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Opt-Out Testing for Human Immunodeficiency Virus in the United States

Progress and Challenges

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HUMAN IMMUNODEFICIENCY virus (HIV) infection and AIDS in the United States remain a major public health crisis, with more than 1 million US individuals estimated to be living with HIV, nearly a quarter of whom remain undiagnosed.¹ On September 22, 2006, the Centers for Disease Control and Prevention (CDC) published recommendations for HIV testing in the United States that favored an “opt-out” strategy, meaning the test will be performed unless the patient declines.¹ The World Health Organization made similar recommendations in May 2007.² The impetus for the CDC’s recommendations was the persistence of the domestic HIV/AIDS epidemic even though there have been substantial advances in HIV treatment and HIV testing technologies. This article is a summary on the current status of the CDC’s recommendations for HIV testing.

The CDC’s New Recommendations

Rationale. The CDC issued specific recommendations for opt-out HIV screen-

The Centers for Disease Control and Prevention (CDC) has recommended human immunodeficiency virus (HIV) testing for all persons aged 13 to 64 years in all health care settings. Signed consent would not be required and counseling with referral would be managed as it is for other serious conditions. The goal of the recommendations is to promote earlier entry into care to reduce unnecessary mortality and facilitate prevention by behavioral changes that accompany knowledge of serostatus. Concerns about the change include laws in some states that mandate signed consent and counseling, a perception that counseling is an effective prevention strategy, variability in payment coverage for the test, concerns about the stigma and discrimination that may accompany the HIV diagnosis, and the possibility that other testing policies would be more effective. Eleven of 16 states have changed legislation to reduce barriers to testing, 35 of 74 national professional societies have endorsed the new recommendations, and multiple demonstration projects have shown feasibility. Metrics to evaluate the health outcomes of the CDC’s recommendations for HIV testing have been defined, but the data necessary to determine the effects on early entry into care, the actual reduction in disease incidence, and the unanticipated consequences are not yet available.

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ing for persons aged 13 to 64 years in all health care settings.¹ The CDC’s rationale is based on several premises. Treatment with highly active antiretroviral therapy is widely available and is more effective when started earlier in the course of HIV infection.³ Several studies have shown that persons who are aware of their HIV infection are much less likely to transmit HIV.⁴ Technical advances in HIV diagnostics, including rapid tests, have made testing more feasible in a variety of venues. Thus, the potential benefits of routine

HIV screening include improved health outcomes and improved disease prevention using technology that is readily available, inexpensive, rapid, and highly

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accurate.⁵ However, a physician survey supported and other data indicated that HIV testing was infrequently performed because of multiple perceived barriers, including legally mandated counseling and the requirement for a separate, signed informed consent.⁶

Screening. The CDC's recommendation is to screen all patients aged 13 to 64 years regardless of risk, in all health care settings in which the yield of screening is likely to be at least 1 per 1000 patients.⁷⁻⁹ This would include most hospital admissions and most patients presenting for care in clinics, emergency departments, and other health care settings. Clinical settings with a prevalence of less than 0.1% should conduct targeted testing based on risk for HIV, including sexually transmitted diseases, behavioral risks, recent immigrants from high-prevalence countries, and patients with tuberculosis.

Repeat Screening. Patients with known risks for HIV infection should be tested at least annually, including injection drug users and their sex partners, individuals who exchange sex for money or drugs, sex partners of HIV-infected persons, men who have sex with men, and heterosexual persons or their sex partners who have not been monogamous since their most recent HIV test.

Consent and Pretesting Information. In health care settings, the general consent for care should be sufficient to encompass HIV screening (as it is for other screening and diagnostic tests), provided that patients are informed orally or in writing (depending on local statutory requirements) that the HIV test will be performed and that they may obtain more information about the test and/or may decline testing. The information provided about the test must be sensitive to the issues of literacy and the language of the patient population. Patients should have access to additional information and may refuse the test without compromising their health care. Importantly, pretest counseling and separate writ-

ten consent are not required. A patient's decision to decline testing should be documented in the medical record.

The standard test is a screening test (enzyme immunoassay or rapid test) followed by a confirmatory Western blot.⁵ Persons with positive screening test results should be promptly informed about the meaning of the test results, which may require a consultation and referral to an HIV specialist. This would be analogous to other screening tests that indicate the possibility of serious diseases.

Observations Supporting the Need to Change HIV Testing Strategies

Late Presentation. Domestic HIV surveillance consistently indicates that nearly 40% of patients receive an AIDS diagnosis within 1 year after their first positive HIV test result.^{1,10} The natural history of HIV infection suggests that an average of 7 to 9 years elapse after infection before diagnosis, during which persons may fail to receive effective therapy and may unknowingly transmit HIV. In the first decade of highly active antiretroviral therapy, effective therapy has saved an estimated 3 million life-years in the United States.^{11,12} However, the average survival rate is about 11 years longer when treatment is started when an individual has a CD4 count of 320 cells/ μ L vs 87 cells/ μ L.¹³ Data from the State of Maryland showed that delayed diagnosis with late entry into care has cost an estimated loss of 2700 life-years^{13,14}; extrapolating these data nationally suggests approximately 100 000 life-years lost in the United States attributed to late presentation.

The diagnosis of HIV often occurs late despite multiple prior visits to health care settings. Of 4315 persons with newly reported HIV infection in South Carolina, 41% had their first HIV test within 1 year of an AIDS diagnosis¹⁵; 1302 of the late testers made a total of 7988 health care visits in the 3 years prior to their HIV diagnosis, making an average of 4 health care visits per person without testing. These health care

visits (79% in emergency departments) constituted numerous missed opportunities to diagnose HIV. Many patients did not perceive themselves to have HIV risk factors, so conventional risk-based testing would not have identified them as candidates for HIV testing, hence the rationale for routine screening.

Testing. The conventional HIV serological test required several days or weeks, and up to one-third of HIV-infected patients in many settings never returned for their test results.^{16,17} Since 2002, 6 rapid HIV tests have received approval from the US Food and Drug Administration including 4 that are waived by the Clinical Laboratory Improvement Amendments. These tests can be performed without special equipment, require only saliva or a drop of blood, and can yield results within 20 minutes with a sensitivity of 99.6% to 100% and a specificity of 99.7% to 100%.⁵ A positive test result requires confirmation, but a negative test result is conclusive. Thus, for practical purposes, the rapid test can provide immediate results at the point of testing in virtually any care setting at low cost with high accuracy and no specialized equipment.

Cost-effectiveness. Analyses of the cost of HIV screening suggest a cost-effectiveness of \$50 000 to \$64 000 per quality-adjusted life-year when the prevalence is 0.05% to 0.1%.⁷⁻⁹ Thus, HIV screening is as cost-effective as other routinely recommended interventions (eg, Papanicolaou test and colonoscopy) when HIV prevalence exceeds 0.1%.

Moving Toward Implementation: Residual Challenges and Concerns

Since the release of the CDC recommendations, at least 5 barriers to implementation have been identified.¹⁸⁻²⁴ These include state and other federal agency laws that conflict with the CDC's recommendations,^{18,19,25} concern about absence of mandated counseling for primary HIV prevention,^{18,19} persistent stigma associated with HIV infec-

tion,¹⁹⁻²³ fears regarding discrimination,^{18,19} and a perception that risk-based testing is more cost-effective.²²

At the time of the CDC's recommendation for opt-out testing, 20 states had laws or regulations that required separate written consent for HIV testing of nonpregnant adults²⁶ (FIGURE). Legislation or regulations to remove these barriers have been enacted in 11 states (Arizona, California, Illinois, Indiana, Iowa, Louisiana, Maine, Maryland, New Hampshire, New Mexico, and North Carolina). Similar legislation was introduced (but not enacted) in 7 additional states (Hawaii, Massachusetts, Nebraska, New York, Pennsylvania, Rhode Island, and Wisconsin). No legislative action was initiated in Connecticut and Michigan regarding the state's requirement for separate written consent.

Advocates have expressed concern that discontinuation of mandated counseling for high-risk patients not infected would lose the benefits of messages that would help these patients avoid HIV transmission.^{22,27} The revised CDC recommendations never advocated that prevention counseling should not be done, but recommend that clinicians use their professional judgment regarding the content of communication as is done with other transmissible infections. Moreover, counseling has not been shown to consistently reduce the rate of HIV acquisition according to a meta-analysis of 27 studies.²⁸ Some have suggested that focusing on counseling and testing only high-risk patients would be more cost-effective.²² However, after steady progress in rates of HIV testing since 1987, overall testing rates have shown little change since 2000²⁹ and remain low among high-prevalence populations.³⁰ Furthermore, the proportion of US individuals with HIV who remain undiagnosed until late in the course of their disease has shown little change,^{14,21} suggesting that continuing this traditional approach will be insufficient.

The CDC and advocates for routine testing do not deny that HIV infection continues to carry significant stigma

with potential for discrimination affecting insurability, employability, and domestic violence.^{18,24} Certain populations may be particularly at risk including socially marginalized populations such as those with substance abuse, undocumented immigrants, individuals with mental illness, and the homeless.³¹⁻³³ The concern is the consequences of the delayed diagnosis with a lethal but treatable disease. A potentially related issue is concern about confidentiality of medical records. This issue has been partially addressed with Health Insurance Portability and Accountability Act regulations, and the CDC is not aware of any breaches in confidentiality testing with name-based reporting in more than 5 years.

The concern that risk-based testing is more cost-effective²² applies to any screening test; the problem is that many patients do not perceive themselves to be at risk and the missed opportunities for testing provide testimony that this method has not worked.

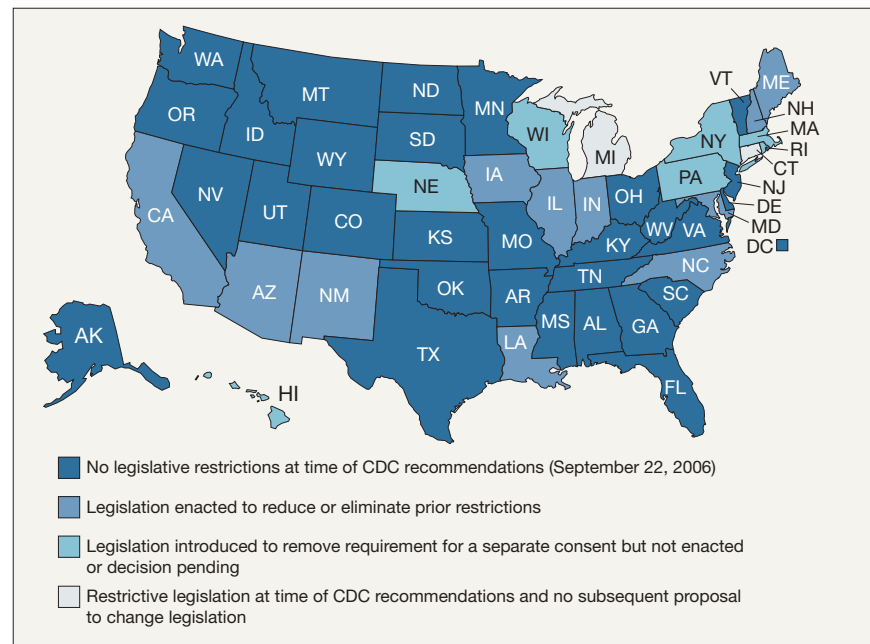
Another concern is third-party reimbursement for testing. Screening tests

for HIV are cost-effective, inexpensive, and highly accurate, but health insurance coverage is highly variable.³³ For example, the Centers for Medicare & Medicaid Services provides coverage for most health screening tests but does not yet classify HIV screening as a covered service. A suggestion is to deal with this as is done with other uncovered laboratory tests because there are substantial variations in different health care systems. Patients should be informed if they need to pay for the test.

Monitoring Progress and Consequences of Adoption of Expanded Screening

The goal of the CDC recommendations is earlier detection of patients with HIV infection to allow earlier access to care and treatment and improved control of this communicable disease. The recommendations have improved awareness, prompted legislative and policy change, and allowed allocation of funds to support expanded HIV testing. However, the long-range goals require metrics that

Figure. Current Status of Legislation to Change Human Immunodeficiency Virus Testing Laws in the United States



CDC indicates Centers for Disease Control and Prevention.

monitor adoption by the medical care community with measurable primary goals such as increased testing, earlier diagnosis, successful entry into the medical care system, and decreased HIV incidence. Changes in the epidemiology of HIV in the United States³⁰⁻³² emphasize the need to prioritize HIV screening at clinical care sites with the highest prevalence and, therefore, yield from screening.

Men who have sex with men accounted for the majority of cases of HIV infection until the mid 1990s and continue to account for about 50% of newly detected cases of HIV infection.³¹ Recent trends show substantial increases in HIV cases attributable to heterosexual contact, particularly among minority races and ethnicities.³⁰⁻³³ Blacks, who account for about 13% of the US population, now comprise about 49% of all AIDS cases. The highest rates of new cases of HIV infection now occur in the Northeast and the rural South.³¹ Settings with high rates of undiagnosed HIV infection in which the yield of testing may be particularly high include emergency departments^{34,35} and inpatient services of general acute care hospitals,³³ as well as traditional screening venues such as sexually transmitted disease clinics, chemical dependency clinics, and correctional facilities. Even before the revised CDC recommendations, the highest proportion of new cases of HIV infection were diagnosed in hospital inpatient settings and emergency departments (27%), community clinics (21%), and physician offices (17%).³¹ In the short term, much may be gained in diagnosing new cases of HIV infection by focusing on these high-yield sites.

Clinical experiences help to provide information about feasibility and establishing standards. Emergency departments are a high priority for testing sites because prior studies have shown high rates of emergency department visits by patients with HIV infection.^{15,34,35} Several demonstration projects have shown a variety

of approaches to address the challenges of testing in the emergency department setting. These include a novel counseling and testing program for adolescents in a pediatric emergency department in Philadelphia, Pennsylvania³⁶; use of an educational video for an inner-city adult population in New York, New York³⁷; a targeted physician-based testing program targeting high-risk adult patients admitted to the emergency department in Denver, Colorado³⁸; and 3 city emergency departments with integration of rapid HIV testing as a component of routine care.³⁹

Despite these apparent successes, the challenges of implementing HIV testing became apparent. These projects generally required dedicated personnel and were funded externally, raising questions about the continuation of HIV testing programs after support is discontinued and about the ability to sustain such programs without supplemental resources.^{36,39} Furthermore, a survey of 120 emergency departments with residency programs indicated limited capacity to refer patients with HIV to treatment and limited personnel to perform screening; only 47% anticipated the ability to offer testing according to the CDC's recommendations in the next 2 to 3 years.⁴⁰

The Federal Response. Additional funding is required to support strategies for sustainable methods to accomplish the goals of the CDC's recommendations. These include (1) \$35 million from the CDC from 2007-2009 for projects in health care settings in 23 US jurisdictions with the highest number of AIDS cases among blacks; (2) \$10 million from the Office of Population Affairs from 2008-2010 for 77 projects in 34 states to expand testing and prevention in family planning projects; (3) provision by the Substance Abuse and Mental Health Services Administration allowing projects to spend up to 5% (\$60 million) of its budget on HIV testing; (4) a commitment from the Substance Abuse and Mental Health Services Administration for an

additional \$60 million from 2007-2012 to expand routine HIV testing in 22 states with a goal to ensure that at least 80% of patients in substance abuse treatment centers are aware of their HIV status; and (5) the Health Resources and Services Administration, through its 11 AIDS Education and Training Centers, have provided training related to HIV screening for 15 700 health care practitioners throughout the country. The AIDS Education and Training Centers National Clinicians Consultation Center (<http://www.nccc.ucsf.edu>) maintains telephone hotlines for clinicians (consultation for clinicians, [800] 933-3413; perinatal screening, [888] 448-8765; and postexposure prophylaxis, [800] 448-8765).

Support From the Medical Community. A review of 74 health professional organizations showed the majority support the new CDC recommendations for routine screening for HIV infection (TABLE). Some groups are awaiting further data, while others have focused on endorsing aspects of the recommendations that are most relevant for their membership. All but 3 organizations endorsed the recommendation for screening all US individuals aged 13 to 64 years at least once.

Metrics. It is too early to document the effect on health outcomes since the publication of the CDC revised recommendations in September 2006. However, explicit and measurable indicators must be used to measure progress on the process and outcomes and to assess adverse consequences over time. Specific indicators reflecting goals of the recommendations are the number of persons tested, the number of false-positive screening test results, the number of patients receiving HIV care as a result of the screening, baseline CD4 count at entry into care, time from first HIV-positive test result to an AIDS diagnosis, estimates of HIV incidence, and studies to evaluate patient satisfaction.

Data for these analyses are from multiple sources. Serial assessments from nationally representative surveys conducted by the National Center for

Health Statistics provide several opportunities for monitoring. The National Health Interview Survey produces annual assessments from household-based probability samples of the number of persons who have been tested for HIV in their lifetimes and in the past year.⁴¹ The annual National Ambulatory Medical Care Surveys will assess the number of HIV tests performed in emergency departments and outpatient facilities.⁴² The National Health and Nutrition Examination Survey generates population-based estimates of HIV prevalence in

Table. Organizational Support for 2006 CDC's Recommendations for HIV Screening Among Adults and Adolescents in Health Care Settings^a

Organization	Screening		Consent and Pretesting	
	All Patients Aged 13-64 y	All Patients Seeking or Initiating Treatment for TB, STDs, or Blood-Related Diseases	Voluntary and Undertaken Only With Understanding That Testing Is Planned	Provide Information and Allow Opt-Out Testing Unless Patient Declines
Full endorsement ^b				
AIDS Education and Training Centers	X	X	X	X
AIDS Healthcare Foundation	X	X	X	X
American Academy of Pediatrics	X	X	X	X
American College of Emergency Physicians	X	X	X	X
American College of Nurse-Midwives	X	X	X	X
American College of Physicians	X	X	X	X
American Medical Association	X	X	X	X
Association of State and Territorial Health Officials	X	X	X	X
Emergency Nurses Association	X	X	X	X
HIV Medicine Association ^c	X	X	X	X
National HIV/AIDS Clinicians' Consultation Center	X	X	X	X
National Medical Association	X	X	X	X
Partial endorsement ^d				
American Academy of Family Physicians		X	X	X
American Academy of HIV Medicine			X	X
American College of Obstetricians and Gynecologists	X			X
Association of Nurses in AIDS Care			X	
Kaiser Family Foundation	X	X		X
National Alliance of State and Territorial AIDS Directors	X	X		
National Association of Community Health Centers	X			
National Association of County and City Health Officials	X			
National Association of People with AIDS	X		X	
National Association of Social Workers	X			
National Business Group on Health	X	X		
National Governors Association	X			
National Minority AIDS Council	X		X	
Parallel partial endorsement ^e				
Council of State Governments	X			
National Black Caucus of State Legislatures	X			
National Hispanic Caucus of State Legislatures	X			
Urban Coalition for HIV/AIDS Prevention Services	X			

Abbreviations: CDC, Centers for Disease Control and Prevention; HIV, human immunodeficiency virus; STD, sexually transmitted disease; TB, tuberculosis.

^aAdapted from data prepared for the CDC by J. Blitstein and J. Harris (both with RTI International) in February 2008. Health care management societies that endorsed the guidelines are not included in this table.

^bThe CDC guidelines were specifically mentioned, and all of the recommendations were supported.

^cPart of the Infectious Diseases Society of America.

^dThe CDC guidelines were specifically mentioned, and only some of the recommendations were supported.

^eThe CDC guidelines were not mentioned, and only some of the recommendations were supported.

the United States, for the general population, and for specific age, race, and ethnic groups.⁴³

Now that all 50 states have name-based HIV and AIDS case reporting, data from the CDC surveillance report⁴⁴ should yield increasingly accurate information about trends in early diagnosis, measured as the percentage of persons (38% in 2006) who receive an AIDS diagnosis within 1 year of their first HIV test.⁴⁵ Surveillance data coupled with state-based laboratory reporting of CD4 counts and viral load test results can provide useful indicators for the number of persons who enter into treatment and remain in medical care for their HIV infection.⁴² Optimally, the CDC's national HIV incidence surveillance program will generate reliable estimates of trends in the number of new cases of HIV.^{46,47} With regard to patient satisfaction, the AIDS Education Training Centers are funded by the CDC to develop a tool for evaluating patient satisfaction.

Particular attention must be paid to ensuring that HIV testing remains voluntary, patients are notified when an HIV test is being performed, and care systems are adequate to provide services to patients after HIV infection is diagnosed through screening. Because no routine surveys or metrics currently exist, novel systems will be necessary to assess patient preferences and outcomes, with appropriate vigilance to detect unintended consequences.

CONCLUSION

The 2006 CDC revised recommendations provide a framework based on traditional public health principles for increasing the number of persons who are aware of their HIV status and for promoting earlier access to effective treatment.¹ As with any other major public health initiative, changes in clinical attitudes and practice will be challenging and incremental and will require concurrent progress in multiple sectors, careful monitoring, and subsequent adjustments. Early experience suggests that success in implementa-

tion will require the identification of clear goals with achievable interim milestones and suitable metrics to measure progress. To date, 11 states have eliminated the requirements for separate signed consent, 35 national professional societies have endorsed the recommendations for routine testing of all US individuals aged 13 to 64 years, and demonstration projects have shown successful but anecdotal examples of practical implementation.

Nevertheless, there is still the challenge of laws that preclude adoption of the recommendations in 9 states. Some third parties including Medicare still do not cover HIV as a screening test and resource limitations are problematic for emergency departments. Issues of stigma and discrimination related to a diagnosis of HIV infection remain sources of continued debate. Given the relatively short interval since the CDC promulgated revised HIV testing recommendations for health care settings, it is too early to fully gauge the benefits and harms of these recommendations. Over the longer term, the penetration and utility of routine HIV testing can be tracked using national probability surveys, serial sampling in high-prevalence settings, and through surveillance of incident infections.

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Study concept and design: Bartlett, Branson, Fenton, Miller, Mayer.

Acquisition of data: Bartlett, Branson.

Analysis and interpretation of data: Bartlett, Branson, Hauschild, Mayer.

Drafting of the manuscript: Bartlett, Fenton, Branson, Mayer.

Critical revision of the manuscript for important intellectual content: Bartlett, Branson, Hauschild, Miller, Mayer.

Administrative, technical, or material support: Bartlett, Branson, Fenton, Hauschild, Miller, Mayer.

Study supervision: Bartlett, Miller.

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