HEPATITIS C SCREENING, DIAGNOSIS AND FOLLOW-UP CARE

BY CONSTANCE M. FLYNN

SCHOLARLY PROJECT SUMITTED TO THE FACULTY OF THE

SCHOOL OF NURSING

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

FOR THE DOCTORATE IN NURSING PRACTICE DEGREE

UNIVERSITY OF MASSACHUSETTS LOWELL

2018

Community Mentor: William DeMarco, DO, SFHM, FACOI, Chief, Hospital Medicine

Berkshire Medical Center, Pittsfield, MA 01201

Scholarly Project Chair: Lori Keough, PhD, M.Ed, FNP-BC, PMHNP-BC

Assistant Professor, Assistant Professor College of Health Sciences

Susan and Alan Solomont School of Nursing, University of Massachusetts, Lowell

Abstract

Chronic Hepatitis C Virus (HCV) infection causes more deaths than all infectious diseases combined. Direct acting antivirals (DAAs) may cure over 90% of HCV infections. The Center for Disease Control (CDC) recommends screening high risk and baby boomer birth cohorts (CDC, 2015a). Those testing positive for HCV antibodies require HCV RNA to confirm infection. Positive HCV RNA necessitates follow-up with a primary care provider (PCP) or HCV specialist. This project was designed to determine if educating a group of PCPs on CDC HCV testing sequence would improve diagnosis and follow-up care. An educational presentation on CDC HCV guidelines was provided to group of PCPs. Rates of HCV screening, diagnosis and follow-up appointments were collected three months pre/post intervention. Descriptive statistics were used to compare rates of HCV screening, RNA confirmation and follow-up care. Although pre-post screening rates were nearly identical with all HCV positive patients receiving confirmatory diagnosis and follow-up, the overall project impact was not anticipated. The end result led to automated reflex HCV RNA confirmatory testing, formation of a hospital/ community task force to examine HCV treatment access, and establishment of a hospital based HCV clinic. In addition, there were multiple HCV educational presentations for providers and allied health personnel. There was increased local media attention (television, newspaper) on the HCV epidemic, which improved community awareness of the need for HCV screening and treatment.

Keywords: HCV birth cohort screening, HCV RNA, CDC HCV sequence, HCV link-to-care

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Viral hepatitis has been a reportable disease since 1982 and is currently considered the most common blood-borne infection in the United States (U.S.) and worldwide. HCV infection affects an aging population and is the fourth leading cause of death in persons aged 45-64 years (Gaetano, 2014). "Of the estimated 3.2 million people chronically infected with hepatitis C in the U.S., approximately 75% were born during 1945-1965" (CDC, 2017a). The World Health Organization (WHO) estimates 71 million people globally have chronic HCV infection, surpassing Human Immunodeficiency Virus (HIV). In 2015, 20% of infected people (14 million) knew their diagnosis, 7.4% (1.1 million) began treatment, while approximately 700,000 people died from HCV-related liver disease (WHO, 2016).

In 2013, HCV-related mortality surpassed the total combined number of deaths from 60 other infectious diseases reported to CDC, including human immunodeficiency virus (HIV), pneumococcal disease, and tuberculosis (CDC, 2016). The prevalence of chronic HCV infection is estimated between 2.7-3.9 million people in the U.S. HCV infection reached peak viremic prevalence in 1994 with approximately 3.3 million infections in the U.S. Although HCV prevalence declined, advanced liver disease increased, with compensated cirrhosis peaking in 2015 and decompensated cirrhosis predicted to peak in 2019 (Razavi et al., 2013).

Following the CDC recommended testing sequence for identifying HCV infections could be an initial step toward eradicating this disease. Primary care providers (PCPs) are essential to screening, diagnosis and referral to follow-up care. Brau (2012) emphasized the value of PCP referrals to infectious disease specialists to provide HCV information, counseling and treatment options, similar to how HIV care was embraced for the past 30 years. Adherence to CDC HCV testing sequence guidelines is essential to decrease prevalence (CDC, 2015a; AASLD, 2016).

Background

The incidence of Hepatitis A Virus (HAV) and Hepatitis B Virus (HBV) declined since vaccines became available (1995 and 1982 respectively). Unfortunately, HCV vaccine development has been difficult due to numerous genotypes. Screening at risk and birth cohorts with known high incidence of HCV has been recommended since 2012, but guideline adherence rates are unknown. "While HCV incidence in America has been steadily declining, it is once again on the rise among young, non-urban white males, mainly because of increasing intravenous drug use in this population" (Shaffer & Ahuja, 2017). Southern et al. (2014) found providers may not adhere to risk-based testing due to the sensitive nature of questions. Improved PCP HCV screening practices for both the high risk and baby boomer population cohorts has never been more important, particularly with the new Direct Acting Antivirals (DAAs) offering high cure rates. Disease stigma may be a barrier to seeking HCV treatment with infected persons labelled by others as undesirably different and subject to exclusion, rejection, blame or devaluation. Many patients describe the clinical encounter as a site of stigmatization, leading to a lack of trust in health care providers (Treolar, Research, Wales, Munchen, & Tal, 2013; Rogal, et al., 2016).

Prevalence of HCV related cirrhosis steadily increased from 5% in 1989, 10% in 1998, to 20% in 2006. The proportion began to rise sharply after 1990, as the age and duration of those infected began to increase (Davis, Alter, El-Serag, Poynard & Jennings, 2010). Without appropriate screening, patients exposed to HCV risk developing cirrhosis, hepatocellular cancer, and other HCV related diseases. Razavi et al. (2013) described the future impact of untreated HCV as a "dichotomy of HCV" due to the fact that overall HCV infections are projected to decline, but there will likely be an increase in advanced liver diseases, liver related deaths, and

healthcare costs. Because the disease has a 20-40-year delay from initial infection to the development of symptoms, 75% of those exposed to the virus between 1970-1990 are unaware they were infected (CDC, 2015b).

After initial HCV antibody screening, the challenge is to determine active infection with HCV RNA testing. It is estimated one third of HCV antibody positive patients did not have follow-up HCV RNA confirmation (Lutchman & Kim, 2015; McGibbon, Bornschlegel, & Balter, 2013). Quantitative HCV RNA test results are needed to confirm active HCV disease and refer patients to follow-up care. The final step is "link-to-care" for those with HCV infection. Less than 50% of patients identified via birth-cohort testing were referred to treatment and less than 10% started HCV therapy. In addition, further hepatic damage may be deterred if PCPs ensure HCV infected patients are immunized against Hepatitis A/B, abstain from alcohol, avoid hepatotoxic medications, and incorporate risk reduction practices. Link-to-care must become a priority to reduce HCV-related morbidity and mortality (Brau, 2013; Coyle, Kwakwa & Viner, 2016; Norton et al., 2016).

There is under-diagnosis and under-treatment of baby boomers, a known birth cohort with a high prevalence of HCV infection (Southern et al., 2015). HCV infection is not only preventable, but treatable and curable. Screening is essential to decrease morbidity, mortality, and cost related to the care of patients with HCV related chronic liver disease. HCV testing and treatment must become as routine as cholesterol and colon cancer screening and treatment. Only then will we see HCV patients living long, healthy lives (CDC, 2016).

Project Purpose

The goal of this project was to improve compliance with CDC HCV high-risk and baby boomer screening and testing sequence (CDC, 2015a) by examining the impact of an HCV

educational intervention for primary care providers on the number of birth cohort patients tested, diagnosed and referred to follow-up care following the presentation. HCV screening, diagnosis and follow-up care for the birth cohort born between 1945 and 1965 was examined at a primary care site in a small, rural county in the Northeast. PCPs have been considered a key component for identifying and managing care of patients with active HCV infection.

Methods

A quasi-experimental design was used to evaluate the effectiveness of an educational intervention designed to increase compliance with CDC recommended HCV testing sequence guidelines.

Setting and Sample

This project was conducted at a primary care practice affiliate with the local medical center in the Northeast part of the country. The population of the town was estimated by U.S. Census Bureau (2015) at 44,057 with a per capita income $26,913 and median household income $43,489. Total practice patient census was just over 4000. Average encounters are approximately 42/day and about 840/month.

The project sample consisted of six primary care providers from one practice who all agreed to participate and de-identified data from Electronic Medical Records (EMR). Data were collected for all patients over 18 years who had an initial HCV screening test during the study time frame. Patients with previously documented HCV infection were excluded.

Attendee Background Data

Two registered nurses (RNs) and six providers including one physician assistant (PA) and five physicians (N=6) attended the Hepatitis C Virus (HCV) educational presentation and

completed a post education survey to evaluate the quality of the program, assess participant prior knowledge of CDC HCV Guidelines and impact on future HCV testing (Table 1).

Attendees included five males/three females; 62% age 21-50; 38% age 51 and over. 84% of providers had 1-10 years' experience and 16% over 30 years' experience.

The five physicians were all medical doctors (MD), with one completing a post-doctoral fellowship in infectious disease but was practicing as a PCP. The PA and two RNs had baccalaureate degrees.

Procedure

Institutional Review Board approval was obtained to ensure participants' confidentiality and human rights protection. First, an educational intervention in the form of a presentation was developed by the researcher as described below. A recruitment letter was emailed to providers one week prior to the presentation. Consent to participate was implied by attendance at the presentation and completion of program evaluation. Information technology (IT) generated a list of patients who had HCV testing three-months pre/post the educational intervention. All records were de-identified prior to review by the researcher for determining RNA confirmation testing and follow-up appointment if indicated.

A flow chart was used to record patient birth years, provider type, and dates/results of HCV screening, RNA confirmation of HCV antibody positive results, and follow-up appointments as needed (Viral Hepatitis, 2016). All data was collected and stored in compliance with the Health Information Portability and Accountability Act (HIPAA). All providers were also de-identified and assigned a number. Pre/post HCV testing records were matched with the provider.

Intervention

The purpose of the study was explained at the beginning of the educational program. Providers attended a 45-minute PowerPoint presentation which included a discussion of objectives, hepatitis facts, CDC HCV screening guidelines, recent media attention, stigmatization, current treatments, disease burden, and initial primary care management. They received handouts depicting CDC HCV screening recommendations and testing sequence as a reminder to test birth cohorts and high-risk individuals. There were interactive questions and answers after the presentation followed by completion of an evaluation by participants.

Data

Provider characteristics included gender, age, role, education level, years of experience in practice. Pre and post-intervention data included participant satisfaction and knowledge surrounding program content and delivery as well as post-intervention evaluation responses of the educational program. Data from the EMR included birth year and gender of patients screened for HCV, follow-up RNA confirmation if indicated, and a match to a provider.

Analysis

HCV antibody testing rates before and after the intervention were compared to determine overall compliance with CDC HCV screening recommendations. Data were reviewed to determine HCV antibody screening rates, birth cohort screening rates, RNA testing and follow-up appointments for those confirmed RNA positive and actively infected.

Data were analyzed using excel and included descriptive statistics on participants as well as their knowledge of HCV screening rates pre and post intervention. Retrospective chart review was done to determine HCV antibody testing for the three months prior to the educational program and then for the following three months after the intervention.

Results

All respondents confirmed familiarity with CDC HCV Guideline and Birth Cohort Screening. 100% of attendees agreed or strongly agreed that the objectives were clear and met, the program was organized, and audiovisual aids/handouts were helpful. 99% of participants agreed or strongly agreed the information was relevant, and they gained new information and understanding of HCV guidelines sequence (Table 1).

Overall screenings rates were nearly identical in pre- and post-presentation periods. A total of 64 patients were screened for HCV antibodies prior to the presentation and were all HCV negative (100%). Following the presentation, 63 patients were screened for HCV antibodies with 59 HCV antibody negative (93.6%) and 4 HCV antibody positive (6.4%). All HCV antibody positive patients were screened with RNA test and referred to follow-up care if indicated as recommended by CDC HCV guidelines.

The majority of patients screened for HCV antibodies were baby boomers in both pre- and post-intervention periods. Of the patients screened for HCV antibodies, 59/64 patients were baby boomers (92%) and 5/64 were not (8%). Following the presentation, 56/63 patients were baby boomers (89%) and 7/63 patients were not (11%). Of the four HCV antibody positive patients, two (50%) were baby boomers; and two (50%) were born after 1965.

Changes in pre and post intervention screening rates among providers were not significant. It is not known how many encounters each provider saw during the time frame and among those how many met criteria for testing. Therefore, there was no benefit in comparing provider screening rates.

Discussion

Six providers and two registered nurses attended the educational intervention which provided information on HCV screening, diagnosis and follow-up care. Most providers were in practice less than ten years, during a time in which increased evidence-based HCV information has been available to the medical community. More recently, the general public has become more aware of higher rates of HCV in the community and curative treatment options.

Screening rates pre and post intervention among providers demonstrated little variation. All providers reported prior knowledge of CDC HCV Screening Guidelines, which may account for the limited change in screening rates. This was not surprising given the numerous educational campaigns sponsored by various entities such as CDC and pharmaceutical companies aimed at increasing knowledge of the need to provide HCV screening and referral to curative treatment.

This project was designed to improve HCV screening rates, confirm active HCV infection and ensure follow-up care by providing an educational intervention to a group of primary care providers. Testing for HCV antibodies was frequently done on patients throughout the health system, but RNA confirmatory testing was often not completed to confirm the presence of active infection. Although improved screening rates did not occur, those individuals who were HCV antibody positive had detectable RNA confirmatory testing with referral to follow-up care if indicated. Screening rates were likely consistent during the pre/post intervention period due to provider prior CDC guideline knowledge identified on post-education survey. The presence of a provider who specializes in infectious disease may have been a factor in this group being proactive in screening patients. An additional influence may have been recent increase in public service announcements and pharmaceutical advertisements about HCV baby boomer screening and treatment, particularly since the introduction of newer Direct Acting Antivirals (DAAs)

ledipasvir/sofosbuvir (Harvoni, 2014) and sofosbuvir/velpatasvir (Epclusa, 2016). Gilead, manufacturer of these medications launched an extensive marketing campaign called "Inside the huge ad blitz for a $1,100-a-pill hepatitis C drug," (2016) which promoted this treatment for HCV on digital/online media, and several magazines (People, Popular Mechanics, Better Homes and Gardens). Television commercials, and advertisements that were similar to public service announcements referred viewers to the Harvoni website for more information.

In 2015, the state where this study was conducted had 8470 confirmed or probable HCV cases with 2625 or 31% in the 15-29-year-old age group. During the same year, the county had 152 HCV confirmed or probable cases with 57 or 37% in the 15-29-year-old age group, the highest in the state. This is consistent with CDC findings that the opioid epidemic may be associated with increased HCV infection in younger PWID (CDC, 2017b) and the local epidemic of HCV infection among this group.

Screening rates may have been lower in the younger age group because there may be fewer of these patients seen at this practice, particularly since the overall population in this county is chronologically the oldest in the state. Additionally, younger persons and those with substance use disorders tend to have less frequent visits to health care providers, while older persons with co-morbidities likely visit providers more frequently. Lower screening rates among this population may also be due to primary care provider (PCP) discomfort asking about risks, particularly illicit drug use.

The most significant impact of this project were changes within the local health care system were not anticipated. Awareness of the prevalence of substance use disorders and co-existing HCV infections in the local community had become more evident.

The goal of the project was to develop a meaningful undertaking that would positively impact the health of individuals with active HCV infection by improving screening rates, RNA diagnosis confirmation when indicated and follow-up care. Prior to the initiation of the project, HCV testing primarily consisted of determining positive or negative HCV antibodies. Providers were not required to order HCV RNA on a patient with a positive HCV antibody, resulting in many patients with unconfirmed diagnosis. Meetings were arranged with the Department of Medicine, Division of Gastroenterology (GI) and Hospital Laboratory Service to discuss HCV testing. This resulted in almost immediate implementation of a mechanism for "reflex" or automatic RNA testing of HCV antibody positive patients to confirm active infection by detecting viral load. After his process was in place, there were additional discussions between these groups to discuss the local HCV epidemic and the anticipated increase in HCV diagnoses with the addition of reflex RNA confirmation and the need to ensure access to treatment. As a result, an HCV treatment task force was convened with representatives from the department of medicine, hospital medicine, quality improvement, infectious disease, GI, and inpatient laboratory services. Various representatives from other disciplines participated in these meetings throughout the next several months including trauma services, pharmacy, the local Regional Planning Commission and Department of Public Health. After more than six months of meetings, the task force recommended creating a clinic within the GI practice designed to manage care for patients with HCV infection. Patients attending the clinic could access care navigation to help with HCV treatment management and financial concerns.

Although overall project pre/post data remained fairly consistent, the response by the health care system to modify HCV laboratory diagnostic practices, increase education and support for providers and patients, and establish an HCV clinic to provide comprehensive care to patients

with active infection was an unexpected positive result. Although the intent of this project was to increase screening and confirmatory testing rates in the Baby Boomer population, the impact was stronger among younger people who inject drugs (PWID). Regardless, on a local level, practice changes will likely increase access to HCV care resulting in decreased virus exposure, transmission, and improved community health in this region.

As awareness of the HCV project became known throughout the healthcare system, requests were received to provide educational programs to area health care personnel and the local media. Multiple presentations were provided during the Summer/Fall 2017 to Advanced Practice/ Primary Care Providers, and Allied Health Personnel as well as interviews with the local newspaper, a regional television health education program, and a presentation at the annual health care system infectious disease conference.

Since DAAs have become available and promise high cure rates, continued research on vaccine development is unlikely. Therefore, education on risk reduction to prevent virus transmission, improved screening practices and appropriate HCV treatment are all essential in managing this epidemic and improving the health of the local community.

Strengths and Limitations

The project was conducted in a primary care practice located in a geographic area identified as an opioid "hot spot' by the Health Policy Commission for having higher than average opioid hospitalizations and deaths. As a consequence, rates of new HCV infections have increased, possibly attributable to lack of a local needle exchange programs (NEP) in an area with high rates of IV drug use at the time of the study. Since 2010, more than 1,100 new HCV cases were reported in the county, with actual numbers probably greater than 2,000 when considering potential unconfirmed cases (Parnass, 2016). HCV information has been increasingly reported in

the local media and members of the health care community have become more aware and interested in managing this public health epidemic on a local level.

The project was implemented in May, which coincides with U.S. Hepatitis awareness month. The educational presentation took place May 19, which is National Hepatitis testing day. The support of a national campaign designed to increase awareness at the same time as the project was initiated may have helped with acquiescence. Project limitations included using a small, single primary care practice in a limited geographical location in a rural community, generalizability is not possible.

Patients screened for HCV antibodies were consistent in the pre/post intervention period. Knowledge of the HCV project was known by the providers several months before completion. This may have been a threat to internal validity due to the Hawthorne Effect in which participant awareness of the expectation for the upcoming project led to a change in HCV screening practices prior to the intervention. This could account for lack of screening rate variation before and after the intervention.

The number of patients who met criteria for HCV screening was unknown. Although it may have been possible to determine the number of baby boomers encounters during the time periods before and after the intervention, it would have been challenging to determine patients who met testing eligibility requirements based on high risk behaviors. Additionally, identifying only baby boomer encounter does not tell the entire story. Even if these individuals were identified as being part of this cohort, there may be many reasons why testing was not completed. For example, the person may have had a one-time screening in the past or recently donated blood, making retesting unnecessary. During the planning stages, this additional data collection was not

considered because it was anticipated HCV screening rates result would increase rather than remain constant.

Conclusions

The tremendous impact of the project toward improving local care for patients with HCV infection was not anticipated. Public awareness of the local hepatitis burden, improved HCV screening, changes in diagnostic procedures, HCV education of health care personnel and patients regarding screening, diagnosis, and prevention strategies, improved access to treatment and collaboration with community agencies were all positive events that occurred as a result of the project.

Overall, the project increased awareness in both the medical community and the general public about the HCV epidemic looming in this beautiful resort area town nestled in the Northeastern mountains. Initiation of the task force and formation of the HCV clinic has changed the care of HCV infected patients locally. Both the cost burden and the adverse health effects associated with HCV makes ending this disease a priority. Implementation of improved diagnostic procedures and increased access to HCV patient care as a result of this project will hopefully help to significantly reduce this serious community health threat in the not so distant future.

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Table 1

HCV Presentation Evaluation Data

Demographic Data

Gender	Age Group	Provider Type	Education	Provider Experience
Male – 5	21-50 – 5	MD – 4	Doctorate/MD – 5	1-10 years – 5
Female – 3	Over 51 - 3	Resident/PA – 2	Baccalaureate – 3	Over 10 - 1
		RN – 2		

Responses to Closed-Ended Questions

1. Prior to this program, were you familiar with CDC HCV Guidelines Sequence? Yes – 6 No - 0
2. Prior to this program, were you familiar with CDC HCV Birth Cohort Screening? Yes - 6 No – 0
3. The educational program objectives were clearly stated? Strongly Agree - 3 Agree - 3
4. The educational program objectives were met? Strongly Agree - 3 Agree - 3
5. The information was presented in an organized manner? Strongly Agree - 3 Agree - 3
6. The presenter was knowledgeable about the topic and open to questions? Strongly Agree - 4 Agree - 2
7. The audiovisual aids and handouts were helpful? Strongly Agree - 3 Agree - 3
8. The information was relevant to my practice? Strongly Agree - 4 Agree - 2
9. I gained new information and understanding about the HCV guidelines sequence? Strongly Agree - 2 Agree - 4
10. I agree with one-time screening of the baby boomers to identify HCV? Strongly Agree - 4 Agree – 2

Responses to Closed-Ended Questions

11. Prior to this program, were you familiar with CDC HCV Guidelines Sequence?
    Yes – 6 No - 0

12. Prior to this program, were you familiar with CDC HCV Birth Cohort Screening?
    Yes - 6 No – 0

13. The educational program objectives were clearly stated? Strongly Agree - 3 Agree - 3

14. The educational program objectives were met? Strongly Agree - 3 Agree - 3

15. The information was presented in an organized manner? Strongly Agree - 3 Agree - 3

16. The presenter was knowledgeable about the topic and open to questions?
    Strongly Agree - 4 Agree - 2

17. The audiovisual aids and handouts were helpful? Strongly Agree - 3 Agree - 3

18. The information was relevant to my practice? Strongly Agree - 4 Agree - 2

19. I gained new information and understanding about the HCV guidelines sequence?
    Strongly Agree - 2 Agree - 4

20. I agree with one-time screening of the baby boomers to identify HCV?
    Strongly Agree - 4 Agree – 2

Open Ended Responses to regarding provider potential HCV screening changes

- Obtain a report of all patients who cover the screening criteria; call and request them to have screening
- Will be more vigilant about HCV screening, especially among patients with substance use disorders and baby boomers
- No change
- Continue to screen for HCV per the CDC recommendations
- Screen more patients
- Give written information about HCV screening along with other routine screenings ordered
- Offer HCV screening to all patients born between 1945-1965

Comments

- Need help with prior authorizations for medications