NIH Public Access
Author Manuscript
Curr Infect Dis Rep. Author manuscript; available in PMC 2012 December 03.

Published in final edited form as:
Curr Infect Dis Rep. 2008 May ; 10(2): 157–163.

Implications and Impact of the Centers for Disease Control and Prevention (CDC) New HIV Testing Guidelines

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Abstract

Of the 1.2 million Americans estimated to be living with HIV in the US, approximately 250,000 are unaware of their diagnosis and therefore unable to access clinical care and life-sustaining treatment [1]. The recently revised 2006 Centers for Disease Control and Prevention's (CDC) guidelines for HIV testing recommend universal, routine, and voluntary HIV screening in public and private healthcare settings for all adults and adolescents between the ages of 13-64 years [2]. These major revisions present new challenges for health care providers, hospitals, government agencies, and community advocacy groups. In this review, we discuss the important issues faced in diverse care venues such as opt-out testing, consent and confidentiality, barriers to treatment, and the financial impact of these new recommendations. The implications of the revised recommendations for HIV testing will be addressed in the context of a fragmented, overstressed and under-funded US healthcare system.

Keywords

HIV/AIDS; Testing; Screening; Access to Care; Cost Effectiveness

Introduction

HIV/AIDS remains a leading cause of illness and death in the United States [2]. At the end of 2003, of the approximately 1.2 million Americans estimated to be living with HIV infection, approximately 250,000 were unaware of their diagnosis and therefore not receiving clinical care and treatment [1]. While the annual number of AIDS cases and deaths has stabilized since 1999, the annual HIV incidence rate has remained stable and cases among racial/ethnic minority populations, as well as among persons exposed through heterosexual contact, has increased [3, 4].

The benefits of HIV diagnosis apply to both individual patients who are infected as well as to those who remain uninfected. From a patient perspective, earlier diagnosis often means earlier access to life-sustaining care [5, 6]. From a population perspective, those who remain undiagnosed continue to transmit the disease [1]. Estimates suggest that 54-70% of new HIV

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cases are transmitted from those who remain undiagnosed [7]. Thus, knowledge of HIV infection may function to decrease the HIV/AIDS disease burden in the United States. This paper will review the challenges of universal testing, consent and confidentiality, access to treatment, barriers to testing, and conclude with a discussion on the rising costs of care and the financial impact of these new recommendations.

CDC Recommendations: Past and Present

Previous CDC HIV testing recommendations have focused on routine counseling and testing for persons at high risk for HIV infection and for those in healthcare settings with an HIV prevalence >1% [2, 8, 9]. However, a study conducted as early as 1998 found that 9% of people with HIV infection in the United States had no known risk factors [10]. Moreover, as the epidemic transitions from one with easily identifiable risk factors to one of more widespread sexual risk, targeted testing has become less feasible [11]. In 2006, the CDC invoked a major revision in their guidelines, specifically recommending routine voluntary HIV screening for all people ages 13-64 years in health care settings. Under the suggested new guidelines, testing would not be required – rather, patients will have the opportunity to "opt-out" after being informed that the test is among standard tests performed on every patient. Such an "opt-out" approach has been successfully employed in pregnant women since 1995 [9, 12]. Under the recommended "opt-out" policy, after verbal consent is obtained, written documentation would be required only of those patients who decline testing.

While the CDC has developed dedicated awareness programs to target at-risk populations, these new recommendations reach out to underserved populations by HIV screening in all public and private healthcare settings, including community clinics, hospital emergency departments (ED), urgent care clinics, and inpatient services [2]. As such, marginalized patients who look to these venues for their primary health care needs would have improved access to HIV screening [14].

Not all government agencies, however, support universal testing – the United States Preventive Services Task Force (USPSTF) differs in its recommendations from those made by the CDC. An initial review of the literature by the USPSTF in 2005 supported the prior CDC recommendations of targeted HIV testing and testing in areas of high prevalence [13]. Earlier this year, the USPSTF re-reviewed the data that had emerged since 2005. The response to the new CDC recommendations was a report stating that while routine universal testing is likely easier to implement, there is not ample evidence to strongly recommend it [15].

The Rapid HIV Test

The shift to universal HIV screening within clinical practices will require acceptable screening test options, a reliable confirmatory testing process, and a clear understanding of the local and regional HIV prevalence. Currently, test options vary with regard to specimen type (oral, fingerstick, and venipuncture), performance characteristics (specificity and sensitivity), and cost.

The Food and Drug Administration (FDA) has now approved four rapid tests, all of which return test results in under an hour: 1) OraQuick Advance Rapid HIV-1/2 Antibody Tests (OraSure Technologies, Bethlehem, Pennsylvania); 2) Reveal G2 HIV-Antibody Tests (MedMira, Inc. Halifax, Canada); 3) Uni-Gold Recombigen (Trinity Biotech Bray, Ireland) and 4) Multispot HIV-1/HIV-2 Rapid Test (Bio-Rad Laboratories, Hercules, California) [16]. These tests have reported high sensitivities (99.3-100%) and high specificities (99.1-100%) making them exceptionally reliable. While all FDA-approved testing options

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can be conducted on blood specimens (whole, serum or plasma), the advantage of the OraQuick is that it can also utilize oral secretions. Two of the rapid tests (OraQuick and Uni-Gold) have been Clinical Laboratory Improvement Amendment (CLIA)-waived, indicating test performance is so simple and accurate that risks of incorrect results due to laboratory error are negligible [16]. CLIA-waiver facilitates test usage, allowing it to be conducted out of the hospital laboratory at points of care and in community-based settings.

Despite their excellent reliability profile, rapid HIV tests require confirmation. The current CDC recommended algorithm is to confirm all reactive rapid HIV test results with either Western blot (WB) or Immunofluorescent assay (IFA), even if an enzyme immunoassay (EIA) is negative [17]. Additionally, the CDC advises follow-up testing within 4 weeks for persons with negative or indeterminate confirmatory test results [17]. This last step is to ensure that the confirmatory protocol does not miss cases of acute HIV infection that the rapid test might not have been sensitive enough to detect. Ensuring confirmatory testing has been a significant obstacle in many pilot screening programs. Because both false positive and false negative rapid results have been reported and because Western Blot results take approximately one week to return, some pilot programs have tried to allay immediate patient anxiety by conducting sequential rapid tests before performing a Western blot [18].

Updated testing methods may facilitate routine HIV testing. However, patients with reactive results still need to present for a follow-up appointment to obtain confirmatory results. Follow-up for test results may be a significant barrier in testing programs. Prior to the availability of rapid tests, the CDC reported that 31% of people did not receive their test results [19]. Other studies have found similar rates, ranging from 10-43% for failure to return [20-22]. The highest rates are often found in those who did not actively seek testing, as might be applicable to routine testing programs. Recent pilot projects have been most effective at increasing return rates when working in collaboration with the local public health departments [22]. Testing programs should provide the capacity for a reliable confirmatory testing protocol with a mechanism in place to contact patients with reactive results who fail to complete the confirmatory testing plan.

Site Specific Screening for HIV Infection

Surveys consistently indicate that the biggest obstacle for providers is time constraints that may be alleviated by the elimination of the need for formal time-intensive pre-test counseling [22, 23]. Feeling ill-equipped to deliver results, physicians have also voiced concerns about post-test and sexual risk counseling [22, 24]. Each setting, from ED to primary care center to hospital inpatients services, faces its own unique challenges to the implementation of universal testing. Thus, ideal testing algorithms should be tailored to the site, and efforts should be focused on where the deficiencies are likely to be in that venue.

Urban EDs provide care to many patients at high risk for HIV infection, including injection drug users, uninsured patients, and patients without primary health care; time constraints remain a significant challenge in this setting [23]. That ED-based routine testing programs would be successful at case identification is indicated by several studies, including one at the Johns Hopkins Hospital Emergency Department where newly identified HIV prevalence was as high as 9.3% [25]. Other sites report ED-identified HIV prevalence from 0.8-3.0% including those in Illinois, Colorado, and California [26-28]. Testing programs have been integrated into the EDs using alternative strategies such as screening by triage nurses or dedicated HIV counselors; one report suggests acceptance rates may vary by the person who offers testing, though further data are needed in this area [28].

The primary care setting may provide a venue with a slower pace than the ED, where providers often have established relationships with patients, easing follow-up and decreasing

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the burden of linkage to care. However, primary care settings have their own unique obstacles to universal testing. Many, for example, do not have on-site phlebotomists to assist with confirmatory testing [29]. Some providers may choose to include HIV testing along with a typical battery of yearly screening tests for diabetes, high cholesterol and thyroid disease as opposed to testing specifically for HIV with a rapid test. In this case, standard testing (rather than rapid) might be sufficient and providers can determine optimal screening frequency based on risk [2]. In the primary care setting, counseling can remain a longitudinal conversation by the provider, in a fashion similar to diabetes and hypertension education or discussions of smoking cessation [30].

The inpatient hospital setting may offer the most flexibility for HIV testing because patients are available for more lengthy and repeated discussions, as well as ample time for receipt of standard test results. With some patients receiving daily phlebotomy, confirmatory testing is simpler. One early study reported on the success of routine voluntary inpatient HIV testing, identifying an undiagnosed HIV prevalence of 3.8% [31]. Another study noted that there were additional benefits to rapid ED testing when compared to standard inpatient testing including higher receipt of test results, decreased length of stay and more rapid HIV follow-up care [32]. It is unclear whether these differences are related to either the setting or the type of test performed and should be examined in future studies.

Documenting HIV Test Results and Reporting to the State

Independent of the testing setting, HIV testing programs should address the challenges of how and if the results will be documented in the medical record. The CDC firmly recommends that test results be reported in the medical record so that they are available to health care personnel involved in clinical care [2]. However, such documentation may influence testing rates as concerns about the insurance implications may deter patients from willingness to test [33]. Furthermore, as rapid HIV screening tests are often performed in the community as point of care tests, it may be more reasonable to work toward the documentation of only confirmatory test results.

Regardless of how the medical record handles the documentation issue, state laws are now mandating name-based reporting of confirmed cases of HIV infection. Historically, state legislative policies differed on how to accomplish this goal. In the early stages of the HIV epidemic, extensive efforts were made to protect the privacy of the individual, with anonymous HIV testing as a fundamental cornerstone. Most states have since moved away from anonymous testing toward confidential testing, which permits better public health surveillance of infected individuals [34]. This year (2007) marks the first time that federal funding has been tied to name-based surveillance of HIV [35]. Currently, thirty-six states have implemented name-based HIV reporting, five use name-to-code systems, two allow client choice of name or code, and seven use a code-only system [36]. By the end of 2007, all 50 states will use a name-based reporting system for HIV surveillance [35]. Proponents of name-based reporting say that it is the only effective means of accurately tracking the epidemic. Opponents are concerned that it will serve as a testing deterrent and feel that the current code-based reporting is adequate [37].

Clinical Care for HIV-infected Persons

Increasing the number of individuals who are screened for HIV infection will result in a concomitant increase in the number of newly HIV-diagnosed patients within the US healthcare system. Access to care is a significant problem affecting those where HIV prevalence remains the highest, including minority populations and those who are uninsured or live in medically underserved areas [38]. Thus, as HIV testing efforts increase, special

programs will be needed to ensure that identified patients are able to link to longitudinal care with adequate access to necessary therapy.

Linkage to Care

The success of any HIV testing program should not be measured by the number of patients identified, but rather by the number of patients reaching HIV clinical care. Though arguably among the biggest challenges to CDC guideline implementation, the recommendations explicitly state that "screening without such linkage confers little or no benefit to the patient" [2]. The obstacles to linkage to care are well-recognized; in one study the mean duration between testing positive for HIV infection and initial presentation to primary care was over 2 years [39]. As pilot testing programs have evolved over the last five years, diverse efforts have been devoted to the linkage issue. In two reported programs, both predating the revised guidelines, linkage to care rates ranged from 47% in Atlanta to 100% in Massachusetts [21, 40]. Two recent pilot studies in emergency departments demonstrate the challenges of linkage to care when testing is done in the acute care setting; in Chicago and Boston, less than 40% of patients identified as HIV-infected in the emergency department made one visit to an infectious disease clinic [18, 41].

Retention in Care

Once a newly identified HIV-infected patient reaches a physician, efforts are still required to ensure that the patient remains engaged in care. Nationally, 1998 estimates indicate that from 36-63% of all HIV-infected patients are seen by a physician every six months [10]. Patient factors such as denial, pill-fatigue, psychiatric disease and chaotic lifestyles may contribute to failed retention [42]. One recent study noted that incomplete access to care is responsible for impressive losses in life expectancy, especially for ethnic minorities. While late initiation to care resulted in an average of 3.7 years of life lost, premature discontinuation of care resulted in an additional 1.1 years of average life lost [43].

In addition to patient-related factors, a lack of trained providers in already overburdened HIV clinics may also play a role in limitations of patients' access to care [44]. While increased HIV diagnoses may exacerbate this problem, among the proposed solutions are increases in state emergency planning funds, creation of incentives to encourage medical residents to go into HIV medicine and "down-referral" from specialists to primary care physicians as is currently done for other chronic diseases such as emphysema, heart disease and diabetes [44].

AIDS Drug Assistance Programs

Once patients are identified with infection, those who meet the treatment guidelines for antiretroviral therapy will accrue an annual drug cost of approximately $15,000 [45]. Unfortunately, Medicaid's strict eligibility criteria effectively deny access to many poor and low-income adults with HIV infection who are not yet disabled by AIDS. For patients without public or private insurance, state-run AIDS drug assistance programs (ADAP) will carry the burden of such costs [46]. ADAPs, funded in large part by the federal Ryan White Care Act, are already maximally stretched. Even in the absence of full scale testing efforts in 2006, 558 people nationally were on ADAP waiting lists; eight additional states were in the process of implementing tighter cost-control measures [46]. Increased case identification of occult HIV disease, coupled with prolonged survival due to improved treatment will serve to create further tensions in medication financing [6, 47]. A common issue raised by opponents of the routine testing guidelines is the inability of current ADAPs to ensure nationally that the people who get tested have adequate access to the benefits of care [48]. A call to

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improve HIV diagnosis should be matched with the commitment to provide necessary funds to treat patients who are identified.

Financial Impact in the Short and Long Term

Short-term Costs

Although diagnostic testing for HIV is generally covered if clinically indicated, Medicaid coverage for HIV screening (in the absence of known reported risk) varies by state [49]. Private insurance companies also vary in their policies; for example, one large HMO will pay for routine screening for other diseases such as hypercholesteroleremia, but does not perform routine screening for HIV infection [50]. If every individual not yet tested in the US accepted a rapid HIV test, the approximate upfront cost would be roughly $4.5 billion dollars for just the screening alone [51]. Other costs of a routine rapid testing program will include training for health care providers, as well as additional nursing time and laboratory resources to perform the testing [18].

Long-term Costs

The long term costs of any HIV testing program consists largely of the costs of medical care for the HIV-infected patients identified by the program. In the absence of a testing program, diagnosis occurs late in the course of HIV infection for many, with upwards of 50% of newly diagnosed patients presenting with advanced AIDS [1]. Individuals diagnosed late in the course of HIV infection have significantly higher mortality and generate 2.5 times more cost of care than those diagnosed early [52]. It is, however, not the case that diagnosis of patients earlier in the course of their disease will save money; rather, these patients will have increased survival, requiring access to expensive therapies for a longer period of time. A recent analysis noted that the undiscounted lifetime costs of HIV care in the US is $567,000-618,900 (2004 US$) depending on CD4 count at the time of starting treatment [52]. About 75% of these costs are attributable to the cost of antiretroviral drugs alone. Ultimately, the principle driver of the costs and benefits of the CDC's recommendations are not due to the increases in testing, but rather the increasing need for care of those identified [52, 53].

Cost-effectiveness

Given these anticipated short- and long-term costs associated with an HIV screening program, it seems reasonable to question whether routine HIV screening would be a cost-effective intervention. Three recent analyses evaluated the cost-effectiveness of HIV screening in both the inpatient and outpatient settings. They concluded that a one-time HIV screen had an estimated cost-effectiveness ratio of $33,000-41,000 per quality-adjusted life year (QALY) [45, 53, 54]. Studies that evaluated screening programs in the context of a potential reduction in HIV transmission rates noted costs as low as $15,000 per QALY [45, 53, 55]. Compared to the cost-effectiveness of other recommended screening interventions, such as those for breast cancer, colon cancer, diabetes and hypertension, the cost-effectiveness of HIV screening compares favorably, even without the benefits of decreased viral transmission [45, 53, 54].

Other Barriers to Implementation

Voluntary, Informed Consent

Though implementation of routine testing may be feasible, many states still have laws prohibitive to the CDC recommendations for true "opt-out" testing. Strictly defined, an "opt-out" HIV testing strategy means that patients are informed that HIV testing is conducted for all patients in that health care setting, unless the patient specifically signs requesting it *not*

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be performed. Despite these recommendations, as of mid-2004, 31 states had laws requiring written informed consent prior to HIV testing [56]. Some of these laws necessitate an additional lengthy pre-test counseling session, with an assessment of the emotional and mental health of the patient prior to testing, and of these, 26 states required a written documentation of this process [56]. While illegal to implement in many regions, data are beginning to emerge that demonstrate that written consent is a true impediment to routine testing. In San Francisco, while chart documentation indicated verbal consent was obtained, ending separate written consent increased testing rates significantly, from 13.5 tests per 1000 patient-visits to 17.9 [57]. These data, coupled with the revised guidelines, have prompted more states, including Illinois, New York, and Maine, into legislative action to revise their laws.

Feasibility, Sustainability, and Staffing

Numerous programs in a variety of health care settings have already demonstrated that routine HIV testing programs are feasible, successful at HIV case identification, and can be easily integrated into the existing clinical infrastructure [22, 28]. Such programs have often been made possible with funding from research grants, implementation projects, or seed money. Continued investments will be required for sustained success of such programs, as well as for the establishment of new ones. For example, at around $15 each, many venues cannot afford the added cost of a rapid HIV test, not to mention the trained staff required to conduct the test [44]. Furthermore, dedicated staffing will play a significant role in improving both linkage of care and care maintenance issues. While aggressive in their intended goals, the success of the new CDC guidelines will be very much determined by the financial dedication necessary to implement them.

Social Context and Discrimination

Despite attempts at the “routinization” of the testing process, HIV and testing still evoke a powerful social stigma [33, 58]. While experience in the perinatal literature suggests that normalization of testing may result in higher acceptance (as high as 98%), extrapolation to the general population may be limited because pregnant women have unique concerns about protecting their babies [59]. Even so, at least one study has documented that when offered routinely in an outpatient setting, HIV test acceptance rates increase over time. In this Massachusetts multi-site study, the urgent care center with the longest testing program in place showed nearly twice the test acceptance rates as the other programs [60]. Similarly, another survey-based study reports that patients prefer to be offered routine testing rather than “risk screening” and testing based on risk assessment [61]. The stigma and discrimination associated with testing may play a significant role within certain communities, predominantly minority populations, and strongly affects how individual patients make decisions with regards to HIV—specifically, test acceptance rates, willingness to have confirmatory testing, linkage to care, treatment compliance, and disclosure of infection to family and support systems [62].

Conclusions

As evidenced by the experience of the HIV epidemic over the last 25 years, the current HIV testing strategies are inadequate to identify all patients who are HIV-infected. New screening guidelines from the CDC in 2006 propose an aggressive approach to HIV case identification. While early evidence suggests some success at increased HIV diagnoses and linkage to care resulting from such recommendations, changes in policy will continue to be accompanied by challenges in legal ramifications, stigma, access to care, and costs. Numerous programs in a variety of health care settings have already demonstrated that routine HIV testing programs are feasible, successful at HIV case identification, and can be

easily integrated into the existing clinical infrastructure. Financing these programs will be essential to their implementation and long-term success.

Acknowledgments

The authors would like to thank Lauren Uhler for her technical assistance with this manuscript.

Grant Support: This research was funded by the National Institute of Mental Health (R01 MH073445, R01 MH65869), and the Doris Duke Charitable Foundation Clinical Scientist Development Award to Rochelle P. Walensky.

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Revisions to CDC Testing Guidelines

- Screening should be performed on *all* patients in *all* health-care settings, but patients will be allowed to opt-out
- Testing should be on an annual basis for those at "high-risk" and every five years for others
- Written consent is no longer required, consent will be implied as a part of general medical treatment
- Counseling is no longer required at the time of the testing encounter, but should be left up to the provider's discretion

Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings, CDC, 2006 [2]