# Increased Acceptance Rates of HIV Screening Using Opt-Out Consent Methods in an Urban Emergency Department

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**Background:** Optimal methods for implementing HIV screening in health care settings remain unknown.

**Objective:** To compare the acceptance rates of emergency department HIV screening when supplemental staff use opt-in and opt-out consent methods.

**Methods:** Experimental equivalent time-sample, conducted in an urban emergency department with an annual census of 80,000 visits. HIV screeners performed nontargeted HIV screening using point-of-care, rapid HIV tests. Eligible patients were medically stable, English or Spanish speaking, ≥13 or ≤64 years, not HIV tested in past 6 months, and not psychiatrically impaired. Screeners offered eligible patients HIV screening using either opt-in or opt-out consent methods on alternate weeks. Main outcome measures were the acceptance rate of HIV screening and the association between opt-out rapid HIV screening and acceptance.

**Results:** Of the eligible patients, 2409 were offered HIV screening, with 1209 (50%) on opt-in days and 1200 (50%) on opt-out days. The mean age was 40 years, 52% were male, 45% were Black, 28% Hispanic, and 15% white. The acceptance rate of opt-in HIV screening was 63% [767 of 1209, 95% confidence interval (CI): 61% to 66%] and the acceptance rate of opt-out HIV screening was 78% (931 of 1200, 95% CI: 75% to 80%), absolute difference 14% (95% CI: 11% to 18%). The acceptance rate of opt-out HIV screening remained greater after adjusting for patient demographics, admission status, acuity, treatment area, privacy of encounter, and screening staff identity (adjusted odds ratio: 2.0, 95% CI: 1.7 to 2.4).

**Conclusions:** Opt-out HIV screening using supplemental staff increases patient acceptance and should be considered as the consent methodology of choice.

**Key Words:** HIV screening, emergency department, opt-out consent

(*J Acquir Immune Defic Syndr* 2011;58:277–282)

Received for publication February 3, 2011; accepted August 4, 2011.

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Supported by a grant (PS 07-768) from the Centers for Disease Control and Prevention.

The Centers for Disease Control and Prevention had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript.

The authors have no conflicts of interest to disclose.

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## INTRODUCTION

The Centers for Disease Control and Prevention recommend routine HIV screening in health care settings.[1] In addition to removing requirements for mandatory pretest counseling and separate, signed written consent, the Centers for Disease Control and Prevention endorses using opt-out rather than opt-in consent methods. HIV screening that employs opt-out consent methods (in which patients are notified that screening will be performed unless they decline) is thought to be less stigmatizing than that using opt-in consent methods (in which patients are offered testing and assent is required).[1,2] Because patients may feel less singled out with opt-out consent, the Centers for Disease Control and Prevention hopes that this switch will lead to increased acceptance and screening rates. HIV screening programs employing opt-out consent methods have reported increased screening rates in specific medical settings.[3,4] For example, antenatal HIV screening rates increased from 35% to 88% when screening changed from an opt-in to an opt-out approach.[3] Similar findings have been demonstrated in a sexually transmitted illness clinic.[4]

In contrast, opt-in screening in emergency departments (EDs)[5–8] seems to outperform the newer opt-out approach.[9,10] Opt-in acceptance rates range from 40% when ED triage nurses offer HIV screening[5] to rates exceeding 60% when offered by supplemental staff at the patient's bedside.[6,7] We recently reported that acceptance rates actually declined from 50% to 30% when changing from a program whereby opt-in HIV screening was routinely offered by supplemental staff in the triage area to a program that integrated opt-out HIV consent methods into the ED registration process.[9] Another ED HIV screening study reported acceptance rates with registration-based opt-out consent to be only 24%.[10] The low opt-out acceptance rates in these ED studies may have been influenced by factors unrelated to the opt-out consent method, but rather by particular protocol characteristics, specifically the integration of HIV consent into the general consent form and reliance on nonclinical registration staff to initiate screening.[9–11]

Emerging consensus seems to support integrating HIV screening into EDs by using a parallel testing model, whereby supplemental staff are hired specifically to perform screening.[11–13] This model is felt to have the least impact on ED processes and to be more feasible when compared with models using existing ED staff. In this study, we compare the acceptance rates of nontargeted, point-of-care rapid HIV

screening when supplemental screening staff employ either opt-in or opt-out consent methods.

## METHODS

### Design Overview

We used an experimental equivalent time-sample design from January 25 through April 25, 2010. The study was approved by the hospital's institutional review board with a waiver of written consent.

### Setting and Participants

The ED at the Alameda County Medical Center-Highland Hospital serves as the regional trauma center in Oakland, CA, with 82,000 visits annually; 47% of patients are Black, 32% Hispanic, 44% female, 2% children (<12 years of age), and 53% uninsured. Different models of HIV screening and physician-initiated HIV testing have been in place since 2005.[5,9] At the time of this study, physicians could initiate diagnostic rapid HIV testing in patients with signs or symptoms suggestive of HIV infection or AIDS. These tests were performed on oral fluid samples during hours when HIV screening staff was on site; otherwise, they were performed in the hospital laboratory on blood samples.

### Interventions

Three supplemental HIV screening staff (1 full- and 2 part-time) performed HIV screening for a total of 80 hours per week of testing. The screening staff was fluent in English and Spanish and certified in HIV test counseling and rapid HIV testing.

Following a standardized protocol, screening staff implemented nontargeted HIV screening[14] using either opt-in or opt-out consent methods on alternating weeks. Screening staff first performed a review of the ED electronic medical record tracking board (Wellsoft Corporation, Somerset, NJ) on all registered patients who were roomed in the ED to determine their primary eligibility for screening. Patients aged ≥13 and ≤64 years, without known HIV, not on a psychiatric hold (5150), and not tested for HIV within the preceding 6 months were flagged as primary eligible. Primary eligible patients were then approached in a systematic manner for screening, moving through the ED according to room number. HIV screening staff then performed a face-to-face assessment to determine the patient's secondary eligibility for screening. Patients were secondary eligible to be offered HIV screening if they were awake, alert, and either English or Spanish speaking. Patients who were confused, somnolent, intoxicated, too medically ill, or those who were discharged or unavailable were not eligible. Determination of secondary eligibility was at the discretion of the HIV screening staff. Screening staff then offered HIV screening to all secondary eligible patients using opt-in or opt-out consent methods, depending on the week. All 3 HIV screening staff followed the same opt-in and opt-out schedules.

During opt-in weeks, HIV screening was offered in the following manner: "My name is Mrs. Gordon. Here at the Highland ER we offer HIV testing to all of our patients. Would you like to get an HIV test today?" During opt-out weeks, patients were notified that HIV screening was to be performed in the following manner: "My name is Mrs. Gordon. Here at the Highland ER we test all of our patients for HIV. I am here to do your HIV test." During the opt-out phase, assent was inferred unless the patient declined. HIV screening staff did not explicitly ask patients if they would like to decline screening.

Beyond the protocol to offer standardized opt-in or opt-out screening, HIV screeners were free to engage patients and answer their questions according to their usual practice. It was not mandated that the benefits of HIV screening be explained. All patients were provided with a pamphlet that included basic testing information and education regarding HIV transmission and infection. The pamphlet emphasized the importance of routine screening, but it did not promote opt-in or opt-out methodologies of consent. In both models, consent was verbal and patient response was documented in the electronic medical record.

HIV screening staff performed point-of-care, rapid HIV testing using the OraQuick Advance HIV 1/2 Antibody Test (OraSure Technologies, Inc, Bethlehem, PA) on oral fluid specimens for all patients who agreed to screening.

The screening staff was trained by the study investigators in both study protocol and the test offering process. They used dialog cards to ensure standardization of procedures; the protocol was available both electronically and in print form. Protocol compliance was monitored during a 7-day pilot period during which screening staff implemented the study and investigators monitored for compliance, retrained as necessary, and made refinements based on feedback. Compliance was further monitored through direct observation by the principal investigator of individual screening staff thereafter on a monthly basis. A meeting was held at the midpoint of the study to answer questions and review the protocol. To minimize bias, the importance of adhering to the study protocol was emphasized during the initial training sessions and during the midpoint review.

### Data Collection and Processing

Screening staff recorded the following HIV-related information in preformed fields with drop-down menus within the electronic medical record: screener identity; screening phase (opt-in or opt-out); primary eligibility; reason primary ineligible (age, recent HIV test, psychiatric hold, HIV positive, or other); reason not assessed for secondary eligibility (screener unavailable, patient discharged, patient unavailable, or physician ordered HIV test); secondary eligibility; reason secondary ineligible (too ill, confused, intoxicated or altered mental status, language barrier, or other); response to screening (accepted or declined); and the results of HIV screening (reactive, nonreactive, or indeterminate). Screening staff also recorded their perception of privacy regarding the screening process (private versus not). Registration and nursing staff also recorded basic demographic information (age, sex, race/ethnicity, marital status, and homelessness), area of treatment within the ED (fast-track area or main ED), Emergency Severity Index score (validated

5-level triage system score with 1 highest and 5 lowest acuity),[15] and disposition (admitted versus discharged).

## Outcomes

The primary end point was the acceptance rate of HIV screening. The secondary end point was the acceptance rate of HIV screening stratified by HIV screener.

## Statistical Analysis

Based on an acceptance rate of approximately 50% (606 of 1178) when supplemental HIV screening staff used opt-in consent methods for HIV screening (pilot data), we determined that 410 patients per group would provide 80% power to detect an absolute difference in acceptance rate of 10% between opt-in and opt-out consent methods, assuming $P < 0.05$.

Data for all ED visits during the 3-month study period were downloaded from the electronic medical record, exported to spreadsheets (Microsoft Excel 2003; Microsoft Corporation, Redmond, WA), and analyzed using Stata version 10.1 (StataCorp LP, College Station, TX). The study population included all secondary eligible patients who were offered screening. Continuous data are reported as means with standard deviations, and categorical data are reported as percentages with 95% confidence intervals (CIs). For the primary and secondary end points, bivariate analyses were performed using the chi-square test and differences in acceptance rates were expressed as absolute differences with associated 95% CIs.

We then performed multivariate regression with the primary outcome variable "acceptance" of HIV screening and the primary predictor variable "screening method" (opt-in versus opt-out). Secondary predictor variables included patient age, sex, race/ethnicity, homelessness, marital status, admission status, acuity, treatment area, privacy of encounter, and the screening staff identity (screener A, B, and C). To account for hypothesized relationships of sociodemographic and clinical characteristics to acceptance, our model specified covariates regardless of their performance on bivariate analysis. If their inclusion in the model had no influence on model performance, we eliminated them in backward fashion. We also performed multivariate regression for the individual HIV screener subgroups using the same variables. Results are presented as odds ratios (ORs) with 95% CIs.

# RESULTS

Figure 1 is a flow diagram illustrating how the study population was obtained from the overall ED population. During the study period, 7197 patients were assessed for primary eligibility, of which 5630 (78%) were eligible. Of these, 2779 (49%) were approached by screening staff and assessed for secondary eligibility. The main reason why primary eligible patients were not approached was because the tester was unavailable (n = 1841). Other reasons included the following: patient unavailable (n = 662), patient discharged (n = 124), and physician ordered HIV test (n = 224).

There were a total of 2409 secondary eligible patients who were offered HIV screening, of which 1209 (50%) were seen on days designated for opt-in screening and 1200 (50%) were seen on days designated for opt-out screening. The mean age of patients offered HIV screening was 40 years, 52% were male, 45% were Black, 28% were Hispanic, 15% were white, 19% were Spanish speaking, and 94% had an

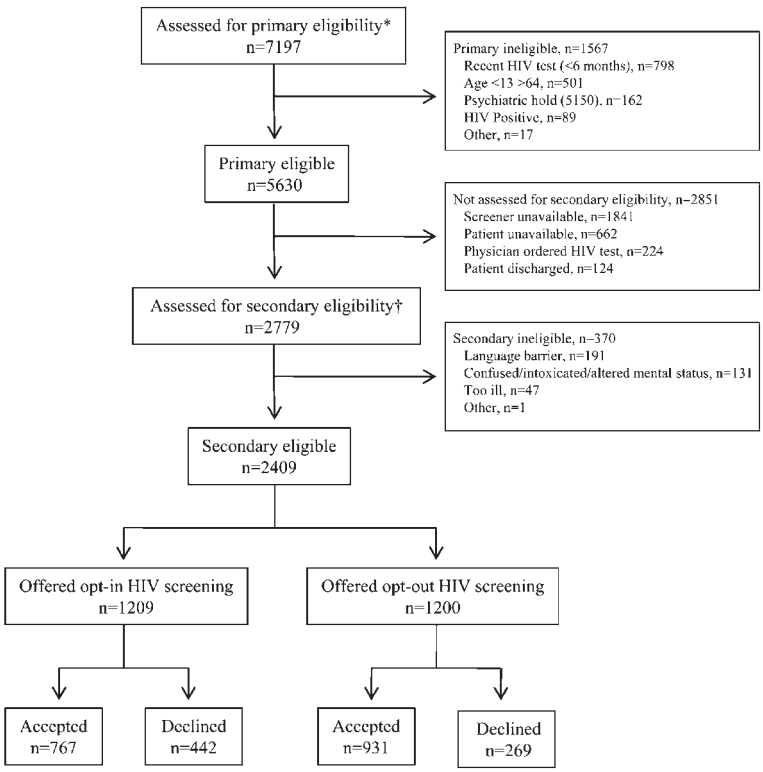


**FIGURE 1.** Flow diagram of patient enrollment. *A primary assessment for HIV screening eligibility was performed by systematic review of the electronic medical record. Patients were primary ineligible for HIV screening if they were aged <13 or >64 years, on a psychiatric hold, had completed ED HIV testing within past 6 months, or were known to have a diagnosis of HIV/AIDS. Primary eligible patients were then approached for HIV screening. †A secondary assessment for HIV eligibility was performed at the bedside. Patients were secondary ineligible for HIV screening if they were too ill; confused, intoxicated, or had altered mental status; or spoke a language other than English or Spanish. Secondary eligibility was up to the discretion of the HIV screener.

Emergency Severity Index score ≥3. Characteristics of patients offered screening were similar between the opt-in and opt-out phases (Table 1).

Overall acceptance rates increased from 63% with opt-in consent methods (767 of 1209, 95% CI: 61% to 66%) to 78% with opt-out consent methods (931 of 1200, 95% CI: 75% to 80%), for an absolute difference of 14% (95% CI: 11% to 18%). All patients accepting HIV screening were tested. One screening test during the opt-in phase (1 of 767, 0.1%) and 1 screening test during the opt-out phase (1 of 931, 0.1%) was reactive; both were confirmed positive with Western blot testing. There were no false-positive screening rapid HIV tests. Of the 224 physician-initiated rapid HIV tests ordered during hours screening staff were on site, 4 were reactive, of which 3 were confirmed positive with Western blot testing (3 of 224, 1.3%) and 1 was confirmed false positive.

For screener A, acceptance rates were similar between phases: opt-in acceptance 71% (502 of 706, 95% CI: 68% to 74%) versus opt-out acceptance 75% (546 of 726, 95% CI: 72% to 78%), for an absolute difference of 4% (95% CI: 0.05% to 9%). For screener B, acceptance rates increased from 55% with opt-in consent methods (165 of 298, 95% CI: 50% to 61%) to 84% with opt-out consent methods (249 of 297, 95% CI: 79% to 88%), for an absolute difference of 29% (95% CI: 21% to 35%). For screener C, acceptance rates increased from 49% with opt-in consent methods (100 of 205, 95% CI: 42% to 56%) to 77% with opt-out consent methods (136 of 177, 95% CI: 70% to 83%), for an absolute difference of 28% (95% CI: 19% to 37%).

The results of multivariate logistic regression are shown in Table 2. An adjustment for covariates resulted in no detectable change in the odds of accepting HIV screening using opt-out over opt-in consent methods (unadjusted OR 2.0, 95% CI: 1.6 to 2.4 and adjusted OR 2.0, 95% CI: 1.7 to 2.4). For the individual screeners, adjusting for covariates also did not influence the acceptance rates (unadjusted OR screener A: 1.2, 95% CI: 1.0 to 1.6 versus adjusted OR screener A: 1.2, 95% CI: 1.0 to 1.5; unadjusted OR screener B: 4.2, 95% CI: 2.8 to 6.1 versus adjusted OR screener B: 4.4, 95% CI: 3.0 to 6.6; unadjusted OR screener C: 3.4, 95% CI: 2.2 to 5.4 versus adjusted OR screener C: 3.9, 95% CI: 2.5 to 6.3).

**TABLE 1.** Comparison of Patients Offered HIV Screening Using Opt-In and Opt-Out Methods (N = 2409)

| Characteristic | Opt-In (n = 1209) n (%) | Opt-Out (n = 1200) n (%) |
|---|---|---|
| Age, mean (±SD), y | 40.5 (12.7) | 40.1 (12.9) |
| Sex | | |
| Male | 647 (53.5) | 613 (51.1) |
| Race/ethnicity | | |
| Black | 528 (43.7) | 563 (46.9) |
| White | 195 (16.1) | 178 (14.8) |
| Hispanic | 355 (29.3) | 330 (27.5) |
| Asian | 59 (4.9) | 61 (5.1) |
| Other/unknown | 72 (6.0) | 68 (5.7) |
| Language | | |
| English | 947 (78.3) | 958 (79.8) |
| Spanish | 237 (19.6) | 231 (19.3) |
| Other | 25 (2.1) | 11 (0.9) |
| Area of care | | |
| Main ED | 1058 (87.5) | 1065 (88.8) |
| Fast-track | 151 (12.5) | 135 (11.3) |
| ESI score | | |
| 3, 4, 5 | 1133 (93.7) | 1136 (94.7) |
| Disposition | | |
| Discharged | 1089 (90.1) | 1063 (88.6) |
| Marital status | | |
| Single | 970 (80.2) | 988 (82.3) |
| Homeless | | |
| No | 1174 (97.1) | 1171 (97.6) |

ESI score, Emergency Severity Index (validated 5-level triage system score with 1 highest and 5 lowest acuity).

## DISCUSSION

In this study, we demonstrated that acceptance rates are 14% higher when supplemental screening staff employ point-of-care, nontargeted rapid HIV screening using opt-out consent methods compared with opt-in consent methods. Despite differences in protocol, an increase in acceptance rates is consistent with the experience in non-ED clinical settings in which opt-out screening is now used.[3,4,16,17] In antenatal clinics, switching to a protocol whereby maternity providers informed patients that HIV testing was performed as part of a routine panel of tests increased HIV testing rates to 88%, compared with a baseline rate of 75% with opt-in consent.[16] A different antenatal study, whereby nurse midwives used a printed discussion protocol and presented HIV testing as routine (making it clear that patients could decline), also reported HIV testing rates of 88%.[3] Shagufta and Mahto[17] demonstrated that HIV testing rates in a genitourinary clinic increased from 66% with opt-in testing initiated by clinicians to 80% with an opt-out protocol utilizing informational pamphlets and signage emphasizing that blood was routinely tested for HIV with reinforcement of the policy during consultation. In a similarly designed study, HIV testing rates of patients attending a genitourinary clinic increased from 35% to 65% after introducing opt-out consent.[4]

The primary outcome in our study, overall acceptance of screening, is driven by differences in rates of acceptance by 2 of the 3 HIV screeners. For screeners B and C, switching to opt-out consent increased acceptance considerably, whereas for screener A, who had baseline high rates of acceptance of testing using the opt-in approach, switching

**TABLE 2.** OR for Acceptance in Opt-Out Screening Model

| | Unadjusted OR (95% CI) | Adjusted OR* (95% CI) |
|---|---|---|
| Overall | 2.0 (1.6 to 2.4) | 2.02 (1.7 to 2.4) |
| HIV screener A | 1.2 (1.0 to 1.6) | 1.2 (1.0 to 1.5) |
| HIV screener B | 4.2 (2.8 to 6.1) | 4.4 (3.0 to 6.6) |
| HIV screener C | 3.4 (2.2 to 5.4) | 3.9 (2.5 to 6.3) |

*Adjusted for age, sex, race/ethnicity, marital status, language, privacy of encounter, and screener identity (overall model only).

to opt-out consent had only a slight influence on acceptance rates. Reasons for the differences between the individual screener's acceptance rates, specifically during the opt-in phase, are not known. We attempted to minimize confounders by implementing a systematic screening protocol that was identical between both phases and identical for each screener. We also implemented intensive training and monitoring of screening staff to ensure protocol adherence in an effort to minimize bias.

The discrepancy among screeners, with respect to acceptance rates, suggests that external factors (beyond consent methods) may influence a patient's willingness to undergo testing. The HIV screeners shared certain traits: they were all females in their late 30s to early 40s and bilingual in English and Spanish. Screeners differed, however, with respect to ethnicity, experience, and personality. Screener A was Black, screener B was Hispanic, and screener C was white. Screeners A and B had more than 15 years of HIV test counseling experience, whereas screener C had less than 2 years of experience. Lastly, differences in personalities between the screeners were notable. Screener A had a dynamic, engaging, and animated personality, whereas screeners B and C were noticeably more reserved in their approach to patients.

Other studies have similarly reported variability in acceptance and testing rates by personnel type, despite standardized protocols.[8,17–19] Variability in midwives has been shown to be an independent predictor of HIV testing uptake in pregnant women,[19] and HIV testing rates have also been shown to differ between individual physicians and nurses who offered screening in a genitourinary clinic.[17] ED patient acceptance of rapid HIV screening has also been shown to vary by which research assistant offered screening.[8] Reasons for these differences remain speculative, and further studies evaluating motivators for patient acceptance and the relationship of personnel offering HIV screening are needed. We believe that factors unique to the screener, such as ethnicity, personality traits, bedside manner, and nonverbal cues, may influence screening acceptance.

Our results with opt-out HIV screening should be generalizable beyond the ED. Because 95% of our subjects were predicted to require very few resources for their care, as demonstrated by a level 3, 4, or 5 Emergency Severity Index score at triage,[20] these results should be reproducible in most outpatient clinics, including primary care offices, genitourinary clinics, and obstetrical/gynecological clinics. Furthermore, the simple, objective, opt-out dialog used in our study can be applied to a variety of testing models, including screening and diagnostic testing. Although we employed HIV screeners, a variety of health care providers, including nurses, physicians, ED technicians, medical assistants, and registration personnel could utilize opt-out dialog when offering HIV screening to maximize patient acceptance. Lastly, health care facilities could easily expand the scope of screening by integrating opt-out consent methods into protocols for hospital admission and preoperative evaluations.

Although our results show that acceptance rates are greater with opt-out consent methods, we were unable to show that the increase in acceptance led to an increase in the diagnosis of HIV. This is not surprising because the positivity rate of HIV screening in our ED (based on several years of screening and encompassing a variety of different protocols) is approximately 0.2%.[5,9] This study, therefore, was not powered to demonstrate differences in positivity rates. Because we believe the 2 populations are equivalent, additional months of study would identify a greater number of HIV-positive patients with opt-out consent, reflecting the relative increase in the number of tests performed.

Our study had several limitations. We performed an experimental equivalent time-sample design instead of a randomized controlled trial. HIV screeners, however, worked the same shifts throughout the study period and adhered to a standardized screening approach. As a result, the patients accepting opt-in and opt-out screening were similar across a variety of characteristics and we therefore believe the study design did not influence the validity of results.

Although the duration of the study was only 6 weeks for each phase, this time period was determined a priori and powered to detect an absolute difference of 10% in the overall acceptance of testing when a small group of trained staff implemented HIV testing using either opt-out or opt-in consent methods. We feel that analyzing the results of the 3 screeners as a group is clinically relevant, especially because most EDs utilize several different people to offer HIV screening. The short study duration, however, limited our ability to determine tester-specific factors that may have influenced acceptance.

Our results are based on the outcomes of 3 screeners with experience in HIV testing and may not be generalizable to EDs that rely on existing staff to carry out HIV testing. Many EDs, however, integrate HIV screening by hiring small number of testers, similar to the staffing utilized in this study. Some experts feel that utilizing small numbers of supplemental testing staff is ideal for HIV screening in busy EDs.[13]

Trained staff was not blinded to the study objectives and may have had biases, which could have impacted outcomes. The HIV screeners were informed during initial training sessions that study investigators would be evaluating the difference in acceptance rate when they used either opt-out or opt-in consent methods. We attempted to minimize bias, however, by not informing them of our initial hypothesis and by not reporting differences in acceptance as it was collected throughout the study. Additionally, screeners were given scripts to follow, and study investigators routinely assessed for protocol adherence.

We did not evaluate patient satisfaction or comprehension with the different consent methods. Although we have previously reported that patients are equally satisfied with opt-in and opt-out processes (D. A. White, A. N. Scribner, T. Tran, et al, unpublished data, 2011), there is the possibility that patients agreed to opt-out screening without fully comprehending that testing was to be performed.[18] This is an important consideration, particularly because with the opt-out script we used, HIV screeners did not explicitly describe to patients that they could refuse testing; rather, acceptance of screening was inferred unless patients verbally declined. Patients may have felt coerced into opt-out screening because of the manner in which it was presented. Although not formally evaluated, feedback from the screening

staff did not report patient dissatisfaction or patient surprise that HIV testing was performed during opt-out periods. Programs that link opt-out verbal consent to blood draws (which may be performed at a later time and by different staff) may have different results and lead to a subset of patients undergoing HIV screening without complete understanding. Additional studies are warranted to formally evaluate patient comprehension with opt-out consent methods.

The magnitude of difference in acceptance rates between opt-in and opt-out consent methods may vary depending on the criteria used to determine eligibility, the health care setting, and whether the process is initiated by registration personnel, ED technicians, nurses, physicians, or supplemental screeners. Furthermore, not all states have legislation supporting the consent and testing processes performed in this study and hospital-based regulations may impose additional limits.[21]

In conclusion, our model of opt-out HIV screening at the bedside with supplemental personnel offers a substantial increment in patient acceptance and should be considered in a wide array of clinical settings.

## ACKNOWLEDGMENTS

*Author Contributions: D. A. E. White 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: *D. A. E. White, T. Sadoun, H. J. Alter.* Acquisition of data: *T. Sadoun, T. Tran.* Analysis and interpretation of data: *D. A. E. White, T. Sadoun, T. Tran, H. J. Alter*. Drafting of manuscript: *D. A. E. White.* Critical revision of the manuscript for important intellectual content: *D. A. E. White, T. Sadoun, T. Tran, H. J. Alter*. Final approval of the version to be published: *D. A. E. White, T. Sadoun, T. Tran, H. J. Alter*.

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