HIV Screening Recommendations

This is a PDF version of the following document:
Module 1: Screening and Diagnosis
Lesson 2: HIV Screening Recommendations

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Background and Definitions

History of HIV Testing in the United States

In 1985, the United States Food and Drug Administration (FDA) licensed the first HIV antibody test for detection of HIV (Figure 1).[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 infections and those who inject drugs; the 1987 recommendations included information regarding counseling, consent, and confidentiality.[2] The 1987 HIV testing recommendations were broadened in 1993 to include HIV testing of hospitalized patients, persons seen in acute care, and persons in emergency room settings.[3] Based on data that emerged showing antiretroviral therapy given to pregnant women with HIV markedly reduced perinatal HIV transmission, the CDC expanded HIV testing guidelines in 2001 and recommended routine HIV testing of all pregnant people.[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 through 64 years of age in all health care settings.[6] Despite the 2006 recommendations, the CDC estimates that from 2006 through 2016 only 39.6% of noninstitutionalized adults in the United States had ever undergone a test for HIV.[7]

Definitions

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

- **HIV Screening**: Performing an HIV test for persons in a defined population.
- **HIV Diagnostic Testing**: Performing an HIV test for persons with clinical signs or symptoms consistent with HIV.
- **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 take specific steps to reduce risks.

Goals of Routine Screening

Identifying persons with HIV is the first step in the HIV care continuum. The primary desired outcomes associated with routine HIV screening are two-fold: (1) improve survival and quality of life for the person with HIV, and (2) prevent the person with HIV from transmitting HIV to others (Figure 2). Persons who have acquired HIV, but have not yet been diagnosed, cannot obtain the benefits of modern antiretroviral therapy while they remain undiagnosed.

Rationale for Routine HIV Screening

Persistent Undiagnosed Fraction

Despite improvements in HIV screening rates and remarkable advances in HIV treatment, in 2019, an estimated 13.3% of persons with HIV in the United States had undiagnosed HIV.[8] In addition, among persons newly diagnosed with HIV during 2020 in the United States, 21.5% had stage 3 (AIDS) as defined by a CD4 count less than 200 cells/mm^3, a CD4 cell percentage of less than 14%, or a clinical AIDS-defining condition (Figure 3).[9] Most individuals who have stage 3 HIV disease at the time of first HIV diagnosis have been living with HIV 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.[10,11,12]

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 with HIV in the United States, including stratification based on awareness of HIV status.[13] For 2016, the estimated overall transmission rate for all persons with HIV was 3.5 per 100 person-years, but among those 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.[13] Using the CDC PATH 2.0 model, the CDC estimated that the 14.5% of persons with HIV in 2016 who were unaware of their HIV status accounted for 37.5% of all HIV transmissions in the United States during that year (Figure 4).[13] Prior models have also shown that persons 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.[14,15]

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.[11,16] In the second phase of the European PARTNER, which focused on enrollment of serodifferent, same-sex male couples who had sexual activity without condoms, 972 couples had condomless anal sex a total of 76,088 times, and there were zero phylogenetically-linked HIV transmissions.[17] All available data now strongly suggest that persons who achieve and maintain undetectable plasma HIV RNA levels do not sexually transmit HIV to others— the concept of Undetectable equals Untransmittable or “U=U”.[18]

CDC HIV Screening Recommendations

Overview of Routine HIV Screening Recommendations

In 2006, the Centers for Disease Control and Prevention issued a recommendation to perform routine HIV screening for all adults and adolescents in all health care settings in the United States.[6] These 2006 recommendations also addressed indications for repeat HIV screening, consent and pretest information, indications for diagnostic tests, and screening of pregnant people.[6] The CDC HIV screening recommendations have been endorsed by numerous prominent national organizations nada have led to a fundamental shift from risk-based screening to universal HIV screening. Further, the recommendation to not require formal written consent for HIV testing facilitated the implementation of HIV testing in busy clinical settings. Studies have shown that requirements for written consent serve as a barrier to HIV testing and that eliminating the requirement for written consent facilitates HIV testing.[19,20,21] The following summarizes the key aspects of these 2006 CDC HIV screening recommendations.[6]

Screening for HIV infection

Routine screening for HIV infection should be performed for the following groups:

- All persons 13-64 years of age and in all health care settings
- All persons diagnosed with tuberculosis.
- All persons seeking treatment for sexually transmitted infections, including all persons attending sexual health clinics.

Repeat Screening

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 for acquiring HIV:

- Persons who inject drugs and their sex partners,
- Persons who exchange sex for money or drugs,
- Sex partners of persons with HIV,
- Persons or their partners who have had more than one sex partner since their most recent HIV test

Note: In 2017, the CDC addressed the frequency of repeated HIV screening in men who have sex with men (MSM) and concluded no change was warranted in the 2006 recommendations.[22,23] 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.[23] Multiple guidelines recommend that all persons taking HIV preexposure prophylaxis (PrEP) medications should have HIV testing every 3 months, unless they acquire HIV.[23,24,25]

Consent and Pretest Information

The following summarizes recommendations regarding the consent and counseling related to pretest information:

- The HIV screening process should be voluntary.
- Persons undergoing HIV testing should be informed that HIV testing will be performed unless they decline (opt-out screening).
- 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.

Note: 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).[26]

Diagnostic Testing for HIV infection

Diagnostic HIV testing should be performed if a person has any of the following:

- Clinical signs or symptoms consistent with chronic HIV, an opportunistic illness characteristic of AIDS
- A clinical syndrome that suggests acute HIV in a person with recent sex or injection drug activity that would increase their risk for acquiring HIV

Note: Diagnostic testing for acute HIV requires laboratory-based testing that includes a plasma HIV RNA test.[27,28]

Screening Pregnant People

The prevention of perinatal transmission of HIV is predicated on knowing the pregnant individual's HIV status so that persons identified with HIV can receive antiretroviral therapy during pregnancy, and protocols for both mother and child can be implemented at delivery and postpartum. The following summarizes key aspects of the 2006 CDC HIV screening and testing recommendations for pregnant people.[6]

- Opt-out HIV screening is recommended for all pregnant people, with HIV testing performed as early as possible in the pregnancy.
- If a pregnant persons declines HIV testing, the medical provider should discuss and address the reasons for declining the test.
- In some circumstances, such as with pregnant individuals who have possible exposure to HIV during pregnancy, the test should be repeated in the third trimester, preferably prior to week 36 gestation.
- If an individual presents in labor and has undocumented HIV status, an expedited HIV test should be performed, unless they decline HIV testing.

Note: The preferred expedited test is an HIV-1/2 antigen-antibody immunoassay.[29] All facilities with a maternity service and/or neonatal intensive care unit should have expedited HIV testing available on a 24-hour basis.[29] If the initial expedited HIV test is positive, then a follow-up HIV-1/2 differentiation immunoassay should be performed.[29]

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 a high risk for HIV acquisition, should be advised to get periodic retesting, and ideally, they should 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 member. 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.

Note: The CDC 2006 recommendations regarding communicating test results do not take into account the current medical environment where many individuals have immediate access to their test results via the