

# HIV Specialist

## Providing Primary Care

for Patients Living with HIV

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Primary Care

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AMERICAN ACADEMY OF HIV MEDICINE

# Facing the Future of HIV Care

For **YOU**

For **YOUR  
PRACTICE**

For **YOUR  
PATIENTS**

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BY JAMES M. FRIEDMAN, MHA  
Executive Director, AAHIVM

# My Success

**A**FTER OVER A DECADE leading the American Academy of HIV Medicine, I recently announced that I will be stepping down as the organization's Executive Director effective January 31, 2019. The decision is bittersweet for me. I wholeheartedly enjoy my job, but after a nearly 50-year career in public health, I feel that now is the time to ease into retirement. I say ease in because I will be reducing my time gradually, continuing to work with the Academy two half days per week. It has been an extraordinary honor to lead this organization and I part with a grateful and full heart.

I could not be more pleased to also announce that the AAHIVM Board has unanimously approved Bruce Packett, our current Deputy Executive Director and Director of Professional Development, to take my place. I am certain he will do an even better job than I have.

A lot has changed since I joined the Academy almost 11½ years ago:

- With respect to our credentialing program, we have created a separate exam for HIV Pharmacists, extended the credential to 3 years, and nearly doubled the number of credentialed to over 3500. I would like to take credit for this, but it was past and current credentialing directors Peter Fox, Ken South and Dan Ebeling who deserve the credit.
- AAHIVM Membership is also up by about 60%. But again it was not me, but Ken South and Aaron Austin who made this happen.
- This magazine was also created under my direction. But it is Communications Director Amber McCracken who has developed and published every issue.
- Though I always thought of myself as a health policy guy, it was Holly Kilness Packett who developed our Policy



James M. Friedman

Platform, managed many White Coat Days, and increased our Advocacy efforts. Since the beginning of this year, Anna Forbes has taken over and has done a spectacular job.

- And we have expanded our educational offering by providing more CME workshops, consistently updating the *Fundamentals of HIV Medicine*, and creating digital tools such as the AAHIVM Core Curriculum. This has been due to the efforts of incoming Executive Director Bruce Packett.

- And finally it was Ericka Nanalig, who organized office management and financial accounting, so that we were able to keep staff morale high, our office organized and our finances on point.

So what have I done?

When I was interviewed by the AAHIVM Board of Directors Executive Committee for this position, I was asked how I thought I could succeed as the executive director. The answer was simple, "if the staff succeeds, then I succeed, and if they fail, then I will fail."

I have succeeded because we have been able to find, keep and challenge really great staff. To them, and to all of you, I am forever grateful. **HIV**

A handwritten signature in black ink that reads "James M. Friedman". The signature is fluid and cursive, with a long horizontal line extending from the end.

# In the NEWS

## IAVI Announces Clinical Trial of Next-Generation HIV Vaccine Candidate Designed to Induce Antibodies to Block HIV Infection

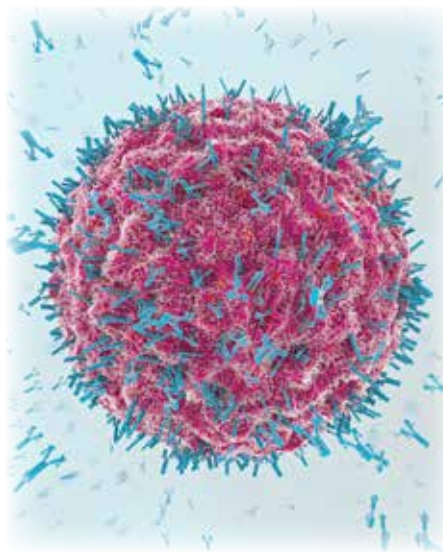
*Phase I Trial to Evaluate Safety and Immunogenicity of Vaccine Candidate Engineered to Elicit Targeted Immune Response Against HIV*

**THE INTERNATIONAL AIDS VACCINE INITIATIVE (IAVI)** announces the start of a Phase I clinical trial (IAVI G001)

to test a novel vaccine candidate designed to stimulate the immune system to initiate a key first step in the generation of potent proteins, known as broadly neutralizing antibodies (bNAbs), against HIV. The trial will evaluate the safety of the candidate and the immune responses it is able to induce. The candidate, known as eOD-GT8 60mer, represents an important step forward in the quest to develop an HIV vaccine.

Researchers widely agree that a vaccine that induces bNAbs will likely be the best way to confer durable protection against the virus. bNAbs are desirable because in laboratory experiments, they are effective against many of the genetically diverse strains of HIV, and in animal studies, they can block infection of a virus similar to HIV.

The IAVI G001 trial will enroll 48 healthy adult volunteers who will receive two



doses of eOD-GT8 60mer, along with the AS01B1 adjuvant developed by the pharmaceutical company GSK, or placebo. Adjuvants are substances used to enhance immune responses induced by a vaccine,

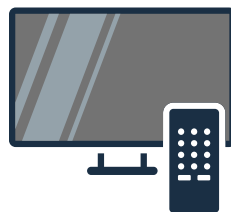
and the AS01 adjuvant is used in licensed vaccines. The doses are spaced two months apart and are administered through intramuscular injection.

The trial is taking place at two sites: George Washington University (GW) in Washington, D.C., and the Fred Hutchinson Cancer Research Center in Seattle, Washington. At GW, the trial is led by Dr. David Diemert, associate professor in the Department of Medicine, who will serve as the principal investigator at this site, and Dr. Jeffrey Bethony, professor in the Department of Microbiology, Immunology, and Tropical Medicine, who will direct the specimen processing and biorepository aspects of the trial at GW. At the Fred Hutchinson Cancer Research Center, the trial is led by Dr. Julie McElrath, senior vice president and director of the Vaccine and Infectious Disease Division.

Results of the IAVI G001 trial are expected in late 2019.

## PhRMA Members Take New Approach to DTC Television Advertising

*PhRMA Board of Directors Adopts New Voluntary DTC Principles and Will Launch New Platform to Provide Patients with Cost and Financial Assistance Information*



**TO HELP PATIENTS** make more informed health care decisions, Pharmaceutical Research and Manufacturers of America (PhRMA) member companies recently announced their commitment to providing more transparency about medicine costs. PhRMA member companies' direct-to-consumer (DTC) television advertisements will soon direct patients to information about medicine costs, including the list price of the medicine, out-of-pocket costs or other context about the potential cost of the medicine and available financial assistance. The biopharmaceutical industry will also launch a new platform that will provide patients, caregivers and providers with cost and financial assistance information for brand-name medicines, as well as other patient support resources.

## Gilead Subsidiary to Launch Authorized Generics of Epclusa and Harvoni

**GILEAD SCIENCES, INC.** announced plans to launch authorized generic versions of Epclusa® and Harvoni®, Gilead's leading treatments for chronic HCV, in the United States, through a newly created subsidiary, Asegua Therapeutics LLC. The authorized generics will launch at a list price of \$24,000 for the most common course of therapy and will be available in January 2019.

# In the NEWS

## Janssen Reports Switching to SYMTUZA™ Results in Maintained High Virologic Suppression and No Resistance Development up to 96-Weeks in Virologically Suppressed Adults with HIV-1

**T**HE JANSSEN PHARMACEUTICAL COMPANIES OF JOHNSON & JOHNSON unveiled new 96-week data for SYMTUZA™ (darunavir 200 mg, cobicistat 150 mg, emtricitabine 200mg, and tenofovir alafenamide 10 mg; D/C/F/TAF), a single-tablet regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) in treatment-naïve and certain virologically suppressed adults, in a presentation at IDWeek 2018 in San Francisco, CA.

Results from the pivotal Phase 3 EMERALD study demonstrate that in adults with HIV-1 who are virologically suppressed, switching to SYMTUZA™ resulted in maintained high virologic suppression (91%, 692/763) and low virologic failure (1%, 9/763) at week 96 (per FDA-Snapshot); low cumulative virologic rebound (3.1%, 24/763); and no resistance development, up to 96-weeks.

This 96-week extension study, which follows on from the earlier 24- and 48-week results, reinforced the long-term efficacy, resistance and safety profile of SYMTUZA™ as a treatment for virologically suppressed adults with HIV-1. The patient population studied in EMERALD included patients who may have experienced prior virologic failure and/or who may have resistance to emtricitabine. SYMTUZA™ was well-tolerated with 2% (14/763) of people experiencing a study drug related grade 3 or 4 adverse event (AE) and 2% (17/763) AE-related discontinuations over 96 weeks.

The most common AEs (all grades, ≥10% of adults) in the extension period were upper respiratory tract infection, viral upper respiratory tract infection, diarrhea, headache and back pain. After initial increases between baseline through to week 48, the lipid profile among

D/C/F/TAF patients remained stable thereafter. Improvements in renal and bone parameters were maintained in the SYMTUZA™ group over 96 weeks and consistent with known tenofovir alafenamide and cobicistat profiles.

In a separate analysis, switching treatment to SYMTUZA™ from the multi-tablet control regimen after 52 weeks achieved comparable efficacy and safety to the 48-week results in the group that switched immediately. In this late-switch group, after 44 weeks of SYMTUZA™ exposure, the virologic suppression and virologic failure rates were 94% (330/352) and 2% (6/352) respectively at week 96 (per FDA-Snapshot), and the cumulative rebound rate was 2.3% (8/352) from switch at week-52 through week 96. Over 44 weeks, in this late-switch group, serious adverse events and adverse event-related discontinuations occurred in 6% (21/352) and 2% (7/352) of adults respectively while on SYMTUZA™.

On September 25, 2017, SYMTUZA™ was approved for the treatment of HIV-1 infection by the European Commission based on results from a bioequivalence study that compared SYMTUZA™ with the combined administration of the separate agents darunavir [D] 800mg, cobicistat [C] 150mg, and emtricitabine/tenofovir alafenamide [FTC/TAF] 200mg/10mg fixed-dose combination. FDA approval was granted on July 17, 2018 based on the results from the two pivotal Phase 3 studies, EMERALD and AMBER.

AMBER is a double-blind, non-inferiority study evaluating the efficacy and safety of SYMTUZA™ in antiretroviral therapy (ART) treatment-naïve patients. Long-term 96-week data from AMBER will be presented at the upcoming HIV Glasgow Congress, taking

place October 28-31, 2018 in Glasgow, UK.

Additionally, interim results from DIAMOND, an ongoing, Phase 3 study assessing the efficacy/safety of SYMTUZA™ 800/150/200/10 mg in a Test-and-Treat model over 48 weeks, were presented at the 2018 International AIDS conference (AIDS 2018). Several studies examining Test-and-Treat models in newly diagnosed, adults with HIV-1 have previously led to improved virologic outcomes, retention in care, and decreased mortality.

## OAR Releases FY 2019/2020 NIH Strategic Plan for HIV and HIV-Related Research

### THE NIH OFFICE OF AIDS RESEARCH

**(OAR)** recently released the FY 2019/2020 NIH Strategic Plan for HIV and HIV-Related Research. The Plan was developed in consultation with a broad network of HIV research stakeholders, including NIH and extramural scientific experts, advisory committee members, community representatives, and people with HIV (PWH). Per its Congressional authorization, OAR coordinates the distribution of HIV research funds across the NIH Institutes, Centers, and Offices to advance the HIV research agenda, ensuring that those funds are aligned with the NIH HIV research priorities. The full Plan can be read on OAR's website.



# Fixed-Dose Doravirine Combination Non-Inferior in Treatment-Experienced Patients

As reported on [www.TheBodyPro.com](http://www.TheBodyPro.com).

**A FIXED-DOSE COMBINATION REGIMEN** containing the newly approved antiretroviral doravirine (Pifeltro) was non-inferior to other triple combination therapies in participants who switched from their current regimen to the new drug, announced Merck, doravirine's manufacturer, at IDWeek 2018 in San Francisco. The once-daily pill Delstrigo contains doravirine, lamivudine (3TC, Epivir) and tenofovir disoproxil fumarate (Viread). Principal investigator Princy Kumar, M.D., of Medstar Georgetown University Hospital, Washington, D.C., presented the data.

All 670 study participants were durably virally suppressed (viral load less than 40 copies/mL for at least six months) on a stable regimen of two nucleoside reverse transcriptase inhibitors plus a boosted protease inhibitor, a boosted elvitegravir (Vitekta), or a non-nucleoside reverse transcriptase inhibitor. They were randomized 1:2 to immediately switch to Delstrigo or continue for 24 weeks on their current regimen and then switch to the study drug. The entire study ran for 48 weeks.

At week 24, viral suppression rates (less than 50 copies/mL) were similar between the immediate-switch arm (93.7% of participants in that arm) and the deferred-switch arm (94.6%). By week 48, 90.8% of those who had immediately changed regimens were still virally suppressed. That result was compared with the 94.6% who were virally suppressed at week 24 on their baseline regimens (i.e., before participants in that arm switched to the new drug). The difference of -3.8% fell within the pre-defined -8%

non-inferiority margin. Forty-eight-week data on viral suppression in the delayed-switch arm were not reported in the abstract or press release.

Lipid levels were significantly better among the immediate-switch arm compared with those in the deferred-switch arm who took a ritonavir (Norvir)-boosted protease inhibitor (PI). Fasting low-density lipoprotein dropped by 16.5 mg/dL in the study drug group compared with 1.9 mg/dL in the PI group. Similarly, non-high-density lipoprotein fell by 24.7 mg/dL on Delstrigo versus 1.3 mg/dL on the PI. Tenofovir disoproxil fumarate, one of the study drug's components, is known to reduce lipid levels.

After 24 weeks, more participants on Delstrigo had dropped out of the study due to adverse events (2.5%) than had those still on their baseline regimens (0.4%). The most common complaints in both arms and at both 24 and 48 weeks were nasopharyngitis and headache. Drug-related headaches occurred in 0.4% of participants on their baseline regimen, 1.6% of those who immediately switched to the new drug, and 2.4% of those who switched later. The non-inferiority shown in this trial means that Delstrigo is an option for people who need to switch their HIV regimen, concluded George Hanna, M.D., of Merck in a company press release.



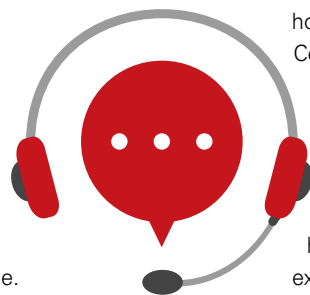
## New York City's Hotline for HIV Exposure a Success, Study Finds

As reported on [www.TheBodyPro.com](http://www.TheBodyPro.com).

**POST-EXPOSURE PROPHYLAXIS (PEP)** is a proven way to prevent HIV transmission after a possible exposure. Though access to PEP has been spotty, a dial-in hotline program in New York City has helped qualified patients access PEP at their local pharmacies, raising the possibility that remote screening methods could be an important way to bolster PEP use.

A detailed analysis of the New York PEP hotline program was presented at IDWeek 2018 in San Francisco by Allison Glaser, M.D., an infectious disease specialist with the Icahn School of Medicine at Mount Sinai Hospital in New York. Notably, Glaser and her colleagues found that the hotline improved access to PEP among New Yorkers who needed it. Even though the Centers for Disease Control and Prevention endorsed PEP in 2005, New Yorkers had reported trouble accessing it in local emergency rooms.

Time is of the essence, as PEP's effectiveness dwindles with every passing hour after a potential HIV exposure, and it can only be taken within 72 hours of exposure to be effective. In 2010, the PEP



hotline was initiated with a grant from the NYC Health and Hospital Corporation. In 2015, Mount Sinai Hospital was awarded a grant from the NYC Department of Health and Mental Health to continue the PEP hotline program, to bring it to scale to help concerned New Yorkers get access to PEP as soon as possible, and to study the effectiveness of such a program.

Here's how the hotline worked: Most patients learned about the hotline by doing an internet search for what to do after a possible HIV exposure. If they called the hotline during business hours, they spoke to a trained patient navigator who would help them schedule a same-day appointment. If they called after business hours, an on-call provider would write an immediate prescription for a PEP starter pack, which patients could pick up free of charge at a local pharmacy.

To assess the effectiveness of the hotline program, Glaser and her colleagues looked at the demographics and outcomes for 1,278 callers over the course of one year. Notably, they found that 96% of callers who were prescribed PEP over the phone went to the pharmacy to pick up their prescription starter packs. Researchers found that people who called the hotline were less likely to start treatment if they were asked to come into a clinic for screening prior to picking up a prescription.

# In the NEWS

## First U.S. Failure of Truvada as PrEP Is Reported at IDWeek

As reported on [www.TheBodyPro.com](http://www.TheBodyPro.com).

**A POSTER PRESENTATION AT IDWEEK**, a yearly conference held by the Infectious Diseases Society of America, revealed that a 21-year-old Latinx man has acquired HIV despite consistently high adherence to pre-exposure prophylaxis (PrEP). This new report is unique for several reasons, primarily because this is the first known HIV seroconversion with verified adherence to PrEP in the U.S.

According to the report, the man initiated PrEP through a city health clinic in San Francisco. He was confirmed as HIV negative at the time he started the drug through rapid antibody testing and HIV RNA testing. He returned for follow up visits and was

confirmed HIV negative at months three, six, and 10, again by antibody and RNA. Upon return at month 13 in early 2018, he tested HIV negative on a rapid test but positive with 559 copies/mL on an RNA test. A secondary test soon confirmed he was HIV positive with 1544 copies/mL. He was immediately initiated on emtricitabine/tenofovir alafenamide (Descovy), dolutegravir (Tivicay), darunavir (Prezista), and ritonavir (Norvir), and according to Robert Grant, M.D., M.P.H., of the University of California San Francisco, he has consistently maintained a suppressed viral load ever since.

The researchers were able to do identify that the man had a strain of HIV containing

reverse transcriptase mutations L74V, L100I, M184V, and K103N. This suggests that he acquired a strain of HIV from a partner who used certain HIV drugs in the past but was not currently taking them.

The patient's primary male partner was reported as living with HIV, not connected to medical care, and living with a strain of HIV resistant to the same mutations as the patient's strain. Upon learning of this occurrence, the partner was re-linked to care and found to have a viral load of 15,000 copies/mL at his first visit. It is not clear whether the partner would have returned to treatment if the patient had not tested positive.

## CDC Publishes New Research on Clinical Outcomes Among Hispanic/Latino Men and Women Receiving HIV Medical Care

**CDC RECENTLY PUBLISHED** "Gender Differences in Sociodemographic Characteristics and Clinical Outcomes among Hispanics/Latinos Receiving HIV Medical Care—United States, 2013–2014." CDC researchers analyzed data from the 2013 and 2014 cycles of Medical Monitoring Project (MMP) to describe demographic, behavioral, and clinical characteristics among Hispanics/Latinos with HIV by gender.

MMP is an annual cross-sectional, nationally representative surveillance system that, in the analysis years, collected information about behaviors, medical care, and clinical outcomes among adults receiving outpatient HIV care. In this analysis, researchers found that Hispanic/Latino women were significantly more likely than men to live in poverty (78% versus 54%) and report not speaking English well (38% versus 21%). Women were also more likely than men to receive interpreter services (27% versus 16%), transportation (35% versus 21%), and food services (44% versus



26%). There were no significant differences between women and men in prescription of antiretroviral therapy (ART) (95% versus 96%) or durable viral suppression (68% versus 73%). Poverty is known to affect management of HIV infection, lack of food can impact adherence to ART regimens that must

be taken with food, and lack of transportation can pose barriers to receiving care.

Although women faced greater socioeconomic and language-related challenges, the clinical outcomes among Hispanic/Latina women were similar to those among Hispanic/Latino men, perhaps reflecting their higher use of ancillary services. Despite the lack of disparity in viral suppression between Hispanic/Latino men and women, levels of viral suppression for Hispanics/Latinos are lower than those found among non-Hispanic whites and lower than the national prevention goal of viral suppression for 80% of persons with diagnosed HIV infection.

This analysis suggests there is a greater need for provider referral to ancillary services as well as an increased need for provider awareness of the challenges faced by Hispanics/Latinos with HIV infection in care. CDC remains committed to reducing new HIV infections among Hispanics/Latinos and to working with states and community-based organizations to increase viral suppression.

# What Is the HIV Medical Providers' Role in Determining Patients' Capacity for Mandatory Work Requirements?

**A**T THE AMERICAN ACADEMY OF HIV MEDICINE (AAHIVM), we believe that the optimal assessment of a patient's physical and/or mental capacity and of the appropriate medical treatment for that patient occurs within the relationship between provider and patient. We support policies that promote provider determination of the optimal course of treatment based on clinical evidence, indicators for the patient's outcomes, and assessment of the safety, efficacy and tolerability of particular drugs and specific regimens for the patient.

In January 2018, the Department of Health and Human Services (DHHS) Centers for Medicare and Medicaid Services (CMS) issued guidance recommending that states consider the adoption of work requirements for Medicaid as a “new policy guidance for states to test community engagement for able-bodied adults.” Several states are responding by submitting such proposals that (once approved) allow them to make Medicaid access in their state conditional on the indigent, able-bodied recipient's ability to participate fully in state-defined activities.<sup>1</sup>

Four states (as of July 2018) have such waivers approved by CMS and another ten have waiver applications pending. Where approved, this policy change requires able-bodied Medicaid recipients—with the exception of those caring for young children (usually six years old or less) or elderly/disabled family members—to either work at least 20 hours per week or devote the same time to job training, school or volunteer work. Some states are also requiring mandatory drug testing and/or payment of premiums to maintain access to their Medicaid coverage. Failure to pay premiums on time, or to meet and promptly document compliance with the work requirements, can result in recipients being “locked out” of Medicaid for time periods up to 9 months.

These measures are described as “punitive and detrimental to patient care” in a joint statement issued by the American College of Obstetricians and Gynecologists, the American College of Physicians, the American Academy of Pediatrics and other organizations.<sup>2</sup> In a court case against DHHS and the state of Kentucky, Federal District Court Judge James Boasburg vacated Kentucky's work requirement waiver,

arguing that the Secretary (of DHHS) had “never adequately considered whether Kentucky HEALTH would in fact help the state furnish medical assistance to its citizens, a central objective of Medicaid. This signal omission renders his determination arbitrary and capricious.”<sup>3</sup> He remanded the matter to HHS for further review.



**Nationally, more than 40% of people living with HIV rely on Medicaid for their medical insurance. The percentage escalates to 56% when considering all people with HIV who rely on Medicaid, Medicare or both as their only coverage.**

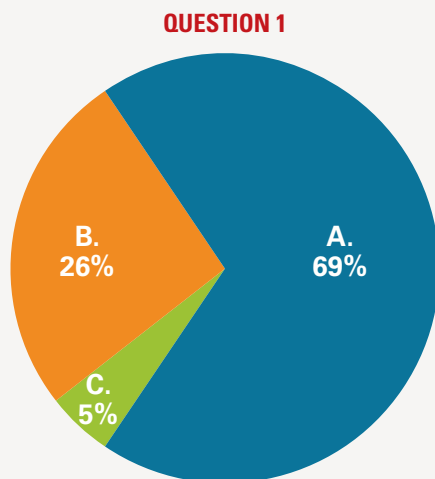
Although Judge Boasburg's decision may be appealed, it raised concern among the three other states already preparing to implement work requirements and the other states that have submitted applications to do so for CMS' consideration.

Nationally, more than 40% of people living with HIV rely on Medicaid for their medical insurance. The percentage escalates to 56% when considering all people with HIV who rely on Medicaid, Medicare or both as their only coverage. This becomes potentially disastrous when considering the number of people who can be forced off of Medicaid when a state (with federal approval) imposes work requirements or other mandatory activities on indigent people enrolled

**FIGURE 1 AAHIVM Members' Views**

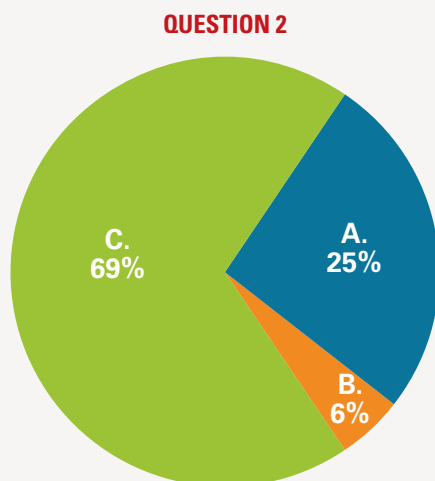
**QUESTION 1:** Do you agree or disagree with this statement: "I am opposed to the implementation of work requirements because I believe that all Americans should have access to medical care."

- A. Agree—**69%**
- B. Disagree—**26%**
- C. Do not know—**5%**



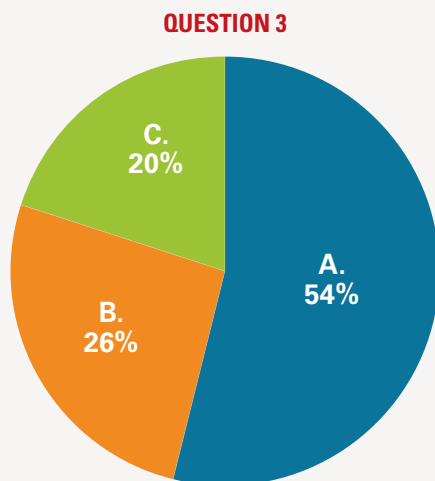
**QUESTION 2:** If a patient asked me to assess her/his medical status and document whether she/he is well enough to be required to comply with Medicaid work requirements, I would:

- A. Decline to do this as a matter of conscience—**25%**
- B. Ask my patient to take this request to another health care provider—**6%**
- C. Do the assessment and document the patient's actual health status—**69%**



**QUESTION 3:** In states where Medicaid work requirements are in place, I think health care providers should have some role in evaluating and reporting on the patient's health but it should be a minor role, such as:

- A. OK for me to be asked to fill out a brief questionnaire that my patient takes to the Medicaid office. But my evaluation should not be the only factor determining whether the person is required to meet work requirements in order to get Medicaid—**54%**
- B. OK for the Medicaid office to provide me with a brief description of the work requirement activities and ask me to "sign off" on whether the patient can do these activities without endangering her/his health—**26%**
- C. No, I do not think that health care providers should have any role in making these decisions. I would decline any level of participation in this process—**20%**



**Diagnosis with HIV commonly results in an individual being characterized as "medically frail" and thus exempted from Medicaid work requirements. "Medically frail" is a broad term, usually referring to people with disabilities, chronic substance use disorders, and/or serious and complex medical conditions.**

in publicly funded health care.

Arkansas' governor, for example, announced last September that—of the 26,000 Arkansans required to accept work requirements to stay on Medicaid—4,353 became ineligible and lost their Medicaid coverage. This outcome appears to be, in large part, a result of the fact that participants were required to report electronically to their Medicaid office about their work activities to stay in compliance. Unfortunately, in Arkansas, 25%–75% of residents (varying by county) do not have access to internet where they live, according to the Federal Communications Commission. As a result, four adults lost their Medicaid coverage for each one who was able to retain it under the new system.

To date, work requirements have not been imposed on people living with HIV, although states can, at their discretion, choose to ignore the exemption that has prevented this to date. Diagnosis with HIV commonly results in an individual being characterized as "medically frail" and thus exempted from Medicaid work requirements. "Medically frail" is a broad term, usually referring to people with disabilities, chronic substance use disorders, and/or serious and complex medical conditions.<sup>4</sup>

CMS has no specific definition of medical frailty, and the federal definition elsewhere is sufficiently imprecise that states could, for example, argue that an individual living with HIV who is in good health and virally suppressed is not medically frail and, therefore, can be subjected to work requirements. Kentucky and Indiana (the first two states to have their work requirement waivers approved) both clearly include HIV on the list of "medically frail" conditions, but not all states do.



**While using PrEP, people should be monitored regularly by health care providers for potential side effects and to make sure they are taking the medication consistently. If this medical follow-up conflicts with the person's work requirements, or if he or she is "locked out" of Medicaid coverage due to bureaucratic confusion of some sort, the resulting gap in professional care can result in further transmission of HIV.**

Another issue that keeps the "medically frail" definition from protecting indigent people living with HIV from being required to participate in mandatory work requirements to ensure their health care is sheer human error.

The extra bureaucracy associated with work requirements inevitably creates more confusing red tape for recipients and Medicaid office staff. It is easy to envision situations in which someone's "medically frail" status is disputed due to loss of proper documentation, a faulty paper-trail, etc. In the ensuing confusion, a person could miss a Medicaid registration deadline and be "locked out" of access to Medicaid for as much as six to nine months, as has occurred in some states.<sup>5</sup>

For people living with HIV, interruptions or deprivation of care, for any reason, can lead to rapid progression of their disease if treatment is stopped, the emergence of drug-resistant viral strains and other serious complications that affect the individual's health. Treatment interruptions also have community-wide implications if drug-resistant strains are transmitted—as we know from recent, localized "outbreaks" where specific HIV or HCV strains spread rapidly among groups.

Issues of medical frailty aside, imposed work requirements can also affect HIV-negative people who would benefit from access to Pre-exposure Prophylaxis (PrEP) for HIV prevention. While using PrEP, people should be monitored regularly by health care providers for potential side effects and to make sure they are taking the medication consistently. If this medical follow-up conflicts with the person's work requirements, or if he or she is "locked out" of Medicaid coverage due to bureaucratic confusion of some sort, the resulting gap in professional care can result in further transmission of HIV.

### **Assessing AAHIVM members' views**

In May 2018, AAHIVM surveyed its membership to assess their positions on the issue of attaching mandatory work requirements to Medicaid eligibility. About 14% of the membership responded. An overview of the un-detailed responses is shown in Figure 1.

### **In the absence of consensus**

The diversity of responses we received to this survey suggests that it is not possible to reach the consensus among the membership with regard to this issue. AAHIVM adopts official policy positions by a vote of the AAHIVM National Board on behalf of the membership of the organization. The positions adopted are "broad in nature yet they allow us to determine our support or opposition to issues based on a core set of guiding beliefs that our members hold as HIV care professionals."<sup>6</sup>

The Purpose and Content section of the AAHIVM Policy Platform recognizes, however, that "Some topics are constantly evolving in ways that are too nuanced for our members to agree on a mutual, permanent position. In those cases, the Academy attempts to represent our membership's position in its truest form. That may involve declining to engage a particular issue or representing the diversity of opinions that may exist among our members."<sup>7</sup>

We will, therefore, relegate this issue to the latter category and represent members' views accordingly. **HIV**

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# PROVIDING PRIMARY

for Patients Living



# CARE with HIV

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## UPDATES and CURRENT PRACTICES

This article was contributed by the Department of Family & Community Medicine at the University of California San Francisco which offers an “HIV Training Track” to second- and third-year residents who are interested in pursuing more HIV-related education opportunities during residency. The Track is composed of multiple training experiences including longitudinal exposure to the Department’s integrated, multi-disciplinary HIV prevention and care clinic and participation with the National HIV Curriculum, as well as the Pacific AIDS Education and Training Center’s HIV Learning Network. The majority of Track graduates have gone on to pursue additional HIV training (through dedicated fellowships) and care opportunities across the country.

**T**HE NEW DIRECTOR of the Centers for Disease Control and Prevention (CDC), Dr. Robert Redfield, has listed HIV primary care as one of the top priorities for his term. The CDC’s Division of HIV/AIDS Prevention Strategic Plan of 2017-2020 lists multiple “indicators of progress” and strategies for HIV care: improved linkage to and retention in care, higher viral suppression rates, integrated care, and increased pre-exposure prophylaxis (PrEP) use.<sup>1</sup> In this article, we summarize current guidelines for HIV primary care and discuss important issues and trends in primary care for persons living with HIV (PLWH).

### Current Guidelines: Overview

Combination antiretroviral therapy (ART) for virtually all PLWH remains the standard of care in the U.S., regardless of CD4 count. Federally-approved medical practice guidelines include specific recommendations on use of antiretroviral agents and opportunistic infection (OI) prevention for adults and adolescents living with HIV.<sup>2,3</sup> The International Antiviral Society-USA (IAS-USA) also publishes clinical practice recommendations on use of antiretroviral agents and OI prophylaxis.<sup>4</sup> Local/regional and state practices may guide and influence ART prescribing patterns, particularly for ART-naïve individuals. Additionally, insurance and/or state ADAP formularies commonly play a role in shaping which agents and combinations are most readily available.

Table 1 compares select DHHS and IAS-USA recommendations regarding treatment of non-pregnant adults living with HIV. Although current recommendations for initial treatment are fairly standardized, every patient’s individual circumstances (including resistance testing results, co-morbid conditions, other prescribed/non-prescribed medications, pregnancy potential, food security) and preferences should be taken into consideration for shared decision-making regarding ART use. Recently, a growing evidence base has been established regarding switch strategies and dual-therapy approaches: interest in these has been driven by a desire to minimize exposure to potentially-toxic agents and simplify/streamline regimens. In general, ART decision-making for treatment-experienced patients—especially highly experienced patients—can be very complex, even when considering a regimen switch. These decisions are best informed by a comprehensive ART history, current and previous HIV resistance testing results, and information regarding medication adherence and virologic response.

Both DHHS and IAS-USA guidelines provide specific recommendations for laboratory testing among PLWH. In addition to routine CD4 and HIV viral load surveillance and monitoring for ART-related toxicity as indicated, all PLWH should receive risk-appropriate screening for sexually transmitted infections (including multi-site testing), viral hepatitis, and tuberculosis as well as recommended immunizations.<sup>5</sup> Regular lipid and glucose/hemoglobin A1c monitoring is recommended, given the potential for ART-related metabolic

effects, as well as generally high rates of hyperlipidemia and diabetes/insulin resistance among PLWH. Chronic kidney and liver disease are also highly prevalent, therefore monitoring of renal and hepatic function is prudent. Some U.S. Preventive Services Task Force recommendations can be applied to PLWH; these include screening for hypertension, breast/lung/colorectal cancer, and abdominal aortic aneurysm. Because of elevated rates of HPV infection and increased risk for anogenital malignancies, cervical and anal cancer screening recommendations for PLWH are distinct from those for the general population. Age-appropriate HPV immunization (the 9-valent vaccine was recently approved for men and women up to 45 years of age) is generally recommended for PLWH, based on the potential benefit of preventing HPV-associated disease and cancer in this population.

Other critical aspects of health and wellness promotion include counseling on physical activity, partner violence, and regular assessments of patients' psychosocial circumstances, mental health, and substance use (including tobacco). Tobacco cessation counseling/treatment is arguably one of the most important preventive interventions that can improve health outcomes of PLWH. Aging-related conditions such as geriatric syndromes, functional and/or neurocognitive and mental health disorders, polypharmacy, and social difficulties are increasingly important clinical considerations, as nearly half of all people in the U.S. diagnosed with HIV are aged 50 and older, and many have been on long-term ART.<sup>6,7</sup>

Baseline bone densitometry screening is recommended for postmenopausal women; men aged  $\geq 50$  years; and patients with fragility fracture history, receiving chronic glucocorticoids, or at high risk of falls. For men 40-49 years and premenopausal women  $\geq 40$ , risk of fragility fracture should be assessed using the FRAX tool.<sup>8</sup> HIV remains strongly associated with elevated cardiovascular risk, and research suggests risk calculators used for the general population may underestimate risk among PLWH (some experts consider HIV to be a coronary heart disease risk equivalent).<sup>9,10</sup> Lifestyle modification and effective treatment of traditional risk factors remain the cornerstone of prevention, however it remains somewhat uncertain whether "usual" risk factor interventions are truly the optimal approach for PLWH. Patients with conditions (i.e. cirrhosis) that increase risk for hepatocellular carcinoma (HCC) should undergo recommended screening.<sup>11</sup> Although HIV infection in and of itself does not appear to confer significant risk for HCC, PLWH have disproportionately high rates of HCC risk factors including viral hepatitis and non-alcoholic fatty liver disease.

For PLWH who have been diagnosed with cancer, in early 2018 the NCCN Guidelines panel released Clinical Practice Guidelines in Oncology<sup>12</sup> that provide recommendations for PLWH who develop non-small cell lung cancer, anal cancer, Hodgkin lymphoma, and cervical cancer. These recommendations also outline principles of HIV therapy and

opportunistic infections prophylaxis for patients with cancer, systemic therapy and drug (i.e. ART) interactions, imaging, radiation therapy, surgery, and supportive care measures.

## Emerging trends in HIV care "Getting to Zero"

The UNAIDS announced its "Getting to Zero" strategic initiative initially in 2010.<sup>13</sup> Now updated to 2020, the overarching vision of this plan includes zero new HIV infections, zero AIDS-related deaths, and zero HIV-related discrimination. In 2014, the UNAIDS declared its 90-90-90 treatment targets:<sup>14</sup> 1) 90% of people living with HIV will know their status, 2) 90% of people who know their status will receive ART, and 3) 90% of people receiving ART will have viral suppression.

Across the U.S., multiple "Getting to Zero" campaigns have been launched. In San Francisco, numerous collaborations and partnerships have been formed to meet the jurisdiction's goals of reducing both HIV infections and deaths by 90% of current levels by 2020. One important component is San Francisco's RAPID (Rapid ART Program Initiative for HIV Diagnoses) Program,<sup>15</sup> which has created a set of "hubs" throughout the city whereby persons newly diagnosed with HIV or out of care can rapidly access ART with a smooth transition to their medical home. Specifically, ART is started within 48 hours if an individual has acute/early infection, or clinical evidence of advanced infection (i.e. opportunistic infection or CD4 count  $< 200$  cells/mL).

For all other individuals diagnosed with HIV, the goal is to start ART within 5 days of diagnosis—many are started on the same day. Early data indicate that San Francisco's roll-out of "rapid" treatment initiation has decreased time to initial viral suppression by over 50%, and has also been associated with decreases in number of new HIV diagnoses and also modest improvement in 1-year care retention rates.<sup>16</sup>

Although current DHHS guidelines view such rapid/immediate treatment initiation strategies as "investigational" (the panel notes that same-day ART initiation is resource-intensive and long-term clinical benefits remain largely unknown), in our experience patients are highly appreciative of the comprehensive and coordinated efforts made to address structural and system-level challenges to accessing treatment and care immediately upon receiving a new HIV diagnosis.

## Trauma-informed care

Another area of innovation among PLWH is trauma-informed care. PLWH are disproportionately impacted by trauma: women and men living with HIV experience intimate partner violence at high rates (68-95% of women, 68-77% of men, 93% of transgender people).<sup>17</sup> Trauma is associated with increased HIV-risk behavior, poor health-related outcomes, and poor adherence to treatment. Particularly vulnerable populations include women, sex workers and men who have

**TABLE 1**  
**Comparison of select DHHS and IAS-USA antiretroviral therapy recommendations**  
**for initial HIV treatment, regimen switching, and dual therapy strategies**

	DHHS	IAS-USA
Date of last update	October 2018	July 2018
Recommended initial regimens for most people with HIV <sup>1</sup> (recommendation/evidence rating)	BIC/TAF/FTC (AI) DOL/ABC/3TC if HLA-B*5701 negative (AI) DOL + tenofovir/FTC (AI) RAL + tenofovir/FTC (AI for TDF, AI for TAF)	BIC/TAF/FTC (AIIa) DOL/ABC/3TC if HLA-B*5701 negative (AIIa) DOL + TAF/FTC (AIIa)
Select recommendations regarding ART “switch” options and dual-therapy combinations with sufficient supporting evidence	<p>If there is uncertainty about prior resistance, it is generally not advisable to switch a suppressive regimen unless the new regimen is likely to be as active against potential resistant virus as the current suppressive regimen.</p> <p>For patients who are currently virologically suppressed but have a history of treatment failure (and no INSTI resistance), EVG/cobi/TAF/FTC + DRV may be considered.</p> <p>2-drug switch regimens which have sufficient supporting evidence include: boosted PI + either FTC or 3TC (BI), as well as DTG/RPV (AI). A boosted PI + INSTI, and DOL + 3TC, cannot yet be recommended until further evidence is available. If used, patients should be closely monitored. DOL + 3TC is now recommended when ABC, TAF, or TDF cannot be used or are not optimal for ART-naïve patients (BI).</p> <p>A ritonavir boosted PI + 3TC may be a reasonable option when the use of TDF, TAF, or ABC is contraindicated or not desirable for ART-naïve patients without baseline resistance mutations or patients with sustained virologic suppression (BI).</p>	<p>In patients with NRTI mutations, switching from a boosted PI-based combination to a regimen containing drugs with low genetic barrier to resistance (e.g., NNRTI, RAL) is not recommended (AIIa).</p> <p>Proactive switching from TDF to TAF is recommended for patients at high risk of renal/bone toxicity (BIa), as long as no change in dosing is required with TAF use.</p> <p>Switching from 3-drug regimens to certain 2-drug regimens in the setting of viral suppression can be used in patients with no prior virologic failure or transmitted drug resistance. Possible 2-drug regimen options include: DOL/RPV (AIIa), boosted PI + 3TC (AIIa), or DOL + 3TC (AIIa).</p> <p>Until further data are available, initial treatment with 2-drug regimens should be reserved for rare situations when individuals cannot take ABC, TAF, or TDF. In this situation, DRV/r + 3TC may be considered, or DRV/r + RAL if HIV RNA &lt; 100,000 copies/mL and CD4 &gt; 200/μL (BIa).</p>

<sup>1</sup>Baseline genotype results, co-morbid conditions and medication use, and renal/hepatic function should be considered when selecting any initial ART regimen. Rating system for DHHS: A = strong; B = moderate; C = optional; I = data from randomized controlled trials; II = data from well-designed non-randomized trials or observational cohort studies with long-term clinical outcomes; III = expert opinion. Rating system for IAS-USA guidelines: A = strong support; B = moderate support; C = limited support; Ia = evidence from 1+ randomized trials published in peer-reviewed literature; Ib = evidence from 1+ randomized trial presented in abstract form at peer-reviewed scientific meeting; IIa = evidence from non-randomized trials or cohort/case-control studies published in peer-reviewed literature; IIb = evidence from non-randomized clinical trials or cohort/case-control studies presented in abstract form at peer-reviewed scientific meetings; III = based on panel's analysis of accumulated available evidence

sex with men.<sup>18</sup> SAMHSA's National Center for Trauma-Informed Care recommends incorporating a framework which includes:<sup>19</sup>

1. A trauma-informed environment that realizes the high prevalence of trauma, understanding the effect of trauma on patients and responding appropriately to trauma with curiosity, trust, respect and transparency;
2. Universal screening for trauma in all PLWH along with both primary and secondary prevention as well as referral to specialty services;
3. Educating patients, ourselves and all clinic staff on the relationships between trauma and behaviors that negatively impact patients' well-being; and
4. Resisting and preventing re-traumatization.

### **Mixed-status couples**

#### **“Undetectable = Untransmittable” (U=U)**

It is now widely accepted amongst HIV experts, practitioners, and advocates that HIV cannot be transmitted sexually from persons who have an undetectable viral load. This knowledge led the Prevention Access Campaign to launch the “Undetectable = Untransmittable” (U=U) campaign

in early 2016.<sup>20</sup> This concept has become increasingly supported in the scientific literature, including results from three large studies examining HIV transmissions between serodiscordant couples. The HIV Prevention Trials Network (HPTN) 052 trial followed 1763 couples over five years after randomly assigning HIV-positive index participants to either early or delayed ART. Significantly, not a single case of transmission was observed when the viral load of the index participant was suppressed.<sup>21</sup> The PARTNER Study observed 1166 serodiscordant couples for 1238 couple-years and over 58,000 instances of condomless sex, again with no occurrences of transmission with an undetectable viral load.<sup>22</sup> Finally, the Opposites Attract Study followed a cohort of 358 MSM living with HIV, through greater than 17,000 sex acts, with no transmission while the HIV viral load was stably suppressed.<sup>23</sup> Taken together, these studies provide overwhelming evidence to support the fact that ART-facilitated viral suppression effectively blocks sexual transmission of HIV.

Currently, there is insufficient evidence to extrapolate the aforementioned findings to other routes of HIV transmission, i.e. shared needle/equipment use and pregnancy/breastfeeding. Earlier this year, Waitt and

colleagues summarized the existing evidence regarding the transmission of HIV through breastfeeding and outlined a plan for addressing remaining gaps in evidence in order to support guidelines for breastfeeding amongst women living with HIV in high-income settings.<sup>24</sup>

Further research and clinical practice guidelines should investigate the knowledge, attitudes and practices of people living with (and at risk for) HIV in regards to the U=U campaign, as well as how U=U is communicated by health care providers and received by patients/families. Recently, Philpot and colleagues examined how serodiscordant couples in Australia navigate viral suppression as a prevention strategy.<sup>25</sup> Confidence in U=U increased over time, and was assisted by repeated condomless sex without transmission [to the negative partner], consistent testing results and retention in care, as well as being in a partnership “framed by trust, commitment, and familiarity”. In our practice, we often include discussions of U=U in our counseling with patients/partners and their families, and we find this is often an empowering and hopeful concept for patients.



### ***Pre-exposure prophylaxis (PrEP)***

Multiple studies described above, as well as earlier studies, have demonstrated the effectiveness of HIV “treatment as prevention”.<sup>22, 26, 27</sup> Additionally, PrEP can be considered as another effective HIV prevention option for serodiscordant couples. This includes partners who are trying to conceive. The Partners PrEP study investigated 1768 serodiscordant heterosexual couples in the pre-conception period, and found no statistically significant difference in rates of pregnancy loss, birth defects, or infant growth in the first year of life between women receiving placebo and women receiving PrEP. Of note, in this study, PrEP was discontinued once pregnancy was identified.<sup>28</sup>

In our practice, as with any medical intervention, the decision to start PrEP is made with shared decision-making between the patient and provider. PrEP is recommended for HIV negative persons who are in ongoing sexual relationships with people living with HIV who are not virally suppressed. This might be especially important for women who are attempting to get pregnant (or are already pregnant) and have a partner who is not virally suppressed. By contrast, for people in serodiscordant relationships in which the partner living with HIV has been virally suppressed, we still discuss the possible benefits and risks of PrEP (as an option), as some people feel more comfortable having an “extra layer” of security and agency.

### ***Integrated care: substance use and hepatitis C treatment***

Medication for addiction treatment (MAT) for PLWH who also have opioid use disorder is not a new idea. The effectiveness and beneficial health outcomes of both methadone and buprenorphine have been demonstrated among PLWH.<sup>29</sup> The Drug Addiction Treatment Act of 2000 allows trained physicians to provide office-based MAT for opioid dependence, and the Comprehensive Addiction and Recovery Act has also expanded access to treatment by extending buprenorphine prescribing privileges to qualifying nurse practitioners and physician assistants.

Over the last several years, a number of primarily HIV-focused practices have accelerated their capacity to offer harm reduction and integrated MAT services. In 2011, a multi-site study showed that providing buprenorphine in HIV clinics was associated with increases in ART initiation/continuation, as well as improvements in CD4 counts.<sup>30</sup> In multiple studies, MAT for opioid use disorder has been associated with viral suppression and increased engagement in care for PLWH.<sup>31-33</sup>

Despite currently shifting attitudes towards substance use and increasing calls for “low threshold” treatment, many substance-involved PLWH still do not have broad access to comprehensive, patient-centered services and continue to experience suboptimal ART-related outcomes.

In the ACCESS study, potential solutions offered to improve ART adherence included building alliances with providers and once daily, single-pill regimens.<sup>34</sup> Fortunately, there are relatively few clinically-significant interactions between commonly-used antiretroviral agents today, i.e. integrase inhibitors, and MAT for opioid use disorder (Table 2). In light of the UNAIDS 90-90-90 goals, integrating MAT and behavioral health into HIV primary care is imperative. Increased access to evidence-based substance use treatment improves HIV care throughout the HIV Prevention and Care Cascades, from decreasing transmissions to delivering co-located, essential health services for PLWH, to improving viral suppression.<sup>35</sup> A 2011 study in San Francisco reported

**TABLE 2**  
**Medication Interactions between MAT for Opioid Use Disorder and Select ART**

Antiretroviral agent	Effect on ART levels	Effect on MAT levels	Management
Integrase Inhibitors			
Bictegravir	No significant changes in ART exposure anticipated with buprenorphine, methadone, or naltrexone co-administration	No significant changes in MAT levels anticipated	No dose adjustment
Dolutegravir		No significant changes in MAT levels anticipated	No dose adjustment
Raltegravir		No significant changes in MAT levels anticipated	No dose adjustment
Elvitegravir/cobicistat		Increases in buprenorphine levels (AUC increased 35%; Cmin increased 66%) and norbuprenorphine levels (AUC increased 42%; Cmax increased 24%; Cmin increased 57%)	No dose adjustment, but clinical monitoring is recommended for signs/symptoms of opioid toxicity.
Protease Inhibitors			
Darunavir (boosted)	None anticipated with buprenorphine, methadone, or naltrexone	Minimal decreases in buprenorphine when co-administered with DRV/ritonavir; modest increases in norbuprenorphine levels  Decreases in methadone levels  Effects unknown if co-administered with DRV/cobicistat: theoretical increase in buprenorphine concentrations	Dose adjustment for buprenorphine may not be necessary when co-administered with boosted darunavir, but clinical monitoring for signs of opioid toxicity is recommended.  If methadone co-administration, monitor for signs/symptoms of opioid withdrawal and adjust methadone dose as necessary.  If using DRV/cobicistat, titrate buprenorphine dose using lowest initial dose.
Atazanavir (boosted and unboosted)	Possible decreases in ATV concentration if buprenorphine co-administered with unboosted ATV	Increased buprenorphine levels if given with ATV/ritonavir  Effects unknown if co-administered with ATV/cobicistat: theoretical increase in buprenorphine concentrations  Increased buprenorphine levels if co-administered with unboosted ATV  Decreases in methadone levels when co-administration with ATV/ritonavir	With boosted ATV, titrate buprenorphine dose using lowest initial dose. Monitor for signs of opioid toxicity.  Do not administer buprenorphine with unboosted atazanavir.  If co-administering ATV/ritonavir with methadone, opioid withdrawal is unlikely but may occur. Monitor closely and increase methadone dose as clinically indicated.  If co-administering ATV/cobi with methadone, titrate methadone dose using the lowest feasible initial dose and monitor closely.
Non-nucleoside Reverse Transcriptase Inhibitors			
EFV	No significant changes in ART exposure anticipated with buprenorphine, methadone, or naltrexone co-administration	Decreases in buprenorphine and methadone levels	Monitor for signs/symptoms opioid withdrawal: increases in methadone dose commonly necessary
ETR		Modest decreases in buprenorphine levels	No dose adjustment; consider monitoring for withdrawal
NVP		Decreases in methadone AUC	Increases in methadone dose commonly necessary
RPV		Slight decrease in AUC of active form of methadone	Monitor for signs/symptoms of withdrawal if co-administered with methadone; consider QTc monitoring (both RPV and methadone can prolong QTc interval)

that stand-alone substance use programs are not enough to provide the necessary care for the number of patients needing MAT.<sup>29</sup>

Providing integrated MAT directly on-site with HIV primary care decreases barriers to care, improves hepatitis C-related outcomes, and also decreases patients' experience of a double stigma (i.e. HIV and substance use).<sup>35</sup> Successful, integrated treatment models suggest having a specific point person or coordinator, and we have had success delivering MAT through a team-based approach.<sup>29</sup>

Historically, approximately one-third of PLWH have been co-infected with hepatitis C. This number has declined in recent years with fewer new HIV infections occurring as a result of injection drug use. There is evidence to suggest that HIV and HCV act synergistically, and that HIV co-infection leads to more rapid progression of HCV-associated liver disease.<sup>36</sup> A study from the Cohort of Spanish HIV Research Network (CoRIS) involving 4382 participants demonstrated that individuals with HIV and HCV co-infection had lower

immunological and sustained virological responses to ART 48 weeks after ART initiation.<sup>37</sup> In contrast, multiple studies have outlined the significant benefits and improvements in overall health among PLWH who achieve SVR after HCV treatment with direct-acting antivirals. A study of 695 participants with HIV/HCV co-infection found that individuals who underwent HCV treatment and obtained SVR had statistically significant reductions in mortality, liver-related events, progression of HIV, and liver fibrosis.<sup>38</sup>

Despite the availability of highly effective oral therapies for hepatitis C, it has been challenging to get some co-infected patients through HCV treatment. Specific challenges include: unstable social/living situations that affect visit and medication adherence, HCV-inexperienced providers, medication costs and insurance/formulary restrictions, substance use, and provider hesitancy to treat both conditions at the same time (i.e. due to medication interaction concerns).<sup>39</sup> Streamlining treatment through co-located, multi-disciplinary care and increasing primary

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care-based treatment can greatly increase HCV treatment uptake and success. Cross-specialty provider education and comfort with treating HCV also must increase,<sup>40,41</sup> and a number of easily-accessible clinical resources are available to providers (i.e. AETC National Curriculum on HIV-HCV Co-infection, “Hepatitis C Online” from the University of Washington).

## Case management

Case management is a central piece to helping PLWH navigate health systems and access other critical resources/programs including community-based social and “wrap around” services. Strengths-based, on-site case management has been associated with improved engagement in HIV care, as well as improvements in ART adherence.<sup>42,43</sup> Activities range from contacting patients (i.e. appointment reminders, check-ins between visits), arranging/referring for services, and advocating for patients.<sup>44</sup> An integrated, team-based HIV care model, where PLWH can receive comprehensive

and coordinated services including substance use and HCV counseling/treatment, as well as ongoing mental health and primary care, can have a profound impact on health outcomes. A retrospective study in five Veterans Affairs facilities showed that veterans living with HIV were more likely to achieve viral suppression when visiting clinics with integrated care.<sup>45</sup>

Additionally, for PLWH who have been incarcerated, integrated case management increases retention in care which may be especially important and impactful for individuals at high-risk for loss to follow-up and structural barriers to accessing care.<sup>46</sup>

## Concluding remarks

With medical advancements over the last 30 years, HIV has become a chronic disease. It is important that all PLWH have access to high quality, comprehensive and patient-centered care, and that current guidelines and practices evolve to effectively address these primary care needs. **HIV**

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# Special Considerations

## The Care of Women and Gender Variant Patients Living with HIV

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**W**OMEN LIVING WITH HIV experience intersecting stigmas and medical comorbidities that affect their health and wellbeing. The advent of highly effective antiretroviral therapy (ART) has changed HIV management to mirror that of other complex chronic health conditions; however, unique challenges to caring for women living with HIV remain. Providers must be mindful of these special considerations, specifically those regarding sexual and reproductive health, organ-specific cancer screening, and age-related concerns.

Providers must also address the unique psychosocial needs of women living with HIV. Structural factors including racism, incarceration, segregation, poverty, and trauma influence risk for HIV acquisition. Once diagnosed with HIV, HIV-related stigma layers on top of these other structural stigmas.<sup>1</sup> Women living with HIV experience disproportionately high rates of substance use, trauma, intimate partner violence, depression and post-traumatic stress disorder. These experiences are associated with higher rates of medication non-adherence and loss of virologic control.<sup>2-5</sup> Addressing these needs is as important as addressing medical needs.

While this article's purpose is to inform the care of women living with HIV, the authors also recognize the limitations of categorizing patients by binary gender. The literature referenced in this article focuses on cisgender women but is often important to the care of transgender patients with relevant anatomy and physiology. Certainly, the implications of intersecting stigmas noted in regard to women living with HIV are even more extensive and violent among transgender patients, especially transwomen. We refer readers to the excellent AAHIVM resources on the care of transgender patients: <https://aahivm.org/transgender-health-resource-center>. We attempt to use gender-neutral language in this article when possible. Quality HIV care for patients of all genders requires providers to consider the unique physiologic and psychosocial factors influencing each patient's wellbeing.



## Sexual and reproductive health

### *Bodily autonomy and family-building desires*

Support for bodily autonomy should be at the core of sexual and reproductive health care for patients living with HIV. Bodily autonomy, as defined by the Positive Women's Network, means "the simple but radical concept that individuals have the right to control what does and does not happen to our bodies."<sup>6</sup> This includes the freedom to choose if, when, and how to form families and raise children, and the right to make empowered and informed decisions about sex and relationships, free from coercion or shaming. Women and transgender patients with HIV face tremendous stigma around their sexual and reproductive choices because of their HIV status, which is compounded by stigma related to gender, race, and poverty.<sup>1</sup>

People living with HIV want to be asked about their fertility and childrearing desires (and have fertility desires and intentions similar to their peers without HIV). However, studies show that providers often do not ask.<sup>7</sup> There is a large unmet need for preconception and contraception counseling.<sup>8,9</sup> Providers should ask patients routinely and non-judgmentally about their sexual practices, sexual partners, and pregnancy and childrearing desires.

## Contraception

For patients who want to prevent pregnancy, providers can engage in shared decision-making to help them navigate contraceptive options.<sup>10</sup> Despite concern about drug-drug interactions between hormonal contraception and ART, nearly every contraceptive option can be used safely and effectively alongside ART.<sup>11,12</sup> The only interaction of clinical concern is between subdermal etonogestrel and levonorgestrel contraceptive implants and the NNRTI - efavirenz. Efavirenz may decrease the efficacy of the contraceptive implant, but it is still more effective than other hormonal contraceptive methods.<sup>13</sup> Efavirenz may also decrease the efficacy of combined hormonal contraception, progestin-only pills, and levonorgestrel emergency contraception, but clinical data are lacking. Patients should be made aware of this interaction, but it is not a contraindication to the use of hormonal contraception in patients taking efavirenz-based ART.

### *Preconception considerations*

For patients who desire pregnancy, or those who want to be prepared in the case of pregnancy, providers should discuss optimization of maternal and fetal health during pregnancy, childbirth, and beyond. The most important intervention is the safe and effective use of ART. While all patients considering childbearing benefit from standard preconception care (immunizations, optimization of chronic medical conditions, folic acid supplementation, STI testing, addressing substance use), there are a few additional considerations unique to patients living with HIV.<sup>12,14</sup>

Sustained HIV viral load suppression should be the primary treatment goal for patients who might get pregnant, both for the patient's health and to decrease the risk of perinatal and sexual HIV transmission. With effective ART beginning before conception, rates of perinatal HIV transmission approach zero.<sup>15</sup> When prescribing ART to patients considering or capable of childbearing, providers should consider the regimen's effectiveness, the patient's hepatitis B status, the potential for teratogenicity, and possible adverse outcomes for mother and fetus. The Department of Health and Human Services (DHHS) publishes updated evidence-based HIV treatment guidelines to help providers and patients choose an appropriate ART regimen.<sup>12</sup> (See figure 1)

In mid- 2018, data from a surveillance study in Botswana found a potential increased prevalence of neural tube defects (NTDs) in association with dolutegravir use from the time of conception.<sup>16</sup> There was no increased prevalence when dolutegravir was started in the first trimester, as the neural tube develops within the first 28 days after conception, or 6 weeks from last menstrual period (LMP).<sup>17</sup> Patients who are on or considering a dolutegravir-based regimen and have the potential to get pregnant should be counseled about the possible risk of NTDs when dolutegravir is taken near the time of conception. Patients who are pregnant, taking

dolutegravir and within 8 weeks from LMP should discuss the risks and benefits of changing their ART. After 8 weeks gestation, patients may initiate or continue dolutegravir without concern for NTD, given that the risk period has passed.<sup>18</sup> Decisions about changing ART in anticipation of pregnancy or early in pregnancy should be shared between the patient and provider, weighing the benefits of changing to a regimen with better safety data against the potential risks of new adverse effects and loss of viral suppression.

### Support for conception among serodiscordant couples

Providers who care for patients living with HIV should be prepared to discuss conception among serodifferent couples, where one partner is living with HIV and the other is HIV-negative.<sup>9</sup> Regardless of pregnancy intentions, providers can offer partner testing to confirm the partner's HIV status, and assist with disclosure of HIV status (as desired by the patient). Sustained use of ART to achieve a suppressed viral load in partners living with HIV, known as treatment as prevention, is associated with zero or near-zero risk of sexual HIV transmission.<sup>19–21</sup> For couples who are currently using condoms and wish to limit their episodes of condomless sex, sex can be timed to correlate with peak fertility.<sup>22</sup>

For individuals or couples who desire additional protection, or when partners living with HIV take ART inconsistently, pre-exposure prophylaxis (PrEP) offers a safe and highly effective method to reduce HIV acquisition risk while allowing for conception.<sup>23</sup> While reproductive technologies such as sperm washing and in vitro fertilization are no longer necessary to allow for safe conception among serodifferent couples, they should still be considered for patients living with HIV when spontaneous conception is not possible.<sup>24</sup>

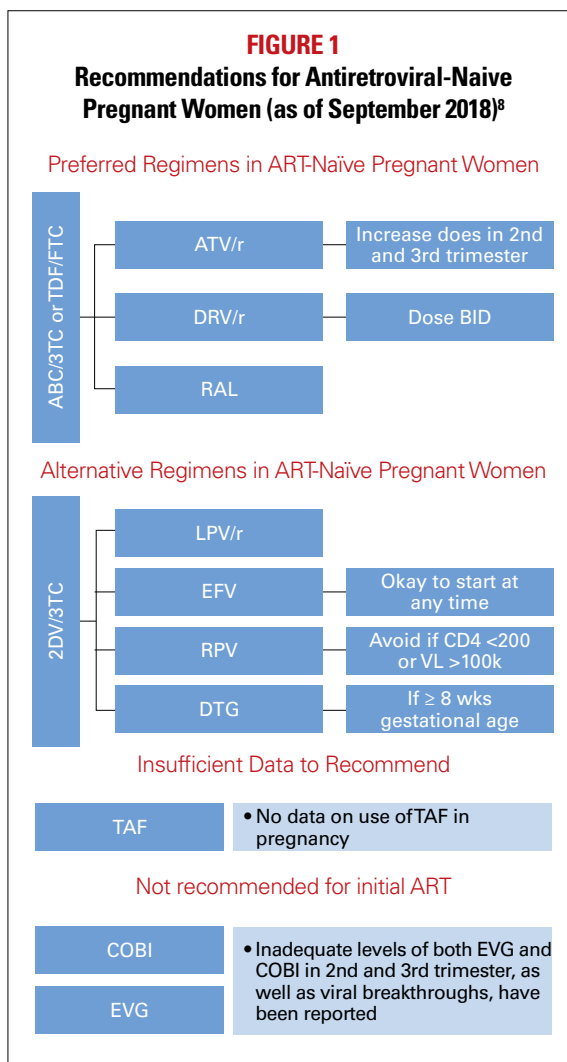
### Cancer screening

Cancer screening guidelines for women living with HIV are similar to cancer screening guidelines for the general public. The main exception is in screening for HPV-related cancers, as complex interactions between the HIV and HPV viruses lead to amplified risk of cervical and anal dysplasia and accelerated progression to cervical and anal cancers.<sup>25,26</sup>

#### Cervical cancer screening:

Patients living with HIV who have a cervix are at greater risk for cervical cancer than the general population, especially in the setting of a low CD4 count.<sup>27</sup> The impact of ART on the risk of HPV persistence and progression to dysplasia is uncertain. HPV vaccination is recommended for its pivotal role in preventing HPV-related cancers. The current recommendations for the vaccine in people living with HIV are the same as for the general population.

Cervical cancer screening can be performed using cytology alone, or for those age 30 years and older, cytology



with HPV co-testing. It is recommended that a cervical pap smear be performed within 1 year of sexual debut, but no later than age 21, or at HIV diagnosis for patients ages 21–29. If the initial pap smear is negative, another should be repeated within 6–12 months. If both pap smears are negative for intraepithelial lesion, then annual screening may follow. If 3 consecutive pap smears are negative, then pap smears may be spread out to every 3 years.

For patients over age 30, HPV co-testing may be performed. As HPV is the causative agent of cervical cancer, a negative HPV test is associated with prolonged reduced risk of cervical cancer. Patients with negative HPV testing and negative pap smear may have their next pap smear in 3 years.

Although cervical cancer screening for the general population ends at age 65, the current recommendations are that screening should continue throughout the lifetime for patients living with HIV.

Abnormalities on cervical cytology or HPV testing should be managed according to the algorithms used in the general population, with one exception.<sup>28</sup> Patients with ASC-US pap

test with negative HPV testing over the age of 30 who do not have HIV are recommended to have repeat co-testing in three years, whereas those with HIV are recommended to have a repeat Pap test in 6-12 months or repeat co-testing in 12 months, with referral to colposcopy for any result  $\geq$ ASC-US.<sup>29</sup>

### Anal cancer screening:

Though it is known that people living with HIV are at greater risk for anal cancer, the effectiveness and cost-effectiveness of routine screening with anal cytology are unknown. The Centers for Disease Control (CDC) and DHHS do not make a recommendation for anal cytology in people living with HIV. The Infectious Disease Society of America (IDSA) and New York State Department of Health both recommend anal cytology at baseline and annually in patients living with HIV who also have a history of cervical dysplasia, receptive anal intercourse, and/or genital warts.<sup>30,31</sup>

### HIV and Aging

With advances in HIV care, the gap between life expectancy for people living with HIV and that of the general population is narrowing. While there have been efforts to expand research and services to older people living with HIV, very little has addressed the specific needs of older women with HIV.<sup>32</sup> Older women with HIV live at the nexus of HIV-related stigma and age-related stigma, with impacts on overall health and wellbeing. Older patients with HIV



have a greater incidence of complications and comorbidities than adults of a similar age who do not have HIV, including differences in the experience of menopause and bone health.

### Menopause

While HIV alone does not impart a higher risk for early menopause, patients may have risk factors for both irregular periods and early menopause: psychosocial stress, smoking, psychotropic medication use, and substance use.<sup>2</sup> Some evidence suggests that older people with HIV experience higher rates and greater severity of menopausal symptoms.<sup>33</sup> Menopausal symptoms may be under-recognized

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or misattributed in the treatment of people living with HIV. Generally, the management of menopause in people living with HIV should not differ from the general population.

### Bone health

Older individuals living with HIV have increased risk for osteoporosis and fractures, even with effective ART, and post-menopausal people living with HIV are likely at highest risk.<sup>34</sup> Both HIV itself and ART seem to contribute to a decline in bone mineral density (BMD). Almost all ART regimens have been implicated, some (tenofovir, efavirenz, boosted protease inhibitors) more than others. Expert guidelines suggest measuring BMD in all postmenopausal women with HIV.<sup>30</sup> In patients found to have osteopenia or osteoporosis, in addition to optimizing non-HIV-specific risk factors and treating with bisphosphonates as indicated, consider changing ART to a more bone-friendly regimen.

### Conclusion

Providers caring for women and gender variant patients living with HIV should understand the ways in which living with HIV impacts health and wellbeing. They should be prepared to address unique needs related to sexual and reproductive health, HPV-related cancer screening, and identification and management of menopause and osteoporosis. Providers must consider the ways in which intersecting discrimination and stigma particularly impact women and gender variant patients living with HIV throughout the life course. **HIV**



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# Immunization Update 2018–2019

From the Advisory Committee on Immunization Practices (ACIP)

**T**HE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP) from the Centers for Disease Control and Prevention (CDC) includes 15 voting members with medical and public health expertise who develop recommendations on the use of vaccines in the United States.<sup>1</sup> Fourteen of the members have backgrounds in vaccinology, immunology, family medicine, infectious diseases, internal medicine, nursing, pediatrics, public health, virology, and preventive medicine. The 15th member is a consumer representative who provides perspectives on the community and social aspects of vaccinations. The ACIP meets three times yearly at the CDC in Atlanta and subsequently works with 30 professional organizations including the AAP, ACP, AAFP, ACOG, and IDSA to “harmonize” the U.S. vaccination schedule. (See Figure below) A comprehensive schedule is released yearly with periodic updates depending on new data or vaccine availability.

The committee’s recommendations stand as public health guidance for safe and efficacious use of vaccines. In more recent years the ACIP has specifically included HIV-infected adults and stratified vaccine recommendations based on CD4+ T-cell counts greater than or less than 200 cells/ mm<sup>3</sup>.

Historically, the IDSA HIV Primary Care guidelines have noted “the likelihood of response to any vaccine is greatest in patients with higher CD4+ T-cell counts and in patient receiving suppressive ART.”<sup>2</sup> Consequently most practitioners would wait until an HIV-infected patient sustained immune recovery with antiretroviral therapy (ART) before giving recommended vaccinations. The majority of people are being diagnosed earlier (thus with higher CD4+ T-cell counts) and thus immunization administration should be standard practice at all clinical sites where HIV care is provided. With the expansion of vaccine accessibility at the pharmacy level, many HIV patients may receive needed vaccines where they obtain their antiviral medications. This can also make reimbursement easier—especially for vaccines that are only covered under Ryan White-funded ADAP or Part D of Medicare. For the newly diagnosed HIV-positive adult the current vaccine recommendations are as noted below:

## **HIV infection and CD4+ T-cell count is 200 or greater or CD4% > 15 %<sup>3</sup>**

- Influenza vaccine—yearly (see discussion below)
- Tdap vaccine—one dose then TD booster every 10 years
- Pneumococcal vaccine polyvalent (13-valent followed by 23-valent)—repeat 23-valent q5 years
- Meningococcal conjugate vaccine—2-dose primary series of serogroups A, C, W, and Y

- Hepatitis A vaccine—2 dose series—primarily in MSM
- Hepatitis B vaccine—2 or 3 dose series (see discussion below)
- HPV vaccine—3 dose series (if > 15 years)—give up to age 26 years
- MMR vaccin—persons born in 1957 or later and who were never vaccinated / lack immunity
- Aricella-zoster vaccines—2 series vaccine (see discussion below)
  - persons born in 1980 or later who were never vaccinated/ lack immunity
  - persons 50 years old or greater

Below is a discussion of some specific updated information regarding influenza, Hepatitis B, Human Papilloma virus, and the new Herpes Zoster (“Shingles”) vaccine

## **Influenza<sup>4</sup>**

The ACIP updates its recommendations for influenza vaccine on a yearly basis. This vaccine is recommended for all persons 6 months of age and older. It is also prudent to recommend this vaccine for household members of HIV-infected persons. There are a number of vaccine products available in the U.S. including trivalent and quadrivalent vaccines and a live attenuated vaccine. The 2017-18 flu season was one of the worst in many years based on case reporting, hospitalizations, and morbidity and mortality data.<sup>5</sup> Using the measure of preventing a respiratory illness requiring medical attention, influenza vaccine was only about 36% effective during the last flu season.<sup>5</sup> Immunocompromised persons including those with HIV should receive influenza vaccine, although immunogenicity may vary based on age (older > younger) and CD4+ T-cell count.<sup>6</sup>



- Immunocompromised persons should receive inactivated influenza vaccine (IIV3 or IIV4) or recombinant influenza vaccine (RIV4).
- Live Attenuated Influenza Vaccine (LAIV4) should NOT be used for immunocompromised persons.
- Immune response to vaccines may be blunted in persons with compromised immune systems.
- Timing of vaccination might be a consideration with some providers or patients preferring to wait until later in the year to vaccinate, although flu season can start as early as October.
- There is no medical contraindication to given influenza vaccine at the same time as other vaccines including Pneumococcal, Tdap, Hepatitis, or Shingles.

### **Hepatitis B<sup>7</sup>**

The ACIP updated its recommendation for Hepatitis B vaccine in 2017 to include persons with chronic liver disease conditions including HCV, NASH, alcoholic liver disease, and autoimmune hepatitis. The HBV vaccine is usually given at 0, 1 and 6 months. In February 2018, another HBV vaccine (HEPLISAV-B™) was unanimously recommended by the ACIP for use in persons > age 18 years. This is the fifth inactivated HBV vaccine FDA-approved for use in the United States. This newer vaccine (HepB-CpG) contains yeast-derived recombinant Hepatitis B surface antigen (HBsAg) and is prepared by combining purified HBsAg with small synthetic immunostimulatory cytidine-phosphate-guanosine oligodeoxynucleotide (CpGODN) motifs (1018)

Recommended Immunization Schedule for Adults Ages 19 years or older—2018–19 <sup>3</sup>					
Vaccine	HIV infection with CD4 < 200 and CD4 > 200 (14%)				
Influenza <sup>1</sup>	1 dose annually				
Tdap <sup>2</sup> or Td <sup>2</sup>	1 dose Tdap each pregnancy	1 dose Tdap, then Td booster every 10 years			
MMR <sup>3</sup>	contraindicated			1 or 2 doses depending on indication	
VAR <sup>4</sup>	contraindicated			2 doses	
RZV <sup>5</sup> (preferred)					2 doses RZV at age ≥ 50 years (preferred)
ZVL <sup>5</sup>	contraindicated				1 dose ZVL ag age ≥ 60 years
HPV—Female <sup>6</sup>		3 doses through age 26 years		2 or 3 doses through age 26 years	
HPV—Male <sup>6</sup>		3 doses through age 26 years		2 or 3 doses through age 21 years	
PCV13 <sup>7</sup>		1 dose			
PPSV23 <sup>7</sup>		1,2, or 3 doses depending on indication			
HepA <sup>8</sup>	2 or 3 doses depending on vaccine				
HepB <sup>9</sup>				3 doses	
MenACWY <sup>10</sup>	1 or 2 doses depending on indication, then booster every 5 years if risk remains				
MenB <sup>10</sup>		2 or 3 doses depending on indication, then booster every 5 years of risk remains			
Hib <sup>11</sup>		3 doses HSCT recipients only			1 dose

adjuvant. Sero-protective antibody to hepatitis B surface antigen (anti-HBs) levels were achieved in 90.0%–100.0% of subjects receiving HepB-CpG.<sup>7</sup> It may produce a better immune response in persons with HIV but more data is needed to confirm this. A key advantage is the need for only 2 immunizations as opposed to three with the older HBV products.

- The HepB-CpG vaccine should be given as TWO doses, one month apart.
- The two-dose series only applies when both doses consist of HepB-CpG. (HEPLISAV-B™)
- A series consisting of a combination of 1 dose of HepB-CpG and a vaccine from a different manufacturer should consist of 3 total vaccine doses and should adhere to the 3-dose schedule minimum with intervals of 4 weeks between dose 1 and 2, 8 weeks between dose 2 and 3, and 16 weeks between dose 1 and 3.
- To assess response to HBV vaccination and the need for revaccination, post-vaccination serologic testing 1–2 months after the final dose of vaccine is recommended for persons with HIV infection. If the titer of anti-HBs is <10 mIU/mL following receipt HBV vaccine the individual should be revaccinated. Revaccination may consist of a second

complete HBV vaccine series followed by anti-HBs testing 1–2 months after the final dose, or simply administration of a single HBV vaccine dose followed by anti-HBs testing 1–2 months later.

### Human Papilloma Virus<sup>8</sup>

Human papilloma virus (HPV) is associated with cervical, vaginal, and vulvar cancer in women and penile, and anal cancer in men. The incidence of some HPV-related cancers is declining but there has been an increase of oral HPV lesions in men and women as well as anal cancers in men.<sup>9</sup> For persons 15 years-old and over, the recommended HPV vaccine is a 3-dose schedule at 0, 1–2 and 6 months. The efficacy of this vaccine is very good and clinical trials have shown close to 100% protection against cervical precancers and genital warts. A recent systematic review found that HPV vaccination in males was moderately effective against persistent anogenital HPV infection and high-grade anal intraepithelial lesions.<sup>10</sup> However, the vaccine was noted to be highly effective in study groups comprising HPV-naïve males.

- HPV vaccine is recommended routinely at age 11 or 12 years. (may start at age 9.)
- HPV vaccine is recommended for females age 13 through

26 years and males age 13 through 21 years who were not adequately vaccinated in the past.

- HPV vaccine is recommended through age 26 years for gay, bisexual, and other men who have sex with men, transgender people, and for immunocompromised persons—including those with HIV infection who were not adequately vaccinated previously.
- In October 2018, the U.S. Food and Drug administration approved the HPV 9-valent vaccine to include men and women aged 27 through 45 years. It is anticipated that the ACIP will vote in favor of this recommendation at an upcoming meeting. This will have significant implications for a large number of adults with HIV who will now be eligible to receive the HPV vaccine series.

### Shingles Vaccine<sup>11,12</sup>

In October 2017, the FDA approved the Zoster Vaccine Recombinant Adjuvanted (Shingrix®) for the prevention of herpes zoster in adults > aged 50 years. This recombinant zoster vaccine (RZV) was evaluated in two large phase 3 trials (N = > 30,000) that included adults > 50 years of age and > 70 years of age. The vaccine efficacy was 97% in the trial of persons 50 years and over, 89% in those 70 years and over. Pooled data showed a vaccine efficacy of 91%. Immunogenicity studies from phase 1 and 2 trials have shown persistence of VZV-specific CD4+ T-cell immunity for 9 years. One of these trials included HIV-infected patients and showed strong antibody responses regardless of low or normal CD4 counts or whether the recipients were on ART.<sup>13</sup> The uptake

of RZV has been very robust and in late September the CDC issued a clinical guidance for providers during the current national shortage of this vaccine.<sup>14</sup>

- Following the first dose of RZV, a second dose should be given 2 to 6 months later.
- RZV can be given to adults who previously received zoster vaccine live (Zostrix™)
- RZV can be given to adults who report a prior episode of herpes zoster.
- It is not necessary to screen for prior evidence of varicella infection.
- As patients with HIV were not included in the two large phase III vaccine trials, ACIP has not yet made specific recommendations regarding the use of this vaccine in HIV-infected patients. This topic is anticipated to be discussed at future ACIP meetings.
- Based on limited data (and personal experience) it is the author's opinion that RZV can be safely given to adults with stable HIV on ART.

Readers are referred to the references below and chart for additional recommendations regarding immunizations for adults with HIV infection.



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# Empowering Family Medicine Residents



## Managing Care for HIV Patients in Underserved Communities

By **JEAN WIGGINS, BSPH, MARIANNA O'REE, MPH, PMP,**  
and **BONZO REDDICK, MD, MPH**

**T**HE STATED MISSION of the Hospital Corporation of America (HCA) is “above all else, we are committed to the care and improvement of human life.”<sup>1</sup> Additionally, Mercer University School of Medicine’s mission is “to educate physicians and health professionals to meet the primary care and health needs of rural and medically underserved areas of Georgia.”<sup>2</sup> HCA is committed to delivering healthcare as it should be: patient-centered and for the good of all people, no matter their circumstance.

HCA and Mercer’s focus is on training physicians for the future. Together they are leaders in efforts to decrease the state’s rural physician provider shortage. As such, HCA/Memorial Health University Medical Center (HCA/MHUMC) and faculty members from Mercer University School of Medicine (MUSM) developed an initiative to endow emerging practitioners with the skills to embrace the state’s growing HIV positive population and to address the increasing need for HIV competent physicians in rural communities across the state.

Therefore, a collaboration between the Family Medicine Residency Program of HCA/MHUMC and MUSM-Savannah campus took place to implement a new longitudinal HIV curriculum. This change in post-graduate training ensures that family medicine residents, who often after graduation go on to practice in rural areas of the state, are well-prepared to address the complex needs of HIV-positive patients.



## HCA/Memorial Health and Mercer Address the HIV Provider Shortage

In 2016, HCA/MHUMC Graduate Medical Education (GME) Program responded to the escalating HIV rates in Savannah and surrounding areas by increasing its focus and approach to HIV management training for Family Medicine Residents. The HIV management residency curriculum was designed by the Family Medicine Residency faculty members, led by Dr. Bonzo Reddick and Dr. Robert Pallay, MUSM associate dean of diversity and MHUMC Family Medicine Residency Program Director, respectively. This change was inspired by the CARE Initiative, an HIV screening program in the MHUMC Emergency Department. During the first year of the CARE Initiative, staff screened over 15,000 patients. It was quickly determined that patients with private insurance were not able to receive care at the local Ryan White Clinic, and they often preferred for their primary care physician (PCP) to care for all their medical conditions. However, most primary care physicians in the area are not comfortable managing HIV patients. Training the residents to manage HIV patients provides an option for care, especially privately insured patients or other patients fearful of the stigma of going to an HIV specialty clinic.

At the onset of training though, residents reported feeling unprepared and uncertain about treating patients with HIV due to the perceived complexity of the disease and its care. An internal survey conducted prior to starting the HIV management training revealed that over a third of the residents felt inadequately prepared to provide HIV outpatient care. Components of the comprehensive HIV management model implemented at HCA/MHUMC Family Medicine Residency Program include didactic training in HIV pharmacotherapy, mental health, and the comprehensive components of the pre-exposure prophylaxis regimen. Moreover, the residents are able to gain hands-on experience treating HIV patients at the on-campus Family Care Clinic and in the HCA/MHUMC Emergency Department. (Figure 1)

As a result of adding HIV management training to the curriculum, current residents reported an increase in confidence while caring for HIV patients leading to more positive patient interactions. Most importantly, the residents are able to recognize the importance of early intervention to improve long-term healthcare outcomes. After participating in the focused curriculum, the 2017 graduating residents demonstrated an increased confidence in their ability to care and treat patients with HIV along with their other primary care needs. (Figure 2)

A further benefit of the HIV management training was identified in exit polls from medical students on interviews for residency positions, who noted the HIV management curriculum as a major factor for selecting MHUMC for residency training. This added benefit of the HIV management

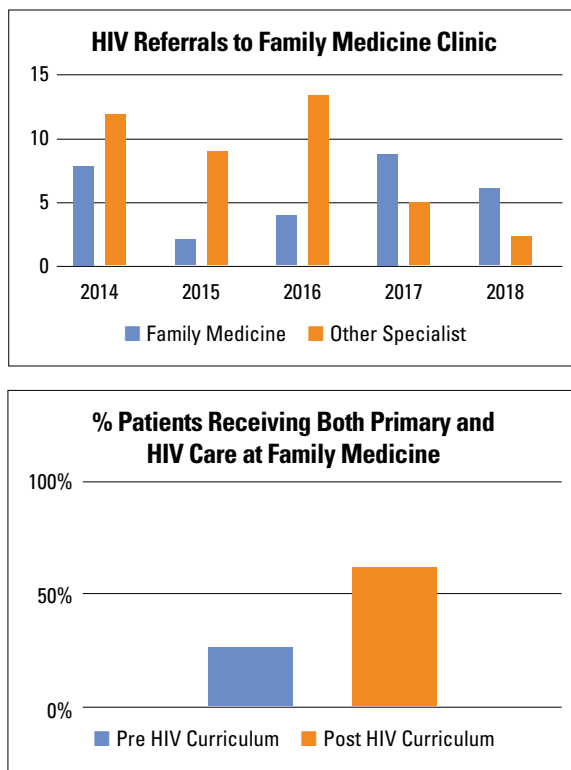
## HIV in the South

The effort to train family medicine physicians in HIV care is timely. In 2015, more than half of the new HIV infections in the United States occurred in the South.<sup>3</sup> The following year, the state of Georgia was exceeded only by the District of Columbia in its rate of new HIV diagnoses per 100,000 people. Current data identifies Chatham county, where HCA/Memorial and the MUSM-Savannah campus are located, as having one of the highest HIV incidence rates outside of the metro Atlanta area.<sup>4</sup> Georgia public health authorities and allied health groups have identified a pressing need to increase the number of HIV providers in metropolitan hotspots such as Fulton county; however, evidence that HIV is also proliferating in rural areas underscores a growing need for HIV providers across the state.<sup>5</sup>

## Providers Not Prepared to Treat HIV

Georgia faces a critical lack of healthcare providers<sup>6</sup>. A paucity of rural clinicians skilled in treating HIV, however, cannot be solely attributed to the overall provider shortage. The Family Medicine Department at the MUSM-Savannah campus, who also serve as faculty members in the HCA/MHUMC Family Medicine Residency Program, created the new HIV curriculum. Rural communities often lack providers who are comfortable caring for people living with HIV. Further, stigma or the perception of stigma from providers can act as a barrier to care for rural HIV patients who may otherwise have access to HIV care providers.<sup>7</sup>

Finally, graduate medical education programs may not be adequately preparing family medicine residents for HIV care. Three quarters of respondents of a 2014 national survey of family medicine residency program directors (n=224) did not believe that residents were being sufficiently prepared to provide HIV care.<sup>8</sup> The perception is that HIV care should be provided by an ID specialist only.



curriculum will ensure a stream of physicians to care for HIV-positive patients in rural and underserved communities for the future. Ultimately, patients who often have limited resources or cannot leave jobs for specialty care are able to gain access to HIV treatment with their local physician. Training Family Medicine Residents to manage HIV eliminates the barrier resulting from a lack of specialists in rural areas. Patients no longer need to travel miles to receive appropriate care.

## Conclusion

Rural southern communities, such as Dougherty county, Georgia, where the 2016 HIV incidence rate was an astonishing 72.2 per 100,000 are increasingly confronting the reality that HIV/AIDS is a disease that knows no boundaries. Barriers to care experienced by patients in such rural communities are multifarious, but not intractable. Tailored training programs like the one at HCA/MHUMC Family Medicine Residency Program can potentially extend lifelines to disparate populations throughout the state as new graduates begin to practice independently in rural communities. Such programs are essential for ensuring that the next generation of medical providers are equipped and empowered to treat HIV in underserved areas. **HIV**



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**Jean Wiggins, BSPH** is the Sr. Administrator for Continuing Medical Education, the Graduate

Medical Education Clinical Learning Environment, and the CARE Initiative at HCA/Memorial Health University Medical in Savannah, Georgia. Ms. Wiggins led the initial program design and implementation of the opt-out HIV Screening Program (CARE Initiative) at Memorial Health's Level 1 Trauma Center. She continues to drive change throughout the organization by promoting expansion of the CARE Initiative to HCA primary care practices and to educate its Internal Medicine residents to provide HIV care in the primary care setting.



**MariAnna O'Ree, MPH, PMP** is the CARE Initiative Coordinator at HCA/Memorial Health University Medical Center in

Savannah, Georgia. Her vast experience of assisting the uninsured and underinsured to receive healthcare services has guided the CARE Initiative Linkage Specialists to work through barriers to meet the needs of all patients. As a certified project manager

professional, Ms. O'Ree identified continuous quality improvement opportunities that enabled the CARE Initiative to increase screening and linkage rates by 7% over the previous year to provide better outcomes.



**Bonzo Reddick, MD, MPH** is the Dean of Diversity and Inclusion at the Mercer University School of Medicine and is a faculty

member at Memorial Health University Medical Center in the Family Medicine Residency Program in Savannah, Georgia. As the Principle Investigator for the CARE Initiative, Dr. Reddick led its development and also the design of the Family Medicine Residency Program HIV Curriculum. Following his passion to provide healthcare for the underserved, Dr. Reddick currently practices at the JC Lewis Community Health Center, a local Federally Qualified Health Center.

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# Testing Teens for HIV

## Are We Doing What We Should?

**I**N 2015, THERE WERE OVER 1.1 MILLION ADULTS AND ADOLESCENTS LIVING WITH HIV in the U.S.<sup>1</sup> Youth aged 13 to 24 accounted for nearly one-fifth of all new HIV infections and an estimated 44% were unaware of their diagnosis.<sup>1,2</sup> A series of guidelines issued by the Centers for Disease Control and Prevention (CDC) in 2006, the American Academy of Pediatrics (AAP) in 2011, and the United States Preventive Service Task Force (USPSTF) in 2013, characterized the best practices for routine HIV testing. Despite these recommendations, discrepancies in HIV testing still exist.<sup>3,4,5</sup>

For physicians, common barriers to HIV testing are attitudes on testing, limited knowledge on testing guidelines, and perceived low prevalence of HIV in their respective communities.<sup>6,7</sup> Patient barriers include factors such as a lack of sexual health knowledge or denial that one may have been exposed to HIV.<sup>7</sup> It is, therefore, crucial to have standardized screening guidelines that minimize these biases and shift testing behavior from risk-based to routine.

Since little is known about how often pediatricians test their patients for HIV, we set out to assess the prevalence of HIV testing among patients aged 13-18 years in a large university-based practice. Additionally, we examined the relationship between known risk factors associated with HIV testing. We hypothesized there would be a higher prevalence of testing in the adolescent clinics compared to the general pediatrics clinics and a proportional increase in testing in 2015 compared to 2010.

### Methods

We conducted a retrospective chart review of patients aged 13 to 18 seen in the pediatric and adolescent medicine clinics that are part of the University of Texas Physicians practice in Houston, TX. Patients that presented for either a well-child check or sick visit from January 1, 2010 to December 31, 2010 and January 1, 2015 to December 31, 2015 were included. Nurse and vaccine-only visits were excluded. The study was approved by the institutional review board and data was abstracted from the electronic medical record.

The primary outcome was whether a patient was tested for HIV by year (2010 vs. 2015) and clinic location (pediatric vs. adolescent). The chi-squared test was used to compare the proportion of HIV testing within each clinic, and then the Mantel-Haenszel (MH) test evaluated if risk ratios (RR) (testing rate in adolescent clinics / testing rate in pediatric clinics) were consistent across years and age



Variable		HIV Test 9.3% (n = 131)	No HIV Test 90.7% (n = 1,723)	p-value
Age Group	13–15	37.4 (49)	66.6 (848)	<0.001
	16–18	62.6 (82)	33.4 (425)	
Sex <sup>a</sup>	Female	59.5 (78)	48.9 (622)	0.053
	Male	40.5 (53)	51.1 (650)	
Race/Ethnicity	Caucasian	3.0 (4)	13.6 (173)	>0.001
	African American	72.5 (95)	57.0 (726)	
	Hispanic	17.6 (23)	17.4 (222)	
	Asian	2.3 (3)	2.8 (35)	
	Unknown/Other	4.6 (6)	9.2 (117)	
Sexual Orientation	Heterosexual	64.1 (84)	27.5 (350)	<0.001
	Homosexual	3.8 (5)	1.2 (15)	
	Bisexual	6.9 (9)	1.0 (13)	
	Unknown	25.2 (33)	70.3 (895)	
Sexual Activity	No	26.0 (34)	52.9 (674)	<0.001
	Yes	70.2 (92)	14.3 (182)	
	Unknown	3.8 (5)	32.8 (417)	
STI (past/present)	No	12.2 (16)	2.9 (37)	<0.001
	Yes	87.8 (115)	97.1 (1,236)	
H/o Smoking	No	87.0 (114)	87.6 (1,085)	0.006
	Yes	6.9 (9)	1.9 (34)	
	Unknown	6.1 (8)	10.4 (154)	
H/o Alcohol Use	No	77.9 (102)	70.8 (901)	<0.001
	Yes	16.0 (21)	4.3 (55)	
	Unknown	6.1 (8)	24.9 (317)	
H/o Illicit Drug use	No	77.1 (101)	70.6 (899)	<0.001
	Yes	19.9 (26)	4.8 (61)	
	Unknown	3.0 (4)	24.6 (313)	

<sup>a</sup>1 patient that reported sex as “other” (0.1%)

groups. Chi-squared and Fisher’s exact tests were used to compare the sociodemographic, substance use, and sexual characteristic variables by the presence or absence of HIV testing. The level of significance was two-sided <0.05 and STATA version 14 SE was used for all analyses.

## Results

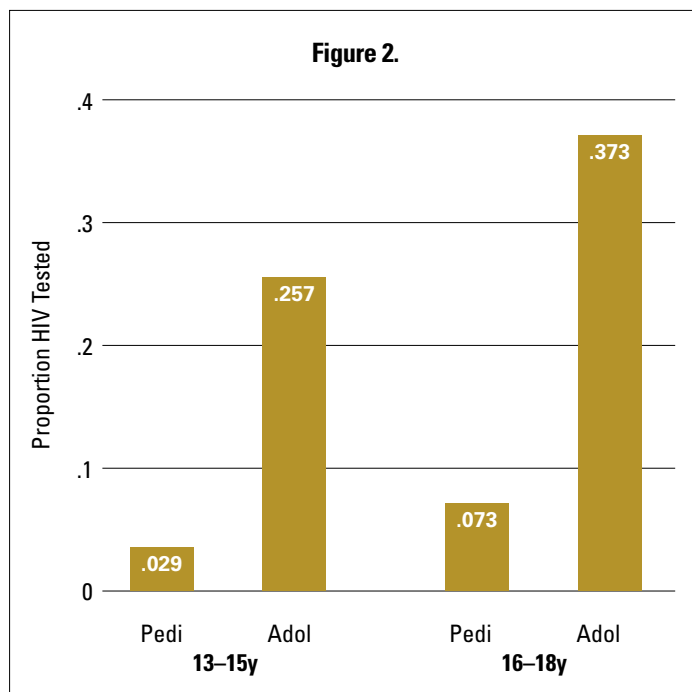
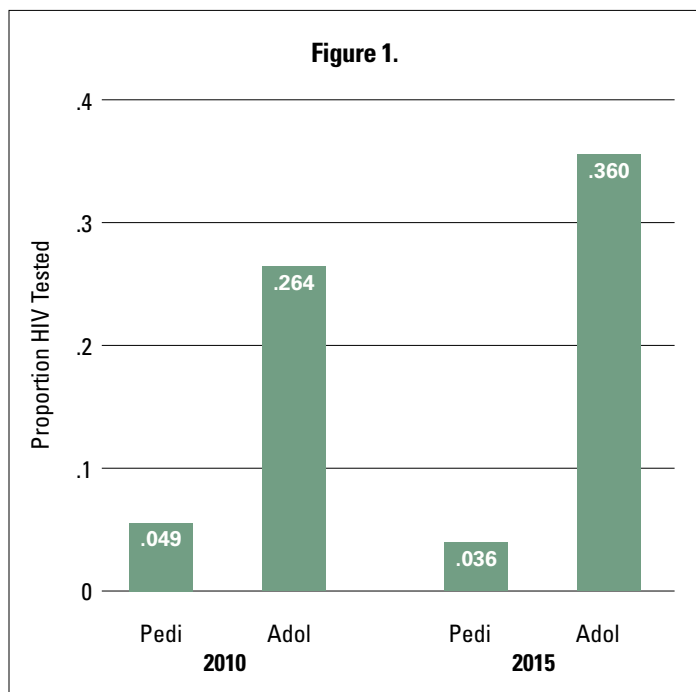
A total of 1404 patients were included in this study (725 in 2015 vs. 679 in 2010). Nearly half (49.9%) were female with a mean age of 14.9. Approximately 58.5% of the patients were African American, 17.5% Hispanic, 12.6% White, 2.7% Asian, and 8.8% Other. The overall testing rate for HIV was 9.3%; patients were more likely to be tested in the adolescent clinics (33% vs 4% in pediatrics, RR=7.69). While both clinics were more likely to test older patients at a slightly higher rate, there was no significant difference in the clinic testing RR between the 13-15 and 16-18 age groups (MH p=0.1013).

In 2010, 4.9% of patients seen in the pediatric clinics were tested for HIV compared to 26.4% in adolescent (RR=5.4). While in 2015, rates decreased to 3.6% in pediatric clinics but increased to 36.0% in adolescent clinics (RR=10.1, MH p=0.0696). Of the 131 patients tested for HIV, the average age was 15.9, 26.7% reported unprotected sexual activity, 70.2% were sexually active, and 44.3% reported condom use at the visit.

## Discussion

In 2016, there were 1,675 teens ages 13 to 19 newly diagnosed with HIV.<sup>1</sup> However, the most recent Youth Risk Behavior Surveillance found that only 10.2% of high school students report ever being tested for HIV in 2015.<sup>2</sup> Identification of positive youth is key for linkage to care, prescribing of and adherence to HIV medication, achieving a non-detectable viral load, and preventing transmission.

Among our clinic groups, the overall testing rate of 9.3%



is comparable to the CDC national data, but within each clinic group the risk of being tested for HIV was 7.7 times higher in teens who were seen in the adolescent compared to the pediatric clinics. A potential element of confounding in this study is whether teens seen in the adolescent clinic were tested because of known risk factors for HIV or because these patients were seen in a more specialized clinic setting. Thus, similar studies in other practice settings to determine how and when physicians

decide to test for HIV will be crucial. This study provides important information on how often teens were tested within this population but may not be generalizable to other settings. Understanding these lessons is important for the future design and implementation of interventions directed towards routine, non-risk-based, screening.

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