# Routine Opt-Out Rapid HIV Screening and Detection of HIV Infection in Emergency Department Patients

Jason S. Haukoos, MD, MSc
Emily Hopkins, MSPH
Amy A. Conroy, MPH
Morgan Silverman, LCSW
Richard L. Byyny, MD, MSc
Sheri Eisert, PhD
Mark W. Thrun, MD
Michael L. Wilson, MD
Angela B. Hutchinson, PhD, MPH
Jessica Forsyth, MSW
Steven C. Johnson, MD
James D. Heffelfinger, MD, MPH
for the Denver Emergency Department HIV Opt-Out Study Group

**Context** The Centers for Disease Control and Prevention (CDC) recommends routine (nontargeted) opt-out HIV screening in health care settings, including emergency departments (EDs), where the prevalence of undiagnosed infection is 0.1% or greater. The utility of this approach in EDs remains unknown.

**Objective** To determine whether nontargeted opt-out rapid HIV screening in the ED was associated with identification of more patients with newly diagnosed HIV infection than physician-directed diagnostic rapid HIV testing.

**Design, Setting, and Patients** Quasi-experimental equivalent time-samples design in an urban public safety-net hospital with an approximate annual ED census of 55 000 patient visits. Patients were 16 years or older and capable of providing consent for rapid HIV testing.

**Interventions** Nontargeted opt-out rapid HIV screening and physician-directed diagnostic rapid HIV testing alternated in sequential 4-month time intervals between April 15, 2007, and April 15, 2009.

**Main Outcome Measures** Number of patients with newly identified HIV infection and the association between nontargeted opt-out rapid HIV screening and identification of HIV infection.

**Results** In the opt-out phase, of 28 043 eligible ED patients, 6933 patients (25%) completed HIV testing (6702 patients were screened; 231 patients were diagnostically tested). Ten of 6702 patients (0.15%; 95% CI, 0.07%-0.27%) who did not decline HIV screening in the opt-out phase had new HIV diagnoses, and 5 of 231 patients (2.2%; 95% CI, 0.7%-5.0%) who were diagnostically tested during the opt-out phase had new HIV diagnoses. In the diagnostic phase, of 29 925 eligible patients, 243 (0.8%) completed HIV testing. Of these, 4 patients (1.6%; 95% CI, 0.5%-4.2%) had new diagnoses. The prevalence of new HIV diagnoses in the opt-out phase (including those diagnostically tested) and in the diagnostic phase was 15 in 28 043 (0.05%; 95% CI, 0.03%-0.09%) and 4 in 29 925 (0.01%; 95% CI, 0.004%-0.03%), respectively. Nontargeted opt-out HIV screening was independently associated with new HIV diagnoses (risk ratio, 3.6; 95% CI, 1.2-10.8) when adjusting for patient demographics, insurance status, and whether diagnostic testing was performed in the opt-out phase. The median CD4 cell count for those with new HIV diagnoses in the opt-out phase (including those diagnostically tested) and in the diagnostic phase was 69/μL (IQR, 17-430) and 13/μL (IQR, 11-15) , respectively ($P = .02$).

**Conclusion** Nontargeted opt-out rapid HIV screening in the ED, vs diagnostic testing, was associated with identification of a modestly increased number of patients with new HIV diagnoses, most of whom were identified late in the course of disease.

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INFECTION WITH THE HUMAN IMMUNODEFICIENCY virus (HIV) remains an important public health problem. It is estimated that more than 1 million people in the United States are infected with HIV, while approximately 230 000 infections remain undiagnosed.[1] Additionally, approximately 56 000 people are newly infected each year.[2]

Testing for HIV infection remains an important preventive strategy, and in 2006, the Centers for Disease Control and Prevention (CDC) published revised guidelines for performing HIV testing in health care settings.[3] The new guidelines represented a substantial

**For editorial comment see 348.**

**Author Affiliations** and **Denver Emergency Department HIV Opt-Out Study Group** members are listed at the end of this article.

**Corresponding Author:** Jason S. Haukoos, MD, MSc, Denver Health Medical Center, 777 Bannock St, Mail Code 0108, Denver, CO 80204 (jason.haukoos@dhha.org).



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shift in HIV testing approach by recommending widespread routine (nontargeted) opt-out HIV screening in settings where the prevalence of undiagnosed infection was 0.1% or greater. To minimize other testing barriers, the CDC also recommended removing the requirement for separate written consent for HIV testing and the requirement for prevention counseling as part of HIV testing.

Emergency departments (EDs) have been an important focus for HIV prevention efforts, including testing and screening initiatives.[4-11] Since 2006, efforts to integrate nontargeted HIV screening into EDs have increased, although limited research supports this practice, and as yet, no comparative study has been conducted to evaluate the current CDC recommendations in an ED setting.[10-13] Thus, it remains unknown if nontargeted opt-out HIV screening, when incorporated into an ED setting, is associated with the identification of patients with HIV infection as a prevention strategy.

The primary goal of this study was to determine whether nontargeted opt-out rapid HIV screening in a high-volume urban ED was associated with identification of more patients with newly diagnosed HIV infection than physician-directed diagnostic rapid HIV testing. A secondary goal of the study included assessing the impact of both testing approaches on ED operational processes.

## METHODS

This study was approved by the research committee and institutional review board (IRB) at Denver Health Medical Center (DHMC) as well as by the CDC's IRB. Both IRBs waived the requirement for consent as part of the integration of HIV testing into routine care. However, consent was obtained for all HIV testing as part of the patient's medical care, and written informed consent was obtained from patients identified with HIV infection to obtain data following diagnosis not reported herein.

### Study Design

We used a quasi-experimental equivalent time-samples design to determine whether nontargeted opt-out rapid HIV screening in the ED was associated with identification of more patients with newly diagnosed HIV infection than physician-directed diagnostic rapid HIV testing.[14] Nontargeted opt-out screening and diagnostic testing were alternated in sequential 4-month time intervals from April 15, 2007, through April 15, 2009. The 2 HIV testing approaches were completely integrated into ED operations on a 24-hour basis involving only existing ED and hospital personnel. Details of the design, implementation, and rationale of this study are described elsewhere.[15]

### Setting

This study was performed in the ED at DHMC in Denver, Colorado. DHMC is a 477-bed urban public safety-net hospital with approximately 55 000 adult ED patient visits per year. DHMC is a regional level I trauma center and a nationally recognized model of the integration of a public hospital, community health center clinics, and a department of public health.[16] A large proportion of patients served by DHMC are racial or ethnic minorities and uninsured, and it has been estimated that approximately 0.7% of those who present to the ED have undiagnosed HIV infection.[17]

### Population

During the study, all patients 16 years and older and capable of providing consent for general emergency medical care were eligible to receive HIV testing. Patients were excluded from HIV testing if they (1) were unable to provide consent for HIV testing as assessed by registration or clinical staff (eg, altered mentation or critical illness), (2) were detainees or prisoners, (3) were seeking medical care after sexual assault, (4) sought care as a result of an occupational exposure, (5) self-identified as being infected with HIV, or (6) left the ED prior to being placed in a treatment room.

### Opt-Out Phase

The opt-out phase consisted of three 4-month periods during which nontargeted opt-out screening was conducted 24 hours per day and in a fully integrated manner using existing ED and hospital personnel. Patients presenting to the ED and meeting criteria for inclusion were informed in the registration process that rapid HIV testing would be conducted unless declined. To decline HIV screening, patients were required to check a box on the consent form and provide a signature or initial indicating they were "opting out." During registration, patients were provided a 1-page informational sheet related to HIV infection in both English and Spanish. Patients in the opt-out phase were provided with details of the testing process by registration staff, including the information that testing was voluntary and free.[15]

An electronic ED patient tracking system (Emergency Medical Services Information System [EMeSIS], Denver Health, Denver, Colorado), available to all ED personnel, was used to indicate those patients who did not opt out of HIV testing. Emergency department nurses and health care technicians identified patients who did not opt out, obtained a blood sample, and sent the samples to the hospital laboratory for rapid HIV testing. For those patients who opted out, physicians had the additional opportunity to diagnostically test them.

Rapid HIV testing was performed by the hospital's laboratory and included a sequential algorithm to potentially improve the predictive value of testing.[15,18] Whole blood was first tested using the Uni-Gold Recombigen HIV Test (Trinity Biotech, Wicklow, Ireland). If the first test was negative, no other rapid test was conducted, the result was reported as nonreactive, and the patient was considered seronegative for HIV. If the first test was reactive, a second rapid test (OraQuick Advance Rapid HIV-1/2 Antibody Test; OraSure Technologies Inc, Bethlehem, Pennsylvania) was immediately

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conducted. If the second test was negative, a third test (Multispot HIV-1/HIV-2 Rapid Test; Bio-Rad Laboratories, Redmond, Washington) was conducted and used as a tiebreaker. Because the predictive value of this algorithm is unknown, any reactive HIV test result was considered to be a preliminary positive result. Patients with negative test results were notified by their treating physicians and no posttest counseling was given. Patients with preliminary positive test results were notified by their physician and a social worker. Social workers provided client-centered HIV prevention counseling, had blood drawn for confirmatory Western blot testing, and linked patients into medical care (as defined by completing an initial HIV clinic visit after preliminary diagnosis in the ED).

### Diagnostic Phase

The diagnostic phase consisted of three 4-month periods during which rapid HIV testing was conducted using a previously described physician-directed diagnostic and targeted approach.[19] This included primarily diagnostic testing but also included targeting patients considered to be at increased risk for HIV infection based on actual or perceived behavioral characteristics ascertained during the patient's evaluation. This approach did not include systematic risk assessment or targeted screening and was chosen as the comparison to nontargeted screening because it was a common ED approach and considered the minimum standard of care in an ED setting.[13,19-22]

Rapid HIV testing was offered to patients identified for testing by emergency physicians as part of their ED care. The physician informed an available social worker if verbal consent was obtained. Consistent with a traditional testing approach (ie, the recommended approach before 2006),[23] the social worker obtained written informed consent, conducted pretest counseling, coordinated the collection of blood that was sent to the hospital laboratory for rapid HIV testing, obtained the test results, participated in delivery of results, provided posttest counseling, and coordinated confirmatory testing and linkage into care for those patients testing preliminarily positive.

### Outcomes

The primary outcome was the number of patients confirmed (via Western blot) with newly identified HIV infection. In the expectation of testing patients previously diagnosed with HIV infection, the secondary outcome included all patients identified with HIV infection stratified by new diagnoses and repeat diagnoses. The primary outcome was also stratified by the proportion of patients identified early in the course of disease (defined as having initial CD4 cell count >350/μL) and the proportion successfully linked into medical care.

### Operational Processes of ED Care

No single criterion is available to measure ED efficiency and patient throughput. As such, several measures were collected, including patient wait time; length of stay; and, for those admitted to the hospital, boarding time (the time between admission and transfer to an inpatient room). Data were collected on the number of patients who left the ED before being placed in a treatment room and on the number of those who left the ED before completion of their evaluation. Data on laboratory turnaround times for rapid HIV tests were collected for patients tested for HIV infection.

The study included use of Emergency Department Work Index (EDWIN), a validated method to quantify the overall crowding of an ED.[24] EDWIN is calculated at the level of the ED, not the individual patient, and thus relies on cross-sectional time sampling. EDWIN was calculated at 1000 randomly sampled hourly time points (a subset of the total 17 520 hourly time points during the entire 2-year study period) to provide an accurate and representative sample of ED crowding.

### Data Management and Statistical Analyses

Data were transferred electronically or entered manually into a database (Access, Microsoft Corporation, Redmond) and transferred into SAS or Stata formats using translational software (dfPower/DBMS Copy, DataFlux Corporation, Cary, North Carolina). All statistical analyses were performed using SAS version 9.2 (SAS Institute, Cary) or Stata version 10 (StataCorp, College Station, Texas).

Patient demographics, including age, sex, and race/ethnicity, were collected to assess demographic distributions for those who completed HIV testing and who were identified with HIV infection. Race/ethnicity was classified by patients using categories defined by DHMC and collected by registration staff as part of standard emergency medical care.

Descriptive statistics for continuous variables were expressed as medians with interquartile ranges (IQRs) and proportions as percentages with 95% confidence intervals (CIs). Observations from the three 4-month opt-out periods and three 4-month diagnostic periods were combined into aggregate groups representing the opt-out phase and the diagnostic phase, respectively, and comparative analyses were performed between the 2 groups. Because this study did not have randomization, multivariable analyses were performed using repeated-measures Poisson regression to estimate the association between the performance of nontargeted screening and identification of patients infected with HIV, while adjusting for potential variation between the study groups. Given the relatively rare outcome of HIV infection, a binary Poisson distribution was used, and to verify the stability of the results, a confirmatory analysis using 1000 bootstrapped data sets was used to estimate the distribution of the point estimate of the association between nontargeted screening and the outcome.

Generalized estimating equations were used to perform all multivariable analyses. Secular trends were evalu-


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ated by including the month of the study in the main regression model. The unit of analysis was the patient unless stated otherwise, but because repeat screening is common in large-scale screening programs in high-volume episodic care settings, some analyses were conducted using ED visits as the unit of analysis.[25]

Race/ethnicity represented the only variable with missing data. Approximately 0.9% of all patients and 4% of all patients tested for HIV infection in the opt-out phase had race/ethnicity data that were unknown or missing, and approximately 0.03% of all patients and 3% of all patients tested for HIV infection in the diagnostic phase had race/ethnicity data that were unknown or missing. This potentially affected only the multivariable modeling, which included 3 race/ethnicity covariates. Three specific approaches were used to assess the impact of these missing data on the models, including exclusion of observations with missing data from the models, grouping the observations with missing data into the other category, and use of multiple imputation. In each instance, the magnitude or direction of the results did not change. No additional missing data methods were used.

The Wilcoxon rank sum test was used to compare waiting time, length of stay, boarding time, laboratory turnaround time, and EDWIN between the 2 study groups. The $\chi^2$ test was used to compare proportions of those who left before being placed in a treatment room and before completing evaluation between study groups.

### Sample Size Assessment

We performed basic simulations (Excel, Microsoft Corporation) using variations in the number of patients who would be eligible for, agree to, and complete HIV testing and the prevalence of HIV infection among those tested in each study phase to estimate the number of patients required for inclusion. The objective of this approach was to identify the smallest number of patients required for HIV testing during the opt-out phase while supporting a statistically significant increase in the number of patients identified with HIV infection during the opt-out phase. Using data from a previous study by Goggin et al[17] in which the seroprevalence of HIV infection in our ED was evaluated, we estimated the prevalence of HIV infection among those tested during the opt-out phase to be 0.7%. In the study by Goggin et al, the results were linked to the Colorado Department of Public Health and Environment statewide HIV registry to remove those samples that were already known to be infected with HIV; thus, the report represented an estimate of the prevalence of unknown HIV infection.

Additionally, using data from an observational study of diagnostic testing in our ED, we estimated the prevalence of HIV infection among patients tested (the proportion of those tested who tested positive) during the diagnostic phase to be 2.2%.[19] Assuming 365 HIV tests would be performed during the 1-year diagnostic phase, we estimated requiring a minimum of 7000 HIV tests performed during the opt-out phase to achieve a 95% power to detect an absolute increase of 21 new HIV infections detected using a 2-tailed $\alpha$ of .05.

## RESULTS

During this 2-year study, 65 163 patients presented to the ED. Of these, 31 472 patients presented during the opt-out phase and 33 691 presented during the diagnostic phase, and 28 043 (89%) and 29 925 (89%) met eligibility criteria, respectively (FIGURE). Of those eligible during the opt-out phase, the median age was 36 years (IQR, 25-49), 56% were male, 40% were white, 37% were Hispanic, 14% were African American, and 9% were of another or unknown race or ethnicity. Of those eligible during the diagnostic phase, the median age was 36 years (IQR, 25-49), 57% were male, 41% were white, 37% were Hispanic, 14% were African American, and 8% were of another or unknown race or ethnicity.

Of the 28 043 eligible patients included in the opt-out phase, 6762 patients (24%) did not opt out of HIV testing, and 6702 patients (99%) were ultimately screened for HIV infection. Of the 6702 patients screened, 16 patients (0.24%; 95% CI, 0.14%-0.39%) were confirmed with HIV infection and 10 patients (0.15%; 95% CI, 0.07%-0.27%) had new diagnoses. Of the remaining 21 281 patients who opted out or were opted out by registration personnel, 231 (1%) subsequently underwent diagnostic testing, and 9 patients (4.0%; 95% CI, 1.8%-7.3%) were confirmed with HIV infection, of whom 5 patients (2.2%; 95% CI, 0.7%-5.0%) had new diagnoses (TABLE 1).

Of the 29 925 eligible patients included in the diagnostic phase, 243 patients (0.8%) underwent testing, and of these, 5 patients (2.1%; 95% CI, 0.7%-4.7%) were confirmed infected with HIV and 4 patients (1.6%; 95% CI, 0.5%-4.2%) had new diagnoses. The overall prevalence of newly detected HIV infection during the opt-out phase (including those diagnostically tested) and during the diagnostic phase was 15 in 28 043 (0.05%; 95% CI, 0.03%-0.09%) and 4 in 29 925 (0.01%; 95% CI, 0.004%-0.03%), respectively.

During the opt-out phase, 28 043 patients made 47 309 visits (median number of repeat visits, 3; IQR, 2-5), and patients did not opt out of HIV testing during 10 237 visits (23%). Overall, 7656 rapid HIV tests (75%) were performed during visits in which patients did not opt out of testing, and 723 of these (9%) were repeat tests performed on patients who had been tested during a previous ED visit in the opt-out phase (median repeat tests, 1; IQR, 1-1). Of the 7656 tests performed, 34 (0.4%) were reactive, 28 (0.4%; 95% CI, 0.2%-0.5%) were confirmed positive, and 6 (0.08%) were falsely positive. Of the 28 confirmed positives, 15 (54%) were new and 13 (46%) were repeat HIV diagnoses (Table 1). Of the 13 patient visits with repeat HIV diagnoses, 6 visits (46%; 95% CI, 19%-75%) were from patients who had fallen out of care and were relinked into care as a result

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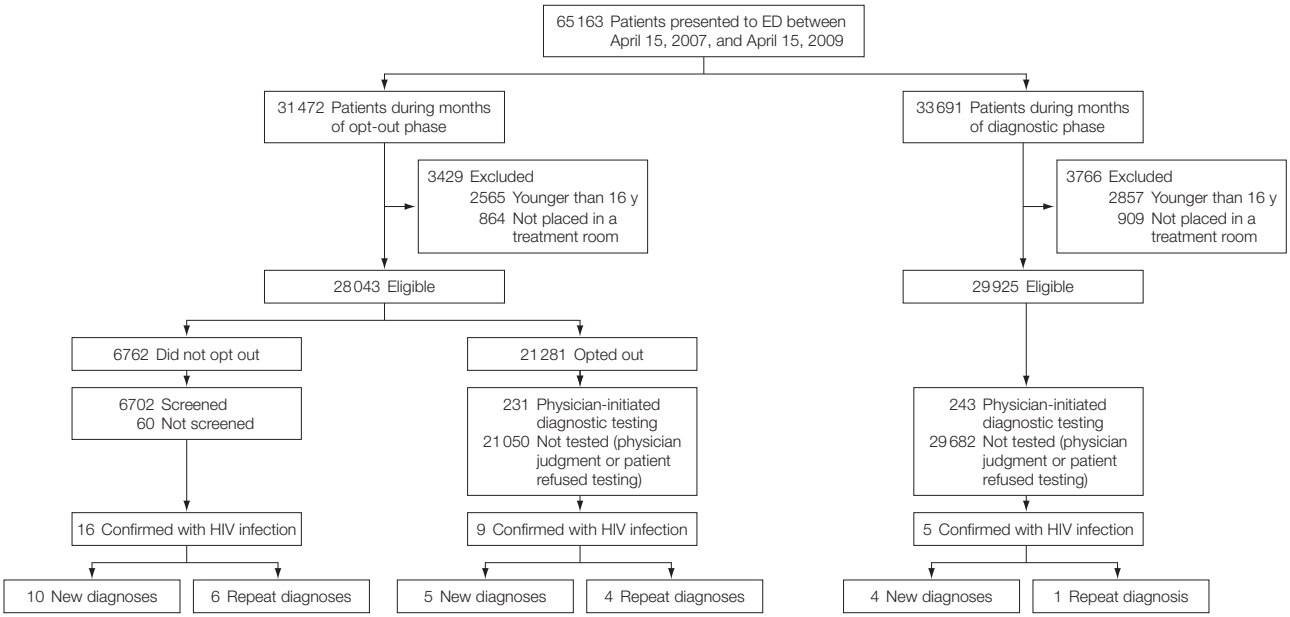
**Figure.** Patient Flow Diagram




Eligible patients included those who were 16 years and older and who were placed in a treatment room in the emergency department (ED). During physician-initiated diagnostic testing, most of the patients not tested were not considered at risk by the physician. HIV indicates human immunodeficiency virus.

**Table 1.** Emergency Department Patients, Patient Visits, and Those Tested for HIV Infection, Linked Into Medical Care, and Confirmed HIV-Infected in the 2 Study Phases

| | Opt-Out Phase | | Diagnostic Phase | |
|---|---|---|---|---|
| Variable | No. (%) | Total No. | No. (%) | Total No. |
| Patients | | 31 472 | | 33 691 |
| Eligible patients[a] | 28 043 (89) | 31 472 | 29 925 (89) | 33 691 |
| Patients not opting out | 6702 (24) | 28 043 | | |
| Patients tested for HIV infection | 6933 (25)[b] | 28 043 | 243 (0.8) | 29 925 |
| Patients with reactive HIV test results | 31 (0.5) | 6933 | 5 (2) | 243 |
| Patients linked into medical care[c] | 30 (0.4) | 6933 | 5 (2) | 243 |
| Patients confirmed with HIV infection | 25 (0.4) | 6933 | 5 (2) | 243 |
| New diagnoses | 15 (60) | 25 | 4 (80) | 5 |
| Repeat diagnoses | 10 (40) | 25 | 1 (20) | 5 |
| Patient visits | | 51 627 | | 50 664 |
| Eligible patient visits[a] | 47 309 (92) | 51 627 | 46 044 (91) | 50 664 |
| Visits with no patients opting out | 10 237 (22) | 47 309 | | |
| Visits with tests for HIV infection | 7656 (16) | 47 309 | 260 (0.6) | 46 044 |
| Visits with reactive HIV test results | 34 (0.4) | 7656 | 5 (2) | 260 |
| Visits with patients linked into medical care[c] | 33 (0.4) | 7656 | 5 (2) | 260 |
| Visits when HIV infection was confirmed | 28 (0.4) | 7656 | 5 (2) | 260 |
| New diagnoses | 15 (54) | 28 | 4 (80) | 5 |
| Repeat diagnoses | 13 (46) | 28 | 1 (20) | 5 |

Abbreviation: HIV, human immunodeficiency virus.
[a] Excluding patients younger than 16 years or those who left before being placed in a treatment room.
[b] Exceeds the number of patients who did not opt out because 231 additional patients received diagnostic tests from physicians during the opt-out phase.
[c] As defined by completing an initial HIV clinic visit after preliminary diagnosis in the emergency department.

of being tested in the ED. Of the 723 repeat tests, 4 (0.6%) were reactive and 3 (0.4%) were confirmed positive, representing 1 new and 2 repeat HIV diagnoses. Only slight demographic differences existed between those who opted out and those who did not. Median age was 40 years (IQR, 27-52) and 38 years (IQR, 27-49), 57% and 52% were male, 41% and 37% were white, 35% and 40% were Hispanic, and 14% and 16% were African American, respectively. No trends in the number of diagnostic tests performed during the opt-out ($P = .72$) or diagnostic ($P = .44$) phases were identified.

Nontargeted opt-out screening was associated with newly identified HIV-infected patients (risk ratio [RR], 3.6; 95% CI, 1.2-10.8) and identification of all HIV-infected patients (RR, 3.5; 95% CI, 1.3-9.3) (TABLE 2). Diagnostic testing performed in conjunction with nontargeted screening during the opt-out phase was also highly associated with newly identified HIV-infected patients (RR, 56.3; 95% CI, 21.1-150.3) and identification of all HIV-infected patients (RR, 71.3; 95% CI, 33.1-153.3).

TABLE 3 reports patient demographics for patients tested for HIV infection and confirmed infected according to study phase. Of the 15 patients with new diagnoses during the opt-out phase, 8 (53%) had been previ-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ously tested for HIV infection, 8 (53%) were men who had sex with men (MSM), 2 (13%) injected drugs, 2 (13%) were homeless, and 2 (13%) had sex with partners with known HIV infection. Of the conventional behavioral risk characteristics associated with transmission of HIV infection (ie, MSM; injection drug use; and high-risk heterosexual behaviors, including prostitution and sex with a partner with known HIV infection), 2 of 10 patients (20%) identified by screening had no conventional risk factors, and for 2 patients, risk factors were unknown. The risk factors indicated by the remaining 6 patients were MSM (n=6), drug injection (n=2), and high-risk heterosexual sex (n=1). Additionally, of the 5 patients identified by diagnostic testing during the opt-out phase, 1 (20%) had no conventional risk factors, and for 2 patients, risk factors were unknown. The risk factors indicated by the remaining 2 patients were MSM (n=2) and high-risk heterosexual sex (n=1). Thus, targeted screening based only on these behavioral risks may miss patients with undiagnosed HIV infection.

The median CD4 cell count was 69/μL (IQR, 17-430) and 13/μL (IQR, 11-15) ($P$=.02), and the median viral load was 108 790 copies/mL (IQR, 56 000-153 562) and 146 000 copies/mL (IQR, 50 700-470 000) ($P$=.87) when comparing new HIV diagnoses during the opt-out and diagnostic phases, respectively. Of the 15 patients identified during the opt-out phase, 9 patients (60%; 95% CI, 32%-84%) had a CD4 cell count of less than 200/μL, 2 patients (13%; 95% CI, 2%-40%) had a CD4 cell count of 200/μL to 350/μL, and 4 patients (27%; 95% CI, 8%-55%) had a CD4 cell count greater than 350/μL. All 4 patients (100%; 95% CI, 40%-100%) identified during the diagnostic phase had a CD4 cell count less than 200/μL.

TABLE 4 reports operational processes during the 2 study phases. There were no differences in the proportions of patients who left before being placed in a treatment room ($P$=.16) or who left

**Table 2.** Association Between Nontargeted Opt-Out Rapid HIV Screening and HIV Diagnoses[a]

| Variable | RR (95% CI) | |
|---|---|---|
| | Newly Diagnosed HIV Infection | All Diagnosed HIV Infection |
| Nontargeted screening | 3.6 (1.2-10.8)[b] | 3.5 (1.3-9.3)[b] |
| Diagnostic testing[c] | 56.3 (21.1-150.3) | 71.3 (33.1-153.3) |
| Age | 1.0 (0.9-1.0) | 1.0 (0.9-1.0) |
| Male sex | 4.6 (1.6-13.2) | 4.5 (1.5-13.5) |
| Race/ethnicity[d] | | |
| African American | 0.9 (0.2-3.4) | 1.5 (0.5-5.1) |
| Hispanic | 1.3 (0.5-3.0) | 1.9 (0.8-4.2) |
| Other[e] | 1.9 (0.4-8.4) | 1.8 (0.4-7.9) |
| Insurance | | |
| State sponsored | 5.4 (1.3-23.8) | 5.1 (1.1-24.5) |
| Uninsured | 1.4 (0.3-7.3) | 2.7 (0.6-13.1) |
| Medicare/Medicaid | 3.6 (0.8-16.7) | 3.4 (0.7-17.2) |

Abbreviations: CI, confidence interval; HIV, human immunodeficiency virus; RR, risk ratio.
[a] Multivariable repeated-measures Poisson regression was used. The reference category for each variable was as follows: nontargeted screening: reference was diagnostic rapid HIV testing; sex: reference, female; race/ethnicity: reference, white; insurance: reference, private; and diagnostic testing: reference, none. Age was included as a continuous variable with 1-year increments beginning at 16 years.
[b] To verify the stability of the results given the relatively small number of outcomes, a confirmatory bootstrap analysis using 1000 resampled data sets was performed and included an RR range from 1.5 to 17.5 for both nontargeted screening estimates.
[c] Diagnostic testing performed during the opt-out phase.
[d] Multiple imputation was used for the small proportion of missing race/ethnicity data (see "Methods" section).
[e] Represents American or Alaskan Native, Native Hawaiian, or non-Hawaiian Pacific Islander.

**Table 3.** Patient Demographics for Those With HIV Infection According to Study Phase

| Variable | Opt-Out Phase | Diagnostic Phase |
|---|---|---|
| Total tested for HIV infection, No. | 6933 | 243 |
| Age, median (IQR), y | 38 (26-49) | 38 (28-47) |
| Male sex, No. (%) | 3522 (51) | 171 (70) |
| Race/ethnicity, No. (%) | | |
| African American | 1126 (16) | 40 (16) |
| Asian | 52 (1) | 1 (1) |
| Hispanic | 2832 (41) | 69 (28) |
| White | 2570 (37) | 122 (50) |
| Other[a] | 103 (1) | 3 (1) |
| Unknown/missing | 250 (4) | 8 (3) |
| Confirmed HIV diagnoses, No. | 25 | 5 |
| Age, median (IQR), y | 38 (29-47) | 39 (37-46) |
| Male sex, No. (%) | 21 (84) | 5 (100) |
| Race/ethnicity, No. (%) | | |
| African American | 4 (16) | 0 |
| Asian | 0 | 0 |
| Hispanic | 11 (44) | 4 (80) |
| White | 8 (32) | 1 (20) |
| Other[a] | 2 (8) | 0 |
| New HIV diagnoses, No. | 15[b] | 4 |
| Age, median (IQR), y | 37 (26-46) | 38 (35-44) |
| Male sex, No. (%) | 13 (87) | 4 (100) |
| Race/ethnicity, No. (%) | | |
| Asian | 0 | 0 |
| African American | 2 (13) | 0 |
| Hispanic | 7 (47) | 3 (75) |
| White | 4 (27) | 1 (25) |
| Other[a] | 2 (13) | 0 |

Abbreviations: HIV, human immunodeficiency virus; IQR, interquartile range.
[a] Represents American or Alaskan Native, Native Hawaiian, or non-Hawaiian Pacific Islander.
[b] Includes 5 of 231 patients who were diagnostically tested during the opt-out phase.

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**Table 4.** Emergency Department Processes of Care Related to Nontargeted Opt-Out Rapid HIV Screening and Physician-Directed Diagnostic Rapid HIV Testing

| Variable | Opt-Out Phase | Diagnostic Phase | *P* Value[a] |
|---|---|---|---|
| Total ED patient visits, No. | 51 627 | 50 664 | |
| Proportion who left before being placed in a treatment room, No. (%) | 1623 (3.1) | 1672 (3.3) | .16 |
| Proportion who left before completing evaluation, No. (%)[b] | 1261 (2.5) | 1253 (2.6) | .72 |
| Waiting time, median (IQR) [range], min[b,c] | 0 (0-7) [0-1545] | 0 (0-1) [0-753] | <.001 |
| Length of stay (not admitted), median (IQR) [range], h[b,d] | 3.5 (2.1-5.9) [0-38.3] | 3.3 (2.0-5.7) [0-41.4] | <.001 |
| Length of stay (admitted), median (IQR) [range], h[b,d] | 6.2 (4.1-9.7) [0-42.8] | 6.4 (4.1-10.9) [0-45.8] | <.001 |
| Boarding time, median (IQR) [range], h[b,e] | 2.4 (1.5-4.5) [0-39.1] | 2.6 (1.6-5.7) [0-46.9] | <.001 |
| ED work index, median (IQR) [range][24] | 0.6 (0.4-0.7) [0.2-2.9] | 0.6 (0.4-0.8) [0.2-2.0] | .68 |
| Laboratory turnaround time, median (IQR) [range], min[f] | 23 (17-35) [10-667] | 25 (18-33) [10-657] | .22 |

Abbreviations: ED, emergency department; HIV, human immunodeficiency virus; IQR, interquartile range.
[a] The Wilcoxon rank sum and $\chi^2$ tests were used to make statistical comparisons for continuous and categorical data, respectively.
[b] Excludes 3295 patients who left before being placed in a treatment room.
[c] Difference between the time the patient presented to the ED and the time the patient was placed in a treatment room.
[d] Difference between the time the patient was placed in a treatment room and the time of discharge from the ED or admission to the hospital. Of the 98 996 patients placed in a treatment room, 77 894 were discharged and 21 102 were admitted to the hospital.
[e] Difference between the time the patient was admitted to the hospital and the time the patient was transferred to an inpatient room.
[f] Difference between the time the blood specimen was received by the laboratory and the time the result was reported for all 7916 rapid HIV tests.

before completing evaluation ($P=.72$). Waiting times for all patients and lengths of stay for all patients who were not admitted were statistically longer during the opt-out phase ($P<.001$), and lengths of stay and boarding times for all those who were admitted were statistically shorter during the opt-out phase ($P<.001$); however, the median differences for each of these parameters were small (ie, <12 minutes each). The EDWIN ($P=.68$) and laboratory HIV test turnaround times ($P=.22$) were also similar between groups.

## COMMENT

Nontargeted opt-out rapid HIV screening in conjunction with diagnostic testing was associated with approximately 30 times the number of rapid HIV tests performed, yet only a few more patients were newly identified with HIV infection when compared with diagnostic testing alone. The total number of patients identified with HIV infection was modest and most of the patients identified with new HIV infection met serological criteria for the acquired immunodeficiency syndrome (ie, CD4 cell count <200/μL) at the time of their diagnoses.

Although a goal of the 2006 CDC recommendations[3] for performing nontargeted opt-out HIV screening was to improve the identification of patients with undiagnosed HIV infection, this approach was not considered to have a high sensitivity (defined as the proportion of all HIV-infected patients identified by the program), and it was uncertain what impact implementation of the approach would have on the epidemic as a whole. A strength of our study is that to our knowledge, it represents the largest ED-based HIV testing study to date and the largest evaluation of the 2006 CDC recommendations to date. In 2007, Brown et al[10] published results from a prospective observational study from Washington, DC, concluding that ED-based HIV screening in a high-prevalence setting was feasible. In their study, 9 of 2476 patients (0.4%) who were tested had confirmed HIV infection. Other reports of rapid HIV screening in ED settings have either been smaller or have used external staff to conduct screening, thus limiting their applicability.[5-7,9,19,26-28] In addition, studies of routine HIV screening in EDs that have been previously reported have been observational, limiting their ability to compare HIV screening with other approaches to HIV testing.[10,11,29-31]

During the study, physicians were permitted to continue to perform diagnostic testing so they could provide standard emergency medical care during the opt-out phase. This allowed physicians to target patients who opted out of testing during registration. Nonetheless, nontargeted screening remained significantly associated with identification of patients with HIV infection after adjusting for the performance of diagnostic testing during the opt-out phase, suggesting that nontargeted screening is useful in identifying patients with unrecognized HIV infection. However, this study did not demonstrate that nontargeted screening identified patients early in the course of disease, as only 4 patients were identified with CD4 cell counts greater than 350/μL. This finding is contrary to what many thought would occur and suggests the need for an alternative testing approach to identify patients earlier in the course of disease. The yield of nontargeted rapid HIV screening may not be as high as alternative targeted testing strategies, although this is still unknown. It is possible, however, that a longer implementation of nontargeted screening would result in a larger proportion of persons with more recent infection being identified, although this also remains unknown.

During the course of the study, approximately 76% of all eligible patients either opted out or were opted out by registration personnel. Although we did not collect data specific to reasons for opting out, it is our impression that a large proportion of eligible patients believed they were not at risk for HIV infection or could not consent to testing due to altered mentation or illness requiring urgent or emergent evaluation or intervention.


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These results are similar to the studies by Brown et al[10] and White et al,[11] which reported 19% testing (2476/13 240) of those who met screening criteria and 18% testing (7923/45 159) of those who were offered testing, respectively, and support the notion that alternative approaches to screening are needed to improve identification of HIV infection among ED patients. A cross-sectional survey involving a convenience sample indicated that similar proportions of patients were willing to be tested with opt-out or opt-in screening approaches; however, explanation of opt-out screening was required for a greater proportion.[32]

Emergency department crowding has received substantial attention over the past decade, and there were concerns that the introduction of a large preventive intervention such as nontargeted screening in this busy clinical environment might interfere with processes of emergency medical care.[33,34] Our results show that ED processes of care remained relatively unchanged when nontargeted screening was implemented. The proportion of patients who did not complete care were similar in both phases, and although waiting, length of stay, and boarding times differed slightly between the 2 study phases, we believe these differences are not clinically meaningful. In addition, use of EDWIN, a validated composite measure of ED crowding, revealed no difference between the study phases.

An important potential limitation of this study was using a quasi-experimental design rather than an experimental design. However, we do not believe this undermines the validity of the findings. Randomization was not possible because the screening program was fully integrated into ED care and because the complexity of providing this service 24 hours a day in a high-volume setting was high. The primary outcome measure, newly diagnosed HIV infection, was not subject to ascertainment bias, and selection bias was minimized by inclusion of all eligible ED patients 16 years and older, and by fully integrating testing methods across several hundred ED staff members, thus mitigating the influence of any individuals on either HIV testing approach.

A potential but unlikely factor that might have compromised the validity of our findings would have been systematic changes in the epidemiology of HIV infection among the patients who sought care in our ED during the study. However, we did not observe any important changes in the epidemiology of HIV infection in our community. Multivariable regression analyses were performed to ensure the validity and robustness of our results. The association between nontargeted screening and diagnosis of HIV infection remained unchanged when modeled using both Poisson and logistic regression analyses and after removing all covariates from the model except whether diagnostic testing was performed during the opt-out phase.

Finally, our study was performed at 1 institution. Although DHMC serves as a model safety-net institution, our results may not be representative of those from other types of institutions or in other settings.

Nontargeted opt-out rapid HIV screening in the ED, compared with diagnostic testing, was associated with identification of only a modestly increased number of patients with newly diagnosed HIV infection, most of whom were identified late in the course of disease.

**Author Affiliations:** Departments of Emergency Medicine (Drs Haukoos and Byyny and Ms Hopkins), Clinical Social Work (Mr Silverman), Health Services Research (Dr Eisert), and Pathology (Dr Wilson), Denver Health Medical Center, Denver, Colorado; University of Colorado School of Medicine, Aurora (Drs Haukoos, Byyny, Thrun, Wilson, and Johnson); Departments of Epidemiology (Dr Haukoos) and Health Systems Management and Policy (Dr Eisert), Colorado School of Public Health, Aurora; Department of Health and Behavioral Sciences, University of Colorado Denver (Ms Conroy); Denver Public Health, Denver (Dr Thrun); Division of HIV/AIDS Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia (Drs Hutchinson and Heffelfinger); Children's Immunodeficiency Program, The Children's Hospital, Aurora (Ms Forsyth); and University of Colorado HIV/AIDS Clinical Program, University of Colorado Hospital, Aurora (Dr Johnson).

**Author Contributions:** Dr Haukoos had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

*Study concept and design:* Haukoos, Conroy, Eisert, Thrun, Wilson, Forsyth, Johnson.
*Acquisition of data:* Haukoos, Hopkins, Conroy, Silverman.
*Analysis and interpretation of data:* Haukoos, Hopkins, Conroy, Byyny, Eisert, Hutchinson, Heffelfinger.
*Drafting of the manuscript:* Haukoos, Conroy, Hutchinson, Heffelfinger.
*Critical revision of the manuscript for important intellectual content:* Haukoos, Hopkins, Conroy, Silverman, Byyny, Eisert, Thrun, Wilson, Hutchinson, Forsyth, Johnson, Heffelfinger.
*Statistical analysis:* Haukoos, Hopkins, Conroy, Hutchinson.
*Obtained funding:* Haukoos, Eisert, Thrun, Wilson.
*Administrative, technical, or material support:* Haukoos, Hopkins, Conroy, Silverman, Byyny, Eisert, Thrun, Wilson, Hutchinson, Forsyth, Johnson, Heffelfinger.
*Study supervision:* Haukoos, Heffelfinger.

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**Current or past members of the Denver Emergency Department HIV Testing Research Consortium and the Denver Emergency Department HIV Opt-Out Study Group:** Bob Bongiovanni, MA; Beth Dillon, MSW, MPH; and Anne Marlow-Geter, MPH, Colorado Department of Public Health and Environment (CDPHE), Denver; Eric Christensen, RN, BSN; Jennifer Saltzsieder, RN; Shawn Ullrich, RN, NPM; and Melinda Whalen, RN, BSN, CEN, Denver Health Medical Center (DHMC), Denver.

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Beebe, PhD, D(ABMM) (CDPHE); Janell Bezdek (CDPHE); Caroline Brandon (DHMC); Brian C. Boyett, MS (CDC); Kris Cambria, MSW (DHMC); Steve Cantrill, MD (DHMC); Kevin P. Delaney, MPH (CDC); Natalie Edgar (DHMC); Anthony Edwards (DHMC); Michael Fuhriman (Denver Public Health [DPH]); Malinda Gonzales (DPH); Amy Graepler, MT(ASCP) (DHMC); Jennifer Guess, MT(ASCP) (DHMC); Erica Higgins, MSW (DHMC); Ellie Jensen, DO (DHMC); Linda Kaufman (DHMC); Roger J. Lewis, MD, PhD (Harbor-UCLA Medical Center); Shane Lieberman, MA (DHMC); Wendy McDermott, MSW (DHMC); Yesenia Mendez (CDPHE); Erin Moore, LCSW (DHMC); Melissa Paddock (DHMC); Pragna Patel, MD, MPH (CDC); Paul Schultz (DHMC); Athena Sheldon, MSW (DHMC); Rachael Slaughter, LCSW (DHMC); Briana R. Sprague (CDPHE); LaTasha Stanley, MSW (DHMC); Cheryl Stephenson, AAS, CHAM (DHMC); Mark Tartletsky, MT(ASCP), MCIS (DHMC); Andrew C. Voetsch, PhD (CDC); Diane Weed, MA, MT(ASCP) (DHMC); Julia Weise, LCSW, MSW (DPH); members of the Colorado Emergency Medicine Research Center; and all ED and laboratory staff at Denver Health Medical Center. Ms Addison, Ms Brandon, Ms Cambria, Dr Cantrill, Ms Edgar, Mr Edwards, Ms Higgins, Dr Jensen, Mr Lieberman, Ms McDermott, Ms Moore, Ms Paddock, Mr Schultz, Ms Sheldon, and Ms Slaughter received compensation for their contributions.

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