# Detecting Unsuspected HIV Infection With a Rapid Whole-Blood HIV Test in an Urban Emergency Department

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**Objective:** To evaluate and compare HIV screening and provider-referred diagnostic testing as strategies for detecting undiagnosed HIV infection in an urban emergency department (ED).

**Methods:** From January 2003 through April 2004, study staff offered HIV screening with rapid tests to ED patients regardless of risks or symptoms. ED providers could also refer patients for diagnostic testing. Patients aged 18 to 54 years without known HIV infection were eligible.

**Results:** Of 4849 eligible patients approached for screening, 2824 (58%) accepted and were tested; 414 (95%) of 436 provider-referred patients accepted and were tested. Thirty-five (1.2%) screened patients and 48 (11.6%) provider-referred patients were infected with HIV (P < 0.001). Of these, 18 (51%) screened patients and 24 (50%) referred patients reported no traditional risk factors; 27 (77%) screened patients and 38 (79%) referred patients entered HIV care. Of HIV-infected patients with CD4 cell counts available, 14 (45%) of 31 screened patients and 37 (82%) of 45 provider-referred patients had <200 cells/ $\mu$ L (P < 0.001).

**Conclusions:** ED screening detects HIV infection and links to care patients who may not be tested through risk- or symptom-based strategies. The diagnostic yield was higher among provider-referred patients, but screening detected patients earlier in the course of disease.

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IV counseling and testing have been the cornerstones of the publicly funded prevention strategy in the United States for nearly 20 years, yet 24% to 27% of the 925,000 to 1,025,000 persons infected with HIV are unaware that they are infected and 39% of infected persons do not receive a diagnosis until late in the course of disease. Of persons with positive results from publicly funded testing, 18% to 38% fail to receive their results. 3-5

Until now, the predominant practice for diagnosing HIV infection in clinical settings has been to test patients with clinical indications, those perceived to be at high risk, or those who request testing. 6-8 Yet persons with risks are often not tested; in a study, only 10% of emergency department (ED) providers recommended HIV testing to patients with sexually transmitted infections. 9 Nor is diagnostic testing (performing an HIV test for persons with clinical signs or symptoms of HIV infection) uniformly available for symptomatic patients. According to a national survey of hospitals, HIV testing was available in only 56.9% of EDs (Gretchen Torres, MMP, personal communication, 2006), even though referrals of ED patients for outpatient HIV testing have been unsuccessful. 11

In contrast to targeted testing based on risks or clinical indications, screening involves recommending testing to all persons in a defined population. Because of the potential medical and public health benefits of early HIV diagnosis, the Centers for Disease Control and Prevention (CDC) recommended voluntary HIV screening in acute care settings more than 10 years ago;<sup>12</sup> in its 2003 Advancing HIV Prevention Initiative;3 and, most recently, in the Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings. 13 The US Preventive Services Task Force, 14 the Public Health and Education Prevention Task Force of the Society for Academic Emergency Medicine, 15,16 the Infectious Diseases Society of America, 17 and others 6,7,18-20 have recommended screening in acute care and other clinical settings with high HIV prevalence. With 2 recent models, investigators demonstrated that HIV screening is cost-effective even in low-prevalence settings in the United States and recommended screening. 17,21

Research on HIV screening has focused on acute care settings because studies of persons recently receiving an HIV

diagnosis reveal that many accessed medical care multiple times in the preceding years, often in EDs and urgent care centers, but were not tested for HIV. $^{22-27}$  Numerous studies in acute care settings have shown that when screening is offered, unrecognized HIV infection is detected in many patients  $(0.6\%-5.4\%).^{28-33}$ 

Point-of-care rapid tests change the landscape for HIV testing in acute care settings because test results can be available in time to influence medical decision making. Furthermore, patients can receive test results immediately, obviating the need for uninfected patients to return for their results and reducing the number of infected patients who do not receive their test results.<sup>34</sup> Locating such patients has been a barrier to HIV testing in EDs.<sup>9,35</sup>

The original objectives of the study were to evaluate the feasibility and effectiveness of screening for HIV infection with rapid tests in the ED and to assess the accuracy of the OraQuick Rapid HIV-1 Antibody Test (Orasure Technologies, Bethlehem, PA)<sup>36</sup> before its approval by the US Food and Drug Administration. Because we suspected that our small testing staff would be unable to offer screening to all patients and that some ED providers might want rapid HIV test results for some patients who might not otherwise be screened, we allowed providers to refer patients to the study staff for rapid HIV testing. Thus, we added additional analyses to compare screening and provider referral with respect to the number, proportion, and characteristics, including stage of disease, of patients newly identified with HIV infection. We hypothesized that (1) the proportion of HIV-infected patients would be greater among referred than screened patients but that the number of HIV-infected patients identified would depend on the relative numbers of patients who were screened and referred and (2) a greater proportion of referred than screened patients would be diagnosed late in the course of disease.

#### **METHODS**

From January 17, 2003 through April 30, 2004, we offered free rapid HIV testing to eligible adult patients in the Stroger (Cook County) Hospital ED, an urban ED serving predominantly low-income patients of minority races and ethnicities. Testing staff comprised 1 man, bilingual in English and Spanish, and 1 English-speaking woman. Neither had prior laboratory experience. Testing was offered from 9:00 AM to 8:00 PM on weekdays. All participants provided written informed consent for study participation and for HIV testing. The Institutional Review Boards of Stroger Hospital and the CDC approved the study protocol.

# Eligibility, Recruitment, and Study Populations

Patients aged 18 to 54 years who spoke English or Spanish were eligible. Patients were excluded if they were known to be HIV infected, in critical condition, in the short-stay unit, or inmates from jails or prisons. Patients were ineligible if they had been tested (verified) in the county system within 3 months, expressed discomfort about receiving same-day HIV test results, or were considered by the study staff to have an inadequate understanding of the study or the

HIV testing process (eg, mentally incompetent or comprehension affected by substance use).

We defined 2 study populations:

- 1. Screened patients: the testing staff used a daily ED census report with basic demographic and clinical details to identify potentially eligible patients without regard to HIV risks or symptoms. Staff approached as many patients as possible for screening. Because of the large patient census (approximately 350 patient-visits a day) and physical size of the ED (135,000 sq ft), testing staff could not approach all potentially eligible patients. Staff therefore offered screening to patients in 2 of 3 physically distinct patient care areas, the fast-track and higher acuity medical areas, because they were closest in proximity and had the highest patient turnover and because fewer patients in the third, less acute medical area were eligible because of age or mental health reasons for admission.
- 2. Provider-referred patients: during study hours, ED providers (residents, physician's assistants, and attending physicians) could also refer eligible patients from throughout the ED for rapid testing. Providers were informed of mechanisms for referral through meetings, lectures, memorandums, and e-mails. Referral was at the discretion of providers; the study included neither a risk screening intervention nor established referral criteria. Patients were classified as referred if they had not already accepted screening.

Procedures were identical for both study populations. At bedside, staff evaluated eligibility, explained the study, offered enrollment and rapid testing, and recorded reasons for ineligibility or refusal.

## **Specimen Collection and Testing**

Before testing, staff briefly described HIV transmission and prevention, the rapid HIV test, and the meaning of test results and assessed preparedness to receive same-day results.<sup>37</sup>

Staff collected 2 tubes of blood by venipuncture\* from each patient. From the first tube, staff performed the rapid test on whole blood at a work station in the ED. Results were read during the 20- to 40-minute reading period. Reactive rapid tests were immediately repeated in duplicate, and the final result was determined by concordance of at least 2 of 3 tests. The second tube was sent to the hospital microbiology laboratory for conventional testing by an IgM-sensitive enzyme immunoassay (EIA; Abbott HIVAB HIV-1/HIV-2 [rDNA] EIA; Abbott Diagnostics, Abbott Park, IL). Specimens that were repeatedly reactive by EIA or rapid test were sent to a reference laboratory for confirmation by Western blot analysis.

HIV infection status was determined by reference test results (ie, Western blot reactivity; if indeterminate, Western blot or viral load testing of later specimens if available).

<sup>\*</sup>Because this study began before the US Food and Drug Administration (FDA) approved the rapid test, the test was performed under the manufacturer's investigational device exemption, which required repeating reactive tests and comparing all test results with conventional test results. The FDA-approved test requires confirmation of reactive ("preliminary positive") results but not repetition or comparison.

#### **Provision of Test Results**

Testing staff provided negative rapid test results to patients during a brief session. Patients were told they could receive conventional test results at the affiliated sexually transmitted disease (STD) clinic in 2 weeks.

When providing results of preliminary positive tests, testing staff explained the meaning of the test result and the need for confirmatory testing and for behaviors to prevent HIV transmission.<sup>37</sup> Patients were scheduled for medical evaluation at the HIV clinic within 2 weeks (when confirmatory results would be available). If patients with positive rapid test or Western blot results failed to keep clinic appointments, testing and clinic staff attempted to contact them.

On a standard form, testing staff recorded the behavioral risk factors reported by patients whose rapid tests were reactive. Reported risk factors were used to classify patients as high risk according to transmission categories used by the CDC for HIV surveillance.<sup>2</sup> Medical records were reviewed to obtain, where applicable, diagnoses at hospital discharge, initial CD4 cell count, and date of the first visit to the affiliated HIV clinic.

# **Data Analysis**

We analyzed each patient visit as a separate encounter. We calculated exact confidence intervals (CIs) around proportions. All  $\chi^2$  tests were 2-sided; when required because of small cells, the Fisher exact test was used. We calculated sensitivity, specificity, and predictive values of the rapid test by comparison with reference tests using standard methods, which exclude unresolved indeterminate Western blot results from analysis.  $^{39,40}$  Data were analyzed with Statistical Analysis Systems, version 9.1 (SAS Institute, Cary, NC).

## **RESULTS**

# **Eligibility for Screening**

There were 154,479 visits to the ED during the study period (Fig. 1). Of 11,424 patient visits evaluated by testing staff for screening eligibility, 4849 (42%) were eligible for study participation: 5090 (45%) were ineligible because of age, 438 (4%) had a previous HIV diagnosis, 341 (3%) did not speak English or Spanish, 337 (3%) could not provide confidential informed consent, 218 (2%) had been tested (verified) within 3 months, and 151 (1%) were ineligible for other reasons.

# **Test Acceptance**

Acceptance was high for all demographic groups (Table 1). Of patients eligible for screening, 2869 (59%) accepted rapid HIV testing (see Fig. 1). The 1980 patients who refused screening provided 2165 reasons for refusal: most commonly, not considering themselves at risk (836 patients), reporting recent HIV testing (unverified, 586 patients), and not wanting venipuncture (222 patients). Of 436 eligible patients referred by providers, 416 (95%) accepted testing.

Venipuncture specimens were obtained from 2824 (98.4%) screened patients and 414 (99.5%) provider-referred patients. All patients with preliminary positive rapid test

results and 98% of those with negative test results received their results while still in the ED.

## **Newly Detected HIV Infection**

HIV infection was newly detected in 35 (1.2%) screened patients and 48 (11.6%) provider-referred patients (P < 0.001; see Table 1). The odds of infection were 8.9 (95% CI: 5.6 to 14.1) times greater among provider-referred than screened patients when adjusted for gender, race/ethnicity, and age by unconditional logistic regression. The proportion of new diagnoses was highest among referred patients, male patients, Africans and African Americans, and patients aged 30 to 39 years.

Of those with newly diagnosed HIV infection, 18 (51%) screened patients and 24 (50%) provider-referred patients were not classified as high risk (Table 2). Twenty-seven (77%) screened patients and 38 (79%) provider-referred patients made at least 1 visit to the affiliated HIV clinic within 4 months after diagnosis.

# Late Diagnosis

Nineteen (54%) screened patients and 34 (71%) provider-referred patients were admitted to the hospital from the ED (P=0.12; see Table 2). Of these, 2 screened and 10 provider-referred patients were found to have an AIDS-defining opportunistic infection: *Pneumocystis* pneumonia (8 patients), Kaposi sarcoma (1 patient), extrapulmonary tuberculosis (1 patient), cryptococcal meningitis (1 patient), and esophageal candidiasis (1 patient). Of patients with available CD4 cell counts, 37 (82%) of 45 provider-referred patients versus 14 (45%) of 31 screened patients had <200 cells/ $\mu$ L (P < 0.001). The odds of having <200 cells/ $\mu$ L was 4.5 (95% CI: 1.3 to 18.0) times greater among provider-referred than screened patients when adjusted for high-risk classification, gender, race/ethnicity, and age by exact logistic regression (data not shown).

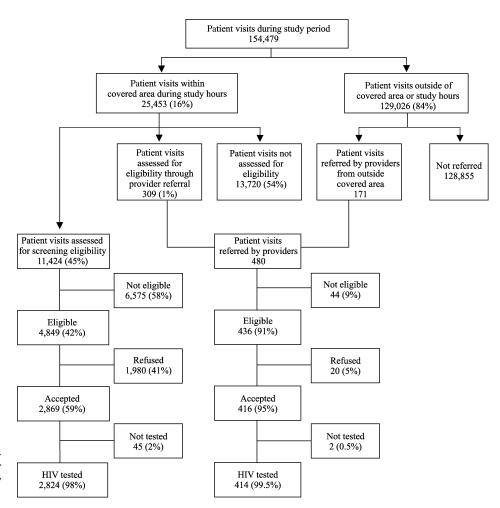
## Accuracy of the Rapid Test†

The sensitivity of the rapid test was 100%, and the specificity was 99.94%. The positive predictive value was 97.2% among screened patients (prevalence of 1.2%) and 98.0% among referred patients (prevalence of 11.6%). The rapid test result was false positive for 2 patients and reactive for 1 patient with a persistently indeterminate Western blot test result despite an HIV viral load of  $>\!750,\!000$  copies/mL and  $<\!200$  CD4 cells/ $\mu$ L.

# **DISCUSSION**

HIV screening and provider referral for diagnostic testing were feasible and effective in Chicago's busiest ED as strategies for identifying persons with undiagnosed HIV infection and linking them to HIV care. Through a combination of screening and provider referral, 3238 ED patients were tested for HIV, and infection was diagnosed in 83 patients, three

<sup>†</sup>Reference test results were available for 2814 (99.6%) screened and 412 (99.5%) referred patients; 1 screened patient with an unresolved indeterminate Western blot test result was excluded from analyses of test performance.



**FIGURE 1.** HIV screening and provider-referred testing in the Stroger Hospital ED, Chicago, IL, January 2003 through April 2004.

quarters of whom were linked to HIV care. Screening identified infection in patients who might not have been tested if testing were targeted to persons based on reported risk behaviors or clinical indications of disease. Providers who took advantage of on-site rapid testing found testing to be clinically useful and more than doubled the number of patients in whom HIV infection was diagnosed. Nonetheless, provider referral detected patients later in the course of disease than did screening. Point-of-care rapid HIV testing was performed accurately when conducted by staff with no prior laboratory experience. Despite concerns about false-positive results when rapid tests are used in screening populations, the positive predictive value among screened patients was 97%. These findings support an expanded role for diagnostic testing and HIV screening using rapid tests in EDs.

Provider referral was remarkably efficient for identifying patients with previously undiagnosed HIV infection, accounting for 58% of diagnoses but only 13% of patients tested. In informal discussions, providers reported that they referred patients for testing because of clinical indications generally related to the chief complaint and determined by physical examination (eg, thrush, hypoxia, skin rash) or patient history (eg, weight loss, substance abuse). Provider recommendations have been shown to influence patients' acceptance of HIV

testing and screening<sup>41–44</sup> and of screening interventions in general. <sup>45–48</sup> In our study, 95% of provider-referred patients accepted testing compared with 58% of those approached only by study staff. The former proportion may be a slight overestimate, because providers may not have told study staff about patients who adamantly refused testing; sicker patients may also have been more likely to accept testing. Most significant, the proportion (11.6%) of provider-referred patients with unrecognized infection is comparable to that among some of the highest risk populations in the United States<sup>49</sup> and indicates that ED providers know which patients to target for diagnostic HIV testing.

Provider referral for diagnostic testing failed to identify many persons who were infected, however. HIV infection in 35 (42%) patients would have gone undiagnosed if screening had not been offered. Furthermore, patients referred because of clinical indications were significantly more likely than those identified through screening to have AIDS at the time of diagnosis. Thus, screening for HIV diagnosed unsuspected infection in additional patients and identified them earlier in the course of their disease.

Expanded screening is important because testing based on risk assessment fails to test many infected persons. <sup>50</sup> In this study, half of the screened patients with undiagnosed infection

**TABLE 1.** Characteristics of Eligible Patients, Tested Patients, and HIV-Infected Patients by Whether Patient Was Screened or Referred by an ED Provider

				Patients			
	Eligible		Accepted and Tested*		HIV Infected		
Characteristic	No. Screened (column %)	No. Referred (column %)	No. Screened (row %)	No. Referred (row %)	No. Screened (row %)	No. Referred (row %)	Adjusted Odds Ratio† (95% CI)
Overall	4849	436	2824 (58)	414 (95)	35 (1.2)	48 (11.6)	
Gender							
Male	2450 (51)	314 (72)	1417 (58)	300 (96)	22 (1.6)	41 (13.7)	2.0 (1.2 to 3.4)
Female	2399 (49)	122 (28)	1407 (59)	114 (93)	13 (0.9)	7 (6.1)	1.0
Race/ethnicity							
African American, not Hispanic	2937 (61)	292 (67)	1624 (55)	274 (94)	27 (1.7)	33 (12.0)	3.7 (1.1 to 12.2)
White, not Hispanic	473 (10)	50 (11)	222 (47)	47 (94)	1 (0.5)	2 (4.3)	1.0
Hispanic	1193 (25)	79 (18)	842 (71)	78 (99)	5 (0.6)	10 (12.8)	2.3 (0.6 to 8.1)
African	79 (2)	8 (2)	50 (63)	8 (100)	1 (2.0)	2 (25.0)	5.9 (1.2 to 32.0)
Other‡	167 (3)	7 (2)	86 (51)	7 (100)	1 (1.2)	1 (14.3)	3.7 (0.6 to 23.5)
Age (y)							
18–29	1311 (27)	98 (22)	865 (66)	94 (96)	5 (0.6)	8 (8.5)	1.0
30–39	1178 (24)	122 (28)	693 (59)	117 (96)	16 (2.3)	16 (13.7)	2.4 (1.2 to 4.7)
40–49	1673 (35)	154 (35)	923 (55)	144 (94)	12 (1.3)	19 (13.2)	1.6 (0.8 to 3.2)
50-54	687 (14)	62 (14)	343 (50)	59 (95)	2 (0.6)	5 ( 8.5)	0.9 (0.3 to 2.3)
Screened							1.0
Referred							8.9 (5.6 to 14.1)

<sup>\*</sup>Venipuncture specimens were obtained from 2824 (98.4%) of 2869 screened patients and 414 (99.5%) of 416 provider-referred patients who accepted testing; characteristics of patients who accepted testing but were not tested did not differ from those of patients who were tested.

might have been missed by risk-based screening because they did not disclose, were unaware of, or did not have such risk factors. In another US hospital, 65% of patients given an HIV diagnosis during hospitalization did not report high-risk behaviors. The decreased likelihood of being tested with risk-based strategies may partly explain (1) why heterosexual men and women are more likely to be diagnosed at a more advanced stage of disease than are men who have sex with men (MSM) or injection drug users \$8,52-54\$ and (2) why testing is more common among MSM who identify themselves as gay than among MSM who do not. Even persons who acknowledge risk behaviors may not be tested through risk-based strategies; in a recent national survey, one third of persons who reported behavioral risks for HIV in the past year also reported never having been tested for HIV.

The efficiency of screening in EDs is high compared with traditional HIV testing venues. From January 1, 2003 through April 30, 2004, the Chicago Department of Public Health performed 31,354 voluntary HIV tests predominantly at STD clinics, HIV testing sites, and through community-based organizations on persons who denied prior HIV-positive test results; the test results of 268 (0.85%) were positive (Carol Ciesielski, MD, personal communication, 2005), which represents a lower proportion than the 1.2% obtained with ED screening (P = 0.04). Compared with health department testing, the combination of HIV screening and provider referral in this single ED detected approximately 30% (83 vs. 268) as many new infections with 10% (3238 vs. 31,354) as many tests and far fewer staff. Several health departments,

including those in Massachusetts, <sup>29</sup> Ohio, <sup>58</sup> New Jersey, Michigan, and Chicago, Illinois (Sindy Paul, MD, MPH [NJ], Liisa Randall, PhD [MI], and Carol Ciesielski, MD [Chicago, IL], personal communication, 2005), now collaborate with acute care settings to offer HIV screening or targeted testing.

Rapid diagnostic HIV testing in the ED was clinically useful. Some ED providers used rapid test results to guide decisions about immediate clinical care. For example, a reactive rapid test result increased a provider's suspicion that a rash was secondary to syphilis and facilitated appropriate referrals; in another case, the reactive test may have prompted the diagnosis of tuberculosis of the cervical vertebrae in a patient with chronic neck pain. For many provider-referred patients, HIV infection might have been diagnosed without ED testing during the ensuing hospitalization; however, another study in this hospital showed that HIV-infected patients who were hospitalized after rapid testing in the ED had a shorter length of stay (mean = 6 days) than patients whose HIV infection was diagnosed with conventional tests after hospital admission (mean = 13 days).<sup>59</sup>

In addition to clinical benefits, expanded HIV screening and diagnostic testing in clinical settings such as EDs are likely to yield important public health benefits. HIV transmission may be reduced as a result of the substantial reductions in high-risk behaviors among persons who learn they are infected with  ${\rm HIV}^{60}$  and of the decreased viral load among patients treated with antiretroviral therapy.

The new CDC guidelines recommend HIV screening in health care settings for all patients aged 13 to 64 years.<sup>13</sup> If it

<sup>†</sup>Unconditional logistic regression model containing all variables listed.

<sup>‡</sup>One HIV-infected patient was an Asian/Pacific Islander; the other reported his race as "Other" but did not specify.

TABLE 2. Specific Risk and Clinical Characteristics of 83 Patients With Newly Diagnosed HIV Infection

	Identified Through Screening			Identified Through Provider Referral	
Characteristic	No.	% (95% CI)	No.	% (95% CI)	P
Total	35	42.2 (32.2 to 53.0)	48	57.8 (47.1 to 67.9)	
Transmission categories*					0.74†
Male-to-male sexual contact	11	31.4 (18.5 to 48.2)	18	37.5 (25.3 to 51.8)	
Injection drug use	5	14.3 (5.9 to 30.0)	3	6.3 (1.6 to 17.6)	
Male-to-male sexual contact and injection drug use	0	0.0 (0.0 to 11.9)	1	2.1 (0.0001 to 12.0)	
Heterosexual contact with a high-risk person‡	1	2.9 (0.0001 to 16.0)	2	4.2 (0.004 to 14.9)	
None of the above	18	51.4 (35.7 to 67.1)	24	50.0 (36.5 to 63.7)	
Entry into care					0.83
Yes	27	77.1 (60.9 to 88.3)	38	79.2 (65.6 to 88.5)	
No	8	22.9 (11.9 to 39.4)	10	20.8 (11.6 to 34.5)	
Admitted to hospital from ED					0.12
Yes	19	54.3 (38.3 to 69.6)	34	70.8 (56.8 to 81.9)	
No	16	45.7 (30.6 to 61.9)	14	29.2 (18.2 to 43.4)	
CD4 cell count at diagnosis§		n = 31		n = 45	< 0.001
<200 cells/μL	14	45.2 (29.3 to 62.4)	37	82.2 (68.5 to 91.0)	
≥200 cells/µL	17	54.8 (37.9 to 71.0)	8	17.8 (9.1 to 31.7)	

<sup>\*</sup>Other transmission categories (eg, hemophilia; receipt of blood transfusion, blood components, or tissue; sex with a person with hemophilia) were not assessed.

were possible to screen all patients routinely, provider referral for diagnostic testing would not be needed. In our study, as in others, <sup>28,30–32</sup> however, only a small percentage of potentially eligible patients could be screened because of small staff size; limited testing hours; and requirements for study informed consent, separate informed consent for HIV testing, and venipuncture for comparing rapid with conventional tests. The CDC's new recommendation for streamlined pretest procedures and inclusion of consent for HIV testing in the general consent for care<sup>13</sup> would likely allow a small staff, or even existing ED staff, to screen more patients.

In response to the new CDC recommendations, programs, institutions, and professional associations are developing new strategies in an attempt to achieve more universal screening. In the interim, until universal screening proves feasible and practical, alternatives are necessary to allocate HIV testing resources to and within institutions. Our study was not designed to evaluate or define optimal criteria for screening or testing in EDs. Nonetheless, our experience yields some considerations regarding clinical, demographic, and behavioral risk characteristics as potential parameters for targeting.

As demonstrated by our study, ED providers are skilled at identifying clinical indications for HIV testing. For programs that lack sufficient resources to screen all patients, making it easier for providers to refer patients for rapid HIV testing could greatly increase the diagnostic yield from acute care settings. We believe that provider referral in our study was contingent on having the screening program in place; ED providers incorporated more HIV testing into their clinical practice and detected more infections when staff were available in the ED to perform rapid tests than before the inception of the screening study. Although we believe that

diagnostic HIV testing is essential for all ED patients with clinical indications of HIV, screening asymptomatic patients is also important for identifying more infected patients and identifying them earlier in the course of disease. We do not have data to assess whether or which clinical criteria might prove useful for targeting screening to subgroups of patients without clinical correlates of HIV.

Targeting HIV screening based on demographic characteristics might increase the efficiency of screening but would likely miss some proportion of infected patients. Nationally, rates of new HIV diagnoses are highest among men, non-Hispanic blacks, and persons aged 25 to 44 years.<sup>62</sup> Not surprisingly, HIV positivity rates were highest among male patients, Africans and African Americans, and those aged 30 to 49 years in our study. Yet if we had screened only male patients, we would have missed 13 (37%) of the 35 infected patients identified through screening; screening only Africans and African Americans would have missed 7 (20%) infected patients; and screening only those aged 30 to 49 years would have missed 7 (20%) infected patients. Screening Africans and African Americans and male and female patients aged 30 to 49 years would have missed 12 (34%) infected patients (data not shown).

Although HIV screening could potentially be targeted to patients who acknowledge certain high-risk behaviors, as previously discussed, risk assessment still requires resources and fails to identify many infected persons who should be tested. Clearly, all patients in whom risks are identified in the course of the routine ED visit, such as patients with symptoms related to an STD or intravenous drug use, should be offered HIV testing. Nonetheless, we believe that limited staff time and resources would be better allocated toward screening more

<sup>†</sup>P value was obtained using the Fisher exact test rather than  $\chi^2$  test because of small cell sizes.

<sup>‡</sup>Defined as heterosexual sex with an HIV-infected person, a bisexual male, or an injection drug user.

<sup>§</sup>CD4 cell count data were not available for 7 patients.

patients rather than attempting to conduct a comprehensive risk assessment in the ED.

Given that screening every patient for HIV is unlikely to be feasible in the near future, some form of targeted screening based on clinical, demographic, and behavioral risk factors is likely. To make this most effective, initiating a period of routine nontargeted screening would be necessary to identify optimal screening criteria for a given setting. Ideally, those criteria would consist of information likely to be collected already as part of routine clinical care.

Our study is subject to several limitations in addition to those mentioned previously. First, our findings may underestimate how many infections could be detected through ED screening programs because we could not offer screening to all patients. Second, although we believe that immediate test results and ancillary staff (who were viewed as part of the ED team) influenced provider practices, we cannot determine which had the greater effect. Third, our findings may not be generalizable to other EDs for many reasons: our ED is one of the busiest in the nation, we did not offer screening in all areas of the ED, and the prevalence of undiagnosed HIV infection differs across regions and settings. Finally, because we did not formally evaluate ED providers' attitudes and practices, we do not know which providers made most of the referrals, we cannot assess how providers determined which patients to refer, and we cannot fully delineate the influences of rapid testing on medical management or hospitalization costs.

The "exceptionalism" accorded to HIV testing is

The "exceptionalism" <sup>19,63</sup> accorded to HIV testing is outmoded in health care settings. Rapid HIV testing is a simple and accurate tool that offers substantial clinical and public health benefits and should not be viewed or performed differently from other tests for serious diseases. <sup>64</sup> HIV screening meets all the generally accepted principles that guide public health screening efforts <sup>6,13,65</sup> and is recommended by the CDC for all adults and adolescents seeking treatment in health care settings. <sup>13</sup> Risk-based testing misses many HIV-infected persons who do not perceive or disclose their risks, and diagnostic testing results in late diagnosis of a disease for which earlier intervention offers substantial benefit. HIV screening and provider referral are complementary strategies for addressing these shortcomings and incorporating HIV tests into routine ED and public health practice.

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#### **REFERENCES**

- Glynn M, Rhodes P. Estimated HIV prevalence in the United States at the end of 2003 [abstract T1-B1101]. Presented at: 2005 National HIV Prevention Conference; 2005; Atlanta.
- Centers for Disease Control and Prevention. HIV/AIDS Surveillance Report. 2005;16:1–46. Available at: http://www.cdc.gov/hiv/topics/ surveillance/resources/reports/2004report/pdf/2004SurveillanceReport.pdf.
- Centers for Disease Control and Prevention. Advancing HIV prevention: new strategies for a changing epidemic—United States, 2003. MMWR Morb Mortal Wkly Rep. 2003;52:329–332.
- Centers for Disease Control and Prevention. HIV Counseling and Testing in Publicly Funded Sites: Annual Report, 1997 and 1998. Atlanta: Centers for Disease Control and Prevention; 2001. Available at: http://www.cdc. gov/hiv/pubs/cts98.pdf.
- Valdiserri RO, Moore M, Gerber AR, et al. A study of clients returning for counseling after HIV testing: implications for improving rates of return. *Public Health Rep.* 1993;108:12–18.
- Freedberg KA, Samet JH. Think HIV: why physicians should lower their threshold for HIV testing. Arch Intern Med. 1999;159:1994–2000.
- Beckwith CG, Flanigan TP, del Rio C, et al. It is time to implement routine, not risk-based, HIV testing. Clin Infect Dis. 2005;40:1037–1040.
- Manavi K, McMillan A, Ogilvie M, et al. Heterosexual men and women with HIV test positive at a later stage of infection than homo- or bisexual men. *Int J STD AIDS*. 2004;15:811–814.
- Fincher-Mergi M, Cartone KJ, Mischler J, et al. Assessment of emergency department health care professionals' behaviors regarding HIV testing and referral for patients with STDs. AIDS Patient Care STDS. 2002;16: 549–553.
- 10. Deleted in proof.
- Coil CJ, Haukoos JS, Witt MD, et al. Evaluation of an emergency department referral system for outpatient HIV testing. J Acquir Immune Defic Syndr. 2004;35:52–55.
- Centers for Disease Control and Prevention. Recommendations for HIV testing services for inpatients and outpatients in acute-care hospital settings. MMWR Recomm Rep. 1993;42:1–6.
- Centers for Disease Control and Prevention. Revised recommendations for HIV testing of adults, adolescents and pregnant women in health care settings. MMWR Recomm Rep. 2006;55:1–17.
- US Preventive Services Task Force. Screening for HIV: recommendation statement. Ann Intern Med. 2005;143:32–37.
- 15. Babcock IC, Wyer PC, Gerson LW, and the Society for Academic Emergency Medicine Public Health and Education Task Force Preventive Services Work Group. Preventive care in the emergency department, part II: clinical preventive services—an emergency medicine evidence-based review. Acad Emerg Med. 2000;7:1042–1054.
- Rothman RE, Ketlogetswe KS, Dolan T, et al. Preventive care in the emergency department: should emergency departments conduct routine HIV screening? A systematic review. *Acad Emerg Med.* 2003;10: 278–285.
- 17. Aberg JA, Gallant JE, Anderson J, et al. Primary care guidelines for the management of persons infected with human immunodeficiency virus: recommendations of the HIV Medicine Association of the Infectious Diseases Society of America. Clin Infect Dis. 2004;39:609–629.
- Sanders GD, Bayoumi AM, Sundaram V, et al. Cost-effectiveness of screening for HIV in the era of highly active antiretroviral therapy. N Engl J Med. 2005;352:570–585.
- Bozzette SA. Routine screening for HIV infection—timely and costeffective. N Engl J Med. 2005;352:620–621.

- Frieden TR, Das-Douglas M, Kellerman SE, et al. Applying public health principles to the HIV epidemic. N Engl J Med. 2005;352:2397–2402.
- Paltiel AD, Weinstein MC, Kimmel AD, et al. Expanded screening for HIV in the United States—an analysis of cost-effectiveness. N Engl J Med. 2005;352:586–595.
- Alexander L, Sattah M, Ziemer DB, et al. Missed opportunities for HIV diagnosis at an inner city hospital in the United States [abstract 43131].
   Presented at: XII International Conference on AIDS; 1998; Geneva.
- Klein D, Hurley LB, Merrill D, et al. Review of medical encounters in the 5 years before a diagnosis of HIV-1 infection: implications for early detection. J Acquir Immune Defic Syndr. 2003;32:143–152.
- Glick NR, Silva A, Zun L, et al. HIV testing in a resource-poor urban emergency department. AIDS Educ Prev. 2004;16:126–136.
- MacDonald SR, Skor A, Socol ML, et al. Human immunodeficiency virus infection and women: a survey of missed opportunities for testing and diagnosis. Am J Obstet Gynecol. 1998;178:1264–1271.
- Kuo AM, Haukoos JS, Witt MD, et al. Recognition of undiagnosed HIV infection: an evaluation of missed opportunities in a predominantly urban minority population. AIDS Patient Care STDS. 2005;19:239–246.
- Jenkins TC, Gardner EM, Thrun MW, et al. Risk-based Human Immunodeficiency Virus (HIV) testing fails to detect the majority of HIV-infected persons in medical care settings. Sex Transm Dis. 2006;33:329–333.
- Kendrick SR, Kroc KA, Couture E, et al. Comparison of point-of-care rapid HIV testing in three clinical venues. AIDS. 2004;18:2208–2210.
- Walensky RP, Losina E, Malatesta L, et al. Effective HIV case identification through routine HIV screening at urgent care centers in Massachusetts. Am J Public Health. 2005;95:71–73.
- Goggin MA, Davidson AJ, Cantril SV, et al. The extent of undiagnosed HIV infection among emergency department patients: results of a blinded seroprevalence survey and a pilot HIV testing program. *J Emerg Med*. 2000;19:13–19.
- Centers for Disease Control and Prevention. Routinely recommended HIV testing at an urban urgent-care clinic—Atlanta, Georgia, 2000. MMWR Morb Mortal Wkly Rep. 2001;50:538–541.
- Kelen GD, Shahan JB, Quinn TC. Emergency department–based HIV screening and counseling: experience with rapid and standard serologic testing. Ann Emerg Med. 1999;33:147–155.
- 33. Mehta SD, Hall J, Lyss S, et al. Adult and pediatric emergency department STD and HIV screening programs: outcomes and behavioral risks [abstract MP-050]. Presented at: International Society for STD Research Conference; 2005; Amsterdam.
- Centers for Disease Control and Prevention. Update: HIV counseling and testing using rapid tests—United States, 1995. MMWR Morb Mortal Wkly Rep. 1998;47:211–215.
- 35. O'Rourke M, Branson B, del Rio C, et al. Rapid fingerstick testing: a new era in HIV diagnostics. *AIDS Clin Care*. 2003;15:19–23, 30.
- OraQuick Advance Rapid HIV-1/2 Antibody Test [package insert, revised]. Bethlehem, PA: OraSure Technologies; 2004. Available at: http://www.orasure.com/uploaded/385.pdf?138&sec=2&subsec=2.
- Centers for Disease Control and Prevention. HIV counseling with rapid tests. Available at: http://www.cdc.gov/hiv/pubs/rt-counseling.htm. 2003.
- 38. Agresti A. Categorical Data Analysis. New York: John Wiley and Sons;
- Albritton WL, Vittinghoff E, Padian NS. Human immunodeficiency virus testing for patient-based and population-based diagnosis. *J Infect Dis*. 1996;174(Suppl 2):S176–S181.
- Granade TC, Phillips SK, Parekh B, et al. Detection of antibodies to human immunodeficiency virus type 1 in oral fluids: a large-scale evaluation of immunoassay performance. *Clin Diagn Lab Immunol*. 1998;5:171–175.
- Fernandez MI, Bowen GS, Perrino T, et al. Promoting HIV testing among never-tested Hispanic men: a doctor's recommendation may suffice. AIDS Behav. 2003;7:253–262.
- Samet JH, Winter MR, Grant L, et al. Factors associated with HIV testing among sexually active adolescents: a Massachusetts survey. *Pediatrics*. 1997;100:371–377.
- Royce RA, Walter EB, Fernandez MI, et al. Barriers to universal prenatal HIV testing in 4 US locations in 1997. Am J Public Health. 2001; 91:727–733.
- 44. Fernandez MI, Wilson TE, Ethier KA, et al, for the Perinatal Guidelines Evaluation Project. Acceptance of HIV testing during prenatal care. *Public Health Rep.* 2000;115:460–468.

- Taylor V, Lessler D, Mertens K, et al. Colorectal cancer screening among African Americans: the importance of physician recommendation. *J Natl Med Assoc.* 2003;95:806–812.
- National Cancer Institute Breast Cancer Screening Consortium. Screening mammography: a missed clinical opportunity. Results of the NCI Breast Cancer Screening Consortium and National Health Interview Survey studies. *JAMA*. 1990;264:54–58.
- Ogedegbe G, Cassells AN, Robinson CM, et al. Perceptions of barriers and facilitators of cancer early detection among low-income minority women in community health centers. J Natl Med Assoc. 2005;97: 162–170
- Bazargan M, Bazargan SH, Farooq M, et al. Correlates of cervical cancer screening among underserved Hispanic and African-American women. *Prev Med.* 2004;39:465–473.
- 49. MacKellar DA, Valleroy LA, Secura GM, et al. Unrecognized HIV infection, risk behaviors, and perceptions of risk among young men who have sex with men: opportunities for advancing HIV prevention in the third decade of HIV/AIDS. *J Acquir Immune Defic Syndr*. 2005;38: 603–614.
- 50. Chen Z, Branson B, Ballenger A, et al. Risk assessment to improve targeting of HIV counseling and testing services for STD clinic patients. *Sex Transm Dis.* 1998;25:539–543.
- Beckwith CG, Lally MA, Flanigan TP. Routine HIV testing among inpatients. Arch Intern Med. 2002;162:2252–2253.
- Centers for Disease Control and Prevention. Late versus early testing of HIV—16 sites, United States, 2000–2003. MMWR Morb Mortal Wkly Rep. 2003;52:581–586.
- Johnson DF, Sorvillo FJ, Wohl AR, et al. Frequent failed early HIV detection in a high prevalence area: implications for prevention. AIDS Patient Care STDS. 2003;17:277–282.
- Samet JH, Freedberg KA, Savetsky JB, et al. Understanding delay to medical care for HIV infection: the long-term non-presenter. AIDS. 2001; 15:77–85.
- 55. Rietmeijer CA, Wolitski RJ, Fishbein M, et al. Sex hustling, injection drug use, and non-gay identification by men who have sex with men: associations with high-risk sexual behaviors and condom use. Sex Transm Dis. 1998;25:353–360.
- 56. Centers for Disease Control and Prevention. HIV/STD risks in young men who have sex with men who do not disclose their sexual orientation—six U.S. cities, 1994–2000. MMWR Morb Mortal Wkly Rep. 2003;52:81–86.
- Anderson JE, Chandra A, Mosher WD. HIV Testing in the United States, 2002. Advance Data from Vital and Health Statistics, no. 363. Hyattsville, MD: National Center for Health Statistics; 2005. Available at: http://www.cdc.gov/nchs/data/ad/ad363.pdf.
- Lyons MS, Lindsell CJ, Ledyard HK, et al. Health department collaboration with emergency departments as a model for public health programs among at-risk populations. *Public Health Rep.* 2005; 120:259–265.
- Lubelchek R, Kroc K, Hota B, et al. The role of rapid versus conventional human immunodeficiency virus testing for inpatients: effects on quality of care. Arch Intern Med. 2005;165:1956–1960.
- 60. Marks G, Crepaz N, Senterfitt W, et al. Meta-analysis of high-risk sexual behavior in persons aware and unaware they are infected with HIV in the United States: implications for HIV prevention programs. *J Acquir Immune Defic Syndr*. 2005;39:446–453.
- 61. Lyss S, Couture E, Kroc K, et al. Influence of point-of-care rapid HIV tests and additional testing staff on ordering of HIV tests by providers in a large, urban emergency department [abstract 180]. American College of Emergency Physicians Research Forum, San Francisco, CA, October 17–18, 2004, San Francisco. Ann Emerg Med. 2004;44:S56.
- Hall HI, Lee LM, Li J, et al. Describing the HIV epidemic: using HIV case data in addition to AIDS case reporting. *Ann Epidemiol*. 2005;15: 5–12.
- Bayer R, Fairchild AL. Changing the paradigm for HIV testing—the end of exceptionalism. N Engl J Med. 2006;355:647–649.
- Manavi K, Welsby PD. HIV testing should no longer be accorded any special status. BMJ. 2005;330:492–493.
- Wilson JMG, Jungner G. Principles and Practice of Screening for Disease. Public Health Papers 34. Geneva, Switzerland: World Health Organization; 1968.