

# HIV Specialist

## Optimizing the Care of Your Patients

HIV &  
Conception

10

HOPE Study

14

Power of  
Technology

18

Interventions for  
Adherence and  
Retention

27

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# CONTENTS

JULY 2017 | Volume 9, No. 2 | [www.aahivm.org](http://www.aahivm.org)

## FEATURES



### 13 Optimizing Care

An Overview

### 18 Tech Award Winner

Using the Power of Technology  
to Improve Patient Care

BY BOB GATTY, EDITOR

### 20 Tech Practice Award

Crowdsourcing to Improve  
HIV Testing Services

BY YILU QIN, MD

### 22 Tech Practice Award

Algorithm Method

BY JASON GILLMAN, MD



### 24 Tech Practice Award

Electronic Medical Record (EMR) Tool to  
Query Hospitalized HIV-Infected Patients

BY ERIC K. FARMER, EMILY HUESGEN AND  
BROOKE N. STEVENS

### 26 Interventions

Improving Adherence and Retention in Care

BY JAMES L. RAPER, PhD, CRNP, JD

## DEPARTMENTS

### 2 LETTER FROM THE DIRECTOR

Roiling Thunder

BY JAMES M. FRIEDMAN, MHA,  
EXECUTIVE DIRECTOR, AAHIVM

### 3 IN THE NEWS

Complimentary "Guide to Hepatitis C Testing"  
Available; HIV Patients Life Expectancy Up by  
10 Years in U.S. and Europe; HIV.Gov Creates  
'Positive Spin' to Tell Stories of PLWH; FDA OKs  
First Generic for HIV Prevention; NIH Awards  
Grant to Curb Alcohol Abuse in HIV+ Patients;  
TAF as Effective as TDF for Viral Suppression;  
Framingham Score Insufficient When Screening  
PLWH; Is HIV Cured or Still Lurking? New Test  
Can Say.

### 8 AT THE FOREFRONT

Taking the Long View

BY DOUGLAS WARD, MD

### 10 ON THE FRONTLINES

HIV & Conception

BY WILLIAM R. SHORT, MD, MPH, AAHIVS AND  
SHANNON WEBER, MSW

### 14 BEST PRACTICES

The HOPE Study

BY JEFFREY T. KIRCHNER, DO, FAAFP, AAHIVS

### 29 CAREER CENTER



BY JAMES M. FRIEDMAN, MHA  
Executive Director, AAHIVM

## Roiling Thunder

**WE HAVE A VERY DIVERSE MEMBERSHIP BASE** at AAHIVM, representing a wide range of ethnicities, geographic locations, practice settings, and professional degrees. But there is one thing that all of our members have in common: the consistent desire to provide optimal HIV care for their patients. This issue of *HIV Specialist* showcases unique ways to optimize your patients' care through communications tactics, cutting edge technologies, and new treatment research.



James M. Friedman

As we celebrate the continued advances in HIV care, I'm troubled as to whether our patients will actually have access to the best care available. While we grow our offerings within our industry, we have outside forces trying to decimate the ability to access care to those that need it most.

I have never been a member of any political party. During my 20 years of service in the U.S. Public Health Service, I worked directly for both democratic and republican Assistant Secretaries for Health. They were all physicians and they were honestly and openly supportive of improving the health of all Americans.

I hardly recognize what is going on today. You know times are bad when the moderates—yes, the moderates—are pushing to hold those who will likely lose health insurance under the “Repeal and Replace” plan down to only 10 million Americans. Combine that with the President's budget, which proposes enormous cuts in funding for health programs that serve the poor, the disabled and children, and you're not left with politics as usual. This is politics that is beyond comprehension.

Recently we partnered with 18 other HIV/AIDS organizations to publish an ad in “Politico” newspaper, a publication that is widely read in DC and in Congress. What is important about this ad is the universality of its message. It does not suggest to keep Obamacare (ACA), nor to accept or reject the House of Representatives bill (AHCA). Rather, it reads “Say no to rolling back protections for vulnerable Americans.” That is a message of which I think all Americans should be supportive.

Well, what should we do? What is the answer? First, don't keep your head down. Do what you have done your entire professional career. Do what is necessary to provide high quality health care to your patients and to your community. And our job at the Academy is to do everything we can to help you provide optimal care for you patients.

We're all in this together.

**HIV**

**DEAR SENATORS:**

# DO THE RIGHT THING.

**Do not take lifesaving healthcare and treatment away from people with HIV and millions of others.**

**Say NO to Medicaid caps and cuts.**

**Say NO to rolling back protections for vulnerable Americans.**

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On behalf of the HIV Health Care Access Work Group, a coalition of over 100 national and community-based organizations.

*James M. Friedman*

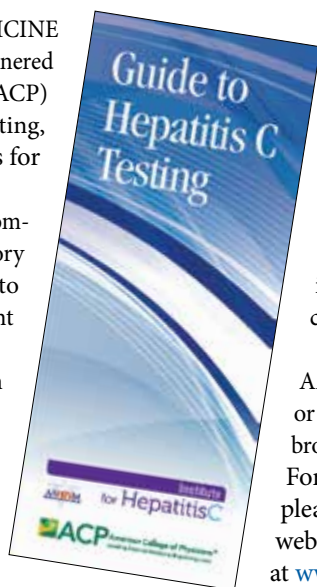
# In the NEWS

## Complimentary “Guide to Hepatitis C Testing” Available from AAHIVM and The American College of Physicians (ACP)

**T**HE AMERICAN ACADEMY OF HIV MEDICINE (AAHIVM)’s Institute for Hepatitis C has partnered with the American College of Physicians (ACP) to release a new Guide to Hepatitis C Testing, which is designed to help clinicians screen patients for hepatitis C (HCV).

The guide includes a summary of the latest testing recommendations, along with diagnostic, billing, and laboratory codes for testing. It provides resources for referrals to HCV-experienced providers and information on patient interactions, education, and case examples.

There are approximately 2.7-3.9 million people in the United States who are infected with Hepatitis C (HCV), many of whom are undiagnosed. The launch of the Guide to Hepatitis C Testing closely follows the recent release of preliminary data from the Centers for Disease Control (CDC) showing that the number of new HCV infections has nearly tripled over five



years, reaching a 15-year high.

“We know there is widespread uncertainty among providers about whom to test and with what labs, and how to get reimbursed. We hope this new resource will give clinicians the information they need to increase office-based testing for Hepatitis C,” said Margaret Hoffman-Terry, MD, FACP, AAHIVS, chair of the AAHIVM Board of Directors and director of the AAHIVM Institute for Hepatitis C. “It is imperative that clinicians are testing indicated patient cohorts, and this guide will help them to do that.”

The complimentary Guide is now available on the AAHIVM website, [www.aahivm.org](http://www.aahivm.org), as a downloadable PDF or in a hard copy brochure. To request a single or bulk order brochures, please email Ericka Nanalg at [ericka@aaahivm.org](mailto:ericka@aaahivm.org). For more information and resources on Hepatitis C, please visit the AAHIVM Institute for Hepatitis C website at [www.aahivm.org/hcv](http://www.aahivm.org/hcv) or visit the ACP website at [www.acponline.org](http://www.acponline.org).

## HIV Patients Life Expectancy Up by 10 years in U.S. and Europe

**LIFE EXPECTANCY** for 20-year-olds initiating treatment for HIV has increased by about a decade in the European Union and North America since the introduction of antiretroviral therapy in the mid-1990s, according to a study co-authored by Yale researcher Dr. Amy Justice and published in *The Lancet HIV*. The increases are among treated individuals compared with untreated individuals, the global team of researchers said.

The study used data for 88,504 people with HIV who started antiretroviral treatment between 1996 and 2010, culled from 18 European and North American studies. To estimate life expectancy, the researchers tracked how many people died during the first three years



of their treatment, their cause of death, HIV viral load, immune status (CD4+ T-cell count), and whether they were infected with HIV through injection drug use.

Fewer people who started treatment between 2008 and 2010 died during their first three years of treatment than those who started treatment between 1996 and 2007. When looking specifically at deaths due to AIDS, the researchers found that the number of deaths during treatment declined over time between 1996 and 2010, likely as a result of newer drugs being more effective in restoring the immune system.

During this time, measures of HIV improved—with the average immune cell count (of CD4 cells in the blood)

increasing after a year of treatment, while the proportion of people with a low HIV viral load increased from 71% to 93%. As a result of these improvements, between 1996 and 2013, the life expectancy of 20-year-olds treated for HIV increased by nine years for women and 10 years for men in the E.U. and North America.

The study authors propose that their findings could help reduce stigmatization and help people with HIV gain employment and obtain medical insurance, as well as encourage those diagnosed to start treatment as soon as possible and continue it fully.

Read the full study at [www.thelancet.com/journals/lanhiv/article/PIIS2352-3018%2817%2930066-8/fulltext?elsca=1+tlpr](http://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018%2817%2930066-8/fulltext?elsca=1+tlpr).

# In the NEWS

## HIV.Gov Creates 'Positive Spin' To Tell Stories of PLWH

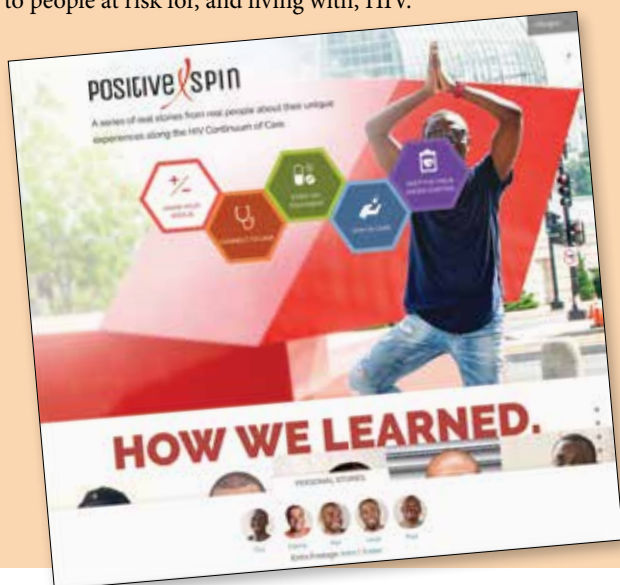
A NEW WEBSITE, [www.positivespin.hiv.gov](http://www.positivespin.hiv.gov), has been created by the U.S. Office of HIV/AIDS and Infectious Disease Policy to tell real life stories of individuals affected by HIV as a way to demonstrate that people who get appropriate and continuous treatment can live well with HIV.

The first series in the *Positive Spin* project focused on stories about five black gay men, a group that has been disproportionately affected by HIV in recognition of the importance of raising awareness, particularly for those at greatest risk, according to Richard Wolitski, Ph.D., Office director.

In a blog on HIV.gov, Dr. Wolitski pointed out that African American gay and bisexual men account for more U.S. HIV diagnoses than any other group defined by gender, race/ethnicity, and transmission risk—39% of all diagnoses in 2015. He also noted that among all black MSM those ages 13–24 had the highest percentage of new diagnoses in 2015—38% of cases.

Among white MSM, there was an 18% decrease in new HIV infections, but among black MSM, new infections were stable, said Dr. Wolitski, who expressed concern about an increase in new HIV infections among Latino MSM. “The stability in new HIV infections among black MSM and the increase among Latino MSM stood in stark contrast to the declines seen in other groups,” he said.

“Sharing this information and the stories of the people whose lives have been affected is an important way of raising awareness,” Dr. Wolitski added. “Creating opportunities that allow people to tell their own life stories are critically important in giving support to people at risk for, and living with, HIV.”



## FDA OKs First Generic for HIV Prevention

THE FOOD AND DRUG ADMINISTRATION (FDA) on June 9th approved a generic version of Truvada™ (tenofovir disoproxil fumarate and emtricitabine), Gilead Sciences' antiretroviral medication used for HIV treatment and prevention. ([www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/default.htm](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/default.htm)). Before the decision, branded Truvada™, was the only medication FDA-approved for PrEP in the United States.

Despite the FDA approval, however, Gilead issued a statement saying the generic would not be immediately available. “It’s important to note that there are a number of factors involved in commercialization that are not tied directly to FDA approval,” the company said.

Gilead noted that the patent for the tenofovir disoproxil fumarate component of Truvada expires in July and that it retains exclusive rights for the drug’s pediatric use until next January. The patent for the other medication in Truvada, emtricitabine, does not expire until 2021, Gilead said.

As a result of FDA’s action, Teva Pharmaceuticals may produce generic Truvada for use as part of an HIV treatment regimen and for PrEP. It would come as a fixed-dose combination tablet, as does the brand-name version.

“While the timeline is uncertain for when a generic drug will be available to consumers, this decision by the FDA is a much-needed breakthrough in our ongoing efforts to expand HIV prevention options, especially for those most vulnerable to HIV and AIDS,” said Mary Beth Maxwell, Human Rights Campaign Senior Vice President for Programs, Research and Training.



## NIH Awards Grant to Curb Alcohol Abuse in HIV+ Patients

A TEAM OF RESEARCHERS from the Department of Psychology at the University of Houston has been awarded a National Institutes of Health (NIH) grant to reduce HIV transmission and progression among hazardous alcohol users. Rates of alcohol abuse among HIV-positive individuals are approximately twice as high as the general population.

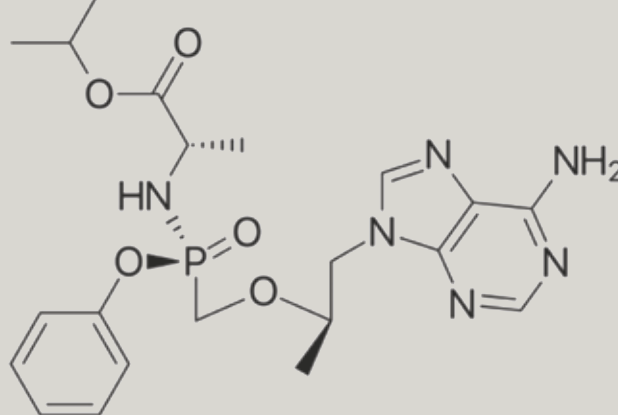
"This population is underserved and can be challenging to reach," said Clayton Neighbors, professor of psychology and director of the Social Influences and Health Behaviors Lab at UH. "However, it's important that we attempt to study this population, because the negative consequences of alcohol abuse can be severe."

Neighbors is a co-principal investigator along with Michael Zvolensky, Hugh Roy and Lillie Cranz Cullen, distinguished professor; and Carla Sharp, professor and director of clinical training in the UH Department of Psychology.

Hazardous alcohol use contributes to problems with HIV medication adherence, risky sexual behavior, psychological problems and physical complications that can lead to increased risk of viral transmission and premature death.

The brief computer-based personalized feedback intervention will be administered at Houston-area HIV clinics. The three-year study, funded by a \$230,784 grant from the National Institute on Alcohol Abuse and Alcoholism (NIAAA), will recruit 150 participants.

"This intervention can help offset problems associated with hazardous drinking among a high-risk group. We hope to reduce problem drinking and increase medication adherence to antiretroviral medications in this patient population," said Zvolensky, director of the Anxiety and Health Research Laboratory/Substance Use Treatment Clinic at UH.



## TAF as Effective as TDF for Viral Suppression

A study published in *The Lancet HIV* found that participants who took a fixed-dose combination of emtricitabine, rilpivirine and tenofovir alafenamide (Odefsey™) had the same rates of viral suppression as those who took the single-tablet regimen of emtricitabine, rilpivirine and tenofovir disoproxil fumarate (Complera). ([www.thelancet.com/journals/lanhiv/article/PIIS2352-3018\(17\)30031-0/fulltext](http://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(17)30031-0/fulltext))

In the multi-country phase 3b trial, more than 600 people whose viral loads had been below 50 copies/mL for at least six months prior to the study were randomly given one of the two medications. By week 48, 94% of participants in each group remained virally suppressed, but *the rate of study-drug related adverse events was twice as high in the TAF arm compared to the TDF group.*

Those in the TAF arm also had better markers of bone mineral density and kidney function than participants who took TDF. However, cholesterol levels were higher among those on TAF than on TDF. This result is consistent with previous studies that found TDF to reduce plasma cholesterol levels. The study was sponsored by Gilead Sciences, which manufactures both study drugs.

## Framingham Score Insufficient When Screening PLWH

STRESS ECHOCARDIOGRAPHY or computed tomography coronary angiography (CTCA) should be used to screen people living with HIV for coronary artery disease (CAD), the authors of an expert opinion, J. Nadel and CJ Holloway, published in *HIV Medicine* (via Medscape) have recommended. ([http://www.medscape.com/viewarticle/876703\\_1](http://www.medscape.com/viewarticle/876703_1))

While PLWH face up to twice the risk of developing CAD than the general population, HIV is not included as an independent factor in tools that assess the risk for acute coronary syndrome (ACS).

Traditional use of the Framingham score to assess cardiovascular risk does not adequately account for the role of chronic inflammation and oxidative stress associated with HIV, or the effect of antiretroviral therapy on ACS risk, the authors explained. They recommended using stress echocardiography in PLWH whose HIV is optimally managed.

CTCA should be used for people with suboptimally managed virus to detect "soft" coronary plaque, which is more common among people with HIV, they said.

# In the NEWS

## Is HIV Cured or Still Lurking? New Test Can Say

**A NEW TEST** sensitive enough to detect “hidden” HIV is faster, less labor-intensive, and less expensive than the current “gold standard.” The findings also show the amount of virus hiding in people who appear to be nearly cured of the virus is about 70-fold larger than previous estimates.

“Globally there are substantial efforts to cure people of HIV by finding ways to eradicate this latent reservoir of virus that stubbornly persists in patients, despite our best therapies,” said senior author Phalgun Gupta, professor and vice chair of the University of Pittsburgh Public Health’s infectious diseases and microbiology department. “But those efforts aren’t going to progress if we don’t have tests that are sensitive and practical enough to tell doctors if someone is truly cured.”

HIV spreads by infecting CD4+ T cells and antiretroviral therapies have advanced to the point that people with the virus can have the virus so well-controlled that they could have as little as one infectious virus per million CD4+ T cells.

However, the majority of HIV DNA integrated into these cells is defective, meaning it wouldn’t cause infection

anyway. Once therapy is working, it becomes critical to determine if the DNA being detected by a test could actually create more virus and cause the person to relapse if therapy is stopped. Therefore, the test must be able to show the virus it detects can replicate—typically by growing the virus from the sample.

To date, the best test available to do this is the “quantitative viral outgrowth assay,” or Q-VOA. But, it may provide only a minimal estimate of the size of the latent HIV reservoir. This test requires a large volume of blood, is labor-intensive,

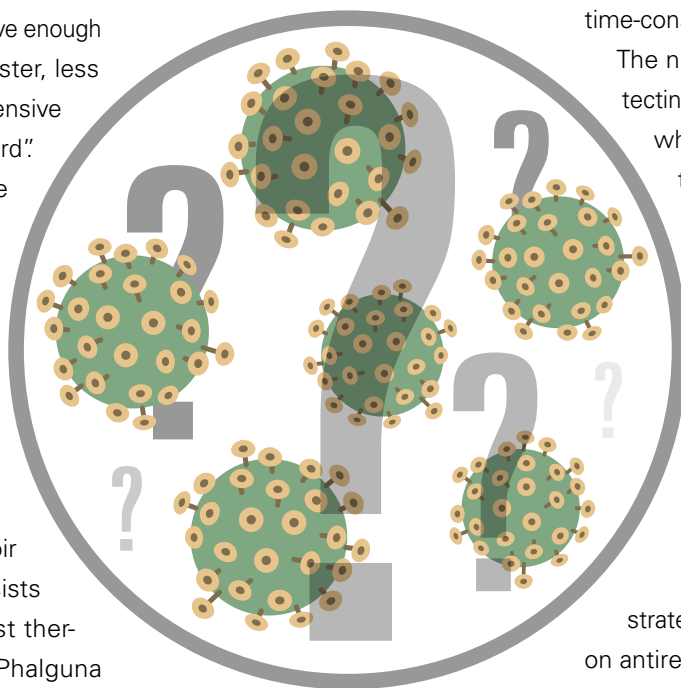
time-consuming, and expensive.

The new test, “TZA,” works by detecting a gene that is turned on only when replicating HIV is present, thereby flagging the virus for technicians to quantify. The TZA test produces results in one week compared to the two weeks needed using the Q-VOA, and at a third of the cost. It also requires a much smaller volume of blood and is less labor-intensive, said Gupta.

“Using this test, we demonstrated that asymptomatic patients on antiretroviral therapy carry a much larger HIV reservoir than previous estimates—as much as 70 times what the Q-VOA test was detecting,” Gupta explained. “Because these tests have different ways to measure HIV that is capable of replicating, it is likely beneficial to have both available as scientists strive toward a cure.”

Because of its low cell requirement, the TZA also may be useful for quantification of replication-competent HIV-1 in the pediatric population, as well as in the lymph nodes and tissues where the virus persists.

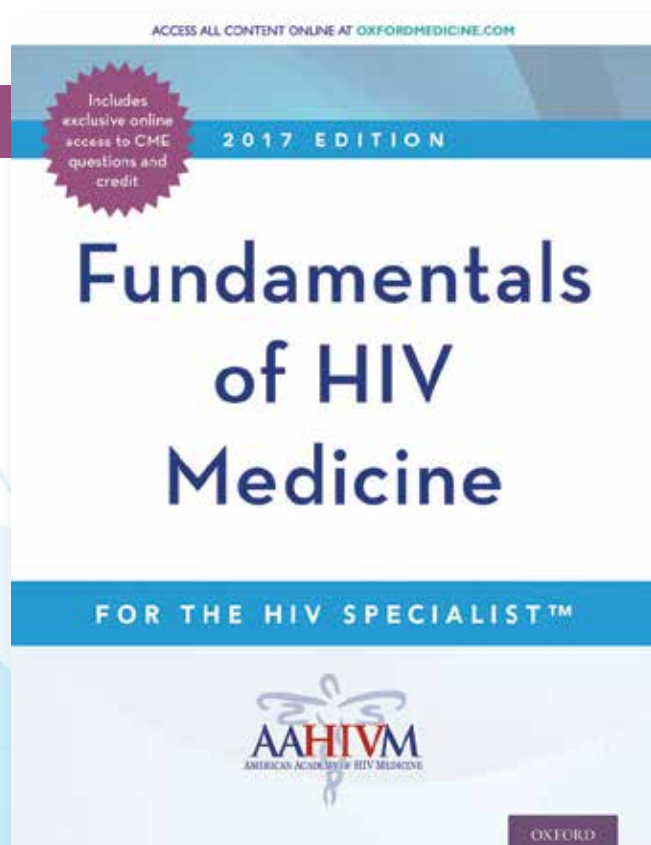
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# Fundamentals of HIV Medicine

Editor in Chief **W. David Hardy, MD, AAHIVS**



Compiled by *American Academy of HIV Medicine*

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ISBN: 9780190493097 | Paperback  
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# Taking the Long View

**With HIV now manageable, the treatment of other chronic conditions, including dyslipidemia, moves to the forefront.**

**P**EOPLE WITH HIV ARE LIVING LONGER due to advances in antiretroviral therapy (ART), with some studies estimating the lifespan of those who achieve virologic suppression may be the same as that of the general population.<sup>1,2</sup>

However, while the virus can be effectively controlled, those living with HIV are at increased risk for other chronic conditions, possibly due to medications or inflammation caused by increased activation of the immune system. Among the most common and challenging conditions to treat is dyslipidemia, which includes elevated blood levels of low-density lipoprotein cholesterol (LDL-C). Dyslipidemia affects eight in 10 people with HIV,<sup>3</sup> putting them at significantly increased risk for cardiovascular disease (CVD),<sup>4,5</sup> the leading cause of death for all Americans.<sup>6</sup> The risk of a myocardial infarction (MI) is twice as high in those with HIV as in people who are uninfected.<sup>7,8</sup>

Managing dyslipidemia is especially challenging among HIV positive adults on ART because of concerns about

drug-drug interactions. Although statin therapy is the recommended first-line treatment for dyslipidemia,<sup>9,10</sup> the potential for drug-drug interactions is increased when statins are used in combination with commonly used antiretroviral agents such as protease inhibitors, other boosted agents, and non-nucleoside reverse transcriptase inhibitors. The reason is that both are metabolized via the cytochrome P450 (CYP) pathway.<sup>11</sup> These drug-drug interactions can lead to toxicity, intolerance and/or reduced efficacy.

Now, new findings from a clinical study published in *The Lancet HIV* in April 2017 have shown that pitavastatin, an FDA-approved statin, significantly reduced LDL-C in adults with HIV and dyslipidemia.<sup>12</sup> Results from the Phase 4 INTREPID (HIV-infected patients and Treatment with Pitavastatin vs.

pravastatin for Dyslipidemia) Trial demonstrated that pitavastatin maintained moderate-intensity LDL-C reduction through a full year of treatment and was well tolerated. Pitavastatin is only minimally metabolized through the CYP450 enzyme system,<sup>13</sup> unlike most other cholesterol-lowering drugs, which depend on this pathway. Additionally, pitavastatin has no restriction, limitation or contraindication with ARTs including protease inhibitors.<sup>14</sup>

To evaluate whether pitavastatin can safely and effectively manage dyslipidemia, as well as stave off CVD in people with HIV, it is being evaluated in the landmark NIH-sponsored REPRIEVE Trial (Randomized Trial to Prevent Vascular Events in HIV). Expected to enroll 6,500 people with HIV at more than 100 sites in the U.S. and globally, the REPRIEVE trial is exploring whether pitavastatin can reduce the risk of major adverse cardiovascular events (e.g., MI, unstable angina and stroke) in people with HIV who are on ART for six or more months, have no history of CVD, and are at low to moderate risk of developing CVD.



## INTREPID Trial: Pitavastatin Improved All Lipid Parameters

The INTREPID Trial assessed the safety and efficacy of pitavastatin on LDL-C and other lipid parameters over 12 months compared with pravastatin. A total of 252 adults with HIV and dyslipidemia (LDL-C between 130-220 mg/dL, triglycerides  $\leq$  400 mg/dL) in the United States and Puerto Rico were randomized to pitavastatin 4 mg or pravastatin 40 mg once daily for 12 weeks.

Results showed pitavastatin demonstrated a statistically significant reduction in LDL-C compared with pravastatin at 12 weeks (31.1 percent vs. 20.9 percent;  $p < 0.0001$ ), with significant differences between the two treatment groups sustained through week 52. Reductions in non-HDL-cholesterol and apo B from baseline were significantly greater with pitavastatin than with pravastatin after 12 and 52 weeks of therapy.

Neither pitavastatin nor pravastatin significantly increased parameters of glucose metabolism or insulin resistance at week 12 or week 52, an important finding as people with HIV are often at increased risk of type 2 diabetes. Both drugs were well tolerated. The safety profile of pitavastatin was generally consistent with that observed in the clinical trials previously conducted in uninfected adults.

## Treating the Whole Patient

While we have made significant strides in treating people with HIV, with a longer lifespan comes comorbidities of aging and complexities of how the disease impacts the body over the long-term. It is increasingly important to treat the whole patient, rather than just focusing on controlling the virus.

People living with HIV who are on ART are clinically complex due to their high prevalence of dyslipidemia and potential for drug-drug interactions. With the encouraging results of the published INTREPID Trial with pitavastatin, we now have another optimal statin treatment option for managing dyslipidemia in adults with HIV. Pitavastatin was shown to be superior to pravastatin in lowering LDL-C and maintaining moderate-intensity LDL-C reductions and also well tolerated. As pitavastatin is only minimally metabolized via CYP450, it can be used at the highest approved dose in patients receiving complex ART.

These findings from a real-world setting should be useful to HIV providers who are making treatment decisions for their patients on ART who have dyslipidemia and thus are at increased risk of CVD. Once results are available from the ongoing REPRIEVE Trial of the use of pitavastatin as a long-term CVD prevention strategy, we

will have additional information about a potentially useful approach to preventing major cardiovascular events in our HIV positive patients.

**HIV**



### ABOUT THE AUTHOR

**Douglas Ward, M.D.**, co-author of the INTREPID trial publication in *The Lancet HIV*, is Clinical Associate Professor of Medicine at George Washington University Medical School and an internal medicine physician at the Dupont Circle Physicians Group in Washington, D.C., where he specializes in treating HIV. He is active in clinical research in the field of HIV and has authored numerous publications.

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**It is increasingly important to treat the whole patient, rather than just focusing on controlling the virus.**



BY WILLIAM R. SHORT, MD, MPH, AAHIVS  
AND SHANNON WEBER, MSW

# HIV & Conception

**Reproductive options for HIV affected couples should be presented to patients.**

**C**ASE: Jose is a 30-year-old male diagnosed with HIV in 2012 and has been virally suppressed on antiretroviral therapy (ART) for more than four years. He and his wife (who is HIV-negative) want to have a child, but are unsure of their options. The couple present to his HIV provider for some guidance on available “safe” conception options.

For patients engaged in care and receiving treatment, HIV is a chronic disease. With appropriate therapy, persons living with HIV can have a good quality of life, anticipate a normal life span and may choose to conceive children. Moreover, studies of both men and women living with HIV have shown they desire children at about the same rate as the general population. After all, parenthood constitutes an important life project for most women and men, and involuntary childlessness is a major life issue associated with strong psychological consequences.

Advances in biomedical treatment and prevention have expanded available safer conception options for persons living with HIV. There is growing evidence that the use of ART to suppress viral load alone or coupled with the use of pre-exposure prophylaxis (PrEP) can virtually eliminate HIV transmission risk among serodifferent (also known as sero-discordant) partners. Since HIV-affected couples desire to have children, it is important that fertility requests be addressed and that safer conception is discussed as part of routine HIV care.

On June 2, 2017 The Centers for Disease Control and Prevention (CDC) released a report on strategies for preventing HIV transmission among HIV-uninfected women attempting conception with male partners living with HIV.<sup>1</sup> Sperm washing (SW) was endorsed as an option, a process involving separating spermatozoa from infectious elements in the semen. After sperm washing, there are three additional assisted reproductive technology procedures to attempt conception: intrauterine insemination (IUI), in vitro fertilization (IVF), and IVF followed by intracytoplasmic sperm injection (ICSI).

The recent Morbidity and Mortality Weekly Report (MMWR) was noteworthy because in 1990 the CDC reported a case of HIV transmission from a man to his HIV-uninfected partner who

underwent SW-IUI.<sup>2</sup>

In this case, suboptimal sperm washing techniques were used, including the omission of density gradient procedures that may have caused infected leukocytes or free virus to not have been removed from the man's semen. Notably, this was also prior to the highly active antiretroviral therapy (HAART) era.

Based on this single case, the CDC recommended in 1990 against the use of insemination with semen from men living with HIV. Since then, the American College of Obstetricians and Gynecologists and the American Society of Reproductive Medicine have said that HIV should not result in discrimination and published guidelines for fertility treatment that should be offered if it is desired. Both professional societies recommend sperm washing + IUI be offered to HIV-serodifferent couples as standard of care.<sup>3,4</sup>

A retrospective analysis of 635 HIV serodifferent couples enrolled in Italy SW-IUI program was published in 2013.<sup>5</sup> The objective was to evaluate the safety of sperm washing for achieving pregnancy when the man is HIV-infected and the woman is HIV negative. The follow-up study evaluated 367 women and confirmed zero HIV transmissions related to SW-IUI.

The reality is that for most individuals living with HIV in the United States who desire children, there are both geographic and financial barriers that prohibit access to assisted reproductive technology services, which usually are not covered by insurance and have very high out-of-pocket costs. In addition, very few assisted reproductive technology centers offer services to HIV-affected couples.

Observational studies, a meta-analysis, and a large randomized clinical trial have demonstrated a significant decrease in the rate of HIV transmission among serodifferent couples where the person with HIV is on ART and has a suppressed viral load.<sup>6</sup>



In fact, there were no linked HIV transmissions among study participants with undetectable viral loads—a prevention method commonly referred to as treatment as prevention (TasP).

Additionally, numerous pre-exposure prophylaxis (PrEP) studies demonstrated this intervention to be safe and highly effective, with CDC and WHO endorsements for offering PrEP to those at risk for acquiring HIV including serodifferent couples. TasP and PrEP, highly effective forms of safer conception whether used alone or in combination, are currently the more widely available options for safer conception and can be used in combination with timed intercourse.

Expanding access to assisted reproductive technologies remains a critical option for HIV-infected and affected individuals. It is imperative that HIV providers keep current with the best science and available guidelines to assist in counselling their patients, including a review of the recent MMWR from the CDC. **HIV**



#### ABOUT THE AUTHORS:

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**Shannon Weber, MSW,** is the Director at [HIVEonline.org](http://HIVEonline.org) and Founder of [PleasePrEPMe.org](http://PleasePrEPMe.org), [PleasePrEPMe.global](http://PleasePrEPMe.global) and [LoveYou2.org](http://LoveYou2.org). Shannon is

passionate about creating a world where women have sex and babies when, where and how they want to.

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# Optimizing Care

## AN OVERVIEW

**WHILE GREAT STRIDES ARE BEING MADE** in the treatment and care of HIV-positive patients, it's not due alone to the scientific advancements that have been made, and continue to be made, in the laboratory. And, of course, it's not due alone to the dedication, perseverance and hard work of the thousands of men and women whose mission is to help those afflicted with the HIV virus to live healthy lives.

Those combined certainly go a long way. But the creativity, imagination and ability to apply technological advances in practical ways help to complete the continuum as clinicians work to help their patients achieve and maintain viral suppression and experience optimal health outcomes.

We are proud to present in this issue of *HIV Specialist* a package of articles prepared by your colleagues that explore many of these advances and achievements.

In "The HOPE Study (HIV Optimized Patient Experience)" by Jeffrey T. Kirchner, DO, FAAFP, AAHIVS, the author discusses in detail the results of an extensive online survey commissioned by ViiV Healthcare. ViiV collaborated with AAHIVM to review the results and identify insights that may enhance understanding and facilitate discussion among patients and providers.

We also offer a package of articles exploring the top entries in the AAHIVM/Institute for Technology in Health Care

HIV Practice Award, including the \$20,000 grant winner, Dr. Kevin Fiscella, MD, MPH, of the University of Rochester faculty, who with his team developed URHealth, an app that makes electronic health records accessible to HIV patients. Reports on other leading entries, written by the applicants themselves, are also included, and all are focused on effective ways of optimizing care.

Finally, this issue's "Best Practices" column, "Interventions to Improve Adherence and Retention in Care" by James L. Raper, PhD, CRNP, JD, discusses ways to reduce HIV-related disparities and health inequities while preventing new HIV infections as clinicians help patients achieve and maintain viral suppression through adherence.

All of these articles contribute in unique ways to the challenge of optimizing care for HIV patients, which is the ultimate objective of every one of us.

HIV

BY JEFFREY T. KIRCHNER,  
DO, FAAFP, AAHIVS

Model used for illustrative purposes only.

# The HOPE Study

## (HIV Optimized Patient Experience)

**O**ver the past decade, HIV treatment has evolved at a rapid pace, helping patients achieve viral suppression, the primary goal of highly active antiretroviral therapy (HAART). Both the Department of Health and Human Services (DHHS) and the World Health Organization (WHO) guidelines reflect this progress.<sup>1,2</sup> As HIV treatment is life-long, it is imperative that providers keep pushing the boundaries of what constitutes the best that HIV care can offer.

In that spirit, ViiV Healthcare (ViiV) commissioned Harris Poll to initiate an extensive online survey—the HIV Optimized Patient Experience (HOPE) Study—to explore present-day HIV care.<sup>3</sup> In addition, ViiV collaborated with the American Academy of HIV Medicine (AAHIVM) to review the results from Harris Poll and identify certain insights that may prove to enhance understanding or facilitate discussion amongst patients and their providers. This article is focused on a particular subgroup of patients defined as the suboptimized patient (Figure 1a).

### **Overarching Goal of the HOPE Study**

**The overarching goal of the study was to understand how patients and providers prioritize treatment goals and how this impacts patients' experiences with treatment.**

## Methodology

The HOPE Study was a market research endeavor conducted in 2016, sponsored by ViiV Healthcare and Harris Poll, and consisted of two surveys. Respondents were paid a small fee for their participation.

The first survey included 1501 patients living with HIV, most of whom (94% or n=1404) were on antiretroviral therapy (ART). This was a national study, with the majority of patients residing in eight US cities (Table 1). Patients were recruited via telephone, national online panels, social media, and through AIDS service organizations. Patients were included regardless of treatment status.

Table 1 Targeted Cities for the Patient Portion of the HOPE Study

Atlanta, GA	Jackson, MS
Baltimore, MD	Miami, FL
Chicago, IL	New York, NY
Dallas, TX	San Francisco, CA

A second survey was completed by 300 providers that included infectious disease physicians, primary care physicians, nurse practitioners, and physician assistants who care for patients with HIV. Providers were recruited via national online panels only. Providers were asked to respond to questions in the context of their patients who had HIV-1 RNA <50 copies/mL and were stabilized on treatment.

The patient and provider cohorts were not matched and did not have to answer all questions.

Participants responded to closed-ended questions, most of which were presented on a Likert scale (e.g., somewhat agree, strongly agree). Patient data were statistically weighted across several variables using demographic points from the US Centers for Disease Control and Prevention to be representative of the national HIV population. Some percentages presented here may have been rounded to the nearest whole number.

Of the 1501 patients who participated in the HOPE Study, 441 (29%) met the study definition of being a suboptimized patient. Of the 441 patients, 77% responded that they were somewhat or very satisfied with their current HIV treatment, but noted at least one of the quality-of-life statements shown in Figure 1a, so they were recategorized as suboptimized. Providers estimated that 71% of their patients were what they regarded as optimized on their current treatment regimen.

Figure 1a Definitions of Suboptimized Patients in the HOPE Study

### SUBOPTIMIZED PATIENTS:

- Current ART user
- Viral load <50 copies/mL
- Have stated dissatisfaction with current ART regimen

OR

- Current ART user
- Viral load <50 copies/mL
- Have stated satisfaction with current regimen
- Have noted at least one of the quality-of-life statements:
  - Taking HIV medications gets in the way of my lifestyle
  - I planned my activities around my HIV medications so that side effects do not interfere with daily activities (e.g., driving, work, running errands)
  - I did not take my HIV medications for one or more days at a time to avoid side effects
  - I changed the type of foods or the way I eat because of my HIV medications
  - I missed an important event, appointment, or meeting due to side effects of my HIV medications

Figure 1b Definition of 'Not Suboptimized' Patients in the HOPE Study

### 'NOT SUBOPTIMIZED' PATIENTS:

- Current ART user
- Viral load <50 copies/mL
- Have stated satisfaction with current regimen
- Have **NOT** noted at least one of the quality-of-life statements listed in Figure 1a

Table 2 HOPE Study Patient Demographics (N=1501)

Average Age	45
Sex	76% male
Sexual Orientation	51% homosexual
Ethnicity	40% white 38% African American
Income	24% <15K annually
Education	37% high school graduate or less
Housing	76% in stable housing
Rx Coverage	81% covered
Work Status	42% employed full time



## Study Results

Although the HOPE Study addressed many aspects of the patient experience, three areas of note were: patient acceptance of side effects, the potential for drug-drug interactions (DDIs), and disruptions in daily routines (Figure 2). The HOPE Study also sheds light on a deeper issue that warrants further discussion: a communication gap that may exist between patients and their healthcare providers.

Figure 2 | Some Key Issues in Suboptimized Patients

Three selected issues of note were:

Acceptance  
of side effects

Potential  
for DDIs

Disruptions to  
daily routines

### Acceptance of Side Effects

Fifty-seven percent of suboptimized patients responded that experiencing drug side effects with their HIV medication is something they have gotten used to. Forty-six percent responded that they just deal with side effects of their HIV medicine because they feel they have no choice. Thirty-two percent of suboptimized patients somewhat or strongly agree that side effects of their HIV prescription medicines are worse than HIV itself. In the provider survey, 56% of providers responded that their virologically suppressed patients have skipped doses in order to avoid medication side effects. These results underscore the need for continued communication with patients about side effects and the importance of HIV treatment.

However, a large number, 81% of suboptimized patients, responded that they were definitely or extremely likely to continue with their current treatment regimen. The most common reasons chosen by suboptimized patients as to why they are on their current HIV treatment were: my current medication is effectively treating my HIV (83%), I have good lab results (76%), and my viral load has decreased on this treatment (71%). These data may suggest that patients are focused on lab results and have grown to accept side effects.

### Potential for DDIs

Over the course of HIV treatment, it may become difficult for providers to track all the medications (both prescription and over-the-counter [OTC]) their patients take when treating comorbid conditions. Patients likely receive prescription medications from other providers. In the HOPE Study, 24% of providers responded they did not know the average number of pills their patients take for other conditions. Forty-one percent responded they did not know the average number of OTC medications their patients were taking. This is potentially important because some medications can interact with some HIV medicines and vice versa.

Further complicating the treatment of patients with HIV is when there is a history of past or current substance abuse. Providers in this study estimated that 27% of their patients

currently have substance abuse problems. Many of the initial ART regimens recommended by the current DHHS guidelines have the potential to interact with commonly abused drugs.<sup>1,4</sup>

Despite the importance of monitoring polypharmacy, DDIs, and substance abuse, these treatment considerations may not get discussed during office visits. Sixty-eight percent of providers responded they discussed DDIs and 59% responded they discussed OTC medication use at more than half of their office visits. Only 62% of providers reported discussing recreational drug use at more than half or at every one of their office visits. These data may suggest there is an opportunity to align with patients around mitigating risks of DDIs.

### Disruptions to Daily Routines

Providers tend to understand that HIV treatment regimens can impact their patients' lives. The HOPE Study found that 63% of providers somewhat or strongly agree that taking HIV medication disrupts their patients' lives and 79% somewhat or strongly agree their patients have difficulty adhering to regimens that don't fit into their daily lives.

Patients in the HOPE Study on suboptimized therapy responded similarly. Sixty-five percent of suboptimized patients responded that it is either absolutely essential or extremely important that their HIV medication regimen fits well into their daily routine. However, 30% responded that they somewhat or strongly agree that taking HIV medication gets in the way of their lifestyle and 54% somewhat or strongly agree that it takes a lot of personal sacrifice to manage their HIV. These data suggest there may be more that can be done to ensure the HIV medications prescribed best match the needs of the patient.

### Communication Gaps Between Patients and Providers

During routine consultations, there is the potential to leave important issues about therapy unaddressed. This may be attributed to a deeper issue behind suboptimized therapy—one of communication. The HOPE Study assessed potential areas for communication gaps between patients and their providers. Three areas of note were patient satisfaction with HIV treatment, patient involvement in treatment decisions, and the patient's perceived initiation of in-office conversations.

- When discussing a patient's level of satisfaction with their current regimen
  - In the patient survey, among current medication users who responded that they were dissatisfied with their HIV medications (n=512), 69% of suboptimized patients (n=201) responded that they've talked with their providers about concerns when they were dissatisfied with their HIV medications. In the provider survey (n=300), only 22% of providers responded that patients told them they were dissatisfied with their HIV medications
- When considering and explaining treatment decisions
  - In the provider survey, 95% of providers responded that they always welcome their patients' input in treatment decisions. However, in the patient survey, only 46% of suboptimized patients responded that they discussed various treatment options with their provider and chose their treatment together

#### ■ When initiating in-office conversations

- In the patient survey, suboptimized patients responded that they usually started conversations about side effects from their HIV treatment (66%), satisfaction or dissatisfaction with their HIV treatment (59%), and concerns about their HIV treatment (52%). In the provider survey, 83% of providers responded that they themselves usually start conversations about concerns, interests, and satisfaction in relation to their patients' HIV treatment

### Benefits to Patients

One finding from the study is that suboptimized patients may be spending more time contending with side effects than the 'not suboptimized' group (see Figure 1b). Among these patients who reported having at least one symptom per week (n=346), the estimated time on average spent dealing with symptoms while taking their HIV medicines (based on a list of potential symptoms provided during the survey) was 83 minutes. In comparison, patients in the 'not suboptimized' group who reported having at least one symptom (n=224) spent an estimated 53 minutes on average per day dealing with symptoms while taking their HIV medicines (based on a list of symptoms provided in the survey). This is a difference of 30 minutes between the two groups.

An additional finding is that, of the list of symptoms provided in the survey, patients in the 'not suboptimized' group (n=389) reported less symptoms at least once a week while taking HIV medications compared with suboptimized patients (n=441), e.g., fatigue, weakness, or tiredness (24% vs 42%); sleeping problems such as trouble falling asleep or waking up in the middle of the night (24% vs 38%); and diarrhea (14% vs 31%), respectively, which were the three most commonly selected symptoms by the suboptimized group from a list of 20 symptoms provided in the survey.

### Time Spent With Patients During the Office Visit

In the HOPE Study, the providers who discussed changing ART with their patients (n=159) reported spending an estimated 23 minutes on average with them during the office visit. This is only two minutes more on average than providers who did not discuss changing ART (n=141). Fifty-one percent of all providers surveyed responded that changing virologically suppressed patients to newer HIV regimens may potentially allow them to focus better on other aspects of their patients' HIV management and 30% responded that changing may potentially reduce the time burden for them and their office staff.

### How can we optimize HIV care beyond viral suppression?

### Discussion

Providers who treat HIV are well-positioned to take a next step in HIV care beyond viral suppression by considering factors including, but not limited to, the patient's normalization of the experience of side effects, the potential to minimize DDIs over the course of long-term therapy, and the possibility of minimizing disruptions to patients' daily routines. The HOPE Study

may suggest a communication disconnect between many patients and their providers, which presents the opportunity to rethink the paradigm of optimized HIV therapy.

In addition to viral suppression, expanding overall treatment goals may be key in further optimizing treatment of patients with HIV. Improving in-office communication to help identify and address issues impacting patients may improve both patient and provider satisfaction and advance overall HIV care. Additionally, expanding care to better fit the realities of the everyday lives of patients with HIV is an important consideration. Treatment continues to evolve and ongoing viral suppression will always remain of paramount importance. A next step in this evolution is to unite with patients to push the boundaries of success in HIV care with the hope of continuing to improve the lives of patients living with HIV.



#### ABOUT THE AUTHOR

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is Medical Director at Penn Medicine/LGHP Comprehensive Care at Lancaster General Hospital, Lancaster, PA. He is the AAHIVM Chief Medical Officer and chairs the HIV Specialist Editorial Advisory Group.

### Figure 3 | Some Key Findings of the HOPE Study

- 46% of suboptimized patients responded that they just deal with side effects of their HIV medicine because they feel they have no choice
- 79% of providers somewhat or strongly agree that their patients have difficulty adhering to regimens that don't fit into their daily lives
- 65% of suboptimized patients reported that it is either absolutely essential or extremely important that their HIV medication regimen fits well into their daily routine
- Suboptimized patients reported spending an estimated 30 minutes on average more per day dealing with symptoms compared with what was reported from the optimized patient group
- Providers who discussed changing ART reported spending an estimated 23 minutes on average with their patients during an office visit. This is on average two minutes more than providers who did not discuss a change in therapy

### This article was sponsored by ViiV Healthcare.

This article is part of a paid engagement between ViiV Healthcare (ViiV) and AAHIVM. Dr Kirchner received no compensation from ViiV for his contributions to this article. ViiV is the sole sponsor of the HOPE Study. Harris Poll conducted the survey on behalf of ViiV. Data collected as part of the HOPE Study were analyzed by ViiV and Harris Poll and provided to AAHIVM. The content of this article was jointly agreed upon by ViiV and AAHIVM.

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BY BOB GATTY

**I**NFORMATION IS POWER and, in this case, the use of today's consumer technology is being used to help HIV patients tap into their own medical information through a powerful new smartphone app that quickly and efficiently helps their clinicians provide the treatment they need.

The app is called URHealth, an electronic patient health record (ePHR) for people living with HIV (PLWH). It uses patients' own data to prompt them to ask their HIV clinicians about specific gaps or needs in care. It currently is in use at Jordan Health, Rochester, NY, and was developed by a team led by Dr. Kevin Fiscella, MD, MPH, a faculty member at the University of Rochester.

For leading the development of URHealth, Dr. Fiscella was selected as the winner of the sixth annual AAHIVM/Institute for Technology in Health Care HIV Practice Award, a \$20,000 grant recognizing his innovative use of technology in caring for people living with HIV.

"While technology plays a vital role in HIV, often patients are socially disadvantaged and many, particularly the older patients, are on the wrong side of the digital divide," said Dr. Fiscella. "I think this award highlights the power of technology, but also the need for technology to be brought to everyone."

Developed through a community-based participatory research approach involving PLWH, clinicians and AIDS organizations, URHealth prompts patients to act when important events occur, such as when their viral load is not detectable or when they are missing key preventive steps. It also provides links to high quality HIV-related information.

In addition, peer-facilitated training sessions help patients understand how to use their smart devices and URHealth. It also served to help patients understand the significance of lab results, various medications and immunizations, and to develop the skills and confidence to discuss their questions and concerns with their HIV clinicians.

Dr. Fiscella has worked under contract at Jordan Health, a federally qualified health center since 1992, where his work has included the provision of HIV-related medical care. Through his clinical work, he began to understand the need for finding a way to help patients increase their participation in their HIV care using their own healthcare information.

# USING THE Power of Technology TO IMPROVE Patient Care





## Project's genesis

Dr. Fiscella stressed that development of URHealth was “absolutely a team and group effort,” and that while he was the project leader, “this very much required the participation of multiple people and entities.” In fact, he stressed, the concept of turning to technology to provide this information was suggested by a patient who was part of a brainstorming session where the need was discussed.

“We were conducting a research a project funded by the National Cancer Institute related to navigation of cancer patients and there was an opportunity to apply for an administrative supplement to address rising rates of cancer in people living with HIV,” he explained. “We have highly effective combination therapy now, but there are many HIV-related cancers and a growing number of more common types of malignancies that are occurring in PLWH more than the general population. That was the focus that they were asking us to address.”

Dr. Fiscella noted that Jordan Health, Trillium Health, Unity Health System (now part of Rochester Regional Health), and the University of Rochester Medical Center serve some 98% of PLWH in the greater Rochester area. So, as a community-based research participatory project, leaders in the HIV treatment community and patients were brought together to discuss the issues relating to cancer and HIV.

“As we all started to brainstorm,” he recalled, “one of my patients said ‘we need a place to secure our information...I don’t want a piece of paper with my name on it floating around. We need a secure way of storing our data and to provide information on how we can prevent cancer in the first place.’”

So the group searched out apps for smart phones and other handheld devices that ran personal health records, but found none that were focused specifically on HIV.

“We said, ‘we can do more than that,’” Dr. Fiscella explained. “Why can’t we have patients enter their data and then use that data to prompt discussions with their physicians?” After further research, the decision was made to develop their own app and to fine tune it based on user feedback. The ultimate result was the URHealth app now in use, which includes password-protection security.

“Based on positive results from several pilots, we applied for funding to evaluate the app among four participating practices in Rochester, and in partnership with the Clinical Directors Network, Inc, which recruited four additional practices (Sunset Terrace Health Center, Metropolitan Family Health Center, Morris Heights Health Center and Acacia Health Center) in New York and New Jersey,” he said. “We then submitted a proposal to the Patient Centered Outcome

Research Institute (PCORI) based on what patients felt was meaningful—to have the skills to use the app, and the knowledge, confidence and tools to be partners in their own care.”

Six weekly group training sessions that included from eight to 12 PLWH in each group, as well as previously trained facilitators were held with 179 patients. About 30 percent of participants had never used a computer or smart phone before and had to be taught the basic skills of how to use the devices. Initially, web-enabled iPod Touch devices were used and ultimately patients began to take a more involved and active role in their visits with their clinicians, Dr. Fiscella said.



Fiscella

## Improving patients' activation

“What we found is that patients who are more sophisticated in technologies help others, and it is inspiring to see patients assume control of their own conditions and come in and ask some really good questions. I’ve been working in this field since 1983 and the sophistication of the questions I get from patients has evolved over time. I think this technology is really helping to facilitate that,” he said.

“When we evaluated it, we found it did improve patient activation, and that’s what we wanted to do,” he explained. “We also had a validated measure of e-health, using electronic sources for training and health information. So, there were some improvements there.”

Funds from PCORI (created under the Affordable Care Act) were used to obtain iPod Touch devices for patients and to help redesign the app so it now runs on Android devices.

While Dr. Fiscella acknowledged that some HIV patients do not have their own smart phones or similar devices, he noted that there are now many inexpensive options and increasingly the rates of use are “pretty high.” Moreover, the federal Lifeline program, which provides free cell phone service to low income consumers, can be utilized by patients who qualify.

## For the future

Now, a new application has been submitted to PCORI for a second round of funding. This will be used to implement and disseminate this program and to help provide mobile devices to patients in need and to help host the app and keep it updated as changes occur in HIV care, including medications. In addition, plans call for developing a Spanish language version for Latino PLWH who prefer to use their native language.

Overall, development and implementation of URHealth has been a five-year process and the \$20,000 Technology in Health Care Practice award will be used to help expand the use of the app beyond the greater Rochester area.

“We are very excited to receive this award,” Dr. Fiscella said. “It will make a big difference as we move this forward.” **HIV**

**It is inspiring to see patients assume control of their own conditions and come in and ask some really good questions. I’ve been working in this field since 1983 and the sophistication of the questions I get from patients has evolved over time. I think this technology is really helping to facilitate that.**

# CROWDSOURCING to Improve HIV Testing Services

BY YILU QIN, MD

**I**N 1906 AT A COUNTY FAIR, 800 people guessed the weight of an ox. The median guess of 1,207 pounds was accurate to within 1% of the actual weight of 1,198 pounds. This demonstrates the power of crowd wisdom in certain contexts.

The main goal of the SESH (Social Entrepreneurship for Sexual Health) project is to leverage and test social entrepreneurial approaches, such as crowdsourcing, to enhance public health services, especially HIV services. Crowdsourcing is the process of obtaining ideas from a large group of people to help accomplish a task, often using an open contest and bringing together multiple sectors.

The SESH team believes that the “top-down” approach where experts develop health interventions could be enhanced using “bottom-up” approaches, such as innovation challenges and open contests that draw upon crowd wisdom from the community to generate new ideas, such as for health campaign material. The crowdsourcing approach directly addresses several problems with conventional HIV messaging:

- Only partial or limited community inclusion in many HIV campaigns organized using social marketing or related expert-driven approaches.
- Limited resources for HIV in the face of declining budgets and competing public health priorities.
- Relatively few programs that are people-centered in their approach.

Recognizing the limitations of a “top-down” approach, SESH was formed in 2011 as a collaboration between

physicians at the Guangdong Provincial STD Control Center and the University of North Carolina Project China. The interdisciplinary team includes individuals from diverse backgrounds including medicine, public health, marketing and communications.

Since launching, the SESH team has organized 18 creative contributory contests (CCCs), most of which have focused on improving HIV services, such as generating demand for HIV self-testing. The contests have three steps (see Figure 1).

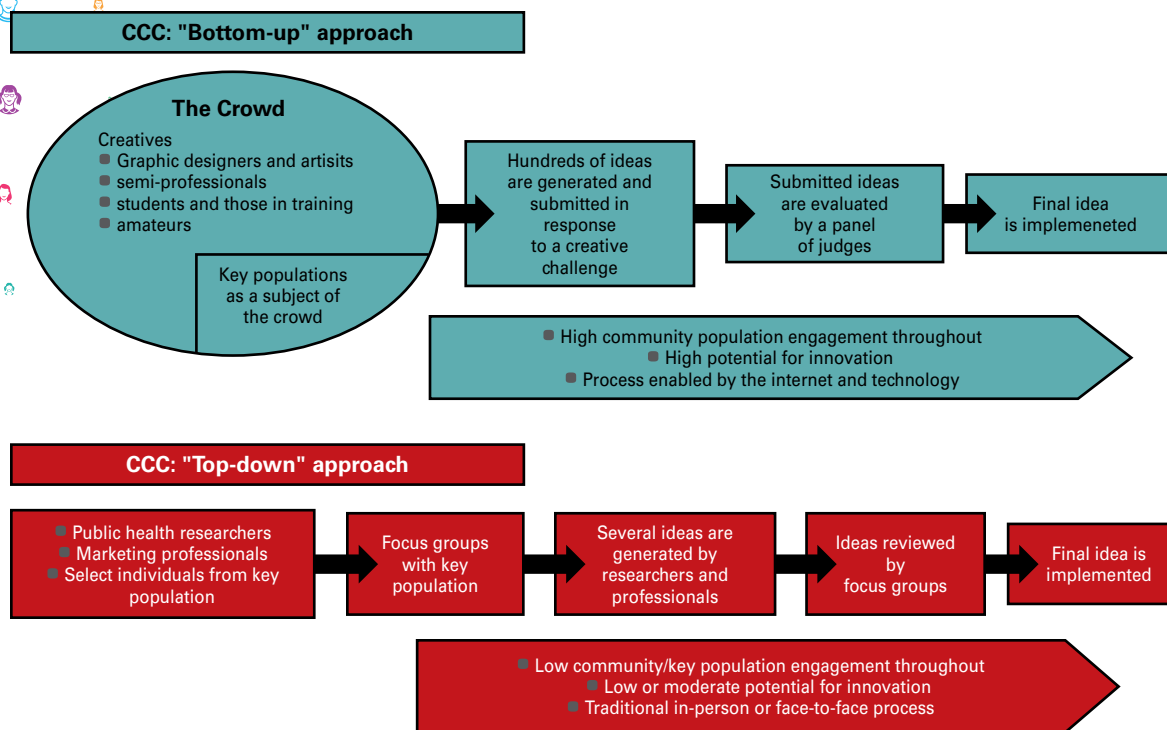
First, the contest is launched as an open nomination call around a specific theme and promoted through a combination of community outreach events, social media, and classroom didactics.

Second, submissions are judged by a panel of experts as well as through an open community vote or discussion.

Final round entries then directly inform the content and format of a planned intervention, such as HIV messaging campaigns.

This bottom-up approach allows for input from a wider range of community members and is more people-centered in its development. In 2013, for instance, SESH Global launched a participatory open contest aimed at encouraging community-based organizations

**Figure 1. Creative Contributory Contest CCC) Passes**



to develop one-minute videos promoting HIV testing in China.<sup>1</sup> The final winning video entry ([www.youtube.com/watch?v=WbDpNrV3avg](http://www.youtube.com/watch?v=WbDpNrV3avg)) told the story of a gay couple and promoted HIV testing in a way that was locally appropriate. It referenced community groups and testing organizations well-known among the gay community in China.).

The crowdsourced HIV test promotion video was evaluated compared to a conventional social marketing video.<sup>1</sup> We found 37% of previously never-tested MSM who viewed the crowdsourced video subsequently received first-time HIV testing within four weeks. This was similar to the testing rate observed in the group that viewed a social marketing video, but cost substantially less. Additionally, qualitative data from our group has shown that crowdsourcing contests empower individuals and engage local communities in sexual health.<sup>2</sup>

Through leveraging the power of community engagement to generate new ideas for promoting HIV testing, crowdsourcing contests can increase HIV testing uptake and frequency.

The tools needed for conducting crowdsourcing contests are accessible in a range of local settings. We have effectively implemented crowdsourcing contests in settings with limited civil society, including China and Vietnam. Social media are useful, but not essential, for organizing crowdsourcing contests.

Our initial contests focused on improving services for MSM because of substantial unmet needs and higher rates of internet use by this population. However, our subsequent HIV crowdsourcing contests have used different solicitation

methods (in-person, paper-based, snail mail, methadone clinics and venues) to effectively engage people who inject drugs, female sex workers, and people living with HIV.

We have published guidance on how to organize crowdsourcing contests,<sup>3</sup> which could be useful for developing a range of sexual health campaigns beyond HIV testing, including condom use, STD testing among key populations, PREP awareness and uptake, and HPV vaccination. Crowdsourcing contests provide a cost-effective, structured mechanism to more transparently and explicitly involve communities in health promotion campaigns to make them more people-centered.

**HIV**



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## Real-Time Automated Calculation of Pooled Cohort Equation Cardiovascular Risk Scores Embedded in an Outpatient Electronic Medical Record

BY JASON GILLMAN, M.D.

**E**ARLY IN THE HIV EPIDEMIC, AIDS-associated malignancies and opportunistic infections were the most common causes of mortality. Since the advent of highly active antiretroviral therapy (ART), life expectancy of HIV-infected individuals now approaches that of the general population in high-income countries.<sup>1-3</sup> Despite this advance, with an aging population we now see non-AIDS complications with greater frequency, including liver disease, non-AIDS malignancy, and cardiovascular disease (CVD).

Cardiovascular disease now accounts for 8%–22% of deaths among HIV-infected patients, and this number appears to be increasing.<sup>4,5</sup> The pathogenesis of this phenomenon is not completely understood, but is not entirely explained by over-representation of traditional risk factors, such as dyslipidemia, smoking, and hypertension.

The direct and indirect effects of anti-retroviral therapy (ART) are thought to play a role, as is the immune activation and inflammation which persists despite suppression of HIV viremia.<sup>6</sup> Given these considerations, it has been shown that common methods of estimating cardiovascular risk such as the Framingham risk score and the 2013 ACC/AHA Pooled Cohort Equations (PCE) often underestimate the true risk of CVD among HIV-infected individuals.<sup>7–8</sup> Despite these limitations, the most major medical organizations recommends one of these tools for estimating a patient's ten-year probability of having a cardiovascular event and determine the indication for statin therapy.

Although the PCE score remains a popular clinical method for estimating CVD risk, implementation typically has required health care providers to manually enter the data for nine variables into a web-based, cell phone-based, or tablet-based application. This requirement is cumbersome for providers in an era of increasing time constraints on the patient encounter.

To facilitate access to an accurate PCE score and bypass the need for manual data entry, we programmed a module in the MEL scripting language, which draws patient data directly from the GE Centricity™ Practice Solution (v12.0) EMR. Age, gender, and ethnicity are pulled from patient registration; blood pressure is pulled from the most recent set of vital signs; the most recent lipid panel is pulled from lab results; diagnosis of diabetes and treatment for hypertension are pulled from the patient problem list; and smoking status is pulled from structured social history.

The script then validates the data, performs the PCE calculations, and auto-populates the results into clinical progress notes where they are immediately available for viewing by healthcare providers. If a result cannot be calculated due to missing data, the script will identify to the user which item is missing from the patient chart. The risk score is updated in

real time with each encounter as patient-level data changes (e.g. a patient quits smoking, a new lipid panel is available, or a patient has a new diagnosis of diabetes added to the problem list). We internally validated the accuracy of the automated score by comparing the result to a manually obtained score in 50 patients, and found 100% concordance. Other outpatient practices that employ the GE Centricity™ Practice Solution EMR could easily integrate our script into their systems with minor customization.

We anticipate that utilization of this programming will allow clinicians to more easily identify patients who are at risk for CVD, and intervene with initiation of statin therapy as primary prevention. In addition, the script can be used to rapidly pre-screen patients for the multi-national REPRIEVE trial, which aims to determine if HIV-infected individuals, who are otherwise thought to be at low risk for CVD, will benefit from statin therapy. One entry requirement for this trial is a PCE risk score of less than or equal to 10%. As an ACTG clinical research site, we have utilized our new methodology to rapidly identify which of our 2,000 clinic patients meet this inclusion criterion.

To follow up on our current work, we also intend to study how these PCE risk scores change over time, which is facilitated by automatic and permanent recording of the results at each patient visit. The increasing sophistication of the EMR, accompanied by wider use of structured data elements, may also make it possible to integrate more complex algorithms. For example, auto-calculation of a FRAX® score without requiring user input would determine more rapidly a patient's risk of osteoporotic fracture. Finally, as new tools for CVD risk estimation become available, we hope to continue to adapt our programming to assist in more accurate and timely clinical decision-making. **HIV**

**Other outpatient practices that employ the GE Centricity™ Practice Solution EMR could easily integrate our script into their systems with minor customization.**



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# Electronic Medical Record (EMR) Tool

## to Query Hospitalized HIV-Infected Patients

BY ERIC K. FARMER, EMILY HUESGEN AND BROOKE N. STEVENS

**T**RANSITIONS OF CARE between inpatient and outpatient settings place patients at increased risk for harm from medication errors. It is estimated that medication errors occur in 26-72% of HIV patient admissions.<sup>1-2</sup>

Consequences of antiretroviral therapy (ART) errors can range from minimal harm, to life-threatening toxicities, virologic failure and the development of drug resistance and HIV-related complications. Lack of adequate resources to streamline medication reconciliation, documentation, and communication between inpatient and outpatient settings is a well-recognized barrier to continuity of care in HIV-infected patients.

Despite the rigorous standardized medication reconciliation process at Indiana University Health, the need for increased scrutiny of antiretroviral medication orders was recognized. A 2011 pilot study at IU Health Methodist Hospital demonstrated a reduction in the number and severity of HIV-related medication errors (total errors pre-intervention vs. post-intervention: 54 vs. 30) following ART assessment performed by an HIV-trained clinical pharmacist during the study interval. Furthermore, EMRs with documentation of the ART assessment were associated with fewer HIV-related medication errors in comparison to charts without notes (16% vs. 40.7% respectively; p-value=0.016).

As a result of the above findings, IU Health developed a tool that queries the EMR database (Cerner) for hospitalized patients with active or a history of ART orders. Once an antiretroviral order has been identified, the tool creates a task list alert, which notifies the clinical pharmacist of the need for an ART assessment. The clinical pharmacist then evaluates the antiretroviral orders for accuracy in relation to the patient's outpatient HIV regimen and completes an

assessment. The pharmacist's assessment includes, but is not limited to: potential medication dosing errors, drug-interactions, renal/hepatic dose adjustment requirements, and the need for opportunistic infection prophylaxis.

The pharmacist also ensures continuity of care by documenting outpatient HIV follow-up appointments in the clinical note and discharge instructions. If the patient does not have a follow-up appointment, an attempt is made to re-engage the patient into care. Following ART assessment and medication reconciliation, the pharmacist will document the findings in the EMR to complete the task and alert the inpatient providers of any necessary changes or interventions. Implementation of this EMR tool and pharmacist-driven ART assessment task list has demonstrated reductions in inpatient HIV-related medication errors, improvement in time-to-resolution of errors, and improved continuity of outpatient HIV regimens with the overall aim of maximizing the number of virologically suppressed patients (NHAS indicator and HIV care cascade metric).<sup>3</sup>

Since the implementation of the ART task list tool, a mean of 22 patients have been evaluated each month at IU Health Methodist Hospital, with an average of 1.4 interventions per patient. The tool was expanded to IU Health system wide in 2015 and an assessment template was embedded within the task to standardize the assessment tool.

An HIV clinical pharmacist currently only reviews ART tasks at IU Health Methodist Hospital; however with additional resources, the plan is to expand this process to the





Academic Health Center and eventually the entire IU Health system. This assessment tool has been recently duplicated for hepatitis C direct acting antivirals due to the high risk, error-prone nature of these medications.

### Technology Accessibility

- Identify a pharmacy IT specialist to help with this project.
- Verify accuracy of all orderable antiretroviral medication formulations in the EMR.
- Based on capabilities of the hospital's EMR, work with IT specialist to create a process that identifies patients with current or previous orders for the antiretroviral medications.
- If available, an HIV clinical pharmacist should review the queried patients a minimum of once daily.
- If an HIV clinical pharmacist is not available, consider embedding a template to ensure the reviewing pharmacist has a standard assessment guide.
- Educate all pharmacy staff on the task and services offered by the HIV specialist.
- Maintain a work group that includes an IT specialist to ensure technology is optimized.

**HIV**



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BY JAMES L. RAPER, PhD, CRNP, JD

# INTERVIEW

## IMPROVING ADHERENCE

**T**HE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) recently reported that the number of annual new HIV infections in the United States fell 18% from an estimated 45,700 in 2008 to 37,600 in 2014 (see Figure, page 28)<sup>1</sup>. The declines in annual infections are believed to be due largely to efforts to increase the number of people living with the virus who know their HIV status and are virally suppressed—that is, their HIV infection is under control through effective antiretroviral treatment (ART). Unfortunately, the number of annual new HIV infections did not decrease for gay and bisexual men, groups at greatest risk of infection. Annual HIV infections remain essentially unchanged at about 26,000 per year among men who have sex with men (MSM) and about 10,000 new infections per year for black MSM. Also discouraging is the increase in the number of new infections in 25–34-year-old MSM (up 35%: 7,200 to 9,700).

Despite the overall hard-earned advance, the HIV epidemic still presents a significant health issue for the United States. As health care providers, we have the opportunity to continue to focus on the critical elements of the HIV care continuum (diagnoses, linkage to care, engagement/retention in care, combination ART and viral suppression) that go hand in glove to achieve optimal health outcomes for our patients living with HIV. We can reduce HIV-related disparities and health inequities while preventing new HIV infections as we help our patients achieve and maintain viral suppression.

Following an HIV diagnosis and linkage to care, a continuum of retention in care and ART adherence support services are essential to meet each patient's adherence/retention needs. Bartlett<sup>2</sup> stated, "The main thing we have to change to end the HIV epidemic is our commitment and approaches to retaining patients in care .... patients living with diagnosed HIV, but are out of care, are the main sources of new infections...Interventions that improve, not just HIV screening, but also retention in care need to be optimized."

Every member of the health care team plays an integral role in successful ART<sup>3</sup> and retention-in-care<sup>4</sup> adherence programs. Many effective ART and retention-in-care adherence interventions can be customized by patient, clinical setting, and provider.

### New Strategies for Improving Retention in Care

As with ART adherence monitoring, research advances indicate multiple strategies for routine monitoring of retention in care that may be used in accordance with local resources and standards. The options include surveillance of visit adherence, gaps in care, missed visits, and the number of visits during a specified period of time.<sup>5</sup> "Data to Care" is a new public health strategy that aims to use HIV surveillance data to identify HIV-diagnosed individuals not in care, link them to care, and support the HIV Care Continuum.<sup>6</sup>

Public health jurisdictions use lists of patients lost to follow-up from multiple providers to match against HIV Surveillance data to identify patients not receiving care from

# ENTIONS

## AND RETENTION IN CARE

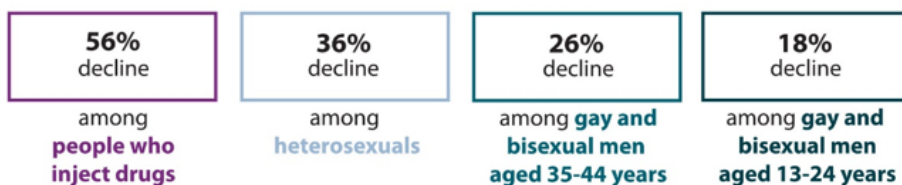
any other provider. They subsequently return the status of the “lost” patient to the health care provider. Health care providers and their clinical settings can then prioritize their re-engagement efforts to contact patients who do not appear

to be in care. Data to Care linkages with the HIV Surveillance database may be conducted on an ongoing iterative basis.

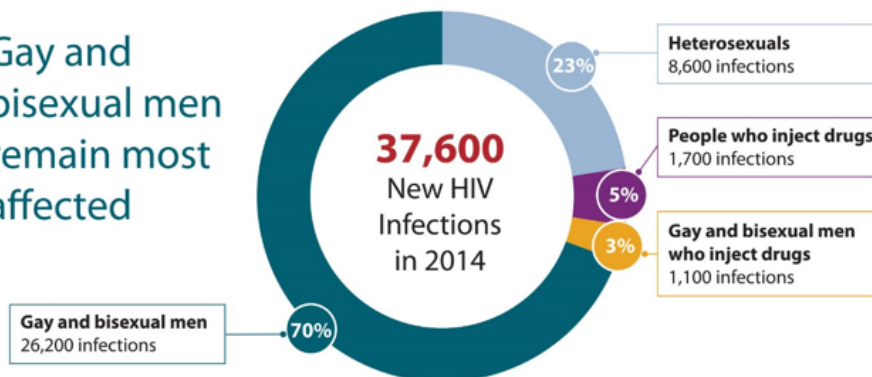
At the University of Alabama at Birmingham 1917 Clinic located in the Southeastern United States, (where 50% of

### Estimated annual HIV infections in the U.S. declined **18%**

Between 2008 - 2014 infections fell from 45,700 to 37,600



Gay and  
bisexual men  
remain most  
affected





## TIPS FOR IMPROVING PATIENT RETENTION

- At each visit, ask patients “What is best telephone number if I need to contact you over the next few days?” as patients change telephones often or have more than one telephone.
- If a patient is late by an hour, contact the patient and show a sense of concern and of how you look forward to seeing him or her.
- Review No-Show appointments each day, as they are predictive of loss to follow up.

new HIV infections occur), we found the need to expand our retention efforts. In late 2016, we conducted an in-depth analysis of our clinic’s retention-in-care quality performance measures using the Department of Health and Human Services/Human Resources and Services Administration HIV/AIDS Bureau definition<sup>7</sup> of the percentage of clients with an HIV diagnosis who had at least one HIV medical care visit in each 6-month period of the 24-month measurement period (with at least 60 days between the first medical visit in the 6-month period and the last visit in the next 6-month period). We found that our retention rates decreased significantly from the previous 12-month reporting period and were lowest among black MSM  $\leq 24$  years of age.

Here are some of the patient-specific and system-wide strategies we implemented to increase retention rates:

- Initiated quarterly analysis of the “Retention in Care” performance measures to monitor for trends and take steps to meet retention goals, in accordance with our Plan-Do-Check-Act (PDCA) quality program,
- Encouraged providers to extend a sincere “thank you for coming to your appointment” at the beginning of each encounter. Positive reinforcement is of great benefit in helping patients maintain high levels of adherence to care rather than focusing solely on adherence to medications.<sup>8</sup>

■ Implemented Retention Coordinators to support the role of our 13 Medical Social Workers (MSW) who each maintain responsibility for an average case load of approximately 275 patients for whom they provide varying degrees of “enhanced contact” interventions to patients. Among other approaches, the case management interventions include brief face-to-face meetings at care visits, and interim-visits, appointment-reminder, and missed-visit calls.<sup>9</sup> With the addition of retention coordinators, we are more successful in monitoring and responding to “No Show” appointments within a 24–72-hour post-No Show appointment while examining why patients are missing visits and assisting patients by rescheduling a timely return visit. Our retention coordinators fulfill linkage and retention duties in concert with our MSWs.

We eagerly await the availability of new, long-acting ART medications.<sup>10</sup> For example, a combination therapy of two long-acting injectable antiretrovirals (cabotegravir and rilpivirine), given intramuscularly once every 4 or 8 weeks to maintain viral suppression, and a standard oral antiretroviral may significantly improve ART and retention adherence. In the interim, we believe that given the number of available single tablet HIV drug regimens along with retention-assessment strategies and interventions,<sup>11</sup> we are taking meaningful steps to select techniques that will provide the best fit retention-in-care strategies for each patient and diverse patient populations.

HIV



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