Creating and Implementing Wisconsin's First Emergency Department-Based Universal Opt-Out HIV Testing Program

Andrew Petroll, MD; MS, Joanna Woodbury, BSW, CSW; Matthew Chinn, MD; Nathan Ledeboer, PhD; Jonathan Rubin, MD; Dawn Zakzesky, MSN, RN; Ian Martin, MD, MBA

ABSTRACT

Background: The Centers for Disease Control and Prevention recommends HIV screening for all patients aged 13 to 64. We sought to improve the health of our patient population by enacting universal HIV screening in our emergency departments.

Methods: Universal opt-out HIV screening was implemented in 7 southeastern Wisconsin emergency departments and included linkage to care for those diagnosed with HIV.

Results: In the first year of this initiative, 57565 patients were screened for possible testing and 24417 patients did not opt out (42.4%). In total, 12406 HIV tests were performed in the first year of the program.

Discussion: Our emergency department opt-out HIV screening initiative identified 23 new cases of HIV, approximately 10% of the average number of incident HIV cases in Wisconsin. We linked 96% of persons newly diagnosed with HIV to HIV medical care.

Lack of awareness of one's HIV status can result in the development of opportunistic infections, HIV-associated cancers, other health complications, and transmission of the virus to others. Individuals aware of their HIV infection should be referred to HIV care to prevent opportunistic infections and other complications of HIV and reduce transmission of HIV to others. Individuals with virally suppressed HIV and preserved CD4+ cell counts have a life expectancy similar to HIV-negative individuals³ and also cannot transmit HIV to others through sexual contact. Thus, diagnosis of HIV and linkage to HIV care

BACKGROUND

The Centers for Disease Control and Prevention (CDC) recommends HIV screening for all patients aged 13 to 64 in all health care settings, unless it is demonstrated that the diagnostic yield of such screening is less than 1 per 1000 persons screened.¹ Of the estimated 1189700 people in the United States living with HIV today, 13% are currently unaware of their HIV status.²

Author Affiliations: Department of Emergency Medicine, Medical College of Wisconsin (MCW), Milwaukee, Wisconsin (Chinn, Rubin, Martin); Emergency Department, Froedtert Menomonee Falls Hospital, Menomonee Falls, Wisconsin (Zakzesky); Emergency Department, Froedtert West Bend Hospital, West Bend, Wisconsin (Zakzesky); Department of Medicine, Division of Infectious Disease, MCW, Milwaukee, Wisconsin (Petroll, Woodbury); Center for AIDS Intervention Research, MCW, Milwaukee, Wisconsin (Petroll); Department of Psychiatry and Behavioral Medicine, MCW, Milwaukee, Wisconsin (Petroll); Department of Pathology and Laboratory Medicine, MCW, Milwaukee, Wisconsin (Ledeboer).

Corresponding Author: Dawn Zakzesky, MSN, RN, CNS-BC, CEN, Froedtert Menomonee Falls Hospital, W180 N8085 Town Hall Road, Menomonee Falls, WI 53051; email dawn.zakzesky@froedtert.com.

results in improved health outcomes for those living with HIV and reduced HIV incidence.

In US jurisdictions that have implemented widespread screening along with rapid and universal HIV treatment or HIV preexposure prophylaxis–such as San Francisco, New York City, and King County, Washington–HIV incidence rates have decreased significantly, up to 70%.⁴⁻⁶ For example, in San Francisco, HIV incidence declined steadily from 480 new cases in 2010 to 173 cases in 2019.

In Wisconsin, the incidence of HIV remained steady during 2011-2020, with an average of 4.0 (range 3.6 - 4.4) new diagnoses per 100000 people⁷ or 213 to 289 incident cases per year. The majority of incident HIV cases occur in southeastern Wisconsin, with the highest number in Milwaukee County, where 110 to 130 individuals are newly diagnosed with HIV annually, an incident rate of 16 to 19 cases per 100000 people.

Prior to the initiative discussed in this manuscript, our emergency departments (EDs) conducted HIV testing for patients who presented with symptoms concerning for HIV or prior to starting HIV post-exposure prophylaxis for individuals potentially exposed to HIV through occupational or nonoccupational means, resulting in an average of 600 HIV tests per year. To better serve citizenpatients and the public health of the state and to adhere to CDC guidelines, beginning in July 2022, Froedtert Health became the first health system in Wisconsin to conduct universal, opt-out HIV screening in the ED, paired with linkage to HIV medical care for those who were diagnosed with HIV. In this manuscript, we describe the outcomes of this screening initiative after 1 year.

METHODS

Project Design and Rollout

To develop and implement a universal HIV screening initiative, we formed an interdisciplinary team that consisted of individuals from multiple academic and administrative departments, including emergency medicine (departmental leadership, physician representatives, advanced practice providers, nursing leadership), infectious diseases (physician, director of HIV prevention services), pathology and laboratory medicine (microbiology leadership, lab managers), and representatives from risk management, compliance, marketing, and information technology). We conducted a needs assessment by reviewing local and regional HIV incidence and previous ED HIV testing data outlined above. During the assessment process, key stakeholders outside of our multidisciplinary team were given an opportunity to review the proposed program and provide feedback. Importantly, members of the frontline staff, including triage nursing staff members and ED providers (resident physicians, faculty physicians, and advanced practice providers), gave feedback on our procedures as they were developed.

After the initial assessment was completed, multiple in-services were conducted with frontline clinicians, trainees, nurses, and staff members within and outside the ED. While training was delivered to all ED staff, our efforts focused specifically on nurses who perform triage duties and ordering clinicians. Program details also were shared with staff by way of informational pamphlets. Workgroup members functioned as champions for the program and used standardized educational presentations to conduct the training. Nursing staff meetings, departmental emergency medicine educational conferences and faculty meetings, and hospital operations meetings were used as venues to introduce the program. The presentations included the following information: (1) current HIV epidemiology, including the percentage of persons living with HIV currently unaware of their HIV status and the percentage of new HIV transmissions estimated to be from persons currently unaware of their status; (2) CDC guidelines for universal HIV screening, success of other ED screening programs, and rationale for implementation; (3) protocol for opt-out testing, including the expected responsibilities of the triage nursing staff, clinicians, and the HIV social services team; (4) specific discussion on HIV test result delivery and protocol for rapid linkage to HIV care; (5) general overview of HIV care. Presentations were most often co-delivered by a nursing leader and social work staff

	All Tests Conducted n=11909 (%)	Persons w Positive HIV Test n=23 (%)
Gender		
Female	2339 (20)	4 (17)
Male	1162 (10)	17 (74)
Transgender female	16 (0.1)	2 (9)
Transgender male	18 (0.2)	-
Other gender	28 (0.2)	-
Unknown	8346 (70)	
Legal sex		
Female	7065 (59)	5 (22)
Male	4844 (41)	18 (78)
Race		`````
Black	5651 (47)	17 (74)
White	5150 (43)	3 (13)
Other	1108 (9.3)	3 (13)
Ethnicity	. ,	
Hisnanic	900 (7.6)	3 (13)
Non-Hispanic	10,969 (92)	20 (87)
Other/unknown	40 (0.3)	20 (07)
Δαο		
18_24	1697 (14)	6 (26)
25_34	2853 (24)	9 (39)
35_44	2703 (23)	7 (30)
45-54	2246 (19)	-
55-64	2358 (20)	1 (4)
Over 64	52 (0.4)	. (.)
County of residence	,	
Kenosha	62 (0.5)	1 (4)
Milwaukee	8495 (71)	20 (87)
Ozaukee	200 (1.7)	
Racine	200 (1.7)	1 (4)
Washington	1011 (8.5)	_
Waukesha	1145 (9.6)	_
Other	796 (67)	1 (4)

member.

In hopes of maintaining staff enthusiasm for the project, we wrote anonymized clinical case vignettes about patients who were diagnosed with HIV, including the time to their first HIV medical visit and first suppressed HIV viral load. These vignettes were distributed to frontline staff on a monthly basis and included the names of the clinicians who had seen the patients.

All patients were screened in triage using a prewritten script that was approved by hospital compliance:

"We screen everyone ages 18 to 64 for HIV if they are having blood work done. This practice is based on the most recent recommendations from the CDC. If you have labs drawn today, we will test you for HIV, unless you ask us not to."

As part of standard triage assessment, nursing staff read the script to patients aged 18 to 64 and documented in the electronic health record (EHR) their decision to opt out or not to opt out of HIV screening. If a patient did not opt out of HIV screen-

ing, an alert prompted HIV order entry when any physician, advanced practice provider, or nurse subsequently ordered a laboratory test that required venipuncture. The alert did not display if patients had HIV documented in their past medical history or problem list, had HIV testing performed within the past 12 months in one of our health system locations, or were assigned the most urgent acuity level. Upon the clinician accepting the prompt to place the order for an HIV test, the test was performed by the lab along with whatever other testing was ordered. For patients who indicated they wished to opt out of HIV screening-also recorded by the triage nurse-no prompt for an HIV test appeared for the ordering clinician.

On a weekly basis, the project team reviewed HIV screening data, including the percentage of patients who did or did not opt out, the number of HIV tests performed, and the number of positive screening tests and confirmatory tests. The team also conducted regular follow-up meetings with frontline staff to address any questions or concerns regarding the process.

Laboratory

HIV testing was performed in the central laboratory (Wisconsin Diagnostics Laboratories, Milwaukee, Wisconsin) using the Roche Elecsys HIV Duo (Roche Diagnostics, Indianapolis, Indiana). The HIV Duo is run on the Cobas e801 system (Roche Diagnostics) and detects HIV-1 p24 antigen and antibodies to HIV-1 and HIV-2 in parallel with independent determinations. Positive results from the HIV Duo are reflexed to the Geenius HIV1/2 Supplemental Assay for Diagnostic Testing (BioRad Hercules, CA) on the Geenius Reader. Patients with a positive HIV Duo but negative Geenius HIV 1/2 Supplemental assay are referred

Figure 1. Best Practice Advisory Display in Electronic Health Record and Subsequent Action to Enter Order for Screening





for nucleic acid amplification testing (NAAT) using the Roche Cobas HIV-1 test, which is run on a Cobas 6800 system. Results for all testing are transmitted directly into the electronic health record (Epic Systems Corporation) and are available immediately for viewing by health care providers and patients. Results of HIV screening tests performed at our EDs within hospitals were available within 1 to 2 hours of specimen collection. For HIV tests performed at freestanding EDs (without a lab conducting HIV tests), results of screening tests were available within 24 hours of specimen collection. Confirmatory results using the Geenius HIV 1/2 Supplemental test were reported within 24 hours of specimen collection.

A charge for the HIV screening was included in the patient bill when conducted. As HIV screening is a "Grade A" recommended test by the US Preventive Services Task Force,⁸ full payment of its costs by insurance plans is required. For patients without insurance, ED visit charges–including HIV screening charges–are handled individually, based on patient circumstances.

Patient Follow-Up

Prior to this initiative, all positive HIV test results in the health system, including ED results, were routed to the infectious disease clinic's HIV Linkage to Care (LTC) program. The LTC program historically has been, and continues to be, responsible for linking patients with HIV to care. The LTC program contacts patients who are newly diagnosed with HIV within 2 business days to provide result notification, counseling and education, assistance with insurance enrollment, clinic scheduling, resources for overcoming barriers to HIV care engagement, and assistance in obtaining and adhering to antiretroviral therapy and other care for HIV. The increase in number of incident HIV cases from the ED universal screening remained within the capacity of the LTC program to link patients with care.

Patients were provided their HIV screening results in multiple ways. If the patient was still in the ED, positive results were delivered by the treating emergency medicine clinician. During business hours, LTC staff accompanied the treating clinician to deliver a positive result to a patient. If the patient was admitted, inpatient clinicians were part of the result delivery. LTC staff would engage with admitted patients during their admission to provide links to HIV services. Patients who were discharged from the ED prior to receiving their HIV test result would be contacted by LTC to deliver positive test results and to link the patient to HIV services. All patients discharged from the ED who had a screening HIV test performed-regardless of the result-were given printed information on their ED after-visit summary, which also was visible through the patient portal (MyChart) to the EHR. This discharge information included details outlining how results could be viewed, as well as contact information for the LTC program. Patients with negative HIV results were not contacted individually but could access their results through the patient portal. Patients who left against medical advice may not have received instructions on how to access their results.

Data Collection

HIV screening data were exported from the EHR from all 7 EDs across the academic health system for the time period of July 13, 2022, to July 13, 2023. One ED was at an academic medical center, 2 were at community hospitals, and 4 were at microhospitals. (Microhospitals are small hospitals with attached EDs that offer ED services as well as a limited range of inpatient medical services in a small, neighborhood footprint. Our system microhospitals have around 10 ED beds and 10 inpatient beds.) Individual ED annual

censuses ranged from 5000 to 76000 patients, with the total annual visits for all EDs totaling approximately 156000 visits. All EDs were located within the southeast Wisconsin geographical area. We also tracked the number of days between each newly diagnosed patient's positive HIV test and the day of their first appointment with an HIV medical provider. Data were aggregated and analyzed using R (R Core Team) and Tableau (Tableau Softward, LLC).

Because our project's aim was to deliver universal HIV screening, which is considered a recommended standard of care, we did not pursue institutional review board approval for this project.

RESULTS

Our screening program resulted in an HIV positivity rate of approximately twice the threshold of 0.1% recommended by the CDC to conduct universal HIV screening. From July 2022 to July 2023, 57 565 patients were offered universal opt-out HIV screening in the ED. During this period, 12 406 tests were performed on 11909 unique patients, comprising 21% of those offered screening. In comparison, before this project, roughly 600 HIV tests were performed annually across the system's 7 EDs. Figure 1 shows the distribution of patients who opted out of testing, met inclusion criteria, and went on to complete blood testing.

Gender, legal sex, race, ethnicity, age, and county of residence were collected for all patients who underwent HIV screening, including those testing positive. The data demonstrate that the majority of persons newly diagnosed with HIV by this program identified as men, legal sex as male, Black, and under age 35. The vast majority of tests were conducted in Milwaukee County, based on the geographic footprint of our institutions, as were the majority–20 of 23–of positive test results. Of the 20 Milwaukee County residents who were newly diagnosed with HIV, 3 received their HIV diagnosis through a facility in a county other than Milwaukee County (Figure 2).

Twenty-two of the 23 newly diagnosed patients were linked to HIV care. After their positive HIV test, 43% were linked to care in less than 3 days, 39% were linked to care in 4 to 7 days, and 13% were linked to care in 7 to 30 days (Figure 3). This timing is similar to that of patients seen by our HIV social services program who are referred from sources other than our ED, which averages 130 patients per year.

DISCUSSION

Successful implementation of universal opt-out HIV screening in our health system EDs included interdepartmental planning and coordination and in-service training for frontline clinicians, trainees, and staff members who would implement the program. Early feedback was solicited from stakeholders and used to modify, enhance, and improve program processes. We worked to overcome potential barriers to implementation. First, to counter the perception of increased workload for ED staff, we worked to streamline the test-ordering process as much as possible and emphasized this in staff trainings. Second, to allay clinicians' worry about how positive test results would be handled and their role in the process, we designed a protocol wherein our HIV social work staff took over the task of delivering HIV test results for those patients who were discharged from the ED prior to test results returning and of linking patients to HIV medical care.

One limitation of the project relates to current legal requirements regarding consent for HIV testing. The state of Wisconsin eliminated the requirement for separate written consent for HIV testing in 2010, but it still requires written documentation in the medical record of a patient's verbal consent or refusal of HIV testing.⁹ It was a concern that this unique requirement would serve as a barrier to the screening program in 2 ways. The demands of a busy ED may make compliance with this Wisconsin-specific requirement more difficult, and patients and even clinicians may perceive stigma around HIV testing due to the unique consent. Whether Wisconsin's HIV consent process limited the number of individuals tested is uncertain but seems likely given that 55% of patients offered testing decided to opt out.

Another potential limitation of our protocol is that we tested patients for HIV only if they were having blood samples collected for other testing. We made this decision for 2 main reasons: (1) to potentially increase the acceptability of the program for patients by not drawing blood exclusively for HIV testing, and (2) to avoid the additional phlebotomy services that would be associated with HIV testing in patients not otherwise having blood drawn. The number of tests completed by our program or others considering implementing screening could be increased by completing HIV screening regardless of whether phlebotomy would otherwise be performed.

Nonetheless, our universal opt-out HIV screening program resulted in an HIV positivity rate of about 0.2%, twice the threshold of 0.1% recommended by the CDC to conduct universal HIV screening.1 Universal HIV screening has been found to be costeffective at positivity rates at or lower than 0.2%.10 That our screening initiative yielded this positivity rate in the Milwaukee metropolitan statistical area (MSA), which is ranked 77th-highest among 114 MSAs in the US for HIV incidence, provides evidence that universal screening should be adopted throughout other health systems in southeastern Wisconsin and other metropolitan areas in the state.11 The Madison, Wisconsin, MSA ranked 97th-highest in HIV incidence, with an incidence rate about 73% of Milwaukee's, and it is likely screening there also would produce positivity rates above the CDC's threshold.¹¹ Regardless of anticipated positivity rates, it is important to consider that the CDC recommends initiating universal HIV screening until it is demonstrated that positivity rates are less than 0.1%.1 A community outbreak of HIV in a rural area of Indiana in 2015 resulted in more than 3% of the population being diagnosed with HIV.12 Universal screening could have played a role in identifying this outbreak at an early stage, potentially averting additional infections.

Anecdotally in conversations with LTC staff, several patients who were newly diagnosed with HIV reported that they previously had not been tested for HIV elsewhere and were not otherwise planning to get an HIV test. This information further supports the impact of universal HIV testing. With new knowledge of their HIV positive status, each patient has an opportunity to address and potentially prevent the negative health consequences of HIV, such as opportunistic infections and certain cancers. They also can prevent transmission of HIV to their sexual partners.

Decreases in the incidence of HIV are attributed to a combination of widely available HIV testing, immediate access to HIV treatment for those who test positive, and HIV prevention for those in whom it is indicated. This study has demonstrated the feasibility of implementing universal opt-out screening in the ED paired with rapid linkage to HIV care services in the state of Wisconsin.

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