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HIV Testing Strategies for Health Departments to End the Epidemic in the U.S.

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Abstract

An important goal of the Ending the HIV Epidemic in the U.S. initiative is the timely diagnosis of all people with HIV as early as possible after infection. To end the HIV epidemic, health departments were encouraged to propose new and innovative HIV testing strategies and improve the reach of existing programs. These activities were divided into 3 core strategies: expansion of routine screening in healthcare settings, locally tailored HIV testing initiatives in nonhealthcare settings, and specific efforts to increase the frequency of testing for individuals with increased potential for acquiring HIV. Because HIV testing is such a crucial part of the core activities of the Centers for Disease Control and Prevention's HIV prevention programs, there are many examples of evidence-based programs and best practices for HIV testing in both clinical and nonclinical settings. This article reviews the evidence base for these strategies and some of the activities proposed under the Diagnose pillar to achieve the goal of diagnosing all HIV infections as early as possible. All other Ending the HIV Epidemic in the U.S. activities start with an awareness of HIV status, which is actually the indicator for which most health departments are closest to the proposed targets. There are both proven and emerging approaches to increasing HIV screening and increasing the frequency of HIV screening available. The Ending the HIV Epidemic in the U.S. initiative provides the motivation, the resources, and a coordinated plan to bring them to scale.

BACKGROUND

Since 2006, the Centers for Disease Control and Prevention (CDC) has recommended that adolescents and adults be screened for HIV infection in healthcare settings at least once in their lifetimes, as well as at least annual rescreening of individuals with increased potential for HIV acquisition.^{1,2} However, data from national surveys and HIV surveillance show that these recommendations have not been implemented fully.^{3–7} An important goal

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SUPPLEMENT NOTE

This article is part of a supplement entitled The Evidence Base for Initial Intervention Strategies for Ending the HIV Epidemic in the U.S., which is sponsored by the U.S. Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (HHS). The findings and conclusions in this article are those of the author(s) and do not necessarily represent the official position of CDC or HHS.

of the Ending the HIV Epidemic in the U.S. (EHE) initiative is the timely diagnosis of all people with HIV as early as possible after infection^{8,9}; yet, the promise of routine testing has not been realized. A CDC analysis in 2019 using data from the Behavioral Risk Factor Surveillance System⁵ assessed the percentage of adults tested for HIV in the U.S. nationwide, compared with the percentage in 50 counties and 7 states that are the focus of Phase 1 of the EHE initiative. This analysis validated that there is much work to be done to meet the 2006 recommendations because testing percentages were low overall and varied widely by jurisdiction, with rates of both ever and past-year testing being lowest in rural areas. A similar analysis of another nationally representative data source³ found that only 62.2% of persons who reported HIV-related behaviors in the past 12 months were ever tested for HIV, and the median interval since the last test in this group was 512 days (1.4 years). The local differences in observed HIV testing history suggest that to achieve national goals and end the HIV epidemic in the U.S., strategies to increase testing must be tailored to meet local needs.

This article provides a broad overview of the landscape of strategies that have been proposed by health departments (HDs) preparing to implement EHE. Other articles in this special supplement provide concrete examples of how these strategies are being implemented in specific jurisdictions. CDC has traditionally provided funding to HDs and directly to community-based organizations for HIV testing through a variety of cooperative agreements, which support both clinical and nonclinical HIV testing activities. A recent analysis¹⁰ found that from 2010 to 2017, tests directly funded by CDC accounted for roughly one third of all new HIV diagnoses annually. However, under EHE, CDC further emphasized the need to develop new and innovative HIV testing strategies as well as further expansion of the reach of existing HIV testing programs.^{8,9,11} The local jurisdictions have been encouraged to develop a mixture of testing options to make HIV testing both accessible and routine.

An HIV test is the first step to HIV medical care and treatment for those who receive a positive test result and provides a gateway to HIV prevention services such as pre-exposure prophylaxis (PrEP) for those who test negative but would benefit from PrEP. Thus, activities under the Diagnose pillar represent a jumping off point for other pillar activities. The Prevent, Treat, and Respond pillars are described in the introduction to this supplement.¹² Figure 1 is similar to the graphical representation of a status-neutral approach to HIV prevention,¹³ by which an individual's needs for prevention and care services are adequately addressed regardless of their HIV infection status. However, in the context of the EHE initiative, the figure highlights the way pillars (rather than individuals) are connected to create an integrated view of HIV prevention, care, treatment, and control. Strategies to expand access to HIV testing to anyone who needs it must incorporate tools to engage the next steps after an HIV test result is obtained. Figure 1 shows this by including not only prevention services to people who test negative but also integrating approaches to offer rescreening for HIV for individuals with increased potential for HIV acquisition. Likewise, a positive test result must be followed by linkage to HIV care and initiation of antiretroviral therapy, leading to viral suppression. For people with HIV who are not engaged in care, community testing strategies such as those implemented in East Baton Rouge Parish, Louisiana and described in this issue¹⁴ represent an opportunity to offer HIV

care re-engagement to achieve viral suppression. The integrated approach also includes the role HIV care providers have in offering HIV tests, PrEP, and other prevention services to their patient's sex or drug-using partners. A first positive test result is also a starting point for Respond pillar activities related to outbreak detection and cluster response¹⁵ because an investigation of clusters may identify a need for targeted testing strategies in communities with active HIV transmission.^{16–20} Better integration of activities related to the Diagnose pillar with the other pillars will be key to EHE.

The Ending the Epidemic CDC funding announcement¹¹ provided recommendations to HDs to develop locally relevant and tailored programs for all pillars. Because HIV testing is such a crucial part of the core activities of CDC's HIV prevention programs, there are many examples of evidence-based programs and best practices for HIV testing in both clinical and nonclinical settings. To end the HIV epidemic, HDs were encouraged to propose new and innovative HIV testing strategies and improve the reach of existing programs. These activities were divided into 3 core strategies: expansion of routine screening in institutional settings, locally tailored HIV testing initiatives in nonhealthcare settings, and specific efforts to increase the frequency of testing for people with ongoing potential for HIV acquisition.

STRATEGY 1: EXPAND OR IMPLEMENT ROUTINE OPT-OUT HIV SCREENING IN HEALTH CARE OR OTHER SETTINGS

Healthcare encounters provide critical opportunities to promote HIV screening. In addition to CDC's 2006 recommendations to screen all individuals at least once in healthcare settings,¹ in 2014 (updated in 2019), the U.S. Preventive Services Task Force recommended that clinicians screen for HIV infection in adolescents and adults aged 15–65 years.²¹ Younger adolescents and older adults who experience an increased potential for HIV acquisition should also be screened. This recommendation received a Grade A rating, which covers cost sharing for tests performed in clinical settings.

Although both CDC and U.S. Preventive Services Task Force recommendations provide strong incentives to promote routine screening in clinical settings, several reports have found lower than the desired uptake. In 2020, CDC analyzed HIV testing trends at visits to physicians' offices, community health centers (CHCs), and emergency departments during 2009–2017 and found that HIV screening occurred at <1% of visits to physicians' offices and in emergency departments and <3% at CHCs.⁶ These missed opportunities are critical to overcome if EHE goals are to be met.

Public health experts and health clinic professionals have identified several areas for improvement. Rizza et al.²² described several barriers, including competing clinical priorities, laws and regulations that support optin rather than opt-out testing, assumptions that behavioral risk–based screening is optimal, and third-party billing. Others^{23–25} have more recently suggested that coupling screenings for HIV with comprehensive care for other routine screenings, integrating screening into the normal clinical flow, being client driven, and using automated computer systems can greatly increase the uptake of healthcare screening.

To address these concerns, CDC and others are investing in systems and methods that can decrease the burden of screening on patients and clinicians, that make HIV testing less exceptional and stigmatized, and that increase uptake. A growing number of healthcare programs have explored the use of clinical decision support systems, which are computer-based information systems designed to help healthcare providers implement clinical guidelines at the point of care.²⁶ Clinical decision support systems can generate specific patient assessments and evidence-based treatment recommendations on the basis of patient data and use an electronic medical record or electronic health record system to populate this information and make it accessible to patient care providers.

The use of clinical decision support systems has been shown to increase HIV screening by using patient data to identify patients eligible for HIV screening and alert or remind their healthcare providers to order HIV tests.²⁷⁻³² There have been a variety of governmental efforts to expand these systems, by the CDC, the Health Resources and Services Administration (HRSA), and their public health partners. The Public Health Institute of Metropolitan Chicago partnered with 7 healthcare systems in Illinois to implement routine HIV screening during 2013–2015, using support from the HHS Secretary's Minority AIDS Initiative Fund's Care and Prevention in the United States (CAPUS) program, and led by CDC.²⁸ Public Health Institute of Metropolitan Chicago healthcare systems used this project to more fully implement routine HIV screening by integrating HIV screening orders and consent documentation into the electronic health record. The transformation of their systems led to a 46% increase in HIV tests performed during 2013–2016. CDC and the HRSA have also worked together to promote the provision of routine HIV screening in CHCs through Partnerships for Care (P4C), a program implemented during 2014–2017. P4C funded HDs and CHCs in jurisdictions funded by the HRSA's Bureau of Primary Health Care.³¹ For example, within the Massachusetts Department of Public Health (MDPH), the P4C program demonstrated the improvements that can be made not only to HIV screening but also to linkage to medical care by moving from earlier models wherein testing, linkage, and care coordination operate as stand-alone programs to models that integrate these into routine, primary care clinical services. P4C CHC providers in MDPH used electronic health record data to generate lists of out-of-care patients, which they then reviewed with MDPH surveillance epidemiologists to identify opportunities to link these patients back to care. The P4C system fostered stronger public health-CHC partnerships and significantly improved MDPH's capacity to link and re-engage people in HIV medical care.

There are also locally funded programs that have implemented improved systems for HIV screening. The Harris Health System in Houston, Texas implemented the Routine Universal Screening for HIV initiative in 2009 with funding from the Texas Department of State Health Services and the City of Houston.²⁹ They provided standing orders for HIV testing for any patient receiving a blood draw unless the patient refused. This system led to an immediate increase in the percentage of patients ever tested for HIV and tested in the past year. In 2016, 35.4% of the >200,000 unique patients in Houston's largest public safety-net healthcare system received an HIV test. Another example is the HIV on the Frontlines of Communities in the U.S. (FOCUS) program, launched in 2010 by Gilead Sciences, Inc. The goals of FOCUS are to facilitate electronic medical records modifications, data management, and continuous quality improvement to make HIV screening a routine practice

An EHE site in East Baton Rouge Parish, Louisiana provides another example.³⁰ HHS Minority HIV/AIDS funds were used to invest \$4.5 million in 3 jump-start sites to implement key foundational activities to accelerate progress toward EHE in their communities.^{12,30} Ochsner Medical Center in Baton Rouge used this opportunity to accelerate its opt-out HIV testing program in 2019; they and other hospitals in the area worked with electronic medical record providers to create a flag for testing so that triage nurses would be automatically notified when a patient is eligible (i.e., aged 13–64 years) to be tested. The program has been so successful that HIV screening is now a part of the day-to-day workflow.

In addition to traditional healthcare settings, there are other clinical settings into which HIV screening can and should be integrated. As part of the EHE initiative, CDC specifically recommended routine opt-out screening in jails. This recommendation is based on years of data^{33–38} showing that routine screening in these settings identifies previously undiagnosed infections and that routine screening at medical intake, in particular, can be effective at identifying undiagnosed HIV in individuals who otherwise may not access health care routinely. This strategy has been shown to be cost effective,^{38,39} and the cost per identified infection is actually lower than that in most other settings.^{40–43} CDC has developed guidance for developing HIV screening programs in correctional settings.⁴⁴ In this issue, Hutchinson and colleagues⁴⁵ provide an example of the impact of a jail screening program and not being able to maintain routine HIV screening in a jail in an EHE Phase 1 jurisdiction.

Likewise, better integration of HIV screening in sexually transmitted disease (STD) clinics is needed. CDC's HIV screening recommendations¹ specifically highlight STD clinics as a healthcare setting in which routine screening should be implemented. CDC's STD treatment guidelines also recommend that all individuals seeking evaluation or treatment for STDs be tested for HIV.⁴⁶ Among CDC-funded testing sites, STD clinics diagnose more new HIV infections annually than any other healthcare setting.^{47,48} A CDC study of HIV testing in a sample of the U.S. population⁴⁹ found that there are many missed opportunities for better integration of HIV and STD screening. Methods to better integrate HIV screening into STD clinic flow are needed and are specifically being piloted in the EHE jump-start sites.⁵⁰

STRATEGY 2: DEVELOP LOCALLY TAILORED HIV TESTING PROGRAMS TO REACH PEOPLE IN NONHEALTHCARE SETTINGS

HIV Self-Testing

Self-testing allows people to take an HIV test and find out their results in their own home or other private location. Although HIV self-tests are available for retail purchase by consumers, CDC encourages HDs to consider HIV self-testing as an additional testing

strategy to reach people most affected by HIV. There are 2 types of HIV self-tests: rapid self-tests and mail-in self-tests.

A rapid self-test is done entirely at home or in a private location and can produce results within 20 minutes. The CDC-funded evaluation of HIV Self-Testing Among Men who have sex with men Project (eSTAMP)⁵¹ was a national RCT designed to evaluate the public health benefits of mailing rapid self-tests to internet-recruited gay, bisexual, and other men who have sex with men (MSM) in the U.S., conducted during 2015-2016. Men who were mailed HIV self-tests tested themselves more frequently and identified significantly more prevalent HIV infections than men in the control arm. Importantly, the study did not find any increase in sexual behaviors with potential for HIV acquisition reported by participants who received HIV self-tests. Furthermore, the eSTAMP study allowed participants to share HIV self-tests with members of their social network, resulting in many more people becoming aware of their HIV infection. There are many examples of HD programs that have successfully distributed HIV self-tests.^{52–55} As part of CDC's HIV Capacity Building Assistance for Health Departments, the New York City Department of Health provided a description of their rapid self-test distribution programs and considerations for other HDs that want to set up similar programs.⁵⁶ A compendium of rapid self-test protocols collected from both HDs and community-based organizations is available from the Denver Prevention Training Centers,⁵⁷ and a summary of these protocols and lessons learned will soon be available on the CDC Capacity Building website.58

In addition to rapid home self-tests, there are many publicly available options for mail-in HIV self-tests. A mail-in self-test includes a specimen collection kit that contains supplies to collect dried blood from a fingerstick at home. The sample is then sent to a laboratory for testing, and the results are provided by a healthcare provider. Mail-in self-tests can be ordered through various online merchant sites. Healthcare providers can also order a mail-in self-test for their patients. One benefit of mail-in self-tests is the option to couple collection of samples for HIV and other STDs. Some laboratories have validated protocols for testing home-collected samples for the panel of tests required for those initiating or continuing PrEP. The National Coalition of STD directors has developed a series of webinars⁵⁹ covering a variety of issues related to HIV and STD testing of self-collected samples. In this issue, Fistonich et al.⁶⁰ describe the program GetCheckedDC, which includes both distributions of rapid HIV self-tests and mail-in sample collection kits for testing for gonorrhea and chlamydia.

HIV Testing in Retail Pharmacies

Rapid self-tests and commercially available mail-in self-tests for HIV can both be purchased at retail pharmacies. However, there are benefits to pharmacist-led testing in these settings, including the possibility for active linkage to HIV care. Another demonstration project from Virginia, funded under the CAPUS program during 2014–2016,⁶¹ showed that a public–private partnership between the HD and a retail pharmacy chain could effectively implement the offer of HIV screening in pharmacies, identifying individuals who had never previously tested and new HIV infections, and could through the HD collaboration provide successful linkage to HIV medical care. As with HIV self-testing, this project built on

previously funded CDC research piloting HIV screening in retail pharmacies,^{62,63} and CDC has developed training for HDs and community-based organizations seeking to partner with retail pharmacies to conduct HIV testing.⁶⁴

Mobile/Outreach Testing Strategies

Mobile/outreach testing has been a cornerstone of HIV prevention for decades. Since the approval of the first rapid HIV test for use outside a laboratory, CDC has sponsored a variety of demonstration projects that have shown the effectiveness of providing targeted outreach testing in numerous settings.^{65–69} Examples of nonclinical settings where HIV testing may be offered include but are not limited to community-based organizations, mobile testing units, churches, bathhouses, parks, shelters, syringe services programs, health-related storefronts, homes, and other social-service organizations. CDC has also developed and piloted interventions such as the social network strategy for recruiting peers who would benefit from HIV testing^{70,71} and has developed trainings for community-based organizations to implement this strategy.⁷² A specific, innovative use of a cohort of peer community health workers to conduct outreach and testing in community settings that was implemented as part of the EHE jump-start in East Baton Rouge Parrish, Louisiana¹⁴ is included in this issue. There are a wide variety of adaptations of these methods, and therefore, there is a need for more implementation science⁷³ to identify the best new strategies to increase testing in outreach settings.

STRATEGY 3: INCREASE AT LEAST YEARLY RESCREENING OF PEOPLE AT ELEVATED RISK FOR HIV PER CENTERS FOR DISEASE CONTROL AND PREVENTION TESTING GUIDELINES IN HEALTHCARE AND NONHEALTHCARE SETTINGS

Although CDC estimates that approximately 1.2 million people in the U.S. have indications for HIV PrEP.⁷⁴ estimates from the Behavioral Risk Factor Surveillance System indicate that there may be >12 million people with past-year risk for HIV and that only 34.2% of this group were tested in the past 12 months.^{4,5} CDC recommends that people who participate in activities that increase the possibility of HIV acquisition test at least annually, but another CDC analysis³ indicated that even among sexually active MSM, only 42% reported testing in the past year, and therefore, the mean time since the last test even among this group was >1 year. This is consistent with a systematic review examining studies from 2005 through 2014 that found that 63%–91% of MSM had ever tested for HIV, but only 39%–67% were being tested annually.⁷⁵ One strategy for increasing the frequency of testing is the provision of HIV self-tests. In the eSTAMP study,⁵¹ participants who were randomized to receive HIV self-tests by mail reported testing more frequently than control participants (mean number of tests over 12 months: 5.3 vs 1.5, p < 0.001). Other observational studies have shown that public health programs perceive benefits of strategies to encourage frequent retesting, particularly among MSM.75 In Seattle, observational data from programs that promote retesting on a regular schedule and through short message service reminders have been shown to increase the frequency of testing.^{76,77} In a recent randomized trial in Thailand,⁷⁸ the combination of both short message service text message reminders and scheduling of

the next HIV test at the time of a negative result was shown to maximize the frequency of rescreening. Evaluation of other modalities, including phone applications that provide reminders to rescreen, the ability to communicate HIV testing information in online profiles, and other methods of reminding people to rescreen for HIV, have shown promise.⁷⁹

The challenge for encouraging rescreening in healthcare settings is that most clinical decision support tools do not routinely collect information indicative of HIV risk, and many patients do not disclose this information to clinicians.⁸⁰ Likewise, in settings such as emergency departments where prevention is not the primary focus of the medical encounter, identifying and testing people engaging in behaviors with potential for HIV acquisition may not be top of mind for either the clinician or the patient. The impact of clinical decision support tools, including a supplemental electronic collection of behavioral risk⁸¹ that can initiate HIV rescreening for individuals who have not been tested in the past year, is another area of active implementation science research that deserves more attention.⁷³

MEASURING IMPACT OF TESTING PROGRAMS

As with other EHE pillars, the indicators used to measure national progress on the Diagnose pillar^{82,83} are derived from data reported to the National HIV Surveillance System and reported quarterly on America's HIV Epidemic Analysis Dashboard.⁸⁴ The most proximal of the 6 EHE indicators for the Diagnose pillar is knowledge of HIV status, which is estimated from the National HIV Surveillance System data as the percentage of people with HIV who have received a diagnosis. The 2025 and 2030 targets for this indicator are for 95% of people with HIV to know that they are infected. Similarly, the Healthy People 2030 HIV objectives and targets⁸⁵ are aligned with indicators in the EHE initiative; Target 02 is to increase the proportion of people who know their HIV status to 95% by 2030. Baseline data for EHE as presented for 2017 and 2018 indicate that the knowledge of status varied between 71.1% in Nevada and 93.2% in the District of Columbia before the start of the EHE initiative. However, as with other EHE indicators, disparities exist by race and age, with a lower proportion of Black and Hispanic individuals being aware of their infection, particularly in the youngest age groups. As the EHE initiative gains momentum, new diagnoses will decrease,⁸⁶ and other measures such as PrEP prescriptions and total tests performed may be more important measures of progress. CDC is working with national data vendors and state and local HDs to evaluate other process measures for the Diagnose pillar⁸⁶ (e.g., the estimated time from infection to diagnosis⁸⁷ and laboratory testing volumes⁸⁸).

COVID-19 AND BEYOND

Plans for the first year of implementation of the EHE initiative were disrupted by the coronavirus disease 2019 (COVID-19) pandemic. Many states and localities issued shelterin-place or stay-at-home orders to reduce the spread of COVID-19, limiting movement outside the home to essential activities. Social distancing also led to disruptions of routine healthcare and nonclinical services such as community-based HIV testing. However, this public health crisis has catalyzed the rapid implementation of new strategies for HIV testing, particularly the distribution of HIV rapid self-tests and mail-in HIV home sample collection kits. In this issue, Fistonich and colleagues⁶⁰ describe how they stood up the

GetTestedDC program with great success in the middle of the pandemic. Other models,⁵⁷ such as the combined offer of HIV and COVID-19 testing at drive-through test sites, and online counselor-led HIV self-testing have shown promise. Hammack et al.¹⁴ describe how they adapted their novel outreach model during the pandemic, including information about options for COVID-19 testing, in a way that makes the entire encounter with the community health workers less about HIV and more about health, a strategy that may reduce the stigma

associated with HIV testing. Leveraging the lessons learned from the COVID-19 pandemic to improve access to and uptake of HIV testing is an opportunity. Models that have grown out of necessity during the pandemic should be further evaluated for their impact on efforts to end the HIV epidemic in the U.S. after the COVID-19 pandemic.

CONCLUSIONS

Ending the HIV epidemic in the U.S. by 2030 is an ambitious goal. The COVID-19 pandemic has slowed initial progress but has also taught valuable lessons about both disparities in access to health care and public health services. All other EHE activities start with an awareness of HIV status, which is the EHE indicator for which the U.S. is closest to its targets. There are proven and emerging approaches to both increasing HIV screening and increasing the frequency of HIV screening available. The EHE initiative provides the motivation, the resources, and a coordinated plan to bring them to scale.

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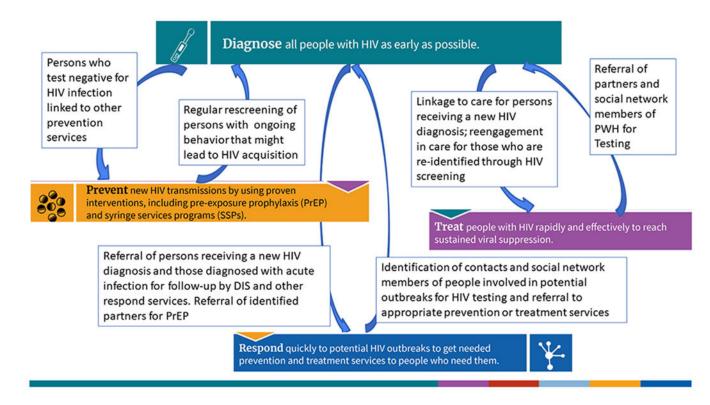


Figure 1.

The integration of the 4 pillars of the initiative to End the HIV Epidemic in the U.S. DIS, Disease Intervention Specialist; PrEP, pre-exposure prophylaxis; PWH, People with HIV; SSP, syringe services program.