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 4,849 eligible patients approached for screening, 2,824 (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.

Key Words: emergency medicine, health care, HIV, HIV diagnostic tests, screening, seroprevalence

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HIV 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.

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. 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. 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.

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; in its 2003 Advancing HIV Prevention Initiative; and, most recently, in the Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings. The US Preventive Services Task Force, the Public Health and Education Prevention Task Force of the Society for Academic Emergency Medicine, the Infectious Diseases Society of America, and others 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.

Research on HIV screening has focused on acute care settings because studies of persons recently receiving an HIV
Numerous studies in 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 jail 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 through 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.37

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).

*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. 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. 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 χ² 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. 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/µL (P < 0.001). The odds of having <200 cells/µL 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/µL.

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...
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 diagnosies 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 and of screening interventions in general. 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 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. In this study, half of the screened patients with undiagnosed infection...
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 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 patients who accepted testing but were not tested did not differ from those of patients who were tested.

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, Ohio, New Jersey, Michigan, and Chicago, Illinois (Sindy Paul, MD, MPH [NJ]), Lisa 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).

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 HIV 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.

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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Eligible</th>
<th>Accepted and Tested*</th>
<th>HIV Infected</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. Screened (column %)</td>
<td>No. Referred (column %)</td>
<td>No. Screened (row %)</td>
</tr>
<tr>
<td>Overall</td>
<td>4849</td>
<td>436</td>
<td>2824 (58)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Male</td>
<td>2450 (51)</td>
<td>314 (72)</td>
<td>1417 (58)</td>
</tr>
<tr>
<td>Female</td>
<td>2399 (49)</td>
<td>122 (28)</td>
<td>1407 (59)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>African American, not Hispanic</td>
<td>2937 (61)</td>
<td>292 (67)</td>
<td>1624 (55)</td>
</tr>
<tr>
<td>White, not Hispanic</td>
<td>473 (10)</td>
<td>50 (11)</td>
<td>222 (47)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>1193 (25)</td>
<td>79 (18)</td>
<td>842 (71)</td>
</tr>
<tr>
<td>African</td>
<td>79 (2)</td>
<td>8 (2)</td>
<td>50 (63)</td>
</tr>
<tr>
<td>Other‡</td>
<td>167 (3)</td>
<td>7 (2)</td>
<td>86 (51)</td>
</tr>
<tr>
<td>Age (y)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18–29</td>
<td>1311 (27)</td>
<td>98 (22)</td>
<td>865 (66)</td>
</tr>
<tr>
<td>30–39</td>
<td>1178 (24)</td>
<td>122 (28)</td>
<td>693 (59)</td>
</tr>
<tr>
<td>40–49</td>
<td>1673 (35)</td>
<td>154 (35)</td>
<td>923 (55)</td>
</tr>
<tr>
<td>50–54</td>
<td>687 (14)</td>
<td>62 (14)</td>
<td>343 (50)</td>
</tr>
<tr>
<td>Screened Referred</td>
<td>1.0</td>
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<td></td>
</tr>
<tr>
<td>Referred</td>
<td>8.9 (5.6 to 14.1)</td>
<td></td>
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</tr>
</tbody>
</table>

*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.

†Unconditional logistic regression model containing all variables listed.

‡One HIV-infected patient was an Asian/Pacific Islander; the other reported his race as “Other” but did not specify.
were possible to screen all patients routinely, provider referral for diagnostic testing would not be needed. In our study, as in others,26,30–32 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 care3 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, we believe that limited staff time and resources would be better allocated toward screening more 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 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 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

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.62 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
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”19,63 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.64 HIV screening meets all the generally accepted principles that guide public health screening efforts65,66 and is recommended by the CDC for all adults and adolescents seeking treatment in health care settings.13 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

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