Background and Definitions

History of HIV Testing in United States

In 1985, the United States Food and Drug Administration (FDA) licensed the first HIV antibody test for detection of HIV.[1] Two years later, in 1987, the United States Public Health Service issued recommendations for HIV testing of individuals with a high risk of acquiring HIV, mainly persons with a history of sexually transmitted diseases and those who inject drugs; the 1987 recommendations included information regarding counseling, consent, and confidentiality.[2] The 1987 recommendations were broadened in 1993 to include HIV testing of hospitalized patients and persons seen in acute care and emergency room settings.[3] Based on data showing antiretroviral therapy given to pregnant women with HIV infection markedly reduced perinatal HIV transmission, the CDC expanded HIV testing guidelines in 2001 and recommended routine HIV testing of pregnant women.[4] In 2003, the CDC shifted from high-risk HIV testing to a new strategy of making HIV testing a routine part of medical care.[5] The 2003 recommendations served as a transition to the 2006 CDC recommendations to perform routine HIV screening for all persons 13-64 years of age in all health care settings.[6] Despite the 2006 recommendations, the CDC estimates that during 2006-2016 only 39.6% of noninstitutionalized adults in the United States had ever tested for HIV.[7]

Definitions

The CDC has generated definitions related to HIV screening and testing.[6] These definitions are listed as follows:

- **Diagnostic Testing**: Performing an HIV test for persons with clinical signs or symptoms consistent with HIV infection.
- **Screening**: Performing an HIV test for persons in a defined population.
- **Targeted Testing**: Performing an HIV test for subpopulations of persons at higher risk, typically defined on the basis of behavioral, clinical, or demographic characteristics.
- **Informed Consent**: A process of communication between patient and provider through which an informed patient can choose whether to undergo HIV testing or decline to do so. Elements of informed consent typically include providing oral or written information regarding HIV, the risks and benefits of testing, the implications of HIV test results, how test results will be communicated, and the opportunity to ask questions.
- **Opt-out Screening**: Performing HIV screening after notifying the patient the test will be performed and providing the patient the opportunity to decline or defer testing. Assent is inferred unless the patient declines testing.
- **HIV Prevention Counseling**: An interactive process of assessing risk, recognizing specific behaviors that increase the risk for acquiring or transmitting HIV, and developing a plan to
Goals of Routine Screening

Identifying persons with HIV infection is the first step in the HIV care cascade. The primary desired outcomes associated with routine HIV screening are two-fold: (1) improve survival and quality of life for the person living with HIV infection, and (2) prevent new HIV infections (Figure 1). Persons who have not been diagnosed with HIV infection will not obtain the benefits from modern HIV clinical care.
Rationale for Routine HIV Screening

Persistent Undiagnosed Fraction

Despite improvements in HIV screening rates and remarkable advances in HIV treatment, an estimated 14.5% of persons living with HIV infection in the United States have undiagnosed HIV infection.\[8,9\] In addition, among persons newly diagnosed with HIV infection, 21% have stage 3 disease (CD4 count less than 200 cells/mm\(^3\), a CD4 cell percentage of less than 14%, or a clinical AIDS-defining condition); only 25% of persons newly diagnosed with HIV infection had stage 1 disease (CD4 count greater than 500 cells/mm\(^3\)) (Figure 2).\[10\] Earlier data from the CDC estimated that 33% of patients newly diagnosed with HIV developed AIDS within 12 months of their HIV diagnosis.\[11,12\] Most patients diagnosed with stage 3 HIV disease at the time of first diagnosis have been living with HIV infection for many years; this delayed diagnosis represents a missed opportunity for receiving antiretroviral therapy that would have reduced their HIV-related morbidity and lowered their risk of transmitting HIV to others.\[13,14,15\]

Undiagnosed HIV and Disproportionate HIV Transmission

Investigators from the CDC have utilized the Progression and Transmission of HIV (PATH 2.0) model to estimate 2016 HIV transmissions and HIV transmission rates among persons living with HIV in the United States, including stratification based on awareness of HIV infection.\[9\] For 2016, the estimated overall transmission rate for all persons living with HIV was 3.5 per 100 person-years, but among those living with HIV who were unaware of their HIV diagnosis the rates were markedly higher—16.1 per 100 person-years for those with acute undiagnosed HIV, and 8.4 per 100 person-years in those with undiagnosed chronic HIV infection.\[9\] Using the CDC PATH 2.0 model, the CDC estimated that the 14.5% of persons living with HIV who were unaware of their HIV infection in 2016 accounted for 37.5% of all HIV transmissions in the United States (Figure 4).\[9\] Prior models have also shown that persons living with HIV who are unaware of their HIV diagnosis have a markedly higher HIV transmission rate when compared with those who are aware of their HIV diagnosis.\[16,17\]

Reduced HIV Transmission with Antiretroviral Therapy

In the HPTN 052 Study, 1,763 HIV serodifferent couples (97% heterosexual) were followed and early initiation of antiretroviral therapy reduced the number of HIV transmissions by 93%, thus demonstrating the profound impact that antiretroviral therapy can have on HIV transmission.\[14,18\] The European PARTNER study evaluated the risk of HIV transmission in serodifferent couples who had sexual activity without condoms; the study enrolled 880 heterosexual couples and 340 same-sex male couples.\[19\] In these couples, the partner with HIV infection was using suppressive antiretroviral therapy: no documented cases of HIV transmission between couples occurred despite 36,000 condomless sex acts in heterosexual couples and 22,000 in men who have sex with men couples.\[19\] All available data now strongly suggest that persons who achieve and maintain undetectable plasma HIV RNA levels do not sexually transmit HIV to others.\[20\]


CDC HIV Screening Recommendations

Routine HIV Screening Recommendations

In 2006, the Centers for Disease Control and Prevention issued a recommendation to perform routine HIV screening for all persons 13-64 years of age in all health care settings in the United States. In addition, screening for HIV was recommended for all patients seeking treatment for sexually transmitted diseases and for all patients initiating treatment for tuberculosis. These 2006 recommendations also addressed indications for repeat HIV screening, consent and pretest information, indications for diagnostic tests, and screening of pregnant women. The CDC HIV screening recommendations have been endorsed by numerous prominent national organizations.

Indications for Repeat Screening

The 2006 CDC recommendations state that repeat HIV testing should be performed at least once a year for persons considered at high risk for acquiring HIV. The following groups are considered at high risk: (1) persons who inject drugs and their sex partners, (2) persons who exchange sex for money or drugs, (3) sex partners of persons with HIV infection, and (4) persons or their partners who have had more than one sex partner since their most recent HIV test. In 2017, the CDC addressed the frequency for repeat HIV screening in men who have sex with men (MSM) and concluded no change was warranted in the 2006 recommendations. These 2017 recommendations note that clinicians can consider the benefits of offering more frequent screening (e.g. once every 3 or 6 months) for MSM at increased risk for acquiring HIV infection.

Multiple guidelines recommend that all persons taking HIV preexposure prophylaxis (PrEP) medications should have HIV testing every 3 months, unless they acquire HIV.

Consent and Pretest Information

The person ordering the HIV test should inform the patient orally or in writing that HIV testing will be performed. The HIV testing process must be considered voluntary and the patient must have an option to decline HIV testing. This process is referred to as “opt-out” screening. Separate written consent for HIV testing should not be required, since the general consent for medical care is considered sufficient to encompass consent for HIV testing. As part of the screening process, prevention counseling should not be required, but should be encouraged, especially with persons who engage in behaviors that place them at risk of acquiring HIV. The state laws regarding consent supersede the CDC recommendations. All states now have HIV testing laws that are consistent with CDC recommendations for consent (e.g. opt-out testing, part of the general medical consent form, and oral consent acceptable) and counseling (e.g. prevention counseling not required prior to HIV testing). Studies have shown that requirements for written consent serve as a barrier to HIV testing and that eliminating the requirement for written consent facilitated HIV testing.

Indications for Diagnostic Testing

Patients should undergo diagnostic HIV testing if they have clinical signs or symptoms consistent with chronic HIV infection, have an opportunistic illness characteristic of AIDS, have engaged in recent high-risk behaviors, or have a clinical illness consistent with acute HIV infection. Individuals suspected to have acute HIV infection require laboratory evaluation for acute HIV.

Screening Pregnant Women

The prevention of mother-to-child transmission of HIV is predicated on knowing the pregnant woman’s HIV status so that women with HIV infection can receive antiretroviral therapy during pregnancy and protocols for both mother and child can be implemented at delivery and postpartum. With all of these interventions, the rate of perinatal HIV transmission is less than 1% in the United States.
States. In the 2006 HIV Screening Guidelines, the CDC recommends universal opt-out HIV screening for pregnant women, with HIV testing performed as early as possible in the pregnancy. In some circumstances, such as possible exposure to HIV during pregnancy, the test should be repeated in the third trimester. If a woman presents in labor and has undocumented HIV status, a rapid HIV test should be performed. If a pregnant woman declines HIV testing, the medical provider should discuss and address the reasons for declining the test.

**Communicating Test Results**

The CDC 2006 document on HIV testing recommends establishing definitive mechanisms to inform patients of their test results.[6]

- **Negative HIV Test Result**: Informing persons of negative HIV test results can be conducted without direct personal contact between the health care provider and the patient. In this situation, persons who test negative for HIV, but are considered to have high risk for HIV acquisition, should be advised to get periodic retesting and ideally they would receive prevention counseling or have a referral for prevention counseling.

- **Positive HIV Test Result**: If the person tests positive for HIV, the positive test results should be communicated confidentially via personal contact from a physician, advanced nurse practitioner, physician assistant, nurse, counselor, or other skilled staff. Part of the process of providing a positive HIV test result is to ensure the newly diagnosed individual is linked to clinical care, counseling, support, and prevention services.

The recommendations regarding communicating test results, which were issued in 2006, did not take into account the current medical environment where many individuals have immediate access to their test results via the electronic medical record. If the person undergoing HIV testing will have access to the test results through the electronic medical record, the medical provider should discuss a plan in advance and always should ensure that direct personal contact occurs for positive HIV test results, even if the patient has already gained access to the test result information.
USPSTF HIV Screening Recommendations

Screening Recommendations

In 2005, the U.S. Preventive Services Task Force (USPSTF) issued recommendations that did not support routine HIV screening, based on the premise that evidence was insufficient (Grade C Recommendation).[33,34] In 2013, based on an updated review of available data[35], the USPSTF issued revised recommendations that support routine HIV screening, specifically stating that clinicians should screen all adults aged 15 to 65 years for HIV infection (Grade A Recommendation).[36] The USPSTF recommends that screening should also be performed for adolescents younger than 15 years of age and persons older than 65, if they have increased risk for acquiring HIV, such as having new sexual partners.[36] The 2013 USPSTF recommendation in support of routine HIV testing has substantial implications for how HIV testing is reimbursed.[37,38]

Screening for HIV in Pregnancy

The 2013 USPSTF recommendations state that all women should be screened for HIV during pregnancy, including women who present in labor and have not previously had testing during the current pregnancy (Grade A Recommendation).[35,36] In addition, HIV screening should occur with each pregnancy (Grade A Recommendation).[36,39]

Screening Intervals

The 2013 USPSTF guidelines suggest repeated screening for those known to be at risk for HIV, persons engaged in risky behaviors, and those who live or receive medical care in an area with an HIV seroprevalence greater than 1%. They suggest a reasonable approach would be to screen those at very high risk at least once a year and those at increased risk every 3 to 5 years.[35,36]
Potential Barriers to Routine Screening

Barriers to Screening

To maximize benefits of early HIV detection, it is important to understand potential barriers to HIV screening. The 1998 National Health Interview Survey (N = 21,408) explored possible barriers to HIV testing and found that the main reason people did not get tested was that they did not perceive themselves to be at risk.[40] Subsequent studies have identified other barriers to testing, which can be broadly categorized as factors influenced by individual concern, by policies and laws, financial, and by counseling and testing strategies.[41] A separate but related challenge to expanding HIV screening is identifying and addressing barriers to screening among clinicians.

Individual Concern (Fear and Discrimination)

Individuals may avoid HIV testing because they are afraid of the result, they are fearful of how others in their lives (friends, family, partners) may react, or because of a lack of knowledge that HIV is a treatable disease. Education about HIV and its treatment can be helpful in alleviating fear. Couples HIV testing is an option for partners who might find it more acceptable to find out their HIV status at the same time. In some settings, such as in the prenatal and hospital setting, patient acceptance rates for HIV testing are greater than 90%.[43]

Legal Barriers

Studies have identified name-based HIV reporting and HIV criminalization as additional barriers to HIV testing. The CDC maintains an extensive list of state criminal law policies on HIV and sexually transmitted diseases.[44] As of November 30, 2018, there were 26 states with laws that criminalize HIV exposure.[44] Most of the HIV criminalization laws impose penalties on persons living with HIV who are aware of their HIV diagnosis and engage in sexual activity with another person without prior disclosure of their HIV status.[44,45] These laws have generated intense public debate, especially since most were passed prior to the publication of multiple scientific studies that have shown persons with HIV who are taking antiretroviral therapy (and have consistently suppressed HIV RNA levels) do not transmit HIV sexually to others.[19,20,46] Further, HIV criminalization policies may reduce the frequency of HIV testing since knowledge of HIV status is required for culpability.

Financial Barriers

Offering free testing may improve screening rates, and educating potential testers about antiretroviral treatment coverage through insurance programs or through the state-based AIDS Drug Assistance Program (ADAP) may encourage them to test. Multiple studies have shown that HIV screening is cost effective.[47,48,49]

Counseling and Testing Procedures

In one study of individuals with high risk for HIV infection at an STD clinic, a needle exchange, and three sex venues for men who have sex with men, participants reported a dislike of counseling, anxiety waiting for results, and venipuncture as reasons to avoid HIV testing.[41] Rapid testing platforms, alternative testing methods, such as oral fluid HIV testing, and the elimination of required written consent and pretest counseling may alleviate some of these concerns.[27,28,29] One study performed in San Francisco showed that elimination of the requirement for written consent resulted in significant and sustained increases in HIV testing rates.[29] Home-based testing kits, which do not require counseling, are also now available, though this method of testing has thus far had minimal impact on testing behavior of persons at high risk for HIV infection; this may be due to lack of awareness of home testing kits as well as to concerns about the cost of the kits and home testing procedures.[41,50]
Barriers to HIV Testing Among Clinicians

Hesitation among physicians to test for HIV is responsible for at least some of the failure to expand HIV testing despite CDC guidelines. A comprehensive review of the literature in 2007 found that policy-level barriers, logistical barriers, and educational barriers were encountered across multiple practice settings (prenatal, emergency department, other medical settings).[51] The need to provide counseling and obtain written consent at the time of HIV screening may serve as a major barrier for busy clinicians, but the 2006 CDC testing recommendations specify that counseling should not be a prerequisite to HIV screening, and written consent should not be required.[6] All 50 states now have had laws that are consistent with the 2006 CDC HIV testing recommendations regarding consent and pretest counseling.[26] Logistical barriers to implementing routine HIV testing by clinicians included insufficient time to discuss the HIV testing process, competing priorities, and language barriers. Educational barriers included lack of medical provider knowledge and training about HIV testing.[52,53]
Partner Services

Overview of Partner Services

Partner services as defined by the Centers for Disease Control (CDC) are a broad array of services that should be offered to individuals with HIV infection and to their partners.[54, 55] Partner notification (also known as contact tracing) is the central activity of partner services, and it is a process whereby the sex and/or drug injection partners of an index case (a person newly diagnosed with HIV) are informed of their exposure to infection and referred for counseling and testing. Other important partner services include prevention counseling, testing for other types of sexually transmitted infections, hepatitis screening and vaccination, timely linkage to medical care for persons newly diagnosed with HIV, and referral and linkage to other services, such as treatment for substance use disorders, housing support, or prenatal services. Partner services must be confidential, free of cost, voluntary, and comprehensive; in addition, even individuals who choose anonymous HIV testing should be offered partner services without being required to disclose their identity. Individuals who test positive for HIV anonymously should be encouraged to transfer to a confidential system to facilitate partner services, but this is not required.

Goals of Partner Services

The CDC notes that HIV partner services has three goals:[56]

1. Provide services to persons diagnosed with HIV, including counseling for risk-reduction, linking them to HIV medical care, and generating referrals to other services the individual may need.
2. Ensure that partners of the person diagnosed with HIV, including sex partners and drug injection partners, are notified of their exposure to a person with HIV infection and assist them with HIV testing and counseling. Any of these partners who test positive for HIV should receive assistance linking them to HIV medical care.
3. Reduce transmission of HIV, both by helping the newly diagnosed person to receive HIV clinical care and to identify partners with HIV and thus make an early diagnosis.

Benefits of Partner Services

Partner services benefit individuals diagnosed with HIV, their partners, and the community as a whole. Individuals who are identified to have HIV infection can be linked to medical care that can ultimately improve their quality of life and their survival. Partners of individuals with HIV infection can learn of their risk of HIV exposure and access testing, treatment, and preventative services. At the community level, partner services can improve disease surveillance and improve targeted screening programs, with the ultimate goal of decreasing community HIV transmission and incidence rates.

Challenges of Partner Services

Key challenges in the implementation of partner services include acceptability to individuals newly diagnosed with HIV as well as concerns about potential harms associated with partner notification, specifically emotional or physical abuse or relationship dissolution. Studies have shown a high level of acceptability among persons with HIV infection and their partners, and fortunately have demonstrated no evidence of harm from contact tracing. Nonetheless, health departments across the United States vary widely in the extent to which they provide partner services, which may be due to ongoing legal and ethical concerns such as confidentiality, criminalization of HIV transmission in some states, state-based statutes regarding duty or privilege to warn, and financial constraints.

Efficacy of Partner Services
Partners of an index patient can be notified through patient referral or provider referral; systematic reviews have concluded that provider referral is more effective than patient referral for ensuring the notification of the sexual partners of individuals diagnosed with HIV infection.[57] An early randomized study in North Carolina found that patient referral was very ineffective, with only 7% of contacts in the patient-referral arm receiving notification of HIV exposure.[58] Not only is provider referral more effective, it is also more cost-effective.
Summary Points

- Increased HIV screening is essential in identifying persons living with HIV infection so they can receive antiretroviral therapy and thereby garner health benefits and reduce the forward transmission of HIV.
- Individuals living with HIV who are unaware of their infection are significantly more likely to transmit HIV than persons living with HIV who are aware of their HIV infection.
- Multiple studies have shown the profound impact of antiretroviral therapy on reducing sexual transmission of HIV. Persons who achieve and maintain undetectable plasma HIV RNA levels do not sexually transmit HIV to others.
- In 2006, the Centers for Disease Control and Prevention issued recommendations for routine HIV screening, and these recommendations are widely endorsed by prominent national organizations.
- The 2006 CDC recommendations also include indications for repeat HIV screening, diagnostic testing, and prenatal testing with each pregnancy.
- Multiple barriers exist for routine HIV screening, including a lack of perception of risk, concerns about social and employment discrimination, concerns about confidentiality, potential legal/criminal ramifications, and dislike of HIV testing procedures.
- Impediments to HIV screening also exist among clinicians and include policy, logistical, and educational barriers.
- Partner notification (also called contact tracing) is the central activity of partner services and is the process whereby the sexual and drug injection partners of an index case are informed of their exposure to HIV and are referred for counseling and testing.
- The aim of partner services is to maximize HIV awareness, improve linkage to care among individuals newly diagnosed with HIV infection, increase disease surveillance, and ultimately decrease HIV incidence rates in the community.
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References


**Figures**

**Figure 1 Goals of Routine HIV Screening**

Identifying HIV infections in persons living with HIV has the two-fold benefit of providing treatment for the person infected and reducing transmission of HIV to others by awareness of HIV status and receipt of antiretroviral therapy.
Figure 2 Stage of Disease at Time of HIV Diagnosis

This graphic shows 2016 CDC data from 39 states and the District of Columbia for new HIV diagnoses. Stage 1 corresponds to CD4 count greater than 500 cells/mm$^3$. Stage 2 equals CD4 count of 200-499 cells/mm$^3$. Stage 3 (AIDS) indicates CD4 count less than 200 cells/mm$^3$, CD4 percentage less than 14, or an AIDS-defining clinical condition.

**Figure 3 Reduction (%) in Unprotected Anal or Vaginal Intercourse (UAV) with Known HIV Diagnosis**

This bar graph shows the reduction in percent of unprotected anal or vaginal intercourse (UAV) based on a model for both adjusted and unadjusted data. The adjusted data was analyzed only for UAV with partners who were not infected with HIV.

**Figure 4 HIV Transmissions in the United States in 2016 Based on Awareness of HIV Infection**

In this Progression and Transmission of HIV (PATH 2.0) model, investigators from the CDC estimated HIV transmissions and transmission rates in the United States in 2016, including stratification based on awareness of HIV infection. As shown, persons unaware of their HIV infection account for a disproportionate percentage of HIV transmissions.