

Screening for HIV in Health Care Settings: A Guidance Statement From the American College of Physicians and HIV Medicine Association

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Description: The American College of Physicians (ACP) developed this guidance statement to present the available evidence on screening for HIV in health care settings.

Methods: This guidance statement is derived from an appraisal of available guidelines on screening for HIV. Authors searched the National Guideline Clearinghouse to identify guidelines on screening for HIV in the United States and used the AGREE (Appraisal of Guidelines Research and Evaluation) instrument to evaluate guidelines from the U.S. Preventive Services Task Force and the Centers for Disease Control and Prevention.

Guidance Statement 1: ACP recommends that clinicians adopt routine screening for HIV and encourage patients to be tested.

Guidance Statement 2: ACP recommends that clinicians determine the need for repeat screening on an individual basis.

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Human immunodeficiency virus (HIV) infection is a major public health problem worldwide. According to the Centers for Disease Control and Prevention (CDC), an estimated 1 million to 1.18 million persons are living with HIV/AIDS in the United States (1, 2). Of these, 24% to 27% have undiagnosed disease and are unaware of their HIV infection. In 2006, persons age 25 to 44 years accounted for the largest proportion of newly diagnosed HIV/AIDS cases in the United States. The incidence rate for HIV was 56 300 cases in 2006 and has been relatively stable over the past decade (3, 4). Of these new infections, at least 20 000 per year are due to transmission of HIV from persons who are unaware that they are infected (5, 6). Data from the CDC indicate that AIDS develops within 1 year after diagnosis in 38% of HIV-positive patients (2), suggesting that these patients have been infected for many years before diagnosis. In 2005, the estimated number of deaths of persons with AIDS in the United States and dependent areas was 17 011, and the cumulative estimated number of deaths of persons with AIDS through 2005 was 550 394.

Testing for HIV consists of an initial enzyme immunoassay followed by confirmatory Western blot or immuno-fluorescent assay. This test sequence has a sensitivity greater than 99% and a specificity greater than 99.99% (7, 8).

The purpose of this paper is to present the available evidence to internists and other primary care clinicians to guide their decisions of screening for HIV in health care

settings. This guidance statement is derived from an evaluation of the guidelines in the United States on screening for HIV developed by the U.S. Preventive Services Task Force (USPSTF) and the CDC. The target population for this guideline is all adult and adolescent (age > 13 years) patients seen in health care settings. This guidance statement was also endorsed by HIV Medicine Association.

METHODS

The American College of Physicians (ACP) Clinical Efficacy Assessment Subcommittee (CEAS) decided to address the clinical topic areas that the Institute of Medicine (IOM) designated as priorities for improvement (9, 10), as well as clinical issues relevant and important to internal medicine. When multiple guidelines are available on a topic or when existing guidelines conflict, the College believes it is useful to provide clinicians with a rigorous review of the guidelines. Human immunodeficiency virus is a major public health problem in the United States, and

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Table 1. Guideline Selection Criteria**Primary criterion**

There is an explicit link between the recommendations and the supporting evidence (AGREE instrument Q12).

Secondary criteria

Systematic methods were used to search for evidence (AGREE instrument Q8).

The criteria for selecting the evidence are clearly described (AGREE instrument Q9).

The methods used for formulating the recommendations are clearly described (AGREE instrument Q10).

The recommendations are specific and unambiguous (AGREE instrument Q15).

The guideline has been externally reviewed by experts prior to its publication (AGREE instrument Q13).

There are explicit quality criteria used to grade the evidence and recommendations (CEAS criteria).

The quality criteria used by the authors to grade the evidence and recommendations are satisfactory (CEAS criteria).

There is no identifiable bias that might have influenced the selection of evidence (CEAS criteria).

The methods used to combine the results from the relevant literature are clearly described and reported (CEAS criteria).

The authors used satisfactory meta-analytic techniques in the evidence review (CEAS criteria).

Tertiary criterion

Meets all criteria, in particular, good methods and good evidence (CEAS criteria).

AGREE = Appraisal of Guidelines Research and Evaluation; CEAS = Clinical Efficacy Assessment Subcommittee; Q = question.

early identification of HIV is essential for patients to receive the maximum benefit from antiretroviral therapy. Thus, the CEAS developed this guidance statement for ACP members and other clinicians to assess the evidence for screening for HIV in health care.

We followed the AGREE (Appraisal of Guidelines Research and Evaluation) Collaboration method to produce this report (11). The AGREE appraisal instrument asks 23 questions in 6 domains: scope and purpose; stakeholder involvement; rigor of development; clarity and presentation; applicability; and editorial independence. Each guideline is scored in each domain. Before conducting the evaluation, the authors agreed on a method of stratifying the ratings into 3 main categories, outlined in **Table 1**. We did not weight scores according to these 3 categories, but note our findings in our overall qualitative assessment of the guidelines as discussed. Specifically, we viewed a lack of an explicit link between evidence and recommendations as a major flaw that makes it difficult to determine whether the guideline recommendations are valid. A second tier of criteria included whether there was a systematic search and explicit criteria for selecting evidence and whether methods for formulating recommendations were described. The remaining AGREE criteria were considered as part of the overall score.

We began by searching the National Guideline Clearinghouse for guidelines on HIV. We reviewed the titles and abstracts of each document. Most of these guidelines

did not address screening for HIV. We also excluded guidelines that were simply restating guidelines from other organizations. We identified 2 guidelines from American College of Obstetricians and Gynecologists (12, 13), which recommended universal screening in women between 19 and 64 years of age. We did not include these guidelines in our review because they did not explicitly review the evidence (12, 13). We selected the 2 major guidelines on screening for HIV developed in the United States: guidelines from the USPSTF (14) and CDC (15). These guidelines were reviewed independently by 4 co-authors using the AGREE method, with a focus on the 3 major categories that the guiding committee viewed as important. Each guideline was scored, and scores were compared (**Table 2**). Although total quantitative scores varied somewhat, the qualitative assessment of guideline quality was consistent among the 4 reviewers; indeed, the overall rankings of the quality of the guidelines were similar.

GUIDELINES FROM OTHER ORGANIZATIONS**U.S. Preventive Services Task Force (2007 Update)**

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. (A recommendation).

The USPSTF makes no recommendation for or against routinely screening for HIV adolescents and adults who are not at increased risk for HIV infection. (C recommendation). [At the time this recommendation was made, a C recommendation from the USPSTF indicated that benefits and harms were such that the USPSTF made no recommendation for or against screening. This interpretation differs from the current use of C recommendation, which indicates a recommendation not to perform an intervention (16).]

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

Comments

The stated purpose of the USPSTF guideline is to evaluate the evidence on the benefits and harms of HIV screening. The USPSTF guideline is based on a rigorous systematic review of the evidence addressing screening for HIV (17, 18). The USPSTF recommendations support the use of individualized assessment of risk factors for HIV infection and support screening in cases where a patient presents in a high-prevalence or high-risk clinical setting, has 1 or more risk factors, or both. The risk factors for HIV include men who have had sex with men after 1975; men and women who have unprotected sex with multiple partners; past or present injection drug use; men and women who exchange sex for money or drugs or have

Table 2. Mean Guideline Scores Across Domains of the AGREE Instrument

AGREE Domain	CDC	USPSTF
Scope and purpose		
1. The overall objective(s) of the guideline is (are) specifically described.	4.0	3.5
2. The clinical question(s) covered by the guideline is (are) specifically described.	2.3	3.8
3. The patients to whom the guideline is meant to apply to are specifically described.	4.0	4.0
Subtotal	10.3	11.3
Stakeholder involvement		
4. The guideline development group includes individuals from all the relevant professional groups.	3.8	3.3
5. The patients' views and preferences have been sought.	3.8	1.3
6. The target users of the guideline are clearly defined.	3.5	3.5
7. The guideline has been piloted among target users.	1.0	1.0
Subtotal	12.0	9.0
Rigor of development		
8. Systematic methods were used to search for evidence.	2.3	3.5
9. The criteria for selecting the evidence are clearly described.	1.5	4.0
10. The methods used for formulating the recommendations are clearly described.	2.5	4.0
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	3.8	4.0
12. There is an explicit link between the recommendations and the supporting evidence.	2.0	4.0
13. The guideline has been externally reviewed by experts before its publication.	4.0	3.8
14. A procedure for updating the guideline is provided.	2.0	2.0
Subtotal	18.0	25.3
Clarity and presentation		
15. The recommendations are specific and unambiguous.	3.5	4.0
16. The different options for management of the condition are clearly presented.	3.3	4.0
17. Key recommendations are easily identifiable.	3.8	4.0
18. The guideline is supported with tools for application.	1.3	1.0
Subtotal	11.8	13.0
Applicability		
19. The potential organizational barriers in applying the recommendations have been discussed.	1.8	1.8
20. The potential cost implications of applying the recommendations have been considered.	3.8	3.8
21. The guideline presents key review criteria for monitoring and/or audit purposes.	1.3	1.3
Subtotal	6.8	6.5
Editorial independence		
22. The guideline is editorially independent from the funding body.	1.8	4.0
23. Conflicts of interest of guideline development members have been recorded.	1.8	2.0
Subtotal	3.5	6.0

AGREE = Appraisal of Guidelines Research and Evaluation; CDC = Centers for Disease Control and Prevention; USPSTF = U.S. Preventive Services Task Force.

sexual partners who do; persons whose past or present sexual partners were infected with HIV, were bisexual, or were injection drug users; persons being treated for sexually transmitted diseases (STDs); and persons with a history of blood transfusion between 1978 and 1985. In addition, the guideline encourages screening patients who request an HIV test, because these patients are likely to include those who are at high risk but are not willing to disclose their at-risk behaviors. High-risk clinical 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.

The guideline acknowledges a lack of evidence for determining the optimal frequency of HIV screening. Although some patients may choose not to disclose high-risk behaviors, fair-quality evidence shows that screening individuals who report risk factors, along with voluntary testing of those presenting in high-prevalence clinical settings, would result in fewer missed diagnoses than risk-based

screening alone (19–21). The evidence also showed that most adults discuss and disclose high-risk behaviors when the issue is brought up by their physician (18); however, 10% to 25% of people testing positive report no high-risk behaviors, which suggests an important limitation of risk-based screening (18). Limited evidence is available on the proportion of patients infected with HIV that was diagnosed by using targeted versus universal screening strategies in low-risk settings, apart from screening pregnant women. Routine opt-out screening has been widely implemented and accepted for pregnant women, and it has been successful in reducing mother-to-child transmission of HIV in the United States. Limited evidence is also available on the acceptability of routine, voluntary HIV screening in low-risk settings. One study focusing on an urgent care setting showed that 67% of patients declined screening for HIV. The most common reason was that patients noted they were not at risk or had been already tested (22). However, a study in an emergency department setting found that

81% of patients said they would accept HIV testing (23). The effect of screening for HIV on transmission rates from tested and untested persons has not been evaluated directly. However, treatment reduces viral load and infectivity, and counseling can reduce risky behavior, although the degree of risk reduction has been uncertain. Unfortunately, one third to one half of HIV-infected patients are not receiving care (18).

Centers for Disease Control and Prevention (2006)

In all health-care settings, screening for HIV infection should be performed routinely for all patients aged 13 to 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 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.

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.

All pregnant women in the United States should be screened for HIV infection.

Comments

The CDC states that the objective of the 2006 guideline is “to increase HIV screening of patients, including pregnant women, in health-care settings.” The method used to reach these guideline recommendations is a combination of a comprehensive review of the literature; expert consensus, including patient input; and lessons learned from CDC-sponsored demonstration projects of HIV screening in health care facilities. The CDC cites several points as the rationale for their recommendations. First, they state that risk-based testing has not been effective, particularly in preventing sexually transmitted HIV infection. Second, universal strategies, such as those used in pregnant women and in the blood supply, have been very effective. Third, they cite studies that suggest that most persons who are aware of their HIV infection substantially reduce risky behaviors. These recommendations may place a higher weight on evidence from observational studies than do other guidelines and may extrapolate more from studies in high-risk patient populations and settings to low-risk patient populations and settings. Also, the recommendation to screen unless the prevalence of undiagnosed

HIV infection in the patient population is less than 0.1% is based on cost-effectiveness studies, some of which take into account transmission as part of the analysis (that is, benefits to others besides the screened patient).

COST-EFFECTIVENESS OF HIV SCREENING

Several good-quality studies of the cost-effectiveness of HIV screening have been published (24–28). A key variation among these studies is whether they consider preventing transmission of infection to others as one of the calculated benefits. One good-quality study showed that early identification and treatment resulted in an increase in life expectancy of 1.52 years in an HIV-infected patient, with a decreased benefit in older patients (27). The study suggests that a one-time screening program would reduce lifetime numbers of transmission from an average of 1.12 to 0.95, 0.35, and 0.12 partners among men who have sex with men, heterosexual men, and heterosexual women, respectively (27). The study found that screening was cost-effective (with a cost-effectiveness ratio of \$50 000 per quality-adjusted life-year [QALY] gained), even at a prevalence as low as 0.05%. A study of the cost-effectiveness of screening among inpatients found that screening would be cost-effective at a prevalence of 0.1% (28). Another study that also did not include benefit from reduced transmission showed that the incremental cost-effectiveness of one-time screening was \$36 000 per QALY gained in a high-risk population with a prevalence of 3.0%, \$38 000 per QALY gained in a population with a prevalence of 1%, and \$113 000 per QALY gained in the general U.S. population with a prevalence of 0.1% (25). More recent analyses that included the benefit from reduced transmission indicated that screening could be cost-effective at a prevalence as low as 0.2%, depending on the extent to which transmission is reduced (24). A study of targeted versus routine screening (29) concluded that targeted screening could prevent more HIV infections if accompanied by pre- and posttest counseling. The study, however, assumed that high-risk patients could be identified at no cost, an assumption that is at odds with the evidence that many high-risk individuals are not identified through targeted screening. Finally, a cost-effectiveness analysis of screening older patients found that screening would cost less than \$60 000 per QALY gained in patients age 65 to 75 years at a prevalence of 0.1%, if patients had a sexual partner at risk and streamlined counseling was used (26). In summary, these cost-effectiveness analyses (24–28) provide good evidence that screening for HIV is cost-effective, even when prevalence is low, in the range of 0.1% to 0.2%.

SUMMARY

Both the USPSTF and CDC guidelines agree on screening for HIV in high-risk groups and settings. However, they differ regarding screening in low-risk groups and settings. The USPSTF concludes that there is no direct

evidence of the benefits of screening for HIV infection in the general population. However, screening individuals who are at increased risk for HIV infection or who present in a high-prevalence or high-risk clinical setting or have 1 or more risk factors is reasonable.

The CDC recommends routine screening of all adults unless the prevalence of undiagnosed HIV in the patient population or health care setting is less than 0.1%. The guideline acknowledges that the prevalence rate is not typically available to clinicians and, therefore, encourages routine screening for HIV for all patients age 13 to 64 years in any health care setting. Progress and challenges in implementation of routine screening were reviewed recently (30).

CONCLUSION

Guidance Statement 1: ACP recommends that clinicians adopt routine screening for HIV and encourage patients to be tested.

The goal of screening for HIV is to identify patients with undiagnosed HIV so that timely treatment is provided and transmission is prevented. Our guidance to perform routine screening of all patients is based on the following rationale and evidence. First, early identification and treatment for HIV provides substantial health benefit by extending the length of life of the person identified as having HIV (25, 27). Modeling studies suggest that identification and successful treatment also probably reduce HIV transmission, both through changes in risk behavior and from suppression of viral load through treatment (27), although the magnitude of the risk reduction has not been assessed directly.

Second, risk-based screening has failed to identify a substantial proportion of people with HIV early in disease. Although risk-based screening has been recommended for more than 15 years, evidence from the CDC and Veterans Affairs indicate that almost half of patients are identified late in the course of disease, when they will no longer receive the maximum benefit from antiretroviral therapy. A retrospective analysis of approximately 14 000 Veterans Affairs patients found that even when risk factors were clearly identifiable from the medical record, only about one third of at-risk patients were tested (31). In addition, 10% to 25% of people testing positive report no high-risk behaviors (17). Thus, the effectiveness of risk-based screening has been limited because providers seldom actually perform risk assessments, and even if providers did such assessments in all patients, a substantial proportion of people with HIV would still be missed because they either are unaware that they are at increased risk or do not wish to disclose risk behaviors.

Third, routine opt-out screening (screening all individuals unless they decline to be tested) has been widely implemented and highly successful for prenatal HIV screening. Acceptance among women has been high (32), and mother-to-child transmission has been nearly elimi-

nated in the United States. Whether specific informed consent for HIV testing is required varies by state (30), and clinicians should be aware of requirements in their practice setting.

Finally, strong evidence indicates that screening is cost-effective, even when the prevalence of HIV is low (24–28). When the benefit from transmission is considered, a study found screening to be cost-effective at a prevalence of 0.05% (27), and another analysis found screening to be cost-effective at a prevalence of 0.2%, with favorable assumptions about the reduction in HIV transmission (24).

We encourage clinicians to counsel patients to reduce risky behaviors when such counseling is feasible.

The CEAS recognizes that further evidence on several aspects of routine screening would be useful. These include the degree to which patients will participate in screening, the effectiveness of routine screening in reducing risky behaviors in low-risk settings, and the prevalence of undiagnosed HIV infection in diverse patient populations. Nonetheless, risk-based screening has failed to identify a substantial proportion of people with HIV and, even if implemented universally, would still miss a substantial proportion of people with HIV. The CEAS judged that the benefits of routine screening outweighed the harms and that routine screening is therefore warranted.

Several aspects of screening deserve particular emphasis.

High-Risk Patients

We note the importance of screening patients who are at increased risk for HIV infection. Many, perhaps most, patients at high risk have not been tested (31, 33), so efforts to reach these patients are especially important. Groups at increased risk include men who have sex with men; men and women who have unprotected sex with multiple partners; past or current injection drug users; men and women who exchange sex for money or drugs or have sexual partners who do; individuals whose past or current sexual partners were infected with HIV, were bisexual, or were injection drug users; persons being treated for STDs; and persons with a history of blood transfusion between 1978 and 1985. Patients who receive health care in high-prevalence or high-risk health care settings are also a high priority for screening. High-risk settings include STD clinics, correctional facilities, homeless shelters, tuberculosis clinics, clinics serving men who have sex with men, substance abuse clinics, and adolescent health clinics with a high prevalence of STDs. High-risk patients who are tested because of a viral syndrome that may represent acute HIV infection may require additional testing in addition to HIV antibody tests, because anti-HIV antibody tests may not be reactive during acute infection (34).

Pregnancy

We also note the importance of screening women who are pregnant. The USPSTF, CDC, and American College of Obstetricians and Gynecologists guidelines recommend

HIV screening during pregnancy. Screening should be performed during each pregnancy.

Age

The CDC recommends that patients age 13 to 64 years be screened for HIV. Less evidence is available on screening older patients, but nationally, approximately 20% of patients with HIV are older than 50 years (15, 26). A recent cost-effectiveness analysis found that screening patients up to age 75 years met conventional cost-effectiveness thresholds if screening was done with streamlined counseling, patients were sexually active, and the prevalence of HIV in the population was greater than 0.1% (26) (see next paragraph). Although data on prevalence in older patients are limited, evidence from a Veterans Affairs population indicates a prevalence of 0.5% among male outpatients 65 to 75 years of age (35).

Prevalence of HIV

The CDC recommends routine screening unless the prevalence of HIV in a population is less than 0.1%. This threshold is reasonable given the evidence from cost-effectiveness analyses. The CEAS recognizes that the prevalence of HIV is not known in most populations. A practical approach to routine screening is to begin screening and if no patients with undiagnosed disease are found after a substantial number of patients have been tested, then the need for screening should be reassessed. If no HIV-infected patients are found after screening approximately 4000 patients, the 95% CI for prevalence will be less than 0.1% (26).

Education About Risk Factors

Clinicians should discuss the risk factors of HIV infection with their patients. Adolescents and older patients in particular may be unaware of behaviors that may put them at increased risk for HIV (36, 37).

Rapid Versus Traditional Testing

Traditional testing (enzyme immunoassay followed by Western blot) has very high sensitivity and specificity (27), so false-positive results are rare. However, results from traditional testing are not rapidly available. Rapid tests provide results within 1 hour (38), an important advantage that increases the number of patients who receive their result. However, a recently published study found relatively high false-positive rates with an oral rapid test (38); other reports have noted increased false-positive rates with oral rapid tests (39). Patients and clinicians should be aware that any positive rapid test result must be confirmed with traditional testing (39).

Guidance Statement 2: ACP recommends that clinicians determine the need for repeat screening on an individual basis.

The importance of repeated HIV screening depends on whether patients have ongoing risk for HIV infection. Higher-risk patients should be retested more frequently than lower-risk patients. The USPSTF does not make recommendations about the frequency of screening. The

CDC guideline recommends that providers screen patients at high risk for HIV at least annually. The CDC defines persons likely to be at high risk as injection drug users and their sexual partners, persons who exchange sex for money or drugs, sexual partners of HIV-infected persons, men who have sex with men, and heterosexual persons who have had or whose sexual partners have had more than 1 sexual partner since their most recent HIV test.

The cost-effectiveness of repeated screening has been evaluated in good-quality cost-effectiveness analyses (24, 27). The cost-effectiveness of repeated screening depends on the incidence of new HIV infection. The difficulty in applying the results of these analyses to specific patient populations is that the incidence of HIV in most patient populations is not known. However, reports from high-risk populations suggest that the annual incidence may be 1% or greater (40, 41). The analysis by Paltiel and colleagues (24) supports the cost-effectiveness of annual screening in such groups, consistent with recommendations from the CDC. Apart from high-risk groups, the decision to retest persons should be based on clinical judgment.

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Note: Guidance statements are “guides” only and may not apply to all patients and all clinical situations. Thus, they are not intended to override clinicians’ judgment. All ACP guidance statements are considered automatically withdrawn or invalid 5 years after publication, or once an update has been issued.

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