



Questions and Answers for Professional Partners: Revised Recommendations for HIV Testing of Adults, Adolescents and Pregnant Women in Healthcare Settings

General Background

1. Why is CDC recommending HIV screening for all adults and adolescents aged 13-64 in all Healthcare Settings?

CDC believes that the adoption of voluntary HIV screening in health care settings will help health care workers identify persons with previously unrecognized HIV infection and link them to clinical and prevention services, and further reduce sexual and perinatal transmission of HIV in the United States.

HIV infection meets all the criteria that justify screening:

- HIV is a serious health disorder that can be diagnosed before symptoms develop;
- HIV can be detected by reliable, inexpensive, noninvasive screening tests;
- HIV-infected patients have years of life to gain if treatment is initiated early, before symptoms develop;
- The costs of HIV screening are reasonable in relation to the anticipated benefits.

Several studies have demonstrated that existing risk-based testing strategies are not sufficient in identifying HIV-infected persons. In fact, persons with HIV infection often visit health care settings years before receiving an HIV diagnosis. Implementation of screening for all patients could help identify infected persons earlier in the course of their disease.

These revised recommendations are based on the success of voluntary HIV screening in pregnant women for detecting maternal HIV infection and preventing mother-to-child transmission. Through the use of HIV screening and appropriate medical care, the number of infants born with HIV infection decreased from a high of 1,650 HIV-infected infants born in 1991 to an estimated 144–236 infants born in 2002.

2. What are the benefits of HIV screening?

HIV screening has many benefits:

- People can receive effective treatment earlier, resulting in improved health and extended life. Currently, many people learn of their HIV infection only after they have developed symptoms (in a large study of HIV-infected persons, 44% reported they were first tested for HIV because of illness).
- Most people, after finding out they have HIV, adopt behaviors that reduce HIV transmission.
- HIV screening will reduce the stigma that is associated with testing based on risk.

3. What evidence is there that HIV screening will help more people learn their HIV status earlier?

Demonstration projects employing HIV screening in hospitals and emergency departments found a high percentage of patients who did not know they were infected. Because patients were rarely seeking HIV testing when screening was offered at these hospitals, many HIV infections were identified earlier than they would have been.

Other research has shown that while targeting HIV testing on the basis of risk behavior finds people who are infected with HIV, it also fails to identify many persons infected with HIV who are unaware they are at risk for infection, or who do not report risk behavior.

4. To what health care settings do the recommendations apply?

Recommendations for HIV screening are intended for all health care providers in the public and private sectors working in settings where other diagnostic and screening tests are performed routinely. These settings include hospital emergency departments, urgent care clinics, inpatient services (including labor and delivery), substance abuse treatment clinics, public health clinics, community clinics, correctional health care facilities, pediatric and adolescent care clinics, prenatal care clinics, and other primary care settings.

5. Is it cost-effective to test almost all adults, adolescents and pregnant women?

Cost-effectiveness models show that HIV screening is cost-effective, even in health care settings in which HIV prevalence is low. For example, in populations for which prevalence of undiagnosed HIV infection is $\geq 0.1\%$, HIV screening is as cost-effective as other established routine screening programs for chronic diseases such as colon cancer and breast cancer.

HIV prevalence in the general U.S. adult population is estimated to be approximately 0.4%. CDC expects few health care settings will have prevalence of $\leq 0.1\%$ (1 per 1,000). In jurisdictions where HIV is rare, CDC recommends performing HIV screening until it is shown that the yield of screening is less than 1 infected person per 1,000 persons screened. In those circumstances, continued screening is not warranted.

6. How do CDC's recommendations for HIV screening differ from those of the United States Preventive Services Task Force (USPSTF)?

CDC and USPSTF recommendations concur with regard to HIV screening for pregnant women, persons with individual risk factors, and persons receiving care in health care settings with HIV prevalence $\geq 1\%$.

CDC's new recommendations encourage screening of all adults and adolescents without regard to risk factors. The USPSTF concluded that, as yet, there is insufficient evidence to recommend either for or against such a policy. Because providers in busy health care settings often lack the time necessary to conduct risk assessments and explicit information regarding HIV prevalence for specific settings typically is not available, CDC's intention with its new recommendations is to decrease requirements that have been shown to be barriers to screening.

In addition, CDC has recommended repeat HIV testing in the third trimester for all pregnant women in jurisdictions with elevated HIV or AIDS incidence.

7. How were these recommendations developed?

These recommendations are the culmination of a lengthy and deliberate process:

- In 1999, the Institute of Medicine (IOM) recommended adopting a national policy of universal testing of pregnant women with patient notification (opt-out screening) and eliminating requirements for extensive pretest counseling and for explicit written consent for HIV testing.
- In 2001, IOM encouraged federal and state agencies to make greater use of cost-effectiveness analyses to guide resource allocation. In 2005, three separate cost-effectiveness analyses all concluded that expanded HIV screening in health care settings, at thresholds lower than those recommended previously, was cost-effective.
- In April 2003, based on evidence of effectiveness, CDC's director issued a Dear Colleague letter strongly encouraging clinicians to screen all pregnant women using an opt-out approach.
- In March 2004, CDC convened a meeting of health care providers, representatives from professional associations, and public health officials to obtain advice about how best to expand HIV testing, especially in high-volume, high-prevalence acute-care settings. Consultants recommended simplifying the HIV testing process to make it more feasible and less costly and advocated more frequent diagnostic testing of patients with symptoms.
- In April 2005, CDC initiated a comprehensive review of the literature relevant to HIV testing in health care settings. On the basis of published evidence and lessons learned from CDC-sponsored demonstration projects of HIV screening in health care facilities, CDC began to prepare recommendations to implement these strategies recommended by the 2004 consultation participants.
- In August 2005, CDC invited health care providers, representatives from public health agencies and community-based organizations (CBOs), and persons living with HIV to review an outline of proposed recommendations for routine testing in health care settings.
- In November 2005, CDC convened a meeting of researchers, representatives of professional organizations, clinicians involved in direct patient care, persons living with HIV, and representatives from community-based organizations and agencies overseeing care of HIV-infected persons to review a draft of CDC's proposed recommendations.
- Before final revision of these recommendations, CDC described the proposed changes at national meetings of researchers and health care providers and, in March 2006, solicited peer review by health care professionals, in compliance with requirements of the Office of Management and Budget for influential scientific assessments. CDC also invited comment from multiple professional and community organizations. The final recommendations were further refined on the basis of comments from these constituents.

Specific Populations

8. How were the age limits determined for recommending HIV screening?

The age group (13-64 years of age) defined in the recommendations encompasses the ages at which persons are most likely to be infected with HIV and not know it.

Many adolescents are sexually active but may not be willing to disclose this information in the presence of a parent. They represent new cohorts of persons at risk for HIV infection. According to CDC's 2005 Youth Risk Behavior Survey (YRBS), 47% of high-school students reported having sexual intercourse at least once and 37% of sexually active students did not use a condom during their last act of sexual intercourse. Offering HIV screening allows adolescents to get tested without forcing them to disclose whether they have been sexually active.

Regarding the upper age limit (64 years of age) of the recommendations, CDC notes that persons aged 50-64 account for 13% of new HIV diagnoses. Many older people do not think they are at risk for HIV or other sexually transmitted diseases (STDs). Studies have shown that physicians do not always address sexual health with their older patients and that their older patients often have limited knowledge about risk factors for HIV transmission. HIV screening for persons over 50 will not only raise awareness of HIV in older persons, but will also, undoubtedly, find new infections in people who thought they were not at risk for HIV.

Because persons age 65 and older comprise less than 2% of new HIV infections, CDC recommends 64 as the cut-off age for screening in persons without risk factors for HIV.

9. Do these recommendations apply to correctional facilities?

Yes, these recommendations apply to correctional health care facilities.

Most inmates undergo health screening when they enter a correctional facility. HIV prevalence among the incarcerated population (2.0%) is nearly five times higher than for the general U.S. adult population (0.4%).

There are special considerations for incarcerated persons related to informed consent, access to care, and discharge planning as well as differences in state laws that must be taken into account when designing screening programs for correctional health care facilities.

10. What does CDC recommend for HIV testing of pregnant women?

CDC recommendations state that:

- 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).

- Repeat HIV screening in the third trimester is recommended for certain high-risk women and in certain jurisdictions with elevated rates of HIV infection among pregnant women.
- Pregnant women should receive oral and written information that includes an explanation of HIV infection, a description of interventions that can reduce HIV transmission from mother to infant and the meanings of positive and negative test results.

If a pregnant woman is infected with HIV, there is still an opportunity to prevent transmission to her infant. Perinatal transmission rates can drop to below 2% if known precautions (prophylactic administration of antiretroviral drugs, scheduled cesarean delivery, and avoidance of breast feeding) are taken.

11. When is a second HIV test during pregnancy recommended?

A second HIV test during a woman's third trimester is specifically recommended for women who meet certain criteria, including: a) residing in specific high-prevalence jurisdictions, b) receiving health care in facilities with at least 1 diagnosed HIV case per 1,000 pregnant women per year, and c) women known to be at high risk for acquiring HIV. Because providers and patients rarely know what jurisdictions have high prevalence, CDC has listed the states in its recommendations and will continue to update them.

12. What does CDC recommend for newborns if the mother's HIV status is unknown at delivery?

CDC recommends that clinicians test for HIV any newborn whose mother's HIV status is unknown. Data demonstrate that detection of HIV infection during pregnancy through HIV testing of all pregnant women affords the best opportunity to deliver interventions when they are most effective. Recent experience from the CDC-funded Mother Infant Rapid Intervention at Delivery (MIRIAD) study indicates that rapid HIV testing of women can be done during labor, and that antiretroviral interventions can be quickly delivered to HIV-infected mothers and their infants. Therefore, for those women whose HIV status is unknown at labor, CDC recommends routine, rapid HIV testing. When the mother's HIV status is unknown prior to the onset of labor and rapid HIV testing is not done during labor, CDC recommends rapid HIV testing of the infant immediately post-partum, so that antiretroviral prophylaxis can be offered to HIV-exposed infants. When intervention begins at the intrapartum (during labor or delivery) or neonatal periods, 9% to 13% HIV transmission rates are achievable based on clinical trial and observational data, representing a 50% reduction in HIV transmission from rates that would be expected without intervention.

Opt-out Screening, Counseling and Consent

13. What is opt-out HIV screening and why is CDC recommending it in Healthcare Settings?

Opt-out screening means performing an HIV test after notifying the patient 1) that the test will be performed and 2) that the patient may elect to decline or defer testing. Opt-in

screening means testing is offered and the patient is required to actively give permission for testing.

Areas that have opt-out testing policies for pregnant women and for recipients of STD services have higher HIV testing rates than those that use opt-in policies (where the patient is given the opportunity to choose the HIV test) or those that require specific counseling for testing. Patients prefer when testing is routine and offered to everyone rather than being singled out for testing because they are perceived to be “at-risk.” For these reasons, CDC believes an opt-out approach provides the best opportunity for more people to know their HIV status.

14. How does CDC's recommendation for prevention counseling differ from previous versions?

CDC recommends that prevention counseling does not have to be linked to HIV testing in Healthcare Settings.

CDC strongly endorses prevention counseling as an intervention to help persons reduce their risks for HIV, but also recognizes that it may not be appropriate or feasible during episodic or acute-care visits in busy health care settings. Medical visits in which prevention counseling is most appropriate are those in which HIV testing and counseling are consistent with the context of the health care visit, such as when the visit is related to a behavioral or clinical risk (e.g., substance abuse or symptoms of an STD) or when other health promotion services are usually offered (e.g., as part of comprehensive health assessments, reproductive health care, or family planning). For this reason, the revised recommendations emphasize provision of information, verbally or in writing, sufficient for an informed patient to decide whether or not to have an HIV test, and more intensive counseling or referral for persons who are diagnosed with HIV.

Prevention counseling is still strongly encouraged for persons at high risk for HIV in settings such as STD clinics. The recommendations do not modify existing guidelines concerning HIV counseling, testing, or referral for persons at high risk who seek testing in non-clinical settings.

15. Is CDC deemphasizing counseling or just separating it from testing?

In health care settings, CDC recommends that counseling and testing be treated as two separate interventions, and emphasizes counseling for persons who are HIV-infected.

Prevention counseling remains important for all persons who are sexually active, but it does not need to be linked with HIV testing in health care settings. Notifying a patient that HIV screening will be performed might result in acknowledgement of risk behaviors and offers an opportunity to discuss HIV infection and how it can be prevented. Patients found to have risk behaviors (e.g., heterosexuals or men who have sex with men (MSM) who have multiple sex partners, persons who have received a recent diagnosis of an STD, persons who exchange sex for money or drugs, or persons who engage in substance abuse) and those who want assistance with changing behaviors should be provided with or referred to HIV risk-reduction services (e.g., drug treatment, STD treatment, and/or prevention counseling).

16. Why is CDC recommending that separate, written informed consent for HIV testing should not be required?

The need for separate, written informed consent for HIV testing generated considerable debate among various constituents during development of these recommendations. Opinions on this issue have been especially polarized. Proponents support maintaining the existing paradigm of separate, written informed consent and pre-test counseling for HIV testing. Opponents, with similar conviction, assert that requiring separate, written consent and pre-test counseling for all patients is a major impediment that makes HIV screening impractical in health care settings.

Further investigation revealed that certain states require written informed consent for all HIV testing; others specifically exempt health care providers from this requirement, and several explicitly state that no separate consent for an HIV test is necessary when a general consent for care is in effect. Additionally, a recent survey by the Kaiser Family Foundation found that 65% of U.S. adults felt that no separate procedures, such as signed permission from the patient, should be necessary for HIV testing.

CDC considers it essential to protect both patient autonomy and to reduce potential barriers that hinder HIV screening. To help strike a balance, CDC emphasizes in the summary statement and throughout the recommendations that the revised recommendations are intended for HIV testing in health care settings where other diagnostic and screening tests are conducted routinely, that patients must be informed of the test, and that testing must be voluntary and free from coercion. In health care settings, CDC recommends that informed consent for HIV testing can be incorporated into the consent for treatment, recognizing that each jurisdiction must carefully consider the legal meaning of informed consent in light of the public health considerations addressed by the recommendations.

17. What do other organizations say about requirements for HIV counseling and separate, written informed consent prior to HIV testing?

In 1999, the Institute of Medicine (IOM) recognized that opt-out screening, the elimination of requirements for extensive pre-test counseling and separate, written consent, afforded the best strategy to increase the proportion of pregnant women tested for HIV. Subsequent studies indicate that these policies, as proposed by IOM and other organizations, such as American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the New York City Department of Health, and others, reflect an ethical balance among public health goals, justice, and individual rights.

18. Will this change in practice mean people will be tested without their knowledge or consent?

No one should ever be tested for HIV without their knowledge. The definition of opt-out screening clearly states that the HIV test will be performed after the patient has been notified that the test will be performed and that the patient may elect to decline or defer testing.

Provider-specific Information

19. Several states have laws that require written informed consent for HIV testing – how can I follow the law and provide the best care for the most patients?

Legislation related to HIV and AIDS has been enacted in every state and the District of Columbia, and specific requirements related to informed consent and pretest counseling differ among states. Certain states, local jurisdictions, or agencies may not allow opt-out screening, or they may impose other specific requirements for counseling, written consent, confirmatory testing, or communicating HIV test results that conflict with these recommendations. Where policies exist that are in conflict with the new recommendations, jurisdictions should examine strategies to best implement these recommendations within current parameters, and initiate steps to resolve conflicts with these recommendations.

20. After an initial test, when should adults be tested again, if they don't have any identified risk behaviors?

Persons without known risk factors should be encouraged to receive HIV screening, based on the clinical judgment of their health care practitioner.

21. Do these recommendations change practices regarding testing for occupational exposure to HIV?

No, these recommendations do not change recommendations for testing and post-exposure prophylaxis. However, CDC hopes the implementation of these recommendations will result in more persons knowing their status before an exposure occurs. Unless recent HIV test results are immediately available, any person whose blood or body fluid is the source of an occupational exposure for a health care provider should be informed of the incident and tested for HIV infection at the time the exposure occurs.

22. Providing results to so many patients may be challenging. Can results be provided by mail or over the phone?

Results of HIV tests, both positive and negative, are already given over the phone in many jurisdictions. Positive test results should always be communicated by personal contact and should never be delivered by mail.

CDC recommends that providers establish mechanisms to inform patients of their test results as they do with other significant medical information. The use of rapid HIV tests can significantly decrease the number of people who fail to learn their test results because the results can be delivered during the visit in which the test took place.

23. How can I learn what care and treatment resources are available in my area?

Your local health department and community-based organizations specializing in HIV/AIDS issues will have that information. For perinatal issues, the University of California, San Francisco hosts the National Perinatal HIV Consultation and Referral Service hotline that operates 24 hours per day, 7 days per week at 888-448-8765. The

National HIV/AIDS Clinicians' Consultation Center has a general hotline at 800-933-3413, a post-exposure prophylaxis hotline at 888-HIV-4911, and a perinatal consultation and referral hotline at 888-448-8765.

24. What should I do if a patient declines HIV testing and I think they are at high risk for infection?

There are many reasons a patient may decline an HIV test, including lack of perceived risk, fear of the disease, concerns about partner violence, potential stigma, concerns about the cost of treatment and/or discrimination. Providers should discuss and address reasons for declining an HIV test. If the patient still opts out, then he or she can be encouraged to be tested at a subsequent visit. The patient's decision should be respected and documented in his or her medical file.

25. Where can I get more information about how to implement HIV screening in specific health care settings?

CDC will offer an implementation guide to the new recommendations, available in spring of 2007. The implementation guide will have examples and information on implementing HIV screening in specific health care settings. Professional organizations, such as the American Medical Association, the National Medical Association, the American Academy of HIV Medicine, the National Association of Community Health Centers, and the American Academy of Pediatrics, will also provide information about implementing the recommendations.

26. Are there any additional requirements for HIV testing?

Certain states, jurisdictions, or agencies may have statutory or other regulatory requirements for pretest counseling, written consent, confirmatory testing, or communicating HIV test results. Sometimes, requirements for pregnant women, newborns, or adolescents may differ from those for adults. CDC recommendations for HIV testing in health care settings also differ from guidelines for non-clinical settings, and state requirements may differ as well. Providers should become familiar with the regulations that apply in their practice setting.

Public Health Implications

27. Is CDC diverting funding from community and public settings to health care and private settings?

No, CDC funds are not being diverted to health care and private settings. CDC continues to support prevention efforts in community and public settings. Because these recommendations are one part of CDC's comprehensive effort to reduce new HIV infections. CDC remains committed to continuing our partnerships with state and local public health departments and community-based organizations.

28. Is CDC changing the Counseling, Testing, and Referral (CTR) guidelines?

These testing recommendations address HIV testing in health care settings only. They do not modify existing guidelines on HIV counseling, testing, and referral for persons at high risk for HIV who seek or receive HIV testing in non-clinical settings (e.g. at community-based organizations or in outreach settings, such as mobile vans). There are plans to modify the guidelines for non-clinical settings to reflect current scientific evidence in practice in non-health care settings. Changes in the guidelines will follow the accepted process of obtaining input from key stakeholders and experts.

29. What about HIV stigma associated with HIV testing?

By making HIV testing part of routine care, CDC believes, and there is research to support this belief, that stigma surrounding HIV testing will decrease. Routine HIV testing reduces the stigma associated with traditional testing that requires assessment of behavioral risks. Focus groups indicate that many patients, especially those who have been tested for other STDs, assume they have been tested for HIV, whether or not such testing was performed. In some communities where HIV infection is common, being screened for HIV is now perceived as a part of routine care, similar to regular mammograms and blood pressure checks.

Reimbursement and Funding Issues

30. Does CDC have estimates of how many people will be diagnosed with HIV if these recommendations are adopted nationwide?

It is difficult to estimate the number of persons who would be diagnosed with HIV due to the new recommendations. Because acceptance and implementation of the guidelines will vary, it is difficult to project the number of new HIV infections that will be found through screening and that would not have been found through the current standards of care.

Even without an estimate of new HIV infections that may be found due to the new recommendations, CDC is working with its federal partners to create a safety net so that all newly diagnosed persons with HIV can be linked to treatment.

31. How will the care and treatment of newly diagnosed HIV-infected persons be paid for?

CDC believes linking newly diagnosed patients to prevention and care is essential. To that end, CDC is working with the Department of Health and Human Services and with health insurance providers to address the issue of HIV treatment coverage.

Currently, it is estimated that 45% of HIV-infected persons have no health insurance, 30% receive coverage through Medicaid, 11% have private insurance, 12% have other insurance, and 2% have Medicare. Funding from the Ryan White CARE Act (RWCA) provides much-needed care and services for those without insurance or not covered by Medicaid or Medicare and is therefore critical to ensuring that persons with HIV receive care and treatment. It is important to note that not all persons newly diagnosed with HIV who do not have insurance will seek care in RWCA programs. Not all newly diagnosed

persons will enter care in the first year following their diagnosis and of those who do enter care, not all will require medication.

The economic benefits of detecting HIV infections early (lowered viral load and better health for the infected person and fewer additional infections for that persons' sexual and/or needle-sharing contacts) are persuasive reasons to encourage testing and early treatment. Although getting patients into care does incur substantial costs, it also triggers survival benefits – including the ability to continue working, to have fewer sick days, etc. Overall, early diagnosis of HIV can slow or avoid disease progression.

It is anticipated that these Recommendations will become a standard of care and that reimbursement will follow, especially among those who fund guideline-concordant care (e.g., Medicaid, private insurers). CDC anticipates that payers will be encouraged to cover screening, either separately or as part of the basis for payment to hospitals. Because HIV screening is cost-effective, some facilities may also choose to absorb the cost, or to redirect funds from other, less cost-effective programs. Public funds will continue to be necessary to support screening programs for indigent persons without health care.

Summary Question

32. What are the potential consequences of not implementing these recommendations?

The number of estimated annual new HIV infections has remained stable at 40,000 for over a decade. These recommendations offer the best opportunity to reduce that number by enabling the 25% of all HIV-infected people in the U.S. who do not know they are infected to know their HIV status and thus be counseled on how to reduce the risk of transmitting the virus to others and to get into treatment to better their health.

Not implementing these recommendations will result in an unchanging spiral of having many people infected with HIV but not knowing their HIV status. They can then unknowingly infect others, they will be diagnosed later in the course of their disease when treatment is not as effective, and they will incur the higher health care costs associated with treating more severe disease.

In summary, implementing these recommendations will allow people to know their HIV status, get into treatment earlier, and prevent new infections.