

# HIV Specialist

## Spirituality, Religion and HIV

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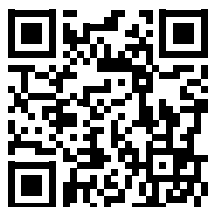
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BY JAMES M. FRIEDMAN, MHA

Executive Director, AAHIVM

## 2017: A Healthcare Rollercoaster

**T**HIS HAS BEEN A YEAR OF UPS AND DOWNS for those of us in the healthcare sector. Much of the Academy's advocacy attention this year concentrated on fighting the ACA Repeal and Replace Bill. We would celebrate each time the Bill would be defeated. I think everyone can remember that infamous final vote by Senator John McCain that ultimately killed the chances of repeal. What a great night!

However, while we were pleased the ACA Repeal and Replace Bill was ultimately defeated in the Senate, it has been substantially injured by the Administration's regulatory changes and funding shortfalls that have undercut the success of the ACA. And with the passage by the Congress of the Tax Cut and Jobs Act (still including the repeal of the ACA Mandate but without much of a tax cut for middle and lower classes) on December 20, thirteen million more Americans will be without any health insurance in the coming years.

For those Americans who are sick, poor, young or on Medicaid, 2017 was a terrible year, with a constant barrage of attacks against the programs and services established to help the most vulnerable. Just consider the healthcare news items from the first week of December:

- "While whipping votes for a GOP tax bill on Thursday, Senate Finance Committee Chairman Orrin G. Hatch (R-Utah) attacked "liberal programs" for the poor and said Congress needed to stop wasting Americans' money." *Washington Post*, December 1, 2017.
- "As the tax cut legislation passed by the Senate early Saturday hurtles toward final approval, Republicans are preparing to use the swelling deficits made worse by the package as a rationale to pursue their long-held vision: undoing the entitlements of the New Deal and Great Society, leaving government leaner and the safety net skimpier for millions of Americans." *Washington Post*, December 1, 2017.
- Nearly 9 million children are insured through CHIP (Children's Health Insurance Program), which covers mostly working-class families. The program has bipartisan support

in both the House and Senate, but Congress let federal funding for CHIP expire in September." *Kaiser Health News*, December 4, 2017.

- "House Speaker Paul D. Ryan (R-Wis.) said that congressional Republicans will aim next year to reduce spending on both federal health care and anti-poverty programs, citing the need to reduce America's deficit." *Washington Post*, December 6, 2017.

Let's hope by the time you read this there has been some improvement in these areas and the rollercoaster ride is nearly over, with all Americans exiting the perilous ride safely.

I also want to end this year on a high note! I am proud of all the accomplishments of our members and our Academy staff this year. Working together, we have achieved so much that will ultimately benefit those living with HIV. This magazine is a big part of educating providers on the frontlines about the clinical and political advances in the HIV field. This last issue of the year branches out a little by discussing the importance and health implications of religion and spirituality in the lives of HIV patients. We are honored to have our cover article written by the premier expert in this area of research, Dr. Magdalena Szaflarski, Associate Professor & Interim Director of Graduate Studies and Scientist at the Center for AIDS Research (CFAR) at the University of Alabama at Birmingham.

On behalf of myself and the entire staff of the Academy, we wish for you and your patients happy holidays and a very healthy (and hopefully less dramatic) 2018! **HIV**



James M. Friedman

*James M. Friedman*

In the **NEWS**

## FDA OKs First Two-Drug Regimen for Certain Patients with HIV

**THE U.S. FOOD AND DRUG ADMINISTRATION** on Nov. 21 approved Juluca from ViiV Healthcare, the first complete treatment regimen containing only two drugs to treat certain adults with HIV instead of three or more drugs included in standard HIV treatment.

Juluca is a fixed-dose tablet containing two previously approved drugs (dolutegravir and rilpivirine) to treat adults with HIV-1 infections whose virus is currently suppressed on a stable regimen for at least six months, with no history of treatment failure and no known substitutions associated with resistance to the individual components of Juluca.

“Limiting the number of drugs in any HIV treatment regimen can help reduce toxicity for patients,” said Debra Birnkrant, M.D., director of the Division of Antiviral Products in the FDA’s Center for Drug Evaluation and Research.

Juluca’s safety and efficacy in adults were

evaluated in two clinical trials of 1,024 participants whose virus was suppressed on their current anti-HIV drugs. Participants were randomly assigned to continue their current



anti-HIV drugs or to switch to Juluca. Results showed Juluca was effective in keeping the virus suppressed and comparable to those who continued their current anti-HIV drugs.

The most common side effects in patients taking Juluca were diarrhea and headache. Serious side effects include skin rash and allergic

reactions, liver problems and depression or mood changes. Juluca should not be given with other anti-HIV drugs and may have drug interactions with other commonly used medications.

“Even with more than 40 FDA-approved HIV medications, there remains a need for continued research into improved HIV treatment that may lead to new agents or new formulations of existing medications,” said Richard Wolitski, Ph.D., Director, HHS Office of HIV/AIDS and Infectious Disease Policy.

“This type of treatment advance provides another option that will work for those who have developed resistance to some medications, make it easier for patients to take their medications as prescribed (such as long-acting medications), have fewer side effects, or are active against hepatitis B or other infections that disproportionately affect people living with HIV,” Dr. Wolitski concluded.

## Placebo Control in HIV Vaccine Trial Helped Avoid Inaccurate Conclusion

**THE USE OF A PLACEBO CONTROL GROUP** in a double-blind trial of a potential therapeutic vaccine against HIV prevented an inaccurate conclusion that the product appeared to be working, according to lead investigator Anthony Fauci, MD, director of the National Institute of Allergy and Infectious Diseases (NIAID).

The results of the vaccine arm of the study that was published in *Science Translational Medicine* were so positive that researchers “would have assumed incorrectly,” based on historical data, that the drug had worked, Dr. Fauci said in an audio statement.

According to the study abstract, “When Sneller et al embarked on their therapeutic HIV vaccine trial, they chose to include a placebo group to get a better understanding of how their vaccine affected viral rebound upon therapy interruption. The vaccine itself generated minimal T cell activation and did not induce protective responses. Somewhat surprisingly, a proportion of individuals

in the placebo arm demonstrated sustained viral suppression, although they were no longer being treated. These results suggest that any future HIV intervention trials would benefit from the inclusion of a placebo arm.”

The study observed that a single-arm study of a candidate therapeutic vaccine combined with the histone deacetylase inhibitor romidepsin showed that 38% of HIV-positive volunteers were able to control their virus for a median of 14 weeks without ART. Compared with historical data, that suggested at least some efficacy for the combination.

However, Fauci’s group said that in their trial, 40% of the placebo patients would have met the same benchmark for viral control, almost identical to the other study, but with no intervention at all.

The study is available at <http://stm.sciencemag.org/content/9/419/eaan8848>.



# In the NEWS

## Philanthropic Funding for HIV/AIDS Sets Record, but Concerns Remain

**FUNDERS CONCERNED ABOUT AIDS (FCAA)** released its *15th annual Philanthropic Support to Address HIV/AIDS* report Dec. 7 showing that HIV/AIDS philanthropic disbursements increased 2% in 2016, representing the third consecutive year of growth and reaching an all-time high of \$680 million.

However, in an environment increasingly inhospitable to global health and development, the organization said the findings showed that the majority of funding still comes from a few major donors, while other contributions decreased significantly.

This year's uptick was driven by significant increases from several of the top 20 funders—primarily ViiV Healthcare, Aidsfonds, and Elton John AIDS Foundation (US and UK)—and carried by a \$41 million increase from the Bill and Melinda Gates Foundation.

“Once again, the majority of philanthropic resources allocated to fighting the epidemic is concentrated among a handful of donors,” said FCAA's Executive Director, John Barnes. “The top 20 funders accounted for 87% of 2016 resources. In fact, without the two largest funders—Gates

Foundation and Gilead Sciences, which, together, represent over half of all funding in 2016—total giving to HIV/AIDS among all other private funders decreased 5% “

Key findings from the 2016 report include:

- For the third year in a row, HIV/AIDS philanthropic funding to the US reached a new high, totaling \$175 million
- Funding to low- and middle-income countries increased by 11% from 2015 to 2016
- The top regional recipient outside of North America was East & Southern Africa
- The top intended use for funding was research (which, at \$249 million, increased 13% from 2015) followed by prevention (a 26% increase at \$169 million)
- Commitments to advocacy and human rights increased by 1%, bringing the total level of resources allocated to this critical issue to a new high of \$125 million
- Funding for all key populations decreased from 2015 to 2016

## Few PLWH Get Prompt Care after Incarceration

**HIV IS MORE COMMON** among individuals in the criminal justice system than among people in the community, but just a fraction of people with HIV in prison or jail receive prompt care after release, say Yale researchers. In a new study published in *The Lancet HIV*, the researchers identified factors that might improve post-release HIV care and outcomes.

While incarcerated, people with HIV can receive treatment for HIV and other conditions such as substance use and psychiatric disorders. Yet, that care is often disrupted upon release.

In this study, the research team focused on people living with HIV who

were released from jails and prisons in Connecticut between 2007 and 2014. By combining comprehensive databases from the state's Departments of Corrections and Public Health, the researchers examined how long it took from the time of release until an individual “linked” to HIV care in the community. They also assessed individuals' viral suppression, which is a measure of optimal HIV treatment.

The researchers found that only one-third of individuals had linked to care within 30 days of release. “The majority of people are not being linked to care quickly enough to avoid disruption of care,” said first author Kelsey Loeliger, an

M.D./Ph.D. candidate at Yale's School of Public Health.

Importantly, he noted, certain potentially modifiable factors were associated with more timely linkage to care. Individuals who received HIV medications and case management in prison were more likely to get care within 14 days after release. People who had medical conditions other than HIV were also more likely to link to care within 14 days following release.

These findings point to the need for more case management and integrated care to effectively treat people with HIV both in and out of prison, the researchers note.

# Gilead Announces \$100 Million Commitment to Address HIV/AIDS in Southern U.S.

**GILEAD SCIENCES, INC.** on Dec. 7 announced the launch of the Gilead COMPASS (COMmitment to Partnership in Addressing HIV/AIDS in Southern States) Initiative, a 10-year, \$100 million initiative to support organizations working to address the HIV/AIDS epidemic in the Southern United States.

Gilead will partner with three coordinating centers to lead the corporate giving program of the initiative: Emory University Rollins School of Public Health, the University of Houston Graduate College of Social Work and the Southern AIDS Coalition. These centers will identify and provide funding to local organizations that are committed to addressing the epidemic throughout the region, focusing on capacity building and shared knowledge; wellbeing, mental health and trauma-informed care; and awareness, education and anti-stigma campaigns.

“HIV/AIDS remains an urgent public health crisis in the United States and this is particularly apparent in the Southern states where rates of new infection rival those seen in the 1980s. In some communities, those rates are actually rising—a chilling reminder that the epidemic is far from a thing of the past,” said Gregg Alton, Executive Vice President, Corporate and Medical Affairs, Gilead Sciences.

According to the Centers for Disease Control and Prevention (CDC), the Southern U.S. accounts for approximately 45% of all people living with HIV in the nation, despite having only one third of the population. Nearly half of all people dying from HIV/AIDS in the United States live in a Southern state.

HIV disproportionately affects Latinos; transgender women; Black women; and Black gay and bisexual men, in part due to stigma, poverty, lack of access to healthcare and racial inequality.<sup>[iv]</sup> Of all Black gay and bisexual men who were diagnosed with HIV in the United States in 2014, more than 60 percent live in a Southern state.

“Limited access to healthcare and information about life-saving advances in HIV treatment and prevention in the most vulnerable communities creates an environment where we, as a society, have the tools in hand to improve lives, but these resources are not being fully utilized to address the epidemic,” said Dr. Charlene Flash, Assistant Professor of Medicine, Division of Infectious Diseases, Baylor College of Medicine. “We must take action and apply these resources to overcome this challenge as too many

vulnerable people in the South cannot access, or worse still, are unaware of the existing life-saving tools to prevent and treat HIV.”

The Gilead initiative has a threefold mission: to build capacity and increase knowledge sharing among organizations in Southern states; to explore interventions that appropriately respond to patients’ needs, including the bundling or reframing of mental health care, as well as the intersection between substance use, the opioid epidemic and HIV/AIDS; and to fund awareness and anti-stigma campaigns. Through this initiative, Gilead plans to dramatically increase the reach of these organizations working to address the epidemic in the region, and ultimately to improve the lives of those affected by HIV/AIDS.



## Three-Year Average Gap Between HIV Transmission and Diagnosis—CDC

**THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)**, in an analysis just out, estimates that in 2015 the median time between HIV acquisition and diagnosis was approximately three years, and that 15% of people living with HIV are unaware that they carry the virus.

That estimate compares to the CDC’s previous estimate that HIV-positive people, unaware of their status, account for 40% of HIV transmissions in the United States.

The new study sought to estimate the period

of delay between HIV transmission and diagnosis. The CDC team used data from the National HIV Surveillance System through June 2017 to estimate the total number of people living with HIV at the end of 2015 and the median number of years between infection and diagnosis among people diagnosed in 2015.

They calculated the number of undiagnosed HIV infections by subtracting reported cumulative diagnoses from estimated cumulative infections. Using data from the National HIV

Behavioral Surveillance (NHBS), they calculated percentages of people at increased risk for HIV who were tested in the past 12 months and percentages with a health care visit in that period who missed opportunities for testing.

Among 1,122,900 people living with HIV in the United States in 2015, an estimated 162,500 (14.5%) did not know they had the virus. The South accounted for half of undiagnosed HIV infections (50.5%). Among 39,720 people diagnosed with HIV in 2015, more than one in five (21.6%) had AIDS.

# In the NEWS

## HIV Prevention Trials Hold Promise for New Options for Women

**TWO NEW EFFICACY TRIALS** officially launched in Africa Nov. 30 with the potential of additional HIV prevention methods in the future.

The two trials—one studying a new vaccine strategy from Janssen/Johnson & Johnson that could protect against multiple strains of HIV and the other with an injectable antiretroviral PrEP strategy every two months from ViiV/GSK—join five other efficacy trials that are hoped to expand the options available to meet the varied needs women and men have for HIV prevention over the course of their lives.

“It is unprecedented to have so much diverse activity in the field, with nearly 25,000 trial participants to be enrolled across all of these trials around the world,” said Mitchell Warren, executive director of AVAC, a global HIV prevention organization. “Equally unprecedented is the level of pharmaceutical engagement within these trial partnerships. While both of these new trials are jointly funded by the U.S. National Institutes of Health and the Bill & Melinda Gates Foundation, the two product developers are active financial partners,” said Warren. “We hope that the

examples of ViiV and Janssen will prompt additional and sustainable industrial partnerships in HIV prevention research.”

“These new trials come at one of the most dynamic times for HIV prevention. There are more trials of new concepts; more programs beginning to deliver daily oral PrEP; a vaginal ring going through regulatory review; record numbers of people on HIV treatment; new guidelines reflecting the scientific evidence behind undetectable = untransmittable; and real-world evidence from Uganda that scaling up treatment and voluntary medical male circumcision can reduce new HIV infection at a population level,” said Warren.

“Both new trials could pave the way for valuable new long-acting prevention options—in addition to, not instead of, the interventions we have today. Now is the time to structure research agendas and networks, oral PrEP programs and comprehensive approaches to HIV prevention in such a way that they lay the groundwork for strategies like those being tested in these trials,” Warren said.

## National Comprehensive Cancer Network Introduces New Guidelines for Patients with Cancer Associated with HIV, AIDS

**THE NATIONAL COMPREHENSIVE CANCER NETWORK® (NCCN)** has created a new resource for patients living with HIV who develop AIDS-related Kaposi sarcoma. Additional NCCN Guidelines, devoted to overall cancer care for people living with HIV, will be released in early 2018.

“These new NCCN Guidelines for AIDS-Related Kaposi Sarcoma are a first step to ensuring that people living with HIV receive appropriate and equitable cancer treatment,” said Gita Suneja, MD, Duke Cancer Institute. Dr. Suneja is Co-Chair of the NCCN Guidelines Panel for AIDS-Related Kaposi Sarcoma.

The Guidelines Panel is comprised of experts from NCCN Member Institutions across the United States, including oncologists, HIV specialists, pharmacists, and patient advocates.

The incidence of AIDS-related Kaposi sarcoma in people living with HIV has fallen

dramatically in the United States in recent years thanks to advancements in HIV treatments. The disease can be limited to skin lesions, which tend to respond well to treatment, but when more advanced it can be difficult to treat. There are also other types of Kaposi sarcoma that affect HIV-negative individuals; treatment recommendations for those cancers will be included in future updates of these guidelines.

NCCN Guidelines Panel Co-Chair Erin Reid, MD, of UC San Diego Moores Cancer Center explained: “The NCCN Guidelines for

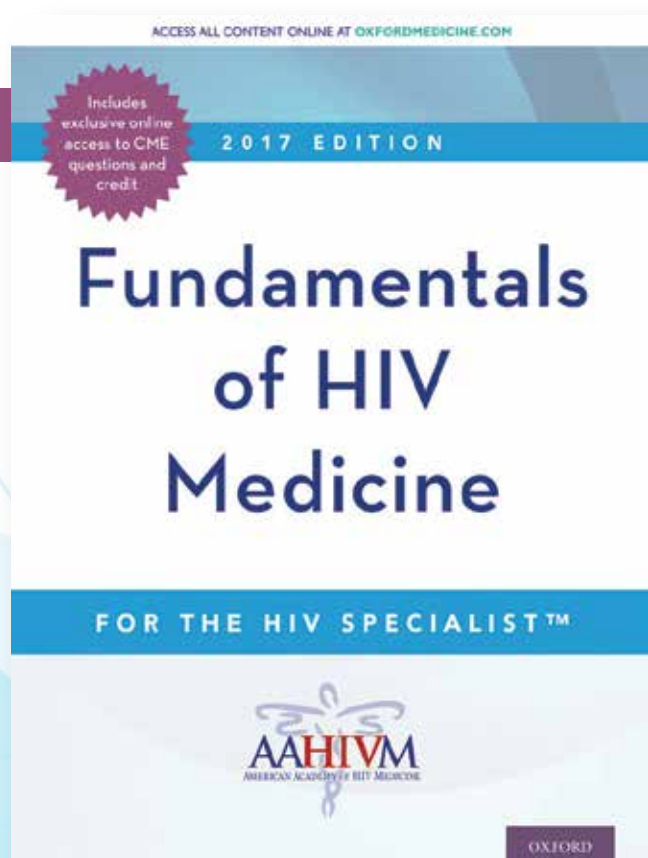
AIDS-Related Kaposi Sarcoma fill an important gap in guidance for care of this rare but important malignancy. Although incidences have decreased, the disease remains one of the most common cancers occurring in persons living with HIV—not only in patients with newly diagnosed HIV infection or inadequate suppression of HIV, but also in people who otherwise appear to have maximum viral suppression and ‘normal’ CD4+ T cell counts.”

As with all NCCN Guidelines, the NCCN Guidelines for AIDS-Related Kaposi Sarcoma are available free of charge for non-commercial use online at [NCCN.org](http://NCCN.org). They can also be viewed via the Virtual Library of NCCN Guidelines mobile app for smartphones and tablets.



# Fundamentals of HIV Medicine

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



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# HIV & Prostate Cancer

## HIV Clinic's PSA Tests Detect Alarming High Rates

**M**ALIGNANCIES are a leading cause of death for patients living with HIV (PLWH)<sup>1</sup>, and while prostate cancer remains the most common cancer among men in the United States<sup>2</sup>, few studies have examined the rate of prostate cancer among PLWH. The aim of this study is to determine the prevalence of prostate cancer among (PLWH) in a county hospital out-patient population.

Beginning with an index case of prostate cancer that was detected by sporadic prostate-specific antigen (PSA) screening, we performed a prospective cohort study from November 2014 through December 2016. We followed Prostate Specific Antigen (PSA) levels and prostate biopsies of African-American (AA) men >45 years of age and non-AA men >50 years. Patients were receiving care at an outpatient HIV primary care county clinic in Oakland, California. Screening was done at the discretion of the provider. One patient with a known history of prostate cancer was excluded from the study.

### Results

During the study period, 112 men (67 AA, 21 Hispanic, 18 Caucasian, 6 Asian) received routine PSA screening. Of these patients, six (5.4%)

had PSA values > 5 ng/ml and all underwent prostatic biopsy. Prostate cancer was found in five of these patients (4.5%), most of whom had advanced disease (Table 1). All patients with prostate cancer had a history of long-term HIV virologic control. Mean age of prostate cancer patients was 62.2 years vs. non-prostate cancer patients (55.8 years) ( $p=0.011$ ). Mean years of living with HIV in prostate cancer patients was 17.4 vs. non-prostate cancer patients (13.9) ( $p=0.163$ ). Rates of prostate cancer were equal (4.5%) for both AA men (3/67) and non-AA men (2/45).

### Conclusions

Routine PSA screening is controversial and not recommended by most major medical organizations including the U.S. Preventive Services Task Force<sup>3</sup>. Other prospective cohort studies of PSA screening in PLWH

**Table 1. HIV-positive patients with prostate cancer detected by prostate-specific antigen (PSA) routine screening.**

Patient	Age at diagnosis	Race	Years with HIV	PSA* (ng/ml)	Abnormal digital rectal exam	Biopsy Gleason score	Risk Factors	Treatment	Surgical pathology	Follow-up
1	64	African-American	24	8.7 (18.9, 14)	yes	3+4	African-American, family history	radical prostatectomy	pT3bN1M0, GS 3+5	on androgen deprivation therapy with undetectable PSA 14 months post-op
2	59	African-American	7	7.6 (6.9, 6.2, 7.2, 9.2, 6.9)	no	3+4	African-American	radical prostatectomy	pT2cN0M0, GS 3+4	undetectable PSA 6 months post-op
3	69	African-American	18	13	yes	3+4	African-American	Radiation	-	PSA 2.2 14 months post-radiation
4	58	Caucasian	19	7.6 (10.1)	no	4+3	None	radical prostatectomy	pT2bN0M0, GS 4+3	undetectable PSA 4 months post-op, transferred care
5	61	Caucasian	19	9.9 (7.0)	yes	3+3	None	transferred care	-	transferred care

\* Initial abnormal PSA screening value followed by (subsequent PSA values prior to biopsy)

have demonstrated mixed results, including in some cohorts a lower incidence of prostate cancer.<sup>4,5,6</sup> Compared to the general population (1/1000 non-AA and 1.7/1000 AA per year), men in our cohort had a 12 times (AA) and 21 times (non-AA) increased risk of prostate cancer. As expected, older age was a significant risk factor for prostate cancer and four of five prostate cancer patients had lived with HIV for 18 or more years.

All prostate cancer patients in our study had aggressive tumors (Table 1). One patient (#5) had a Gleason score of 6 with all biopsy specimens positive for cancer. Three patients (#2, 3, 4) had Gleason scores of 7, and one patient (#1) had Gleason scores 7 and 8 on screening and surgical biopsy, respectively, and was found to have metastasis to a lymph node. None of these patients met the criteria for “watch and wait” or “active surveillance” monitoring that may be applied to a sub-group of HIV-negative men with low-grade prostate cancer. Moreover, the aggressive disease seen in our patients suggests that observation only may not be an appropriate strategy in HIV patients.

With the advent of antiretroviral medications, PLWH are living longer and 45% of this population are now over 50 years old. Since advancing age is a significant risk factor for prostate cancer, re-evaluating the utility of routine PSA screening of this cohort should be considered. Additionally, at least one study found that HIV patients with prostate cancer present with more advanced disease and have increased mortality compared to their HIV negative counterparts.<sup>7</sup> Early detection of prostate cancer could improve outcomes in PLWH. Lastly, PSA screening in our study was highly sensitive, with a false-positive rate of <1%.

Given the results in this study we suggest implementing routine PSA screening in HIV patients age > 50 (non-AA) and age >45 (AA). Furthermore, clinicians should consider screening younger patients if they have additional risk factors for prostate cancer.

## Addendum

One additional patient, a 43-year old AA male with a family history of prostate cancer was screened in the post-study period (PSA 4.4 and 4.8 ng/ml) and was found to have prostate cancer. Gleason score was 6 and all specimens were positive for cancer. Radical prostatectomy was recommended, and treatment is pending.

**HIV**



### ABOUT THE PRIMARY AUTHORS:

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# Spirituality, Religion and HIV

BY MAGDALENA SZAFLARSKI, PH.D.

## *Why We Care, What We Know, and How We Are Addressing It*

**S**PIRITUALITY AND RELIGION are important to many people living with HIV (PLWH). Health professionals across the different fields—medicine, nursing, social work, and public health—have already identified the need for, but often struggled with finding, appropriate spiritual and faith-based HIV interventions.

The nature of interventions remains unclear, partly because they are not universally accepted or supported, and partly because the relationship between spirituality/religion and HIV-related outcomes is not well understood. This article defines the concepts of religion and spirituality; describes the scientific evidence regarding the role of spirituality and religion in HIV; and, discusses HIV prevention and care approaches that incorporate spirituality and religion, as a way to curb infections and improve outcomes in PLWH.



## Definitions

Religion and spirituality are distinct but overlapping concepts<sup>1,2</sup>. *Religion* is often defined as a belief in the Sacred, the Divine, God, or Higher Power, as well as practices and institutional arrangements (organized religion, religious institutions) that are involved in the expression of that belief.

Beliefs and trust in a higher power are also referred to as *faith*. Religion is typically grounded in a set of scriptures or teachings that provide the meaning to the world and a moral code that guides followers' behaviors. To be religious means to have faith, engage in religious practices (e.g., church attendance, prayer/meditation), and rely on religion in one's life.

While religion is the formal, institutional, and outward expression of belief in a higher power, *spirituality* denotes the internal, personal, and emotional side of the sacred. Spirituality was traditionally understood as a religious form (going back to early or "elementary" religions<sup>3</sup>). However, contemporary definitions of spirituality extend beyond and often have little to do with religion<sup>1</sup>.

Spirituality has been defined as meaning and purpose in life, inner peace and comfort, connection with others, social support (received or given), feelings of love or happiness, and so on. This definition of spirituality works well in clinical settings because some patients are spiritual but non-religious, and sometimes they do not distinguish between "religious" and "spiritual."

## Evidence

There is a growing body of scientific research examining spirituality/religion in relation to HIV<sup>4</sup>. Several distinct themes are noted in this literature: (1) meaning and impact of spirituality/religion in PLWH; (2) associations between spirituality/religion and HIV-related outcomes; (3) assessment of spirituality/religion in PLWH; and, (4) design and efficacy of spiritual and faith-based interventions to improve HIV prevention, care, and health outcomes.

For example, some studies based on qualitative interview or narrative data have explored the meaning and impact of spirituality/religion in PLWH and at-risk populations, in particular men who have sex with men (MSM), racial/ethnic minorities, women, youth, and people living in the areas of expanding HIV epidemics (e.g., the South/Southeast).

In one study<sup>5</sup>, young black MSM living in the deep South implicated religious doctrine, churches, and faith leaders as significant sources of homophobia and discrimination toward gays. This view was expressed despite their high religiosity and religious involvement. Some of these men accepted the doctrinal rejection of homosexuality and internally struggled to explain their lifestyles within a religious framework. Religious or spiritual struggles are often noted among PLWH who are trying to understand their HIV status in the context of their religious faith.

In another study<sup>6</sup>, HIV-positive African American women discussed the importance of faith and religious affiliation in their lives. The women described their spirituality as a journey or connection to God, spiritual expression of their faith (e.g., church attendance), and spiritual benefits, such as healing and support.

Notably, the women reported that HIV brought them closer to God, a finding corroborated in other studies<sup>7-9</sup>. In general, qualitative research has shown that spirituality/religion is a significant source of support as well as stress among PLWH<sup>10,11</sup>, and it is a barrier to or facilitator of HIV prevention, diagnosis, and treatment<sup>12,13</sup>. PLWH also rely on their faith as a way to cope<sup>12,14</sup> and find meaning and peace toward end of life<sup>15</sup>.

In addition to qualitative reports, quantitative studies have examined the importance of spirituality/religion to PLWH and mechanisms linking spirituality/religion and HIV patient outcomes. These studies have used standardized assessments (e.g., scales) of spirituality/religion and other psychosocial correlates of HIV outcomes, such as coping or stigma. In quantitative research, strong associations have been found between spirituality/religion and will to live among PLWH<sup>16</sup> and feeling that "life is better" post- compared with pre-HIV diagnosis<sup>2</sup>.

Further research has clarified that spirituality shapes the view of HIV as a positive or negative turning point in one's life<sup>17</sup>. The results of this research show that PLWH who experienced increased spirituality after HIV diagnosis perceived their infection as the most positive turning point in life, while those who experienced declines in spirituality saw HIV as the most negative turning point in their lives. A subsequent study demonstrated that a positive view of God predicted slower, while a negative view of God predicted faster, HIV disease progression.

Other quantitative research considered spiritual peace as a coping resource that might buffer the negative effects of stress and HIV-related stigma on mental well-being<sup>18</sup>. The results showed that spiritual peace and pro-active coping predicted lower, while HIV stigma predicted greater, likelihood of severe depressive symptoms. In addition, at high levels of stigma, persons reporting high spiritual peace were less likely than those reporting low peace to have severe depressive symptoms. These findings suggest that spiritual peace-based interventions might benefit PLWH.

Some research also has considered the role of spirituality/religion in successful aging<sup>19,20</sup>. Although levels of spirituality/religiosity did not vary significantly by age and HIV status, spirituality/religion in the HIV-positive group was associated with larger social networks, better mood, higher self-reported health, and fewer medical problems. Additional research showed that spirituality and positive reframing predicted better psychological

adaptation than reliance on social support among HIV-positive women<sup>21</sup>.

Spirituality/religion has also been studied in the context of HIV treatment. While higher spirituality has been found to be associated with returning to HIV care in US settings<sup>22</sup>, in some non-Western regions, spirituality has shown associations with concurrent use of alternative therapies and less adherence to antiretroviral treatments<sup>23</sup>.

Measurement of spirituality/religion has been challenging. Spirituality/religion is a multidimensional concept, which is not easy to assess. Global and disease- and population-specific measures have been advocated. There are several studies and review articles that help to validate and/or clarify the existing spirituality/religion measures for use in HIV populations<sup>2,24,25</sup>. The dimensions of spirituality/religion that have been shown salient in PLWH include: meaning and peace, tangible connection to the Divine, positive religious coping, love and appreciation, negative religious coping, positive congregational support, negative congregational support, and cultural practices.

## Interventions

Considering the important role of spirituality/religion among PLWH and its strong links to HIV outcomes, two types of interventions have emerged to enhance HIV prevention, care, and outcomes. First, there have been calls for incorporating spirituality/religion into the management of HIV disease as a way of coping to improve physical and mental outcomes of PLWH. Another body of work has focused on engaging faith communities in HIV prevention and care to improve both individual and population-level outcomes.

The literature describing spiritual interventions among PLWH is limited. One reason for this has been mixed support for conducting spiritual assessments and providing spiritual care in healthcare settings. The existing studies tend to be small, targeted clinical trials.

For example, in one study, patients shared personal and communal views of spirituality as a way to connect with the self, nature, and God<sup>26</sup>. However, the study found only limited support for the cause-effect relationship of spiritual intervention to participants' well-being. Another,





***Medical centers and public health agencies have begun partnering with black churches to reduce HIV stigma, offer HIV education and testing, and encourage counseling and support<sup>28-30</sup>.***

mantram-based program was shown to help participants to increase calm and peace, adjust behaviors, manage symptoms, and enhance social relationships<sup>27</sup>. However, there were no differences between the intervention and control groups in decreases in anxiety and perceived stress in this program. Despite limited evidence, spiritual interventions are believed to be beneficial in certain populations and settings, especially in children receiving palliative care. Further work is under way to develop and test such interventions.

The second type of interventions are partnerships that engage faith communities in HIV prevention and care. Survey research indicates that over 10,000 US congregations have PLWH, and congregations located in high HIV-risk areas are more likely to have PLWH<sup>28</sup>. Religious and faith-based organizations, in particular black churches, are uniquely suited to address HIV-related needs of their communities.

PLWH often rely on congregations for spiritual and social support, but congregations have not always responded to or welcomed PLWH. On the one hand, religious organizations were the first ones to care for people dying of AIDS. On the other hand, stigma of HIV is pervasive in faith communities, especially in conservative black churches, and it hampers HIV prevention and care.

Black churches have played a central role in the social life of African American communities and in advancing

social justice goals. With the HIV epidemic concentrated in African American communities, strong efforts are needed to engage relevant community stakeholders. Medical centers and public health agencies have begun partnering with black churches to reduce HIV stigma, offer HIV education and testing, and encourage counseling and support<sup>28-30</sup>.

Even though black Protestant congregations are more likely than other types of congregations to offer HIV programming, the majority of them, have no HIV programs<sup>31</sup>. Furthermore, research indicates diverse views on HIV and PLWH across U.S. congregations.

Studies have found HIV-related attitudes in congregations ranging from highly judgmental and exclusionary to accepting<sup>32</sup>, again indicating faith communities' mixed responses to HIV. Stigma has been closely linked with the level of congregational engagement in HIV work, with low-activity congregations being more likely to view homosexuality as a sin and promoting sexual abstinence before marriage, medium-activity congregations shifting to understanding and acceptance, and high-activity congregations more fully engaging in advocacy and stigma reduction on behalf of PLWH. However, stigma has also been reported in high-activity congregations<sup>32</sup>.

One approach to reduce stigma in faith communities is to educate faith leaders and engage them in the development of community interventions. Researchers in Philadelphia worked with faith leaders to discuss HIV stigma and design a strategy to address HIV prevention and care using a faith-based approach<sup>33</sup>.

The proposed plan of action included the following recommendations from faith leaders: enhancing leadership and advocacy efforts; normalizing HIV testing and sexuality-related discussions in congregations to reduce stigma;

tailoring programs to individual congregations/denominations; and encouraging, interfaith collaborations. Similar collaborative frameworks have been proposed based on pilot programs in different parts of the country<sup>24,29,30,33</sup>. However, systematic evidence about the effectiveness of faith-community engaged interventions remains limited.

## Future Directions

Research clearly shows that spirituality and religion play a multi-faceted role in HIV, and that spiritual and faith-based interventions can be beneficial at the individual and population level. However, there are still gaps in the literature and frameworks for interventions.

First, the knowledge is spread across disciplines, and its tightening is recommended through state-of-the-art evidence reviews.

Second, certain populations (e.g., bisexual men and transgenders) have been largely absent in the current research. Further systematic assessment of these populations' issues related to spirituality/religion is recommended.

Third, use of advanced methods, such as randomized controlled trials (RCTs) in intervention studies, and longitudinal and multilevel studies, would strengthen the knowledge of the social and

individual-level impacts of spirituality/religion on PLWH.

Fourth, any studies and interventions should be developed by engaging various community stakeholders.

Finally, clinical and policy implications of spirituality/religion-based approaches in different settings deserve further attention (how to afford and finance such interventions; what works/what doesn't; compare programs and outcomes across settings and populations; etc.).

HIV



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# PrEP Update

## What the Latest Studies for HIV Prevention Have Found

BY PHILIP BOLDUC, MD, AAHIVS

This article is reprinted from the October issue of *HIV Specialist* in order to give greater context to the new PrEP articles that appear in the pages to follow.

**H**IV PRE-EXPOSURE PROPHYLAXIS (PREP) with tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) was first approved by the Federal Drug Administration (FDA) in 2012 for “at risk” sexually active adults. Soon after, additional guidelines for heterosexual men and women and injection drug users were issued. In 2014, the Centers for Disease Control (CDC) issued the first practice guideline on PrEP.<sup>1</sup> This intervention has become a critical component of HIV prevention over the past three years. This article covers some recent highlights from the recent PrEP literature and studies presented at the 9th IAS Conference on HIV Science held this past summer in Paris.

### Potent Prevention: PrEP and HIV Treatment

Tenofovir disoproxil fumarate / emtricitabine (TDF/FTC) used for PrEP has consistently been shown to be a safe and highly effective prevention tool. Early PrEP trials that had poor results, especially with women, were marked by poor adherence. With consistent medication adherence, protection from HIV ranged from 74-92% in the Bangkok, Partners, and IPrEx PrEP trials. Two recent studies, including an observational cohort from Kaiser Permanente California, showed no PrEP failures and the PROUD study among high-risk MSM in London found an 86% HIV infection risk reduction that actually lead to early study termination.<sup>2,3</sup> Treatment of HIV with ART has also been shown to be a powerful tool to prevent viral transmission as seen with the HPTN 052 study. This international study found no linked HIV transmissions after six months of viral suppression.<sup>4</sup> More recently the “Opposites Attract” cohort study presented at the IAS meeting, found no HIV transmissions among 16,889 acts

of condomless anal intercourse when the HIV+ partner was virally suppressed.<sup>5</sup>

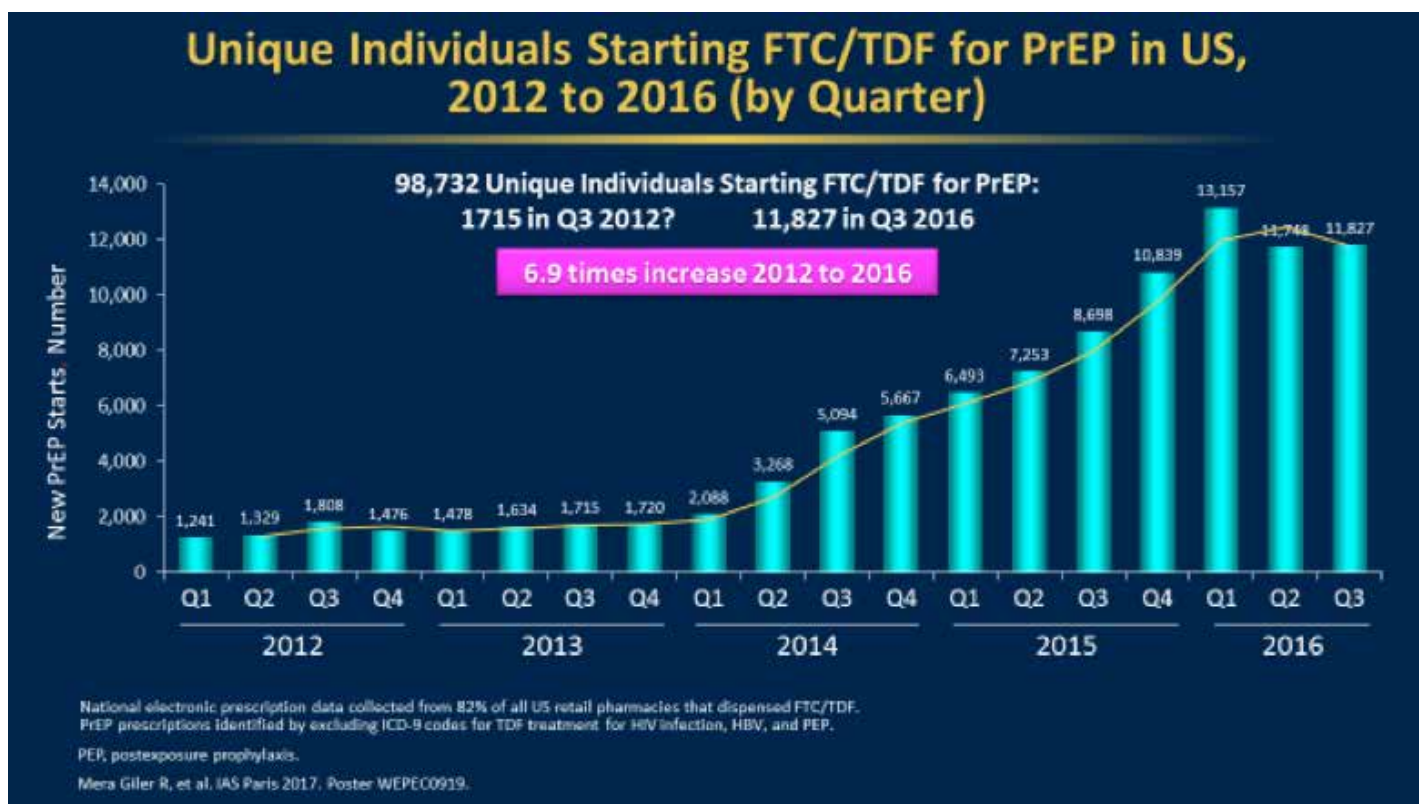
The 2014 PrEP guidelines currently recommend PrEP for the uninfected member of an HIV serodiscordant couple without mention if the HIV+ person is fully suppressed on ART.<sup>1</sup> In light of new data, PrEP for the uninfected partner should be an individualized decision based on the reliability of both the viral suppression in the HIV-infected person and the degree of monogamy of the couple.

### PrEP Uptake and Cost-Effectiveness

The cost-effectiveness of PrEP has been questioned since its FDA approval. This remains a complex issue and is dependent on many factors including variable drug pricing, HIV testing and linkage to care rates, and, most importantly, local HIV prevalence and individual risk behavior. The CDC has recommended PrEP for at-risk individuals since its approval without regard to cost. A study from the CDC (see Table 1) found that approximately 1.2 million adults



FIGURE 1



in the U.S. should be considered for PrEP based on risk.<sup>6</sup> However, as of the 3rd quarter of 2016, only 96,782 individuals in the U.S. had been started on PrEP in nearly four years, or roughly 7.9% of eligible persons (See Figure 1).<sup>7</sup>

While PrEP uptake in 2012 and 2013 was quite slow, steady increases in 2014-2015 were followed by a concerning and unexplained downturn in the 2nd and 3rd quarters of 2016. To whatever extent the cost of PrEP has been a concern for some clinicians, the June 2017 FDA approval of generic TDF/FTC should reduce the cost of PrEP, although no generic product is currently available. The number needed to treat (NNT) with PrEP to avoid one HIV infection, estimated at 10-70 depending on risk level per Elion.<sup>8</sup> This is quite favorable compared to other common medical interventions, such as an NNT of 104 for statins for primary prevention of heart disease. Therefore, even at current pricing, with a low NNT and the additional \$229,800 lifetime cost of an HIV diagnosis, PrEP is likely to be cost-effective when prescribed for at-risk individuals.<sup>9</sup>

### Finding Patients at Risk for HIV

To identify at-risk patients, clinicians must obtain a comprehensive, non-judgmental sexual history. "Don't ask, won't know" is a cautionary reminder that we need to ask, and keep asking, our patients about their sexual and substance use behaviors in order to identify those patients

who would benefit from PrEP (see Table 1).

While all patients should be asked at every visit, clinicians also need to be aware of who is at the highest risk of HIV infection. White and minority MSM together account for 66% of new HIV diagnoses despite being only 2% of the population. U.S. Latinos (24%) and especially Blacks (44%) are markedly disproportionately represented among new HIV diagnoses compared to their percentage of the US population (17% and 14%, respectively).<sup>10</sup> Finally, HIV incidence in the U.S. has risen dramatically and is highest in the Southeastern US. Taken together, the highest-risk individuals are southern black MSM. The CDC estimates that at current rates, 50% of all black gay and bisexual men living today will become HIV-infected in their lifetime. For a moving look at the particularly vulnerable population emblematic of these epidemiologic trends in the U.S, see the June 6, 2017 *NY Times Sunday Magazine* article by Linda Villarosa, America's Hidden H.I.V. Epidemic, at <https://www.nytimes.com/2017/06/06/magazine/americas-hidden-hiv-epidemic.html?mcubz=0>.

This leads us to reflect on whether the benefits of PrEP have reached the highest-risk patients. Whites comprised 73% of PrEP usage in 2016 but only 26% of new HIV infections in 2015. Latinos and Blacks lagged far behind with PrEP usage (13% and 10% of PrEP prescriptions, respectively) compared to their share of new HIV infections.<sup>7</sup> The flipped ratio of risk to PrEP uptake must be addressed by identifying and promoting

TABLE 1

	MSM	Heterosexual Women and Men	IDU
<b>Consider for HIV-negative people at substantial risk for acquiring HIV infection</b>	<ul style="list-style-type: none"> <li>■ HIV-positive sexual partner</li> <li>■ Recent bacterial STI</li> <li>■ High number of sex partners</li> <li>■ Inconsistent or no condom use</li> <li>■ Commercial sex work</li> <li>■ High-prevalence area or network</li> </ul>		<ul style="list-style-type: none"> <li>■ HIV-positive sexual partner</li> <li>■ Sharing infection equipment</li> <li>■ Recent drug treatment (but currently injecting)</li> </ul>
<b>Clinically eligible</b>	<ul style="list-style-type: none"> <li>■ Documented negative HIV test result before prescribing PrEP</li> <li>■ No signs/symptoms of acute HIV infection</li> <li>■ Creatinine clearance &gt;60 mL/min; no contraindicated medications</li> <li>■ HBV status known and, if appropriate, vaccination given</li> </ul>		
<b>Regimens preferred</b>	<ul style="list-style-type: none"> <li>■ Emtricitabine/tenofovir DF (200/300 mg) qd</li> <li>■ Daily, continuing, oral dose ≤90-day supply</li> </ul>		
<b>Alternative</b>	None	<ul style="list-style-type: none"> <li>■ Tenofovir DF (300 mg) qd</li> <li>■ Daily, continuing, oral dose ≤90-day supply</li> </ul>	

TABLE 2

	MSM	Heterosexual Women and Men	IDU
<b>Specific tests</b>	Oral/rectal gonorrhea and chlamydia NAAT, and syphilis serology	<ul style="list-style-type: none"> <li>■ Assess pregnancy intent</li> <li>■ Pregnancy test every 3 months</li> </ul>	Access to clean needles/syringes and drug treatment services
<b>Other services every 3 months</b>	HIV antibody test <sup>a</sup> , medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment		
<b>At 3 months and every 6 months thereafter</b>		Assess renal function	
<b>Every 6 months</b>		Test for bacterial STIs	

PrEP more effectively in persons at the highest risk of becoming infected with HIV.

In considering hard-to-reach patients, it is also worth noting the reasons for not using PrEP. In a national on-line survey of 2,926 MSM in the U.S., 75% reported condomless anal sex twice or more in the last 3 months, but 85% had never used PrEP and 22% were unaware of PrEP altogether.<sup>11</sup> Black, less-educated, and foreign-born MSM were more likely to lack access to PrEP, whereas older MSM were more concerned about drug side effects.

Another population with increasing rates of HIV infection in the U.S. is adolescents and young adults, yet the majority of PrEP trials to date have excluded persons less than 18 years old. In the Adolescent Trials Network Study 113, 78 youth aged 15-17 were enrolled in an open-label

PrEP study. They found PrEP to be safe, well-tolerated, and effective when taken, although adherence waned from 54% at 4 weeks to 22% at 48 weeks, highlighting adherence challenges in this age group.<sup>12</sup>

### PrEP Concerns

An early predicted consequence of PrEP was the phenomena of risk compensation, i.e. that individuals taking PrEP would increase their sexual risk-taking behavior. This was not seen in the iPrEx PrEP study, nor in Partners PrEP.<sup>13,14</sup> In both trials, PrEP and placebo participants demonstrated decreasing risk behavior through the study (which included risk-reduction counseling). Other PrEP studies have seen increased sexually transmitted infection (STI) rates, but no greater than increases in the baseline population, e.g. not attributable to

being on PrEP. In actuality, being engaged in proper PrEP care, which includes every six month STI screening and treatment, was shown in a modeling study to have the potential to reduce overall STI rates by 40-42% by finding and reducing the community burden of STIs.<sup>15</sup>

Another concern when PrEP first arrived was that it would foster resistance to tenofovir. Fortunately, this has not been seen. There have been only three reported cases of PrEP failure in the setting of good adherence. Two cases involved transmission of a rare HIV strain that was already resistant to tenofovir. A third case involved a patient infected with wild-type virus that is as yet unexplained.<sup>16</sup> Regardless of adherence level, there have been no case reports of PrEP both failing and leading to de novo tenofovir resistance in the newly infected individual.

### New Directions: On-Demand PrEP

In a study of on-demand PrEP by Molina (ANRS IPERGAY), 361 men and transgender women who have sex with men participated in this randomized trial from France and Canada.<sup>17</sup> This is an open-label extension study of TDF/FTC, with two tablets taken 2 to 24 hours before sexual intercourse and one tablet each at 24 and 48 hours after the initial dose. Compared to the placebo group of the randomized IPERGAY phase, this method of on-demand PrEP reduced HIV infections from 6.60 to 0.19 per 100 person-years, a relative reduction of 97%. Fourteen percent of participants reported self-limited gastrointestinal side effects and only four (1%) discontinued PrEP. Although condomless sex increased from 77% to 86% of participants in the extension study, an observed bacterial STI increase (from 49 to 59 per 100 person-years) did not reach statistical significance.<sup>17</sup>

The IPERGAY study would seem to prove that on-demand PrEP is highly effective. However, study participants took a median of 18 pills per month, which is an average of one 4-pill course of Truvada per week. However, we know from an open-label extension of the iPrEx study, that subjects who took four or more doses of Truvada per week achieved a 100% HIV risk reduction.<sup>18</sup> This raises the question as to whether the patients in IPERGAY were simply taking enough on-demand TDF/FTC each week to achieve the same drug levels found to be protective when taken in a non-event-driven fashion in the iPrEx study, whose participants took the medication daily.

This question was addressed in an abstract presented by Antoni at IAS.<sup>19</sup> In a subgroup analysis of the IPERGAY open-label extension study, in people taking fewer than 15 pills per month (9.5 on average), on-demand PrEP still provided 100% protection against HIV infection, although the study size was small (134 patient-years). This data implies that on-demand PrEP is effective even when used less often than once weekly. This will hopefully be borne out as more patient-year data accrue in this study. Although many clinicians feel this data is compelling enough to support off-label on-demand PrEP by their patients, FDA labeling and CDC recommendations remain to prescribe PrEP as one tablet daily.

### Other Future PrEP Directions

Areas of active PrEP research include long-acting injectable agents, dapivirine vaginal ring, and use of tenofovir alafenamide fumarate (TAF) in TDF. Although no clinically significant nor durable renal toxicity has

been seen from TDF in multiple PrEP trials, longstanding experience in HIV treatment recognizes renal toxicity with TDF, primarily in patients with concomitant renal disease. TAF is more effectively concentrated in target CD4 cells than TDF, allowing for 1/12th of the administered dose, lower serum and renal tubular concentrations, and thus less renal toxicity. Co-formulated TAF/emtricitabine (Descovy™) is already available for HIV treatment, but its use for PrEP is not yet FDA-approved pending completion of an efficacy trial ("Discover" Study, which fully enrolled in June 2017).

Under study in HPTN-077 is the safety and tolerability of the experimental long-acting integrase inhibitor cabotegravir. It can be given as an injection of either 600 or 800mg every 8 or 12 weeks, respectively. Mild to moderate injection site reactions were common but diminished over time. Only one of 199 study subjects discontinued the drug due to side effects.<sup>19</sup> An efficacy study (HPTN-083) is now underway. Even if cabotegravir proves to be a potent PrEP agent, there are concerns about the drug's several months' long "tail" of diminishing drug levels and the possibility that INSTI resistance might occur if someone becomes infected with HIV during this period. This will be monitored during an open-label follow-up phase. Finally, the Hope and Dream studies are both enrolling women for study of the dapivirine vaginal ring. **HIV**



#### ABOUT THE AUTHOR:

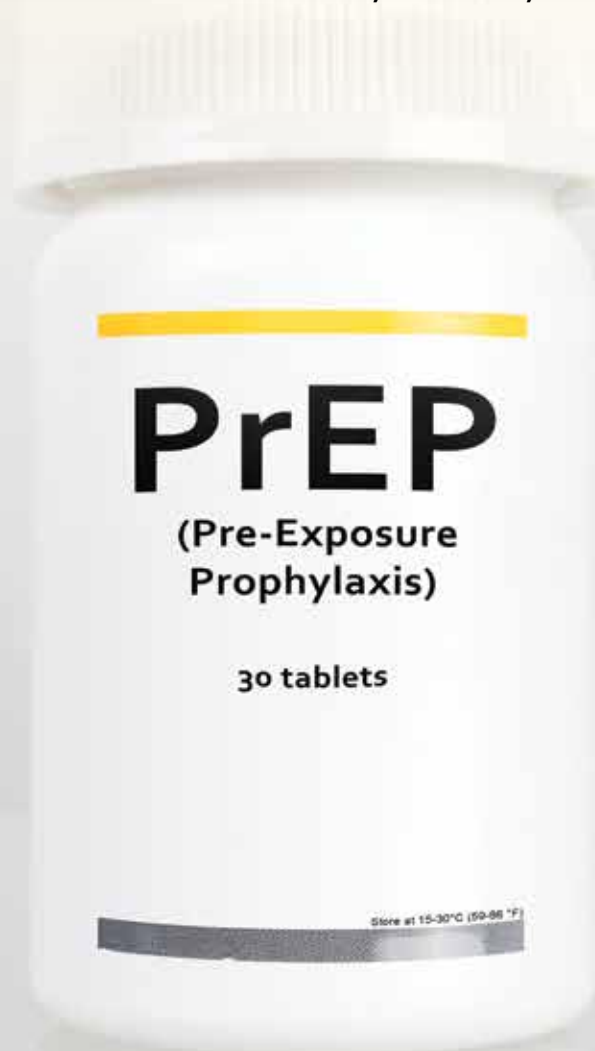
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# Doctors Often Uncomfortable Prescribing PrEP

BY RAPEEPHAN MAUDE, MD MSC, DTM&H



**P**RE-EXPOSURE PROPHYLAXIS (PrEP) against HIV infection, an HIV-prevention strategy in which antiretroviral medication is administered to protect high risk HIV-negative people from acquiring HIV infection has been proven to be effective.

Studies have shown that PrEP can prevent HIV infection in various populations, including men who have unprotected anal sex with men,<sup>1</sup> men and transgender women who have sex with men,<sup>2</sup> and injected drug users<sup>3</sup>.

However, due to either lack of knowledge or adverse attitudes towards PrEP among providers,<sup>4</sup> this mode of HIV prevention may not be offered during clinical encounters to people at risk who could benefit.

The purpose of our study was to assess the baseline knowledge of, attitudes towards and practice of medical providers at Tufts Medical Center, Boston, regarding HIV PrEP. Eighty healthcare providers working at Tufts Medical Center were surveyed anonymously with a short, self-administered questionnaire in May 2017.

Participants comprised 55% physicians (M.D./D.O.), 20% physician assistants (P.A.), 9% registered nurses, 7% medical students and 9% others, including nurse practitioners (N.P.), medical assistants, P.A. students and a research coordinator. Sixty-one percent of respondents were female. The median age was 31 years (IQR 28-34.5, range 22-71). The ethnicity of participants was Caucasian, 60%, and Asian, 20%.

Sixty-eight percent of the study participants had heard of PrEP. This was highest for M.D./D.O.s with 82% (36/44) having heard of PrEP. Forty-six percent of participants responded correctly that PrEP should be given daily. Sixty-nine percent answered correctly that Tenofovir disoproxil fumarate plus emtricitabine (TDF/FTC; Truvada®) is the standard regimen.

Among M.D./D.O.s, 32% were not comfortable prescribing PrEP. The top three barriers reported for prescribing PrEP were: not having enough knowledge (73%), lack of experience (56%), and that it is not covered by insurance (18%). Of 61 participants who were eligible to prescribe medications (M.D./D.O., P.A., N.P.), only 16% had prescribed PrEP prior to the survey. Furthermore, more than 75% of all participants said they would refer patients to infectious diseases and other providers for prescription of PrEP, which may lead to missed opportunities to start PrEP as early as possible.

It was surprising that, despite PrEP having been widely publicized in the medical literature and media, just over two thirds of healthcare providers had heard of it. As expected, more M.D./D.O.s were aware of it; however less than half were aware of the correct dosing regimen. We found a low level of awareness of the potential benefits of PrEP and about a third of doctors said they were uncomfortable asking their patients about behavior associated with high risk of HIV transmission.

Not adequately discussing risk could be a major reason why some people at high risk of HIV infection are not identified during healthcare encounters.

To increase PrEP prescribing, it is essential to increase knowledge and improve attitudes about PrEP among medical providers. This could be done through multidisciplinary educational programs for potential prescribers of PrEP, particularly medical students, residents, emergency room and primary care physicians who are likely to be the first point of contact for eligible patients.

Additionally, encouraging providers to work collaboratively with infectious disease specialists should help to increase their comfort in identifying high-risk individuals who might benefit from PrEP.

This study had several limitations, including a relatively small sample size and that it only included staff from a single academic tertiary referral hospital. This is likely to not be reflective of the wider medical community. Further studies are needed in different settings and with larger sample sizes to understand in more detail about differences between different groups of healthcare providers.

Nonetheless it is evident that many healthcare providers are not sufficiently familiar with PrEP, likely leading to under-prescribing and suggesting that there is a need for educational solutions to increase knowledge and improve attitudes.

**HIV**

**We found a low level of awareness of the potential benefits of PrEP and about a third of doctors said they were uncomfortable asking their patients about behavior associated with high risk of HIV transmission.**

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# Huge Increase in New York City PrEP Prescriptions

But There is Still Room to Improve

BY PAUL SALCUNI, MPH

**I**N JUNE 2014, PROPELLED BY COMMUNITY ACTIVISTS and their allies, Gov. Andrew M. Cuomo announced New York State's Ending the Epidemic (EtE) initiative, a plan to decrease the prevalence of HIV/AIDS in New York State.<sup>1</sup>

One of the EtE initiative's primary objectives is to facilitate access to pre-exposure prophylaxis (PrEP) for HIV-negative individuals at risk of infection. The only FDA-approved PrEP regimen at present, daily oral tenofovir disoproxil fumarate/emtricitabine, has been shown to be up to 90% effective in reducing sexual HIV transmission.<sup>2</sup>

Guided by the EtE initiative, and bolstered by local political support, the New York City (NYC) Health Department remains committed to scaling up PrEP in a way that ensures equitable access to this important prevention strategy for all New Yorkers who are HIV-negative and may be exposed to HIV.

To help inform the continuous improvement of our PrEP promotion and implementation efforts, NYC Health Department examined trends in PrEP prescribing at 602 ambulatory care practices in NYC from 2014 to 2016 using an innovative system called the Hub Population Health System. This system allows ad hoc queries of aggregate patient counts from a convenience sample of practices that use a single electronic health record (EHR) vendor called eClinicalWorks.<sup>3</sup>

We found that for every 100,000 medical visits in Q1 2014, roughly 39 involved a patient being prescribed PrEP. In Q2 2016, 419 of every 100,000 medical visits at those same

**FIGURE 1. PrEP prescription rates per 100,000 patients seen in 602 ambulatory care practices, overall, NYC, 2014–2016.**



practices involved a PrEP prescription, a relative increase of 976% in their overall PrEP prescribing rates since Q1 2014 (Figure 1).

In addition to trends over time, we also examined associations between PrEP prescribing rates and available patient and practice characteristics. This included patient age, gender, and race/ethnicity; and practice location, type, number of on-site infectious disease specialists, and the proportion of the practice's patient population living in high-poverty neighborhoods. Statistically significant increases in PrEP prescribing were observed across all patient and practice groups examined.

## Population Disparities

Despite these increases, some groups of patients among these practices were less likely to be prescribed PrEP after controlling for other sociodemographic characteristics. For example, in Q2 2016, women made up only 5% of observed PrEP prescriptions, despite receiving nearly 20% of new HIV diagnoses each year in NYC (Figure 2).<sup>4</sup>

Similarly, men of color were about half as likely as white men to be prescribed PrEP at these practices, despite their overrepresentation in the NYC HIV epidemic (Figure 3). People receiving health care at smaller private practices or practices outside of Manhattan (the city center) were also less likely to be prescribed PrEP.

These results should be interpreted with caution, since this sample does not include some key clinical practices known to reach the underserved or known for PrEP prescriptions. NYC Health Department's eight Sexual Health Clinics, which

offer PrEP initiations and/or referrals, also are absent from the sample. However, the trends shown here justify the need for specific programming to ensure equitable access to PrEP for men of color, for women, and for people with inadequate access to services in or near the city center.

## Resources

The NYC Health Department believes that raising PrEP awareness through our “Be Sure, Play Sure, Stay Sure” sexual health media campaigns is one strategy that can inform and empower patients to ask their providers about PrEP if they feel they are at risk for HIV infection.

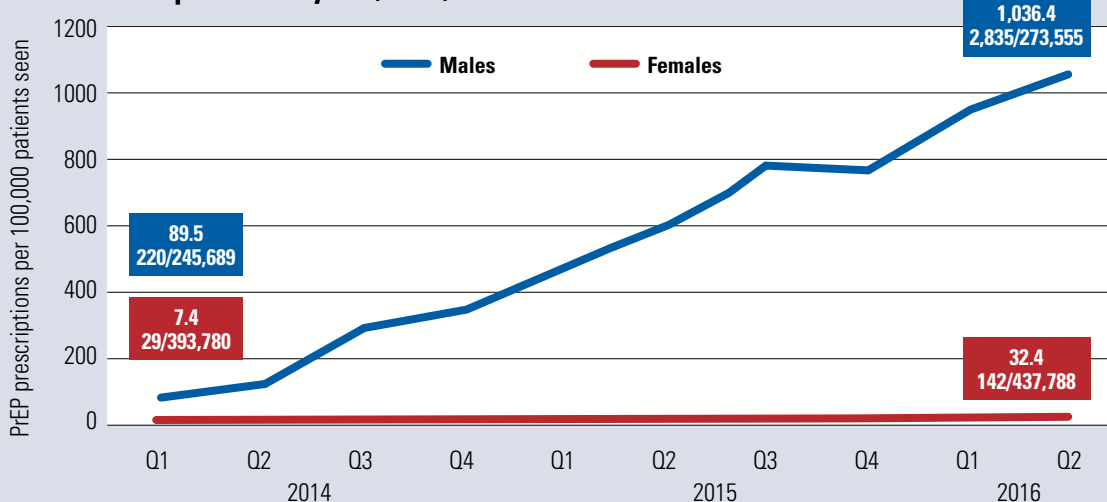
Our “Bare It All” campaign encourages lesbian, gay, bisexual, transgender or queer (LGBTQ) patients to have open and honest discussions with their providers—including details about their sex lives and drug use that may motivate a discussion about PrEP.

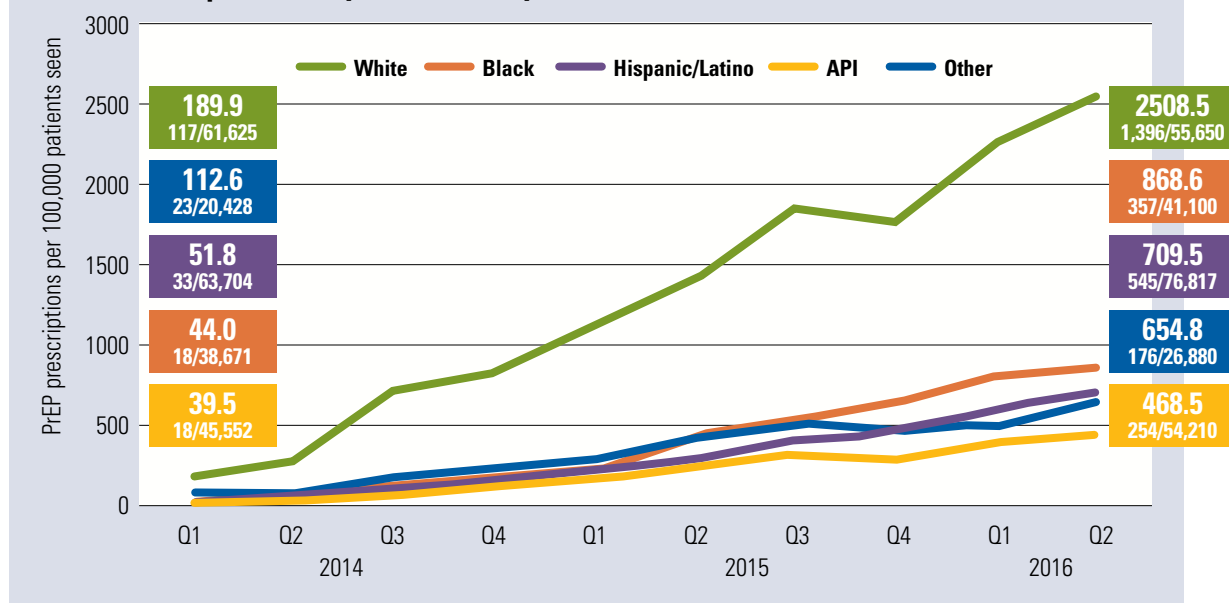
New Yorkers can use NYC Health Department's HealthMap to locate providers with experience providing PrEP and LGBTQ-knowledgeable care. Currently, the NYC HealthMap lists 93 PrEP providers and 125 LGBTQ-knowledgeable sites across the city.

Clinicians also play critical roles in ensuring equitable access to PrEP by initiating sexual health discussions that include PrEP, thereby unburdening patients of that responsibility. Clinicians, particularly primary care providers, must routinize their sexual history-taking so that they can more wholly address their patients' health care needs, identify patients who may be candidates for PrEP, educate them about PrEP, and offer PrEP to those who want it.

**We found that for every 100,000 medical visits in Q1 2014, roughly 39 involved a patient being prescribed PrEP. In Q2 2016, 419 of every 100,000 medical visits at those same practices involved a PrEP prescription, a relative increase of 976% in their overall PrEP prescribing rates.**

**FIGURE 2. PrEP prescription rates per 100,000 patients seen in 602 ambulatory care practices by sex, NYC, 2014–2016.**



**FIGURE 3. PrEP prescription rates per 100,000 males seen in 602 ambulatory care practices by race/ethnicity, NYC, 2014–2016.**

To address barriers that providers may experience, we launched a campaign in October 2014 to provide primary care and infectious disease practices with resources to support PrEP and post-exposure prophylaxis (PEP) through public health detailing, consisting of one-on-one educational visits to practices using a NYC Health Department-developed PrEP and PEP Action Kit.

To date, the campaign has visited more than 2,500 providers at more than 1,300 clinical sites across the city. To achieve the greatest impact, we visited providers known to have recently diagnosed HIV among men of color who have sex with men, a group disproportionately affected by HIV in NYC. In our ongoing detailing efforts, we continue to prioritize high-poverty neighborhoods and primary care providers, who have been shown in other studies to be less comfortable prescribing PrEP compared to infectious disease specialists, despite their unique position to identify potential patients.

While this analysis of EHR data offers insights into PrEP prescribing trends in NYC and informs future programmatic directions, more research is needed. Since these data come from a select sample of NYC practices, it is important to continue developing strategies for tracking PrEP prescriptions across the city, including strategies to measure PrEP eligibility and identify incongruities between PrEP prescription and HIV incidence. Leveraging and triangulating other data sources is key to building a more comprehensive understanding of PrEP utilization.

Effective, culturally responsive services, programming, and outreach strategies are also needed to address disparities in PrEP awareness and uptake, with a focus on women and men of color. For example, in order to better address the limited awareness and utilization of PrEP among women, NYC Health Department is currently planning to launch a new

PrEP and PEP detailing campaign focusing on women's health providers in order to address the disparity in prescribing by gender. Additionally, as PrEP use increases, it is also crucial to research and support retention among PrEP patients.

Our data suggest that PrEP prescribing rates are rising steadily in NYC, but disparities have emerged. NYC Health Department remains committed to supporting all programs, including those described above, that harness the momentum of PrEP uptake and channel it into efforts that help to end the epidemic of HIV and improve sexual health of diverse populations more broadly.

**HIV****ABOUT THE AUTHOR:**

**Paul Salcuni** is Lead Analyst for Prevention of the Bureau of HIV/AIDS Prevention and Control at the New York City Department of Health and Mental Hygiene. He presented research "Trends and Associations with PrEP Prescription Among 602 New York City (NYC) Ambulatory Care Practices, 2014-16" at the recent IDWeek 2017 in San Diego.

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# Missed Opportunity

## Emergency Medicine Physicians Overlooked in PrEP Education Efforts

BY BRETT TORTELLI, BA

**H**IV PRE-EXPOSURE PROPHYLAXIS (PrEP) is a once-daily pill containing tenofovir disoproxil fumarate and emtricitabine that has been proven to be more than 90% effective at preventing HIV infection in clinical trials.<sup>1</sup> While an estimated 1.2 million adults in the United States are at risk for HIV infection and could benefit from PrEP<sup>2</sup>, only about 10% of these individuals are currently taking the preventative therapy.<sup>3</sup> In order to increase this number, new strategies of identifying and initiating individuals into the PrEP continuum of care are required.<sup>4</sup>

Emergency departments (ED) see many individuals at risk for HIV infection. Currently HIV prevention strategies in the ED are focused on diagnosing new infections and linking those individuals to care, but the ED also offers an opportunity to identify HIV-uninfected individuals at risk for acquiring HIV in the future.

These at-risk individuals would benefit from PrEP and Emergency Medicine physicians can facilitate PrEP awareness, plant the seed of PrEP initiation and link individuals to PrEP care. To facilitate these interactions, provider training interventions focusing on emergency physicians are needed.

Effectively designing PrEP provider training interventions for these physicians will require an understanding of provider PrEP awareness, prescribing knowledge and comfort in discussing sexual health practices. However, studies of provider awareness and willingness to prescribe PrEP have focused on infectious diseases, HIV and primary care physicians, so little is known about the level of awareness and acceptance of PrEP among physicians specializing

in emergency medicine.

In our study, we sought to assess provider comfort in discussing PrEP with at-risk individuals among physicians working in an urban emergency department in Missouri. We conducted an online survey among providers in a St. Louis emergency department and evaluated predictors of physician comfort discussing PrEP with patients. We found that there was a moderate level of awareness of PrEP, but also high levels of discomfort discussing PrEP with patients.

Our findings suggested that when designing future provider training interventions, we should focus on addressing misinformation surrounding concerns of efficacy and drug resistance and providing local referral resources for comprehensive PrEP patient care.

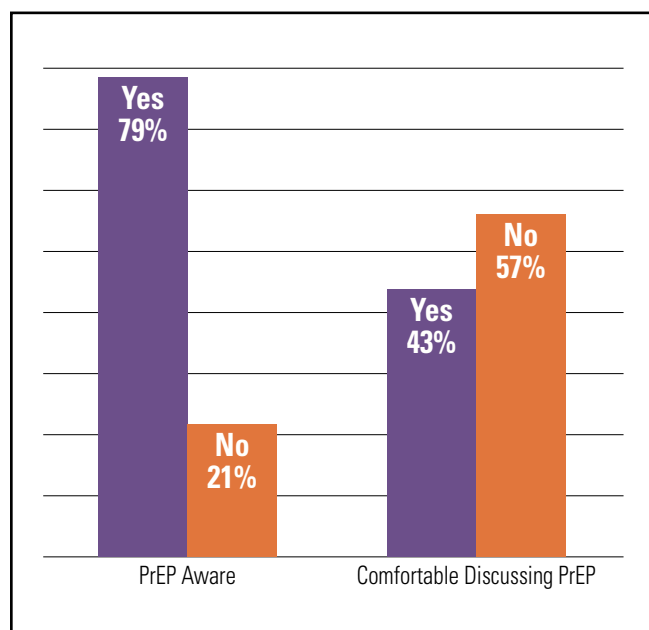
Applying these newfound insights will help us to more effectively leverage the emergency department's potential as an HIV prevention resource to reduce the national HIV incidence. **HIV**

### ABOUT THE AUTHOR:

**Brett Tortelli** is an M.D./Ph.D. candidate at Washington University, St. Louis. He recently presented his research, "Comfort Discussing HIV Pre-Exposure Prophylaxis with Patients Among physicians in an Urban Emergency Department" at IDWeek 2017 in San Diego.

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# New National HIV and PrEP Navigation Landscape Assessment Developed

BY CHIP LEWIS

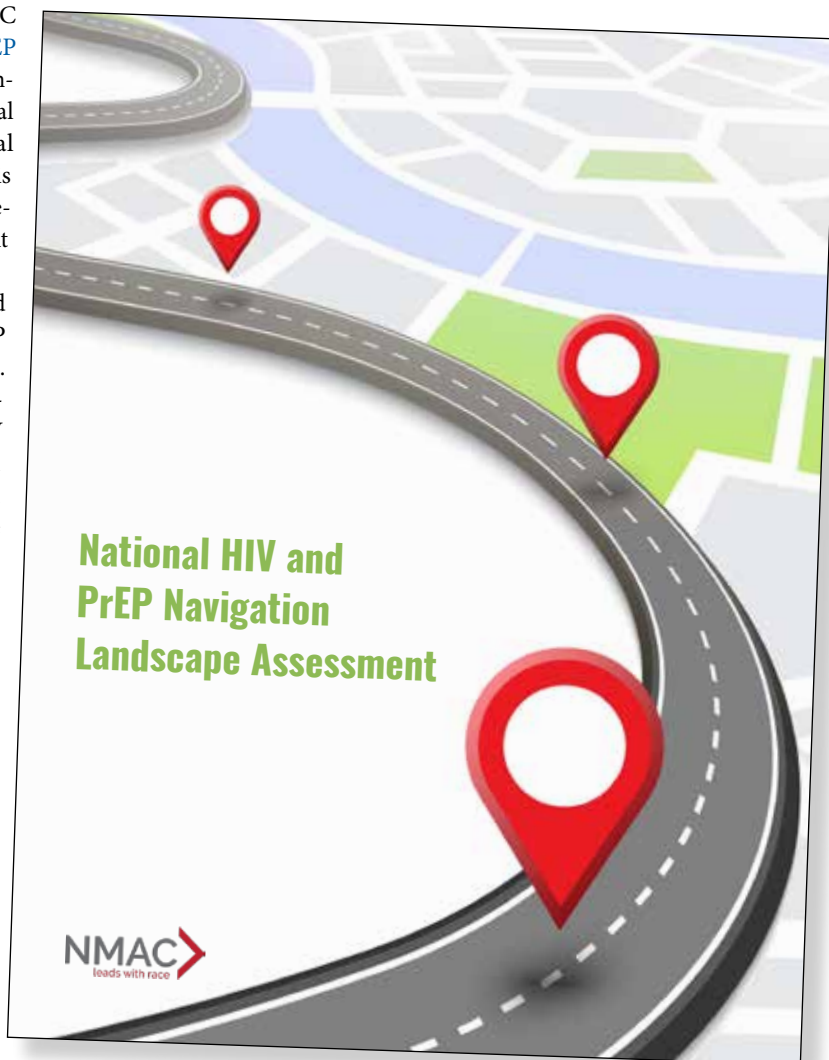
**ENDING AIDS MUST BE MORE THAN A SLOGAN.** It requires real plans, community mobilization, funding, and collaboration between the communities highly impacted by HIV. This endeavor must include community based organizations (CBOs), health departments, healthcare providers, researchers, industry, the federal government, people living with HIV, HIV activists, and people on PrEP.

To inform such planning, NMAC has released its [National HIV and PrEP Navigation Landscape Assessment](#), compiled in collaboration with the National Library of Medicine at the National Institutes of Health (NIH). The tool is intended to help CBOs and health departments better understand the current state of PrEP and HIV navigators.

Before we go any further, we should make the distinction between PrEP Navigators and HIV Care Navigators. PrEP Navigators work with HIV-negative people at greater risk for HIV infection. Care Navigators work with people who have been diagnosed with HIV. Each of these Navigators must take different approaches to their work and the clients they serve.

## Here are some of the Assessment's recommendations:

Since the promotion of navigation services is largely informal, one-on-one consumer discussions and nearly half of respondents indicated that their navigation services are Never or Rarely promoted. Organizations would greatly benefit from capacity-building resources that provide a mix of successful and up-to-date print, online, and social/mobile media reports.





There are variations in how a potential consumer is identified as someone who could benefit from PrEP (i.e., nearly one out of five respondents rely on individuals to ask for PrEP, and over a third provide information about PrEP to certain consumers based on documented risk information). Two-way messaging strategies can be added to expand capacity.

While cultural competence skills were indicated by many respondents as a primary qualification for navigators, this was not a universal core requirement. Thus, organizations would greatly benefit from capacity-building resources that focus on cultural competence, particularly for the many PrEP and HIV navigators that respondents indicated have *No Experience, Between 0-1 Year, and Between 1-2 Years*.

Given the variation in how often navigators receive formal training updates (nearly one in 10 respondents indicating *Weekly* and nearly half each indicating *Monthly and Annually*), organizations should seek a mix of capacity-building resources that provide more frequent brief updates with in-depth semi-annual state-of-the-field summaries. Since peer engagement (i.e., a person who uses his or her lived experience related to HIV, plus skills learned in formal training, to deliver services) is a recurring need in the field and nearly a third of respondents indicated they do not use peer navigators, organizations would further their work with capacity-building resources that focus on how to develop peer engagement.

Since respondents indicated that employed peers are underused to assist with PrEP and ART medication follow-up, this component can be added to expand capacity. While respondents indicated that much of the emphasis of navigators' core job duties and responsibilities is on linkage (i.e., to medical and social support services), PrEP and HIV navigators are less engaged in community-based outreach, HIV testing, and medication adherence. Organizations should adopt capacity-building resources that focus on stage-based approaches across the PrEP/HIV care continuum.

Given the many types of barriers to PrEP and HIV navigation that consumers experience, in addition to the specific steps that are needed to connect with consumers who disengage with PrEP/HIV navigator services or are "lost to care" (e.g., missed appointments), organizations would improve their results with capacity-building resources that focus on preventing disengagement and monitoring the effectiveness of follow-up methods.

There are wide variations in whether (or when) a consumer's PrEP and HIV navigation case/file is suspended (e.g.,

marked inactive or closed) after a period of time without any contact. Case-load management best practices are needed as a component of capacity-building.

Given the variation in the frequency and timing of follow up regarding PrEP medication adherence (e.g., never, weekly, monthly depending on insurance, every three months, no specific timeline created yet), best practices for follow-up are needed as a component of capacity-building.

**Since the promotion of navigation services is largely informal, one-on-one consumer discussions and nearly half of respondents indicated that their navigation services are Never or Rarely promoted.**

Additional priority training, technical assistance, and capacity-building topics/resources that would be helpful for PrEP Navigators include:

- Consumer/provider communication/education regarding PrEP;
- to conduct outreach/engagement with diverse populations; and
- Training/updates for new navigators.

Additional priority training, technical assistance, and capacity-building topics/resources that would be helpful for HIV navigators include:

- How to conduct outreach/engagement with diverse populations;
- How to best use reliable, evidence-based resources; and
- How to evaluate navigation programs.

Developing best practices and replicable service models for both HIV and PrEP Navigators will help to standardize this important work nationwide and lead to better outcomes for people living with or at risk for HIV. **HIV**

*NMAC wants to thank the National Library of Medicine and Gilead for their support of this project.*



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**Chip Lewis** is the Director of Communications at NMAC. He first became involved with the HIV community nearly 20 years ago.

BY ELVIN GENG, MD, MPH,  
OLIVER BACON, MD, MPH AND  
MONICA GANDHI, MD, MPH

# Rapid Initiation of HIV Treatment

**O**UR EVOLVING UNDERSTANDING of HIV disease through both clinical trials and pathophysiological studies has made it clear that treatment as soon as possible is of clinical benefit<sup>1,2</sup>. The current frontier of reducing the public health impact of HIV, as recently recommended by the World Health Organization<sup>3</sup>, centers on how to offer high-quality, rapid treatment (preferably same-day as diagnosis) for all patients<sup>3</sup>.

Given challenges with health systems, which are fragmented in the United States and fragile in many international settings with high HIV prevalence, adopting practices that allow for rapid antiretroviral therapy (ART) initiation is not always simple. Moreover, the task at hand is not just starting ART immediately, but to encourage health systems to exercise flexibility—even with their limitations—to accommodate immediate ART initiation while supporting patients to remain on treatment over the long term.

The opportunity posed by starting ART rapidly should not be missed: unlike other steps in the HIV care cascade (such as testing), rapid initiation of ART after HIV diagnosis is entirely under the control of health systems, and therefore, achievable.

## Clinical Benefits of Rapid Treatment

The clinical risks of ART are lower and the benefits clearer than ever before. Today's first-line antiretrovirals, such as integrase inhibitors and tenofovir alafenamide, are less toxic than earlier drugs. In addition, emergence of resistance to new-generation integrase inhibitors, with a sufficiently robust nucleoside backbone, is rare. Moreover, there is increasing evidence as to the benefits of treating HIV infection earlier and earlier for both the individual (in terms of reducing morbidity and prolonging lifespan) and public health (via decreasing the risk of forward transmission).

With regard to individual-level benefits, an observational study as early as 2009 suggested that treating individuals with a CD4 level of >500/ul compared to waiting until levels fell below 500/ul nearly halved the risk ratio of death<sup>4</sup>. A subsequent randomized trial of 4,685 patients published in 2015 found that among those with a CD4 >500/ul, immediate treatment reduced the combined endpoint of AIDS, non-AIDS events, and deaths by approximately 0.78 events per 100 person-years<sup>1</sup>.

For patients diagnosed shortly after infection, rapid

treatment also minimizes the size of the latent reservoir, which is likely to have a number of salutary effects. These effects include decreasing long-term inflammation, minimizing organ damage, and positioning patients to take advantage of future certain potential cure strategies<sup>2,5</sup>.

In addition to benefits for the infected person, treatment initiation at high CD4 levels also reduces forward transmission. HIV Prevention Trials Network (HPTN) 052, conducted among 1,763 sero-discordant partnerships, and published in 2011, found that treatment of an infected partner at CD4 levels between 350/ul and 550/ul reduced transmission by 96% compared to deferring ART until CD4 levels were less than 350/ul<sup>6</sup>.

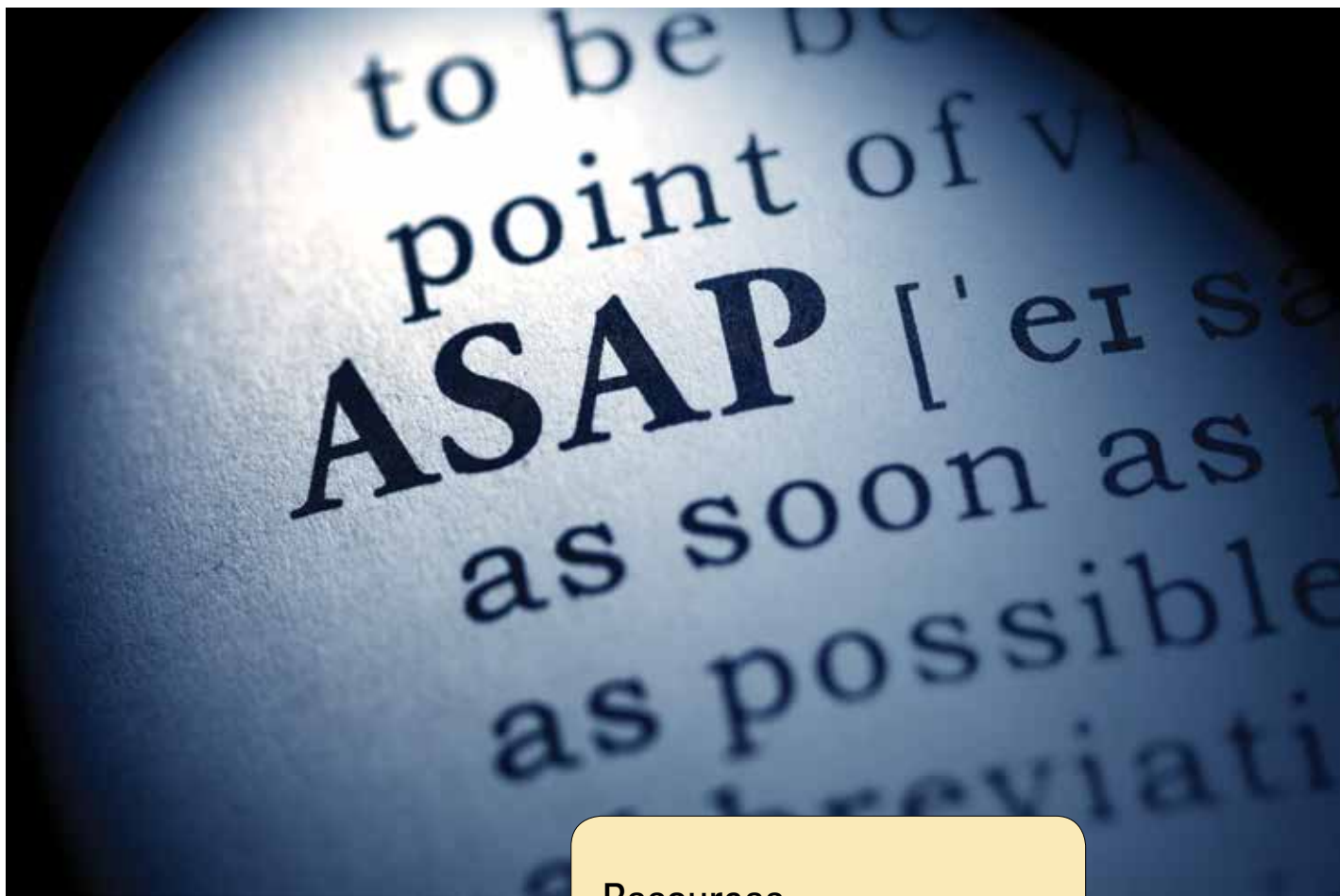
The PARTNER study showed that, among serodiscordant heterosexual and men-who-have-sex-with-men (MSM) couples in which the HIV-positive partner was on antiretroviral therapy with an HIV viral load <200 copies/mL, there were no documented cases of HIV transmission despite condomless sex<sup>7</sup>.

Finally, the Opposites Attract Study examined 343 MSM HIV serodiscordant couples reporting 16,889 condomless sex acts and not a single HIV transmission occurred<sup>8</sup>. There are, therefore, both individual and public health benefits to the strategy of early treatment.

## Treatment and Patient Engagement

In addition to the clinical effects, a number of studies suggest that rapid ART initiation improves engagement in care: treatment appears to have an effect on behavior and biology. Work published in 2017 by Koenig and colleagues in Haiti found that initiating treatment the same day as diagnosis improved a combined outcome of retention in care and viral load suppression at one year by 9%<sup>9</sup>.

In a study in South Africa, Jacob Bor and colleagues exploited the natural variability of CD4 levels to compare outcomes among patients falling just above and just below



the treatment threshold, which should otherwise be similar; they found that eligibility itself improved retention from 32% to 50%, and that the act of starting treatment improved retention from 21% to 91%<sup>10</sup>.

Mody and colleagues compared patients immediately before and after the guideline change regarding when to start (so the patients should therefore be putatively exchangeable) and found that eligibility improved retention in care as well. It has often been said in the HIV epidemic that behavior trumps biology<sup>11</sup>.

In the real world, treatment improves clinical outcomes, but mainly at a higher CD4 count, through its effects on behavior.

### The San Francisco Experience

Treating everyone rapidly while ensuring long-term success requires that we adapt health systems to meet the needs of communities. In San Francisco—a highly-resourced city with a comprehensive safety-net health care system alongside private, nonprofit networks—rapid initiation of ART (often on the day of diagnosis) is now the standard of care.

Rapid treatment initiation is a goal made possible by widespread municipal leadership; community, provider, and patient support; and the availability of tolerable, safe ART with high resistance barriers. The health insurance landscape in California also enables rapid ART initiation by supporting low-income patients (through expanded Medicaid) and those

## Resources

Link to the “Getting to Zero, San Francisco” RAPID Committee page. Includes two downloadable resources: the citywide RAPID Protocol, and the Provider Detailing Brochure <https://www.gettingtozerosf.org/rapid-committee/>

Link to the SAMHSA/HRSA Center for Integrated Health Solutions (CIHS). A national training and technical assistance center that promotes the development of integrated primary and behavioral health services <https://www.integration.samhsa.gov/>

Link to the World Health Organization’s Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy. July 2017. <http://www.who.int/hiv/pub/guidelines/advanced-HIV-disease/en/>

with incomes too high to qualify for Medicaid (through temporary sliding scale programs, commercial Affordable Care Act (ACA) plans, and employer-sponsored insurance).

Acceptability in San Francisco for the rapid ART initiation program is evidenced by a striking and municipal-wide reduction in days to starting care, starting therapy, and

achieving an undetectable viral load over the past 4 years<sup>12</sup>.

San Francisco's collective impact program, titled "Getting to Zero," organizes initiatives to get to zero new infections of HIV, zero deaths from AIDS, and zero stigma from HIV in the city of San Francisco<sup>13</sup>. Several rapid-initiation hubs in San Francisco exist, along with a citywide linkage team that connects patients from decentralized community testing sites to participating HIV practices across the city.

At their first care visit, patients' blood is drawn for baseline labs—including genotyping for antiretroviral resistance mutations, viral load, CD4 count, and HLA-B5701 testing (which can predict the risk of hypersensitivity reactions to abacavir)—and ART is started. We use emtricitabine and

and high-quality setting and on the same day of the diagnosis is one way to reach that goal.

HIV



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**"The task at hand is not just starting ART immediately, but how to encourage health systems to exercise flexibility—even with their limitations—to accommodate immediate ART initiation while supporting patients to remain on treatment over the long term."**

tenofovir alafenamide (or disoproxil fumarate) and either an INSTI or boosted PI based on the low prevalence of transmitted resistance to these drugs.

At certain treatment hubs, we can enroll uninsured patients in temporary Medicaid or in a low-cost sliding scale program (if Medicaid-ineligible), pending enrollment in more established insurance. We tailor our care, support, and clinic choice to the individual in question and have sustained positive outcomes, both in terms of early achievement of virologic suppression rates and patient satisfaction.

### Person-Centered Public Health

Rapid ART initiation clarifies that public health's job is more than just setting up the infrastructure for delivery. Public health must also help to shape and guide what people want—based on the best medical evidence—and how they understand their health, illness, and treatment.

Early in the HIV epidemic, treatment was seen as burdensome, a stigmatized marker of serious illness, and a toxic "lesser of two evils." Today, treatment is less toxic, better tolerated, more convenient, and more effective.

Treatment can reduce the risk of transmitting HIV to sexual partners to essentially zero<sup>14</sup> and can thereby decrease internalized stigma. We need to ensure that treatment is viewed as such in the context of people's lives. Through this lens, treatment can mean freedom from fear of illness, accessed through a welcoming health system, and a path to life's goals and aspirations.

A public health system offering treatment in a compassionate

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# Preventing Heart Disease

## How HIV Clinics Can Improve Primary Prevention

**A**THEROSCLEROTIC CARDIOVASCULAR DISEASE (ASCVD) is a leading cause of death in persons living with HIV (PLWH).<sup>1</sup> These patients likely have a higher risk of heart disease compared to the general population even in the setting of good virological control, and have a high prevalence of traditional ASCVD risk factors including smoking, hypertension, dyslipidemia, diabetes mellitus, and excess body weight.<sup>2-7</sup> The need for better ASCVD prevention strategies for this population is being widely recognized and represents new challenges for HIV care providers.<sup>8</sup>

This quality improvement project was conducted at an urban Ryan White funded infectious disease clinic that provides care to greater than 2100 HIV infected patients. We wanted to document the prevalence of ASCVD risk factors among clinic patients with HIV disease and to identify opportunities for primary prevention.

Despite the impression by the clinical staff that most patients were being prescribed statins according to guidelines and that lifestyle factors were being addressed, we identified significant gaps in preventive care and a need for better processes to address these gaps

### Approach

We conducted a retrospective chart review on a random sample of clinic patients who were HIV infected and were age 40 years or greater. IRB approval was obtained prior to initiating the study. We used exclusion criteria related to the number of visits to clinic to ensure the providers had adequate time to control their HIV disease and begin to address lifestyle factors. We also excluded patients who had existing ASCVD, non-cardiac vascular disease, and other major heart conditions.

Charts were reviewed in random order until we reached 100 charts with sufficient information that allowed us to calculate the patients' 10-year ASCVD risk score according to 2013 American College of Cardiology (ACC) and American Heart Association (AHA) guidelines.<sup>9</sup> This information included age, race, gender, systolic blood pressure (SBP), HDL, total cholesterol, smoking status, diagnosis of diabetes mellitus (DM), and treatment for hypertension. We also reviewed clinical notes from the previous year to determine if the provider documented an assessment or intervention for lifestyle factors including physical activity (PA), diet, smoking, and weight loss.

Out of 1509 potentially eligible patients, we had to review 186 charts in order to reach our predetermined target of 100 charts with necessary data. Eighteen were excluded for

existing heart disease, 26 for insufficient clinic visits, and 42 lacked data on lipids to calculate a risk score.

### Hypertension and Diabetes Mellitus

In the sample of 100 charts, we found 42 patients with a documented diagnosis of hypertension. Based on the existing guidelines at the time which defined hypertension as SBP > 140 or diastolic blood pressure (DBP) > 90, 20 of 42 (48%) were not adequately controlled. Six of the 42 (14%) required three or more anti-hypertensive medications, but only three of six (50%) were well controlled. Four of the remaining 58 patients (6.9%) without a documented hypertension diagnosis, would have qualified for the diagnosis.

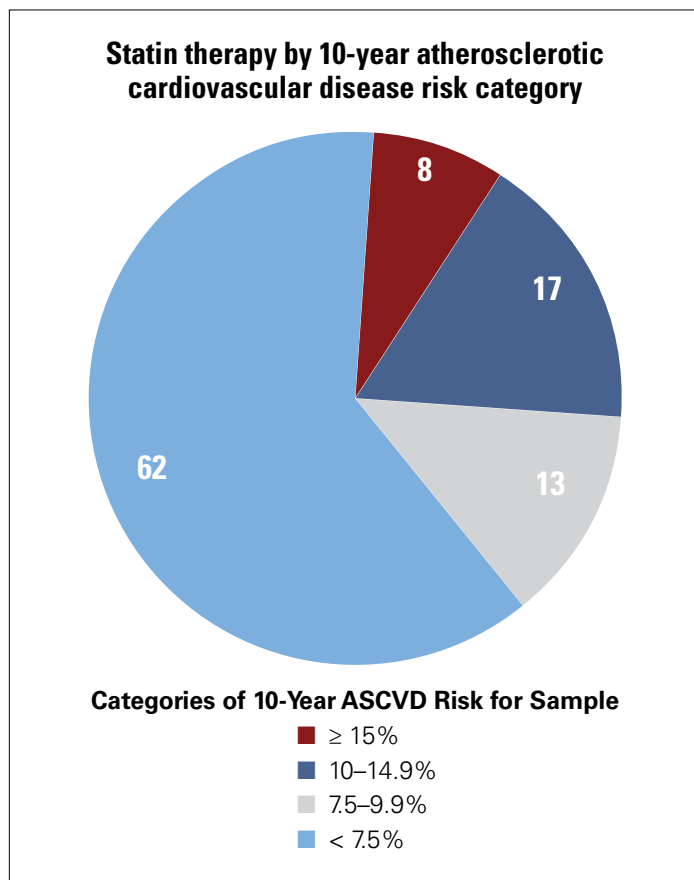


Very few patients had a documented DM diagnosis, but all with a diagnosis had Hemoglobin A1C checked within the past year. We also found only a few patients with a pre-diabetes diagnosis, which likely greatly underestimates the true prevalence. Applying the appropriate diagnosis to the patient chart will certainly help prompt the care team to address that problem, and should be encouraged.

### Statin therapy

Because our chart review was retrospective, we were unable to assess the patient's risk score at the onset of statin therapy. We analyzed patient charts based on their status at the time of the review. We then used stratified cut-off values of ASCVD





risk scores to assess the clinic's performance in initiating statin therapy.

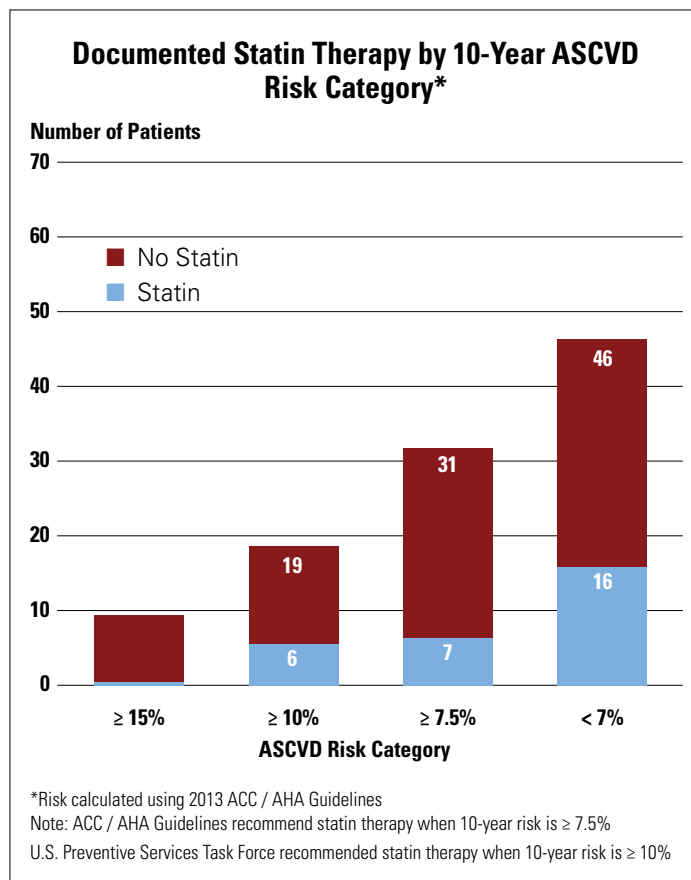
ACC/AHA guidelines recommend beginning statin therapy at a 10-year risk score of 7.5% or greater for most patients.<sup>9</sup> The U.S. Preventive Services Task Force (USPSTF), however, recommends beginning at a score of 10%.<sup>10</sup> Sixteen of 62 patients below the 7.5% risk score threshold were on statin therapy, and these likely represented adequate statin therapy and appropriate control of dyslipidemia.

Of 38 patients above the 7.5% 10-year risk score threshold, only seven (18%) were on statin therapy; and 6/25 (24%) patients above the 10% risk score level were being treated with statins (figure). Most concerning, of the small number of patients who represent high-risk categories; including risk scores above 15%, diabetic patients with LDL-C in the 70–189 mg/dL range, and patients with LDL-C above 190 mg/dL,<sup>9</sup> only one was on statin therapy.

## Lifestyle factors

We reviewed the clinical notes in the first 100 charts of the 142 eligible patients. We did not restrict this review to patients with complete data to calculate a risk score in order to maintain the benefits of randomization. Overall, we found that less than 30% of eligible patients had documented evidence of an assessment or intervention for physical activity, diet, or weight loss. Interventions could include advice given, goals set, or prescription medicine provided.

Our patient sample was fairly evenly split across the body mass index (BMI) categories. Underweight or normal weight (BMI < 25) included 34% of the sample, overweight (BMI 25–29.9) was 35%, and obese (BMI 30



or greater) was 31%. Only 23% of “obese” patients had documentation of an assessment for PA and diet, and 16% had a documented intervention.

Patients in the “overweight” category had fewer documented assessments and interventions. These percentages likely underestimate the actual assessments and interventions given as many are not recorded in the notes. Documentation, however, is an important component and can prompt health care team to continue the discussion in subsequent visits, and track any goals achieved or lack thereof.

One area where the clinic performed consistently well was in assessments and interventions for smoking status. All patients had documented assessment of smoking status at intake by their nurse. Of the 31 active smokers, 27 (87%) received an educational sheet from the nurse. Providers supplemented the nurses' efforts by documenting an assessment of smoking status in 61 of the 100 patients (61%) and an intervention to 19 of the 31 active smokers (61%).

A major reason for the clinic staff's stellar performance in this area was that the process was included in the standard intake process. Smoking status was communicated by nurses to providers prior to seeing the patient. This provides an example of the effectiveness of a system-based approach and the benefits of multidisciplinary care. This model can be easily replicated to address some of the other deficiencies in providing optimal preventive care.

## Limitations and lessons learned

The size of our sample was small, but is likely a fair representation of the clinic population due to the randomized process and similarities in

the demographic factors of race, sex, and age in the sample compared to the clinic.

While some of these patients may have had primary care providers addressing these cardiovascular risk factors, we still hope to encourage all HIV providers to enhance their preventive efforts. Our review revealed strengths in the clinic staff's approach to preventive care of HIV patients and these will need continued refinement.

There were multiple missed opportunities identified as well. Gaps were found in initiating statin therapy based on risk scores, which may actually represent an underestimation of the true risk for a patient with HIV.<sup>6</sup> In the absence of specific guidelines addressing statin initiation in PLWH, providers should strive to at least meet the current AHA/ACC guidelines for the general population. Without such quality improvement reviews, the clinical staff would remain unaware of gaps in care that could be better addressed. We were also able to provide a baseline to measure the effects of future interventions.

It is important going forward to consider the functionality of the EHR system tracking these patient encounters. We were unable to electronically generate reports that would have provided information on other relevant parameters and allowed us to include a larger number of charts and thus increase the sample size. Given the limitations, we were able to collect a reasonable amount of actionable useful information from a relatively simple randomized chart review.

This type of analysis represents the first step in developing individualized systems-based strategies to effectively manage ASCVD risk factors with a goal to provide a longer, higher quality life for PLWH.

HIV



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# TREAT ASAP

Treating as soon as possible is the standard of care for HIV treatment according to the DHHS Guidelines.<sup>1</sup> It's important to educate patients regarding antiretroviral therapy (ART) and adherence. Treatment may be deferred on a case-by-case basis, as clinically appropriate.

Visit [HelpStopTheVirusPro.com/treatASAP](https://www.HelpStopTheVirusPro.com/treatASAP) for more information.

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