

Routine HIV Screening American College of Preventive Medicine Position Statement

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ABSTRACT

Introduction: Although HIV prevalence is increasing, the overall incidence remains stable. Estimated new infections exceeded 56,000 in 2006 with certain groups being disproportionately affected: ethnic minorities, men who have sex with men (MSM), intravenous drug users, adolescents, and sexually active older adults. In 2006, the Centers for Disease Control and Prevention (CDC) issued *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*¹ calling for routine HIV screening in all health care settings. Despite these recommendations, legal, socioeconomic, practical and political barriers persist. Consequently, low HIV test rates, lack of HIV serostatus awareness, and late diagnosis of HIV infection remain problematic. **Methods:** A literature review of English language articles from January 1993 to March 2011 was performed using PubMed, Ovid, organizational websites, and pertinent review articles. **Results:** The following key issues related to routine HIV screening were identified: screening program requirements, testing methods, consent process, prevention counseling, linkage to care, and repeat testing. Important findings included: 1) risk-based targeted testing as a sole method for identifying people infected with HIV is inadequate and results in low test rates, lack of serostatus awareness and late diagnosis; 2) timely access to antiretroviral therapy decreases HIV transmission, morbidity and mortality, 3) rapid testing, opt-out consent and streamlined counseling are cost-effective measures which increase HIV testing rates and facilitate serostatus awareness and entry into care. Despite evidence supporting a shift from targeted HIV screening based on risk stratification, to routine screening based on prevalence and incidence thresholds, recommendations for repeat testing are not yet available, with only a few, albeit significant, studies examining cost effectiveness and incidence rates. These studies suggest a rationale for routine screening at least annually for high-risk populations and every five years for the general population. **Conclusions:** ACPM finds sufficient evidence to support routine HIV screening of all adolescents and adults ages 13-64 years, and pregnant women in all health care settings. ACPM encourages practitioners to screen adults age 65 and older, if these adults have risk factors for HIV or are sexually active with a partner at risk for HIV transmission. ACPM supports policies and procedures that increase testing rates and improve cost effectiveness of screening including: use of rapid tests, an opt-out procedure with a general medical consent, “unlinking” prevention counseling from screening processes, and establishing a link to treatment as a vital part of HIV screening programs. The ACPM recommends annual repeat testing for persons at high risk. In addition, the ACPM recommends repeat testing every five years for the general population.

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Purpose

The American College of Preventive Medicine (ACPM) presents this position statement for routine HIV screening on the basis of current evidence for routine Human Immunodeficiency Virus (HIV) screening. This document will address the following: risk-based testing, screening benefits, cost effectiveness, opt-out consent, pre-test counseling, repeat testing, current policy, and a statement and a rationale for screening. English language articles from January 1993 to March 2011 were searched using PubMed, Ovid, organizational websites, and pertinent review articles.

Introduction

CDC estimates that 1.1 million adults and adolescents (prevalence rate: 448 per 100,000 population) were living with diagnosed or undiagnosed HIV infection in the United States in 2006.¹ HIV and AIDS also disproportionately affect ethnic minorities, men having sex with men (MSM), and intravenous drug users. HIV prevalence in blacks (1,715.1 per 100,000) was almost eight times and in Hispanics (883 per 100,000) was nearly three times that of whites (224 per 100,000).¹

The number of children reported with AIDS due to perinatal HIV transmission decreased from 945 in 1992, to 48 in 2004 mainly because of an increase in the identification of HIV-infected pregnant women and their subsequent treatment with antiretroviral medication to reduce vertical HIV transmission. The number of persons aged 50 years and older living with HIV/AIDS has increased in recent years partly due to highly active antiretroviral therapy (HAART), which has made it possible for many HIV-infected persons to live longer, and partly due to newly diagnosed infections or engagement in high risk transmission behavior in persons over the age of 50.¹ There is evidence to suggest that sexually active older adults may engage in high risk transmission behaviors.²

Routine opt-out HIV screening was first recommended in 2001 by the Institute of Medicine and then in 2003 by the CDC.³ Evidence cited included: 1) low test rates,⁴⁻¹² 2) large number of HIV-infected persons who were unaware of their diagnosis^{10, 12-14} and, 3) large number of persons diagnosed late in their infection.^{13, 15-17} Despite CDC's 2003 recommendations, HIV testing rates in the U.S. have remained approximately less than 25%.^{18, 19} In 2006, an estimated 71.5 million persons (40.4%) of U.S. adults reported ever tested.²⁰ One in five (21%) of those ever tested living with HIV are unaware of their infection.¹, even among high risk populations.²¹ Late diagnosis of HIV infection remains a critical concern.²²⁻²⁷ Of all HIV infections diagnosed in 2006, 38% of those persons progressed to Acquired Immune Deficiency Syndrome (AIDS) within 12 months of their first positive HIV test.¹ Other identified barriers to HIV testing include: insufficient time, burdensome consent process, lack of knowledge/training, lack of patient acceptance, pretest counseling requirements, competing priorities, and underfunded services.^{28, 29}

Early knowledge of HIV sero-conversion enables HIV-infected individuals to access interventions to reduce morbidity and mortality. To reduce the burden of late and undiagnosed HIV infection, CDC issued HIV screening recommendations in 2006 for routine medical care for all persons aged 13-64 years regardless of risk, in all health care settings where the screening yield is likely to be a least 1 per 1000 patients.³⁰

Background

Routine Screening Benefits

Screening benefits for HIV infection are consistent with established public health screening principles:³¹⁻³³ 1) HIV infection is a serious disorder with significant morbidity and mortality that can be diagnosed before advanced clinical stages of HIV develop, 2) infected patients have years of life to gain if timely treatment is initiated, 3) HIV can be detected by reliable inexpensive and noninvasive screening methods acceptable to patients and, 4) the costs of screening are reasonable relative to anticipated benefits, 5) earlier screening reduces further transmission.

Opt Out with General Medical Consent

In an opt-out approach, patients are informed that HIV screening is part of routine medical care, and must be specifically declined. In 2001, the Institute of Medicine recommended an opt-out approach to HIV testing and recommended eliminating written consent, and in 2006, the CDC recommended an opt-out approach to HIV testing in the U.S.³⁰ Several professional organizations have also made recommendations for screening and some have supported the opt-out approach (see Table 1). Although controversial,^{34, 35} the shift to opt-out screening is justified by the need to expand HIV testing, circumvent barriers associated with HIV testing, and destigmatize the HIV testing processes.³⁶ It is estimated that with adoption of an opt-out policy, the number of infected individuals learning their HIV status will increase by at least 25% in some U.S. regions over the next several years.³⁷ Settings in which opt-out testing was implemented show increased detection of HIV positive cases.³⁸⁻⁴⁴ To date, 12 states have eliminated the requirements for separate signed consent while the laws in 30 states remain neutral neither hindering nor supporting an opt-out consent process.^{45, 46}

Table I. Organizational Support of HIV Screening Among Adults and Adolescents in Health Care Settings³⁰

Organization	Routine Screening (13-64 years)	Voluntary Opt-Out Consent ^a	Pre-test Information Only	Repeat Testing	Pregnant Women
American College of Preventive Medicine	X	X	X	X	X
World Health Organization/Joint United Nations Program on HIV/AIDS ^{99, 100}	X ^{b,d}	X	X	X ^c	



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Institute of Medicine	X	X	X		
*US Preventive Services Task Force (USPSTF) ^{101, 102}					X
American College of Physicians and HIV Medicine Association ¹⁰³	X ^d			X ^e	
American Academy of Family Physicians ¹⁰⁴	X ^f	X	X		
American College of Obstetrics and Gynecology ¹⁰⁵	X ^g	X		X ^h	
American Medical Association ¹⁰⁶	X	X	X		
American Academy of HIV Medicine ¹⁰⁷	X	X	X		
American College of Emergency Physicians ¹⁰⁸	X	X			
<p><i>Abbreviations: CDC, Centers for Disease Control; HIV Human Immunodeficiency Virus; AIDS Acquired Immunodeficiency Syndrome; US United States</i></p> <p><i>*Makes no recommendation for or against routinely screening for HIV adolescents and adults who are not at increased risk for HIV infection.</i></p> <p><i>^aGeneral consent for medical care encompasses HIV screening. Separate consent not required. Testing is voluntary, patients are informed orally or in writing, and the patient has the right to decline testing.</i></p> <p><i>^bDepends on level of epidemic in area</i></p> <p><i>^cEvery 6-12 months for those at risk</i></p> <p><i>^dNo age limits specified</i></p> <p><i>^eDetermined on individual basis</i></p> <p><i>^fOnly where prevalence of HIV infection is high (e.g., STD clinics)</i></p> <p><i>^gWomen 19-64 Years</i></p> <p><i>^hAnnual review of risk factors</i></p> <p><i>ⁱHIV testing should be similar to testing for other conditions. No specifics outlined.</i></p>					

Issues with Targeted or Risk Based Screening

Targeted or risk-based screening is defined as performing HIV tests for subpopulations at higher risk, characterized by demographic, behavioral, or clinical characteristics.³⁰ However, reliance on targeted testing leads to late diagnosis.^{16, 25, 47-50} Risk-based HIV testing strategies have not achieved targeted prevention levels because: 1) persons may not perceive their behavior as risky or are reluctant to disclose personal information, 2) health care providers do not consistently conduct comprehensive risk assessments, 3) targeted testing based solely on risk factors or clinical presentation are inadequate in identifying those with HIV infection, and 4) focusing on targeted testing based on HIV risk factors or AIDS clinical presentation results in late diagnosis of HIV.

Reliable, Inexpensive, Noninvasive Screening Test Acceptable to Patients

Since February 2008, six rapid HIV antibody tests have been approved by the Federal Drug Administration (FDA) using whole blood, serum and plasma or oral fluid, with sensitivities (99.3% - 100%) and specificities (98.6% - 100%) sufficient for screening purposes.⁵¹⁻⁵⁵ Prior to the use of rapid testing, “failure to return” rates for test results was high,⁵⁶⁻⁶⁰ contributing to more patients being unaware of HIV status or diagnosed late in the course of the infection. During 1994 and 1995, before rapid testing was available, an estimated 13.1% of those tested annually for HIV infection did not receive their test results.⁶¹

Rapid testing is acceptable to patients,^{38, 42, 62-71} even among adolescents and their guardians.⁷² Use of rapid tests has been shown to be cost effective for screening programs.^{38, 64, 73-80} Rapid testing reduces the resources necessary for follow-up,^{38, 64, 70, 81-83} and enables patients to receive result-specific counseling during the initial visit.^{63, 68} Most importantly, rapid testing leads to more people knowing their serostatus^{38, 63, 66, 68-70, 81, 82, 84, 85} and facilitates entry of newly identified HIV patients into routine health care.^{38, 64, 65, 67, 81, 84, 86} The costs of lab testing is less than \$1 for HIV serotesting, \$4 for *Orasure*, or \$15 for rapid test. These prices are relatively small compared to the associated costs of pre- and post-testing provider time.⁸⁷

Economic studies using different mathematical models and independently derived data for model inputs showed routine voluntary HIV testing is economically justifiable with the cost ranging from \$60,700 per Quality Adjusted Life Year (QALY)⁷³ to \$64,000 per QALY⁸⁸ in populations with a prevalence of 0.1%, which is comparable to costs of common chronic disease screening interventions.^{74, 88} HIV screening in persons older than 55 years is cost effective when counseling is streamlined and if screened patients have at risk partners.⁸⁹ One study found lead time and length-time bias were not substantial.⁸⁸ Since indirect HIV costs are substantial, the true economic costs of screening are far lower than direct expenditures.⁹⁰ Direct lifelong HIV treatment costs are estimated at \$1 million per patient.⁹¹ Indirect costs are generally a factor of three or more times that amount.⁹¹

Streamlined Counseling

Counseling has some benefits, but some studies report that the costs of linking counseling with testing outweighs the benefit; therefore, in 2001, the Institute of Medicine recommended eliminating extensive pretest counseling, and in 2006, the CDC recommended that prevention counseling not be linked to HIV testing, but that HIV positive patients should be linked to clinical care, counseling, support, and prevention services.³⁰ Pretest information is not however prevention counseling. Prevention counseling means as an interactive process of assessing risk, recognizing specific behaviors that increase the risk for acquiring or transmitting HIV, and developing plans to take specific steps to reduce risks.⁹² Separating counseling from HIV testing allows patients to benefit from patient-centered risk reduction counseling and has been demonstrated to be more effective than standard counseling in reducing HIV transmission rates.⁹³⁻⁹⁶ Effectiveness of high-intensity behavioral counseling has been documented and recommended for prevention of all sexually transmitted infections (STI's) by the U.S. Preventive Services Task Force (USPSTF).⁹⁷

Frequency of Repeat Testing

CDC recommends repeat HIV tests annually for patients with known risks for HIV, and based on clinical judgment for persons not at high risk of HIV.³⁰ While prevalence data are used to identify the threshold determining cost effectiveness of initial screening, incidence data are utilized when constructing guidelines for repeat screening. In an ideal situation, the frequency of HIV testing is determined by the incidence of undetected HIV infections in communities or facilities where testing is conducted.⁹⁸ Recommendations for repeat testing based on incidence thresholds are not yet available. The only evidence-based guidance available at this point is provided by cost effectiveness studies examining incidence rates.

Statement

ACPM concludes that there is an ample evidence of the failure of targeted testing in addressing issues of low HIV test rates, HIV status awareness, or late HIV diagnosis. These issues raise concerns, given that the rate of HIV is increasing among minorities and older age groups (incidence of HIV in men and women over 50 years old increased 14% from 2005 to 2008¹⁸⁴). Targeted testing is likely to miss HIV diagnosis within several groups that lack access to routine care. Thus, the College fully supports routine HIV screening for adults, adolescents, and pregnant women. Specifically, the ACPM takes the following positions:

1. Conduct routine HIV screening of adolescents and adults ages 13-64 years.
2. Screen adults >65 years, if risk factors present or sexually active with partners who may or may not be at risk for HIV.
3. Include routine HIV screening in the routine panel of prenatal screening tests for all pregnant women.
4. Support policies and procedures which increase testing rates and improve cost effectiveness of screening including opt-out consent procedures for general medical care, use of the HIV rapid test, “unlinked” prevention counseling to screening processes, and established linkage to treatment for screening programs.
5. Conduct repeat testing at least annually in those likely to be at high risk in venues where incidence is likely to be sufficiently high and risk assessment is routine, (e.g., jails, prisons, clinics serving patients such as MSM and patients at high risk of STI’s, etc).
6. Conduct routine repeat testing every five years for the general population. These recommendations are based on limited but significant cost effectiveness studies and pilot programs in which incidence rates have determined incidence thresholds within the general population to be sufficient. Repeat testing every five years avoids the potential for targeted testing bias. ACPM does acknowledge that these recommendations may be preliminary but feel they are prudent and justified and look forward as future studies build a body of evidence.

Rationale

Routine screening programs utilizing rapid testing, opt-out consent and streamlined counseling have been successfully implemented across a variety of medical settings. Routine testing with opt-out consent have the added benefit of reducing the stigma associated with HIV testing and sero-conversion.



Routine HIV screening meets requirements for screening programs since HIV is a disease with significant morbidity and mortality that can be diagnosed early, before symptoms develop. Routine screening demonstrates increased testing rates which identify HIV sero-conversion before symptoms appear. Early identification of HIV infection is necessary for timely access to life-prolonging therapy and to decrease viral transmission. Antiretroviral therapy dramatically improves survival with HIV disease and the initiation of timely therapy improves life expectancy and quality of life.

Rapid testing is reliable, non-invasive, inexpensive, and acceptable to patients. Rapid testing provides patients the opportunity to know their HIV status the day of testing, enabling those found to be positive to be linked to care so they may benefit from early treatment and risk reduction counseling. Routine screening with rapid testing has been shown to be cost effective.

Conclusion

Based on the current evidence, the American College of Preventive Medicine believes the policy recommendations described above are reasonable interventions for prevention and to decrease the incidence, morbidity, and mortality of HIV and AIDS in the U.S. In addition, enhancing efforts to develop effective, practical population-based strategies and policies to reduce HIV transmission rates should be a public health priority in all healthcare institutions and community-based settings.

† The following members of the ACPM Prevention Practice Committee participated in the development of this Position Statement: Ronit Ben Abraham-Katz, MD, CIE, FACPM, Gershon Bergeisen, MD, MPH, FACPM, V. James Guillory, DO, MPH, FACPM, and Lionel S. Lim, MD, MPH, FACPM

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