

New Testing Guideline Recommendations for HIV

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Summary

New guidelines have been published by the Centers for Disease Control (CDC) that recommend more extensive population screening for human immunodeficiency virus (HIV) infection. The major changes in the testing recommendations include testing a wider range of people, using an opt-out method for consent rather than opt-in, and eliminating the need for an HIV-specific consent for testing. There are significant cost implications to expanded testing which will identify more cases at an earlier point in the disease process.

Key Points

- Awareness of HIV infection decreases viral transmission
- Early detection and treatment of HIV infection is associated with decreased morbidity and mortality
- Routine, voluntary HIV testing is needed and cost-effective, even at an HIV prevalence as low as 0.1percent
- Rapid HIV tests have significantly improved the feasibility of testing in different care settings with quick turnaround time for test results
- Providers must carefully consider the laws and regulations related to HIV testing, confidentiality, and the principles of informed consent that might limit the implementation of these recommendations

HIV REMAINS A LEADING CAUSE OF ILLNESS and death in the United States. As of 2004, 944,306 persons have received a diagnosis of acquired immunodeficiency syndrome (AIDS) and more than half a million have died (Exhibit 1).¹ During the past 20 years, the overall prevalence of persons living with HIV/AIDS has steadily increased.¹ This is partly attributed to the advent of modern antiretroviral regimens that have dramatically reduced the death rate from AIDS. However, the fact that prevalence is steadily increasing also can be attributed to a relative lack of success at preventing transmission.

Since 1998, the estimated number of new HIV infections has remained stable at approximately 40,000 a year. It is important to note that since 1994 the annual number of cases among blacks, members of other racial/ethnic minorities, women, and persons exposed through heterosexual contact has increased.

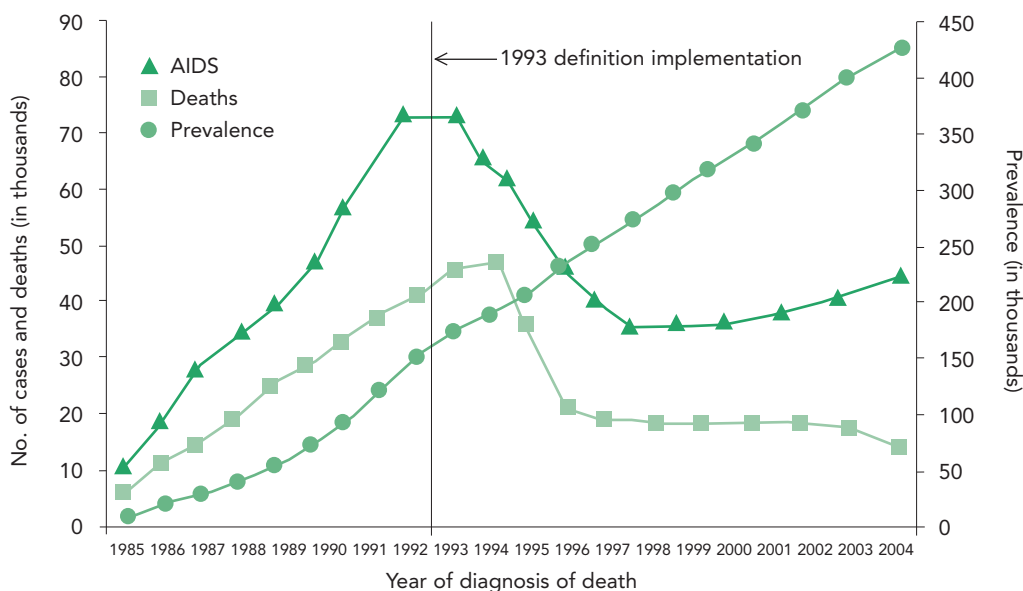
Revised HIV testing guidelines were published in September 2006. The revisions took into consideration the advice of a panel of physicians, many of

them emergency medicine physicians, to simplify the process of HIV testing. Previously, there were too many barriers to getting HIV testing done and notifying patients of their results. These recommendations also took into consideration an extensive review of the literature and demonstration projects from across the United States.

The CDC noted several pieces of evidence for revising and expanding the testing recommendations.² Many HIV-infected persons access health care but are not tested for HIV until symptomatic. From data over the years, routine HIV screening is easy to do, reliable, and cost effective. Additionally, effective treatment is available. Data also have shown that automatically offering testing and allowing people to choose to not be screened (opt-out method) increases testing rates compared with allowing people to seek testing (opt-in method). Lastly, HIV awareness has proved to be a significant factor in decreasing transmission.

The CDC estimates that more than a million people are infected with HIV in the United States.²

Exhibit 1: Estimated Number of AIDS Cases, Deaths, and Persons Living with AIDS, 1985-2004, United States



US Center for Disease Control and Prevention
 Note: Data adjusted for reporting delays.

Twenty-five percent of these people are unaware that they are HIV-infected. It is estimated that 54 to 75 percent of the new cases that are documented every year in the U.S. are transmitted by people who are unaware of their infection.³ Thirty-two thousand new infections yearly are attributed to sexual transmission in the United States. This is one of the reasons to make people aware of their HIV disease and, hopefully, change behaviors that decrease transmission of the disease.

The prevalence of high-risk sexual behavior is reduced substantially after people become aware they are HIV positive. An analysis of behavioral data from 11 studies found that once a person knows he or she is HIV positive, they reduce their rate of unprotected intercourse (vaginal or anal) by 53 percent.⁴ These data confirm that HIV transmission can be substantially reduced by increasing the percentage of persons who are aware of their seropositive status. If infected persons are not aware of their status, behavior does not change.

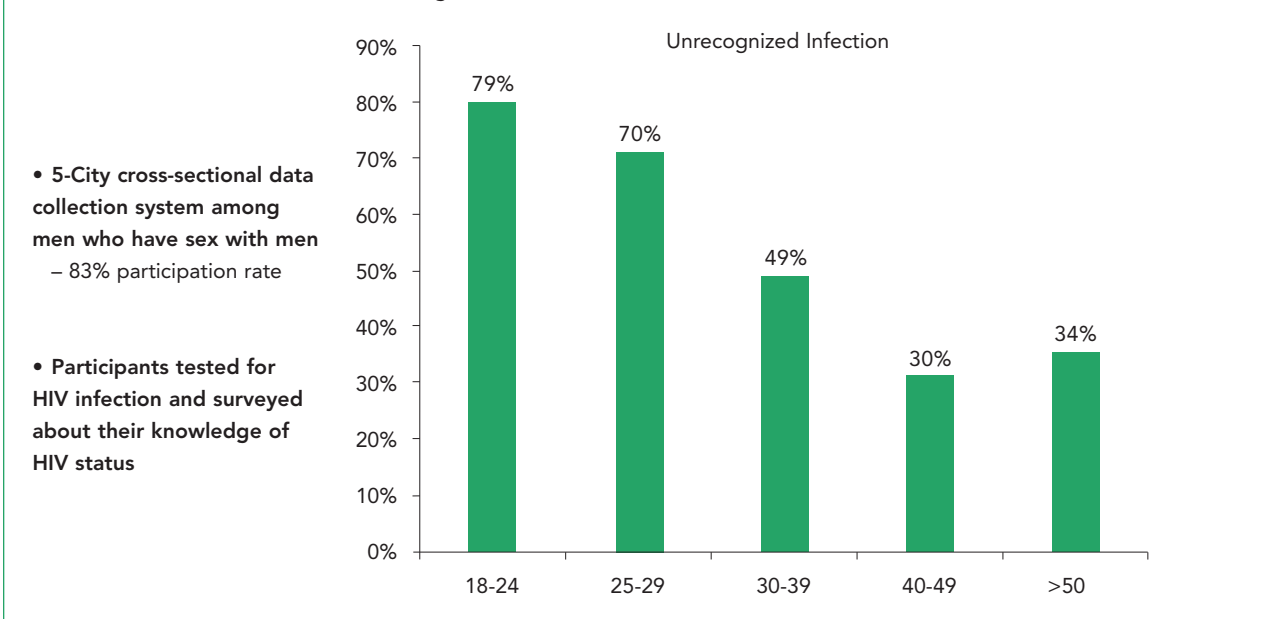
In the CDC HIV Behavioral Surveillance survey performed in 2004 to 2005, among men who had sex with other men, 14 percent of men aged 18 to 24 were infected with HIV.⁵ Almost 80 percent of these young men who tested positive were unaware they were infected. From this survey, the rate of unrecognized HIV infection was highly dependent on the age of the person (Exhibit 2). The percentage of unaware people decreased steadily by age group through age 49, then increased slightly in older men.

Treatment of AIDS has improved survival rates dramatically, especially since the introduction of highly active antiretroviral therapy (HAART), but progress in obtaining earlier diagnosis has been insufficient. Persons who receive an AIDS diagnosis within 12 months of gaining a diagnosis of HIV infection account for 40 percent of individuals identified as infected.⁶ Male injection drug users were most likely to receive a late diagnosis of HIV infection, followed by men acquiring HIV disease through heterosexual contact. A greater percentage of women tend to receive an “early” diagnosis (≥ 12 months from HIV diagnosis to AIDS diagnosis). Since effective treatment is available, a significant impact on infected patients would occur if diagnosis occurred earlier.

Prevention strategies that incorporate universal HIV screening have been highly successful. The best example of effective screening and prevention in the U.S. has been the significant reduction in prenatal transmission. Since the time that therapy was shown to be effective for preventing mother-to-child transmission and universal screening was recommended, there has been a 95 percent reduction in the number of perinatally-acquired AIDS cases.⁶ Another method, screening blood donors for HIV, has nearly eliminated transfusion-associated HIV infection. These successes contrast with a relative lack of progress in preventing sexual transmission of HIV for which screening is not commonly performed.

The new CDC recommendations for HIV testing include routine voluntary screening for all persons

Exhibit 2: Unrecognized HIV Infection: National HIV Behavioral Surveillance



aged 13 to 64 years of age. Highlights of the revised recommendations can be found in Exhibit 3.² The age range is based on surveillance data but does not exclude testing people outside that range. The recommended testing age was lowered because multiple behavioral studies have proved that adolescents are sexually active before many people want to admit. By eighteen years old, between 70 and 80 percent of adolescents have been sexually active and 37 percent did not use condoms during their last sexual act.⁷ Persons aged 50 to 64 account for 13 percent of new HIV cases, yet many people in that age group do not think they are at risk for HIV and other sexually transmitted diseases.⁶ People over 65 comprise less than 2 percent of new cases. Many providers feel uncomfortable discussing sexual practices or other risk factors for HIV with older patients.

The most important reason for expanded screening for HIV infection is the effectiveness of therapy. There has been a significant decrease of death rates attributed to the implementation of HAART (Exhibit 1). People infected with HIV can live long and productive lives today because of the medications that are available.

Screening should be conducted irrespective of risk factors. In contrast to previous recommendations, consent for testing should be based on an opt-out scheme, and HIV consent should be part of the general consent for care. According to the revised CDC recommendations, specific informed consent to do HIV testing is not required. Many states do still require a separate consent for HIV. Health care providers must carefully consider state and federal laws and regula-

tions related to HIV testing, confidentiality and the principles of informed consent that might limit the implementation of these recommendations.

Based on the limited resources in most health care settings, testing has been limited because of required pretest counseling. Many providers do not feel comfortable with the amount of training they have to complete for this kind of counseling and because of that they are not doing counseling. Pre-screening counseling is no longer required for routine screening, although it should be offered when requested or when patients are at high risk. It is recommended that persons at high risk be screened annually.

HIV screening should be discussed with all adolescents and encouraged for those who are sexually active. Confidentiality laws and legal precedents allow for evaluation and treatment of minors for sexually transmitted disease (STD) without parental knowledge or consent. Not every state has defined HIV infection explicitly as a condition for which testing or treatment may proceed without parental consent.²

A substantial number of persons who are HIV infected do not perceive themselves to be at risk or do not disclose their risk. Targeted testing based on risk behaviors fails to identify a significant number of persons who are infected with HIV. The new recommendations call for opt-out instead of opt-in screening. Opt-out screening is preferred because all patients are considered candidates for screening. Opt-out screening does not require the healthcare provider to make an assessment of an individual's risk of HIV infection. Patients can still decline screening, but the test will be performed unless the patient

Exhibit 3: Major Revisions From Previously Published HIV Screening Guidelines

For patients in all health-care settings

- HIV screening is recommended for patients in all health-care settings after the patient is notified that testing will be performed unless the patient declines (opt-out screening).
- Persons at high risk for HIV infection should be screened for HIV at least annually.
- Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing.
- Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings.

For pregnant women

- HIV screening should be included in the routine panel of prenatal screening tests for all pregnant women.
- HIV screening is recommended after the patient is notified that testing will be performed unless the patient declines (opt-out screening).
- Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing.
- Repeat screening in the third trimester is recommended in certain jurisdictions with elevated rates of HIV infection among pregnant women.

specifically refuses to be tested. Rates of HIV screening have been consistently higher in prenatal and STD service settings using opt-out screening.

Opt-out screening replaces the CDC's previously recommended standard of opt-in testing, where patients must be specifically counseled to receive an HIV test. Opt-in screening may be routinely offered in many settings, but usually takes more staff time to administer.² One of the best benefits of using an "Opt-out" approach is that it will decrease the stigma that is associated with HIV testing. When people do not feel singled out because of their behavior, they are more agreeable to being tested.

Routine screening procedures and prevention counseling for HIV should be a part of all primary care providers' overall well-care strategy. This means engaging each patient in a conversation that includes risk factors, sexual history, and practices of the patient. HIV screening provides opportunities to intervene in patients' risky behavior. Offering or arranging referral for infected patients to appropriate counseling and risk reduction services can reduce transmission of HIV.

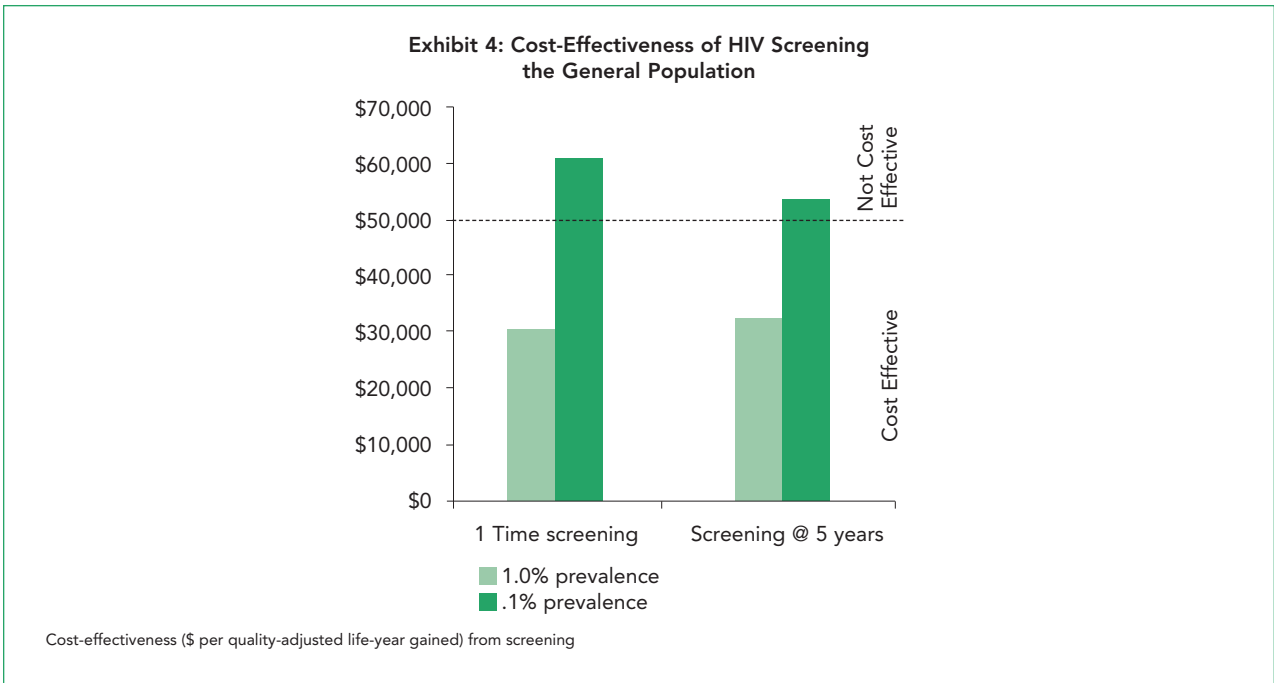
Screening also is recommended for emergency departments, inpatient services, and urgent care settings, as well as locations where HIV testing has traditionally been concentrated, such as STD and tuberculosis clinics. These recommendations do not change existing guidelines concerning HIV testing in non-clinical settings such as outreach settings or mobile vans. The CDC recommends routine screening can be discontinued in communities that have a documented prevalence less than 0.1 percent.² This type of data is not currently available but should be available once community wide screening is implemented.

For pregnant women, the recommendations are more complex. Universal opt-out screening during each pregnancy is recommended. For those women who are considered to be high risk or who are living in communities of high prevalence, screening should be repeated during the third trimester. It is also recommended that if a woman gets to labor and delivery without knowing what her status is, a rapid test be done so the infant can be treated. Antiretroviral prophylaxis should be initiated within 12 hours of birth on the basis of rapid test results.

The availability of rapid tests has allowed universal screening. The rapid tests allow results to be reported within 30 minutes. Rapid screening has a much higher rate of acceptance among patients. In addition, rapid testing improves the "return" rate of patients to receive the results of the test, compared with the traditional testing system.⁸ Rapid tests not only increase patient receipt of test results but also allow increased identifications of infected pregnant women so they can receive effective prophylaxis, increased feasibility of testing in acute care settings such as emergency rooms, and increase the number of venues where testing can be offered.

There are six tests approved for rapid testing. Four of these are approved for point of care testing. When a rapid test is positive, the patient is told this is a preliminary result that will need to be confirmed with a second test, usually a standard laboratory test. HIV-positive test results should be communicated confidentially through personal contact by a clinician, nurse, mid-level practitioner, counselor, or other skilled staff.

CDC recommendations for HIV/AIDS surveillance have not changed significantly. Risk factor



assessment to guide public health risk reduction efforts, HIV/AIDS case reporting, and pediatric exposure reporting are all recommended with mandatory reporting required in all states.

Like other sexually transmitted diseases, partner notification is an important component of HIV control. Providers should encourage patients who test positive to notify current and prior sex partners. Local health departments offer confidential partner notification and referral services.

Providers should notify patients they may be approached by local health departments for voluntary interviews regarding partner notification

There are concerns about the costs of universal screening in the United States. There is no doubt that implementing these new guidelines is going to increase the need for funding. Implementing routine testing will dramatically increase the funding needs of screening programs. Additionally, effective HIV screening programs do not work unless patients are effectively linked to appropriate care and prevention services. Currently, it is estimated that close to 50 percent of HIV positive patients have no health insurance. Identifying more patients will increase demand on public funding to support the cost of care and medications.

Although identifying and moving patients into care will substantially increase costs, getting patients into care early will reduce morbidity, mortality, and per-patient cost of care. The antiretroviral medications work better when used early in the course of the disease. Treating at later stages increases the chance of HIV resistance. Late in the disease, higher

numbers of hospital admissions, cancers, and opportunistic infections also drain the budget. In addition, early treatment increases survival. Another cost benefit of early detection of HIV infection is the potential for fewer cases caused by unaware transmission. Additionally, decreasing viral load among the infected with medications may decrease the rate of transmission of HIV in the U.S.

Paltiel and colleagues confirmed that implementing universal screening at a rate of one-time screening or screening every five years was cost effective (Exhibit 4).⁹ The model made the assumption that society would consider a cost of \$50,000 or less per quality-adjusted life-year gained to be cost-effective. This analysis included the costs of prescreening counseling, which is no longer routinely recommended. The authors concluded that routine rapid HIV testing is recommended and cost-effective when the prevalence of HIV is greater than or equal to 0.2 percent.⁹ Other studies have suggested screening to be cost effective on populations with a prevalence of 0.1 percent. The HIV prevalence in the general US population is approximately 0.4 percent.

To be able to provide cost-effective treatment and competent care for HIV infected patients, HIV specialty centers must be adequately staffed and funded. Data suggest patients cared for by HIV specialists have better outcomes. They do better in terms of survival and have lower morbidity. Specialists are usually faster in adopting new guidelines and therapies. They also are somewhat better at addressing adherence issues with this population. Experience in providing HIV care is essential for the management of

the complexities of HIV disease and the appropriate use of HIV therapies. Recommended therapy for this disease changes very frequently. In fact, there are two new classes of medications ready to be approved and there are many implications as to when these agents should be used. An expert panel convened by the Department of Health and Human Services recommends that primary HIV care be provided by clinicians with expertise in the disease. The level of expertise is variably defined as those with at least 20, but preferably at least 50 patients.

Since the treatment of HIV infection is highly variable and changes within the field occur relatively rapidly, ongoing continuing education in HIV therapy also is recommended. The AIDS Education Training Center (AETC) provides educational services nationwide. The AETC web site, www.aids-ed.org, provides an extensive library of online training resources. Funding through the AETC also provides a national HIV consultation service for health-care professionals. This service provides individual case consultation, and is offered free of charge to healthcare professionals.

Conclusion

Routine HIV testing is needed and is cost effective. Rapid tests have significantly improved the feasibility of HIV testing at the point of care. Awareness

of HIV status does have a significant implication and will reduce transmission of HIV disease. Early detection is associated with decreased morbidity and mortality, and is cost effective. **JMCM**

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