

Gilead's FOCUS Program

Increasing Routine HIV and HCV Screening and Linkage to Care



Gilead Sciences is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet need. As a leader in developing therapies for HIV and chronic hepatitis C virus (HCV) infection, Gilead is committed to helping ensure access to life-saving screening and care services for people who could benefit from them.

HIV

Routine HIV screening is the practice of offering HIV testing to adults and adolescents as part of regular care in clinics, hospitals and other health care settings. Experts believe that routine screening is essential to slowing and ultimately ending the HIV/AIDS epidemic in the United States by helping to identify undiagnosed infection, one of the major drivers of the disease. Nearly one in six HIV-positive Americans, approximately 180,900 people, does not know that he or she is infected.¹ It is estimated that these individuals are responsible for up to two-thirds of sexually transmitted HIV infections because they do not know that they are putting others at risk.²

Diagnosis also enables those who are infected to begin antiretroviral therapy, which lowers the amount of HIV in the body (viral load). In addition to improving the health of people with HIV, lowering viral load can significantly reduce their chances of transmitting HIV to others.^{3,4} A landmark clinical study found that, among heterosexual couples in which one partner was HIV-positive and the other HIV-negative, the rate of HIV transmission to the negative partner was 96 percent lower in couples where the positive partner started treatment right away compared to couples where the positive partner delayed treatment.⁵

In recent years, interest in “test and treat” strategies to prevent HIV infections and reduce AIDS deaths has grown significantly. The federal government’s National HIV/AIDS Strategy, which was released in 2010, the Institute of Medicine, the Centers for Disease Control and Prevention (CDC) and the U.S. Preventive Services Task Force (USPSTF) have all expressed strong support for expanding HIV screening and linkage to care, especially in high-risk communities.^{6,7,8,9}

Chronic Hepatitis C

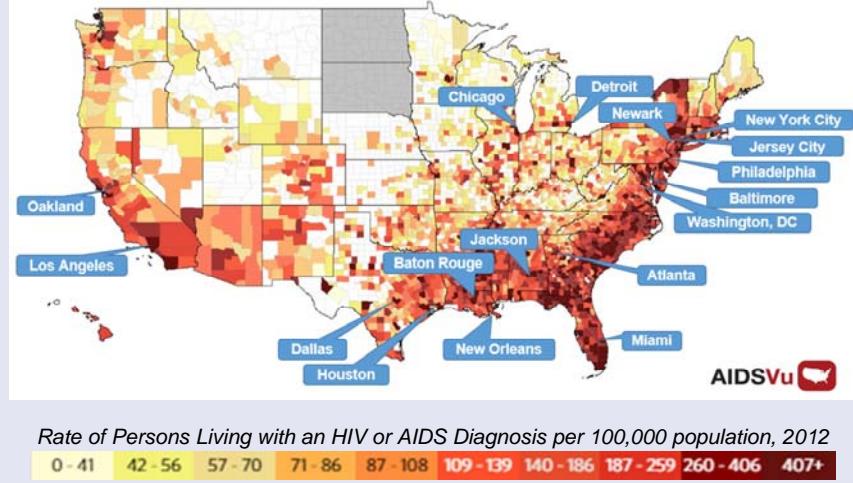
Chronic hepatitis C is a potentially life-threatening but curable liver disease that is caused by HCV.¹⁰ For 75-85 percent of people who contract HCV, it becomes a chronic infection that, over time, can lead to serious and life-threatening complications, including liver failure, liver cancer or liver transplantation.¹¹ HCV affects approximately 3.2 million Americans and is now responsible for more U.S. deaths each year than HIV.^{12,13} Many people with HCV do not have obvious symptoms for many years and it is estimated that half of Americans with HCV do not know that they are infected, which keeps them from getting care and treatment.^{14,15} HCV is a blood borne virus, and can be spread through blood-to-blood contact, including injection drug use.¹⁶

Adults born between 1945 and 1965 (baby boomers) comprise around 75 percent of all HCV cases in the United States.¹⁷ Approximately three-quarters of HCV-related deaths in the United States occur among baby boomers, and the median age of death is 57 years – approximately 20 years less than the average American’s lifespan.¹⁸ However, there is low awareness about the disease in this group: 80 percent of baby boomers do not consider themselves to be at any risk for HCV.^{19,20} To address this, both CDC and the USPSTF have recommended that all baby boomers get a one-time HCV test.^{21,22} It is estimated that one-time screening could identify 800,000 cases of HCV and prevent up to 120,000 deaths.²

Program Overview

Gilead launched the FOCUS program in 2010 to develop replicable model programs that embody best practices in HIV screening and linkage to care. The program now has 96 partner organizations in 17 cities across the United States that are heavily impacted by HIV, including Atlanta, Baltimore, Baton Rouge, Chicago, Dallas, Detroit, Houston, Jackson, Jersey City, Los Angeles, Miami, New Orleans, New York, Newark, Oakland, Philadelphia and Washington, D.C. In 2014, more than 60 partnerships across all FOCUS cities began incorporating HCV screening initiatives into their programs.

FOCUS Partnership Cities



FOCUS aims to:

- Make routine HIV screening for adults and adolescents a standard of medical care
- Make one-time HCV screening for baby boomers a standard of medical care
- Reduce the number of undiagnosed individuals with both diseases, decrease the number of those who are diagnosed late and ensure strong linkages to care and treatment
- Generate dialogue among healthcare systems and other stakeholders on increasing diagnosis and access to care
- Change public perceptions and overcome stigma that may discourage people from getting tested for HIV and HCV

FOCUS Partnerships at a Glance

- **200** partnerships to date;
96 current partnerships
- **1.7 million** HIV tests conducted
- **13,000** individuals diagnosed with HIV, with **80** percent linked to care
- **150,000** HCV tests conducted
- **10,000** positive HCV tests

Priorities

Routinizing HIV and HCV Screening in Primary Care and other Clinical Settings

The federal government recommends making HIV testing as routine as screening for cholesterol, blood pressure and certain cancers. CDC issued guidelines in 2006 recommending that an HIV test be offered to all Americans ages 13-64 as a routine part of their healthcare visits.²⁴ CDC also recommends that individuals likely to be at high risk of HIV infection, including men who have sex with men, injection drug users and sexual partners of HIV-positive individuals, be screened for HIV at least annually. In 2012, the USPSTF supported these recommendations by giving routine HIV screening an "A" grade, which requires most public and private insurers to cover the test without charging a co-payment to the recipient or requiring other cost-sharing.^{25,26}

In August 2012, CDC issued guidelines recommending a one-time HCV test for all baby boomers.²⁷ The next year, the USPSTF backed CDC's recommendation by giving HCV testing of baby boomers a "B" grade, which, like the "A" grade for HIV screening, requires most public and private insurers to cover the service without charging recipients.²⁸ Additionally, the U.S. Department of Health and Human Services recently renewed its Viral Hepatitis Action Plan to improve testing, care and treatment for HCV. The plan's priorities include ensuring that testing is offered to baby boomers at Veterans Affairs health facilities as well as reforms to Medicaid to improve coverage of HCV testing and treatment.²⁹

Screening Challenges

- Only 60 percent of health care providers say they offer HIV screening to all adult and adolescent patients.³⁶
- Nearly half of adults who have been tested for HIV say they have to ask their doctor for an HIV test.³⁷
- Routine HIV screening is extremely rare in emergency departments, with less than one percent of patients not known to be infected offered testing.³⁸
- A recent CDC analysis found that only half of Americans identified as ever having had HCV received follow-up testing to confirm whether they were still infected.³⁹

FOCUS partners with other institutions and community organizations to develop innovative programs that promote and normalize HIV and HCV screening and linkage to care. Integrating screening into routine care at hospitals and community health centers offers the opportunity to standardize one-time HCV testing for baby boomers while also increasing the chances that patients will be screened for HCV and HIV in the same visit.

Integrating HIV and HCV Tests with Other Health Screenings

For most of the history of the epidemic, HIV testing has been offered in isolation from screenings for other conditions with similar routes of transmission and prevalence, such as sexually transmitted diseases (STDs) and viral hepatitis, including HCV. Despite high rates of co-infection – one third of people with HIV are also infected with HCV – many prevention strategies focus on diagnosing and treating just one of these infections.³⁰

Uniting these services can simplify existing processes, improve disease prevention and have a greater overall impact on the well-being of people with these infections. In addition to primary care providers, FOCUS partners with STD clinics, community organizations, family planning centers, pharmacies and hospitals to integrate HIV and HCV screening into the standard set of routine health screenings.

Normalizing Attitudes Toward and Ending Stigma Associated with HIV and HCV Screening

Both HIV and HCV are often associated with social stigma due to their transmission routes, misperceptions about these

diseases and lack of awareness of who may be at risk. These challenges can prevent people from getting tested and seeking care.

TEST: FOUR PILLARS OF ROUTINE SCREENING

TESTING INTEGRATED INTO NORMAL CLINICAL FLOW

To promote the normalization and sustainability of testing.

ELECTRONIC MEDICAL RECORD MODIFICATION

To prompt testing, automate processes, populate lab orders and track performance.

SYSTEMIC POLICY CHANGE

A multi-level, organization-wide commitment to implement routine testing and linkage to care.

TRAINING, FEEDBACK & QUALITY IMPROVEMENT

To identify best practices and motivate staff.

FOCUS FOUR PILLARS, GILEAD SCIENCES, 2014

As with many diseases in the United States, HIV/AIDS disproportionately affects certain communities. Researchers at CDC recently found that there is a generalized HIV epidemic among heterosexuals living in impoverished urban areas in 23 of the largest U.S. cities.³¹ A generalized epidemic is one in which the prevalence rate is at least one percent; in these cities, more than two percent of heterosexuals living in poverty areas are infected with HIV. This suggests that individuals may be at increased risk of HIV infection simply by virtue of where they live.

With HCV, some people may assume that an individual with the disease is an active user of illicit injection drugs. In fact, HCV can be acquired in several ways – including use of injection drugs just one time many years ago, from tattooing, or from receiving contaminated blood or blood products before 1992, when widespread screening of the blood supply began.³² Many people with HCV do not know when or how they were infected.

When whole communities and age groups – not just individuals – are at risk, it is important to adopt community-wide approaches and solutions. For HIV, routine screening coupled with access to treatment not only reduces an individual's viral load but also decreases a community's viral load, thereby decreasing transmission rates.^{33,34} And for HCV, one-time screening of all baby boomers helps to diagnose the disease while reducing the focus on stigmatized risk behaviors.

FOCUS works with community organizations to offer HIV and HCV testing in impoverished urban communities. Recognizing the continuing impact of HIV- and HCV-related stigma and fears that may prevent people from seeking testing, FOCUS supports innovative public education campaigns that seek to normalize social attitudes about both diseases.

Partnerships

The 17 cities served by FOCUS were selected based on their HIV burden as well as an assessment of unmet need in terms of undiagnosed and untreated HIV infections. These cities are home to 35 percent of people in the United States diagnosed with HIV and many more who have not yet been diagnosed.³⁵ Over the last year, FOCUS partners have worked to incorporate HCV testing and linkage to care services. The burden of HCV is considerable in FOCUS cities but surveillance systems for the disease are not always comprehensive.

FOCUS partnerships include:

- **New York City – Urban Health Plan (UHP):** This network of community health centers in the South Bronx serves more than 48,000 patients each year. With support from FOCUS, UHP integrated HIV testing into standard clinical practices and now offers routine screening system-wide. Between 2011 and 2013, UHP tested more than 32,500 patients, a five-fold increase over the preceding three-year period. In 2013, UHP initiated a multi-disciplinary learning collaborative aimed at scaling up and sharing best practices in routine HIV screening across five health centers in New York City.
- **Atlanta – Grady Hospital:** One of the largest public hospitals in the southeastern United States, Grady Hospital provides services to more than 160,000 patients a year. Through its FOCUS partnership, the hospital has implemented routine HIV screening in its emergency department (ED) and primary care center, testing three times the number of patients in the first year of implementation than in the previous three years combined. In 24 months, Grady tested 44,000 patients and identified 350 new diagnoses.
- **Baltimore – University of Maryland:** The Preparing the Future program has integrated an HIV education curriculum that emphasizes routine screening and linkage to care across the University's medical and academic campuses. The University has also implemented routine HIV screening in eight inpatient units and at its dental clinic, utilizing the latest testing technology that can identify early-stage HIV infection. Since routine testing began in September 2013, the percentage of people tested rose from three percent to 50 percent.
- **Philadelphia – Do One Thing:** Led by researchers at Brown University and Drexel University College of Medicine, Do One Thing is an HIV and HCV testing campaign in a neighborhood in southwest Philadelphia that is heavily affected by both diseases. The campaign offers testing for both diseases block by block and works with a local federally-qualified health center to implement routine HIV screening. Do One Thing also created the city's first community HCV testing program and developed best practices in immediate confirmatory testing for HCV,

which other organizations are now replicating.

- **Houston – Memorial Hermann Health System (MHHS):** MHHS is a network of 12 hospitals in Houston and is the largest non-profit hospital system in Southeast Texas. MHHS recently expanded routine HIV screening for patients visiting its EDs to all inpatient admissions. Through its FOCUS partnership, it became the first hospital system in Texas to implement one-time HCV screening for baby boomers in one of its EDs. Based upon the success of this pilot initiative, MHHS is expanding its HCV screening program system-wide. More than 7,000 HCV tests have been conducted to date, with 10 percent of patients testing positive.

To learn more about Gilead Sciences and our efforts to help ensure access to screening and care services for people living with HIV and HCV, please visit www.gilead.com or call 1-800-GILEAD-5 or 1-650-574-3000.

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