

THE AMERICAN ACADEMY OF HIV MEDICINE ■ SUMMER 2024

HIV

SPECIALIST



HIV and
Aging

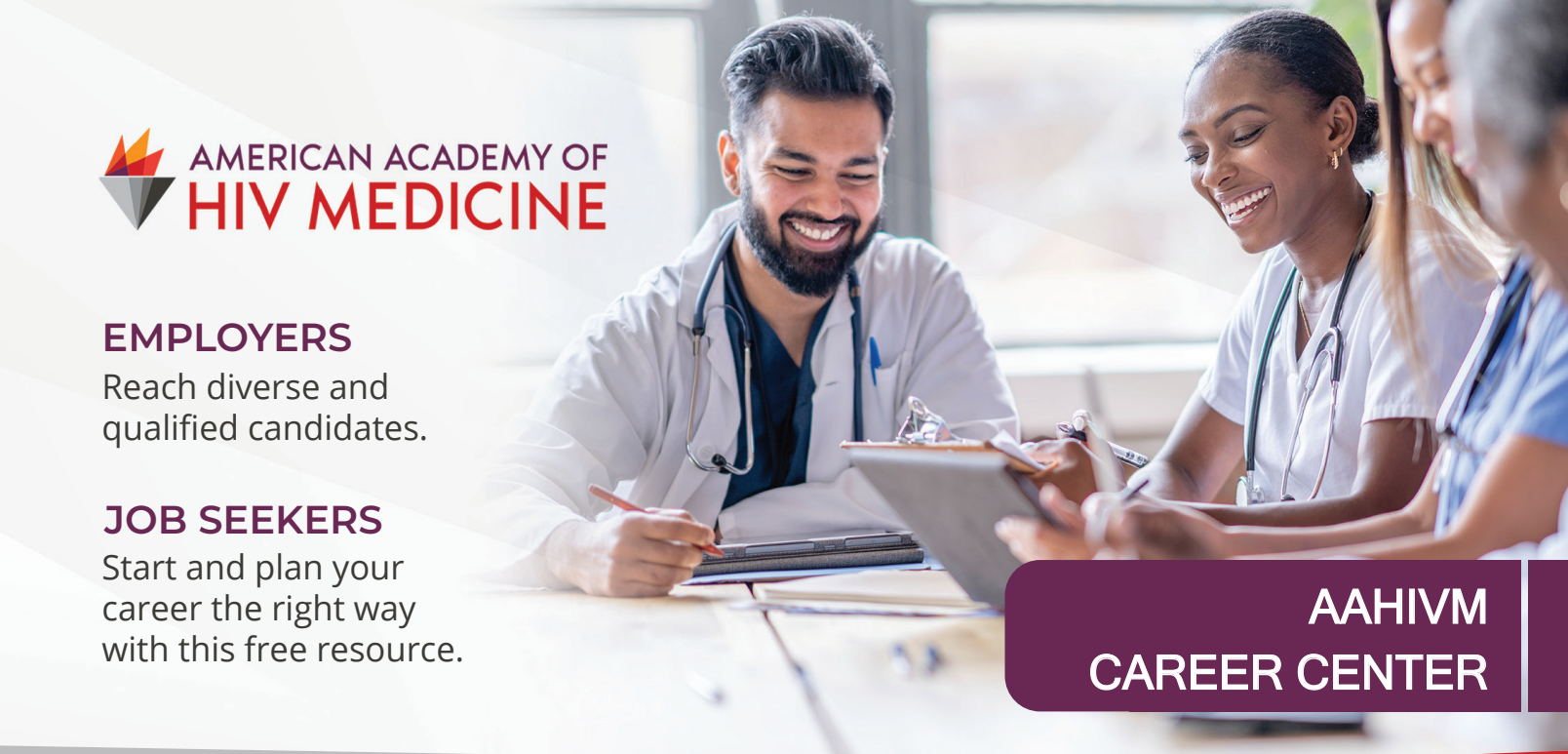


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A photograph of three medical professionals, two men and one woman, all wearing white lab coats and stethoscopes. They are sitting at a table, looking at a tablet together and smiling. The background is a bright, out-of-focus indoor setting.

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Aging Well with HIV

THE FEAR, COMPLEXITY, SENSE OF MORTALITY AND VULNERABILITY that accompany the process of getting older are universally human experiences; but for each person it is nevertheless an individual journey. I am personally very deeply concerned with and attentive to getting older and the inevitable physical, mental, and social changes that come with it. These anxieties are inevitably compounded for your clients and patients who are long-term HIV survivors or who are aging into their grayer years with, or then acquire, HIV. A chronic, lifelong virus complicates and catalyzes the “normal” aging process.

In this issue of *HIV Specialist*, we tried to address both the clinical complication and amplification of aging-related health issues in people with HIV, and the very human and social elements of the experience, that we believe providers and others in the HIV community should be aware of.

Looking at the specific articles within, starting with “Fighting for Our Lives: The Work Continues,” Cecilia Dennis, Michael Maginn, and Aracelis Quiñones look closely at the effect of stigma, where, despite significant progress, it continues to hinder many older adults with HIV from receiving the care they need. They highlight the lack of care coordination and structural barriers that impede access to essential services for this group. The key takeaway is that we must be aware and proactive in supporting the specific needs of our aging HIV community.

Dr. Britt Gayle’s article, “Impact of Age-Associated Comorbidities upon Quality of Life,” provides a comprehensive overview of the myriad comorbidities that accompany aging with HIV. Dr. Gayle demonstrates that a holistic care approach (that addresses both the medical and social determinants of health) is needed to effectively manage these conditions, while also offering valuable insights and interventions for health care providers to implement in improving quality and dignity of life and health outcomes.

Gary Bucher, MD, in “The Looming Shadow: Anal Cancer as a Comorbidity in Older Adults with HIV,” focuses on the heightened risk of anal cancer within this population, particularly among men who have sex with men. Dr. Bucher zooms in on the necessity of regular screening and a multifaceted approach to detection and treatment, which is crucial in mitigating this significant health concern and risk.

Jaymee Leak Matthews, DNP, APRN, FNP-C, directly addresses menopause, a topic often overlooked in HIV care. In “Women, Menopause, and HIV,” she explores how menopause affects women with HIV differently, and specifically looks at the increased risks of cardiovascular disease and bone loss. Dr. Matthews writes that more research and data is required to better support women



By Bruce J. Packett II
Executive Director, AAHIVM

with HIV as they navigate menopause and is urging providers to be attentive to these specific health needs.

Clinical Pharmacist Carly Cloud Floyd shares her extensive experience in “Chronic Disease Management in an Aging Population: Perspectives from a Pharmacist Clinician.” Her strategies for managing complex cases and her evolving approach to patient care allows us to see the significant importance of building personal connections with patients. This article exigently reminds us that compassionate, patient-centered care is essential for supporting older individuals with HIV.

In our At the Forefront section, Evan Hall, BS, MPH, examines disparities in HIV pre-exposure prophylaxis (PrEP) uptake among racial and ethnic groups. Their research highlights the gaps in PrEP coverage and provides critical insights

into how current experiments and initiatives are either bridging or widening these gaps. Evan Hall’s work is a reminder of the ongoing need to ensure equitable access to HIV prevention tools for all communities.

Lastly, we honor the rich legacy of longtime AAHIVM member and leader Hermeyone T. Bell, APRN, BC, AAHIVS, with a heartfelt tribute by her colleague, Dr. Zandraetta Tims Cook. Ms. Bell’s dedication and contributions to the field of HIV care have left an indelible mark, inspiring all of us to continue striving for excellence and compassion in our work.

As you are navigating the difficult clinical, social, and individual pressure points of HIV and aging, we hope that you can draw from the knowledge and experiences shared in this issue to help deal with those anxieties and complexities. Mostly, we hope you can use these perspectives to help advance the care and quality of life for our aging HIV community, and to ensure that equitable access to health and dignity is available to all people, regardless of age. **HIV**

IN THE NEWS

Justice Department Secures Agreement with Shelby County, Tennessee, District Attorney General to Cease Enforcement of State Law that Discriminates Against People with HIV

THE JUSTICE DEPARTMENT ANNOUNCED [on May 16, 2024] that the Shelby County, Tennessee, District Attorney General (DA) has agreed to cease prosecution of individuals living with human immunodeficiency virus (HIV) under Tennessee's aggravated prostitution law. The DA will also adopt reforms to correct discrimination against people living with HIV who were subjected to discriminatory and harsher penalties under the law.

This agreement resolves the Justice Department's finding that the Shelby County DA violated the Americans with Disabilities Act (ADA) by enforcing Tennessee's aggravated prostitution law that imposed enhanced criminal penalties based on a person's HIV status. The prosecutions were carried out without consideration of risk of transmitting HIV, and the harsher penalties included being charged with a felony (as opposed to a misdemeanor) and being required to register for life as a sex offender.

"Living with HIV is not a crime and the continued enforcement of laws that criminalize a person based on their HIV status, regardless of risk, perpetuate bias, stereotypes, and ignorance about HIV," said Assistant Attorney General Kristen Clarke of the Justice Department's Civil Rights Division. "We are pleased that Shelby County District Attorney has agreed to cease enforcement of this discriminatory law, and that future

prosecution decisions will reflect the significant advances made in HIV prevention and treatment, consistent with the ADA."

Under this agreement, the DA will not prosecute individuals under the aggravated prostitution law or for violations of the sex offender registry requirements that have resulted from prior convictions under that law. The DA will also notify anyone eligible of their ability to petition for vacatur of their convictions, termination of the remainder of their sentences and elimination of fees owed.

This agreement also requires the Shelby County DA to adopt policies and train prosecuting attorneys on the ADA's anti-discrimination requirements relating to HIV, a disability under the ADA. Under the agreement, the DA will also report its compliance with the agreement to the department.

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



IN THE NEWS

U.S. Clinical Trials Begin for Twice-Yearly HIV Prevention Injection

Studies will focus on priority populations underrepresented in HIV clinical research.

TWO CLINICAL TRIALS HAVE LAUNCHED to examine a novel long-acting form of HIV pre-exposure prophylaxis (PrEP) in cisgender women and people who inject drugs. The mid-stage studies will assess the safety, acceptability, and pharmacokinetics (how a drug moves through the body) of lenacapavir, an antiretroviral drug administered by injection every six months. The studies are sponsored and funded by Gilead Sciences, Inc., and implemented through the HIV Prevention Trails Network (HPTN). The HPTN is supported by grants from the National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID), with scientific collaboration on this study and others from the National Institute on Drug Abuse (NIDA) as well as co-funding from NIDA and other NIH institutes.

Lenacapavir is already approved by the Food and Drug Administration for HIV treatment, in combination with other antiretroviral therapy, of heavily treatment-experienced individuals, whose HIV infections cannot be successfully treated with other available treatments due to resistance, intolerance, or safety considerations with other drugs and developed multidrug resistance. Lenacapavir is the first of a class of drugs called capsid inhibitors to be FDA-approved for treating HIV infection. It is the first long-acting injectable to be offered with administration just once every six months. Cisgender women—people who self-identify as female and were assigned female sex at birth—and people who inject drugs accounted for 18 percent and seven percent of new HIV diagnoses in the United States in 2021, respectively. Both population groups have been underrepresented in HIV clinical studies, as have transgender people, pregnant people, and U.S. communities of color. Both trials complement ongoing large efficacy studies and are intended to provide insights on how these two priority populations experience lenacapavir-based HIV PrEP.

The studies will take place at HPTN sites in the United States and enroll people who might benefit from taking PrEP. The first trial will enroll

cisgender women, with a focus on making enrollment accessible to women who self-identify as Black and/or Latina. The second trial will enroll a diverse group of people who inject drugs. In both studies, participants will be randomly assigned to receive either injectable lenacapavir or an FDA-approved PrEP formulation consisting of oral tenofovir disoproxil fumarate and emtricitabine. Participants' health will be monitored closely throughout the study. Participants will provide laboratory samples and give qualitative feedback on their experience taking each form of PrEP.

The studies will add important clinical data to a global manufacturer-led clinical development program for lenacapavir as HIV PrEP. NIH is supporting the implementation of these two studies through its clinical trials networks to help ensure the meaningful inclusion of diverse and representative populations in clinical research, so that everyone can contribute to scientific progress and benefit from its applications.

For more information about these trials, please visit ClinicalTrials.gov study identifiers NCT06101329 and NCT06101342.

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

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.



New Report Flags Major Increase in Sexually Transmitted Infections, Amidst Challenges in HIV and Hepatitis

Global HIV, viral hepatitis epidemics, and sexually transmitted infections (STIs) continue to pose significant public health challenges, causing 2.5 million deaths each year, according to a new WHO report – Implementing the global health sector strategies on HIV, viral hepatitis, and sexually transmitted infections, 2022–2030.

NEW DATA SHOW THAT STIs ARE INCREASING in many regions. In 2022, WHO Member States set out an ambitious target of reducing the annual number of adult syphilis infections by ten-fold by 2030, from 7.1 million to 0.71 million. Yet, new syphilis cases among adults aged 15–49 years increased by over one million in 2022 reaching eight million. The highest increases occurred in the Region for the Americas and the African Region.

Combined with insufficient decline seen in the reduction of new HIV and viral hepatitis infections, the report flags threats to the attainment of the related targets of the Sustainable Development Goals (SDGs) by 2030.

“The rising incidence of syphilis raises major concerns”, said WHO Director-General Dr. Tedros Adhanom Ghebreyesus. “Fortunately, there has been important progress on a number of other fronts including in accelerating access to critical health commodities including diagnostics and treatment. We have the tools required to end these epidemics as public health threats by 2030, but we now need to ensure that, in the context of an increasingly complex world, countries do all they can to achieve the ambitious targets they set themselves.”

Increasing incidence of sexually transmitted infections

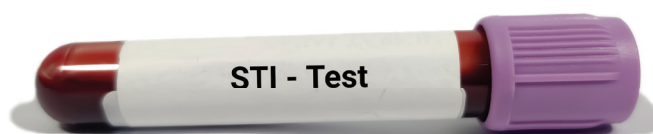
Four curable STIs—syphilis (*Treponema pallidum*), gonorrhea (*Neisseria gonorrhoeae*), chlamydia (*Chlamydia trachomatis*), and trichomoniasis (*Trichomonas vaginalis*)—account for over one million infections daily. The report notes a surge in adult and maternal syphilis (1.1 million) and associated congenital syphilis (523 cases per 100,000 live births per year) during the COVID-19 pandemic. In 2022, there were 230,000 syphilis-related deaths.

New data also show an increase in multi-resistant gonorrhea. As of 2023, out of 87 countries where enhanced gonorrhea antimicrobial resistance surveillance was conducted, nine countries reported elevated levels (from 5% to 40%) resistance to ceftriaxone, the last line treatment for gonorrhea. WHO is monitoring the situation and has updated its recommended treatment to reduce the spread of this multi-resistant gonorrhea strain.

In 2022, around 1.2 million new hepatitis B cases and nearly one million new hepatitis C cases were recorded. The estimated number of deaths from viral hepatitis rose from 1.1 million in 2019 to 1.3 million in 2022 despite effective prevention, diagnosis, and treatment tools.

New HIV infections only reduced from 1.5 million in 2020 to 1.3 million in 2022. Five key population groups — men who have sex with men, people who inject drugs, sex workers, transgender individuals, and individuals in prisons and other closed settings — still experience significantly higher HIV prevalence rates than the general population. An estimated 55 percent of new HIV infections occur among these

populations and their partners. HIV-related deaths continue to be high. In 2022, there were 630 000 HIV related deaths, 13 percent of these occurring in children under the age of 15 years.



Gains in Expanding Service Access

Efforts by countries and partners to expand STIs, HIV, and hepatitis services are bringing formidable gains. WHO has validated 19 countries for eliminating mother-to-child transmission of HIV and/or syphilis, reflecting investments in testing and treatment coverage for these diseases among pregnant women. Botswana and Namibia are on the path to eliminating HIV, with Namibia being the first country to submit a dossier to be evaluated for the triple elimination of mother-to-child transmission of HIV, hepatitis B, and syphilis.

Globally, HIV treatment coverage reached 76 percent, with 93 percent of people receiving treatment achieving suppressed viral loads. Efforts to increase HPV vaccination and screening for women with HIV are ongoing. Diagnosis and treatment coverage for hepatitis B and C have seen slight improvements globally.

Sustainability planning across the three disease areas needed

The report outlines the following recommendations for countries to strengthen shared approaches towards achieving the targets:

- Implement policy and financing dialogues to develop cross-cutting investment cases and national-level sustainability plans.
- Further consolidate and align disease-specific guidance, plans, and implementation support within a primary health care approach.
- Accelerate efforts to address ongoing criminalization, stigma, and discrimination within health settings, particularly against populations most affected by HIV, viral hepatitis, and STIs.
- Expand multi-disease elimination approaches and packages, drawing from lessons learned from the triple elimination of mother-to-child transmission.
- Strengthen the focus on primary prevention, diagnosis, and treatment across the diseases to raise awareness especially for hepatitis and STIs.

While the ambitious targets set by member states for 2025 and 2030 are helping to drive progress—the progress is patchy across disease areas. With many indicators remaining off-track to achieve global targets, more political will and commitment are to urgently accelerate the efforts.

IN THE NEWS

Biden-Harris Administration Expands Access to Mental Health and Substance Use Services with Addition of 10 New States to CCBHC Medicaid Demonstration Program

THE BIPARTISAN SAFER COMMUNITIES ACT gave HHS the authority to add 10 states to the CCBHC Medicaid Demonstration program every two years, starting with the 10 being announced on June 4, 2024

The U.S. Department of Health and Human Services (HHS), through the Centers for Medicare & Medicaid Services (CMS) in partnership with the Substance Abuse and Mental Health Services Administration (SAMHSA), welcomed 10 new states into the Certified Community Behavioral Health Clinic (CCBHC) Medicaid Demonstration Program, after they successfully developed the necessary state-level infrastructure and worked with providers in their states to develop programs that meet CCBHC standards: Alabama, Illinois, Indiana, Iowa, Kansas, Maine, New Hampshire, New Mexico, Rhode Island, and Vermont. The CCBHC Medicaid Demonstration Program provides states with sustainable funding that helps them expand access to mental health and substance use services, supporting President Biden's Unity Agenda and the Biden-Harris Administration's efforts to tackle the country's mental health and addiction crises. The expansion of the program directly supports the President's national strategy to transform our behavioral health system and builds on the Administration's previous work to build a better crisis continuum of care, including through the transition to the 988 Suicide & Crisis Lifeline, add a new mobile crisis benefit to Medicaid, and new crisis codes to the Medicare program.

"Certified Community Behavioral Health Clinics have significantly improved behavioral health treatment in our country, and today's announcement will dramatically expand and improve access to equitable, quality care for Americans with serious mental health and substance use treatment needs," said HHS Secretary Xavier Becerra. "Thanks to the Bipartisan Safer Communities Act, we are adding 10 new states to this groundbreaking demonstration across the country, ensuring our CCBHCs can serve more Americans who need our help."

CCBHCs must ensure access to a comprehensive range of services, providing care coordination when needed and incorporating evidence-based practices and other supports based on a community needs assessment. This includes crisis services that are available 24 hours a day, seven days a week. CCBHCs are also required to provide routine outpatient care within 10 business days.

"Certified Community Behavioral Health Clinics serve anyone who requests care for mental health or substance use conditions. With sustainable funding, CCBHCs in participating states will now be able to connect more people to the care they need," said HHS Deputy Secretary Andrea Palm. "This is another example of our commitment at HHS to transforming behavioral health and ensuring all Americans have access to behavioral health resources."

The Bipartisan Safer Communities Act (BSCA), signed into law by President Joe Biden, gave HHS the authority to add 10 new states to



the CCBHC Medicaid Demonstration program every two years, starting with the 10 being announced on June 4, 2024. All of these states had previously received planning grants, including grants authorized by BSCA in 2022 to address the country's behavioral health crisis. The 10 states added today join eight states that are already currently in the CCBHC Medicaid Demonstration program: Michigan, Missouri, Kentucky, Nevada, New Jersey, New York, Oklahoma, and Oregon.

In March 2023, SAMHSA used BSCA funding to award 15 CCBHC state planning grants. The CCBHC planning phase assists states in certifying clinics as CCBHCs, establishing prospective payment systems for Medicaid reimbursable services, and preparing an application to participate in a four-year demonstration program. A notice of funding opportunity to award 15 additional states with planning grants is expected to be posted this summer for award early in Fiscal Year 2025, and 10 more states will have the opportunity to join the CCBHC Demonstration Program in Fiscal Year 2026. These expansions will build more CCBHCs across the country and, along with the SAMHSA CCBHC expansion grant program, will support increased adoption of this model.

"For our communities to thrive, behavioral health, including mental health, needs to be prioritized," said CMS Administrator Chiquita Brooks-LaSure. "That requires an all-hands-on-deck approach, which is why it's so encouraging to see more states support person- and community-centered solutions like CCBHCs. Aligned with the Biden-Harris Administration's commitment to mental health, CCBHCs equip communities with the tools they need to tackle many of society's most entrenched challenges—from substance use disorders and mental health crises to housing insecurity, public safety, and the more efficient use of our health care resources."

"We're pleased to welcome these 10 states in the CCBHC Medicaid Demonstration Program and look forward to adding more in the years to come. CCBHCs provide a model of care that supports wellness for the entire community and connects people to care. They guarantee access to services to individuals and families regardless of ability to pay," said Miriam Delphin-Rittmon, PhD, HHS Assistant Secretary for Mental Health and Substance Use and the leader of SAMHSA. "Equity is a significant and overarching priority in all that we do, and expanding and improving the CCBHC model across America helps us to continue our path forward to make quality behavioral health care for everyone even more widely available."

CCBHCs increase access to crisis and behavioral health care in the community. They have been shown to reduce homelessness and substance use among the people they serve and decrease use of emergency rooms and hospitalization. In September, HHS, through SAMHSA, awarded \$127.7 million to expand CCBHCs across the U.S.

The CCBHC Demonstration Program provides reimbursement through Medicaid for the full cost of services that CCBHCs provide, at higher, more competitive rates than community mental health centers previously received for Medicaid eligible individuals. This sustainable funding also ensures CCBHCs can provide a more comprehensive range of services rather than fragmented services driven by separate billing codes.

CCBHCs were created to transform mental health and substance use treatment across the country and provide sustainable funding for robust community outpatient mental health treatment. They are required to meet federal standards for the range of services that they provide. CCBHCs offer a no-wrong-door approach because they must serve anyone who requests care for mental health or substance use conditions, regardless of their ability to pay, place of residence, or age.

In 2017, the first CCBHCs were funded under Medicaid, with 67 clinics operating across eight states. Today, there are more than 500 CCBHCs across 46 states, the District of Columbia, and Puerto Rico, most of which are supported through SAMHSA's CCBHC Expansion Grant program.

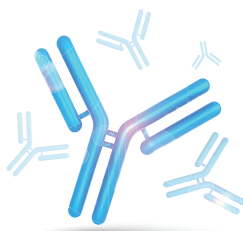
Novel Vaccine Concept Generates Immune Responses that Could Produce Multiple Types of HIV Broadly Neutralizing Antibodies

NIH-funded animal model results will inform vaccine development in humans.

USING A COMBINATION OF CUTTING-EDGE immunologic technologies, researchers have successfully stimulated animals' immune systems to induce rare precursor B cells of a class of HIV broadly neutralizing antibodies (bNAbs). The findings, published [on May 30, 2024] in *Nature Immunology*, are an encouraging, incremental step in developing a preventive HIV vaccine.

HIV is genetically diverse making the virus difficult to target with a vaccine, but bNAbs may overcome that hurdle because they bind to parts of the virus that remain constant even when it mutates. Germline targeting is an immune system-stimulating approach that guides naïve (precursor) B cells to develop into mature B cells that can produce bNAbs. A class of bNAbs called 10E8 is a priority for HIV vaccine development because it neutralizes a particularly broad range of HIV variants. The 10E8 bNAb binds to a conserved region of the glycoprotein gp41 on HIV's surface involved in its entry into human immune cells. Designing an immunogen—a molecule used in a vaccine that elicits a specific immune system response—to stimulate production of 10E8 bNAbs has been challenging because that key region of gp41 is hidden in a recessed crevice on HIV's surface. Prior vaccine immunogens have not generated bNAbs with the physical structure to reach and bind to gp41.

To address this challenge, the researchers engineered immunogens on nanoparticles that mimic the appearance of a specific part of gp41. They vaccinated rhesus macaque monkeys and mice with those immunogens and elicited specific responses from the 10E8 B cell precursors and induced antibodies that showed signs of maturing into bNAbs that could



reach the hidden gp41 region. They observed similar responses when they used mRNA-encoded nanoparticles in mice. The researchers also found that the same immunogens produced B cells that could mature to produce an additional type of gp41-directed bNAb called LN01. Finally, their laboratory analysis of human blood samples found that 10E8-class bNAb precursors occurred naturally in people without HIV, and that their immunogens bound to and isolated naïve human B cells with 10E8-like features.

Together these observations suggest that the promising immunization data from mice and macaques has the potential for translation to humans.

The research was conducted by the Scripps Consortium for HIV/AIDS Vaccine Development, one of two consortia supported by the National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID). The research also was supported by collaborating partners including the Bill & Melinda Gates Foundation and other NIH Institutes and Offices. According to the authors, these findings support the development of the immunogens as the first part of a multi-step vaccine regimen for humans. Their work further supports research in developing a germline-targeting strategy for priming the immune system to elicit a bNAb called VRC01. This bNAb was discovered by NIAID researchers almost 15 years ago. The goal of this line of research is to develop an HIV vaccine that generates multiple classes of bNAbs to prevent HIV.

Article

Schiffner et al. Vaccination induces broadly neutralizing antibody precursors to HIV gp41. *Nature Immunology* DOI: 10.1038/s41590-024-01833-w (2024).

IN THE NEWS

Low Incomes, Little Savings: Medicare Beneficiaries Have Modest Financial Resources to Draw Upon in Retirement

A NEW KFF ANALYSIS [from February 5, 2024] shows that most Medicare beneficiaries live on relatively low incomes and have modest financial resources for retirement—posing a risk to their economic well-being, particularly if they were to have a major, unanticipated expense, such as a need for long-term nursing home care.

The financial picture is especially bleak among Black and Hispanic Medicare beneficiaries, who tend to have lower incomes, savings, and home equity than White beneficiaries, the analysis shows. Women have lower incomes and less savings than men, and beneficiaries' income and savings tend to decline with age.

Key takeaways from the analysis include:

- Overall, one in four Medicare beneficiaries, or 16.3 million people, lived on incomes below \$21,000 per person in 2023, while half (32.6 million people) lived on incomes below \$36,000 per person. Median per capita income was higher among White Medicare beneficiaries (\$40,750) than among Black (\$27,250) or Hispanic (\$19,800) beneficiaries, and lower among women than men (\$33,750 vs. \$38,950).
- One in four Medicare beneficiaries had savings below \$16,950 per person in 2023, while half had savings below \$103,800 per person. Ten percent of seniors had no savings at all or were in debt.

- Disparities in savings by race and ethnicity were substantial. Median savings among White beneficiaries (\$158,950 per person) was more than seven times higher than among Black beneficiaries (\$22,100), and more than eight times higher than among Hispanic beneficiaries (\$20,050). More than one in five Black and Hispanic beneficiaries (22% and 21%) had no savings or were in debt, compared to seven percent of White beneficiaries.

Having limited income and savings may prove challenging for Medicare beneficiaries as they grow older, particularly for older women, who tend to live longer than men and may be more likely to need expensive long-term services and supports. Nationally, the median annual cost of a private room in a nursing home was \$108,405 in 2021—more than the average Medicare beneficiary has in savings — and \$54,000 for an assisted living facility. (Medicare does not cover such care except in limited circumstances. Some poorer beneficiaries may also qualify for Medicaid, the nation's primary payer for nursing home care.)

The full analysis of the income, assets, and home equity of Medicare beneficiaries, overall and by age, race and ethnicity, and gender, is available on [kff.org](https://www.kff.org). The analysis relies on data derived from the Urban Institute's Dynamic Simulation of Income Model (DYNASIM4) for 2023.



A Tribute to the Legacy of Ms. Hermeyone T. Bell

BY ZANDRAETTA TIMS COOK, MD, MPH

THE HIV COMMUNITY SUFFERED SOUL-WRENCHING LOSSES OF TWO SERVICE ICONS this past February. Ms. Hydeia Broadbent, legendary HIV activist, made her heavenly transition on February 20, 2024, in Las Vegas, Nevada. Within 24 hours of her passing, our nation's HIV service community learned of the sudden passing of Ms. Hermeyone Bell in Seabrook, Texas.

Hermeyone had been interwoven into the fabric of the HIV treatment community in Atlanta since the 1990s. She had trained as a nurse and emergency medical technician in the U.S. Army and was self-motivated to broaden her scope of practice as a family nurse practitioner. She often spoke of her early years as a provider in the emergency department of Grady Memorial Hospital. This was at a time in our HIV history when the most a provider could offer to a patient diagnosed with HIV was a dignified way to die. When Hermeyone would speak of those early years, she spoke in spirited fashion of the anticipation of researching novel HIV treatments at the AIDS Research Consortium of Atlanta and eventually prescribing some of the first effective HIV treatments as highly active antiretroviral therapy (HAART).

It was inarguably through this process that Hermeyone cultivated her legendary devotion to the care and well-being of her patients. She evolved a care ethic that epitomized an ideal in health care provision that we all venture to attain. Hermeyone was a founding member of several local and national nursing, medical, and public health organizations, including the Atlanta Area Outreach Initiative, formerly the African American Outreach Initiative, and the Ryan White Planning Council. She contributed exceptional service as a nurse practitioner at several practices in Atlanta before opening her solo practice, Bell Primary Care, in May 2020. Here, she crafted a care home for her patients that was uniquely her mark. It was customary for her to make routine house calls, "find" free medicines, challenge pharmaceutical research conclusions, or confront unprincipled practices to do the right thing for patients.

In late 2022, Hermeyone resolved that she had served Atlanta faithfully for nearly three decades and that she had earned the

privilege of retirement. She spoke excitedly about her goal to be near her beautiful daughter, Erika, and her grandson in Texas and to be immersed in quality family time. As I consider it in hindsight, she tidily closed out business in Atlanta throughout 2023.

She carefully selected new caretakers for her cherished possessions, like her plants and her furnishings. She also meticulously chose new medical homes for her patients. I had joked with her that she would be back in Atlanta in due time, that service was an inescapable part of her existence. Hermeyone simply laughed each time I said it and remained resolute that it was indeed time to go.

The Atlanta community had a final opportunity to celebrate Hermeyone this past December during the relaunch of the Elite Society of the Undetectables ceremony. Hermeyone was presented with a well-deserved lifetime service award by Ms. Jessica Cole as her namesake award, the Hermeyone Bell Award. I believe it blesses our collective soul to know our Atlanta community was able to extend this final nod to Hermeyone's service legacy and allow her to proudly bask in the recognition that she had so befittingly earned.

As the word spread of Hermeyone's passing on February 21, 2024, calls poured in to her prior Atlanta office that we shared expressing shock and disbelief that such a bedrock of the community was gone. Patients wept. Colleagues mourned. Conference audiences fell silent in moments of tribute to a life supremely lived in service. And it is this great measure of service by which Hermeyone will always be remembered. **HIV**



HIV and HCV Epidemics Thrive While Testing Lags

In 2021, an estimated **32,100 new HIV infections** occurred in the U.S. Although the number of new HIV infections overall declined by 12 percent from 36,500 in 2017 to 32,100 in 2021, HIV continues to remain an epidemic in the United States.

Notably, approximately 40 percent of those newly diagnosed with HIV acquired it from someone with HIV who is undiagnosed. (Ref 1). One of the significant challenges for meeting the Centers for Disease Control and Prevention goal of reducing new HIV infections by 90 percent by 2030, is to get a far greater number of people tested (Ref 2).

Similarly, the World Health Organization aims to eliminate viral hepatitis C (HCV) by 2030 (Ref 3) and recognizes that testing must exponentially increase. The HCV epidemic also continues to **flourish where the incidence rate of acute hepatitis C has more than doubled since 2013.**

Routine testing is an important first step in stopping the HIV and HCV epidemics. Rapid point-of-care tests, like the CLIA-waived **OraQuick Advance® HIV-1/2 Rapid Antibody test** and **OraQuick® HCV Rapid Antibody test**, offer health care providers a powerful means to address these testing challenges. Whether it's diagnosing HIV, HCV, or another common co-infection -- syphilis -- rapid testing allows for critically needed expedited results.

Capturing Coinfection – 1 Fingerstick 2 Results

For example, consider the Health Betterment Initiative (HBI)'s use of the **OraQuick Advance® HIV-1/2 Rapid Antibody test** and **OraQuick® HCV Rapid Antibody test** in their overall work-flow when working with medically underserved communities. Both tests are run in parallel using a **small blood sample from one fingerstick with 2 results in 20 minutes.** Participants learn their status for HIV and HCV in a single visit, which is critical for providing a continuum of care and stopping the spread of disease.

"Our health care workers can get both results from a single sample," says Sandra Marrero-Ashford, MPA, MPH, MA, executive director of HBI. "We can also do other health screenings, like glucose testing, and educate our clients in this time. If there's a long line, we can start batch testing to make sure everyone is cared for."

Both HIV and HCV can be transmitted through shared risk behaviors, such as injecting drugs. While sexual transmission of HCV is less common, HCV viral loads are higher in semen when HIV is present.

Early Detection and Treatment

Early detection of co-infections with the **OraQuick Advance® HIV-1/2 Rapid Antibody test** and **OraQuick®**

HCV Rapid Antibody test provides information leading to faster intervention strategies, like initiating antiretroviral therapy for HIV and direct-acting antiviral medications for HCV. Both medications are highly effective in controlling HIV and HCV infections. Even people who test HIV negative can be linked to pre-exposure prophylaxis (PrEP), condoms, and harm reduction programs (e.g. clean syringe services), offering providers a pathway to support regular prevention.



Increased Testing Accessibility

The HIV and HCV epidemics are far reaching and the need for proactive measures is great. Rapid tests are easy to administer outside traditional health care settings, like community organizations or mobile units, increasing testing accessibility and encouraging more people to know their status.

With rapid point-of-care testing, health care providers can identify undiagnosed individuals promptly, initiate necessary treatments, and ultimately enhance health outcomes for individuals and communities.

OraSure is proud to offer diagnostic devices that support the research and wellbeing of sexual health. For more information regarding the entire infectious disease portfolio, please view OraSure's **Rapid Infectious Disease Products**. If you are interested in case studies, webinars and other industry perspective, please visit **IDX Insights**.

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The OraQuick® HCV Rapid Antibody Test is the only point-of-care hepatitis C test on the market today, detecting HCV antibodies in fingerstick and venipuncture whole blood.

When used together, healthcare providers can batch test and optimize each patient visit.

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Fighting



for Our Lives

The Work Continues

BY CECILIA DENNIS, MICHAEL MAGINN, AND ARACELIS QUIÑONES

LAUNCHED IN 2020, with the support of NMAC, formerly known as the National Minority AIDS Council, the National HIV & Aging Advocacy Network (NHAAN) is a grassroots network of individuals advocating for our collective and cumulative interests as persons aging with HIV. We envision a world in which all people thrive as we age with HIV: physically, socially, financially, spiritually, emotionally, and in all aspects of our lives.

Continuing Our Work

Though NHAAN is a relatively new network, many of us are no strangers to this fight. We have been working in HIV activism for more than 40 years—demanding treatments, designing and implementing prevention programs for our most vulnerable communities, and training ourselves and others on how to access care and support services.

After 40 years, we are proud of all the work we have accomplished in changing the course of the HIV epidemic. Our work has resulted in real gains for people with HIV (PWH). The work, however, is not complete.

In 2030, less than six years from now, it is predicted that 70 percent of all PWH will be older than 50.¹ The current systems of care for older adults are not equipped to serve PWH. We've heard from NHAAN members and other long-term survivors (LTS) about the HIV-related stigma that complicates access to specialist care from providers, especially when addressing aging-related co-occurring conditions. As PWH develop potentially severe co-occurring conditions as we age, we cannot afford any barriers to care, including stigma, poor coordination of care, and structural barriers like lack of housing or transportation that prevent older PWH and LTS from reaching services and appointments.²

What follows are several key areas that we, as members of NHAAN, believe need to be addressed to better serve older PWH and/or LTS.

Updated Schedule of Aging-Related Assessments

NHAAN has heard time-and-time again from LTS and older PWH that we are not receiving the screenings necessary to identify and address chronic co-morbidities. After suffering from chronic, debilitating pain in his joints, a NHAAN member from Texas recently asked his provider for a bone density scan. His health care provider was skeptical of the necessity for such an assessment due to the person's age and only agreed after further pressing. When the test results came back, it showed that the patient, a LTS in his late 50s, had a severe form of arthritis that typically shows up in patients who are much older. Identifying this underlying arthritis necessitated a new treatment plan to address this person's chronic pain.

Aging-related assessments—frailty, cognition, bone health, and others—must correlate to the physiological experiences of LTS and older PWH, rather than that person's chronological age. This is especially important for lifetime survivors and Dandelions (a term in the HIV community used to describe people who have lived with HIV their entire lives) who often face severe and chronic co-occurring conditions in their 20s, 30s, and 40s. Providers must be trained to assess and treat LTS with this framework, or else risk not catching and treating aging-related complications with sufficient time.

New York State's Department of Health AIDS Institute's Clinical Guidelines Program is a good example of clinical care guidelines that providers should adopt for all PWH.³

Reduce Stigma in Services Designed for Older Adults

The Older Americans Act (OAA), passed in 1965 and last reauthorized in 2020, is an important program for older adults and their caregivers. The OAA is administered via the national Aging Network, which is comprised of more than 56 state and territorial offices of aging, over 600 Area Agencies on Aging (AAAs), over 270 Title VI Native American Aging Programs, and thousands of community organizations.⁴ The OAA, through the Aging Network, helps fund nutrition programs (such as Meals on Wheels), transportation services, case management, home repair programs, and much more.⁵

We support efforts by NMAC, Services & Advocacy for GLBT Elders (SAGE), the Federal AIDS Policy Partnership (FAPP), and many other partners to push for PWH's inclusion as a group of greatest social need in the next reauthorization of the OAA. While it is important under the OAA that each state has flexibility to develop its own programs to implement and provide services, all state programs should operate under a guiding set of national policies that ensure economic and social justice and each state should be required to develop plans on how they will engage and serve people of greatest social need in their states. This could allow PWH over 60 the opportunity to access support services funded in part by the OAA.

In the meantime, we support the recent rule by the Administration for Community Living (ACL), which implements the OAA, that directs state agencies and AAAs to focus attention, advocacy, and service provision toward those in greatest economic need and greatest social need, including PWH.⁶ State offices of aging and others in the Aging Network should be held accountable for integrating PWH into their state aging plans. As the OAA faces reauthorization in 2024, we will continue to advocate for the ACL's rule to be written into law.

Support services for older adults must also be safe and welcoming to PWH.



Ageism in health settings, including in HIV testing programs, contributes to people 45 and up accounting for 66 percent of all late HIV diagnoses.

Community-based organizations, elder justice organizations, HIV organizations, and public officials should provide training and resources to aging-related organizations and offices designed to eliminate HIV stigma in their service delivery.

Housing & Aging in Place

Housing is consistently listed as one of the most pressing needs for NHAAN members and other LTS. Access to affordable housing, that is safe and accessible for people with varying physical needs, is a big concern for many older PWH.⁷

It's estimated that at least one in four PWH experience housing service or shelter needs.⁸ Among the PWH who reported housing needs in Georgia, 60 percent reported that those needs went unmet. Other PWH who live in Southern jurisdictions also reported similar levels of unmet need.

We support an increase in funding for the Housing Opportunities for People with AIDS (HOPWA) and urge the Housing and Urban Development Administration (HUD) to work with LTS networks and HIV and aging organizations on how HOPWA service delivery can be improved throughout the country and Puerto Rico.

The Centers for Disease Control and Prevention (CDC) defines aging in place as "the ability to live in one's own home and community safely, independently, and comfortably, regardless of age, income, or ability level." Aging in place will require the wrap-around services funded, in part, by the OAA and administered by the AAAs. We also advocate for an increase in funding for the OAA.

Finally, there are several successful models of how organizations have collaborated with advocates, local and state leaders, and federal agencies to create culturally appropriate housing communities for older PWH and LTS. Housing Works and Marty's House are just two examples of these types of housing justice organizations, and we strongly urge for more to be created throughout the United States, including in locations outside big metropolitan areas.

HIV Prevention for Older Adults

Though our work is focused on improving the lives of PWH, we also acknowledge that older adults are not being served by current HIV prevention programs. Ageism in health settings, including in HIV testing programs, contributes to people 45 and up accounting

for 66 percent of all late HIV diagnoses.⁹ Women 45 and older, the majority of them Black women, made up 36 percent of all new diagnoses among women in 2019.¹⁰

HIV prevention advocates and organizations must intentionally integrate older adults into their campaign materials, outreach plans, testing programs, and pre-exposure prophylaxis (PrEP) education programming.

Older adults should also be referred to PrEP prescribers if they so desire. To that point, we support the Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) for PrEP, which would allow Medicare to cover the costs of PrEP (whether oral or injectable) and up to seven HIV testing and education counseling sessions.¹¹ PrEP has been prohibitively expensive for many older adults who could benefit from the medication and Medicare should cover the full costs of all PrEP modalities.¹²

SAGE has also done great work advocating for the removal of the upper age limit in the CDC's HIV testing guidelines.¹³ Promoting a culture of regular HIV testing and instructing providers to offer testing to anyone having sex will go a long way in helping older PWH learn their status before their conditions progress to late-stage HIV.

Conclusion

Many LTS first started our advocacy in order to survive. Some of us spent our time working in our communities, doing outreach, education, and testing, while others went into the halls of Congress, the Federal Drug Administration, and pharmaceutical companies to demand funding for research and treatments. All of us, though, were joined by a shared sense of urgency to take care of ourselves when others could not and would not.

Having the chance to utilize these skills again, this time to advocate for the needs of older PWH and LTS, has taught us that, though the epidemic might look very different, at root is still a shared urgency we feel to take care of one another. Being a part of NHAAN has given us a wonderful opportunity to sharpen our advocacy skills, learn new ways of organizing, and to study the ways policies and practices need to be changed to better serve our community. There is still a lack of

education and understanding about HIV. Aging-related services need to begin making their services and care delivery responsive to the needs of PWH, and HIV organizations need to begin prioritizing the needs of PWH over 50, who already make up the majority of PWH in the U.S.

One thing we've learned in re-engaging this advocacy work is that our collective voices still matter. It's our responsibility, having lived for many years with HIV, to educate and inform our community and allies about our own needs. At the core of our Network's mission is a strong faith that we can change the course of this epidemic for older PWH and LTS. We've already done it once, and we know it can be done. **HIV**



CECILIA DENNIS is a member of the Weitzman Institute Associate Faculty, Virginia Community HIV Planning Group, and VCU Medical Center Ryan White Planning Council. Passionate about bodily autonomy and social equity, Cecilia focuses on ensuring equal access to health insurance and advocating for comprehensive health care models for people living and aging with HIV. As Chair of NHAAN, Cecilia envisions a world where all individuals thrive as they age with HIV in every aspect of their lives. Her mission is to educate, empower and nurture women, while creating rejuvenating spaces for rest and relaxation.



MICHAEL MAGINN serves as HIV Prevention Director and HIV Prevention Lead Agent with the Illinois Public Health Association. Before joining IPHA, Mike served as Executive Director/CEO of Central Illinois FRIENDS of People with AIDS for ten years, a community-based organization serving the needs of individuals living with HIV in Central Illinois. He is actively involved with local, state and national organizations including the Illinois Commission on LGBTQ+ HIV Aging, the Chicago Area HIV Integrated Services Council, and NHAAN. Mike has been involved in the HIV health field for over twenty years.



ARACELIS QUIÑONES has been living with HIV for the past 36 years and never thought she would get to see herself aging with HIV. In addition to serving as an officer with NHAAN, she is also the Coordinator for Poder Latino at the Latino Commission on AIDS. Above all, she is an advocate who has dedicated her working life to helping those in need, especially people afraid to disclose their HIV status due to stigma.

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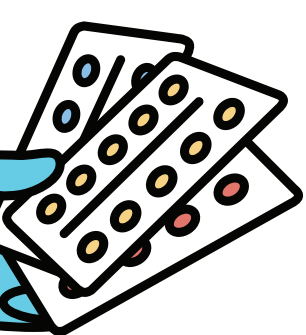
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Impact of Age-Associated Comorbidities upon Quality of Life

BY BRITT GAYLE, MD, MPH, AAHIVS

THE DEVELOPMENT AND AVAILABILITY of modern antiretroviral therapy (ART) and its prompt initiation has resulted in dramatic improvements in the life expectancy gap. According to the Centers for Disease Control and Prevention (CDC), 53 percent of Americans diagnosed with HIV were at least 50 years old in 2021. Many comorbidities occur earlier, more frequently, and progress more aggressively among people with HIV (PWH), with many of them being cardiometabolic conditions, such as metabolic syndrome (MetS), Type 2 diabetes (DM2), dyslipidemia (DLD) and metabolic dysfunction-associated steatotic liver disease (MASLD). This results in the primary focus of HIV primary care transitioning from the management of sequelae of immunocompromise to the management of chronic, noncommunicable comorbidities. This disparity in comorbidity burden can be viewed as a manifestation of HIV-associated accelerated and/or accentuated aging, where there's an earlier onset of comorbidities and/or a persistently increased prevalence of comorbidities at any age respectively. A recent analysis of Medical Monitoring Project (MMP) data focusing on PWH aged 55 years or older concluded that almost 27 percent of cisgender older PWH have an unmet need for non-HIV medical services.¹



Management of these comorbidities is complicated by disparities in social drivers of health; 42 percent of clients who are at least 50 years old who receive Ryan White funded services have incomes below the federal poverty level. The MMP analysis discovered that almost 38 percent of cisgender older PWH have an unmet need for ancillary services, with almost 27 percent needing subsistence services, such as transportation, food assistance, and shelter/housing assistance. Of those who participated in the study, 10.3 percent were unemployed, 32.7 percent were unable to work and 40 percent had household incomes below the federal poverty limit. The prevalence of unmet needs was 42 percent higher among Black persons, 35 percent higher among Latinos and 63 percent higher among those classified as multiracial when compared to White older PWH. Interestingly, those aged 65 years or older were 19 percent less likely to express a need for ancillary services compared to those aged 55 to 59 years.

Weight Gain and Adipose Tissue Dysfunction

Weight gain is a complex physiological phenomenon whose magnitude and impact are influenced by a variety of factors such as pre-ART viral load, nadir CD4 count,

age, gender, ethnicity, diet, activity, etc. The majority of documented weight gain occurs within the first year of ART and is associated with beneficial and detrimental outcomes. For example, weight gain post-ART initiation among those who were initially normal weight or underweight was associated with a survival benefit while similar weight gain among those who were overweight or obese prior to ART initiation did not result in a “return to health” effect.² Up to 67 percent of adult PWH are estimated to be overweight or obese by BMI criteria.³

Early in the HIV epidemic, PWH developed metabolic alterations that were primarily associated with early thymidine analog nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs) and protease inhibitors (PIs), resulting in phenomena such as wasting, defined as weight loss of greater than 10 percent or having a weight less than 90 percent of one's calculated ideal body weight. While modern ART regimens have nearly eliminated the occurrence of ART-induced lipodystrophy, it is important to note that PWH exposed to early ART regimens may experience persistent ART-associated lipoatrophy as a legacy effect that is only partially reversible via ART changes.

PWH are at increased risk of experiencing changes in the mass and composition of adipose tissue depots, including regional loss (lipoatrophy), gain

(lipohypertrophy), and mixed lipodystrophy. In addition to the increase in fat deposits in visceral adipose tissue (VAT), dorsocervical region, trunk and/or breasts, lipohypertrophy among PWH is also more likely to include ectopic lipid deposition in organs such as the liver, skeletal muscle, and heart. Lipoatrophy, the loss of at least 30 percent of limb fat, is characterized by decreased subcutaneous adipose tissue in the face, limbs, and buttocks and is associated with a long-standing history of stigmatization. The increased visceral adipose tissue is associated with increased insulin resistance and cardiovascular disease (CVD) risk compared to those without HIV. Complicating assessments of visceral adiposity are increased visceral adiposity to BMI ratios that result in underestimations of total adiposity when using indirect measuring strategies. As in the general population, VAT accumulation is associated with increased systemic and tissue level inflammation and activation of the renin-angiotensin system, increasing the risk of insulin resistance and cardiometabolic disease.

Cardiac Fat Accumulation

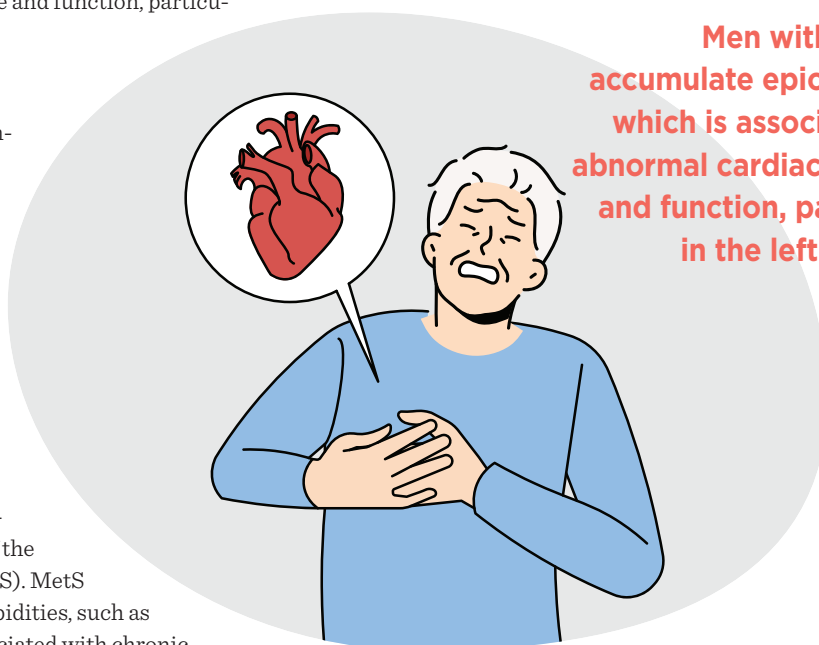
HIV intramyocardial steatosis is associated with diastolic dysfunction. The REPRIEVE trial identified markedly increased intramyocardial triglyceride content (IMTC) among 22 percent of participants with identified risk factors, including age, overweight/obesity, history of injection drug use, and CD4 count < 350 cells/mm.³ Of those with markedly increased IMTC, 72 percent had a normal range waist circumference. Men with HIV also accumulate epicardial fat, which is associated with abnormal cardiac structure and function, particularly in the left ventricle.

Metabolic Syndrome

While the specific definition varies, MetS generally consists of the following components: central obesity, dyslipidemia, insulin resistance, and hypertension. The prevalence among PWH is estimated to be between 16.7 percent and 31.3 percent and continues to increase.² The increased prevalence of MetS among PWH is believed to be associated with multiple physiological changes associated with HIV infection, including a persistent pro-inflammatory state that is reduced but not eliminated by modern ART, endothelial dysfunction, adipocyte dysfunction, and increased activation of the renin-angiotensin, aldosterone system (RAAS). MetS has a causal association with medical comorbidities, such as DM2 and CVD, and is epidemiologically associated with chronic kidney disease (CKD) and MASLD.

Metabolic Dysfunction-Associated Steatotic Liver Disease

Chronic liver disease is the second leading cause (13%) of non-HIV related mortality among PWH.³ Up to 60 percent of PWH have aminotransferase abnormalities at some point in their care, and the prevalence of MASLD, defined as steatosis of at least five percent of the liver parenchyma, has varied between 30 to 65 percent among PWH depending on the study population, diagnostic method, etc.⁴ MASLD is an independent risk factor for CVD, DM2, and all-cause mortality. Similar to other metabolic comorbidities, PWH with MASLD have higher aminotransferase elevations, serum triglycerides, and rates of steatohepatitis. There is also a higher prevalence of “lean MASLD” or MASLD at normal range BMI, with one cohort study discovering that 45 percent of patients with hepatic steatosis had a BMI less than 30kgm.² The increased prevalence, earlier onset, and accelerated progression of liver disease with higher prevalence of metabolic dysfunction-associated steatohepatitis (MASH) among PWH is largely attributed to increased visceral adipose tissue accumulation and insulin resistance.⁵ Importantly, hepatocellular carcinoma can develop from MASLD/MASH without the prior detection of cirrhosis, though fibrosis stage is associated with long-term mortality, with 12.1 percent of those with F3 fibrosis and 45 percent of those with cirrhosis developing decompensated liver disease over 20 years.⁴ A recent meta-analysis estimated a MASH prevalence among PWH of 42 percent and another study identified an association between MASH and duration of HIV infection.



Men with HIV also accumulate epicardial fat, which is associated with abnormal cardiac structure and function, particularly in the left ventricle.

Weight loss has a significant beneficial impact upon MASLD, with a 10 percent weight loss associated with MASH resolution in 90 percent of patients and a one-stage fibrosis reduction after one year.

Diagnosis

Non-invasive imaging modalities used to identify MASLD include abdominal/liver ultrasound, non-contrast computed tomography scan, and MRI. Currently there is no U.S. guideline that recommends MASLD screening for PWH. However, the European Acquired Immune Deficiency Syndrome Clinical Society recommends screening all PWH with MetS for MASLD with ultrasound and, if positive, performing a follow-up evaluation. Predictive models, serum-based assays, and radiologic studies can be used to identify and stage hepatic fibrosis. However, these noninvasive strategies, such as the aspartate aminotransferase to platelet ratio index, FIB-4, and MASLD Fibrosis Score, have variable performance among PWH. The Enhanced Liver Fibrosis score is a newer serum-based test that has not yet been validated in PWH.³ Transient elastography (with controlled attenuation parameter for assessment of steatosis), shear wave elastography, and MR elastography (with proton density fat fraction for assessment of steatosis) are radiographic noninvasive tests that can be used to estimate liver fibrosis. Liver biopsy, while less frequently used, remains the gold standard for diagnosing and staging MASLD.

Pharmacologic Management

Tesamorelin, a growth hormone releasing analog that is Food and Drug Administration approved for the treatment of HIV-associated lipohypertrophy, decreases radiographic liver fat among PWH, and in a 2019 study published in the *Lancet HIV*, was found to prevent fibrosis progression over one year.⁶ The recently published SLIM Liver study found that a weekly injection of 1mg of semaglutide resulted in a 31 percent reduction in liver fat among PWH with MASLD, with 29 percent of participants experiencing complete resolution of MASLD (a reduction in liver fat to five percent of overall liver content) and 58 percent of participants experiencing at least a 30 percent reduction in liver fat.

Beneficial Lifestyle Modifications

Weight loss has a significant beneficial impact upon MASLD, with a 10 percent weight loss associated with MASH resolution in 90 percent of patients and a one-stage fibrosis reduction after one year. A weight loss of three to five percent is associated with an improvement in steatosis.⁴ There is also evidence from a meta-analysis concluding that exercise has a beneficial impact independent of weight loss, and another study finding that a doubling in the amount of time spent performing vigorous exercise was associated with a decreased risk of advanced fibrosis. However, increased prevalence of frailty and sarcopenia in PWH may complicate the uptake of physical activity recommendations.

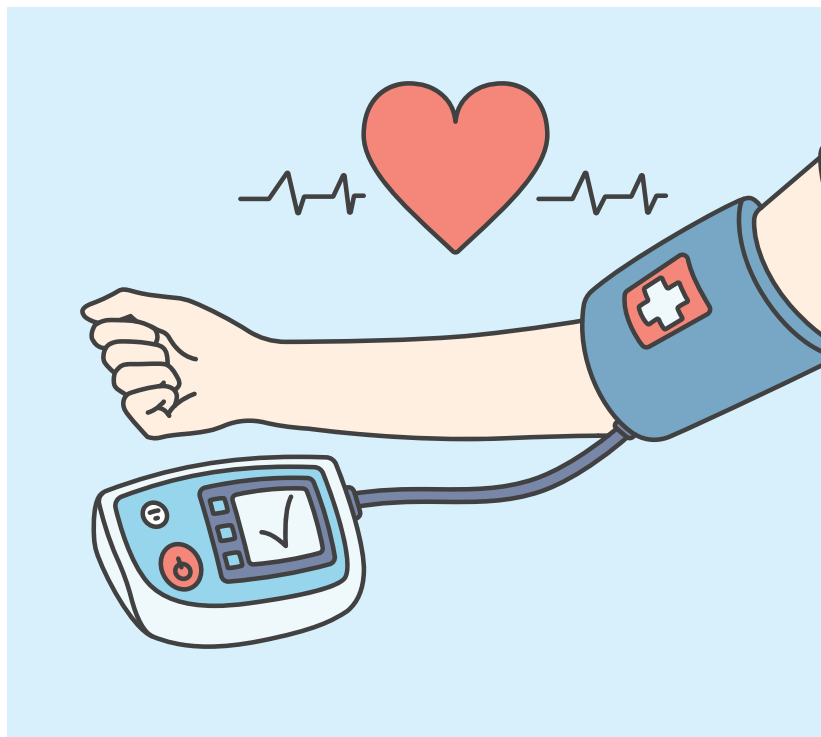


A hypocaloric diet with a goal weight loss of 0.5–1.0 kg/week is generally recommended. Minimization of sugar sweetened beverage consumption is also advised, while the consumption of whole grains is associated with a decrease in MASLD risk and improvements in insulin sensitivity. Lower overall fat intake is associated with a lower risk of developing MASLD. Minimization of alcohol consumption is also advised, as even mild consumption may accelerate liver fibrosis progression. Coffee consumption was found to have a protective effect on liver fibrosis, which was observed in multiple studies.⁷ Cirrhotic patients should receive diagnosis specific nutritional counseling.

A cross sectional analysis of data from the Swiss HIV Cohort Study demonstrated a twofold increased risk of steatosis among those not meeting the European Association for the Study of the Liver physical activity guidelines per self-report. A 16 percent increase in liver steatosis risk per additional hour of daily sitting time was also observed, as was a 24 percent decrease in liver steatosis risk for every additional 5,000 MET-min per week. The associations between MET-min, hours of daily sitting time and risk of liver steatosis persisted when the analysis was restricted to the subpopulation of participants with lean MASLD (29.3%).⁸

Cardiovascular Disease

Multiple studies have identified an increased prevalence of hypertension (HTN), DLD, and insulin resistance among PWH, however these risk factors only partially account for the three-fold increase in atherosclerotic cardiovascular disease (ASCVD) risk among PWH compared to individuals without HIV, demonstrating that HIV infection represents an independent ASCVD risk enhancer. The risk of ASCVD is further elevated among individuals with low current or



nadir CD4 counts. None of the current risk management models estimate ASCVD risk among PWH with comparable accuracy to the general population, and the most recent CVD risk model, the PREVENT risk calculator that incorporates cardiovascular-kidney-metabolic syndrome and heart failure risk into its estimations, has not yet been assessed among PWH in a published study. Discordance between risk models such as the Framingham score and coronary artery calcium score has been observed.⁴

Pharmacologic Management

The EXTRA-CVD study evaluated the impact of a nurse-led strategy to deliver a blood pressure reduction intervention consisting of clinical care coordination and medication titration among PWH with HTN and elevated cholesterol in Ohio and North Carolina and observed a significant difference in systolic blood pressure at four months, with those randomized to the nurse intervention being almost three times more likely to reach goal BP and experiencing a blood pressure reduction corresponding to an estimated 14 percent reduction in CVD risk.⁹

The REPRIEVE study, a randomized control study that examined the impact of pitavastatin upon the CVD risk of PWH with low-moderate ASCVD risk observed a 35 percent decrease in first major adverse cardiovascular events (MACE) among those randomized to the pitavastatin group, a decrease greater than anticipated from the

magnitude of low-density lipoproteins (LDL) lowering. The data resulted in the U.S. Department of Health and Human Services (HHS) Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV recommending that those aged 40 years and older with a 10-year ASCVD risk of at least five percent should be started on moderate statin therapy, due to the study's number needed to treat of 53 among those with a 10-year ASCVD risk of five to 10 percent.

Type 2 Diabetes Mellitus

Like other cardiometabolic comorbidities, PWH are at increased risk of developing DM2. Diagnosis is complicated by the fact that hemoglobin A1c (HbA1c) is more likely to underestimate mean glycemia among PWH, resulting in missed diagnoses. The American Diabetes Association and the HHS HIV Guidelines recommend screening PWH for prediabetes and diabetes with a fasting glucose prior to ART initiation, when switching ART regimens, and three to six months after switching ART regimens. Patients with normal screening results are advised to undergo repeat screening annually.¹⁰ The decreased reliability of HbA1c among PWH may also result in some limitations when using the test to monitor responses to treatment. Some PIs and NRTIs, particularly the older generation, are associated with an increased risk of diabetes. Management of DM2 among PWH is generally the same as the general population, with attention given to potential medication interactions, such as between dolutegravir (DTG) and metformin, and the potential consideration of ART regimen modification to improve DM2 management.

Impact of ART

First generation NRTIs were associated with metabolic and hepatotoxicity. First generation PIs were also associated with DLD, insulin resistance, MetS, and MASLD. Multiple studies have established a firm association between abacavir and CVD risk.

A randomized switch study between efavirenz (EFV) and raltegravir (RAL) observed a decrease in controlled attenuation parameter scores among the group randomized to switch to RAL, despite similar to greater weight gain in the RAL group. Additional and larger studies examining the association between integrase strand transfer inhibitors (INSTIs) and MASLD are needed, especially in light of data suggesting an association between second generation INSTIs and weight gain.

Studies examining the switch between tenofovir disoproxil fumarate (TDF) and tenofovir alafenamide fumarate (TAF) have identified an increase in lipids, weight,

steatosis and, in some studies, insulin resistance, though there was no documented increase in risk of DM2 during the 18 months of follow up.¹¹ There is also some data identifying the presence of some weight loss and decrease in serum lipids following a return to TDF from TAF, likely as a result of TDF's appetite suppressant effects.

While the details of the association between second generation INSTIs and weight gain are still being elucidated, elvitegravir (EVG) and RAL appear to be associated with an increased risk of hepatosteatosis. A 2022 meta-analysis also concluded that the risk of weight gain is significantly more frequent among those receiving DTG and bictegravir (BIC) compared to EVG or RAL. Cabotegravir (CAB) has so far demonstrated a more favorable metabolic profile. Eighty week data from a phase 2 trial identified an association between lenacapavir (LEN) and weight gain, particularly when used in combination with TAF.

Conclusion

PWH have experienced a dramatic improvement in life expectancy due to improvements in ART regimens, their availability, and the timing of their initiation. However,

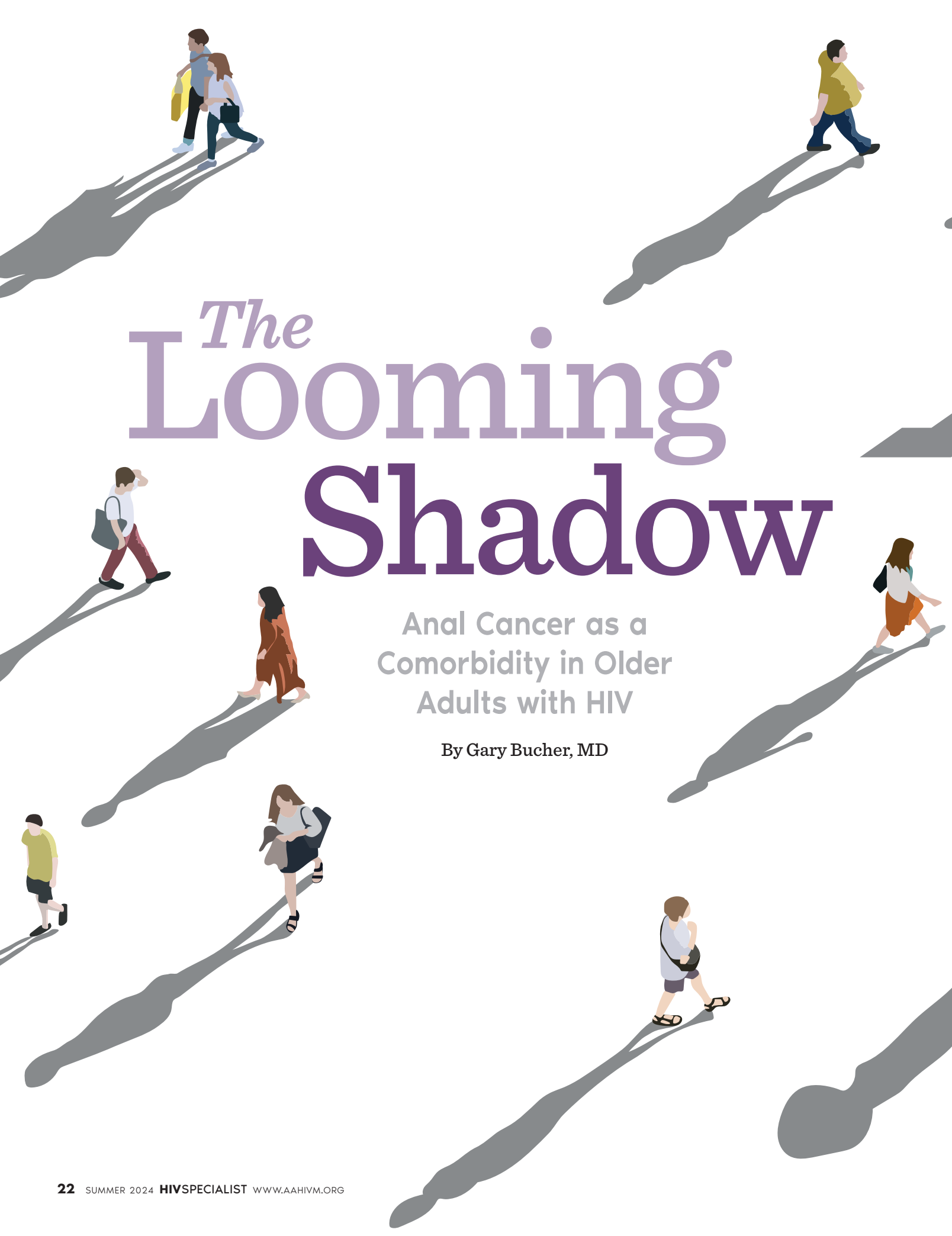
the prevalence and aggressiveness of metabolic comorbidities are significantly higher among PWH, with HIV-associated inflammation and disorders in fat deposition serving as some of the major contributors driving the bidirectional relationship between MetS and cardiometabolic comorbidities. While some pharmacologic agents have recently been shown to reduce the risk and even reverse the impact of the aforementioned comorbidities, significant benefits from lifestyle modifications remain, requiring HIV providers to be proficient in both management areas and for patients/clients to have access to the necessary support services in order to gain maximal benefit from the full spectrum of evidence-based treatments. **HIV**



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An illustration featuring several stylized human figures in various poses and colors (blue, yellow, brown, orange, grey, green) walking across a white background. Each figure casts a long, dark grey shadow that extends diagonally across the frame, creating a sense of depth and movement. The shadows are positioned around the central text, framing it from all sides.

The Looming Shadow

Anal Cancer as a
Comorbidity in Older
Adults with HIV

By Gary Bucher, MD



THE LANDSCAPE OF HIV MANAGEMENT has transformed dramatically in recent decades. Effective antiretroviral therapy (ART) has drastically reduced morbidity and mortality, allowing people with HIV (PWH) to achieve near-normal lifespans. However, this success story brings a new set of challenges: the growing prevalence of age-related comorbidities. Among these, anal cancer stands out as a significant threat for older PWH.

Epidemiology of Anal Cancer

Anal cancer incidence is markedly elevated among PWH, particularly among men who have sex with men (MSM). A large study across nine U.S. areas found the incidence was 19 times higher in PWH compared to the general population.² Incidence increased steeply from 1996-2000 after the introduction of ART, plateaued from 2001-2008, and then declined modestly from 2008-2012.² The risk is highest among PWH who are older, MSM, and those who have a history of nadir CD4+ T-cell counts of less than 200, with the cumulative five-year risk reaching 0.32-0.6 percent for MSM with HIV aged 45 and older.² A multicenter cohort study showed MSM with HIV had a 4.7 times higher risk of anal cancer compared to MSM without HIV in the antiretroviral era.³ Anal cancer incidence was also substantially higher among PWH in the antiretroviral era versus the pre-antiretroviral era, likely due to increased longevity.³ The elevated risk underscores the importance of anal cancer screening and prevention efforts in this population.^{1,2,3,4}

Transgender women with HIV are another high-risk group for anal cancer. Similar to MSM, they may have a history of receptive anal intercourse which increases human papillomavirus (HPV) exposure. Studies have shown a concerning prevalence of anal HPV and anal precancer in transgender women with HIV. This underscores the critical need for inclusive health care practices that incorporate anal cancer screening into routine care for transgender women with HIV.

Pathogenesis of Anal Dysplasia



The pathogenesis of anal dysplasia in PWH is primarily driven by persistent infection with high-risk HPV types, particularly HPV-16. PWH, especially MSM, have a higher prevalence of anal HPV infection compared to the general population.^{5,6} HIV-induced immunosuppression facilitates HPV persistence and progression to anal precancer or anal intraepithelial neoplasia (AIN).^{6,8} Lower CD4+ T-cell counts are associated with an increased risk of anal dysplasia and higher rates of progression from low-grade squamous intraepithelial lesions (LSIL) to high-grade squamous intraepithelial lesions (HSIL).^{6,7}

Anal HPV infection is more common in PWH due to factors such as higher rates of anal intercourse, multiple sexual partners, and other sexually transmitted infections (STIs) that compromise the mucosal barrier.⁷ MSM with HIV have a particularly high burden, with over 70 percent estimated to have anal HPV infection and a high prevalence of HSIL.⁷ The impaired immune response in PWH allows for increased HPV persistence, integration into the host genome, and accumulation of genetic mutations that drive malignant transformation.^{6,8}

Increased Risk for Anal Cancer in Older PWH

Several factors contribute to the rising concern of anal cancer in older PWH. Aging itself leads to a decline in immune function known as immunosenescence. Immunosenescence can potentially increase susceptibility to HPV infection and progression. Long-term HIV, even with a controlled viral load, may have a cumulative effect on immune competence that further elevates anal cancer risk. Early ART regimens could have immunosuppressive effects that potentially impact long-term immune function. As well, smoking is an independent risk factor for anal cancer.⁹

Importance of Anal Cancer Screening

Anal cancer screening provides significant benefits for PWH. Screening allows for identification of anal HSIL, which are precursors to invasive anal cancer. Early detection and treatment of anal HSIL can prevent progression to anal cancer.^{10,11} The landmark ANCHOR study demonstrated that screening for precancerous lesions and early treatment reduced the risk of developing anal cancer by 57 percent in PWH aged 35 and older.¹⁰ By detecting anal cancer at an earlier, more treatable stage, screening can lead to improved survival and reduced morbidity from invasive disease.^{11,12} Early-stage cancers have better prognosis and treatment options. Screening can identify high-risk individuals, such as older patients,

MSM, and those with low CD4 counts, who may benefit most from intensive surveillance and prevention efforts.¹¹ Screening programs raise awareness about anal cancer risk among PWH, promoting prevention through HPV vaccination, safe sexual practices, and smoking cessation.^{10,11}

The IANS Anal Cancer Screening Guidelines

The International Anal Neoplasia Society (IANS) recently published evidence-based guidelines for anal cancer screening among various high-risk groups.¹³ PWH were included in the guidelines. The key recommendations are:

Risk-Based Screening Initiation

- Screening initiation at age 35 for MSM and transgender women with HIV
- Screening initiation at age 45 for other people with HIV, and MSM and transgender women without HIV
- For solid organ transplant recipients, screening initiation from 10 years post-transplant
- For those with a history of vulvar precancer/cancer, screening within one year of diagnosis
- Shared decision-making for screening those aged ≥45 with a history of cervical/vaginal HSIL or cancer, perianal warts, persistent cervical HPV16, or autoimmune conditions

Screening Methods

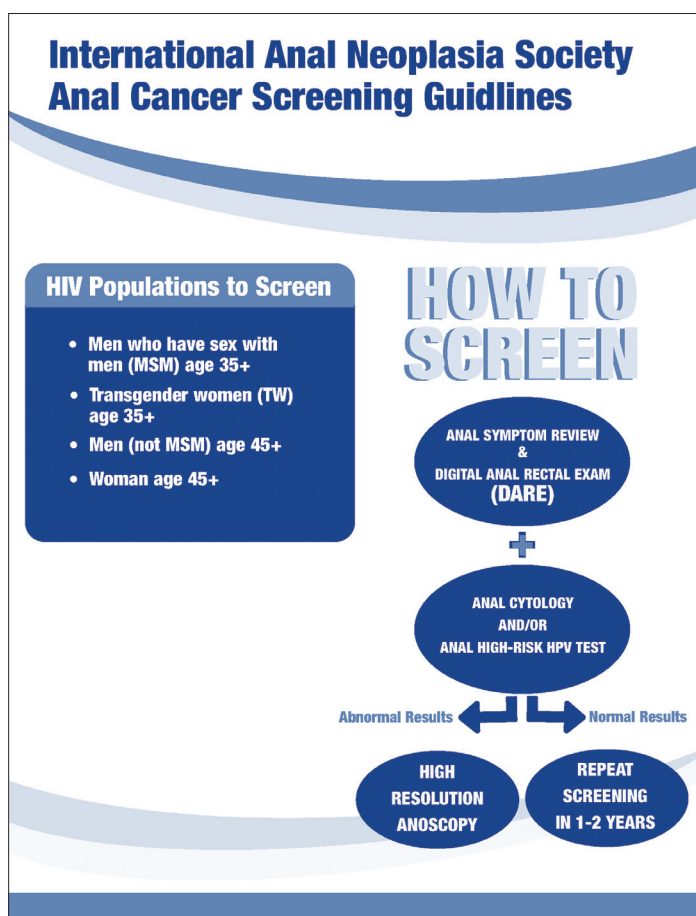
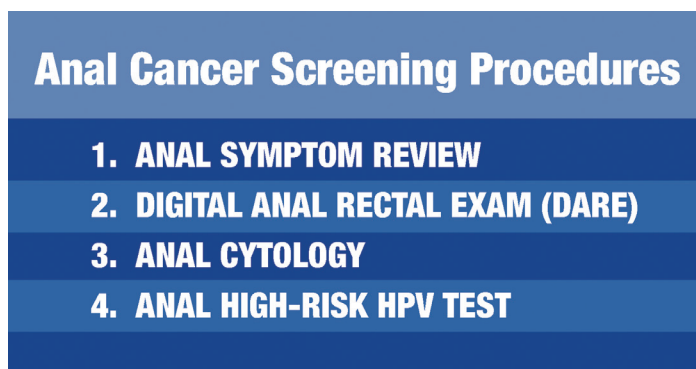
- Anal cytology, high-risk HPV testing (including HPV16 genotyping), and HPV-cytology co-testing
- Digital anal rectal exam (DARE)¹⁴
- Anal symptom review

The upcoming revision of the HPV section in the Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV is expected to mirror IANS anal cancer screening guidelines for PWH.¹⁵

Considerations for Implementing Anal Cancer Screening in PWH

Implementing anal cancer screening among PWH requires careful consideration of several factors. Firstly, the establishment of official screening guidelines is crucial, as many health care providers are uncertain about the appropriate screening methods and their implementation due to the lack of designated guidelines.¹⁶ Secondly, education and awareness campaigns targeting both providers and PWH are essential. Providers need to be educated on topics such as HPV infection, the increased risk of HPV-related cancers in PWH, and the importance of screening.¹⁶ PWH, on the other hand, need to be informed about their elevated risk of anal cancer, the availability of screening tests, and the potential benefits of early detection and treatment.^{11,16}

Another critical consideration is the availability of trained providers and facilities capable of performing high-resolution anoscopy (HRA), the gold standard diagnostic tool for detecting anal HSIL.^{11,16} Capacity issues, such as a lack of trained providers and long waiting times for HRA appointments, can pose significant barriers



to effective screening implementation.^{11,16} Additionally, patient-level barriers, such as lack of knowledge about anal cancer screening, absence of symptoms, and fear of diagnosis, need to be addressed through education and counseling.¹⁶

Overall, implementing anal cancer screening in PWH requires a multifaceted approach involving the development of evidence-based guidelines, provider and patient education, capacity building for diagnostic procedures, and addressing patient-level barriers to ensure successful implementation and adherence to screening recommendations.

Anal Precancer Treatment

There are several treatment options available for anal precancer or HSIL. Ablative therapies are commonly used, which involve removing or destroying the abnormal tissue. Office-based electrocautery, where heat from an electric current is applied to the lesion, is a frequently employed method.¹⁰ Other ablative techniques include cryotherapy (freezing), laser therapy, and surgical excision under anesthesia for larger or more extensive lesions.

Topical therapies like imiquimod cream, which stimulates the immune system, or trichloroacetic acid can be used for smaller lesions, especially perianal lesions. Topical treatments may have lower efficacy but can be repeated as needed.

The choice of treatment depends on factors like the size, location, and extent of the lesions, patient preference, and provider experience. A combination of methods may be used for more extensive disease.

Active Surveillance for Anal Precancer

Active surveillance is an important strategy for managing anal precancer. It involves regular monitoring with anal symptom checks, DARE, anal cytology, high-risk HPV testing, and HRA to detect any progression or recurrence of HSIL.

After initial diagnosis and treatment of HSIL, patients undergo

periodic follow-up with HRA, typically every six to 12 months. HRA allows for visualization of the entire anal canal and perianal region, and any suspicious areas can be biopsied. Ongoing surveillance is crucial because HSIL can recur in up to 60 percent of cases within two years, even after treatment.¹⁷

Active surveillance aims to identify any recurrent or persistent HSIL lesions early, before potential progression to invasive anal cancer. If HSIL is detected during follow-up, further treatment with ablative therapies like electrocautery, topical agents, or surgical excision may be recommended.

This approach of close monitoring and timely re-treatment when necessary is particularly important for high-risk groups like PWH, MSM, and those with other HPV-related cancers or precancers. Adherence to regular surveillance is essential to maximize the benefits of early detection and prevention of invasive anal cancer.

Conclusion

In conclusion, anal cancer poses a significant threat for older adults living with HIV. Increased awareness, regular screening, and early intervention are crucial for reducing morbidity and mortality from this preventable cancer. Implementing the evidence-based IANS guidelines, along with educational initiatives for both providers and patients, is essential to ensure successful screening program adoption and adherence. Early detection through screening allows for timely treatment of precancerous lesions, ultimately preventing the development of invasive anal cancer and improving patient outcomes. By prioritizing anal cancer screening in older PWH, we can significantly improve their quality of life and long-term health. **HIV**



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Women, MENOPAUSE & HIV



USE,



BY JAYMEE LEAK MATTHEWS, DNP, APRN, FNP-C

OVER HALF OF THE 38.4 MILLION PEOPLE WITH HIV (PWH) globally are persons assigned female at birth (women).¹ Women will normally experience the end of their menstrual cycles usually between 45 and 55 years of age. However, the average age of a woman whose menstrual cycles have stopped is 51 years old in the United States.² Growing older in optimal health is ideal and desired. However, having HIV increases the risks for other disease processes, such as kidney issues, diabetes, osteoporosis, and cardiovascular disease, for older persons, particularly women. HIV (human immunodeficiency virus) was once a perceived and literal death-associated disease, but is now managed as a chronic condition with normal life expectancy for those who remain stable on potent and highly effective antiretroviral therapy (ART). Available and effective ART has produced a demographic shift in PWH who are now living into their seventh and eighth decades of life, or longer.

Women living longer with and without HIV, unfortunately, may experience bothersome vasomotor symptoms before, during, and after menopause. Menopause is a natural part of a female's reproductive life, but this transition can have multiple negative effects on a female's quality of life. According to the authors of a literature review on menopause and women with HIV (WWH), "The menopause transition is a complex physiological process resulting from decreased ovarian secretion of the hormones estrogen and progesterone and a decline in circulating testosterone levels."³ Menopause is clinically defined as at least 12 consecutive months without menstruation (amenorrhea) with no other obvious pathologic or physiologic cause.⁴ Symptoms of menopause can include irregular periods, vaginal dryness, mood changes, hot flashes, and night sweats.² This article discusses the relationship of virally-suppressed WWH who are experiencing menopause.

Data on HIV and Menopause

The Stages of Reproductive Aging Workshop (STRAW) + 10 defines the different menopausal stages as: (1) Pre-menopausal women have regular, consistent cycles of menstruation during the previous 12 months; (2) Perimenopause manifests as women having irregular, inconsistent menstruation happening within the previous 12 months; (3) Post-menopause is defined as no menstruation in the past 12 months.¹⁵ There appears to be an abundance of research on the different effects of menopause and its varying stages on the physical, psychosocial, and mental capacity of women who do not have HIV. However, data concerning WWH and experiencing menopause has lagged in previous years and the relationship between HIV and menopause needs more investigation. In any event, there is some evidence documented of self-reported menopausal symptoms in pre-, peri-, and post-menopausal WWH having a higher prevalence and severity of psychological symptoms and sleep disorders than women in the general population.⁵ Knowledge deficits must be addressed in order to determine clinical guidelines for symptoms that adversely affect a woman's quality of life and mitigate the risk of age-related comorbidities.^{3,4}

Despite advances in ART, HIV still has no cure, and WWH may experience an earlier menopause and a higher symptom burden than in women who do not have HIV.³ Anyone taking ART is considered virally-suppressed when lab results show a viral load (measurement of virus in the blood) of HIV so low that it is not detectable by a blood-drawn lab test. Virological suppression in HIV means that the chronic immune activation (inflammation) experienced in uncontrolled HIV is reduced. WWH

may transition through the phases of menopause slightly differently compared to women who do not have HIV. However, even when HIV is virologically suppressed, studies have still shown challenges in diagnosing menopausal status. Abnormal bleeding and amenorrhea patterns are common in WWH, while HIV symptoms are increasingly more difficult to distinguish from generalized menopausal symptoms.¹ HIV compromises a woman's health and well-being without menopause and with menopause WWH may be misdiagnosed due to a prolonged amenorrhea at about a 20 percent higher rate than the general population.⁷ Multiple factors are of concern for WWH transitioning through menopause. Sub-optimal patient self-management of HIV results in an uncontrolled viral load and corresponding chronic immune activation systemically where opportunistic infections and other comorbidities go unchecked.⁶

WWH, particularly post-menopausal women, are at an increased risk for cardiovascular disease and osteoporosis. However, menopausal hormone therapy (MHT) has been researched and evidence suggests a protective benefit in bone and cardiovascular health that outweighs risks like blood clots.¹ MHT is demonstrated effective and safe for treatment of problematic vasomotor symptoms in healthy women but is rarely offered to WWH.⁴ Synthetic and biosimilar estrogen and progesterone were once published and presented to the public as "relative" risk for strokes and embolism, which led to decreased use of MHT. The underuse of MHT in WWH has been attributed to a lack of comfort in managing menopause by providers who may not be knowledgeable about HIV, menopause, MHT, or a combination of some or all of these in the management of WWH and menopause. Overall, providers either lack knowledge of management guidelines or are apprehensive over ART and MHT drug interactions.^{1,4}

Additionally, there is a lack of consensus guidelines for diagnosing and/or managing menopause in WWH. Scofield et al. conducted a comparative guideline review using five HIV and six general menopause management guidelines, published between 2015 and 2023.¹ Their findings reported that none of the 11 guidelines offered guidance to effectively diagnose menopause or to differentiate HIV symptoms from menopausal-related symptoms. Particularly in post-menopausal women, HIV guidelines do not specifically offer a diagnosis methodology for menopause or menstrual cycle assessment.¹ Providers' lack of knowledge in managing HIV and menopause coupled with inconsistent diagnosing and management guidelines of WWH experiencing menopause leaves providers being inconsistent in the assessment and treatment of menopausal symptoms in WWH.¹





Current clinical practice guidelines follow the Menopause Society position statement, which states:

“Hormone therapy remains the most effective treatment for vasomotor symptoms (VMS) and the genitourinary syndrome of menopause and has been shown to prevent bone loss and fracture. The risks of hormone therapy differ depending on type, dose, duration of use, route of administration, timing of initiation, and whether a progestogen is used. Treatment should be individualized using the best available evidence to maximize benefits and minimize the risks, with periodic reevaluation of the benefits and risks of continuing therapy. For women aged younger than 60 years or who are within 10 years of menopause onset and have no contraindications, the benefit-risk ratio is favorable for treatment of bothersome VMS and prevention of bone loss...”⁸

Increased Bone Loss

There are negative effects of having HIV, taking ART, and the hormonal changes during menopause on a woman's skeletal integrity. The intricate relationship between HIV, ART, and bone disease necessitates the need for early diagnosis and preventative strategies to mitigate the increased risk of osteopenia, osteoporosis, and fractures in WWH.⁹ Changes in bone mineral density (BMD) during

menopausal transitions have been noted in total body (TB) BMD in WWH than in women who do not have HIV. Madanhire et al. published a longitudinal study of urban-dwelling women of South Africa and concluded that bone-loss related to menopause was greater in WWH.¹⁰ Based on the findings from that study the authors suggest that providers should conduct routine bone health assessments as menopausal WWH are at greater risk for osteoporotic fractures.¹⁰

In another study conducted by Cabrera et al., which enrolled 104 WWH on long-standing ART and 212 women without HIV aged 40 years old or older, dual X-ray absorptiometry tests were obtained to assess BMD at the lumbar spine (LS), femoral neck (FN), and total hip (TH). A subset of enrolled patients also obtained lateral thoracolumbar X-rays. WWH in that study had an increased prevalence of vertebral fracture and a 0.032 g/cm² lower FN BMD ($p = 0.012$) and 0.034 g/cm² lower TH BMD ($p = 0.041$) compared to the group of women without HIV. However, the study authors recommended the need for larger studies to inform prevention guidelines.¹¹

Bone demineralization results from direct HIV effects. HIV infects osteoblast precursors and disrupts immune system interactions and normal bone formation leading to impaired osteogenesis (bone formation) which can lead to bone turnover and bone loss. HIV immune-facilitated systemic processes appear to stimulate osteoclasts

(break down bone tissue) which disrupt the bone remodeling process, leading to an increased risk of osteopenia, osteoporosis, and bone fractures.¹² MHT is beneficial to prevent bone loss and reduce fractures. MHT with estrogen prevents osteoclastic bone resorption, while progesterone works by promoting osteoblast-mediated bone formation.⁴

However, certain ART medications do have a contributory role in bone disease. Tenofovir disoproxil fumarate (TDF), a nucleoside reverse transcriptase inhibitor (NRTI) used in combination with emtricitabine (FTC) (another NRTI) in HIV pre-exposure prophylaxis and in combination ART medications used to treat HIV was shown to cause decreased BMD considerably more than other HIV medications.¹³ A systematic review and meta-analysis conducted by Baranek et al. was specifically done to quantify the impact of oral TDF/FTC on BMD and the risk of osteoporosis, low bone mass, and fractures in patients taking it as PrEP, HIV treatment, and hepatitis B virus (HBV) treatment.¹³ The study illustrates the adverse effects of TDF on BMD. This information, when pooled with the understanding of bone demineralization experienced in menopause and concomitant HIV interconnectedness, requires providers to routinely assess for risk of osteoporosis and menopausal status. Comprehensive management strategies can increase overall quality of life for WWH through early diagnosis and prevention.

Cardiovascular Risks

The negative effects of having HIV, taking ART, and the hormonal changes during menopause on a woman's cardiovascular risk continues to be studied. Research conducted in the early 2000s showed HIV as an independent risk factor for cardiovascular disease (CVD) and risk of stroke, heart attack, or heart failure.¹⁶ However, more research is needed to understand the link between CVD and HIV and how these are affected by post-menopausal status. Even in the context of virological suppression, CVD has a higher relative risk (1.5 to 2 fold) in WWH among a range of disease phenotypes compared to women without HIV.¹⁶ CVD can be related to chronic HIV risks and sex-specific risks which medical providers must understand as multifactorial pathways of traditional risks of CVD. Providers must be well-versed on presentation of overt symptoms. Again, HIV compromises a woman's health and well-being without menopause, and with menopause WWH may be misdiagnosed due to lack of provider knowledge and inconsistent clinical management guidelines.

MHT, while beneficial, is controversial in its use and effect on CVD. However, evidence does support



the protective effect of MHT on the goal endpoints of cardiometabolic research in women less than 60 years of age and when MHT was started within 10 years of menopause onset. Estrogen-based hormone therapy has been associated with a slower progression of subclinical atherosclerosis over time.¹⁷ Premature reproductive ageing (attributed to HIV) and severe vasomotor symptoms are guideline-approved indications for menopausal hormone therapy (MHT) but is not utilized by providers as often as it should be.

The Women's Health Initiative (WHI), published in 2002, consisted of randomized controlled trials of two hormone therapies (conjugated estrogen alone versus placebo, and estrogen-progestin versus placebo) for asymptomatic menopausal women. The findings of these trials were disseminated widely and raised the source of concern for MHT increasing the risk of blood clots and breast cancer. This concern led to the decreasing use of MHT in all women with menopause, whether symptomatic or not.⁴ Studies performed after the WHI established a low risk for CVD in women with no history of CV events and when MHT is initiated early in menopause. Every woman in menopause should be assessed if vasomotor symptoms have indicated the benefit of MHT, particularly in WWH as HIV is suggested to promote early menopause. MHT should be discussed and started in early menopause to be optimized in alleviation of the effects of menopausal symptoms.

Disparities in HIV and Menopausal Care

Gaps in literature, lack of provider confidence, and differing clinical recommendations have resulted in inequitable menopausal care for WWH. None of the HIV guidelines researched for this article offered a definitive definition of menopause, nor a method of diagnosing menopause or assessing menopausal phases.¹ The accepted post-menopausal definition is in women of a certain age without menstrual cycle for a continuous 12 months with no other biological or psychological cause. Medical providers surveyed lacked confidence in assessing menopausal status and symptoms, and managing menopause in women with HIV.^{1,4,14} Furthermore, the criteria for the stages of menopause vary in the scientific literature and are defined inconsistently, which represents a challenge for determining clinical assessment tools to effectively diagnose, stage, and treat menopause in WWH.³

The goal of addressing menopause in WWH should be to achieve/maintain viral suppression while integrating a proactive patient-centered, multi-disciplinary strategy into HIV care to address bone and cardiac health. In an effort to ultimately enhance the quality of life of WWH experiencing menopause, providers must employ consistent, evidence-based strategies that focus on risk identification, vigilant screening, effective preventive measures, tailored treatments, and informed decision-making.⁹ Until further evidence is made available on the effects of

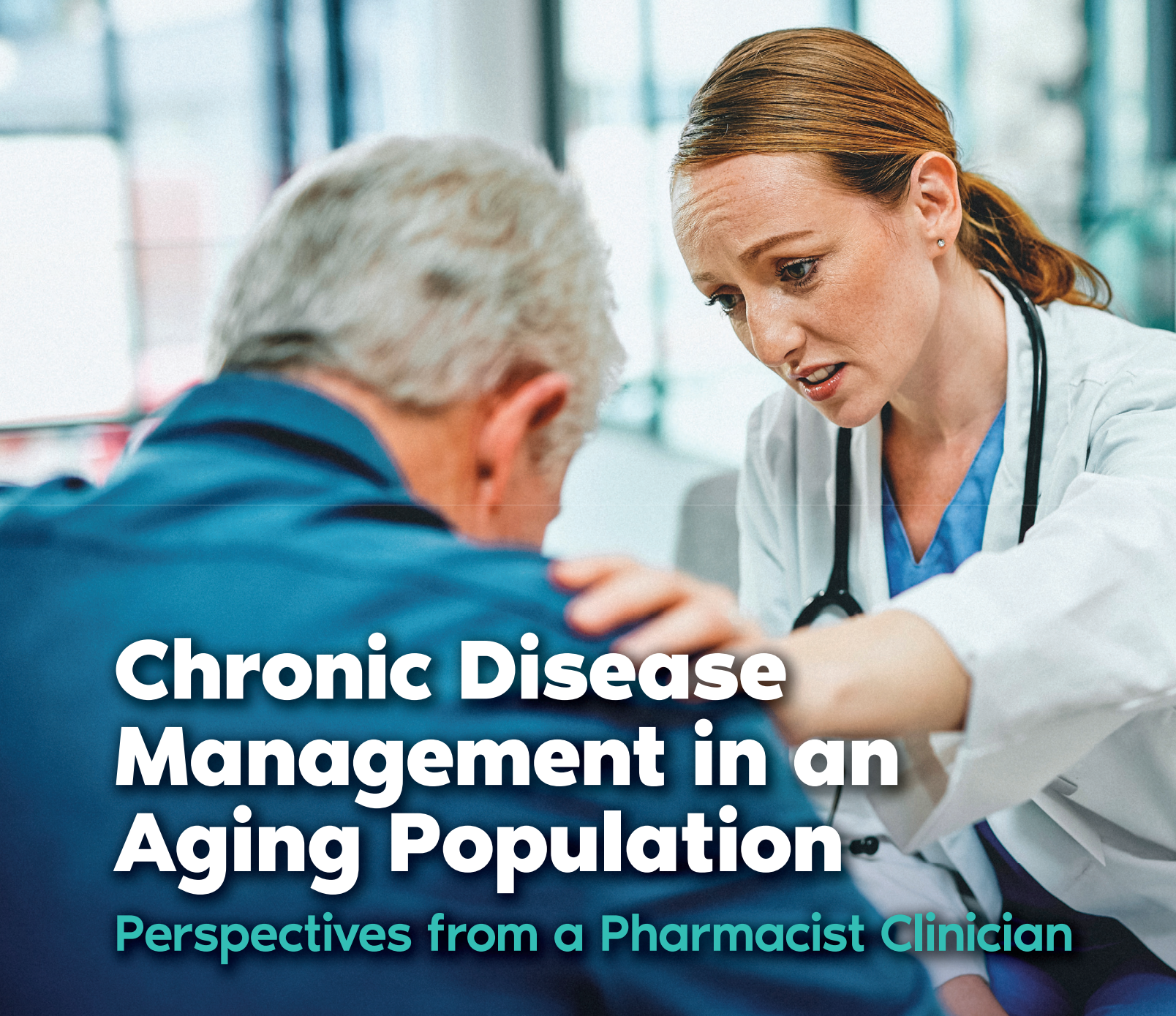
HIV in conjunction with ART and MHT in the context of menopause, providers should use bone assessment screenings and assess cardiovascular event risks. There is no contraindication for increased CVD risk and MHT. Providers must discuss and offer MHT as indicated in current evidence-based guidelines in HIV and menopause management. Providers should monitor WWH and without HIV closely at the initiation of MHT and throughout treatment assessing for changes in bone and cardiovascular health.⁴ Furthermore, providers should utilize current available evidence in their discussions with WWH and the risks and benefits of all applicable disease processes and related potential comorbidities. As with any disease process, women must educate themselves and have informed discussions with their medical provider to advocate competently for themselves to strive for optimal health outcomes. **HIV**



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Chronic Disease Management in an Aging Population

Perspectives from a Pharmacist Clinician

BY CARLY CLOUD FLOYD, PHARMD, PHC, AAHIVP, CDCES, TTS

IMAGINE YOU'RE A PROVIDER in a busy clinic seeing a 65-year-old person with well-controlled HIV diagnosed in 1991. This is their first visit with you to establish care and discuss new onset diabetes with a hemoglobin A1c (HbA1c) of 7.9 percent. They also have high blood pressure, hyperlipidemia, neuropathy, chronic kidney disease (CKD), osteoarthritis, depression, and anxiety. Your patient shares that they take 15 different pills throughout the day and they regularly have appointments with five outside providers. They recently got Medicare and their prior authorization (PA) for the antiretroviral therapy (ART) they've been on for years was denied, so they tell you they are giving up. Your patient's partner is present today and is also frustrated, especially since they have noticed your patient forgetting simple tasks in the last two months. Your next patient is in 10 minutes and you have a busy clinic day ahead of you. How would you approach this scenario? What are your priorities?



Pharmacy Practice and Pharmacist Clinicians

Pharmacists are well-known to be an integral part of the interdisciplinary care team, especially in the treatment of HIV.¹⁻³ As the field of HIV treatment has had many scientific advances over the last 43 years, including prevention and more recently long-acting injectable (LAI) treatment, the roles of pharmacists within this field have also grown. HIV pharmacists can practice in a variety of settings, including in hospital and retail pharmacies, as clinical pharmacists on an infectious disease (ID) team at the hospital, in outpatient primary care clinics, in administrative roles, and also by participating in clinical research, to name a few. Additionally, many states have HIV pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) pharmacist prescriptive authority, allowing prescribing of medications (via statewide protocol) to prevent HIV acquisition after successful training and certification.⁴

Four states (New Mexico, California, Montana, and North Carolina) have advanced practice licenses for pharmacists.⁵ In 1993, New Mexico was the first state to pass legislation called the Pharmacist Prescriptive Authority Act (PPAA), which created a new designation, the Pharmacist Clinician (PhC), for licensed pharmacists completing additional training requirements, including training in diagnosis and physical assessment equivalent to that of physician assistants. And in 2000, North Carolina passed their Clinical Pharmacist Practitioner Act (CPPA).⁵ I am fortunate to be practicing in New Mexico as a PhC since 2010, one of a few hundred practicing PhCs in the state.

Starting Out as a New Practitioner

It's really amazing to see how far we have come in HIV care as I reflect back on my career, and yet I am intimately aware that we still have so much work to do. When I moved to the border town of El Paso, Texas, in 2009 to start my community-based pharmacy residency focused on HIV care, I was not sure what to expect to learn. I vaguely remembered my didactic lectures on HIV medications, opportunistic infections, and all the pictures of side effects from protease inhibitors. As a resident, I spent late nights studying brands and generics and recall how hard it was to keep all the abbreviations straight. The very first single tablet regimen (STR), Atripla (efavirenz/tenofovir DF/emtricitabine), hit the market a few years before, and a completely new class of medications called integrase inhibitors were introduced during my third year of pharmacy school when raltegravir was approved. There were positive advances in HIV care happening and I would personally get to help people with HIV (PWH) experience them. I couldn't wait to share my knowledge with patients!

I wasn't prepared for the impact that the people, the

While this is a completely hypothetical scenario, it's a very plausible one, as I've seen many folks like this over the last 15 years as a pharmacist clinician. When I started my career 15 years ago, my priorities would have been to immediately switch ART regimens and to go over diabetes basics. I would have likely prescribed more medication for diabetes (metformin twice a day at minimum) and scheduled a follow up with me in a few days so I could teach this patient and their partner how to use the new glucometer I would be prescribing.

Today, I approach complex cases like this one in a completely different manner. Before I share my evolving clinical strategies, I want to first explain how my training in pharmacy and my experience has changed my perspective.

real-life humans, would begin to make in my life. About three weeks into my residency, I remember one of the patients came in to get cryotherapy (removal) of his anal warts. He was so nervous and very ashamed. My preceptor later explained to me that because of this patient's religion, he carried so much shame and stigma. The patient was worried that if word got out about his status, people would think he was gay, and he would then be ostracized from his church community.

This was the moment I started understanding how the stigma of having HIV can cause so much more damage than the virus itself. Humans, whether with HIV or without, want to be in community, and when that is in jeopardy because of a chronic health condition, people will hide parts of themselves and carry secrets full of shame just to survive. I wish I could say this has changed and that in 2024 we don't see this in the real world, but sadly, it's one of the most common threads I've continued to address in patient care as a PhC.



My first role after residency was primarily to focus on ART regimen optimization and adherence. I'd review genotypes and phenotypes and pull up mutation charts to figure out the puzzle of which medications might be the best for each person with the least amount of side effects. I'd focus on drug-drug interactions, especially with boosted ART.

Taking a New Approach Now

Thankfully, PWH are living longer. Data from the Kaiser Life Expectancy Cohort from 2000 to 2016 has tracked almost 40,000 PWH and compared them to almost 400,000 people without HIV.⁶ The overall life expectancy gap is narrowing to a 9.1 year difference between groups, and even smaller at 6.8 year difference in PWH who started ART when their CD4 counts were greater than 500. However, what is not improving over time is that PWH live 16 fewer comorbidity-free years than people without

HIV. Liver, kidney, lung, and cardiovascular disease as well as diabetes and cancer occur earlier in PWH, likely as result of chronic inflammation, even with consistent viral suppression on ART.

Today, I actually spend only a small portion of my time focusing on ART optimization and drug-drug interactions. Instead, mostly I focus on chronic disease state management. Here are some clinical pearls I've adopted in my approach to caring for PWH (and even for those without):



People want to be active participants in their care.

PWH, especially those who have lived with HIV for decades, want to maintain a good quality of life. For the most part, they want to take part in medical decision-making, and

for good reason. It's their body, and they should be central in deciding the next step after an informed discussion of the options.

In my practice, I like to spend a few minutes going over the best options, and share the pros and cons of each, then let them decide what they prefer. Often, I'll think one will prefer a pill over an injection, but I've been surprised time and again when I hear from people that the thought of one more pill is too much and they won't take it.



People take too many pills.

I doubt this comes as a shock to most people reading this article. While we've had great advances in ART with STRs and LAI, there are plenty of other medications on their list.

I have a hard time taking my six medications and vitamins once a day. Just ask my partner, who routinely texts me and says, "Hey, you forgot your pills. Should I bring them to you at work?" I have a tiny glimpse into what my patients feel and the struggles they have day in and day out, and I don't need to take things multiple times a day like many of them do.

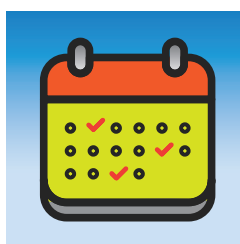
When I review medication lists, my first question to myself is always "How can I make their pill burden and frequency easier?" I think about combination tablets on the market that might make their pill box less full and look for once-a-day/long-acting formulations instead of twice-a-day so that they are set up for success in adherence. I also consider what medications they are on because "they've always been on them" and whether any of them are treating side effects of one medication with another.



People need an advocate.

Sometimes those combination pills or extended-release, once-a-day formulations require a PA, which means someone needs to fight for them to have a better quality of life. Insurance companies see a form but I'm seeing

a person in front of me, so I make it my mission to use verbiage that the insurance reviewers want or need to see to approve the medication. I don't always win these battles, but I definitely try hard. Obviously, advocating requires time that we don't have, but I'll anticipate when a PA might be needed and copy and paste into my visit note specific language to hopefully get an approval the first time.



People are tired of having appointment after appointment.

As PWH age, they start to "collect" specialist providers, which leads to appointment after appointment...and exhausted people. Their lives become consumed by medical and therapy

appointments. I am always just one more visit to add to their growing list.

My strategy to combat appointment fatigue is to coordinate my appointments on the same day as their primary care provider or specialist when possible. I also use telemedicine when possible to allow my patients to stay at home and save time and money. Sometimes I assist with communication between providers or reach out to my interprofessional team to help when I am running late or behind.



People want to share their stories.

We are in a busy medical field with clinician shortages, burnout, turnover, and lack of resources. The push is to do more with less time, which means we rarely have time to listen to people. Often providers

have 15-minute visit slots which translate to maybe five to 10 minutes directly with the patient.

When they make it to my appointment, I make it part of my job to listen so the person in front of me can feel heard. Sometimes I'm just a safe place for them to vent. I'll admit, this is challenging even today as I don't have the luxury of unlimited time. However, if they give permission, I try to get to know them and learn even one thing about their lives. Sometimes they just want to have someone who cares about what they are going through.

Building Connections for Better Care

Let's go back to the initial scenario: a 65-year-old on 15 medications, ART denied by insurance, and now diabetes is on their ever growing list of medical conditions. Today, I would start by asking what are the top one or two things that they'd like to focus on and prioritize listening. I would empathize with them; they are clearly tired and frustrated. What is the ART regimen that was denied? Is it a newer medication not on formulary? I could schedule a peer-to-peer with the insurance to learn more about the denial. Maybe it's an older ART regimen that isn't widely available. I might be able to gain some trust and help them find a simpler, better tolerated regimen.

While diabetes is a clinical priority, today we can just talk about it. I want to prioritize the questions the patient and partner have first and not overwhelm them with all the details they'll eventually need to hear. I might start by asking what they know about diabetes and what their fears are, so we can talk about it openly and honestly. If the patient is eager to start a medication, we could discuss options today and prescribe if desired, but it also could wait a few weeks given the HbA1c is not critical. At the end of the day, the patient is in the driver's seat and I will do my best to keep them safe in their medical journey.

Ultimately, my hope for the next 15 years as a PhC is that I never lose sight of the fact that each of my patients is a whole person, one with complexities and desires, hopes, and dreams. **HIV**



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Grounding Current HIV Pre-Exposure Prophylaxis Uptake

BY EVAN HALL, BS, MPH

SYSTEMIC RACISM is a dominant force in research practices, and studies pertaining to pre-exposure prophylaxis (PrEP) are no exception.¹ It is important to look closely at sample demographics used in current studies of PrEP use. The rates of PrEP uptake in Black and Latino populations in the United States cannot be considered, though, without the influence of medical mistrust, the legacy of slavery, and the discriminatory policies from the U.S. government.^{2,3,4,5} The extent of these influences cannot be discussed fully in this article, yet they should frame future conversations on how providers, public health professionals, and others work to end the HIV epidemic.

PrEP is a once-daily pill or bimonthly injection to prevent HIV infection upon exposure through sexual behavior or injection drug use.^{6,7} As a highly effective biomedical intervention, PrEP adds to the toolkit of HIV prevention methods and is an essential element to ending the HIV epidemic in the U.S. The United States Preventive Services Task Force (USPSTF) designated oral PrEP as a grade A medication for prescribing to adolescents and adults at increased risk of HIV.⁸ Under this rating, insurance companies must cover PrEP and ancillary services (e.g. doctors' visits, labs) without cost sharing.

Despite these advancements to increase PrEP uptake, startling disparities persist among racial and ethnic groups, especially for Black and Latino people. In 2022, PrEP coverage for White men who have sex with men (MSM) reached 94 percent of those who could benefit compared to 24 percent of Latino and 13 percent of Black individuals.⁹ These discouraging contrasts in PrEP coverage coincide with a disproportionate burden in the percentage of new HIV transmissions among Black (40%) and Latino (29%) individuals.

Discrete choice experiments (DCE) are qualitative methods that weigh the trade-offs of individuals when engaging in a decision by choosing an alternative of a product or service that affords greatest benefit or utility. DCEs are increasingly utilized in health care settings to describe preferences for health care programs and products.¹⁰ The results from DCEs inform the health and non-health outcomes of new and existing drugs, which subsequently supports relevant policy for implementation.¹¹

This article will examine the designs and results of current oral PrEP DCEs in the U.S., and how they support (or contradict) current PrEP coverage.

Cost, Time, and More of Current PrEP DCEs Population of Interest & Sample Demographics

In the four of the five DCEs reviewed for this article, the focus was on MSM populations, with one study interested in high-risk drug

users.^{12,13,14,15,16} Although many races/ethnicities (White, Black or African American, American Indian or Alaskan Native, Asian, Hispanic/Latino) were included in these five DCEs, only White, Black, and Latino were of interest to this study. All other demographics are aggregated under the categorization as 'Other.' In all of the DCEs, White individuals comprised the majority of participants, ranging from 54.7 percent to 87.4 percent. Black individuals totaled a range of 7.4 percent to 18.2 percent, while Latino individuals ranged from 14.1 percent to 27.5 percent. It is important to note that some studies did not disaggregate Latinos within racial categorization as an ethnicity.

Attributes of DCEs

Across the five studies, there were a total of 17 unique attributes. The most common attributes were cost (4); dosing (4); PrEP treatment location (3); side effects (2); and dispensing venue (2). Other singular attributes included: mode of transportation; efficacy; frequency of HIV testing; prescription practices; adherence support; PrEP insurance coverage; insurance privacy; PrEP timeliness; provider type; and lab evaluation location.

Results of DCEs

Cost was either the most important attribute or was included in the package most selected by participants in three out of the five DCEs. For Gutierrez et al., the dosing method was the most important attribute.¹⁵ One study indicated that a majority of the participants had "no-preference" to cost, time, side effects, or mode of transportation.¹³ Following cost, Shrestha et al. indicated efficacy of PrEP and side effects as important to participants.¹⁶ Similarly, after cost, Asiago-Reddy et al. showed that same day access and online PrEP were other critical attributes.¹² Daily tablet and on-base military care were found as highly ranked attributes by Gutierrez et al.¹⁵ Other preference categories by Dawit et al. were side effect-conscious and cost and time-conscious in order of ranking by participants.¹³



Dominance of Cost and Impacts to PrEP Uptake

Despite the majority of new HIV transmissions in the U.S. being among Black individuals, our study reveals that DCEs for oral PrEP were primarily comprised of White participants (54.7% to 87.4%), while Black individuals comprised a smaller percentage in each DCE (7.4% to 18.2%). Similarly, Latino individuals accounted for 14.1 percent to 27.5 percent of participants in DCEs, while also sharing a disproportionate burden of new HIV transmissions. Cost was the highest ranked attribute across a majority of the DCEs in our study. Interestingly, one study indicated that no preference to cost was ranked highest as compared with effect-conscious and cost and time-conscious. This same study indicated that racial/ethnic minority gay, bisexual, and MSM as well as those with lower educational attainment were less likely to be side effect-conscious. No other DCE described racial/ethnic differences in attribute selection. It is important to note that cost was not a factor in Gutierrez et al. because military MSM are insured by Veteran Affairs, where no cost is incurred for PrEP medication or ancillary services.¹⁵ Thus, these results may not generalize to the broader U.S. population.

Sociocultural and Structural Influences on PrEP Uptake

Many qualitative studies have examined the sociocultural and structural influences on PrEP uptake for Black people in the U.S. While PrEP awareness for Black individuals remains low, one study found that the majority of patients screened for PrEP were white

MSM, even though the epidemic disproportionately burdens Black Americans more.^{17,18,19} Even if individuals are screened for PrEP, the gaps in the PrEP care continuum are concentrated in populations bearing the greatest burden of the epidemic.²⁰ One study found that medical students stereotype Black MSM as more likely than White MSM to engage in increased condomless sex when on PrEP, which was also found to promote racial bias and decrease willingness to pay.²⁰ The basis of medical and research mistrust for many Black MSM inhibits future clinical trials for PrEP from recruiting those who could most benefit.²¹

More generally, stigma, homophobia, mistrust of health care systems, negative attitudes from health providers, access and transportation issues, poverty, and misinformation compound to reasons why Black individuals do not have high PrEP uptake.^{18,21,22,23} Although cost was ranked in these qualitative studies, factors such as community/social network influences and stigma remained more pervasive as deterrents to accessing PrEP.²³ One study indicated that 38 percent of Black community members were more than a one-hour drive from a PrEP provider.¹⁸ When cost was outlined in these studies, it expressed concern for those living in Southern states without Medicaid expansion and the lack of awareness of payment support programs for those who are uninsured.^{19,23} These qualitative studies plainly spell out the types of sociocultural and structural barriers that Black individuals face accessing PrEP.

As Latino MSM also face a disproportionate burden of new HIV transmissions, it is critical to examine how qualitative research frames barriers to access and care for PrEP. Similarly to Black populations, Latino individuals had low knowledge and uptake of PrEP.²⁴ Additionally, stigma remained a persistent issue of concern for Latino MSM.²⁵ One study indicated six unique themes among Latino MSM with regards to PrEP initiation: (1) perception that PrEP users engage in risky sexual behaviors; (2) PrEP-induced conflict in relationships; (3) perception that PrEP users are HIV-positive; (4) generation differences in attitudes toward HIV prevention; (5) experiences of discomfort, judgment, or homophobia from medical providers; (6) gay stigma related to PrEP disclosure to family.²⁵

These barriers were not captured within any attributes of the studies found for our analysis. There is a large discrepancy, one survey found, in the interest and knowledge of PrEP (62%) and admitting using or having used PrEP (2.6%).²⁴ This same study indicated that much of PrEP messaging focuses on negative aspects of Latino culture, which can subsequently inhibit sociocultural acceptance or normalization of PrEP. Interestingly, within the Latino population, Latino-only individuals have a lower odds of PrEP eligibility and first prescription compared to White-Latino individuals.²⁶ The stark contrast in PrEP eligibility and prescription rate suggest underlying decisions beyond the individual's control, such as stigma, is driving a decision of PrEP uptake.

Data on PrEP coverage and uptake exists in the U.S.⁹ As mentioned previously, in 2022, PrEP coverage for White MSM reached 94 percent of those who could benefit compared to 24 percent of

Latino and 13 percent of Black individuals. The existing DCEs on oral PrEP commonly promoted how cost was the most important factor in preference decision making.^{12,14,16} Whether these results informed policy changes to significantly reduce PrEP costs, which are nearly \$0 for those on insurance, the major strides to increase PrEP access on a national scale only relates to cost.

Hence, while some may be surprised at the sizable gap in PrEP coverage, our study communicates the predictability of this outcome. The majority of participants across all DCEs in our study were White. When cost is communicated as the most influential attribute, our study suggests this selection is based on the sizable influence of the majority of participants who were White. Therefore, when policy changes on cost for PrEP occur, those who were primarily influenced by cost will benefit from this change, while those who were not, including Black and Latino individuals, will not increase PrEP coverage.

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Where We Must Go with PrEP DCEs

The sample demographics of future PrEP DCEs must be representative of those who are disproportionately burdened by the HIV epidemic, and not entirely focused on those who are already benefiting from the latest prevention modality. In other words, Black and Latino individuals should be prioritized in both the development of attributes and options/packages in qualitative research and in DCEs on PrEP. Hypothetical bias could be mitigated if a more accurate set of attributes are presented to participants, while also pushing for a non-hypothetical DCE on PrEP to examine other possible solutions to real preferences and payment. Qualitative evaluation should act as a tool of progress in PrEP uptake, continually assessing the best metrics on the PrEP continuum to make such a decision. **HIV**



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UPDATE

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FEATURED LITERATURE

Hernandez AL, Hilton JF, Scott C, et al. Prevalence of anal HPV infection and anal HSIL among MSM 50 years and older living with or without HIV. *JAIDS*. 2024 May 2. doi: 10.1097/QAI.0000000000003450.

This report provides baseline data from the Anal HPV, HIV, and Aging (AHHA) Study evaluating the prevalence and incidence of anal HPV infection and anal HSIL in a cohort of men who have sex with men $\geq$ 50 years of age with and without HIV. Participants completed a behavioral health questionnaire and underwent collection of anal swabs for cytology and HPV DNA genotyping, and DARE. HRA with guided biopsy of visible lesions was also performed. There were 238 participants enrolled (129 with HIV and 101 without HIV); 54 percent were ages 50-59, 36 percent were 60-69, and 10 percent were 70+ years of age.

Most participants with HIV had an undetectable HIV viral load at enrollment (median CD4 was 585 cells/mm³). Men who have sex with men (MSM) with HIV had a significantly higher prevalence of any oncogenic anal HPV infection compared with MSM without HIV (70.9% vs. 57%). Overall, prevalence of biopsy-confirmed anal HSIL was 42.6 percent; after accounting for HIV status and CD4, HSIL prevalence did not differ significantly between MSM with and without HIV. Multivariate analyses indicated that HPV-16 (and other oncogenic HPV infection) was associated with increased odds of prevalent anal HSIL. Increasing age was not associated with prevalent HSIL, HPV-16, or other oncogenic HPV infections.

AUTHOR'S COMMENTARY

Consensus guidelines from the International Anal Neoplasia Society were released earlier this year recommending commencement of anal cancer screening at 35 years of age for MSM and transgender women with HIV (and 45 years of age for MSM and transwomen without HIV). These results from the AHHA study, which was unique in that it specifically enrolled participants $\geq$ 50 years of age (both with and without HIV), reaffirm the high prevalence of anal HSIL in these populations. The number of people eligible for anal cancer screening is likely to increase in the future. Therefore, it is critical that access to timely follow-up evaluation by experienced providers not continue to be a barrier to offering equitable cancer prevention and treatment interventions.

FEATURED LITERATURE

Lowenthal ED, Chapman J, Ohrenschaal R, et al. Acceptability and tolerability of long-acting injectable cabotegravir or rilpivirine in the first cohort of virologically suppressed adolescents living with HIV (IMPAACT 2017/MOCHA): a secondary analysis of a phase 1/2, multicentre, open-label, non-comparative dose-finding study. *Lancet HIV*. 2024 Apr;11(4):e222-e232. doi: 10.1016/S2352-3018(23)00301-6. PMID: 38538161.

The international More Options for Children and Adolescents (MOCHA) study evaluated long-acting cabotegravir and rilpivirine (LA-CAB, LA-RPV) in adolescents ages 12-17 years. This secondary analysis describes LA-CAB and LA-RPV tolerability and acceptability among participants. Quantitative data were collected from staff-administered questionnaires; in-depth interviews with U.S.-based participants and parents/caregivers were conducted. Twenty-nine out of 53 (55%) participants completed a questionnaire regarding reasons for switching; they indicated their primary reason was so they did not have to take daily pills. At week four, 43/52 (83%) reported the injection did not hurt or hurt a little bit.

Themes from in-depth interviews included not having to worry about hiding pills from peers and avoiding the stress of monitoring adolescents' daily medication-taking. A common concern was the ability to maintain a routine injection schedule, particularly in the event of college relocation. Pre-study disagreements were noted between adolescents and parents/caregivers regarding whether the adolescent should initiate long-acting ART. For parents/caregivers with a higher level of hesitancy, trust in their health care provider was a key factor. Injection location was the most consistent concern among adolescents. However, all interviewees indicated they would recommend long-acting formulations to peers. A few noted that more frequent clinic visits could add to the stress related to living with HIV.

AUTHOR'S COMMENTARY

Data from a MOCHA study interim analysis led to the expanded indication for use of long-acting cabotegravir/rilpivirine among virologically suppressed adolescents with HIV. Results of this secondary analysis help guide implementation for providers and programs that deliver adolescent services by highlighting not only what drives interest in long-acting injectable therapies, but also what factors (e.g., trust in health care providers, the injection environment, and adaptability/flexibility) might be especially important for decision-making and sustainability. Injection-related symptoms, although common, did not seem to adversely impact quality of life. In-depth interviews were limited to a small number of U.S. participants, and additional evaluations in other contexts and across diverse sub-populations (such as younger adolescents) are needed to inform how to best support adolescents who opt to start long-acting ART.

FEATURED LITERATURE

Roen AO, Peters L, Wandeler G, et al. Chronic liver enzyme elevation and use of contemporary ARVs among persons living with HIV. *Open Forum Inf Dis*. 2024 June 8. Online ahead of print. <https://doi.org/10.1093/ofid/ofae308>

Data from participants in the International Cohort Consortium of Infectious Diseases (RESPOND) collaboration were analyzed to determine chronic liver enzyme elevation (cLEE) incidence and associated factors, focusing on commonly prescribed contemporary ARVs. cLEE was defined as chronic ALT elevations greater than the upper limit of normal (ULN) at two or more visits across at least six months and within two years of baseline. People newly initiating DTG, RAL, EVG/c, BIC, boosted DRV or ATV, RPV, or EFV were considered for inclusion (TDF and TAF use was also examined). There was complete data for 17,106 individuals who initiated a new ARV after 2012. Overall, 1,932 (11.3%) developed cLEE during 87,924 PYFU; this corresponded to an incident rate (IR) of 22.0/1000 PYFU. Fifty-one percent had less than Grade 1 severity ($>ULN$ to $1.25\times ULN$) and 40 percent had Grade 1 (1.25 – $2.5\times ULN$). Investigators did not observe any cumulative association between longer ARV use and cLEE for any of the considered ARVs. For all ARVs of interest, cLEE IR was highest in the first six to 12 months after medication initiation and declined thereafter. No association was observed between use of any INSTIs and cLEE; TDF use was associated with increased risk, and use of boosted DRV was associated with decreased risk. Viral hepatitis status, dyslipidemia, and BMI were also associated with cLEE.

AUTHOR'S COMMENTARY

Chronic liver enzyme elevation remains prevalent with currently used ARVs. This large multi-national study, which included people initiating newer INSTIs and followed for a median of five years, observed generally low-grade ALT elevations particularly in the first year after new ARV initiation. After adjustment, INSTI initiation was not associated with short-term risk of cLEE. Consistent with prior studies, use of EFV, RPV, and TDF in this cohort were associated with increased risk of cLEE (point estimates for EFV and RPV were not significant however). Although this analysis is limited by lack of additional detail (i.e., exposure to known hepatotoxic substances) and minimal participant diversity ($> 75\%$ were European males), it is reassuring to note that liver enzyme changes were modest and appeared to stabilize/improve after the first year.

FEATURED LITERATURE

McCartney EM, Ralton L, Dawe J, et al on behalf of the EC Australia partnership. Point of care testing for hepatitis C in the priority settings of mental health, prisons and drug & alcohol facilities—the PROMPt Study. 2024 Mar 21;ciae155. doi: 10.1093/cid/ciae155. PMID: 38513072.

PROMPt was a prospective cohort study evaluating point of care HCV antibody and RNA on testing rates and acceptability, linkage to care, and treatment in three priority settings: prison, an inpatient alcohol and drug unit, and inpatient mental health services in South Australia. Study teams (composed of HCV-experienced nurses and peer educators) provided pre- and post-test counseling, harm reduction education, and administered point of care testing (POCT). The HCV antibody screen utilized 10 μ l capillary whole blood; participants with positive antibody result were offered an RNA test (100 μ l capillary whole blood); participants with detectable HCV RNA were linked to care with the local viral hepatitis nurse service.

Among 1,549 participants, 98 percent indicated a preference for same-day HCV POCT compared to standard venipuncture and lab/instrument-based testing. There were 264 (17%) participants who tested antibody positive and 100 percent underwent reflexive RNA testing, with 55 (4% overall, 21% of antibody-positive participants) testing RNA positive. Across all three settings, there was an approximate three-fold increase in the rate of HCV antibody testing per year (and two-fold increase in RNA testing) in the intervention period compared to the historical control period, largely driven by increases in the inpatient alcohol and drug unit setting. For the 55 RNA-positive participants, 91 percent were linked to care and 86 percent initiated treatment; median time from referral to treatment was 14 days.

Author's Commentary

Streamlined HCV screening and testing can facilitate linkage to care, especially among populations that might not routinely access traditional “brick and mortar” clinics. These PROMPt Study results demonstrate that combined point of care antibody and RNA testing, delivered by interprofessional nursing and peer educator teams, are highly acceptable among individuals in priority settings and can expedite linkage to additional HCV care and treatment. Interventions such as these are necessary to help address the various systems-level and structural challenges which have precluded optimal integration and implementation of HCV elimination efforts.

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