MMWR

Recommendations and Reports

September 22, 2006 / 55(RR14);1-17

Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings

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Summary

These recommendations for human immunodeficiency virus (HIV) testing are intended for all health-care providers in the public and private sectors, including those working in hospital emergency departments, urgent care clinics, inpatient services, substance abuse treatment clinics, public health clinics, community clinics, correctional health-care facilities, and primary care settings. The recommendations address HIV testing in health-care settings only. They do not modify existing guidelines concerning HIV counseling, testing, and referral for persons at high risk for HIV who seek or receive HIV testing in nonclinical settings (e.g., community-based organizations, outreach settings, or mobile vans). The objectives of these recommendations are to increase HIV screening of patients,

including pregnant women, in health-care settings; foster earlier detection of HIV infection; identify and counsel persons with unrecognized HIV infection and link them to clinical and prevention services; and further reduce perinatal transmission of HIV in the United States. These revised recommendations update previous recommendations for HIV testing in health-care settings and for screening of pregnant women (CDC. Recommendations for HIV testing services for inpatients and outpatients in acute-care hospital settings. MMWR 1993;42[No. RR-2]:1--10; CDC. Revised guidelines for HIV counseling, testing, and referral. MMWR 2001;50[No. RR-19]:1--62; and CDC. Revised recommendations for HIV screening of pregnant women. MMWR 2001;50[No. RR-19]:63--85).

Major revisions from previously published guidelines are as follows:

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.*

Introduction

Human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS) remain leading causes of illness and death in the United States. As of December 2004, an estimated 944,306 persons had received a diagnosis of AIDS, and of these, 529,113 (56%) had died (*1*). The annual number of AIDS cases and deaths declined substantially after 1994 but stabilized during 1999--2004 (*1*). However, since 1994, the annual number of cases among blacks, members of other racial/ethnic minority populations, and persons exposed through heterosexual contact has increased. The number of children reported with AIDS attributed to perinatal HIV transmission peaked at 945 in 1992 and declined 95% to 48 in 2004 (*1*), primarily because of the identification of HIV-infected pregnant women and the effectiveness of antiretroviral prophylaxis in reducing mother-to-child transmission of HIV (*2*).

By 2002, an estimated 38%--44% of all adults in the United States had been tested for HIV; 16--22 million persons aged 18--64 years are tested annually for HIV (*3*). However, at the end of 2003, of the approximately 1.0--1.2 million persons estimated to be living with HIV in the United States, an estimated one quarter (252,000--312,000 persons) were unaware of their infection and therefore

unable to benefit from clinical care to reduce morbidity and mortality (*4*). A number of these persons are likely to have transmitted HIV unknowingly (*5*).

Treatment has improved survival rates dramatically, especially since the introduction of highly active antiretroviral therapy (HAART) in 1995 (*6*). However, progress in effecting earlier diagnosis has been insufficient. During 1990--1992, the proportion of persons who first tested positive for HIV <1 year before receiving a diagnosis of AIDS was 51% (*7*); during 1993--2004, this proportion declined only modestly, to 39% in 2004 (*1*). Persons tested late in the course of their infection were more likely to be black or Hispanic and to have been exposed through heterosexual contact; 87% received their first positive HIV test result at an acute or referral medical care setting, and 65% were tested for HIV antibody because of illness (*8*).

These recommendations update previous recommendations for HIV testing in health-care settings (*9*,*10*) and for screening of pregnant women (*11*). The objectives of these recommendations are to increase HIV screening of patients, including pregnant women, in health-care settings; foster earlier detection of HIV infection; identify and counsel persons with unrecognized HIV infection and link them to clinical and prevention services; and further reduce perinatal transmission of HIV in the United States.

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Background

Definitions

Diagnostic testing. Performing an HIV test for persons with clinical signs or symptoms consistent with HIV infection.

Screening. Performing an HIV test for all persons in a defined population (*12*).

Targeted testing. Performing an HIV test for subpopulations of persons at higher risk, typically defined on the basis of behavior, clinical, or demographic characteristics (*9*).

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 that 1) the test will be performed and 2) the patient may elect 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 (*13*).

Evolution of HIV Testing Recommendations in Health-Care Settings and for Pregnant Women

In 1985, when HIV testing first became available, the main goal of such testing was to protect the blood supply. Alternative test sites were established to deter persons from using blood bank testing to learn their HIV status. At that time, professional opinion was divided regarding the value of HIV testing and whether HIV testing should be encouraged because no consensus existed regarding whether a positive test predicted transmission to sex partners or from mother to infant (*14*). No effective treatment existed, and counseling was designed in part to ensure that persons tested were aware that the meaning of positive test results was uncertain.

During the next 2 years, the implications of positive HIV serology became evident, and in 1987, the United States Public Health Service (USPHS) issued guidelines making HIV counseling and testing a priority as a prevention strategy for persons most likely to be infected or who practiced high-risk behaviors and recommended routine testing of all persons seeking treatment for STDs, regardless of health-care setting (*15*). "Routine" was defined as a policy to provide these services to all clients after informing them that testing would be conducted (*15*).

In 1993, CDC recommendations for voluntary HIV counseling and testing were extended to include hospitalized patients and persons obtaining health care as outpatients in acute-care hospital settings, including emergency departments (EDs) (*10*). Hospitals with HIV seroprevalence rates of >1% or AIDS diagnosis rates of >1 per 1,000 discharges were encouraged to adopt a policy of offering voluntary HIV counseling and testing routinely to all patients aged 15--54 years. Health-care providers in acute-care settings were encouraged to structure counseling and testing procedures to facilitate confidential, voluntary participation and to include basic information regarding the medical implications of the test, the option to receive more information, and documentation of informed consent (*10*). In 1994, guidelines for counseling and testing persons with high-risk behaviors specified prevention counseling to develop specific prevention goals and strategies for each person (client-centered counseling) (*16*). In 1995, after perinatal transmission of HIV was demonstrated to be substantially reduced by administration of zidovudine to HIV-infected pregnant women and their newborns, USPHS recommended that all pregnant women be counseled and encouraged to undergo voluntary testing for HIV (*17*,*18*).

In 2001, CDC modified the recommendations for pregnant women to emphasize HIV screening as a routine part of prenatal care, simplification of the testing process so pretest counseling would not pose a barrier, and flexibility of the consent process to allow multiple types of informed consent (*11*). In addition, the 2001 recommendations for HIV testing in health-care settings were extended to include multiple additional clinical venues in both private and public health-care sectors, encouraging providers to make HIV counseling and testing more accessible and acknowledging their need for flexibility (*9*). CDC recommended that HIV testing be offered routinely to all patients in high HIV-prevalence health-care settings. In low prevalence settings, in which the majority of clients are at minimal risk, targeted HIV testing on the basis of risk screening was considered more feasible for identifying limited numbers of HIV-infected persons (*9*).

In 2003, CDC introduced the initiative Advancing HIV Prevention: New Strategies for a Changing Epidemic (*19*). Two key strategies of this initiative are 1) to make HIV testing a routine part of medical care on the same voluntary basis as other diagnostic and screening tests and 2) to reduce perinatal transmission of HIV further by universal testing of all pregnant women and by using rapid tests during labor and delivery or postpartum if the mother was not screened prenatally (*19*). In its technical guidance, CDC acknowledged that prevention counseling is desirable for all persons at risk for HIV but recognized that such counseling might not be appropriate or feasible in all settings (*20*). Because time constraints or discomfort with discussing their patients' risk behaviors caused some providers to perceive requirements for prevention counseling and written informed consent as a barrier (*12*,*21*--*23*), the initiative advocated streamlined approaches.

In March 2004, CDC convened a meeting of health-care providers, representatives from professional associations, and local health officials to obtain advice concerning how best to expand HIV testing, especially in high-volume, high-prevalence acute-care settings. Consultants recommended simplifying the HIV screening 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 regarding HIV testing in health-care settings and, on the basis of published evidence and lessons learned from CDC-sponsored demonstration projects of HIV screening in health-care facilities, began to prepare recommendations to implement these strategies. In August 2005, CDC invited health-care providers, representatives from public health agencies and community organizations, and persons living with HIV to review an outline of proposed recommendations. In November 2005, CDC convened a meeting of researchers, representatives of professional health-care provider organizations, clinicians, persons living with HIV, and representatives from community organizations and agencies overseeing care of HIV-infected persons to review CDC's proposed recommendations. Before final revision of these recommendations, CDC described the proposals 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, and invited comment from multiple professional and community organizations. The final recommendations were further refined on the basis of comments from these constituents.

Rationale for Routine Screening for HIV Infection

Previous CDC and U.S. Preventive Services Task Force guidelines for HIV testing recommended routine counseling and testing for persons at high risk for HIV and for those in acute-care settings in which HIV prevalence was ≥1% (*9*,*10*,*24*). These guidelines proved difficult to implement because 1) the cost of HIV screening often is not reimbursed, 2) providers in busy health-care settings often lack the time necessary to conduct risk assessments and might perceive counseling requirements as a barrier to testing, and 3) explicit information regarding HIV prevalence typically is not available to guide selection of specific settings for screening (*25*--*29*).

These revised CDC recommendations advocate routine voluntary HIV screening as a normal part of medical practice, similar to screening for other treatable conditions. Screening is a basic public health tool used to identify unrecognized health conditions so treatment can be offered before symptoms develop and, for communicable diseases, so interventions can be implemented to reduce the likelihood of continued transmission (*30*).

HIV infection is consistent with all generally accepted criteria that justify screening: 1) HIV infection is a serious health disorder that can be diagnosed before symptoms develop; 2) HIV can be detected by reliable, inexpensive, and noninvasive screening tests; 3) infected patients have years of life to gain if treatment is initiated early, before symptoms develop; and 4) the costs of screening are reasonable in relation to the anticipated benefits (*30*). Among pregnant women, screening has proven substantially more effective than risk-based testing for detecting unsuspected maternal HIV infection and preventing perinatal transmission (*31*--*33*).

Rationale for New Recommendations

Often, persons with HIV infection visit health-care settings (e.g., hospitals, acute-care clinics, and sexually transmitted disease [STD] clinics) years before receiving a diagnosis but are not tested for HIV (*34*--*36*). Since the 1980s, the demographics of the HIV/AIDS epidemic in the United States have changed; increasing proportions of infected persons are aged <20 years, women, members of racial or ethnic minority populations, persons who reside outside metropolitan areas, and

heterosexual men and women who frequently are unaware that they are at risk for HIV (*37*). As a result, the effectiveness of using risk-based testing to identify HIV-infected persons has diminished (*34*,*35*,*38*,*39*).

Prevention strategies that incorporate universal HIV screening have been highly effective. For example, screening blood donors for HIV has nearly eliminated transfusion-associated HIV infection in the United States (*40*). In addition, incidence of pediatric HIV/AIDS in the United States has declined substantially since the 1990s, when prevention strategies began to include specific recommendations for routine HIV testing of pregnant women (*18*,*41*). Perinatal transmission rates can be reduced to <2% with universal screening of pregnant women in combination with prophylactic administration of antiretroviral drugs (*42*,*43*), scheduled cesarean delivery when indicated (*44*,*45*), and avoidance of breast feeding (*46*).

These successes contrast with a relative lack of progress in preventing sexual transmission of HIV, for which screening rarely is performed. Declines in HIV incidence observed in the early 1990s have leveled and might even have reversed in certain populations in recent years (*47*,*48*). Since 1998, the estimated number of new infections has remained stable at approximately 40,000 annually (*49*). In 2001, the Institute of Medicine (IOM) emphasized prevention services for HIV-infected persons and recommended policies for diagnosing HIV infections earlier to increase the number of HIV-infected persons who were aware of their infections and who were offered clinical and prevention services (*37*). The majority of persons who are aware of their HIV infections substantially reduce sexual behaviors that might transmit HIV after they become aware they are infected (*5*). In a meta-analysis of findings from eight studies, the prevalence of unprotected anal or vaginal intercourse with uninfected partners was on average 68% lower for HIV-infected persons who were aware of their status than it was for HIV-infected persons who were unaware of their status (*5*). To increase diagnosis of HIV infection, destigmatize the testing process, link clinical care with prevention, and ensure immediate access to clinical care for persons with newly identified HIV infection, IOM and other health-care professionals with expertise (*25*,*37*,*50*,*51*) have encouraged adoption of routine HIV testing in all health-care settings.

Routine prenatal HIV testing with streamlined counseling and consent procedures has increased the number of pregnant women tested substantially (*52*). By contrast, the number of persons at risk for HIV infection who are screened in acute-care settings remains low, despite repeated recommendations in support of routine risk-based testing in health-care settings (*9*,*10*,*15*,*34*,*53*,*54*). In a survey of 154 health-care providers in 10 hospital EDs, providers reported caring for an average of 13 patients per week suspected to have STDs, but only 10% of these providers encouraged such patients to be tested for HIV while they were in the ED (*54*). Another 35% referred patients to confidential HIV testing sites in the community; however, such referrals have proven ineffective because of poor compliance by patients (*55*). Reasons cited for not offering HIV testing in the ED included lack of established mechanisms to ensure follow-up (51%), lack of the certification perceived as necessary to provide counseling (45%), and belief that the testing process was too time-consuming (19%) (*54*).

With the institution of HIV screening in certain hospitals and EDs, the percentage of patients who test positive (2%--7%) often has exceeded that observed nationally at publicly funded HIV counseling and testing sites (1.5%) and STD clinics (2%) serving persons at high risk for HIV (*53*,*56*--*59*). Because patients rarely were seeking testing when screening was offered at these hospitals, HIV infections often were identified earlier than they might otherwise have been (*29*). Targeted testing programs also have been implemented in acute-care settings; nearly two thirds of patients in these settings accept testing, but because risk assessment and prevention counseling are time-consuming, only a limited proportion of eligible patients can be tested (*29*). Targeted testing on

the basis of risk behaviors fails to identify a substantial number of persons who are HIV infected (*34,35,39*). A substantial number of persons, including persons with HIV infection, do not perceive themselves to be at risk for HIV or do not disclose their risks (*53*,*56*,*59*). Routine HIV testing reduces the stigma associated with testing that requires assessment of risk behaviors (*60--63*). More patients accept recommended HIV testing when it is offered routinely to everyone, without a risk assessment (*54*,*56*).

In 1999, to increase the proportion of women tested for HIV, IOM recommended 1) adopting a national policy of universal HIV testing of pregnant women with patient notification (opt-out screening) as a routine component of prenatal care, 2) eliminating requirements for extensive pretest counseling while requiring provision of basic information regarding HIV, and 3) not requiring explicit written consent to be tested for HIV (*12*). Subsequent studies have indicated that these policies, as proposed by IOM and other professional organizations (*12,64,65*), reflect an ethical balance among public health goals, justice, and individual rights (*66,67*). Rates of HIV screening are consistently higher at settings that provide prenatal and STD services using opt-out screening than at opt-in programs, which require pre-test counseling and explicit written consent (*52*,*68--74*). Pregnant women express less anxiety with opt-out HIV screening and do not find it difficult to decline a test (*68,74*). In 2006, approximately 65% of U.S. adults surveyed concurred that HIV testing should be treated the same as screening for any other disease, without special procedures such as written permission from the patient (*75*).

Adolescents aged 13--19 years represent new cohorts of persons at risk, and prevention efforts need to be repeated for each succeeding generation of young persons (*63*). The 2005 Youth Risk Behavior Survey indicated that 47% of high school students reported that they had had sexual intercourse at least once, and 37% of sexually active students had not used a condom during their most recent act of sexual intercourse (*76*). More than half of all HIV-infected adolescents are estimated not to have been tested and are unaware of their infection (*77,78*). Among young (aged 18--24 years) men who have sex with men (MSM) surveyed during 2004--2005 in five U.S. cities, 14% were infected with HIV; 79% of these HIV-infected MSM were unaware of their infection (*56*). The American Academy of Pediatrics recommends that clinicians obtain information from adolescent patients regarding their sexual activity and inform them how to prevent HIV infection (*79*). Evidence indicates that adolescents prefer to receive this information from their health-care providers rather than from their parents, teachers, or friends (*80*). However, fewer than half of clinicians provide such guidance (*81*). Health-care providers' recommendations also influence adolescents' decision to be tested. Among reasons for HIV testing provided by 528 adolescents who had primary care providers, 58% cited their provider's recommendation as their reason for testing (*82*).

The U.S. Preventive Services Task Force recently recommended that clinicians screen for HIV all adults and adolescents at increased risk for HIV, on the basis that when HIV is diagnosed early, appropriately timed interventions, particularly HAART, can lead to improved health outcomes, including slower clinical progression and reduced mortality (*24*). The Task Force also recommended screening all pregnant women, regardless of risk, but made no recommendation for or against routinely screening asymptomatic adults and adolescents with no identifiable risk factors for HIV. The Task Force concluded that such screening would detect additional patients with HIV, but the overall number would be limited, and the potential benefits did not clearly outweigh the burden on primary care practices or the potential harms of a general HIV screening program (*24,83*). In making these recommendations, the Task Force considered how many patients would need to be screened to prevent one clinical progression or death during the 3-year period after screening. On the basis of evidence available for its review, the Task Force was unable to calculate benefits attributable to the prevention of secondary HIV transmission to partners (*84*). However, a recent meta-analysis indicated that HIV-infected persons reduced high-risk behavior substantially when they became

aware of their infection (*5*). Because viral load is the chief biologic predictor of HIV transmission (*85*), reduction in viral load through timely initiation of HAART might reduce transmission, even for HIV-infected patients who do not change their risk behavior (*86*). Estimated transmission is 3.5 times higher among persons who are unaware of their infection than among persons who are aware of their infection and contributes disproportionately to the number of new HIV infections each year in the United States (*87*). In theory, new sexual HIV infections could be reduced >30% per year if all infected persons could learn their HIV status and adopt changes in behavior similar to those adopted by persons already aware of their infection (*87*).

Recent studies demonstrate that voluntary HIV screening is cost-effective even in health-care settings in which HIV prevalence is low (*26,27,86*). In populations for which prevalence of undiagnosed HIV infection is ≥0.1%, HIV screening is as cost-effective as other established screening programs for chronic diseases (e.g., hypertension, colon cancer, and breast cancer) (*27,86*). Because of the substantial survival advantage resulting from earlier diagnosis of HIV infection when therapy can be initiated before severe immunologic compromise occurs, screening reaches conventional benchmarks for cost-effectiveness even before including the important public health benefit from reduced transmission to sex partners (*86*).

Linking patients who have received a diagnosis of HIV infection to prevention and care is essential. HIV screening without such linkage confers little or no benefit to the patient. Although moving patients into care incurs substantial costs, it also triggers sufficient survival benefits that justify the additional costs. Even if only a limited fraction of patients who receive HIV-positive results are linked to care, the survival benefits per dollar spent on screening represent good comparative value (*26,27,88*).

The benefit of providing prevention counseling in conjunction with HIV testing is less clear. HIV counseling with testing has been demonstrated to be an effective intervention for HIV-infected participants, who increased their safer behaviors and decreased their risk behaviors; HIV counseling and testing as implemented in the studies had little effect on HIV-negative participants (*89*). However, randomized controlled trials have demonstrated that the nature and duration of prevention counseling might influence its effectiveness (*90,91*). Carefully controlled, theory-based prevention counseling in STD clinics has helped HIV-negative participants reduce their risk behaviors compared with participants who received only a didactic prevention message from health-care providers (*90*). A more intensive intervention among HIV-negative MSM at high risk, consisting of 10 theory-based individual counseling sessions followed by maintenance sessions every 3 months, resulted in reductions in unprotected sex with partners who were HIV infected or of unknown status, compared with MSM who received structured prevention counseling only twice yearly (*91*).

Timely access to diagnostic HIV test results also improves health outcomes. Diagnostic testing in health-care settings continues to be the mechanism by which nearly half of new HIV infections are identified. During 2000--2003, of persons reported with HIV/AIDS who were interviewed in 16 states, 44% were tested for HIV because of illness (*8*). Compared with HIV testing after patients were admitted to the hospital, expedited diagnosis by rapid HIV testing in the ED before admission led to shorter hospital stays, increased the number of patients aware of their HIV status before discharge, and improved entry into outpatient care (*92*). However, at least 28 states have laws or regulations that limit health-care providers' ability to order diagnostic testing for HIV infection if the patient is unable to give consent for HIV testing, even when the test results are likely to alter the patient's diagnostic or therapeutic management (*93*).

Of the 40,000 persons who acquire HIV infection each year, an estimated 40%--90% will experience symptoms of acute HIV infection (*94--96*), and a substantial number will seek medical care.

However, acute HIV infection often is not recognized by primary care clinicians because the symptoms resemble those of influenza, infectious mononucleosis, and other viral illnesses (*97*). Acute HIV infection can be diagnosed by detecting HIV RNA in plasma from persons with a negative or indeterminate HIV antibody test. One study based on national ambulatory medical care surveys estimated that the prevalence of acute HIV infection was 0.5%--0.7% among ambulatory patients who sought care for fever or rash (*98*). Although the long-term benefit of HAART during acute HIV infection has not been established conclusively (*99*), identifying primary HIV infection can reduce the spread of HIV that might otherwise occur during the acute phase of HIV disease (*100,101*).

Perinatal HIV transmission continues to occur, primarily among women who lack prenatal care or who were not offered voluntary HIV counseling and testing during pregnancy. A substantial proportion of the estimated 144--236 perinatal HIV infections in the United States each year can be attributed to the lack of timely HIV testing and treatment of pregnant women (*102*). Multiple barriers to HIV testing have been identified, including language barriers; late entry into prenatal care; health-care providers' perceptions that their patients are at low risk for HIV; lack of time for counseling and testing, particularly for rapid testing during labor and delivery; and state regulations requiring counseling and separate informed consent (*103*). A survey of 653 obstetrical providers in North Carolina suggested that not all health-care providers embrace universal testing of pregnant women; the strength with which providers recommended prenatal testing to their patients and the numbers of women tested depended largely on the providers' perception of the patients' risk behaviors (*21*). Data confirm that testing rates are higher when HIV tests are included in the standard panel of screening tests for all pregnant women (*52*,*69*,*104*). Women also are much more likely to be tested if they perceive that their health-care provider strongly recommends HIV testing (*105*). As universal prenatal screening has become more widespread, an increasing proportion of pregnant women who had undiagnosed HIV infection at the time of delivery were found to have seroconverted during pregnancy (*106*). A second HIV test during the third trimester for women in settings with elevated HIV incidence ($\geq$17 cases per 100,000 person-years) is cost-effective and might result in substantial reductions in mother-to-child HIV transmission (*107*).

Every perinatal HIV transmission is a sentinel health event, signaling either a missed opportunity for prevention or, more rarely, a failure of interventions to prevent perinatal transmission. When these infections occur, they underscore the need for improved strategies to ensure that all pregnant women undergo HIV testing and, if found to be HIV positive, receive proper interventions to reduce their transmission risk and safeguard their health and the health of their infants.

Recommendations for Adults and Adolescents

CDC recommends that diagnostic HIV testing and opt-out HIV screening be a part of routine clinical care in all health-care settings while also preserving the patient's option to decline HIV testing and ensuring a provider-patient relationship conducive to optimal clinical and preventive care. The recommendations are intended for providers in all health-care settings, including hospital EDs, urgent-care clinics, inpatient services, STD clinics or other venues offering clinical STD services, tuberculosis (TB) clinics, substance abuse treatment clinics, other public health clinics, community clinics, correctional health-care facilities, and primary care settings. The guidelines address HIV testing in health-care settings only; they do not modify existing guidelines concerning HIV counseling, testing, and referral for persons at high risk for HIV who seek or receive HIV testing in nonclinical settings (e.g., community-based organizations, outreach settings, or mobile vans) (*9*).

Screening for HIV Infection

- In all health-care settings, screening for HIV infection should be performed routinely for all patients aged 13--64 years. Health-care providers should initiate screening unless prevalence of undiagnosed HIV infection in their patients has been documented to be <0.1%. In the absence of existing data for HIV prevalence, health-care providers should initiate voluntary HIV screening until they establish that the diagnostic yield is <1 per 1,000 patients screened, at which point such screening is no longer warranted.
- All patients initiating treatment for TB should be screened routinely for HIV infection (*108*).
- All patients seeking treatment for STDs, including all patients attending STD clinics, should be screened routinely for HIV during each visit for a new complaint, regardless of whether the patient is known or suspected to have specific behavior risks for HIV infection.

Repeat Screening

- Health-care providers should subsequently test all persons likely to be at high risk for HIV at least annually. Persons likely to be at high risk include injection-drug users and their sex partners, persons who exchange sex for money or drugs, sex partners of HIV-infected persons, and MSM or heterosexual persons who themselves or whose sex partners have had more than one sex partner since their most recent HIV test.
- Health-care providers should encourage patients and their prospective sex partners to be tested before initiating a new sexual relationship.
- Repeat screening of persons not likely to be at high risk for HIV should be performed on the basis of clinical judgment.
- 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.

Consent and Pretest Information

- Screening should be voluntary and undertaken only with the patient's knowledge and understanding that HIV testing is planned.
- Patients should be informed orally or in writing that HIV testing will be performed unless they decline (opt-out screening). Oral or written information should include an explanation of HIV infection and the meanings of positive and negative test results, and the patient should be offered an opportunity to ask questions and to decline testing. With such notification, consent for HIV screening should be incorporated into the patient's general informed consent for medical care on the same basis as are other screening or diagnostic tests; a separate consent form for HIV testing is not recommended.
- Easily understood informational materials should be made available in the languages of the commonly encountered populations within the service area. The competence of interpreters and bilingual staff to provide language assistance to patients with limited English proficiency must be ensured.
- If a patient declines an HIV test, this decision should be documented in the medical record.

Diagnostic Testing for HIV Infection

- All patients with signs or symptoms consistent with HIV infection or an opportunistic illness characteristic of AIDS should be tested for HIV.
- Clinicians should maintain a high level of suspicion for acute HIV infection in all patients who have a compatible clinical syndrome and who report recent high-risk behavior. When acute retroviral syndrome is a possibility, a plasma RNA test should be used in conjunction with an HIV antibody test to diagnose acute HIV infection (*96*).

- Patients or persons responsible for the patient's care should be notified orally that testing is planned, advised of the indication for testing and the implications of positive and negative test results, and offered an opportunity to ask questions and to decline testing. With such notification, the patient's general consent for medical care is considered sufficient for diagnostic HIV testing.

Similarities and Differences Between Current and Previous Recommendations for Adults and Adolescents

Aspects of these recommendations that remain unchanged from previous recommendations are as follows:

- HIV testing must be voluntary and free from coercion. Patients must not be tested without their knowledge.
- HIV testing is recommended and should be routine for persons attending STD clinics and those seeking treatment for STDs in other clinical settings.
- Access to clinical care, prevention counseling, and support services is essential for persons with positive HIV test results.

Aspects of these recommendations that differ from previous recommendations are as follows:

- Screening after notifying the patient that an HIV test will be performed unless the patient declines (opt-out screening) is recommended in all health-care settings. Specific signed consent for HIV testing should not be required. General informed consent for medical care should be considered sufficient to encompass informed consent for HIV testing.
- Persons at high risk for HIV should be screened for HIV at least annually.
- HIV test results should be provided in the same manner as results of other diagnostic or screening tests.
- Prevention counseling should not be required as a part of HIV screening programs in health-care settings. Prevention counseling is strongly encouraged for persons at high risk for HIV in settings in which risk behaviors are assessed routinely (e.g., STD clinics) but should not have to be linked to HIV testing.
- HIV diagnostic testing or screening to detect HIV infection earlier should be considered distinct from HIV counseling and testing conducted primarily as a prevention intervention for uninfected persons at high risk.

Recommendations for Pregnant Women

These guidelines reiterate the recommendation for universal HIV screening early in pregnancy but advise simplifying the screening process to maximize opportunities for women to learn their HIV status during pregnancy, preserving the woman's option to decline HIV testing, and ensuring a provider-patient relationship conducive to optimal clinical and preventive care. All women should receive HIV screening consistent with the recommendations for adults and adolescents. HIV screening should be a routine component of preconception care, maximizing opportunities for all women to know their HIV status before conception (*109*). In addition, screening early in pregnancy enables HIV-infected women and their infants to benefit from appropriate and timely interventions (e.g., antiretroviral medications [*43*], scheduled cesarean delivery [*44*], and avoidance of breastfeeding* [*46*]). These recommendations are intended for clinicians who provide care to pregnant women and newborns and for health policy makers who have responsibility for these populations.

HIV Screening for Pregnant Women and Their Infants

Universal Opt-Out Screening

- All pregnant women in the United States should be screened for HIV infection.
- Screening should occur after a woman is notified that HIV screening is recommended for all pregnant patients and that she will receive an HIV test as part of the routine panel of prenatal tests unless she declines (opt-out screening).
- HIV testing must be voluntary and free from coercion. No woman should be tested without her knowledge.
- Pregnant women should receive oral or 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 and should be offered an opportunity to ask questions and to decline testing.
- No additional process or written documentation of informed consent beyond what is required for other routine prenatal tests should be required for HIV testing.
- If a patient declines an HIV test, this decision should be documented in the medical record.

Addressing Reasons for Declining Testing

- Providers should discuss and address reasons for declining an HIV test (e.g., lack of perceived risk; fear of the disease; and concerns regarding partner violence or potential stigma or discrimination).
- Women who decline an HIV test because they have had a previous negative test result should be informed of the importance of retesting during each pregnancy.
- Logistical reasons for not testing (e.g., scheduling) should be resolved.
- Certain women who initially decline an HIV test might accept at a later date, especially if their concerns are discussed. Certain women will continue to decline testing, and their decisions should be respected and documented in the medical record.

Timing of HIV Testing

- To promote informed and timely therapeutic decisions, health-care providers should test women for HIV as early as possible during each pregnancy. Women who decline the test early in prenatal care should be encouraged to be tested at a subsequent visit.
- A second HIV test during the third trimester, preferably <36 weeks of gestation, is cost-effective even in areas of low HIV prevalence and may be considered for all pregnant women. A second HIV test during the third trimester is recommended for women who meet one or more of the following criteria:
  --- Women who receive health care in jurisdictions with elevated incidence of HIV or AIDS among women aged 15--45 years. In 2004, these jurisdictions included Alabama, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Illinois, Louisiana, Maryland, Massachusetts, Mississippi, Nevada, New Jersey, New York, North Carolina, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Tennessee, Texas, and Virginia.[†]
  --- Women who receive health care in facilities in which prenatal screening identifies at least one HIV-infected pregnant woman per 1,000 women screened.
  --- Women who are known to be at high risk for acquiring HIV (e.g., injection-drug users and their sex partners, women who exchange sex for money or drugs, women who are sex partners of HIV-infected persons, and women who have had a new or more than one sex partner during this pregnancy).

--- Women who have signs or symptoms consistent with acute HIV infection. When acute retroviral syndrome is a possibility, a plasma RNA test should be used in conjunction with an HIV antibody test to diagnose acute HIV infection (*96*).

Rapid Testing During Labor

- Any woman with undocumented HIV status at the time of labor should be screened with a rapid HIV test unless she declines (opt-out screening).
- Reasons for declining a rapid test should be explored (see Addressing Reasons for Declining Testing).
- Immediate initiation of appropriate antiretroviral prophylaxis (*42*) should be recommended to women on the basis of a reactive rapid test result without waiting for the result of a confirmatory test.

Postpartum/Newborn Testing

- When a woman's HIV status is still unknown at the time of delivery, she should be screened immediately postpartum with a rapid HIV test unless she declines (opt-out screening).
- When the mother's HIV status is unknown postpartum, rapid testing of the newborn as soon as possible after birth is recommended so antiretroviral prophylaxis can be offered to HIV-exposed infants. Women should be informed that identifying HIV antibodies in the newborn indicates that the mother is infected.
- For infants whose HIV exposure status is unknown and who are in foster care, the person legally authorized to provide consent should be informed that rapid HIV testing is recommended for infants whose biologic mothers have not been tested.
- The benefits of neonatal antiretroviral prophylaxis are best realized when it is initiated $\leq$12 hours after birth (*110*).

Confirmatory Testing

- Whenever possible, uncertainties regarding laboratory test results indicating HIV infection status should be resolved before final decisions are made regarding reproductive options, antiretroviral therapy, cesarean delivery, or other interventions.
- If the confirmatory test result is not available before delivery, immediate initiation of appropriate antiretroviral prophylaxis (*42*) should be recommended to any pregnant patient whose HIV screening test result is reactive to reduce the risk for perinatal transmission.

Similarities and Differences Between Current and Previous Recommendations for Pregnant Women and Their Infants

Aspects of these recommendations that remain unchanged from previous recommendations are as follows:

- Universal HIV testing with notification should be performed for all pregnant women as early as possible during pregnancy.
- HIV screening should be repeated in the third trimester of pregnancy for women known to be at high risk for HIV.
- Providers should explore and address reasons for declining HIV testing.
- Pregnant women should receive appropriate health education, including information regarding HIV and its transmission, as a routine part of prenatal care.

- Access to clinical care, prevention counseling, and support services is essential for women with positive HIV test results.

Aspects of these recommendations that differ from previous recommendations are as follows:

- HIV screening should be included in the routine panel of prenatal screening tests for all pregnant women. Patients should be informed that HIV screening is recommended for all pregnant women and that it will be performed unless they decline (opt-out screening).
- Repeat HIV testing in the third trimester is recommended for all women in jurisdictions with elevated HIV or AIDS incidence and for women receiving health care in facilities with at least one diagnosed HIV case per 1,000 pregnant women per year.
- Rapid HIV testing should be performed for all women in labor who do not have documentation of results from an HIV test during pregnancy. Patients should be informed that HIV testing is recommended for all pregnant women and will be performed unless they decline (opt-out screening). Immediate initiation of appropriate antiretroviral prophylaxis should be recommended on the basis of a reactive rapid HIV test result, without awaiting the result of confirmatory testing.

Additional Considerations for HIV Screening

Test Results

- **Communicating test results.** The central goal of HIV screening in health-care settings is to maximize the number of persons who are aware of their HIV infection and receive care and prevention services. Definitive mechanisms should be established to inform patients of their test results. HIV-negative test results may be conveyed without direct personal contact between the patient and the health-care provider. Persons known to be at high risk for HIV infection also should be advised of the need for periodic retesting and should be offered prevention counseling or referred for prevention counseling. HIV-positive test results should be communicated confidentially through personal contact by a clinician, nurse, mid-level practitioner, counselor, or other skilled staff. Because of the risk of stigma and discrimination, family or friends should not be used as interpreters to disclose HIV-positive test results to patients with limited English proficiency. Active efforts are essential to ensure that HIV-infected patients receive their positive test results and linkage to clinical care, counseling, support, and prevention services. If the necessary expertise is not available in the health-care venue in which screening is performed, arrangements should be made to obtain necessary services from another clinical provider, local health department, or community-based organization. Health-care providers should be aware that the Privacy Rule under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits use or disclosure of a patient's health information, including HIV status, without the patient's permission.
- **Rapid HIV tests.** Because of the time that elapses before results of conventional HIV tests are available, providing patients with their test results can be resource intensive and challenging for screening programs, especially in episodic care settings (e.g., EDs, urgent-care clinics, and STD clinics) in which continuing relationships with patients typically do not exist. The use of rapid HIV tests can substantially decrease the number of persons who fail to learn their test results and reduce the resources expended to locate persons identified as HIV infected. Positive rapid HIV test results are preliminary and must be confirmed before the diagnosis of HIV infection is established (*111*).
- **Participants in HIV vaccine trials.** Recipients of preventive HIV vaccines might have vaccine-induced antibodies that are detectable by HIV antibody tests. Persons whose test results are HIV positive and who are identified as vaccine trial participants might not be

infected with HIV and should be encouraged to contact or return to their trial site or an associated trial site for the confirmatory testing necessary to determine their HIV status.

- **Documenting HIV test results.** Positive or negative HIV test results should be documented in the patient's confidential medical record and should be readily available to all health-care providers involved in the patient's clinical management. The HIV test result of a pregnant woman also should be documented in the medical record of her infant. If the mother's HIV test result is positive, maternal health-care providers should, after obtaining consent from the mother, notify pediatric care providers of the impending birth of an HIV-exposed infant and of any anticipated complications. If HIV is diagnosed in the infant first, health-care providers should discuss the implications for the mother's health and help her to obtain care.

Clinical Care for HIV-Infected Persons

Persons with a diagnosis of HIV infection need a thorough evaluation of their clinical status and immune function to determine their need for antiretroviral treatment or other therapy. HIV-infected persons should receive or be referred for clinical care promptly, consistent with USPHS guidelines for management of HIV-infected persons (*96*). HIV-exposed infants should receive appropriate antiretroviral prophylaxis to prevent perinatal HIV transmission as soon as possible after birth (*42*) and begin trimethoprim-sulfamethoxazole prophylaxis at age 4--6 weeks to prevent *Pneumocystis* pneumonia (*112*). They should receive subsequent clinical monitoring and diagnostic testing to determine their HIV infection status (*113*).

Partner Counseling and Referral

When HIV infection is diagnosed, health-care providers should strongly encourage patients to disclose their HIV status to their spouses, current sex partners, and previous sex partners and recommend that these partners be tested for HIV infection. Health departments can assist patients by notifying, counseling, and providing HIV testing for partners without disclosing the patient's identity (*114*). Providers should inform patients who receive a new diagnosis of HIV infection that they might be contacted by health department staff for a voluntary interview to discuss notification of their partners.

Special Considerations for Screening Adolescents

Although parental involvement in an adolescent's health care is usually desirable, it typically is not required when the adolescent consents to HIV testing. However, laws concerning consent and confidentiality for HIV care differ among states (*79*). Public health statutes and legal precedents allow for evaluation and treatment of minors for STDs without parental knowledge or consent, but not every state has defined HIV infection explicitly as a condition for which testing or treatment may proceed without parental consent. Health-care providers should endeavor to respect an adolescent's request for privacy (*79*). HIV screening should be discussed with all adolescents and encouraged for those who are sexually active. Providing information regarding HIV infection, HIV testing, HIV transmission, and implications of infection should be regarded as an essential component of the anticipatory guidance provided to all adolescents as part of primary care (*79*).

Prevention Services for HIV-Negative Persons

- **Risk screening.** HIV screening should not be contingent on an assessment of patients' behavioral risks. However, assessment of risk for infection with HIV and other STDs and provision of prevention information should be incorporated into routine primary care of all sexually active persons when doing so does not pose a barrier to HIV testing. Even when risk

information is not sought, notifying a patient that routine HIV testing 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., MSM or heterosexuals 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 prevention counseling).

- **Prevention counseling.** In health-care settings, prevention counseling need not be linked explicitly to HIV testing. However, because certain patients might be more likely to think about HIV and consider their risks at the time of HIV testing, testing might present an ideal opportunity to provide or arrange for prevention counseling to assist with behavior changes that can reduce risks for acquiring HIV infection. Prevention counseling should be offered or made available through referral in all health-care facilities serving patients at high risk for HIV and at facilities (e.g., STD clinics) in which information on HIV risk behaviors is elicited routinely.

HIV/AIDS Surveillance

- **Risk-factor ascertainment for HIV-infected persons.** CDC recommends that providers ascertain and document all known HIV risk factors (*115*). Health-care providers can obtain tools and materials to assist with ascertainment and receive guidance on risk factors as defined for surveillance purposes from HIV/AIDS surveillance professionals in their state or local health jurisdiction. This risk-factor information is important for guiding public health decisions, especially for prevention and care, at clinical, local, state, and national levels.
- **HIV/AIDS case reporting.** All states require that health-care providers report AIDS cases and persons with a diagnosis of HIV infection to the state or local health department. Case report forms are available from the state or local health jurisdiction.
- **Pediatric exposure reporting.** CDC and the Council for State and Territorial Epidemiologists recommend that all states and territories conduct surveillance for perinatal HIV exposure and contact providers after receiving reports of exposed infants to determine the infant's HIV-infection status. Information concerning dates of maternal HIV tests, receipt of prenatal care, maternal and neonatal receipt of antiretroviral drugs, mode of delivery, and breastfeeding is collected on the pediatric HIV/AIDS case report form (*115*).

Monitoring and Evaluation

Recommended thresholds for screening are based on estimates of the prevalence of undiagnosed HIV infection in U.S. health-care settings, for which no accurate recent data exist. The optimal frequency for retesting is not yet known. Cost-effectiveness parameters for HIV screening were based on existing program models, all of which include a substantial counseling component, and did not consistently consider secondary infections averted as a benefit of screening. To assess the need for revised thresholds for screening adults and adolescents or repeat screening of pregnant women and to confirm their continued effectiveness, screening programs should monitor the yield of new diagnoses of HIV infection, monitor costs, and evaluate whether patients with a diagnosis of HIV infection are linked to and remain engaged in care. With minor modifications, laboratory information systems might provide a practical alternative for clinicians to use in determining HIV prevalence among their patients who are screened for HIV.

Primary Prevention and HIV Testing in Nonclinical Settings

These revised recommendations are designed to increase HIV screening in health-care settings.

Often, however, the population most at risk for HIV includes persons who are least likely to interact with the conventional health-care system (*47*,*116*). The need to maintain primary prevention activities, identify persons at high risk for HIV who could benefit from prevention services, and provide HIV testing for persons who are at high risk for HIV in nonclinical venues remains undiminished. New approaches (e.g., enlisting HIV-infected persons and HIV-negative persons at high risk for HIV to recruit persons from their social, sexual, and drug-use networks for counseling, testing, and referral) have demonstrated considerable efficacy for identifying persons who were previously unaware of their HIV infection (*117*).

Regulatory and Legal Considerations

These public health recommendations are based on best practices and are intended to comply fully with the ethical principles of informed consent (*67*). Legislation related to HIV and AIDS has been enacted in every state and the District of Columbia (*118*), and specific requirements related to informed consent and pretest counseling differ among states (*119*). Certain states, local jurisdictions, or agencies might have statutory or other regulatory impediments to opt-out screening, or they might impose other specific requirements for counseling, written consent, confirmatory testing, or communicating HIV test results that conflict with these recommendations. Where such policies exist, jurisdictions should consider strategies to best implement these recommendations within current parameters and consider steps to resolve conflicts with these recommendations.

Other Guidelines

Issues that fall outside the scope of these recommendations are addressed by other USPHS guidelines (Box 1). Because concepts relevant to HIV management evolve rapidly, USPHS updates recommendations periodically. Current updates are available from the National Institutes of Health at http://AIDSinfo.nih.gov. Additional guidelines have been published by CDC and the U.S. Department of Health and Human Services, Office for Civil Rights (Box 2).

Acknowledgment

Ida M. Onorato, MD, Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (proposed), contributed to the writing and revision of this report.

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* To eliminate the risk for postnatal transmission, HIV-infected women in the United States should not breastfeed. Support services for use of appropriate breast milk substitutes should be provided when necessary. In international settings, UNAIDS and World Health Organization recommendations for HIV and breastfeeding should be followed (*46*).

† A second HIV test in the third trimester is as cost-effective as other common health interventions when HIV incidence among women of childbearing age is ≥17 HIV cases per 100,000 person-years (*107*). In 2004, in jurisdictions with available data on HIV case rates, a rate of 17 new HIV diagnoses per year per 100,000 women aged 15--45 years was associated with an AIDS case rate of at least nine AIDS diagnoses per year per 100,000 women aged 15--45 years (CDC, unpublished data, 2005). As of 2004, the jurisdictions listed above exceeded these thresholds. The list of specific jurisdictions where a second test in the third trimester is recommended will be updated periodically based on surveillance data.

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Box 1

BOX 1. Recent U.S. Public Health Service HIV treatment guidelines

- Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents
- Guidelines for the use of antiretroviral agents in pediatric HIV infection
- Recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV-1 transmission

SOURCE: National Institutes of Health, Bethesda, Maryland. Available at http://AIDSinfo.nih.gov.

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Box 2

BOX 2. Other guidelines and recommendations

- CDC. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis. MMWR 2005;54(No. RR-9):1–17.
- CDC. Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States: recommendations from the U.S. Department of Health and Human Services. MMWR 2005;54(No. RR-2):1–20.
- CDC. Incorporating HIV prevention into the medical care of persons living with HIV: recommendations of CDC, the Health Resources and Services Administration, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. MMWR 2003;52(No. RR-12):1–24.
- US Department of Health and Human Services, Office for Civil Rights. National standards to protect the privacy of personal health information. Available at http://www.hhs.gov/ocr/hipaa.
- US Department of Health and Human Services, Office for Civil Rights. Guidance to federal financial assistance recipients regarding Title VI prohibition against national origin discrimination affecting limited English proficient persons. Available at http://www.hhs.gov/ocr/lep/revisedlep.html.

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Date last reviewed: 9/12/2006

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