A HEPATITIS C VIRUS SCREENING TOOL IMPLEMENTED FOR AN UNINSURED POPULATION

A Scholarly Project

Submitted to the

Faculty of Liberty University

In partial fulfillment of

The requirements for the degree

Of Doctor of Nursing Practice

By

Kimberly B. Babcock-Nobles

Liberty University

Lynchburg, VA

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Scholarly Project Chair Approval:

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ABSTRACT

Hepatitis C virus (HCV) is a public health epidemic effecting 3.5 million people in the United States alone. The uninsured, underserved residents of a rural county in North Carolina have limited access to screening and early detection for HCV. Through collective efforts, a free medical clinic partnered with a grant funded, nonprofit organization to provide free hepatitis C testing by use of a mobile medical unit. The aim of this study was to determine if use of an HCV screening tool would increase the number of patients screened for testing as compared retrospectively to the number of patients screened without use of the HCV screening tool. Methods included retrospective data from chart audit, patient survey of at-risk HCV behaviors including the birth cohort 1945-1965, and a pretest/ posttest measure of provider knowledge on HCV before and after an educational intervention. The sample population consisted of a retrospective group R(n=52) and a prospective group P(n=49). The screening outcome of each group resulted the following: R(n=52) confirmed screening 13 out of the 52 (25%) participants without use of a screening tool while the P(n=49) group captured 43 out of 49 (82.7%) participants with the implementation of a screening tool. Participant gender for the study included males 44.6% and females 55.4 %. The most common risk factor for HCV was birth cohort (1945-1965) 30.2% followed by Intravenous drug use 11.6%. Lastly, results of the pretest / posttest exhibited a 20.8% increase in HCV provider knowledge.

Keywords: baby boomer, birth cohort 1945–1965, free medical clinic, HCV screening, hepatitis C, IV drug abuse, medically uninsured

Dedication

Jesus. The great physician. He who cared for the meek, the ill, and the poor without judgment. He led the blind and carried the crippled. The riches I possess may comfort my head, but my heart aches for the lost. I hope to continue to help others and along the journey show them the way. God is good all the time.

Acknowledgments

I must express my gratitude for the unwavering support and sacrifice my husband, children, family, and friends have bestowed on me during my quest for higher education. Thank you for allowing me the opportunity to gain advanced knowledge and leadership skills that hopefully will inspire others to seek higher education.

To my preceptor, Dr. Paula Correa, you are nothing short of amazing. Your servant leadership style incorporates committed social and emotional intelligence, and your constant enthusiasm empowers others to strive to be better. PC, you are a true mentor, and I am so blessed that God allowed us to cross paths. You have opened my mind to new possibilities. Thank you for sharing your knowledge, your leadership skills, and your faith.

To my editor, Emily, though we have never officially met, this truly would not have been possible without your patience and dedication to detail in my shortcomings. Bless you for your guidance, knowledge, and understanding.

To Liberty University, thank you for the Christian atmosphere in which to learn and serve the Lord. Your professors are among one the greatest assets you have. Each one of the inspiring professionals I encountered gifted me an appreciation to openly center Christ in all things I do. Their positive encouragement and leadership never ceased. Opening every meeting in prayer made the daily struggles of life fade away and revived my focus on the task at hand. I truly thank each of you.

Most of all, glory to God for the sacrifice of his only begotten son for saving my eternity. I seek to serve by leading others to Christ.

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List of Abbreviations

Advancing Life. Fighting Aids (ALFA)

Centers for Disease Control and Prevention (CDC)

Direct-Acting Antiviral (DAA)

Emergency Department (ED)

Hepatitis C Virus (HCV)

Institutional Review Board (IRB)

Nurse Practitioner (NP)

Nucleic Acid Testing (NAT)

Primary Care Physician (PCP)

Samaritan Free Medical Clinic (SFMC)

Samaritan Free Medical Clinic Hepatitis C Screening Tool (SFMC-HCV-ST)

Sustained Virologic Response (SVR)

Syringe and Needle Exchange Program (SNP)

U.S. Preventive Services Task Force (USPSTF)

World Health Organization (WHO)

SECTION ONE: INTRODUCTION

Lack of access to medical care for uninsured and underserved populations in rural counties continues to burden the entire health care system. In the United States, millions have been infected by hepatitis C virus (HCV), but less than half have been diagnosed (Turner, Craig, Makanji, Flores, & Hernandez, 2017). Despite the recommendations of the Centers for Disease Control and Prevention (CDC) and the U.S. Preventive Services Task Force (USPSTF), accessibility and resources for HCV screening are not at all equitable across populations. A public health epidemic, an estimated 3.2 million Americans are living with HCV infection, and approximately 19,000 people die from HCV-associated liver cancer or chronic liver disease each year (Jorgensen, Carnes, & Downs, 2016). Early detection, diagnosis, and treatment of HCV are far more cost effective than treating the grave end-stage sequalae. HCV often goes undiagnosed due to lack of presenting symptoms until the late stages of disease progression. Consequently, failing to timely diagnose HCV will lead to unbearable symptomatic liver disease, cirrhosis, hepatocellular carcinoma, and/or death, all of which could be avoided with appropriate screening. Increased awareness and strict adherence to screening policies in baby boomers and high-risk populations are paramount in order to diagnose HCV infection early, offer therapy, and prevent HCV-related mortality and morbidity (Mahgoub et al., 2018).

Accessibility and equity in rural areas are multifactorial. Aside from the lack of available providers and services, unemployment and poverty create barriers to funding and insurance. The Appalachian foothills of North Carolina are filled with small towns that historically developed around a single industry such as furniture or textiles. The rural county of Petersboro suffered significantly in the 1990s when industries began moving overseas, leaving workers jobless. Further demise of the local economy resulted from the loss of two major automotive sport races in 1996. This loss of revenue caused people to leave and businesses to close, thus crippling the economy in the immediate area. Over 20 years later, the community still struggles. In 2017, the rates of unemployment and poverty in Petersboro County, North Carolina, were higher than the rates of unemployment and poverty in the United States as a whole (U.S. Census Bureau, 2018). This is not a new trend in rural geographical locations. Statistical data of unemployment and poverty rates of the Petersboro area correlate with the accessibility and equity of healthcare in the community. Also noteworthy is the uninsured rate (Table 1; U.S. Census Bureau, 2018). Urban America believes they extend service outreach to fill this equity gap, but the statistical disparity of rural America tells another story.

Table 1

Comparison of Demographics of Petersboro County and the United States

	Peters County (%)	United States (%)
Unemployment	4.3	4.1
Poverty	21.1	12.3
Uninsured	27.4	10.2
Disabled	18.7	12.6

Note. The data are adapted from U.S. Census Bureau, 2018.

In many areas, Appalachian mountain health practices are still culturally acceptable, and modern-day preventive healthcare historically has been viewed as nonessential. Often, families use treatment methods passed down generation to generation to avoid the cost of medical care. Lack of knowledge of preventive healthcare services, coupled with the burden of screening cost, contribute to this view of traditional healthcare as unnecessary. This lack of accessibility, equity, and community knowledge led to the creation of the Samaritan Free Medical Clinic (SFMC) in Petersboro County. Created in 2010 by a local doctor who wished to help the less fortunate and hurting in the community, the clinic offers completely free medical care services to anyone, regardless of income. SFMC operates as a 501(c)(3) with monetary donations from local community businesses and churches, and 100% of donations are used to treat patients. Local providers, nurses, lab technicians, medical assistants, and office personnel volunteer to serve those in need of medical care. Screening is vital to promote prevention and, more importantly, the quality of life in the foothills. Improving adherence to screening recommendations and the manner in which they are conveyed to the public is critical to implementing the national viral hepatitis action plan and thereby increase diagnoses and avert new infections (Martin, Norcott, Khalid, & O'Connell, 2017).

Background

HCV has been called a silent epidemic. Unfortunately, most HCV-infected persons are asymptomatic and unaware of their status (Ditah et al., 2015). Due to the expansion of illicit drug use and contaminated transfusions that occurred in the 1970s and 1980s, HCV infection is particularly prevalent in the baby boomer population (those born between 1945 and 1965); this birth cohort accounts for up to 75% of all HCV infections (Galbraith et al., 2015). As HCV is a curable public health epidemic, screening can lead to treatment of individuals infected with the virus and prevent the progression of liver disease to cirrhosis, hepatocellular carcinoma, and the associated morbidity and mortality (Joshi, 2014).

Hepatitis-acute versus chronic. Variations of HCV include acute and chronic disease processes. Acute HCV occurs within the first six months after exposure to the HCV and is a short-term illness (CDC, 2016). Unfortunately, 75%–85% of acute infections convert to chronic HCV disease, which, when left untreated, causes severe health problems including liver-related death (Dan, Moses-Eisenstein, & Valdiserri, 2015). Due to the lengthy lag time between infection and the appearance of symptoms, it is expected that rates of cirrhosis and hepatocellular cancers will increase over the next 10–13 years (Moyer, 2013).

Risk factors. The USPSTF (2016) has stated with moderate certainty that screening for HCV infection in adults at increased risk for infection and one-time screening in adults in the 1945–1965 birth cohort has moderate-net benefit. The USPSTF identifies HCV as a grade of B to medical providers, which states best practice is to provide HCV screening (USPSTF, 2016). The CDC also recommends screening and list guidelines for HCV screening. According to CDC (2017), at risk-adults are those who meet one or more of the following criteria:

- past or current injection drug use
- received a blood transfusion before 1992
- long-term hemodialysis
- born to an HCV-infected mother
- incarceration
- intranasal drug use
- got an unregulated tattoo
- other exposures (needle sticks, surgery born universal precautions)
- sex with an injection drug user
- born between 1945 and 1965

Patients born between 1945 and 1965 are more likely to be diagnosed with HCV infection, either because they received a blood transfusion before the introduction of screening in 1992 or because they have a history of other risk factors for exposure from decades earlier (Moyer, 2013). Lack of symptoms is a barrier to screening. According to findings from a study reported in the *Journal of Viral Hepatitis,* the most common reason for not testing among all participants was "I do not think I have any risk factors" (Grannan, 2017, p.634). To help implement HCV guidelines and recommendations, the CDC developed *Know More Hepatitis*, a national, theorydriven multimedia education campaign aimed to ultimately reduce the morbidity and mortality associated with HCV by increasing testing among baby boomers so those who are infected can receive life-saving care (CDC, 2016).

Testing. Administering HCV screening to determine if diagnostic testing is warranted currently requires a two-step process. The CDC's updated algorithm for screening recommends subjects who test HCV positive from point-of-care testing then complete a nucleic acid testing (NAT) to determine whether chronic HCV infection is present (Khuroo, Khuroo, & Khuroo, 2015). NAT is also termed HCV-RNA testing. The World Health Organization (WHO) is working toward simplifying the testing process to one step in the near future with the goal of making screening both cost effective and easily accessible (Hellard, Chou, & Easterbrook, 2017).

Treatment. Appropriate screening and early detection will allow HCV-positive patients to seek linkage to care for access to appropriate treatment. The primary goal of treating HCV patients is to achieve sustained virologic response (SVR), which has been shown to reduce the risk of downstream advanced liver complications, including mortality (Younossi, Yushan, Smith, Stepanova, & Beckerman, 2015). Tremendous advancement has been made with the availability of sensitive diagnostic tests and highly effective direct-acting antivirals (DAAs) capable of achieving SVR in more than 95% of patients (Saab, Le, Saggi, Sundaram, & Tong, 2018). The new DAA treatments fall into three main classes of target-specific drugs that disrupt the viral replication cycle of HCV: NS5A, NS5B, and NS3 protease inhibitors. Treatment of HCV usually includes a combination of at least two of the three drug classes with or without Ribavirin for 12–24 weeks of therapy. Achieving SVR, or no detectable virus (HCV-RNA) in the blood 12 weeks after completion of therapy, renders the individual cured of HCV (Surjadi, 2018). Development of novel DAA oral drugs, proven to be safe and highly effective, further supports the increased benefit of screening patients at risk and includes the essential one-time screening for baby boomers (Cornett, Bodiwala, Razuk, Shukla, & Narayana, 2018).

Problem Statement

Less fortunate patients in rural Petersboro County do not receive the CDC- and USPSTF-recommended HCV screening. Lack of accessibility to care and/or knowledge of the disease process along with key barriers of unemployment, low socioeconomic levels, and absence of insurance lead to disparity in health care between regions. Unbeknownst to many, federal and state funding is often available in higher-poverty areas; only about half of people eligible for income-related programs actually enroll (Wilensky, 2017). Patients with undiagnosed HCV will suffer end-stage liver morbidity and accrue more publicly funded healthcare expense, both of which could be prevented with screening, early detection, linkage to care, and treatment.

Purpose of the Project

The purpose of this project is to determine if using a screening tool would create an increase evaluation effort at the SFMC. The objective was to utilize the HCV screening tool to increase the number of patients screened during the April 13, 2019, clinic period.

Clinical Question

At Samaritan Free Medical Clinic, how does the implementation of an HCV screening tool affect the HCV screening rate over a single clinic period when compared the previous clinic month when no screening tool for HCV was utilized?

SECTION TWO: LITERATURE REVIEW

Search Strategy

A comprehensive electronic database search was conducted using the following databases: CINAHL, Healthsource, Medline, and PubMed. A search for articles written in

English within the past five years using the search terms *baby boomer*, *birth cohort*, *hepatitis C screening*, *injection drug use*, *underserved population in healthcare*, and *medically uninsured* resulted in a list of 135,733 journal articles. To taper the search, the search term *and* was added in advanced settings, followed by the removal of *injection drug use* and *population in healthcare*, reducing the count to 594 articles. Articles were narrowed down further according to the quality of the study and relevance to the topic. Bibliographies were scanned as another source of review. A search concentrating on only peer-reviewed scholarly publications with full text ultimately returned 74 articles, of which 29 contained relevant information and were utilized in the literature review.

Critical Appraisal

The literature search uncovered various types of evidence to support the necessity of alternative approaches for HCV screening. Importantly, it would be unethical to provide screening without ability to test and treat. Efficacy for point-of-care HCV-antibody testing, HCV-RNA confirmation testing, and treatment with DAAs has made HCV curable for even the uninsured through alternative approaches. All articles were reviewed for quality and appraised using the Iowa Model Attachment 5.2: Summary and Synthesis Tool (Iowa Model Collaborative, 2017). Each article was also examined for level of evidence according to Melnyk's system of hierarchy (University of Michigan Library, 2018). The literature findings included systematic reviews, clinical practice guidelines, controlled trials, mixed-method studies, and observational/ descriptive studies pertaining to HCV testing and the at-risk, uninsured population.

Systematic review. Elimination of HCV is not an unreachable goal. Tremendous advancements with DAA agents can achieve an SVR over 90% in HCV infections, and tolerability has increased the pool of patients eligible for therapy (Saab et al., 2018). A systematic review by Saab et al. (2018) reported on the elimination efforts of HCV in an effort to ascertain the possibility of eliminating HCV using established public health qualifying criteria (Saab et al., 2018).

Saab et al. (2018) described criteria of technical feasibility to include practical and sensitive diagnostic testing and a surveillance program. While the diagnostic tests themselves are sensitive and specific, there is still room for improvement in the way these tests are used to increase case identification and link patients to specialized care (Saab et al., 2018). A study from the University of California Los Angeles Health reported an increase in HCV screening of 145% after successful implementation of an HCV screening reminder in the electronic health record (as cited in Saab et al., 2018). Methods to increase HCV screening still need further exploration.

HCV surveillance in the United States has been ongoing since 1982, but the program is chronically underfunded, as only seven jurisdictions are funded by the CDC (Saab et al., 2018). HCV infection is more prevalent among marginalized groups, such as the homeless, prisoners, and intravenous drug users, who have little or no access to health care (Saab et al., 2018). Utilization of health departments, emergency departments (EDs), and free clinics create a lack of reporting; thus, the prevalence rate of HCV is inaccurate. This study highlighted the need for additional community outreach programs to administer screening tests among high-risk populations along with the employment of a dedicated database for HCV surveillance (Saab et al., 2018).

Effective interventions to prevent the transmission of disease include syringe and needle exchange programs (SNPs), opioid substitution therapy, and mental health services. For example, SNPs have been demonstrated to reduce HCV transmission rates among injectable drug users by as much as 29% (Saab et al., 2018). Significant barriers to public interventions include state laws prohibiting pharmacy sale of syringes and needles and lack of funding for interventions programs and screenings. Furthermore, without SNPs, reinfection with continual intravenous drug users is of high concern.

Saab et al. (2018) disclosed field-proven strategies reported from organized efforts in Georgia, Egypt, and Australia that have made progress toward the elimination of HCV. Initial success has been achieved by establishing national committees with strong government support and university health care systems. Georgia launched a national campaign in 2015 to target high-risk groups (e.g., intravenous drug users, prisoners, patients with HIV) that led to the identification of 50,962 HCV antibody–positive individuals, with 59% of those confirmed to have chronic HCV infection (Saab et al., 2018). By partnering with pharmaceutical industry, the campaign offered DAAs free of charge, which increased the average number of patients receiving treatment monthly by 300% in 2016 (Saab et al., 2018). Egypt established a National Committee for Council of Viral Hepatitis and opened more than 54 centers to manage 800,000 chronic HCV patients. The committee also uses a national database to monitor HCV elimination progress (Saab et al., 2018). Australia has had success through two strategies: funding and access. First, the government invested 1.6 billion USD to expand HCV treatment access to all affected adults and negotiated lower DAA prices. Second, the medical community was able to increase the proportion of DAA treatment prescribed by a general practitioner from 8% to 31%, thus increasing treatment accessibility tenfold from the previous year (Saab et al., 2018).

In the United States, Saab et al. (2018) mentioned the efforts of the Veterans Affairs health care system, which has screened 2.9 million patients (53% of the total Veterans Affairs population) for HCV; of those with HCV viremia, 23% have initiated treatment, which is reported as higher than the national average (Saab et al., 2018). Despite the screening efforts, a significant barrier in the Veterans Affairs system is high treatment cost, which forces providers to prioritize patients that receive treatment. All the aforementioned efforts certainly present learning opportunities moving forward.

The final leg of this Saab et al.'s (2018) review discussed the social and political challenges surrounding the stigma of HCV populations. The readiness of DAAs is hopeful, but they only help if patients have funding and access to screening and medical care. The current lack of political support and pervasive social stigma continue to pose significant barriers for interventions to reach the most vulnerable populations (Saab et al., 2018). Legislators and social advocates must focus efforts to change policy on SNPs and funding. In 2016, the National Academy of Science, Engineering, and Medicine published a national strategy report that identified HCV as a significant threat to public health that must be addressed. The report explored the feasibility and barriers that must be overcome to eliminate HCV in the United States (Saab et al, 2018). The WHO published a similar advocacy brief highlighting an elimination strategy, and the CDC has made several attempts to promote HCV awareness. May has been designated by the CDC as Hepatitis C Awareness Month to encouraging screening of high-risk populations. Saab et al. (2108) stated correctional facilities are an ideal setting to screen and educate a high-HCV prevalence population, but this opportunity has been largely neglected; any intervention program in this population will be highly impactful (Saab et al., 2018).

The results of this systematic review highlight the need for additional community outreach programs to administer screening among high-risk populations and the need for technical feasibility, economic considerations, and social and political attention to accomplish this goal (Saab et al., 2018). Several countries have taken steps to eliminate HCV; however, with its technological advances and existing infrastructure, the United States has the potential to become the first nation to eliminate HCV if it can secure public support and political commitment (Saab et al., 2018).

Meta-analysis. Khuroo et al. (2015) conducted a comprehensive systematic review and meta-analysis of studies that assessed the diagnostic accuracy and applicability of point-of-care tests for HCV. Khuroo et al. (2015) found enough information to enable an evaluation of the performances of several individual tests and established a protocol that included several aspects of the meta-analysis, following the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis.

In the meta-analysis, all the tests performed better in studies that were conducted in developed countries than in underdeveloped countries. It is well known that the performance characteristics of any test vary markedly with the prevalence of the condition in the population being assessed (Khuroo et al., 2015). In the end, performances varied widely among individual point-of-care tests for diagnosis of HCV infection, and physicians should consider this when using specific tests in clinical practice (Khuroo et al., 2015). A secondary HCV-RNA confirmation test is necessary to determine acute versus chronic disease state prior to treatment evaluation.

The Agency for Healthcare Research and Quality commissioned two systematic reviews on screening for and treatment of HCV infection in asymptomatic adults (Moyer, 2013). This study analysis focused on evidence gaps identified in the previous USPSTF recommendations and new studies published since 2004 (Moyer, 2013).

Moyer (2013) disclosed that the USPSTF found limited evidence on the harms of screening for HCV; however, potential harms could include anxiety, patient labeling, and feelings of stigmatization (Moyer, 2013). The USPSTF found adequate evidence that antiviral therapy regimens are associated with a high rate of harms, such as fatigue, headache, flu-like symptoms, hematologic events, and rash; however, Moyer (2013) further affirmed that when antiviral therapy is given for a defined duration, serious adverse events are uncommon, and adverse events are self-limited and typically resolve after treatment is discontinued. Moyer (2013) stated adequate evidence is found that these harms of treatment are small.

Moyer (2013) asserted that as treatment of HCV continues to evolve, “more research is needed to understand which persons benefit the most from treatment and when treatment should begin in asymptomatic persons” (p. 352). Other research gaps include a focus on long-term harms associated with antiviral regimens and an exploration of the frequency of testing in high-risk populations (Moyer, 2013). These specific topics are currently being explored.

The indirect chain of evidence explored by USPSTF reveals significant benefits of screening through improvement of the intermediate outcome of SVR after triple-regimen antiviral treatments and a reduction in liver-related mortality and hepatocellular carcinoma (Moyer, 2013). The USPSTF determined that the new evidence supports a moderate magnitude of net benefit for the 1945–1965 birth cohort as well as for high-risk persons (Moyer, 2013).

Clinical practice guidelines. Although the meta-analysis from the USPSTF was discussed previously by Moyer (2013), it is essential to describe the actual clinical practice guidelines from the meta-analysis outcomes. Clinical practice guidelines developed from USPSTF recommendations include screening for HCV infection in persons at high risk for infection as well as offering one-time screening for HCV infection to adults born between 1945 and 1965 (USPSTF, 2016). The USPSTF makes recommendations about the effectiveness of specific preventive care services for patients without related signs or symptoms and bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance (USPSTF, 2016).

The rationale for these recommendations is that HCV is the most common blood-borne pathogen in the United States and a leading cause of complications from chronic liver disease including death. It further reports that according to data collected from 1999 to 2008, about three fourths of patients in the US living with HCV infection were born between 1945 and 1965 (USPSTF, 2016). One screening strategies is to target persons with risk factors for HCV infection, including past or present injection drug use (even if just one time), sex with an injection drug user, blood transfusion before 1992, and now, birth cohort 1945–1965. Additional risk factors include long-term hemodialysis, being born to an HCV-infected mother, incarceration, intranasal drug use, getting an unregulated tattoo, and other percutaneous exposures (Moyer, 2013). The financial burden of undiagnosed HCV far exceeds the cost of treating for a cure.

Screening for HCV should be voluntary and with the patient’s understanding that HCV testing is planned. Patients should be informed that HCV testing will be performed unless they decline (opt-out screening). The USPSTF believes that before HCV screening, patients should receive an explanation of HCV infection, how it can (and cannot) be acquired, the meaning of positive and negative test results, and the benefits and harms of treatment (Moyer, 2013). Patients should also be offered the opportunity to ask questions and to decline testing (Moyer, 2013). The USPSTF decided to upgrade HCV screening to a Grade B as there is high certainty that the net benefit to screening is moderate or there is moderate certainty that the net benefit is moderate to substantial (USPSTF, 2016).

As part of a broader global public health response, the WHO (2014) published *Guidelines for the Screening, Care and Treatment of Persons with Hepatitis C Infection* to provide a framework that can allow for the expansion of clinical services to patients with HCV infection. These guidelines provide key recommendations on HCV and considerations for implementation of screening, care, and treatment. The WHO (2014) aims to ensure a comprehensive and sustainable response to viral hepatitis with focus on low- and middle-income countries. WHO guidelines align with those of other global public healthcare organizations seeking to impact the HCV epidemic.

In 2012, the CDC updated recommendations for HCV guidelines. The amended testing recommendations include one-time HCV testing for all persons born 1945–1965 regardless of other risk factors (CDC, 2013). The CDC issued this update in light of (a) changes in the availability of certain commercial HCV antibody tests, (b) evidence that many persons who are identified as reactive by an HCV antibody test might not subsequently be evaluated to determine if they have current HCV infection, and (c) significant advances in the development of antiviral agents with improved efficacy against HCV (CDC, 2016). The CDC and WHO provide evidence-based findings to assist policy makers, governments' and other public health systems for best practice outcomes.

In 2013, the *Journal of Nurse Practitioners* published an update of HCV screening and guidelines. Karen Hande DNP, ANP-BC, gave the latest CDC screening guidelines update for clinical practice. The CDC guidelines recommend that initial HCV testing should be done with a Food and Drug Administration–approved test for an antibody to HCV (anti-HCV Ab) due to its highly sensitive and specific laboratory-based assay reported as reactive or nonreactive (Hande, 2014). Nonreactive anti-HCV Ab results require no further testing, as it indicates the patient is negative for HCV infection. However, patients with risk for ongoing or recent HCV exposure or persons who are severely immunocompromised may have false negative anti-HCV Ab test results and warrant an HCV-NAT due to high suspicion of HCV infection (Hande, 2014). Understanding the pathway of results is as follows: a reactive anti-HCV Ab is considered to either indicate the patient has a current HCV infection or has had an HCV infection in the past. Both warrant serum HCV-NAT testing. Hande (2014) reported if serum HCV-NAT is negative, then this confirms patient has at some point had an HCV infection that has resolved. HCV clears in 15%–25% of acutely infected persons. Important to note is that anti-HCV Ab testing does not distinguish between persons with a past infection that self-resolved and persons currently infected with HCV (Hande, 2014). Only HCV-NAT can make this determination. In conclusion, early identification, linkage to care, education, and clinical evaluations are critical disease prevention interventions that nurse practitioners (NPs) can provide to patients (Hande, 2014).

Cross-sectional study. A study conducted by Galbraith et al. (2015) describes the early experience with an integrated, opt-out HCV screening and linkage-to-care program of baby boomers in an urban ED. This is the first study to broadly and systematically screen ED baby boomer patients for HCV and provide linkage to HCV care (Galbraith et al., 2015).

Galbraith et al. (2015) confirms the large-scale, targeted testing of the baby boomer birth cohort has further revealed racial and health care coverage disparities among the newly HCV-diagnosed populations in the ED. ED HCV screening has many inherent challenges, including the costs of screening, the competing priorities of ED care, and the development of a linkage-to-care infrastructure (Galbraith et al., 2015).

Randomized control trials. The objective of the ASCEND trial (A Phase IV Pilot Study to Assess Community-Based Treatment Efficacy in Chronic Hepatitis C Mono-infection and

Coinfection with HIV in the District of Columbia) was to determining efficacy of HCV treatment independently provided by NPs, primary care physicians (PCPs), or specialist physicians using DAA therapy was conducted in 13 urban, federally qualified health centers in Washington, DC. This open-label clinical trial initiated in 2015 with a referred sample of 600 patients, of whom 96% were black, 69% were male, 82% were treatment naive, and 20% had cirrhosis (Kattakuzhy et al., 2017). Patients were assigned in a nonrandomized but specified manner to receive treatment from one of five NPs, five PCPs, or six specialists (Kattakuzhy et al., 2017). All providers underwent an identical three-hour training session based on guidelines and patients received treatment with ledipasvir-sofosbuvir, which was provided on site, according to U.S. Food and Drug Administration labeling requirements (Kattakuzhy et al., 2017). Measurements were based on SVR.

The primary efficacy end point was SVR, defined as an undetectable HCV-RNA viral load 12 weeks after treatment completion, and patients with detectable HCV-RNA at the SVR time point were considered to have viral relapse (Kattakuzhy et al., 2017). Secondary end points, according to Kattakuzhy et al. (2017), included evaluation of efficacy by subgroups: provider type, treatment duration, HIV serostatus, cirrhosis, and adverse events. The trial was sponsored by the National Institutes of Health Clinical Center, approved by the Institutional Review Board (IRB) of the National Institute of Allergy and Infectious Diseases, and conducted in compliance with the provisions of the Declaration of Helsinki good clinical practice guidelines and local regulatory requirements (Kattakuzhy et al., 2017)

Kattakuzhy et al. (2017) described the following results. Six hundred patients were assigned to receive ledipasvir-sofosbuvir from an NP (*n* = 150, 25%), a PCP (*n* = 160, 27%), or a specialist (*n* = 290, 48%) and of the 600, 516 (86%) achieved SVR. The other 84 patients did not achieve the primary end point due to (a) lost to follow up (45, 54%), (b) viral relapse (*n* = 35, 42%), or (c) death (*n* = 4, 4%). Provider-prescribed SVR outcome ratios were NP = 89.3%, PCP = 86.9%, and specialists = 83.8%. Little difference was noted between providers for HIV coinfected or cirrhosis patient outcomes. Interestingly, patient treatment adherence was noted to be highest with NP providers (73.9%), followed by PCPs (63.1), and specialists had the lowest adherence to treatment (55.9). The data collected have the potential for multiple variations for analysis.

This study reports to be the first clinical trial to demonstrate a high rate of SVR among patients of PCPs and NPs providing independent HCV care using DAAs (Kattakuzhy et al., 2017). The high cure rate achieved by non-specialist providers was maintained even with HIV/cirrhosis coinfections. The study was conducted within the setting and time limitations of standard medical practice, without the use of patient navigators, in federally qualified health centers serving an urban, socioeconomically challenged population, thus demonstrating the feasibility of delivering DAA treatment in these existing sites (Kattakuzhy et al., 2017).

The ASCEND investigation suggests that provider restrictions for prescribing DAAs to treat HCV are not supported by evidence and stand as an unnecessary barrier in the treatment of HCV. Seeking alternative treatment options is the only way to eliminate HCV.

Quasi-experimental trials. A descriptive analysis of a community clinic providing HCV treatment to poor and uninsured patients by Sims, Melton, and Ji (2018) described a multidisciplinary approach at Mercy Health Center in Northeast Georgia to provide therapy for the uninsured. Mercy Health Center is a nonprofit community clinic that provides primary and specialty care services, including an HCV team, free of charge to patients who are uninsured, at or below 150% of federal poverty level, and reside within the six-county service area (Sims et al., 2018).

Of the 69 HCV patients found HCV positive in the Sims et al. (2018) study, a large majority were baby boomers born between 1945 and 1965 (67%), and nearly half acquired HCV due to illicit drug use (Sims et al., 2018). More than a third of patients received HCV treatment, of which 81% completed treatment with 85% of completers achieving SVR. The treatment team successfully secured free HCV medications from pharmaceutical patient assistance programs for all patients who completed assessments. Despite comorbidities and psychological disorders, the vast majority achieved SVR (Sims et al., 2018).

With appropriate support, it appears poor and uninsured patients living with HCV, who are often regarded as *difficult-to-treat*, can achieve HCV treatment completion and SVR rates similar to those of insured HCV patients (Sims et al, 2018). Unfortunately, patients living with HCV who are characterized as difficult-to-treat are often denied or deferred treatment due to their complex economic, psychosocial, medical, and psychosocial needs; thus, a multidisciplinary approach is ideal for optimal patient care (Sims et al, 2018).

A common theme repeated in the Sims et al. (2018) study and many others is the lack of a federally funded comprehensive care system available for uninsured patients living with HCV comparable to the widely available programs for uninsured HIV patients. Limitations reported by Sims et al. (2018) for this study include its retrospective study design, small sample size, and absence of available data on substance type for history of substance abuse. Other limitations include a single site setting that limits the generalizability of findings to broader populations (Sims et al., 2018). The conclusion of this study reiterates the urgency of finding methods to secure HCV screening and treatment therapy. In the coming years, access to costly HCV medications will likely determine how wide or narrow the gap will be between those who are cured of HCV and those who will continue to suffer from HCV-related liver disease (Sims et al., 2018). Advocacy for funding and policy change along with attempts to find alternative approaches to reach difficult-to-access HCV populations will help close the gap.

Other evidence. Several articles regarding testing and guidelines have been published to educate on and create awareness of HCV. Dan et al. (2015) developed a resource for continuing education titled “Viral Hepatitis: New U.S. Screening Recommendations, Assessment Tools, and Treatments” designed to inform and educate medical professionals. The Institute of Medicine reported viral hepatitis as an underappreciated public health problem, highlighted multiple barriers to viral hepatitis prevention and control, and provided specific recommendations to improve efforts to stop the spread of viral hepatitis (Dan et al., 2015). The *National Viral Hepatitis Action Plan* was devised by Health and Human Services and was last updated in 2014. The action plan sets goals within six major priority areas and provides a framework upon which stakeholders can their focus efforts (Dan et al., 2015). Dan et al. (2015) reported that as providers “work to understand the true burden of HCV in the United States and how to better target the use of limited resources, accurate diagnosis and appropriate reporting are paramount” (p. 31). Nurses play a pivotal role in all six priority areas; as educators, care coordinators, and health care providers, they are uniquely positioned to provide critical leadership in advancing our nation’s efforts to address the silent epidemic of viral hepatitis (Dan et al., 2015).

Further discussion on HCV guidelines is provided by Hellard et al. (2017). Support for use of health-related goals is the premise for pursuing HCV elimination by 2030. In late 2015, world leaders at the United Nations adopted the 2030 Agenda for Sustainable Development. Specifically, Sustainable Development Goals 3.3 aims to ensure healthy lives and promote well-being at all ages and highlights the need to combat viral hepatitis (Hellard et al., 2017). The WHO, in response, developed the first-ever *Global Health Sector Strategy on Viral Hepatitis, 2016–2021*, which was endorsed by the World Health Assembly in May 2016 (Hellard et al., 2017). WHO's vision is for a world where viral hepatitis transmission is halted, and everyone living with viral hepatitis has access to safe, affordable, and effective prevention, care, and treatment services (WHO, 2016). The challenge in moving this agenda forward has been the quantity and quality of data to inform the testing recommendations, and the guidelines in Hellard et al.'s (2017) article highlight the evidence and research gaps to create an agenda for the future. The goal of elimination of HCV by 2030 is feasible, and the WHO testing guidelines inform elimination strategies at individual health services facilities and at national and regional levels (Hellard et al., 2017).

Also noteworthy is an article specifically on appropriate screening simply titled "Hepatitis C Screening" by Shoba N. Joshi (2014). Joshi (2014) stated, "Screening is characterized by interventions in a group of individuals with no signs and symptoms of disease to identify unrecognized disease" (p. 664). Screening is not intended to be diagnostic; it is to detect the possibility of HCV exposure based on risk behaviors, exposure potentials, and birth cohort. Although most clinicians have extensive experience with disease diagnosis and management of disease, Joshi (2014) stated that "they have limited experience with screening for disease" (p. 664). The article creates awareness of the WHO, CDC, and USPSTF guidelines. The hope is that by appropriate identification of HCV before the onset of signs and symptoms, morbidity and mortality can be reduced (Joshi, 2014).

Synthesis

The literature review establishes that the single most important factor in the battle against HCV is screening. Without a solid screening approach, the elimination of HCV is just an idea. Currently, too many people are excluded from the recommended screening. The literature reveals that the setting of HCV screening has a big impact on the uninsured population. Hepatologist, oncologist, and even PCP offices are the most common settings for HCV screening. Nevertheless, the evidence in the literature supports alternative approaches to reaching the underserved population of the uninsured. Research reports utilization of the ED and a new outreach approach, mobile medical clinics, are useful methods to reach the difficult-to-access population. Further literature exploration revealed key barriers to HCV screening includes lack of provider awareness and/or knowledge of the severity of HCV and recommendations for care.

Settings for HCV screening. Literature supports the idea that alternative approaches to reach and screen populations at risk for HCV are necessary. Primary care clinics are standard sites for screening, but if there are not enough PCPs in a given community, a large underserved population is created. Simplifying approaches to offering immediate screening in alternative settings is essential to capture the uninsured and underserved at-risk group. Morano et al. (2014) determined "while there was no difference in HCV prevalence among the type of HCV testing strategy selected, those selecting point-of-care testing were significantly more likely (93.8 vs. 18.2 %; p\0.0001) to be linked to HCV specialty care" (p. 928). Point-of-care testing peovides immediate results, leading to more accountability for personal health. Morano et al. (2014)'s article also disclosed findings that patients "accepting HCV testing were positively and significantly correlated with having been diagnosed with a STI [sexually transmitted infection], being US born, and being a PWID [person who injects drugs]" (Morano et al., 2014, p. 923). Settings difficult-to-access populations may frequent include EDs, free clinics, and mobile units.

Emergency department settings. HCV screening initiatives in settings such as the ED can play a crucial role in identifying infected patients. The ED acts as a health care safety net for many difficult-to-access patients who do not seek medical care services outside the ED (Cornett et al., 2018). Cornett et al. (2018) was the first study conducted in a nonurban/epicenter ED on HCV screenings. Previous studies were all conducted in "large urban hospitals that serve many patients known to be at higher risk for HCV infection, including injection drug users, minorities, and persons of low income" (Cornett et al., 2018, p. 2). The aim of Cornett et al. (2018) study was to determine whether routine HCV screening of the baby boomer birth cohort is warranted in EDs located outside large urban cities (Cornett et al., 2018). The results showed positive findings in support for HCV screening and indicate that EDs outside large urban hospitals are important sites to increase identification of patients with HCV (Cornett et al., 2018). To date, there remain very few studies on rural ED screening measures. Owing to the higher unemployment rate, poverty level, and rate of lack of insurance in these remote areas, it seems logical that rural ED may be a strong source to capture hard-to-reach individuals.

Primary care settings. Primary care health centers continue to be target sites for HCV screenings, yet routine testing is not carried out. In one study, five federally qualified health centers in Pennsylvania integrated a model developed from the CDC testing and linkage initiative and successfully identified a large number of HCV-positive patients, which confirmed that testing in health clinics is an important way to identify people previously undiagnosed (Coyle, Kwakwa, & Viner, 2016). Prior to integrating HCV testing, the researchers took three steps: (1) training health center staff members about HCV etiology and epidemiology, as well as project goals and model implementation plan; (2) negotiating with commercial laboratories that were paid with grant funding on pricing for HCV tests performed on uninsured patients; and (3) deciding if universal or risk-based HCV testing was the most efficient testing method (Coyle et al., 2016). The buy-in of health staff supported the model's success. Participating centers all represented at-risk populations in a large urban county; therefore, portions of this model may not be able to be replicated in different settings or other areas of the country (Coyle et al., 2016). To implement new models promoting recommended HCV screening requires specific design methods in alternative settings and for targeting setting populations.

New alternative mobile setting. New opportunities to reach high-risk marginalized populations outside traditional health care settings have emerged with the development of a highly sensitive and specific rapid, point-of-care HCV antibody test (Morano et al., 2014). Medical mobile clinics are growing in attractiveness as an alternative resource in underserved rural communities. MMCs are nontraditional healthcare units that increase healthcare access by removing geographic and social barriers associated with traditional brick-and-mortar settings (Morano et al., 2014). By providing preventative healthcare and treatment services, MMCs play a critical role in delivering health care to the poor, the homeless, migrant workers, the underserved, and uninsured patients that are otherwise "limited by location, cost, insurance status, literacy, stigma or other structural barriers such as proximity and access to transportation" (Morano et al., 2014, p. 923). A New Haven, Connecticut study reported, "MMCs are highly acceptable to medically disenfranchised patients and provide immediate point of care treatment for patients across a range of medical conditions, including HCV screenings" (Morano et al., 2014, p. 928). Reducing healthcare disparities and inequalities in rural communities can be achieved with alternative delivery settings and can further assist with the WHO's goal to eradicate HCV.

Knowledge deficit. Evidence also suggests that vast knowledge deficit from health care professionals is a topic relevant to HCV screening. A recent qualitative study of "personal experiences and challenges confronted by predominantly uninsured and racial-ethnic minority baby boomers newly diagnosed with chronic HCV reveals multiple opportunities to improve education and support" from healthcare professionals (Turner et al., 2017, p. 4609). Health care professionals' lack of knowledge of and comfort level in addressing HCV is a struggle. Changing guidelines and revolving best practice policies leave professionals uncertain of what information to utilize. Innovations in HCV treatment have made it the disease the first chronic viral infection to be reliably curable through pharmacotherapy with newer DAA medications, which demonstrate cure rates approaching 100% (Naghdi et al., 2017). Nevertheless, without education and knowledge of available screening tests and treatment options, HCV will continue to burden society. The results of the study by Naghdi et al. (2017) highlight several areas where health care professionals perceive a high need for training in areas including screening, patient education, and treatment. Naghdi et al. (2017) reported "different levels of confidence" in the various screening recommendations and found that "overall, there was a need for further education, particularly for primary care physicians, to maximize the role that they can play in screening, testing, and treatment of hepatitis C" (p. 1). Even with rapid advances in HCV science, including new treatment modalities, ensuring that the treatments are reaching individuals who would most benefit from them presents a challenging educational problem (Naghdi et al., 2017).

Screening tool innovation. The USPSTF increased screening recommendations to include the birth cohort 1945–1965/baby boomers in the category of at-risk persons, but lack of funding remains a key barrier. “Having health insurance or not was the only factor that determined whether an individual pursued downstream care or not following a positive [HCV] result” (Ditah et al., 2015, p. 1131). These findings reveal further evidence that the uninsured population requires resources beyond what is currently available. Development of screening tools tailored for alternative settings will help capturing patients that may go unscreened. The CDC (n.d.) has made available on their website a hepatitis risk assessment tool for health care providers to use for guidance. This particular tool emcompasses hepatitis A, B, and C virus concerns. There were no risk assessment tools specifically for HCV discovered, only repeated recommedations.

Conceptual Model

Less fortunate patients in rural Petersboro County do not receive the CDC- and USPSTF-recommended HCV screening. Lack of accessibility, equity, and/or knowledge of the disease process leads to disparity in health care. The purpose of this project is to determine if using a screening tool will create a tangible reminder to increase evaluation efforts at the SFMC. The objective was to utilize the HCV screening tool to increase the number of patients screened during the April 13, 2019, clinic period.

The Iowa Model of Evidence-Based Practice was applied as the conceptual framework to address this problem and achieve the objective. The Iowa Model embodies the necessary content to execute putting research into practice. With health care practices evolving, major professional and health care organizations as well as federal agencies and policy-making governing bodies are emphasizing the importance of evidence-based practice (Fineout-Overholt, Melnyk, & Schultz, 2005). Developing a program to support best outcomes for patients requires a collaborative approach with organizational and individual buy-in from leadership and staff. The Iowa Model, collaborative in nature, contains both problem- and knowledge-focused triggers that steer questioning of current practice and ask whether patient care could be improved using evidence-based research (Clanton, 2014). There is a constant challenge in the practice setting to provide measurable care and outcomes of the highest standard in an evidence-based manner (Doody & Doody, 2011). The seven steps of the Iowa model promote challenging current norms to improve quality of care. For evidence-based practice to be implemented, the value of "providing high quality care based on best practice must be a priority and this is the responsibility of each practitioner in any given situation" (Doody & Doody, 2011, p. 665). Permission to use the Iowa Model conceptual framework was granted on May 24, 2018, by the University of Iowa Department of Nursing (see Appendix A).

The team formed was an interdisciplinary group of medical staff at SFMC led by a Doctor of Nursing practice student. The task force team consisted of two medical doctors, one Chiropractor, one Doctor of Nursing Practice student, four registered nurses, and one lab technician. Each team member showed efficacy in HCV knowledge, utilization of the screening tool, and the intervention design through pre- and post-testing.

The HCV Screening Tool was developed based on recommendations and guidelines retrieved from the CDC, USPSTF, and WHO. Pre- and posttest surveys were created by the lead investigator (see Appendix G).

Staff were verbally recruited prior to implementing the pretest. Next, a training session was conducted, and then a posttest survey was administered to the task force group to ensure they had an appropriate knowledge base. Review of completed posttest forms were in real time and reeducation was not needed. The HCV Screening Tool was utilized in the clinic to screen patients for HCV testing.

Utilizing statistical software for data analysis included entry of data collected on HVC screening form and pre/post test data. Findings are disseminated in the form of a scholarly dissertation.

Summary

Implementing HCV screening recommendations from the CDC and the USPSTF is essential to eliminate suffering from end-stage liver disease from untreated chronic HCV. Recent literature reveals the need to seek alternative settings for HCV screening of asymptomatic patients born within the birth cohort 1945–1965 and those with at-risk lifestyle behaviors. Development of a screening tool designed for specific settings was necessary to ensure target population testing efficacy. The literature review supports the need for this project to utilize a paper HCV screening tool to evaluate HCV at-risk patients at SFMC.

SECTION THREE: METHODOLOGY

Design

Utilizing the Iowa Model for Evidence-Based Practice, an HCV screening intervention was implemented at SFMC. The Iowa Model guides clinical decision-making and evidence-based processes from both the clinician and system perspectives (Iowa Model Collaborative, 2017). The research design was nonexperimental. Categorical data was gathered through a tool developed by the lead investigator based on the current CDC and USPSTF guidelines to screen persons for at-risk behaviors.

Prior to the screening tool intervention, a volunteer board member at SFMC who is a registered nurse performed a retrospective chart audit for a previous month to determine the number of patients screened for HCV and the total number of patients seen in the clinic. The morning of screening implementation, the lead investigator presented a pretest of 12 questions regarding HCV to the clinical staff before clinic opened. Pretests were collected, and then an educational session was conducted using handouts from the CDC on HCV. Information included what HCV is and is not, the need for screening, and use of the screening tool were discussed. A 12-question posttest was utilized to determine the clinical staff's comprehension of the HCV training session to ensure all screeners were using the same criteria.

The Samaritan Free Medical Clinic Hepatitis C Screening Tool (SFMC-HCV-ST) was printed on light purple paper and attached to the front of each patient chart upon check-in. Task force members volunteered to assist with this project through verbal recruitment. No funding was needed for the screening tool project. Outcome data collected on the SFMC-HCV-ST were collected by an assigned task force member to ensure no personal identifying information was transcribed. Patients had the opportunity to opt out of screening.

Measurable Outcomes

1. After completion of the April 13, 2019, HCV screening tool intervention, a greater percentage patients' in the SFMC will be screened for HCV. This will be evidenced by the number of patients screened with use of the screening tool as compared to the number of patients screened previously without use of a screening tool.
2. After completion of the educational program on HCV, clinic staff will show an increase in knowledge about HCV, the screening process, and the use of the screening tool. This will be evidenced by a score of 91.5% or better on all posttests.

A retrospective chart audit was performed to establish the number of persons registered for evaluation, their birth year, documented history of HCV, and whether HCV screening was conducted at the clinic during February 2019. The aim was to gather information for comparison of the variable in a two-group sample. Data from the audit were collected on an Excel spreadsheet template and stripped of all identifiable data by a clinic board member.

Setting

SFMC offers completely free medical services to all patients, regardless of income, in Petersboro County, North Carolina. SFMC came about as a result of an effort and desire by a local doctor to help those who are less fortunate and hurting in the community. The entire clinic is run by volunteer services. Donations from many churches, civic groups, and community organizations have helped keep the clinic open as a nonprofit 501(c)(3). The goal is to help maintain good health, and the mission statement addresses the need to address community health through individuals. Implementing the HCV screening tool aligns with the organization's efforts to offer care that would not otherwise be possible. A copy of the project site letter of support is provided in Appendix B.

Population

The uninsured and underserved patients of Petersboro County utilizing the SFMC was the population of interest. Lack of resources for preventive services is a common burden, and with the SFMC-HCV-ST and partnership with Advancing Lives. Fighting Aids (ALFA), the population will be a step closer to healthcare equality. A convenience sample including all registered patients on the select day of screening was used for ease of accessibility. All patients meeting the HCV screening criteria were referred to ALFA Red Van for HCV point-of-care testing. ALFA uses their own informed consent for testing.

Clinical task force members enlisted included two medical doctors, one chiropractor, one doctor of nursing practice student, five registered nurses, and one lab technician. The Doctor of

Nursing practice student led this intervention project. To assure task force members understood the intervention dynamics, an education session covering the HCV disease process, recommendations for HCV screening, use of the HCV screening tool, and implementation process was conducted on the morning prior to clinic opening.

Ethical Considerations

The Doctor of Nursing Practice project team (student and project chair) completed research ethics training to ensure protection of human subjects, Collaborative Institutional Training Initiative certificate is provided in Appendix C. Further, the project was submitted to and received approval from the Liberty University IRB. A copy of the IRB approval letter is provided in Appendix D.

Ethical considerations for the protection of human subjects, consent, and data confidentiality were reviewed across multiple stages of data collection to ensure no identifying personal information was obtained. Informed consent was obtained for HCV screening, and a separate consent was required by the ALFA organization to perform point-of-care testing. The SFMC has patients sign consent for treatment as part of the registration process.

Retrospective and real-time data are protected by a numeric system starting with the month and day of visit followed by 01, 02, 03, 04, etc. The coded number (e.g., 0413-01, 0413-02, 0413-03, etc.) was placed at the top of each screening tool by lead investigator. Further, a HIPAA-compliant computer was used for data entry into the IBM-SPSS software and was also password protected. Information forms were shredded once data entry into SPSS was completed. Data entry information will be kept for three years as required and then deleted. No patient or staff information will be reported in any future presentations or publications.

Data Collection

Patients registered for medical treatment were given a recruitment letter to read while waiting. The HCV screening tool and consent form were placed on each chart by intake nurse, who then completed the screening tool after consent was obtained. Data were gathered in real time on the HCV screening form. Final collected data forms were reviewed to ensure no personal identifying information was present. Each patient was given the opportunity to opt out of screening.

Tools

HCV screening tool. The review of the literature for current screening tools resulted in limited findings: Only the CDC and the USPSTF guidelines were located. These guidelines were utilized for creation of SFMC-HCV-ST, which was developed using Epi Info 7 public software. The template is provided in Appendix E. An algorithm approach was chosen for simplicity as the foundation of the form's development.

Pretest and posttest. A pretest and posttest were developed to assess provider knowledge gained during the education session. This style of evaluation was chosen for ease of use, high efficacy, and reliability with qualitative analysis. Both tests were developed by the Doctor of Nursing Practice student using Epi Info 7 public software and can be found in the Appendix F.

Retrospective audit tool. A preintervention audit was conducted retrospectively for the February 2019 clinic month to determine how many patients were screened for HCV. Only pertinent information was collected, including birth year, recorded history of HCV or intravenous drug use, and whether HCV screening took place during that visit. Data were collected on an Excel spreadsheet.

Intervention

The collaboration between the ALFA mobile medical unit and SFMC is a practical agreement to improve the quality of care for the underserved community. The clinic patients are not receiving recommended preventative HCV screenings due to funding constraints that the grant-funded ALFA mobile medical clinic could provide. Working together to offer necessary health care services to the less fortunate aligns with both organizations' missions and represents a step toward HCV screening equality. Utilizing the CDC and USPSTF guidelines, a screening tool was developed using Epi Info 7 software by the lead investigator. After securing IRB approval, training began with the clinical task force members the morning before clinic opened. To assure clinical task force members understood the intervention dynamics, an open education session covering the HCV disease process, recommendations for HCV screening, and the use of the HCV screening tool was conducted. Assignment of task force members took place on the morning of implementation. Every effort was made to secure the same task force members for the entirety of the data collection period. Consistency aids in reliability and the validity of data collection.

Timeline of project stages. In alignment with the Iowa Model, the doctor of nursing practice student, who was the team leader, identified the problem-focused trigger, determined it was a priority topic for the organization, created a team, formulated research, reviewed the available literature, and decided there was enough of a research base to continue with the project.

Preparation. In preparation for the investigation, the following steps were executed based on the previously determined timeline:

- January 30, 2019: Completed primary defense with chair

- February 4, 2019: Submitted proposal to University's IRB
- February 13, 2019: Revisions sent per IRB request
- February 24, 2019: Revisions sent per IRB request
- March 13, 2019: Revisions sent per IRB request
- April 10, 2019: Submitted proposal and university's IRB acceptance letter to site (no site IRB),

Implementation. In alignment with the Iowa Model, the evidence-based practice project was implemented. The following steps were executed based on the previously developed timeline:

- April 10, 2019: Collected chart audit (retrospectively for January 12, 2019) from designated individual at SFMC.
- April 13, 2019: Conducted educational session with clinical staff at the SFMC and surveyed before and after the session.
- April 13, 2019: Began utilizing the HCV screening tool.

Evaluation. In alignment with the Iowa Model, the evidenced-based practice project was evaluated. The following steps are in the process of being executed based on the proposed timeline:

- By April 13, 2019: Analyzed postintervention data.
- April 18, 2019: Finished the written scholarly project, completed editing and sent to the editor.
- April 24, 2019: Editor returned paper with recommendations.
- April 29, 2019: Final defense conducted.
- April 29, 2019: Final revisions completed, and project posted to the Scholars Crossing

- May 30, 2019: Disseminate to key stakeholders

Feasibility analysis. The resources needed to carry out this intervention included but were not limited to the SFMC-HCV-ST, the pretest and posttest, and enough copies of the SFMC-HCV-ST for each registered patient on paper that was donated to the clinic. Task force members were all volunteers and required no compensation. Computer analysis of data was carried out by the lead investigator using her personal laptop and previously purchased statistical software. The feasibility analysis for this project required no real money exchange.

Data Analysis

Analysis began with the immersion of collected data. After careful review, data were coded for entry into a statistical software program. Each collected form had the date of visit and number code; for data input the date was dropped and the remaining number became the numerical identification. Retrospective data were entered into the statistical software program from the Excel spreadsheets, which included the following labels: form identification code, gender, birth year, reported history of HCV, and screened this visit. After immersion in the prospective collected data, dependent variables included form identification code, gender, race, birth year, reported history of HCV, screened this visit, one risk behaviors, and two or more risk behaviors. For the statistical computations, gender, race, reported history of HCV, and screened this visit labels were coded to numerical data responses under the value tab. Risk behaviors were also coded numerically. Analysis of descriptive statistics included frequency of patients screened and the creation of graphs to compare the differences between the data sets.

Measurable Outcomes

1. After completion of the April 13, 2019, HCV screening tool intervention, a greater percentage patients in the SFMC will be screened for HCV. This will be evidenced by

the number of patients screened with use of the screening tool as compared to the number of patients screened previously without use of a screening tool.

2. After completion of the educational program on HCV, clinic staff will show an increase in knowledge about HCV, the screening process, and the use of the screening tool. This will be evidenced by a score of 91.5% or better on all posttests.

SECTION FOUR: RESULTS

Presentation of the data analysis will include the categorical survey results through various descriptive statistics with frequency. This section will first discuss the results for the main premise of the study. The aim of this project was to compare of two groups of data for significant differences that resulted from the independent variable, the screening tool. Demographics and the percentage of HCV guideline questions will be disclosed, and lastly, results of the clinic staff pretest and posttest will be analyzed for knowledge growth.

Retrospective data collected by chart audit for the clinic day of February 9, 2019 were entered into a statistical software program from an Excel spreadsheet. The data entry process was repeated for the prospective data collected in real time on April 13, 2019 and included coding the screening questions based on HCV guidelines. After data entry was complete, the two groups were analyzed multiple times for validity, and a statistician reviewed computations from the software program with manual calculations on a statistical calculator. Findings were identical, which ensured reliability of the software and eliminated the possibility of investigator mathematical error.

Table 2

Retrospective Group: No Screening Tool 02/19

Valid?	Frequency	Percent	Valid %
Yes	13	25	25
No	39	75	75
Total	52	100	100

Table 3

Prospective Group: With Screening Tool 04/19

	Frequency	Percent	Valid %
Yes	43	82.7	87.8
No	6	11.5	12.2
Total	49	94.2	100.0
Missing	3	5.8	
Total	52	100	

The tables above display the collected data for each group. The retrospective group had a total of 52 patient visits, of which 13 included screening for HCV; 39 did not include screening. The prospective group had a total of 49 patient visits, 43 of which included screening, and six of which did not. The significant change variable was the use of a screening tool for the prospective group. Importantly, there were no missing data, only fewer patients visits on the day of prospective data collection. The valid percent in the prospective group shows the correct percentage of 87.8%, which is the total percentage of patient visits that included the use of the screening tool. The missing value of 3 was added to create an equal number of subjects between groups, as removal of 3 would create bias.

Further analysis with descriptive statistics was limited. Categorical dichotomous variables have only two unordered responses, making many statistical tests invalid for qualitative data. Frequency tables give a better understanding of how often data occur and calculates statistics including the mean, standard deviation, variance, and skewness of each data set. Skewness is a measure of how evenly distributed the data are or the shape of the bell curve for a normal distribution. Table 4 expresses the skewness of each group. Table 4

Group Data Frequency Statistics

	Prospective	Retrospective
N		
Valid	49	52
Missing	3	0
Mean	1.12	1.75
SEM	.047	.061
Median	1.00	2.00
SD	.331	.437
Variance	.110	.191
Skewness	2.377	-1.189
Std. Error of Skewness	.340	.330
Range	1	1

Other tests included demographics and HCV guideline–specific questions with frequency percentage shown in Tables 5–7.

Table 5

Gender Ratio: Retrospective vs. Prospective Group

	Retrospective Group			Prospective Group			
	Male	Female	Total	Male	Female	Missing	Total
Frequency	22	30	52	23	26	3	52
Percent	42.3	57.7	100.0	44.2	50.0	5.8	100.0
Valid percent	42.3	57.7	100.0	46.9	53.1		
Cumulative percent	42.3	100.0		46.9	100.0		

Table 6

Prospective Group: Risk Behaviors for HCV

	Frequency	Percent	Valid Percent	Cumulative Percent
1945–1965	13	26.5	30.2	30.2
Blood/Organ prior to 1990	2	4.1	4.7	34.9
IV drug use or stuck with needle	5	10.2	11.6	46.5
Multiple or same sex partners	1	2.0	2.3	48.8
Live with HCV positive person	1	2.0	2.3	51.2
None	21	42.9	48.8	100.0
Total	43	87.8	100.0	
Missing	6	12.2		
Total	49	100.0		

Only the prospective group has data on guideline specific questions (Table 6) as well as clinic staff pretest/posttest analysis.

The morning of clinic April 13, 2019, clinical staff were verbally recruited to participate in pretest/posttest portion of the HCV screening tool intervention. After immersion of the data, overall analysis started with comparing the pretest and posttest outcomes shown below in Table 7.

Table 7

Pretest/Posttest Descriptive Statistics

	N	Range	Minimum	Maximum	Mean	*SD*	Variance
Pretest Scores	8	6	6	12	9.00	2.000	4.000
Posttest Scores	8	1	11	12	11.63	0.518	0.268

Pretest and posttest data were gathered in real time. Clinic staff underwent an HCV education session after the pretest to establish baseline knowledge for HCV, and a posttest was given to assess education session knowledge gain. Eight clinical staff providers participated as the sample. The mean score of the pretest was 75%, and the mean score of the posttest was 95.8%.

SECTION FIVE: DISCUSSION

This project sought to determine if a screening tool would increase the rate of HCV screening in a rural free medical clinic. A retrospective chart audit for February 9, 2019, and a prospective clinic intervention on April 13, 2019, were the sources of data for comparison.

After careful analysis, the findings suggest the use of a screening tool increased the screening rate by 62.8% at SFMC. Use of a visual aid to prompt providers for screening was the necessary addition to elicit this increase. The difficult-to-access populations generally have no insurance and seek alternative settings for healthcare or misuse the EDs for health care needs. This places greater strain on the health care sector. Clinical providers are overloaded with guidelines, and each new patient brings another best-practice pathway to pull from memory. Providing small interventions will revive the forgotten guiding principles recommended in an ever-changing health care structure. Utilizing a pretest/posttest survey with a very brief educational session resulted in a knowledge increase of 20.8% in screening providers. Small interventions like this project support best outcomes and offer an equitable approach to serve those with health care disparities.

A conceptual model was utilized as a guide for this project. The clinical decision-making and evidence-based practice processes of the Iowa Model aided both the clinical providers and organization through a multidisciplinary approach. This model steers questioning of current practice in order to determine whether patient care could be improved using evidence-based research (Clanton, 2014). Development of a screening tool based on CDC and USPSTF guidelines coupled with an educational intervention to ensure current clinical provider knowledge aligns with the model chosen to guide this project. Seeking alternative platforms to capture difficult-to-access populations is the only way the United States will have the opportunity to make an impact on HCV. Small interventions like this project assist the global efforts to end the HCV epidemic.

Implication for Practice

Underfunded settings can use these findings as an example upon which to build alternative partnerships with other community services for treating difficult-to-access populations in collaboration. Developing specific screening tools will offer reminders to clinical providers in practice. Governing agencies must recognize uninsured and underserved populations in rural America are not getting nationally recommended screenings and preventive health care services. Policy change for rural equity is long overdue, and public health nurses need to advocate for reform. Educational opportunities are multiple. From academic settings to small rural clinics, clinical reminders and educational opportunities play an important role in screening cues. Implementing a revolving educational mindset will assist practice clinicians to accept the constantly changing health care structure. Lastly, evidence-based practice in research can use small projects like this to build and grow opportunities to improve the future of health care. The implications for practice are innumerable.

Limitations

Limitations of this evidence-based study include that it assessed only one rural setting and, therefore, may not be representative of other settings or population. The sample size and number of data collection days are also viewed as limitations. Having more collected data over a longer period would assist other areas of research with similar topics and narrow the results further. Patients in the data groups could be represented more than once if they presented during both clinic days. Funding is a large limitation in duplicating this project for HCV screening, as it is unethical to offer screening without the ability to provide testing and linkage-to-care. Testing for HCV in uninsured patients leaves the patient or facility to absorb the cost.

Conclusion

In the United States, millions of Americans have been infected by HCV, and less than half have been diagnosed (Turner et al., 2017). The most unfortunate truth about the above statement is that HCV is curable. The United States of America is a powerhouse with abundant resources in the world, and yet millions of people die a horrific death unnecessarily. The suffering caused by end-stage liver disease is brutal. The disease trajectory includes fluid-overload ascites filling the abdomen, pushing the diaphragm into the chest cavity causing shortness of breath; nausea and vomiting; and severe itching of the skin with jaundice as organs fail until the body shuts down. End-stage HCV is not a quick process can drag out over several years. The constant emotional, social, and family stress of waiting for the next debilitating episode to occur without warning, causing yet another hospitalization, can be prevented. Watching several patients experience this terrible death caused a great passion to advocate and drive change in the lead investigator. The reality of HCV is anyone can get infected, and without screening for risk behaviors and early detection, millions will continue to suffer needlessly.

Rural areas are heavily burdened with uninsured populations living in poverty. Advanced nursing providers have a duty to care for all in need, including the less fortunate, ill-educated, and suffering. Creating alternative approaches to achieve equity for the uninsured and underserved should be a priority when suffering can be avoided.

Dissemination Plan

Dissemination presentation will take place at the next regularly scheduled board meeting to all stakeholders at SFMC on May 30, 2019, at 6:30 p.m. SFMC staff and ALFA mobile medical team will receive dissemination findings on next clinic day after disclosure to board members. This paper will be published in Liberty University's Scholars Crossing no later than May 8, 2019. Other presentations may include poster submission, and podium presentations at up coming healthcare opportunities.

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Appendix A: Permission to Use Iowa Model

You have permission, as requested today, to review and/or reproduce *The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care.* Click the link below to open.

The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care

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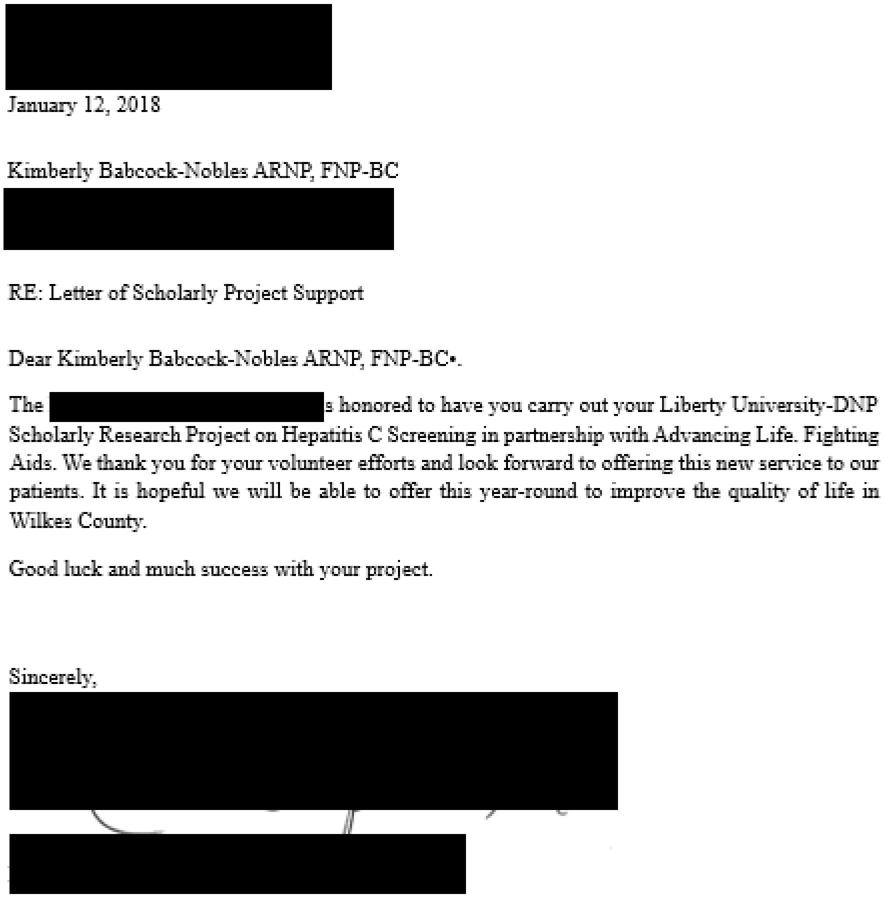
Please contact UIHCNursingResearchandEBP@uiowa.edu or 319–384–9098 with questions.

Appendix B: Letter of Support



[redacted]

January 12, 2018

Kimberly Babcock-Nobles ARNP, FNP-BC
[redacted]

RE: Letter of Scholarly Project Support

Dear Kimberly Babcock-Nobles ARNP, FNP-BC.

The [redacted]s honored to have you carry out your Liberty University-DNP Scholarly Research Project on Hepatitis C Screening in partnership with Advancing Life. Fighting Aids. We thank you for your volunteer efforts and look forward to offering this new service to our patients. It is hopeful we will be able to offer this year-round to improve the quality of life in Wilkes County.

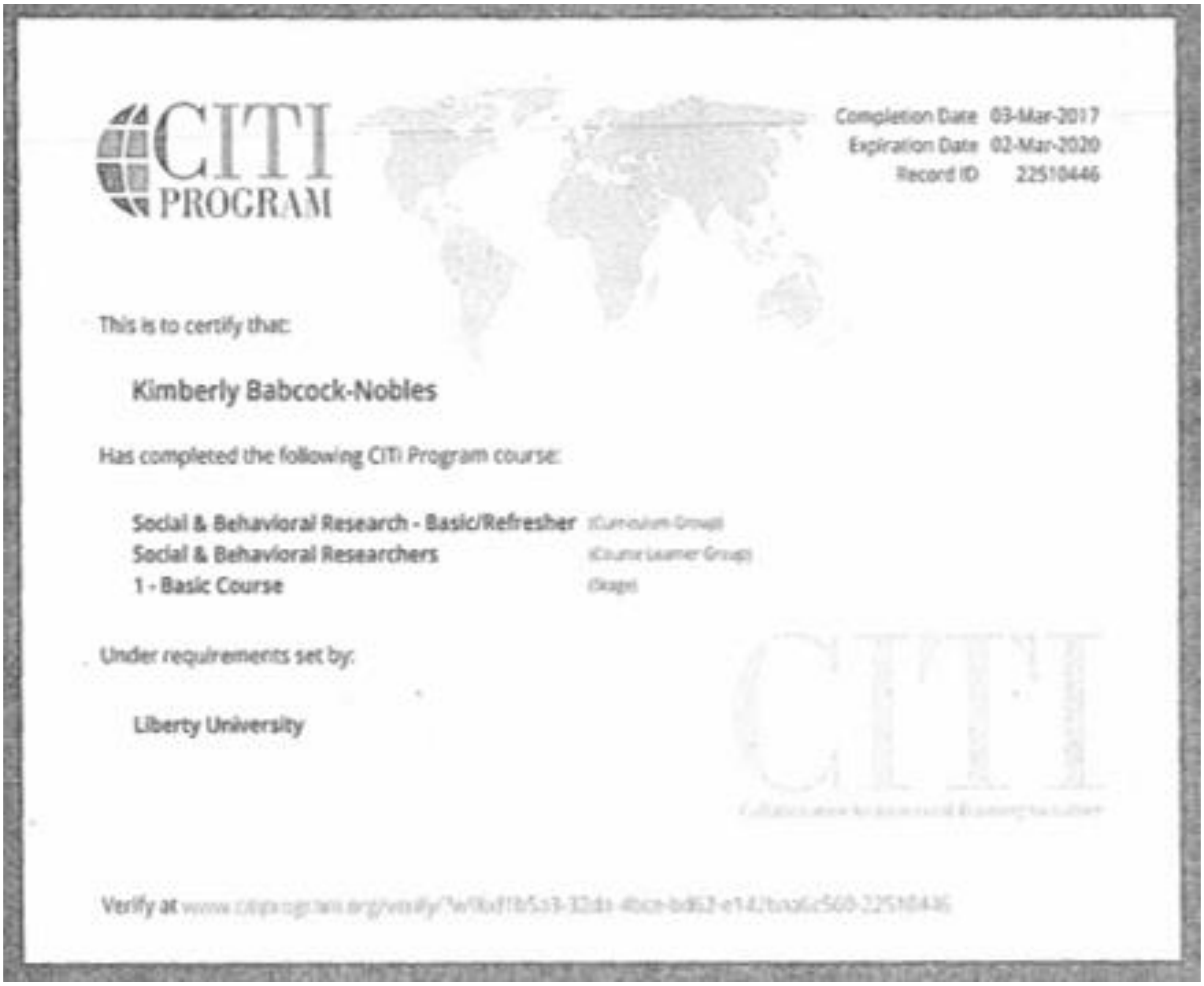
Good luck and much success with your project.

Sincerely,

[redacted]

[redacted]

Appendix C: Collaborative Institutional Training Initiative Completion Diploma



CITI PROGRAM

Completion Date 03-Mar-2017
Expiration Date 02-Mar-2020
Record ID 22510446

This is to certify that:

Kimberly Babcock-Nobles

Has completed the following CITI Program course:

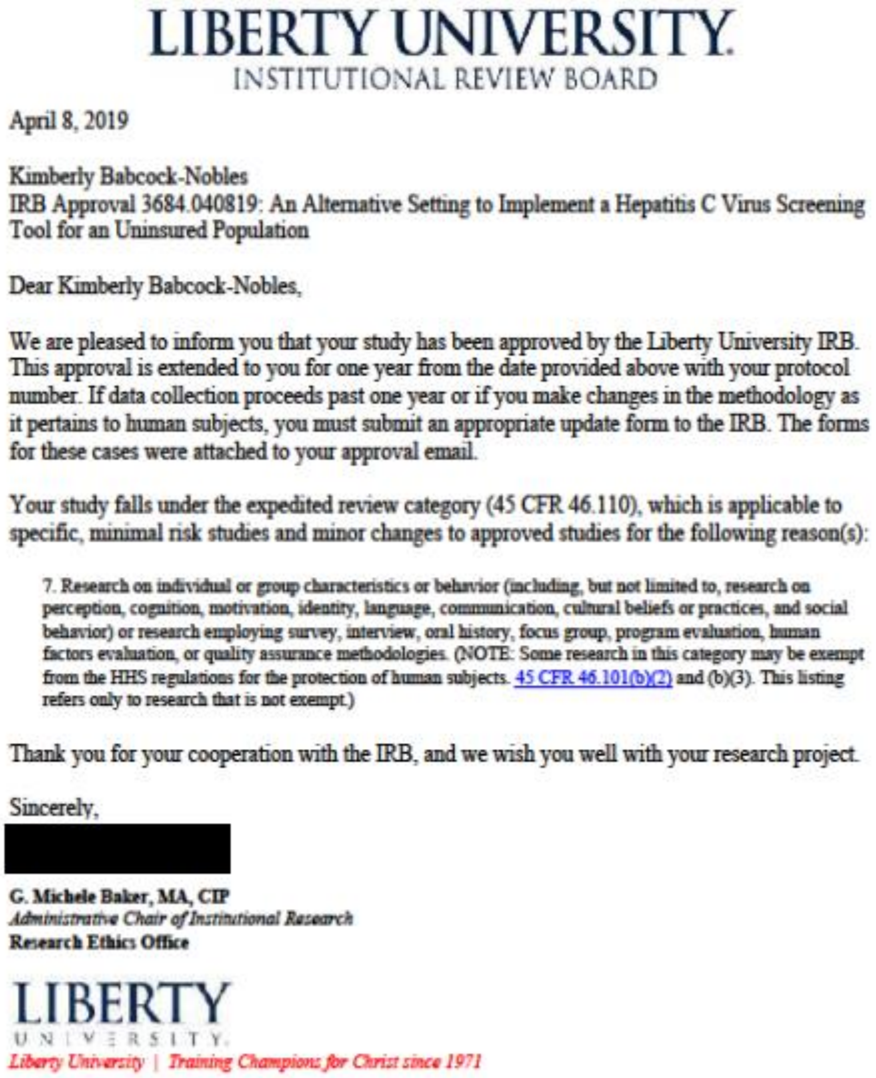
Social & Behavioral Research - Basic/Refresher (Curriculum Group)
Social & Behavioral Researchers (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

Liberty University

Verify at www.citiprogram.org/verify/?[illegible]-22510446

Appendix D: IRB Approval Form



LIBERTY UNIVERSITY.
INSTITUTIONAL REVIEW BOARD

April 8, 2019

Kimberly Babcock-Nobles
IRB Approval 3684.040819: An Alternative Setting to Implement a Hepatitis C Virus Screening Tool for an Uninsured Population

Dear Kimberly Babcock-Nobles,

We are pleased to inform you that your study has been approved by the Liberty University IRB. This approval is extended to you for one year from the date provided above with your protocol number. If data collection proceeds past one year or if you make changes in the methodology as it pertains to human subjects, you must submit an appropriate update form to the IRB. The forms for these cases were attached to your approval email.

Your study falls under the expedited review category (45 CFR 46.110), which is applicable to specific, minimal risk studies and minor changes to approved studies for the following reason(s):

> 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Thank you for your cooperation with the IRB, and we wish you well with your research project.

Sincerely,

[redacted]

G. Michele Baker, MA, CIP
Administrative Chair of Institutional Research
Research Ethics Office

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Appendix E: SFMC-HCV Screening Tool

Form #

[redacted] HCV SCREENING TOOL

Date of Visit

Year of Birth

Race
- ○ African American
- ○ Caucasion
- ○ Hispanic
- ○ Other

Gender
○ Male ○ Female

Have you ever been tested for Hepatitis C Virus?
○ YES ○ NO

If YES, when and where?

Have you…(check all that apply)
- ○ Were you born between 1945- 1965?
- ○ Have you received a blood transfusion or organ donation prior 1990?
- ○ Have you even once used intraveous drugs or ever been stuck with a dirty needle?
- ○ Had mutiple sexual partners or same sex sexual encounters?
- ○ Have you ever been told a loved one has Hepatitis C Virus?

Is there a positive risk for HCV?
○ YES ○ NO

Is patient to receive referral to ALFA for point-of-care testing?
○ YES ○ NO

Appendix F: Pre- and Posttest

Test Number

Title MD, DO, NP, RN,

Hepatitis C Pre-Test

1. Hepatitis C is a global epidemic affecting more than 3.2 million people in the US alone.

O True O False

4. Hepatitis C is called a silent epidemic because people can get infected and not know it?

O True O False

7. Alt people born between 1945-1965 should have at least a one-time screening test for hepatitis C (unless previously documented)

O True C) False

10. Intravenous drug use is the most common risk-factor for contracting hepatitis C?

O True O False

2. Hepatitis C can only be transmitted from drinking/ eating after someone that is Hepatitis C positive?

O True O False

5. People that received blood products after 1999 are at risk for exposure to hepatitis C and should be tested?

O True O False

8. Lack of symptoms are actually a barrier to screening for hepatitis C?

O True O False

11. Risk-behaviors for exposure to hepatitis C include all of the following: IV drug use, men having sex with men multiple sexual partners, blood products received before 1992. and birth cohort 1945-1965?

O True O False

3. Hepatitis C is a curable disease with early screening and treatment?

O True O False

6. Some people that get infected with hepatitis C are able to clear. or naturally rid the virus. but most people who get infected develop a chronic lifelong, infection.

O True C) False

9. A non-reactive. or negative. result on a hepatitis C point-of-care test requires a second test to confirm negative results?

O True O False

12. Do you think you have a strong knowledge base when it comes to screening for hepatitis C?

O yes
O No
O could use more education

Test

Title

Hepatitis C Post-Test

1. Intravenous drug use is the most common risk-factor for contracting hepatitis C?

O True O False

2. A non-reactive. or negative result on a hepatitis C point-of-care test requires a second test to confirm negative results?

O True O False

3. Lack of symptoms are actually a barrier to screening for hepatitis C?

O True O False

4. All people born between 1945-1965 should have at least a one-time screening test for hepatitis C (unless previously documented)

O True O False

5. Some people that get infected with hepatitis C are able to clear. or naturally rid the virus, but most people who get infected develop a chronic lifelong. infection.

O True O False

6. People that received blood products after 1999 are at risk for exposure to hepatitis C and should be tested?

O True O False

7. Hepatitis C is called a silent epidemic because people can get infected and not know it?

O True O False

8. Hepatitis C is a curable disease with early screening and treatment?

O True O False

9. Hepatitis C can only be transmitted from drinking/ eating after someone that is Hepatitis C positive?

O True O False

10. Hepatitis C is a global epidemic affecting more than 3.2 million people in the U.S. atone.

O True O False

11. Risk-behaviors for exposure to hepatitis C include all of the following: IV drug use. men having sex with men, multiple sexual partners, blood products received before 1992. long-term hemodialysis. and birth cohort 1945-1965?

O True O False

12. Do you think you have a strong knowledge base when it comes to screening for hepatitis C?

O yes
O No
O need more education

Questionnaire created from the CDC Hepatitis C Guidelines using EpiForm7.