

# It Is Time to Implement Routine, Not Risk-Based, HIV Testing

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**Approximately one-quarter of a million persons in the United States who are infected with human immunodeficiency virus (HIV) do not know it. To decrease the number of such persons, primary care providers should make HIV testing a routine component of health care. HIV testing should also be offered routinely in other settings, such as emergency departments, jails, and substance abuse treatment centers. Currently, the Centers for Disease Control and Prevention and the Infectious Diseases Society of America recommend routine HIV testing only in settings where the prevalence of HIV infection is  $\geq 1\%$ ; in settings where the prevalence of HIV infection is  $< 1\%$ , testing should be based on risk assessment. Because of the impracticality of strategies for testing that are based on estimates of prevalence, and because of the inaccuracy of risk assessment, we propose that HIV testing be routinely offered to any person who is sexually active. As an adjunct to the implementation of routine testing programs, counseling practices need to be streamlined, and rapid HIV testing needs to be implemented in the appropriate settings.**

Establishment of routine testing for HIV infection is essential to reduce the number of persons living in the United States who are infected with HIV but are unaware of their HIV serostatus. However, in 2005, HIV testing is still largely based on the pretesting probability that the patient is infected with HIV. Typically, an HIV test is offered to a patient when a history of risky behavior, such as unprotected sex, injection drug use, or intercourse with a partner of the same sex, is elicited from a patient or when a patient presents with clinical findings suggestive of an opportunistic infection or an AIDS-defining malignancy. Persons who engage in risky be-

havior may also seek HIV testing from health care providers, but this is often not the case, because patients may be reluctant to self-identify risk. Continued reliance on risk-based testing limits the ability of the health care community to diagnose HIV infection. These missed opportunities to diagnose HIV infection before the patient develops a disease that is an indicator of HIV/AIDS increase health care costs and allow transmission of HIV to continue.

Recently, the Centers for Disease Control and Prevention (CDC; Atlanta, GA) and the Department of Health and Human Services (Washington, DC) updated recommendations for HIV counseling and testing. Changes in the epidemiology of HIV infection have been the impetus for these new recommendations. The number of persons living with HIV infection in the United States continues to increase [1], and, for approximately one-quarter of these patients, HIV infection remains undiagnosed [2]. Recent data from the CDC

reveal an increase in the number of new diagnoses of HIV infection during 1999–2002 [3]. Thirty-five percent of the new cases of HIV infection that were diagnosed in 1999–2002 were acquired heterosexually, and these cases account for the majority of new cases of HIV infection among women [4]. Since the early 1980s, the proportion of individuals who have become infected with HIV through heterosexual transmission has continued to increase relative to the proportions noted for other groups of individuals at risk for HIV infection [5]. From 1989 to 1999, the percentage of AIDS cases that were attributable to heterosexual transmission increased 265% [6].

An alarming number of persons with newly diagnosed HIV infection present late in the course of the disease. In 2001, according to the CDC, 39% of persons who received a diagnosis of HIV infection developed AIDS within 12 months of receiving the diagnosis [1]. Early diagnosis of HIV infection provides opportunities

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for secondary prevention counseling; initiation of antiretroviral therapy, when appropriate; and prevention of opportunistic infections. Furthermore, studies have shown that testing positive for HIV leads to changes in risk-taking behavior, which may decrease transmission of HIV [7, 8].

In 2001, the CDC released “Revised Guidelines for HIV Testing, Counseling, and Referral and Revised Recommendations for HIV Screening of Pregnant Women” [9]. These guidelines called on health care providers to perform routine HIV counseling and testing in areas where the prevalence of HIV infection is  $\geq 1\%$  and for persons with increased behavioral and clinical risks for HIV infection, regardless of the prevalence of HIV infection. Also in 2001, the CDC released the “HIV Prevention Strategic Plan through 2005” [10], which outlined goals to decrease the number of new cases of HIV infection that develop annually from 40,000 to 20,000 and to increase the proportion of HIV-infected persons who are aware of their HIV-positive serostatus. By 2003, it had become clear that the number of new HIV infections was not decreasing and that the proportion of infected persons who were aware of their HIV serostatus had not changed appreciably.

This prompted the CDC to launch its initiative “Advancing HIV Prevention: New Strategies for a Changing Epidemic—United States, 2003” [11, 12]. The 2003 prevention initiative called for the following strategies intended to increase early diagnosis of HIV infection and linkage to care: (1) make HIV testing a routine part of medical care in communities where the prevalence of HIV infection is high (i.e.,  $\geq 1\%$ ); (2) implement new models for the diagnosis of HIV infection outside of medical care settings, including rapid HIV testing; (3) prevent new infections by working with persons who receive a diagnosis of HIV infection, as well as the partners of such persons; and (4) decrease perinatal HIV transmission.

More than 10 years ago, the CDC made a similar recommendation to perform

routine HIV testing in settings where the prevalence of HIV infection was high [13]; this recommendation was never adapted or implemented. The most recent Infectious Diseases Society of America guidelines also call for routine testing to be performed in areas and facilities where the prevalence of HIV infection is  $\geq 1\%$  [14]. The recommendation to routinely test when the local prevalence of HIV infection is  $\geq 1\%$  is impractical, is difficult to implement, and limits our ability to diagnose HIV infection in more persons. To comply with CDC and Infectious Diseases Society of America guidelines, health care providers must have specific knowledge of population-based estimates of the local prevalence of HIV infection; such estimates are not easily accessible. It is very difficult for a physician working in a primary care practice or in an urgent care center in a mid-sized American city to know whether he or she is dealing with a community with a “high prevalence” of HIV infection or to determine what the risk of HIV infection is for a given patient, on the basis of estimates of local prevalence.

Risk for HIV infection is largely based on the social networks and risk behaviors of an individual, as well as the prevalence of HIV infection within his or her social network. Social networks with a relatively high prevalence of HIV infection can reside within communities with a low prevalence of HIV infection. For example, the CDC recently identified a social network of black college students in North Carolina with high rates of HIV transmission [15]. Determining the risk attributable to social networks is not something that health care providers can do during the course of a brief encounter with a patient. Implementation of routine testing solely on the basis of HIV prevalence risks missing the diagnosis of HIV infection in a substantial number of persons.

Because strategies for testing that are based on estimates of prevalence are not “user friendly” and, therefore, have not been implemented, health care providers more commonly offer testing when there is a percep-

tion of an increased clinical or behavioral risk of HIV infection. This practice relies on accurate risk assessment; however, risk assessment is fraught with difficulties. Some persons who seek medical care may not be willing to share information about their personal risk for infection, or they may not realize their risk. Studies demonstrate that persons who receive a diagnosis of HIV infection late in the course of the infection often do not perceive themselves as having been at risk for HIV infection [16]. Persons who are infected with HIV through heterosexual transmission often consider themselves to be at low risk for HIV infection [16, 17]. Adolescents, even high-risk adolescents, have little understanding of their risk for HIV infection and may not seek testing on their own [18].

Not only can patients be reluctant to self-identify risk, health care providers may not seek information regarding the risk of HIV infection. Risk assessment done by health care providers is often inadequate [19]. If patients do not reveal risky behavior, if patients do not perceive themselves to be at risk, or if health care providers cannot elicit accurate information regarding risk from patients, HIV testing based on risk assessment will fail. Furthermore, health care providers may avoid offering HIV testing, independent of risk assessment, because of such factors as the anxiety created by offering HIV testing, the fear of treating an HIV-positive patient, the fear of informing a patient that he or she is HIV positive, pretest counseling requirements, the need for informed consent, and the time constraints of a typical patient visit [20–22].

We propose a new policy whereby health care providers routinely offer HIV testing, irrespective of perceived risk. HIV testing should be performed on an indiscriminate basis and should be offered to all sexually active persons. The HIV test needs to become commonplace in the primary care setting, similar to other screening tests, such as the Papanicolaou smear, mammography, and lipid-profile analysis. To access all individuals who are at risk

for infection, routine testing should be offered at various clinical sites, including primary care offices, health clinics, hospitals, urgent care centers, emergency departments, and clinics for the treatment of sexually transmitted diseases, as well as at alternative sites, such as substance abuse treatment centers and correctional facilities.

By broadening the criteria for offering routine voluntary HIV testing, more HIV infections will be diagnosed. Routine testing has been successful in prenatal settings where women are routinely offered HIV testing in a way that allows them to opt out of testing [23]. Studies have demonstrated the effectiveness of routine testing programs in urgent care centers [24, 25] and inpatient centers [26]. Two recent studies clearly demonstrated that routine HIV testing in health care settings is cost effective even in areas where the prevalence of HIV infection is low [27, 28]. Routine inpatient and antenatal testing have also been shown to be cost effective in settings where the prevalence of HIV infection is low [29, 30]. Furthermore, patients prefer routine testing to risk-based testing [31], and routine testing decreases the stigma associated with being offered an HIV test and with accepting an HIV test [32–35].

The standard HIV testing algorithm (EIA followed by confirmatory Western blot analysis) is one of the best-performing diagnostic tests available, with a specificity and a sensitivity approaching 100% for persons tested outside the “window” (i.e., preseroconversion) phase of early HIV infection [36]. New rapid HIV tests have similar sensitivities and specificities. Rapid HIV tests should be used for routine testing in venues where clients may not return for test results. Sites such as urgent care centers, emergency departments, jails, and short-term residential treatment programs should use rapid testing technology with delivery of test results to the point of care. Rapid tests provide final negative results and preliminary positive results, typically within 1 h of testing. Preliminary positive

results are subsequently confirmed by Western blot analysis [37].

By increasing the number of tests performed through strategies for routine testing, there will be more false-positive results of EIA screening tests. By confirming positive results of EIA by use of Western blot analysis, as the algorithm dictates, true false-positive results will be rare. For persons who have a positive result of EIA and an indeterminate result of Western blot analysis, the use of follow-up serological tests and adjunctive diagnostic tests, such as PCR analysis for determination of the viral load, helps to clarify the diagnosis [9].

Paramount to successful implementation of routine HIV testing, current counseling practices need to be changed. In practical terms, the performance of routine testing in a setting with a high patient volume, such as a primary care office, does not allow for extensive pretest and posttest counseling, given time constraints. The HIV testing process can be performed with minimal counseling during the consent process. An opportunity to answer questions regarding HIV testing needs to be provided; however, in-depth counseling can occur when persons receive a positive HIV test result, when counseling is requested by the patient, or when counseling is deemed appropriate by the health care provider. Additional counseling will be required if an indeterminate confirmatory test result or a preliminary positive result of a rapid HIV test is obtained. Strategies for routine rapid HIV testing must also have mechanisms in place to streamline confirmatory testing and linkage to care.

Strategies for routine testing need to be covered by private medical insurance and by Medicare and Medicaid programs. HIV screening should be compensated in a manner similar to the compensation for other, well-funded screening programs, such as the Papanicolaou smear. Furthermore, HIV testing is relatively inexpensive, compared with other screening tests [38].

With accurate, inexpensive, and, now, rapid testing capabilities, HIV testing

needs to be incorporated into everyday health care delivery. Increasingly, the challenge for the health care community is not how to prevent progression of HIV disease in a person with known infection, but, rather, is how to identify persons who are unknowingly infected with HIV. Early diagnosis provides an opportunity for linkage to care, with the goal of preventing opportunistic infections and the development of severe immunosuppression. Early diagnosis also allows for risk-reduction counseling, which can reduce transmission of the HIV virus. HIV testing should be performed *routinely* for all sexually active persons, to diagnose HIV infection and to prevent AIDS.

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