continues innovating and providing new programs and services that embody its tagline, "One home for HIV wellness." In 2015, Damien Center established a separate 501(c)(3) organization, Damien Cares, to operate a medical clinic and related services. Together, Damien Center and Damien Cares provide a wide variety of medical and supportive services, including non-medical case management (care coordination), medical case management, mental health and substance use counseling, legal services, housing assistance, emergency financial assistance, nutrition assistance, transportation assistance, primary medical, and prevention services. As its tagline indicates, Damien aims to provide a home for clients, a safe place with people that care.

This personalized, one-stop-shop approach is vital to Damien Center's success in this community, particularly in reaching and effectively serving our most vulnerable or systemically marginalized neighbors. Clients experience multiple barriers to care, including lack of transportation, housing instability, mental health and substance issues, language barriers, systemic discrimination, and other socio-economic barriers. For example, at any time, 10–16 percent of people with HIV in central Indiana are homeless, and 10 percent of Damien clients have a history of incarceration. Fifty percent identify as having mental health needs, and 40 percent have substance use issues. In addition, 57 percent of Damien clients live in poverty for their household size, and 89 percent are below the level used to determine ALICE (Asset Limited, Income Constrained, Employed) households.

## A Proven Strategy to Improve Health Outcomes

These barriers, plus the additional stressors placed on patients by the COVID-19 pandemic, have led to an entire group of patients no longer accessing care. Telemedicine has the potential to counteract some of

this attrition. Before the pandemic, Damien had made steps toward a telemedicine option to decrease barriers to care, retain more patients in care, and ultimately maintain viral suppression for more clients.

Mobile health interventions have greatly improved retention in care benchmarks and viral load suppression rates in HIV patients. In 2018, *PositiveLinks: A Mobile Health Intervention for Retention in HIV Care and Clinical Outcomes with 12-Month Follow-Up*<sup>1</sup> was one of the first studies to demonstrate that a mobile health intervention can have a positive impact on retention in care (which improved from 51 percent at baseline to 88 percent at six months and 81 percent at 12 months) as well as clinic outcomes (the percentage of patients with suppressed viral loads increased from 47 percent at baseline to 87 percent at six months and 79 percent at 12 months). This supports CDC data showing that people with HIV who received ongoing, regularly scheduled care had significantly lower viral loads, higher CD4 cell counts, and reduced morbidity and mortality than those who missed even one medical visit over two years.<sup>2</sup>

However, it is essential to note that while telehealth can improve health outcomes, it remains inaccessible to many people. For example, a 2020 survey of Indiana AIDS Service Organizations revealed that approximately 50 percent of all clients do not have access to either technology (e.g., laptop/notebook, etc.) or connectivity to interact with their clinicians. For this reason, Damien has offered technology and technical support along with its telehealth program.



# Telehealth



**How this Indiana HIV  
service organization broke  
down barriers to keep its  
patients engaged in care**

### COVID-19 Creates a Gap

As the pandemic hit, Damien saw barriers grow for so many people that we serve. Seemingly overnight, many lost their jobs, struggled to get the nutrition they need, and experienced increased mental health stressors. Though Damien remained open to serve clients through phone calls, online connections, and in-person socially distanced interactions, many clients struggled to access the technology or internet connections necessary to support telehealth activities.

Patients must continue to engage in medical care and remain adherent to medications, as even a short lapse in the use of HIV medications can cause an increase in HIV viral load. A recent report from the WHO emphasized that COVID-19 only increases the risks faced by people with HIV, as anyone with HIV is at a higher risk of COVID-19.<sup>3</sup>

### Breaking Down Barriers to Prevention

Before the pandemic, Damien also implemented a tele-PrEP program that allows for at-home labs, provider appointments, and mailed PrEP medications. As a result, in 2020, 73 percent of new clients were retained after six months, and less than 10 percent of PrEP exits were negative/lost to care.

### Tablets Expand Service Delivery

Damien's telehealth program remotely provides patients with a range of technology and support that they need to access their providers (including medical, mental health, housing assistance, substance and addictions counseling, insurance enrollment, and other case management). The program has provided 100 tablets, 4G connectivity, and all accompanying accessories to patients who would not otherwise have access to these types of devices, with a particular focus on providing tablets to those who are at the highest risk for complications and those who are low-income or otherwise unable to access similar devices. This technology keeps these patients engaged in care and supportive services, ultimately improving their health and wellness outcomes.

To do this, Damien has partnered with Continuud, a company that provides the

tablets and assists staff in managing the technology and software involved in the program. The program provides patients with eight-inch tablets with an unlimited data connection to providers. Devices ship with a secured environment and limited functionality customized by the health care provider to include tools that clients need to access care. Instructions are easy to understand and personalized to meet client needs, including language and literacy level. Data is secure and in line with HIPPA regulations and client privacy concerns. In addition to direct access to providers, the tablets provide clients with access to educational videos, complete Google searches for medication and disease-related sites, and most importantly, access to an online portal for their medical records for the first time. This allows patients access to their viral load data and provider notes, helping to facilitate their knowledge and interaction with other providers.

### An Integral Part of Patient Care

Damien's telehealth initiative is ongoing, and outcomes will take time to assess; however, a survey in early 2021 of participating clients gives a sense of their satisfaction. Overall, 81 percent were satisfied with their tablet, and 87 percent agreed that it helped them stay engaged in care. In addition, 88 percent of people with HIV in care at Damien were virally suppressed (VL<200), and 89 percent of telehealth patients (who had labs done during this period) were virally suppressed. This indicates that clients in the program experienced good outcomes despite the extraordinary circumstances created by COVID-19.

For Damien and other ASOs, telehealth is an effective tool to help overcome barriers to retention in care. A partnership like the one between Damien and Continuud helps ensure equitable access by supplying clients with devices and support. Telehealth has been more critical than ever during the COVID-19 pandemic, as the pandemic has simultaneously increased barriers and the risks that people with HIV face. Even when the immediate threat from COVID-19 is resolved, the move towards telehealth will continue, as the obstacles overcome by telehealth, particularly those related to transportation and access to quality medical care, will continue. As Damien completes its first year of the telehealth program, we are confident that the results will be similar to those in other studies, with significant increases in retention in care and decreases in viral load. **HIV**



**ALAN WITHEY** joined Damien Center as the President & CEO in 2018 and has more than twenty years of experience working to improve health and social inequities with low-income populations. With a wealth of experience in HIV, LGBTQ+ needs, housing, and nonprofit leadership, Alan has a unique understanding of community needs and how to meet them.

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PHARMACIES



# The Government Mandates Coverage of PrEP

**An important step towards more HIV prevention**

By Alexandra Broadus, PharmD  
and Brad McElya, PharmD

**I**N JULY, the U.S. government published guidance reiterating that the two approved pre-exposure prophylaxis (PrEP) drugs for HIV prevention, Truvada® and Descovy®, and any associated generics, must be covered by nearly all health insurers. In addition, the guidance clarified that coverage extends beyond the drugs themselves, including clinical visits and lab tests essential to the effective prescription and ongoing maintenance of PrEP. This move signifies a significant advancement that will help more people access care and ultimately help end the decades-long HIV epidemic.

### Why This is so Important

Forty years since the first AIDS case was documented in 1981, the HIV epidemic is far from over. Approximately 1.2 million people in the U.S. have HIV, and nearly 13 percent of them are not aware of their status.<sup>1</sup> However, game-changing developments in HIV prevention and treatment tools, including PrEP, can significantly reduce the risk of HIV transmission when used consistently and have resulted in decreasing rates of HIV diagnosis in the U.S.

Today, though, PrEP prescriptions only reach 18 percent of the one million Americans considered at risk.<sup>2</sup> Without intervention, another 400,000 Americans will be newly diagnosed over the next 10 years despite available tools to prevent HIV.<sup>3</sup>

As frontline HIV care providers, we know that the reasons for the ongoing epidemic are multiple and complex. Lack of awareness, social stigma, and costs can discourage at-risk individuals from learning their HIV status and accessing information and care about prevention, testing, and treatment. Embedded in the community, pharmacists are one of the most accessible and trusted healthcare providers that offer direct services. For example, during the COVID pandemic, Walgreens pharmacy team members completed more than 9 million COVID tests, demonstrating the sheer volume of people regularly seen in the community. And, when it comes to HIV prevention, several states have passed PrEP prescriptive authority statutes, allowing pharmacists to take a more proactive role in helping people access PrEP. This is just one example of how pharmacists can play a role in reducing barriers for at-risk individuals.

This recent announcement by the U.S. government mandating insurers cover all PrEP costs is a significant milestone in helping to address the financial barrier specifically, particularly for insured at-risk individuals with low income.

### The High Price of Costs

At Walgreens, we have historically tried to ease the burden of healthcare costs through proactive care, working closely with payors, prescribers, and other partners to lower overall costs. We also provide services that reduce financial burden, such as identifying

**When it comes to HIV prevention, several states have passed PrEP prescriptive authority statutes, allowing pharmacists to take a more proactive role in helping people access PrEP. This is just one example of how pharmacists can play a role in reducing barriers for at-risk individuals.**



lower-cost medication alternatives and connections to financial assistance programs.

Though it's just one of many factors, cost also plays a significant role in limiting access to PrEP and perpetuating the HIV epidemic. For example, a recent study exploring the associations between PrEP use and state policy variables of Medicaid expansion and state Drug Assistance Programs found that if people can access PrEP at a lower cost or free, they are more likely to take it.<sup>4</sup>

For the uninsured, the *Ready, Set, PrEP* program established by the U.S. Department of Health and Human Services in December 2019 has been a literal lifesaver. To qualify for *Ready, Set, PrEP*, a person must test negative for HIV, have a valid prescription for the medication, and not have prescription drug coverage. Medications are fully covered for qualifying participants, but necessary doctor's visits and lab tests can incur a fee, depending on a person's income. As a supporter of the program, Walgreens also donates dispensing fees to further offset the costs of accessing PrEP. So, while this program goes a long way in reducing costs and eliminating that barrier, some financial burden remains for those who must cover their additional services.

For those with insurance, this new mandate extends beyond the drugs to be all-inclusive of their HIV prevention treatment, easing the burden further and essentially eliminating the cost barrier.

### The Importance of the Care Team Collaboration

The COVID-19 pandemic has resulted in a health crisis unlike any other experienced in the past century. With many people experiencing negative consequences such as job loss, food insecurity, and inability to manage existing health conditions, some of the most disadvantaged in the COVID-19 era are people with HIV and other immunocompromising diseases. As the pandemic has led to significant changes in health service delivery and amplified fears of increased death and illness, the health inequities and the consequences of these changes among those with or at risk of HIV have had a devastating effect. In 2018, Black Americans comprised 42 percent of new HIV diagnoses despite representing only 13 percent of the U.S. population, and the COVID-19 pandemic has heightened these inequities further.<sup>5</sup>

Pharmacists are playing a more significant role in healthcare to tackle these challenges and setbacks than ever before. They are



often the most relied upon and accessible healthcare providers for people seeking help managing chronic diseases, providing guidance and medication support, administering life-saving immunizations, and providing education and counseling. Looking at Walgreens alone—with 85,000 pharmacy team members in communities across the country—there is a Walgreens pharmacist within five miles of approximately 78 percent of Americans. For many Americans, their pharmacist may be their only—or their most convenient—health touchpoint to provide care for those with or at-risk of HIV.

When it comes to effective HIV prevention and treatment, the incorporation of the pharmacist in the overall care team cannot be overlooked. Pharmacists are an integral component to accessing testing services, helping with the adherence necessary for HIV prevention, and helping to end the HIV epidemic. At Walgreens, for instance, our pharmacists can monitor the proportion of days covered of antiretroviral medications within our clinical platform and identify those who are at-risk for non-adherence, then reach out to the person directly or alert the prescribing healthcare provider.

Supporting the benefits of this medical care team and pharmacy collaboration, research on a new care model by Walgreens in partnership with the Centers for Disease Control and Prevention, the University of North Texas Health Science Center's System College of Pharmacy, and HealthHIV revealed a positive impact of collaborative efforts between specially trained community-based pharmacists and medical care providers on HIV care and viral suppression.<sup>6</sup> It showed that even when people with HIV receive care from multiple healthcare providers, they often receive all their medicines from one pharmacy, making the pharmacist a key point of contact. In addition, people who had multiple visits with their pharmacist had improved overall retention in care and viral suppression through developing action plans and implementation. It ultimately revealed that collaborative efforts between community-based pharmacists and medical care providers can improve outcomes for people with HIV. Pharmacists offer local assets in nearly every community and continuously

work to reduce barriers to access and treatment by providing proactive care, copay assistance, adherence monitoring, and education, all in a stigma-free manner.

Pharmacists must continue to work closely with payors, medical healthcare providers, and other partners to improve care and access while lowering overall costs for those with or at risk for chronic health conditions such as HIV. Testing, coupled with this policy direction that covers the cost of clinic and lab tests necessary for those starting PrEP, may prove to improve our chances of ending this long epidemic significantly.

## An Epidemic End is Possible

The announcement from the government on mandated insurance coverage for PrEP, helping to reduce cost barriers for PrEP treatment, is without question an advancement in the fight against HIV. State legislatures, such as those in California and Colorado, are also taking further action by authorizing pharmacist prescriptive authority to provide expanded PrEP services, including proper reimbursements for these services.

To move us closer to the end of the HIV epidemic, we must take advantage of all the available tools that a pharmacist brings to the healthcare team: access to our communities, instilled trust, and an integrated, collaborative approach. **HIV**



**ALEXANDRA BROADUS, PharmD**, Walgreens Senior Director of Specialty Health Solutions, leads cross-functional efforts to develop innovative strategies and plans for clinical solutions for specialty conditions. Alexandra has led the company's HIV clinical programs, including the launch of Walgreens network of HIV-specialized pharmacies and partnerships with community-based organizations on advocacy efforts. Alexandra joined Walgreens in 2000 as a pharmacy technician and has previous experiences in store operations, field leadership as well as collaborations with health plans and health systems.



**BRAD MCELYA, PharmD**, Walgreens Director of Specialty Health Solutions, has been at Walgreens for over 20 years and in HIV treatment and prevention for four years. As a pharmacist who practiced in communities in Indiana and North Carolina, he understands the critical role the pharmacist plays as a highly accessible healthcare provider across America. In his current role, he oversees Walgreens HIV treatment and prevention efforts and is involved in the trainings that Walgreens pharmacy teams undergo to provide compassionate and confidential care, including an understanding in cultural competency and enabling stigma-free experiences.

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# MONOCLONAL ANTIBODIES

## Resources for HIV Care Providers

By The Federal COVID-19 Response Team

**T**HE AMERICAN ACADEMY OF HIV MEDICINE has been engaged with the Federal COVID-19 Response (FCR) Team to help ensure all healthcare providers have access to the latest information about the use of monoclonal antibodies to treat high-risk patients with mild to moderate cases of COVID-19.

To stay up-to-date on the research, we encourage providers to regularly visiting the Combat COVID website (Combatcovid.hhs.gov/) and PHE.gov. Additionally, weekly HHS/ASPR stakeholder engagement calls provide regular updates about therapeutics such as monoclonal antibodies and address inquiries from healthcare providers. To join either of the weekly calls, please contact ASPR@hhs.gov for inclusion on:

- The HHS/ASPR update call regarding allocation, distribution, drug administration of therapeutics for healthcare and hospital association/organizations (WED 3:15 p.m. to 4 p.m. Eastern)
- HHS/ASPR Office Hours – An opportunity to get your questions answered (THURS 2 p.m. to 2:30 p.m. Eastern)

As efforts continue to ensure high-risk patients with COVID-19 have access to available treatments, the PHE.gov and CombatCOVID.hhs.gov websites remain as frequently updated resources.

The following Q&A is a combination of information currently on the Combat COVID website and new content provided to the Academy by the FCR specifically related to the use of monoclonal antibodies for people with HIV (PWH).

### What monoclonal antibody treatments are authorized for use?

The U.S. Food and Drug Administration (FDA) has granted emergency use authorizations (EUAs) for the following monoclonal antibodies to treat patients with mild to moderate COVID-19 and at high risk of developing severe symptoms. The first two are available at no cost. These treatments include:

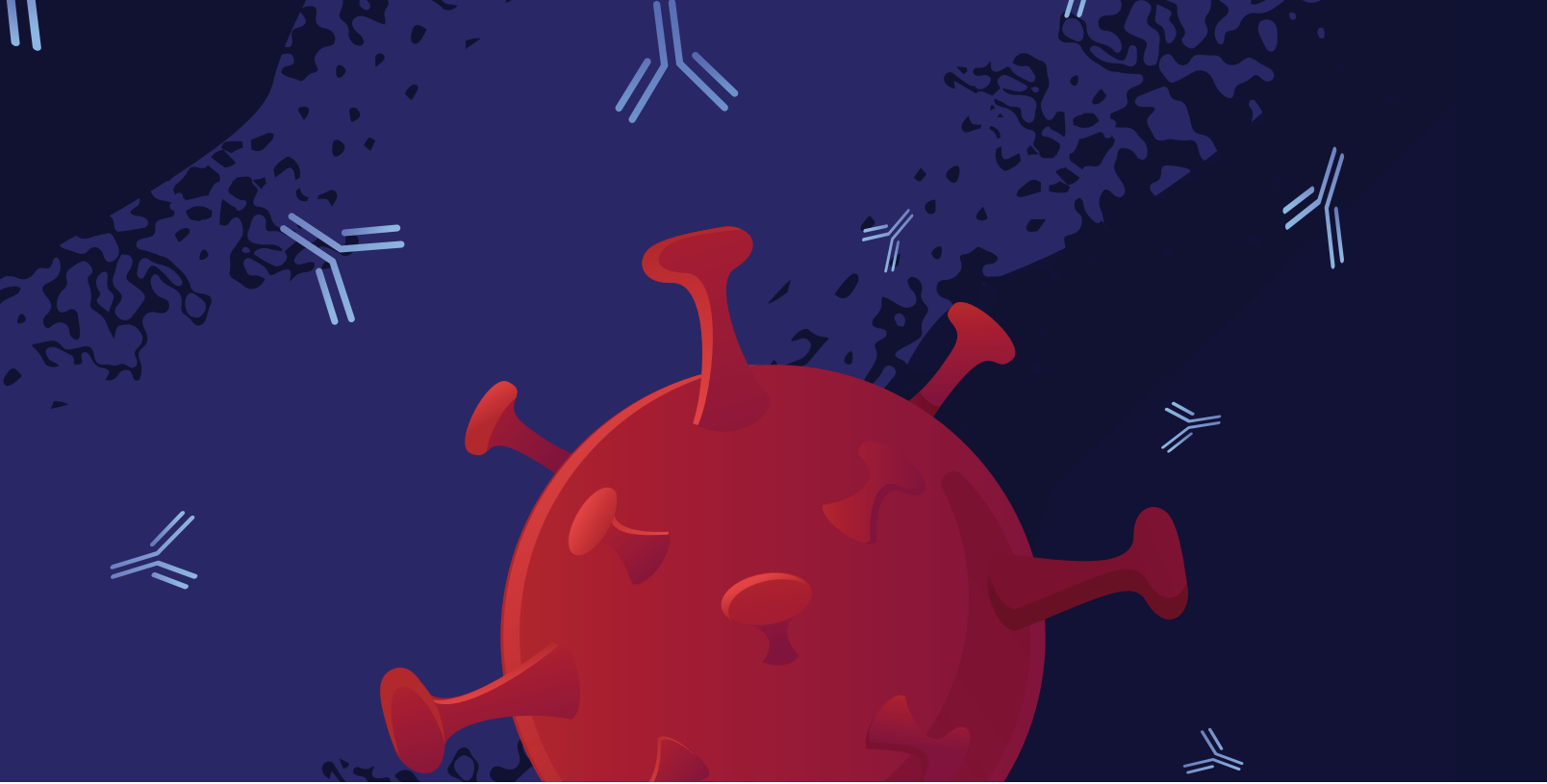
- REGEN-COV™ (Casirivimab and Imdevimab)
- Bamlanivimab and Etesevimab
- Sotrovimab

### What methods of administration are available?

The FDA has authorized intravenous (IV) infusion of monoclonal antibody treatments for emergency use. IV infusion is strongly recommended. The FDA also authorized subcutaneous injection for specific monoclonal antibody treatments that are currently available.<sup>1</sup> Subcutaneous injection is an alternative route of administration when IV infusion is not feasible and would lead to a delay in treatment.

### Are monoclonal antibodies effective against new SARS-CoV-2 variants?

The science on this question is evolving. Some circulating SARS-CoV-2 variants may be associated with resistance to monoclonal



antibodies. The FDA recently authorized updates to the fact sheets for healthcare providers, including Antiviral Resistance information in Section 15 of the fact sheets for each of the currently available treatments under emergency use. For further information, please reference the information on CDC variant classifications and definitions.<sup>2</sup>

### **Which patients can be treated with the authorized monoclonal antibodies?**

Monoclonal antibodies are authorized to treat mild to moderate COVID-19 in adult or pediatric (age 12 years and older and  $\geq 40$  kg) patients with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progressing to severe COVID-19 and/or hospitalization.<sup>3,4,5</sup> Treatment must be given within ten days of symptom onset, so it is critical to identify eligible patients at the point of diagnosis and inform them about the availability of monoclonal antibody treatment.<sup>6,7</sup>

### **Would all people with HIV be considered “at high risk of clinical progression” and therefore recommended for monoclonal antibody therapies?**

The CDC lists HIV as a risk factor for progression to severe COVID-19 (see People with Certain Medical Conditions |

CDC: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>). Observational studies have shown HIV to be associated with higher rates of severe COVID-19, hospitalization, and mortality from COVID-19. Clinicians should be mindful that comorbid conditions frequently seen in persons with HIV infection (e.g., cardiovascular disease) have been associated with the development of severe COVID-19.

### **Are there any issues with treating people with HIV with monoclonal antibody therapies?**

Persons with HIV should be considered potential candidates for monoclonal antibodies similar to those without HIV. HIV is not a contraindication to monoclonal antibody therapies. There is no documentation of increased adverse reaction with monoclonal antibody administration in this population (it is not stated whether it was studied; however, the rate of adverse events overall in the clinical trials was very low).

### **If a person with HIV received their third vaccination (booster shot), would their treatment plan change if they were to become COVID-19 positive?**

Anyone who develops COVID-19 infection with mild to moderate symptoms after vaccination (regardless of where they are in the

vaccination process) is considered a breakthrough infection and eligible for treatment (if they meet inclusion criteria). **HIV**

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# HIV & the COVID-19 Vaccine

## Answers to Your Patients' Most Frequently Asked Questions

**THE HIV MEDICINE ASSOCIATION** (HIVMA) and Infectious Diseases Society of America (IDSA) developed the following Frequently Asked Questions (FAQ) in response to inquiries from HIV clinicians, and as a resource for HIV clinicians to respond to patient questions regarding the Pfizer-BioNTech COVID-19 vaccine approved for use in the U.S. by the Food and Drug Administration and the Moderna and Johnson and Johnson/Janssen COVID-19 vaccines authorized for use in the U.S. The two mRNA vaccines are referred to by the manufacturer's names: Moderna and Pfizer-BioNTech, and the Johnson and Johnson/Janssen adenoviral-vector vaccine is referred to as J&J/Janssen. Unless otherwise specified, the information provided is applicable to all three vaccines. This resource does not cover COVID-19 vaccines that have not been authorized for use in the U.S. The World Health Organization (WHO) is a resource for information on other COVID-19 vaccines.

Thank you to HIVMA for allowing *HIV Specialist* to reprint a portion of this document. Please visit [www.hivma.org](http://www.hivma.org) for the complete list of questions and answers.



## Are the COVID-19 vaccines safe for people with HIV?

- In clinical trials, COVID-19 vaccines were found to be safe and effective. Given these data and extensive experience following vaccine authorization, people with HIV should receive the COVID-19 vaccine. There are no data to suggest that the vaccines are not safe and effective for people with HIV, including adolescents between 12 and 15 years.
- There have been no links between HIV or other types of immunosuppression with any of the rare serious adverse events for the COVID-19 vaccines. Data compiled by the WHO from 37 countries indicate that people with HIV are likely at increased risk for severe illness due to COVID-19. For that reason, it is important that people with HIV receive the COVID-19 vaccine.
- The CDC guidance advises that people with HIV may receive the vaccine as long as they do not have other conditions that would exclude them, such as a known severe allergic reaction or immediate allergic reaction of any severity after a previous dose or to a component of the COVID-19 vaccine. The vaccines authorized for use in the United States do not contain infectious virus so they are safe in people with low CD4 cell counts.
- People with stable HIV have been included in the COVID-19 vaccine clinical trials, so information specific to people with HIV should become available in the future.

## Do the vaccines protect against the Delta variant?

- The COVID-19 vaccines approved or authorized for use in the U.S. are highly effective at preventing serious illness from COVID-19, and all individuals with HIV should be encouraged to get vaccinated to protect their health and their family and friends. According to CDC, the Delta variant is more than twice as transmissible as other variants and is now the dominant variant in the U.S. COVID-19 infections in fully vaccinated individuals are uncommon. A small percentage of fully vaccinated individuals may become infected with the Delta variant and may be able to transmit the virus to others. The Moderna and PfizerBioNTech vaccines are strongly protective against serious illness and hospitalization from the Delta variant. Data on the effectiveness of the J&J/Janssen vaccine against the Delta variant are still being evaluated, but this vaccine protects against severe disease caused by other variants.

## Is a supplemental shot recommended for people with HIV?

- FDA updated the EUA for the mRNA vaccines (Pfizer-BioNTech and Moderna) to authorize a third vaccine shot for individuals with certain immunocompromising conditions, including those who

have undergone a solid organ transplant or who have conditions considered to cause a similar level of immunocompromise. The FDA full approval of the Pfizer-BioNTech vaccine does not cover third vaccine doses. The age eligibility is the same as the initial EUA for each vaccine: 12 years and older for Pfizer-BioNTech; and 18 years and older for Moderna

- Following the change to the EUA, CDC updated its clinical COVID-19 vaccine guidance to recommend that individuals who are moderately to severely immunocompromised, including people with advanced or untreated HIV, who received either of the mRNA vaccines receive a third dose.

- Many experts consider people with HIV whose CD4 cell count is cell count is <200/mm<sup>3</sup> or CD4 percentage is 14 or less to have advanced disease. People with HIV who are not receiving treatment for their HIV should start antiretroviral medications as soon as possible to protect themselves from complications from HIV. In addition to reducing the likelihood of medical problems related to HIV, antiretroviral therapy is expected to improve immune responses to the COVID-19 vaccine and to protect against severe COVID-19 in people with HIV.

## What about individuals who received the J&J/Janssen vaccine?

- There are insufficient data to recommend a supplemental dose for individuals who received the J&J/Janssen vaccine, but FDA and CDC are actively investigating this issue. It is anticipated that more guidance will be coming shortly. When individuals who are immunocompromised are considered fully vaccinated?
- People with conditions that compromise their immune systems are still considered fully vaccinated after receiving two doses of one of the mRNA vaccines or one dose of the J&J/Janssen vaccine.

## Should all people with HIV consider getting a third shot?

- The current CDC recommendation applies to individuals with immunocompromising conditions that are moderate to severe.

- There are still insufficient data to determine whether people with HIV on effective antiretroviral therapy need a third shot. Data from a small study comparing the antibody responses to the Pfizer-BioNTech vaccine for people with HIV to people without HIV found a similar response in both groups, suggesting that the mRNA vaccines are protective for people with HIV. What is the difference between the supplemental doses being recommended now for immunocompromised individuals and the booster shots that are expected to start in mid-to late September?

- The supplemental vaccine doses are being recommended for individuals who did not mount a sufficient response to the initial mRNA series because they have moderately to severely weakened immune systems. The booster doses are being recommended due to data suggesting that the level of immunity initially seen for fully vaccinated individuals drops over time, although the vaccines remain highly effective at preventing severe illness, including hospitalizations. In light of these data, the Department of Health and Human Services announced that they are developing plans to administer booster doses beginning on or after Sept. 20, 2021, if they are authorized by FDA and recommended by CDC.

- Booster doses are not currently available for the general population. The top priority continues to be ensuring that everyone who can be vaccinated against COVID-19.

## What can I do when I am fully vaccinated?

- The COVID-19 vaccines authorized for use in the U.S. are highly effective at preventing serious illness from COVID-19, and individuals with HIV should be encouraged to get vaccinated to protect their health and their family and friends.

- In response to new data on the transmissibility of the Delta variant including among fully vaccinated individuals, CDC updated its guidance to recommend that unvaccinated and fully vaccinated individuals wear masks in indoor public spaces in areas with substantial and high transmission to stop community spread of the virus. To prevent widespread community transmission, IDSA urges that in communities with moderate transmission rates, all individuals, even those who are vaccinated, wear masks in public indoor spaces.

- Data considered by CDC's Advisory Committee on Immunization Practices indicate that people who are immunocompromised are at higher risk for serious illness due to COVID-19 and more likely to have breakthrough infections when fully vaccinated. Individuals with HIV who are untreated or who may not be virally suppressed should be encouraged to take extra precautions, including wearing a mask in public indoor spaces and maintaining a safe physical distance from others.

## Will I have more side effects because I have HIV?

- The effects of the vaccines on people with HIV are still being studied, so we do not yet know if any of them will affect people with HIV differently. So far, no data suggest that people with HIV have more side effects than the general population.

- Side effects common among all study participants included pain and swelling at the injection site, fatigue and headache. A smaller number reported having a fever. These side effects did not last longer than a few days at most.

## Should I wait for another COVID-19 vaccine since I have HIV? Have any of the other vaccines been found to be safer or more effective for people with HIV?

- Based on the current data available, the vaccines authorized for the U.S. are safe and effective.

- Rare cases of a serious blood clotting disorder and of the neurological disorder GBS have been reported through the Vaccine Adverse Event Reporting System (VAERS) in individuals receiving the J&J/Janssen vaccine.

- Data specific to people with HIV are not yet available, but the vaccine trials included people with treated HIV so additional data should become available in the future.

- The majority of HIV providers strongly recommend that people with HIV receive one of the currently available vaccines rather than wait for further data.



**The CDC guidance advises that people with HIV may receive the vaccine as long as they do not have other conditions that would exclude them, such as a known severe allergic reaction or immediate allergic reaction of any severity after a previous dose or to a component of the COVID-19 vaccine.**

### **I've heard my HIV medicines protect me from getting COVID-19, so do I even need the vaccine?**

■ There is no evidence that HIV medications can prevent or treat COVID-19. Some HIV medications, such as a combination of tenofovir/emtricitabine, are currently being studied to see if they can treat COVID-19 but the results of these studies are pending. Studies on lopinavir/ritonavir, a protease inhibitor combination, have not found it to be effective. Read more in the CDC's What to Know About HIV and COVID-19.

■ Because there is no evidence that HIV medications can treat or prevent COVID-19, guidelines recommend against changing your HIV treatment regimen to prevent or treat COVID-19. More information on HIV treatment recommendations and COVID-19 is available in the HHS Interim Guidance on COVID-19 and Persons with HIV.

### **Will the vaccine be contraindicated by my HIV medications? Should I stop taking them while I am getting the vaccine doses?**

■ The three authorized vaccines have no interactions with HIV medications. It is not recommended that people with HIV stop their HIV medicines when they receive a COVID-19 vaccine. Stopping your HIV medications could put you at greater risk for HIV-related illnesses and at greater risk for serious infection due to COVID-19.

### **Will the vaccine be effective or recommended if I have CD4 < 200 / A low immune system?**

■ The CDC advises that people who are immunocompromised, including people with HIV, be eligible to receive the vaccine because of their potential increased risk for serious illness due to COVID-19. The safety and effectiveness in immunocompromised populations is not yet known, however, particularly whether the protection from COVID-19 will be as strong as it is for the general population.

### **Does the COVID-19 vaccine increase the risk of contracting HIV?**

■ There is no reason to think COVID-19 vaccines will increase a person's risk of acquiring HIV, nor are there any data to suggest that this is the case. A third mRNA vaccination is recommended for people with HIV with untreated HIV or with advanced HIV disease, which is generally defined to include those whose CD4 cell count is <200/mm<sup>3</sup> or whose CD4 percentage is 14 or less.

■ These concerns have been raised because a previous adenoviral-vector vaccine being studied to prevent HIV about a decade ago may have increased risk for HIV infection, but that vaccine was constructed differently and was not related to the structure of the COVID-19 vaccines authorized in the U.S.

### **Will I have to pay when I get vaccinated? Is it covered by my insurance or the Ryan White Program?**

■ The federal government is covering the cost of the vaccines for everyone. There may be a fee for administering the vaccine, but that fee should be charged to your health insurance provider, including Medicaid or Medicare. If you are uninsured, your provider should bill the Provider Relief Fund that is administered by HRSA, or your Ryan White Program may be covering it.

### **A COVID-19 vaccine was developed in less than a year, but we still don't have an HIV vaccine after 40 years. Why can't they develop an HIV vaccine as quickly? When is an HIV vaccine going to be approved?**

■ The virus that causes COVID-19 is very different than HIV. The body rids itself of the virus that causes COVID-19 within weeks while HIV stays in the body and is not removed or eradicated and has a complex way of undermining the immune system. These differences, and many others, make creating an HIV vaccine much more complicated.

■ Work on developing an HIV vaccine continues and some of the early work in developing an HIV vaccine contributed to the creation and the success of the COVID-19 vaccines. We also have learned a lot from the development of the COVID-19 vaccines that should contribute to the future development of other effective vaccines, including for HIV. **HIV**

## Charmaine Miller-Spencer, BSN, MTh, MS, APRN, ANP-C, AAHIVS Dallas, Texas

**CHARMAINE MILLER-SPENCER** has worked in healthcare for four decades. She has served communities in Texas in many different ways over the years, as a healthcare provider and an ordained deacon with the United Methodist Church. She attended Incarnate Word University in San Antonio for nursing school and Texas Woman's University in Dallas for her Master of Science and nurse practitioner programs. As a registered nurse at the University of Texas San Antonio, Charmaine worked as a study coordinator in the Infectious Disease division. After becoming a nurse practitioner, she worked in an oncology clinic and also had the opportunity to provide HIV care at the Dallas County jail. Charmaine recalls, "It proved to be a great place to hone my skills. It was also a place where I could blend my pastoral background with my healthcare background to provide the compassionate care that was needed." Charmaine remembers taking care of her first patient with HIV in 1983 as an RN in a hospital setting, and in 2006, she began specializing in HIV care as a nurse practitioner.

"Over the 40 years that I have worked in healthcare, I have touched the lives of people living with HIV at different times in my career. I've seen the suffering in the early days of the disease. I've seen the devastation of a new diagnosis. I have always been aware of the need of these individuals to feel accepted, respected, and valued. I believe it is my personal calling to provide these elements while delivering healthcare," says Charmaine, "It is my personal goal to treat everyone with dignity and respect."

Today, Charmaine works in a Parkland Hospital HIV Clinic in southeast Dallas. Together with a physician, she is one of two prescribing providers. They are joined by one RN and one LVN. Additionally, they are staffed with a RN case manager and a clerk. Her practice consists entirely of patients who have been diagnosed with HIV. Charmaine shares about her patients' demographics, "The majority of our patients are minorities. We have approximately 80 percent male and 20 percent female. We see adults, starting at age 17 years. About half of our patients are over 50 years

**"I have always been aware of the need of these individuals to feel accepted, respected, and valued. I believe it is my personal calling to provide these elements while delivering healthcare. It is my personal goal to treat everyone with dignity and respect."**

of age. Over the 14 years that I have been at this practice, we have seen a steady increase in the number of patients over the age of 60 years. The majority of our patients are below the poverty level and qualify for Ryan White funding and/or Medicaid."

Charmaine and her team try to maintain an open-door policy. If a patient shows up

without an appointment, they will see them. "Some of our patients face a lot of challenges, so we try and help make life easier and see them when they can come," shares Charmaine, "Seeing patients when they show up has increased patient access to care and our show rates."

Charmaine supports her patients' adherence to treatments by first recognizing the complexity of the issues often at play. "If I can get to the root of







what is preventing my patients from taking their medications, then I can help find a solution,” says Charmaine. “Sometimes it’s treating depression. Sometimes it’s providing ways for them to disguise their medications. Sometimes it’s giving them tools, such as smartphone apps, that remind them. Sometimes it’s just hanging in there with them and not giving up on them.”

For Charmaine, one of the most rewarding parts of her job is helping someone with a new HIV diagnosis to move from a sense of “my life is over” to living life to the fullest. “I love being able to say to patients, ‘whatever you had planned for your life before your diagnosis, you can still do.’ I love when I walk in the room, and my patients smile and get off the table and hug me. I love when mothers who initially came to appointments with their young adult children stop coming because they trust the care they are receiving.” As for obstacles, Charmaine believes not speaking Spanish is one of her greatest. “While we have translators available, I think feelings and emotions get lost in translation.” Charmaine shares she has two goals she would like to accomplish before retirement. Learning to speak Spanish is one; the other, at which she is already working, is becoming a certified diabetes educator.

Looking to the future, Charmaine thinks HIV will become more mainstream and that caring for people with HIV will happen more regularly in primary care clinics. She believes there will be an essential role for HIV Specialists within these clinics but that a shift to primary care will help reduce stigma around HIV. Outside of her work in healthcare, Charmaine provides pastoral care and grief counseling at her church. She also serves as president of a non-profit organization that provides scholarships to students attending college or technical programs.

Asked why she joined AAHIVM as an Academy member, Charmaine shares, “I joined the Academy because I wanted to be part of the organization that credentials providers as HIV Specialists. After joining, I became aware of all the work the Academy does, so I stayed a member.” Today Charmaine provides leadership for the Academy as a member of the Texas Steering Committee and the Academy Council for Racial Equity. **HIV**

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

Miller-Spencer  
(third from right)  
with the working  
group in her office.





## UPDATE

CAROLYN CHU, MD, MSC, AAHIVS

Incoming AAHIVM Chief Medical Officer

## FEATURED LITERATURE:

**Mounzer K, Brunet L, Wyatt CM, et al. To dose-adjust or not to dose-adjust: lamivudine dose in kidney impairment. *AIDS*. 2021 Jul 1; 35(8): 1201-1208. doi: 10.1097/QAD.0000000000002871. PMID: 33710017.**

This study aimed to estimate the association between lamivudine (3TC) dose and incidence of adverse diagnoses and laboratory abnormalities among people with HIV (PWH) with baseline CKD-EPI eGFR between 30-49 mL/min per 1.73m<sup>2</sup> at 3TC initiation. Investigators reviewed routine clinical data from electronic health records of 539 eligible PWH; participants received care at 85 U.S. clinics in 19 states and one territory and were followed as part of the OPERA (Observational Pharmaco-Epidemiology Research and Analysis) cohort. No significant difference was observed in the incidence of lactic acidosis, paresthesia, peripheral neuropathy, pancreatitis, rhabdomyolysis, anemia, neutropenia, thrombocytopenia, nausea, or severe laboratory abnormalities by 3TC dose (full-dose 300 mg vs. adjusted-dose 150 mg daily, IRR: 1.51, 95% CI: 0.59-3.92). However, the risk of [additional] gastrointestinal symptoms and moderate lab abnormalities differed: for people receiving full-dose 3TC, the incidence rate was three times that for the adjusted-dose group (IRR: 3.07, 95% CI: 1.12-8.40). In addition, dose-adjusted 3TC was prescribed more frequently for women and PWH with higher viral loads, lower eGFR, higher Veterans Aging Cohort Study index, and/or higher likelihood of several comorbid conditions.

## AUTHOR'S COMMENTARY:

Current ART guidelines and package inserts recommend dose adjustment of 3TC/FTC (XTC) for CrCl < 50 mL/min. Given the prevalence of renal impairment and chronic kidney disease among PWH and the presence of XTC in nearly all currently available single-tablet, fixed-dose regimens, the decision of whether to dose adjust XTC (which would require 'unbundling' combination formulations at times) is commonly encountered. 3TC is generally a well-tolerated drug with a wide therapeutic index, and many experienced HIV providers defer dose adjustment for patients who appear to be stable on therapy. This study suggests no difference in risk of severe events for full vs. adjusted-dose 3TC; however, gastrointestinal symptoms and/or moderate lab abnormalities may be more likely with full-dose 3TC. Clinical judgment and careful assessment of potential adherence and medication access challenges versus possible toxicity are key to ensuring that patients remain virologically suppressed without experiencing bothersome symptoms and/or concerning laboratory abnormalities.

## FEATURED LITERATURE:

**Kim J, Lesko CR, Fojo AT, et al. The effect of buprenorphine on HIV viral suppression. *Clin Infect Dis*. 2021 Jun 25; ciab578. doi: 10.1093/cid/ciab578. PMID: 34171087.**

This analysis examined buprenorphine efficacy on viral suppression among people with HIV followed by the Johns Hopkins HIV Clinical Cohort (JHHCC). Two hundred seventy-nine participants initiating buprenorphine between 2002 and 2017 were matched with a comparison cohort (n=2422) of individuals who did not initiate buprenorphine; investigators also performed sensitivity analyses restricting the control group to people with injection drug use as an HIV acquisition factor. [In 2009, a buprenorphine program was integrated into JHHCC's clinical services, with prescriptions provided by designated on-site HIV providers coupled with on-site group counseling. Most participants filled buprenorphine prescriptions at the HIV clinic's co-located pharmacy.] Overall, both buprenorphine initiation and time on buprenorphine were consistently associated with a higher prevalence of viral suppression. Specifically, estimated prevalence was 14 percent higher after buprenorphine initiation and 19 percent higher at 90 days (comparing viral load measurements during periods participants were on buprenorphine, i.e., 'BUP periods,' to measurements before buprenorphine initiation). Prevalence ratios were also noted to increase over time. Among participants not on ART at buprenorphine initiation, investigators observed a 31 percent increase in viral suppression prevalence.

## AUTHOR'S COMMENTARY:

These findings add to existing evidence associating buprenorphine with HIV care engagement and ART uptake and adherence, and the association between buprenorphine retention and viral suppression. Authors suggest, based on this analysis, buprenorphine may increase the prevalence of viral suppression. This causal relationship would significantly strengthen the case and recommendations for integrated opioid use disorder treatment (OUD) and HIV care. Incorporating buprenorphine into HIV care settings represents a uniquely powerful and life-saving opportunity to promote cross-disciplinary collaboration and training (e.g., increasing OUD management skills/knowledge among HIV providers and increasing HIV skills/knowledge among substance use providers). Recent changes in buprenorphine [practice guidelines](#) allow for an alternative notification of intent pathway for eligible providers seeking to treat up to 30 patients: now, such providers may forego previously required federal certification requirements related to training, counseling, and other ancillary services (more information [here](#)). HIV clinicians and programs, especially those with limited local/specialty substance use referral networks, should strongly consider integrating substance use disorder treatment—especially OUD treatment—into their practices.

#### FEATURED LITERATURE:

**Parienti JJ, Fournier AL, Cotte L, et al. Forgiveness of dolutegravir-based triple therapy compared to older antiretroviral regimens: a prospective multicenter cohort of adherence patterns and HIV-RNA replication. *Open Forum Infect Dis*. 2021 July 1; ofab316. doi: 10.1093/ofid/ofab316.**

This international, multicenter prospective study aimed to assess dolutegravir adherence patterns associated with viremia. Participants received triple therapy, and three subgroups were examined: (a) ART-naïve PWH; (b) treatment-experienced PWH undergoing regimen modification due to virologic failure; and (c) virologically suppressed PWH undergoing regimen switch. Participants were followed with electronic adherence monitoring; results were compared to raltegravir-, boosted PI-, or NNRTI-anchored combinations. At six months, 92 percent of participants on dolutegravir had VL  $\leq 50$  copies/mL. The proportion of subgroup participants with VL between 51 and 200 copies/mL were: 8 percent for ARV-naïve participants; 17 percent for participants with prior virologic failure; and 2 percent for the switch subgroup. For participants with low-level viremia and successful genotype sequencing, no INSTI mutations were found. Adherence to dolutegravir-based therapy did not predict virologic suppression; this was in strong contrast to older regimens. Further, dolutegravir use was significantly and independently associated with a lower risk of viremia than other ART in participants with lower ( $\leq 95\%$ ) adherence levels. Investigators concluded that dolutegravir-based triple therapy appears to be more forgiving [over the short-term] to missed doses, either by average adherence or treatment interruptions, compared to older ARVs. The risk of viremia was consistent with the previously suggested  $>80\%$  level of average adherence reported in other studies.

#### AUTHOR'S COMMENTARY:

For various reasons, including a high barrier to resistance, potency, low pill burden, and favorable tolerability and pharmacokinetic profiles, dolutegravir remains a preferred anchor agent among many HIV treatment guidelines. This “real world” study of adherence using electronic drug monitoring devices helps characterize short-term virologic outcomes and dolutegravir’s “forgiveness” with missed doses. Findings add to our current understanding of the durability and risk of HIV drug resistance development seen thus far with dolutegravir-based regimens. They may be especially applicable for the care of PWH, who may have less than high levels of medication adherence. Further, as experience with dolutegravir-containing two-drug regimens increases, it will be essential to understand whether and how varying adherence patterns with two-drug regimens affect virologic and resistance outcomes.

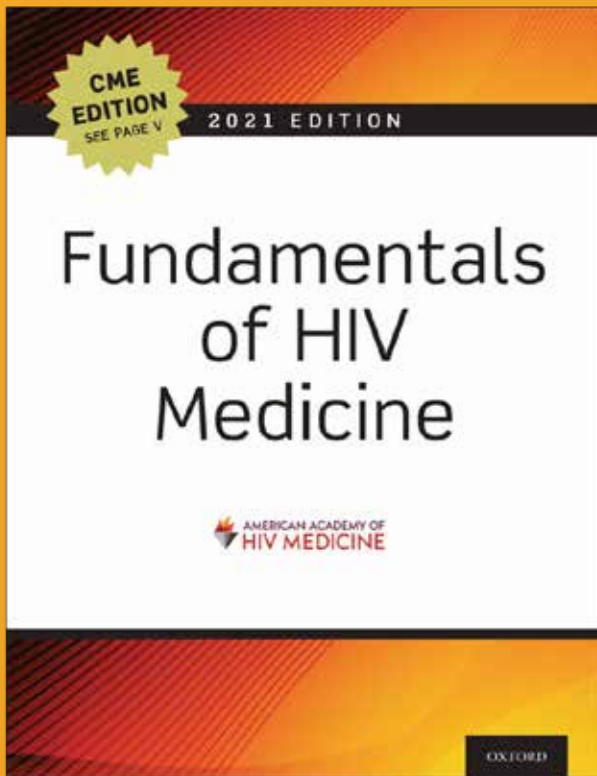
#### FEATURED LITERATURE:

**Battalora L, Armon C, Palella F, et al. Incident bone fracture and mortality in a large HIV cohort outpatient study, 2000-2017, USA. *Arch Osteoporos*. 2021 Aug 2; 16(1): 117. doi: 10.1007/s11657-021-00949-y. PMID: 34337687.**

Investigators with the HIV Outpatient Study (HOPS) sought to evaluate the association of bone fracture with mortality. This analysis included 6,763 participants contributing 51,443 person-years of follow-up: 504 (7.5%) had an incident fracture recorded. Of the 504 fractures, 135 (26.8%) were major osteoporotic fractures. At baseline, participants who later experienced incident fracture were older and more likely to be a current or prior smoker, have seven or more alcoholic beverages per week at HOPS cohort entry, have been diagnosed with HIV for a longer duration, have an AIDS diagnosis, be ART experienced, and have a lower nadir CD4. An incident fracture was associated with a nearly 50 percent increase in the risk of all-cause mortality. Subset analysis of participants who experienced fracture revealed a mortality rate of 2.97 (CI 0.86-2.05) per 100 PY for persons with major osteoporotic fractures. In addition, all-cause mortality was significantly associated with having any of the following chronic conditions: cardiovascular disease, chronic kidney disease, HCV coinfection, pulmonary disease, or history of non-AIDS cancer.

#### AUTHOR'S COMMENTARY:

Post-fracture mortality in the general population has been linked to various comorbidities; however, the relationship between fractures and mortality among PWH is less clear. This study is unique because its primary aim was to evaluate mortality rates after fracture in a large, prospective cohort of PWH well-engaged in care. Findings reinforce the importance of prevention (especially counseling and treatment to reduce tobacco and alcohol use and education on the importance of physical activity), screening, and treatment of bone density loss. Routine assessment of fall risk is also prudent. Further studies examining this issue are important to help improve health outcomes and medical care of aging PWH. **HIV**



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