

ORIGINAL RESEARCH

Infectious Disease

Aligning an emergency department hepatitis C and human immunodeficiency virus testing quality improvement initiative with universal screening recommendations

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Abstract

Objective: The interactions among hepatitis C virus (HCV), human immunodeficiency virus (HIV), and the ongoing injection drug epidemic have created a syndemic that significantly affects the Appalachian region of the United States. The purpose of this work is to describe a successful Kentucky program that aimed to increase HCV and HIV testing for people visiting an urban emergency department (ED) who were screened, diagnosed, and linked to care after diagnosis with special consideration for substance use disorder.

Methods: The Plan-Do-Study-Act model for quality improvement was used to create a streamlined process for testing, reporting results, and linking people to care. The program was refined and expanded across 3 phases.

Results: Across all phases, a total of 25,685 patients were eligible for testing and did not opt out. Of those, 17,090 had HCV antibody (Ab) testing; 3460 (20.2%) had HCV Ab; 1750 (50.8%) had HCV RNA, and an average of 31% of patients were linked to care within 30 days. The program found 54 new cases of HIV infection.

Conclusions: Universal HCV and HIV testing and linkage to care is possible within an ED. In areas affected by the syndemic, EDs may serve as a public health safety net to identify affected individuals and ensure they receive follow-up care. Testing in this center uncovered an exceptionally high prevalence of HCV infection and new HIV case identification.

KEYWORDS

emergency department, hepatitis C, HIV, syndemic, universal screening, universal testing

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1 | INTRODUCTION

1.1 | Background

A syndemic is the occurrence of 2 or more diseases overlapping with adverse social factors that reinforce poor outcomes.¹ Syndemic theory supports the notion that human immunodeficiency virus (HIV) and hepatitis C virus (HCV) infections cannot be addressed without also addressing the problem of substance use disorder (SUD), and vice versa, while considering disease interactions and the impact on personal and public health.² It is increasingly important to address the HCV, HIV, and SUD syndemic through integrated approaches as the problems are interdependent and lead to high health care use.¹ Kentucky has long ranked in the top 10 states for new HCV infections and has 54 counties at high risk for rapid HIV and HCV transmission among people who inject drugs (PWID).³ Emergency departments (EDs) serve as a stop gap for finding people at risk for worse health outcomes secondary to the syndemic through ED-based screening, interventions, and linkage-to-care services.⁴

Beyond PWID with recent or ongoing use, adults may be at risk for having HCV and/or HIV from past substance use or other risk behaviors such as unsanitary tattooing. Before 2020, the Centers for Disease Control and Prevention (CDC) screening recommendations directed HCV screening toward people with identified risk factor(s) and adults born between 1945 and 1965.⁵ Yet, the greatest increase in new HCV infections was found in younger adults with clear ties to substance use.^{6,7} The CDC has recommended universal screening for HIV in health care settings for adolescents and adults since 2008. New HIV infections had been on a downward trajectory despite increasing rates of injection drug use; however, this trend has been threatened with several HIV outbreaks among PWID in Appalachian states since 2018.^{8,9}

1.2 | Importance

The national epidemiology of HCV has shifted from the older birth cohort born 1945–1965 (now aged 57 to 77 years) to those under the age of 45 years with nearly equal gender distribution.⁶ People affected by the syndemic are typically of childbearing potential but not reaching testing and linkage services at a high rate. Simultaneously, older adults may have never been evaluated, aware of their HCV status, or have not received treatment because of being told, many years ago, that they were ineligible for treatment or were unwilling to receive interferon-based therapy.¹⁰ As HCV and HIV treatment are increasingly available, investigators determined a quality improvement program was needed to enhance testing and care.

1.3 | Goals of this investigation

The primary goal of this program was to increase the number of people tested for HCV and HIV within the 5-year grant period. A secondary goal was to eliminate dependence on external funding by successfully

The Bottom Line

Emergency department (ED) screening for hepatitis C virus (HCV) and HIV is important to improve linkage to care and outcomes. In this description of ED HIV and HCV screening in Louisville, a total 25,685 patients were screened; 20.2% had HCV antibodies, 50.8% had HCV RNA, and 31% were linked to care within 30 days. The program also found 54 new cases of HIV infection. This study demonstrated the effectiveness of ED HIV and HCV screening.

setting up the program in a self-sustaining manner before the end of the funding period (up to 60 months). The program addressed the primary goal by expanding HCV and HIV testing to a universal approach in alignment with the 2020 CDC HCV and 2008 HIV guidelines. Anyone testing reactive for HCV antibody received reflex diagnostic testing with HCV RNA polymerase chain reaction (PCR). Anyone testing reactive for HIV 1 or 2 antibody was reflexively tested for antigen. The secondary goal was addressed with a financial proforma.

2 | METHODS

2.1 | Design

Using a syndemic framework to illustrate the interdependence of substance use, HIV, and HCV infections, investigators sought to routinize screening, automate diagnostic testing for positive screens, then link affected individuals to practitioners able to address the primary problem (ie, someone with SUD wanting addiction care could be linked to services before they might wish to be linked for HCV treatment). Investigators assumed that people newly diagnosed with HCV and those who were aware of their diagnosis, but not aware of curative HCV treatment, would want to be linked. Investigators further assumed people known to be living with HIV were aware and already in care, but a proportion of people living with HIV would be out of care and desired linkage to HIV services.

The Plan-Do-Study-Act method of continuous quality improvement was used to develop and refine the program.¹¹ The team collaborated with affected hospital departments (ED, laboratory, informatics, billing, and leaders from infectious disease and hepatology). Literature and guideline reviews helped determine approaches; local epidemiology was reviewed, and the team planned and implemented the program. The program used a Research Data Capture (REDCap) database where variables (including demographics, testing results, and linkage to care disposition such as deceased, linked to a practitioner, incarcerated, or declined to be linked) were continuously collected. Team members performed a monthly review to minimize protocol variations while also identifying areas for improvement to achieve maximum impact. The program underwent several iterations leading to universal HIV and HCV testing and linkage to care.

Hep C Risk Screening, ULH

<p>Have you ever been told that you have hepatitis C?</p> <input type="radio"/> No <input type="radio"/> Yes	<p>Have you ever had any tattoos or body piercings that were placed outside of a licensed business or by an unlicensed professional?</p> <input type="radio"/> No <input type="radio"/> Yes	<p>Have you ever been exposed to someone else's blood through your work or recreational activities?</p> <input type="radio"/> No <input type="radio"/> Yes
<p>Have you ever been told your liver enzymes (or liver tests) were elevated?</p> <input type="radio"/> No <input type="radio"/> Yes	<p>Have you ever, even if just once or a very long time ago, injected or snorted drugs?</p> <input type="radio"/> No <input type="radio"/> Yes	<p>Have you lived with someone who has been diagnosed with hepatitis C virus infection?</p> <input type="radio"/> No <input type="radio"/> Yes

Say to the patient:
"If you have blood drawn during your ER visit, we will test you for Hepatitis C as part of our Standard of Care. If your test comes back positive, you will be notified by a member of your healthcare team."

<p>Does the patient voice any objections?</p> <input type="radio"/> No- Patient does not object to screening <input type="radio"/> Yes- Patient objects to screening	<p>Hepatitis C Screening Comment</p> <input style="width: 100%;" type="text"/>
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Hepatitis C Screening Education
*All of the education topics below **MUST** be covered and documented if the patient does not opt out.*

<input type="checkbox"/> This test will be done only if you have blood drawn during your ER visit. <input type="checkbox"/> This test will be charged to the patient care grant. <input type="checkbox"/> You can contact the Hep C Navigator at the number provided. <input type="checkbox"/> You will only be contacted with positive test results. <input type="checkbox"/> Other.	<p>Hep C Navigator, Kim: (502) 509-1166</p>
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FIGURE 1 Phase 1 triage questionnaire. The initial phase of the program was limited to adults 45 years or younger with a risk factor for hepatitis C infection

2.2 | Setting

The ED is located within a Level One Trauma Center in an urban area of Kentucky. The 348-bed hospital sees more than 60,000 patients annually through the ED and uses Cerner for electronic medical record (EMR) keeping. Cerner uses adaptable programming to operate order sets, algorithms, display practice alerts, and generate reports. Patients entering the hospital via the ED will first register, then see a triage nurse who interacts with Cerner. Alerts and forms are programmed to display based on patient demographics and other specifications.

The hospital uses a central laboratory with a barcode-based automated conveyance system to transport specimens to designated machines for specimen identification, navigation to appropriate lab machinery, and results upload to the EMR. The system was structured to reflex screening tests to diagnostic testing on a subsequent machine or move the specimen to another area of the lab for complete testing. Once test results are available, reports may be generated from Cerner that group patients with specific test results together for clinical care.

2.3 | Intervention

Before implementation of the program, patients visiting the ED were not routinely tested for HCV or HIV. For all of 2018, when the CDC

recommendation was to screen for HCV in people born between 1945 and 1965 and risk-based testing for others, ED baseline measures show 514 patients were screened for HCV antibody and 150 HCV RNA tests ordered. No linkage program existed at the time. HCV antibody to HCV RNA reflex testing orders became available in late 2018; before that, practitioners had to enter HCV RNA separately from antibody. HCV antibody testing alone was removed as an order option from Cerner in January 2019.

Investigators used a stepwise approach to increase the volume of tested patients while ensuring the program was operating effectively. Investigators first developed an algorithm to identify eligible HCV-testing patients. The first iteration of the program occurred from quarter one through quarter four of 2020. If requirements were met, a pop-up questionnaire (Figure 1) was displayed for the triage nurse to complete with the patient. Patients not opting out would have an order for HCV antibody with reflex to HCV RNA PCR generated by the system, but labs would be drawn only if the patient had other labs drawn as part of their ED care. If a patient did not have labs drawn, the system would auto-cancel the orders at discharge. System-generated orders for HCV and HIV testing were visible to the care team.

The second iteration of the program lasted from quarter one to two of 2021. It expanded the testing algorithm to include questions about HIV status. The final program began in quarter three of 2021. Figure 2 displays the final questionnaire.

Hep C/ HIV Risk Screening, ULH

Patient alert and able to answer questions at this time.

Patient able to answer questions
 Patient unable to answer questions.

Have you ever been told that you have Hepatitis C or HIV?

No Yes- Hepatitis C
 Yes- Both Hepatitis C and HIV Yes- HIV

Have you ever had any tattoos or body piercings that were placed outside of a licensed business or by an unlicensed professional?

No Yes

Have you ever been exposed to someone else's blood through your work or recreational activities?

No Yes

Have you ever been told your liver enzymes (or liver tests) were elevated?

No Yes

Have you ever, even if just once or a very long time ago, injected or snorted drugs?

No Yes

Have you lived with someone who has been diagnosed with Hepatitis C virus infection?

No Yes

Say to the patient:

"If you have blood drawn during your ER visit, we will test you for Hepatitis C and/or HIV as part of our Standard of Care. If your test comes back positive, you will be notified by a member of your healthcare team."

Does the patient voice any objections?

No- Patient does not object to screening
 Yes- Patient objects to screening

Hepatitis C/ HIV Screening

Have you previously been linked to care?

No Yes- Hepatitis C
 Yes- Both Hep C and HIV Yes- HIV

FIGURE 2 Phase 2 triage questionnaire. The team recognized that some patients were inappropriate for participation in the screening program if they could not opt out. Adding items about patient ability to respond to questions, HIV disclosure, and linkage information helped to advance the program quality. Abbreviation: ULH, UofL Health University of Louisville Hospital.

To operationalize linkage to care, a patient navigator was hired to evaluate reports for HCV antibody positive and HCV RNA positive patients. Antibody positive patients received education on HCV exposure and prevention and HCV RNA patients received education on exposure, transmission, treatment, and harm reduction. A second navigator was hired to help manage the workload added when HIV testing began. By the time universal screening began, both navigators had a well-defined workflow and system in place for providing patient results, education, referrals, and harm reduction resources.

2.4 | Study of the intervention

The initial phase of the testing program began in January 2019 and focused on HCV testing among people aged 18–45 years visiting the ED who endorsed at least 1 HCV-related risk factor, had blood drawn as part of routine ED care, and did not opt out. The second phase of the program began in late November 2020 with the inclusion of HIV testing. The questionnaire was edited to include items about HIV. The final phase of the program began in July 2021. Patients were able to opt out of testing across all phases. With each expansion of the program, investigators discussed successes and challenges, identified staffing education needs, and clarified best practices in approaching patients about testing and results and linkage to care options. A nurse informaticist updated the Cerner algorithm logic and tested the programming to ensure functionality. ED staff members, including nursing, phlebotomy, and house staff were updated on upcoming changes to the program the week before implementation.

Testing costs were billed to insurance. For patients without insurance, testing costs were covered by grant funding until the program

became self-sustaining. The program was considered self-sustaining after a proforma concluded the costs of testing, navigation, and administrative support (phone, fax, printing) were below the revenue margin generated from services resulting from linkage-to-care efforts (including, in part, 340-B pharmacy rebates) at 40 months. At that time, the hospital began covering the costs for testing when insurance did not pay and for patients without insurance. Most patients had insurance through commercial plans, Medicare, Medicaid, and corrections. Those plans covered testing costs at nearly 100%. HCV antibody with reflex costs were \$42.84 per patient and HIV antibody combo 1 and 2 costs were \$6, consistent with Medicare rates.

Costs for care navigation were initially covered by the grant; once the program reached full efficiency (phase 3), the hospital took over navigator salaries (\$139,000 combined) as their cost was not reimbursable but was offset by downstream revenue. The health system has linkage sites that include addiction care, mental health services, women's health services, primary care, and specialty care such as infectious disease and hepatology. For patients wishing to link to care outside of the health system, the hospital still provided testing and linkage services at no cost to the patient. Figure 3 displays the final workflow of the program.

2.5 | Measures

Patients were eligible for HCV and HIV testing if they were 18 years or older, had not been tested for HCV antibody in the past 90 days within the health system, and did not opt out of testing. Age (initially 18–45 years, then 18 and older) and HCV antibody test results were used to trigger the questionnaire while avoiding repeat testing within

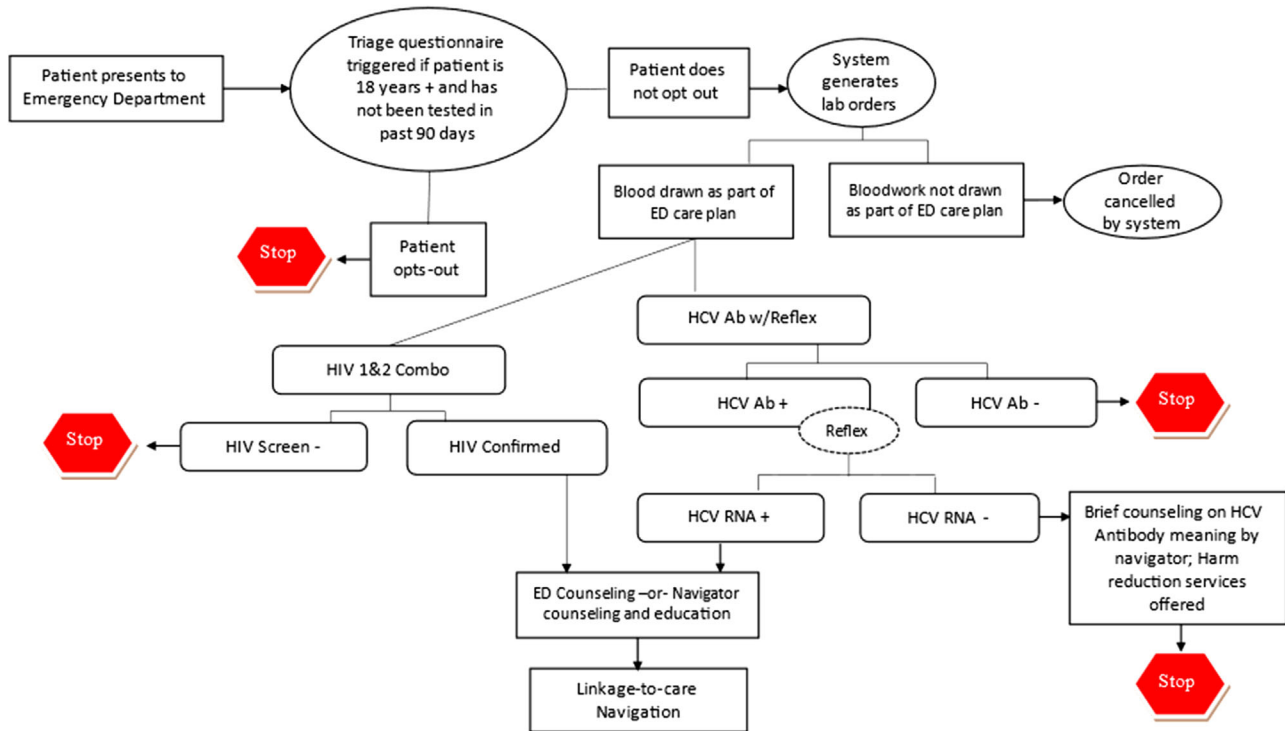


FIGURE 3 Testing and diagnosis flow diagram. Abbreviations: ED, emergency department; HCV, hepatitis C virus

the 90-day window. If a patient opted out of testing, they were not eligible. A patient could not request only HIV or only HCV testing; the algorithm was designed to order both tests in recognition of the syndemic. Linkage-to-care navigation took place for patients testing positive for HCV RNA, and/or HIV; education was provided to HCV antibody positive patients. People living with HIV were considered eligible for linkage services whether or not they had a new diagnosis. The number of patients entering the ED, responding to questionnaires, and receiving testing, results, and linkage information were all used as measures to document progress.

2.6 | Analysis

Each month, Cerner and REDCap were queried to generate reports. Data were downloaded as CSV files and analyzed in Excel for univariate statistics. At monthly team meetings, the reports facilitated discussion and aided in identifying potential workflow problems. Reports included the number of triage questionnaires conducted, opt-outs, and the number of HCV antibody, HCV RNA, and HIV tests completed. Testing volumes were stratified by reactive/non-reactive for HCV and HIV and age group demographics (18–45 years, 46 years and older). Linkage-to-care data were reported by number linked, where linked, and reasons for non-linkage. Patients were considered linked to care if they kept an appointment within the first 30 days after diagnosis. This approach allowed the team to identify areas of success, areas for improvement, and areas in which changes should be considered to improve efficiency. The program process included multiple hospital departments that

could be approached when changes were needed: registration, nursing, phlebotomy, central laboratory, informatics, hospital physicians and advanced practice providers, and facilities receiving referrals.

With each new quarter of the calendar year, Cerner and REDCap were queried for outcomes from the previous quarter. This updated report allowed for capture of monthly volumes and reporting outcomes. This measure helped overcome linkage-to-care reporting limitations with monthly reporting in cases where a patient might have been diagnosed during the last week of one month and linked within the first 2 weeks of the following month.

The team's frequent review of program measures allowed for inferences at each step in the care navigation process. After each change, data were tracked for trends. Unexpected changes in trends were discussed and potential explanations determined. Changes in trends were detected through month-to-month comparison of outcome measures. If an issue was determined to be related to the questionnaire, the questionnaire would be changed to ensure clear communication between triage nurses and patients. If a trend change was suspected to be related to a specific department, members of the team would reach out to the department of concern to clarify any issues and implement corrective action. Actions could be training of unfamiliar staff, clarification of the program protocol, providing team member contact information for questions, and participating in staff meetings to highlight program successes and generate buy-in. Data were reviewed for expected changes in trends. Expected changes include comparison of total ED volumes in each month and the volumes of questionnaires completed. When monthly ED volumes decreased, a dip in questionnaires administered was expected. After expansion of

TABLE 1 HCV antibody positive patient demographics and testing cascade volumes

	Phase 1 n (%) Q1-4 2020	Phase 2 n (%) Q1-2 2021	Phase 3 n (%) Q3 2021-Q1 2022
Demographics for HCV antibody positive patients			
Males	522 (63.0)	267 (64.0)	1022 (66.3)
Females	306 (37.0)	150 (36.0)	519 (33.7)
Age range (years)	19–48	22–73	19–96
Median (years)	43	36	46
Mean (years)	45.8	38.1	47.9
Questionnaires administered	21,856	24,557	30,753
Eligible patients (ie, did not opt out)	4658 (21.3)	4659 (19.0)	16,368 (53.2)
HCV Ab tests conducted	3036 (65.2)	1830 (39.3)	12,224 (74.7)
HCV Ab positive	1073 (35.3)	728 (39.8)	1659 (13.6)
HCV RNA positive	679 (63.2)	329 (45.2)	742 (44.7)
HIV tests conducted	204 *HIV testing started late in Q4 2020	1890 (40.6)	12,461 (76.1)
Newly identified HIV positive	3 (1.5)	21(1.1)	31 (0.02)
HCV RNA positive linked to care within 30 days	211 (31.1)	91 (27.7)	262 (35.3)

Note: Baseline HCV Ab testing was 514 patients for the entire 2018 year; 150 HCV RNA tests were ordered during that period. Patients were eligible for program testing if they had not opted out, had not been tested within the hospital in the past 90 days, and met risk and age-based criteria relevant for each phase of the program (refer to Figure 4). Aggregate data may contain duplicate case counts. Demographics data are based on unique patients testing positive for HCV antibody within each phase.

Abbreviations: Ab, antibody; HCV, hepatitis C virus.

testing, increased volumes of screening questionnaires and the remaining measures of the navigation program were expected. This qualitative iterative process had quantitative outcomes reflected in data.

2.7 | Ethics statement

This quality improvement program was reviewed by the University of Louisville Institutional Review Board and deemed non-human subjects research.

3 | RESULTS

From January 2020 through March 2022, 2587 patients tested positive for HCV antibody and 1427 had detectable HCV RNA (Table 1). Table 1 describes patient demographics and testing cascade results for each phase of the program. An additional 57 individuals were not tested for HCV antibody or HCV RNA as they were known to be living with HCV based on screening questionnaire responses. From November 2020 (when HIV testing was added to the program) through March 2022, the team identified 165 people living with HIV: 54 were newly diagnosed. Each phase of the screening program increased volumes of people screened, diagnosed, and linked to care. Numeric decline in patients eligible for testing was observed in phase 3. Figure 4 demonstrates the 3 expansion phases of the program and highlights key changes aimed at increasing the number of patients tested and linked to care. Linkage rates were considered stable throughout the program

although a slight decrease was observed in phase 2. This is attributed to fluctuations in staff coverage secondary to the COVID-19 pandemic. Figure 5 displays monthly metrics.

3.1 | Limitations

This quality improvement program and findings are met with several limitations. First, linkage to care within the first 30 days is challenging. Linkage speed is slowed or delayed by several factors including patient condition, willingness to be linked to a practitioner, transportation barriers, and availability of practitioners to refer to. Many linkage efforts in the first 30 days were left as “in-progress” to demonstrate linkage to care efforts were underway but would fall outside of the 30-day window. Often, patients reported as “in-progress” were linked to care within 90 days. Those not linked to care were most often incarcerated; despite program navigators’ best efforts to relay information through the prison or jail health manager, it was unclear how many people incarcerated at the time of diagnosis were linked to care within the prison or jail health system. Linkage to care was further affected because the program is staffed during usual business hours by the care navigators and not around the clock. Second, owing to the COVID-19 pandemic with frequent shifts in patient volumes and ED staffing levels, the opt-out rates for the program fluctuated more than anticipated. The team attempted to address increases in opt-out rates by ensuring new or traveling nurses were aware of the screening program and the importance of following the questionnaire script and

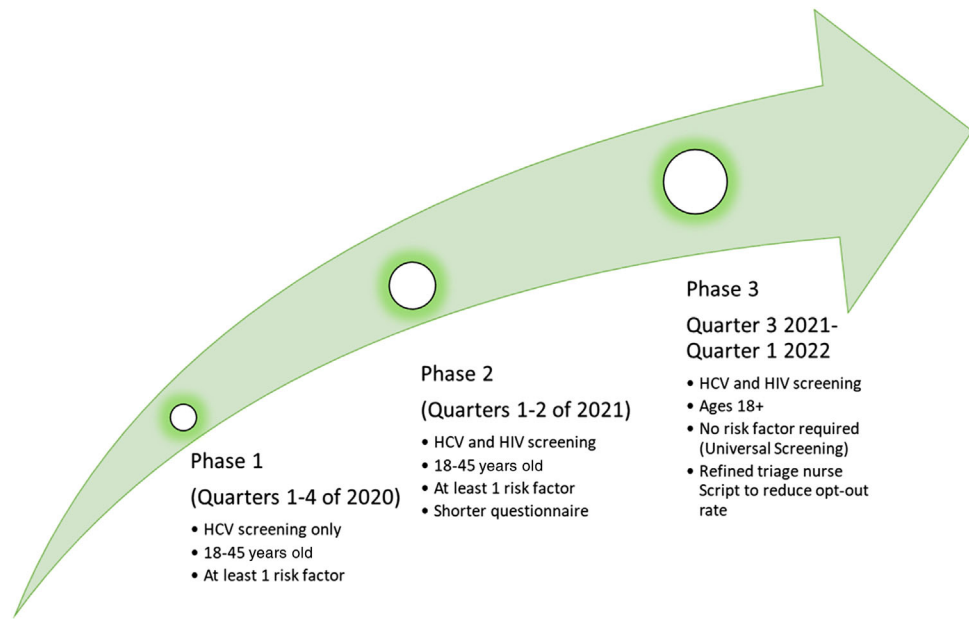


FIGURE 4 Program phases and description of approach. Abbreviation: HCV, hepatitis C virus

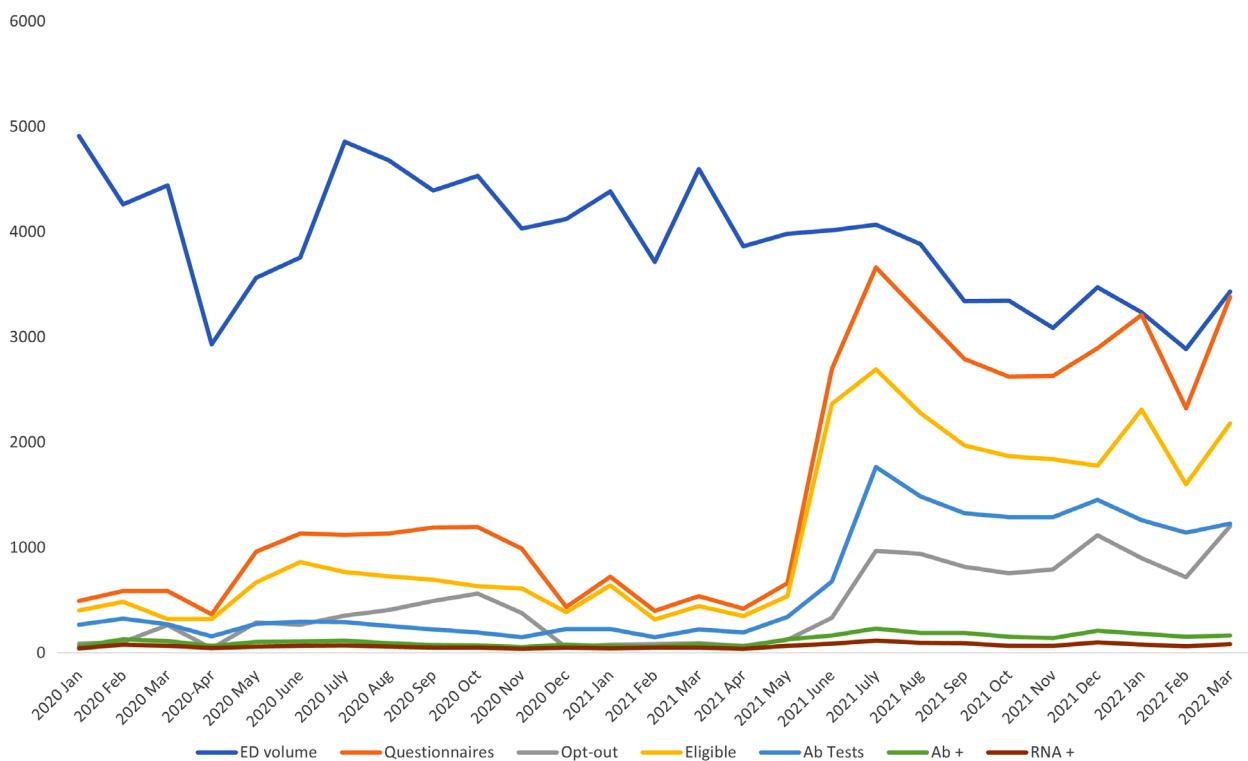


FIGURE 5 Hepatitis C testing metrics. Monthly emergency department volume and changes in questionnaire completion, testing, and case finding over the 3 phases of the testing program. Note: Ab, antibody; RNA, hepatitis C virus RNA polymerase chain reaction

prompts. Third, patients were eligible for testing if they had not had an HCV antibody test in the EMR in the past 90 days. As such, some testing volumes do not necessarily represent unique patients. The care navigation database is used to discern patients already in the care navigation program from new patients. Testing volumes may appear higher than the volume of positive patients truly in need of navigation.

4 | DISCUSSION

The Plan-Do-Study-Act model of quality improvement implementation allowed the team to pragmatically adjust programming to optimize testing and linkage rates with each phase of the program. Few hospital systems have reported on non-targeted, universal HIV and HCV

screening within their ED programs. Nonetheless, ED programs are recognized as critical in screening and linkage services and having dual HIV and HCV screening may help improve linkage rates.¹² Other health systems have successfully implemented universal HCV screening programs in the ED and have found increases in new HCV infections after leveraging their EMR to prompt testing, billing insurance for testing, making use of opt-out rules, and care navigators.¹³

Leveraging the ED as a place for delivering public health interventions is an important consideration in addressing the syndemic of viral hepatitis, HIV, and SUD. Universal testing for HCV and HIV in the ED ensures a large capture, a mechanism for repeat testing in at-risk and high-risk individuals, and the opportunity to reduce stigma by routinizing testing procedures and workflow. Care navigation is an essential service that is easily integrated into ED and hospital workflow as navigators can receive test results quickly and discuss planning needs with affected patients within a brief period of time. The program described here is reproducible in health systems using electronic health records, and automated lab conveyance and results reporting.

AUTHOR CONTRIBUTIONS

Barbra Cave contributed to the conceptualization, methodology, investigation, original draft, review, and editing of this work. Kimberly Laun, Brianna Sheahan, and Ashlee Melendez contributed to conceptualization, methodology, investigation, and review. Ashlee Melendez contributed to conceptualization, methodology, review, and editing.

CONFLICT OF INTEREST

Barbra Cave is in the speaker bureau for AbbVie and Gilead Sciences. She receives research support from AbbVie, Intercept, Bausch/Salix, and Durect. None of the other authors have disclosures.

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