

Less Encouraging Lessons From the Front Lines: Barriers to Implementation of an Emergency Department-Based HIV Screening Program

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Objective: We describe barriers to, and discuss recommendations for, implementing a limited emergency department (ED)-based HIV screening program.

Methods: A pilot program was designed to study the feasibility of integrating HIV screening into ED care among patients aged 18 to 64 years at an urban academic emergency department with an annual census of 50,000 patients.

Results: During the first 12 weeks of the pilot program, 395 patients were screened. Of those, 2 (0.5%; 95% confidence interval 0.06% to 1.8%) received a positive test result for HIV. Both were contacted by telephone, and one was seen for result notification, posttest counseling, and further care in the local health department. Of the patients who received a negative test result, 98% were contacted about their results. We encountered numerous barriers to implementation, which we categorized as departmental, public health, legal, institutional, test limitations, and infrastructure.

Conclusion: Understanding potential barriers and making plans for dealing with them are critical to the successful implementation of an HIV screening program in the ED. [Ann Emerg Med. 2011;58:S44-S48.]

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INTRODUCTION

Although some emergency departments (EDs) have initiated HIV screening,¹⁻⁵ most do not routinely test patients for HIV, even those with documented risk factors or with indications for diagnostic testing.⁶⁻⁸ To determine whether the prevalence of undiagnosed HIV infection in our ED meets the threshold for universal screening recommended by the Centers for Disease Control and Prevention (CDC),⁹ we implemented a pilot program for integrated HIV screening using only existing resources in a population with low estimated HIV prevalence in a jurisdiction that requires written informed consent for HIV testing. Our review of the literature led us to expect barriers in the areas of resource availability and emergency medicine culture.^{2,6,7} However, we also encountered barriers in the areas of public health culture, HIV testing laws, and institutional research requirements.

METHODS

A pilot program was designed to determine both the feasibility of integrating HIV screening into ED care and the prevalence of undiagnosed HIV infection among our ED population. The project received approval from our institution's institutional review board (IRB). All patients provided written

informed consent for participation in a research study and provided, in accordance with state law, signed informed consent for HIV testing.

Free HIV screening was performed at a single urban academic ED with an annual census of 50,000 patients. The ED patient population is 53% female, 63% white, and 34% black. Eligible patients were aged 18 to 64 years, medically stable, able to provide informed consent, and able to speak and understand English. Prisoners and patients who reported HIV infected were excluded. Eligible patients were approached by ED providers to provide informed consent. The patients who provided consent completed a brief confidential survey about demographic information and HIV risk factors and were provided with oral and written HIV pretest counseling. Initially, only emergency physicians and nurses were oriented to the program and instructed in using the OraSure HIV-1 Oral Specimen Collection Device (OraSure Technologies, Bethlehem, PA). This recruitment approach failed, so we trained 2 research associates to enroll patients.

Specimens (without personal identifiers) were sent to the local health department for processing, and a study investigator matched the results and contacted patients 10 to 14 days after their ED visit. Negative results and standardized posttest

counseling were conveyed by telephone, e-mail, or postal mail. All subjects were offered face-to-face posttest counseling. Patients who received a positive test result were referred to the local health department for result notification, posttest counseling, and further care. This referral program was an existing service provided by the health department for anyone with HIV or other sexually transmitted infections. The pilot program was partially funded by the local health department, which provided the collection devices and processed the specimens. An undergraduate work-study student performed data entry.

RESULTS

Enrollment began on June 1, 2009. During the first 12 weeks, 395 patients were enrolled. Of those, 2 (0.5%; 95% confidence interval 0.06% to 1.8%) received a preliminary positive test result. Both were contacted by telephone, and one was seen for result notification, posttest counseling, and further care in the local health department. Results were conveyed to 98% of the patients who received a negative test result. We have not enrolled enough patients to document HIV prevalence in our ED. Our local health department director estimated the prevalence of undiagnosed HIV in the local population to be 0.7%. On the assumption that the prevalence of undiagnosed HIV infection in our ED population is at least 0.7%, a sample of 1,000 has adequate power to define this value. On the basis of published acceptance rates for HIV testing—58% to 95%—we estimate that to enroll 1,000 patients, we need to approach approximately 2,000 patients.

DISCUSSION

We encountered various barriers to implementation. For organizational purposes, we grouped these barriers into broad categories, realizing that many factors may overlap among categories: departmental, public health, legal, institutional, test selection, and infrastructure. A central issue was a lack of HIV awareness and activism in our community. An underlying concern was the combination of ED crowding and limited resources. Although the selection of a test and the determination of infrastructure needs are typical considerations for most EDs, other barriers we describe—specifically, public health culture and institutional requirements—may be less relevant in areas with heightened HIV awareness.

Departmental Barriers

Implementing a sustainable HIV screening program in an academic ED requires a core group of coordinators, involvement and support from administration, and broad buy-in from faculty and staff. Our awareness of testing champions among the ED staff led us to believe that a pilot program would be feasible. In addition to ourselves (B.E.M. and B.P.S.) as physician coordinators, we enrolled the help of an ED nurse practitioner and an ED charge nurse, both of whom were motivated to help implement an HIV screening program. The

nurse practitioner served as a champion for patient enrollment, and the charge nurse educated the staff. The additional insight they provided about the limitations and potential usefulness of the nursing staff was incorporated into our study protocol.

Both our department chair and our nurse manager supported the project. Their support was critical, but it was not sufficient to motivate all ED faculty and staff members to participate. We initially solicited participation with department-wide e-mails and fliers posted in the ED. To encourage involvement, we offered training sessions in person at departmental faculty meetings and electronically through self-guided tutorials. We also distributed a sheet of frequently asked questions. We sent biweekly e-mails to faculty and staff to recognize those who assisted enrollment, to update faculty on progress, and to highlight areas for improvement.

Departmental Recommendations

Securing support from administrative leaders is necessary, but successful implementation requires the involvement of ED technicians, nurses, and physician extenders and emergency physicians. One or more respected leaders in each group should encourage their peers to participate. Representatives from each group should be involved early so that concerns can be addressed during development rather than during implementation. Patient enrollment should be as streamlined and straightforward as possible. For example, we created enrollment packets that contain step-by-step instructions, color-coded study forms, a pen, and an OraSure oral specimen collection device. Frequent communication with ED team members is critical both to convey progress and to solicit feedback.

Public Health Barriers

A comprehensive team approach including representatives from the infectious diseases division, public health division, and legal counsel has been recommended for a successful HIV screening program.¹⁰ Following others' advice and experience, we initially consulted our affiliated school of public health, division of infectious diseases, and county health department. We also sought guidance from a colleague who had instituted an HIV testing program in a similar low-prevalence setting.³ The director of our county health department guided us in interpreting state laws about consent and counseling for HIV testing. He also provided 1,000 HIV tests kits and processing and accepted referrals for care for patients who received a positive test result.

Although the director of our county health department was supportive of the program, his team lacked the resources to follow up the patients who tested negative. Also, although the county health department provides an organizational center for the follow-up care of HIV patients, the center is not integrated with either of the major health systems in our area. This lack of integration created the potential for the failure of follow-up care.

Our efforts to develop relationships with our affiliated school of public health and the division of infectious diseases presented difficulties as well. Although the school of public health had the

expertise in HIV counseling to assist in training ED personnel, it required that all participating ED faculty and staff attend a 3-day training session. Similarly, the infectious diseases physicians insisted on at least 1 full day of training. Organizing such sessions to accommodate faculty and staff schedules was nearly impossible, and we had no means of incentivizing participation. We tried to engage the division of infectious diseases' HIV/AIDS clinic in the follow-up process for patients who received a positive test result because the clinic is the primary referral group for patients (ED or inpatient) for whom a diagnostic HIV testing result is positive. Concerned about the adequacy of pretest counseling, the clinic leadership was unwilling to provide results or posttest counseling for patients who had received HIV screening in the ED. Although both the school of public health and the division of infectious diseases were well intentioned, we found it difficult to convey the importance of patient flow and the realities of prioritizing acute care in the ED.

Public Health Recommendations

In academic settings, the public health and infectious diseases communities often have resources, both financial and practical, to contribute to the development of an HIV screening program. However, their understanding of ED circumstances and willingness to modify their HIV testing protocols should be assessed. To ensure the success of this relationship, meetings should be arranged between study coordinators and those involved in all stages of the study protocol, from secretaries to laboratory technicians to follow-up nurses. Last, consideration should be given to methods for recording HIV test results in patients' medical records. For example, a hospital that has a procedure for recording the results of sexually transmitted infection tests performed at an external agency might expand that procedure to the results of HIV tests performed in the ED.

Legal Barriers

HIV screening programs must comply with state laws about HIV testing. Our state requires signed informed consent and pretest counseling, essentially eliminating the possibility of opt-out HIV screening. Counseling must include information about the "prevention of, exposure to and transmission of HIV," as well as an explanation of the HIV test. State law also mandates "a good faith effort" to provide positive and negative results and "the immediate opportunity for individual, face-to-face [posttest] counseling" (35 Pa. Code §7601 to 7605). Last, confidential reporting of HIV-positive individuals by name is mandatory; this public health law supersedes IRB requirements about patient confidentiality.

To ensure that our protocol complied with state law, we sought counsel from a lawyer at our school of public health, representatives from our division of infectious diseases, and the director of our county health department, all of whom are versed in legal matters concerning HIV testing. However, we received conflicting interpretations of the law.

Regarding pretest counseling, the representatives from infectious diseases and the school of public health believed that patients should receive at least 30 minutes of individualized pretest counseling in a private room. Although we agreed that this format might benefit some patients, we considered it unnecessary for most patients and unrealistic in an ED setting. Furthermore, we were concerned that extensive pretest counseling might stigmatize patients and lead them to refuse HIV screening altogether.¹¹ Taking into account CDC's recommendation that prevention counseling should not be required as part of HIV screening programs in health care settings,⁹ we ultimately decided that oral discussion of the HIV consent document and information sheet provided patients with adequate pretest information.

We found similar differences in interpretation and practice about notification of test results and posttest counseling. The health department's practice is to provide notification of negative HIV results and brief posttest counseling by telephone and to offer an appointment for face-to-face counseling at the health department. In contrast, the infectious diseases HIV/AIDS clinic discloses all results in person and recommended that all ED patients return to the ED to receive their test result. Given the challenges inherent in bringing every patient back to the ED or the county health department for result disclosure, we decided to modify the health department's model. We also believed that more patients would receive their results if the results could be delivered by telephone, e-mail, or postal mail. We worked closely with the local health department to ensure that same-day face-to-face counseling would be available for any patient who requested it.

Legal Recommendations

Individual state laws governing HIV testing must be consulted. The pretest counseling, result notification, and posttest counseling practices of various local agencies that perform HIV testing may provide a model for the ED. However, if none of these protocols is suitable for an ED-based screening program, a novel approach that still falls squarely within legal requirements should be developed.

Institutional Barriers

An HIV screening program often requires previous approval from the quality improvement committee, IRB, or other regulatory bodies because the program involves identifiable patient information, clinical laboratory testing, and the collection of personal information unrelated to the patient's ED evaluation. The HIV screening protocol, in addition to adhering to the laws discussed above, must adhere to the regulations set forth by these bodies.

We initially sought approval for the project as a quality improvement initiative, given that we planned to modify our ED's HIV screening practices if warranted by our findings. Because neither we nor the ED had funding to guarantee the project's sustainability beyond the pilot program and because the quality improvement chairperson had concerns about the

risks of HIV testing, we were asked to submit our protocol to the IRB. In talking with members of the IRB, we became aware that a new diagnosis of HIV infection might be “psychologically devastating” to patients and might pose more than “minimal risk.” We proposed that study investigators, emergency physicians, and trained ED nursing staff be authorized to obtain consent with a single consent form for both HIV testing and study participation. The IRB required that patients complete 2 consent forms—one for HIV testing and one for study participation—rather than the streamlined single consent we proposed. The IRB suggested that only investigators obtain consent for HIV testing and study participation. Ultimately, all emergency physicians, but not ED nursing staff, were allowed to obtain informed consent. Additionally, all emergency physicians were required to complete online training in human subjects research and research integrity before enrolling patients in the study.

Institutional Recommendations

Early consideration should be given to institutional requirements because navigating the approval process can be time and effort intensive. If approval from the quality improvement committee or the IRB is necessary, the chairpersons should be consulted before formal applications are submitted. Open discussion of the rationale for the specifics of the screening protocol may help to alleviate the concerns of these individuals and their respective committees. If the quality improvement route is chosen, investigators should consider possible ramifications of the program’s results, including the need to sustain and finance an ongoing HIV screening program.

Limitations of HIV Test

Multiple factors must be weighed in choosing the appropriate HIV test for an ED-based screening program. Both rapid and conventional tests are available. Ideally, the chosen test will have both high sensitivity and high specificity, particularly when it is to be used in a low-prevalence population. The selection of the method of specimen collection—oral swab, fingerstick, venipuncture—may affect patients’ acceptance of HIV screening and the sensitivity and specificity of the test itself.

We initially intended to use the OraQuick Advance Rapid HIV-1/2 Antibody Test (OraSure Technologies). However, given recent reports of higher-than-expected rates of false positivity,^{12,13} we were hesitant to use OraQuick Advance in a population with suspected low HIV prevalence. Our local health department director strongly preferred OraSure HIV-1 Oral Specimen Collection Device for its increased specificity and for the “reflection time” created by the processing delay. The OraSure device significantly reduced the burden on ED staff by eliminating the time for test processing and interpretation, and it also eliminated the need for disclosure of preliminary positive test results and extensive posttest counseling in the ED. Given our IRB’s concerns about emotional harm to subjects, we also believed that the OraSure device would eliminate emotional distress caused by a false-positive

preliminary result from OraQuick Advance. We thought that any anxiety experienced while awaiting the OraSure result would be less severe than that caused by a preliminary positive OraQuick result. In choosing the OraSure device, we acknowledged that some patients might be lost to follow-up during the processing period. However, the need to store and transport OraSure specimens created an additional barrier; this situation worsened 8 weeks into the program, when the health department laboratory moved across the city from the hospital.

Recommendations About Test Selection

First, the advantages and disadvantages of the rapid versus conventional testing protocols should be considered. Second, a decision should be made about the use of oral fluid, fingerstick, or venipuncture specimens. ED resources, including space, personnel, and time, should be assessed carefully as part of this process. Third, a test with very high specificity should be used in populations with low HIV prevalence.

Infrastructure Barriers

The continuing success of an HIV screening program depends on financial and human resources. Personnel were needed for patient recruitment, specimen collection and processing, result notification, posttest counseling, and data entry.

Our initial plan was for ED faculty and staff to enroll patients by using a streamlined consent process. As described above, our protocol was modified so that only IRB-certified physicians could obtain consent, and 2 consent forms were required. Our initial physician recruitment was quite successful: more than 80% of emergency physicians obtained IRB certification and volunteered to enroll patients. However, within a few weeks of the project’s implementation, the closure of a nearby ED led to a rapid 20% increase in our volume. Because no compensatory changes had been made to physician or nursing schedules, ED providers were unable to devote time to enrolling patients in the study. We were fortunate to recruit 2 student volunteers for the summer, and they ultimately facilitated enrollment of all but a few patients. Consecutive patient enrollment, albeit for a limited time each day, would not have been possible without their assistance. Finding someone with time to enroll patients and collect the OraSure specimen without compromising patient care or ED flow was the most significant barrier to universal screening in our pilot program, and it contributed to the relatively low enrollment during the first 12 weeks. Because the enrollment, questionnaire completion, and collection of oral specimen had to take place in a private setting, patients in hallway beds were temporarily moved to a private room. Similarly, patients in treatment rooms remained in those rooms to complete the study rather than being moved to a hallway location.

Another complication concerned our follow-up protocol. We had initially arranged for our ED follow-up nurse to notify HIV-negative patients of their results. However, her position was terminated just before the study was implemented. As a result, follow-up contact for all study patients fell to study

investigators. We recruited another nurse to assist with telephone calls and established a dedicated callback number with a recorded message for the HIV-negative patients we were unable to reach personally. We also amended our protocol to include an option for e-mail notification and contacted 25% of our HIV-negative patients with the secure e-mail account. Although we did not have the resources to hire work-study students exclusively for this project, we arranged for the department's undergraduate work-study students to assist with packet preparation, specimen handling, and data entry.

Infrastructure Recommendations

The resources required to sustain an HIV screening program should not be underestimated. Engaging all ED faculty and staff—including technicians, nurses, physician extenders, and physicians—not only distributes the workload but also provides everyone with a sense of ownership in the project. The possibility of performing testing procedures in existing private space in the ED should be pursued, especially in an ambulatory treatment area with high turnover. The possibility of using other existing resources in the ED or the institution, such as follow-up nurses and work-study students, should also be explored. When possible, nonfinancial incentives (eg, continuing education credits, course credits toward degree programs) should be arranged.

Conclusion

In conclusion, implementing an HIV screening program in the ED presents many barriers, but they can be addressed with planning and perseverance. We successfully developed a pilot program to determine the feasibility of integrating HIV screening into ED care and the prevalence of undiagnosed HIV infection among our ED population. However, in the absence of financial or personnel resources, we have not fully overcome the barriers to implementing a universal screening program. Review of our experiences may benefit other EDs interested in developing a program for HIV screening. Future studies should examine the effect of patient crowding on the delivery of preventive care in the ED. The feasibility of widespread ED-based HIV screening programs depends on changes in resource availability, public health culture, institutional requirements, and HIV testing law.

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