Screening for HIV: Recommendation Statement: United States Preventive Services Task Force

United States Preventive Services Task Force

Citation

Abstract

This statement summarizes the USPSTF recommendations on screening for HIV and the supporting scientific evidence, and updates the 1996 recommendations contained in the Guide to Clinical Preventive Services, second edition ($_1$). Explanations of the ratings and of the strength of overall evidence are given in Appendix A and Appendix B, respectively. The complete information on which this statement is based, including evidence tables and references, is included in the summaries of evidence ($_{49}$, $_{50}$) and evidence syntheses ($_{51}$, $_{52}$) on this topic, available through the USPSTF Web site (http://www.preventiveservices.ahrq.gov). The recommendation is also posted on the Web site of the National Guideline Clearinghouse™ (http://www.guideline.gov). Recommendations made by the USPSTF are independent of the U.S. Government. They should not be construed as an official position of AHRQ or the U.S. Department of Health and Human Services. This recommendation statement was first published in Ann Intern Med. 2005;143:32-37.

Figure 3

Agency for Healthcare Research and Quality

Figure 2

US Department of Health and Human Services

SUMMARY OF RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians screen for human immunodeficiency virus (HIV) all adolescents and adults at increased risk for HIV infection (see Clinical Considerations for discussion of risk factors). A recommendation.

The USPSTF found good evidence that both standard and U.S. Food and Drug Administration (FDA)-approved rapid screening tests accurately detect HIV infection. The USPSTF also found good evidence that appropriately timed interventions, particularly highly active antiretroviral therapy (HAART), lead to improved health outcomes for many of those screened, including reduced risk for clinical progression and reduced mortality. Since false-positive test

results are rare, harms associated with HIV screening are minimal. Potential harms of true-positive test results include increased anxiety, labeling, and effects on close relationships. Most adverse events associated with HAART, including metabolic disturbances associated with an increased risk for cardiovascular events, may be ameliorated by changes in regimen or appropriate treatment. The USPSTF concluded that the benefits of screening individuals at increased risk substantially outweigh potential harms.

The USPSTF makes no recommendation for or against routinely screening for HIV adolescents and adults who are not at increased risk for HIV infection (see Clinical Considerations for discussion of risk factors). C recommendation.

The USPSTF found fair evidence that screening adolescents and adults not known to be at increased risk for HIV can detect additional individuals with HIV, and good evidence that appropriately timed interventions, especially HAART, lead to improved health outcomes for some of these individuals. However, the yield of screening persons without risk factors would be low, and potential harms associated with screening have been noted (see above). The USPSTF concluded that the benefit of screening adolescents and adults without risk factors for HIV is too small relative to potential harms to justify a general recommendation.

The USPSTF recommends that clinicians screen all pregnant women for HIV. A recommendation.

The USPSTF found good evidence that both standard and FDA-approved rapid screening tests accurately detect HIV infection in pregnant women and fair evidence that introduction of universal prenatal counseling and voluntary testing increases the proportion of HIV-infected women who are diagnosed and are treated before delivery. There is good evidence that recommended regimens of HAART are acceptable to pregnant women and lead to significantly reduced rates of mother-to-child transmission. Early detection of maternal HIV infection also allows for discussion of elective cesarean section and avoidance of breastfeeding, both of which are associated with lower HIV transmission rates. There is no evidence of an increase in fetal anomalies or other fetal harm associated with currently recommended antiretroviral regimens (with the exception of efavirenz; see below). Serious or fatal maternal events are rare using currently recommended combination therapies. The USPSTF concluded that the benefits of screening all pregnant women substantially outweigh potential harms.

BACKGROUND

In 1996, the USPSTF recommended routine counseling and screening for all persons at increased risk for HIV infection (an "A" recommendation) and routine counseling and screening for high-risk pregnant women, as well as those residing in communities where the prevalence of seropositive newborns is increased (an "A" recommendation) [1]. At that time, the USPSTF found insufficient evidence to recommend for or against routine HIV screening for persons without identified risk factors (a "C" recommendation) and insufficient evidence to recommend for or against universal prenatal screening in low-prevalence communities (a "C" recommendation). Testing infants born to high risk mothers was recommended when the antibody status of the mother is unknown (a "B" recommendation). Since then, the USPSTF approach to making recommendations has changed [2] and significant new evidence on screening for and treating HIV infection has been published in the medical literature. Therefore, this recommendation statement has been updated and revised based on a new review of the literature, using the current USPSTF methodology.

CLINICAL CONSIDERATIONS

- A person is considered at increased risk for HIV infection (and thus should be offered HIV testing) if he or she reports 1 or more individual risk factors or receives health care in a high-prevalence or high-risk clinical setting.

- Individual risk for HIV infection is assessed through a careful patient history. Those at increased risk (as determined by prevalence rates) include: men who have had sex with men after 1975; men and women having unprotected sex with multiple partners; past or present injection drug users; men and women who exchange sex for money or drugs or have sex partners who do; individuals whose past or present sex partners were HIV-infected, bisexual, or injection drug users; persons being treated for sexually transmitted diseases (STDs); and persons with a history of blood transfusion between 1978 and 1985. Persons who request an HIV test despite reporting no individual risk factors may also be considered at increased risk, since this group is likely to include individuals not willing to disclose high risk behaviors.

- There is good evidence of increased yield from routine HIV screening of persons who report no individual risk factors but are seen in high-risk or high-prevalence clinical settings. High-risk settings include STD clinics, correctional facilities, homeless shelters, tuberculosis clinics, clinics serving men who have sex with men, and adolescent health clinics with a high prevalence of STDs. High-prevalence settings are defined by the Centers for Disease Control and Prevention (CDC) as those known to have a 1% or greater prevalence of infection among the patient population being served. Where possible, clinicians should consider the prevalence of HIV infection or the risk characteristics of the population they serve in determining an appropriate screening strategy. Data are currently lacking to guide clinical decisions about the optimal frequency of HIV screening.

- Current evidence supports the benefit of identifying and treating asymptomatic individuals in immunologically advanced stages of HIV disease (CD4 cell counts < 200 cells/mm3) with HAART. Appropriate prophylaxis and immunization against certain opportunistic infections have also been shown to be effective interventions for these individuals. Use of HAART can be considered for asymptomatic individuals who are in an earlier stage of disease but at high risk for disease progression (CD4 cell count < 350 cells/mm3 or viral load >100,000 copies/mL), although definitive evidence of a significant benefit of starting HAART at these counts is currently lacking.

- The standard test for diagnosing HIV infection, the repeatedly reactive enzyme immunoassay followed by confirmatory western blot or immunofluorescent assay, is highly accurate (sensitivity and specificity ? 99%). Rapid HIV antibody testing is also highly accurate; can be performed in 10 to 30 minutes; and, when offered at the point of care, is useful for screening high risk patients who do not receive regular medical care (eg, those seen in emergency departments), as well as women with unknown HIV status who present in active labor.

- Early identification of maternal HIV seropositivity allows early antiretroviral treatment to prevent mother-to-child transmission, allows providers to avoid obstetric practices that may increase the risk for transmission, and allows an opportunity to counsel the mother against breastfeeding (also known to increase the risk for transmission). There is evidence that the adoption of "opt-out" strategies to screen pregnant women (who are informed that an HIV test will be conducted as a standard part of prenatal care unless they decline it) has resulted in higher testing rates. However, ethical and legal concerns of not obtaining specific informed consent for an HIV test using the "opt-out" strategy have been raised. While dramatic reductions in HIV transmission to neonates have been noted as a result of early prenatal detection and treatment, the extent to which detection of HIV infection and intervention during pregnancy may improve long-term maternal outcomes is unclear.

DISCUSSION

Of the estimated 850,000 to 950,000 persons in the United States infected with HIV-1, 25% are thought to be unaware of their status ([3], [4]). If untreated, almost all infected individuals will eventually develop acquired immunodeficiency syndrome (AIDS), defined by opportunistic infection or severe immune dysfunction. Despite significant recent advances in treatment, AIDS is the seventh leading cause of death in persons aged 15 to 24 years, and the fifth leading cause of death in persons aged 25 to 44 years in the United States ([5]).

HIV incidence rates (an estimated 40,000 new infections annually) have remained steady in the United States over the last decade ([6]). This figure includes infection via mother-to-child (vertical) transmission, with approximately 300 infants infected each year. Women are the fastest-growing group of persons with new HIV diagnoses, and an estimated 6,000 to 7,000 HIV-positive women give birth each year in the United States ([7], [8]). Effective interventions are available to reduce rates of vertical transmission for women diagnosed with HIV infection. However, in 2000, 40% of infected infants were born to mothers not known to have HIV infection before delivery ([9]).

To update its 1996 recommendations on HIV screening, the USPSTF examined the evidence from 1983 through June 2004 on the benefits and harms of screening and of currently available interventions for HIV infection in adults,

adolescents, and pregnant women. Relevant studies on risk factor assessment and the accuracy and acceptability of testing were also reviewed.

The USPSTF review found that standard testing for HIV infection has a sensitivity and specificity greater than 99% and that false-positive test results are rare, even in low risk settings ([10], [11]). While indeterminate results may occur a little more frequently among parous and pregnant women, the diagnostic accuracy of standard HIV testing is thought to be similar for pregnant women and non-pregnant women and men ([12]). Alternative FDA-approved screening technologies are also highly accurate and may increase testing acceptability. Compared with standard HIV testing, the reported sensitivities of rapid tests on blood specimens range from 96% to 100%, with specificities greater than 99.9% ([13],[14],[15]). Reported sensitivities and specificities of oral fluid HIV tests are also high (> 99%), although the diagnostic accuracy of urine tests appears lower than that of standard testing ([16], [17]). One good-quality study of the only FDA-approved home collection kit, using finger-stick blood spot samples, found it to be highly accurate compared with standard testing ([18]).

A large, good-quality U.S. study found that risk factor assessment can identify individuals at substantially higher risk for HIV, but still misses a significant proportion (20% to 26%) of HIV-positive clients who report no risk factors ([19]) (since some patients may choose not to disclose high risk behaviors and others, especially women, may be unknowingly at risk from an infected sex partner) ([20]). There is fair evidence to indicate that a broader strategy targeted to individuals who report risk factors, combined with routine (voluntary) testing of those being seen in high-prevalence clinical settings, would result in substantially fewer missed diagnoses ([21],[22],[23]). In 2 good-quality studies, HIV screening of populations with a 1% prevalence rate was found to be cost-effective (in terms of acceptable cost per quality-adjusted life-year) compared with no screening ([24], [25]). One study ([25]) found that screening populations with even lower prevalence rates is also cost-effective if one assumes secondary transmission benefits. Neither study, however, reported on the incremental cost-effectiveness of screening lower-risk versus higher-risk patients.

The wide adoption in 1995 to1997 of the use of HAART regimens with 3 or more antiretroviral agents has been associated with a marked decline in morbidity and mortality of HIV-infected patients in the United States ([3]). Good

quality evidence has shown HAART regimens to be consistently effective in reducing clinical progression and mortality in persons with CD4 cell counts less than 200 cells/mm^3 ([26], [27]); the percentage of patients found in studies to be candidates for HAART regimens at the time of HIV diagnosis has ranged from 12% to 43% ([20], [28]). In addition, 2 good-quality systematic reviews found that the use of antibiotic medication to prevent opportunistic infections (eg, Pneumocystis carinii pneumonia and disseminated Mycobacterium avium-intracellulare complex) is effective in persons with advanced disease ([29], [30]). Theoretically, asymptomatic patients in an earlier stage of disease at the time of diagnosis (CD4 cell counts between 200-350 cells/mm^3 or viral load >100,000 copies/mL) may also benefit from HAART regimens. However, there are no completed trials showing clinical benefit from treatment versus no treatment in such patients. Data from the Strategies for Management of Anti-Retroviral Therapy (SMART) trial, which focuses on this group, will not be available for a few more years.

The standard of care in the United States for preventing vertical HIV transmission in seropositive pregnant women has evolved from monotherapy (zidovudine) to combination antiretroviral regimens, including HAART regimens, starting at 14 to 34 weeks' gestation through labor and augmented with 6 weeks of neonatal prophylaxis with zidovudine ([31]). Avoidance of breastfeeding is recommended for seropositive women since observational studies have shown that breastfeeding increases transmission rates even when adjusted for other factors, including antiretroviral use. A good-quality randomized clinical trial has demonstrated that elective cesarean section also reduces vertical transmission, compared with other modes of delivery, by minimizing contact between the fetus and infected maternal bodily fluids ([32]), although the benefit appears small in women with undetectable viral loads. There is fair to good evidence that the newer regimens, in combination with formula feeding and elective cesarean delivery, are associated with a reduction in perinatal transmission of 14% to 25% without interventions to 1% to 2% with interventions.

Information about the consequences of false-positive HIV test results (ie, anxiety, labeling) is mostly anecdotal, although true-positive HIV test results have been shown to result in anxiety, depression, social stigmatization, changes in relationships with sexual partners, and discrimination ([33]). Evidence suggests that persons testing positive for HIV

(especially heterosexual serodiscordant couples) are more likely than others to avoid risky sexual behavior. On the other hand, optimistic beliefs about the effectiveness of HAART regimens have been shown to be associated with increased risky behaviors in individuals known to be seropositive [34, 35]. All antiretroviral drugs and drug combinations are associated with specific harm profiles, although most harms are short term or self limited and effective alternatives can often be found [36]. Metabolic disturbances (hyperlipidemia and diabetes) related to HAART regimens have been associated with an increased incidence of cardiovascular events, especially with longer exposure [37]. The estimated 3-year benefits of HAART regimens appear, however, to greatly outweigh the cardiovascular complications.

No significant increases in the rates of congenital anomalies, neonatal conditions, or other fetal harm have been associated with in utero exposure to FDA-approved regimens of antiretroviral drugs [38], with the exception of those including efavirenz. Efavirenz has recently been re-classified as Class D in pregnancy (positive evidence of human fetal risk). Although studies have demonstrated no ill effects of limited exposure to zidovudine monotherapy in women followed postpartum for as long as 6 years, no studies have evaluated the effects of limited exposure to combination antiretroviral drugs during pregnancy on the long-term clinical outcomes of HIV-infected women.

RECOMMENDATIONS OF OTHER GROUPS

Counseling and HIV testing of high risk individuals (as defined in the Clinical Considerations section) are recommended by the CDC [39], the Canadian Task Force on the Periodic Health Examination (now the Canadian Task Force on Preventive Health Care) [40], and numerous professional organizations, including the American Medical Association (AMA) [41], the American Academy of Family Physicians (AAFP) [42], the American College of Obstetricians and Gynecologists (ACOG) [43], the American College of Physicians (ACP) [44], and the Infectious Diseases Society of America (IDSA) [45]. Also, the American Academy of Pediatrics (AAP) [46] considers all sexually active adolescents to be a high risk group and recommends they be counseled and offered HIV testing. In addition, the CDC recommends that routine, voluntary testing be offered to all patients seen either in health care facilities where the prevalence of HIV infection is 1% or greater or in settings serving client populations at increased behavioral or clinical HIV risk.

The CDC, AMA, AAFP, ACOG, IDSA, AAP [47] and the American College of Nurse-Midwives [48] recommend that all pregnant women be routinely counseled and encouraged to have HIV testing. ACOG, AAP, and the CDC go further in recommending that HIV testing be part of a routine battery of prenatal blood tests unless declined (ie, an "opt-out" approach). The CDC and ACOG also recommend retesting women in their third trimester of pregnancy who are known to be at high risk for acquiring HIV, as well as rapid HIV testing in labor for women with undocumented HIV status.

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APPENDIX A

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS AND RATINGS

The Task Force grades its recommendations according to one of 5 classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms):

A. The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.

B. The USPSTF recommends that clinicians provide [the service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

C. The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.

D. The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that

harms outweigh benefits.

I. The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that [the service] is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

APPENDIX B

U.S. PREVENTIVE SERVICES TASK FORCE STRENGTH OF OVERALL EVIDENCE

The USPSTF grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor):

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor: Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

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