

# HIV Specialist

## Preparing for a Healthier Future

New report *HIV: The Long View* explores prevention and treatment in the next two decades

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◆ My HIV was undetectable.  
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related to my treatment.

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The virus is suppressed. But what about side effects? Drug interactions? Dosing concerns?

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# The Long View to End the Epidemic

I am writing this article on November 22nd, a date that has meaning to many in our country. It was on this day 53 years ago that President John F. Kennedy was assassinated.

Those of us of a certain age remember where we were when we heard of the President's passing. The nation was steeped in shock and turmoil. It is in times like these when we find ourselves pessimistic about our future, afraid of what tomorrow may or may not bring. Looking back, we can see that in the wake of that difficult time President Johnson created two of our most important public health programs—Medicare and Medicaid.

The recent election season, and the vitriol expressed across media platforms during this period has left many people concerned over the direction of our divided country -- myself included.

I worry about access to care and treatment for HIV-infected patients. I worry about the cost of treatment for HCV-infected patients. I worry about access to PrEP for those who are at high-risk of contracting the disease. I worry about the 20 million Americans who may lose their health insurance if the Affordable Care Act is repealed. I worry about the continued funding of HIV research and prevention, and services programs for HIV patients.

Having worked in D.C. for my entire career in public health, however, I can attest to the fact that each new administration brings with it new challenges, but also new opportunities.

Since the early days of HIV in the U.S., we have had Republicans and Democrats, liberals and conservatives serve as President. During those same three-plus decades, we have seen remarkable advances in the care and treatment of HIV in the United States, and worldwide.

The first President Bush signed into law the Ryan White Care Act, which President Clinton significantly expanded. Later President George W. Bush created the

President's Emergency Plan For AIDS Relief (PEPFAR). President Barack Obama created the U.S. National HIV/AIDS Strategy, the domestic response by the federal government to the HIV epidemic coordinating efforts across federal agencies to focus on education, prevention, care, treatment, and stigma of HIV.

I believe that the HIV community must always remain focused on the long view – on bringing about the end of HIV/AIDS for all, both domestically and internationally. The last 30 years has brought more progress in this area than could have been imagined at the beginning of the epidemic. Today, the long view on HIV care and treatment is a positive one.

Featured in this issue of *HIV Specialist* is "HIV: The Long View," a forward-looking report created by the Academy, HealthyWomen, National Black Leadership Commission on AIDS, Gay Men's Health Crisis and the National Council on Aging, in partnership with Gilead Sciences.

The report investigates future health-care trends in order to evaluate potential implications, opportunities and challenges for HIV treatment, prevention and education today. In other words, it forces us to consider the challenges we will face in the future so we can start identifying solutions now.

In the spirit of the holiday season, I urge all of us in the HIV community to work hard to meet those challenges and take advantage of the opportunities before us. I urge President-elect Trump to work towards policies and programs that will bring about end the HIV/AIDS epidemic in our lifetime. And I wish all of us a happy holiday season, as well as the strength and courage to create our future.

**HIV**



James M. Friedman

*James M. Friedman*

# In the NEWS

## No AAHIVM HIV Program and Policy Update Event for Members and Friends at CROI 2017



Unfortunately, IAS-USA, the organization that manages CROI, has denied AAHIVM's request to host our annual Program and

Policy Update meeting for our members and friends at the conference this February. This meeting has been a long tradition for the Academy. According to correspondence with IAS-USA, our update meeting would "violate CROI policies," in spite of the fact that it has been held after CROI program hours and does not conflict programmatically with the CROI content.

Historically, AAHIVM has hosted a variety of speakers to address relevant program and policy topics in order to bring valuable insight and education to our members and guests. The event also created a networking opportunity for our providers from across the country to connect with peers and AAHIVM staff. We regret we will not be able to do the same this year.

We have no recourse but to accept the decision of IAS-USA. However, we hope to have future discussions with them so that our tradition may continue in 2018.

Thank you for your understanding.



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## ViiV Healthcare Evaluates Long-acting, Injectable HIV Treatment Regimen

**ViiV HEALTHCARE** has announced the start of two phase III clinical studies designed to evaluate an investigational long-acting, injectable regimen of cabotegravir (ViiV Healthcare) and rilpivirine (Janssen Sciences Ireland UC) for the treatment of HIV-1 infection.

The two studies, FLAIR (First Long-Acting Injectable Regimen) and ATLAS (Antiretroviral Therapy as Long-Acting Suppression), will examine the safety and efficacy of monthly dosing with the two-drug, injectable regimen in both treatment-naïve and treatment-experienced patients.

This investigational, long-acting, injectable regimen is being co-developed as part of a collaboration with Janssen Sciences Ireland UC.

While fixed-dose oral combination therapies have advanced HIV treatment by providing streamlined dosing through reduced pill burden, adherence to therapy continues to be essential to achieving viral suppression, and reducing the emergence of resistance mutations.

"Currently the treatment of HIV involves life-long therapy with multiple antiretrovirals, so it is important that we

continue to improve on the durability, safety, tolerability, and convenience of treatment regimens," said John C Pottage, Jr, MD, chief scientific and medical officer, ViiV Healthcare. "This phase III program with long-acting cabotegravir and rilpivirine as a potential HIV treatment regimen is part of ViiV Healthcare's broader development program evaluating two-drug treatment regimens and we look forward to seeing results from the ATLAS and FLAIR studies in 2018."

In FLAIR, treatment-naïve patients will be given a 20-week daily oral dolutegravir/abacavir/lamivudine (Triumeq®) regimen, and will then be randomized to switch to a regimen of long-acting, injectable cabotegravir and rilpivirine, or remain on oral therapy.

In ATLAS, treatment-experienced patients with suppressed viral load will be randomized to switch from their existing antiretroviral therapy (ART) to long-acting, injectable formulations of cabotegravir and rilpivirine or remain on oral ART. Participants will be enrolled from investigative sites across Africa, the Americas, Asia and Europe.

# Polypharmacy in HIV+ 50 or Older Linked to Lower CD4s, Higher CVD Rate

**HIV PATIENTS 50 YEARS OR OLDER** who took more than 10 medications, had a lower CD4+ T-cell count, higher cardiovascular disease (CVD) rate, more adverse drug effects, and more drug-drug interactions than older people taking fewer medications, according to a study recently presented at IDWeek 2016. Presented by Michael Wilcox Pharm D and colleagues, their study found that a lower proportion taking more than 10 drugs tended to have an undetectable HIV load in this 100-patient comparison. As HIV patients age, they acquire more comorbidities and often take more medications that may cause side effects, drug-drug interactions, and create adherence challenges. This study involved HIV-positive adults followed at an Infectious Disease clinic in Chicago between June 2013 and January 2014. The cohort included 100 patients, 65 who were taking 10 or fewer medications and 35 taking ten or more daily medications. The median age was 61 years in the group taking more than 10 medications and 57 years in the comparison group. The more heavily medicated group took a median of 12 drugs not

including antiretrovirals, compared with only four drugs in the less medicated group. Patients taking > 10 medications had a lower median CD4+ T cell count (351 versus 561) and a longer median duration of HIV infection (19.5 versus 15 years). Compared with patients taking < 10 medications, those taking > 10 had a higher prevalence of cardiovascular disease (69% versus 45%), diabetes mellitus (23% versus 9%), and chronic kidney disease (23% versus 9%). Forty-eight patients taking ≤ 10 medications had a viral load <20 IU/mL compared to 21 participants on >10 medications (84% vs 68%, p=0.07). Patients taking >10 medications were more likely to report an adverse event (45.7% vs 26.5%), taking medications that were contraindicated in older adults (Beers List) (71% vs 42%), and report drug-drug interactions (94% vs 68%). Adherence did not differ significantly between groups, but was not documented in about one quarter of all participants.

Reference: Wilcox ML et al. Evaluating the Effect of Polypharmacy on Outcomes in HIV-Infected Patients Age 50 and Older. Abstract # 1496.

## Study Debunks 'Patient Zero' as Launching AIDS Epidemic

**A NEW STUDY** in the journal *Nature* debunks the idea that a young flight attendant named Gaetan Dugas became infected abroad in 1979 and transmitted HIV to numerous sexual partners who passed it on others, thus launching the U.S. AIDS epidemic.

In the new study, originally presented at CROI 2016 in Boston, researchers used genomic sequencing of blood samples from that era to reconstruct

a "family tree" of the virus in detail. This work, led by Michael Worobey of the University of Arizona and Richard McKay from the University of Cambridge, determined that HIV came to the U.S. from the Caribbean and that the initial outbreak was in New York City, not San Francisco.

They believe HIV circulated within the U.S. borders for nearly a decade before it was officially recognized by the first cases reported in June, 1981. The study showed that the HIV-subtype B—found in men who have sex with men (MSM)—likely spread from Africa to Haiti and then to New York, and from there to many other areas in the U.S.

The study can be found at [www.nature.com](http://www.nature.com).

Reference: *Nature*. October 27, 2016. Volume:538:428; doi:10.1038/538428a



## AIDS United Names New President & CEO



**AIDS United Board of Trustees has named Jesse Milan, Jr., as president & CEO. Milan, a 30-year HIV/AIDS community advocate and speaker on HIV/AIDS policies and programs, has served as interim president & CEO since June 20, 2016. He takes the helm in the permanent position effective immediately.**



# In the NEWS

## Recommendations Updated for Meningococcal Vaccine in HIV-infected Persons

**THE U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION'S** Morbidity and Mortality Weekly Report has presented new recommendations for meningococcal conjugate vaccination among HIV-infected individuals. Jessica R. MacNeil, M.P.H., from the CDC in Atlanta, and colleagues said increasing evidence suggests increased risk for meningococcal disease in HIV-infected individuals, and thus modified recommendations on vaccination with meningococcal conjugate vaccine. They recommended that all HIV-infected individuals aged  $\geq 2$  months should receive meningococcal conjugate vaccine (serogroups A, C, W, and Y) and that a multi-dose schedule should be used for children aged younger than two years. In addition, a two-dose primary series of meningococcal conjugate vaccine is recommended for individuals younger than two years. A booster dose should be given at the earliest opportunity (at least eight weeks after the previous dose) for persons with HIV who have been previously vaccinated, they said. Boosters should continue at appropriate intervals. A booster dose should be administered three years later if the most recent dose was received before age 7 years. If the most



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recent dose was received at age  $\geq 7$  years, a booster should be given five years later and every five years thereafter. The recommendations for children aged two months through two years and persons aged  $\geq 25$  years are based on expert opinion. Of note, the vaccine was not studied in HIV-infected persons in these age groups.



### William G. Powderly, MD, FIDSA, Named IDSA President

The Infectious Diseases Society of America (IDSA) has named William G. Powderly, MD, FIDSA, as its next president. Dr. Powderly will work with IDSA's board of directors to reach the new administration and Congress to help shape their understanding of the challenges and opportunities facing infectious disease medicine. Currently co-director of the Washington University School of Medicine's Division of Infectious Diseases, St. Louis, Dr. Powderly was the inaugural chair of the HIV Medicine Association (HIVMA) and a founding member of the St. Louis Infectious Diseases Society. He is interested in advancing care in HIV, focusing on long-term complications and antiretroviral therapy; fungal infections, especially cryptococcosis; and the translation of clinical advances to public health and public policy.



# The REPRIEVE Trial

## The Last Word on Cardiovascular Disease in HIV-positive Persons (hopefully)

**Y**OUR 50 YEAR-OLD, FEMALE, HIV-POSITIVE PATIENT, presents for a follow-up visit. She has heard that the risk of cardiovascular disease is increased among people living with HIV and asks if this is true and if she should be concerned.

### Background on HIV and Cardiovascular Disease

Advances in the clinical management of HIV infection over the past two decades have greatly improved life expectancy of people living with HIV. Antiretroviral therapy has dramatically reduced AIDS-related morbidity and mortality while changing the nature of a diagnosis of HIV from an acute illness with high risk for morbidity to a chronic condition that can be managed with very few pills a day. Recent findings from the NA-ACCORD cohort demonstrated that life expectancy for people with HIV on antiretroviral therapy (ART) increased from approximately 36 years in 2000-2002 to 51 years in 2006-2007.<sup>1</sup>

At the same time that these major advancements in HIV treatment have been made, a parallel increase in non-AIDS conditions also have been observed. In particular, rates of cardiovascular disease (CVD) are reported to be increased and CVD is a significant cause of death among people living with HIV. Large epidemiological studies consistently report that HIV-positive individuals have a 1.5 fold (50%) increase in the rate of cardiovascular events compared to control populations.<sup>2-5</sup> With respect to age, HIV-positive individuals experience CVD at an earlier age. In fact, coronary heart disease has been found to be most pronounced among patients with HIV over the age of 45 years.<sup>2</sup> In particular, women infected with HIV have a heightened risk of myocardial infarction (MI) based on a US retrospective cohort from the Partners Health Care System: HIV-infected women had almost 3.0 times the risk of MI versus women without HIV.<sup>4</sup>

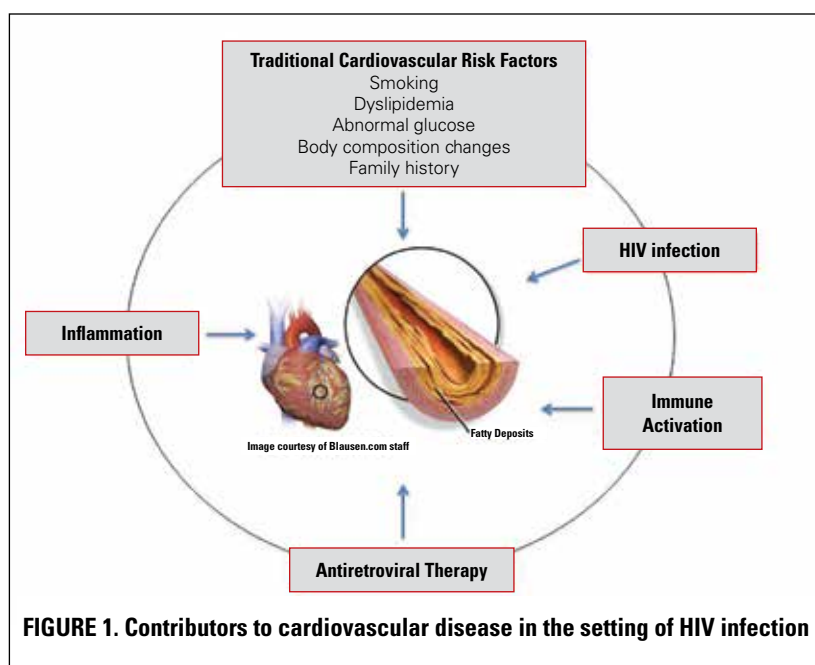
Studies using coronary CT angiography (CCTA) to assess plaque in the coronary arteries found, among a group of HIV-positive and -negative individuals without known history of CVD and with similar traditional CVD risk factors, an increased prevalence of coronary plaque in the arteries of

the individuals infected with HIV. Sixty percent of persons with HIV had plaque present in their arteries compared to 30% of the patients without HIV.<sup>6</sup> In addition, the type of plaque (non-calcified) found in the coronary arteries of the patients with HIV had characteristics that made it more prone to rupture and cause a vascular occlusive event.<sup>7</sup> This may possibly explain the increased rates of CVD events in persons with HIV, but studies are needed to determine if this relationship is true.

### What is Behind Cardiovascular Disease in HIV?

The etiology of cardiovascular disease in HIV is likely related to a number of different elements including traditional cardiovascular risk factors, and the effects of HIV itself, including inflammation and immune activation (Figure 1). Each likely contributes to the elevated risk of cardiovascular disease in the setting of HIV.

Traditional cardiovascular risk factors such as hyperglycemia, dyslipidemia, hypertension, body composition changes and increased rates of smoking have been observed among individuals with HIV more commonly than in HIV-negative individuals. Traditional CVD risks may develop due to genetic propensity, effects of HIV itself and/or are HIV specific. Several older studies among ART-naïve individuals demonstrated lipid abnormalities such as decreased HDL and increased triglycerides,<sup>8-10</sup> while U.S. and European cohort-based studies have reported up to a 40% prevalence of smoking,<sup>11,12</sup> which is higher than that in the general population. Studies evaluating HIV-specific risk factors include: 1) nadir CD4+ T-cell count,<sup>13</sup> 2) poor control of HIV,<sup>14</sup> and 3) protease inhibitors (PIs). Some nucleoside analogs have also been implicated in increasing traditional CVD risk factors including risk of diabetes, blood pressure, and body fat changes.



**FIGURE 1. Contributors to cardiovascular disease in the setting of HIV infection**

### Unique Factors Contributing to Cardiovascular Disease in the Setting of HIV *The Trickle Down of Immune Activation and Inflammation*

HIV infection causes a state of residual, chronic immune activation, which prompts an inflammatory response coinciding with CD4<sup>+</sup> T-cell depletion, which occurs despite successful inhibition of HIV by ART. HIV infection activates the immune system by multiple mechanisms including, but not limited to, HIV replication, response to reactivated infections such as cytomegalovirus, and microbial translocation due to loss of mucosal integrity in the gastrointestinal tract. This chronic immune activation activates endothelial cells, monocytes, platelets, and T-cells and is likely to result in plaque formation in the arteries. Several studies have demonstrated a strong relationship between markers of immune activation and inflammation and measures of cardiovascular disease among HIV-positive individuals.<sup>15-18</sup>

### Tools for the Assessment of Cardiovascular Risk

Cardiovascular disease prevention is essential for people with HIV, especially as people live well into their 70s, 80s, and beyond. Tools have been developed to incorporate unique features of HIV infection,<sup>19</sup> although they are not widely utilized to screen for cardiovascular disease at the present time. The 2013 American College of Cardiology/American Heart Association (ACC/AHA) guidelines, developed for the general population, is another potential tool to assist in predicting the 10-year likelihood of experiencing a myocardial

infarction or stroke. While this tool can be used to provide a general estimation of CVD risk and should be utilized for HIV-positive patients, it does not incorporate a measure of persistent inflammation and immune activation unique to HIV infection. Studies that have applied the 10-year ASCVD risk score to HIV cohorts have shown different results when predicting the risk of CVD for HIV-positive patients.<sup>20-22</sup> Once developed and validated, cardiovascular risk prediction tools developed specifically for HIV-positive individuals, which predict a range of cardiovascular disease will have a significant impact on cardiovascular preventative strategies in this at-risk population.

### Potential Tools for the Prevention of Cardiovascular Disease

While lifestyle modification, such as diet and exercise as well as smoking cessation, may assist in improving cardiovascular risk,<sup>23,24</sup> these modalities may not prove sufficient to prevent cardiovascular events for people living with HIV.

Statins have been studied extensively in the general population and studies exploring the benefits of statins on measures of CVD and immune activation/inflammation among people with HIV have recently been published.<sup>25,26</sup> Statins are known to lower LDL cholesterol, a well-known risk factor for CVD, and were shown in the JUPITER trial, to prevent future CVD events by 44% among participants (without HIV) with moderate to low LDL (< 130mg/dL) and evidence of inflammation by elevated C-reactive protein.<sup>27</sup> Using similar entry criteria as the JUPITER trial, the SATURN-HIV study showed that 96 weeks of rosuvastatin improved a marker of immune activation, soluble CD14 (sCD14), and arrested progression of plaque in the carotid artery.<sup>26</sup> In another study among people with HIV and coronary plaque already present, atorvastatin improved non-calcified plaque as well as Lp-PLA2, a marker of vascular inflammation after 12 months.<sup>25</sup> While both of these studies are encouraging with respect to statins' capacity to improve measures of CVD and inflammation/immune activation, neither of these studies were designed to assess whether or not statins prevent CVD events in the setting of HIV.

### How Will We Know if Statins Prevent CVD Events in HIV? The REPRIEVE Trial

Recognizing the escalating epidemic of CVD and the crucial need to prevent CVD among individuals with HIV, the **REPRIEVE trial (Randomized Trial to Prevention Vascular Events in HIV)** was designed by clinical investigators at the Massachusetts General Hospital, Duke University, University of Cincinnati, University of Alabama and other institutions. **REPRIEVE is an ongoing trial intended to**

**test a cardiovascular disease prevention strategy among people living with HIV.** REPRIEVE is supported by the National Institutes of Health and is a collaboration between the National Heart Lung and Blood Institute (NHLBI) and the National Institute for Allergy and Infectious Diseases (NIAID). Over 100 sites from the AIDS Clinical Trials Group (ACTG), as well as other NIH Division of AIDS (DAIDS)-approved sites, are participating in the US, Canada, Brazil, South Africa, Thailand, and Botswana.

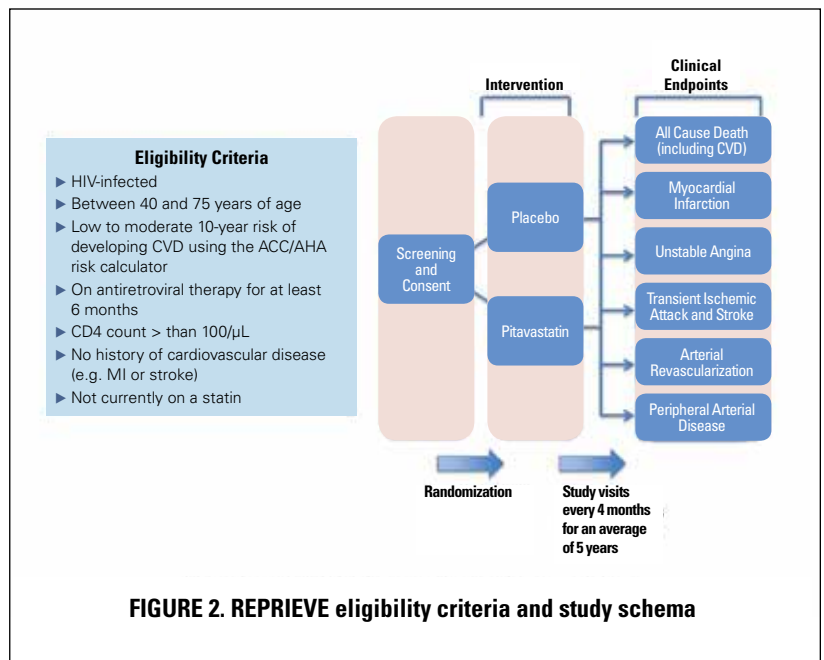
REPRIEVE will enroll 6,500 participants and will be the largest study to date on HIV and cardiovascular disease. REPRIEVE will test whether statins, in particular, pitavastatin, prevents major adverse cardiovascular events (MACE) among people with HIV. Participants who qualify for REPRIEVE (Figure 2) will be randomized to pitavastatin, 4mg, once a day or a matching placebo pill. Participants are evaluated approximately every four months for an average of five years in the study. At every visit, participants are asked if they have experienced any potential cardiovascular events such as myocardial infarction, unstable angina, stroke, peripheral artery disease, or cardiac revascularization.

Pitavastatin was chosen for REPRIEVE because of its safety and tolerability profile. This newer statin has less interactions with ART and because of the way it is metabolized, it may not have negative effects on glucose and diabetes which has been observed with other statins.

## What is Unique about REPRIEVE?

REPRIEVE includes several sub-studies focused on improving the health of the aging population of people living with HIV. One of the sub-studies of 800 participants embedded in REPRIEVE will be using coronary CT angiography to measure coronary plaque at entry and again at two years after study initiation to investigate the mechanism of action of pitavastatin; biomarkers of immune activation will also be measured. Three additional sub-studies recently received funding by the NIH will explore statin effects on muscle function, kidney function, as well as to explore sex-specific mechanisms of CVD.

Another feature unique to REPRIEVE is that this trial is being conducted largely at sites more familiar with HIV infection than cardiovascular disease. This provides an excellent opportunity to educate sites on the epidemic of CVD among HIV-positive individuals. Also, REPRIEVE is evaluating the effects of statins on clinical CVD endpoints, such as myocardial infarction, transient ischemic attack and stroke. This explains the longer duration of REPRIEVE and why the REPRIEVE study team is going to extra lengths to educate participants and site staff about the importance of reporting and collecting any of the primary events or even



**FIGURE 2. REPRIEVE eligibility criteria and study schema**

potential events. This way REPRIEVE will accurately answer the clinical question as to whether or not statins prevent CVD events in the setting of HIV.

## Where Does REPRIEVE Stand?

REPRIEVE enrolled its first participant in April 2015. Currently, there are well over 2,000 participants enrolled and while this initial enrollment demonstrates that the HIV community is involved and behind this landmark trial, enrollment will not be complete until 6,500 participants are enrolled. As sites continue to open in the U.S. and internationally, we expect enrollment to continue to be robust.

## Summary

People with HIV are living longer due to improvements in the treatment of HIV. Consequently, AIDS-related complications are declining. In fact, non-AIDS-related complications are becoming increasingly prevalent both in the US and other parts of the world. Therefore, developing unique strategies to prevent non-AIDS-related complications is essential to maintain the progress that has been made in the clinical management of HIV. REPRIEVE provides the opportunity to develop a prevention strategy for CVD uniquely tailored for people living with HIV and will additionally provide insights into other non-AIDS-related complications such as muscle function, kidney disease, and unique features of CVD among both males and females. The results of REPRIEVE will be available 5-6 years from now and will likely have a significant impact on preventative strategies for CVD and other non-AIDS complications for the HIV community.<sup>HIV</sup>



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### ABOUT THE AUTHORS

**Ms. Fitch** is a Clinical Research Nurse Practitioner in the Massachusetts General Hospital Program in Nutritional Metabolism. Ms. Fitch's research has focused on assessment of metabolic complications in HIV; she was named outstanding researcher in 2015 by the Association of Nurses in AIDS Care for her numerous contributions. Currently, she is the Project Manager of the Clinical Coordinating Center of REPRIEVE.



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**Dr. Hardy** currently serves as Senior Director of Evidence-based Practices, ACTG clinical research site (CRS) leader, MACS co-investigator and HIV/primary care provider at Whitman-Walker Health in Washington, D.C. He holds an Adjunct Professor of Medicine appointment at Johns Hopkins University School of Medicine in Baltimore and a Clinical Professor of Medicine at George Washington University School of Medicine and Health Sciences. Dr. Hardy has cared for persons with HIV infection since 1982 and conducted research on the disease since 1984, initially focusing on treatment and prevention of opportunistic infections and currently on antiretroviral agents, immunotherapies and hepatitis treatments, and retroviral vector research and gene therapy. Dr. Hardy is a Site Leader of REPRIEVE at the Whitman-Walker CRS.



**Dr. Grinspoon** is Professor of Medicine at Harvard Medical School, Director of the MGH Program in Nutritional Metabolism, and Director of the Nutrition Obesity Research Center at Harvard. Dr. Grinspoon's research career has been focused on mechanisms of metabolic and cardiovascular complications in HIV. He has led NIH RO1-funded studies investigating HIV-infected patients for over 20 years and is currently the Co-Principal Investigator of the Clinical Coordinating Center for REPRIEVE.



With HIV at a crossroads,  
a new report charts a course  
for success in the years ahead

BY LONG VIEW COALITION MEMBERS

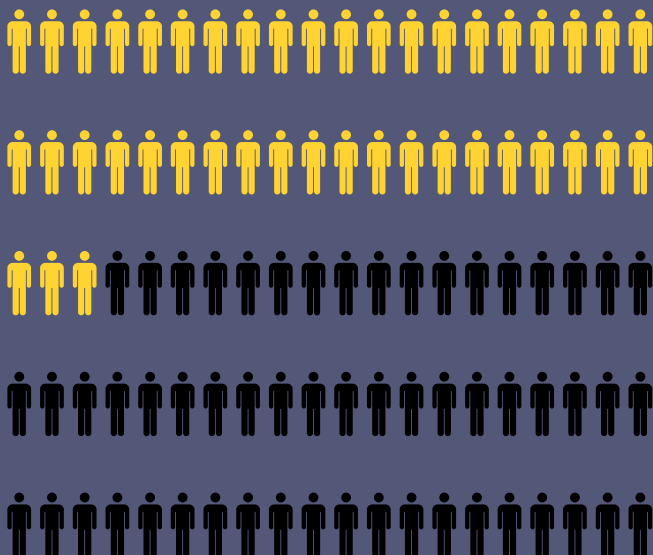
# Preparing for a Healthier Future

**T** HIS SUMMER MARKED THE 35<sup>TH</sup> ANNIVERSARY since the first report of the disease we now know as AIDS, and HIV specialists see everyday how drastically the implications of a HIV diagnosis have improved since that time. In fact, the heavy human toll and widespread nature of the epidemic demanded that government, advocacy groups, professional organizations and pharmaceutical companies work together with unparalleled urgency.

## SOME GOOD NEWS

The survey data collected by the Future Foundation shows that the American public overall is generally optimistic about the future, is willing to be engaged in driving healthcare progress forward and supports access to healthcare.

**43%** of Americans believe the quality of healthcare will improve over the next 20 years.<sup>5</sup>



**54%** of Americans are willing to donate their own healthcare data to help fuel progress.<sup>5</sup>



Now HIV is at a crossroads: while a common purpose brought tremendous treatment innovation and improved access to medicines over three decades, significant awareness, treatment, healthcare access and stigma-related challenges remain unaddressed. Furthermore, advances in care and improved life-expectancy are leading to complacency among those at high HIV risk, especially young people.<sup>1</sup>

It is with this in mind, the American Academy of HIV Medicine (AAHIVM) joined other HIV advocates and stakeholder groups including Gay Men's Health Crisis, HealthyWomen, National Council on Aging and the National Black Leadership Commission on AIDS, in partnership with Gilead Sciences, to develop a new, forward-looking report called, *HIV: The Long View* (available via [www.HIVTheLongView.com](http://www.HIVTheLongView.com)).

The report is the result of an in-depth research process that explored future trends in healthcare to determine a potential future state of HIV in 20 years. The report drew from quantitative and qualitative analyses conducted by the

global research firm, The Future Foundation, on five upcoming healthcare trends central to continued improvement in HIV treatment and care:

- Access to affordable, high-quality health care.
- Personalized medicine.
- Preventative medicine technologies.
- Chronic diseases and related health challenges.
- Progress against infectious diseases.

The research was further informed by insights from notable HIV and public health experts and a national survey assessing how Americans feel about the future of healthcare.

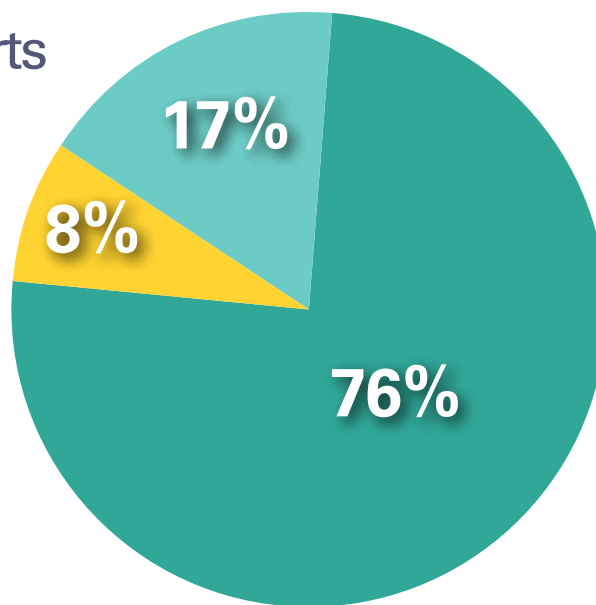
Of particular interest to HIV specialists, the report examines the rise of chronic diseases and the importance of supporting long-term health for people living with HIV as they age.

Today more than 25 percent of people living with HIV in the United States are over the age of 50, and as this population ages—along with younger generations—the report stresses that the medical community will face new challenges



# The American public supports equal healthcare for all

- Everybody should receive the same quality medical care
- It is acceptable for different people to receive medical care of different quality
- I don't have an opinion



Figures are rounded to reach whole numbers

with not only their underlying HIV infection, but also other age-related chronic conditions like hypertension, heart disease and diabetes.<sup>4</sup>

The *HIV: The Long View* Coalition believes this will translate into a need for more resources for prevention and management of chronic conditions over the next 20 years, and that quality of life will become a much more important measure of health for people living with HIV.

In its conclusion, the report emphasizes the role of healthcare providers, their professional societies, patient advocates and policymakers for promoting healthy living and encouraging proactive choices by those at risk and living with HIV— and especially underserved communities.

The *HIV: The Long View* report and its partners also call for accelerated action in five key areas to improve the long-term outlook for HIV in the United States:

- **Eradicating stigma related to sexual behavior, sexual health and HIV status** so everyone who needs HIV care and counseling about prevention will be comfortable using it.
- **Ending the “one size fits all” approach to HIV prevention, treatment and education** by tailoring HIV-related efforts to specific at-risk populations whenever possible.
- **Pushing for 100 percent adoption of evidence-based guidelines** in every U.S. healthcare practice to ensure access to prevention counseling and care, regular HIV testing, and immediate connection and retention in care for those who test positive.
- **Developing pathways to collect more HIV patient data** to enhance the body of knowledge about HIV, inform treatment algorithms and ensure people with HIV have every opportunity to benefit from advances in personalized medicine.

- **Educating and empowering every person at risk of or living with HIV** to take charge of their prevention and care now, to prevent or delay the onset of chronic conditions in the future.

“We need to remove all the stigma and judgment in the healthcare system and in our society that holds people back from coming in and talking honestly to physicians,” said Theresa Mack, MD, MPH, an HIV/AIDS physician in New York City and member of AAHIVM who contributed to the development of the report. “Overcoming this and other access barriers is so important because HIV testing as well as early and ongoing treatment with antiretroviral therapy benefits not only individuals with HIV over the long term but also helps control the HIV epidemic itself.”

AAHIVM is a proud partner of *HIV: The Long View* and supports its calls to improve long-term health and improved health outcomes for the HIV community. We encourage you to explore and consider the full report at [www.HIVTheLongView.com](http://www.HIVTheLongView.com). HIV

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# Looking Ahead, Questions Remain

*Following the issuance of the HIV: The Long View report, representatives from the Long View Coalition participated in a webinar to share insights about the trends, opportunities and challenges for achieving a healthier future regarding HIV education, prevention and care. Following is a summary of the webinar dialogue*

# “W

**E ARE AT A TRANSFORMATIVE TIME FOR U.S. HEALTHCARE**, where scientific advances are happening rapidly and access to care is evolving and expanding,” said webinar moderator and former journalist Jeff Bloch. “It is a time of tremendous opportunity, both to accelerate progress and tackle emerging challenges that can hamper future progress. Individuals living with or at risk for HIV are front and center at this crossroad.”

Bloch continued, “Advances in treatment and prevention, combined with increased availability of educational resources and access to healthcare, have helped improve the lives of many over the past three decades, but the epidemic and the challenges of living with HIV are far from over.”

“With early detection and proper treatment, HIV can now be a long-term, manageable chronic disease for many,” said Bloch. “But not everyone with HIV is getting tested, receiving optimal care and continuing that essential care. There continues to be infection risks and care gaps across all populations, and certain groups are particularly hard hit.”

Per the report, particularly at-risk groups include men who have sex with men, African Americans, Latinos, transgender women, urban poor and rural residents, especially in the South.

The Long View report set out to answer such questions as:

- What will our healthcare environment look like in 20 years and what will it mean for HIV?
- What will the most vexing challenges be?
- What will our greatest achievements be?
- How can we learn from our successes and our failures and pass our knowledge on to future generations?
- How can we harness today's tools to ensure better health for everyone in decades to come, particularly those living with, or at risk for, HIV?

Many of these questions were discussed during the webinar, where the Coalition pointed out that *HIV: The Long View* stresses the importance of advancing the HIV dialogue beyond viral status to focus on long-term goals that can positively impact the health of people living with HIV over time, improve quality of life and reduce loss of life. The goal, he said, is to help ensure improved future health outcomes for people living with HIV by supporting and encouraging dialogues on solution-based initiatives.

These include overcoming stigma; utilizing personalized medicine; increasing patient access to prevention information, testing and care; collecting and analyzing patient data to improve treatment decisions; and engaging underserved minority and at-risk communities.

At the conclusion of the webinar session, Bloch conducted a question-and-answer session with panelists. Participating Long View Coalition representatives were:

- Kelsey Louie, MSW, MBA, Chief Executive Officer, Gay Men's Health Crisis;
- Jonathan Appelbaum, MD, FACP, AAHIVS, Member, Board of Directors, American Academy of HIV Medicine;
- C. Virginia Fields, MSW, President and Chief Executive Officer, National Black Leadership Commission on AIDS;
- Beth Battaglini, RN, President and Chief Executive Officer, HealthyWomen;
- Kathleen Zuke, MPH, Program Associate, National Council on Aging.

Here's a summary of that dialogue, discussing each of the report's calls to action:

## ERADICATE STIGMA

*Eradicate stigma related to sexual behavior, sexual health and HIV status so that everyone who needs HIV care and counsel about prevention will be comfortable seeking it.*

### Q. Why is it so important that we focus on eradicating stigma?

**Kelsey Louie**—Fear of judgment and discrimination prevent individuals living with or at risk for HIV from seeking appropriate medical care, speaking openly with their healthcare team or even getting tested. It is essential that they can access the healthcare system for current health needs to give them the best chance for a healthier future.

Reducing stigma will also help patients feel more secure in sharing their personal data, which is vital to developing personalized medicine options for everyone living with HIV.

### Q. Is there evidence regarding how to reduce stigma? It remains as powerful today as it was in the '80s for many populations.

**Kelsey Louie**—The question itself underscores the difficulty that stigma presents to the HIV community. Stigma is hard to measure. But wherever there are concrete steps or policies that we can implement to reduce stigma, such as the FDA blood donation policy, or any prevention messages that show images of resiliency and love as opposed to hyper-sexualization of these populations are important. It's important to talk about these issues, to talk about sex, and encourage people to discuss them so they can seek the care or the prevention efforts that they need.

## END THE 'ONE SIZE FITS ALL' APPROACH

*Ending the "one size fits all" approach to HIV prevention, treatment and education by tailoring HIV-related efforts to specific at-risk populations whenever possible.*

### Q. Why is it so important that we work to end the "one size fits all" approach?

**C. Virginia Fields**—The population living with HIV is diverse. Highly impacted populations like African Americans, Latinos, men who have sex with men and transgender women each have unique educational needs and factors that will motivate them to action. But even as information is tailored to specific audiences, including those of younger and older ages, it should be harmonized in its underlying messages.

**Beth Battaglini**—For women living with HIV, it is especially important to take regular preventative health care measures due to the effect of long term infection and treatment and the natural progression of age-related conditions.

**C. Virginia Fields**—In African Americans, stigma has consistently shown to deter people from getting tested, not knowing their status, and then when they are tested they are at the point of late-stage AIDS and that has had an impact in terms of the death rate.

### Q. Why is it so difficult for many people, especially younger people, to appreciate the importance of prevention?

**Kelsey Louie**—The younger generation today did not live through the '80s when an entire community was decimated. Add to that today's pill culture and the idea that HIV is no longer a death sentence. All of those things combined will



**Kelsey Louie, MSW, MBA**, is Chief Executive Officer of Gay Men's Health Crisis. Kelsey has over 13 years of professional experience in the fields of HIV/AIDS prevention and care, behavioral health, addiction services, homelessness, LGBTQ issues, and family and children services.



**C. Virginia Fields, MSW**, is President and Chief Executive Officer of the National Black Leadership Commission on AIDS, Inc. (NBLCA) and former two-term Manhattan Borough President. She was at the forefront of community battles in the early 1980s to secure housing for people with AIDS and continues to serve the community today.



lead to the younger generation not understanding the importance of HIV prevention and care. However, we do have statistics that tell us that they should be thinking otherwise. We have 40,000 new HIV infections across the country each year; we have 1.2 million people in the U.S. living with HIV. So, we need to reduce stigma and have more conversations with the younger generation so that they can be made aware of HIV and AIDS and know how to take care of themselves.

**Q. What do you see as the outlook for older individuals, age 50 and over, who are living with HIV?**



**Jonathan Appelbaum, MD, FACP, AAHIVS** is Professor of Internal Medicine at Florida State University's College of Medicine in Tallahassee, FL. He is also Vice-Chair of the AAHIVM Board of Directors and Website Medical Co-Director of [HIV-Age.org](http://HIV-Age.org).

**Dr. Jonathan Appelbaum**—Unfortunately, as you get older you tend to develop other health care problems like high blood pressure, diabetes and bone disease. These problems seem to be more prevalent in patients who are HIV infected. There is an impact on the health care system in cost. Trying to prevent HIV infection, trying to anticipate these diseases and educating our providers so they can treat them early, I think are key.

**Q. With the aging epidemic, how can other providers for aging individuals be brought to the table to collaborate with HIV providers?**

**Dr. Jonathan Appelbaum**—AAHIVM has worked with other organizations, including the American Geriatric Society and ACRIA, to come up with treatment strategies and guidelines for the care of older patients with HIV. Part of our mission in working with some of the other organizations here at the table is to educate around the issues of aging. Some of this is happening, but we still have a lot of work to do.

**Q. How does ageism work into stigma for the emerging older adult population?**

**Kathleen Zuke**—Stigma may be compounded for people as they age and experience more ageism. They might feel even worse if they have been diagnosed with HIV at an older age when they didn't think that HIV was an issue for them and perhaps are feeling the effects of HIV and social isolation.

**Kelsey Louie**—Data tells us that people diagnosed over age 50 tend to get tested late based on their seropositivity, which often means they get tested when they have advanced HIV. We need to remember that people over 50 are having sex and target HIV prevention messages to them.

**PUSHING FOR GREATER ADOPTION OF EVIDENCE-BASED GUIDELINES**

*Pushing for 100% adoption of evidence-based HIV guidelines in healthcare practices to ensure access to preventive counseling and care, regular HIV testing and immediate connection to and retention in care for those who test positive.*

**Q. Why is it so important that we achieve 100% adoption of evidence-based guidelines?**

**Dr. Jonathan Appelbaum**—Early HIV testing and antiretroviral treatment are the cornerstone of good patient care and essential to controlling the HIV epidemic. But HIV patients require more—their fully integrated care includes counseling and self-management education to prevent or delay the onset of age-related conditions that disproportionately affect people with HIV even more so than those who are HIV-negative. HIV specialists and nonspecialists, who will be called on to provide more HIV care in the coming years, need to be educated and prepared to deliver the best care possible.

**COLLECT MORE DATA**

*Developing pathways to collect more HIV patient data to enhance the body of knowledge about HIV, inform treatment algorithms, and to ensure people with HIV have every opportunity to benefit from advances in personalized medicine.*

**Q. Why is it so important to collect more HIV patient data?**

**Beth Battaglini**—The general public is uncomfortable sharing their health information; we can expect this to be an even bigger issue for people with HIV due to the long history of stigma attached to an HIV diagnosis and even seeking HIV prevention counseling. Establishing pathways



**Elizabeth Battaglini, RN**, is President and Chief Executive Officer of HealthyWomen. Beth has worked in the health care industry for nearly 20 years, helping to define and drive public education programs on a broad range of women's health issues.

to collect more HIV data from patients is not just about technical capacity to collect and integrate electronic health data; it will rely on our ability to remove stigma and ensure that data are not used in any punitive way against people with HIV.

## EDUCATE & EMPOWER

*Educating and empowering every person at risk of and living with HIV to take charge of their prevention and care now, to prevent or delay the onset of chronic conditions in the future.*

### **Q. Why is it so important that we focus on education and empowerment when it comes to HIV?**



**Kathleen Zuke, MPH**, is a Program Associate for the National Council on Aging's National Chronic Disease Self-Management Education Resource Center. Kathleen's experience includes women's health, volunteer management, clinical care evaluation, and health literacy.

**Kathleen Zuke**—Better access to healthcare prevention and treatment, including counseling and self-management education, provides consumers with an opportunity to take a more active role in their healthcare. Changing media, including social media, are facilitating delivery of more focused messages to the diverse groups that make up the HIV community. This combination of heightened communication with healthcare professionals, whether in-person or virtual, and increased uptake of communications messages, provides an opportunity to educate and empower more people living with HIV or at risk to make more informed decisions for their long-term health now.

### **Q. HIV treatments have had a large impact on the epidemic, but the evidence also tells us that psycho-social factors also significantly impact outcomes. What about the issues of mental health, social isolation and substance use? These are not always amenable to drug treatment.**

**Dr. Jonathan Appelbaum**—These are very important conditions that can play a big role. Mental health, social isolation and substance use can affect any patient with HIV regardless of age or social-economic status. We need to be aware of them and provide services that deal with them.

**Kelsey Louie**—Like stigma, untreated mental health and substance use are drivers of the epidemic. Add to that, there is stigma around mental health and substance abuse issues. With people living longer lives, the prevalence of these issues will increase, so we must pay attention to the intersection of mental health, substance abuse as well as HIV.

### **Q. The efficacy of HIV treatment is great and people do quite well on them. But does this affect the urgency that people feel about taking care of themselves, about their own status, the urgency of the product community of focusing on the HIV population, even the urgency of health care providers to be aggressive about how they treat HIV?**

**C. Virginia Fields**—There is a sense of complacency that HIV is no longer a problem. Many of the younger generation believe that if they become infected all they have to do is take a pill. I'm not seeing a sense of urgency in our work. Complacency is there. We no longer see it addressed in the media the same way. And some of the more notable people in the media, Magic Johnson and others, look so well that people think that all they have to do is take medication without thought to the long-term impact.

**Dr. Jonathan Appelbaum**—Where I do see a sense of urgency is among the provider groups. My organization is very concerned about the workforce and who is going to be caring for these patients as they continue to age and develop additional co-morbidities. We see a sense of urgency to educate the provider work force about following national treatment guidelines and the recommendations in this report.

**Beth Battaglini**—With the rate of new HIV diagnoses among women still at around 20 percent, we definitely see the need to better educate women and think through what is needed in education. We know it's not one size fits all. What's working for gay men as far as education and awareness is not going to work for the transgender woman and/or females overall whether they are black or Latino. Making sure that we understand what the gap of knowledge is and creating better education programs is needed so we can begin those conversations with both patients and health care providers.

**HIV**

## POLICY OUTLOOK

# Looking Towards the Future

## The New Congress, President, and Administration

BY HOLLY KILNESS PACKETT, MA

**S**INCE the election results came in this November, much has changed in the outlook for public health policy, the field of healthcare, and HIV care and treatment generally over the next four years. As the new President-elect assembles his cabinet, and the Congress looks forward to next year, there is still much that is unknown, and new developments are happening each day. Here is what we know so far:

### The Trump Administration

President-elect Trump has been busy identifying his likely nominees for various cabinet positions, and sub-cabinet positions, such as agency heads. These nominations will be subject to examination and confirmation by the U.S. Senate after the New Year.

#### HHS

Trump has named orthopedic surgeon and Republican Congressman Tom Price of Georgia as his nominee for Secretary of Health and Human Services (HHS).

Born in Lansing, MI, Price went to college and medical school at the University of Michigan, did his residency at Emory University in Atlanta and was medical director of the orthopedic clinic at Grady Memorial Hospital in Atlanta. As a surgeon from the suburbs of Atlanta, Price has said he was drawn to politics because he felt lawmakers wielded too much power over his actions as a doctor.

Price has been a Member of Congress since 2005 and is the current House Budget Committee chairman. Several physician groups, including the American Medical Association (AMA) and the American Academy of Dermatology, are among Price's largest campaign donors. As a former Georgia state senator, Price often aligned with the positions of AMA and the Medical Association of Georgia.

A severe critic of the Affordable Care Act (ACA), Price's regular complaint is that it puts the government in the middle of the doctor-patient relationship,

and interferes with the ability of patients and doctors to make medical decisions.

"We believe that patients and doctors should be in control of health care," Price said previously. "People have coverage, but they don't have care."

While in Congress, Price penned an ACA replacement proposal known as the Empowering Patients First Act, which included promotion of health savings accounts, and state-run high-risk pools. Favorably, Price has supported the idea of requiring insurers to cover people with pre-existing conditions. He has also said he is not wedded to his own ideas and is open to compromise.

In his new role, Price would likely play a key part in crafting an ACA replacement. The head of HHS will oversee writing the rules to implement whatever legislation is eventually passed to replace Obamacare, and in the meantime has wide latitude to enforce (or not enforce) parts of the existing law.

Price strongly opposes abortion rights, and he supports privatization of Medicare. He has introduced legislation that would make it easier for doctors to defend themselves against medical malpractice lawsuits and to enter into private contracts with Medicare beneficiaries, allowing doctors to charge more than the amounts normally allowed by the program's rules.

The Secretary of HHS oversees not only the mammoth department, but also the 16 health agencies under HHS purview, including the Food and Drug Administration (FDA), the National Institutes of Health (NIH),



the Centers for Disease Control (CDC), and the Health Resources and Services Administration (HRSA).

### **CMS**

Trump has selected Indiana health policy consultant Seema Verma to run the Centers for Medicare and Medicaid Services (CMS). An Indian-American woman, Verma is the president and founder of SVC, Inc., a national health policy consulting company based in Indianapolis.

Verma received her Master's degree in Public Health, with a concentration in health policy and management from Johns Hopkins University, and her Bachelor's degree in Life Sciences from the University of Maryland. Prior to consulting, Verma worked for the Health and Hospital Corporation of Marion County, Indiana and the Association of State and Territorial Health Officials in Washington, D.C.

Verma's chief professional pursuit has been work on re-designing Medicaid programs in states that have chosen to expand the program. She was the chief architect of Indiana's Medicaid expansion under Obamacare —Healthy Indiana Plan (HIP), a so-called consumer directed Medicaid program. The HIP created savings accounts for recipients, requiring them to make premium-like payments and more carefully budget their use of health services. Verma also helped develop the 1115 Medicaid waiver proposals in Iowa, Ohio, Michigan, and Tennessee. She has also worked on a highly controversial reform package in Kentucky.

A blog post Verma co-wrote talks of “setting a fair expectation of personal investment and engagement in his or her own well-being” for beneficiaries or Medicaid. “Contributions are a way for members to demonstrate personal responsibility, but they also encourage members to stay engaged with their health plan.”

In addition to Medicaid, Medicare, and CHIP, CMS oversees such things as how hospitals are rated and reimbursed for their care, federal quality benchmarks, and doctor compensation.

### **The 115th Congress**

The Congress did not change significantly in terms of sheer numbers in the elections. Both chambers will have a Republican majority. There are still several races around the country that have not yet closed. The House, at present has 194 Democrats, and 240 Republicans, with a few races still outstanding due to automatic run-offs. This leave the House Republicans in a very comfortable position since only 218 votes are needed to achieve majority vote in the House.

The Senate at present has 51 Republicans and 48 Democrats, with one run-off still pending, although it is predicted to go to the Republican candidate. This will probably leave a Senate with 48 Democrats and 52 Republicans.

In the Senate, 60 votes are needed to invoke cloture on debate, or stop a filibuster of a piece of legislation. However, only a simple 50 vote majority is needed for certain other procedures, such as passing a budget reconciliation bill.

### ***The Agenda of the 115th Congress:***

The early part of the next year will see a Congressional agenda largely dominated by two things—spending and healthcare issues.

### ***FY 2017 Federal Funding Bills***

The 2017 fiscal year is already under way, but the current lame duck Congress has yet to pass federal spending bills this year for the remainder of FY2017. House Republicans recently settled on a plan to fund the government through March 31 by passing a continuing resolution, or CR, a stopgap spending bill to temporarily fund the government at current levels. However, it may not be a “clean” CR. Several members have called for more defense spending, as well as additional relief for flood victims, or are pushing to complete the President's request for supplemental war spending.

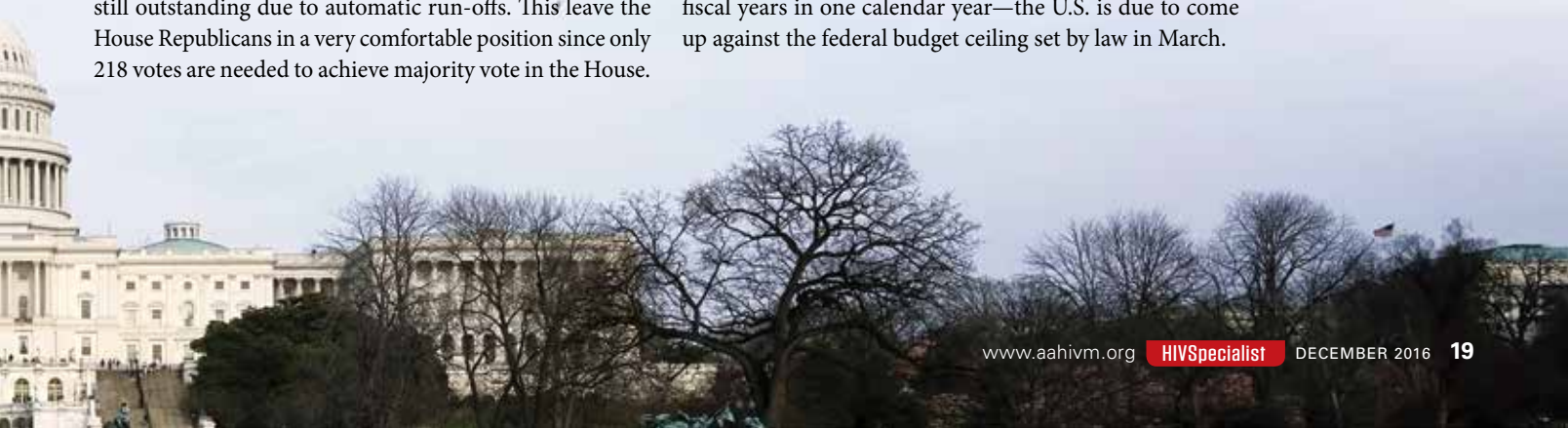
This short-term move will allow the newly minted President Trump and the 115th Congress to come into office with an immediate opportunity to affect federal spending for the remainder of the 2017 fiscal year by passing their own funding levels within the first few months of their term.

### ***FY 2018***

Immediately after passing funding for FY 2017, the new Congress will have a second opportunity to affect federal spending. The FY 2018 budget process will begin in the spring. Traditionally, a new incoming President does not present a full federal budget to Congress during his first year in office, as he will in subsequent years. However, the FY2018 budget process and appropriations may not follow the same pattern as we have usually seen.

### ***Debt Ceiling***

One additional significant fiscal challenge sits before the new Congress, in addition to responsibility for addressing two fiscal years in one calendar year—the U.S. is due to come up against the federal budget ceiling set by law in March.



In the past, the debt ceiling was used by Republicans to impose harsh cuts in federal program funding. Congress also has used the debt as a vehicle to make changes to the Medicaid program.

### **The Future of the Affordable Care Act**

Republicans in Congress have spent the last six years challenging the law at every turn. The GOP-led House has voted more than five dozen times to rescind the ACA. With Trump's victory, and control of Congress, Republicans have their first real opportunity to "repeal and replace" the law as they have promised for years. House Speaker Paul D. Ryan (R-WI) returned to that point late in his comments on Wednesday morning following the election.

#### **ACA Repeal Plans**

Congressional Republican leaders have revealed part of their strategy to fulfill campaign promises to repeal and replace Obamacare in two stages starting early next year.

Republicans plan to focus on an immediate repeal of the law, using an expedited budget process early next year. However, the replacement of the law will wait until a later time, and be done through separate legislation.

Using the process known as "budget reconciliation," Republicans can move legislation through the Senate with only a simple majority vote (51 votes), instead of the super majority 2/3 vote (60 votes). However, budget reconciliation can only be used to advance legislation directly tied to the federal budget. So the legislation will have to focus on only the parts of the law with a direct fiscal impact.

The "replacement" legislation—outlining a new specific health care system with many parts—will have to go through the normal legislative process. Republicans plan to post-date the repeal to take effect at some later point, giving them time to develop a viable and agreed-upon alternative replacement plan and work it through Congress.

Republicans tested this road map to repeal significant parts of the law last year and successfully got it through the House and Senate, but it was vetoed by President Obama. Presumably, President-elect Trump would not do so.

#### **Trump's Role in Repeal**

During the election, President-elect Trump promised to scrap President Obama's Affordable Care Act on his first day in office. If the budget reconciliation strategy is successful and swiftly carried out, he actually may have that opportunity.

Trump has said he favors keeping one key aspect of the law—the discrimination protections for people with preexisting medical problems. But the insurance industry has long said it would have a hard time abiding by this rule unless all Americans are required to have insurance.

#### **Effects of Repeal**

It is far from clear how the public would respond if the law is actually undone and millions end up with no insurance, or at least none they can afford.

But it's not just the people who have gotten health coverage who'd be affected. Rolling the health law back would create chaos in the health care sector—hospitals, insurers, doctors, some state governments—that have started to adjust to life under the ACA. That's not a small concern, given that health care is about one-fifth of the economy.

The law also cut hospital Medicare payment rates and other funding to offset the costs of treating the uninsured. An outright repeal of the law would erase those cuts.

Some hospitals and insurers benefited from an influx of newly insured patients under the law. Hospitals saw patient volume growth with fewer unpaid bills. For-profit hospitals also saw a sharp fall in their stock prices on the Wednesday following the election.

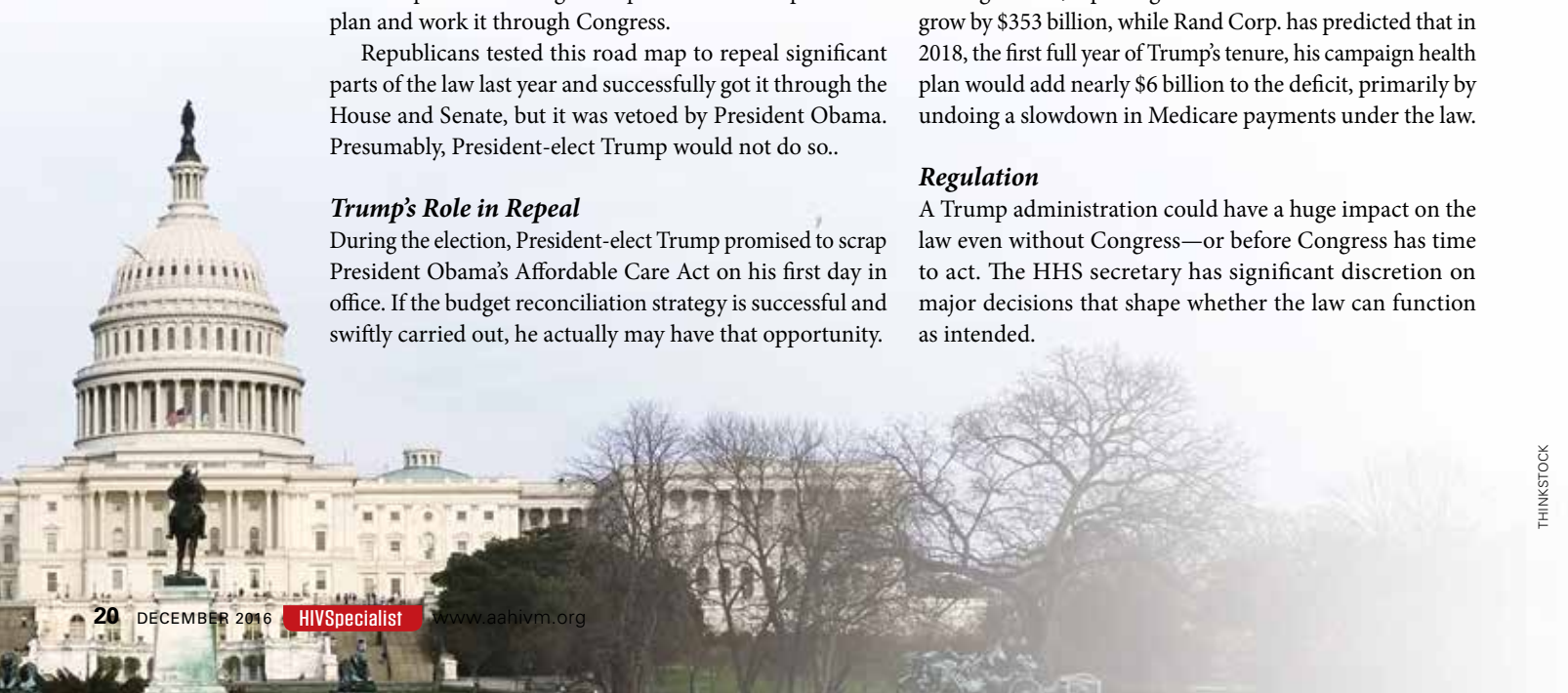
Similarly, the insurance companies that have profited under the ACA expansion, such as Molina Health, saw stock prices fall. In a statement, America's Health Insurance Plans, the lobbying group for the industry, said it would "work across the aisle—with every policy maker and the new administration—to find solutions that deliver affordable coverage and high-quality care for everyone."

#### **Cost of Repeal**

The Congressional Budget Office forecast that, over the coming decade, repealing the law would cause the deficit to grow by \$353 billion, while Rand Corp. has predicted that in 2018, the first full year of Trump's tenure, his campaign health plan would add nearly \$6 billion to the deficit, primarily by undoing a slowdown in Medicare payments under the law.

#### **Regulation**

A Trump administration could have a huge impact on the law even without Congress—or before Congress has time to act. The HHS secretary has significant discretion on major decisions that shape whether the law can function as intended.



For instance, a Republican administration could relax requirements on Medicaid. CMS, under the Obama Administration has habitually rejected proposals by some states to include Medicaid expansion provisions like work requirements for beneficiaries. A CMS under Trump's leadership might be more willing to accept them.

In an unprecedented and some would say, hostile move, House Majority Leader Kevin McCarthy and other House committee chairmen sent a letter to executive agencies warning them against speeding through new regulations in the waning days of the Obama administration. "Should you ignore this counsel, please be aware that we will work with our colleagues to ensure that Congress scrutinizes your actions—and, if appropriate, overturns them—pursuant to the Congressional Review Act," they wrote.

## Other Health Issues

While the ACA will certainly be a target of the new Congress, the positioning of other health care issues under a Trump Presidency is unclear. The new the 115th congress will have many items to address in their first two years beyond the ACA and federal funding.

### CHIP

The Children's Health Insurance Program (CHIP) has long received support from both sides of the aisle. Federal funding for CHIP expires in September 2017. However, as states renew their agreements with the federal government on CHIP in the late spring, renewal of the program will likely have to be addressed before then. In recent years, Republicans have proposed "greater flexibility" for states, which often results in diminished benefits within the program. Republicans have also tried to tie CHIP funding to Medicaid.

### Drug and Medical Device Industry User Fees

Congress will be tasked with approving the next five-year renditions of user fee agreements for prescription drugs, medical devices, generic drugs and biosimilars. This is an all-consuming focus for the pharmaceutical and medical manufacturing industries as the laws pertain to the fees charged by FDA in return for performance commitments by the agency. Agreements are directly negotiated between the FDA and

stakeholders, then approved by Congress, so they can impact how drugs and devices are developed, approved and reimbursed for years to come.

### Other ACA Law Provisions

Some aspects of the Affordable Care Act are unavoidable legislative requirements over the next two years. In 2015, Congress temporarily suspended or delayed three controversial taxes that were created to help pay for the law.

One of those taxes, a fee levied on health insurers, is suspended for 2017, while a 2.3 percent tax on medical devices was suspended for 2016 and 2017. Both industries lobbied heavily for the deferrals, arguing that the taxes boosted the prices of their products.

Also on hold is the so-called "Cadillac Tax" that levies a 40 percent penalty on very generous health insurance plans. The initiative aimed to prevent consumers who pay little out of pocket because of their coverage from overusing health care services and driving up overall health costs. The tax was put off from 2018 to 2020, but experts say pressure will begin to mount next year for reconsideration because employers will need a long lead time if they are to change benefits to avoid paying it.

### Medicaid

The repeal of the Medicaid expansion under the ACA may be far from the only change to the program. House members have made statements about their desire to shift federal funding of the program into block-grants to states. It is possible that Republicans may take up this effort as part of the overall ACA repeal and/or replacement efforts. Or it may be addressed through one of the other spending opportunities next year, or entirely separately. The concept, though, would have significant impact for HIV patients across the country, as Medicaid is the largest payer of HIV care and treatment.

### Medicare

Republicans may be gearing up for a fight over Medicare as well. Remarks by Republican House Speaker Ryan that the ACA and Medicare are entwined raised the prospect that the popular seniors' health program may be on the table. Ryan has advocated an overhaul of Medicare in the past, says the health insurance program for the nation's elderly has "serious problems"

that are related to the Affordable Care Act, and he thinks they must be addressed during the GOP's efforts to repeal the Affordable Care Act.

## Questions For HIV/AIDS Care

Many questions remain about how HIV/AIDS policy will develop under the new President and Congress. Below are just a few of the issues on the table for policy operatives.

### National HIV/AIDS Strategy

The Obama Administration created the first ever U.S. National HIV/AIDS Strategy during their first term. It included specific actions and goals for many federal agencies on HIV as well as national goals such as a 90% reduction in new infections. The Obama Administration released a 2.0 update to the Strategy aimed at continuing this work into and beyond the next administration. A clear question for advocates will be the Trump Administration's commitment to continuing the work of the NHAS and advancing its goals.

### Ryan White

The federal Ryan White program has remained expired in its authorization for many years. This was part of deliberate efforts by advocates and administration officials to protect the program from exposure to cuts and negative changes by a perceived unfriendly Congress and funding environment in recent years. Nevertheless, the program has survived and even grown during this time due to ongoing federal funding.

However, a new Congress and President determined to cut federal spending and reign in federal programs does not bode well for funding of the program. Reauthorization of the law may be even more concerning, with many of the original supporters of the law no longer in Congress.

That does not mean the program is doomed. Continued funding, even at a loss, will still allow the program to operate. And there are many actions for change within the program that can be undertaken by HRSA, through internal authority. However, this will be a main focus for advocates over the next four years.

**HIV**



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## THE AFFORDABLE CARE ACT

# A Snapshot of 2017



*The 2017 enrollment period for the Affordable Care Act (ACA) opened on Tuesday, November 1, 2016, and ends Jan. 31, 2017.*

The U.S. Department of Health and Human Services (HHS) claims that 20 million Americans have gained coverage under the ACA law so far in its first few years. However, 30 million Americans still remain uninsured. Of the 30 million, about 10.7 million are eligible for Exchange coverage, and 9 million of those persons for tax credits.

Polls taken in early 2016 still show a concerning lack of awareness of the tenants of the ACA, and its offerings to consumers. Nearly 40% of the uninsured were not aware of the Insurance Exchanges, and nearly 50% did not know about the availability of financial assistance for low-income purchasers.

The tax penalty fees for lacking minimum essential coverage have increased sharply for the 2017 tax year. For 2017, consumers without coverage will pay the higher of \$695 per adult or \$347.50 per child under 18 (maximum: \$2,085) or 2.5% of household income. This penalty applies only to individuals whose household income is above \$10,150 for individuals, \$20,300 for couples.

However, the open-enrollment period began amid reports of expected premium increases for many, and smaller

networks for others.

HHS made an announcement that premium rates for consumers purchasing insurance plans on [HealthCare.gov](http://HealthCare.gov) would go up an average 25 percent next year. Most consumers (more than 8 in 10) will still receive tax subsidies that will help to cushion costs. However, consumers in many areas could see up to double-digit percentage increases for premiums.

Despite increases, Exchange premiums are lower than what the Congressional Budget Office initially predicted when ACA was passed. Even if premiums go up by 25%, nearly 75% of Exchange enrollees expected to be able to find a plan for \$75 per month. The average premium increases in some states are expected to be far lower than 25 percent.

Why the increases? Several reasons have been offered by experts. First, the risk corridors promised under the law have not worked out as promised. Now, insurers are adjusting plans' pricing for loss of reinsurance and the lack of promised risk corridor payments under the law.

Second, a loss of competition: In the last year, there has been significant insurer flight from Exchanges—Aetna,





UnitedHealth and Humana all have withdrawn from participation citing unsustainable financial losses. This leaves near monopolies in some states, failing to produce competition among the plans for consumers, as envisioned.

This drop-out of many insurers also has had significant impact on consumer choice options in some states. An estimated 19% of Exchange enrollees will have only one insurer available in their 2017 state Exchange. Only 62% will have three or more insurers to choose from.

Third, the failure of the insurance co-ops has contributed to a lack of competition, and to consumer disarray. The state co-op experiment has sustained high-profile failures in most states, with only six co-ops remaining nationwide.

Finally, the patient pool participating in the exchanges is not what was expected. The patients enrolled in the exchanges are what estimates predicted before the law's passage. The risk pools have turned out to be older, and more medically needy (and therefore more costly) than anticipated in some states. This is partly due to the fact that far more small employers have retained employer-sponsored insurance than was estimated. So overall, there has been a lower than expected shift of young healthy employees into the Exchanges.

Some positive changes are happening in the 2017 enrollment, however. CMS is piloting a network breadth

indicator in the federally-run Marketplace plans available on **Healthcare.gov** to assist consumers with plan selection. It will be piloted in four states: Maine, Ohio, Tennessee, and Texas. The network breadth indicator will measure the relative size of provider networks for each Marketplace plan compared to other Marketplace plans in that county. In 2018, it may incorporate additional specificity, such as adding an indicator that a plan has an integrated provider delivery system.

A final new change in 2017 affects state's participation in the Medicaid Expansion. Beginning in 2017, states will be required to share cost of the Medicaid expansion populations for the first time since the passage of the ACA. The cost of the Medicaid expansion was paid for 100% for the first few years of the law. In 2017, however, states will have to pay 5% of expansion population's costs. The states' cost share rises slowly until 2020, when they will pay 10% of the costs of the expansion population thereafter.

This does not affect the budget for the original Medicaid population covered before the ACA went into effect—the cost of which is still shared equally by the state and the federal government.

Interestingly, in states that expanded Medicaid, Marketplace premiums are about 7% lower than in other states. **HIV**



# The Affordable Care Act and HIV

## What do HIV medical providers know?

BY KATHLEEN A. MCMANUS, MD, MSCR  
UNIVERSITY OF VIRGINIA

**B**EFORE THE PATIENT PROTECTION AND AFFORDABLE CARE ACT (ACA), which aims to provide affordable insurance coverage to uninsured or underinsured individuals, was implemented, there were many questions about how it would affect persons living with HIV (PLWH).

Since PLWH are disproportionately represented among the uninsured, many hoped they might benefit substantially from this federal legislation.<sup>1</sup> On the other hand, there were concerns about how the ACA would interact with the United States' current complex, comprehensive HIV healthcare delivery system, such as Ryan White-funded clinics and AIDS Drug Assistance Programs (ADAPs), which are funded by the Ryan White Comprehensive AIDS Resources Emergency Act.<sup>2</sup>

Giving states the option to expand Medicaid left many low-income PLWH without health insurance, especially in the Medicaid non-expansion states. State ADAPs are a safety net to ensure that underinsured and uninsured PLWH receive key medications, such as anti-retroviral therapy. Many ADAPs incorporated the ACA into their healthcare delivery model by funding clients' ACA Qualified Health Plans (QHPs).<sup>3,4</sup>

In Virginia, we were uncertain how the ACA would affect PLWH, so we partnered with colleagues at the Virginia Department of Health to study how Virginia ADAP's implementation of the ACA would impact individuals' HIV outcomes. Virginia ADAP formed a Health Insurance Marketplace Assistance Program (HIMAP) and encouraged its clients to enroll in QHPs. Virginia ADAP paid insurance premiums, deductibles and medication copayments under the ACA's federal health insurance marketplace.

By spring 2015, we had the preliminary findings of our two-year study of the 3,933 ADAP clients who were eligible for ADAP-funded QHPs in Virginia. We found that patients enrolled in QHPs through Virginia ADAP's HIMAP had higher rates of viral suppression (85%) than those who received only medications for HIV through the state's Direct ADAP plan (79%).<sup>5</sup>

Our study determined that QHP enrollment

was affected by many demographics known to affect linkage and engagement in care, such as age, race, gender and progression to an AIDS diagnosis.<sup>6</sup> We also found that QHP enrollment was affected by such healthcare delivery factors as the 2013 ADAP coverage program they used, the federal tax credits received and the specific HIV clinic where they received care.

Based on this, we questioned what might affect clinic-level differences in PLWH's QHP enrollment. Would medical provider knowledge and attitudes influence ADAP clients' QHP enrollment? We surveyed HIV medical providers' knowledge and attitudes about the ACA on a national level.<sup>7</sup> Results of this study were presented at AIDS 2016 in Durban, South Africa in July 2016 and at IDWeek 2016 in New Orleans, Louisiana in October 2016.

For our study, HIV medical providers (physician assistants, nurse practitioners, fellow physicians, and attending physicians) at academic hospitals with Infectious Diseases fellowship training programs were e-mailed a web-link to the survey. These providers were chosen due to the difficulty in obtaining contact information for HIV private practice providers across the nation.

The study was approved by the University of Virginia Institutional Review Board for Social and Behavioral Sciences and surveys were conducted during August and September 2015.

Respondents were surveyed on their sources of ACA information as well as their main source of ACA information. They were also asked ACA knowledge questions about tax credits, pre-existing conditions, Medicaid expansion, and its interaction with Ryan White-supported care. To gauge respondents' attitudes about the ACA, they were asked to agree or disagree with the following statements on a five point scale (1- strongly disagree, 2- disagree, 3- neutral, 4- agree, 5- strongly agree): "The Affordable Care Act will improve the United States' health outcomes;" "The Affordable Care Act will improve my HIV patients' HIV outcomes;" and "The Affordable Care Act will improve my HIV patients' non-HIV outcomes."

There were 253 survey respondents from 35 of the 50 states and the District of Columbia. The five states that were the most represented among respondents were New York, Virginia, California, North Carolina, and Massachusetts. Sixty percent of respondents were from Medicaid-expansion states. Two thirds of respondents were attending physicians. Providers had varying amounts of

experience with one-third reporting 0-5 years, one third reporting between 5-20 years, and one-third reporting 20 or more years.

In terms of sources of ACA knowledge, two-thirds reported using websites and newspapers/magazines. Almost half reported using clinic case managers, while a third reported using the radio. Interestingly, almost a third obtained ACA knowledge from their clinic patients. When asked about their main source of ACA knowledge, providers reported websites (32%), newspapers or magazines (23%), and case managers (12%). The majority of respondents (61%) answered all four knowledge questions correctly, but approximately one-third answered "I don't know" to at least one question.

Over 15% did not know that the ACA provides tax subsidies to people with low incomes, and more than 10% were not sure if the ACA eliminated the Ryan White Program. Seventy percent knew if their state had elected to expand Medicaid. There remain considerable knowledge gaps in HIV providers' understanding of the ACA and its relation to HIV healthcare delivery in the United States.

In terms of ACA attitudes, the mean response for agreeing or disagreeing with the statement that "the ACA would improve national health outcomes" was close to four, which was associated with the response "agree." For the statement about the ACA improving HIV patients' non-HIV outcomes, the mean response was similar. These two attitudes did not vary based on whether a provider was in a Medicaid expansion or non-expansion state.

In terms of whether providers thought the ACA would improve their patients' HIV outcomes, the mean response in Medicaid non-expansion states was 3.4 compared to 3.8 in Medicaid expansion states. This was statistically significant and indicates that providers in Medicaid expansion states were more optimistic about the ACA improving their patients' HIV outcomes.

Our survey sample may be biased towards HIV providers who felt they were knowledgeable about the ACA, and therefore may overestimate the correct knowledge about the ACA. Even with that possible limitation, knowledge gaps were identified.

But, to effectively advise patients on ACA-related questions, providers should have basic ACA-related knowledge regarding tax credits,

pre-existing conditions, Medicaid expansion, and its interaction with Ryan White Care Act. Education about the ACA for HIV medical providers could be disseminated through currently used resources (websites, newspapers/magazines, and case managers) to improve knowledge of this important health system shift and to enhance systems-based practice. **HIV**

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## Funding

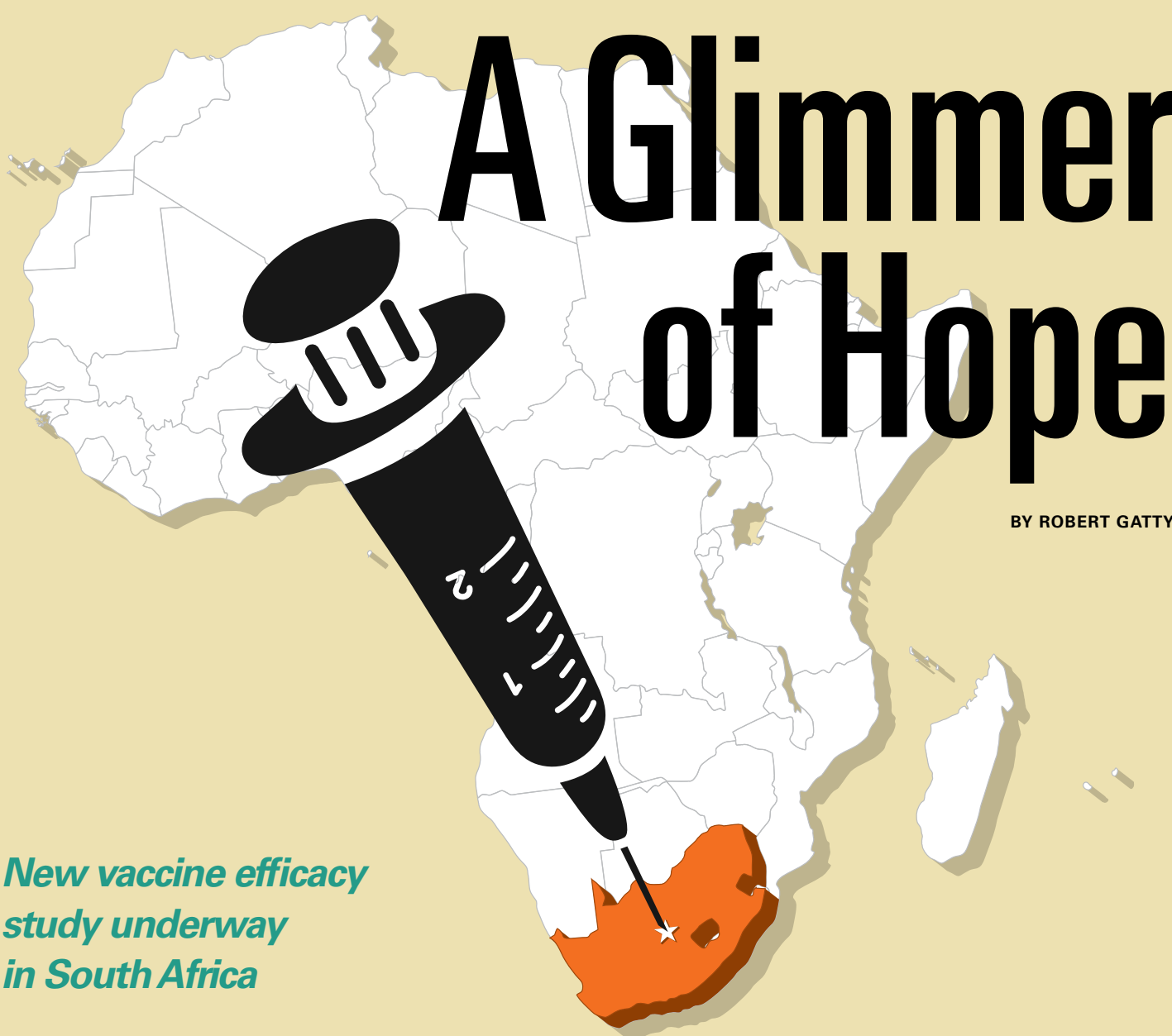
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# A Glimmer of Hope

BY ROBERT GATTY

## *New vaccine efficacy study underway in South Africa*

**A STUDY** to determine the efficacy of a new version of the only HIV vaccine candidate ever shown to provide some protection against the virus has been launched in South Africa. This is the first such study to be undertaken anywhere in the world over the last seven years.

Known as HVTN 702, the study will enroll 5,400 men and women in South Africa, a country where more than 1,000 people become infected with HIV every day. The experimental vaccine regimen being tested is an updated version of one investigated in the RV144 clinical trial in Thailand that was led by the U.S. Military HIV Research Program and the Thai Ministry of Health. That trial found in 2009 that for the first time a vaccine could prevent HIV infection. However, the experimental vaccine regimen tested was only found to be 31.2 percent effective at preventing HIV infection over the 3.5-year follow-up after vaccination. In the HVTN 702 study, the design, schedule and components of the RV144 vaccine regimen have been modified in an effort to increase the magnitude and duration of vaccine-elicited protective immune responses.



"If deployed alongside our current armory of proven HIV prevention tools, a safe and effective vaccine could be the final nail in the coffin for HIV," said Anthony S. Fauci, M.D., director of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health and a co-funder of the trial. "Even a moderately effective vaccine would significantly decrease the burden of HIV disease over time in countries and populations with high rates of HIV infection, such as South Africa."

The new regimen aims to provide greater and more sustained protection than the RV144 regimen and has been adapted to the HIV strain (subtype C) that predominates in southern Africa, a region that includes the country of South Africa.

"The people of South Africa are making history by conducting and participating in the first HIV vaccine efficacy study to build on the results of the Thai trial," said HVTN 702 Protocol Chair Glenda Gray, M.B.B.C.H., F.C.Paed. (SA).

"HIV has taken a devastating toll in South Africa, but now we begin a scientific exploration that could hold great promise for our country. If an HIV vaccine were found to work in South Africa, it could dramatically alter the course of the pandemic." Dr. Gray is president and chief executive officer of the South African Medical Research Council; research professor of pediatrics at the University of the Witwatersrand, Johannesburg; and a founding director of the Perinatal HIV Research Unit at Chris Hani Baragwanath Hospital in Soweto, South Africa.

Co-chairing the protocol with Dr. Gray are Linda-Gail Bekker, M.D., Ph.D.; Fatima Laher, M.D.; and Mookho Malahleha, M.B.Ch.B., M.P.H. Dr. Bekker is deputy director of the Desmond Tutu HIV Centre at the University of Cape Town and chief operating officer of the Desmond Tutu HIV Foundation in Cape Town, South Africa. Dr. Laher is a director of the Perinatal HIV Research Unit at Chris Hani Baragwanath Hospital. Dr. Malahleha is deputy director of Setshaba Research Centre in Soshanguve, South Africa.

### 'A Historic Event'

"If this study shows efficacy... this would be a tectonic, historic event for HIV," Nelson L. Michael, director of the U.S. Military HIV Research Program, which led the Thailand study, told *The Washington Post*. Should the vaccine prove to be even 50 percent to 60 percent effective, experts say, that would be sufficient for drug makers Sanofi Pasteur and GSK to begin licensing negotiations with the South African government, *The Post* reported. While such a rate is well below the acceptable margin for other vaccines, experts told *The Post* it would still be worth producing in South Africa because of the extraordinarily high rate of HIV infection. Then that agent could be adjusted again to use against viral subtypes that circulate elsewhere, including in the United States.

## OTHER TRIALS UNDERWAY

HVTN 702 is one of many NIAID-supported HIV prevention trials in progress in southern Africa. These include the AMP Studies, which are testing infusions of the VRC01 antibody; the open-label HOPE study, which is examining a dapivirine vaginal ring; and HPTN 076 and 077, which are studying long-acting injectable rilpivirine and cabotegravir, respectively.

In a study called ASPIRE, researchers tested flexible silicone rings that continuously release dapivirine with women ages 18 to 45 living in Malawi, South Africa, Uganda and Zimbabwe.

However, questions about its practical use in the bedroom remain, even though Dr. Fauci says that the less obtrusive a form of prevention is, the easier it is to convince people to use it. "Something not noticeable is great," he said.

While interviews with 214 of the 2,629 ASPIRE participants said that sex with the ring wasn't much different, physically, from sex without it, some women reported worrying about what would happen if their partners discovered it, fearing that they would be interrogated in the middle of having sex.

"Given that right now we have nothing, we'd be happy if this vaccine were even 45 or 50 percent effective," Gita Ramjee, director of the HIV Prevention Research Unit at the Medical Research Council in Durban, which is running two of the 15 trial sites, told *The Post*. "Even a modestly effective vaccine like that would have a huge impact here."

As the regulatory sponsor of HVTN 702, NIAID is responsible for all operational aspects of this pivotal Phase 2b/3 trial, which is enrolling HIV-uninfected, sexually active men and women aged 18 to 35 years. The NIAID-funded HIV Vaccine Trials Network (HVTN) is conducting the trial at 15 sites across South Africa. Results are expected in late 2020.

HVTN 702 begins just months after interim results were reported for HVTN 100, its predecessor clinical trial, which found that the new vaccine regimen was safe for the 252 study participants and induced comparable immune responses to those reported in RV144.

### Study Details

HVTN 100 and HVTN 702 are part of a larger HIV vaccine research endeavor led by the Pox-Protein Public-Private Partnership, or P5—a diverse group of public and private organizations committed to building on the success of the RV144 trial. The P5 aims to produce an HIV vaccine that could have a significant public health benefit in southern Africa and to advance scientists' understanding of the immune responses associated with preventing HIV infection. P5 members include NIAID, the Bill & Melinda Gates Foundation, the South African Medical Research Council, HVTN, Sanofi Pasteur, GSK and the U.S. Military HIV Research Program.

The HVTN 702 vaccine regimen consists of two experimental vaccines: a canarypox vector-based vaccine called ALVAC-HIV and a two-component gp120 protein subunit vaccine with an adjuvant to enhance the body's immune response to the vaccine. The vaccines do not contain HIV and therefore do not pose any danger of HIV infection to study participants.

Both ALVAC-HIV (supplied by Sanofi Pasteur) and the protein vaccine (supplied by GSK) have been modified from the versions used in RV144 to be specific to HIV

***The P5 aims to produce an HIV vaccine that could have a significant public health benefit in southern Africa and to advance scientists' understanding of the immune responses associated with preventing HIV infection.***

subtype C, the predominant HIV subtype in southern Africa. Additionally, the protein subunit vaccine in HVTN 702 is combined with MF59 (also supplied by GSK), a different adjuvant than the one used in RV144, in the hope of generating a more robust immune response. Finally, the HVTN 702 vaccine regimen includes booster shots at the one-year mark in an effort to prolong the early protective effect observed in RV144.

The study volunteers are being randomly assigned to receive either the investigational vaccine regimen or a placebo. All study participants will receive a total of five injections over one year.

The safety of HVTN 702 study participants will be closely monitored throughout the trial, and participants will be offered the standard of care for preventing HIV infection, according to NIAID. Study participants who become infected with HIV in the community will be referred to local medical providers for care and treatment and will be counseled on how to reduce their risk of transmitting the virus. **HIV**



SHUTTERSTOCK

# Q&A with NIAID

**Q. What will happen to study participants who acquire HIV infection during the trial?**

A. Study participants who become HIV-infected in the community will be referred to local medical providers for care and treatment and will be counseled on how to reduce their risk of transmitting the virus. The study team will follow these participants for about six months after confirmation of diagnosis.

**Q. How is the study team ensuring the safety of study participants?**

A. An independent Data and Safety Monitoring Board (DSMB) will monitor participants' safety. A DSMB is composed of clinical research experts, statisticians, ethicists and community representatives who meet periodically during a study to review safety and efficacy data as it is gathered. A statistician who is not part of the study team presents interim data to the DSMB. Because the study team is blinded to interim study data, they are excluded from portions of meetings when data are presented. The DSMB alerts the study team if anything appears to compromise the safety of study participants, if there is compelling evidence that the study intervention is effective, or if it becomes clear that the study cannot answer one of the questions it was designed to address. In addition, a Protocol Safety Review Team (PSRT) designated for HVTN 702 is conducting ongoing oversight of the safety of study participants. The PSRT

includes a medical officer from NIAID's Division of AIDS, the study's protocol chair and co-chairs, and principal investigators and clinicians from study sites. Regular reports of safety data will be sent to the Medicines Control Council, the South African national regulatory authority for medications.

**Q. What are the components of the HVTN 702 investigational vaccine regimen? How are they intended to improve upon the regimen tested in the RV144 clinical trial?**

A. The HVTN 702 vaccine regimen consists of two experimental vaccines: a canarypox-vector based vaccine called ALVAC-HIV and a two-component gp120 protein subunit administered in an adjuvant to enhance the body's immune response to the protein subunit. The vaccines do not contain HIV and therefore do not pose any danger of HIV infection to study participants. Both ALVAC-HIV (supplied by Sanofi Pasteur) and the protein subunit (supplied by GSK) have been modified from the versions used in RV144 to be specific to HIV subtype C, the predominant HIV subtype in southern Africa. Additionally, the protein subunit in HVTN 702 is combined with MF59 (also supplied by GSK), a different adjuvant than the one used in RV144, in the hope of generating a more robust immune response. Finally, the HVTN 702 vaccine regimen will include booster shots at the one-year mark in an effort to prolong the early protective effect observed in RV144.

**Q. Has the HVTN 702 vaccine regimen been tested previously?**

A. Yes, the HVTN 702 vaccine regimen was previously tested in the HVTN 100 study. HVTN 100 is an early stage, Phase 1/2 clinical trial that sought to determine whether or not the investigational vaccine regimen was safe and elicited a set of key immune responses that were comparable to the immune responses elicited by the RV144 vaccine regimen. Once it was clear that the regimen in HVTN 100 met these criteria, the study's funders decided to go forward with plans to test the safety, tolerability and efficacy of the regimen in the much larger HVTN 702 clinical trial. HVTN 100 is ongoing, and investigators will continue to monitor the data emerging from it to inform HVTN 702.

**Q. What is the P5 and its relationship to HVTN 702?**

A. P5 stands for the Pox-Protein Public-Private Partnership, a diverse group of public and private organizations committed to building on the success of the RV144 trial. The P5 aims to produce an HIV vaccine that could have a significant public health benefit and to advance scientists' understanding of the immune responses associated with preventing HIV infection. HVTN 702 is part of the P5 research program. P5 members are NIAID, BMGF, SAMRC, HVTN, Sanofi Pasteur, GSK and the U.S. Military HIV Research Program. NIAID, BMGF and SAMRC fund the P5.




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# What's Ahead for Hepatitis C Treatment?

Physics  
Botany  
Chemical Technology  
Geology  
Environmental Science  
Marine Science  
Biochemistry  
Material Science  
Microbiology  
Photographic Science and Printing Technology  
Genetics





## Implementation of a novel, multidisciplinary Hepatitis C mono-infection program in an established HIV program

**T**HE PREVALENCE OF CHRONIC HEPATITIS C INFECTION (HCV) in the United States is estimated to be 1.0% of the general population, or approximately 2.7 million individuals<sup>1</sup>—without accounting for high-risk, institutionalized individuals, including those who are homeless or incarcerated.

The creation of a dedicated HCV program within an established Ryan White funded HIV program in an urban environment is a novel model of HCV care delivery. This multidisciplinary, patient-centered model of care, recognized to provide high quality and successful HIV care,<sup>4,5,6</sup> is also a valuable model to embrace when treating HCV mono-infected patients.<sup>7,8,9</sup> The provision of comprehensive care to patients with HCV mono-infection contributes to excellent HCV treatment outcomes—comparable to clinical trial results with new generation directly acting antivirals (DAAs). Our program in Delaware serves as an example of what can be accomplished through appropriate care integration and providing access to treatment.

Delaware began to report cases of chronic HCV to the Division of Public Health in 2004, yet remains one of many states where there is inconsistent case reporting and limited hepatitis C screening. Delaware facilities providing substance abuse treatment are not required to screen for HCV. In 2013, only 33% (14 out of 41) of such facilities reported availability of hepatitis C screening for clients,<sup>2</sup> while available estimates from 2013 suggest there are at least 2,750 persons who inject drugs (PWID) in Delaware.<sup>3</sup> With the advent of DAAs allowing for short courses of tolerable and highly effective HCV treatment, there is a concerted statewide effort to increase screening of high-risk individuals and to actively report cases of HCV. Surveillance data from the Delaware Electronic Report Surveillance System (DERSS) from January 1, 2016 through March 31, 2016 identified 8 suspected cases of acute HCV and 789 suspected cases of chronic HCV.<sup>3</sup> The lack of a functional referral system to link HCV-infected patients to care—specifically recently incarcerated individuals, PWID, and persons engaged in substance abuse treatment—is an acknowledged state-wide challenge. The HIV Community Program, part of the Christiana Care Health System (CCHS), has been caring for patients with HIV and HIV/HCV co-infection since 1989. The HIV Community Program is the only Ryan White-funded HIV treatment program in Delaware and cares for over 1,650 people living with HIV/AIDS (PLWHA).

### Bridging the Gap

In response to the growing unmet need to link persons with HCV mono-infection to specialty care, we sought to bridge this gap through the development of a dedicated HCV program nested within the HIV Community Program in Wilmington. In 2013, discussions about expanding programmatic capabilities to provide care to those with HCV mono-infection began. In March 2014, we evaluated the first patient with HCV mono-infection—a direct referral from the Department of Corrections (DOC) at the time of release from incarceration. In May 2015, following a period of programmatic development, the long-envisioned HCV program officially opened to the public.

Since its official inception, the HCV program has grown to be a multi-disciplinary care team comprised of one administrative assistant, one nurse, one nurse practitioner, one pharmacist, and two physicians with active board certification in Infectious Diseases. HCV clinic is held every Friday morning and is open to any individual with HCV over the age of 18.

The HCV Program immediately adopted and embraced the HIV Ryan White care model for the management of patients with HCV mono-infection. We offer comprehensive care including, but not limited to vaccinations, harm-reduction counseling, access to social work and pharmacy services. We also provide assistance with obtaining health insurance and a primary care physician, and referrals for appropriate screening procedures and specialist consultation. Our care team performs weekly rounds to facilitate real-time follow through on patient cases, and to support the ongoing evaluation of work flow processes and the development of relevant databases.

### Evaluating the Impact

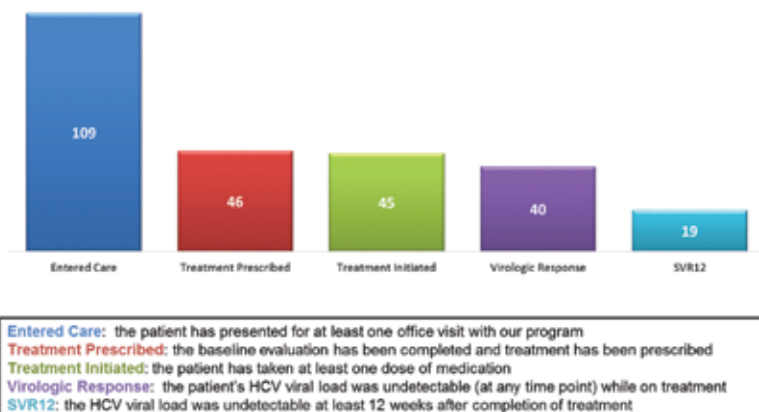
In an effort to evaluate the impact of employing the HIV care model in the real-world treatment of HCV mono-infected patients in an urban setting with high HCV prevalence, we

**Table 1: Baseline Characteristics of HCV Patients**

	n = 109 (%)
<b>Sex</b>	
Male	73 (67%)
<b>Birth Year</b>	
Before 1945	1 (1<1%)
1945–1965	81 (74%)
1966–1985	20 (19%)
After 1985	7 (6%)
<b>Referral Source</b>	
CCHS	41 (38%)
Community Provider	35 (32%)
DOC	14 (13%)
Substance Abuse Treatment Facility	12 (11%)
Self-Referral	7 (6%)
<b>Fibrosis Stage</b>	
F0	15 (14%)
F1	16 (15%)
F2	26 (24%)
F3	11 (10%)
F4	24 (22%)
Pending	5 (4%)
Not Required	12 (11%)

performed a retrospective chart review of all patients evaluated in the HCV Program from March 1, 2014 through September 14, 2016. We evaluated patient demographics, sources of HCV care referrals, and HCV disease and treatment status. All data were extracted from electronic medical records and specific programmatic databases, which are updated on a weekly basis. We then utilized these data to create a HCV Program care cascade to aid in identifying barriers to care and areas for programmatic improvement. Our patient population is reflective of the bimodal distribution of the present HCV epidemic and encompasses a wide range of referral sources as well as disease states as determined by serologic staging (Table 1). Nearly half of patients who entered into care for evaluation of chronic HCV have been successfully prescribed HCV treatment (Figure 1). Lack of insurance coverage due to early stage liver disease has been the most significant barrier to HCV treatment (Figure 2). To date, all patients on HCV treatment for 4 or more weeks have achieved an initial virologic response. The majority (90.5%) of patients who have completed treatment with a documented SVR12 have achieved cure (Figure 3).

**Figure 1: HCV Program Care Cascade**



## Looking Ahead

The development of a HCV care cascade helped our program to identify barriers to care, programmatic strengths, challenges and opportunities for improvement as the HCV program expands within the HIV Community Program and satellite clinics statewide. The cascade highlights common ongoing challenges of capacity building, access to DAAs, and maintaining patient engagement in care during and following HCV treatment.<sup>10</sup> As we look toward the future, our program continues to utilize the HIV care model in our care of HCV mono-infected patients. We seek innovative ways to expand our clinical capacity and address the ever-growing need of providers to evaluate and treat those with chronic HCV. Finally, we strongly advocate for HIV care providers to offer the same level of high-quality multidisciplinary care provided to PLWHA to individuals with HCV mono-infection.

HIV

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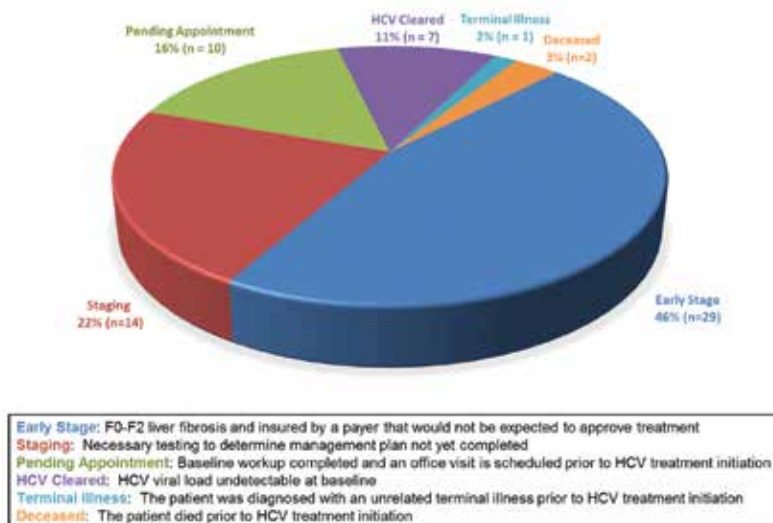
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## ABOUT THE AUTHORS

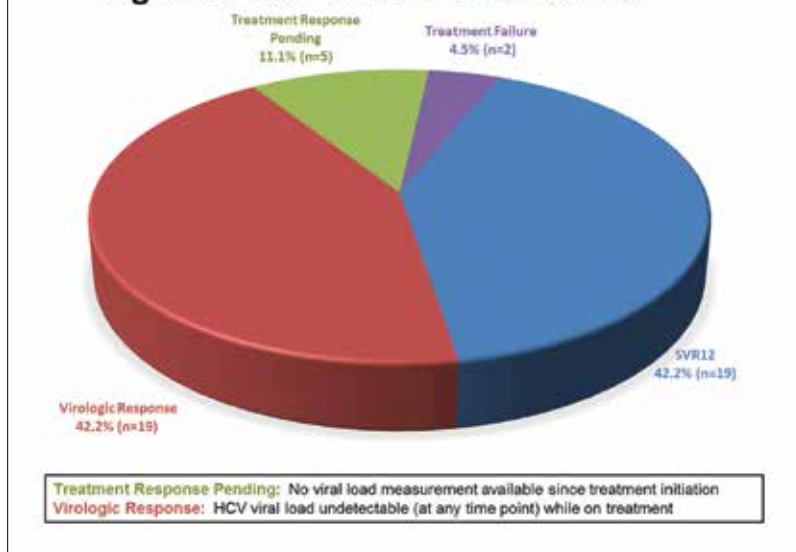
**Christopher James** received his Bachelor of Science in September 1998 and Doctor of Pharmacy in May 1999 from Philadelphia College of Pharmacy at the University of Sciences in Philadelphia and completed a pharmacy practice residency at Baylor University Medical Center. Currently, Chris works as clinical pharmacy specialist for the HIV Community Program, Christiana Care Health System and holds an adjunct faculty appointment for University of the Science in Philadelphia.

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**Figure 2: Patients Without Prescribed Treatment**



**Figure 3: HCV Treatment Outcomes**



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# Observational Cohorts

## What they have taught us about HIV disease

**T**HE OBSERVATIONAL COHORT study design has served HIV clinicians and our patient communities for over 30 years by teaching us a great deal about HIV disease and its complications.

While randomized controlled trials (RCT) remain the gold-standard in medical research, they are often impractical or in some cases unethical to perform when it comes to HIV-related clinical questions. Since the first observational cohort was started in 1984 (MACS—see below), the research community has garnered a vast amount of information from groups of HIV-infected men and women who have been followed longitudinally. They have answered many questions related to HIV pathogenesis and natural history. There are now numerous HIV cohorts that provide basic science and clinical information in persons living long-term with HIV and many of the associated co-morbidities. The majority of these studies are still recruiting new participants. What follows is an overview of some of the key HIV observational cohorts.

### Multicenter AIDS Cohort Study (MACS)

<https://idstudies.northwestern.edu/sites/1/pages/home>

The MACS began recruiting participants in 1984 when 4,954 gay or bisexual HIV-positive men were enrolled from clinical sites in Baltimore (Johns Hopkins), Chicago (Northwestern), Pittsburgh (University of Pittsburgh), and Los Angeles (UCLA).

They were followed with data collection, including laboratory and clinical parameters performed on a semi-annual basis. The MACS was the first to look at the natural history of untreated HIV disease. Early data gathered from this cohort includes anal intercourse as a risk for HIV infection, rates of CD4+/T-cell decline, use of prophylaxis for Pneumocystis, progression to AIDS, and survival from time of diagnosis.

In more recent years the MACS has expanded to including several sub-studies. These include aging with HIV, co-morbidities of cancer, cardiovascular and neurological diseases, and oral health. Funding for the MACS is primarily from the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health. Over 1,400 papers have been published from the MACS, including most recently those noted below:

- Peckham-Gregory EC, et al. [MicroRNA-related polymorphisms and non-Hodgkin lymphoma susceptibility in the Multicenter AIDS Cohort Study \(MACS\)](#). Cancer Epidemiol. Oct.1, 2016; 45:47-57.

- Zhang L. et al. [Vitamin D Deficiency and Metabolism in HIV-infected and -uninfected Men in the Multicenter AIDS Cohort Study \(MACS\)](#). AIDS Res Hum Retroviruses. Oct. 2016.
- Akhtar-Khaleel WZ, et al. [Long-Term Cigarette Smoking Trajectories among HIV-Seropositive and Seronegative MSM in the Multicenter AIDS Cohort Study \(MACS\)](#). AIDS Behav. 2016; 20(8):1713-21.
- Slama L et al. [Longitudinal Changes Over 10 Years in Free Testosterone among HIV-Infected and HIV-Uninfected Men](#). J Acquir Immune Defic Syndr. 2016; 71(1):57-64.

### Women's Interagency HIV Study

<http://statepiaps.jhsph.edu/wihs/index-cohort-info.htm>

The Women's Interagency HIV Study (WIHS) was established in August 1993 to carry out wide-ranging investigations on the impact of HIV infection and its clinical, laboratory, and psychosocial effects in women.

The WIHS began enrolling patients in October 1994 and the initial cohort included 2,625 women (2,056 HIV-positive and 569 HIV-negative). The original WIHS sites included Bronx, NY, Los Angeles, CA, Chicago, IL, San Francisco/Oakland CA, and Washington, DC and is the largest and longest ongoing study of HIV-infected women in the U.S.

Participants have follow-up visits at six-month intervals. Information obtained from these women include socio-demographics, sexual behaviors, gynecological, obstetrical and contraceptive history, as well as alcohol, tobacco and drug use. Some key data from WIHS has been cervical and lung cancer risks in HIV-positive women.

WIHS is co-sponsored by five NIH Institutes including the NIAID, National Cancer Institute (NCI), Eunice Kennedy Shriver National Institute of Child Health and Human Development, the National Institute on Drug Abuse, and the National Institute of Mental Health. More recently, new sites were added that better reflect the demographics of the HIV epidemic include Atlanta, GA, Chapel Hill, NC, and Jackson, MS. Over 600 publications have come out of the WIHS cohort, including these recent papers:

- Dale SK et al. [Abuse, nocturnal stress hormones, and coronary heart disease risk among women with HIV](#). AIDS Care. October 2016; 13:1-5.





- Vance DE et al. [Aging and Neurocognitive Functioning in HIV-Infected Women: a Review of the Literature Involving the Women's Interagency HIV Study](#). Curr HIV/AIDS Rep. October 2016.
- Weitzmann MN et al. [Bone Loss among Women Living With HIV](#). Curr HIV/AIDS Rep. Sept 2016.
- Torre P et al. [Speech audiometry findings from HIV+ and HIV- adults in the MACS and WIHS longitudinal cohort studies](#). J Commun Disord. July 2016.

## North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD)

<https://statepiaps7.jhsph.edu/naaccord/>

The NA-ACCORD was founded in 2006 as a regional representative of the International epidemiologic Databases to Evaluate AIDS (IeDEA).

NA-ACCORD is composed of 25 cohorts (including the WIHS and MACS) from the U.S. and Canada. Over 200 sites from all 50 states, three U.S. territories and nine Canadian Provinces contribute data on over 130,000 HIV-infected patients. These sites include both academic and community-based facilities that deliver primary and specialty HIV care.

The NA-ACCORD combines epidemiological and clinical HIV cohorts, includes both HIV-seropositive and seronegative

persons, and is complemented by specimen repositories for conducting translational research. Funding for the NA-ACCORD is from NIAID and the NCI. According to their website, NA-ACCORD is open to collaboration with additional clinical sites.

A sentinel publication that came out of this cohort was the 2009 paper [MM Kitahata et al. *Engl J Med* 2009; 360:1815-1826] that found early initiation of antiretroviral therapy before the CD4+ count fell below 350 and 500 cells/mm3 significantly improved survival, as compared with deferred therapy. Recent publications from NA-ACCORD include:

- Buchacz K et al. [Incidence of AIDS-Defining Opportunistic Infections in a Multicohort Analysis of HIV-infected Persons in the U.S. and Canada, 2000-2010](#). J Infect Dis. 2016 15; 214(6):862-72.
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## Veterans Aging Cohort Study (VACS)

<http://medicine.yale.edu/intmed/vacs/>

The VACS is a prospective, observational cohort of HIV-positive and HIV-negative veterans in care with the Veterans Administration health system in the United States.

The primary aim of the VACS is to understand the role of comorbid medical and psychiatric diseases and their effects on HIV-related clinical outcomes. The VACS is primarily funded by the National Institute on Alcoholism and Alcohol Abuse. The principle investigator of the VACS is Dr. Amy Justice from the VA Connecticut Healthcare System and Yale University School of Medicine.

The VACS consists of two ongoing cohorts. The first began in 1997 and includes 40,000 HIV-positive veterans and a one-to-two matched sample of uninfected controls. The VACS also has a sub-study cohort of patients from nine VA medical centers ("VACS-9") that include Atlanta, Baltimore, Bronx, Dallas, and Los Angeles.

When new veterans with HIV infection present for care, they are offered enrollment in one of the two cohorts. A key research tool of the VACS is the "VACS Index" – a clinical scoring system that predicts all-cause mortality, cause specific mortality, and other outcomes in those living with HIV infection. The VACS Study Index creates a score by summing pre-assigned points for age, CD4 count, HIV-1 RNA, hemoglobin, platelets, hepatic function, renal function, and viral hepatitis C infection. Several recent published studies by the VACS include:

- Kahler CW et al. [Direct and Indirect Effects of Heavy Alcohol Use on Clinical Outcomes in a Longitudinal Study of HIV Patients on ART](#). *AIDS Behav.* July 2016.
- Marquine MJ, et al. [The Veterans Aging Cohort Study \(VACS\) Index and Neurocognitive Change: A Longitudinal Study](#). *Clin Infect Dis.* 2016; 63(5):694-702.
- Montoya JL, et al. [Elevated Biomarkers of Inflammation and Coagulation in Patients with HIV Are Associated with Higher Framingham and VACS Risk Index Scores](#). *PLoS One.* 2015; 10(12).

## Data Collection on Adverse events of Anti-HIV Drugs (D:A:D)

<http://www.cphiv.dk/Studies/DAD/About>

D:A:D is a prospective multi-cohort study primarily focused on the recognition of adverse events related to HIV disease and also complications specifically related to ART.

The original study population of 23,000 patients was enrolled between December 1999 and April 2001. The data center is based in Denmark and is composed of 11 cohorts including EuroSIDA, Aquitaine, ATHENA, and ICONA. The U.S. member of D:A:D is the Community Programs for Clinical Research on AIDS (CPCRA). The total current enrolment is approximately 50,000 patients that represent 212 clinics from 33 countries.

**There are now numerous HIV cohorts that provide basic science and clinical information in persons living long-term with HIV and many of the associated co-morbidities.**

According to the D:A:D web site, funding comes from "The Oversight Committee for The Evaluation of Metabolic Complications of HAART", and several pharmaceutical companies that produce anti-retroviral drugs.

The data collection for D:A:D takes place about every eight months and is merged to a central database in Copenhagen. Core data in D:A:D is information on incident cases of cardiovascular disease, which are reported immediately to the coordinating office.

The data collection also includes information on risk factors for cardiovascular disease, such as previous myocardial infarction or stroke, diabetes, dyslipidemia, family history, hypertension, and smoking. In more recent years, D:A:D has collected information on non-AIDS defining malignancies, renal disease, liver disease and death.

A sentinel study from D:A:D was the 2007 publication noting an increased risk of myocardial infarction from certain HIV therapies including protease inhibitors. [Friis-Moller N, *N Engl J Med.* 2007 Apr 26; 356(17):1723-35]. The D:A:D Study has produced several hundred key papers and presentations since 2003 and continues to do so. Some recent publications from the D:A:D include:

- Boettiger DC, et al. [Is nelfinavir exposure associated with cancer incidence in HIV-positive individuals?](#) *AIDS.* 2016 Jun 19; 30(10):1629-37. **D:A:D Study Group.**
- Mocroft A et al. [Cumulative and current exposure to potentially nephrotoxic antiretrovirals and development of chronic kidney disease in HIV-positive individuals with normal baseline estimated GFR](#). *Lancet HIV.* 2016; 3(1):e23-32. **D:A:D Study Group.**
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# Targeted Interventions

## Reengagement in Care of People Living with HIV

**T**O BETTER GUIDE clinical activities to improve engagement and retention in care, the *International Advisory Panel on HIV Care Continuum Optimization* published guidelines for optimizing the HIV care continuum in adults.<sup>1</sup> In these guidelines, “systematic monitoring of retention in HIV care” was recommended with “proactive engagement and reengagement of patients who miss clinic appointments...”<sup>1</sup> Case management and intensive outreach were mentioned as possible interventions.

In the area of outreach and contact interventions, several methods have been successful, but there is no consensus as to which should be implemented. Due to the busy schedule of clinic staff and interventions that often are time intensive, the amount of time dedicated to these programs may be restricted by current funding limitations. Given the diversity of the HIV clinics across the country, some of the evidenced-based interventions may be more effective in some settings than others. Thus a succinct, universally applicable, and highly successful intervention is ideal.

Globally, there has been a focus on targeted interventions and strategies to improve each step in the HIV treatment cascade. Improvements in testing, linkage, and retention will improve clinical outcomes for individuals with HIV as well as decrease HIV transmission.<sup>2</sup> A recent study using mathematical modeling predicted that 61% of all new infections with HIV were transmitted from HIV patients who were not retained in care.<sup>3</sup> There are evidence-based services known to improve engagement and retention in care, including case management, mental health services, substance abuse treatment, drug assistance programs, and food, housing, and transportation assistance<sup>4</sup>.

### On the Ground

At the Medical University of South Carolina Ryan White HIV clinic, we have HRSA funding to provide care to more than 1,200 patients annually without regard to pay. Our service area is primarily in the greater Charleston area with extension into the three surrounding counties. The Ryan White clinic offers the above mentioned evidence-based services along with access to dedicated board-certified infectious disease providers, women's healthcare, and nephrology as well as multidisciplinary care with social workers, pharmacist, nurses, and support staff.

Despite these evidence-based strategies to improve retention in care having already been implemented, there are still poorly retained patients in need of intervention

and reengagement. In South Carolina, in 2012, only 53% of patients in the state were retained in care.<sup>6</sup> Studies focusing on retention in care have indicated there are a multitude of reasons for loss to follow-up and poor retention,<sup>5</sup> many of which could be addressed by available services if we could bring the patient back into care. To that end, we piloted an intervention using an outreach coordinator who was a licensed professional counselor (LPC) with experience working with people living with HIV<sup>7</sup>. Initially, we piloted a phone, letter, and home visit intervention to patients lost to care in the previous five years, but found low response rates, possibly due to out-of-date contact information and longer times since last appointment.<sup>7</sup> We suspected that outreach interventions may be more successful with patients at risk of falling out of care, with timely intervention close to the last visit to ensure we could find the patient. To target these patients, we defined “at risk of falling out of care,” as missing a clinic visit in 2015 and having intervention from the outreach coordinator. The coordinator used phone call and letter interventions to contact patients for outreach, visit reminders, and missed visits to engage and reengage patients. She recorded the amount of time used for interventions in 15-minute intervals.

The main outcomes were reengagement (having a visit in 2015) as well as retention in care (HRSA definition of two visits divided by 90 days in 2015). Of more than 1,200 patients cared for at our clinic in 2015, 61(5%) met the definition of “at-risk of falling out of care”. The mean intervention time was an hour, the median 45 minutes. Fifty patients (82%) of the patients were reengaged and 22 (36%) were retained in 2015.<sup>7</sup> As phone calls and letters are simple interventions and the mean intervention per patient was one hour, this intervention was both succinct and successful.

**Outreach interventions may be more successful with patients at risk of falling out of care, with timely intervention close to the last visit to ensure we could find the patient.**



**While there is clearly evidence for contact based interventions to reengage out-of-care patients and maintain engagement for at risk patients, retention in care remains a large problem nationally.**

## Other Experiences

Several studies have looked at interventions in patients with a recent history of missed clinic visits or those without evidence of retention in care, a population similar to our study on those at risk of falling out of care. For example, Gardner and colleagues published a randomized trial that included both newly diagnosed patients and “at risk” patients, with either missed clinic visits or gaps in care, to receive standard-of-care appointment reminders, enhanced contact (EC) with a dedicated person, or EC plus a one-hour skills session.<sup>9</sup> They demonstrated improvements in visit constancy, another measure of retention in care, for those patients with EC (56% vs 46%) but not with the additional skills session. These authors also published evidence of cost-effectiveness as the average cost per patient retained over the standard of care was \$3,834.<sup>10</sup>

Bradford and colleagues presented analysis of four programs enrolling patients at risk of falling out of care to receive navigation interventions from peers or paraprofessionals.<sup>11</sup> They demonstrated improvements in undetectable HIV viral load (35% to 53%) as well as increased attendance of two or more visits in six months (64% to 79%).<sup>11</sup>

In addition to these studies focusing specifically on those at risk for falling out of care, there is also literature that supports intervention beyond the initial at-risk period. For example, Udeagu and colleagues reported results of a loss to follow-up intervention utilizing case management to reengage patients who had fallen out of care.<sup>12</sup> They describe a city-wide effort from the public health department with a similar outreach intervention to that reported in our study. They used case-workers in a step-wise process with a phone call, letter, and home visit intervention and were able to reengage 57% of those lost to follow-up over an almost three-year period.<sup>12</sup>

The inclusion criteria for this study was absence of care over the previous nine months using a lab surrogate for care, a CD4 count or HIV viral load.<sup>12</sup> As a result of this definition 33% of the patients initially identified were currently in care. They excluded patients they were unable to contact<sup>12</sup>.

Our study had comparatively good results using an LPC with a total reengagement of 82%, with 36% retention in care in 2015—although the patients were not necessarily out of care for the same duration as that presented by Udeagu and colleagues.

Another study, reported by Giordano and colleagues, tested an intervention for peer mentoring to out-of-care patients with HIV during hospitalization which did not show an effect on retention in care and viral load outcomes.<sup>14</sup> Finally, a report from Wohl and colleagues focused on over 1100 out of care patients over an enrollment period of 32 months and found 78 were lost to care and able to be contacted for an intervention. They demonstrated interventions by trained navigators resulted in 82% retention in care following the series of extensive reengagement services and interventions.<sup>13</sup>

## National Problem

While there is clearly evidence for contact based interventions to reengage out-of-care patients and maintain engagement for at risk patients, retention in care remains a large problem nationally.

One of the key findings in the published data is that contact interventions using trained staff or peers can effectively engage or reengage patients. Moreover, early intervention and high intensity intervention may result in improvement of the ultimate outcome. As each clinical practice site may have a different approach to contact interventions for engagement in care, it is important that the information is shared with other HIV providers. We should ideally collaborate so as to provide the most cost-effective and universally acceptable interventions to our patients in this era of funding limitations and uncertainty. **HIV**

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# Older Adults

Attention must be paid!

**Maybe you didn't know.**

**Maybe you were listening but didn't really *hear* an important, but often overlooked, fact about the HIV epidemic.**

***Half of all people with HIV in New York State are over 50 years old.  
That's also the case nationally.***

**And it's estimated that number will rise to 70% by 2020.  
In addition, one in every six new HIV diagnoses in New York occurs in older adults.**

There's another important fact about people over 50: the older they get the less likely they are to be offered an HIV test. And older adults are more often likely to be diagnosed with AIDS at the same time they first find out they have HIV. This "concurrent diagnosis" highlights the lack of testing efforts targeting older adults, since people often take ten years or more to develop AIDS once they have HIV.

Unfortunately, studies also show that condom use drops significantly in people over 50, while sexual activity (and HIV and STD risk) continues into their 80s and beyond. Still, most doctors don't talk to their older adult patients about their sex lives. One reason is discomfort with the subject, and another is the myth that older adults just don't have sex.

The needs of older adults should have been an important part of New York State's Plan to End the Epidemic (ETE) by 2020. But if you look at the "Blueprint to End the Epidemic"—a document of 30 recommendations the ETE Task Force created in 2015—you won't find a single reference to older adults. In the original 44 Blueprint recommendations (distilled from over 300 community recommendations) older adults were mentioned four times, but the final document included only 30 of those recommendations, and all mention of older adults disappeared. If there's one thing we know about advocating for scarce funding, it's that if you aren't named you don't get the resources.

## Addressing the Needs of Older Adults

During the six months after the Blueprint was accepted by Governor Cuomo in April 2015, ACRIA and other community-based organizations that focus on HIV and aging got to work to change this. The NYS Department of Health AIDS

Institute responded to concerns about the impact of the epidemic on older adults. In December, they helped ACRIA establish an "Older Adults and HIV Advisory Group", to write a report on strategies that would make the Blueprint relevant to older adults. It was essential that their needs not be forgotten in the ETE planning and implementation process. Older adults would be named!

The Advisory Group started as a handful of organizations led by ACRIA, including SAGE, LiveOnNY, AARP NYS, NYS Office of the Aging, Housing Works, the NYC Department of Health, and the AIDS Institute, but quickly grew to over 70 people representing HIV, aging, faith, and community-based organizations, along with community members from across the state.

The group was divided into Core and Full groups, with Core members agreeing to do the majority of the work, to meet monthly in Albany and NYC, and to write a report within six months. The Core group made decisions by consensus, and brought in outside experts to address knowledge gaps in areas like the Delivery System Reform Incentive Program, how to work with current and former inmates, and how to address the needs of older transgender adults. Their report, *Older Adult Implementation Strategies*, was presented to the NYS AIDS Advisory Council ETE Subcommittee on August 12, and was approved by the full Council on October 7.

## Key Elements

The Report is broken down into 67 strategies specifically for older adults. Let's look at four areas where these strategies have already begun:

**Editor's Note:** This article is reprinted with permission from ACRIA's publication, *ACHIEVE*.

### Education

The report included a number of strategies to offer providers training on older adult issues such as:

- Sexual health
- Initial HIV infection
- HIV treatment and prevention
- Chronic disease self-management
- PEP and PrEP
- Use of multiple medications
- Transgender issues

Training HIV providers about aging issues, and training aging providers about HIV issues, is also key since one often doesn't know much about the other's issues. Other service providers who have been left out of the HIV and aging loop also need to be targeted for training: correctional facilities and re-entry programs, long-term care facilities, care coordination programs, senior centers, faith-based and community based organizations, and "Health Homes" providers.

**"We have to remember that older adults are not just one group, but many—including LGBT older adults, Black and Latino older adults, and older adults in their 50s to 90s. Groups with specific and different needs, whose common ground is that they are aging with HIV."**

**—Advisory Group Member**

ACRIA has provided HIV and aging education, training, technical assistance, and capacity building to NYC HIV and aging providers for the last nine years, with funding from the NYC Council. The programs help organizations through HIV treatment and prevention education, along with social media campaigns, such as the "Age Is Not a Condom" campaign, in high-risk neighborhoods. ACRIA also provides direct services to older adults through HIV testing and education.

In 2008, AARP sponsored the SAGE National Conference on LGBT Aging to send a message to the LGBT community and to show that AARP was paying attention. Since then, AARP and SAGE have worked to deepen this partnership. SAGE is providing online training to AARP State Offices on subjects including:

- Introduction to LGBT Aging
- Embracing LGBT Older Adults of Color
- Transgender Aging: What Service Providers Need (and Don't Need!) to Know Respected and Whole:
- Preventing Anti-LGBT Bias Between Constituents, Staff, and Across Aging Services
- Asking Demographic Questions about Sexual Orientation and Gender Identity

AARP publications such as *AARP Bulletin* and *AARP The Magazine* now include LGBT voices in their mix of 50+ people and stories, and their web-site features an LGBT section ([aarp.org/pride](http://aarp.org/pride)).

### Targeted Testing

Another strategy that has had success is testing and prevention tailored to the needs of older adults. SAGE currently offers case management, caregiver support, bereavement support, friendly visiting, and E-LINC, which provides comprehensive health services to LGBT individuals over 50.

Senior centers serve people age 60 and up, but the largest group of older adults with HIV are between the ages of 50 and 60. SAGE recognized this and arranged to have HIV testing in all five of its New York City centers, often through E-LINC or health fairs, offering testing in each site at least annually.

The newly revitalized SAGE Positive program coordinates all SAGE HIV-related services, including E-LINC, under one umbrella that mirrors the Governor's plan to end the AIDS epidemic. SAGE Positive relies on collaborating with community partners, including AARP, to provide its services.

In addition, the "End AIDS NY 2020 Community Coalition" has advocated for the State to change HIV testing law to address the needs of adults over age 64. After over a year of advocacy from this coalition of more than 65 organizations, New York State is finally in the process of lifting the age limits mandated for routine HIV testing, changing them from age 13 to 64, to 13 and up. The bill has been passed by both legislative houses and is currently waiting to be delivered to the governor for his signature.

### Data and Needs Assessment

A needs assessment tool is critical to create the evidence base of data to develop targeted interventions (such as getting people linked to care, on treatment, and virally suppressed) that older adults with HIV need. Recognizing this over a decade ago, ACRIA launched its seminal Research on Older Adults with HIV (ROAH) study in 2006. ROAH was the first, largest, and most comprehensive study of its kind and remains so to this day. Over a year ago, ACRIA began an update entitled ROAH 2.0. Its goal is to improve the services provided to older adults with HIV. The study directly coincides with the ETE plan and the Advisory Group's report. ROAH 2.0 plans to study three groups in New York: 500 older adults with HIV from NYC whose responses will be paired with their clinical records from Weill Cornell Medical College; 500 older adults with HIV recruited from NYC community-based organizations; and an upstate/ rural sample of 450 older adults with HIV. Given the lack of focus on upstate and rural areas, this last sample has significant importance.

ACRIA also plans to establish a long-term cohort with data collected every few years. This will enable the study to monitor participants as they age into their 70s and 80s.

ACRIA has raised funds for the first two groups, and data collection has begun. Funding for the upstate/rural sample is still pending.

### Targeted PrEP

At present little emphasis is placed on offering PrEP to older adults. The Report's introduction states five reasons to change this:

1. Half of men over 40 have erectile dysfunction, making condom use problematic.
2. Research shows that few older men or women use condoms, and use decreases with age.
3. Providers are not discussing sexual health with the majority of their older patients.
4. Older women may have difficulty negotiating condom use, which could lead to abuse. PrEP allows older women to be empowered about their sexual health.
5. HIV testing rates among adults over 50 are very low. Encouraging PrEP will increase HIV testing, since regular testing is an important part of PrEP.

The AIDS Institute ran a social marketing campaign titled "HIV Prevention Just Got Easier" in 2015 that did include older men. It targeted Black and Latino trans-women and men who have sex with men, and, significantly, two of its 13 models were older adults. These bus shelter and transit ads were also placed in Rochester, Albany, Buffalo, Hudson Valley, and Long Island—targeting high prevalence counties outside of New York City.

### Where Do We Go from Here?

How will the Older Adults and HIV Advisory Group be used, and by whom? What will happen to the Group's members now that their initial task is completed? The answers involve public health policy and the politics of advocating for scarce resources. The ultimate goal is that the report will be taken by the AIDS Institute and used as a template for ETE work with older adults throughout New York State and the U.S. From the beginning, ACRIA believed this would be an evolving process that extended into the future, and would include current and future members of the Advisory Group. ACRIA believes the Report should serve as a tool for advocacy and education, and should be distributed

**One in every six new HIV diagnoses occurs in someone over 50: 40% are White, 39% Black, and 17% Latino. 25% are women, and nearly 60% are gay and bisexual men.**

at conferences. It's essential that its recommendations lead to change and are not simply left on the shelf to gather dust. Action needs to be taken to make sure there is follow-through—to ensure that policy makers, providers, and leadership continue to listen and to hear the needs of older adults at risk for and living with HIV.

One action is the evolution of the Older Adults and HIV Advisory Group into a statewide Older Adults and HIV Coalition. This coalition could then advocate for both the implementation of the Report and the implementation of high-priority strategies.

Another strategy is to address areas outside of New York City with high HIV rates, such as Westchester, Dutchess, Nassau, Suffolk, Erie, Monroe, and Albany counties, where resources

for older adults are limited. We must also address depression and social isolation. Older adults with HIV report depressive symptoms at five times the rate of the larger community and HIV-positive older adults are often socially isolated due to stigma (homophobia, racism, AIDS-phobia, ageism, etc.). Over 70% live alone, and fewer than 20% have a spouse or partner, with many estranged from their families. Screening to identify these conditions and interventions to address them as the population continues to age is critical.

The second action—and a priority task of the new coalition—is sending the Report to HIV, aging, faith, and community-based organizations across the state and the U.S. This low-cost action will:

- Raise awareness of the needs of older adults at risk for and living with HIV.
- Educate them on strategies to address these needs.
- Develop collaborations in programs, advocacy, and applications for funding.

### Conclusion

We must remember that more than 65,000 New Yorkers with HIV are over 50. We're optimistic that the steps discussed in this article will contribute to the ETE Blueprint goal of achieving fewer than 750 new infections per year by 2020. But we are also aware that much remains to be done. The needs of older adults aging with HIV are present in the here and now. They are dealing with issues of treatment and prevention, multiple illnesses, depression and isolation, too many pills, and a sometimes lower quality of life. Any plan to end the epidemic must include their concerns. **HIV**



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