

Risk-Based Human Immunodeficiency Virus (HIV) Testing Fails to Detect the Majority of HIV-Infected Persons in Medical Care Settings

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Objectives: To evaluate opportunities for earlier human immunodeficiency virus (HIV) diagnosis within a comprehensive public health care system.

Study Design: Retrospective review of newly diagnosed HIV-infected patients between September 2001 and December 2003.

Results: One hundred twenty of 348 (34%) newly diagnosed HIV-infected patients had medical care within our system in the 3 years before diagnosis. One hundred five of 120 (88%) patients had at least 1 prior encounter in the emergency department or urgent care center, whereas just 12 (10%) HIV diagnoses were made in these 2 sites. Only 33 (28%) patients previously presented with an HIV clinical indicator condition or sexually transmitted infection.

Conclusions: Although one-third of newly diagnosed HIV-infected patients had clinical visits in the 3 years before diagnosis, few presented with clinical conditions typically associated with HIV infection. Targeted testing based on clinical presentations is not likely to result in substantially earlier HIV diagnosis. Routine screening in high prevalence settings could be more effective.

EARLIER DIAGNOSIS OF HUMAN immunodeficiency virus (HIV) infection is an important public health goal. Diagnosis and appropriate posttest counseling results in decreased risk behavior^{1,2} and is, therefore, an important step in decreasing further HIV transmission. In addition, diagnosis at an earlier stage and linkage to appropriate care should have marked benefits for the HIV-infected individual; antiretroviral therapy is more successful if started before severe immunodeficiency.^{3,4} In 2001, 46% of persons aged 18 to 64 in the United States reported ever having been tested for HIV, while 28% reported having received an HIV test in the preceding 12 months.⁵ Although these numbers are reflective of a significant effort to increase HIV testing, the Centers for Disease Control and Prevention (CDC) estimates that up to 280,000 persons in the United States are unaware of their HIV infection.⁶ As a result, late diagnosis remains common; in one report, 51% of newly diagnosed HIV-infected patients had the acquired immunodeficiency syndrome (AIDS) within 1 year.⁷

In the United States, most HIV testing in clinical settings has been based on targeted or risk-based testing of persons with behavioral risk factors for HIV acquisition and those with clinical

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conditions associated with HIV infection (e.g., herpes zoster, bacterial pneumonia). However, many health care providers do not perform routine behavioral risk assessment.^{8,9} In addition, the effectiveness of using clinical indicator conditions as a way to screen for HIV infection is uncertain. We evaluated opportunities for earlier diagnosis of HIV infection in a large urban public health care setting.

Materials and Methods

Setting and Population

Denver Health is a comprehensive urban health care system.¹⁰ Patients can access care at multiple sites, including an emergency department and 350-bed hospital, urgent care center, 10 community health centers, 11 school-based clinics, subspecialty clinics, and the public health department with a sexually transmitted diseases clinic and confidential HIV testing program. HIV testing can be performed in any of these clinical settings. In addition, Denver Public Health has outreach testing at local bathhouses and other locations. During the period of this study, rapid testing for HIV was not in use. The Denver Health network is linked by a computerized health information system. HIV testing in our population is offered to persons believed to be at risk for HIV infection (i.e., targeted or risk-based testing).

Patients who were diagnosed with HIV infection between September 2001 and December 2003 were identified from a comprehensive public health surveillance database. Patients who were eligible for inclusion either tested positive within our system or were diagnosed at an outside location and established HIV care within Denver Health. Our population of interest was patients with 1 or more clinical encounters in the 3 years before HIV diagnosis. The Colorado Multiple Institutional Review Board approved this study.

Data Collection

Baseline demographics, including race/ethnicity (as recorded in the patient's medical record), date of HIV diagnosis, location of testing, initial CD4 count, and viral load, were obtained by medical record and laboratory review. In patients with at least 1 encounter

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in the 3 years before HIV diagnosis, further data collection included the number and location of visits and the primary diagnosis at each visit. All laboratory data in the 3 years before HIV diagnosis were reviewed. Among patients with a negative HIV test during the 3 years before a positive test, records dating back to the negative test were reviewed; visits before the negative HIV test were not included. Instances of patient refusal of HIV testing were recorded. Diagnoses at prior encounters were categorized by the organ system of involvement or other general characteristics.

Definitions

Clinical indicator conditions associated with chronic HIV infection have been proposed and include pneumonia, oral infection (candidiasis or oral hairy leukoplakia), night sweats, unexplained fever, seborrheic dermatitis, herpes zoster, and unexplained weight loss.¹¹ In addition to these, sexually transmitted diseases were considered to be indicators of increased risk of HIV infection. Sexually transmitted diseases included gonorrhea, chlamydia, pelvic inflammatory disease, epididymitis or orchitis, genital human papillomavirus infection, syphilis, and genital herpes simplex virus infection. Due to limited prior laboratory analyses, it was not possible to evaluate whether potential laboratory markers of HIV infection occurred at visits before HIV diagnosis.

In an attempt to identify instances when patients may have been seen with acute HIV-seroconversion illness before the time of HIV diagnosis, we defined the 6 most common symptoms of acute HIV infection based on 4 published reports as the following: fever, fatigue, sore throat, myalgias, weight loss, and rash.^{12–15} Patients were considered to have potentially been seen during acute HIV seroconversion illness if they had at least 3 of these 6 symptoms recorded at a single prior visit.

Statistical Analysis

Comparisons of baseline characteristics between patients with and without prior encounters were performed using a 2-sample *t* test, χ^2 test, or the Wilcoxon rank sum test where appropriate. For patients with prior encounters, assessment of the number and location of encounters, primary diagnoses, and presence of HIV clinical indicator conditions or sexually transmitted diseases were evaluated using descriptive statistics.

In order to look at factors associated with a late diagnosis of HIV infection, patients with prior encounters were dichotomized as having AIDS (initial CD4 count <200 cells/mm³) or earlier HIV infection (initial CD4 count \geq 200 cells/mm³) at diagnosis. An adjusted logistic regression model assessing predictors of late diagnosis was performed including all factors associated with late diagnosis (*P* <0.20) in univariate analysis. Factors assessed included demographics and HIV transmission risk category. All data were analyzed with SAS Version 8.1 (SAS Institute, Cary, NC).

Results

Of the 348 patients diagnosed with HIV infection (295 diagnosed within Denver Health, 53 tested positive elsewhere but established HIV care within Denver Health), 120 (34%) patients had at least 1 clinical encounter within Denver Health in the 3 years before diagnosis. Nine (8%) of the 120 patients with prior encounters had a documented negative HIV test during the 3 years before eventual HIV diagnosis. The majority of the patients in the study were white or Hispanic males with an HIV transmission risk factor of having sex with men (Table 1). There were no significant differences in age, race, primary language, or HIV transmission risk factors between patients with and without prior encounters. A

TABLE 1. Demographic and Clinical Characteristics of Patients Diagnosed With HIV Infection, Denver Health, 2001–2003

Characteristic	Patients With Prior Encounters (n = 120)	Patients Without Prior Encounters (n = 228)	P Value
Age at diagnosis*	36 (30–43)	35 (28–42)	0.23
Female†	27 (22)	25 (10)	0.001
Race/ethnicity††			0.23
White	52 (43)	81 (36)	
Hispanic	44 (37)	44 (19)	
Black	19 (16)	20 (9)	
Other/unknown	5 (4)	83 (36)	
Primary language††			0.54
English	98 (82)	100 (44)	
Spanish	20 (17)	25 (11)	
Other/unknown	2 (2)	103 (45)	
HIV risk factor††			0.67
MSM	68 (57)	107 (47)	
IDU	14 (12)	18 (8)	
Heterosexual	22 (18)	27 (12)	
MSM + IDU	5 (4)	12 (5)	
Other/unknown	11 (9)	64 (28)	
Median CD4+ cell count*	370 (144–605)	458 (228–669)	0.01
Median log ₁₀ HIV RNA*	4.7 (4.2–5.3)	4.5 (4.0–5.0)	0.06

IDU = injection drug users; MSM = men who have sex with men.

*Median (interquartile range).

†No. (%).

†Statistical analysis excludes patients in other/unknown category.

significantly higher proportion of patients with prior encounters were female. Patients with prior encounters had a significantly lower median CD4 count at diagnosis, though initial HIV RNA levels were similar. Although 34% of the overall population had a prior visit, 32 (46%) of 69 patients with AIDS at diagnosis had been seen in the 3 years before HIV diagnosis.

Among the 120 patients with a prior clinical encounter, there were 519 visits with a median of 2 per patient (range, 1–29), and 34 (28%) patients had 5 or more visits. The median duration between the first prior visit and eventual HIV diagnosis was 437 days (interquartile range, 169–692 days). There were marked differences between the sites of prior clinical encounters and the sites of eventual HIV diagnoses (Fig. 1). Seventy (58%) of 120

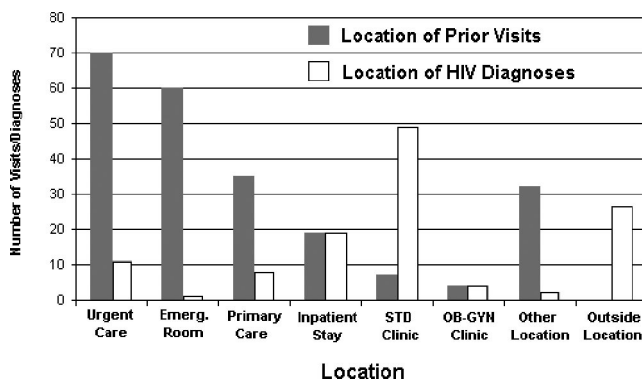


Fig. 1. Number of patients with at least 1 prior visit at each location and the number of patients with eventual HIV diagnosis at each location, Denver Health 2001–2003 (STD = sexually transmitted diseases; OB-GYN = obstetrics and gynecology).

patients presented to the urgent care center and 60 (50%) presented to the emergency department at least once in the 3 years before diagnosis; 105 (88%) patients had 1 or more encounters in either of these locations. Thirty-five (29%) patients were seen at least once in a primary care clinic, whereas 19 (16%) had 1 or more inpatient admissions before HIV diagnosis. Having a prior encounter in the sexually transmitted diseases clinic without HIV testing was uncommon, occurring in 7 (6%) of 120 patients.

In contrast to the location of prior medical encounters, the most common location of HIV diagnosis was the sexually transmitted diseases clinic (which includes outreach testing), where 49 (41%) of 120 patients were diagnosed (Fig. 1). Nineteen (16%) patients with prior encounters were diagnosed in the inpatient setting, 11 (9%) in the urgent care center, 8 (7%) in primary care clinics, and 1 (1%) in the emergency department. Although 105 (88%) patients with prior encounters had been seen at least once in the urgent care center or emergency department, only 10% of patients were diagnosed in one of these locations. Patients without prior medical encounters within Denver Health were most likely to be diagnosed through the sexually transmitted diseases clinic or its outreach testing services (174 [76%] of 228).

The most frequent diagnoses at prior encounters were common infections, being diagnosed at 141 (27%) of 519 visits (Table 2). Uncomplicated upper respiratory tract infections were most common ($n = 37$), followed by soft-tissue infections ($n = 30$), sexually transmitted infections ($n = 19$), and dermatological infections ($n = 17$). Orthopedic and trauma-related encounters were also common, occurring at 90 (17%) prior visits. Overall, primary diagnoses were diverse, as demonstrated in Table 2. Fourteen (12%) of 120 patients had at least 1 prior visit that met our definition of potentially being seen during acute HIV seroconversion illness. In 3 of these 14 instances, the care provider considered HIV infection; 1 of these 3 patients refused HIV testing.

Eighteen (15%) of 120 patients presented with an HIV clinical indicator condition, and 19 (16%) presented with a sexually transmitted disease at least 1 time before HIV diagnosis. Thirty-three (28%) patients presented with either an HIV clinical indicator or sexually transmitted disease; 6 (18%) of these patients refused HIV testing at a visit before eventual HIV diagnosis. Herpes zoster was the most common HIV clinical indicator; 7 patients were seen

for herpes zoster at 12 separate encounters. Eighty-seven (73%) of the 120 patients in our study were identified as belonging to traditionally high-risk groups, men who have sex with men or injection drug users, at the time of HIV diagnosis.

One hundred eleven (93%) of 120 patients with prior visits had baseline CD4 cell counts at the time of HIV diagnosis available for review. Thirty-two (29%) of 111 patients had a baseline CD4 cell count indicative of AIDS (less than 200 cells/mm³). In univariate analysis, predictors of having AIDS at initial diagnosis included older age, being Spanish speaking, and being of Hispanic origin (Table 3). In adjusted analysis, both older age and being Spanish speaking were independently associated with late diagnosis. For every 10-year increase in age, the odds of having AIDS at initial diagnosis were 1.8 (95% CI 1.0–3.1) times higher. In Spanish-speaking patients, the odds of having AIDS at initial diagnosis were 4.8 (95% CI 1.3–17.8) times that of English-speaking patients (Table 3).

Discussion

One-third of patients with newly diagnosed HIV infection had received medical care within our health care system during the 3 years before diagnosis. However, less than 30% of these patients presented with an HIV clinical indicator or sexually transmitted disease before diagnosis. Although infectious diseases were frequent reasons for prior encounters, most were common infections that are not considered to be associated with HIV-related immunodeficiency. The majority of patients had prior encounters in either the urgent care center or the emergency department, but few HIV diagnoses were made in these locations. Late diagnosis was more likely to occur in older and Spanish-speaking individuals.

The CDC estimates that there are up to 280,000 HIV-infected patients who do not know their serostatus.⁶ Although our study involved only 1 institution, it suggests that enhanced HIV testing during medical encounters might allow earlier diagnosis in a significant number of persons with undiagnosed HIV infection. Furthermore, our study underestimated the proportion of persons who had at least 1 medical encounter in the 3 years before an HIV diagnosis because we could only access the medical care records of 1 of many health care agencies in the Denver area. However, up to two-thirds of patients did not have a clinical visit before HIV diagnosis, and strategies to identify these patients earlier need to be developed. It is encouraging that these patients without prior medical encounters had less advanced disease at diagnosis and were more likely to self-identify risk behavior, as evidenced by their attendance in the sexually transmitted diseases clinic or an outreach testing venue.

Despite the fact that nearly 90% of patients had prior encounters in either the urgent care center or emergency department, only 10% of patients were diagnosed with HIV infection in either of these locations. Because the urgent care center and emergency department frequently serve as the primary source of medical care for patients in underserved settings, it is not surprising that most patients had 1 or more prior encounters in one of these locations. A prior study in Boston has similarly shown a large proportion of encounters leading up to HIV diagnosis occurred in the emergency department or urgent care clinic.¹⁶ Despite the frequency of medical encounters among persons with undiagnosed HIV infection in our study, the primary diagnoses made at most encounters were for conditions not known to be associated with HIV infection.

At eventual diagnosis, almost three-quarters of our patients identified themselves as belonging to a traditionally high-risk group for HIV-infection. In a health care system where risk-based testing is the norm, lack of elicitation of this information or lack of acting on this

TABLE 2. Primary Diagnostic Categories at 519 Prior Encounters in 120 Patients Eventually Diagnosed With HIV Infection

Diagnostic Category	Number of Diagnoses, No. (%) (n = 519)
Infectious diseases	141 (27)
Orthopedic/trauma	90 (17)
Gastroenterology	46 (9)
Dermatology	36 (7)
Cardiology	25 (5)
Neurology	24 (5)
Genitourinary	24 (5)
Mental health	23 (4)
Ophthalmology	23 (4)
Miscellaneous	19 (3)
Ear, nose, throat	16 (3)
Pulmonary	12 (2)
Substance abuse	12 (2)
Renal	8 (2)
Hematology	8 (2)
Lymphatic	4 (1)
Rheumatology	4 (1)
Dental	3 (1)
Endocrine	1 (0)

TABLE 3. Univariate and Multivariate Logistic Regression of Predictors of Late Diagnosis (CD4+ T-Cell Count <200/mm³) in 111 Patients With Prior Clinical Encounters and Baseline CD4 Counts

Characteristic	Late Diagnosis (n = 32)	Nonlate Diagnosis (n = 79)	P Value	Adjusted Odds Ratio (95% CI)
Age at diagnosis*	37 (33–44)	34 (28–42)	0.04	1.8 (1.0–3.1) [†]
Female [‡]	8 (25)	17 (22)	0.69	
Race/ethnicity ^{‡§}			0.03	1.5 (0.5–4.6)
White	9 (28)	40 (51)		
Hispanic	19 (59)	25 (32)		
Black	3 (9)	11 (14)		
Other/unknown	1 (3)	3 (4)		
Primary language ^{‡§}			<0.001	4.8 (1.3–17.8)
English	20 (63)	70 (89)		
Spanish	12 (38)	8 (10)		
Other/unknown	0 (0)	1 (1)		
HIV transmission risk ^{‡§}			0.27	
MSM	15 (47)	48 (61)		
IDU	4 (13)	10 (13)		
Heterosexual	8 (25)	12 (15)		
MSM + IDU	0 (0)	5 (6)		
Other/unknown	5 (16)	4 (5)		
CD4+ T-cell count (cells/ μ l)	40 (20–96)	518 (346–646)	<0.001	—
HIV RNA (log ₁₀ copies/ml)	5.3 (4.8–5.8)	4.5 (4.0–5.0)	<0.001	—

IDU = injection drug users; MSM = men who have sex with men.

*Median (interquartile range).

[†]Per 10-y increase in age.

[‡]No. (%).

[§]Statistical analysis excludes patients in other/unknown category.

^{||}Not included in multivariate analysis, because patients were grouped by severity of disease.

information hinders the effectiveness of this strategy. In addition, the strategy of targeted testing based on clinical presentations in the urgent care center or emergency department would have led to an earlier HIV diagnosis in a minority of patients. Rather, the frequency of prior encounters in these locations suggests that routine screening, regardless of clinical presentation, may have a major impact on rates of earlier HIV diagnosis.

The CDC and US Preventive Services Task Force (USPSTF) have published guidelines recommending that all individuals be routinely offered HIV testing in settings with an HIV prevalence of $\geq 1\%$.^{17,18} Studies have shown HIV seroprevalence in some emergency departments (including at Denver Health¹⁹) and urgent care centers of approximately 2–5%.^{19–21} Furthermore, counseling, testing, and referral programs in emergency departments and urgent care centers with a high prevalence of HIV have been shown to be feasible and effective.^{17,20,22,23} Nonetheless, most emergency departments and urgent care centers have yet to implement routine screening programs.²⁴ In addition, more recent studies have shown that HIV screening may be cost-effective in populations with an even lower prevalence of HIV infection.^{25,26} Our data highlight that expanded testing programs, particularly in emergency departments and urgent care clinics, are necessary.

Barriers to routine HIV testing include provider time constraints, expense, logistics of follow-up, and medicolegal implications.²⁴ However, in certain settings, routine HIV testing has become standard and widely accepted by patients. Denver Health uses a verbal opt-out system that has proven to be very effective in obtaining permission for HIV testing of pregnant women. Providers inform patients that HIV testing is recommended during all pregnancies, and patients give verbal consent or refuse to have an HIV test performed. Using this system, 12,000 (98%) of 12,221 pregnant women who delivered over a 4-year period were screened.²⁷ Programs that require written consent have shown substantially lower rates of HIV screening.²⁸ Given our findings, a similar program implementing a general recommen-

dation by providers for HIV testing, combined with a simple patient consent process, appropriate and targeted counseling, and the use of a rapid test, may be effective and feasible in urgent care and emergency department settings. Further studies are needed to test such a program and to explore patient acceptability of routine testing in these locations.

Our data show increased risk of late diagnosis in older patients. This may be explained by decreased diagnostic suspicion of HIV infection among older persons. Additionally, we found that Spanish-speaking patients are at risk for late diagnosis. Hispanic race was not associated with late diagnosis in multivariate regression, suggesting that language barriers, rather than ethnic background, may be leading to less frequent HIV testing in Spanish-speaking patients. Both older age and being an ethnic minority (black or Hispanic) have been associated with late AIDS diagnosis in prior research.²⁹ Our findings further support the conclusion that routine screening rather than targeted testing may lead to earlier HIV diagnosis by eliminating factors that lead to late diagnosis in select populations.

This study has several limitations. The data are representative of only 1 comprehensive urban health care system and therefore may not be generalizable to all health care settings. However, we believe that our population is likely representative of many populations with poor access to health care—the same populations that may have a higher prevalence of HIV infection. In addition, as this is a retrospective study, we are unable to determine when patients were infected with HIV in relation to prior clinical encounters. However, the median CD4 count of 370 cells/mm³ in patients with prior encounters suggests most patients had been infected with HIV for some time before diagnosis. Another limitation is absence of data for prior encounters that occurred outside of Denver Health, which would cause us to underestimate the percentage of patients with prior clinical encounters. Finally, our criteria used to assess prior visits when patients were potentially seen during acute HIV seroconversion illness are insensitive and nonspecific.

One third of newly diagnosed HIV-infected patients had medical encounters in our health care system in the 3 years before HIV diagnosis, affording potential opportunities for earlier diagnosis. The broad range of clinical diagnoses at prior visits precludes effective targeted HIV testing based on specific clinical scenarios. A high percentage of prior encounters occurred in the urgent care center or emergency department, whereas relatively few HIV diagnoses were made in these locations, suggesting that there should be broader implementation of routine screening programs in these settings.

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