

# HIV



# Specialist

## Getting to

# ZERO

**Bridging the  
"Implementation Gap"  
to End New  
HIV infections**

**CA: The  
Leader  
of the Pack**

**8**

**The Empire State  
Strikes Back**

**20**

**Southern  
Discomfort**

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**U=U**

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# SAVE THE DATE!

## 13th ANNUAL AMERICAN CONFERENCE FOR THE TREATMENT OF HIV (ACTHIV)

**April 11 - April 13, 2019**  
**Hilton Downtown Miami**  
**Miami, FL**

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\*developed for the American Academy for Addiction Psychiatry
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Executive Director, AAHIVM

## A New Chapter

**WOULD LIKE TO USE THE FIRST LINE IN MY FIRST COLUMN** as the new Executive Director of AAHIVM to thank all of our hardworking member providers for everything they do for their patients and in fighting the HIV epidemic. It inspires all of us on staff to work hard, in parallel, to support the HIV medical profession.

So far in 2019, we've made a strong impact on the HIV policy landscape in DC, publicly and broadly underscoring the possible disconnect between the Administration's plan to end the epidemic, and the ongoing efforts to restrict access to prevention, care and treatment through cuts and changes to Medicaid, Medicare and the ACA.

In February, AAHIVM launched an extensive advertising campaign in beltway media (including the *Washington Post*, *Politico*, *The Hill* and others) targeted to policymakers to fight the proposed changes to Medicare Part D's Six Protected Classes. At the same time, many of the providers undertook an organized grassroots effort to offer public comment, submit op-eds to local media and contact their legislators asking them to block the changes. It powerfully demonstrates that the Academy is a constituency-driven organization that derives its strength from the passion and commitment of its membership of HIV clinicians.

The Academy also continues to be committed to supporting the profession by providing cutting-edge clinical/medical education programs in HIV and its co-conditions. We are growing our med-ed offerings in the digital space in 2019, including the launch of a new Provider Education Center, aimed at offering the latest in HIV guidelines, research and science, as well as useful clinical information in the space of treating older adults with HIV, and in dealing with the primary care issues of the HIV patient.

Additionally, a new edition of the *Fundamentals of HIV Medicine for the HIV Specialist* will be published in May by Oxford University Press.

The Board of Directors and staff of AAHIVM have begun a strategic planning process, looking at the future

of the organization and the HIV clinical profession, with an eye towards growing and evolving with the changing epidemic. We know that we not only need to make sure that HIV treaters are able to care for the entire patient as they live and grow into older age, but also on the flip side, that a

new generation of expert HIV care givers is fostered in community clinics and other venues of primary, preventative and general care.

We will need to evolve as a specialty professional association to deal with broader issues of sexual health, mental health and substance abuse.

It's imperative, too, that we make sure that HIV providers have a clear and powerful voice at the table of the Administration's effort to end the HIV epidemic in a decade. This issue of *HIV Specialist* focuses on the future goals,

past successes and current challenges that exist as we try to achieve zero new infections.

In back to back speeches at CROI and the CDC's HIV Prevention conference, Dr. Anthony Fauci reminded the care community that we have all the tools necessary to stop this disease in its tracks.

While this may be true thanks to the treatment as prevention model and PrEP, our work is still cut out for us; but our members, board and staff are up to the challenge.

I invite all those working in the HIV care space, and other readers of the *HIV Specialist*, to call and write me with thoughts and suggestions as we move forward with our work. Our greatest asset is our network and the collective knowledge of our members and other providers of care, and we will need help from all of you to get to where we want to go over the next – the THIRD – decade of AAHIVM's existence. **HIV**





# In the NEWS

## Special “In The News” From CROI 2019

JEFFREY T. KIRCHNER, DO, FAAFP, AAHIVS

**T**he 26th Conference on Retroviruses and Opportunistic Infection (CROI) was held from March 4th to the 7th in Seattle, WA. This annual conference was started in 1993 to provide a forum for basic scientists, translational researchers, epidemiologists, clinical investigators, public health experts, and clinicians to present, discuss, and critique new research into different aspects of HIV disease and its complications. In recent years, CROI has also addressed emerging infections such as Hepatitis C.

This year CROI included almost 1,100 presentations including a pre-conference workshop for young investigators, plenary lectures, symposia, themed discussion and oral abstracts. Below are several key studies from this year's meeting that have immediate relevance to clinical practice.

### Optimal Lung Cancer Screening Criteria among Persons Living with HIV. Sellers SA. Abstract # 15

The U.S. Preventive Services Task Force currently recommends screening for lung cancer with low-dose chest CT in adults ages 55-80 who have at least a 30 pack-year smoking history and are currently smoking or quit within the last 15 years. Several observational studies have found that Persons living with HIV (PLWH) are at increased risk for lung cancer. This study used patient data from the U.S. Women's Interagency HIV Study (WIHS) and the Multicenter AIDS Cohort Study (MACS) cohort to evaluate the performance characteristics of the USPSTF lung cancer screening criteria. They also examined alternative thresholds to improve lung cancer detection rates.

The study selected confirmed cases of lung cancers among PLWH who were current or former smokers and  $\geq 40$  years of age at time of cancer diagnosis. For the controls, the authors selected an equal number of PLWH from the two cohorts, matched by 5-year age groups and without a lung cancer diagnosis at all follow-up visits. Clinical and demographic characteristics, and proportions meeting lung cancer screening criteria, were compared. The performance characteristics of the current USPSTF screening recommendations and alternative thresholds including reductions in age, pack-years, and quit dates were applied to the subjects.



There were 44 women (WIHS) and 17 men (MACS) diagnosed with lung cancer. This was an incidence of 270/100,000 person-years in women and 104/100,000 in men. Compared to same sex controls, women with lung cancer had significantly lower median CD4 counts but not viral loads. In men, there were no differences in CD4 counts or viral loads between cancer cases and controls. Only 16% of women and 24% of men with lung cancer actually met USPSTF screening criteria. Applying optimal age and pack-year screening criteria in women (ages 49-75,  $\geq 16$  pack-year history) improved sensitivity to 52% sensitivity and specificity to 75% for lung cancer screening. In men, optimal criteria (ages 43-75,  $> 19$  pack-year history) yielded a sensitivity of 82% and specificity 76% for screening.

The authors conclude that current USPSTF lung cancer screening guidelines performed poorly in PLWH as  $< 25\%$  of lung cancer cases from these two cohorts met current criteria. Alternative thresholds for age, duration of smoking, and quit dates could better identify PLWH who may benefit from lung cancer screening. This study demonstrates the need for risk prediction modeling incorporating sex and markers of HIV infection to identify high-risk PLWH who would benefit most from lung cancer screening.

**Author's comment: this is important data that needs further prospective validation. However, we have data from several observational cohorts**

# In the NEWS

**showing an increased incidence of lung cancer in PLWH as well as many other malignancies. Screening methods and intervals for some cancers may need to be more aggressive for PLWH. Regardless, continued efforts toward smoking cessation in PLWH remain critically important as it is a co-factor with many of these malignancies.**

## **Sudden Cardiac Death Among HIV-Infected and Uninfected Veterans. Freiberg, M. Abstract #32**

There is a strong association between cardiovascular disease (CVD) and HIV infection although the mechanisms and impact of other co-morbidities remains unclear. This study looked specifically at sudden cardiac death (SCD) in 144,362 adults (30% with HIV infection) from the Veterans Aging Cohort Study (VACS). The VACS is a prospective study of HIV+ veterans who are matched with uninfected veterans by age, sex, race/ethnicity and clinical site.

This study followed veterans from their first clinical encounter beginning in April 2003 until SCD, non-SCD death, or censoring through the end of 2014. Sudden cardiac death was determined using death certificates (citing a cardiac cause of death) plus manual review of VA electronic medical records. Participants were excluded if death occurred in hospital, hospice, or nursing home or if the death was due to an accident, overdose, suicide, or homicide. Additional exclusion criteria included an AIDS diagnosis or CD4 count < 50 within six months of death, a diagnosis of metastatic cancer within a year of death, or on hemodialysis. Final exclusion criteria were DNR/DNI, a new significant health condition one month before death, or a "life altering event" within one year if the event resulted in an end stage disease or severe disability. Rates of SCD were calculated using Cox proportional hazards regression to model the association between HIV infection and SCD, adjusting for demographics, prevalent CVD and SCD risk factors.

A secondary analysis was done comparing incidence of SCD in the HIV+ subgroups defined by time-updated viral load and CD4 cell counts. Participants were predominantly male (97%) with a mean age of 50±10.7 years, and 47% were African American. The median time of follow-up was 9.0 years.

After adjustment for demographics, prevalent CVD, SCD risk factors, and other possible confounders, HIV+ veterans had a 15% higher risk of SCD compared to uninfected veterans and this risk was highest among those with sustained high HIV viral loads and low CD4 cell counts. Additional risks for SCD included male sex, smoking, obesity, alcohol use disorder, and Hepatitis C.

Having sustained suppressed HIV viremia or high CD4 cell counts did not increase risk of SCD. The mechanisms for SCD remain to be determined.

**Author's comment: this large study contributes to the on-going association of HIV with CVD, MI, and SCD. Aggressive risk factor reduction can mitigate some of this risk as does treating with ART. More research is needed to better define mechanisms and therapeutic interventions.**

## **Randomized controlled trial of Dolutegravir versus Efavirenz-based therapy initiated in late pregnancy. DOLPHIN-2. Kintu, K. Abstract # 40**

Mother to Child transmission of HIV remains a significant issue for many women around the world. Late initiation of ART increases this risk due to the failure to achieve viral suppression at time of delivery. The DOLPHIN-2 study is an open-label trial, randomizing women 1:1 at 28 weeks gestation to start dolutegravir (DTG) or efavirenz (EFV) plus 2NRTIs. Viral load (VL) was measured at baseline, one week, four weeks and 36 weeks after ART initiation, at time of delivery, then 6 weeks post-partum. The primary endpoint was a VL<50 copies at delivery and occurrence of drug toxicity in mothers and infants.

The study enrolled 266 mothers of whom 237 were included in the final efficacy analysis. There were no baseline differences in gestational age (mean of 31 weeks), VL, or CD4 counts. The median time on ART at delivery was 52 (DTG) versus 59 days (EFV). The number of mothers with a VL<50 copies at delivery was 74% with DTG (90/122) compared to 43% with EFV (49/115). Having a VL<1000 copies at delivery was more likely in women on DTG (93%) vs EFV (83%). Both drugs were well-tolerated with no differences in frequency of adverse events. There were no significant differences between DTG and EFV arms in median gestational age at delivery (40 weeks for both arms), or premature births (<34 weeks). There were four 4 stillbirths, all in the DTG arm of which the etiology remains unclear. There were just three cases of HIV MTCT were detected at birth. These were all in the DTG arm but considered to be in-utero transmissions. Of 270 live births, congenital anomalies occurred in 17 infants (8 with DTG and 9 with EFV). No neural tube defects were observed. The authors conclude that DTG is well-tolerated in pregnancy and produces more rapid viral suppression before delivery compared to EFV.

**Author's comment: This study is reassuring following earlier data from Botswana that suggested an association between DTG and neural tube defects**

**(NTDs). There were other studies presented at CROI (abstracts # 39LB and 747) which found no occurrences of CNS defects or NTDs in a large number of live birth outcomes with INSTI exposure during pregnancy. These data are supportive of current U.S. DHHS and WHO guidelines that recommend INSTI-based regimens as preferred options for ART-naïve pregnant women.**

### **The Phase 3 Discover Study: Daily F/TAF or F/TDF for HIV Preexposure Prophylaxis. Hare CB. Abstract # 104.**

Emtricitabine/tenofovir disoproxil fumarate (F/TDF) is known to be highly effective in preventing the acquisition of HIV when used as daily pre-exposure prophylaxis (PrEP). The newer formulation of tenofovir alafenamide (TAF) has higher intracellular tenofovir levels and better renal and bone safety compared to F/TDF when used for HIV treatment. This study compared F/TAF to F/TDF for PrEP in men who have sex with men (MSM) and transgender women (TGW) at risk for acquiring HIV.

This randomized double-blind study was conducted at 94 sites in the U.S., Europe, and Canada. Entry criteria were 2 or more episodes of condomless anal sex in the past 12 weeks and being diagnosed with a sexually transmitted infection including rectal gonorrhea/chlamydia or syphilis in past 24 weeks. The participants took F/TAF or F/TDF every day along with a matching placebo tablet. Adherence

was monitored by blood levels and pill counts. The primary endpoint was the rate of new HIV infections per 100 person years at 96 weeks. Renal function, bone mineral density, three-site STI testing and risk behaviors were assessed every 12 weeks. HIV surveillance data from the CDC were used to calculate the background 'HIV incidence rate' in at-risk individuals not on PrEP for comparison.

There were 5,387 persons in the study with a mean age of 36 years and range of 18-76 years. Prior use of PrEP was allowed. Ninety percent of participants completed ≥48 weeks on study and the median follow up was 84 weeks. There were 7 HIV infections in the F/TAF group and 15 in the F/TDF group which is an infection rate of only 0.26/100 person years (PY). The majority of these infections were determined to be present at baseline or occurred in persons with low-levels of study drug. Based on CDC data, the expected background rate of new HIV infections in non-PrEP patients was 4/100 PY. There were significantly better outcomes in bone and renal function among the F/TAF group. This study is on-going but currently concludes that F/TAF is non-inferior to F/TDF for preventing HIV infection and represents a safer option for PrEP in MSM and TGW.

**Author's Comment: This is certainly data we have been waiting for and it is very encouraging. However, as generic FTC/TDF becomes available, cost issues versus the safety benefits of FTC/TAF will have to be addressed.**

**There are 279 webcasts presentation that can be viewed on-line. I have included several that are truly worth viewing due to their clinical importance. The link is <http://www.croiwebcasts.org/>. These presentations can be easily found in the search engine by typing in the abstract number.**

#### **Recommended Webcasts:**

1. Ending the HIV Epidemic: A Plan for the United States (Abstract # 2010) Anthony S Fauci, *NIH, Bethesda, MD*. **Opening Session**
2. Bernard Fields Lecture: Discovery and development of HIV broadly neutralizing antibodies (Abstract # 10) Michel Nussenzweig *Rockefeller University, New York, NY*. Opening Session
3. Denial, Doom, or Destiny" Resurgent STIs in HIV Care and Prevention (Abstract # 12) Jeanne M Marrazzo. *University of Alabama, Birmingham, AL*. Plenary
4. Inflammation and HIV: Taming the Flames (Abstract # 13). Irini Sereti. *National Institute of Allergy and Infectious Diseases, Bethesda, MD*. Plenary
5. The challenges of HIV Treatment in an era polypharmacy. (Abstract # 120) David Back. *University of Liverpool, Liverpool, UK*. Plenary
6. NeuroHIV: What the virus tells us. (Abstract # 121). Ronald Swanstrom. *University of North Carolina at Chapel Hill, Chapel Hill, NC*. Plenary
7. Tobacco Smoking: The Silent Killer (Abstract # 66) Lene Ryom; *CHIP, Department of Infectious Diseases, Copenhagen, Denmark*. Symposium
8. ART Options and Treatment decisions for women of reproductive potential. (Abstract # 60). Monica Gandhi, *University of California San Francisco, San Francisco, CA*. Symposium
9. The Story of U=U: Scientific Underpinnings. (Abstract # 116) Pietro L. Vernazza *Cantonal Hospital St. Gallen, St. Gallen, SG, Switzerland*. Symposium
10. Weight gain during treatment among 3,468 treatment-experienced adults with HIV. (Abstract # 671). Grace A. McComsey, *Case Western Reserve University, Cleveland, OH*. Themed Discussion
11. Risk Factors for excess weight gain following switch to Integrase-based ART. (Abstract # 669). Jordan E Lake. *University of Texas, Houston, Houston, TX*. Themed Discussion
12. Sustained HIV-1 remission following homozygous CCR5 Delta32 allogeneic HSCT. (Abstract # 29). Ravindra K Gupta. *University College London, London, UK*. Oral Abstract "The HIV Cure"



# Getting to

## Bridging the “Implementation Gap” to End New HIV Infections. Can it Work?

BY ANNA FORBES, AAHIVM  
PUBLIC POLICY DIRECTOR

**O**N MARCH 4, Dr. Anthony Fauci announced at the opening plenary of the annual Conference on Retroviruses and Opportunistic Infections (CROI 2019) that “...this is the right people in the right place at the right time,” to end AIDS in the U.S. He said that, for the first time, “an accelerated effort to implement [HIV] treatment and prevention in the United States has been simultaneously undertaken by multiple HHS agencies that are focusing on highly specific and concentrated target populations” and concluded that “we now have the science and the tools to squash the rate of new HIV infections in the United States; we just have to tackle the implementation gap.”



The new federal plan, first mentioned in the President's February 4 State of the Union Address, proposes to halt new HIV infections by focusing on "geographic hotspots," identified as 48 counties in the U.S. These, together with Washington, D.C. and Puerto Rico, are home to more than 50% of people who acquired HIV in 2016-2017.

This massive initiative, called "Ending the AIDS Epidemic: A Plan for America," will not officially launch until the \$291 million proposed to fund it is approved in the 2020 federal budget. Its stated goal is to reduce new HIV diagnoses in the U.S. by 75% by 2025. Then, the program will be fine-tuned and rolled out more broadly with the goal of reducing all new HIV diagnoses in the U.S. by 90% by 2030.

Dr. Fauci said this could be achieved through a combination of early diagnosis, rapid treatment and use of pre-exposure prophylaxis (or PrEP) to protect those at high risk of HIV, as well as identifying and responding rapidly to "disease clusters" where they are found. He emphasized that this approach relies on "implementation science," which current HIV research defines in part as 'a multidisciplinary scientific field that seeks generalizable knowledge about the magnitude of, determinants of and strategies to close the gap between evidence and routine practice for health in real-world settings.'

But how do federal programs propose to suddenly change "routine practice" in the very populations that our government has been ignoring, excluding, criminalizing, mistreating, and robbing of their previous available entitlements? Will these populations immediately see the value of adopting new behaviors and complying with new directives because the government tells them to?

Roll Call reported that Rep. Barbara Lee, (D-CA and Co-chair of the Congressional HIV Caucus) said, "the Trump Administration has repeatedly undermined our progress in ending the epidemic — whether it's proposing a Medicare Part D rule that would push lifesaving drugs out of reach for people living with HIV, redirecting critical funding away from Ryan White and other key programs, or pursuing discriminatory policies against the LGBTQ community. If the administration is serious about addressing HIV, it should start with ending the counterproductive attacks on these crucial programs and fully funding them at home and abroad."

Ending current federal initiatives designed to punish populations most vulnerable to HIV would certainly be a good place to start. Gay or bisexual men, for example, make up about two thirds of the one million plus Americans now living with HIV. Since taking office, the current administration has rescinded nondiscrimination regulations created to protect LGBTQ people, prohibited transgender people from military service and promoted "religious refusal" policies that deprive LGBTQ individuals and same-sex couples of care and services. The administration is still struggling mightily to undermine the Affordable Care Act – legislation that has reduced the rate of being uninsured by half among LGBTQ people. This track record does not inclined LGBTQ people to view the administration as having their best interests at heart.

About 20% of all people living with HIV in the U.S. are women. Of those, most (59%) are black women. Many of them live in states that have not expanded Medicaid and that offer little, if any, publicly funded family planning services.

About 60% of U.S. women use family planning providers as their "usual form of health care". For 41%, a family planning clinic is their only source of health care. Almost all (92%) of family planning providers the U.S. offer HIV testing while 97% test for and treat other STDs, including HPV.

On Feb. 22, the Trump administration approved its "final rule" revisions to Title X that bar providers performing abortions, making abortion referrals or even discussing abortion with clients from receiving any federal family planning funding. Abortion services typically make up a minuscule part (3% in the case of Indiana) of the services provided in Title X funded clinics.

Similar bans have been occurring in various states, rendering clinics to close due to lack of funding. A national ban, unless overturned, will defund and close far more clinics, leaving women without access to health care, including HIV testing. Does closing the doors of the clinics women trust and rely on engender trust? Will they go to new providers who offer them HIV testing and care but not the family planning services they urgently need?

Motivating people to comply with governmental directives is difficult in any environment — and especially so when their recent experiences with governmental services have been more harmful than helpful. Dr Fauci, however, insists that this can be overcome with implementation science.

An activist with the Human Rights Campaign observed that, "no real public health agenda can ever include dangerous cuts or discrimination against those who need services the most." It is unrealistic to envision success for a new federal plan to end new HIV infections until the administration acknowledges that many of its current actions directly undermine the program's goals.

This contradiction was further reinforced by the President's budget proposal presented on March 11. While including the \$291 million for many HIV treatment and prevention programs, it also proposed steep cuts in Medicare and Medicaid funding over the coming decade. Currently, about two-thirds of Americans living with HIV rely on those programs for their public insurance.

His budget proposal also includes a \$4.5 billion reduction in NIH funding over the next decade, a \$500 million cut in mental health treatment and \$100 million less in SAMSHA's budget for substance use treatment, among other relevant areas.

Eradication of HIV transmission in the U.S. by 2030 cannot be achieved without addressing the numerous factors—many of them initiated and/or exacerbated by this administration—that are fueling the epidemic now.

Twenty-two HIV and AIDS patient advocacy groups drafted a joint statement regarding the President's HIV Plan for America. It said, "We stand ready to work with [President Trump] and his administration if they are serious. But to date, this administration's actions speak louder than words and have moved us in the wrong direction." **HIV**



#### ABOUT THE AUTHOR

**Anna Forbes** is the public policy director for the American Academy of HIV Medicine. A seasoned professional with over thirty years in the public health sector, Ms. Forbes oversees the AAHIVM policy department in its efforts to leverage the perspective and the powerful voices of HIV health care providers to influence health policy that affects HIV practitioners and the care they deliver.

BY ANNE DONNELLY, PROJECT INFORM



CALIFORNIA HAS

LONG BEEN A LEADER in progressive health care

policy. The state aggressively implemented the Affordable Care Act (ACA), including expanding Medi-Cal (California's Medicaid program) prior to the passage of the ACA, creating a strong active purchaser state-based marketplace, and expanding coverage of benefits and populations where possible. As a result, California reduced its uninsured rate by over half in four years, from 17.2% in 2013 to 7.2% in 2017, the largest decline in uninsured people in the nation.<sup>1</sup> Increased access to care makes it possible for people living with and at risk for chronic and communicable disease, such as HIV, hepatitis C (HCV) and sexually transmitted diseases (STDs) to gain access to necessary and life-saving preventative services, care and treatment.

# The Leader of the Pack

## *Addressing HIV, HCV and STDs in California*

However, California is currently doing a poor job of adequately funding and supporting the public health efforts that are necessary to address communicable diseases. Despite efforts by the California State Office of AIDS and Viral Hepatitis Branch to develop strategic plans to address HIV and HCV, the state has failed to bring together currently siloed state departments, such as the Department of Health Care Services, the Department of Public Health, the Department of Corrections and Rehabilitation, Covered California, the Department of Education, and others in order to develop a cross-departmental, strategic approach to communicable diseases.<sup>2</sup>

Due, in part, to the lack of investment in a cross departmental, community informed strategic plan, California is falling behind other states (and some California jurisdictions, such as San Francisco), in health care quality improvements that are necessary to make headway against communicable diseases. For example, since Governor Cuomo established a task force to end the HIV epidemic by 2020 in New York, new HIV infections have dropped by more than 20% in four years. California by contrast has seen only a 3% drop in new infections over the same time period. New York has also established an HCV elimination task force based upon the success of the HIV strategic plan.

Recognizing that California needed to do more, a state-wide working group of 50 public health and community leaders convened in Los Angeles in April 2018, to discuss and garner support for a strategic plan to end the HIV and HCV epidemics in California. At the meeting, it became clear to the group that ending these epidemics would not be possible without also addressing STDs. The group agreed that California has stalled in its efforts to address HIV, has done far too little to address HCV, and is in the midst of an unprecedented increase in STDs, noting that:

- Over 151,000 Californians are now living with HIV. Roughly 13 percent are unaware of their HIV status and nearly half (46 percent) lack consistent care or access to treatment.<sup>3</sup> California has the highest annual number of new HIV diagnoses in the U.S., with over 5,000 people newly diagnosed each year.
- Over 400,000 Californians are living with HCV. Most do not know it.<sup>4</sup> Nearly 34,000 cases of chronic HCV were reported in 2015.<sup>5</sup> The opioid crisis has led to dramatic increases in HCV and increased vulnerability to HIV outbreaks in rural parts of the state.<sup>6</sup>
- There were more than 300,000 reported STD cases in California in 2017, a 45% increase since 2013.<sup>7</sup> California ranks first in all states for the total number of cases of



chlamydia, gonorrhea, and syphilis.<sup>8</sup> Cases of congenital syphilis have increased rapidly in recent years, from 33 in 2012 to 283 in 2017, with California leading the country in reported cases.<sup>9</sup>

The group also concurred that the most effective strategy for ending these epidemics was to treat them as a syndemic - or synergistic epidemic - two or more concurrent epidemics in a population, increasing the prevalence and the burden of disease. The syndemic approach differs from the biomedical approach in that it treats diseases concurrently. It also addresses health inequities and social determinants of health that exacerbate epidemics in vulnerable populations.

There is extensive evidence supporting the syndemic approach for HIV, HCV, and STDs. These epidemics have biomedical interactions. For example, having an STD increases the likelihood of acquiring HIV.<sup>10</sup> Among those living with HCV and HIV, HCV progresses faster and more than triples the risk for cirrhosis, hepatic failure, and liver-related death.<sup>11</sup> They are also driven by similar social and economic conditions and disproportionately impact many of the same disadvantaged communities:

- Gay and bisexual men are at increased risk for both HIV and STDs, accounting for roughly three-quarters of HIV and early syphilis cases.<sup>12</sup> Approximately 25% of transgender women, and more than half of black transgender women, are estimated to be living with HIV.<sup>13</sup>
- People of color are disproportionately affected by HIV, HCV, and STDs. Blacks have rates of new HIV diagnoses,

chlamydia, and gonorrhea that are nearly five times those of whites.<sup>14</sup> And while blacks are just under 6 percent of the population in California, they account for nearly twelve percent of HCV cases.<sup>15</sup> Rates of new HIV diagnoses among Latinx people are nearly double those of whites.<sup>16</sup>

- Young people have seen increasing rates of HIV, HCV, and STDs in recent years. Rates of newly reported chronic HCV increased 50 percent among young people (15 – 29 years) from 2011- 2015, likely due to increases in injection drug use.<sup>17</sup> Over half of reported chlamydia cases in 2016 were among people under 25. People who use drugs are at increased risk for HIV and HCV.<sup>18</sup>
- Women in California are increasingly at risk for STDs and HCV. Rates of early syphilis and HCV among women of childbearing age (15-44) increased 450 and 148 percent, respectively, from 2012-2016.<sup>19</sup> Syphilis, when transmitted from mother to child, can cause pre-term birth, birth defects, and death.<sup>20</sup> The number of infants born with congenital syphilis in California has increased for five years in a row.<sup>21</sup>

The statewide working group recognized that California has an unprecedented opportunity to respond to HIV, HCV and STDs. Highly effective treatments, proven prevention tools, and a clear understanding of the negative impact of stigma, health inequities, and social determinants of health can allow us to end these epidemics. We also have an opportunity to model the efficacy and importance of a statewide strategy that addresses HIV, HCV, and STDs simultaneously.



However, California's strategy will only work if it is endorsed by the state's Governor and Legislature and brings all relevant stakeholders to the table—including government and public health officials, health care and social service providers, researchers, the private and nonprofit sectors, and most importantly, individuals most impacted by these health conditions.

Since the initial meeting, public health and community leaders have formed a coalition, "End the Epidemics: Californians Mobilizing to End HIV, HCV and STDs". On March 6, the coalition of over 130 organizations released a community consensus statement calling on Governor Newsom and the State Legislature to create and implement a blueprint for a collaborative, cross-departmental, community informed set of strategies to end these epidemics.<sup>22</sup>

The consensus statement calls on the Governor and the Legislature to empanel a task force that includes all relevant state agencies. The task force must also include significant participation from community stakeholders, with individuals and communities most impacted involved in leadership, planning and decision-making at every level. The task force would be charged with the development and the initial implementation of a collaborative strategic plan to address these syndemics and identifying needed resources and opportunities for better leveraging current resources.

The coalition has developed six goals for the strategy that would be discussed and moved forward in the formal statewide task force process. We are gathering and refining specific recommendations from the community for each goal, which will be shared in the future.

- Increase the number of people living with HIV, HCV, and STDs who are aware of their status;
- Increase access to comprehensive HIV, HCV and STD prevention services;
- Ensure linkage to and retention in culturally competent, quality health care for everyone living with and vulnerable to HIV, HCV, and STDs;
- Increase training and capacity building to strengthen and integrate the HIV, HCV and STD provider workforce;
- Address social determinates of health that impact people living with and at increased risk for HIV, HCV, and STDs;

- Develop and track metrics to assess progress toward ending the HIV, HCV, and STD epidemics.

The End the Epidemics coalition has had many successes thus far. Some of the notable ones include:

- Community agreement that the syndemic approach is the most effective and innovative way to address these three epidemics in California. We have also received very positive feedback from key staff in state agencies and the Legislature.
- Governor Newsom supported the concept during his campaign and has continued to indicate support for moving forward.
- Community and public health leaders have embraced the idea of a new statewide coalition to work on the strategic plan and its implementation as well as the state budget requests that we bring forward each year.
- There is a concurrent effort at the Department of Public Health to integrate HIV, HCV and STD into one department, which we support and believe will be helpful to our public health program efficacy.

Members of the End the Epidemics coalition are committed to sharing successes and challenges with other state advocates as we move forward. We are indebted to New York and several other states for sharing their experiences, Contact Ryan Clary at [clarystrategies@gmail.com](mailto:clarystrategies@gmail.com) for more information about the California End the Epidemics initiative. **HIV**



#### ABOUT THE AUTHOR

**Anne Donnelly** has worked in HIV health care policy for 30 years and HCV health care policy for more than 10 years. She has worked on research reform, drug development, access and pricing, and health care and public health systems with an eye toward culturally competent, quality programs that address the whole person. Currently her work focuses on optimizing health care and public health programs to serve people living with and risk for HIV and HCV. She believes that effective policies and program reform must be informed by the people whose health and lives depend on them.

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## News regarding the Advocacy and Educational Work of Project Inform

We, the former staff of Project Inform, want to let you know that our tenure at Project Inform has ended and the organization is likely to close. We wish to honor and celebrate nearly 35 years of service to people living with and at risk for HIV and a decade-plus service to people at risk for and living with hepatitis C.

Despite the continued success and evolution of our work in HIV and HCV – two of the most stigmatized diseases in the United States—we have not been able to successfully navigate the current funding environment.

We want to acknowledge the partnerships that have played such a large part in the success of our work. We've been proud to work with colleagues who are among the most creative, strategic, committed and passionate volunteers, advocates, providers, educators, and decision-makers in the country. We appreciate our funders and donors who have generously supported Project Inform. We are also grateful to all those living with and at risk for HIV and HCV and their loved ones who have worked beside us from the beginning—always informing our work.

While we recognize that vital work

remains unfinished, we know it will continue in capable hands and hope to be part of that work.

When Martin Delaney and Joe Brewer founded Project Inform in 1984, they couldn't have imagined the great changes that would grow out of their urgent desire for people with HIV to be able to take charge of their own health and work toward better health for their peers.

Thirty-five years hence, life with HIV is counted in decades rather than weeks or months and HIV can't be transmitted when viral suppression is achieved. As well, people wishing to protect themselves from HIV transmission have an additional powerful tool, pre-exposure prophylaxis (PrEP). Hepatitis C is curable and people who use drugs may soon have greater access to services that will keep them alive.

Above all, the millions of pieces of print and electronic publications we've offered people freely, the videos we've disseminated, the trainings we have developed and participated in, and the thousands of hours spent counseling individuals on the phone or by chat have helped ensure that people know about these facts, can understand and navigate their

health care and services and can positively impact their own lives and the lives of the people they love or provide care for.

Our leadership expanding and transforming health care through multiple government and private programs has helped to make ending the HIV/HCV epidemics a reality. We focused on the provision of culturally competent and trauma-informed care. That leadership has also helped to ensure that the HIV and HCV, and hepatitis C communities and public health leaders have come together in California to form the End the Epidemics coalition, which has launched a bold initiative that calls for a community-informed statewide task force to develop and implement strategies to end HIV, hepatitis C and STDs in California. Responding to these epidemics jointly—as a syndemic—makes their end truly possible.

When an organization touches so many lives around the globe for so many years, it is impossible to assess its legacy. We trust, however, that the legacy of Project Inform legacy will resound for years to come and to influence our own work and that of countless others who have dedicated so much and continue to do so.



# Ending the HIV EPIDEMIC

## NOTES FROM A “HOT SPOT”

BY BRIAN J. DOWNS, DO, MBA, AAHIVS

**P**RESIDENT TRUMP’S State of the Union address on February 5th boldly committed to ending AIDS in the United States by 2030. This commitment was conceived by the Center for Disease Control’s (CDC) leadership following discussions to coordinate an effective means of HIV control and eradication from the United States (U.S.). The goal aims at reducing new HIV infections by 75% in 5 years and 90% in 10 years. The CDC reports that this would be accomplished by a concentrated laser- focused multiagency governmental effort. This push toward those goals would focus on 48 counties in the U.S., Washington D.C., and a municipality in Puerto Rico—locations that account for half of the 40,000 new infections in the U.S. These locations, are referred to as “Hot Spots.”

This is conceptually promising, but whether this is a realistic goal is yet to be determined. A December 12<sup>th</sup> issue of *Medical Economics* raised some degree of skepticism. Brian Williams PhD, authored an article in *The Lancet* titled “Ending AIDS: Myth or Reality.” In it, Williams cautioned against optimism, noting that a 2016 report indicates that despite \$100 billion spent globally to fight AIDS from 2010 to 2015, new infections in five targeted regions of the UN program were unchanged during that same period except for in Eastern Europe where the number of new cases is actually rising.

How then can we expect to eradicate HIV/AIDS within the United States? Showering money toward that goal hasn’t produced the intended results globally. Funding is clearly needed, but strategic measures via information sharing seems as though it may be more critical to the solution.

St. John’s Well Child and Family Center has been providing primary care health services to the medically under-served population of Los Angeles for more than 25 years. Those areas include Watts, Compton, and South Central. St John’s also has clinic services within local high schools and community colleges, and a mobile clinic for the homeless. In its commitment to providing health care to the entire community it

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expanded its services to those patients living with HIV since 2013.

As a designated area with a higher prevalence of HIV, we are a designated “hot spot.” We have been allocated resources to deal with the epidemic at its core. Our patient population is predominantly African- American and Hispanic. Migrants from Mexico and Central America are among the Hispanic population, many of whom are undocumented immigrants. Our services have since expanded to treat patients with hepatitis C, and more broadly to Transgender care and the homeless. Additional services included mental health, PrEP/PEP, and substance abuse. These services are offered in our Primary Care community-based clinic setting in South Central LA and at the Transgender clinic in the Watts area.

We hope to eradicate HIV in the community we serve and look forward to participating in that process. We are indeed on the frontline of this battle. The question remains, is that possible, or is it more realistic to concentrate on containment? Will this mandate open the doors to cooperative sharing of information and effective strategies between clinics to meet the CDC goal?

St. John’s Well Child and Family Center’s CEO, Jim Mangia, has spearheaded the commitment to address our community HIV incidence and prevalence. Our HIV/hepatitis C clinic, referred to as the “Prime Clinic”, addresses each area of need, from prevention to treatment, and by government-funded case management. Barriers to care and prevention have been formidable, but we have identified best practices for making a difference.

Treating our patients within their community allows easier access to a continuum of care. We cannot reasonably expect patients to travel to academic medical centers or over-burdened Infectious Disease specialists to seek ongoing care. Commuting to a center that provides these services is indeed a barrier to care. Many of our patients use public transportation and find it difficult to travel outside their community for medical and other services.

Mobile clinics also serve the homeless and provide HIV testing and enrollment in insurance coverage. The mobile clinic has partnered with Homeboy Industries. They employ persons who have recently been released from incarceration and those who have forgone gang affiliations. Those who wish to reconnect with health services do so through a societal re-entry program in our South LA clinic.

Partners of our HIV patients, MSM, and Transgender patients are targets of HIV risk reduction. Routine HIV testing is available to all patients via Federal and Pharmaceutical grants. Risks assessments are done at the time of testing and PrEP is discussed. Recent governmental legislation allows youth aged 13 and older to access services and start PrEP if desired and warranted.

St. John’s has implemented The South Los Angeles youth (SLAY) program which seeks to identify at risk youth by educational intervention at the high school level focusing on the 13-17 year-old age group. This allows teens to participate informally with their peers to learn about HIV and STIs, condom usage and PrEP. Effective options are introduced to these teens in non-judgmental informative group meetings.

### **Retention of younger and homeless HIV/HCV patients has always been a factor in viral load suppression.**

Additionally, California’s title 10 provides funding for peer educators to meet with teens at their schools to offer informal education that addresses STIs, condom usage, and partner abuse identification. Students are free to ask questions in a non-judgmental atmosphere. Reducing isolation through group participation and assessable resources is the main goal. Adults living with HIV are encouraged to attend group meeting as well. At present these meetings are held in both Spanish and English.

Retention of younger and homeless HIV/HCV patients has always been a factor in viral load suppression. We utilize case management to connect patients with clinic services. The case managers conduct medical case management to identify barriers to care. They supply smart phones to those who have none. They contact patients regularly, and allow patients to call them to express concerns regarding transportation to and from the clinic, as well as, linkage to care for suspected STIs, behavior health, and housing. The AIDS Drug Assistance Program (ADAP) covers the cost of clinic visits and medications.

We have a specialty pharmacy that reduces the need to obtain medications at outside pharmacies. Patients pick up their meds the day of the clinic visit. Alternatively, medications can be mailed to their homes, or delivered to a

designated area by a courier. Patients will meet the courier at an area of the patient’s choice, to maintain confidentiality of their HIV/HCV status. A specialty pharmacist is assigned to the Prime clinic to monitor drug- drug interactions. Proper storage and usage of medications is also the specialty pharmacist’s task.

Sexually transmitted infections (STIs) are known to increase the probability of acquiring HIV infection. Routine STI monitoring is done with each clinic visit. Throat, rectal, and urine chlamydia (CT) and gonorrhea (GC), and serum RPR monitoring is done in accordance with CDC guidelines. Patients are offered CT and GC treatment packets for all sexual contacts free of charge. Condoms are all dispensed free of charge.

Given all the services we offer, the populations we care for and the positive progress I’ve witnessed, I can honestly say that I hadn’t entertained the thought of eradication. Keeping our heads above water via containment strategies has been our reality. I cannot foresee eradication of AIDS within the U.S. unless there is a concerted effort to train more primary care physicians with the necessary skills to treat HIV within their practice settings. Additionally, it is evident that under-treatment of psychiatric illness due to a shortage of mental health providers also makes the goal of eradication difficult. Academic centers such as the University of Southern California (USC) in partnership with the Pacific AIDS Education and Training Center (PAETEC) provide week long mini-internships on a monthly basis that tailor basic HIV education and consultative resources to all health providers. We have utilized these educational opportunities for all interested providers.

I look forward to hearing from other centers who have employed effective means of HIV containment. Together as a community of committed physicians, nurse practitioners, and physician assistants we may reach that 2030 goal of AIDS eradication. Please email me at [bdowns@wellchild.org](mailto:bdowns@wellchild.org) to share your best practices for ending the epidemic. **HIV**



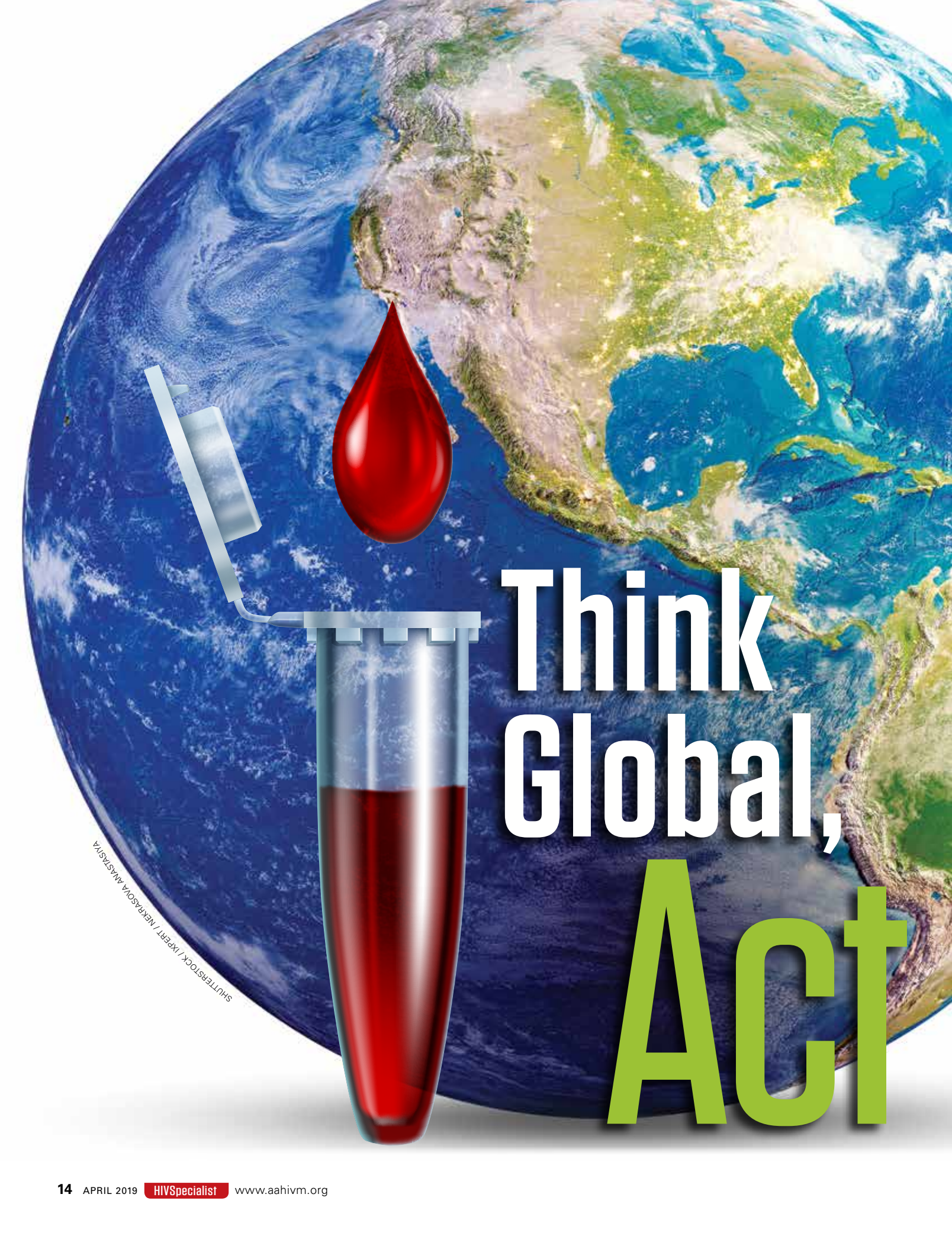
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# Think Global, Act

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## *Sowing the Seeds of an HCV Elimination Movement in San Diego County*

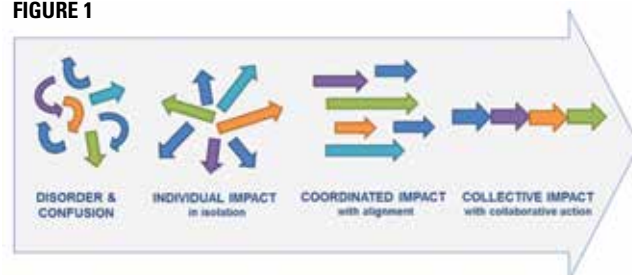
**T**HOUGH IT BEGAN AS A SLOGAN to galvanize grassroots support for the health of the planet, this simple phrase aptly describes how the nascent movement took hold in San Diego focused on community health and HCV elimination. Inspired both by the World Health Organization's (WHO) charge to eliminate viral hepatitis as a public health threat by 2030, the US National Strategy to Eliminate Hepatitis B and C, as well as the growing HCV elimination projects in New York State, San Francisco and elsewhere, officials from a diverse coalition of public and private sectors in San Diego have coalesced around the idea that now is the time to eliminate HCV in our region.<sup>1,2</sup>

### **Early Discussions:**

#### **Sowing the Seeds for Collective Impact**

Though many clinicians, public health officials, patients, and advocates agree with the general goals and spirit of disease elimination, organizing a response is often inherently challenging. Following the example of San Francisco's "End Hep C SF Initiative," a collective impact model utilizing public and private partners was felt to be essential (figure 1). Scott Suckow, Executive Director of the American Liver Foundation's (ALF) Pacific Coast Division stated, "To eliminate HCV in our community, all partners need to be involved with the development, and eventually the implementation of the plan. To ensure stakeholders are engaged, our local planning efforts

**FIGURE 1**



embraced a Public-Private Partnership model, which honors everyone's unique contributions."

As early as 2016, the ALF Pacific Coast Division approached the County of San Diego's Health and Human Services Agency about organizing a local hepatitis C initiative when the San Francisco initiative's plan was finalized. Initially the timing just wasn't right. A local Getting to Zero campaign to eliminate HIV was on the brink of launching, and the two initiatives involved many of the same stakeholders. Local planning efforts were again put on hold while the community responded to a hepatitis A outbreak in early 2017. This was certainly not the time to engage the public health authorities as they battled to get the hepatitis A outbreak under control. As that local public health emergency wound down, stakeholders began to organize—at first casually in hallways and meeting rooms after grand rounds—then more formally as more public health leaders came forward.

The first order of business was to build a case to put before the County Board of Supervisors for approval. Given that the local public health authority was essential to a public-private partnership, local government buy-in was the most important

**BY CHRISTIAN B. RAMERS,  
MD, MPH, AAHIVS**

# Local



step to launching the initiative. Stakeholders selected the ALF to serve as the convening agency, serving in a facilitating role and supporting a 12-month planning process that would develop a roadmap to eliminate hepatitis C in the county. ALF was selected because of their focus on promoting liver health and disease prevention through research, education and advocacy including viral hepatitis. In addition, their ability to work with unserved and underserved communities made them an ideal partner.

Finally, as a non-profit 501(c)3 entity, ALF was able to seek out support for the initiative on its own, unburdening the county and other partners from this task. For the planning phase of the initiative taking place through the end of 2019, funding was secured through unrestricted educational grants from a coalition of organizations including the Alliance Healthcare Foundation, AbbVie and Gilead Sciences.

### Fertile Ground for Elimination

As discussion began among stakeholders, several key conditions propelled the movement forward. First was a strong network of committed clinical champions. San Diego enjoys a high concentration of world-renowned liver disease experts, a vibrant academic and infectious disease community, a strong network of HIV providers attuned to HCV risk factors and treatment, and a major academic medical center with a strong tradition in HCV research. Indeed, many of the clinical trials ushering in the modern, interferon-free era of Hepatitis C treatment were conducted at the Scripps Institute, the UCSD Anti-Viral Research Center (AVRC), or Southern California GI & Liver Centers. Given the now-accepted safety and efficacy of Direct Acting Antivirals (DAAs), this cutting-edge expertise is certainly not a prerequisite to HCV elimination. However facilitated discussion added clinical champions to the cause.

## World Health Organization Calls for Elimination of Hepatitis

**IN 2016**, the global community took a bold step forward in combatting viral hepatitis when the United Nations General Assembly adopted the *Global Health Sector Strategy on viral hepatitis*. In this document, the overarching vision is elimination of hepatitis B and C as public health threats by 2030. The following year, the World Health Organization (WHO) released the first ever *Global Hepatitis Report, 2017*, providing comprehensive epidemiologic statistics on hepatitis B and C and calling attention to the poor access to treatment for the 257 million people suspected of having hepatitis B and the 71 million with hepatitis C.

In these reports, the WHO notes that in 2015 viral hepatitis was responsible for 1.34 million deaths worldwide, a number comparable to those caused by Tuberculosis, and actually greater than those caused by HIV. They also lay out concrete interventions in the areas of testing, treatment, and prevention, as well as concrete targets to be achieved by 2020 and 2030. These strategies are evidence-based interventions that should be achievable for country programs with a modest investment of health budget. A follow-up publication entitled Progress Report on Access to hepatitis C Treatment detailed the absolutely remarkable price reductions that have been achieved for the Direct-Acting

Antiviral (DAA) agents now widely used for treatment of hepatitis C.

Why was WHO able to be so bold in its call to action? Perhaps because we now have a highly effective vaccine for hepatitis B and largely affordable curative treatment for hepatitis C. The full implementation of these strategies will take a tremendous amount of work, and many are easier said than done. For example, though we now have simple rapid tests for both hepatitis

B and C, due to stigma, poor access to healthcare, low perceived risk, and other factors, 90% of hepatitis B and 80% of hepatitis C infections are undiagnosed. If the campaign for elimination of viral hepatitis is to be successful, even with scale-up of treatment services, we must increase awareness, testing, and linkage to care to have a chance at realizing the true potential of our powerful prevention and treatment interventions.

**Table 1. Global service coverage targets that would eliminate HBV and HCV as public health threats, 2015–2030**

Level	Areas	Indicators	Baseline 2015	2020 Target	2030 Target
Service coverage	Prevention	1. Three-dose hepatitis B vaccine for infants (coverage %)	82%	90%	90%
		2. Prevention of mother-to-child transmission of HBV; hepatitis B birth-dose vaccination or other approaches (coverage %)	38%	50%	90%
		3a. Blood safety: donations screened with quality assurance (coverage %)	89%	95%	100%
		3b. Injection safety: use of engineered devices (coverage %)*	5%	50%	90%
		4. Harm reduction (sterile syringe/needle sets distributed per person per year for PWID)	20	200	300
	Testing and treatment	5a. Diagnosis of HBV and HCV (coverage %)	<5%	30%	90%
		5b. Treatment of HBV and HCV (coverage %)	<1%	5 million (HBV 3 million (HCV))	80% eligible treated
Impact leading to elimination	Incidence	Incidence of chronic HBV and HCV infections	6–10 million	–30%	–90%
	Mortality	Mortality from chronic HBV and HCV infections 1.46 MILLION	1.46 million	–10%	–65%

HBV: hepatitis B virus; HCV: hepatitis C virus; PWID: persons who inject drugs

\*While the service coverage target is about output (adoption of reuse-prevention injection devices), the c.5 indicator focuses on outcome (provision of safe injections).

San Diego enjoys a rich network of community health centers dedicated to underserved populations throughout the county. These facilities are community-based, with strong outreach and decades of trust among residents of diverse neighborhoods. Beginning in 2014, a series of HCV testing grants—funded by various sources: the Centers for Disease Control (CDC), the California Department of Public Health, the County of San Diego, and the Gilead Sciences FOCUS program—helped create a patchwork infrastructure of HCV testing and linkage to care, largely overlapping with the primary care safety net.

Fortuitously, these projects bridged the often siloed and competitive healthcare environment, encouraging academic medical centers, community clinics, and other service providers to work together for the community. Powered by these grants, teams of test-counselors, phlebotomists, and

insurance enrollment specialists spread out across the county in clinic settings, health fair events, and through partnerships with mental health and drug treatment programs, bringing HCV testing to the ground level, normalizing screening and linkage as an important and relevant activity.

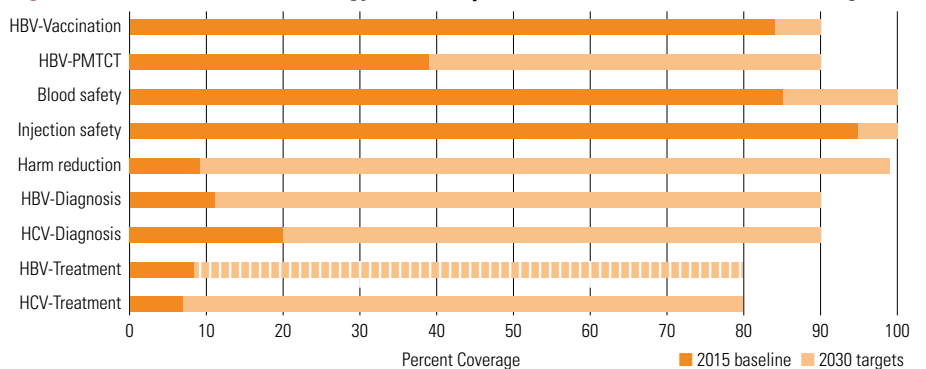
On the care and treatment side, as the literature supporting DAA regimens amassed, a group of primary care-based clinician champions emerged, seeking training, mentoring and support from HCV experts. With newfound skills and dedication to the cause, many newly trained HCV treaters began incorporating HCV care into their primary care practice, with impressive results and an infectious positive feedback loop of enthusiasm. In a study presented at the November 2018 American Association for the Study of Liver Diseases (AASLD) meeting, primary care providers achieved Sustained Virologic Response (SVR12), or cure rates which

# B and C by 2030

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3. March 2018 Progress Report on Access to Hepatitis C Treatment – <https://apps.who.int/iris/bitstream/handle/10665/260445/WHO-CDS-HIV-18.4-eng.pdf?sequence=1>
4. Potential Figures to use for this side bar:
5. Graphic taken from page #23 of 2017 WHO Global Hepatitis Report
6. <https://apps.who.int/iris/bitstream/handle/10665/255016/9789241565455-eng.pdf?sequence=1>
7. Graphic taken from page #54 (figure #12) of 2017 WHO Global Hepatitis Report
8. <https://apps.who.int/iris/bitstream/handle/10665/255016/9789241565455-eng.pdf?sequence=1>
9. Graphic taken from page #23 (figure #6) of 2015 WHO Global sector Strategy on Viral Hepatitis 2016-2021
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11. Additional WHO infographics:
12. <https://www.who.int/hepatitis/news-events/global-hepatitis-report2017-infographic/en/>

**Figure 1. Global Health Sector Strategy on viral hepatitis: 2015 baseline toward the 2030 targets**



\*Measurement of progress on HBV treatment target currently limited by the absence of data on the proportion of persons eligible and the absence of a functional cure

**Figure 2. Targets for reducing new cases of and deaths from chronic viral hepatitis B and C infection**

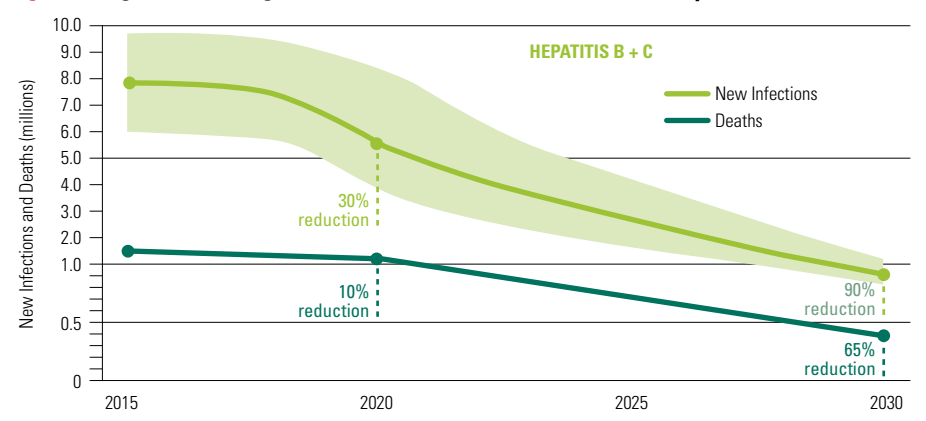
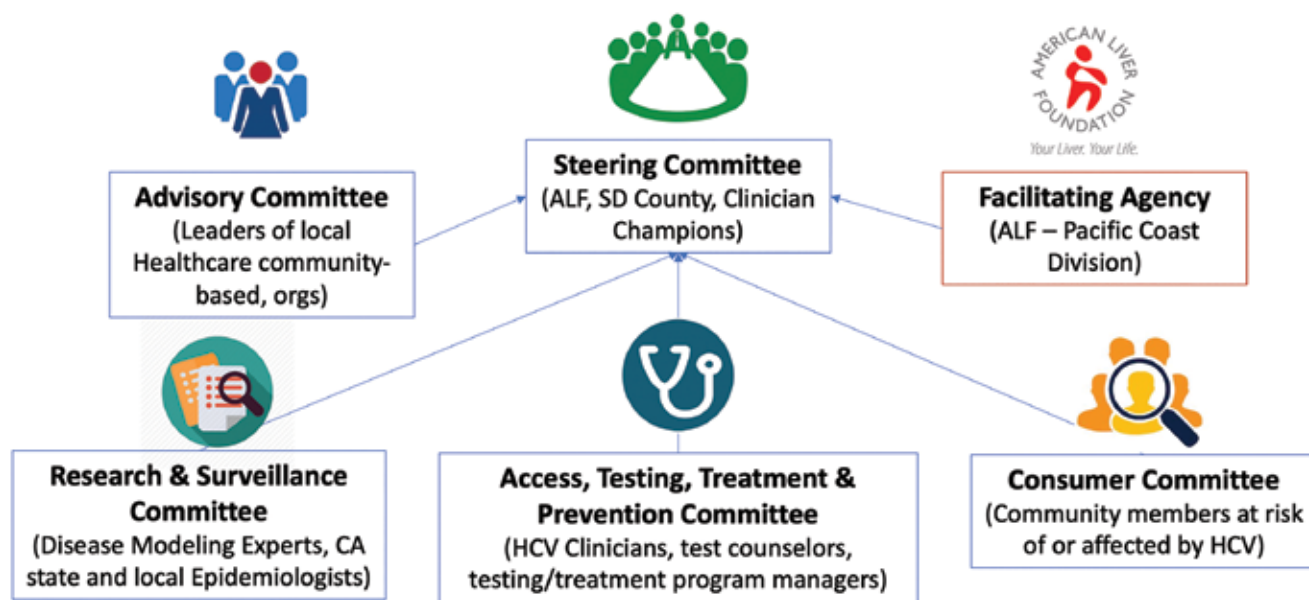


FIGURE 2

## Eliminate Hepatitis C San Diego: Committee Structure



were statistically identical to specialists (95–99% vs. 95–98%), including in advanced cirrhotic patients.<sup>3</sup>

One such HCV treater, Dr. Brenda Green based at the Chula Vista Family Health Center notes, “Caring for HCV patients is one of the most gratifying aspects of my family medicine practice. It has helped me grow as a person and as a physician to serve this population and continue my learning through this program that integrates specialist care with primary practice.” Although these limited grant-funded demonstration projects were insufficient to propel the county towards elimination, the seed had been planted, and a scaffolding of viral hepatitis treatment infrastructure within primary care centers and HIV clinics had been created.

Several structural and policy changes occurred at just the right time to ensure access to HCV treatment once patients were screened, diagnosed and linked to care. First and foremost, the State of California expanded Medicaid, ensuring that for most low-income individuals, access to medical care because of lack of insurance was not a barrier. Medicaid access proved to be necessary, but not sufficient to ensure access to HCV treatment. Due to the initially very high cost of DAAs, many Medicaid programs implemented severe restrictions to HCV care, generally relating to fibrosis (HCV treatment only available for those with severe liver fibrosis), provider type (HCV treatment only available if prescribed by a specialist), and sobriety (a verified period

of sobriety prior to ‘qualifying’ for HCV treatment). These restrictions are tracked and mapped in a state-by-state fashion at [www.stateofhepc.org](http://www.stateofhepc.org).<sup>4</sup>

Responding to the chilling effect of these restrictions, advocacy groups such as the California Hepatitis Alliance and Project Inform worked together to revise Medicaid HCV treatment policies, eliminating formulary restrictions which are major barriers. The also collaborated with state officials such as Chief of the Office of Viral Hepatitis Prevention, Rachel McLean, MPH, to focus on the importance of HCV treatment as prevention, especially for PWID and women of childbearing age. Through several iterative drafts, the California Medicaid allowed for increasing access, culminating in the July 1, 2018 policy which fully removed restrictions to HCV treatment.<sup>5</sup> Finally, with broader availability of DAAs, evidence began to grow regarding the feasibility of achieving high cure rates, in key populations such as People Who Inject Drugs (PWIDs).

Simultaneously, mathematical modeling studies showed that treating PWIDs will be essential to achieving HCV elimination. Taken together, these two streams of evidence compelled the AASLD/IDSA HCV Guidelines Committee to specifically recommend treatment for PWIDs, noting, “Active or recent drug use or concern for reinfection is not a contraindication to HCV treatment (evidence rating IIa, B).”<sup>6</sup> Although this key population of PWIDs had been historically difficult to engage via specialist clinics, the primary



care HCV treatment model lent itself well to self-contained screening, linkage, and treatment activities, with specialist consultation available at arm's length.

### And Now, the Planning Begins

After presenting a formal proposal letter to the San Diego County Board of Supervisors, the initiative received approval to conduct planning activities throughout the year with a mandate to present findings, recommendations, and a roadmap to elimination back to the Board in December 2019. Activities are well underway and have been organized into several committees, modeled on the work of End Hep C SF (figure 2).

Bringing together C-suite leaders of healthcare organizations, corrections facilities, border health advocates, social service and homeless organizations and many others, the Advisory Committee will serve as a critical link between the initiative and local service delivery partners. Co-chaired by Dr. Wilma Wooten, the county public health officer as well as Paul Hegyi, MBA, CEO of the San Diego County Medical Society, this committee ensures bidirectional communication regarding the initiative's activities, and facilitate rapid dissemination of recommendations, educational materials, and relevant activities.

Natasha Martin, DPhil, Associate Professor in UCSD's Division of Global Public Health leads the Research and Surveillance Committee. This group accesses multiple data sources to define current burden of disease and help set parameters by which the initiative can measure progress. In 2017, 3,112 new cases of HCV cases were reported in San Diego County, and HCV was listed as an underlying cause of death annually in 70 to 100 deaths in the region. The committee seeks to move beyond these passively reported statistics to model the true incidence of HCV in the region, the prevalence in various sub-populations, and ultimately to model what pace of diagnosis and treatment will be necessary to reach elimination, defined as an 80% reduction in incidence, and a 65% reduction in mortality, in line with WHO benchmarks.

A Consumer Committee led by community members Rick Nash and Tara Stamos-Buesig, will be critical to ensure that interventions, plans, and the roadmap towards elimination are responsive to the needs and concerns of those affected by HCV. Consumer Committee meetings serve to generate ideas and define community needs to report to the Steering Committee, but also to serve as a sounding board to gather reflections on overall initiative planning.

As Assistant Medical Director at the Family Health Centers of San Diego, I chair the Access, Testing, Treatment and Prevention Committee. This committee consists of specialist and primary care HCV treaters, harm reduction advocates, program managers, and HCV test/counselors, and seeks to fully define the landscape of HCV testing, linkage and treatment throughout the county. This committee has developed an organizational practices survey to be deployed

to hundreds of organizations in an attempt to define access, gaps, and attitudes related to HCV. This committee will also be instrumental in designing awareness, education and training interventions to be implemented at health and social service facilities throughout the county.

Finally, the ALF, and the Steering Committee of the initiative will ensure ongoing progress, organize the many diverse voices, and coalesce the planning activities into a final report and operational roadmap that will guide San Diego County towards elimination of HCV by 2025. Following the Public-Private model, this committee is co-chaired by myself, ALF Executive Director Scott Suckow, and Deputy Public Health Officer Dean Sidelinger.

As the planning work continues through 2019 and reports back to local government officials, realization of the goal to eliminate HCV will depend on the ability of partners to collaborate across siloes, to engage the most marginalized populations, and to work together to achieve an intimidating, but achievable goal. Without verticalized hepatitis programming at a Federal level, it will be up to an army of local and grassroots efforts to achieve elimination. As the initiative's consultant Ryan Clary states, "It is critical that states and localities step up to establish their own initiatives. San Diego County is one of those leaders ensuring the public threat of Hepatitis C is eliminated and that people living with and at risk for Hepatitis C have the services and support to live healthy lives." **HIV**



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# THE EMPIRE STATE STRIKES BACK

BY JOSEPH S. CERVIA, MD, MBA, FACP, FAAP, FIDSA, AAHIVS and  
JOSEPH McGOWAN, MD, FACP, FIDSA, AAHIVS

**F**OR DECADES FOLLOWING THE RECOGNITION OF THE HIV/AIDS EPIDEMIC, New York State (NYS) has been its epicenter in the United States. By the early 1990s, nearly 15,000 individuals were being diagnosed annually. As recently as 2013, there were approximately 3,300 newly diagnosed with HIV infection in NYS, with an estimated 3,000 incident infections. In 2012, NYS had the highest HIV prevalence rate among all U.S. jurisdictions with HIV reporting (810 per 100,000 population). While the state had seen declines in new HIV diagnoses, as a result of enhanced treatment and improved survival, the total number of infected people had increased from 110,000 in 2002 to over 132,000 by 2012. NYS continues to have more people living with HIV (PLWH) than any other state.

Over the last decade, NYS has made great progress in decreasing infection rates, and enhancing access to and retention in care for those infected with HIV. In 2014, Governor Andrew M. Cuomo announced a three-point plan to end the HIV/AIDS epidemic in NYS by the end of 2020:

- Identify persons with HIV who remain undiagnosed and link them to health care;
- Link and retain persons diagnosed with HIV to health care and get them on antiretroviral therapy (ART) to maximize viral suppression so that they remain healthy and do not further transmit infection.
- Facilitate access to Pre-Exposure Prophylaxis (PrEP) and non-occupational post-exposure prophylaxis (nPEP) for high-risk persons to keep them HIV-negative.



# STATE BACK

## Ending the HIV/AIDS Epidemic in New York

The end of the HIV/AIDS epidemic was further defined as the achievement of the goal of having the total number of new HIV infections fall below the number of HIV-related deaths (projected to number approximately 750 per year by the end of 2020, an 80% reduction from 2012 levels).<sup>1</sup> In addition to the priceless human value of this achievement, using the published estimate for lifetime HIV-related medical costs of \$357,000 per individual,<sup>2</sup> reducing the annual rate of new infections to 750 from 3,000 would result in a medical cost saving of over \$804 million. The grand vision is one of maximally leveraging testing, treatment and prevention efforts in transforming NYS from a place suffering the worst epidemic of HIV in the nation, to one where new infections are rare, and infected individuals enjoy healthy lives and normal life expectancies. By early 2019, how far have we come toward achieving these goals, and what is being done to bring the HIV/AIDS epidemic in NYS to a conclusion?

### The Blueprint

Once the goal of ending AIDS in NYS was announced, the implementation process had to begin. To achieve success it became clear that a top down approach was not going to be

effective. The NYS Department of Health's AIDS Institute conducted 17 "Listening Forums" around the state in which community members, clinicians, social service providers and advocates participated. The AIDS Institute received 294 recommendations on how to proceed. They convened a multidisciplinary Task Force to write up the Blueprint: End AIDS: Get Tested; Treat Early; Stay Safe, released in 2015.<sup>1</sup>

The Blueprint is a road map that identifies key populations, regions, public health issues, financing, monitoring and metrics that allow a coordinated approach to achieve success. Based on this plan, resources were earmarked to address specific identified barriers, including legal issues, diagnosis, linkage and retention and prevention. Laws and regulations had to be changed, such as: prohibiting possession of condoms to be used as evidence against commercial sex workers; changes to health regulations that now allow minors to consent to HIV treatment, PEP and PrEP without parental consent; and removing the upper age limit for mandatory offer of HIV screening.

The initiatives are data driven, so that, even though key populations were identified, such as young MSM of color, transgender persons, women of color, and injection drug



users, it was recognized that membership alone in a group did not equate with risk and that the social determinants of health that led to disparities had to be addressed. Specific recommendations to address barriers were recommended:

**For Testing:** Increase commitment and develop digital prompts to improve routine HIV testing rates and fund projects to target HIV testing to key populations, make all testing venues referral and engagement centers.

**For Linkage and Retention:** Address acute infection by changing the testing algorithm to the 4th generation assay. Issue a “Call to Action” policy statement setting same day ART initiation as the standard for all confirmed HIV diagnoses. (<https://www.health.ny.gov/diseases/aids/providers/prevention/ria.htm>). Fund grants to care providers to establish linkages of case management and clinical care such as LRTA (Linkage, Retention and Treatment Adherence), RAP (Retention and Prevention) and YGetit? (a SPNS project targeting social media promoting treatment adherence to youth with HIV). Promote training and allow advanced practice providers to prescribe buprenorphine. Require agencies to develop and submit their own HIV Care Cascades to indicate where they stand regarding achievement of 90-90-90 goals in their populations.

**For Prevention:** Develop PrEP-AP program to fund access to clinical care and monitoring for uninsured persons to get PrEP. Target provider training in PEP and PrEP through its Clinical Education Initiative (CEI), and allow pharmacies to dispense emergency seven- day nPEP through non-patient specific clinician orders.

NYS negotiated the return of \$6.2 billion in savings from the Federal Government generated by its Medicaid Programs switching to a Managed Care model to develop the Delivery System Reform Incentive Payment (DSRIP) Program ([https://www.health.ny.gov/health\\_care/medicaid/redesign/dsrip/providers\\_professionals.htm](https://www.health.ny.gov/health_care/medicaid/redesign/dsrip/providers_professionals.htm)). DSRIP provides enhanced payments for regional groups who decrease avoidable hospital admissions for specific disease states (including HIV) over a 5 year period. One health system in NYC established a community wide collaborative with neighborhood service agencies that demonstrated significantly enhanced case finding and retention through this funding.

### Monitoring and Metrics

In order for any ETE effort to achieve success it must be data-driven. The data must be up to date and widely disseminated to allow new initiatives to be developed and refocus existing programs to address need as the epidemic contracts. Invariably as we make end roads into the remaining vestiges of an epidemic it focuses on the most vulnerable and hard to engage parts of the community. Targeted and novel interventions that are developed in collaboration with members of the affected community must be implemented. They should engage local popular opinion leaders and

influencers to deliver the message and information on how to access services.


NYS has established the ETE Dashboard (<http://etedashboardny.org/>) to update stakeholders on goals and progress to date on Bending the Curve, graphics, as well as hosting members’ blogs for agencies to promote their initiatives and data. For example the latest data from 2017 (2 years after the Blueprint was released) compared with 2013 indicate a drop in HIV incident cases from 3,347 to 2,269 (2020 goal: 750); linkage to care within 30 days of diagnosis from 69% to 81% (goal 90%); Progression to AIDS within 2 years of diagnosis from 10.4% to 6.9% in 2015 (goal 5.1% - a 50% reduction).

### Efforts to End the Epidemic in High-Risk Groups

Young men who have sex with men (YMSM) ages 13-29 make up a considerable percentage of new HIV diagnoses in NYS. Nearly 28%, of new HIV diagnoses in 2013 were among YMSM. In fact, between 2012 and 2013 YMSM represented the only high-risk group where new HIV diagnoses increased, by 5% statewide.<sup>1</sup> Nationally it has been estimated that only 10% of high school students and 21% of YMSM have been tested for HIV.<sup>3</sup> In addition, although in May 2018, the Food and Drug Administration approved an indication for Truvada for PrEP in adults and adolescents who weigh at least 35 kg (77 lb),<sup>4</sup> only approximately 8-9% of YMSM use PrEP.<sup>3</sup>

To enhance educational efforts that address these challenges, the proposed Healthy Teens Act amends the NYS Public Health Law by requiring all local school districts to develop age-appropriate and medically-accurate sex education curricula. The bill would award funding for school districts, boards of cooperative education services and community-based organizations to provide comprehensive sex education programs. This would support young people in making healthy choices about sexual behavior and avoid negative outcomes including HIV, STIs, and unintended pregnancies. Access to evidence-based education, LGBTQ sexual health information, as well as knowledge of prevention interventions such as PrEP, nPEP and effective condom use would be included, with the goal of enabling youth to live sexually-healthy lives.<sup>5</sup>

Furthermore, according to NYS’s “Getting to Zero” goals, competent minors, who are already able to consent to both STI and HIV testing without parental consent, would be guaranteed the right to consent to HIV treatment and prophylaxis. A process or policy must be in place that allows for all young people to gain access to HIV and STI treatment, as well as prevention services, without parental consent so that confidentiality is preserved. Protections must be in place to ensure that insurance information, such as explanation of benefits (EOB) documents, are sent to the patient (i.e. young person) rather than to the policy holder (i.e. parents) if that young person is using parental insurance to support HIV treatment or prevention services.<sup>1</sup>



**The drive to end the epidemic in NYC by reducing the prevalence of HIV infection must account for the vastly improved survival of infected individuals. The overall death rate for PLWH in NYC has decreased by 68% from 2001 to 2015.**

NYS has assembled an Ending the Epidemic - Young Adult Advisory Group to implement strategies for appropriate, policies and programs to end the HIV/AIDS epidemic in NYS by the end of 2020. The group has circulated detailed, specific recommendations regarding policy, housing, treatment and prevention, and marketing strategies aimed at addressing the needs of the state's youth.<sup>6</sup> With an estimated less than one third of infected youth aged 13-24 virologically suppressed, much work remains to be done to engage asymptomatic young people in transmission route- and outreach-based testing with enhanced linkages to and engagement in care.

Heat maps and other regional data demonstrate that new diagnoses of HIV and prevalence of unsuppressed HIV (community viral load) are inextricably linked with social determinants of health such as poverty, education, housing, engagement in the criminal justice system, trauma, as well as mental illness and substance use. Initiatives to address health disparities and stigma must be included in any successful ETE effort. In 2016, NYS expanded access to housing, nutritional and transportation support to all people living with HIV in New York City, no longer limited to persons with AIDS or documented hardship in recognition of the critical role these services play in achieving and maintaining viral suppression.

Residents of high-incidence HIV communities are often unaware of their local statistics. The lack of media attention to HIV since the advent of effective therapy has left individuals unable to assess their own risk. For example, a study of MSM found that black MSM were nine times more likely than white MSM to be HIV- infected despite having significantly fewer sexual partners.<sup>7</sup> Less risky behavior can place one at higher risk depending on the community in which they live. Delivery of treatment and prevention into key populations must be planned and implemented with community participation and involvement so that at risk individuals actually receive the services they need. This requires engagement of stakeholders who may not know they are affected. Programs must be community specific, for example, using dating and hook-up apps to conduct outreach to young MSM may be very successful but would not work to engage women of color.

### **Ending the Epidemic in New York City**

Almost 110,000 PLWH make their homes in the Big Apple.<sup>8</sup> Yet here, according to surveillance data presented by Demetre C. Daskalakis, MD, MPH, Deputy Commissioner, Disease Control for New York City at a recent meeting of the Physicians' Research Network, the annual number of

new diagnoses continues to decline, dropping from 2,493 in 2015 to 2,279 in 2016 (8.6%).<sup>9</sup> This reporting period also featured a 14.8% decline in new diagnoses among MSM, the steepest year to year drop ever observed. Remarkably, 76% of PLWH were virologically suppressed in 2016, including 84% of those in care (an increase from 76% in 2012).<sup>9</sup>

The drive to end the epidemic in NYC by reducing the prevalence of HIV infection must account for the vastly improved survival of infected individuals. The overall death rate for PLWH in NYC has decreased by 68% from 2001 to 2015.<sup>9</sup> Strategies being employed to end the epidemic include: transforming sexually transmitted disease clinics into destination clinics for sexual health services and efficient hubs for HIV prevention and treatment, increasing the delivery of PrEP and nPEP, employing novel strategies to support high-risk populations, enhancing rates of viral suppression, and employing HIV status neutral cycles for engagement in prevention or treatment.<sup>9</sup>

With rates of STIs rising in parallel to those of the nation, utilizing the city's sexual health clinics as hubs for initiation of PrEP, nPEP, and ART for newly diagnosed individuals, along with linkages to long-term care has become a critical strategy for ending the epidemic. In addition, PrEP prescription rates in NYC's ambulatory care clinics have recently surged, from 38.9 in 2014 to 418.5 in 2016 per 100,000 patients visiting; nevertheless, only 30% of those considered candidates in 2016 were on PrEP.<sup>9</sup> Outreach to communities at risk has included a "Bare it All" marketing campaign. This program encourages LGBTQ patients to speak openly with their doctors about all health matters, and includes a publication of an LGBTQ Health Care Bill of Rights and a directory of facilities with experience in serving these populations. Programs such as ReCharge feature peer outreach for harm reduction at sex clubs and parties to those using crystal meth and other substances. Finally, NYC has enthusiastically embraced the U=U campaign, and brought focus to HIV status neutral prevention and treatment cycles for at risk and infected populations.<sup>9</sup>

### Excelsior: Ending the Epidemic in the Empire State

The state of New York has made great strides in decreasing infection rates, and enhancing access to and retention in care for those infected with HIV. In operationalizing the three-point plan to end the HIV/AIDS epidemic in NYS by the end of 2020, government, health care professionals and the community have actively collaborated in efforts to identify persons with HIV who remain undiagnosed and create linkages to timely and comprehensive health care for them, to link and retain persons already diagnosed with HIV to health care and get them on ART to maximize viral suppression, and to enhance outreach to at-risk populations in order to facilitate access to PrEP and nPEP.

Building a successful ETE Program requires activism and innovation. Governments, Legislators, Public Health Officials, donors and public figures must be educated and encouraged to make ending HIV a priority that not only can be done but should be done. The commitment to ETE must be long-term, and the goal dates of 2020 in New York or 2030 (National plan) are just the start. One of the most challenging and costly interventions is lifelong retention in care and adherence to ART. For this reason simplified and novel dosing strategies, and ultimately cure, are future challenges. Partnerships and persistence have been at the heart of the substantial progress made throughout the course of the HIV epidemic. There is ample evidence that these same qualities will continue to boost continued advances, "ever upward" in bringing the epidemic to a conclusion in NYS. **HIV**



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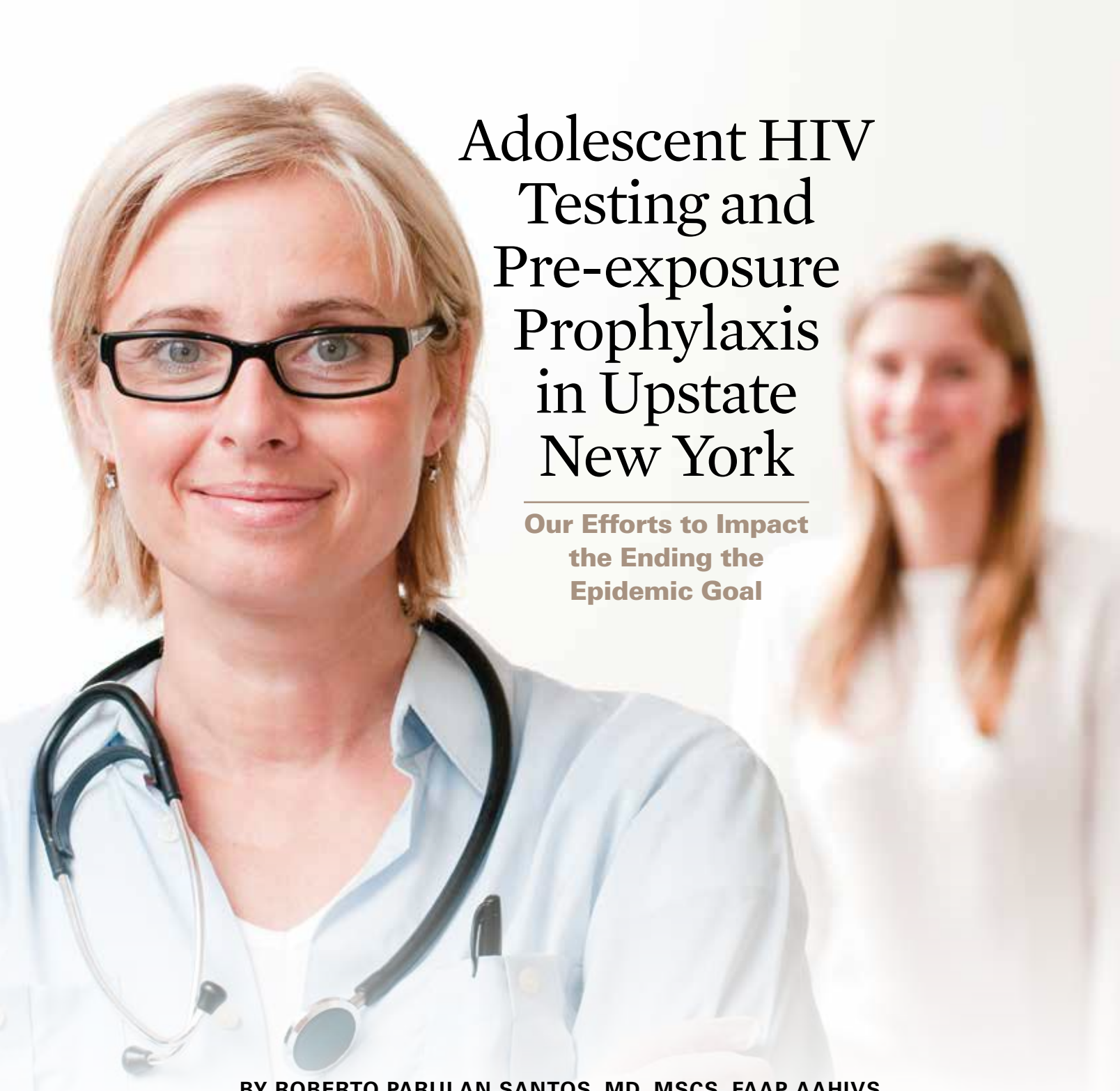


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# Adolescent HIV Testing and Pre-exposure Prophylaxis in Upstate New York

**Our Efforts to Impact  
the Ending the  
Epidemic Goal**

**BY ROBERTO PARULAN SANTOS, MD, MSCS, FAAP, AAHIVS**

**E**ARLY DIAGNOSIS AND TREATMENT as well as prevention of HIV infection among adolescents can be achieved through routine HIV testing. Adolescents engage in sexual risk behaviors that may result in unintended health outcomes such as HIV infection.<sup>1</sup> Four out of 10 high school students (40%) surveyed in 2017 had sexual intercourse. Ten percent reported four or more sexual partners during their young life, and only half (54%) used condoms during their last sexual intercourse.<sup>1</sup> In 2016, adolescents 13-24 years old accounted for 21% of new HIV infections in the US.<sup>2</sup> In New York State (NYS), the rate of adolescents (13-19 years) living with HIV infection is almost twice the national rate (35.6 vs. 18 per 100,000).<sup>3</sup>

To be consistent with the 2006 recommendations from the Centers for Disease Control and Prevention (CDC), NYS enacted a mandate in 2010 offering HIV testing initially to all persons 13–64 years of age then eventually amended to include those older than 64 years.<sup>4–6</sup> To further streamline HIV testing for adolescents and adults, consent procedures were changed in 2014 to remove written consent for routine HIV testing in NYS.<sup>5</sup> Also, the 2017 amendment expanded the list of sexually transmitted disease (STD) that allows providers to directly offer HIV testing to patients less than 18 years-old if he/she has the capacity to give consent.<sup>7,8</sup>

### HIV Testing in Adolescents

Guidelines or mandates to increase HIV testing should be assessed for challenges in implementation particularly among vulnerable populations like adolescents. Following the enactment of the NY State 2010 mandate for HIV testing, we reported the actual number of adolescents tested was only 10% from 2012 to 2015.<sup>9</sup> (Figure 1) This is comparable to the 2017 Youth Risk Behavior Survey which found that in the US 9.3% of high school students had ever been tested for HIV.<sup>1</sup> In 2014, we conducted a survey using a 10-item multiple choice validated questionnaire among adolescents in our General Pediatric Clinic in Upstate NY to assess their knowledge and utilization of HIV tests. We also asked about barriers in implementation after the 2010 NY State mandate offering HIV testing to all people 13 years and older.

Of the 248 adolescents who participated in the anonymous survey, about half (46%) reported that HIV testing was offered to them during their clinic visit but less than half (22%) agreed to be tested ( $P=0.004$ ).<sup>9</sup> In our study, 22% reported having a history of HIV testing prior to the survey which is twice as much as the number of those who were tested during their routine adolescent clinic appointment. It is possible that they may have had HIV testing at another location such as the emergency room, primary care setting, or as an in-patient.

### Barriers to HIV Testing in Adolescents

Adolescents seems to have a reasonable knowledge about HIV and HIV testing. From the cross-sectional survey we conducted, most responded correctly, acknowledging HIV as the virus that causes AIDS (88%), that there are available treatments for HIV infection (77%), and that HIV testing is voluntary (62%). The most common reason for declining HIV tests in adolescents is that they “feel as though I do not need to be tested.” (Figure 2) This demonstrates a great opportunity for providers to educate and guide their young patients on the importance of knowing their HIV status and make HIV testing a routine part of the adolescent clinic visit.<sup>9</sup> However, in another cross-sectional survey done in New York City in 2013 the researchers noted the limited

experience of clinicians on current screening guidelines may contribute to low HIV testing among adolescents.<sup>10</sup>

### Utilization of HIV Testing by Adolescent Providers

In 2017, we conducted an online and paper-based survey using a 19-item multiple choice validated questionnaire among adolescent providers in our Children’s Hospital in Upstate NY. Our goal was to assess their knowledge and utilization of HIV tests as well as barriers in implementation after the 2010 NY State mandate. Of the 115 providers who participated in the anonymous survey, about 6 out of 10 (59%) offered HIV tests to adolescents as “frequently as they can.” Figure 3 summarizes their responses regarding knowledge of the HIV testing law.<sup>11</sup> It is interesting that providers who were older ( $>30$  years old,  $P<0.05$ ) and in medical practice longer ( $>10$  years,  $P<0.005$ ) were more likely to routinely offer HIV testing to their adolescent patients.<sup>11</sup>

### Barriers to Implementing HIV Tests Amongst Adolescent Providers

Adolescent providers had several concerns regarding implementation of the 2010 NY State mandate for HIV testing. Twenty-one percent of providers noted that their patients are unwilling to have HIV testing done (see figure 4). Despite optimal knowledge of HIV testing laws, at least 10% of providers gave limited experience as a perceived barrier for offering HIV testing.<sup>11</sup> Limited experience was likewise reported by other researchers which contributed to low HIV testing among adolescents in NYC.<sup>10</sup> Together with logistical issues in their local clinic settings such as time, parental presence in the room, and limited time capacity, multiple avenues are present for provider-initiated quality improvement.<sup>11</sup> Scaling up HIV testing into pediatric health services through provider-initiated program has been reported to be feasible.<sup>12</sup>

### Acceptance of PrEP in Adolescents

Once the HIV status of adolescent patients is known to be negative, medical providers should offer appropriate prevention interventions such as pre-exposure prophylaxis (PrEP) in addition to other risk reduction strategies for contracting HIV infection. Adolescents are particularly vulnerable to HIV infection and offering PrEP can significantly impact new HIV infection rates on a population-level.<sup>13</sup> To test the hypothesis that at-risk adolescents may not be utilizing PrEP and barriers exist to adopting it, we conducted an online and paper-based survey from August 2017 to May 2018 using a 13-item validated questionnaire.<sup>14,15</sup>

We reported that while the majority of adolescents had been seen by a physician in the past 12 months (90%) usually at their primary providers’ clinic, most had never been HIV tested (59%).<sup>14,15</sup> Most had not heard of medication as a way to prevent HIV infection (57%), many had not heard of PrEP

(57%) and many of the adolescents did not know how to access more information about PrEP (56%). The majority had not been offered PrEP (87%) and adolescents were equally split in adopting PrEP (Yes 50% vs. No 50%). However, more than half (57%) expressed interest in attending educational program on PrEP (57%). Among the 103 adolescents who participated in our survey their willingness to adopt PrEP was associated with the offering of PrEP ( $P=0.03$ ), their awareness of PrEP ( $P=0.03$ ), and their knowledge of where to go to learn more about PrEP ( $P=0.04$ ).<sup>14,15</sup>

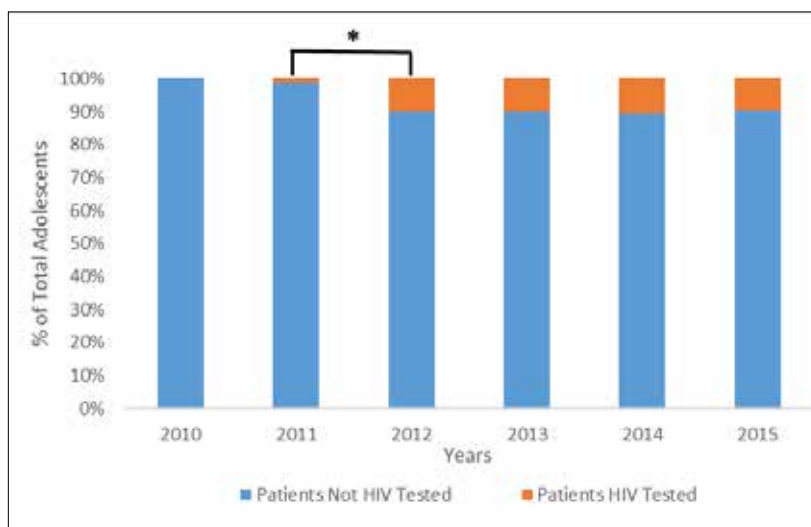
### Barriers to PrEP Amongst Adolescents

Adolescents' limited knowledge about PrEP was a significant barrier to adopting it. They were willing to embrace and accept PrEP only if someone offered it to them and provided them with more information about it. Various reasons why adolescents may not agree to starting PrEP are shown in Figure 5.<sup>14,15</sup> Again, the impact of healthcare providers cannot be overemphasized in educating and guiding their young patients regarding the use of PrEP in preventing HIV infection. Almost half (46%) of the responses regarding why do they not want PrEP highlighted the need for direction and guidance: "I don't need PrEP" (21%), "Prefer not to start PrEP" (16%), and "I can't have HIV infection" (9%).<sup>14,15</sup> (Figure 5)

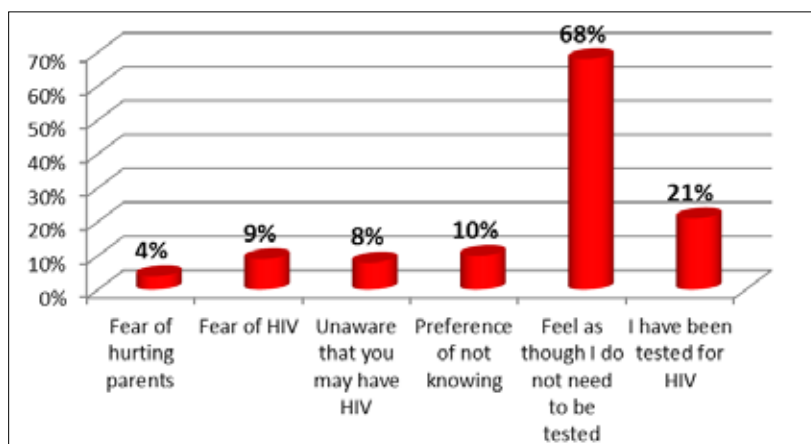
### Offering PrEP by Adolescent Providers

There is a growing body of medical evidence on the safety of oral PrEP among adolescents. Several international groups (CDC, World Health Organization) recommend special considerations regarding PrEP for adolescents and young adults under 18 years old.<sup>16</sup> Further, the US Food and Drug Administration have expanded the indication of oral emtricitabine/tenofovir disoproxil fumarate (Truvada, 200 mg/300 mg) to include PrEP to at-risk adolescents.<sup>16</sup> Anecdotally, we received several correspondence from our local pediatric providers and college health centers regarding referral to our subspecialty clinic to prescribe PrEP to their sexually active adolescents and college students. The concurrent diagnosis and treatment for STDs including syphilis, chlamydia and gonorrhea is a clear indication for initiating PrEP.

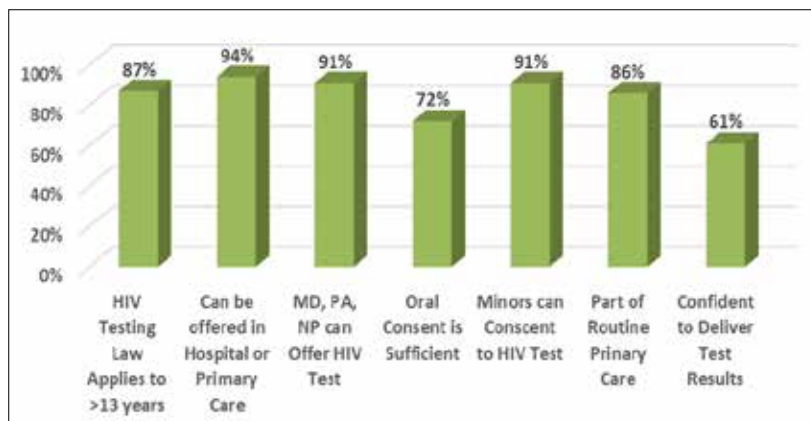
To test the hypothesis that providers may not be offering PrEP to at-risk adolescents and that barriers in implementing PrEP remain, we conducted an online and paper-based survey from August 2017 to May 2018 using a 16-item validated questionnaire.<sup>17,18</sup> We reported excellent knowledge of PrEP among the 104 participating medical providers. The majority were aware of PrEP (81%) and that treatment with PrEP reduces the risk of HIV infection (100%) and that it is >90% effective if taken daily (82%).<sup>17</sup> Further, almost all of the participants agreed that PrEP combined with harm reduction practices can further lower the risk of HIV infection (99%) and most correctly disagreed that PrEP prevents other STDs (94%).<sup>17,18</sup>



**FIGURE 1.** HIV Tests Performed Among Adolescents in a General Pediatric Clinic. The actual number of adolescents tested in the pediatric clinic significantly increased from 1.2% (21 out of 1693) in 2011 to 9.9% (180 out of 1826) in 2012. (\* $p<0.0001$ )

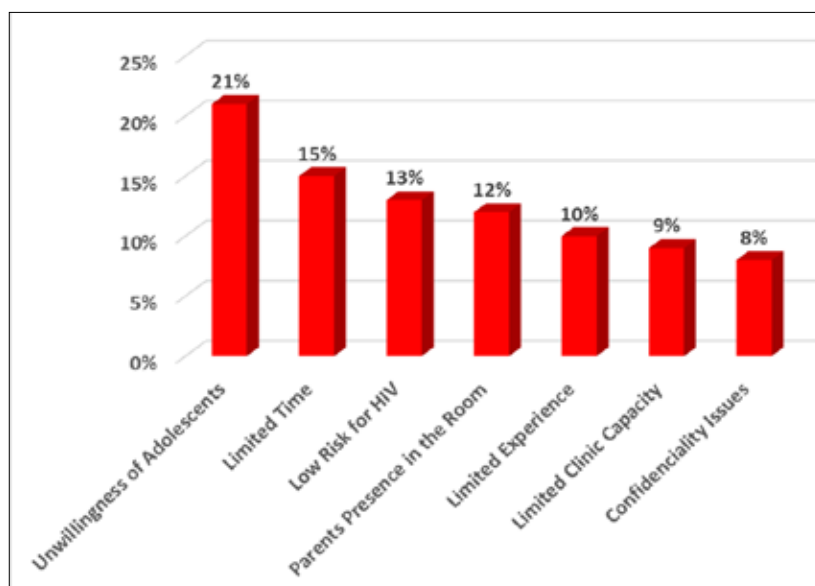


**FIGURE 2.** Most Common Reasons for Declining HIV Tests in Adolescents. The responses are not mutually exclusive.

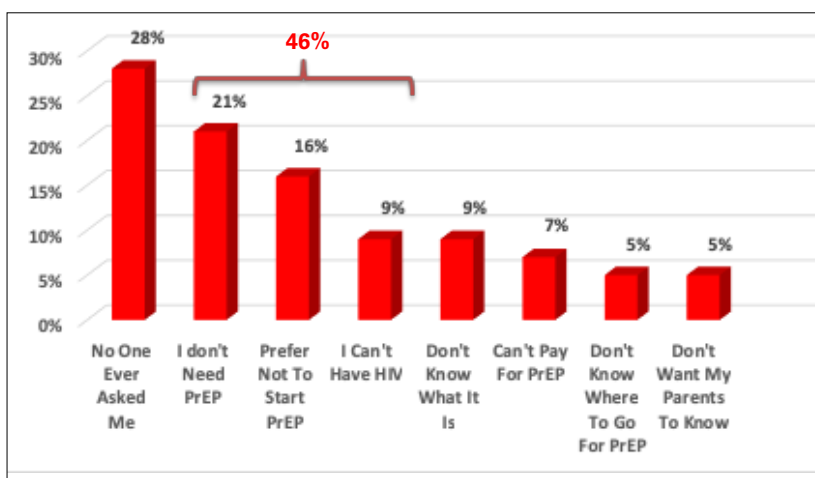


**FIGURE 3.** Optimal Responses of Adolescent Providers on Their Knowledge of HIV Testing Law. The responses are not mutually exclusive.





**FIGURE 4.** Barriers to Implementing HIV Tests Amongst Adolescent Providers.



**FIGURE 5.** Several Reasons Why Adolescents are not Agreeing to Start Pre-exposure Prophylaxis or PrEP. The responses are not mutually exclusive.

### Barriers to Offering PrEP by Adolescent Providers

Despite the excellent knowledge of PrEP among the adolescent providers its adoption as part of adolescent health services remains suboptimal. The majority have not offered PrEP (85%) and have not prescribed it to adolescents (93%) as most do not feel confident to offer it (75%) despite their belief that it's an important part of routine care (83%).<sup>17,18</sup> What providers consider barriers in implementing PrEP to adolescents are shown in Figure 6.<sup>17,18</sup> Further, the providers' willingness to offer PrEP is associated with their confidence to implement it to adolescents during their clinic visits ( $P < 0.005$ ).<sup>17,18</sup> Hosek and colleagues reported that the clinicians' comfort with prescribing and monitoring uptake of PrEP in adolescents remain limited despite FDA-approval of Truvada for PrEP.<sup>13</sup>

### Educational Programs and Practical Tips on HIV Testing and Offering PrEP

Recognizing the needs of adolescent providers in Upstate NY and addressing practical issues on HIV testing and implementation of PrEP at clinic visits, we embarked on educational programs based on USPHS/CDC guidelines intended to successfully start and follow patients on PrEP.<sup>19,20</sup> Travelling strategically to nine different clinics (Figure 7) allowed us to cover the 17 counties in our catchment area.<sup>17</sup> Information on the evolution of HIV testing requirements that streamline offering HIV tests to adolescents were provided.<sup>4-8</sup> Further, practical information was made available including ICD 10-CM codes, PrEP payment options, online resources for PrEP (HIV Clinical Resource <https://www.hivguidelines.org>, CDC PrEP for Providers <https://www.cdc.gov/hiv/risk/prep/index.html>), PrEP line (888-HIV PREP) and PrEP tool kits. Pens and lip balm branded with our local adolescent center's contact number were also distributed. Our team consisting of a dedicated case manager, social worker, nurses, and pediatric HIV specialists provides initial evaluations and PrEP initial prescriptions before sending the patient back to community providers. Patient access to our local adolescent center appears to be addressing confidence issues among adolescent providers who have been hesitant to prescribe or recommend PrEP to their patients.

### Summary

Adolescents are disproportionately affected with new HIV infections in the US. Routinely offering HIV testing remains a key part of ending the HIV epidemic in our country. Knowing the HIV status of our patients leads to HIV prevention, prompt linkage to care and treatment with ART for those who are infected. PrEP remains an important HIV transmission prevention tool in addition to other risk reduction strategies including condom use and testing and treating sexually transmitted infections. There are unique challenges in offering HIV test and PrEP to adolescents which can be avenues for additional research and interventions. Provider-initiated programs can effectively address many of the barriers to ending the HIV epidemic. **HIV**



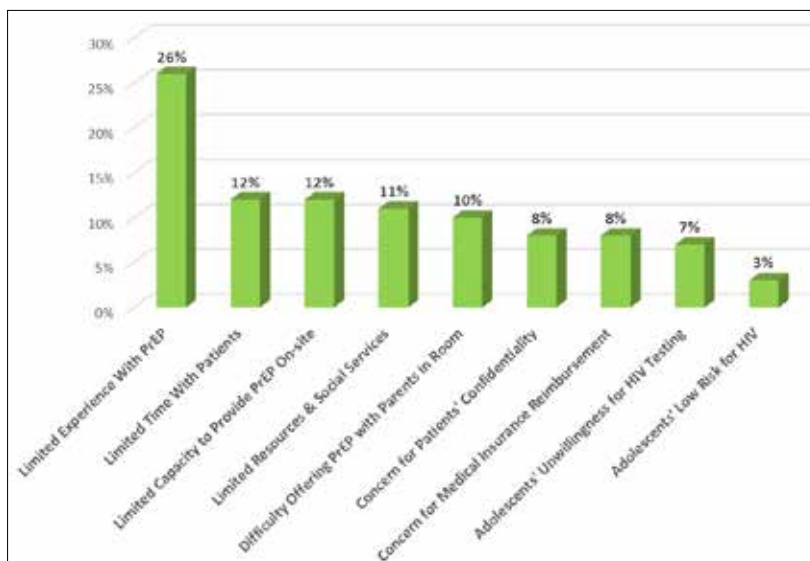
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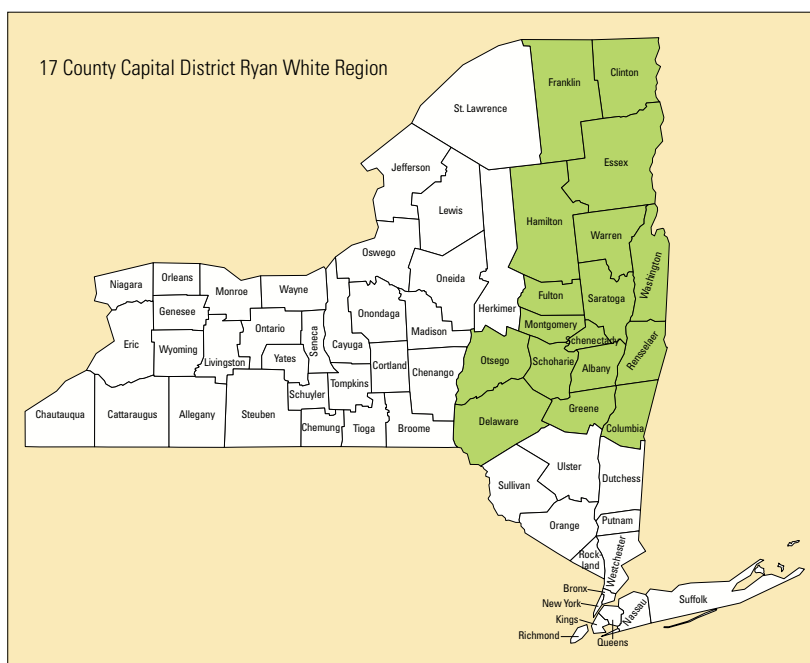
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**FIGURE 6.** Several Reasons That Medical Providers Consider Barriers in Implementing Pre-Exposure Prophylaxis (PrEP) to Adolescents



**FIGURE 7.** Educational Programs Given to Adolescent Providers from 17 Counties of Upstate New York Ryan White Region (• Plattsburg, Lake Placid, Queensbury, Saratoga, Gloversville, Oneonta, Albany, Troy, Hudson)

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# Southern Discomfort

*HIV and  
Mental Health  
in Alabama*

BY KATHIE HIERS AND MITCH TARVER

**T**HE SOUTHERN UNITED STATES consistently reports disproportionate HIV rates in comparison to other parts of the country, making the challenge of getting to zero new infections extremely challenging in this geographic area. Surveillance data from the Centers for Disease Control and Prevention (CDC) indicate the South accounted for 46% of all living cases of HIV in 2015 and 52% of all new HIV infections during the 2017 calendar year.<sup>1</sup>

Alabama, along with eight other Southern states, has been identified as having HIV diagnoses reaching “crisis proportions.”<sup>2</sup> Alabama Department of Public Health (ADPH) data from the 2017 calendar year found 13,299 individuals diagnosed with HIV.<sup>3</sup> Alabama DPH statistics indicate that African American accounted for 61% of all infections, despite only representing 26.8% of the Alabama State population.<sup>4,5</sup> Males, specifically men who have sex with men (MSM), account for 54.2% of all new infections in the state, and 47.1% have been found to be 29 years of age or younger. Additionally, of those retained in care, only 73% reached viral suppression as of 2017.<sup>6</sup>



Alabama's poverty rate continues to rank well-above the national average at approximately 16.9%, meaning that nearly one-in-six residents live in poverty.<sup>7</sup> While research has demonstrated that health disparities are exaggerated in individuals living with HIV in low socio-economic status, there are other major obstacles to retention in care.<sup>8</sup>

Mental health problems appear to be the biggest challenge for Alabama service providers. Research indicates that mental health diagnoses among individuals living with HIV decrease retention in care and consequently decreases positive health outcomes.<sup>9</sup> A 2015 Alabama statewide needs assessment indicated that at least 45% of individuals living with HIV identify as having some type of mental health problem.<sup>10</sup> This finding aligns with other research conducted in Birmingham, Alabama, the state's largest outpatient HIV clinic, which found that 39% of patients report with mood/anxiety diagnoses and 21% with substance use disorder (SUD) diagnoses, including 8% with co-morbid mood and SUD diagnoses.

Of patients with mood/anxiety diagnoses, 76% had clinically prevalent depression.<sup>11</sup> Service providers and researchers have identified a strong correlation between depression and HIV. Some studies have estimated that individuals living with HIV have rates of depression two to three times higher the general population.<sup>12</sup> Research has also found that traumatic and stressful life events are highly prevalent among persons who become HIV-positive as well as those who have a higher risk for contracting HIV.<sup>13,14</sup> Individuals who have experienced trauma have higher a likelihood of using a substance to deal with mental health issues.<sup>15</sup> Additionally, substance abuse is "highly prevalent" in individuals living with HIV and creates obstacles to treatment adherence and retention.<sup>16</sup>

Another barrier in the South that complicates access to care is the number of HIV cases found in rural areas. Alabama has the greatest percentage of cases outside of the urban area at 68% of the state's total cases.<sup>17</sup> Many rural counties have no appropriate systems of care, forcing patients to find transportation to urban settings to receive essential medical services. Alabama is not alone in dealing with this rural conundrum. The southern states bear a heavier burden of HIV cases outside urban settings.<sup>18</sup> North Carolina ranks in the top ten states, yet 46% of those persons living with HIV are outside of the urban areas.<sup>19</sup>

Although the Centers for Disease Control and Prevention acknowledge that the South has higher HIV rates in suburban and rural areas than the rest of the country, much of the CDC funding is available only in high-impact, urban areas, such as Birmingham.<sup>20</sup>



## Successes

Despite barriers to HIV care retention, AIDS Alabama continues to work to fill the gaps in mental health care needs of their patients. AIDS Alabama opened the Living Well Outpatient Center (LWOC) in May 2016 in response to the increasing needs of consumers with mental health, substance abuse, relationship, and other psychosocial problems. LWOC has allowed staff to wrap services around active consumers receiving outpatient substance abuse, case management, and other ancillary services offered through AIDS Alabama.

Opening the clinic also allowed the agency to start the *Living Well MISSION* in October 2017, which attempts to ensure that individuals living with HIV who have a co-occurring mental health and substance abuse disorder are provided with treatment, wraparound services, and the opportunity to gain stable housing. The MISSION (Maintaining Independence and Sobriety through Systems Integration, Outreach, and Networking) Model is an evidence-based treatment model intended to provide clients with stability



through six components: (a) Dual Recovery Therapy (DRT); (b) Critical Time Intervention (CTI) Case Management; (c) Peer support; (d) Rapid Re-housing; (e) Vocational and educational support; and (f) Trauma-Informed Care. Since the LWOC began providing services, the staff has enrolled over 200 clients in outpatient mental health services.

In order to address the mental health of Alabama residents living in rural areas, AIDS Alabama began providing telemedicine services to clients living in the most southern part of the state. AIDS Alabama South, an extension of AIDS Alabama, operates in Mobile, Alabama, and covers a 12-county area, serving approximately 700 clients per year. Telemedicine services are now being provided to clients from AIDS Alabama South's catchment area to provide psychosocial support and other services necessary to cope with everyday situations and to emphasize the importance of adhering to medical treatment.

Unless these mental health challenges are met, the ability to get to no new HIV infections remains low. **HIV**



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**Kathie Hiers** is Chief Executive Officer of AIDS Alabama, a statewide nonprofit that provides housing, mental health, and services to low-income persons with/at-risk of HIV/AIDS.

Kathie was selected in 2010 by President Obama to serve on the Presidential Advisory Council on HIV/AIDS. She serves as Chair of the Federal AIDS Policy Partnership, as Board Chair for Southern AIDS Coalition, and on the Convening Committee for the International AIDS Conference 2020.



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# Undetectable = Untransmittable

## *A Cure for HIV Stigma?*

BY MARIAH WILBERG

**FELT LIKE MY LOVE WAS POISON.** At 19, I was diagnosed with HIV. I believed I was a danger to my partners and that I could never have a 'normal' relationship. This message was reinforced by my care team, who urged me to protect others by using condoms for the rest of my life. Overwhelmed, I refused HIV treatment and care. By 25, my HIV had progressed to AIDS. I started treatment, but HIV was still my shameful secret.

It wasn't until I learned about U=U that I finally accepted my HIV status. I cried as relief washed away years of shame, stigma and fear. I went on to meet and eventually marry my HIV-negative partner, something that would never have been possible before I learned that undetectable means untransmittable.

### **'Why didn't anyone tell me?'**

Combination antiretroviral therapy (ART) marked a new era in the global HIV epidemic. Seemingly overnight, HIV was transformed from a death sentence to a chronic but manageable condition. We are in the midst of another revolution. The power of ART is again



redefining what it means to be a person living with HIV by way of the international Undetectable = Untransmittable (U=U) campaign. U=U conveys the consensus that people living with HIV who achieve and maintain an undetectable viral load have no risk of sexually transmitting HIV.

The U=U movement was born when founder Bruce Richman was concerned that he may have put a partner at risk. He was shocked when his HIV care provider informed him there was no risk of transmission because he was undetectable. His reaction, shared by millions of people living with HIV across the globe, was simple: “Why didn’t anyone tell me?”

The fact that viral suppression prevented sexual HIV transmission was no secret to researchers and clinicians, but the message was not reaching the people it was intended to benefit. In response, Richman founded the Prevention Access Campaign in early 2016 to ensure that all people living with HIV have access to accurate and meaningful information about their social, sexual, and reproductive health.

**The fact that viral suppression prevented sexual HIV transmission was no secret to researchers and clinicians, but the message was not reaching the people it was intended to benefit.**

Led by a steering committee of advocates living with HIV, the group worked with global experts to create the *Risk of Sexual Transmission of HIV from a Person Living with HIV who has an Undetectable Viral Load* consensus statement.<sup>1</sup>

The consensus statement served to clarify confusion about the safety and efficacy of viral suppression for sexual HIV prevention. To date, over 840 public health bodies, research associations, and nongovernmental organizations from 97 countries

have endorsed the consensus statement and joined the U=U campaign. Leading health organizations such as the Centers for Disease Control (CDC), National Institutes of Health (NIH), UNAIDS, HIV Medicine Association (HIVMA), and the World Health Association agree that people living with HIV who are on treatment and have an undetectable viral load are not transmitting HIV to their sex partners.

Despite this hopeful news, many socio-cultural, political, economic, and systemic barriers still prevent people from hearing this life-changing message. Shifts in attitudes, beliefs, and behaviors take time, especially when impacted by the unprecedented trauma of the AIDS epidemic. After 35 years of deeply ingrained fear of HIV, it can be difficult to accept that people living with HIV can be no risk to their sexual partners.

### Getting to Zero with U=U

Treatment access and reducing population viral load are a critical part of any Getting to Zero initiative. Increasing the number of people living with HIV who are ultimately virally suppressed is the impetus of global 90-90-90 targets. Models suggest that the HIV epidemic would be over within a decade if 90 percent of all people living with HIV were

aware of their status, 90 percent of people aware of their status received ART, and 90 percent of people on ART achieved viral suppression.<sup>2</sup>

We cannot harness the true power of U=U and its individual and public health benefits until all people living with or at risk for HIV have access to this message. We must also remove barriers to treatment and care so all people living with HIV have the option to benefit from U=U. This will require a coordinated effort between researchers, public health, health care, AIDS service organizations, advocacy organizations, and other allies.

### People overestimate HIV infectiousness

People tend to overestimate HIV infectiousness. The ACTG A5257 study explored the relationship between HIV viral load and perceptions of infectiousness in 1,809 treatment naïve patients. Participants rated their perception of infectiousness on a visual analog scale ranging from 0-100. Categories were defined as high (67-100), medium (34-66), low (1-33), and non-infectious (0).

At baseline, 84 percent of participants perceived a high or medium level of infectiousness, 10 percent low, and 6 percent non-infectious. At week 48, 91 percent of participants were undetectable. Despite this, 58 percent still perceived a high or medium level of infectiousness, 32 percent low, and only ten percent believed they were non-infectious. Interestingly, researchers found no association between a person’s viral load and their perception of infectiousness.<sup>3</sup>

A recent survey among men who have sex with men in New York City found that only 39.1 percent of respondents perceived that treatment as prevention offered “a lot” or “complete” protection from HIV. In contrast, 70 percent of respondents indicated that daily PrEP offered “a lot” or “complete” protection.<sup>3</sup>

### The impact of U=U

U=U is more than a catchy slogan. It’s bigger than an HIV prevention method. Many people living with HIV, regardless of viral load or whether they are sexually active, are transformed by U=U. It reduces stigma, shame, and alleviates years of anxiety about transmitting HIV. Many people have an easier time disclosing their HIV status because of U=U. It can improve patient self-esteem and mental and emotional wellbeing. It offers a powerful incentive to be adherent to treatment and engaged in care.

Even the most effective messaging campaign will never reach everyone it could benefit. Similarly, there is no way to discuss all the nuances of HIV medical care in a static advertisement. There is, however, one guaranteed opportunity to reach all people living with HIV who are in care. The HIV care setting is the ideal place where patients and partners can receive accurate, consistent, and unambiguous information about what an undetectable viral load means for their health and the health of their sexual partner(s).

## Tips for discussing U=U during clinic visits

Clinicians play a vital role in educating patients and moving us to zero. You have the power to change lives and improve mental and physical health by sharing a simple message. Starting the conversation is easy, you could ask:

- Have you heard about U=U? Do you have any questions about what that means?
- Are you familiar with all the options available for sexual HIV prevention?
- What method of HIV prevention do you use/plan to use with your partner(s)?  
Other items to keep in mind:
- The threshold for U=U is under 200 copies/ml, synonymous with viral suppression.
- U=U only applies to sexual transmission, not perinatal transmission or transmission from sharing syringes.
- U=U may not exempt people living with HIV from disclosure laws.

## Be clear and consistent

Use definitive and easily understood phrases such as “can’t pass it on” “will not transmit,” and “no risk.” Avoid phrases that convey even a slight risk or are ambiguously defined such as “extremely low,” and “virtually impossible.” The world’s leading scientists and organizations are saying “zero.”

- Dr. Anthony S. Fauci: *“From a practical standpoint, the risk is zero.”*<sup>4</sup>
- Dr. Alison Rodger (lead author of PARTNER 1 and 2): *“If you’re on suppressive ART, you are sexually noninfectious. The risk is zero,”*<sup>5</sup> and again *“It’s very, very clear the risk is zero.”*<sup>6</sup>
- Dr. Carl D. Dieffenbach: *“For somebody who is in a discordant couple, if the person [with HIV] is virologically suppressed, durably”—means there is no virus in your system, hasn’t been for several months—your chance of acquiring HIV from that person is ZERO, let’s be clear about that: ZERO.”*<sup>7</sup>
- The British HIV Association: *“We recommend consistent and unambiguous terminology when discussing U=U such as ‘no risk’ or ‘zero risk’ of sexual transmission of HIV, avoiding terms like ‘negligible risk’ and ‘minimal risk.’”*<sup>8</sup>

## Avoid overly cautious phrases

It’s important to convey that once undetectable status is achieved, maintained, and monitored, a person living with HIV and their sexual partner(s) can feel confident about having sex without risk of HIV transmission. Overly cautious attitudes undermine the message and can have a profound negative impact. We call these the “big erasers”: “I believe U=U, but use a condom and/or PrEP just in case” conveys doubt about U=U. Combining HIV prevention methods can provide an extra sense of security and shared responsibility. It may be appropriate for STI or pregnancy prevention, if multiple sex partners are involved, or if adherence challenge are present. However, durable viral suppression is sufficient for sexual

HIV prevention, even in the absence of condoms or PrEP.

## Viral load does not equal value

We must be conscious not to shame people living with HIV who are not undetectable, whether by choice or because of circumstances out of their control. All people living with HIV have options for safer sex, including condoms and PrEP in some parts of the world. Treatment is a personal choice, not a public health responsibility. Therefore, it is important to reduce stigma and judgement so that patients feel more comfortable coming into the clinic regularly and remaining on treatment if feasible.

## Get involved

Your connection with patients allows you the incredible opportunity to improve their lives. We thank you for sharing this revolutionary message and your commitment to improving the lives of people living with HIV. If your organization is interested in becoming a U=U community partner, please visit [www.preventionaccess.org/community](http://www.preventionaccess.org/community). **HIV**



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# Antiretroviral Treatment Considerations for Women Living With HIV Who Are of Childbearing Potential

## Some Points To Ponder

**A** 32-YEAR-OLD FEMALE LIVING WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV) and currently receiving fixed dose tenofovir alafenamide/emtricitabine and dolutegravir presented to the clinic with secondary amenorrhea and was found to have an unplanned pregnancy. She had been diagnosed five months prior by routine HIV screening and was started soon after on ART. Her current CD4 count was 300 cells/mm<sup>3</sup> and her HIV viral load was < 20 copies/ml. Based on the date of her last menstrual period and first trimester ultrasound she was determined to be 14 weeks pregnant.

Her primary provider switched her to co-formulated tenofovir disoproxil Fumarate/Emtricitabine once daily and raltegravir twice-a-day – a preferred regimen per current DHHS guideline. [1] At her next office visit, she admitted to frequently missing her second dose of raltegravir because she would fall asleep. Her repeat HIV viral load was 250 copies/ml. With enhanced adherence support and counseling, she started taking all her doses of her ART regimen and her HIV viral load at 34 weeks prior to delivery was < 20/ml. She delivered a healthy male infant and his HIV testing was negative at birth, one month, and four months.

### Discussion

Over the past two decades, we have made significant progress in preventing vertical transmission of HIV. In the United States (US), HIV testing coupled with the use of antiretroviral therapy (ART), cesarean delivery when indicated, and the avoidance of breastfeeding has led to rates that are < 2%. In 2016 there were fewer than 100 reported cases of perinatally acquired HIV infection [2] This case, however, highlights the current complexities in managing women of child-bearing age who are living with HIV as well as management during pregnancy.

Providers must engage patients in a conversation about their fertility desires. Any patient encounter with a non-pregnant woman of reproductive potential is an opportunity to counsel about their health, which may improve reproductive and obstetrical outcomes if they choose to become pregnant. Every provider should ask the following question: “Would you like to become pregnant in the next year?”

If a woman does not desire pregnancy, options should be discussed to prevent an unintended pregnancy including contraception. If a pregnancy is desired, careful considerations must be given when choosing antiretrovirals. Forty years ago, the thalidomide catastrophe occurred and since that time there has been raised concern about the safety of medications used during pregnancy. [3] Of the antiretrovirals FDA-approved, only one has an indication in pregnancy, zidovudine (AZT), and for all others there is the statement “use in pregnancy only if the benefit outweighs the risk”. Before a drug is approved, we often have limited data on its use in pregnancy. Animal studies can provide substantial amount of information about the teratogenic effects of drugs but these data

ART Regimen Component	ART for pregnant women who have never received ARV drugs and who are initiating ART for the first time	ART for pregnant women who have never received ARV drugs and initiating ART for the first time
<b>NRTI</b>		
ABC		Preferred
FTC		Preferred
3TC		Preferred
TDF		Preferred
ZDV		Alternative
TAF		Insufficient data
<b>INSTIs Used in combination with dual-NRTI backbone</b>		
DTG		Preferred after the first trimester
RAL		Preferred
BIC		Insufficient data
EVG/COBI		Not recommended
<b>Pis Used in combination with dual-NRTI backbone</b>		
ATV/r		Preferred
DRV/r		Preferred
LPV/r		Alternative
ATV/COBI		Not recommended
DRV/COBI		Not recommended
<b>NNRTI Used in combination with dual-NRTI backbone</b>		
EFV		Alternative
RPV		Alternative
DOR		Insufficient data
ETR		Not recommended
NVP		Not recommended
<b>Entry and Fusion Inhibitors</b>		
IBA		Not recommended
MVC		Not recommended
T-20		Not recommended





<b>ART Regimen Component</b>	<b>ART for pregnant women who are trying to conceive</b>	<b>ART for pregnant women who have never received ARV drugs and initiating ART for the first time</b>
<b>NRTI</b>		
ABC		Preferred
FTC		Preferred
3TC		Preferred
TDF		Preferred
ZDV		Alternative
TAF		Insufficient data
<b>INSTIs Used in combination with dual-NRTI backbone</b>		
RAL		Preferred
BIC		Insufficient data
EVG/COBI		Not recommended
<b>Protease Inhibitors Used in combination with dual-NRTI backbone</b>		
DTG		Not recommended
ATV/r		Preferred
DRV/r		Preferred
LPV/r		Alternative
ATV/COBI		Not recommended
DRV/COBI		Not recommended
<b>NNRTI Used in combination with dual-NRTI backbone</b>		
EFV		Alternative
RPV		Alternative
DOR		Insufficient data
ETR		Not recommended, except if needed for resistant patients
NVP		Not recommended, except if needed for resistant patients
<b>Entry and Fusion Inhibitors</b>		
IBA		Not recommended, except if needed for resistant patients
MVC		Not recommended, except if needed for resistant patients
T-20		Not recommended, except if needed for resistant patients

cannot be extrapolated from animals to humans. Many associations have shown to be false positive such as the initial association of efavirenz with neural tube defects. In pre-marketing human trials, pregnant women are typically excluded and the numbers are too small to detect teratogenicity. There is a greater paucity of data from women with HIV and pregnancy.

Delaying ART until the second trimester is no longer recommended by the DHHS guidelines. [1] Treatment during the peri-conception period is recommended to allow for viral suppression and management of treatment-related adverse events prior to conception. Therefore, providers must take into consideration fertility desires and knowledge about the safety of ART. By the time most women realize they are pregnant, organogenesis has begun or completed and prevention strategies are ineffective at that point.

Dolutegravir is an integrase strand transfer inhibitor (INSTI) that is recommended as a first-line option for most people living with HIV by the DHHS adult and adolescent guidelines due to its efficacy, tolerability, and low potential drug-drug interactions.[3] This drug was previously listed as an alternate regimen to use during pregnancy. Data from a National Institute of Health (NIH) funded study of birth outcomes among pregnant women on ART in Botswana suggest that a possible increased risk of neural tube defects (NTDs) in infants born to women who were receiving dolutegravir at the time of conception due to a signal seen with preconception use. This study and the case above highlight the importance of pregnancy safety research. It is critically important that we continue to collect prospective non-biased data

on new antiretrovirals when they are approved so it does not take years before we are able to safely use a drug in pregnancy. The Antiretroviral Pregnancy Registry (APR) is an international, voluntary exposure registration study and has a comparator group. It can be accessed at [www.apregistry.com](http://www.apregistry.com). HIV providers who care for pregnant women are encouraged to report their data to this registry. **HIV**



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# The BLOCK HIV/HCV Initiative

## Bringing Local Communities Together to Eliminate Coinfection Through Knowledge and Partnerships

**M**ODERN HCV THERAPIES UTILIZING DIRECT-ACTING ANTIVIRAL (DAA) DRUG REGIMENS have revolutionized treatment, ushering in an era in which cure is nearly universal and hepatitis C virus (HCV) elimination is a tangible consideration. Yet, concurrent with these opportunities, HCV remains the leading cause of mortality related to a chronic viral illness in the U.S., surpassing HIV-related deaths in 2007.<sup>1</sup> While efforts to educate, engage, and treat the historically high-risk baby boomer birth cohort (those born between 1945 and 1965) continue, other key risk groups—people who inject drugs (PWID) and persons living with HIV (PLWH)—have now grown dramatically.<sup>2</sup> Moreover, since 2010, a dramatic increase in HCV incidence has been seen across the U.S. in previously atypical locales.

Often, those most impacted today are nonurban communities confronted with poverty, high rates of substance use, and limited access to medical care.<sup>3,4</sup> Nowhere is this convergence of socioeconomic factors more evident than in the correctional setting, the crossroads of vulnerable populations and marginalized individuals at greatest risk for HCV.<sup>5</sup> Thus, the character of the U.S. HCV epidemic continues to shift

and merge with the HIV and opioid epidemics, creating a *syndemic*, the intersection of two or more epidemics that exacerbates the impact of each disease.<sup>6</sup> This raises the stakes for effective educational and practical strategies to combat HCV infection in these diverse and challenging patient populations.

The **BLOCK HIV/HCV** initiative—**Bringing Local Communities Together to Eliminate Coinfection Through Knowledge and Partnerships**—was designed to address the educational gaps and needs associated with effective tailoring of HCV treatment to individuals within these high-risk populations. The overarching goal of the **BLOCK** program is to *optimize the identification and treatment of patients infected with HCV, specifically in the context of HIV/HCV coinfection*.

In 2018, three program sites were chosen based on differences in HCV epidemiology and demographics, access to HCV therapy, local expertise in HCV care and substance use disorder treatment, and resource availability. Resources considered included academic buy-in and support, potential collaborators, and local networking infrastructure. Access to DAA therapies was assessed in terms of state-specific Medicaid restrictions, as available through national data published by the Center for Health Law



and Policy Innovation and the National Viral Hepatitis Roundtable.<sup>7</sup> Consultation with local experts and evaluation of regional data were used to judge other site-suitability criteria.

The three sites chosen for 2018 BLOCK HIV/HCV programs were Charleston, West Virginia (WV); Boston, Massachusetts (MA); and Atlanta, Georgia (GA). Charleston represents an economically depressed rural

region with high rates of HCV and opioid use disorder, as well as enthusiastic community and academic support. Boston, a highly resourced, academically advantaged urban center with broad reach throughout the state, represents a region with high rates of HIV/HCV coinfection and extensive networking potential. Atlanta is a rapidly growing, highly diverse, southeastern urban hub impacted by the HIV/HCV/opioid syndemic. Atlanta benefits from the local presence of the Centers for Disease Control and Prevention (CDC) and provides regional extension of healthcare services into underserved rural areas.

Central to the potential success of the BLOCK programs were the advance efforts to both reach and engage a multidisciplinary participant base that would reflect the key stakeholders for each program site. Thus, outreach efforts targeted medical professionals—HCV and/or HIV treaters and referrers—from community, correctional, and academic settings; pharmacists; patient-support providers including case managers, social workers, and patient educators/navigators; addiction services providers and harm-reduction specialists; community-based HCV/HIV advocates; governmental agency representatives; and payers. A robust mix of participants was ultimately engaged for each of the three sites.

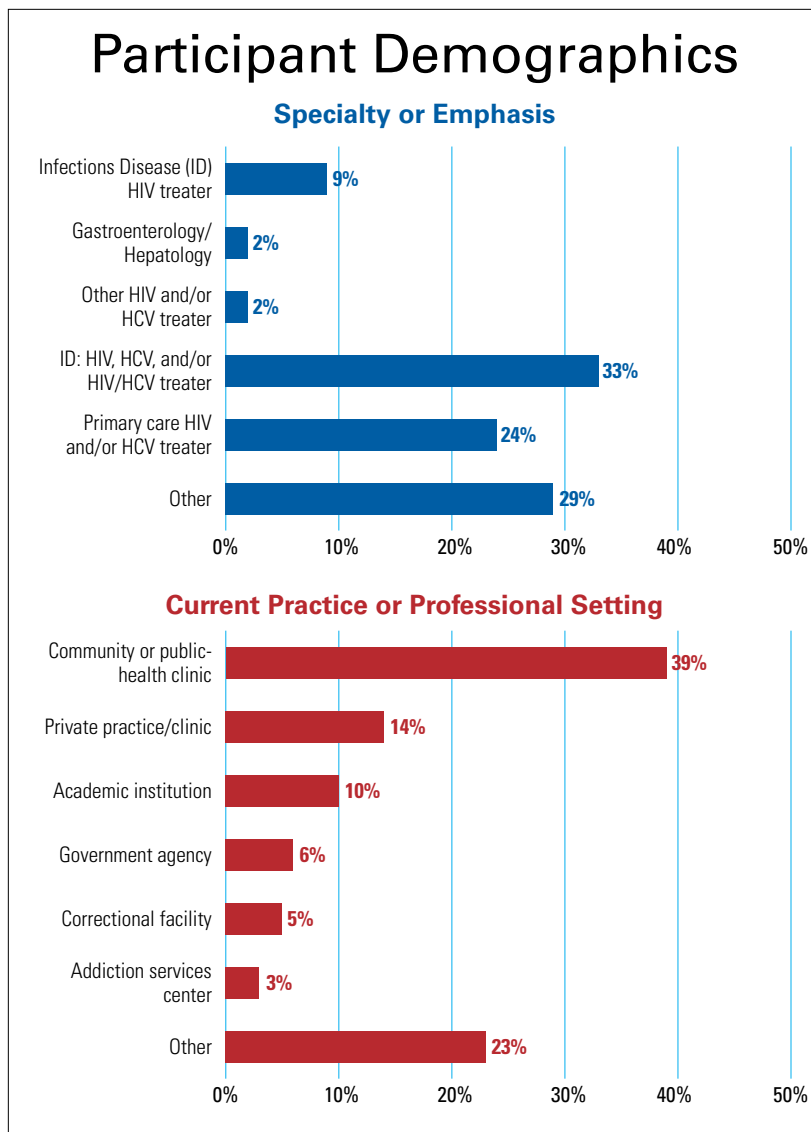
Of the 183 total participants, 93 (51%) were current HCV +/- HIV treaters, representing both specialty (infectious diseases, gastroenterology, and hepatology) and primary care providers (Figure 1A). The diverse practice/service settings reported among all participants—treaters and nontreaters—confirmed success of the advance efforts to establish a broad community base in each locale (Figure 1B).

The **BLOCK** curriculum was modified according to the specific needs of each program site, while core content remained aligned with the initiative's overarching educational objectives:

1. Describe epidemiologic trends in HCV monoinfection and HIV/HCV coinfection within at-risk populations, including men who have sex with men (MSM), people who inject drugs (PWID), and incarcerated individuals
2. Screen MSM, PWID, and incarcerated individuals for HCV and HIV infection
3. Provide guideline-based treatment for HCV monoinfection and HIV/HCV coinfection
4. Identify patient, provider, and healthcare system barriers to effective management of HCV monoinfection and HIV/HCV coinfection
5. Implement strategies to overcome risk cohort-specific challenges to the treatment of HCV monoinfection and HIV/HCV coinfection

Didactic content was presented by national and regional experts, covering all subtopics pertinent to the BLOCK program's educational objectives. Site-specific epidemiologic data were reviewed by regional experts. HCV in the criminal justice system was addressed by regional experts in the Atlanta and Boston programs. Effective approaches to community outreach and capacity-building were emphasized across all three sites.

Significant post-activity gains in knowledge were demonstrated at all BLOCK program sites, as evidenced by a composite 40% increase over baseline in key knowledge areas including HCV epidemiology, management of HIV/HCV coinfection, and effective approaches to overcoming HCV treatment barriers (eg, insurance/prescribing restrictions and infrastructure deficits and obstacles). A composite 94% increase over baseline was seen in individuals' confidence in their own abilities to actively address barriers to HCV care within their practice sites. A lesser increase over baseline



(19%) was demonstrated in participants' confidence in their communities'/healthcare networks' abilities to collectively reduce barriers to HCV care. Site-to-site variability in both self and collective efficacy may reflect local barriers (notably Medicaid restrictions), healthcare infrastructure and resources, and geographic challenges to provision of services, especially in West Virginia.

Importantly, hand in hand with participants' increased knowledge and confidence, enthusiastic plans for local collaboration and action sprung from small group, cross-disciplinary workshops. Across the BLOCK program sites there were three overarching action-oriented themes: education, advocacy, and collaboration. As expected, notable differences were found among the action items under each theme for each location (Table 1). A prime example of this is 38% and 55% of Charleston and Atlanta participants, respectively, plan to advocate for elimination of private insurance and/or Medicaid restrictions. A corresponding change was not anticipated in Boston, as Massachusetts does not have significant restrictions to HCV drug access. In contrast, Boston participants cited several more specific opportunities to



**Table 1. Key Action-Oriented Themes and Selected Site-Specific Action Items**

	EDUCATION	ADVOCACY	COLLABORATION
<b>Charleston</b>	Enhance public, patient, provider, and payer education on HCV; including formation of a task force to look into education starting in middle school	Remove WV Medicaid restrictions on HCV treatment	<ul style="list-style-type: none"> <li>Provide patient transportation and/or offer mobile screening/treatment services in rural areas</li> <li>Implement an official HCV referral program</li> <li>Colocate services; eg, MAT and HCV</li> </ul>
<b>Boston</b>	Use program slides to educate internal stakeholders and legislators/policy makers	Join advocacy and awareness efforts surrounding upcoming legislative vote on mandatory universal screening	<ul style="list-style-type: none"> <li>Connect attendees with AETC/Boston DPH education and capacity-building resources</li> <li>Coordinate Victory Programs resources to provide screening in Suffolk County prison system</li> </ul>
<b>Atlanta</b>	Create outreach and education to support new treaters	Petition public and corporate decision-makers to fund and establish system-based EHR prompts for HCV screening and confirmatory testing	<ul style="list-style-type: none"> <li>Establish an HCV-treater network; create a directory for referring clinicians, practices, and addiction centers</li> <li>Provide support for new treaters via ECHO and GA Academy of Family Physicians conferences</li> </ul>

AETC, AIDS Education and Training Center; DPH, Department of Public Health; ECHO, Extension for Community Healthcare Outcomes; EHR, electronic health record; MAT, medication-assisted treatment.

optimize linkages between existing/emerging services and funding, reflective of the robust existing infrastructure. Using specific needs-based feedback from each program site, BLOCK coordinators procured and/or developed *Action and Advocacy* materials and resources that were disseminated to participants—and other interested parties—via an online Clinical Resource Center.<sup>8</sup>

The BLOCK HIV/HCV initiative thereby succeeded in its foundational goal of going beyond the provision of didactic education. Such targeted education, however, was essential for motivating and empowering participants. Coupled with follow-up materials and resources, the BLOCK program is anticipated to have a lasting impact at the local level.

Having established the feasibility and reproducibility of facilitating and motivating collaborative efforts to locally expand and enhance HCV services, the BLOCK program developers are now focusing on further expansion of the model. Lessons learned from the 2018 program will be carried over to the 2019 program and beyond. These lessons have reinforced the central importance of ongoing curriculum enhancement and refinement in line with the needs of diverse program settings. As well, this feedback has underscored the critical step of providing supplemental materials and resources as soon as feasible following each live program, thereby sustaining the enthusiasm and tangible goals

established onsite. Looking forward to 2019 programming in five regions, the BLOCK initiative is proactively seeking an expanded collaboration and funding base.

BLOCK HIV/HCV has established the viability of its innovative model for optimizing the identification and treatment of patients infected with HCV, specifically in the context of HIV/HCV coinfection. Local organizers are encouraged to engage in their own grassroots efforts to bring stakeholders together and inspire an enthusiastic call to action for HCV elimination in their communities and regions.

For further information regarding the BLOCK HIV/HCV initiative, please visit <http://blockhivhcv.com/>. This site includes links to a studio-produced BLOCK video presentation, references, and Action and Advocacy resources for clinicians and community stakeholders. **HIV**



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*Central to the potential success of the BLOCK programs were the advance efforts to both reach and engage a multidisciplinary paraant base that would reflect the key stakeholders for each program site.*

# What's New in the DHHS GUIDELINES?

## Changes to the Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents.

### Pneumocystis Pneumonia

Pneumocystis pneumonia (PCP) once common in persons with HIV infection is caused by the fungus *Pneumocystis jirovecii*. Previously referred to as *Pneumocystis carinii*, this species is now known to only infect rats. *Pneumocystis jirovecii* is the species that infects humans but the abbreviation "PCP" is still commonly used. Infection with *P. jirovecii* usually occurs in early childhood and about 60% of healthy children have antibodies to *P. jirovecii* by age 4 years. Disease in patients with PCP may represent reactivation of latent infection or new acquisition of the pathogen. The incidence of PCP has declined significantly over the past 10 years or so due to widespread use of PCP prophylaxis and most importantly antiretroviral therapy (ART). Most cases of PCP now occur in patients who are either unaware of their HIV infection, not taking ART or have more severe immunosuppression (CD4 counts <100 cells/mm<sup>3</sup>) despite ART.

### Indication for Primary Prophylaxis

HIV-infected adults and adolescents with a CD4 count <200 cells/mm<sup>3</sup> should receive chemoprophylaxis against PCP (AI). Those with a CD4 cell percentage <14% should also be considered for PCP prophylaxis (BII). Trimethoprim-sulfamethoxazole (TMP-SMX) is the recommended agent for PCP prevention (AI). The preferred regimen is one double-strength (DS) TMP-SMX tablet daily (AI). This dose is also protective against toxoplasmosis and other respiratory bacterial pathogens. One single-strength tablet daily is also effective and is often better tolerated than the DS (AI). One DS tablet three times weekly is also acceptable dosing (BI). For patients unable to tolerate TMP-SMX, alternative regimens are dapsone (BI), dapsone plus pyrimethamine plus leucovorin (BI),<sup>9</sup> aerosolized pentamidine (BI), and atovaquone (BI).

### Discontinuing Primary Prophylaxis

Primary prophylaxis can be discontinued in patients who have an increase in CD4 counts to >200 cells/mm<sup>3</sup> for at least 3 months while on ART (AI). This recommendation is supported by both observation data and randomized trials. In these studies, at time of discontinuation of prophylaxis, median CD4 count was >300 cells/mm<sup>3</sup>. Most subjects also had a CD4 cell percentage ≥14% and sustained viral suppression. These studies were published almost 20 years ago. Benefits to stopping TMP-SMX including reduction of pill burden, cost, toxicity, drug-drug interactions, and selection of drug-resistant pathogens. Prophylaxis should be reintroduced if the patient's CD4 count decreases to <200 cells/mm<sup>3</sup> (AIII).

A combined analysis of newer data from European cohorts, a small RCT, and case series

found a low incidence of PCP in patients with CD4 counts between 100 cells/mm<sup>3</sup> and 200 cells/mm<sup>3</sup>, who were receiving ART and had HIV plasma viral loads <50 to 400 copies/mL, and who had stopped or never received PCP prophylaxis. **These data suggest that both primary and secondary PCP prophylaxis can be safely discontinued in patients with CD4 counts between 100 cells/mm<sup>3</sup> to 200 cells/mm<sup>3</sup> and HIV plasma RNA levels below limits of detection.** Data on which to base specific drug recommendations are not available however one reasonable approach would be to stop primary prophylaxis in patients with CD4 counts of 100 cells/mm<sup>3</sup> to 200 cells/mm<sup>3</sup> if HIV plasma RNA levels remain below limits of detection for ≥3 months to 6 months (BII).

**Author's comment:** This new recommendation is a significant change from what we have been doing for many years regarding discontinuation of pneumocystis prophylaxis. Prophylaxis for persons with a CD4 count < 200 has also been a core performance measure from HRSA for Ryan White-funded programs. This specific core measure should likely be changed or perhaps eliminated in the future. In recent years most HIV providers have learned that the best prophylaxis against all opportunistic infections is ART.

Readers are referred to Reference #1 below section B for the complete discussion on the prevention and treatment of *Pneumocystis pneumonia*.

### REFERENCES

1. Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents: Recommendations from the CDC, NIH, and HIV Medicine Association of the IDSA. Available at [http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult\\_o.pdf](http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_o.pdf) Accessed (March 28, 2019) pg. B1-B18.
2. Furrer H, et al. Discontinuation of primary prophylaxis against *Pneumocystis carinii* pneumonia in HIV-1-infected adults treated with combination antiretroviral therapy. Swiss HIV Cohort Study. *N Engl J Med*. 1999;340(17):1301-1306. Available at
3. Chaiwarith R, et al. Discontinuation of primary and secondary prophylaxis for opportunistic infections in HIV-infected patients who had CD4+ cell count <200 cells/mm<sup>3</sup> (3) but undetectable plasma HIV-1 RNA: an open-label randomized controlled trial. *AIDS Patient Care STDS*. 2013; 27(2):71-76.
4. D'Egidio GE, et al. *Pneumocystis jirovecii* pneumonia prophylaxis is not required with a CD4+ T-cell count < 200 cells/ml when viral replication is suppressed. *AIDS*. 2007; 21(13):1711-1715.
5. Miro J, et al. Opportunistic Infection Team of the Collaboration of Observational HIV Epidemiological Research in Europe (COHERE) in EuroCoord. Safety of Stopping Primary T. gondii Prophylaxis with Suppressed Viremia and CD4>100. Presented at: CROI; 2016; Boston, MA.

### SUMMARY

#### Indications for Initiating Primary Prophylaxis for PCP:

- CD4 count <200 cells/mm<sup>3</sup> (AI) or
- CD4 percentage <14% of total lymphocyte count (BII) or
- CD4 count >200 cells/mm<sup>3</sup>, but <250 cells/mm<sup>3</sup> if ART initiation must be delayed and if CD4 count monitoring (e.g., every 3 months) is not possible (BII).

#### Preferred Therapy:

- TMP-SMX, 1 DS tablet PO daily (AI) or
- TMP-SMX, 1 SS tablet PO daily (AI)

#### Alternative Therapy:

- TMP-SMX 1 DS tablet PO three times weekly (BI) or
- Dapsone 100 mg PO daily or dapsone 50 mg PO twice a day (BI) or
- Dapsone 50 mg PO daily with (pyrimethamine 50 mg plus leucovorin 25 mg) PO weekly (BI) or
- (Dapsone 200 mg plus pyrimethamine 75 mg plus leucovorin 25 mg) PO weekly (BI) or
- Aerosolized pentamidine 300 mg via Respigard II™ nebulizer every month (BI) or
- Atovaquone 1500 mg PO daily with food (BI) or
- (Atovaquone 1500 mg plus pyrimethamine 25 mg plus leucovorin 10 mg) PO daily with food (CIII).

#### Indication for Discontinuing Primary Prophylaxis:

- CD4 count increased from <200 cells/mm<sup>3</sup> to ≥200 cells/mm<sup>3</sup> for ≥3 months in response to ART (AI)
- Can consider when CD4 count is 100–200 cells/mm<sup>3</sup> and HIV RNA remains below limit of detection of the assay used for ≥3 months to 6 months (BII)

#### Indication for Restarting Primary Prophylaxis:

- CD4 count <100 cells/mm<sup>3</sup> regardless of HIV RNA (AIII)
- CD4 count 100–200 cells/mm<sup>3</sup> and HIV RNA above detection limit of the assay used (AII)

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