# Scaling Up HIV Testing in an Academic Emergency Department: An Integrated Testing Model with Rapid Fourth-Generation and Point-of-Care Testing

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## ABSTRACT

**Objective.** We evaluated two approaches for implementing routine HIV screening in an inner-city, academic emergency department (ED). These approaches differed by staffing model and type of HIV testing technology used. The programmatic outcomes assessed included the total number of tests performed, proportion of newly identified HIV-positive patients, and proportion of newly diagnosed individuals who were linked to care.

**Methods.** This study examined specific outcomes for two distinct, successive approaches to implementing HIV screening in an inner-city, academic ED, from July 2012 through June 2013 (Program One), and from August 2013 through July 2014 (Program Two). Program One used a supplementary staff-only HIV testing model with point-of-care (POC) oral testing. Program Two used a triage-integrated, nurse-driven HIV testing model with fourth-generation blood and POC testing, and an expedited linkage-to-care process.

**Results.** During Program One, 6,832 eligible patients were tested for HIV with a rapid POC oral HIV test. Sixteen patients (0.2%) were newly diagnosed with HIV, of whom 13 were successfully linked to care. During Program Two, 8,233 eligible patients were tested for HIV, of whom 3,124 (38.0%) received a blood test and 5,109 (62.0%) received a rapid POC test. Of all patients tested in Program Two, 29 (0.4%) were newly diagnosed with HIV, four of whom had acute infections and 27 of whom were successfully linked to care. We found a statistically significant difference in the proportion of the eligible population tested—8,233 of 49,697 (16.6%) in Program Two and 6,832 of 46,818 (14.6%) in Program One. These differences from Program One to Program Two corresponded to increases in testing volume ($n$=1,401 tests), number of patients newly diagnosed with HIV ($n$=13), and proportion of patients successfully linked to care (from 81.0% to 93.0%).

**Conclusion.** Integrating HIV screening into the standard triage workflow resulted in a higher proportion of ED patients being tested for HIV as compared with the supplementary staff-only HIV testing model. New rapid fourth-generation testing technology allowed the identification of acute HIV infection and same-visit confirmation of a positive diagnosis.

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An estimated 1,144,500 people are living with human immunodeficiency virus (HIV) in the United States, which includes an estimated 49,273 newly diagnosed cases (in 2011) and more than 180,000 individuals who remain unaware of their HIV status.[1] Emergency departments (EDs) often serve as the sole source of primary care for certain sectors of the population, particularly those at increased risk for contracting HIV,[2–4] and have been found to be one of the most common sites of missed opportunities for HIV diagnosis.[5] Despite the notable prevalence of undiagnosed HIV in the ED and the Centers for Disease Control and Prevention's (CDC's) broad-reaching recommendations[6] that non-targeted, opt-out HIV screening be offered as part of all routine health care (including ED visits), the overall rate of ED-based HIV testing remains exceedingly low at 0.2%.[7]

During the past decade, widely varying approaches have been attempted in an effort to scale up HIV screening in EDs across the United States. Program components that result in key outcomes (i.e., overall proportion of eligible patients tested, proportion of newly diagnosed HIV infections, and proportion of newly diagnosed patients linked to care) include a staffing model for initiating screening, the location of the HIV test offer within the ED workflow, the screening model's ability to provide 24/7 coverage, the method of patient selection, the process of obtaining consent, the type of testing platform (technology) used, and the funding source.[8–13] The relative contribution of these varied components on programmatic outcomes remains unclear. Two specific factors that have received increased attention in the recent literature,[10] and have been proposed by medical professionals to be critically important for scaling up non-targeted screening, are integrated staffing models[2,14] and newly advanced, rapid, blood-based testing technologies.[15]

In this article, we describe an approach to implementing scaled-up HIV testing in an ED that has historically employed supplementary HIV testing staff members for bedside, oral point-of-care (POC) testing. We also discuss programmatic outcomes of each approach, including total volume and proportion of patients tested, the proportion of newly diagnosed cases of HIV, and the proportion of those newly diagnosed who were successfully linked to care. The programmatic components leveraged to scale up testing included the addition of a triage-integrated, nurse-driven HIV testing model, and the introduction of rapid-turnaround, laboratory-based, fourth-generation testing technology. An additional programmatic improvement made during the scale-up phase was the creation of a more robust and timely linkage-to-care (LTC) process, which guaranteed the availability of an HIV specialty clinic appointment within one business day of a new HIV diagnosis.

## METHODS

### Setting and population

The Johns Hopkins Hospital ED in Baltimore, Maryland, handles approximately 65,000 visits annually, and provides care for a population comprising mainly socioeconomically and otherwise disadvantaged individuals. Approximately 75% of the ED population self-identifies as African American and 15% are prior or current injection drug users; the ED has a prior reported HIV seroprevalence of 11%–12% and a rate of new diagnoses of approximately 0.6%–2.2%.[16]

### Outcome measures and evaluation

Outcomes reported in this article (for each of the two programs studied) include total volume of patients tested, proportion of eligible patients tested, average number of tests performed per month, total number of newly diagnosed HIV infections, and proportion of newly diagnosed patients linked to care. All ED patients aged 18–65 years who were not critically ill (i.e., triage acuity level 3–5) were eligible for testing. We used Fisher's exact test to calculate the ratio of the proportion of eligible patients in Program 2 compared with Program One (described hereinafter).

### Interventions

Outcomes associated with two distinct and temporally successive approaches to implementing HIV screening in an inner-city, academic ED are reported in this article. The two screening programs were evaluated for a period of one year and assessed using the same ED population. Program evaluation phases took place from July 2012 through June 2013 (Program One), followed by a one-month transition period (July 2013), and from August 2013 through July 2014 (Program Two). Patients were screened using the same aforementioned eligibility criteria during both phases. The overarching goal of both programs was to conduct non-targeted HIV screening and to offer and test as many patients as possible. Although we used a broad definition of eligibility for programmatic data comparisons, HIV testing staff members and triage nurses were instructed to exclude patients who had been tested within the past three months, had a previous diagnosis of HIV/acquired immunodeficiency syndrome (AIDS), or were unable to provide informed consent.

**Program One: supplementary staff-only HIV testing model with POC testing**

Trained HIV testing staff members approached eligible patients—determined via electronic medical record (EMR) chart review and patient interview—at the bedside and offered them confidential HIV testing. HIV testing staff members performed the HIV test using the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test (OraSure Technologies, Bethlehem, Pennsylvania), a rapid POC oral fluid test with 99.3% sensitivity and 99.8% specificity. HIV testing staff members obtained oral consent only, recorded basic risk-assessment information, provided pretest education, collected the specimen, and processed the test. Staff members also documented consent and requisitioned and reported the test results via the laboratory reporting system, which was interfaced with the patient's EMR.

HIV testing staff members informed patients of nonreactive screening test results in real time (in accordance with device operating instructions) and provided brief posttest education, supplemented by an informational brochure. For any reactive screening test, HIV testing staff members would first communicate the result with the attending physician and then assist (when requested) in providing the patient with his or her preliminary result. Once the patient was informed of the result, oral consent for confirmatory Western blot testing was obtained, and the test was ordered. HIV testing staff members would then arrange for the patient to return within 2–3 days to receive the confirmatory test result in the ED. Patients with a confirmed positive diagnosis were offered the earliest possible appointment at the HIV specialty clinic, usually within 1–5 weeks. HIV testing staff members were responsible for calling patients to remind them of their first visit.

**Program Two: triage-integrated, nurse-driven HIV testing model with fourth-generation blood and POC testing**

In July 2013, we transitioned from an exclusively supplementary staff-only HIV testing model for ED HIV screening to an integrated staffing model in which triage staff members initiated screening (including test offer, consent, and order) that was integrated into the ED workflow. We allowed for a one-month rollout period for nurse training and education. We evaluated the screening program from August 2013 through July 2014.

Program Two integrated HIV screening into the routine triage process by incorporating the HIV test offer into the mandatory screening questions asked of all patients. The triage-based HIV screening process was integrated into the EMR system (Allscripts, Chicago, Illinois), which included a script for the HIV test offer and informed oral consent that was consistent with Maryland State law and institutional requirements. Patients were also given a pretest informational brochure that included general information on HIV/AIDS and the importance of routine screening, as well as other locations within Baltimore City for free HIV testing. For patients who consented, nurses placed one of two orders in the EMR system; the OraQuick rapid POC test (also used during Program One) or a blood-based, rapid, fourth-generation HIV Ag/Ab Combo ELISA (Abbott Laboratories, Abbott Park, Illinois), which has 99.8% specificity and 100% sensitivity.

The test method (i.e., blood vs. POC) was determined based on the type of patient visit. If the triage nurse ordered any laboratory work for the patient that required venipuncture, the nurse ordered the blood-based HIV test; if no other clinical blood tests were ordered, the nurse would select the POC test. The POC test order triggered an immediate paging communication with HIV testing staff members, who followed the same testing protocol as described in Program One. HIV testing staff members were trained to review the EMR and provide offers to patients at the bedside if no HIV test offer had been made at triage.

The testing algorithm for Program Two followed CDC's newly updated recommendation for laboratory testing for diagnosis of HIV infection.[15] If the initial screening test was reactive, the algorithm reflexed to a confirmatory Multispot HIV-1/HIV-2 Rapid Test (Bio-Rad, Hercules, California). If the Multispot test was nonreactive, nucleic acid testing was performed as a final confirmatory test and a positive nucleic acid test result determined acute infection status (as defined by CDC[15]). The fourth-generation, blood-based assay was completed with whole blood in the hospital laboratory, and the average turnaround time for the laboratory-based test was approximately 1–2 hours.

HIV blood tests were entered in real time into the EMR via the laboratory information system for clinical staff members. For reactive tests, the laboratory technician immediately notified HIV testing staff members and the HIV program director (via the hospital paging system) to ensure that every confirmed positive test result was communicated to the treating clinician and the patient. The HIV testing staff members would follow the aforementioned protocol for informing patients of their results.

The LTC protocol was modified along with implementation of the triage-integrated approach to be more streamlined and active, and involved close collaboration with the hospital's HIV specialty clinic and establishment of an ongoing quality-improvement

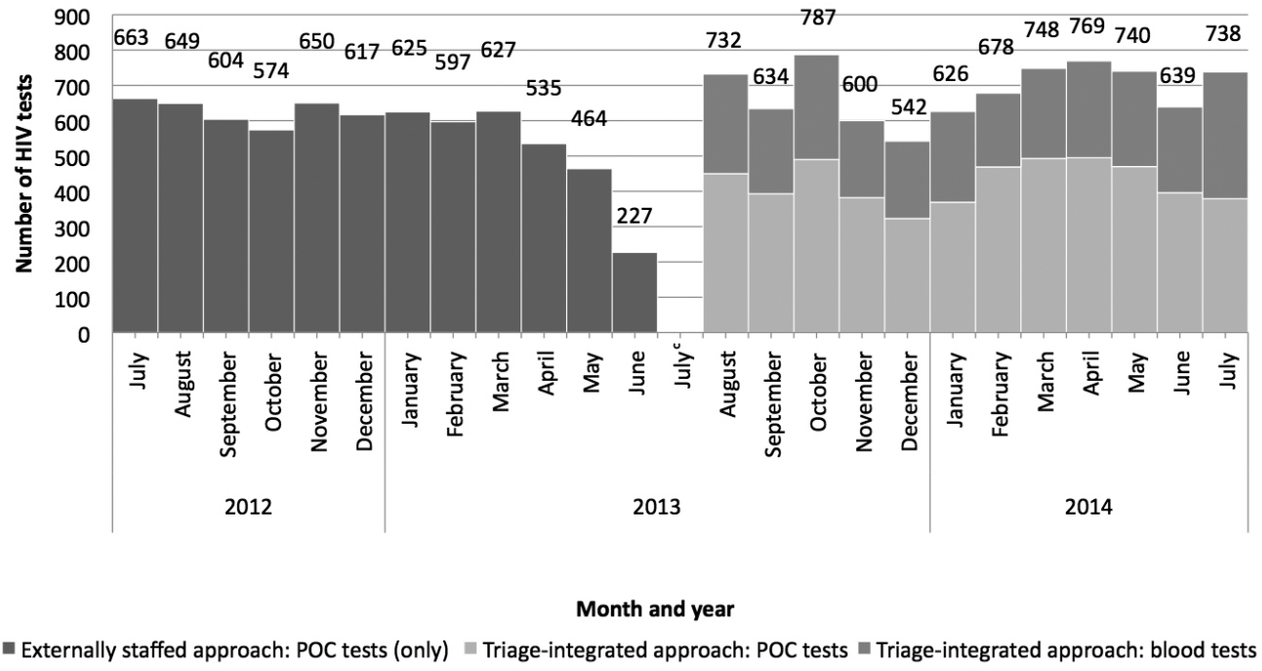
program made possible by increased efforts from HIV program staff members. In the improved LTC process, HIV program staff members contacted the specialty clinic prior to providing the patient with his or her results and arranged for a clinic nurse to meet with the patient in person in the ED on the same day as the diagnosis. During evenings, nights, and weekends, the initial clinic nurse encounter would be arranged for the next business day via both e-mail and pager communications. The HIV clinic nurse would provide further counseling and arrange a follow-up visit for the patient, guaranteeing an appointment within one business day.

## RESULTS

### Supplementary staff-only HIV testing model; POC testing (Program One)

The one-year evaluation period included 67,844 ED visits. A total of 46,818 (69.0%) patients met age and triage acuity eligibility criteria, and 6,832 (15.0%) of those eligible received a rapid POC oral HIV test. An average of 569 tests were performed each month (range: 219–663) (Figure). Nineteen of the 6,832 POC tests were reactive, of which 16 (0.2%) were confirmed HIV positive by ribonucleic acid (RNA) testing and three were determined to be false positives due to nonreactive RNA testing. Of the 16 confirmed cases, 13 were successfully linked to HIV specialty care (Table).

**Figure. Number of HIV tests per month during counselor-based/point-of-care (July 2012–June 2013) and triage-integrated (August 2013–July 2014) testing[a] at an academic emergency department in Baltimore, Maryland[b]**




[a]POC refers to a rapid point-of-care oral HIV test (OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test, OraSure Technologies, Bethlehem, Pennsylvania). Blood tests refer to blood-based, rapid, fourth-generation HIV Ag/Ab Combo ELISA (Abbott Laboratories, Abbott Park, Illinois).

[b]The data are expressed as total numbers of tests conducted by month. During the period described in the externally staffed approach, 67,844 patients attended the emergency department (ED), of whom 46,818 met age and acuity criteria and were eligible for HIV testing. During the period described in the triage-integrated approach, 69,442 patients attended the ED, of whom 49,697 met age and acuity criteria and were eligible for HIV testing. Thus, although the tests were not standardized to numbers of patients, the patient populations during each phase were of comparable size.

[c]In July 2013, we transitioned from an exclusively supplementary staff-only HIV testing model for ED HIV screening to an integrated staffing model in which triage staff members initiated screening (including test offer, consent, and order) that was integrated into the ED workflow. We allowed for a one-month rollout period (in July) for nurse training and education, and evaluated the screening program from August 2013 through July 2014.

HIV = human immunodeficiency virus

POC = point of care

**Table. Testing outcomes of a supplementary staff-only HIV testing model (Program One) and a triage-integrated, nurse-driven HIV testing model (Program Two) at an academic emergency department, Baltimore, Maryland, 2012–2014**

| *Variable* | *Program One July 2012–June 2013* | *Program Two August 2013–July 2014* |
|---|---|---|
| Total number of emergency department visits | 67,844 | 69,442 |
| Number of patients eligible for HIV testing (percent) | 46,818 (69.0) | 49,967 (72.0) |
| Number of HIV tests completed (percent of eligible patients) | 6,832 (14.6) | 8,233 (16.6) |
| Number of rapid point-of-care HIV tests (percent of tests completed) | 6,832 (100.0) | 5,109 (62.0) |
| Number of blood-based HIV tests (percent of tests completed) | 0 (0.0) | 3,124 (38.0) |
| Number of reactive HIV tests[a] | 19 | 30 |
| Number of confirmed positive HIV tests (percent of HIV tests completed)[b] | 16 (0.2) | 29 (0.4) |
| Number of HIV-positive patients linked to care | 13 (81.0) | 27 (93.0) |
| Average number of HIV tests per month | 569 | 686 |

[a]Number of reactive HIV tests includes any reactive HIV screening test (including both rapid point-of-care and blood-based screening tests).

[b]Number of confirmed positive HIV tests refers to the total number of reactive screening tests (either rapid point-of-care or blood-based) that were confirmed by a second positive HIV test (either a Western blot, Multispot, or nucleic acid test).

HIV = human immunodeficiency virus

**Triage-integrated, nurse-driven HIV testing model with blood and POC testing (Program Two)**

A total of 69,442 visits were made to the ED during the one-year evaluation period; of those, 49,697 (72.0%) met eligibility criteria, and 8,233 patients (17.0% of those eligible) were tested. A total of 3,124 (38.0% of eligible patients tested) received HIV blood tests, and 5,109 (62.0%) received rapid POC tests. An average of 686 tests were performed each month (range: 542–787) (Figure). Out of 30 reactive screening tests, 29 were confirmed positive via RNA testing and one was a false positive. Of the 29 patients who were confirmed positive, four were acute infections, and 27 were linked to care. We also examined the characteristics of those newly identified with acute vs. non-acute HIV infection. Of the 29 patients with confirmed HIV infection, 17 (59%) were male, 19 (66%) were 25–44 years of age, and 23 (79%) were black. Four (14% of those testing positive) were acute HIV infections. Notably, among those with acute HIV infection, the median viral load was 1,091,614 copies/milliliter (mL).

Comparing the proportion of the eligible population tested during the triage-integrated, nurse-driven HIV testing model (Program Two) with the supplementary staff-only HIV testing model (Program One) revealed a statistically significant ($p<0.001$) increase from Program One (6,832 of 46,818 [14.6%]) to Program Two (8,233 of 49,697 [16.6%]), and a prevalence ratio of 1.14 (95% confidence interval 1.10, 1.17). We found an upward trend in the proportion of newly diagnosed HIV infections from Program One (16 of 6,832 patients [0.2%]) to Program Two (29 of 8,233 patients [0.4%]), and a higher proportion of patients in Program Two (27 of 29 [93.0%]) than in Program One (13 of 16 [81.0%]) was successfully linked to care (Table).

## DISCUSSION

The program components that were changed (from Program One to Program Two) included the *type of staffing model* and the *HIV testing technology* used. Our scaled-up screening program engaged triage nurses to optimize our ability to reach the maximum number of patients and added a new testing technology (e.g., fourth-generation, blood-based testing) that could be easily integrated into clinical workflow, alongside point of care testing. Although this study was not specifically designed to compare the two approaches, we observed interesting trends.

While Program Two was primarily triage-based, it was complemented by supplementary HIV testing staff who provided POC testing for patients who did not have blood drawn as part of their clinical visit. This combined approach permitted us to reach a greater proportion of patients than we otherwise would have using a supplementary staff-only or triage-integrated blood-based-only HIV testing model. Overall, we tested more than 1,400 additional patients in the scaled-up model (Program Two), representing a more than 20% increase in total test volume and a 14% increase in the proportion of eligible ED patients tested (estimated by the ratio of proportions tested). We also

observed a relative increase in new HIV infections detected, reporting 13 (81%) more new HIV diagnoses in Program Two than in Program One. Finally, we saw an improvement in LTC from 81% to 93%, from Program One to Program Two. The relatively low LTC rate observed during Program One was likely due to the much longer wait time until the patient's first HIV clinic appointment (1–5 weeks). During Program Two, we were able to direct additional HIV program staff time and efforts to enhance the ED-HIV specialty clinic collaboration. This reallocation of resources was permitted, in part, by freeing up HIV testing staff time associated with the triage-integrated nurse-driven HIV testing model.

Detecting acute HIV infection is especially important for public health because of the extremely high transmissibility associated with this stage of the disease, which has an infectivity probability up to 26 times higher than established HIV infection.[17,18] In addition, individuals in the acute phase of infection are responsible for up to 50% of HIV transmissions and subsequent infections.[19–22] A major advantage of Program Two is the integration of blood-based fourth-generation testing, which permitted detection of acute HIV infection (i.e., in the several-week window period, where third-generation antibody tests would be negative). We reported that 14% of our newly identified HIV-positive patients were acutely infected and had extremely high viral loads (>1 million copies/mL). Our findings support and are consistent with those of another large urban ED in Phoenix, where an even higher proportion (23%) of acute infections were discovered as part of routine screening.[23] Notably, one of the acutely diagnosed patients in our program had a nonreactive POC test just one day prior to a positive fourth-generation test. Such inadvertent misses of acute infections have significant adverse public health and clinical consequences, most notably substantially higher rates of disease transmission, and delayed patient diagnosis and treatment.

Implementing scaled-up, ED-based HIV testing programs has both practical and regulatory issues. Practical barriers to large scale-up have been widely discussed,[13] some of which have begun to break down based on adaptation of integrated approaches to testing and newer testing technologies. However, the need to attend to state laws and institutional regulations regarding HIV test offers, consent, and reimbursement can pose challenges. Although federal guidance from CDC supports opt-out, and streamlined testing processes,[6] certain states, including our own at the time this work was carried out, did not yet support an opt-out approach to screening. This inconsistency added complexity to the process and likely served, at least in part, as a practical impediment to a larger scale-up. In states where opt-out HIV consent has been in place (e.g., Texas), early reports of more robust scale-up have been published.[24] A few states (e.g., New York) have also enacted legislation that mandates HIV testing be offered, with assured reimbursement, to all people seeking hospital or primary care services, including the ED. However, even in states with such legislation, the ability to reach the larger ED population has been challenged, as exemplified by one recent report in which both legislative mandates and electronic hard stops in the EMR still yielded only 10% of the ED population being tested[25]—fewer than that demonstrated in our own study.

Ultimately, the extent of HIV testing scale-up is significantly affected by buy-in from those offering the test. Although we did not formally evaluate testing staff or triage nurse buy-in, informal observations during Program One and Program Two suggest substantial variability in patient acceptance rates between our supplementary HIV testing staff and nursing team. This phenomenon has been reported previously, although definitive conclusions regarding which staff type can achieve optimal rates of acceptance have not yet been established. One study evaluating scale-up of HIV screening in counselor-initiated, versus provider initiated programs concluded that counselor-based offers were more likely to be accepted; principle barriers associated with relatively lower provider-initiated acceptance rates included insufficient time during patient encounters and concerns regarding overall workload.[14] Other studies have reported that in HIV screening programs that employ clinical staff (i.e., nurses and/or providers), staff attitudes substantially affect rates of patient acceptance.[26,27] Future exploration of offer and acceptance rates in our mixed model, which included both provider and supplementary staff testing, will be important for guiding further scale-up.

From the standpoint of public health investments in HIV testing programs, it is relevant to note that use of supplementary staff has historically been the primary model employed. Such initiatives have principally been funded via federal, state, and local grant programs; however, support for those programs has recently declined and, ultimately, may cease to exist. Accordingly, one critical advantage of triage nurse driven HIV test ordering is the ability to decrease the number of supplementary staff required for testing (a resource generally not available 24/7, and a model which ultimately is unable to reach as many patients as the

triage-integrated nurse-driven HIV testing approach). Although we did not formally assess what proportion of the increased tests observed in Program Two were related to tests completed when supplementary staff were unavailable, it is likely that some of the observed increase was attributable to off-hour testing achieved via the triage-integrated nurse-driven HIV testing model.

Another value of integrated testing is that supplementary staff may be freed up to dedicate time and resources to improving LTC. Although allocation of supplementary staff resources was not formally evaluated, our improved LTC program was, in part, attributable to the additional time made available for HIV testing staff to dedicate to both quality improvement and quality control. Going forward, an economic analysis of alternative staffing models would be beneficial.

### Limitations

This study was subject to several limitations. First, we used a broad definition of eligibility for purposes of programmatic evaluation (all ED patients aged 18–65 years who were not critically ill), because we were able to reliably capture these data across programs. That broad eligibility definition did not take into account the multiple exclusions (i.e., patients who had been tested within the past three months, had a previous diagnosis of HIV/AIDS, or were unable to provide informed consent) used in practice by triage and HIV testing staff members that we were unable to capture due to the lack of a reliable method for documenting exclusions in the EMR at the time of this study. Furthermore, the variability between programs in the process of approaching patients could have affected our outcomes. We were also unable to report proportions of ED patients who were offered an HIV test or accepted testing. Although our EMR system included an option for recording these criteria, direct observations of individual nurses indicated that nurse documentation compliance was highly variable. These limitations restricted a more robust analysis and comparison of program elements that may have been successful, or where opportunities for improvement exist.

Finally, it is important to note that our study was an observational analysis and not specifically designed or powered to evaluate whether or not one testing approach was superior to another (i.e., other potential confounders existed that we could not fully control).

## CONCLUSIONS

Our findings provide one example of a means to scale up ED testing. Further opportunities for improvement remain when considering the full potential population of ED patients that could be tested and the ongoing challenges of reaching those with HIV who remain undiagnosed.

The Johns Hopkins University HIV Testing Team included Leigh Curvin, RN; Tina Tolson, RN; Kathy DeRuggiero, RN, MSN; Peter Hill, MD; Antoine Simmons, BA, BS; Megan Gauvey-Kern, MS; Kisten Nolan, MPH, RN; and Bonnie Bradley, RN.

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