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ORIGINAL PAPER

Increasing Birth Cohort Screening for Chronic Hepatitis C in a Primary Care Clinic with Panel Management

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Abstract
Chronic hepatitis C affects millions of people worldwide and patients born between 1945 and 1965 are at elevated risk. Hepatitis C infection can lead to health complications including liver cirrhosis and hepatocellular carcinoma. Recent advancements in direct-acting antiviral treatments have placed the spotlight on primary care providers to identify undiagnosed patients with chronic hepatitis C for treatment and attaining a sustained-virologic response. Primary care providers do not routinely screen patients born between 1945 and 1965 for hepatitis C despite CDC recommendations. To evaluate the effectiveness of a hepatitis C screening protocol implemented in a primary care setting with no prior protocol. A multidisciplinary team was used to implement a hepatitis C screening protocol for patients born between 1945 and 1965 (birth cohort screening). A retrospective analysis was conducted to compare the rate of hepatitis C screening 2 years before and 2 years after the protocol was implemented. Frequency data were collected monthly and tracked in a run chart noting relevant events that affected screening. In the 2 years before the screening protocol began, 81 patients were screened (average = 3 per month); and in the 2 years after the intervention was implemented, a total of 637 patients were screened (average = 25 per month). The protocol was successful in increasing screening rates from 15 to 66% in the 2 years post-intervention. This quality improvement study demonstrated that targeting the birth cohort population was a successful method for increasing hepatitis C screening in a primary care clinic.

Keywords Hepatitis C/diagnosis · Primary health care · Mass screening/methods

Background

Problem

Chronic hepatitis C (HCV) is a public health concern affecting 3.5 million Americans and 71 million people worldwide [29]. In 2018, the Centers for Disease Control and Prevention (CDC) estimated that 1.75 million Americans were HCV infected, but unaware [8]. Each year approximately 399,000 people die as a result of HCV, primarily due to cirrhosis and hepatocellular carcinoma [29].

Hepatitis C infection that has been present for less than 6 months is considered an acute infection and may clear without treatment in 15% to 25% of cases [7]. However, according to the Centers for Disease Control and Prevention [7], 75 to 85% of people infected with HCV will develop a chronic infection and 10 to 20% will develop cirrhosis over two to three decades. Among patients who develop cirrhosis, the annual risk of hepatocellular carcinoma is 1 to 5%; and roughly 3.6% of cirrhotic patients will develop hepatic decompensation with a mortality rate of 15 to 20%.

Contributing Factors

The most common risk factors for HCV include history or receipt of: intravenous or inhaled drug use, blood transfusion or organ donation before 1992, clotting factors before 1987, long-term hemodialysis for kidney failure, HIV, piercing

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or tattoo with unsterile equipment, born to HCV-positive mother, incarceration (e.g., unregulated exposure to tattoos and piercings in prison), needle stick injury among health care workers, and adults born between 1945 and 1965 due to a high risk of exposure to infected blood products and unsterile medical equipment [3, 5, 8, 10, 15, 16, 19–21, 23, 31]. Less common risks include history of or current: sexual contact with a person infected with HCV, sharing razors, toothbrush, or other personal care items that may have come into contact with blood from a HCV infected person [2, 11, 24]. After exposure, the exact time it takes the virus to progress can vary [27] and because patients are typically asymptomatic in the early stages, patients are often undiagnosed [29].

CDC Guidelines

In 1998 the CDC released HCV screening guidelines that recommended screening patients based on risk factors only [9]. After a systematic literature review concluded that 808,580 more cases of HCV were identified using birth cohort screening compared to screening patients based solely on risk factors, the CDC updated their HCV screening guidelines to recommend a one-time screening of patients born between 1945 and 1965 [23].

Birth Cohort Screening

Adults born between 1945 and 1965, or the birth cohort group, have the highest incidence of HCV infection compared to groups with other risk factors and due to the many different possible modes of HCV transmission, many adults born between 1945 and 1965 do not know when or how they were infected. This birth cohort accounts for three-fourths of all identified HCV infections [8].

A retrospective record review by Mahajan et al. [18] examined the indication for birth cohort testing to identify patients with current or past HCV. The researchers collected HCV screening data from a national database from four states: Colorado, New York, Connecticut, and Minnesota [18]. By tracking the indications for HCV test orders, the researchers were able to observe the difference between birth cohort screening and screening based on risk factors per past CDC recommendations [18]. There were 110,223 cases of past or present HCV infections from 2004 to 2010. The results showed that testing those in the birth cohort as well as patients with a history of IV drug use (62% of sample) accounted for 74% of all cases of HCV. A total of 77% were identified when combining birth cohort screening with any CDC risk indication. This analysis indicated that 68% of patients with HCV would have been detected using birth cohort screening criteria, but only 27% would have been screened using risk-based screening criteria [18].

A prospective cohort study conducted by Turner et al. [26] tested the effectiveness of HCV screening among the birth cohort population in a large public hospital serving low-income patients in south Texas. The findings substantiated the high incidence of HCV infection among the birth cohort population and identified a number of significant predictors for infection.

These results indicate that there is a high prevalence of HCV among patients in healthcare settings that serve a low-income population [26]. Screening the birth cohort population in a low-income setting is important because there are other factors that may be associated with a higher HCV prevalence, such as being uninsured, male, and being Hispanic. The results of this study offer evidence for HCV screening in the birth cohort population and the advantage of screening within a low-income care setting [26].

A randomized control trial by Yartel et al. [30] compared the use of three targeted interventions to usual care on the effect of screening the birth cohort population for HCV: (1) integrated electronic medical record (EMR) best practice alert system (BPA) (n = 8992), (2) repeated mailing (n = 14,475), and (3) outreach and patient solicitation (n = 8873).

The investigators found that any of the three interventions were eight times more likely to identify HCV compared to usual care (relative risk for screening [RR] = 8.0; 95% CI 2.8–3 adjusted for any of the 3 interventions [$p = 0.27\%$] versus usual care [$p = 0.03\%$]). These interventions showed birth cohort screening was effective in identifying patients who were previously undiagnosed with HCV. The large sample size and randomized design provide credible evidence to favor birth cohort screening versus risk factor screening that is often the standard of practice in usual care.

Cost

Screening patients with HCV is also important because it can help prevent long term liver complications, such as cirrhosis and hepatocellular carcinoma [29]. Birth cohort screening can also be cost-effective. Smith et al. [23] found that cohort screening with a one-time screening test and linkage to care and treatment, can identify an estimated 800,000 infections and prevent 120,000 HCV related deaths. This can potentially save $1.5 to 1.7 billion in liver-related mortality.

HCV Screening in Primary Care

Despite CDC recommendations, primary care providers do not routinely screen patients for HCV [4]. This lack of screening for HCV is not only because the disease is asymptomatic during the early stages, but also because of barriers that exist, such as inadequate provider knowledge, patients' lack of health insurance, and lack of CDC-adherent

guidelines or policies for HCV screening in the practice setting [4, 13]. Furthermore, Jewett et al. [13] found that even when primary care providers do screen patients for HCV risk factors, they still fail to assess for all HCV risk factors, further reducing opportunities for early detection and treatment. In two studies of primary care providers in multiple primary care locations, only 59% reported that they assessed for HCV risk factors and 92% of patients who had HCV risk factors did not get tested for HCV [1, 22].

Objective

There is a push for Federally Qualified Health Centers (FQHC) to increase birth cohort screening rates for HCV as the standard of care [28]. This recommendation is consistent with the 2012 CDC Guidelines. Despite these recommendations, many primary care settings do not currently adhere to the guidelines for birth cohort HCV screening. The purpose of this study was to evaluate the effectiveness of a HCV screening protocol implemented in a primary care practice setting.

Methods

Design

This retrospective analysis used a repeated measures design. Outcomes were measured for each of the 2 years prior to and after HCV Protocol implementation (November 2014–November 2018: 48 months total).

Setting

This project was implemented at a primary care outpatient community clinic that serves a diverse urban population, a federally qualified health center in Northern California. The population consisted of: 47% Latino, 21% Native American, 20% African American, 12% Euro American, 9% Asian/Pacific Islander, and 1% unknown patients.

The clinic staff included five nurse practitioners, two physicians, and five medical assistants, one HCV clinic champion, one clinical data manager, two administrators/schedulers, and two panel managers. There was no HCV protocol in place prior to November 2016. Results were not evaluated prior to this study.

Subjects

De-identified and aggregated data for all adults seen at the clinic born between 1945 and 1965 with no history of HCV antibody screening (anti-HCV) were included in analyses. During the study period, there were 968 patients who were eligible for screening (born between 1945 and 1965) with 550 total in the period before implementation with increasing patient enrollment in subsequent years. The university institutional review board approved this study.

Intervention

The HCV screening protocol was developed by the HCV clinic champion based upon the 2012 CDC guidelines that included screening patients who were born between the years of 1945 and 1965 [23]. Additionally, the protocol outlined steps for optimal HCV screening including a detailed step by step process of required lab orders, diagnosis codes, staff responsibilities and their documentation. The protocol also included information on when to screen a patient based on risk factors and abnormal liver function tests. (Though the protocol included a treatment algorithm for patients who screened HCV positive and a general overview of screening patients based on risk factors and unknown elevation of liver enzymes, this study focused only on screening.)

Procedures

Training

A mandatory, 15-min in-service training was provided during an all-staff meeting with panel managers, medical assistants, and providers. The training included the purpose, practice guidelines, and procedures for the HCV protocol. All staff received hard copies of the protocol and an electronic copy was saved to a shared drive for future reference.

Panel Managers

Panel managers identified eligible patients born between 1945 and 1965 in the electronic medical record and contacted them by phone by phone to schedule a provider visit for HCV antibody testing. Thereafter, panel managers called to remind patients of scheduled appointments and to follow-up when a patient did not keep the scheduled appointment.

Panel managers also managed workflow for providers. They added standing orders to electronic medical records that alerted providers and medical assistants to required labs and HCV screening needed and generated daily reports to guide protocol-related tasks for the day based upon the patients scheduled. When HCV screening was completed, panel managers removed patients from contact lists and removed standing orders for screening.

HCV Clinic Champion

The HCV clinic champion facilitated efficient workflow by checking in regularly with staff on the floor, answering

questions, and reinforcing training as needed. HCV Management Team meetings were held every quarter to ensure adherence to the protocol and to discuss updates or improvements in workflow as needed.

Data Collection

The frequency of HCV screening was measured each month for 48 months (24 before and 24 after implementation). Data were extracted by panel managers using i2iTracks software, data analytics and tracking software that uses risk stratification and analytics through predictive models and stratification logic to identify relevant patient data [12].

Analysis

The frequency of patients screened each month was calculated. Microsoft Excel was used for data storage and analysis. A run chart was used to examine screening rates 2 years before and after the intervention noting protocol changes and relevant events that affected screening.

Results

In the 2 years before the screening protocol began, 81 patients were screened (average = 3 per month); and in the 2 years after the intervention was implemented, a total of 637 patients were screened (average = 25 per month). The run chart (See Fig. 1) displays the month-to-month screening frequency including noteworthy events that occurred throughout the evaluation period. The greatest increase in screening occurred after the initial implementation in November 2016 with periodic decreases when there was turnover in the panel manager position.

The screening rate summary chart is displayed in Fig. 2. Prior to the implementation, 15% of all eligible patients (n = 550) were screened for HCV. The screening rate for patients post-intervention was 66% of all eligible patients (n = 968) were screened for HCV.

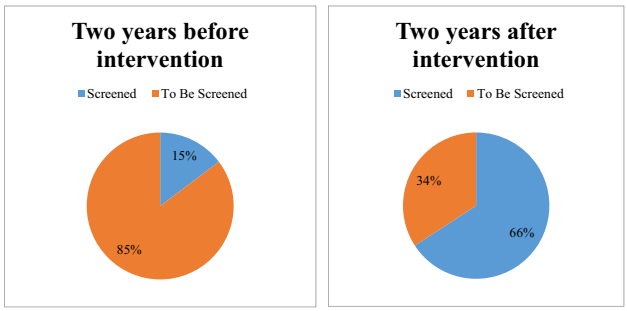

Fig. 2 Pre- and post-intervention HCV screening effectiveness (Color figure online)

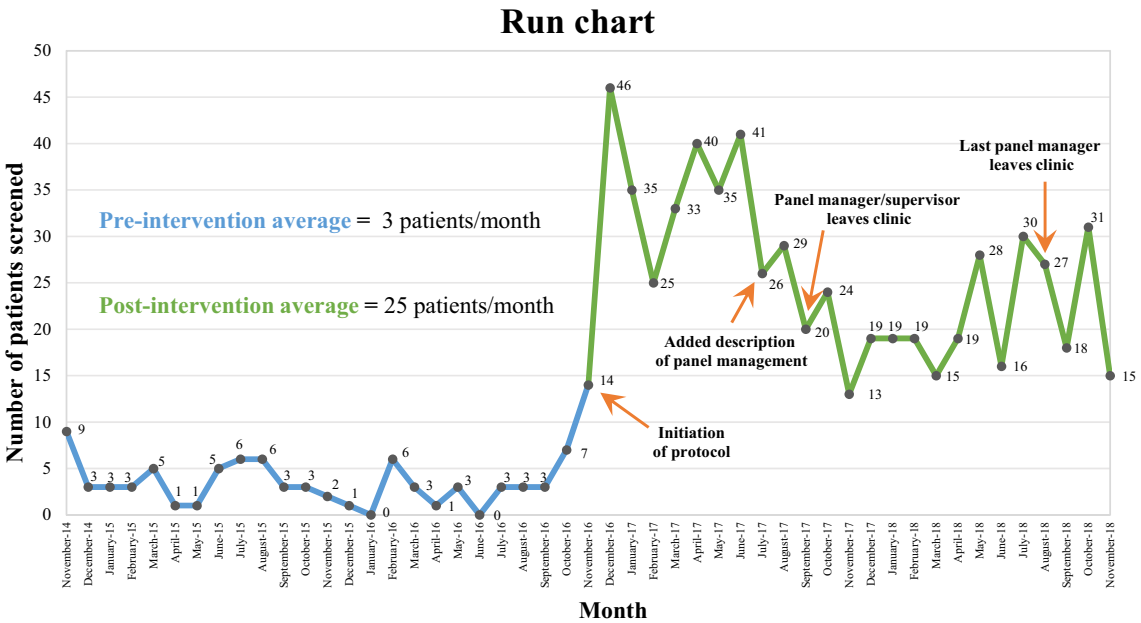

Fig. 1 Monthly frequency of patients screened for HCV before and after protocol implementation (Color figure online)

Discussion

The purpose of this study was to evaluate the effectiveness of a HCV screening protocol in a primary care clinic. The protocol was successful in increasing screening rates from 15 to 66% in the 2 years post-intervention. These results are consistent with a study by Trinh and Turner [25] that found that implementing an HCV screening protocol increased HCV screening rates from 24 to greater than or equal to 90%.

Screening and Panel Management

HCV screening decreases following panel manager turnover indicates that this facet of the intervention could have weighed heavily in the screening intervention's effectiveness. When both panel managers left the clinic in July 2017 and August 2018, the largest decreases occurred in patients screened. The results of a study by Litaker et al. [17] supports the role of panel management in chronic disease care. The investigators found that teams consisting of a nurse practitioner, physician and patient management personnel were effective in reducing hemoglobin A1C (−0.7%, $p = 0.02$) among patients with diabetes.

No-Show Rates

Some decreases in screening rates could also be attributed to the number of patients who did not keep scheduled appointments. According to clinic staff, the no-show rate at the study site was 36% (B. Trinclisti, personal communication, December 6, 2018). A study by Cachay et al. [6] found that among patients with HCV and HIV diagnoses, predictors of high no-show rates included: ongoing drug use, being non-white, and a history of psychiatric disorders. Also, a study by Kheirkhah et al. [14] found that primary care had the highest no-show rates compared to other specialty clinics. This evidence further supports the value of panel management that includes reminder phone calls and follow-up for no-shows, strategies used by panel managers in this study.

Limitations

This study should be considered in the context of a few limitations. The funding received to implement the HCV Protocol provided financial resources for electronic health records, data analytic software, and laboratory blood draws. As a result, it might be difficult to replicate in a practice site that lacks these resources.

Further, staff turnover, the continuous flow of patients into and out of the service, and the dynamic nature of the protocol implementation contributed to HCV screening variability from month to month. It is unknown if one aspect of the protocol was more effective than another in achieving the final results; however, the increase in screening rates after implementation were consistently above pre-intervention levels. This allowed HCV positive patients who might not have been otherwise identified by risk factors alone to receive treatment.

Finally, not all patients who were eligible for screening had a working telephone number in the electronic health record and the panel manager was unable to make outreach and follow-up calls. Nonetheless, panel managers continued to create standing orders for patients to alert providers for the need for screening even if they could not be reached by phone.

Conclusion

This quality improvement study demonstrated that targeting the birth cohort population was a successful method for increasing HCV screening in a primary care clinic. There was a significant increase in HCV screening after the intervention was initiated. It is believed that that this was in large part due to panel management, both its oversight and ongoing evaluation. Panel management is a strategy that can be applied in similar settings to meet chronic disease screening objectives. Future research should also include the use of panel management for its role in increasing HCV treatment and cure once detected.

Compliance with Ethical Standards

Conflict of interest The authors in this study have no conflict of interest or financial gain to report.

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