Routine HIV Screening in the Emergency Department Using the New US Centers for Disease Control and Prevention Guidelines

Results From a High-Prevalence Area

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Background: In 2006, the US Centers for Disease Control and Prevention (CDC) released new recommendations for routine HIV testing. Among these were recommendations that emergency departments (EDs) offer routine opt-out HIV screening to their patients. We established a screening program implementing these recommendations at an urban university hospital ED in Washington, DC. We report the results of this program.

Methods: During a 3-month period, ED patients being treated for a wide range of conditions were approached by trained HIV screeners and offered point-of-care rapid HIV testing. Patients with positive results were referred to hospital or community resources for confirmatory testing and treatment.

Results: During the program period, 14,986 patients were treated in the ED and 4151 (27.6%) were offered HIV screening. The mean patient age was 37.5 years; 48.5% were black, 39.0% were non-Hispanic white, 4.1% were Hispanic, 1.7% were Asian, and 6.7% responded as being other race. A total of 56.1% were female, and most lived within the Washington, DC metropolitan area. Of the patients offered HIV screening, 2476 (59.7%) accepted the test. Of the 26 patients with a preliminary positive screen, 13 were lost to follow-up, 9 were confirmed positive by Western blot, and 4 were confirmed negative by Western blot. Eight of the 9 patients with confirmed HIV infection were successfully linked to follow-up care.

Conclusions: The implementation of the CDC recommendations establishing routine opt-out HIV screening programs in EDs is feasible. Further efforts to establish routine ED HIV testing are therefore warranted.

Key Words: epidemiology, HIV screening, public health

(*J Acquir Immune Defic Syndr* 2007;46:395–401)

The US Centers for Disease Control and Prevention (CDC) recently issued new recommendations that radically alter the approach to HIV screening in the United States.[1] These recommendations have evolved over the past decade, and they differ from those that had previously recommended the routine testing and counseling of all patients or the targeted testing of high-risk populations.[2,3] The new recommendations responded to the perceptions that time constraints, physician discomfort with discussing risk behaviors, and the lengthy requirements for written informed consent had all contributed to a poor response to prior screening recommendations.[1]

The new CDC recommendations expand routine HIV screening to virtually all outpatient settings, including the emergency department (ED). Routine ED HIV screening in specific high-volume and high-prevalence settings was endorsed by the Society for Academic Emergency Medicine Public Health and Education Task Force in 2000,[4] but few EDs had initiated any type of screening program, and some even have policies prohibiting routine HIV screening.[5] Many of the CDC recommendations released in September 2006 affect EDs. It was recommended that screening for HIV infection be routinely performed for all patients aged 13 to 64 years and that screening should be initiated unless the prevalence of undiagnosed HIV infection in the patient population is documented to be $<0.1\%$. All patients initiating treatment for tuberculosis should be routinely screened for HIV infection, and all patients seeking treatment for sexually transmitted diseases should be routinely screened for HIV during each visit for a new complaint, regardless of whether the patient is known or suspected to have specific behavioral risks for HIV infection.

Testing programs are recommended to use an opt-out approach, wherein patients are informed that the test is going

Received for publication April 22, 2007; accepted August 13, 2007.

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Supported by the Department of Health, District of Columbia, and an unrestricted grant from Gilead Sciences.

Jeremy Brown had full access to all the data in the program and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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to be done unless they decline. It was also recommended that neither a specific signed consent form for HIV testing nor an elaborate prevention counseling program be required for screening programs in health care settings such as EDs. The recommendations emphasize that screening should be voluntary and undertaken only with the patient's knowledge and understanding.

This article describes the results of an ED-based testing program using all these CDC recommendations.

METHODS

Program Design

A clinical program was designed with the primary objective of detecting previously undiagnosed HIV infection in ED patients at The George Washington University Hospital in Washington, DC. Our goals are to report the numbers of newly identified HIV cases, the rates of acceptance of the screening test among ED patients, and the costs of the program.

Program Subjects

All patients between the ages of 13 and 64 years who presented to the ED at The George Washington University Hospital were eligible to be offered an HIV screening test if they spoke English or Spanish. Patients who knew they were HIV-positive, who had an altered mental status, or who required urgent medical intervention were excluded from screening.

Procedures for Screening

Figure 1 depicts the procedures adopted in the ED for HIV screening. Screening was offered by specially trained additional staff from 8:00 AM through midnight daily, and 2 screeners were assigned to periods of peak activity in the ED. The screening staff members were made up of undergraduate health sciences students who had received an 8-hour orientation that covered HIV epidemiology, research regulations, and point-of-care testing.

Ambulatory patients and those arriving by ambulance were informed of the availability of a free HIV screening test and were given written information about HIV disease and the importance of HIV testing by the triage nurse if they met screening criteria. At a subsequent mutually convenient point during the ED evaluation, which varied from patient to patient, the HIV screener approached the patient and reiterated that an HIV screening test was being offered to all ED patients regardless of their perceived risk of infection and that the patient could opt out of the screening test if he or she wished.

Patients who accepted screening were tested with an oral swab using the OraQuick Rapid HIV-1/2 Antibody test (OraSure Technologies, Bethlehem, PA). Testing was performed in parallel to the provision of standard ED care. Results were available within 20 to 40 minutes, and negative results were relayed to the patient by the screener. All patients who had a negative screening test result were given additional written information about preventing HIV infection, and the results were noted on the ED record. Positive results were reviewed by a second screener and the ED attending physician. If there was agreement about the result, the ED attending physician informed the patient of the preliminary nature of the positive result in a confidential area. Patients who had a weakly positive test result were screened a second time; if positive twice, they were recorded as having a preliminary positive test result. All patients with a preliminary positive test result were given instructions to follow up with the hospital's Division of Infectious Diseases or a local free-care clinic, where a confirmatory Western blot test could be obtained.

Data on age, gender, race, zip code of residence, acceptance or refusal of HIV testing, and the test results were collected for each patient by the screening personnel. For ease of interpretation, age was categorized into quartiles, which were subsequently collapsed into tertiles if contiguous categories were similar. The χ^2 test and logistic regression analyses were used to assess associations between acceptance of HIV screening, a preliminary HIV-positive test result, and demographic characteristics. All data analyses were conducted using STATA 9.0 (Stata Corporation, College Station, TX).

RESULTS

Screening Population

Between September 12, and December 11, 2006, 14,986 patients were seen in the ED. A total of 13,240 (88%) were in the targeted group aged 13 to 64 years, and 4187 (31.4%) met screening criteria and were offered routine testing (Fig. 2). The demographic characteristics of the population offered screening are shown in Table 1. Of those individuals, the average age was 37.5 (±12.9 SD) years; nearly half (48.5%) were African American, 39.0% were non-Hispanic white, 4.1% were Hispanic, 1.7% were Asian, and 6.7% responded as other race (American Indian/Native American or mixed race). More than half (56.1%) were female, and most screened patients lived in the tristate area (District of Columbia, Maryland, or Virginia).

Acceptance of HIV Screening

Among those offered routine HIV screening, 2486 (59.7%) accepted and 1701 (40.3%) declined to be tested. Individuals who declined to be tested for HIV were more likely to be older ($P < 0.001$), to be Asian ($P = 0.01$), and to live outside the tristate area ($P < 0.001$) than individuals who agreed to be tested. Multivariate analyses revealed that older age groups were significantly less likely to agree to be tested for HIV compared with individuals <25 years old (odds ratio [OR] for those aged 26 to 35 years = 0.7, 95% confidence interval [CI]: 0.6 to 0.9; OR for those aged ≥36 years = 0.6, 95% CI: 0.5 to 0.7). African Americans were marginally more likely to accept HIV screening (OR = 1.15, 95% CI: 0.99 to 1.32) than whites, whereas Asians were significantly less likely to accept screening compared with whites (OR = 0.52, 95% CI: 0.33 to 0.86). Adjusting for race, age, and gender, local residents were significantly more likely to accept screening compared with individuals from outside the tristate area (OR = 1.46, 95% CI: 1.15 to 1.84).

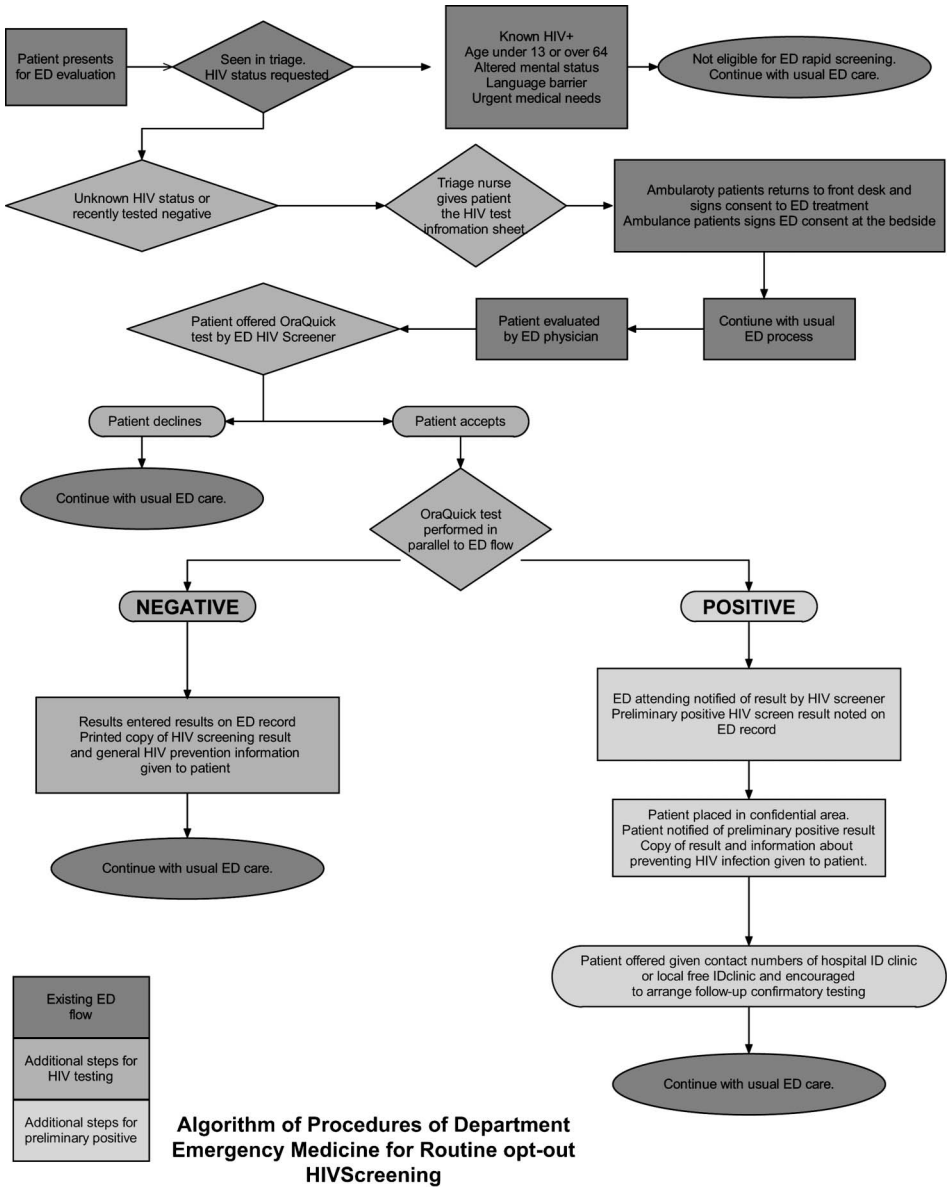

FIGURE 1. Algorithm of procedures of Department of Emergency Medicine for opt-out HIV screening.

Preliminary Positive HIV Screens

All patients who had a preliminary positive test result in the ED received their results. As detailed in Table 2, 26 patients (1.1%) had a positive preliminary HIV screen in the ED. Patients who had a preliminary positive test result for HIV were significantly more likely to be male (1.7% vs. 0.6% for female; $P = 0.007$) and African American (1.9% vs. 0.3% for white; $P = 0.001$). After adjusting for age and residence, African Americans were still significantly more likely than whites to have a preliminary positive test result (adjusted odds ratio [AOR] = 8.9, 95% CI: 2.5 to 32.0), whereas female patients were less likely to test positive (AOR = 0.3, 95% CI: 0.1 to 0.8). Among the individuals testing positive for HIV, 13 (50.0%) could be reached for follow-up; there were 4 confirmed false-positive test results and 9 (69.2%) patients who reported a positive Western blot test result.

Estimated Costs

The costs associated with this model of an ED HIV screening protocol reflect the costs of dedicated screeners and the costs of the screening kits themselves. The test kits were provided to the ED through the District of Columbia's Department of Health, and the screeners were provided by the Department of Emergency Medicine. Assuming a cost of $12 per test kit and $7.50 per hour for the staff, the total added expense for the initial 12-week program (providing 156 hours per week of staffing) was approximately $44,000. This reflects a cost per preliminary positive test result of approximately $1700 and a cost of $4900 per confirmed case of HIV infection.

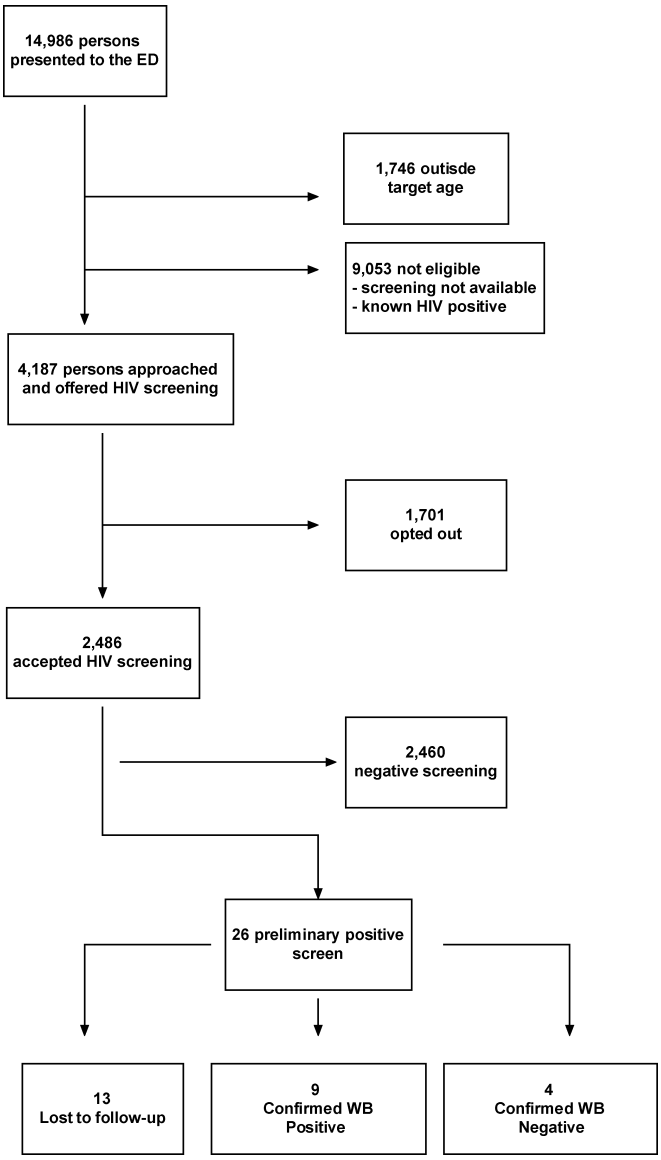

FIGURE 2. Results of initial 3 months of routine HIV screening.

DISCUSSION

This is the first program to report the characteristics of a routine opt-out ED HIV screening program that does not require written informed consent. We found that almost 60% of the patients who were eligible for screening agreed to be tested for HIV in the ED. The preliminary HIV-positive rate was 1.1%, but because the ED was not equipped to conduct the confirmatory Western blot test, most preliminarily positive patients were referred to a local free clinic for confirmatory testing. A considerable number of patients were lost to follow-up. EDs across the nation are the most likely source of medical services for indigent and low-income populations,[6] and these populations are disproportionately affected by HIV infection.[7–9] Because of this, offering HIV screening to all patients in the ED is likely to reach large numbers of patients who may be infected with HIV and who otherwise would never be screened.

Washington, DC has one of the highest AIDS case prevalence rates in the United States,[10] and our results suggest that ED HIV screening in this high prevalence area is well accepted by patients. The cost per case detected is low; for example, nucleic acid amplification has been used for early detection of HIV infection at a cost of >$17,000 per index case identified.[11] Several areas of concern were identified, however.

Linkage to Care

HIV screening cannot be regarded as an end in itself. The success of a screening program should be measured not only by how many patients agree to be tested but, more importantly, by how many of those found to be positive are linked to long-term care. Of the 9 patients who we were able to confirm as being HIV positive, 8 were seen by an infectious disease specialist and the ninth patient was given 2 appointments at an HIV clinic that he failed to keep. Although these numbers are small and need to be replicated, they demonstrate that patients can be successfully linked to care if accurate follow-up information is available. Our program also demonstrated a large number of patients (13 of 26) who were lost to follow-up after a positive HIV screening test result, however. Vigorous efforts were made to contact these patients by means of telephone or registered mail; however, despite this, they could not be traced. In an effort to reduce the number of patients with a preliminary positive result who are lost to follow-up, we have made several modifications to our protocol. Telephone numbers and contact information of all patients with a preliminary positive screen are reviewed and verified together with the patient, and all patients are now offered a confirmatory Western blot test while still in the ED. When the screening program first began, the number of patients who would have a preliminary positive test result was not known. Further, there was no supporting ED infrastructure to accommodate the possible large numbers of Western blot test results that would need to be communicated back to the patients. As a result, the ED management initially required patients who had a preliminary positive test result to obtain a confirmatory test at a later time in a setting to be decided by the patient. Once it became clear that only 2 or 3 patients each week required a confirmatory Western blot, however, a new policy was introduced that allowed a Western blot to be drawn immediately. One ED physician undertook the responsibility for communicating this result to the patient. A second change was the protocol of contacting a physician from the Division of Infectious Diseases while the patient is in the ED. This physician, who is usually able to see the patient briefly while in the ED or to speak with the patient by telephone, makes arrangements with the patient for a clinic appointment, usually within 24 hours. We are currently studying the effects of these protocol modifications in reducing the number of patients who are lost to follow-up.

Test Characteristics

The rapid HIV screening test has never been advertised as other than a screening tool. The test manufacturers and the CDC have made it clear that a preliminary positive test result should be followed by a confirmatory blood test before making

TABLE 1. Demographic Characteristics of Patients Offered Routine ED HIV Testing

	Total n (%)	Accepted HIV Test n (%)	Declined HIV Test n (%)	χ^2 Test, *P*	AOR (95% CI)
Total	4151 (100.0)	2476 (59.6)	1675 (40.4)	—	
Age, quartiles					
≤25 years old	980 (23.6)	659 (67.2)	321 (32.8)	<0.001	1.0
26 to 35 years old	1009 (24.3)	620 (61.5)	389 (38.6)		0.7 (0.6 to 0.9)
≥36 years old	2162 (52.1)	1197 (55.4)	965 (44.6)		0.6 (0.5 to 0.7)
Gender					
Male	1821 (43.9)	1071 (58.8)	750 (41.9)	0.33	1.0
Female	2330 (56.1)	1405 (60.3)	925 (39.7)		1.1 (0.9 to 1.2)
Race*					
White	1614 (39.0)	959 (59.4)	655 (40.6)	0.01	1.0
Black	2008 (48.5)	1224 (61.0)	784 (39.0)		1.1 (1.0 to 1.3)
Hispanic	171 (4.1)	103 (60.2)	68 (39.8)		1.0 (0.8 to 1.5)
Asian	70 (1.7)	31 (44.3)	39 (55.7)		0.5 (0.3 to 0.9)
Other	276 (6.7)	152 (55.1)	124 (44.9)		0.8 (0.6 to 1.2)
Residence					
DC, VA, MD area	3046 (73.4)	1876 (61.6)	1170 (38.4)	<0.001	1.0
Outside DC, VA, MD area	357 (8.6)	195 (54.6)	163 (45.4)		0.7 (0.6 to 0.9)
Missing	748 (18.0)	405 (54.1)	343 (45.9)		0.7 (0.6 to 0.9)

*n = 9 individuals were missing racial identification. American Indian/Native American race was collapsed with "other" race because of small numbers.
AOR indicates adjusted odds ratio.

a definitive diagnosis of HIV infection. In a prior study of the OraQuick test, it was reported as being 99.8% specific.[12] Assuming that all the negative test results were true-negative results, the ED performance of the OraQuick test demonstrated a specificity of 99.8% and a positive predictive value of 69%. The false-positive rate in our program is not unexpected when studying a population in an ED, especially when considering that known HIV-infected individuals were not studied. These findings emphasize the need for patients to understand that the result is only preliminary and that confirmatory studies are absolutely necessary before the diagnosis can be established. When evaluating this false-positive rate, it should be compared with other tests used in the early detection of HIV infection. For example, in a study of nucleic acid amplification for the

TABLE 2. Preliminary Positive HIV Results

	Preliminary HIV+ Test n (%)	HIV− Test n (%)	χ^2 Test, *P*	AOR (95% CI)
Total	26 (1.1)	2440 (98.9)	—	
Age categories				
≤25 years old	7 (1.1)	648 (98.9)	0.97	1.0
26 to 35 years old	7 (1.1)	612 (98.9)		1.0 (0.3 to 2.8)
≥36 years old	12 (1.0)	1180 (99.0)		0.8 (0.3 to 2.1)
Gender				
Male	18 (1.7)	1053 (98.3)	0.008	1.0
Female	8 (0.6)	1387 (99.4)		0.3 (0.1 to 0.8)
Race*				
White	3 (0.3)	953 (99.7)	0.003	1.0
Black	23 (1.9)	1195 (98.1)		8.9 (2.5 to 32.0)†
Hispanic	0 (0.0)	103 (100)		
Asian	0 (0.0)	31 (100)		
Other	0 (0.0)	151 (100)		
Residence				
DC, VA, MD area	18 (1.0)	1847 (99.0)	0.30	1.0
Outside DC, VA, MD area	1 (0.5)	193 (99.5)		0.5 (0.1 to 3.7)
Missing	7 (1.7)	400 (98.3)		1.8 (0.8 to 4.4)

*n = 9 individuals were missing racial identification. American Indian/Native American race was collapsed with "other" race because of small numbers.
†Because there were no preliminary positive cases among Hispanics, Asians, and other race, analyses were conducted for blacks versus whites only.

early detection of acute HIV infection, 2 patients among a group of 25 RNA-positive patients were found to have a false-positive result.[11] We have changed our protocol to require that all tests with a weakly positive result be repeated with a specimen of whole blood, and we are currently collecting data on the outcomes.

Acceptance Rate

Although the CDC recommends that routine opt-out HIV testing require no special written consent or pretest counseling, at least 14 states require either or both of these. The clinical program described herein required neither written inform consent nor pretest counseling, and under these conditions, the acceptance rate was 60%. Nevertheless, it must be noted that during the period of this program, the District of Columbia Department of Health sponsored an advertising campaign emphasizing the need for everyone to be have an HIV test. It is certainly possible that the acceptance rate could be considerably lower in states or cities that require other steps such as written informed consent or in which there was no HIV testing campaign. A study done in Chicago, which used rapid HIV testing utilizing whole blood, had an almost identical acceptance rate of 59%, however.[13] In contrast to our protocol, that study did require written informed consent before HIV screening. The acceptance rate was 64% in an ED-based program that provided targeted HIV testing in Ohio.[14] The different study protocols and staffing patterns used in these other programs make comparisons somewhat difficult; however, together with our results, these findings suggest that a large number of patients are willing to be screened for HIV infection while in the ED. Furthermore, when considering the acceptance rate in our clinical program, it must be recognized that none of the patients who agreed to be screened for HIV had arrived at the ED requesting this test. Given these facts, we view the acceptance rate of 60% as encouraging. Further studies are needed to determine the reasons why 40% of patients decline to be tested, and further modifications to the program should aim to increase the acceptance of routine testing among ED patients.

This clinical program tested approximately 31% of the patients who were in the target test range. Those patients not offered testing include those who were already known to be HIV-positive, those whose urgent medical needs took priority, those with an abnormal mental status or a language barrier, and those who were otherwise eligible but were missed by the screening personnel (although the proportions were not recorded). To screen a higher percentage of eligible patients, more staff would be needed, and this would add to the costs of the program.

Costs and Sustainability

Routine HIV testing has repeatedly been shown to be cost-effective, even in low-prevalence settings.[15–17] This program is the first to demonstrate that compared with other methods of early detection, routine opt-out screening in the ED is also cost-effective. The low costs of $<$\$5000 per confirmed HIV-positive patient identified demonstrate support for earlier theoretic models that provided an economic evaluation of prior CDC HIV screening guidelines. For example the model by Walensky et al[16] demonstrated that routine HIV screening had a cost-effectiveness ratio of \$35,400 to 64,500 per quality-adjusted life-year (QALY) gained. These numbers compare favorably with cost-effectiveness estimates for other routine screening programs for diseases, such as type II diabetes (\$70,000 per QALY gained), hypertension (\$80,400 per QALY gained), and colon cancer (\$57,700 per QALY gained). Despite the clear cost-effectiveness of ED HIV screening, programs such as the one we describe here, they are not going to be sustainable unless EDs are able to recover the full costs of screening, including the costs of the test kits and extra personnel. This issue has already been identified by the CDC as being of major concern, (Bernard Branson, personal communication, December 2006), and the future of routine ED HIV screening should ultimately depend on reimbursement rates negotiated between hospitals and payers. Until then, it is unlikely that individual EDs are going to be able to bear the extra costs of providing routine HIV screening for their patients, however successful these programs may be in identifying new cases of HIV infection.

CONCLUSIONS

An ED-based opt-out HIV screening program in accordance with the 2006 CDC guidelines is feasible, cost-effective, and well received by patients. Emphasis needs to be placed on increasing the number of patients who agree to be screened and ensuring continuity of care for patients with a positive test result. Before wider dissemination of these screening programs, hospital managers need to obtain a secure method of funding and overcome ED service delivery challenges.

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