

Implementing HIV Screening

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The recommendations for human immunodeficiency virus (HIV) testing in the United States were recently revised. An important goal of these revisions is to reduce the proportion of individuals infected with HIV who are unaware of their infection. In the new guidelines, screening is recommended for all individuals aged 13–64 years in any health care setting, provided that they are notified that testing will be performed and do not decline testing. It was further recommended that individuals at high risk for HIV infection be screened annually. Through wider screening, the identification of persons with unrecognized HIV is expected to facilitate treatment and allow better targeting of HIV prevention strategies.

Of the 1–1.2 million individuals in the United States infected with HIV, it is estimated that 252,000–312,000 are unaware of their positive HIV status [1]. In some studies of risk groups, such as men who have sex with men (MSM) and adolescents, the proportion of individuals unaware of their positive HIV status has been reported to be as high as 50% [2, 3]. Increasing the proportion of HIV-infected individuals who are aware of their infection is an important step toward controlling the HIV infection epidemic. Individuals unaware of their infection pose a greater risk of engaging in activities, such as unsafe sex, that are associated with the spread of HIV. Moreover, once infection is known, individuals reduce their high-risk behavior [4].

Although AIDS-associated morbidity and mortality rates decreased precipitously in the United States with the introduction of effective antiretroviral drug regimens [5], the estimated annual incidence of HIV infection has remained relatively unchanged for more than a decade [6]. The disappointing persistence in the rate of new infection is the key obstacle to ending the public health threat posed by HIV in the United States and elsewhere. Public education campaigns, although

effective for reducing risky behavior [4, 7], have not yet translated into a reduced rate of new infection on the national level. In an effort to increase the effectiveness of programs to prevent HIV infection, there is an increasing focus on HIV testing and improved targeting of interventions that reduce risk.

HIV testing is an effective tool for reducing rates of HIV transmission. It is through testing that transmission of HIV via blood transfusion has been nearly eliminated [8]. In pregnant women, screening for HIV, followed by initiation of antiretroviral therapy to those with positive test results, has made possible the large reductions in rates of mother-to-child transmission [9]. In modeling studies, a 30% reduction in new infections that occur via sexual activity is predicted if all HIV-positive individuals are made aware of their status and adopt risk-avoidance behavior currently engaged in by individuals who know they are infected with HIV [10].

The need to expand HIV screening in the US adult population is apparent, given the substantial proportion of individuals infected with HIV who will not be identified by targeted testing [11, 12]. In a setting where targeted testing with prevention-counseling programs was made available, the number of patients tested was low even when testing acceptance rates were high, because of time constraints imposed by counseling [13]. In general, current data suggest that HIV testing performed in hospitals serving a population with a high prevalence of HIV infection produces a higher yield of positive test results than testing at sexually transmitted disease (STD) treatment centers or HIV counseling centers [14, 15].

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By identifying infected individuals, HIV testing will permit HIV-prevention strategies to be more effectively targeted, with the ultimate goal of ending the epidemic spread of HIV. It will also permit earlier treatment and increase the potential for better outcomes in the nearly one half of HIV-positive patients who now become aware of their infection through diagnostic testing conducted because of illness [16]. Antiretroviral therapy to control infection and prevent late-stage AIDS will also reduce the pool of individuals at high risk of spreading disease.

KEY COMPONENTS OF THE REVISED RECOMMENDATIONS

Screening guidelines introduced by the US Public Health Service (USPHS) in 1987 targeted persons engaged in high-risk behaviors and persons seeking treatment for STDs [17]. In the 20 years since the initial guidelines were published, several revisions have addressed new information about prevention interventions, populations at risk for HIV infection, and strategies to reduce the spread of HIV once an individual discovers they are infected [18–21]. The revised guidelines [22], which are part of a larger public health strategy to better contain the epidemic, are specifically written to increase the proportion of adolescents and adults tested for HIV.

According to the new recommendations, voluntary HIV screening should now be offered to all persons 13–64 years of age, regardless of health care setting or risk factors. Screening is recommended even in settings where the prevalence of HIV infection is presumed to be low. However, in populations where the yield from screening proves to be <1 HIV-positive person per 1000 individuals screened (i.e., <0.1%), continued screening is not considered to be warranted (table 1).

Repeat screening on an annual basis is recommended for all patients likely to be at high risk for HIV infection. This includes injection-drug users and their sex partners, persons who exchange sex for money or drugs, sex partners of HIV-infected persons, and MSM or heterosexual persons who or whose sex partners have had >1 sex partner since their most recent HIV test.

Testing for HIV must be voluntary and performed only with the person's consent and knowledge. Before conducting an HIV test, sufficient information should be provided in either oral or written form to facilitate the patient's understanding of the nature of HIV infection and the significance of a positive or negative test result. Questions about HIV infection and the testing procedure should be permitted in order to ensure that the patient's consent to undergo testing is informed. The patient's decision to accept or decline an HIV test should be included in their medical records.

Completion of a separate consent form for HIV testing is not required or recommended. Rather, general consent for medical care is considered sufficient. Test results should be

Table 1. Key Centers for Disease Control and Prevention recommendations for HIV screening.

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|--|
| Screening is recommended for all individuals aged 13–64 years, regardless of risk. |
| Screening should be performed annually for patients known to be at risk for HIV infection. |
| Screening is appropriate in all health care settings. |
| Screening should be initiated even in areas in which the prevalence of HIV infection is assumed to be low. If the yield of persons with a positive test result is <1 per 1000 individuals screened, continued screening in these areas is not warranted. |

communicated to patients in the same way as results of other diagnostic and screening tests are provided. Prevention counseling should not be required in order to provide HIV screening programs in health care settings, but if the patient has a positive HIV test result, clinicians should be prepared to deliver clinical care and counsel the patient on preventing HIV transmission or to provide a reliable referral to a qualified health care professional.

HIV screening should now be considered part of the routine panel of prenatal screening tests to be performed for all pregnant women except those who decline. Again, although HIV testing should be performed with the patient's knowledge and consent, consent for HIV testing should be considered implicit in the general consent for medical care rather than required in writing. A repeat screening in the third trimester is appropriate for women at high risk of infection, such as those with multiple sex partners or those whose sex partner has >1 sex partner.

Although the new recommendations are designed to widen screening to include populations beyond those identified as candidates in previous guidelines, it is important to recognize that the greatest yield from screening is expected to remain within populations with traditional risks for HIV infection, such as individuals who engage in unsafe sex or use injection drugs. The guidelines are appropriate for use as a national screening policy, but an immediate emphasis on rapid implementation in regions of the country where the prevalence of HIV infection remains greatest is being encouraged in order to limit, in these areas, the inevitable delay that occurs as health care facilities and professionals digest the revisions associated with a substantial change in standard practice and put them into practice.

Similarly, although these recommendations are intended for all health care settings, the initial emphasis will be placed on community health care centers and acute care settings, where patients at highest risk for HIV infection are likely to interact with the medical system. Screening for HIV in inpatient settings serving high-risk patients is also appropriate. This emphasis is not intended to diminish the importance of screening for HIV outside of other settings, but it is intended to direct attention during the early stage of guideline adoption to settings where

screening promises to have the greatest impact. Although it is hoped that the revised guidelines will be adopted rapidly, realistic estimates suggest that broad implementation may require a year or more as education about the need for guidelines and the recommended methods of deployment is disseminated.

OBSTACLES TO THE NEW GUIDELINES

The guidelines were expressly written to be readily adopted in a broad range of settings, but there are several potential obstacles to national implementation. For example, HIV testing without written consent is now prohibited in 14 states. Other states require testing only if the test is performed in the context of counseling specifically about HIV. In addition, reimbursement remains a substantial barrier for the wider testing coverage envisioned by the new guidelines. The effort to remove these political and economic barriers will require cooperation among a coalition of interested parties.

Several regional experiences that support the benefits of broad HIV testing coverage may prove useful in demonstrating why barriers should be removed. In New York City, a program consistent with the goals of the newly revised guidelines was initiated in 2005 by the Health and Hospitals Corporation, the largest municipal health care system in the United States (J. Ohmie, personal communication). The facilities of the Health and Hospitals Corporation, which include affiliated hospitals, STD clinics, and jails, serve ~1.3 million New Yorkers. In an opt-out HIV testing program administered independent of risk factors, the number of tests performed increased by 57% in a single year. More importantly, the number of new diagnoses of HIV infection doubled from the previous year. Of persons who tested positive and were given an appointment for primary care for HIV infection, 76% kept the appointment.

The state-specific impact of HIV testing restrictions on implementation of the revised guidelines should be evaluated on a case-by-case basis. In Texas, for example, one code prohibits testing for HIV antibodies without first obtaining informed consent from the person tested, but a separate code specifies that a consent form specific for HIV testing is not needed during a time in which a general consent for performance of medical tests is in effect. As a result, the language of the law ultimately permits voluntary, opt-out HIV testing, similar to the recommendation in the new revised guidelines. In fact, the Texas State Health Department has been funding this type of opt-out testing in STD clinics for more than a decade.

At Denver Metro Health Clinic, the STD clinic in Denver, Colorado, there is a specific consent option for HIV testing on the standard consent form for medical services. Although the revised guidelines recommend that testing be offered without a specific consent for HIV testing, the Denver form requires patients to actively decline HIV testing by checking a box and

then providing a second signature independent of the one indicating consent to medical services (figure 1). If the box is not checked and if there is no second signature, consent for HIV testing is assumed.

The impetus for state regulations concerning consent for HIV testing was likely driven by concerns about stigmatization and restrictions, including denial of health care insurance, for individuals with positive test results. Evidence that HIV infection is a treatable disease, particularly when therapy is initiated before immune dysfunction advances, may be an impetus for such regulations to be reconsidered. Obstacles to broader HIV testing have substantial potential to impair the outcome of persons who are infected and to facilitate the spread of disease. These advantages may drive legislative changes to remove obstacles in states with restrictions that impair full implementation of the revised guidelines.

Of the potential hurdles to broad application of the revised guidelines, lack of reimbursement for HIV testing may be the most formidable. Obtaining reimbursement for testing is considered critical to widespread adoption of the revisions. For that reason, the Centers for Disease Control and Prevention (CDC) has been interacting with third-party payers, including private insurers and agencies that provide public funding, to encourage payment for HIV testing offered according to the revised guidelines. Such funding is already widely available for HIV screening of pregnant women. Additional current procedural terminology codes are being sought to cover testing of other persons, particularly to compensate for the labor of point-of-care rapid testing for single individuals.

Covering the costs of HIV testing in the uninsured population is more problematic. The CDC has been active in advocating partnerships that can fund HIV testing in individuals who do not have health insurance, but the CDC is not organized or funded to address this need directly. Because of the potential benefits to public health, health departments at the federal, state, and local levels may wish to consider strategies to marshal resources for HIV testing in individuals unable to pay. Although several health departments, including those of Massachusetts, Michigan, and New Jersey, have been active in directing public monies for HIV testing to sites where the prevalence of HIV infection is high, broader availability of funds for testing of uninsured individuals may circumvent the need for these types of choices.

There are legitimate concerns about broader HIV testing coverage, including the fear that testing provided in the absence of counseling and care for HIV infection may cause distress and harm to the infected individual. The CDC considers these concerns to be serious and has been active in working with community organizations to evaluate risks and consider modifications in the implementation of the guidelines, where ap-

**DENVER METRO HEALTH CLINIC
REGISTRATION FORM**

| | | | | | | | | | | | | | | |
|--|-------------|----------------|------------------------|----------------|-------------------------|--|-----|-----|---|-----|-----|------|-------|-----|
| Office Use Only: | | | | | | | | | | | | | | |
| Date _____ | Log # _____ | Fee Code _____ | Medical Record # _____ | Person # _____ | | | | | | | | | | |
| TRIAGE: | NV | FU | EXP | FP | VSR | | HIV | RPR | STAT RPR | FTA | HCV | NONE | | SSO |
| <u>CONSENT FOR SERVICES</u> | | | | | | | | | | | | | | |
| <p>In consideration for services to be rendered to me by Denver Health and its staff, I hereby apply for and consent to such diagnostic tests, including HIV testing (unless declined below) and medical treatment as the physicians of Denver Health prescribe. I understand that positive gonorrhea, chlamydia, syphilis and HIV results are reported to the Colorado Department of Public Health and Environment by law. I understand the clinic is required by law to report known instances of domestic violence, sexual abuse or sexual assault, and statutory rape.</p> | | | | | | | | | | | | | | |
| Signature _____ | | | | | Witness Signature _____ | | | | | | | | | |
| <p>Check box and sign below only if you are requesting that the HIV test <i>not</i> be performed:</p> <p><input type="checkbox"/> I DO NOT want an HIV test today Decline HIV test signature _____</p> | | | | | | | | | | | | | | |
| <p><u>Please complete the following information and wait for your number to be called:</u></p> | | | | | | | | | | | | | | |
| Last Name _____ | | | First Name _____ | | | Middle Initial _____ | | | | | | | | |
| Date of Birth _____ | | | Age _____ | | | Marital Status: <input type="checkbox"/> Single <input type="checkbox"/> Married | | | Gender: <input type="checkbox"/> Female <input type="checkbox"/> Male | | | | | |

Figure 1. HIV testing consent form used at Denver Metro Health Clinic (Denver, CO). Reprinted with permission from the Denver Metro Health Clinic.

appropriate. Dialogue and cooperation with regional and national organizations are being pursued.

STRATEGIES FOR GUIDELINE IMPLEMENTATION

The CDC has embarked on an ambitious program to promote adoption of the revised guidelines. The broad array of strategies includes enlisting the support of professional medical organizations, such as the American Medical Association, the National Medical Association (NMA), the American College of Physicians, the American Academy of Pediatrics, the American Academy of HIV Medicine, and the National Association of Community Health Centers. In addition to seeking an endorsement from these organizations, the CDC is entering into active partnerships in order to ensure the feasibility of the revised guidelines and to address issues as they develop.

A partnership developed with the NMA serves as an example. NMA affiliates in Atlanta, San Francisco, Chicago, New York, and Washington, D.C., have joined with the CDC to assess the knowledge, attitudes, and practices of African American primary care professionals. The goal is to develop, within the context of the revised guidelines, practice standards regarding HIV testing. These standards will then be translated into training materials for African American physicians and nurses and

for all health care professionals serving African American communities.

A similar cooperative program has been developed with the Health Research and Educational Trust of the American Hospital Association to generate a series of regional workshops with emergency department staff. Again, the goal is to develop a training program that will be broadly applicable on a national scale to emergency departments, particularly those serving populations with a high prevalence of HIV infection. Other cooperative agreements are envisioned to help tailor application of the recommendations to other specific patient groups and settings. Eventually, the goal will be to develop modules appropriate for STD clinics, substance abuse treatment centers, community health centers, correctional facilities, primary care clinics, and other facilities where HIV screening is to be performed.

Such initiatives will build on HIV testing programs already established by the CDC at large institutions in cities with a high prevalence of HIV infection. A screening program recently initiated at George Washington University Hospital (Washington, DC) resulted in a new diagnosis of HIV infection for 1.1% of patients screened (table 2). At centers where programs have been in place for longer periods, the percentage of new diagnoses of HIV among screened patients was 2.3% in the emer-

Table 2. Results of rapid screening for HIV infection in acute care settings.

| Study site | Percentage of new diagnoses among screened patients |
|--|---|
| Cook County Hospital emergency department, Chicago | 2.3 |
| Grady Memorial Hospital emergency department, Atlanta | 2.7 |
| The Johns Hopkins Hospital emergency department, Baltimore | 3.2 |
| Kind-Drew Medical Center, Los Angeles | 1.3 |
| Alameda County Medical Center, Oakland | 1.2 |
| George Washington University Hospital, Washington, D.C. | 1.0 |
| Sites funded by the Centers for Disease Control and Prevention | 1.1 |

gency department of Cook County Hospital in Chicago, 2.7% in the emergency department of Grady Memorial Hospital in Atlanta, and 3.2% in the emergency department of The Johns Hopkins Hospital in Baltimore. In contrast, new diagnoses were received by 1.1% of clients screened in CDC-funded testing sites, including STD clinics and anonymous test sites.

In addition to the initiatives already outlined, CDC's comprehensive plans to support the revised guidelines include a brochure to explain testing and the significance of results to patients, a Web site to support implementation of HIV testing, podcasts for both patients and health care providers, publications in professional journals, and programs to encourage implementation of the guidelines by providers that will grant continuing medical education credits. The CDC also has plans to cooperate with a variety of federally funded programs, such as the National Network of STD/HIV Prevention Training Centers and the AIDS Education and Training Centers, to support the goal of expanded HIV testing. Other initiatives, such as telephone-referral hotlines, may be added to maintain the momentum for nationwide implementation of the guidelines.

TESTING AS THE FIRST STEP

Expanded HIV testing is an essential step toward identifying those individuals who require the care and prevention services needed to reduce the spread of infection. It is not an isolated step, and it will fail if not integrated with other initiatives to provide care and alter risk behavior. In particular, although being tested for HIV suggests that an individual has interacted with the health care system, access to care and prevention services cannot be assumed. It is therefore important not only to monitor implementation of the revised guidelines but also to evaluate whether those who tested positive receive essential services.

As a building block toward controlling the HIV infection epidemic, identification of HIV-positive individuals establishes a number of opportunities to intervene in the chain of HIV transmission that will continue to fuel the epidemic if not interrupted. For example, partners of individuals who test pos-

itive can be notified for services, including testing and counseling. Broad testing for HIV also has the potential to reveal previously unrecognized clusters of infection to which care, counseling, and prevention programs can be rapidly directed.

HIV infection is best characterized as an STD, with >80% of infections transmitted by sexual contact [1]. The risk of infection can be greatly diminished by safe-sex practices [7], but it is important that HIV infection be perceived as a shared public health threat. One potential advantage of a policy of testing all individuals aged 13–64 years is that it may work to reduce the stigmatization of being tested, by conveying that HIV infection can affect people from all walks of life.

The revised HIV testing recommendations are an important piece of a larger comprehensive national program to reduce new transmission of HIV and bring the epidemic under control. The persistent rate of new infections over the past decade has demonstrated that the efforts to control the spread of HIV have not been sufficient. Although HIV infection can now be controlled with existing antiretroviral agents in the majority of patients, it cannot be cured. The currently available antiretroviral therapies are associated with a substantial risk of adverse events and are costly. Because of the need for lifelong drug therapy, studies have shown that HIV screening is cost-effective if the prevalence of undiagnosed infection is >0.1% [23, 24].

SUMMARY

The revision of the guidelines for HIV testing in the United States represents an important evolutionary step forward in the effort to end the HIV epidemic. Effective implementation of the guidelines will require a substantial reorientation among clinicians, health care institutions, third-party payers, and other stakeholders in public health policy. Although there are obstacles to rapid nationwide application of the revised guidelines, such as uncertain funding and local restrictions regarding consent, the revisions are expected to contribute substantially to the control of HIV by more-effective targeting of care and prevention strategies at persons who need them and, in turn, to reduce future infections.

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