

Updated CDC Guidelines for HIV Testing: A Review for Wisconsin Practitioners

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ABSTRACT

An estimated 250,000 people in the United States are living with undiagnosed human immunodeficiency virus (HIV) infection. Those who are unaware they are HIV-infected miss opportunities for early treatment and may unknowingly infect others. Early identification of HIV-infected individuals benefits both the infected individuals and the health of the public. To decrease the number of individuals unaware that they are HIV-infected, the Centers for Disease Control and Prevention (CDC) recently revised its recommendations for HIV testing in health care settings. Changes in the CDC-recommended HIV testing protocol include expanding the population to be routinely tested and streamlining the testing and consent process. This article discusses the CDC recommendations, current Wisconsin laws regarding HIV testing, challenges associated with reconciling these laws with current CDC guidelines, and ethical concerns surrounding the guidelines. The authors conclude that Wisconsin health care professionals should adopt the CDC recommendations for HIV testing. However, to fully implement the revised CDC testing protocol, Wisconsin law will need to be amended. Adoption of these recommendations would increase the number of people in Wisconsin who are aware of their HIV-positive status and can then receive timely treatment and information about preventing HIV transmission.

INTRODUCTION

In the past decade, significant advances have been made in the treatment of individuals with human immunodeficiency virus (HIV) infection. When successfully implemented, today's HIV care practices can slow the clinical progression of the disease, improve the quality of life of persons living with HIV, and reduce HIV-related mortality. Under the traditional model of risk-based HIV testing (testing only those patients who report practicing HIV risk behaviors), many HIV-infected individuals are not diagnosed with HIV until they have advanced HIV infection or acquired immune deficiency syndrome (AIDS).¹⁻³ For example, 45% of all patients diagnosed with AIDS between 2000 and 2003 were first diagnosed with HIV less than 1 year prior to being diagnosed with AIDS, an advanced stage of immunosuppression during which opportunistic infections often occur.³ Thus, for many HIV-infected persons, access to clinical HIV care and timely information on preventing HIV transmission are significantly delayed because they are unaware of their HIV status.

At present, approximately 250,000 people in the United States are living with an undiagnosed HIV infection.⁴ These individuals are at risk for complications of untreated HIV, and of unknowingly transmitting the virus to others. The Centers for Disease Control and Prevention (CDC) estimates that more than half of the approximately 32,000 new sexually-transmitted HIV infections that occur each year result from the sexual activities of persons with HIV who are unaware of their serostatus.⁵ Many HIV-positive persons, once aware of their HIV infection, decrease high-risk sexual behaviors with HIV-negative partners.⁶⁻⁷ Thus, diagnosing prevalent HIV infections is an essential tool for reducing new transmissions.

The availability of reliable, inexpensive, and noninvasive HIV antibody tests and effective HIV therapy has led many public health leaders to advocate for

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the expansion of routine, voluntary HIV screening.⁸⁻⁹ Screening involves performing a test for HIV antibodies on either blood or oral fluid in asymptomatic patients. Rapid tests are available that can provide results in about 20 minutes in appropriate settings. Those patients who are positive must undergo confirmatory testing with a Western Blot test.

In 2006, the CDC issued revised HIV testing recommendations to encourage the adoption of universal screening for patients age 13-64 years, without regard to risk behavior, and in all medical settings. These guidelines recommend changes regarding who should be tested for HIV, the consent process for HIV testing, and whether HIV prevention counseling should accompany all HIV testing.

Here we provide a synopsis of the CDC's recommendations and the rationale underlying the specific protocol advanced by the CDC. We then discuss current Wisconsin law regarding HIV testing, challenges associated with reconciling state law with current CDC guidelines, and ethical concerns surrounding the guidelines.

THE CDC RECOMMENDATIONS

The essential elements of the 2006 CDC *Revised Recommendations for HIV Testing* are:

1. All patients ages 13-64 years should be screened for HIV, in all medical settings, without regard to risk.
2. Separate written consent for HIV testing should not be required.
3. HIV prevention counseling should not be a prerequisite for HIV testing.¹⁰

All 3 elements represent significant changes from prior CDC recommendations. In prior guidelines, routine testing was recommended only in specific circumstances, and written consent and prevention counseling for each tested person was recommended as a standard practice.¹¹ Table 1 presents an overall summary of key differences and similarities between the 2006 recommendations and previous CDC guidelines. Details regarding the changes are provided below.

Who Should Be Tested

The 2006 guidelines recommend that health care professionals perform routine HIV screening for all patients ages 13-64, without regard to a patient's stated history of HIV transmission risk. All patients should be tested at least once and patients who may be at high risk for HIV should be tested annually. Those considered at high risk for HIV include injection-drug users and their sex partners, people who exchange sex for money or drugs, sex partners of HIV-infected persons, and people who

have had more than 1 sex partner since their most recent HIV test or whose sex partners have had more than 1 sex partner since their most recent HIV test.

These recommendations apply to all health care settings, including emergency departments, urgent care clinics, inpatient services, and primary care settings. Institutions or practices that can demonstrate that the prevalence of undiagnosed HIV infection in their patient population is <0.1% are exempt from the recommendations. In settings without such data, professionals are encouraged to begin screening and continue until such time as their testing experience shows that <1 in 1000 of their patients are HIV-positive.

Previously, the CDC had recommended that hospitals with high AIDS diagnosis rates (>1 per 1000 patient discharges) institute routine, universal screening of all patients age 14-54.¹¹ Institutions with lower AIDS diagnosis rates were advised to test patients based on their reported HIV risk behaviors.

Consent for Testing

In their previous (2001) HIV testing guidelines, the CDC recommended that consent for an HIV test be procured after a discussion with the patient about HIV testing.¹² Further, once the patient consented to be tested, professionals were advised to document that consent with the patient's signature on a form specifically designated for HIV testing consent.

The 2006 CDC guidelines streamline this process. After providing brief information about HIV testing (including information on HIV infection and the meaning of positive and negative test results), physicians are advised to inform patients that a routine HIV test will be administered unless the patient chooses to decline such testing. If the patient does not actively decline testing, it can be performed. (This "opt-out" approach is discussed further below.) Furthermore, the CDC no longer advises that physicians document a patient's consent for HIV testing with a signature on a specific HIV testing consent form. Instead, the patient's general consent for medical care, coupled with his or her lack of dissent when informed that a routine HIV test will be conducted, implies consent for HIV testing.

It should be noted that the elimination of signed documentation of consent is in conflict with current Wisconsin law, which requires a designated consent form for HIV testing. This and other legal aspects of HIV testing consent and its documentation are discussed in more detail later in this article

HIV Prevention Counseling

The revised CDC recommendations further streamline

Table 1. Essential Elements of 2001 and 2006 CDC HIV Testing Guidelines

	2001 Guidelines	2006 Guidelines
Population to be tested	<ul style="list-style-type: none"> • All high-risk patients • All patients in high-prevalence settings (>1%) • In other settings: based on individual risk 	<ul style="list-style-type: none"> • All patients ages 13 to 64, without regard to risk • High-risk patients, annually^a
Pretest information	<ul style="list-style-type: none"> • An explanation of HIV and the meanings of positive and negative test results should be discussed • Patient questions should be answered 	<ul style="list-style-type: none"> • Same as previous guidelines
Consent	<ul style="list-style-type: none"> • Written consent should be documented on HIV-specific consent form 	<ul style="list-style-type: none"> • Consent is inferred by general medical consent, once HIV testing is discussed and the patient did not dissent^b
HIV prevention counseling	<ul style="list-style-type: none"> • Should accompany HIV testing 	<ul style="list-style-type: none"> • Not required, but encouraged for high-risk patients and in high-risk settings (eg, STD clinics)

^a Patients at high risk for HIV include: injection-drug users and their sex partners, persons who exchange sex for money or drugs, sex partners of HIV-infected persons, and persons who themselves or whose sex partners have had more than 1 sex partner since their most recent HIV test.

^b This CDC recommendation conflicts with current Wisconsin law.

the testing process by eliminating the requirement of HIV prevention counseling in conjunction with ordering HIV tests. HIV prevention counseling is an interactive process that consists of: (1) assessing an individual's risk for acquiring or transmitting HIV based on a discussion of his or her risk behaviors, and (2) developing an individualized plan to reduce these risk behaviors.¹² Although health care professionals have the discretion to discuss HIV risk behaviors with patients, prevention counseling is no longer considered a prerequisite for HIV testing. However, prevention counseling is still encouraged for patients known to be at high risk for acquiring HIV. Moreover, the guidelines continue to recommend that pretest information be provided to patients, including an explanation of HIV infection and the meanings of positive and negative test results. Patients also should have an opportunity to ask questions about testing prior to being given the option to decline it.

RATIONALE FOR REVISED TESTING PROCEDURES

Routine Screening

Routine screening refers to testing all patients in a particular setting without regard to the risk of any individual patient. When applied in other settings, namely with blood donors and pregnant women, routine HIV screening programs have been quite successful.^{11,12}

Universal screening of all blood donors in the United States, first with antibody tests and more recently with more sensitive nucleic acid tests, has essentially eliminated transfusion-related HIV transmission.¹⁴ Routine screening of pregnant women has allowed health care professionals to take appropriate prophylactic measures to prevent HIV transmission to infants, such as administering perinatal antiretroviral therapy to HIV-positive women and prophylactic antiretrovirals to newborns. Universal prenatal screening and the subsequent prevention efforts that follow have dramatically decreased cases of perinatal HIV-transmission in the United States, from a peak of 1650 cases in 1991 to an estimated 144-236 cases in 2002.¹⁵⁻¹⁷ The CDC cites these successes as a primary rationale for expanding routine screening to the general population.

Opt-out Testing and Elimination of Written Consent

The CDC recommends that health care professionals adopt an "opt-out" approach to HIV screening. In "opt-out" screening, patients are informed that they will be tested for HIV unless they specifically decline testing. This approach contrasts with "opt-in" testing in which patients must actively agree to testing by giving their assent. Both "opt-in" and "opt-out" testing can be coupled with a policy of routine testing (testing all patients without regard to risk) or with risk-based testing.

Routine HIV testing implemented through an "opt-

out” approach may reduce patients’ anxiety about HIV testing, and may in turn result in higher rates of testing. Pregnant women offered HIV tests in an “opt-out” program reported feeling less embarrassed because they did not have to affirmatively request or consent to testing.¹⁸ In addition, a higher proportion of women had HIV tests performed when “opt-out” testing was instituted.

The elimination of separate consent for HIV may further increase the number of HIV tests performed. The San Francisco Department of Public Health Medical Care System observed a significant increase in the rate of HIV testing after that system abandoned requirements for designated written consent and separate laboratory requisitions for HIV tests.¹⁹ The CDC cites these findings to support the changes in the current recommendations, reasoning that these changes will make HIV testing more acceptable and more routine to patients, ultimately resulting in more individuals being tested.

Elimination of Prevention Counseling Requirements

Simplification of the HIV testing process in health care settings includes removing the requirement that prevention counseling accompany testing. This change is based on the questionable efficacy of prevention counseling performed in health care settings. Individually tailored behavioral prevention messages, especially when delivered to HIV-positive persons, have been shown to be effective in reducing sexual risk behaviors.^{7,20} However, physician-delivered prevention counseling to HIV-negative patients in health care settings has not been proven effective.²⁰ (Currently, such counseling is only provided with approximately 35% of all HIV tests performed by health care professionals.²¹) In addition, elimination of the counseling requirement should decrease the time needed for the testing process, which could increase professionals’ willingness to offer the test to their patients.

Cost-effectiveness

The CDC also considered the cost-effectiveness of implementing universal HIV screening for persons ages 13-64. HIV testing using a rapid HIV antibody assay costs approximately \$33 per HIV-negative patient, with higher costs for patients who test HIV-positive.²² Based on published cost-effectiveness studies of HIV testing, the CDC concluded that HIV screening in populations with a prevalence of undetected infection of 0.1% or more is as cost-effective as screening for other diseases such as hypertension and colon cancer.²³⁻²⁴ When the prevalence of undetected infection equals 1%, the cost-effectiveness ratios for HIV screening range from

\$15,078 to \$38,000 per quality-adjusted life-year saved.

To determine whether expanded HIV screening would have a similar cost-effectiveness ratio in Wisconsin, the state’s HIV prevalence needs to be considered. The prevalence of diagnosed HIV infection in Wisconsin varies widely.²⁵ The lowest prevalence is found in the northern, northeastern, and western counties, with an HIV prevalence of approximately 0.04% to 0.05%. Southern Wisconsin is estimated to have a prevalence of 0.11% and southeastern Wisconsin has a prevalence of 0.18%. The highest prevalence in the state is found in the north-central part of the city of Milwaukee among persons age 25-34, where the prevalence is estimated to be 1.6%.²⁶

The prevalence of undiagnosed infection is expected to be approximately a third as large as the prevalence of diagnosed infection.⁴ Conversely, throughout Wisconsin, it is likely that the actual prevalence of HIV in the age group targeted by the CDC guidelines (ages 13-64) is greater than the estimates given above. Those rates are for the general population, which includes children and the elderly, groups that are known to have a lower rate of HIV infection than the target population.

In summary, it is unclear whether implementing the CDC recommendations for testing in every area of Wisconsin would be cost-effective. However, the cost-effectiveness of routine HIV screening in southern and southeastern Wisconsin is likely to be acceptable. Moreover, elimination of the requirement for prevention counseling should decrease costs and thereby improve the cost-effectiveness of HIV screening.²⁷

WISCONSIN’S HIV TESTING LAW

Under current Wisconsin law, patients or their health care agents must provide written, informed consent prior to being tested for HIV.²⁸ The law requires documentation of patient consent on a form designed specifically for consent to HIV testing. The consent form must include the patient’s name, the consenting person’s signature, and the date of the signing. The consent form also must describe circumstances under which disclosure of HIV test results may be permissible, such as when a health care worker is significantly exposed to the patient’s blood or body fluids²⁹ or when a victim of specified sexual crimes is significantly exposed to the perpetrator’s blood or sexual body fluids.³⁰ If health care professionals prefer, the consent form can specify that materials outlining permissible HIV test result disclosures are available on request. Individuals 14 years of age and older can consent to be tested without parental consent.³¹ Consent from a legally authorized adult

is normally required prior to testing children under 14 years of age.

Wisconsin law also requires health care professionals to provide patients with information on HIV and pertinent resources during the HIV testing process. According to the statute, any provider or agency that tests people for HIV must “provide counseling about HIV and referral for appropriate health care and support services as necessary.”³² The HIV counseling and referral requirement does not describe how or when such information is to be provided or the circumstances under which counseling and referrals are deemed “necessary.”

For the most part, Wisconsin law related to HIV testing could support the new CDC testing guidelines. In Wisconsin, health care professionals have the discretion to offer HIV tests to all of their patients as long as the patients are informed that they will be tested and provide consent. Thus Wisconsin law is consistent with the CDC guidelines, which require health care professionals to inform patients that an HIV test will be conducted and that they have the right to decline. Wisconsin law also requires persons administering HIV tests to offer information and referrals to patients when appropriate. Although the nature of the information and when it is to be shared is left unspecified, the Wisconsin Department of Health and Family Services has adopted the CDC position that prevention counseling should not be a barrier to HIV testing (written communication, Michelle Llanas, Wisconsin Division of Public Health, March 2007). In short, if prevention counseling is not practicable, health care professionals are encouraged to forgo counseling and administer the HIV test rather than not testing the patient at all. This position is consistent with the CDC’s new policy.

The explicit provisions in the Wisconsin legal code that require documentation of informed consent for HIV testing are in conflict with the CDC guidelines. Wisconsin law requires patients to sign a specific form to document that they are aware of permissible disclosures of HIV test results and that they consent to be tested. In contrast, the CDC guidelines suggest that a patient’s general consent for health care serve as consent to be tested for HIV. To bring Wisconsin law in line with the CDC recommendations, provisions requiring professionals to document consent to HIV testing differently than they document general consent for diagnosis and treatment would need to be eliminated. For the sake of clarity, the statute could also be amended

to specify that prevention counseling is not required in general medical settings.

ETHICAL CONCERNS

Some physicians may be troubled about the new “opt-out” consent process and the elimination of the specifically designated consent form.³³ Historically, there has been considerable resistance to universal HIV screening programs in the United States.³⁴ The most common concerns are that the rights of people identified as HIV-positive will be compromised or violated and that HIV-positive persons will be subject to abuse and discrimination.³⁵ The history of HIV-related stigma and discrimination in the United States supports these concerns. HIV-positive persons have been evicted from housing, banned from schools, rejected by health care professionals, and terminated from jobs, largely because of the misperception that they pose a threat to the health and welfare of others.³⁶⁻³⁷ At various times during the US epidemic, HIV-positive persons’ rights, including the right to privacy, have been severely compromised.³⁶

One of the premises on which the newest CDC HIV testing recommendations are built is that the US social climate for persons living with HIV is more positive than it was in the early years of the US epidemic. In the last 20 years, a variety of laws have been enacted to protect HIV-positive persons against discrimination.³⁸ In Wisconsin, for example, there are penalties for health care professionals who breach state HIV testing laws or discriminate against persons living with HIV. These penalties are designed to deter or to punish inappropriate disclosure of HIV test results to others³⁹ or to prohibit HIV-related discrimination by persons to whom an individual’s positive serostatus has been disclosed.⁴⁰ Instances of the most overt forms of HIV-related discrimination in Wisconsin and elsewhere have become relatively rare.

Still, mechanisms to protect the confidentiality of information related to HIV status and to deter and punish HIV-related discrimination remain important. Although the CDC guidelines advocate a streamlined HIV testing process, nothing in the guidelines suggests limiting existing protections against inappropriate disclosure of HIV test results or HIV-related discrimination. With expanded testing, these protections become even more critical. If changes in Wisconsin law are made to support the full adoption of the CDC’s new testing guidelines, an assessment of the adequacy of Wisconsin laws to protect HIV-positive persons against discrimi-

nation and breaches of confidentiality should be conducted as well.

DISCUSSION

Wisconsin practitioners should consider adopting the revised CDC guidelines to make HIV testing a routine part of patient care. Routine screening could reduce the risk of HIV-transmission to uninfected individuals and improve the health of those living with HIV disease. If HIV-infected individuals are diagnosed earlier during the course of infection, they will have a greater opportunity to benefit from antiretroviral therapy, which can preserve immune system function, prevent opportunistic infections, and increase quality and length of life. In addition, these individuals will then have the opportunity to receive appropriate prevention education and to make informed behavioral choices, which could decrease new HIV transmissions.

Wisconsin law will support the implementation of the revised recommendations, for the most part. However, Wisconsin law continues to require health care professionals to obtain written consent for HIV testing on a separate consent form. Therefore, full adoption of the CDC recommendations, including the streamlined consent process, will require changes to existing Wisconsin law. Amendments to state law to allow full implementation of the CDC guidelines are being considered (written communication, Joseph P. Hoey, Office of Wisconsin State Representative Sheldon Wasserman, June 5, 2007), but until the law is amended, health care professionals must continue to obtain written informed consent for testing on an HIV testing consent form. If the requirement of written consent specific to HIV testing is eliminated, a review of the legal protections regarding patient confidentiality and disclosure of HIV diagnoses should be conducted.

Even in the absence of a legal requirement for separate written consent, it remains the responsibility of health care professionals to properly inform patients about HIV testing, to answer patients' questions regarding testing, to allow for dissent prior to testing, and to maintain the confidentiality of test results. As health care professionals, it is our duty to balance efficient and comprehensive diagnosis and treatment, health promotion and disease screening, and the autonomy and individual rights of our patients.

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