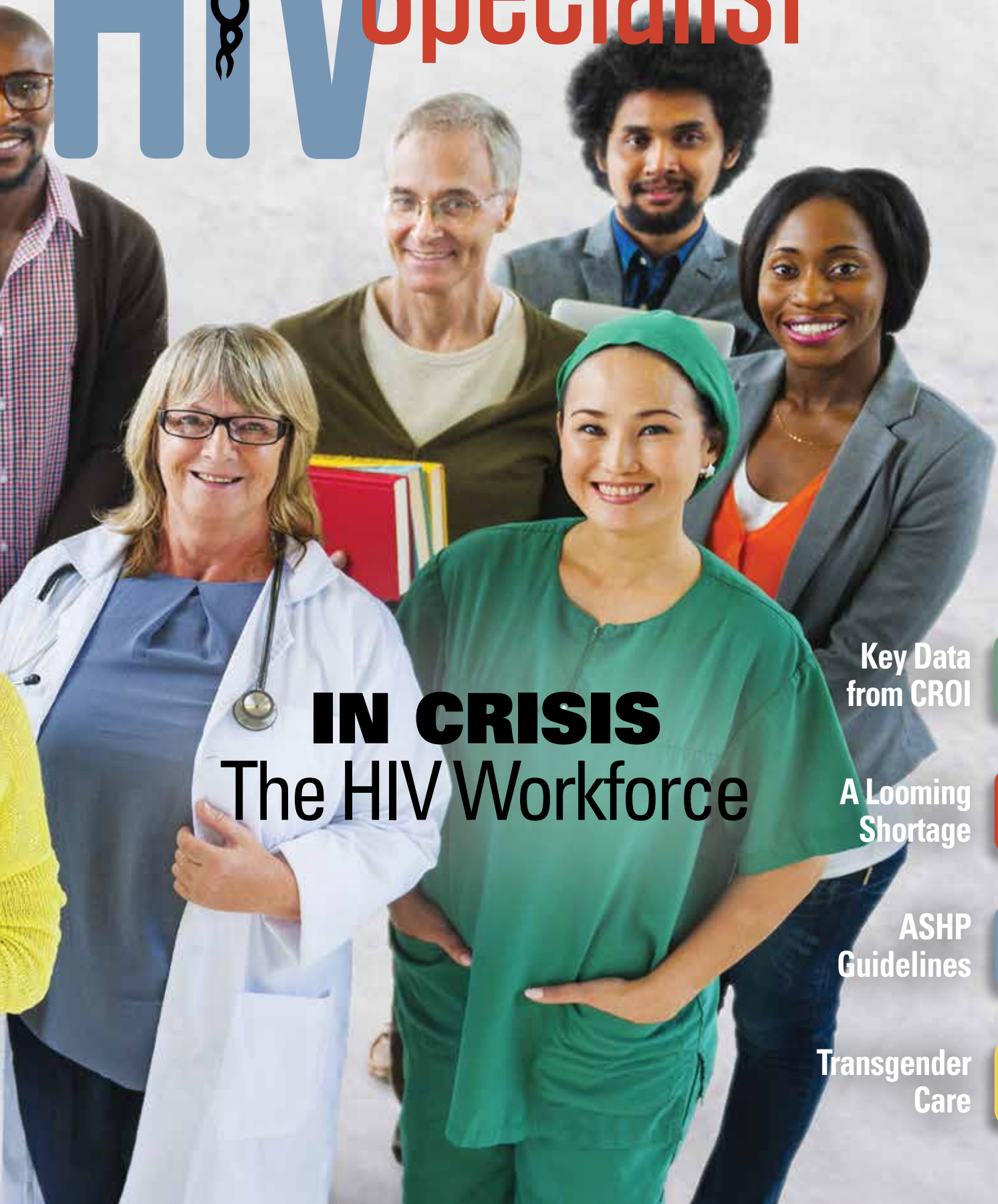


# HIV Specialist



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# Are Your Patients Pregnant and HIV-Positive?

We are seeking your professional consideration in the referral of patients for a study to assess the pharmacokinetics of darunavir and cobicistat, in HIV-1 Infected pregnant women.

The program is open to HIV-positive pregnant women who:\*

- Are at least 18 years, and in their first six months of pregnancy
- Are already taking darunavir and cobicistat
- Have a normal physical exam and ultrasound
- Are receiving care for their pregnancy and HIV from an obstetrician and/or a primary HIV provider, and agree to continue doing so during the study
- Are willing to continue taking their darunavir and cobicistat—as well as their other medicines—during the study

\* This is not a complete list of the inclusion/exclusion criteria

For more information please contact Keith Dunn at Janssen Scientific Affairs at [kdunn1@its.jnj.com](mailto:kdunn1@its.jnj.com) or visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (ClinicalTrials.gov Identifier: NCT00855335)

Open sites are recruiting patients in the following cities:

- Syracuse, NY
- Savannah, GA
- Chicago, IL
- West Palm Beach, FL
- Philadelphia, PA
- Greensboro, NC
- Daytona Beach, FL
- Miami, FL
- San Juan, PR
- New York, NY
- Houston, TX

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BY JAMES M. FRIEDMAN, MHA  
EXECUTIVE DIRECTOR, AAHIVM

## Looking Forward

**T**HIS ISSUE OF *HIV SPECIALIST* focuses on the HIV workforce, harkening back to the very first issue of our magazine in February 2009, which also focused on the same topic. The 2009 issue reported on two AAHIVM surveys—one of HIV practitioner students and what they were looking for in a career, and the other of our members and how satisfied they have been in their careers. The comparison between the two surveys demonstrated that our members reported experiencing exactly what the students were seeking—a fulfilling and meaningful career.

That part hasn't changed over time. While our members experience challenges within the HIV field, we also consistently hear that they leave their settings of care with a sense of pride in their work and admiration for their patients. That's the good news.

The bad news is the somber statistics we forecasted in February of 2009 are becoming a reality. There is a shortage of HIV care providers and we anticipate it getting worse before it gets better. More HIV Specialists are retiring and fewer students are choosing to specialize in HIV care. This issue tackles those realities head on.

The same is true for the Academy as a whole. We are constantly looking at ways to expand our reach to more providers that might be encountering HIV patients or students that may be considering entering the field. For instance, we created a webinar program with Medscape to provide the basics of HIV care to primary care practitioners. Our *Fundamentals of HIV Medicine* will be published through Oxford University Press this summer and will have a broader reach than in the past. In addition, our HIV-Age blog provides guidance on managing the chronic diseases of older HIV patients.

Along with many other training programs and recruitment initiatives, we know we are making

progress. For example, a Centers for Disease Control and Prevention (CDC) study presented at CROI reported that rates of HIV suppression on the latest

viral load test climbed from 72% in 2009 to 80% in 2013 in a nationally representative U.S. sample studied by the CDC. Another CDC report at CROI indicated that we could reduce the annual HIV infection rate by up to 70% by 2020 if certain conditions are met.

But as always, we all need to do more if we are to eliminate the HIV epidemic in the U.S. And we will. We recently hosted Dr. Carl Dieffenbach, director of the Division of AIDS at the

National Institutes of Health (NIH), as the guest speaker for the Academy's HIV Update event at the CROI conference. Dr. Dieffenbach shared his enthusiasm for the latest HIV research and his optimism for future advances. In that same vein, the Academy has just started a new strategic planning process that will help us adjust our efforts to better meet the needs of our members to end the HIV epidemic in this country. We recently met with our Board of Directors at CROI to discuss the best way to align the Academy to achieve this goal. Feel free to send me your insights and suggestions—[jfriedman@aahivm.org](mailto:jfriedman@aahivm.org).



James M. Friedman

**More HIV Specialists are retiring and fewer students are choosing to specialize in HIV care. This issue tackles those realities head on.**

**New** from **CDC:**  
**Prevention IS Care Resource Kit**



# **HIV Care**

## **IS BUILT ON SMALL TALKS**

Newly developed by CDC, this updated suite of materials for providers and patients will help HIV-infected patients live longer, healthier lives. Topics include:

- ▶ Improving patient adherence to ART
- ▶ Promoting safer sexual behaviors
- ▶ Helping patients remain in ongoing care

**To order FREE materials,**  
visit [www.cdc.gov/actagainstaids/pic](http://www.cdc.gov/actagainstaids/pic)  
or call 1-800-CDC-INFO (232-4636)



# In the NEWS

## As many as 185,000 new HIV infections in the U.S. could be prevented by expanding testing, treatment, PrEP

Reaching the National HIV/AIDS Strategy (NHAS) targets for HIV testing and treatment and expanding the use of daily Pre-Exposure Prophylaxis (PrEP) could prevent an estimated 185,000 new HIV infections in the United States by 2020—a 70 percent reduction in new infections, according to researchers at the Centers for Disease Control and Prevention (CDC).

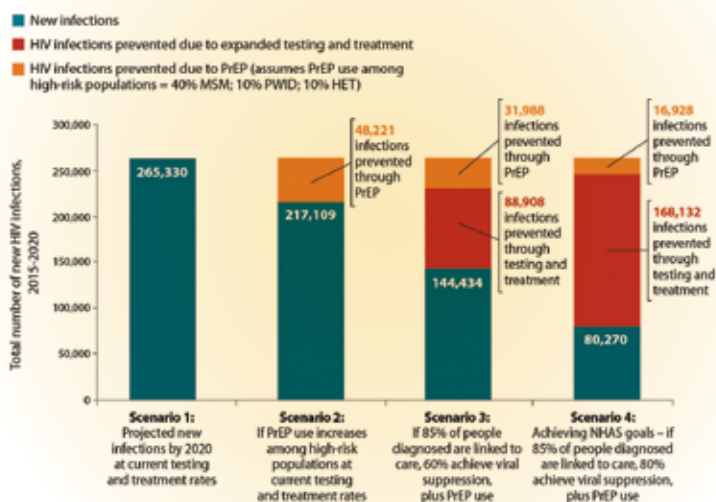
The study, presented at the Conference on Retroviruses and Opportunistic Infections in Boston, uses a forecasting model to predict the impact of these key prevention strategies. Based on the reach of each strategy, CDC researchers examined the impact of fully achieving NHAS goals, as well as several alternate levels of success (Graphic: Four Scenarios of the Potential Impact of Expanded HIV Testing, Treatment and PrEP in the US, 2015-2020).

Reaching the nation’s treatment goal of ensuring 80% of all of those diagnosed with HIV achieve viral suppression alone would prevent an estimated 168,000 infections over the next five years. Increasing the use of PrEP, a daily anti-HIV pill, among people who are uninfected but at high risk could prevent an additional 17,000 infections over the same time span.

Currently, however, less than a third of Americans with HIV are on sustained treatment that effectively keeps their virus suppressed. And too few people who are at substantial risk for HIV and who could benefit from PrEP are receiving it.

“If we expand the use of our current prevention strategies today, we can significantly reduce new HIV infections tomorrow,” said Jonathan

**Four Scenarios of the Potential Impact of Expanded HIV Testing, Treatment and PrEP in the United States, 2015-2020**



Source: Centers for Disease Control and Prevention

Mermin, M.D., director of CDC’s National Center for HIV/AIDS, Viral Hepatitis, STD, and Tuberculosis Prevention. “This study confirms that we have the right tools to dramatically reduce new HIV infections, but we have a long way to go in order to make those reductions a reality.”

## JUSTICE DEPARTMENT SETTLES HEP-C DISCRIMINATION CASE

**THE U.S. JUSTICE DEPARTMENT** has reached an agreement with Kemper Moving Systems Inc., a Huntsville, Alabama, franchise of Two Men and a Truck, to resolve allegations that the moving company violated the Americans with Disabilities Act (ADA) when it refused service because of a customer’s Hepatitis-C.

Under the terms of a two-year consent decree filed Feb. 2 in the U.S. District

Court for the Northern District of Alabama, Two Men and a Truck will adopt a series of non-discrimination training and policy reforms. The company must also pay \$10,000 in compensation to the victim and a \$3,500 civil penalty to the United States.

“The ADA prevents public accommodations, including moving companies, from denying service to people because of their disability status,” said Principal Deputy Assistant Attorney General Vanita Gupta, head of the Justice Department’s Civil Rights Division. “The

Department of Justice stands firmly committed to protecting the rights of people who live with Hepatitis-C by combating unlawful discrimination, addressing unfounded stereotypes and eradicating the painful stigma that interferes with their daily lives.”

“The Americans with Disabilities Act was passed just over 25 years ago with the promise of opening up all aspects of American life to individuals with disabilities,” said U.S. Attorney Joyce White Vance of the Northern District of Alabama. “Our office is committed to ensuring that this promise is kept and that those individuals with disabilities are given equal access to accommodations and services.”



## HIVMA Recommends Doctors, Patients Discuss Need for Common Tests

The HIV Medicine Association (HIVMA) has released recommendations on commonly ordered, but not always necessary tests and procedures, to help patients and medical providers make the most of healthcare opportunities and resources, as part of the ABIM Foundation's Choosing Wisely® campaign.

The five recommendations serve as a starting point for conversations between patients and their providers about evidence-based care, HIVMA said.

Developed through input from specialists in HIV care, and the most recent recommendations for HIV management, HIVMA has identified five tests that physicians and patients should question:

- **Avoid unnecessary CD4 tests**

CD4 monitoring is not necessary for patients who have stable viral suppression. For the first two years after treatment initiation, the CD4 count should be monitored every three to six months. After two years, if the viral load is undetectable, the CD4 count should be measured yearly if it is 300–500 cells/mm<sup>3</sup>. If it is consistently above >500 cells/mm<sup>3</sup> then further monitoring is optional.

- **Don't order complex lymphocyte panels when ordering CD4 counts**

Order only CD4 counts and percentages rather than ordering other lymphocyte panels.

- **Avoid quarterly viral load testing of patients who have durable viral suppression, unless clinically indicated**

Viral load testing should be conducted before initiation of treatment, two to eight weeks after initiation or modification of therapy, and then every three to four months to confirm continuous viral suppression. In clinically stable patients who have durable virological suppression for more than two years, clinicians may extend the interval to six months.

- **Don't routinely order testing for glucose-6-phosphate dehydrogenase (G6PD) deficiency for patients who are not predisposed due to race/ethnicity**

G6PD deficiency testing is recommended upon entry into care or before starting therapy with an oxidant drug only in HIV-infected patients who are predisposed to this genetic disorder that can cause hemolytic anemia. G6PD most frequently occurs in populations of African, Asian and Mediterranean descent and is most likely to affect HIV-infected patients with one of these racial or ethnic backgrounds.

- **Don't routinely test for Cytomegalovirus (CMV) IgG in HIV-infected patients who have a high likelihood of being infected with CMV**



Cytomegalovirus (CMV) IgG testing is recommended only in patients who are at lower risk for CMV to detect latent CMV infection. CMV IgG testing is not necessary in patients at higher risk for CMV, because they can be assumed to be CMV positive. Testing for CMV antibody in low-risk populations is recommended to foster patient counseling in avoidance of CMV infection through practicing safe sex and to avoid transfusion except with CMV-negative blood products. Patients at lower risk for CMV infection should be tested for latent CMV infection with an anti-CMV IgG upon initiation of care.

"Providing high quality care to our patients also means not ordering unnecessary tests. Implementing these principles in our practice will save money by avoiding unnecessary tests," HIVMA Chair Dr. Carlos del Rio said.

## STUDY: High-Risk Sex 10X More Likely for Young Men Than Women

A new study of the sexual habits of nearly 85,000 young people suggests that males are at least ten times more likely to engage in high-risk sexual behavior than their female counterparts.

Writing in the *SAHARA-J: Journal of Social Aspects of AIDS/HIV*, Yifru Berhan and Asres Berhan sifted through data from the Demographic and Health Surveys data (21 from sub-Saharan Africa plus Bolivia, Cambodia, Guyana, Haiti and Vietnam) to understand how the practices of young males and females differed. They also

investigated the influence that age, wealth and educational background had on their sexual behaviour.

The researchers found that males aged 15–19 were 27 times more likely than females the same age to indulge in high-risk behavior, defined as having unprotected heterosexual sex with non-regular partners during the last year. The data also suggested that living in an urban area, being well educated, belonging to a higher economic group and, importantly, just being a young male, made a person more likely to take chances.

The authors conclude: "In the

majority of the included countries, the susceptibility of male youths to higher risk sex was significantly higher than the female youths regardless of the assessed independent variables (sex, age, education, residence and wealth index) ... The consistent and strong association of higher risk sex with male youth is probably strong evidence to surmise that being a male youth is a strong predictor of practicing higher risk sex than the other assessed variables."

Read the full article: <http://tandfonline.com/doi/full/10.1080/17290376.2015.1123641>



# In the NEWS

## FDA OK's Gilead's Second TAF-Based Single Tablet Regimen for HIV

**G**ILEAD SCIENCES, INC. announced Mar. 1 that the U.S. Food and Drug Administration (FDA) has approved Odefsey(R) (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir alafenamide 25 mg or R/F/TAF) for the treatment of HIV-1 infection in certain patients.

Emtricitabine and tenofovir alafenamide are from Gilead Sciences and rilpivirine is from Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen). Odefsey, Gilead's second TAF-based regimen to receive FDA approval, represents the smallest pill of any single tablet regimen for the treatment of HIV.

Odefsey is indicated as a complete regimen for the treatment of HIV-1 infection in patients 12 years of age and older who have no antiretroviral treatment history and HIV-1 RNA levels less than or equal to 100,000 copies per mL. Odefsey is also indicated as replacement for a stable antiretroviral regimen in those who are



virologically-suppressed (HIV-1 RNA less than 50 copies per mL) for at least six months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Odefsey. No dosage adjustment of Odefsey is required in patients with estimated creatinine clearance greater than or equal to 30 mL per minute.

Odefsey has a boxed warning in its product label regarding the risks of lactic acidosis/severe hepatomegaly with steatosis, and post treatment acute exacerbation of hepatitis B.

TAF is a novel targeted prodrug of tenofovir that has demonstrated high antiviral efficacy similar to and at a dose less than one-tenth that of Gilead's Viread(R) (tenofovir disoproxil fumarate, TDF). TAF has also demonstrated improvement in surrogate laboratory markers of renal and bone safety as compared to TDF in clinical trials in combination with other antiretroviral agents. Data show that because TAF enters cells, including HIV-infected cells, more efficiently than TDF, it can be given at a much lower dose and there is 90% less tenofovir in the bloodstream.

"As people are living longer with HIV, there is an increasing need to develop new treatments that are tolerable and help address long-term health for patients," said John C. Martin, PhD, chairman and chief executive officer, Gilead Sciences. "Odefsey's safety, efficacy and tolerability profile offers a new treatment option to support the needs of a range of patients and represents Gilead's commitment to innovation in the field of HIV."

## FDA to Make Decision in June on Gilead's Hep C Combo Drug

THE FOOD AND DRUG ADMINISTRATION (FDA) is expected by June 28 to make a decision on Gilead Sciences' experimental hepatitis C combination drug, a combination of Sovaldi with velpatasvir. The FDA earlier gave that drug combination treatment breakthrough therapy designation, which is granted to experimental medicines that may offer major advances over existing options.

## Gay Man Adhering to Daily Truvada Contracts Drug-Resistant HIV

**R**esearchers have for the first time documented a case of an individual contracting HIV, a multi-drug resistant strain, while apparently adhering well to the daily regimen of Truvada (tenofovir/emtricitabine) as pre-exposure prophylaxis (PrEP). The scientists concluded that it is indeed possible for individuals who are adherent to PrEP to contract HIV when they are exposed to a virus that is resistant to both drugs included in Truvada.

While this case is concerning, experts in the PrEP field believe that such failures of PrEP will likely remain rare.

David Knox, MD, an HIV specialist at the Maple Leaf Medical Clinic and the lead author of the case study, presented findings at the 2016 Conference on Retroviruses and Opportunistic Infections (CROI) in Boston.

Evidence suggests that the individual in question, a 43-year-old Canadian man who has

sex with men, adhered well to PrEP over the long-term. Nevertheless, after 24 months on Truvada he tested positive for HIV. Initial tests indicated that he was acutely (very recently) infected: He tested positive for the p24 antigen, which appears within about three weeks of HIV infection and disappears a few weeks afterward; and at that time he tested negative for HIV antibodies, which typically appear two to eight weeks after infection.



## AAHIVM and the Institute For Technology in Health Care Announce the 2016 HIV Practice Award Winner

### THE AMERICAN ACADEMY OF HIV MEDICINE

is pleased to announce Dr. Jason Leider, MD, PhD, FACP, of the Jacobi Medical Center ACS Clinic in the Bronx, NY, as the winner of the fifth annual AAHIVM/Institute for Technology in Health Care HIV Practice Award. Dr. Leider will receive \$20,000 in recognition of his innovative use of technology in HIV care.

Alongside his colleague, Dr. Yvette Calderon, Dr. Leider developed Project BRIEF which stands for Behavior intervention, Rapid HIV test, Innovative video, Efficient cost and health care savings, Facilitated seamless linkage to outpatient HIV care. Project BRIEF is an innovative testing and linkage to care model that uses multimedia education and Public Health Advocates (PHAs) to counsel and test patients for HIV in the Emergency Department (ED), Inpatients wards (IP) and community pharmacies.



Dr. Jason Leider

The HIV epidemic in the Bronx is significant with 25,000 of the Bronx's 1.3 million population living with HIV, ranking only behind the states of Florida, Texas, and California. Dr. Leider's challenge was to provide HIV testing in chaotic environments to a population at high risk for HIV that also faces significant barriers to testing such as stigma, poor access to care, and low literacy.

Since Project BRIEF's inception in 2005, over 200,000 people have been tested. Acceptance for HIV testing has been 93.8% via Project BRIEF, with impressive satisfaction scores. The BRIEF model allows quality of care, sensitive to the individual's needs and challenges, to be addressed while maintaining high levels of linkage to care. Dr. Leider and his colleagues have been able to replicate the model in other clinical settings, both regionally, nationally and internationally.

"BRIEF helps curb the epidemic, by educating diverse populations about HIV and risk reduction, increasing HIV testing volume, linking HIV positive individuals to expert HIV care via an open access system, thus aiding in reduction of community viral load," stated Dr. Leider. "I am honored to be recognized for the program's success and will utilize the award funds to expand the program to even more people."

According to the award committee, the goal is to acknowledge those who have created, adapted and/or used innovative technology in their HIV practice and to share that technological knowledge with others in the practice of HIV medicine to improve patient care.

As the winner of the AAHIVM/Institute for Technology in Healthcare HIV Practice Award, Dr. Leider will be presenting on Project BRIEF at the 2016 ACTHIV Conference in Dallas, Texas on April 28-30th.

"We recognize that through the creative and effective use of technology, Dr. Leider has been able to treat patients in need despite many obstacles," stated James M. Friedman, AAHIVM executive director. "The hopeful continuation of this award for years to come gives us the privilege to share HIV care providers with the best practices in technology, thereby constantly improving the quality of patient care for all."

HIV

Project  
B.R.E.F.  


# Key Data from CROI

## New scientific and clinical information offered

**T**HE 23RD CONFERENCE ON RETROVIRUSES AND OPPORTUNISTIC INFECTIONS (CROI) was held in Boston February 22-25 with approximately 4,000 attendees from around the world, including many members of the AAHIVM board and staff, and was filled with a great deal of new scientific and clinical information.

Following is a synopsis from several key studies, including an interesting update on the origin of HIV in the United States. In addition, I encourage readers to visit the CROI website (<http://www.croiconference.org>) where you can view all 1,023 the abstracts and watch webcasts of the plenary presentations, press conferences, symposia, workshops, themed discussions, and oral abstracts.



### Switching Tenofovir DF to Tenofovir Alafenamide in Virologically Suppressed Adults – 48 week data.

*Gallant JE et al. Abstract #29*

Emtricitabine/Tenofovir DF (Truvada™) is a commonly used, first-line combination nucleoside reverse transcriptase inhibitor, but it has been associated with renal and bone toxicities. Tenofovir alafenamide (TAF) the recently FDA-approved tenofovir prodrug achieves 90% lower plasma drug levels than tenofovir DF (TDF) and in clinical trials had minimal effect on renal function and bone mineral density compared to TDF.

This study randomized virologically suppressed patients (HIV-RNA < 50 copies) who were receiving FTC/TDF-containing regimens to fixed-dose FTC/TAF or continuing FTC/TDF while remaining on the same third agent that was either a PI, ISI, or NNRTI. The primary endpoint was virologic success at week-48 by Intention-to-Treat analysis.

The study randomized 633 patients into two arms. Median age was 49 years and 15% were women. Median estimated GFR (eGFR) was 100 mL/min. Through Week-48, virologic suppression was maintained in 94.3% of patients on TAF and 93% on TDF. Resistance was extremely rare (0.3% vs 0), as were drug-related serious adverse events (0 vs 0.3%). There were no cases of proximal renal tubulopathy in either group. The median eGFR improved by +8.4 mL/min in the TAF group and +2.8 mL/min in the TDF group. Quantitative measures of proteinuria improved in the TAF group, but not in the TDF group. Bone mineral density (BMD) increased at the hip (1.14%) and spine (1.53%) in the TAF group, but declined slightly in the TDF group.

The study showed that in switching from TDF to TAF virologic suppression was maintained at 48 weeks, while renal and bone safety parameters improved. The complete 96-week data will be presented later this year.



### Aspirin Fails to Impact Immune Activation or Endothelial Function in Treated HIV (ACTG A5331)

*O'Brien MK et al. Abstract #44LB*

Immune activation persists despite optimally treated HIV infection and predicts non-AIDS co-morbidities, including CVD and malignancies. Activated platelets play a key role in thrombosis and inflammation, and HIV induces platelet activation by direct and indirect mechanisms. Aspirin (ASA) is a known inhibitor of platelet activation.

This study hypothesized that oral ASA would reduce immune activation and improve endothelial function in persons suppressed on ART. Participants included 121 HIV-infected adults (on ART for >48 weeks with viral load < 50 copies/ml) randomized to 100mg or 300 mg of daily ASA or placebo for 12 weeks, followed by a 4-week washout.

The primary outcome was level of soluble CD14 (sCD14), a marker for monocyte/macrophage activation. Secondary outcomes included measurement of D-dimer, IL-6, sSD163, flow-mediated dilation (FMD), and thromboxane (a direct indicator of cyclooxygenase inhibition). The ASA was well-tolerated with only one person reporting GI bleeding from the placebo arm. Serum thromboxane levels were significantly inhibited by aspirin, suggesting good drug adherence by the participants. There were NO consistent differences between the 100mg or 300mg ASA arms vs. placebo for sCD14, FMD, or any other laboratory endpoints.

Interactions by current smoking, sex, age, and ART regimen were assessed, with ASA showing less of an increase in sCD163 among smokers and women, and greater reductions in D-dimer among smokers. The authors concluded that 12 weeks of ASA therapy did not significantly impact immune activation or endothelial function in ART-suppressed persons.

These data do NOT support the use of ASA as an anti-inflammatory in patients with HIV infection. There may be some subgroups, perhaps those with higher degrees of CVD risk, that derive benefit from ASA, which should be explored in future studies.



### Recovery of Bone Mineral Density after Stopping Oral HIV Preexposure Prophylaxis

Grant R et al. Abstract #48LB

Oral pre-exposure prophylaxis (PrEP) with emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) is associated with small decreases in bone mineral density (BMD) compared with placebo. Whether BMD recovers after stopping PrEP is not known and has been a concern regarding its use in HIV-negative individuals.

The iPrEx trial was the first RCT of daily oral FTC/TDF PrEP versus placebo among MSM. The randomized phase of this study was followed by an open-label extension - iPrEx OLE. A sub-study of iPrEx measured BMD by dual-energy X-ray absorptiometry (DXA) every 24 weeks during PrEP use, 24 weeks after stopping PrEP, and at the beginning of iPrEx OLE.

A concentration of tenofovir-diphosphate (TFV-DP) of 16 fmol/m in PBMCs was associated with a 90% reduction in HIV incidence and indicated use of at least two to three tablets per week. Bone Mineral Density in participants with week-24 tenofovir levels above 16 fmol/m were compared with those randomized to receive FTC/TDF who had lower drug concentrations and to those who got placebo.

There were 498 persons enrolled in the iPrEx DXA sub-study in whom BMD decreased during the first 24 weeks of PrEP use. Of these, 352 had follow-up DXA scans 24 weeks after stopping FTC/TDF and 289 (58%) had DXA scans at the start of iPrEx OLE, which was at a median of about 17 months after stopping the study drugs.

For those who maintained tenofovir levels > 16 fmol/m at week 24, (then stopped PrEP), the average BMD recovery was 1.81 % in the spine (P=0.01 vs. placebo) and 1.13% in the hip (P=0.002 vs. placebo). In this group, average spine BMD recovered completely within six months after stopping PrEP. By the start of iPrEx OLE, there was full recovery in both the hip and spine BMD that persisted after adjusting for differences in study retention by age and drug concentrations.

**The authors conclude that loss in BMD does occur with levels of FTC/TDF that are near the minimum required for providing protection from HIV, but BMD normalizes after PrEP is stopped.**





## High Efficacy of HCV Treatment by Primary Care Providers: The ASCEND Study

*Kattakuzhy S Abstract # 538 LB*

There has been an increased availability of newer directly acting antiviral (DAAs) agent approved by the FDA for treating chronic hepatitis C (HCV), but their utilization is limited by the number of physicians willing to provide treatment to patients with this disease.

Kattakuzhy and colleagues conducted this study to evaluate the efficacy and safety of HCV treatment by medical providers, including primary care physicians (PCPs), nurse practitioners (NPs), and Infectious Disease/Hepatology specialists. The trial included HCV-infected patients followed at several community health centers in Washington, DC.

The patients were divided in a non-randomized manner to receive HCV treatment from either a PCP, NP, or ID/GI specialist. All providers received specific training on current IDSA-AASLD HCV treatment guidelines. The patients were treated with ledipasvir and sofosbuvir (LDV/SOF) once a day.

The primary outcome was having an undetectable HCV-RNA viral load 12 weeks after completion of therapy (SVR-12). Adherence to visits at four, eight, and 12 weeks was categorized by a composite score of attendance. There were 600 patients who started treatment with LDV/SOF from May 2015 to November 2015. Patients were predominantly black (96%) and had HCV genotype 1a (72%); 24% were HIV/HCV-coinfected, 20% had cirrhosis.

Of 181 patients for whom results were available, 169 achieved SVR-12 (93.4% per protocol; 86.7% intention-to-treat). Fourteen patients stopped treatment early (4 to AEs and 1 death). Of 12 patients with virologic failure, 1 had breakthrough and 11 had relapse. **There was no significant difference ( $p=0.67$ ) between provider type: NPs (47/49; 95.9%), PCPs (36/38; 94.7%), and specialists (86/94; 91.5%) and protocol attainment of SVR-12.**

Co-infection with HIV did not impact collective SVR-12 or SVR-12 by provider type. Of 419 patients who completed 12 weeks of LDV/SOF, composite adherence was significantly associated with provider type which was 50% in NPs, 41% in PCPs, and 19% in specialists ( $p < 0.001$ ).

This is the first study to demonstrate that oral HCV C therapy administered by PCPs and NPs is safe and effective, inclusive of specific subpopulations and within the largest African-American cohort described to date. Community-based non-specialist providers could significantly expand the scale of HCV therapy for eligible patients.



## 1970s HIV-1 Genomes Reveal the Early History of the North American HIV/AIDS Epidemic

Worobey, M. M et al. Abstract # 140  
(Session 0-11)

The exact origins of the HIV/AIDS pandemic in the Western hemisphere remain controversial. Phylogenetic studies, based upon HIV-1 sequences sampled after the recognition of AIDS in the U.S. and Canada in 1981 have suggested a lengthy period of circulation through the 1970s, and an older presence in the Caribbean region. However, no complete evolutionary genomic analysis of HIV-1 in North America close to the emergence of the virus in the late 1970s has been possible, since no non-African HIV-1 complete genomes from that time have been sequenced.

Dr. Michael Worobey and colleagues used combined methodologies from molecular biology, phylogenetics, and historical analysis to investigate the timing and geography of the emergence of HIV-1 group M subtype B in the U.S.

They recovered near-full length HIV-1 genome sequences from eight U.S. patient serum samples from 1978-79 (8 of the 9 earliest HIV-1 group M genomes sequenced worldwide to date) and also from the person historically referred to as “Patient 0”—and made famous by Randy Shilts 1987 book *And the Band Played On*.

They used maximum likelihood and Bayesian molecular clock phylogenetic and phylogenomic methods to determine geography and timing of the HIV specimens. Their early “genomic snapshot” of HIV-1 revealed that by 1978-79 the AIDS epidemic in the U.S. already exhibited extensive genetic diversity, (especially in New York City) – after emerging around 1970 from a founder strain of HIV traced to an older, more diverse subtype B epidemic in the Caribbean (Haiti).

Of note, there is neither biological nor historical evidence that “Patient 0” was the primary case in the U.S. or for HIV subtype B as a whole. The authors believe their findings reveal a series of key originator events in the genesis of the HIV-1(subtype B) epidemic, with a single virus moving from the Africa to the Caribbean by 1967 [~ 1964-1970]. This was followed by a single virus moving from the Caribbean to create the epidemic in New York City by 1971 [~ 1969-73], and another single virus moving from there to San Francisco by 1975. There was extensive geographical mixing of the virus soon thereafter.

At an oral abstract session, (see Webcast February 25, 2016 10:00 AM-12:00 PM) Worobey discussed, in the context of their research, the genesis and persistence of beliefs about “Patient 0” that are not supported by his data.



## Increased HIV Viral Suppression among US Adults Receiving Medical Care, 2009-2013

Bradley H et al. Abstract #53

Persons living with HIV who achieve virologic suppression have significantly improved health outcomes and decreased risk of transmitting HIV to others. Increasing the number of persons living with HIV who are virally suppressed is a major aim of our national HIV prevention goals.

Bradley presented this study from the CDC that used Medical Monitoring Project (MMP) data from 2009 through 2013 to estimate the percentage of HIV-infected persons in medical care who had achieved HIV viral suppression (< 200 copies/mL) at their last test and at all viral load measurement in the prior 12 months.

Data were collected from 23,125 persons using interviews and medical records. Temporal trends in viral suppression were assessed by age, gender, race/ethnicity, and sexual behavior/orientation.

**The authors found that the proportion of persons whose HIV virus was suppressed at the most recent test increased from 72% in 2009 to 80% in 2013.** This positive trend was statistically significant for all age groups; non-Hispanic blacks, non-Hispanic whites and Hispanics; MSM, and heterosexual men and women. The largest increase in rates of suppression was among 18–29 year olds. The proportion of persons whose HIV virus was suppressed at ALL tests during the previous 12 months increased from 58% to 68% during these 4 years. The greatest increases in viral suppression were among 18–29 year olds (32% to 51%), 30–39 year olds (47% to 63%) and non-Hispanic blacks (49% to 61%).

The study concluded that persons with HIV receiving consistent medical care are progressively more likely to attain viral suppression. Most encouraging was that young people and non-Hispanic blacks, who had the poorest levels of suppression in 2009, showed the most improvement over time. Continued efforts to engage persons living with HIV in medical care and promote early ART likely contributed to these encouraging increases.

Several other studies at CROI (see abstract #1002) had similar findings, especially for patients cared for at Ryan White-funded programs.

**HIV**



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# A Loomi

**S** EVEN YEARS AGO in its inaugural issue, *HIV Specialist* warned that a critical shortage of practitioners who treat HIV/AIDS patients in the United States was looming, predicting that more than 32% of today's HIV clinicians would stop providing that care over the next 10 years.

That report was based on a survey by the American Academy of HIV Medicine (AAHIVM) of its members and suggested this would happen as the HIV workforce ages and increasing numbers of clinicians reach retirement age. Although the survey showed that specializing in HIV has been professionally rewarding by the majority of HIV clinicians, that sense of satisfaction apparently has not resulted in enough medical students (and residents) planning to pursue a career in HIV medicine to replace those who are retiring.

In fact, only about one-third of students who decided to join AAHIVM said they planned to pursue a career in HIV medicine, with two of three saying that medical school debt would influence their ultimate choice of careers, prompting them to choose specialties that would pay a higher annual salary than working in HIV medicine.

Sadly, it appears not much has changed and, in fact, the warnings issued by AAHIVM seven years ago are beginning to materialize. In April 2011, the Institute of Medicine (IOM) report *HIV Screening and Access to Care* said projections of the U.S. HIV care workforce, as well as the primary care workforce generally, indicate there will be a shortage of providers needed to handle the number of people in the U.S. who need to be tested and treated.

The report noted that many among the "first generation" of HIV providers are reducing their practices or retiring, and that relatively few new health professionals are choosing to specialize in HIV care.

# ng Crisis

**Searching for solutions to solve the growing shortage of HIV physicians**

BY BOB GATTY



“The majority of providers receive little training or practical experience in HIV care, especially in outpatient clinics where most HIV care now occurs,” the report’s summary stated. “Thus many of them may be uncomfortable with taking sexual histories and providing HIV tests to patients.”

The report went on to say that to meet workforce demands, health professionals need to be increasingly exposed to outpatient HIV care during their training and that continuing education needs to be provided throughout their careers.

**“The majority of providers receive little training or practical experience in HIV care, especially in outpatient clinics where most HIV care now occurs. Thus many of them may be uncomfortable with taking sexual histories and providing HIV tests to patients.”**

“There also is a need to reach beyond the primary care physicians (Family Medicine or Internal Medicine) and Infectious Disease specialists who provide HIV care and to utilize advance practice registered nurses and physician assistants to the full extent of their training abilities,” the report added. “Registered nurses, dentists, pharmacists, and social workers are among the large number of providers necessary to provide quality HIV care in a variety of settings. It also may be desirable to provide better financial and other incentives to encourage more health professionals to enter and remain in HIV care.”

That report was published in 2011. Another workforce study by the Health Resources and Services Administration (HRSA) has been underway for some time and is expected to be released soon.

### ‘Alarming Reality’

There are no indications that the shortages predicted in the IOM report have been overcome, and it can be assumed unless remedial steps are taken, they can only be expected to worsen.

As an example, the *Los Angeles Times* reported in January that since last May, Dr. Robert Bolan, medical director at the Los Angeles LGBT Center, has been trying to hire a physician to treat HIV patients, as one of the physicians on his staff moved away last year.

“I just haven’t been able to land somebody and put them in a clinic,” Dr. Bolan told *Times* reporter Soumya Karlamangla, noting a shortage of primary care physicians—particularly primary care physicians who want to provide HIV care as part of their clinical practices.

Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, noted that L.A. County has more than 60,000 people infected with HIV. The *Times*

story said Dr. Katz trained as a physician at the height of the AIDS crisis, but now new physicians are looking to enter better paying specialties.

“I didn’t set out to be an HIV doctor either, but the emergence of the epidemic is what led us to do what we do,” Dr. Katz told the *Times* reporter. “My concern is what does that look like into the future.”

The *Times* article went on to report that the Los Angeles County Department of Health Services is launching a two-year fellowship to train physicians in HIV medicine, a step consistent with the recommendations of the IOM report. Funded by a \$7.5 million grant from pharmaceutical company ViiV Healthcare, the program will train physicians how to care for HIV patients at L.A. county facilities. The five-year grant will train 10 to 18 physicians who already have completed a Primary Care residency. The expected start date is July 2016.

The grant funding, Dr. Katz explained, also will help fellows pay off loans. Upon completing the program, if they work in underserved areas anywhere in the U.S., they can get up to \$50,000 a year toward reducing their medical school debt.

Dr. Andrew Zolopa, ViiV Healthcare’s global medical director, said the program is the first of its kind and that he hopes it will become a national model, benefiting the county, doctors, and patients.

In a news release announcing the grant, ViiV Healthcare warned that “this impending physician shortage will have an impact on communities across the country, including major cities like Los Angeles.”

“The growing deficit of physicians specializing in HIV is an alarming reality, as it will impede efforts to improve community-based care for people living with HIV,” said Dr. Katz. “The program will offer real-life training to emerging primary care providers specializing in HIV, to help improve the health of people in Los Angeles and other areas across the country for many years to come.” Additional information on this program is available at <http://www.lachivphfellowship.com/>

### National HIV/AIDS Strategy

The shortage of healthcare providers focused on HIV also was highlighted as a key issue in the *White House’s National HIV/AIDS Strategy for the United States: Updated to 2020*. This report calls for “deliberate steps to increase the capacity of systems as well as the number and diversity of available providers of clinical care and related services for people living with HIV.”

- The White House strategy establishes these goals:
- Reducing new HIV infections
  - Increasing access to care and improving health outcomes for people living with HIV
  - Reducing HIV-related disparities and health inequities
  - Achieving a more coordinated national response to the HIV epidemic



A study presented by CDC researchers at the recent Conference on Retroviruses and Opportunistic Infections (CROI) in Boston stated that reaching the National HIV/AIDS Strategy targets for HIV testing and treatment and expanding the use of daily Pre-Exposure Prophylaxis (PrEP) could prevent an estimated 185,000 new HIV infections in the U.S. by 2020—a 70% reduction in new infections. (CROI 2016, abstract # 1051). But how can those goals be realized without a sufficient and well-trained HIV workforce?

### **Are Family Physicians the Answer?**

The National HIV/AIDS Strategy also calls for increasing engagement of Family Medicine physicians in the care and treatment of HIV-infected patients, integrating HIV care into primary care services as a way to improve overall access to and quality of HIV care.

But, cautioned Dr. Jeffrey T. Kirchner, medical director of Penn Medicine/LGHP Comprehensive Care at Lancaster General Hospital, a Ryan White funded clinical program in Lancaster, PA, in order for this shift to occur effectively, family physicians need greater exposure and better training in HIV medicine.

That need was highlighted by research published last year in *Clinical Infectious Diseases*, which found that physician experience is associated with the quality of care provided to HIV+ patients. Investigators from this study done in New York State noted, “Our findings suggest that the quality of care associated with providers who prescribe ART for <20 patients is lower than that provided by more experienced providers. Access to experienced providers as defined by patient volume is an important determinant of delivering high-quality care and should guide HIV workforce policy decisions...we found that the majority of LVPs (low volume providers) practiced in primary care settings and were not infectious diseases (ID) specialists or identified as HIV specialists,” commented the authors. “Our study highlights the need to monitor data and trends in the HIV workforce. Ongoing research is needed to examine strategies to guarantee a capable provider workforce for delivering effective care to HIV-positive patients over time and identify best practices.” (O’Neil M et al. *The HIV workforce in New York State: does patient volume correlate with quality?* *Clin Infect Dis.* (2015) 61 (12): 1871-1877)

AAHIVM sought to address this need by launching their Clinical Consult Program, which allows providers seeing fewer



**Many Family Medicine colleagues would like to provide care for their HIV-infected patients, but don't have the time to obtain the additional CME needed in this field that historically has changed quite rapidly with the development of new therapies. In addition, most work under a 15-minute per-patient schedule—yet another barrier to providing the complete care patients with HIV require, including prevention counseling.”**

than 20 HIV patients to be eligible to earn their HIV Specialist credential by agreeing to be “paired” with a highly experienced, credentialed Academy member during the exam session and for the 3-year life of the earned credential. The program is an initiative to foster larger numbers of medical providers to meet a minimum standard of knowledge in advanced HIV care, particularly in rural or underserved settings, or regions where providers see relatively few HIV patients.

### Timing Issues

Yet another barrier for training is the amount of time necessary to stay current on therapies.

“Primary care physicians are already expected to acquire and maintain an extensive knowledge-base, so that many see HIV/AIDS as another major area of medicine that they do not have time keep up with,” said Dr. Kirchner. “I believe many of my Family Medicine colleagues would like to provide care for their HIV-infected patients, but don’t have the time to obtain the additional CME needed in this field that historically has changed quite rapidly with the development of new therapies. In addition, most work under a 15-minute per-patient schedule—yet another barrier to providing the complete care patients with HIV require, including prevention counseling.”

Consequently these physicians are sending these patients to other clinicians to manage the HIV disease,” Dr. Kirchner pointed out.

“As a Family Medicine physician who has been doing HIV care since I finished my training in 1989, I truly understand this,” he said. “There is an ever-growing number of curriculum requirements for Family Medicine residents that we must cover within a three-year period of time. This ranges from prenatal care and pediatrics to palliative care and pain management.”

With today’s medical advances and the ability to treat most patients with one or two pills a day, one might assume that for the Family Physician providing this additional care should not be a significant burden.

“I think from the physicians’ perspective, unless you are doing this on a day-to-day basis, prescribing ART is not something that you feel comfortable with,” Dr. Kirchner observed.

He pointed out that the American Academy of Family Physicians has an HIV/AIDS curriculum guideline that he helped author and update. However, he said, there are no specific requirements as to how this information is incorporated into the training of Family Medicine Residents.

“The degree of exposure residents get to HIV care is extremely varied—from extensive to very little or perhaps even none—depending on where they do their post-graduate training,” he observed.

### Training Opportunities

Dr. Kirchner pointed out that Family Medicine graduates are not eligible for ID fellowships. “This limits post-graduate training options in HIV medicine” he observed.

However, he noted, there are existing and evolving models for training Family Medicine graduates in HIV care, such as the new Fellowship noted above in California, as well as several others around the country. For example, the Family Medicine Residency of Idaho (FMRI) HIV Primary Care Fellowship is a 12-month post-residency training opportunity that provides training for the Family Medicine physician to gain experience

in providing comprehensive care to persons living with HIV/AIDS.

Last year, AAHIVM partnered with the California Academy of Family Physicians (CAFP), and Medscape Education to develop a customized educational curriculum, *Expanding the HIV Provider Base: Preparing Clinicians for HIV Care*, directed at Primary Care and Family Medicine physicians to help them identify, evaluate and manage patients with HIV. The program comprised a curriculum of four educational activities tailored for clinicians practicing in the areas of infectious diseases and primary care, who are positioned to identify and treat individuals at risk for or living with HIV infection. The Academy hopes to continue adding training modules like this one to reach a greater number of family medicine practitioners.

The IDSA/HIVMA Clinical Fellowship program supports newly trained physicians with gaining HIV clinical experience working with medically underserved patient populations. The program’s goal is to boost the population of HIV physicians and strengthen the commitment to provide clinical care to HIV-infected patients in minority communities. HIVMA awards grants to support one-year of HIV clinical training to up to two fellows per year. Like the new program in Los Angeles County, the HIVMA fellowship historically has been funded by pharmaceutical grants.

Lancaster General Health and several other Residency programs, including University of California, San Francisco (UCSF) and Wooster, MA offer HIV clinical tracks or “Area of Concentration” (AOC) for third year residents who wish to gain additional experience in HIV care. Dr. Kirchner’s AOC program at LGH has trained 11 residents to date, all of whom have become certified as HIV specialists by AAHIVM.

“If there was funding for an additional fourth year of training in primary care for physicians who want to focus on HIV care, that could make a significant difference in addressing some of the shortages,” Dr. Kirchner said. “However, you would also need to have curricula in place and faculty who are HIV specialists to provide this training.”

Dr. Kirchner stressed that for most patients, HIV is a chronic disease that can be well-managed in an outpatient ambulatory setting. In his opinion, Family Physicians and General Internal Medicine physicians are best trained to work in those settings, although many ID/HIV physicians, as well, have elected to spend less time in the hospital and provide both HIV and primary care to their patients. This is particularly true for those who are part of the aging patient population.

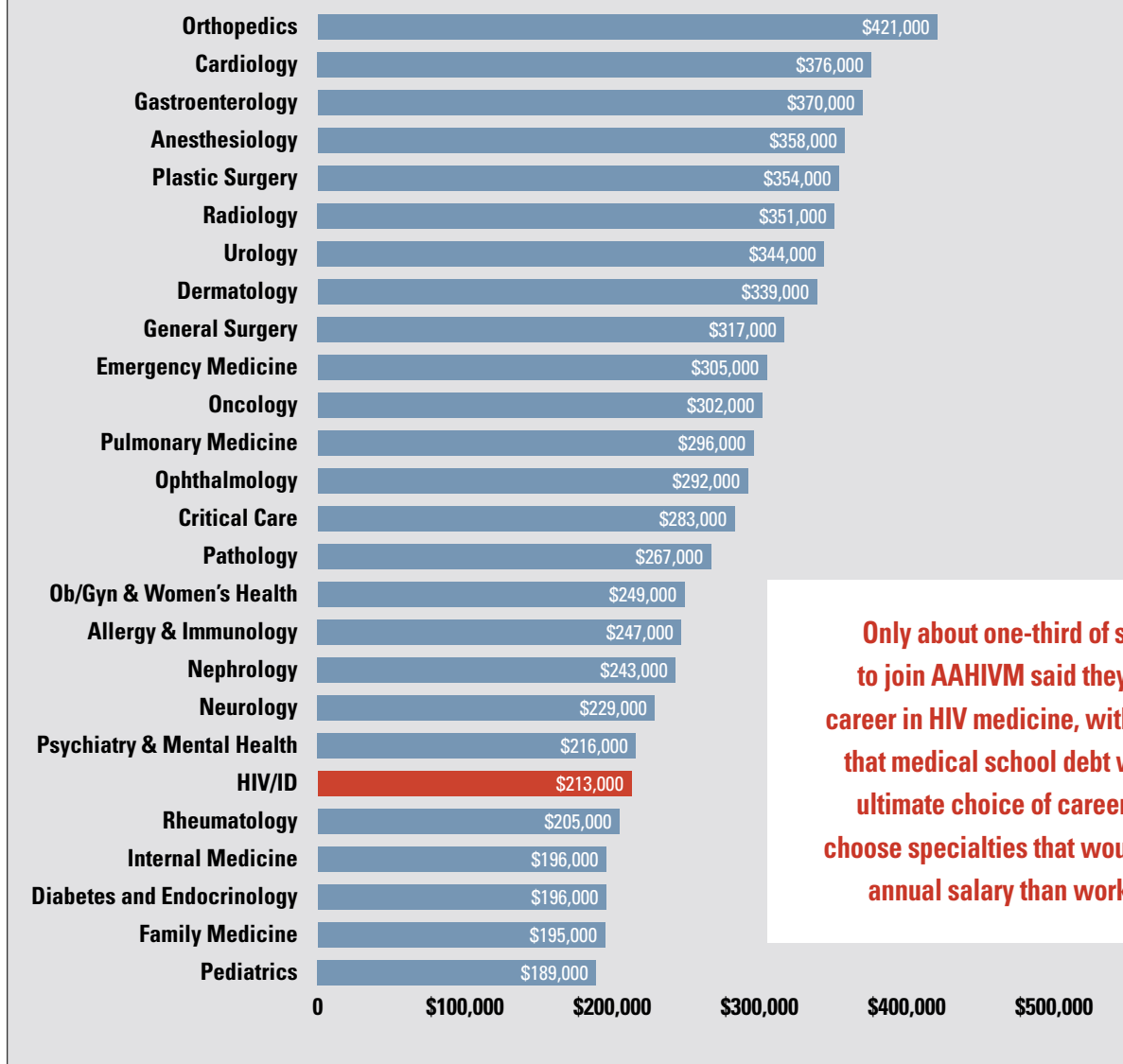
“If we can develop effective HIV training programs, I believe it will be from these two areas of primary care that most of the future HIV providers will come from,” he said. “We need to be training these physicians whether it is during residency or with post-graduate fellowships - as a solution to HIV physician shortage. We must also convince third party and other federal payers that if there are good systems in place with fair reimbursement we can provide excellent long-term, cost-effective care of HIV- patients. There is extensive data from the medical literature and Ryan White Programs that offer proof of this.”

### About the Money

Another major factor that plays into the growing shortage of HIV physicians is the disparity in financial compensation, Dr. Kirchner pointed out, noting that ID physicians typically tend to be at the “lower end of the pay scale compared to other medical specialist.”

Cardiology, oncology, and gastroenterology tend to be much more

## Figure 1. Medscape Survey Data 2015



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lucrative areas of practice in most cases making twice the salary of ID and Primary Care. In the face of significant financial debt from medical school, many students increasingly go into areas of medicine where they are paid more. This has been supported by numerous surveys of medical students and practicing physicians over the past few years. (See Medscape figure)

The National Resident Matching Program (NRMP) numbers announced last December bear that out, as 117 of the 335 ID fellowship positions went unfilled, many at highly prestigious institutions.

According to Wendy Armstrong, MD, FIDSA, FACP, professor of medicine at the Emory University School of Medicine and vice chair of education and integration, the root cause has to do with the money future specialists can expect to be paid. “There are fewer ID clinicians acting as attendings on medical services,” she said. “It’s the money.”

“We are all concerned,” said Dr. Armstrong, who chairs the Infectious Diseases Society of America’s Task Force for Recruitment to ID. “In the

specialty, this is a significant topic of conversation. We are concerned that this could become a crisis.”

“Historically in the U.S. health system, physicians have been paid much more for doing procedures rather than cognitive skills and the education and counseling patients, and those are key components of office-based medical care,” Dr. Kirchner pointed out. Still, for him and many others who have specialized in treating HIV patients over the years, many other factors influence what they do.

“Taking care of HIV patients is never going to be about the money,” said Dr. Kirchner. It has remained intellectually challenging and a very satisfying part of my work over the past 25 years.”

HIV



**ABOUT THE AUTHOR:**

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**IN CRISIS**

The HIV Workforce

# One Solution to Looming Physician Shortage

**INCORPOR**

**A**CCORDING TO A 2009 SURVEY of primary care physicians, one-third stated they expected to retire within the next 10 years.<sup>1</sup> As well, many of the physicians who provided care for patients infected with Human Immunodeficiency Virus (HIV) and/or Acquired Immune Deficiency Syndrome (AIDS) from the start of the epidemic in the early 1980s, are also expected to retire within the next ten to fifteen years.<sup>2</sup> The concern is then raised, who will take on the care of the 1.2 million Americans currently infected with HIV in the United States in the coming years? And, more specifically, who will provide the HIV care for the approximately 50,000 newly infected HIV patients in the U.S. annually?<sup>3</sup>

Care of the HIV patient today differs significantly from even just 10 years ago. Even though the initial care of the HIV patient has not changed over the decades (the need for baseline testing, laboratory monitoring, and continued evaluation of the immune status throughout the patient's lifetime), what has changed is our current arsenal of medications that are now safer and more tolerable than ever before. HIV patients today are living longer, more productive lives, and those lives often parallel those not infected with HIV. The simplified antiretroviral therapy (ART) regimens available today, including six FDA-approved once daily single-tablet regimens, have served to improve patient adherence which studies have shown leads to improved patient compliance and fewer regimen failures due to resistance.<sup>4</sup> Further, it has now been shown that more than 50% of the patients diagnosed with HIV today will most likely die of a non-HIV related condition rather than an AIDS-defining condition, highlighting the need to consistently address the primary care needs of today's HIV patient.<sup>5</sup>

### Potential Solutions

One solution to the looming shortage of HIV specialists is to engage more nurse practitioners and physician assistants into HIV care. It has been shown that the care provided by these non-physician providers (NPP) is on a par with HIV physician specialists and even better than non-HIV specialists.<sup>6</sup>

However, there are limits to the nurse practitioners (NP) scope of autonomous practice. Each state governs the NPs scope of practice (SOP), which is defined as autonomous, reduced, or restricted and governs both clinical practice and prescribing privilege. According to a Kaiser Foundation Issue Brief (January, 2015), only 50% of the states in the US allow nurse practitioners autonomous SOP. However, of the top three states in which HIV is most prevalent (New York, California, and Florida), only California licenses NPs

with full SOP. In the 31 states in which NP's SOP is either restricted or reduced, the NP is required to be in collaborative practice with a physician.<sup>7</sup>

Another viable solution to the shortage in physicians who are experts in HIV care may be to train primary care residents during their three years of residency.

In 2010, the results of a survey were published describing how Internal Medicine residency program directors felt about incorporating HIV training into their medical residency programs.<sup>8</sup> The results of this nationwide survey that included 230 program directors, found 42% agreed it was important to incorporate HIV training into residency programs and 56.5% reported exposing their residents to outpatient HIV care was a priority. However, at that time only 18.8% of directors believed their graduates were well-equipped to provide HIV care upon graduation and 76% thought that residents interested in providing HIV care should pursue an Infectious Disease fellowship.<sup>8</sup>

### Evaluation

A search of the literature revealed many U.S. Internal Medicine residency programs today are incorporating some form of HIV training into their curricula. But to date, published evaluations of those programs are lacking. An early article published in 2004 described the results of an HIV training program conducted at the University of Minnesota between the years of 1997 through 2000. A total of 214 residents were observed over the three-year training program with some participants receiving the full three years of HIV-training (n=43) and others, depending on their year of residency, received either two or one year of training. The HIV training consisted of 18 teaching modules spread over three years and an elective rotation in clinical care or service. At the start of the program an HIV Knowledge Questionnaire was given to assess the resident's current level of HIV knowledge and

**ATE HIV TRAINING INTO MEDICAL RESIDENCY PROGRAMS**

given again at the end of the program to measure the amount of HIV knowledge gained. The instrument (1991) was updated by HIV specialists at the University of Minnesota to reflect the practice patterns, epidemiology, prevention, and treatment changes in 1997. The Midwest AIDS Training and Information Education Center (MATEC) developed a tool to assess the resident's attitudes and confidence to provide HIV care. Of note, at the end of the program, the most significant finding was a significant increase in HIV knowledge as

**The American Academy of HIV Medicine (AAHIVM) offers an HIV Specialist certification (AAHIVS) exam that is available to all physicians, NPs, and PAs who meet the requirements to take the exam. The examination is rigorous and comprehensive; and updated continuously to represent current practice in HIV medicine.**

ascertained from comparing pre-HIV knowledge tests to post-program HIV knowledge tests ( $p < 0.01$ ). Another important finding from an analysis of this program was that by the end of residency training, the number of HIV-ELISA tests ordered by residents had increased by 45%.<sup>9</sup> Although this is an older study, it is important because it describes the evaluation process and the outcomes of HIV training on medical residents during their residency.

As noted above, many U.S. internal medicine residency programs today are now incorporating some of HIV training into their medical residency curricula. The programs range from training throughout their residency (Yale School of Medicine) to an HIV Primary Care Rotation during a resident's second year of residency (Emory University School of Medicine).<sup>10,11</sup> The idea of incorporating HIV training into medical residency programs appears to be very appealing to the government as well. In 2011, the Health Resources and Services Administration (HRSA) released \$5.1 million explicitly for the purpose of expanding HIV training. Part of that grant was given to three U.S. medical schools to expand their primary care residency training to include HIV training.<sup>12</sup>

Currently, there are nine U.S. HIV training sites listed on the Infectious Diseases Society of America (IDSA) website. They vary in scope and include both one and two year HIV-fellowships as well as "Areas of Concentration" (AOC) in HIV/AIDS, which occurs during the third year of residency. The Family Medicine program at Lancaster General Hospital has been successfully using this model for six years.

Currently, the University of Washington has incorporated an HIV medical track for Internal Medicine residents in primary care who are interested in providing HIV care for patients. Of note, the goal of the program is not to increase requests for ID fellowships, but rather is designed for general internists who anticipate providing

care for HIV patients. In this program, PGY-1 and PGY-2 residents are given an HIV clinical practice experience at the Madison Clinic at Harborview Medical Center. The Madison Clinic provides care for over 2,000 HIV patients per year and is an ideal setting for the training of primary care residents in HIV care.<sup>14</sup>

St. John Hospital & Medical Center in Detroit recently established a two-year HIV training program (2012 to 2014) incorporated into its medical residency program. A final analysis of this program is expected in the Spring of 2016.

As an adjunct to offering HIV training during medical residency, the American Academy of HIV Medicine (AAHIVM) offers an HIV Specialist certification (AAHIVS) exam that is available to all physicians, NPs, and PAs who meet the requirements to take the exam. The examination is rigorous and comprehensive; and updated continuously to represent current practice in HIV medicine. The criteria for eligibility to take the certification exam includes direct patient care for at least 20 HIV patients, and the completion of a minimum of 30 credits of HIV-related Category 1 CME/CEU/CE within 24 months preceding the date of application.<sup>13</sup>

### Old Arguments Now Moot?

Many of the previous arguments raised by primary care and ID physicians regarding the provision of care for HIV patients are gradually declining. The management of ART, although challenging, has been simplified and most patients are being treated with single-table regimens. Monitoring for drug side-effects and toxicities remains important, however, and is a key part of the management of HIV patients. Unlike the side effects of first and second generation antiretroviral drugs (e.g. facial lipoatrophy, fat redistribution syndromes, peripheral neuropathy, renal calculi, and, lactic acidosis), the newer ART combinations are less toxic, more potent, and far more tolerable for the majority of patients. The other primary care needs of these patients, including management of hypertension, hyperlipidemia and diabetes, can be well-managed by primary care providers.

There remains a growing and emergent need to train primary care physicians (PCP) in HIV care and ideally that training should be incorporated into their Residency programs. There are several residencies that have initiated HIV training programs, but the results of these educational models have not been prospectively evaluated. More data and information regarding such issues as curriculum content, length of training, extent of clinical exposure and expertise of faculty are still needed to determine the best and most efficient way to prepare physician trainees for careers in HIV medicine. **HIV**



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## Why I Entered the Field of HIV

BY ASHLEY DAY MSN, RN, FNP

It's safe to say that most people don't grow up dreaming of working in infectious disease. I certainly didn't. That all changed when I was an 18 year-old student at Elon University in North Carolina. After meeting a professor who was conducting research on women in America living with HIV, it quickly became very clear that my education, and ultimately my career path, would focus on my newfound passion for public health and infectious disease.

I began volunteering at a community health outreach program in rural North Carolina. I handed out condoms and assisted in free rapid HIV testing. I was fascinated by the demographic of people in my home state who were living with HIV. I was simply unaware of how many of my peers were affected by this disease.

As a nurse in the emergency department at a local hospital, I had additional interaction with HIV positive patients, usually at some of their sickest and most vulnerable moments. This experience solidified my desire to better understand HIV infection.

My ultimate career goal was to go back to my MSN degree in primary care so I could focus on health promotion and disease prevention. As a provider, I wanted to improve patients' quality of life and, if possible, keep them out of the hospital. I was thrilled to learn that Duke University School of Nursing was offering a new specialty in HIV/AIDS for nurse practitioners which was perfectly aligned with my own professional goals and interests.

The family nurse practitioner curriculum at Duke University allowed me to learn primary care management skills, while the HIV concentration allowed me to learn the specifics of HIV management. The program exceeded all of my expectations in the classroom. I was taught by expert instructors who provided me with the strong foundation I needed to begin my career as an advanced practice nurse. Through clinical rotations I received almost four hundred extra clinical hours in HIV care.

I currently work outside of Charlotte, NC as a family nurse



practitioner at Rosedale Infectious Disease where I predominately manage the primary and specialty care of people living with HIV. The majority of our HIV positive patients are low income with approximately one-third being covered by Ryan White. With one infectious disease doctor, one internal medicine doctor and myself, we are blending HIV specialty and primary care for optimal patient outcomes.

I am thankful for the path, and people, that led me to this point in my career and feel privileged to work as a FNP in this field.

## References

1. Workforce Capacity in HIV: Health Resources and Services Administration (HRSA); April 2010.
2. Infectious Disease Society of America. *Averting a crisis in HIV care: a joint statement of the American Academy of HIV Medicine and the HIV medicine association on the HIV medical workforce*. 2009. <http://www.idsociety.org> (accessed 8 Jun 2011).
3. Centers for Disease Control & Prevention (CDC&P) 2012. *New HIV Infections in the United States*, December, 2012.
4. Sax, P., et al. (2012) Elvitegravir/cobicistat/emtricitabine/tenofovir (QUAD) has non-inferior efficacy and favorable safety compared to efavirenz/emtricitabine/tenofovir in treatment-naïve HIV-1+ subjects. CROI 2012, Abstract 101.
5. Neuhaus, J., Angus B., Kowqalska, JD, et al. (2010). Risk of all-cause mortality associated with nonfatal AIDS and serious non-AIDS events among adults infected with HIV. *AIDS* 2010; 24: 697.
6. Wilson, IB, Landon, BE, Hirschhorn, LR, Mcinnes K, Ding, L., Marsden, PV, Cleary, PD. (2015) Quality of HIV care provided by nurse practitioners, physician assistants, and physicians. *Ann Intern Med*. 2005 Nov 15;143 (10): 729-36.
7. VanVleet, A, Paradise, J. (2015) Tapping Nurse Practitioners to Meet Rising Demand for Primary Care. *Henry J. Kaiser Foundation, News Brief*, Jan 20, 2015.
8. Adams, J, Chacko, K, Mretchennd, M, Aagaar, E. (2009) Training Internal Medicine Residents in Outpatient HIV Care: A Survey of Program Directors. *J Gen Intern Med* 25(9): 977-81.
9. Feldman, J, Miner, M, Millis, M. (2004). Training Family Practice Residents in HIV Care. *AIDS Patient Care and STDs*, 18, (7): 2004.
10. Yale School of Medicine, HIV Training Track. Yaleim.primarycare@yale.edu.
11. Emory University, School of Medicine: HIV Distinction in HIV Medicine 2013. [slivingston@emory.edu](mailto:slivingston@emory.edu).
12. US Department of Health and Human Services (HRSA). *HRSA awards \$1.5 million to bolster HIV/AIDS training and technical assistance programs*. HRSA News Room; News Release, September 07, 2011.
13. Infectious Diseases Society of America Website. IDSA : HIV Training Programs. [http://www.idsociety.org/HIV\\_Training\\_Program/#sthash.Y2Q2UQWN](http://www.idsociety.org/HIV_Training_Program/#sthash.Y2Q2UQWN).
14. University of Washington Internal Medicine Program. HIV Medicine Pathway. <http://depts.washington.edu/uwmedres/programs/tracks.htm>
15. American Academy of HIV Medicine (AAHIVM). The Practicing HIV Specialist (AAHIVS). <http://www.aahivm.org/aahivs>.

# AASHP GUIDELINES

## *Expanding the role of the pharmacist in HIV care*

**IN THE EARLY DAYS OF TREATING PEOPLE LIVING WITH HIV,** and dying from AIDS, there was little help that a pharmacist could offer beyond being a caring, humanistic healthcare provider.

However, as more treatments became available, and later becoming quite complicated, the pharmacists' role started to expand. With HIV-infected patients living longer, primary care providers needed to see more and more patients, and each patient required significant care.

It was during this time that the need of having a pharmacist on the HIV healthcare team became evident. These patient care teams needed someone experienced in managing complex drug interactions to support prescribers as well as patients. Additionally, the complexities of these regimens made it more difficult for patients to take all of the medications helping to suppress the virus.

This type of need for pharmacists continued for quite a while. Many publicly-funded or academic-based HIV-specialty clinics secured funding for clinical pharmacists, and felt that they could not manage without them. Some private medical practices were utilizing pharmacists, but not as many for a variety of reasons (including issues with funding these positions and the perceived lack of need to bring in someone else to do what they could do).

But these pharmacists who were brought in to work with HIV-treatment groups often saw as many patients as the prescribers, and often more regularly. Pharmacists became more than just drug interaction and adherence experts, but became an essential part of the process of starting any patient on antiretroviral therapy...including

recommending therapies based on resistance testing and patients' needs and capabilities.

Also during this time, pharmacists in other specialties were taking on greater roles. This included working with patients on diabetes management, controlling lipids, bringing blood pressure down to safer levels, and reducing admissions and readmissions due to congestive heart failure. The profession of pharmacy was evolving, and the role that pharmacists were playing in the HIV arena was a part of that evolution.

Around 2008 or 2009, the landscape of HIV treatment changed. Options for treatment-naïve individuals with HIV had reached a threshold of being simple to take, well-tolerated, and less complicated compared to other medications/regimens effective against HIV.

While one could say this has been a linear process since the introduction of AZT in 1987, I signified this particular time period due to the introduction of integrase inhibitors. Admittedly, while there is still a reasonably sized cohort of patients at many clinics who remain complicated to treat due to long histories of treatments coupled with treatment







failures, overall more and more patients were just doing better overall.

As was seen in the mid-1990s, people with HIV were living longer (with many researchers indicating that they had almost the same lifespan as someone without HIV), resulting in more and more patients scheduled on the appointment books of HIV care providers.

Again, pharmacists stepped up and started to work with these patients in different ways. Pharmacists learned from their colleagues in other therapeutic specialties and began assisting with the management of other primary care-related conditions in HIV patients such as Hepatitis C, diabetes, and lipids. To this day, pharmacists who have dedicated their professional lives to patients with HIV are usually integrated into the overall therapeutic management of the whole patient, and not just one singular disease state. This is what pharmacists were trained for, and this is where they can truly demonstrate their expertise and skills.

Pharmacists are not diagnosticians. Our training includes overviews of the physiology, pathophysiology, and symptomatology of diseases. We are typically provided enough information to monitor drug therapy and assess for response. As a profession, we strive to improve the care of patients through the appropriate use of medications (which includes not using them, when appropriate). We strive to be recognized across the board as a member of the healthcare team that helps manage patients, not just providing bottles of tablets and capsules.

Recently, guidelines were commissioned by the American Society of Health-System Pharmacists, drafted primarily by pharmacist clinicians of AAHIVM, and endorsed by the leadership of AAHIVM. These guidelines lay out the role of the pharmacist as part of an interdisciplinary health care team that assists in the areas of HIV testing, treatment of HIV infection (including special populations), treatment failure, management of complications, treatment and prevention of opportunistic infections, prevention of HIV infection, HIV education, social services and professional engagement.

These guidelines are a reflection of the value trained pharmacists on the HIV care team can provide. As the Chair of the AAHIVM Pharmacists Committee, I applaud the Academy for its endorsement and hope these guidelines help all members of AAHIVM recognize the role that the pharmacist can play in helping to optimize the health of HIV patients.

**HIV**



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# Aging with



BY EUGENIA L. SIEGLER, MD AND HARJOT K. SINGH MD, SCM

***MORE THAN 40% OF PEOPLE LIVING WITH HIV OR AIDS***

(PLHA) in the United States in 2012 were at least 50 years of age,<sup>1</sup> and approximately 18% of new HIV infections occurred in this same age group.<sup>1</sup> But that is just the beginning.

In light of near-normal lifespans for PLHA, a recent Dutch study projected that by 2030, 73% of those infected with HIV will be at least 50 years of age and 39% will be 60 years or older.<sup>2</sup>

Those who are over 50 years of age must contend with HIV infection and aging simultaneously, and the current workforce is unprepared to care

for this aging population. It is also unlikely that a sizeable cohort of physicians or advanced practice nurses currently in training will graduate with expertise in both aging and HIV care.

So, how can we expand the capabilities of HIV practices to meet the needs of an aging population?

# HIV *Preparing to Care for an Aging HIV Population*

## **Establishing a Clinical Program for People Aging with HIV**

At the Center for Special Studies (CSS), the adult HIV practice at Weill Cornell Medicine/New York Presbyterian Hospital, we are attempting to meet our aging patients' needs by establishing an Aging with HIV program.

At CSS, 61% of patients are 50 years or older; more than one-third of them, nearly 500 patients, are at least 60 years old. CSS provides interdisciplinary care, with social workers, psychiatrists, gynecologists, and nutritionists on site. At the end of the workday, each patient is discussed in group rounds, attended by all staff.

We first explored the idea of a program to help older patients by talking with HIV physicians and making geriatric consultation available to HIV providers on an ad-hoc basis at the outpatient CSS practice. We also visited community agencies that specialized in supportive HIV and/or aging care. We then crafted a proposal and obtained funding from the Fan Fox and Leslie R. Samuels Foundation to implement an HIV aging program that started in July 2015. The program has several components:

- **Embedding a geriatrician in the HIV practice.**

The geriatrician consults one afternoon a week on site, documents in the shared electronic medical record, and joins afternoon rounds.

- **Performing a needs assessment.**

We interviewed representatives of CSS staff and met with each discipline individually to determine what they felt they needed and how they wanted to participate in the program. We are conducting patient



focus groups in both English and Spanish among MSM, women, and heterosexual men.

- **Educating staff.** Nurse practitioners from the Division of Geriatrics and Palliative Medicine will train CSS nurses. One of us (Dr. Siegler) lectured to physicians on frailty and aging. In addition, ACRIA, a community organization with expertise in HIV and Aging (<https://www.acria.org/>), provided an in-service training to CSS social workers.
- **Working with community agencies.** We are collaborating with SAGE (Services and Advocacy for Gay, Lesbian, Bisexual and Transgender Elders, <http://www.sageusa.org/nyc/>), to create joint educational programs for people aging with HIV infection.

We are also creating research partnerships, exploring funding opportunities with other foundations, and considering relationships with insurers and providers of long-term care.

**The workforce challenges and how we approached them remain relevant to any practice interested in expanding its offerings to meet the needs of elderly. Irrespective of practice size or location, caring for the aging HIV-infected adult will necessitate reaching out to those who have aging expertise, with whom HIV experts can collaborate and from whom they can learn.**

### Meeting Workforce Challenges as the HIV-infected Population Ages

We recognize that the CSS HIV clinic has several advantages over other practices that might wish to enhance care of older patients: an extensive history of collaboration, an academic setting where proximity to geriatricians facilitated contact, and foundation assistance for startup.

Nonetheless, the workforce challenges and how we approached them remain relevant to any practice interested in expanding its offerings to meet the needs of elderly. Irrespective of practice size or location, caring for the aging HIV-infected adult will necessitate reaching out to those who have aging expertise, with whom HIV experts can collaborate and from whom they can learn. HIV practices might wish to consider the following:

**ADDING OUTSIDE GERIATRICS EXPERTISE.** Geriatricians can assist with establishing priorities, recognizing geriatric syndromes and functional and cognitive decline, discussing end-of-life wishes, and devising creative means of accessing community-based services and long term care. Geriatricians can help manage conflicting advice regarding multi-morbidity, especially when multiple subspecialists are involved in patient care.

Accessing and utilizing the existing geriatric workforce is the most basic approach, but has its own complexities. An HIV practice could establish a linkage with a provider with expertise in aging, referring out to the geriatrics practice or embedding

the clinician in the clinic itself. One must first find a geriatrician or an adult-gerontological nurse practitioner (NP) interested in HIV disease and willing and able to expand a practice to include care of HIV-infected. One must then negotiate the relationship between the HIV providers and the geriatric specialist, including determining who will be responsible for primary care of the aging HIV-infected patient, where the specialist will see the patient, and how providers will communicate.

Unfortunately, the number of geriatricians is not keeping pace with the geriatric population. In 2010, the ratio of geriatricians to elderly (65 years and older) was estimated to be 1:5955; because the number of graduating geriatrics fellows has stabilized or even decreased even as the population ages, the ratio is expected to considerably increase.<sup>3</sup>

The advanced practice nurse may be a more feasible solution to the dearth of geriatricians; the adult NP workforce is increasing, and it has been recommended as a model for training more geriatricians.<sup>4</sup> Adult nurse practitioners are skilled at collaboration and can manage many geriatric conditions,<sup>5</sup> and then sought to improve, clinical practice for common geriatric conditions. A critical component of the ACOVE intervention for practice improvement was an emphasis on the delegation of specific care processes, but the independent effect of delegation on the quality of care has not been evaluated. This study analyzed the pooled results of prior ACOVE projects from 1998 to 2010. Totaled, these studies included 4,776 individuals aged 65 and older of mixed demographic backgrounds and 16,204 ACOVE quality indicators (QIs but gerontological NP training programs have now been folded into adult primary care NP programs<sup>6</sup> and there is no data about how many will specialize in geriatric care.

**ENHANCING HIV PROVIDERS' KNOWLEDGE OF GERIATRIC CARE.** There are several means by which HIV providers can acquire geriatrics expertise:

- **Complete a mini-fellowship in geriatrics.** Four medical schools, via the Consortium for Faculty Development to Advance Geriatric Education (FD-AGE) offer these programs. (<https://www.pogoe.org/fdage>). None is specifically geared toward HIV care, but these fellowships are often flexible and designed to meet the trainee's specific practice needs.
- **Obtain geriatric training through a Geriatrics Workforce Enhancement Program (GWEP).**<sup>7</sup> Institutions that have funding through the Health Resources and Services Administration (HRSA) to provide geriatrics training through their GWEP program are charged to advance primary care of older individuals. A list of GWEP awardees can be found on their website (<http://bhpr.hrsa.gov/grants/geriatricsalliedhealth/0715awards.html>).
- **Utilize other HIV-based training programs.** The federally funded AIDS Education and Training Centers offer an HIV and Aging Toolkit (<http://aidsetc.org/toolkit/aging/home>). Regional AETCs may offer special training for those



interested in caring for aging HIV-infected patients (<http://aidsetc.org/directory/regional>). NICHE (Nurses Improving Care for Healthsystem Elders) can also provide support and gerontological education (<http://www.nicheprogram.org/>).

**EDUCATING SOCIAL WORK STAFF.** Just as the physician workforce must learn to care for older patients, so must social workers. One of the ironies of living long enough with HIV infection is that many of the long-term care programs designed for those who were expected to become disabled and die from AIDS were eliminated when antiretroviral therapy enabled recovery and return to a full life.

The HIV services network and the aging services network have functioned independently, as their respective clients' needs have differed over the past few decades. As skilled as they may be in accessing services for HIV-infected patients, social workers may not be familiar with the aging services network. It is best to look locally first, but there are some national programs that can provide assistance:

- ACRIA has developed educational training programs.<sup>8</sup>
- The National Center for Gerontological Social Work Education sponsors a number of workforce initiatives: (<http://www.cswe.org/CentersInitiatives/GeroEdCenter/Initiatives/WorkforceDevelopment.aspx>).
- The Hartford National Center on Gerontological Social Work Excellence is another resource: (<http://www.gswi.org/>).

**REACHING OUT TO COMMUNITY AGENCIES THAT SERVE OLDER PATIENTS.** Staff can learn to access community based supports and services to meet individual needs of each patient<sup>9</sup> and can partner with local senior centers that will offer patients opportunities to socialize and improve their nutritional status. In addition, staff members can develop closer ties by offering lectures or collaborating on educational programs.

These are just some initial steps programs can take to meet the needs of their aging HIV-infected patients. Whether and how we can create a workforce truly capable of caring for all older PLHA are fundamental, and as yet unanswerable, questions. **HIV**



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**References**

1. Centers for Disease Control and Prevention. *HIV Surveillance Report*, 2013. Vol 25.; 2015. <http://www.cdc.gov/hiv/library/reports/surveillance/>. Accessed November 9, 2013.
2. Smit M, Brinkman K, Geerlings S, et al. Future challenges for clinical care of an ageing population infected with HIV: a modelling study. *Lancet Infect Dis*. 2015 Jul; 15(7): 810–818.
3. Lee W-C, Sumaya CV. Geriatric Workforce Capacity: A Pending Crisis for Nursing Home Residents. *Front Public Health*. 2013; Jul 29;1:24. doi:10.3389/fpubh.2013.00024.
4. Golden AG, Silverman MA, Issenberg SB. Addressing the Shortage of Geriatricians: What Medical Educators Can Learn From the Nurse Practitioner Training Model. *Acad Med*. 2015;90(9):1236-1240.
5. Lichtenstein BJ, Reuben DB, Karlamangla AS, Han W, Roth CP, Wenger NS. Effect of Physician Delegation to Other Healthcare Providers on the Quality of Care for Geriatric Conditions. *J Am Geriatr Soc*. 2015;63(10):2164-2170.
6. Auerhahn C, Mezey M, Stanley J, Wilson LD. Ensuring a nurse practitioner workforce prepared to care for older adults: Findings from a national survey of adult and geriatric nurse practitioner programs. *J Am Acad Nurse Pract*. 2012;24(4):193-199.
7. HHS awards \$35.7 million to improve care for older adults. <http://www.hrsa.gov/about/news/pressreleases/150713geriatricworkforce.html>. Accessed November 10, 2015.
8. Seidel L, Karpiak SE, Brennan-Ing M. Training Senior Service Providers about HIV and Aging: Evaluation of a Multi-Year, Multi-City Initiative. *Gerontol Geriatr Educ*. September 2015. epub doi:10.1080/02701960.2015.1090293.
9. Siegler E, Lama S, Knight M, Laureano E, Reid C. Community-Based Supports and Services for Older Adults: A Primer for Clinicians. *J Geriatr*. 2015;2015:1-6. doi:10.1155/2015/678625.

SHUTTERSTOCK/ELDAR NURKOVIC

# Demystifying HIV Care for Transgender Persons

**A**CCORDING TO RECENT ESTIMATES AND STATISTICS issued by the Centers for Disease Control and Prevention (CDC), transgender persons, and in particular transgender women are the highest risk demographics group in the United States for the acquisition of HIV.

According to the CDC, in 2010, the highest percentage of newly identified HIV-positive test results was among transgender people (2.1%), with the highest percentages of newly identified positives occurring among racial and ethnic minorities, most notably black transgender women.<sup>1</sup>

Due to a lack of standardized collection of gender identity data, detailed information is lacking on the number of transgender people in the United States infected with HIV or seeking HIV-related health services across the care continuum.<sup>1</sup> A meta-analysis and review of available data reported a mean HIV prevalence of 27.7% in transgender females in four studies, where HIV testing was performed in this population. HIV prevalence was highest among black transgender women, with a mean estimate of 56.3%.<sup>2</sup>

In addition, a recent review of studies of HIV infection in countries with data available for transgender people estimated that HIV prevalence for transgender women was nearly 50 times higher than for other adults of reproductive age.<sup>1</sup> Yet despite their well-documented risk, this population remains often overlooked, poorly understood, and at-risk for the receipt of suboptimal or inadequate health care services.

In this article, we outline a five-point plan to help clinicians care for transgender people who seek care for HIV-related prevention and treatment services.

## 1. Understanding the Complexity of HIV Risk and Barriers to Care

When working with transgender persons within a clinical environment, it is important to recognize that a broad range of psychosocial and environmental challenges often complicates the social realities of these patients.

Transgender persons, in particular transgender women, often report limited sources of social support, high rates of unstable housing, economic instability, and limitations on mobility relating to the use of public transportation.<sup>3</sup> These factors underlie an increased risk of psychological distress that often manifests in the form of depression, anxiety, post-traumatic stress, or suicidal ideation.

Each of these factors as well as a denial of gender affirmation can be linked to alcohol and substance use and risky sexual activities and challenge access and retention to health care services.<sup>4</sup>

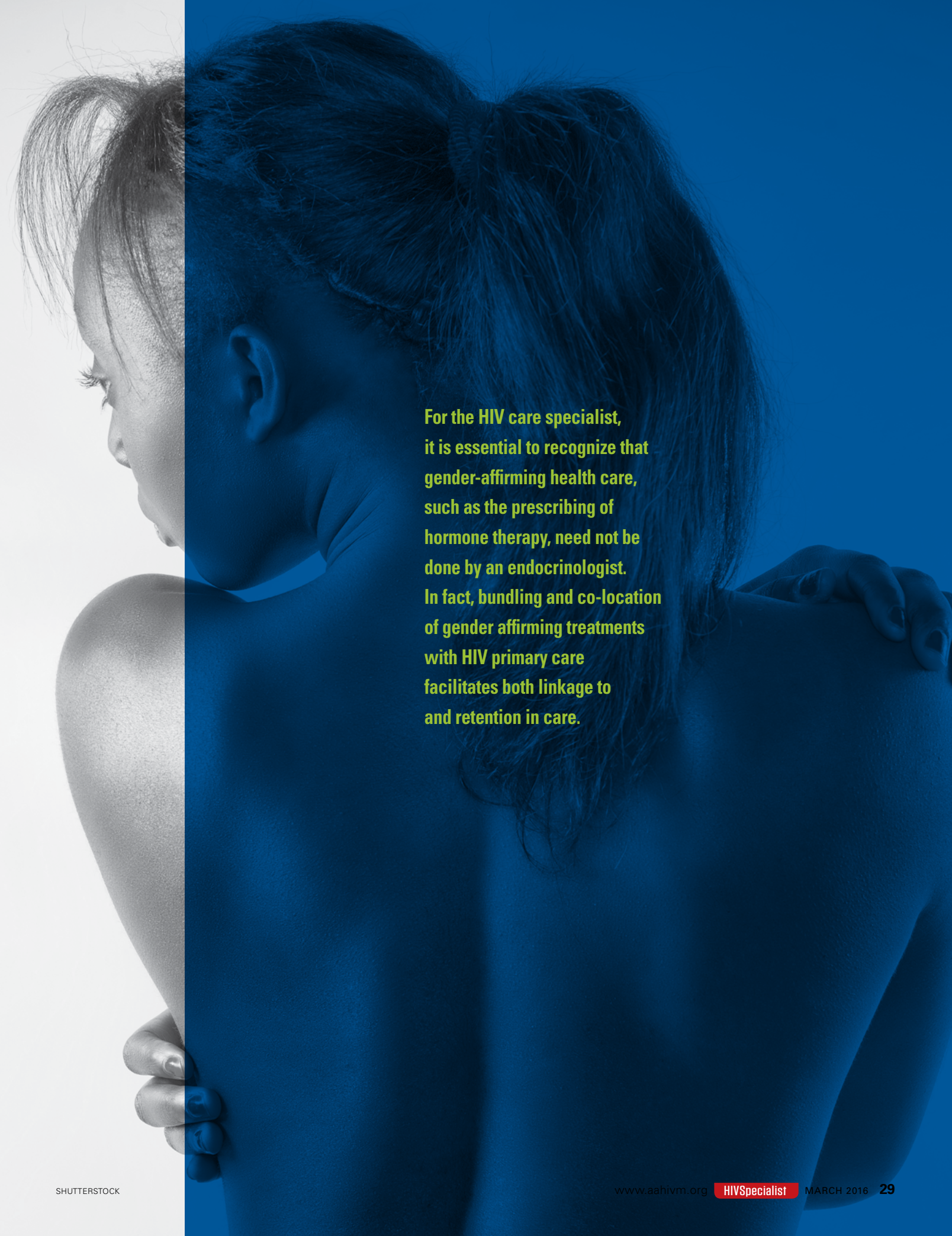
For some, an inability to obtain or maintain adequate employment in the context of societal stigma or a lack of legal protections results in high rates of commercial sex work and other transactional sex to obtain food, shelter, and income. In addition to the inherent HIV risk associated with sex work, transgender women may face additional risks such as earning more money for condomless receptive anal sex—as well as increased risk of interpersonal violence.<sup>5</sup>

Sex work is a particularly difficult risk factor to modify due to the strong financial incentives, as well as the gender affirmation many transgender women receive from such activity.<sup>4</sup> Understanding the social realities facing transgender persons, ideally in conjunction with community engagement, can help inform the development of risk reduction messages that are non-judgmental and with adequate cultural humility.

## 2. Integration of Health Care Services

Barriers to accessing HIV primary care and antiretroviral treatment (ART) among HIV-positive transgender people are well-documented.<sup>6</sup> Discrimination from health care providers, a lack of knowledge about transgender needs, and the outright refusal of many health insurance providers to cover the cost of gender-related care all represent barriers to adequate care.

For the HIV care specialist, it is essential to recognize that gender-affirming health care, such as the prescribing of hormone therapy, need not be done by an endocrinologist. In fact, bundling and co-location of gender affirming treatments with HIV primary care facilitates both linkage to and retention in care. Even for those transgender patients who do not seek hormones or surgery, other basic steps to support gender affirmation, such as a system to identify patients by their preferred name and pronoun can have a profound impact on retention in care.<sup>7</sup>



**For the HIV care specialist, it is essential to recognize that gender-affirming health care, such as the prescribing of hormone therapy, need not be done by an endocrinologist. In fact, bundling and co-location of gender affirming treatments with HIV primary care facilitates both linkage to and retention in care.**

HIV care providers should acquaint themselves with available guidelines such as the World Professional Association for Transgender Health (WPATH) Standards of Care,<sup>8</sup> Endocrine Society Guidelines,<sup>9</sup> or the University of California San Francisco's Protocols,<sup>10</sup> and integrate these into their practice and the HIV care continuum.

The WPATH Standards are easily digestible and can help willing providers better understand a range of transgender care and cultural issues, including determining readiness and appropriateness for gender affirming treatments, obtaining informed consent, and an overview of potential side effects that may arise from hormone therapies. While a detailed discussion of these protocols is beyond the scope of this short commentary, these resources are readily available, and HIV care providers might find them useful when caring for transgender persons.

### 3. The Medical Evaluation and Physical Examination

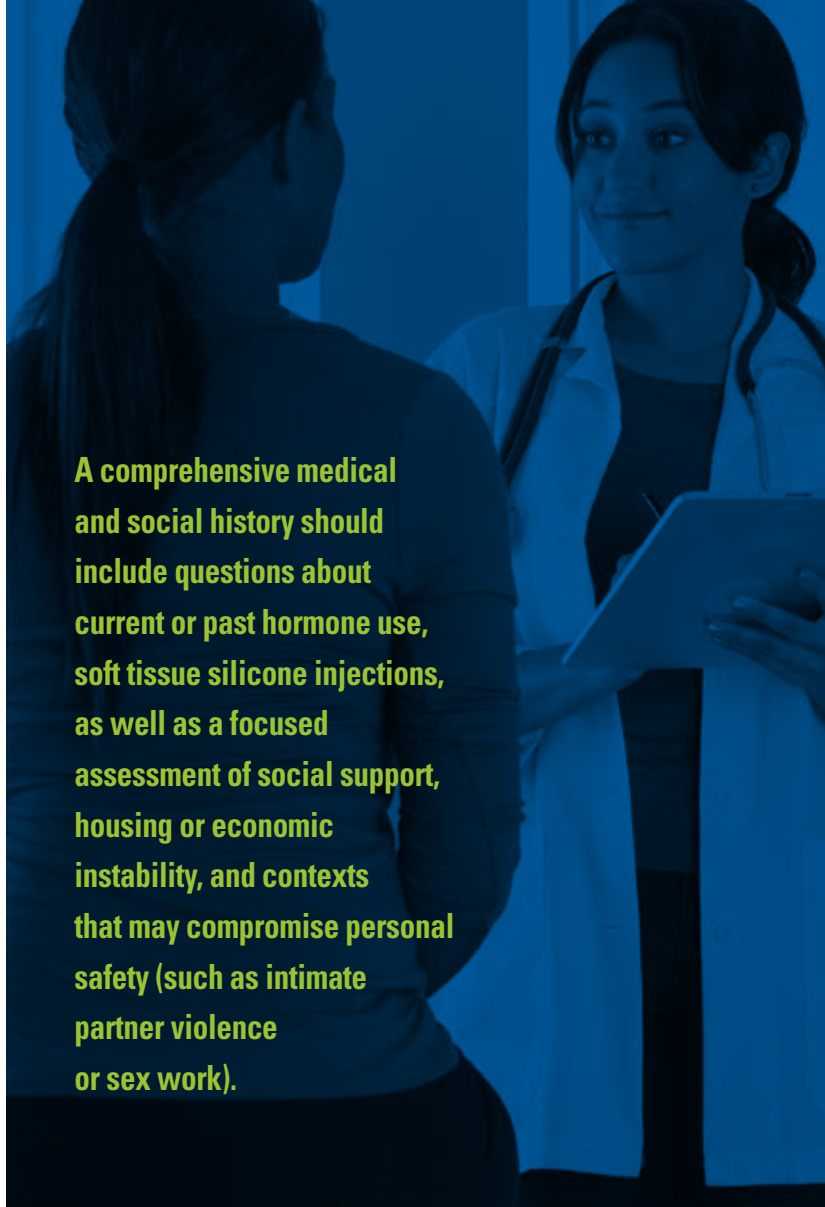
With regard to the medical evaluation, the use of appropriate language is of critical importance to the transgender patient.

In particular, using the correct name and pronoun is critically important to establishing rapport and respecting the affirmed gender of a transgender patient. Clinics should have a system in place to properly collect and use name and pronoun in cases where these differ from legal documents. Assumptions of gender identity or pronoun use based on appearance or other subjective features should be avoided; instead providers should rely on self-provided information.

Some patients may prefer non-binary (neither male nor female) terms such as “they/them” or “zie/hir”. In cases where a provider accidentally uses the wrong term or pronoun, it is best to be upfront and apologize (for example, “I’m sorry. I did not mean to be disrespectful.”).

When taking an initial medical history, it is important to gain an understanding of the patient’s gender identity, including an assessment of any ongoing or unaffirmed gender dysphoria. A comprehensive medical and social history should include questions about current or past hormone use, soft tissue silicone injections, as well as a focused assessment of social support, housing or economic instability, and contexts that may compromise personal safety (such as intimate partner violence or sex work).

Providers should take a detailed surgical history, with special attention to any prior gender affirming surgeries, and



**A comprehensive medical and social history should include questions about current or past hormone use, soft tissue silicone injections, as well as a focused assessment of social support, housing or economic instability, and contexts that may compromise personal safety (such as intimate partner violence or sex work).**

maintain a current organ inventory on all patients. Knowledge of a patient’s current anatomy and sexual practices is essential to inform diagnostic workups; for example, a transgender male presenting with abdominal pain may require a workup for ovarian or uterine pathology, and a transgender woman with a prostate may require a rectal exam.

Providers may choose to defer an examination of the genitalia unless warranted by a specific complaint or concerns, as this may cause considerable stress for the transgender patient.

While there is no data on the interactions between gender-affirming hormones and ART, data from studies of the effects of oral contraceptives on ART are generally reassuring.<sup>11,12</sup> Conversely, there is some data that suggests that ART may result in reduced estrogen levels, which could result in reduced ART adherence, since transgender women may prioritize hormone therapy over other treatments.<sup>4</sup>

One study found up to 48% reduction in serum estradiol levels with the use of ritonavir-containing regimens. While prescribing ART, providers may monitor hormone levels and make adjustments in order to manage symptoms and maintain estradiol levels in the desired range.



## 4. It's All About the Environment

Transgender patients decide whether a clinical setting feels safe and respectful long before they meet their health care provider. Therefore, all staff and personnel should be well versed in ways in which to make health care settings welcoming to transgender people, and have basic cultural competency and understanding of the use of correct name and pronoun.

Posting nondiscrimination policies inclusive of gender identity in the public and high-traffic areas can help make the transgender patient feel at ease. Intake forms should allow for responses that include a spectrum of gender identities rather than only the male-female binary. Offering gender-neutral bathrooms, or having a clearly posted policy indicating bathroom use based on self-identified gender, can improve transgender patient comfort and also avoid or diffuse confrontations with other clinic patients.

A zero-tolerance policy is essential for language that could be viewed as hostile, offensive, or derogatory and should be established and enforced for both staff and patients.

## 5. A Word about Pre-Exposure Prophylaxis (PrEP)

In addition to behavioral HIV prevention interventions, PrEP, using a once daily fixed combination of tenofovir disoproxil fumarate and emtricitabine (TDF/FTC), has been shown to significantly reduce the risk of HIV transmission.

Studies of PrEP specifically in transgender women have not been conducted. The iPrEx study of PrEP in men who have sex with men and transgender women found a 44% risk reduction using an intention-to-treat analysis.<sup>13</sup> A subanalysis of the transgender women only found no efficacy using an intention-to-treat analysis; however, none of the transgender women who contracted HIV in the randomized trial had detectable drug levels at the time of seroconversion.<sup>14,15</sup>

Further study of PrEP in transgender women should include examination for interactions between gender-affirming hormones and TDF/FTC are warranted. However, in 2014, CDC released clinical guidelines recommending that PrEP be considered for people who are HIV-negative

and at substantial risk for the acquisition of HIV, including anyone who is in an ongoing sexual relationship with a HIV-positive partner.

In that context, those caring for HIV-positive transgender persons should offer education on PrEP, review the clinical guidelines, and help assess whether there is a sexual partner or partners in need of PrEP as a HIV preventive strategy.<sup>16</sup>

While many HIV care providers may have limited experience with transgender care, the increased risk for the acquisition of the virus in this population warrants special awareness and attention. The framework and five-point plan presented here aims to help providers offer culturally competent comprehensive care to the HIV-positive transgender patient. ■



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## References

- Centers for Disease Control and Prevention. HIV Among Transgender People in the United States Fact Sheet. Atlanta, GA 2013.
- Herbst JH, Jacobs ED, Finlayson TJ, et al. Estimating HIV prevalence and risk behaviors of transgender persons in the United States: a systematic review. *AIDS and behavior*. 2008;12(1):1-17.
- Garofalo R, Deleon J, Osmer E, et al. Overlooked, misunderstood and at-risk: exploring the lives and HIV risk of ethnic minority male-to-female transgender youth. *The Journal of adolescent health : official publication of the Society for Adolescent Medicine*. 2006;38(3):230-236.
- Sevelius JM. Gender Affirmation: A Framework for Conceptualizing Risk Behavior among Transgender Women of Color. *Sex roles*. 2013;68(11-12):675-689.
- Poteat T, Wirtz AL, Radix A, et al. HIV risk and preventive interventions in transgender women sex workers. *Lancet*. 2015;385(9964):274-286.
- Melendez RM, Exner TA, Ehrhardt AA, et al. Health and health care among male-to-female transgender persons who are HIV positive. *American journal of public health*. 2006;96(6):1034-1037.
- Deutsch MB, Green J, Keatley J, et al. Electronic medical records and the transgender patient: recommendations from the World Professional Association for Transgender Health EMR Working Group. *Journal of the American Medical Informatics Association : JAMIA*. 2013;20(4):700-703.
- The World Professional Association for Transgender Health. *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People*. 7th Version. 2011.
- Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. *The Journal of clinical endocrinology and metabolism*. 2009;94(9):3132-3154.
- Center of Excellence for Transgender Health. *Primary Care Protocol for Transgender Patient Care*. University of California San Francisco, Department of Family and Community Medicine 2011.
- Chu JH, Gange SJ, Anastos K, et al. Hormonal contraceptive use and the effectiveness of highly active antiretroviral therapy. *American journal of epidemiology*. 2005;161(9):881-890.
- Whiteman MK, Jeng G, Samarina A, et al. Associations of hormonal contraceptive use with measures of HIV disease progression and antiretroviral therapy effectiveness. *Contraception*. 2015.
- Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *The New England journal of medicine*. 2010;363(27):2587-2599.
- Grant RM, McMahan V, Liu AY, et al. Completed observation of the randomized placebo-controlled phase of iPrEx; daily oral FTC/TDF pre-exposure HIV prophylaxis among men and trans women who have sex with men. 6th IAS Conference on HIV Pathogenesis, Treatment and Prevention. Rome 2011.
- Deutsch MB, Glidden DV, Sevelius J, Keatley J, McMahan V, Guanira J, Kallas EG, Chariyalertsak S, and Grant RM for the iPrEx Study Team. HIV pre-exposure prophylaxis in transgender women: A subgroup analysis of the iPrEx trial. *Lancet HIV*. In Press.
- Centers for Disease Control and Prevention. *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2014 Clinical Practice Guideline* 2014.

# What's New in HCV Treatment?

**T**HE TREATMENT OF HEPATITIS C VIRUS (HCV) infection has evolved over the years from patients having to use Interferon-based regimens, which basically meant experiencing fatigue and flu-like syndrome for 48 weeks, with suboptimal response rates. Addition of ribavirin improved the response rate, but at the cost of additional toxicities including anemia which further lead to a poor quality of life. Moreover, only about 30% of patients co-infected (HIV/HCV) responded to these regimens and many failed to complete them due to the drug side-effects noted above.

Good news spread quickly in 2011 within the medical community and the hopes of HCV-infected individuals spiked when the first direct acting agents (boceprevir and telaprevir) were approved by the FDA. Virologic response rates improved significantly, but these treatment modalities still included interferon and introduced a host of new and complex adverse events such as dermatological reactions and severe blood dyscrasia. Some of those regimens required a high-fat meal, TID dosing, and a high pill burden. Response-guided therapy was yet another challenge with the first generation DAAs. So the optimistic news of DAAs did not last very long as enthusiasm for these new agents quickly waned.

Starting with the approval of Sofosbuvir in December 2013, there have been new agents to treat HCV that are well-tolerated, have minimal toxicities, and most importantly have produced cure rates consistently greater than 90%. Two recent additions to the family of HCV therapies include daclatasvir (Daklinza™) and the combination of elbasvir and grazoprevir (Zepatier™) as a single-tablet regimen.

## Daklinza™ (daclatasvir, DCV):

- Method of Action (MOA):** Daclatasvir (DCV) is a direct acting antiretroviral agent (DAA) against HCV. Daclatasvir is an inhibitor of NS5A - a nonstructural protein encoded by the virus. Daclatasvir binds to the N-terminus of NS5A and subsequently inhibits both viral RNA replication and virion assembly.
- Indication:** Daclatasvir is indicated for use with sofosbuvir, with or without ribavirin, for the treatment of patients with chronic HCV genotype 1 or HCV genotype 3 infection.
- Limitation of use:** Sustained virologic response (SVR12) rates are reduced in HCV genotype 3-infected patients with cirrhosis receiving DCV in combination with sofosbuvir for 12 weeks.
- Resistance testing prior to therapy initiation:** For HCV genotype-1 patients with cirrhosis the manufacturer note that screening should be “considered” for the presence of NS5A polymorphisms occurring at amino acid positions

M28, Q30, L31, and Y93.

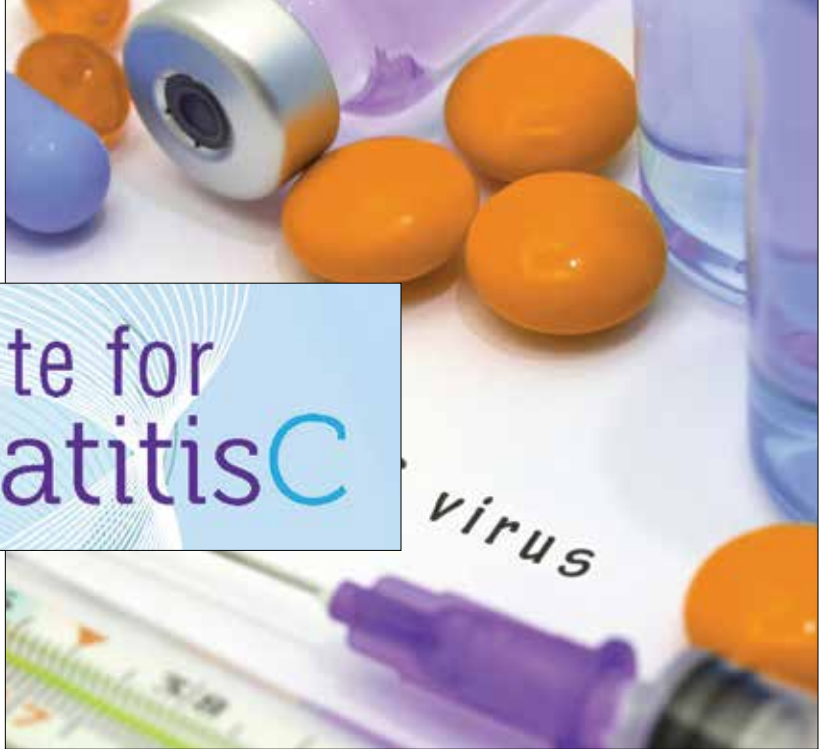
- Treatment duration and dosage:** The recommended dosage for DCV is 60 mg orally, once daily. It can be taken with or without food.

Recommended Treatment Regimen and Duration for Daklinza in Patients with Genotype 1 or 3 HCV		
<b>Genotype 1</b>	Without cirrhosis	DCV + SOF for 12 weeks
<b>Genotype 1</b>	Compensated (Child Pugh A) Cirrhosis	DCV +SOF + RBV for 12 weeks
<b>Genotype</b>	Decompensated (Child Pugh B or C Cirrhosis)	DCV +SOF +RBV for 12 weeks
<b>Genotype 1</b>	Post-transplant	DCV + SOF+RBV for 12 weeks
<b>Genotype 3</b>	Without cirrhosis	DCV + SOF for 12 weeks
<b>Genotype 3</b>	Compensated (Child Pugh A) or decompensated (Child Pugh B or C) cirrhosis	DCV + SOF + RBV for 12 weeks
<b>Genotype 3</b>	Post-transplant	DCV + SOF + RBV for 12 weeks

## Dosage Modification Due to Drug Interactions

Concomitant Drugs	Daklinza Dosage
Strong CYP3A inhibitors and certain HIV antiretroviral agents	30 mg once daily
Moderate CYP3A inducers and nevirapine	90 mg once daily
Strong CYP3A inducers	Contraindicated

- Adverse Reactions:** Adverse events to daclatasvir were relatively infrequent in clinical trials. These most commonly were headache (14%), fatigue (14%), nausea (8%), and diarrhea (5%). Most side effects were mild to moderate and no subjects in the ALLY-2 or ALLY-3 studies discontinued therapy due to adverse events. In ALLY-1, only 2 subjects discontinued all study drugs, one due to headache and the other post-transplant.




# Institute for Hepatitis C

## Elbasvir-Grazoprevir : ( Zepatier™)

- Mechanism of action:** Zepatier™ is a two-drug, fixed-dose combination product containing 50 mg of elbasvir and 100 mg of grazoprevir. Elbasvir is an inhibitor of HCV NS5A, which is essential for viral RNA replication and virion assembly. The mechanism of action has been characterized based on cell culture antiviral activity and drug resistance mapping studies. Grazoprevir is an inhibitor of HCV NS3/4A protease which is necessary for the proteolytic cleavage of the HCV encoded polyprotein (into mature forms of the NS3, NS4A, NS4B, NS5A, and NS5B proteins) and is essential for viral replication.
- Indication:** Zepatier™ is indicated with or without ribavirin for the treatment of chronic HCV genotype 1 or HCV genotype 4 infection in adults.
- Resistance testing prior to therapy initiation in Genotype-1a infected patients:** Testing patients with HCV Genotype 1a infection for the presence of virus with NS5A resistance-associated polymorphisms is recommended prior to initiation of treatment to determine dosage and duration.
- Treatment duration and dosage:** The recommended dose of Zepatier™ is one tablet taken orally once daily with or without food. Zepatier is used in combination with ribavirin in certain patient populations.

## Drug interactions: Drugs that are contraindicated with Zepatier™:

Anticonvulsants:	phenytoin; carbamazepine
Antimycobacterials	Rifampin
Herbal Products	St.John's Wort ( <i>Hypericum perfor</i>
HIV Medications	Efavirenz
HIV Medications	Atazanavir; Darunavir; Lopinavir; Saquinavir; Tipranavir
Immunosuppressants	Cyclosporine

- Adverse Reactions:** Fatigue, headache, and nausea were the most common adverse events reported for patients taking this combination drug. For those concurrently receiving ribavirin, the most common adverse events were anemia and headache. Elevation in hepatic transaminase levels occurred in about 1% of patients in clinical trials. **HIV**

Recommended Treatment Regimen and Duration for Zepatier in Patients with Genotype 1 or 4 HCV		
Genotype 1a: treatment-naïve or PegIFN/RBV-experienced without NS5A polymorphism	Zepatier	12 weeks
Genotype 1a: treatment-naïve or PegIFN/RBV-experienced with NS5A polymorphism	Zepatier +RBV	16 weeks
Genotype 1b: Treatment-naïve or PegIFN/RBV-experienced	Zepatier	12 weeks
Genotype 1a or 1b: PegIFN/RBV/PI-experienced	Zepatier +RBV	12 WEEKS
Genotype 4: Treatment-naïve	Zepatier	12 weeks
Genotype 4: PegIFN/RBV-experienced	Zepatier +RBV	16 weeks



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## References:

- Wyles DL et al. Daclatasvir plus Sofosbuvir for HCV in Patients Coinfected with HIV-1. *N Engl J Med.* Aug 2015; 373(8):714-25.
- Smith, MA. Daclatasvir: A NS5A Replication Complex Inhibitor for Hepatitis C Infection. *Ann Pharmacother.* 2016; 50(1):39-46.
- Rockstroh JK, Efficacy and safety of grazoprevir (MK-5172) and elbasvir (MK-8742) in patients with hepatitis C virus and HIV co-infection (C-EDGE CO-INFECTION): a non-randomised, open-label trial. *Lancet HIV.* 2015 Aug; 2(8):e319-27.
- Sulejmani M Jafri SM, Gordon SC. Pharmacodynamics and pharmacokinetics of elbasvir and grazoprevir in the treatment of hepatitis C.
- Expert Opin Drug Metab Toxicol. 2016; 12(3):353-61.

## An Uphill Battle to Serve the Underserved

MICHELLE COLLINS-OGLE, MD, FAAP, AAHIVS  
Warren-Vance Community Health Center, Inc.  
Henderson, North Carolina

**W**ITH A POPULATION OF A LITTLE OVER 15,000, Henderson is situated in the northern part of North Carolina. Here, Warren-Vance Community Health Center, Inc. (WVCHC) is a rural clinic located in a Medically Underserved Area (MUA) and Health Professional Shortage Area (HPSA) and is the only HIV specialty clinic within a 45-mile radius.

Headed by Clinic Director Dr. Michelle Collins-Ogle, all clinic services provided at WVCHC are based upon a team management approach to address the medical and psychological needs of each patient. The clinic is staffed by one full-time Infectious Disease physician, one part-time DNP (Doctor of Nursing Practice), and one PA-C. The clinic is fortunate to have a full-time program manager, who also supervises case management services; a full-time RN, in house phlebotomist and medical case manager. The team is rounded out with a part-time case manager and receptionist/administrative assistant.

Dr. Collins-Ogle attended Wayne State School of Medicine and completed her residency and Pediatric Infectious Disease Fellowship at Children's Hospital of Michigan and initially treated infants and children with perinatally-acquired HIV in the late 1980s in Detroit.

Says Dr. Collins-Ogle, "I've always had a special interest in the diagnosis and treatment of perinatal HIV-infected children. In the early years of HIV, I cared for infants who basically became part-time residents of the Infectious Disease Unit at Children's Hospital. These babies often lived with other family members because their mothers and fathers were too sick or died from the virus.

"There wasn't much we could do for these precious angels until 1990 when AZT became available for treatment in infants and children;

AZT also made these babies so sick. It was gut wrenching, holding and caring for these babies who looked like me, or my children, and literally watching them die or giving them medication that made them worse.

"I made a promise to those babies that I would remain in this fight until no more babies or children were dying from HIV disease."

She has been caring for infants, adolescents and adults for about 25 years now. Over the course of her career, Dr. Ogle worked in an urban medical center and community hospital/suburban settings in Michigan before relocating to North Carolina. Since 2001, she has directed the Ryan White funded HIV clinic, providing medical care to adolescents and adults.

The rural location of Dr. Collins-Ogle's practice at WVCHC requires outside-of-the-box thinking in creating programs that may encourage patient participation in their HIV care. Approximately one in five North Carolinians lack access to enough food. Since 2013, when food stamp benefits were slashed, they've seen an increase in the number of clinic patients who are food insecure.

The clinic's Food Pantry was started in 2014 to help provide basic dietary needs for their patients living below the poverty level. That has helped lead to a dramatic improvement in viral load suppression and compliance with medical visits, which has been sustained over the past year.



In Dr. Collins-Ogle's service area, ethnic minorities are the overwhelming majority (87%), and access to health care is a serious problem for them all. Of her patient pool, she says, "About 31% of our patients lack health insurance and 30% receive Medicaid. The percentage of the service area population living 200% and below the federal poverty level (FPL) is grim at 44.62%."

In the catchment area, adolescents (age 13-24) composed 4% of the HIV-infection rates for 2013 and this rate has remained steady through 2015. However, in young adults (age 25-29), there was an increase in the HIV infection rate from 29% to 33% during the same time period. In addition, its MSM population has grown and represents about 25% of total clinic demographic.

"There is a clear need to improve meaningful, comprehensive and effective HIV prevention efforts targeting young MSM of color, particularly those living in the south," continued Collins-Ogle. "We must acknowledge the role stigma plays in the willingness of young MSM of color to seek prevention

and treatment. Children and youth of color continue to be at risk for exposure and infection with HIV. Despite the many challenges that exist in providing care in the rural south, as an African-American physician, a mother and advocate for children, I feel a personal obligation to continue fighting against the spread of HIV disease.”

The clinic has also expanded to provide comprehensive medical care to a growing trans-female population. WVCHC also recently hosted a “Trans-Celebration” where their trans-female patients were encouraged to bring a partner for free HIV testing along

with lunch, a medical visit, and “girl talk.”

Dr. Collins-Ogle motivates her patients to be adherent to their treatment regimens by encouraging them to actively participate in their care plan. Providing education and emphasizing the consequences of non-adherence is key in understanding the importance of complete viral suppression.

“It is extremely important to recognize barriers and patient’s medical literacy in setting expectations for adherence,” she says. “Addressing hunger, lack of housing, stigma and access to medication are just a few of the hurdles our patients must get over

to achieve adherence in their regimen. We become partners in dealing with these challenges so patients don’t feel alone, making the relationship a shared responsibility in achieving adherence.”

Looking to the future, Dr. Collins-Ogle would like to see universal access to healthcare for all Americans. “It is gross irresponsibility and negligence that 19 states currently refuse to expand Medicaid under the provisions of the Affordable Care Act,” she says. “Of these, 10 states are in the south leaving millions of Americans without access to quality, lifesaving medical treatments.

“North Carolina legislators voted to not allow state based marketplace insurance exchanges. The result is only three insurance companies with marketplace plans,” she said. “These plans are expensive and are not options for our uninsured patients with such low incomes. These legislators do not care about the HIV epidemic and how it negatively impacts the citizens in the south who are also their constituents. I am not hopeful that this bleak picture will change anytime soon because of partisan politics and profit driven insurance companies.”

Dr. Collins-Ogle has been appointed to the President’s Advisory Council on HIV/AIDS under the leadership of ONAP Director, Mr. Douglas Brooks. She also serves as President of the Board for the Central Children’s Home in Oxford, North Carolina. Founded in 1883, it is the second oldest Children’s Home in the state and the oldest black home in the U.S.

Asked why she is an AAHIVM Member, Dr. Collins-Ogle says, “As an advocate for people living with HIV, I’m honored to be a part of an organization dedicated to promoting excellence in HIV/AIDS health care. AAHIVM is committed to supporting health care providers in HIV medicine and promotes an environment for the standardization of care for those living with HIV. As an Academy member, I continue to learn from others involved in all aspects of delivering HIV care.” **HIV**



# Why It Is Important for an HIV Care Provider to Become an AAHIVM HIV Specialist™

BY DONNA SWEET, MD, AAHIVS

**A** LITTLE OVER FIFTEEN YEARS AGO a group of HIV care providers, many of whom had been in practice at the dawn of the AIDS epidemic, came together to discuss ways they could harness their nearly three decades of knowledge, experience and insight to document and improve standards of HIV care delivery, while cultivating a new generation of HIV care providers.

What resulted was the formation of the American Academy of HIV Medicine (AAHIVM), and the development of the Academy's HIV Specialist™ Credentialing Program. Open to physicians, nurse practitioners, physician assistants and pharmacists, the AAHIVM HIV Specialist™ credential remains the only one of its kind nationwide, establishing a standard by which all HIV care providers should deliver quality HIV care. The credentialing program has three simple – but important – objectives:

- To improve the quality of HIV care,
- To broaden patient access to quality care, and
- To expand the number of HIV-specialized medical care providers.

We live in an increasingly complex health care environment that demands that we keep up with its rapid evolution. Treating HIV is not the same as it was 30 years ago, as many HIV care veterans know. Breakthroughs in treatment and care that combat HIV and extend life are often followed by perplexing trends, drug interactions and trends in new toxicities and drug interactions. Social and cultural responses to HIV have a direct impact on both our HIV-positive and negative patients. This in turn affects how we provide – and how our patients receive – HIV care and treatment, as well as our messages of wellness, risk reduction and prevention. Increased life expectancy for people living with HIV has presented a growing list of issues that includes: treatment adherence, hepatitis B/C co-infection, cardiovascular disease, and more. The definition of quality HIV care, then, must necessarily evolve as people live longer with the disease. It also must integrate the complexities of HIV with health risk factors typically associated with the normal aging process.

Guidelines and resources are indeed available to help health care providers in treating HIV/AIDS (particularly in the use of antiretroviral therapy), but these guidelines are no substitute for the judgment of an expert in the care of people living with HIV. Even the guidelines themselves stress that, where possible, the treatment of HIV patients should be directed by an expert in HIV care.

Becoming an Academy-credentialed HIV Specialist™ is a way to remain current, demonstrate frontline experience, and evolve with changes in HIV technology, with discoveries of new treatments and with shifts in the nation's health care system. The AAHIVM HIV Specialist™ credential demonstrates to patients, colleagues, employers and third party payers a care provider's commitment to maintaining continuing competency through ongoing learning, experience and self-assessment.

Most of us already know from other professional credentialing opportunities that an objective credentialing program with rigorous standards establishes documented accountability for quality care delivery. Patients have become active in their care and treatment, and those with a choice in health care providers are increasingly seeking out experts with verification of HIV-specific knowledge and experience. Health plans and

medical clinics also are beginning to encourage, or even require, that those serving patients with HIV become AAHIVM HIV Specialists™.

To apply for the credentialing exam a provider must actively care for more than 20 HIV patients over the last two years. In fact, 55% of AAHIVM HIV Specialists™ have fewer than 150 HIV patients, and only 20% have more than 300. The reality is, then, that the average credentialed AAHIVM Specialist™ is an HIV-specific practitioner for only a part of his or her time.

Becoming credentialed through a process like the Academy's program demonstrates to the medical community-at-large that we as HIV care providers voluntarily seek to establish for ourselves a rigorous, uniform national standard for the knowledge and experience base expected of all practitioners serving on HIV care teams. Developing a universal assessment tool of HIV knowledge for physicians, nurse practitioners, physician assistants and pharmacists also helps reduce barriers to entry into this specialized area of care. The AAHIVM HIV Specialist™ designation is available to health care professionals from diverse health care settings, educational backgrounds and frontline care experience. Credentialing improves our professional development, benefits our patients' care, and provides a foundation for the creation of better treatment and care access opportunities.

Those of us who have cared for patients living with HIV know that this disease is unlike any other. Those who continue to care for people living with HIV, despite HIV's clinical, social and epidemiological challenges, know that we must act now to ensure we have a new generation of HIV care providers who have the knowledge, tools and resources they need to effectively deliver quality HIV care. Becoming credentialed is a simple, yet powerful, action we can take both as individuals and as a profession, to improve HIV care quality and grow the number of knowledgeable, qualified HIV providers.

Applications for the AAHIVM HIV Specialist™ credentialing exam, as well as program eligibility requirements and frequently asked questions, are available at the Academy's Web site, [www.aahivm.org](http://www.aahivm.org).



#### ABOUT THE AUTHOR:

**Dr. Sweet** is currently Professor of Medicine, University of Kansas School of Medicine – Wichita; Director of Internal Medicine Education at Via Christi Regional Medical Center - St. Francis; Medical Director, UKSM-W MPA HIV Program; Principle Investigator/Director, The Kansas AIDS Education and Training Center, Wichita, Kansas. She is the current Chair of the AAHIVM Credentialing Committee and past Chair of the AAHIVM Board of Directors. Dr. Sweet was recognized by the American Medical Association with the "Pride in the Profession" national award in 2000. She was recently honored as one of the "Shocker Top 40" by Wichita State University, an honor given to just 40 graduates of the last century.



## Considering Credentialing With AAHIVM? The Application Period Begins April 15!

It has never been more important to be credentialed with AAHIVM, especially with regard to today's health policy landscape. Your status as an HIV Specialist™ is considered in regards to...

- Prescriber access to restricted curative medications
- Affordable Care Act requirements for provider network inclusion
- Reimbursement rates by certain payers and coverage entities
- Quality measures and accountable care models

If you are interested in becoming a certified HIV Specialist™, HIV Pharmacist™ or HIV Expert™, the AAHIVM credentialing application period begins on April 15th.

Go to [www.aahivm.org/about](http://www.aahivm.org/about) to learn more about the credentialing program, eligibility and key dates for the coming year.

**Remember, your credential is now valid for three years!**

### Why Credential with AAHIVM?

- **Communicate to patients**, colleagues, employers, governments and third-party payers an up-to-date core knowledge HIV care.
- **Demonstrate support** (on the part of the certified provider) of a uniform national standard for HIV care, and offers appropriate recognition of this highly technical sub-specialty.
- **Protect the healthcare consumer** by creating a publicly identifiable professional standard of HIV care, which is awarded by an objective, transparent process and can be readily identified by a provider's AAHIVS, AAHIVE or AAHIVP titling.
- **Promote professional visibility** of providers working in HIV care.
- Support efforts to **reform current reimbursement structures** for specialized HIV care by creating a mechanism to determine the validity of expertise among an aggregate population of certified providers.

***“The Academy’s program is the only widely recognized, statistically sound and defensible measurement program available in HIV-focused medical care. On average, about 2000 providers are actively maintaining an AAHIVM credential, a majority of which principally identify as an HIV provider. In 2016, most US HIV-positive patients are now under the care of an Academy-certified provider.”***



# ACTHIV

THE AMERICAN CONFERENCE  
FOR THE TREATMENT OF HIV

**Congratulations to Jason Leider, MD, PhD, FACP,**  
the 2016 AAHIVM/Institute for Technology in Health Care HIV Practice Award Winner!

Dr. Leider will present his program, Project BRIEF,  
at the upcoming ACTHIV Conference in Dallas, Texas:

**"Better Client Care with New Technology"**

Thursday, April 28th  
12:00pm

To learn more about Dr. Leider's award-winning program,  
please visit our website at [www.aahivm.org](http://www.aahivm.org).