Complete Summary

GUIDELINE TITLE

Screening for HIV: recommendation statement.

BIBLIOGRAPHIC SOURCE(S)

U.S. Preventive Services Task Force. Screening for HIV: recommendation statement. Am Fam Physician 2005 Dec 1;72(11):2287-92. PubMed

US Preventive Services Task Force. Screening for HIV: recommendation statement. Ann Intern Med 2005 Jul 5;143(1):32-7. [48 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previously published guideline: U.S. Preventive Services Task Force. Guide to clinical preventive services. 2nd ed. Baltimore (MD): Williams & Wilkins; 1996. Chapter 28, Screening for human immunodeficiency virus infection. p. 303-24. [159 references]

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Human immunodeficiency virus (HIV) infection

GUIDELINE CATEGORY

Prevention
Screening

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Managed Care Organizations
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To summarize the U.S. Preventive Services Task Force (USPSTF) recommendations on screening for human immunodeficiency virus (HIV) and the supporting scientific evidence
- To update the 1996 recommendations contained in the *Guide to Clinical Preventive Services*, Second Edition

TARGET POPULATION

Asymptomatic adolescents, adults, and pregnant women seen in primary care

INTERVENTIONS AND PRACTICES CONSIDERED

1. Screening for human immunodeficiency virus (HIV) using rapid screening tests among:
    - Adolescents and adults at increased risk (Recommended)
    - Adolescent and adults not at increased risk (No recommendation made for or against routine provision of the service)
    - Pregnant women (Recommended)
2. Treatment interventions discussed but not specifically recommended include:
    - Highly active antiretroviral therapy (HAART)
    - Prenatal counseling regarding elective cesarean and avoidance of breastfeeding

MAJOR OUTCOMES CONSIDERED

Screening for Human Immunodeficiency Virus (HIV) in Asymptomatic Adolescents and Adults

- **Key Question 1**: Does screening for HIV infection in asymptomatic adolescents and adults reduce premature death and disability or spread of disease?
- **Key Question 2**: Can clinical or demographic characteristics (including specific settings) identify subgroups of asymptomatic adolescents and adults at increased risk for HIV compared to the general population?
- **Key Question 3**: What are the test characteristics of HIV antibody test strategies?
- **Key Question 4**: What are the harms (including labeling and anxiety) associated with screening? Is screening acceptable to patients?
- **Key Question 5**: How many newly diagnosed HIV-positive patients meet criteria for antiretroviral treatment or prophylaxis against opportunistic infections? How many patients who meet criteria for interventions receive them?
- **Key Question 6**: What are the harms associated with the work-up for HIV infection?
- **Key Question 7a**: How effective are interventions (antiretroviral treatment, counseling on risky behaviors, immunizations, routine monitoring and follow-up, more frequent Papanicolaou testing, or prophylaxis against opportunistic infections) in improving clinical outcomes (mortality, functional status, quality of life, symptoms, opportunistic infections, or transmission rates)?
- **Key Question 7b**: In asymptomatic patients with HIV infection, does immediate antiretroviral treatment result in improvements in clinical outcomes compared to delayed treatment until the patient is symptomatic?
- **Key Question 7c**: How well do interventions reduce the rate of viremia, improve CD4 counts, or reduce risky behaviors?
- **Key Question 8**: What are the harms associated with antiretroviral therapy?
- **Key Question 9**: Have improvements in intermediate outcomes (CD4 counts, viremia, risky behaviors) been shown to reduce premature death and disability or spread of disease?
- **Key Question 10**: What is the cost-effectiveness of screening for HIV infection? (Excluding pregnant women, patients undergoing dialysis, and patients receiving transplants.)

Prenatal Screening for HIV

- **Key Question 1**: Does screening for HIV in pregnant women reduce mother-to-child transmission or premature death and disability?
- **Key Question 2**: Can clinical or demographic characteristics (including specific settings) identify subgroups of asymptomatic pregnant women at increased risk for HIV infection compared to the general population of pregnant women?
- **Key Question 3**: What are the test characteristics of HIV antibody (HIV ab) test strategies in pregnant women?
- **Key Question 4**: What are the harms (including labeling and anxiety) associated with screening? Is screening acceptable to pregnant women?
- **Key Question 5**: How many HIV-infected pregnant women who meet criteria for interventions receive them?
- **Key Question 6**: What are the harms associated with the work-up for HIV infection in pregnant women?
- **Key Question 7a**: How effective are interventions (antiretroviral prophylaxis [to prevent mother-to-child transmission] or treatment [to improve maternal

outcomes]; avoidance of breastfeeding, elective cesarean section [in selected patients], or other labor management practices; counseling on risky behaviors; immunizations; routine monitoring and follow-up; or prophylaxis against opportunistic infections) in reducing mother-to-child transmission rates or improving clinical outcomes (mortality, functional status, quality of life, symptoms, or opportunistic infections) in pregnant women with HIV infection?

- **Key Question 7b**: Does immediate antiretroviral treatment in HIV-infected pregnant women result in improvements in clinical outcomes compared to delayed treatment until the infected woman becomes symptomatic?
- **Key Question 7c**: How well do interventions reduce the rate of viremia, improve CD4 cell counts, or reduce risky behaviors? How does identification of HIV infection in pregnant women affect future reproductive choices?
- **Key Question 8**: What are the harms (including adverse effects from in utero exposure) associated with antiretroviral drugs and elective cesarean section?
- **Key Question 9**: Have improvements in intermediate outcomes (CD4 cell counts, viremia, or risky behaviors) in HIV-infected pregnant women been shown to improve clinical outcomes or reduce mother-to-child transmission?

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): Systematic reviews of the literature were prepared by the Oregon Evidence-based Practice Center (EPC) and Oregon Health & Science University for the Agency for Healthcare Research and Quality (AHRQ) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Companion Documents" field).

Asymptomatic Adolescents and Adults

The literature search was guided by an analytic framework and key questions developed specifically for screening for human immunodeficiency virus (HIV) in this population. The EPC identified relevant studies from MEDLINE (1983 through 30 June 2004) and the Cochrane Clinical Trials Registry (2004, issue 2), reference lists, hand searches of relevant journals, and suggestions from experts. They selected studies that provided evidence on the benefits and harms of screening, risk factor assessment, accuracy of testing, follow-up testing, interventions, acceptability of HIV testing, and cost-effectiveness of screening in outpatient settings in the highly active antiretroviral therapy (HAART) era. For interventions, they focused on studies of HAART. EPC staff also reviewed studies on the effectiveness of counseling on risky behaviors and prophylaxis against opportunistic infections. (See Appendix A of the companion document "Screening

for HIV: a review of the evidence for the U.S. Preventive Services Task Force" for more information.)

Pregnant Women

The literature search was guided by an analytic framework and key questions developed specifically for screening for HIV in this population. The EPC identified relevant studies from MEDLINE (1983 through 30 June 2004) and the Cochrane Clinical Trials Registry (2004, issue 2), reference lists, hand searches of relevant journals, and suggestions from experts. They selected studies that provided evidence on the benefits and harms of screening, risk factor assessment, follow-up testing, interventions, and the acceptability of prenatal HIV testing. For interventions, EPC staff focused on studies of the safety and effectiveness of antiretroviral prophylaxis. They also reviewed studies on the safety and effectiveness of elective cesarean section and avoidance of breastfeeding. (See Appendix A of the companion document "Prenatal screening for HIV: a review of the evidence for the U.S. Preventive Services Task Force" for more information.)

NUMBER OF SOURCE DOCUMENTS

Asymptomatic Adolescents and Adults

- Key Question #1: None
- Key Question #2: Four studies
- Key Question #3: 16 studies
- Key Question #4: Ten studies
- Key Question #5: 17 studies
- Key Question #6: None
- Key Question #7a (1): Seven studies
- Key Question #7a (2): Four studies
- Key Question #7a (3): Nine studies
- Key Question #7a (4): Eleven studies
- Key Question #7b: Four studies
- Key Question #7c: Eleven studies
- Key Question #8: Two studies
- Key Question #9: Seven studies
- Key Question #10: Two cost-effectiveness analyses

Pregnant Women

- Key Question #1: None
- Key Question #2: Eight studies
- Key Question #3: Three studies
- Key Question #4: Six studies
- Key Question #5: Six studies
- Key Question #6: None
- Key Question #7a (1): Six studies
- Key Question #7a (2): Four studies
- Key Question #7a (3): Four studies
- Key Question #7a (4): None
- Key Question #7a (5): None
- Key Question #7b: None

- Key Question #7c: Five studies
- Key Question #8: Ten studies
- Key Question #9: None

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The U.S. Preventive Services Task Force (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.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): Systematic reviews of the literature were prepared by the Oregon Evidence-based Practice Center (EPC) and Oregon Health & Science University for the Agency for Healthcare Research and Quality (AHRQ) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Companion Documents" field).

Asymptomatic Adolescents and Adults

EPC staff assessed the internal validity and relevance of included studies using predefined criteria developed by the USPSTF (see Appendix C of the companion document "Screening for HIV: a review of the evidence for the U.S. Preventive

Services Task Force"). They rated the overall body of evidence for each key question using the system developed by the USPSTF. The results of the evidence review were used to construct an outcomes table estimating the effects of one-time screening for human immunodeficiency virus (HIV) infection in hypothetical cohorts of adolescents and adults. EPC staff then calculated numbers needed to screen (NNS) and treat (NNT) to prevent 1 case of clinical progression or death or to cause 1 cardiovascular complication for each cohort. The point estimates and 95% CIs for NNS and NNT were based on Monte Carlo simulations.

Pregnant Women

EPC staff assessed the internal validity and relevance of included studies using predefined criteria developed by the USPSTF (see Appendix C of the companion document "Prenatal screening for HIV: a review of the evidence for the U.S. Preventive Services Task Force"). They rated the overall body of evidence for each key question using the system developed by the USPSTF. The results of the evidence review were used to construct an outcomes table estimating the effects of one-time screening for HIV infection in hypothetical cohorts of pregnant women. EPC staff then calculated numbers needed to screen (NNS) and treat (NNT) to prevent 1 case of mother-to-child transmission or to cause 1 complication from interventions. The point estimates and 95% CIs for NNS and NNT were based on Monte Carlo simulations.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Balance Sheets
Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

When the overall quality of the evidence is judged to be good or fair, the U.S. Preventive Services Task Force (USPSTF) proceeds to consider the magnitude of net benefit to be expected from implementation of the preventive service. Determining net benefit requires assessing both the magnitude of benefits and the magnitude of harms and weighing the two.

The USPSTF classifies benefits, harms, and net benefits on a 4-point scale: "substantial," "moderate," "small," and "zero/negative."

"Outcomes tables" (similar to "balance sheets") are the USPSTF's standard resource for estimating the magnitude of benefit. These tables, prepared by the topic teams for use at USPSTF meetings, compare the condition specific outcomes expected for a hypothetical primary care population with and without use of the preventive service. These comparisons may be extended to consider only people of specified age or risk groups or other aspects of implementation. Thus, outcomes tables allow the USPSTF to examine directly how the preventive service affects benefits for various groups.

When evidence on harms is available, the topic teams assess its quality in a manner like that for benefits and include adverse events in the outcomes tables.

When few harms data are available, the USPSTF does not assume that harms are small or nonexistent. It recognizes a responsibility to consider which harms are likely and judge their potential frequency and the severity that might ensue from implementing the service. It uses whatever evidence exists to construct a general confidence interval on the 4-point scale (e.g., substantial, moderate, small, and zero/negative).

Value judgments are involved in using the information in an outcomes table to rate either benefits or harms on the USPSTF's 4-point scale. Value judgments are also needed to weigh benefits against harms to arrive a rating of net benefit.

In making its determinations of net benefit, the USPSTF strives to consider what it believes are the general values of most people. It does this with greater confidence for certain outcomes (e.g., death) about which there is little disagreement about undesirability, but it recognizes that the degree of risk people are willing to accept to avert other outcomes (e.g., cataracts) can vary considerably. When the USPSTF perceives that preferences among individuals vary greatly, and that these variations are sufficient to make trade-off of benefits and harms a "close-call," then it will often assign a C recommendation (see the "Recommendation Rating Scheme" field). This recommendation indicates the decision is likely to be sensitive to individual patient preferences.

The USPSTF uses its assessment of the evidence and magnitude of net benefit to make recommendations. The general principles the USPSTF follows in making recommendations are outlined in Table 5 of the companion document cited below. The USPSTF liaisons on the topic team compose the first drafts of the recommendations and rationale statements, which the full panel then reviews and edits. Recommendations are based on formal voting procedures that include explicit rules for determining the views of the majority.

From: Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) 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.

COST ANALYSIS

Cost-Effectiveness of Screening for Human Immunodeficiency Virus (HIV) Infection

In two good-quality studies, the cost-effectiveness of one-time HIV screening in outpatients with 1% prevalence compared to no screening was $38,000 to $42,000 per quality-adjusted life-year. One of these studies found that the cost-effectiveness improved to $15,000 per quality-adjusted life-year when secondary transmission benefits were directly incorporated into cost-effectiveness ratios, and they remained less than $50,000 per quality-adjusted life-year even when screened populations had HIV prevalences substantially lower than seen in the general population. The other study, which did not directly incorporate secondary transmission benefits into cost-effectiveness ratios, found that the incremental cost-effectiveness of one-time screening in the general population was greater than $100,000 per quality-adjusted life-year.

Neither study incorporated long-term cardiovascular risks associated with highly active antiretroviral therapy (HAART) into their models. One study found that the model was sensitive to the effects of screening on secondary transmission and the benefits of early identification and therapy.

The 1996 U.S. Preventive Services Task Force (USPSTF) guidelines recommended screening persons who report high-risk behaviors. Neither of the two reviewed studies evaluated the incremental cost-effectiveness of a strategy of screening only higher-risk persons compared to broader screening strategies in different populations. One of the studies found that the incremental cost-effectiveness of

testing every 5 years compared to one-time screening exceeded $50,000 per quality-adjusted life-year.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Peer Review. Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center and the Agency for Healthcare Research and Quality send a draft systematic evidence review to 4 to 6 external experts and to federal agencies and professional and disease-based health organizations with interests in the topic. They ask the experts to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the Task Force in memo form. In this way, the Task Force can consider these external comments and a final version of the systematic review before it votes on its recommendations about the service. Draft recommendations are then circulated for comment from reviewers representing professional societies, voluntary organizations, and Federal agencies. These comments are discussed before the whole USPSTF before final recommendations are confirmed.

Recommendation of Others. Recommendations for screening for human immunodeficiency virus (HIV) from the following groups were discussed: the Centers for Disease Control and Prevention (CDC); the Canadian Task Force Preventive Health Care (CTFPHC); the American Medical Association (AMA); the American Academy of Family Physicians (AAFP); the American College of Obstetricians and Gynecologists (ACOG); the American College of Physicians (ACP); the Infectious Diseases Society of American (IDSA); the American Academy of Pediatrics (AAP); and the American College of Nurse-Midwives.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and the quality of the overall evidence for a service (good, fair, poor). The definitions of these grades can be found at the end of the "Major Recommendations" field.

The USPSTF strongly recommends that clinicians screen for human immunodeficiency virus (HIV) all adolescents and adults at increased risk for HIV infection (see Clinical Considerations below 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 in 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. 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 "Potential Harms" field). 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.

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/mm^3) 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 $\geq$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 (e.g., 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.

Definitions:

Strength of Recommendations

The USPSTF 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.

Strength of Evidence

The U.S. Preventive Services Task Force (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.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is identified in the "Major Recommendations" field.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- The U.S. Preventive Services Task Force (USPSTF) found good evidence that both standard and U.S. Food and Drug Administration (FDA)-approved rapid screening tests accurately detect human immunodeficiency virus (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.
- 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.

POTENTIAL HARMS

- Information about the consequences of false-positive human immunodeficiency virus (HIV) test results (i.e., 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. 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 highly active antiretroviral therapy (HAART) regimens have been shown to be associated with increased risky behaviors in individuals known to be seropositive. 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. Metabolic disturbances (hyperlipidemia and diabetes) related to HAART regimens have been associated with an increased incidence of cardiovascular events, especially with longer exposure. 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 U.S. Food and Drug Administration (FDA)-approved regimens of antiretroviral drugs, 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.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Recommendations made by the U.S. Preventive Services Task Force are independent of the U.S. Government. They should not be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the Agency for Healthcare Research and Quality will make all U.S. Preventive Services Task Force (USPSTF) products available through its Web site. The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access U.S. Preventive Services Task Force materials and adapt them for their local needs. Online access to U.S. Preventive Services Task Force products also opens up new possibilities for the appearance of the annual, pocket-size *Guide to Clinical Preventive Services*.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources
Pocket Guide/Reference Cards
Tool Kits

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

U.S. Preventive Services Task Force. Screening for HIV: recommendation statement. Am Fam Physician 2005 Dec 1;72(11):2287-92. PubMed

US Preventive Services Task Force. Screening for HIV: recommendation statement. Ann Intern Med 2005 Jul 5;143(1):32-7. [48 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

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GUIDELINE DEVELOPER(S)

United States Preventive Services Task Force - Independent Expert Panel

SOURCE(S) OF FUNDING

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GUIDELINE COMMITTEE

U.S. Preventive Services Task Force (USPSTF)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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**Members of the USPSTF at the time this recommendation was finalized.* For a list of current Task Force members, go to www.ahrq.gov/clinic/uspstfab.htm.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The U.S. Preventive Services Task Force has an explicit policy concerning conflict of interest. All members and evidence-based practice center (EPC) staff disclose at each meeting if they have an important financial conflict for each topic being discussed. Task Force members and EPC staff with conflicts can participate in discussions about evidence, but members abstain from voting on recommendations about the topic in question.

From: Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previously published guideline: U.S. Preventive Services Task Force. Guide to clinical preventive services. 2nd ed. Baltimore (MD): Williams & Wilkins; 1996. Chapter 28, Screening for human immunodeficiency virus infection. p. 303-24. [159 references]

GUIDELINE AVAILABILITY

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site. Also available from Annals of Internal Medicine Online.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Screening for HIV: a review of the evidence for the U.S. Preventive Services Task Force. Ann Intern Med 2005 Jul; 143(1):55-73. Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site.
- Prenatal screening for HIV: a review of the evidence for the U.S. Preventive Services Task Force. Ann Intern Med 2005 Jul; 143(1):38-54. Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site

Electronic copies are also available from the Annals of Internal Medicine Online.

Background Articles:

- Woolf SH, Atkins D. The evolving role of prevention in health care: contributions of the U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):13-20.
- Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.
- Saha S, Hoerger TJ, Pignone MP, Teutsch SM, Helfand M, Mandelblatt JS. The art and science of incorporating cost effectiveness into evidence-based recommendations for clinical preventive services. Cost Work Group of the Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):36-43.

Electronic copies: Available from U.S. Preventive Services Task Force (USPSTF) Web site.

The following are also available:

- The guide to clinical preventive services, 2006. Recommendations of the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2006. 228 p. Electronic copies available from the AHRQ Web site.
- A step-by-step guide to delivering clinical preventive services: a systems approach. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2002 May. 189 p. Electronic copies available from the AHRQ Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site.

Print copies: Available from the Agency for Healthcare Research and Quality Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

The Electronic Preventive Services Selector (ePSS), available as a PDA application and a web-based tool, is a quick hands-on tool designed to help primary care clinicians identify the screening, counseling, and preventive medication services that are appropriate for their patients. It is based on current recommendations of the USPSTF and can be searched by specific patient characteristics, such as age, sex, and selected behavioral risk factors.

PATIENT RESOURCES

The following are available:

- The pocket guide to good health for adults. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2003. Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site. Copies also available in Spanish from the USPSTF Web site.

  Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

- Summaries for patients. Screening for HIV: U.S. Preventive Services Task Force recommendations. Ann Intern Med 2005 Jul; 143(1):I-30. Electronic copies: Available from the Annals of Internal Med Online Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on June 24, 2005. The information was verified by the guideline developer on July 1, 2005.

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