The New York Times

San Francisco Is Beating H.I.V. Why Can't Houston?

We know how to fight the epidemic, but patients in the South still aren't getting the treatment they need.

By Charlene Flash
Dr. Flash is a specialist in infectious diseases.

March 1, 2019

HOUSTON — In his State of the Union address, President Trump surprised Congress by asking for a "commitment to eliminate the H.I.V. epidemic in the United States within 10 years." I'm a physician who specializes in H.I.V. and AIDS prevention in a city with one of the highest infection rates in the country, so that's music to my ears. But the president needs to know that we're going to fail if we don't start working much harder.

After nearly 40 years, we finally have the biomedical tools and the public health strategies to end the H.I.V. epidemic in America. The winning strategy goes like this: Increase the number of people who get tested for H.I.V., and start those who test positive on antiretroviral therapy as soon as possible, which helps prevent transmission of the virus. Those who test negative but are vulnerable to infection because of sexual activity should take pre-exposure prophylaxis, or PrEP, the daily drug regimen that reduces the risk of getting H.I.V.

The tragedy is that those tools are sitting on the shelf in many parts of the country, especially the South, where H.I.V. rates are still rising among some groups and where AIDS disproportionately afflicts African-Americans. Just this week the Centers for Disease Control and Prevention reported that the "progress in H.I.V. prevention has stalled."

Big cities on both coasts — where AIDS was concentrated when it was officially recognized as a health condition in the early 1980s — have deftly managed the disease. San Francisco was once ground zero, yet in 2017 new H.I.V. diagnoses there fell to 221, a record low. The city's Department of Public Health credits PrEP and a rapid-start program that gets those who test positive for H.I.V. into care within five days.

Other urban areas have made similar strides. In New York City, new H.I.V. infections dropped 26 percent from 2012 to 2016. In the city's clinics, people are offered treatment as soon as the virus is diagnosed. Demetre Daskalakis, the deputy health commissioner for disease control, said this program is working with "staggering success."

The H.I.V. epicenter in the United States has instead shifted to the South, which now accounts for more than half of new infections and nearly half of deaths directly related to H.I.V. Eight of the 10 states and all of the 10 metropolitan areas with the highest rates of new H.I.V. diagnoses are in the South. The region had 20,000 new cases in 2017, compared with 6,000 cases in the Northeast.

Even after learning they have the disease, Southerners face serious hurdles to getting care. A lack of public transportation, in both big cities and rural areas, makes going to the doctor more difficult. The cost of medications can be prohibitive, especially in a state like Texas, which has the highest uninsured rate in the nation. Not enough H.I.V. -positive patients are beginning treatment within a month of diagnosis, even though research shows that doing so improves health and reduces the risk of transmission. Far too few people who could benefit are taking PrEP.

And of course, there is lingering stigma that keeps people who need help on the margins.

Over the past few years there has also been a demographic shift. African-Americans

now represent 44 percent of all people infected with H.I.V., nearly four times their proportion of the population; Hispanics, 18 percent of the population, account for 26 percent of infections. Houston's population is 44 percent Hispanic and 23 percent black, and H.I.V. rates among young people of color here are rising. H.I.V. rates among black women are 17 percent higher than among white women.

We are making slow, steady progress. The Joint United Nations Program on H.I.V./AIDS last year honored the Ponce De Leon Center in Atlanta, which serves more than 6,000 people a year, most of them living in poverty and uninsured or underinsured. The center provides not only H.I.V. diagnosis and treatment but also financial counseling and nutrition.

And nationwide, while we don't yet have a cure, the medical breakthroughs around H.I.V. are impressive. Thousands of Americans are living happy, successful, long lives with the infection.

But this makes some of the cases I see all the more distressing. I had a patient who died last year of an AIDS-related cancer at age 31. Another woman, who has been infected with H.I.V. for 15 years, is 41 years old and unable to get out of bed. Little can be done for these women, the infection having been diagnosed late in their illness.

So, yes, we can meet the president's goal of ending AIDS in a decade, but only if we race to get our new tools more efficiently and equitably to those who need them.

Charlene Flash is an infectious-disease doctor and associate chief medical officer at Legacy Community Health, and a clinical assistant professor at Baylor College of Medicine.

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San Francisco could become the first US city to eliminate new HIV infections

By Maria L. La Ganga

Los Angeles Times

(TNS)

SAN FRANCISCO — In a different city, in a different decade, the news would have changed David's life forever.

Instead the graduate student, who dreams of some day acting and teaching, told himself one thing as he waited for test results in the San Francisco General Hospital emergency room: "If it comes back and it's positive, just do what you can to stay healthy. ... If it comes back negative, be even more careful."

David's HIV test was positive.

Two days later, he met with a social worker in Ward 86 — the first dedicated HIV clinic in the U.S., founded in 1983. He got help, that same day, to sign up for insurance he can afford. He got a starter pack, that same day, of antiretroviral therapy and a prescription for more medication.

When his pharmacist told him there would be a $1,195 co-payment, his social worker made the co-pay go away. David, who is 33 and spoke on the condition that his last name not be used, takes two tablets each day: Descovy, a sky blue rectangle with rounded corners, and Tivicay, a small circle of corn silk yellow.

After two weeks, the virus was undetectable in David's blood. As long as he stays on medication, HIV will not determine his future. Just as important, he will not transmit the disease to anyone else.

David's success is San Francisco's success. This city is on course to be the first in the country to eliminate new HIV infections — or at least come close. President Donald Trump pledged in his State of the Union speech that the U.S. will "eliminate the HIV epidemic ... within 10 years." San Francisco is in position to get there first.

More than 2,300 new, full-blown AIDS cases were diagnosed here in at the peak of the epidemic in 1992. The most recent statistics available, from 2017, showed that 221 people were diagnosed with HIV that year, the virus that causes AIDS. When the 2018 statistics are released in September, that number is expected to be around 190.

"San Francisco is a model for the rest of the nation," said David C. Harvey, executive director of the National Coalition of STD Directors. "Some states and cities ... do not have the resources of San Francisco and will have a problem replicating the exact model. But places like San Francisco, New York City and Seattle — with San Francisco leading the pack — are important jurisdictions at showing the rest of the country what is possible."

The immediate goal of the city's Getting to Zero campaign is to reduce new HIV

diagnoses by 90 percent between 2013, when there were 394 cases, and 2020. San Francisco is only about halfway there, but is moving faster than the nation as a whole and any other big city.

The first step in its three-pronged approach is rapid testing and antiretroviral therapy to keep people healthy and stop the spread of infection. Next is the widespread prescription of PrEP, a.k.a. pre-exposure prophylaxis, a pill that keeps healthy people from getting infected. And finally, a network of outreach workers find people who have stopped regular HIV testing and work to get them back into care.

The city's greatest success has been in reducing the rate of infection among gay men. And the biggest challenges? Reaching African American men, whose infection rate is the highest, and making sure infected homeless people receive the medical care they need. That effort was strengthened last week with the announcement of San Francisco's first POP-UP clinic, under the direction of Dr. Monica Gandhi, medical director of Ward 86. (POP-UP stands for Positive-health Onsite Program for Unstably housed Populations.)

Trump's State of the Union address devoted just 81 words to the subject of HIV. But his pledge to eradicate the disease resonated here in the city where AIDS ended so many young lives and galvanized generations of scientists, doctors and activists.

Dr. Diane Havlir, a co-founder of Getting to Zero, was a young medical resident here during the epidemic's darkest days.

The AIDS patients she saw were her age, she said, "and they were sick and they were dying and some were blind and some had purple spots all over their bodies and we knew about some of the infections, but we had no treatment. And once we started getting treatment, the treatment was very, very rough on the patients."

Havlir, who is a professor at the University of California, San Francisco and head of the HIV program at San Francisco General, was heartened by Trump's pledge, which she said "broke the silence" about HIV that this administration has had. But pledges alone aren't enough, she said. "We need science. We need community involvement. We need funding."

Trump's 2020 budget asks for $291 million for the effort in its first year. But it also proposed cuts to Medicaid and other programs that are central to the fight against HIV. The result, said the Act Now End AIDS Coalition, is a federal budget that "fundamentally undermines the ambitions" expressed by the Trump administration.

However, Harvey said, the administration has since said it will reallocate some funding to HIV eradication in the 2019 fiscal year. "This is good news," he said.

David, who is working toward his masters of fine arts degree, received care through the Rapid ART Program Initiative for HIV Diagnoses. Its goal is to make sure that people who test positive are offered antiretroviral therapy within five days of diagnosis.

RAPID has had a significant impact. From 2013 to 2016, the percentage of patients linked to care within a month of being diagnosed with HIV rose from 72 percent to 83 percent. The median number of days between starting medical care for the infection and receiving antiretroviral therapy dropped from 27 days to zero, according to the San Francisco Department of Public Health.

And then there is PrEP.

When Rand Hunt talks about the pre-exposure medication, he sounds as if he has just witnessed a miracle.

He was born in 1984, the year HIV was identified as the cause of AIDS, and has lived his entire life in the shadow of the epidemic. He is a web designer, an activist in San Francisco's leather culture, and he is HIV negative. He does not foresee his status changing.

All because of a small blue pill, Truvada. The Centers for Disease Control and Prevention says that when it is taken consistently "it has been shown to reduce the risk of HIV infection in people who are at high risk by up to 92 percent." When used with a condom, it is even more effective.

"I never had a gay reality without HIV, and now I'm immune," Hunt said. "The awareness is like the dawn, the sun coming up, the plague being over. ... For me, it means that I can be present when I have sex instead of being, like, 'The condom's gonna break and I'm gonna die.'"

Dr. Susan Buchbinder, who directs the health department's Bridge HIV program and co-founded Getting to Zero, said the city has gone from an estimated 4,400 people on the drug in 2014 to between 16,000 and 20,000 people today.

Among the largest providers is Magnet, a men's sexual health clinic in the Castro district run by the nonprofit San Francisco AIDS Foundation. Because it is not government funded, there are no restrictions on who it can serve, although it tends to focus on what Pierre-Cedric Crouch describes as clients on the "gay, bi and transmasculine spectrum."

Crouch, who is Magnet's director of nursing, said "half of what we do every day is PrEP. There's a big demand."

Florida's 'Test And Treat' Program Helps People Get Immediate Care

A revolutionary new program implemented by the Florida Department of Health will enable people to get on medication the same day they are diagnosed with HIV.

By Desirée Guerrero
MAY 11 2017 6:17 AM EDT
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As many as 30 percent of people living with HIV in the U.S. do not return to the doctor to start receiving care after their initial diagnosis, according to research by the CDC. Many factors could be the reason for this — things like a lack of health coverage, or emotional issues like fear, denial, or lack of a support system. But a new program in Broward County, Florida, aims to cut through the red tape and help close this gap by getting on treatment the very same day they are diagnosed.

"We want to close the loop and take that patient right over to be linked to care and get started on medication the same day," Dr. Deberenia Allen told CBS Miami, who is the director for Memorial's Rapid HIV Testing program in Dania, FL.

The program, called "Test And Treat," was put forth by Florida's Department of Health in Broward County, in partnership with the Ryan White Part A program. With Test And Treat, which began on May 1st, FDOH-Broward staffers can meet up with an individual who has just been diagnosed, and will actually go with them to a physician for a follow-up exam. They will then accompany them to a pharmacy for a 30-day supply of medication. The staffer will also request that the individual take their first pill that day. Even if they do not have health coverage, the individual will still receive the medication through the federally funded Ryan White program.

And the program is not just for the newly diagnosed. Test And Treat also aims to get people back on care after a long gap, or to get them on treatment if they never went back to the doctor after their initial diagnosis. The program eliminates many issues which often prevent people from getting care, such as long waits for follow-up test and doctor's appointments.

The program also aims to be very effective in using the treatment-as-prevention (TasP) method. Getting an individual immediately on antiretroviral medication is beneficial in many ways. The sooner they start takings their meds, the more easily the virus is suppressed in the body — which not only reduces their chances of developing AIDS, but will increase their chances of becoming "undetectable." This means one's viral load has reached undetectable levels, which means there is then an almost zero chance of transmitting the virus. It's also proven that people who start treatment immediately have a much higher chance of staying on treatment.

Test and Treat Guidance

PREPARED BY: THE HIV/AIDS SECTION – MEDICAL TEAM
BUREAU OF COMMUNICABLE DISEASES
DIVISION OF DISEASE CONTROL AND HEALTH PROTECTION
FLORIDA DEPARTMENT OF HEALTH

One of the Four Key Components to eliminate HIV Transmission and Reduce HIV-related Deaths

Florida HEALTH

Guidance on Florida's Test and Treat Program for Antiretroviral (ART) Initiation
HIV/AIDS Section
HIV Program Component 03

INTRODUCTION
Florida has a plan with Four Key Components to eliminate HIV Transmission and Reduce HIV-related Deaths; Test and Treat (T&T) is one of the four key components. T&T is a clinical program providing immediate linkage to HIV care and initiation of ART at the time of HIV diagnosis and/or at the time of returning to care after a gap in services. The program benefits the patient's health and the community by providing initial ART while working through the issues of eligibility and linkage to ongoing HIV care.

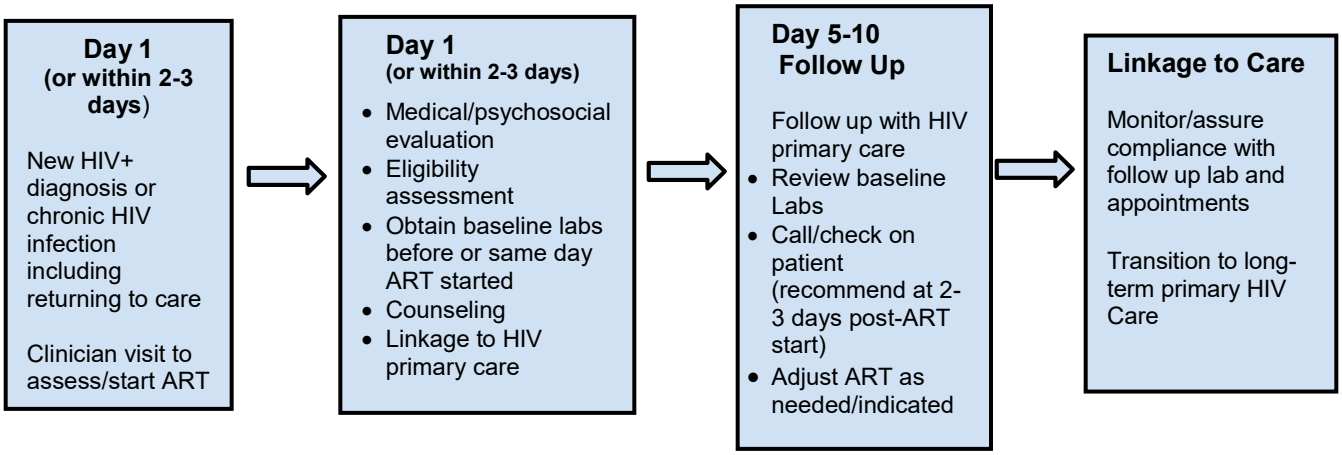
PURPOSE OF THIS GUIDANCE
- To provide the medical and public health rationale for T&T.
- To serve as a practical guide for the medical, counseling and care planning components of the statewide program.

RATIONALE FOR TEST AND TREAT PROGRAM FOR ART INITIATION
The HIV Department of Health and Human Services (DHHS) Guidelines currently recommend universal ART for all people living with HIV regardless of CD4 count as soon as possible. Increasing data show a medical benefit to the patient when immediate ART is initiated, particularly during acute/early HIV infection. There is also a community-level public health benefit of reduced HIV transmission. Many patients report that the decision to start ART and the rapid achievement of viral suppression provides them with the first experience of empowerment to live successfully with HIV.

ELIGIBILITY FOR TEST AND TREAT

Newly diagnosed HIV patients defined as:
- Acute Infection: antibody (-)/RNA (+).
- Recent Infection: antibody (+) with last documented antibody (-) within prior 6 months.
- Chronic Infection: antibody positive with no prior HIV test result or last documented antibody (-) > 6 months ago (inclusive of patients lost to follow up and returning to care).

No available clinical trial to which the patient can be enrolled, or patient declines clinical trial enrollment.



Note: The goal of the T&T Program is for a newly diagnosed patient or a patient newly re-engaged into HIV care to see an HIV clinician, be offered ART, receive counseling and agree on a sustainable care plan on the day of diagnosis/re-engagement, or within 2 to 3 days if same-day initiation is not possible.

TEST AND TREAT PROGRAM CONSISTS OF 3 BASIC STEPS FOLLOWING CONFIRMATION OF HIV DIAGNOSIS:

1. Communication of a new diagnosis from the testing site to a T&T team member (a single point of contact—such as a dedicated staff person(s) with a cell phone/pager/other).

2. The initial T&T visit with ART initiation or, if ART cannot be provided, immediate navigation to a clinic where ART is available.

3. Expedited linkage to ongoing HIV primary care (which may continue at T&T site if available, or at another HIV primary care site appropriate for and acceptable to the patient and/or required by insured status). Some details of the process will differ depending on where the patient is diagnosed with HIV infection and where he or she can receive immediate ART.

STEP ONE: TEST AND TREAT – PATIENT REFERRAL

A. Patients who test HIV positive at a testing site and receive post-test counseling can be referred to a T&T clinic site. The T&T team is contacted during hours of operation and informed of the HIV-positive test result. Determination of whether the diagnosis is a new chronic diagnosis or whether it is likely to be an acute infection is then made.

B. Upon arrival, the patient is welcomed by a clinical team member and then will see a clinician for assessment and determination for starting ART. After seeing the clinician, there will be additional post-test counseling and education, assessment of eligibility and insurance/coverage and linkage to ongoing care planning. The T&T team members will vary by County Health Department (CHD) based on available staffing/resources. The team may include a nurse, case manager, Disease Intervention Specialist (DIS), eligibility staff, clinician and other staff who will assist with linking the patient to care services. If not already done, counseling for Partner Services (PS) should occur during this visit.

C. Advice on making T&T work is for the receiving clinic to designate a “TEST AND TREAT DESIGNEE of the DAY,” a team member who will be the single point of contact for receiving the referral and will organize the rapid response. This person may be a case manager, clinic designee or other staff who will call upon the personnel needed to treat the patient that day (medical evaluation, counseling on starting ART, phlebotomy, eligibility and benefits counseling, navigation, scheduling and notification of PS).

   Instead of performing the majority of the counseling up front before therapy starts, counseling begins after diagnosis and continues after a patient is started on treatment. With this approach, all standard individualized counseling components are covered, initiation of ART is not delayed and there is an opportunity to continue counseling while the patient is initiating therapy.

D. A sustainable, long-term care plan should be established. Successful outcomes in HIV depend not only on the rapid initiation of therapy but also upon the establishment of a sustainable HIV-care plan. Based on the initial assessment of potential barriers for successful linkage to care, a plan is put in place with the HIV staff/case manager to address both immediate and long-term barriers. This may include emergency housing, immediate access to insurance and drug benefits, expedited access to mental health services or residential drug treatment programs, counseling and referrals to deal with other concerns.

E. Based on the identification of barriers to linkage and retention in care, a contingency plan is identified for potential problems such as missed appointments, missed doses of ART and inability to fill medications at the pharmacy. Patients are given clear guidance on how to get help, support and remain connected to the clinic.

STEP TWO: INITIAL TEST AND TREAT CLINIC VISIT

A. Medical Evaluation:

HIV history: An HIV risk/prevention history will be taken and recorded, including:

- Date of last negative HIV test and prior HIV test(s)/result(s)
- PrEP use
- PEP use
- Sexual practices and serostatus of partners, if known

B. Psychosocial Evaluation:

- Substance abuse/mental health assessment
- Housing/food
- Readiness to start ART

C. Medical history/targeted exam:

A quick medical history/targeted exam will be taken, particularly since patients will be started on ART before most laboratory test results have returned:

- Co-morbidities (especially renal/liver problems)
- Medications
- Drug allergies
- Review of systems (to alert for the presence of opportunistic infections (OIs) or HIV-seroconversion symptoms) and targeted clinical exam for HIV-related signs (for example, thrush, lymphadenopathy and skin lesions)

D. Counseling on the risks and benefits of immediate ART:

A full discussion occurs with the patient regarding the risks and benefits of immediate ART. The role of viral load monitoring will also be included in this discussion to introduce the concept of ongoing monitoring and therapy goals. The patient is informed about the possibility of developing an immune-reconstitution syndrome. The patient is also reminded about the importance of being in close contact with the health system during early months of treatment should any complications arise related to medication or HIV disease. Emphasis is placed upon listening to patient concerns and conveying to the patient that he or she will likely have additional questions through this process and the team is available to address these.

E. Initiation of immediate ART:

The provider reviews the patient's plan for long-term ART and follow-up care.

If there is no clear contraindication and the patient does not decline, the provider offers, selects (in consultation with the patient) and prescribes/dispenses immediate ART.

Selection of ART: The selection of a particular ART regimen for an individual patient will depend upon the patient's preferences, co-morbidities, potential drug interactions and drug allergy history.

Because most patients will be initiated on ART before the results of laboratory tests are available (in particular the HIV viral load, genotype, creatinine, liver function tests and HLA-B*5701 test for predisposition to abacavir hypersensitivity), the following are recommended T&T ART regimens.

The T&T regimens outlined below have been purchased and are available for CHDs from Central Pharmacy in 30-day starter packs. ***The attached CHD order form must be completed to request the ART regimens to be shipped from Central Pharmacy to your CHD site.***

RECOMMENDED 30-DAY ART REGIMENS FOR TEST AND TREAT:

- **Dolutegravir 50 mg once daily (Tivicay®) + tenofovir alafenamide/emtricitabine (Descovy®) one (1) tab once daily or**
- **Darunavir/cobicistat (Prezcobix®) once daily + tenofovir alafenamide/emtricitabine (Descovy®) one (1) tab once daily or**
- **Bictegravir + tenofovir alafenamide/ emtricitabine (Biktarvy®) one (1) tablet taken once daily with or without food**

In cases of high level known resistance, at the provider's discretion, combinations of PI/INSTI plus or minus NRTI may be dispensed

F. Laboratory studies: See AIDSinfo Laboratory Testing for initial assessment and monitoring of HIV-infected patients on ART at
https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/3/tests-for-initial-assessment-and-follow-up

G. Prescribing and/or Dispensing Initial ART

Medication Available On-Site

- Once an ART regimen has been selected, the clinician/health care team dispenses a 30-day supply of medication. The goal is to provide sufficient ART until the patient's AIDS Drugs Assistance Program (ADAP)/insurance/coverage is able to supply continuing medication.
- The patient is encouraged to take the first dose of ART during the initial visit.
- CHDs must maintain medication logs showing drug was dispensed to qualified patients for the T&T Program.
- **NOTE**: If an additional 30-day supply of ART medication is required (additional 30-day starter pack), documentation should be provided as to why there was a delay over 30 days for the patient's medication coverage.

- DHHS HIV/AIDS Treatment Guidelines may be accessed at https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0

STEP THREE: LINKAGE TO CARE/FOLLOW UP

Day one to three days after ART Initiation: A member of the health care team assesses/provides medical/psychosocial support, arranges for eligibility assessment and obtaining baseline labs and/or referring for initial lab work. Provide resources/support for the patient to coordinate filling their ART prescription. Any medical symptoms or questions are conveyed to the provider for the appropriate follow up.

Day 5 through 10: The patient has an appointment with the medical provider to follow up on clinical care and laboratory tests. At that visit, lab results are reviewed with the patient. An assessment is done for HIV and any medication side effects. Treatment may be adjusted as appropriate. If the CHD or clinic that initiated T&T will be following the patient for their ongoing HIV care, appointments can be made accordingly. If the patient will be following up with another HIV medical provider, the case manager should assist with arranging a clinic appointment for follow up on days 5 through 10. Care resumes with the provider for routine primary HIV care with an emphasis on retention in long-term care.

Ongoing: Access to a medical case manager is provided during this time period and over the next three or more months to continue with the stabilization plan, to provide ongoing support and education for coping with stigma, partners/family/friends' disclosure and other barriers.

Appointment reminders are made and immediate follow up is completed for any missed appointment(s), including outreach and home visits.

For medication adherence, the Care4Today website is one resource you may share with patients including a mobile technology application for use. The link is https://www.care4today.com/mhm.

For patients at risk for poor retention in care, make referrals to case managers and provide overlapping support until the patient has established a relationship with the case manager.

Test and Treat Intervention Components

- Facilitation of same day/next day appointments
- Flexible scheduling for providers (on call/back up)
- ART regimens pre-approved for use prior to genotyping or lab testing
- Available onsite ART
- Accelerated process for Ryan White eligibility/health insurance coverage
- Recommendation for first dose to be taken observed in the clinic

Data Outcomes

Time to specific milestones: The T&T program tracks dates at which each patient achieves specific care milestones. This allows analysis of the time delays that occur at each step of the disclosure, referral, linkage and engagement process. Dates for the following milestones are collected (they need not occur in order):

- First positive diagnostic test

- Test result disclosure
- Last negative HIV test result
- Clinic contact/referral
- First clinic visit
- First clinic medical provider visit
- First ART prescription date (after diagnosis of infection)
- First viral load suppression <200 cells/mm^3
- Linkage to primary HIV care within 30 days and documentation patient maintained in care, through data collection over 12-month period
- Engagement in care at 12 months
- Viral suppression <200 cells/mm^3 and <lowest limit of detection defined by lab, through data collection over 12-month period

Technical Assistance, Training and Resources

Technical assistance and training may be requested by calling the HIV/AIDS Section Medical Team at (850) 901-6676 or email Roselyn.Jasmin@flhealth.gov
Test and Treat ART medications: Central Office in Tallahassee has arranged a stable supply of starter packs available to the CHDs through Central Pharmacy. See the T&T order form to place an order for the T&T regimens from Central Pharmacy.

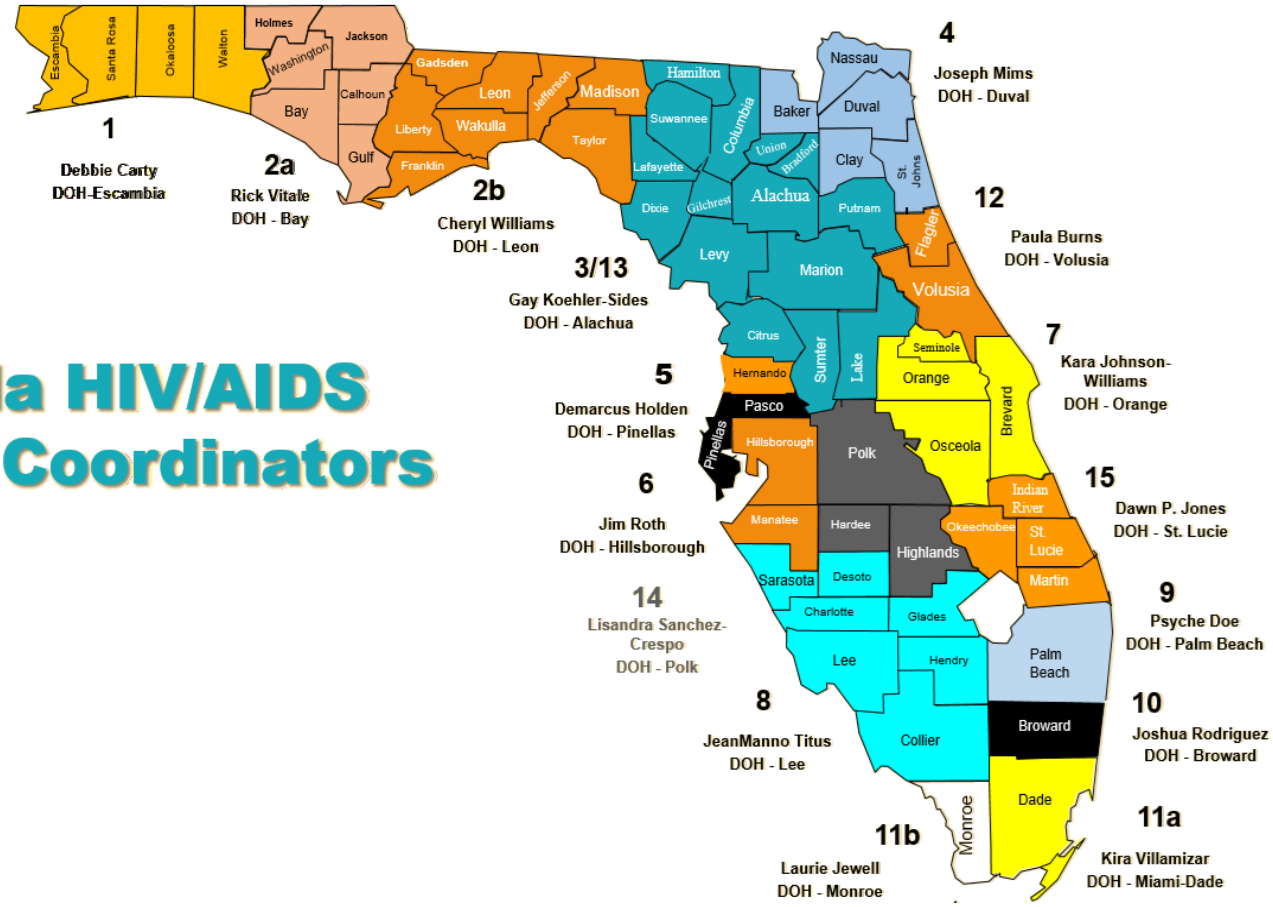
Training is available through the Southeast AIDS Education and Training Center (SE AETC) http://aidsetc.org/directory/regional/southeast-aids-education-and-training-center through the following SE AETC Florida Partner Sites:

- North Florida AETC: call (352) 273-7845 or http://aetc.medicine.ufl.edu/
- South Florida AETC: Martia West, MHP, Administrator (305) 582-2233 or Lissette Lahoz, MPH, Program Manager (610) 248-2776

Phone consultation on HIV/AIDS management is available to clinicians at the Clinician Consultation Center (CCC) at (800) 933-9413, Monday–Friday, 9:00 a.m.–8:00 p.m. EST. The website link to CCC is http://nccc.ucsf.edu/clinician-consultation/hiv-aids-management/

For the Florida Department of Health HIV/AIDS Program Coordinators statewide contact information, please call Debbie Norberto at (850) 901-6681 or email Debbie.Norberto@flhealth.gov

Florida HIV/AIDS Program Coordinators



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Costs of Living With HIV Can Be Mitigated by Rapid Initiation of ART Post Diagnosis

Christina Mattina

A trio of posters presented at the Academy of Managed Care Pharmacy Managed Care & Specialty Pharmacy Annual Meeting show that high healthcare utilization leads to substantial costs among individuals living with HIV, but prompt initiation of antiretroviral therapy (ART) regimens after diagnosis can help contain costs in both Medicaid-covered and commercially insured patients.

In a poster describing an analysis of multistate Medicaid data combined with results of a literature review,[1] researchers estimated the costs of healthcare resource utilization among patients living with HIV in the United States. These costs were comprised of costs per inpatient day and costs per emergency department (ED) and outpatient visit. Outpatient care included services from general care providers and specialists, HIV care, and procedural and social services.

From the 21,513 Medicaid claims analyzed, the researchers found that mean costs were $2035 per inpatient day, $212 per ED visit, and $85 per outpatient visit. Within the 7 US studies identified by the targeted literature review, mean costs for those 3 types of utilization ranged from $1849 to $3451, $704 to $828, and $130 to $417, respectively.

Because the literature review was not limited to Medicaid data, the authors noted that mean costs for inpatient days were similar in both Medicaid and the broader US population, but Medicaid had lower costs for outpatient and ED visits. This “could be related to changes in treatment guidelines and in the provision of healthcare services, as well as improvements in overall health” in this population, they wrote.

“Combining both sources provided a robust range of costs for [people living with HIV], which is important for decision-makers,” the authors concluded. They suggested that further research could explore the financial effects of changing treatment guidelines and use of new single-tablet regimens.

Another poster explored healthcare costs of Medicaid patients with HIV, specifically focusing on how quickly they began ART after being diagnosed with HIV-1.[2] In an interview with *The American Journal of Managed Care*®, Keith J. Dunn, PharmD, BCPS, AAHIVE, of Janssen, senior author of the 3 posters, defined rapid initiation as a new paradigm in which “providers start treatment prior to having full laboratory results or resistance testing records available.”

According to Dunn, the researchers looked at the economic impacts of rapid initiation because “previous

studies have shown that when you start patients rapidly, they have a higher rate of retention in care, so coming back to see the doctor; improvements in virologic outcomes, like decreased time to virologic suppression; and decreased rates of morbidity and mortality."

The 627 eligible patients were separated into 4 cohorts based on their time to ART initiation post diagnosis; 20.4% were rapid initiators (RI; ≤14 days), 36.4% were moderately rapid initiators (mRI; 15-60 days), 26.0% were moderately delayed initiators (mDI; 61-180 days), and 17.2% were delayed initiators (DI; 181-360 days).

Dunn noted that the 7-day mark is the widely accepted definition of rapid initiation in sources like the World Health Organization guidelines, but the authors' use of the 14-day mark to define rapid initiation in this cohort was due to longer times to initiation seen among Medicaid patients.

"We actually had to change the window in which we defined rapid initiation in the Medicaid population, from 7 days to 14 days, because there were so few patients starting treatment within 7 days," Dunn said.

Medical costs increased across all follow-up time points after diagnosis, but they were always greater among the DI group than the RI group (6 months, $9124 vs $7757; 12 months, $15,989 vs $10,836; 24 months, $27,797 vs $16,220; 36 months, $43,067 vs $23,447, respectively). DI patients had lower pharmacy costs, and the medical costs of the DI/mDI patients accounted for more than half of their total healthcare costs, whereas the RI/mRI patients had pharmacy costs that were higher than their medical costs.

By the time of follow-up at 36 months post diagnosis, the increased pharmacy costs in the RI group were offset by lower medical costs, resulting in lower total healthcare costs compared with their DI counterparts (DI, $83,157; RI, $74,093). These results highlight "the long-term economic benefits of rapid ART initiation post–HIV-1 diagnosis," the authors wrote.

To make rapid initiation the standard of care, and potentially lower downstream spending by Medicaid, the authors suggested that future efforts should focus on "reducing barriers to treatment initiation, such as time spent waiting for test results and counseling."

Finally, another poster looked at characteristics of and healthcare costs among commercially insured US patients with HIV who were treated within 60 days of diagnosis.[3] This was among the first studies to specifically examine the financial implications of ART initiation timeliness in patients with commercial insurance, who comprise a larger proportion of the population with HIV than the Medicaid patients who are more commonly examined in similar cost-related studies.

In this study, the RI group was defined as patients who started ART therapy within 7 days of diagnosis, whereas the mRI group included those who started between 8 and 60 days after diagnosis.

Of the 6743 eligible patients, 18.3% were RI and 81.7% were mRI. Nearly three-quarters (74.3%) were started on single-tablet regimens. RI patients were more likely to start on protease inhibitor–based regimens, mRI patients were more likely to start on integrase strand transfer inhibitor–based regimens, and the groups were equally likely to start nonnucleoside reverse transcriptase inhibitor–based regimens. Total healthcare costs, defined as the sum of medical and pharmacy costs, were lower in the RI group than in the mRI group ($109,456 vs $116,870, respectively) over the 36 months after diagnosis.

The authors pointed to opportunities for improvement in ART initiation, including increasing the percentage of patients who start therapy within 7 days. They also noted that many of the RI patients used agents considered "suboptimal" due to their "low rather than high genetic barrier to resistance, demonstrating a need to optimize HIV treatment with antiretrovirals having high genetic barrier to resistance." They suggested that "opportunities exist to educate healthcare providers about which antiretrovirals have a high genetic barrier to resistance, have fewer testing barriers, and can provide adherence benefits through their availability in single-tablet form."

The message that rapid initiation of ART was associated with lower healthcare costs "is really important because some payers are looking at formulary management and trying to contain access to various regimens," said Dunn.

"These findings highlight the importance of starting treatment rapidly after diagnosis and should hopefully encourage payers to provide unrestricted access to HIV treatment options that are recommended for rapid initiation per national and international treatment guidelines…. If there are active management strategies put in place like prior authorization or preferred tiering, that may result in further delayed receipt of care and also really prevent rapid initiation from taking place."

References

1. Benson C, Emond B, Lefebvre P, et al. Estimating costs of health resource utilization for patients living with human immunodeficiency virus. Poster presented at: Academy of Managed Care & Specialty Pharmacy Annual Meeting; March 25-28, 2019; San Diego, CA.
2. Benson C, Emond B, Romdhani H, et al. Long-term benefits of rapid antiretroviral therapy initiation among Medicaid-covered patients with human immunodeficiency virus. Poster presented at: Academy of Managed Care & Specialty Pharmacy Annual Meeting; March 25-28, 2019; San Diego, CA.
3. Benson C, Emond B, Lefebvre P, et al. Rapid initiation of antiretroviral treatment following diagnosis of human immunodeficiency virus among commercially insured patients in the United States. Poster presented at: Academy of Managed Care & Specialty Pharmacy Annual Meeting; March 25-28, 2019; San Diego, CA.

Patient Navigation Intervention

Highlights from the Special Projects of National Significance (SPNS) Program

This fact sheet contains highlights from the Virginia Department of Health's *Patient Navigation* Intervention, focused on using patient navigation in linking newly diagnosed persons to care within 30 days of diagnosis. This intervention also targets those who have fallen out of care, who have never received care, or are at risk of being lost-to-care.

Setting: Central and Southwest Regions of Virginia

Target Population: Newly diagnosed PLWH; PLWH who have fallen out of care, have never received care, or are at risk of being lost to care

Theoretical Basis: Collaborative Learning Model

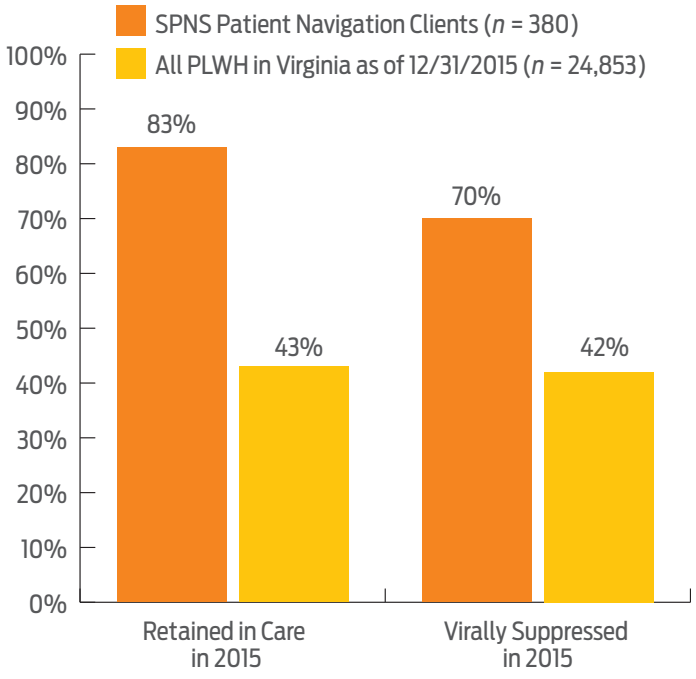
Background

Following a diagnosis of HIV, linking people living with HIV (PLWH) to HIV services is the next step on the HIV care continuum. Early initiation of HIV treatment is associated with improved outcomes along the HIV care continuum. Lower CD4 T cell counts at the time of treatment initiation is associated with shorter life expectancy and a lower likelihood of full rebound of CD4 counts.[1,2] Thus, linkage to care soon after diagnosis can be an important strategy for supporting PLWH. HHS guidelines indicate that all PLWH should be initiated in treatment, and as early as possible. Patient navigation support for PLWH has been demonstrated to improve efficiency and effectiveness of linkage to care interventions.[3] The Virginia Department of Health sought to promote timely linkage to and retention in care through the guidance and support of health workers known as Patient Navigators.

Unmet Needs

Underserved populations, including many racial, ethnic, and sexual minorities, face numerous structural, financial, and cultural barriers that impede their linkage to and engagement in care.[4] As such, addressing these key areas by increasing social support services; integrating one-stop-shop care delivery; removing structural barriers; providing financial support services; and using peer navigators or care coordinators, can help improve linkage to care for PLWH.

HIV Care Outcomes Among VDH SPNS Patient Navigation Clients Served 9/1/2013–8/31/2015



U.S. Department of Health and Human Services
Health Resources and Services Administration
HIV/AIDS Bureau

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Intervention Objectives

The objectives of the *Patient Navigation* Intervention were to create more timely and effective linkages to and retention in medical care for PLWH through the guidance and support of Patient Navigators.

Key Considerations for Replication

- **Engage potential partners and stakeholders** early in the planning process, and include diverse planning partners (e.g., service providers, community members, PLWH)
- **Research the availability of similar interventions** in the local area to avoid duplication or confusion and identify opportunities for partnerships and coordination
- **Develop a clear and comprehensive protocol** for Patient Navigators to follow
- **Client encounters should take place routinely** (more frequently at the start of navigation), be face-to-face whenever possible, and documented by the Patient Navigator
- **PLWH may enter the intervention at varying stages of the HIV care continuum,** and may need to re-engage with the intervention at some point
- **Navigators and PLWH work collaboratively** to develop a linkage-to-care plan; clients should be informed during intake that the transitioning out (once appropriate) will take place
- **Linkage to non-HIV-related services** (e.g., mental health, housing, transportation, education) can be facilitated by the Patient Navigator

Intervention Staff Requirements

To replicate the Virginia Department of Health's Patient Navigation intervention, the following positions and capacity are necessary.

- **Patient Navigators**—must possess specific knowledge and skills including being able to solve problems creatively and effectively; direct clients to community resources/information; and build working relationships. **Programs may be able to rely on community health workers or other staff dedicated to linkage-to-care efforts if a patient navigator is not available.*
- **Patient Navigator Supervisors**—A variety of staff serve to manage/supervise Patient Navigators including administrative staff, nurse managers, and physicians.

RESOURCES

This fact sheet is part of the ***Improving Health Outcomes: Moving Patients Along the HIV Care Continuum and Beyond*** resources from the Integrating HIV Innovative Practices (IHIP) project.

- **SPNS Initiative: Systems Linkages and Access to Care, 2011–2016: https://hab.hrsa.gov/about-ryan-white-hivaids-program/spns-systems-linkages-and-access**
- **VDH Active Referral Intervention Case Study: http://careacttarget.org/ihip**

Notes

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HIV prevention study finds universal “test and treat” approach can reduce new infections

News Release

Tuesday, March 5, 2019

NIH-sponsored trial suggests home-based HIV testing and referral to care works at population level.

Image of blood being captured in a capillary tube

A PopART study health worker draws blood from the finger of a study participant for an in-home HIV test. Kim Cloete

New HIV infections declined by 30 percent in southern African communities where health workers conducted house-to-house voluntary HIV testing, referred people who tested positive to begin HIV treatment according to local guidelines, and offered other proven HIV prevention measures to those who tested negative. Local guidelines evolved during the study from offering HIV treatment based on immune health to offering immediate treatment for all.

Surprisingly, the investigators found that new HIV infections did not decline in communities where those who tested positive were offered immediate treatment throughout the study. Analyses are under way to try to explain this puzzling outcome.

These results from the large clinical trial called Population Effects of Antiretroviral Therapy to Reduce HIV Transmission (PopART), or HPTN 071, were announced today at the Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle. The findings also will be presented Wednesday as an oral abstract at the conference.

“The results of the PopART study suggest that conducting population-wide, home-based HIV testing and offering treatment to those diagnosed with HIV could help control the epidemic in certain settings,” said Anthony S. Fauci, M.D., director of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. “These findings indicate that a universal test-and-treat strategy could be an important addition to our toolbox of proven HIV prevention modalities.”

The goal of PopART was to learn whether conducting HIV testing throughout a population and promptly offering treatment to all who test positive would achieve a high level of community-wide HIV suppression, thereby reducing the rate of new infections in the population.

NIAID sponsored and co-funded PopART, which was funded primarily by the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), administered by the Office of the U.S. Global AIDS Coordinator and Health Diplomacy in the U.S. Department of

State. Leading the study were Richard Hayes, M.Sc., D.Sc., F.Med.Sci., professor of epidemiology and international health at the London School of Hygiene & Tropical Medicine; and Sarah J. Fidler, M.B.B.S., Ph.D., professor of HIV medicine at Imperial College London.

The PopART study took place from 2013 to 2018 in 21 urban and peri-urban communities in South Africa and Zambia. Each community had an average of roughly 50,000 residents for a total study population of about 1 million. The communities were clustered into seven groups of three — "triplets" — matched by geographical location and estimated HIV prevalence. The communities in each triplet were assigned at random to one of three study groups. The first group received annual house-to-house voluntary HIV testing and counseling, linkage to care for those who tested positive and the opportunity to immediately begin treatment, and the offer of a suite of proven HIV prevention measures to those who tested negative. The second group received the same services as the first, except treatment was offered according to national guidelines. The third group served as a control and received HIV prevention and testing services according to the local standard of care as well as HIV treatment according to national guidelines.

At the beginning of the trial, the national guidelines for HIV treatment in Zambia and South Africa specified that people living with HIV should start antiretroviral therapy (ART) when their CD4+ T-cell count — a measure of immune health — had declined to 350 cells per microliter. That threshold was raised to 500 cells/µL in 2014. Then in 2016, the countries recommended that everyone diagnosed with HIV begin ART immediately, regardless of CD4+ T-cell count. Consequently, the first and second groups of communities in the PopART study received the same intervention during the last two years of the trial.

To measure the impact of the PopART interventions, the investigators recruited a random sample of 48,300 adults ages 18 to 44 years from the overall study population, including roughly 2,300 adults from each community. Members of the study team visited these participants, called the "population cohort," at the start of the trial and then once a year for three years to collect data through a questionnaire and blood testing, including a test for HIV infection.

Between the first and third years of the study, 553 new HIV infections occurred in the population cohort during nearly 40,000 person-years of follow up for an incidence rate of 1.4 infections per 100 person-years (p-y). Investigators found that HIV incidence was 7 percent lower in group 1 than in the control group (1.5/100 p-y versus 1.6/100 p-y), but this difference was not statistically significant. In contrast, investigators found that HIV incidence was 30 percent lower in group 2 than in the control group (1.1/100 p-y versus 1.6/100 p-y), and this difference was highly statistically significant and consistent across all seven matched triplets.

Among those members of the population cohort who tested positive for HIV by the second year of the study, the investigators determined the proportion who had an undetectable level of virus in their blood. Viral suppression was achieved by 72 percent of these study participants in group 1, 68 percent in group 2 and 60 percent in the control group.

"We found very strong evidence of an effect in the group that received treatment according to national guidelines, said Dr. Hayes. "The absence of a clear reduction in HIV incidence in the group that received the most intensive HIV prevention intervention is surprising and inconsistent with the group's rate of viral suppression.

Further analyses of qualitative and quantitative data from the study communities may help us better understand this unexpected result."

The study data include information on mobility and migration as well as findings from an ongoing study of the genetic evolution of circulating HIV strains in the study population.

"The HPTN 071 (PopART) study, the largest HIV prevention study conducted to date, highlights the importance of conducting large-scale studies that aim to measure the impact of an integrated prevention strategy," said Wafaa El-Sadr, M.D., M.P.H., M.P.A. Dr. El -Sadr is co-principal investigator of the NIH-funded HIV Prevention Trials Network (HPTN) and professor of epidemiology and medicine at Columbia University. "Achieving HIV epidemic control will require the integration of various evidence-based interventions tailored to the needs of specific populations," she added.

The PopART study was conducted by HPTN investigators in collaboration with the London School of Hygiene & Tropical Medicine, Imperial College London, the Zambia AIDS-Related Tuberculosis Project and the Desmond Tutu TB Centre of South Africa. HIV care and treatment were provided by government health services in the study communities with support from PEPFAR under the direction of the U.S. Agency for International Development and the U.S. Centers for Disease Control and Prevention.

In addition to PEPFAR and NIAID, study funders included the International Initiative for Impact Evaluation with support from the Bill & Melinda Gates Foundation, as well as the National Institute on Drug Abuse and the National Institute of Mental Health, both part of NIH.

For more information about the PopART clinical trial, please search ClinicalTrials.gov using study identifier NCT01900977.

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