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ORIGINAL ARTICLE

Screening for hepatitis C as part of an opioid stewardship quality improvement initiative: Identifying infected patients and analyzing linkage to care

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Abstract

Screening patients with opioid use disorder (OUD) for HCV can potentially decrease morbidity and mortality if HCV-infected individuals are linked to care. We describe a quality improvement initiative focused on patients with OUD, incorporating an electronic health record decision-support tool for HCV screening across multiple health care venues, and examining the linkage to HCV care. Of 5829 patients with OUD, 4631 were tested for HCV (79.4%), (compared to a baseline of 8%) and 1614 (27.7%) tested positive. Two hundred and thirty patients had died at the study onset. Patients tested in the acute care and emergency department settings were more likely to test positive than those in the ambulatory setting (OR = 2.21 and 2.49, $p < 0.001$). Before patient outreach, 279 (18.2%) HCV-positive patients were linked to care. After patient outreach, 326 (23.0%) total patients were linked to care. Secondary end points included mortality and the number of patients who were HCV-positive who achieved a cure. The mortality rate in patients who were HCV-positive (12.2%) was higher than that in patients who were HCV-negative (7.4%) (OR = 1.72, $p < 0.001$) or untested patients (6.2%) (OR = 2.10, $p < 0.001$). Of the 326 with successful linkage to care, 113 (34.7%) had a documented cure. An additional 55 (16.9%) patients had a possible cure, defined as direct acting antiviral ordered but no follow-up documented, known treatment in the absence of documented sustained viral response lab draw, or documentation of cure noted in outside medical records but unavailable laboratory results. A strategy utilizing electronic health record decision-support tools for testing patients with OUD for HCV was highly effective; however, linking patients with HCV to care was less successful.

Abbreviations: BPA, best practice advisory; CI, confidence interval; DAA, direct-acting antiviral; EHR, electronic health record; IDU, injection drug use; MAT, medication-assisted therapy; OUD, opioid use disorder; PCP, primary care provider; SVR, sustained viral response

INTRODUCTION

Despite the development and widespread use of direct-acting antiviral drugs (DAAs), HCV remains a major cause of liver-related morbidity and mortality. DAAs have changed the landscape of HCV treatment with shorter durations of therapy, reduced adverse effects, and cure rates approaching 100%.[1–3] However, major barriers to reducing the global burden of HCV persist, including identifying and screening patients who are at the highest risk, linking those who have been infected with HCV to care, and obtaining access to treatment.

As the incidence of opioid use disorder (OUD) has increased since the 1990s, there has been a concomitant increase in injection drug use (IDU) as nonmedical use of opioid pain relievers is frequently associated with subsequent use of injection heroin.[4] IDU has been the primary driver of increasing rates of HCV across the United States.[5–8] Estimated positive HCV seroprevalence in those who use injection drugs is greater than 50% worldwide.[9] In one report, IDU accounts for at least 60% of acute HCV infections in the United States and ~50% of all infected persons are unaware that they have HCV.[10,11]

Although the peak prevalence age of HCV-infected patients from 1999 to 2002 was 40–49,[12] epidemiological data from 2020 reveal a shift to peak prevalence in ages 20–39, mirroring those age groups at highest risk for opioid overdose and initiation of IDU.[7] Patients with substance abuse disorders, including OUD, are less likely to receive preventive health services and treatment for chronic conditions with a primary care provider (PCP).[13–16] Given this lack of engagement with primary care, it is imperative that HCV screening efforts and subsequent referral for treatment be maximized in venues such as emergency departments, medication-assisted therapy (MAT) clinics, homeless shelters, needle exchange programs, prison clinics, federally qualified health centers, and acute care hospitals. Recent studies have highlighted the efficacy of hepatitis C screening in these settings.[17–23] Socioeconomic barriers prevalent in the OUD population often contribute to poor treatment adherence. Successful linkage to care strategies that use tools to overcome these barriers is imperative for good patient outcomes.

In addition, because advanced liver disease and hepatocellular carcinoma cause significant morbidity and mortality associated with HCV, a robust screening program engaging a high-yield population, such as patients with OUD, has the potential to significantly impact these sequelae.[24] Even modest increases in successful HCV treatment in those individuals who inject drugs can result in substantial public health impact.[10]

We describe a quality improvement initiative focused on patients with OUD, which incorporated HCV screening across multiple health care venues and examined the linkage to HCV care and treatment.

METHODS

This organizational quality improvement project focused on patients diagnosed with OUD and screened for HCV at Novant Health between 2018 and 2020 as part of a system-wide goal focused on opioid prescribing. The goal included four components: decreasing the quantity of opioids prescribed at hospital discharge, increasing the utilization of an opioid use disorder risk screening tool for those receiving more than 8 days of opioid therapy, increasing the use of opioid treatment agreements, and increasing testing for HCV and HIV in patients with OUD. Novant Health is a regional health care system in the southeastern United States composed of 15 inpatient medical centers and ~700 ambulatory locations. As part of this initiative, physicians and advanced practice providers were prompted to screen patients with OUD at any encounter (acute or ambulatory) for HCV and HIV if they had not been screened within the previous 12 months. Patients with OUD were identified using the F11.xxx and a subset of the T40.2X series of International Classification of Diseases, Tenth Revision codes, recorded at the point of encounter or present as a historical diagnosis.

A best practice advisory (BPA) in the electronic health record (EHR) (EPIC® EHR) prompted providers to order an HCV antibody test (anti-HCV) with reflex to qualitative real-time polymerase chain reaction (PCR) to detect current HCV infection, as well as HIV screening with an HIV p24 antigen/antibody with reflex to confirmation test (Laboratory Corporation of America, Burlington, North Carolina) (Figure 1). Providers could decline the BPA with the provided choices of “patient refused” or “defer to other provider.” All HCV serology test codes were included in the data collection, not just those generated by the BPA, as providers may have opted out of the BPA in favor of ordering an alternate HCV test. No further guidance on follow-up care, referral, or treatment was provided to clinicians when a patient tested positive for HCV or HIV.

The initial data collection (baseline assessment) was completed in March 2022. Patient outreach was performed between March 2022 and October 2022. The final data collection (postintervention) was conducted in December 2022.

The primary endpoint was the number of patients with OUD who had a positive HCV screening test and were successfully linked to care with an HCV specialist. The disposition of those patients who screened positive included (a) previously treated and cured unbeknownst to the ordering provider, (b) positive HCV antibody screening but subsequent negative HCV RNA in the absence of any known prior therapy, suggestive of

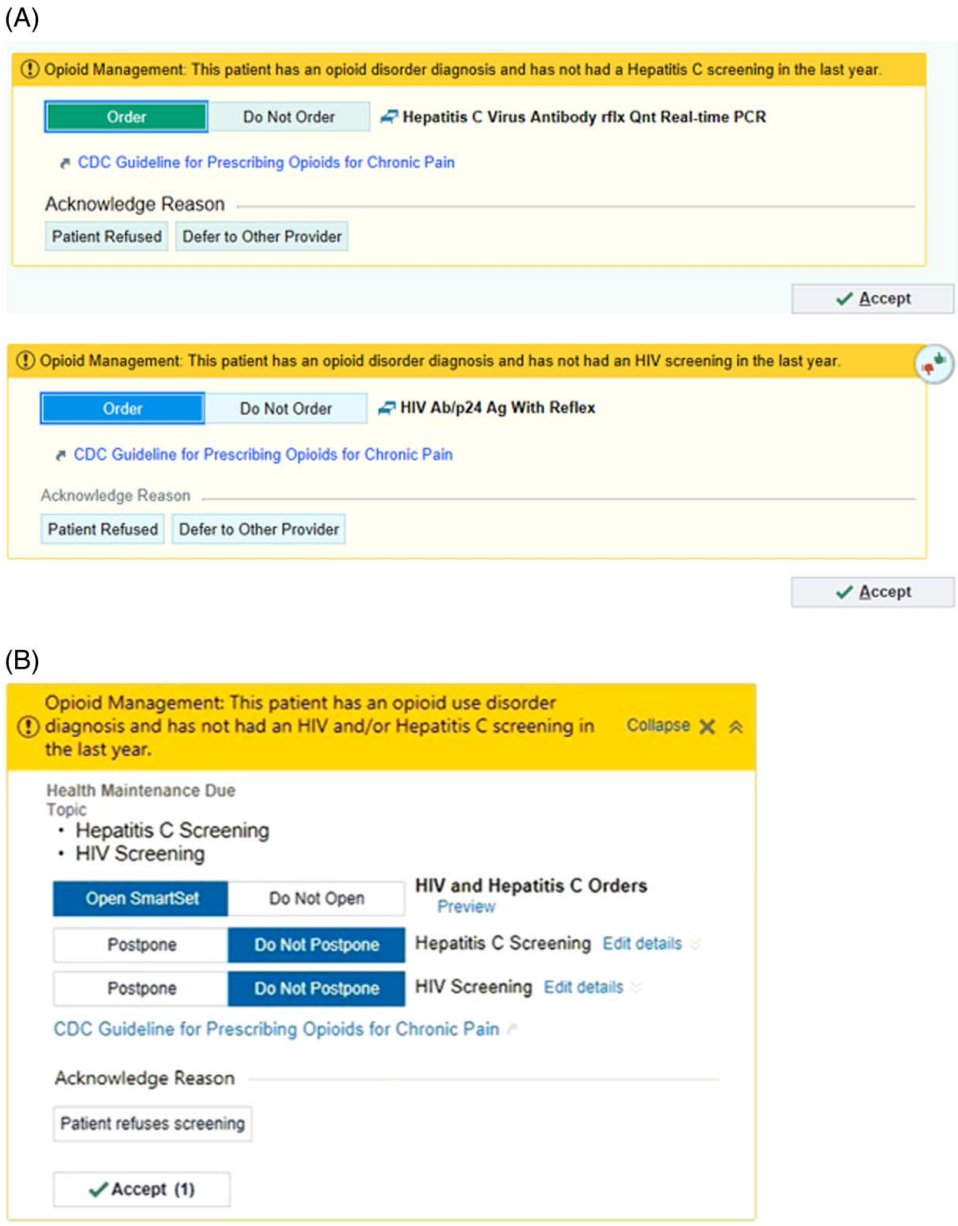

FIGURE 1 BPA: (A) Acute care and (B) Ambulatory (EPIC® EHR). Abbreviations: BPA, Best practice advisory; EHR, electronic health record.

spontaneous clearance, (c) successful linkage to an HCV specialist for evaluation and treatment, (d) unsuccessful linkage to care due to patient nonadherence (such as patient-directed discharges or outpatient no-shows), and (e) unsuccessful linkage to care due to lack of appropriate referral. Successful linkage to care was defined as at least one completed visit with an HCV specialist to discuss treatment.

The secondary end points included overall mortality during the study period and the number of patients who were HCV-positive who achieved a cure. The cure was defined as dispensed DAA with a sustained viral response (SVR) ($\geq$ 12 wk after completion of treatment). A possible cure was defined as DAA ordered but no follow-up documented, known treatment in the absence of documented SVR lab draw, or documentation of cure noted in outside medical records but unavailable laboratory results. Patients with oncologic comorbidities were excluded from the analysis.

For groups (d) and (e), attempts were made to refer patients to an HCV specialist through 3 primary methods: contacting their PCP or HCV specialist (defined as a gastroenterologist or infectious disease provider who had an established relationship with the patient for other clinical reasons) through the EHR, EHR patient portal message, or telephonic outreach. Lastly, the number of patients in groups (d) and (e) who were successfully linked to care due to the post hoc intervention was noted. Final data extraction was performed to analyze mortality and HCV cure rates. Statistical analysis was performed using the R Statistical Software (R package version 4.2.1; R Core Team 2022).

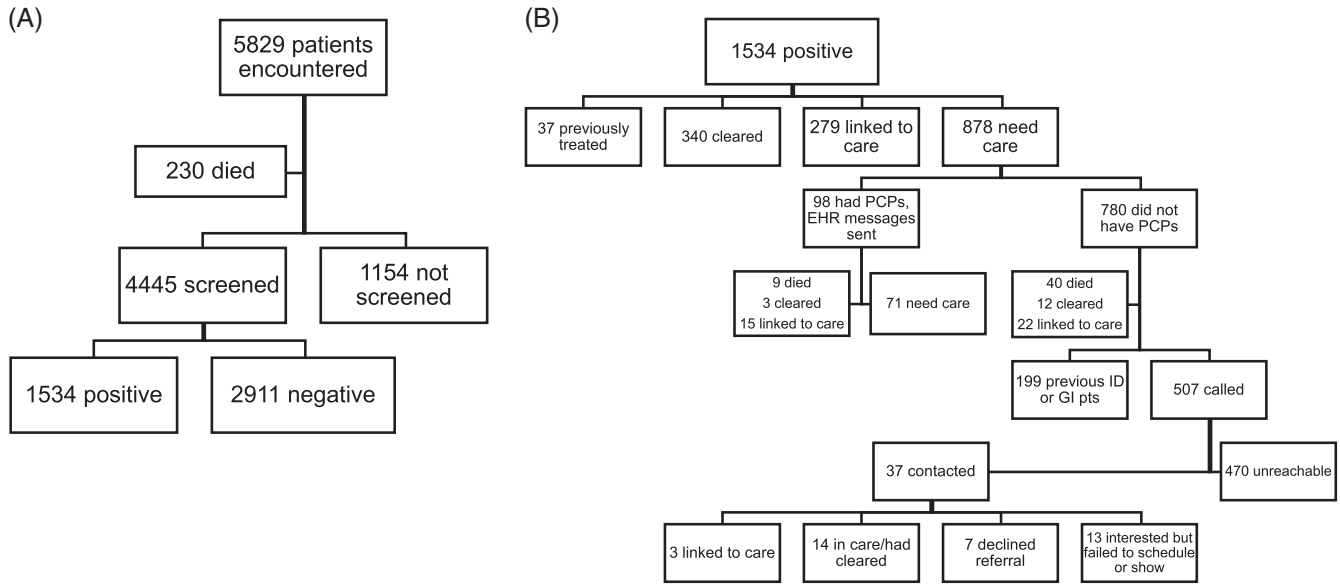

FIGURE 2 (A) Patients by HCV screening status. (B) Disposition of patients who are HCV-positive. Abbreviations: EHR, electronic health record; PCP, primary care provider.

This project was part of a quality improvement initiative and was reviewed by the local Institutional Review Board.

RESULTS

Between May 16, 2018, and November 30, 2020, 5829 unique patients with OUD had encounters within the health system, of whom 4631 were tested for HCV (79.4%) (Figure 2A). The baseline screening rate in the population with OUD over the 2 years prior to our intervention was 8%. Testing locations included: 2421 (52.3%) in acute care, 422 (9.1%) in an emergency department, and 1788 (38.6%) in an ambulatory clinic. Patients tested in the acute care and emergency departments settings were more likely to test positive than those tested in the ambulatory setting (OR = 2.21, 95% CI [1.93, 2.54], $p < 0.001$ and OR = 2.49, 95% CI [2.00, 3.10], $p < 0.001$, respectively).

At the time of baseline data extraction, 230 patients (3.9%) had died. Of the deceased patients, 80 were positive for HCV, 106 were negative, and 44 were not screened. Of the remaining patients (n = 5599), 48.9% were female; the average age was 40.9 years; 73.7% were White, 21.8% were Black, and 4.4% were other (Table 1). Of the 5599 patients, 4445 were screened and 1154 were not screened. Of the 4445 patients, 1534 patients (34.5%) tested positive for HCV (46.6% female; average age 39.9 y; 86.4% White, 11.1% Black, 2.5% other) (Table 1). White patients made up a greater proportion of the seropositive cohort than the seronegative (OR = 3.08, 95% CI [2.61, 3.63], $p < 0.001$) and untested cohort (OR = 2.32, 95% CI [1.91, 2.82], $p < 0.001$).

Concurrent HIV screening yielded forty positive results. Of these, 16 (40.0%) were falsely positive, 13 had a known HIV diagnosis (32.5%), 6 were deceased (15.0%), and 5 (12.5%) were newly diagnosed and referred for care.

Primary endpoint, linkage to care

At baseline, 279 (18.2%) patients in the seropositive cohort were linked to care with an HCV specialist, 340 (22.2%) had known spontaneous viral clearance, 37 (2.4%) had been previously treated unbeknownst to the ordering provider, and 878 (57.2%) were not successfully linked to care (Figure 3). Of those patients not

TABLE 1 Age, sex, and race, by cohort

	Entire population,[a] n = 5599	Seropositive population, n = 1534	Population linked to care, n = 326
Average age (y)	40.9	39.9	40.3
Sex, n (%)			
Male	2863 (51.1)	819 (53.4)	168 (51.5)
Female	2736 (48.9)	715 (46.6)	158 (48.5)
Race, n (%)			
White	4129 (73.7)	1325 (86.4)	283 (86.8)
Black/AA	1223 (21.8)	171 (11.1)	38 (11.7)
Other	247 (4.4)	38 (2.5)	5 (1.5)

[a]Number of living patients at the time of primary analysis, excluding 230 deceased from the initial population (n = 5829).
Abbreviation: AA, African American.

linked to care, 540 (61.5%) had a lack of appropriate referral, and 338 (38.5%) were not adherent to the medical care plan (patient-directed discharges or outpatient no-shows).

Results of patient outreach

Attempts were made to link patients who were HCV-positive to care for those who had a PCP or a previous relationship with an HCV specialist (Figure 2B). Ninety-eight patients had in-network PCP. Messages in the EHR were sent to these PCPs to explain the test results, the next steps, and the referral process. Of the 780 patients without in-network PCPs, 40 were found to be deceased, 12 spontaneously cleared, and 22 were linked to care. Of the 706 remaining patients, 199 had pre-existing relationships with an HCV specialist. Requests were made to these specialists to schedule patients for office visits. Telephonic outreach was administered to 507 patients. For telephone numbers that were no longer in service or unanswered calls, a secure message was sent if the patient had an active EHR patient portal account. Thirty-seven patients were contacted: three had successful linkage to care, 14 were in care or had been told they had HCV viral clearance by a provider outside of our system, four declined referral stating they would seek care on their own, 3 declined referral stating they could not afford the visit, and 13 expressed interest in treatment but ultimately failed to attend a scheduled visit or did not respond to requests to make an appointment. The remaining 470 patients were unreachable by phone or through the EHR patient portal.

After patient outreach, 326 total patients were linked to care (23.0%), 368 (26.0%) had known spontaneous viral clearance, 34 (2.4%) had been previously treated unbeknownst to the ordering provider, and 689 (48.6%) were not successfully linked to care (Figure 3). From the initial seropositive cohort (n = 1534), 117 patients died (n = 1417). Patients who had an established PCP had a linkage rate of 16.9% compared to 8.0% for patients without an established PCP. Notably, the primary care clinic with the highest linkage rate, (60%, 6/10) also had a robust medication-assisted (MAT) program. Of the 326 patients linked to care, 158 (48.5%) were female, 283 (86.8%) were White, 38 were Black (11.7%), and 5 (1.5%) were of other races. The average age was 40.3 years (range 20–72) (Table 1).

Secondary endpoint: cure

Of the 326 with a successful linkage to care, 113 (34.7%) had a documented cure for HCV. An additional 55 (16.9%) patients had a possible cure.

Secondary endpoint: mortality

The overall mortality rate was 8.5% (495/5829). Patients who were HCV-positive had a mortality rate of 12.2% (197/1614) compared to those without HCV, who had a mortality rate of 7.4% (224/3017). Untested patients had a mortality rate of 6.2% (74/1198). Overall, there was a significantly higher rate of mortality in the seropositive cohort than in both the seronegative cohort (OR = 1.72, 95% CI [1.41, 2.11], $p < 0.001$) and the untested cohort (OR = 2.10, 95% CI [1.59, 2.77], $p < 0.001$).

DISCUSSION

We incorporated HCV and HIV testing into our enterprise-wide clinical workflow as part of an opioid quality initiative at our health care organization. While previous studies have examined the effect of implementing EHR clinical decision-support tools on HCV testing rates, the study populations have been limited by birth cohort (ie,

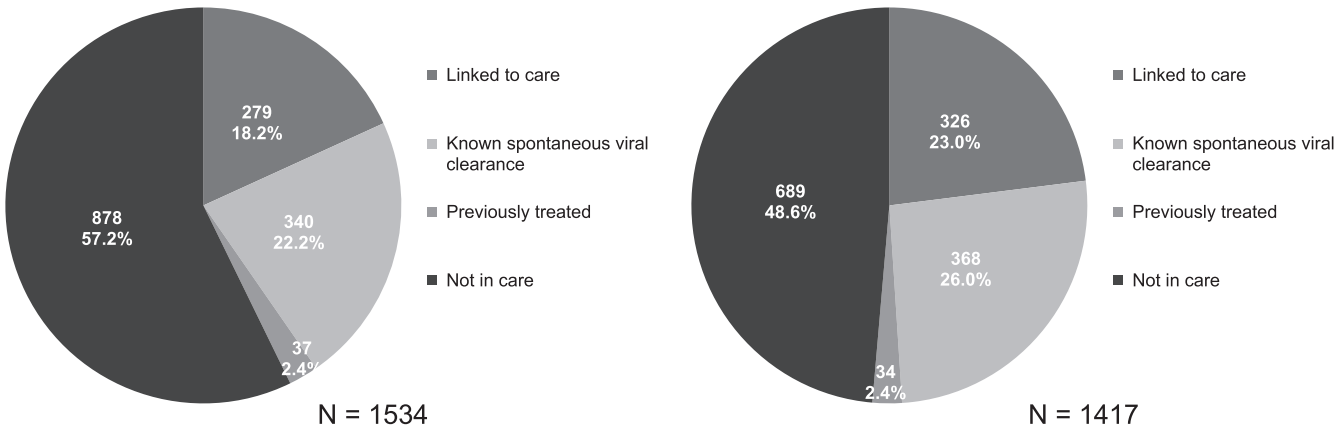

FIGURE 3 Positive HCV screens by disposition, at the time of baseline data analysis (n = 1534) (left), and after attempted linkage to care (n = 1417) (right).

baby boomers) or specific settings of care.[25–31] Our review revealed that a workflow implementation strategy was highly successful in screening patients, with 79.4% of patients with OUD tested for HCV during the study period, a sharp contrast from the two-year preintervention period, when baseline screening for HCV in the population with OUD across settings was 8%. In addition, 27.7% of patients who were screened tested positive for HCV, a rate similar to other studies, lending further evidence that a strategy of using EHR interventions to identify patients with OUD who are HCV-positive is worth pursuing.[10] Utilizing screening for HCV across care settings allowed for the identification of patients with HCV who often did not have access to or an established relationship with a PCP. Patients in the acute care setting and emergency departments were more than twice as likely to test positive compared to those in the ambulatory setting, suggesting that these venues of care remain vital locations for identifying HCV-positive patients.

It is also notable that at the time of initial data extraction, 3.9% of individuals with OUD had already died and by the end of the study, 8.5% had died. The seropositive cohort was 72% more likely to die compared to the seronegative cohort and was more than twice as likely to die compared to the untested cohort. This indicates the devastating effect of OUD on patient mortality. It is likely that these numbers underrepresent the true mortality rate, as patients may have died in settings outside of our health system.

After the initial HCV testing, in the absence of additional patient outreach, only 18.2% of patients were linked to care, a number lower than that noted in other studies.[32,33] Several factors likely played a role in this. First, patients with substance abuse disorders are disproportionally affected by homelessness, lack of medical resources, behavioral health comorbidities, and social vulnerabilities.[14,20] Second, many of these patients were tested in acute care settings when more urgent or emergent medical problems were being addressed, making follow-up care for HCV evaluation and management less of a priority for health care providers. Finally, many of these younger patients did not have established PCPs to facilitate further management of HCV infection in ambulatory settings.

Even after efforts were made to contact patients to get them into care, only 23% of patients were linked to care, most of whom were linked outside of project-specific interventions. This finding is similar to other studies where screening in nontraditional settings, such as an MAT clinic and the emergency department, was highly effective at identifying and diagnosing patients with HCV, but the linkage to care in this population remained low.[20–22]

Additional barriers to patient outreach were also encountered. There was a long interval from when patients tested positive for HCV in clinical settings to the attempted outreach time. This delay led to changes in the patient contact information, which was frequently inaccurate. When facilitating contact through their PCP, patient medical records were not always up-to-date, and patient relationships with the listed PCP were not current.

Not included in the BPA prompt or laboratory results was concurrent provider education on the rationale and interpretation of HCV laboratory testing, which patients were appropriate for HCV specialist referral, or how to make those referrals. Point-of-care education and a simplified referral process utilizing EHR decision support would likely have increased the percentage of patients with HCV linked to care. Provider education efforts targeting high-yield specialties such as Behavioral Health, Emergency Medicine, Hospital Medicine, and Obstetrics would be particularly helpful in keeping providers up to date with best practices, reminding them of the outstanding success rate of DAAs, and updating outdated views on HCV therapy, such as active substance use being a contraindication to treatment.[10] A growing body of evidence strongly supports HCV treatment for active or recent IDU, as SVR rates at 12 weeks are comparable to those without current IDU.[34]

Although the sample size was small, we note that patients who had an established primary care relationship with a provider who prescribed MAT were more likely to be linked to HCV care after patient and provider outreach. This may be because these patients have developed trust in their provider, more reliable follow-up, and better control of their substance use disorder through MAT. In addition, these providers may be more well-versed in the current HCV therapy guidelines. There is emerging evidence that concurrent initiation of MAT with HCV treatment in people with injection drug use can result in high rates of SVR while also reducing risks associated with IDU.[35]

There were higher positive HCV rates among the White population. While 73.7% of the patients who were screened were White, they comprised 86.8% of those who were positive. Patients in the seropositive cohort were more than twice as likely to be White compared to those in the untested cohort, and about three times as likely to be White compared to the seronegative cohort. This likely reflects the higher prevalence of injection drug use among non-Hispanic Whites.[36]

Despite the challenges identified in this study, 168 patients were either cured or likely cured. HCV cure is associated with a reduction in the long-term sequelae of HCV infection, including cirrhosis and HCC, as well as reduced health care costs.[37] It is estimated that 20–25% of patients with HCV will go on to develop cirrhosis, suggesting that ~40 patients in this study avoided cirrhosis and its complications.[38] The cure/possible cure rate was still relatively low (51.6%) in the population that was linked to care. This highlighted the difficulty in maintaining adherence to care after the initial visit. Improving the opportunity patients with HCV have

in receiving DAAs is vital, given how successful this treatment can be even in the absence of traditional providers and laboratory follow-up. The foundational MINMON trial recently demonstrated that upon dispensing DAA therapy, over 99% of the patients initiated treatment and 95% had an SVR despite no lab or follow-up visits during the treatment course, arguing that if the drug is dispensed, then a cure is likely.[39] Likewise, updated Infectious Diseases Society of America-American Association for the Study of Liver Diseases guidance supports a minimal monitoring approach as leading to safe and effective treatment with SVR rates comparable to traditional approaches.[34]

Study limitations

This retrospective review relied on both automated and manual chart audits. When determining disposition, incomplete medical records and the challenges posed by multiple EHRs across health systems may have contributed to misclassification. Some patients may have been misclassified as spontaneously cleared if they had been treated and cured elsewhere. In addition, patients may have been linked to care in outside health systems, which is not evident in the EHR.

When looking at mortality, although the entire dataset was queried to obtain deaths at the end of the study period, manual chart reviews were performed solely on the seropositive cohort. Some patients discovered to be deceased had not been designated as such in the chart. This may have led to more deaths in that cohort than in the others.

CONCLUSION

In this study, we found that testing patients with OUD using an EHR decision-support tool across multiple sites of care was highly effective in identifying patients with HCV. However, linking patients with HCV to care was less successful, likely due to significant social challenges in this population, as well as a lack of education and decision support to assist providers in making those referrals. Patients with OUD who used MAT were those most likely to be linked to care. The mortality burden of patients with OUD remains high. We recommend continued use of EHR tools to facilitate HCV testing and more prescriptive decision support to facilitate linkage to care for patients with OUD.

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CONFLICTS OF INTEREST

The authors have no conflicts to report.

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